TYPES OF INTERVENTION

Primary Intervention

Screening for Impaired Glucose Tolerance (IGT)

1

TITLE: Effectiveness of Screening for Diabetes. Gerken, K.L.; Van Lente, F. *Archives of Pathology and Laboratory Medicine*. 114(2): 201-203. February 1990.

OBJECTIVE: To evaluate the diagnostic yield from screening patients for diabetes by measuring their fasting serum glucose and hemoglobin A1c levels during routine health surveillance. To compare the oral glucose tolerance test and repeat fasting glucose determination as a follow-up to screening.

CATEGORY: Primary intervention.

> **Type of Study:** Retrospective.
> **Methodology:** Cost-effectiveness analysis.
> **Perspective:** Health care system.

CONCLUSION: Oral glucose tolerance testing was as cost effective and more efficient for diagnosing diabetes after an abnormal fasting serum glucose test than were repeat fasting serum glucose determinations. Hemoglobin A1c did not reliably predict impaired or diabetic glucose tolerance.

RECOMMENDATION: If mass screening for diabetes is instituted, obligatory oral glucose tolerance testing must be made part of the follow-up protocols for positive findings on a fasting serum glucose test.

ABSTRACT: The authors analyzed the effectiveness of screening for diabetes mellitus in an executive health surveillance program by examining laboratory records for 6,445 patient visits from 1985 to 1988. They retrospectively identified 336 persons with borderline high (6.6 to 7.6 mmol/L) or high (7.7 mmol/L or higher) fasting serum glucose levels; 29 of these persons had no further records, and 110 were known to have diabetes. Of the remainder, 61 had a follow-up fasting serum glucose test and 33 had an oral glucose tolerance test. Ninety-three persons had hemoglobin A1c (HbA_{1C}) tested. Among borderline high individuals, on repeat fasting serum glucose, 38 percent had levels of 6.1 mmol/L or less; 55 percent had 6.2 to 7.6 mmol/L; and 7 percent had 7.7 mmol/L or greater. Comparable results for persons with high initial fasting serum glucose were 14, 25, and 61 percent, respectively. Follow-up oral glucose

tolerance tests resulted in normal, impaired, and diabetic glucose levels in 32, 40, and 28 percent of the borderline high persons and 25, 0, and 75 percent of the persons with high values, respectively. Significantly different levels of HbA_{1C} ($p < .01$) were found between the two groups of persons (borderline high and high), but only 3 percent of those with borderline high fasting serum glucose and only 64 percent of those with high fasting serum glucose had increased HbA_{1C}. From screening, 30 new cases of diabetes and 10 new cases of impaired glucose tolerance were identified, a total of 40 (0.6 percent) of 6,445 patients screened. The overall rate of identification of abnormal serum glucose was 0.6 percent. The cost per case found (based on Medicare reimbursement rates) was $488.04 with repeat fasting serum glucose and an oral glucose tolerance test and $484.54 with a follow-up oral glucose tolerance test alone. The oral glucose tolerance test is as cost effective as repeat fasting serum glucose with oral glucose tolerance testing as needed and more diagnostically efficient than repeating that test Addition of HbA_{1C} increased cost to $522 and cannot be recommended. The oral glucose tolerance test should be made obligatory to follow-up abnormal initial serum glucose tests. 3 tables, 12 references.

2

TITLE: Technical and Clinical Evaluation of Fructosamine Determination in Serum. Desjarlais, F.; Comtois, R.; Beauregard, H.; Nguyen, M.; Letellier, G. *Clinical Biochemistry.* 22(4): 329-335. August 1989.

OBJECTIVE: To evaluate the effectiveness of a serum fructosamine (glycated serum proteins) assay for diagnosis and follow-up of patients with diabetes; to compare its effectiveness with a serum glycosylated hemoglobin measurement.

CATEGORY: Primary intervention.

> **Type of Study:** Nonrandomized clinical trial.
> **Methodology:** Cost-effectiveness analysis.
> **Perspective:** Health care system.

CONCLUSION: The serum fructosamine assay is simple, rapid, and cost efficient.

RECOMMENDATION: The serum fructosamine assay should be a valuable addition to monitoring glucose control in patients with diabetes.

ABSTRACT: Researchers evaluated a serum fructosamine assay and compared the results with those of glycosylated hemoglobin for diagnosing and managing diabetes. Blood samples were drawn from 375 participants with or without diabetes (total: 514 samples). The serum fructosamine assay was not significantly affected by hemolysates, but high lipemia and addition of bilirubin decreased and increased the values, respectively. In 48 normal participants, the correlation between serum fructosamine and serum protein or serum albumin was statistically significant, with a linear correlation of 0.809 and 0.746, respectively. Overall, the linear correlation between serum fructosamine and glycosylated hemoglobin was 0.794;

when fructosamine was corrected for protein, the value was 0.838. Among 16 patients with diabetes hospitalized to improve blood glucose control, the linear correlation of the percent decrease for glycosylated hemoglobin and blood glucose was 0.28 ($p > 0.05$); for fructosamine and blood glucose, it was 0.64 ($p < 0.01$). Using a fructosamine concentration cutoff of 2.70 mmol/L (the normal mean plus two standard deviations), this test had a 96 percent specificity and a 90 percent sensitivity for patients with overt diabetes but only an 11 percent sensitivity for patients with diabetes by glucose tolerance test but normal fasting glucose levels. When applied to gestational diabetes, fructosamine had a specificity of 95 percent but a sensitivity of just 21 percent. Because the assay for fructosamine can be automated, it is easy and fast to use and the average per-patient cost is $0.93, including protein measurements. The glycosylated hemoglobin test is performed manually, is difficult to interpret, and the per-patient cost is $6.15. The serum fructosamine assay is simple, reliable, and economic for measuring ambient glucose concentration in stable and unstable diabetes mellitus. It may be useful in diagnosing diabetes when the fasting blood glucose exceeds 7.8 mmol/L (overt diabetes). In such cases, a concomitant fructosamine evaluation might preclude the need for a second fasting glucose. 5 figures, 2 tables, 30 references.

Secondary Intervention

Screening and Diagnosis for Type 2 Diabetes

3

TITLE: Comparison of glycosylated Hemoglobin and Fasting Plasma Glucose with Two-Hour Post-Load Plasma Glucose in the Detection of Diabetes Mellitus. Simon, D.; Coignet, M.C.; Thibult, N.; Senan, C.; Eschwege, E. *American Journal of Epidemiology*. 122(4): 589-593. October 1985.

OBJECTIVE: To compare the use of a glycosylated hemoglobin (HbA_{1C}) test alone with a combination of that test and a plasma glucose measurement in a diabetes screening program.

CATEGORY: Secondary intervention.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Using the combination of an HbA_{1C} measurement and a fasting plasma glucose measurement increases the specificity and predictive value of a positive diagnosis of diabetes over that obtained by glycosylated hemoglobin alone.

RECOMMENDATION: Longitudinal surveys should be performed to assess the validity of

HbA_{1C} as a measurement tool for diabetes screening.

ABSTRACT: From September 15, 1981, to April 1, 1984, 333 outpatients were recruited from the screening diabetes center of the Hôtel-Dieu Hospital in Paris. Patients filled out a questionnaire; underwent a physical exam; had blood drawn for fasting plasma glucose, HbA_{1C}, cholesterol, and triglyceride measurements; and took an oral glucose tolerance test with a 75-g glucose load. With 2-hour plasma glucose values as a reference, sensitivities of the fasting plasma glucose measurement, HbA_{1C}, and a combination of fasting plasma glucose and glycosylated hemoglobin were, respectively, 52 percent, 60 percent, and 40 percent; the specificities were 98.7 percent, 90.9 percent, and 99.4 percent; and the predictive values for a positive diagnosis were 76.5 percent, 34.9 percent, and 83.3 percent. Taking into account the economic and psychosociologic implications of a diagnosis of diabetes, it is better for a screening test for asymptomatic diabetes to have a high degree of specificity and a high predictive value for a positive diagnosis than to have good sensitivity but poor specificity. As an oral glucose tolerance test is time-consuming for patients and nurses, measurements of HbA_{1C} by chromatography and of fasting plasma glucose appear to be less expensive (about 5 versus 10 U.S. dollars). Longitudinal surveys are needed to assess the validity of HbA_{1C} as a tool for diabetes screening. 1 table, 32 references.

4

TITLE: Comparison of Screening Tests for Non-Insulin-Dependent Diabetes Mellitus. Hanson, R.L.; Nelson, R.G.; McCance, D.R.; Beart, J.A.; Charles, M.A.; Pettitt, D.J.; Knowler, W.C. *Archives of Internal Medicine*. 153(18): 2133-2140. September 27, 1993.

OBJECTIVE: To compare four screening tests for type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Population screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Fasting plasma glucose was the best test for screening, but glycated hemoglobin and quantitative urine glucose also provided high specificity with sensitivities approximately 80 percent or higher.

RECOMMENDATION: The choice of a particular screening test should depend on assay cost, convenience, and availability.

ABSTRACT: The authors compared the sensitivity of measuring quantitative urine glucose, dipstick urine glucose, fasting plasma glucose, and glycated hemoglobin to screen for diabetes in Pima Indians, a tribe at high risk for type 2 diabetes. Fasting plasma glucose concentrations and glycated hemoglobin (HbA_1 or HbA_{1C}) were compared in 2,092 fasting participants;

glycated hemoglobin, quantitative glycosuria, and dipstick glycosuria were compared in 237 nonfasting participants. Among nonfasting participants, at specificities of 98 or 99 percent, sensitivities for detecting diabetes were 80.6 percent for quantitative glycosuria, 64.3 percent for dipstick glycosuria, and 92.9 percent for HbA_1. For detecting diabetes with severe hyperglycemia, sensitivities for the 3 tests ranged from 85.0 percent (HbA_1) to 96.0 percent (quantitative glycosuria), with similar specificities. Among fasting participants, at a specificity of 98.3 percent the sensitivity of fasting plasma glucose was 88.0 percent; at similar specificities, HbA_1 had a sensitivity of 78.8 percent and HbA_{1C}, 80.3 percent. For detecting diabetes with severe hyperglycemia, all 3 tests had a sensitivity of 94.6 percent or greater with specificity of 98 percent. The slightly higher sensitivity of fasting plasma glucose (versus glycated hemoglobin) is probably of minimal significance because fasting plasma glucose is a less convenient test. glycosuria assays have limited ability to detect diabetes with moderate hyperglycemia, but they reliably detect severe hyperglycemia. 4 figures, 4 tables, 41 references.

5

TITLE: Effectiveness of glycosylated Hemoglobin, Fasting Plasma Glucose, and a Single Post Load Plasma Glucose Level in Population Screening for Glucose Intolerance. Modan, M.; Halkin, H.; Karasik, A.; Lusky, A. *American Journal of Epidemiology*. 119(3): 431-444. March 1984.

OBJECTIVE: To determine which of the following methods is the most effective screening test for glucose intolerance (impaired glucose tolerance and type 2 diabetes): glycosylated hemoglobin, fasting plasma glucose, combination of fasting plasma glucose and glycosylated hemoglobin, plasma glucose 1-hour post oral glucose load, and plasma glucose 2-hour post oral glucose load.

CATEGORY: Secondary intervention.

Type of Study: Population screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The most effective screening methods were the 1- and 2-hour post oral glucose loads. The 1-hour post oral glucose load worked better for detecting glucose intolerance, and the 2-hour post oral glucose load was better for detecting diabetes.

RECOMMENDATION: For clinical diagnosis, a two-stage screening using a fasting or random blood glucose test and an oral glucose load may be adequate, but for epidemiologic studies a full oral glucose tolerance test that includes a fasting test and two post-load levels is preferred.

ABSTRACT: The study population included a sample group of 2,040 people, aged 40-70 years, who were participating in the Israel Study of Glucose Intolerance, Obesity and

Hypertension. Members of the sample group who were not known to have diabetes underwent a glucose tolerance test based on a fasting test and 1-hour and 2-hour post oral glucose loads. In 1,058 participants, glycosylated hemoglobin was also measured. Results showed that glycosylated hemoglobin alone is inefficient and inferior to a fasting plasma glucose test to determine glucose intolerance. Although glycosylated hemoglobin increased with glucose intolerance, there was considerable overlap in the distributions between newly identified patients with diabetes and patients with normal tolerance. The combination of the glycosylated hemoglobin test with the fasting plasma glucose test did not perform any better than the fasting test alone. However, testing fasting plasma glucose is not a satisfactory screening method because of its low specificities at adequate sensitivity levels compared with the 1- and 2-hour post glucose load tests. Of these tests, the 2-hour post glucose load level is more reliable when screening for diabetes alone, and the 1-hour post glucose load is more effective in screening for impaired glucose tolerance. Adding a fasting test to the 1- and 2-hour post glucose load tests raised the cost less than 5 percent, and the risk analysis showed that the venipunctures needed for the tests were not associated with any problems in patients. If a distinction is desired between impaired glucose tolerance and diabetes, a two-stage screening is indicated. In this method, everyone gets a 1-hour post load and the positive subgroup is retested by a full oral glucose tolerance test. For purposes of epidemiologic screening, a full oral glucose tolerance test is preferred over any "shortcut" method. 1 figure, 6 tables, 28 references.

6

TITLE: The glycosylated Hemoglobin as a Diagnostic and Monitoring Tool for Diabetes: Evidence from Claims Data (abstract). Altan, A.E.; Carlson, A.M.; Nettles, A. *AHSR FHSR Annual Meeting Abstract Book*. 1996; 13:11.

OBJECTIVE: To investigate how often the glycosylated hemoglobin (HbAlc) test is used to diagnose type 2 diabetes and the extent to which it is used to monitor diabetes control.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Claims review.
Perspective: Health care system.

CONCLUSION: The HbAlc test may be misused as a diagnostic tool for type 2 diabetes and underused as a tool to monitor diabetes control.

RECOMMENDATION: None.

ABSTRACT: The investigators examined claims records of 81,039 persons enrolled in three 1993 managed care plans located in large metropolitan areas in the western, midwestern, or eastern United States. The researchers identified individuals with diagnosed diabetes (both insulin-treated and noninsulin-treated); those who had received the oral glucose tolerance test, the recognized diagnostic test for diabetes; and those who had received the HbAlc test.

Among enrollees identified as not having diabetes (n = 70,068), 1,141 received an HbAlc test; of these persons, 4 percent (44 enrollees) also were given an oral glucose tolerance test. Of the 10,970 persons identified as having diabetes, 40 percent had had at least one HbAlc test during the year.

7

TITLE: Immunization to Prevent Insulin-Dependent Diabetes Mellitus? The Economics of Genetic Screening and Vaccination for Diabetes. England, W.L.; Roberts, S.D. *Annals of Internal Medicine*. 94(3): 395-400. March 1981.

OBJECTIVE: To determine the relative value of several strategies for preventing diabetes through the use of vaccine.

CATEGORY: Secondary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Vaccinating all children at age 3 was preferable, both economically and for disease prevention, to strategies that involved histocompatibility leukocyte antigen (HLA) screening prior to vaccination or to no vaccination at all.

RECOMMENDATION: Health programs and technologies need to be analyzed (e.g., for cost and risk) before they become available.

ABSTRACT: Numerous studies have shown an association between type 1 diabetes and viral infections, which suggests that vaccination for diabetes may be possible. The principal assumption behind the present paper is that viruses are involved in precipitating diabetes and that a vaccine for them can be developed. The author calculated an incidence rate for new cases of diabetes and program costs for 12 approaches to vaccination, 10 involving screening — the other 2 were vaccinating everyone and vaccinating no one. A decision tree analysis framework was used: the cost analysis considered the direct cost of diabetes, vaccine production and immunization, screening for predisposition to diabetes (measures evaluated included eight types of HLA tests, the Lewis negative erythrocyte phenotype, and the presence of diabetes in a parent or sibling), and side effects. The investigators used data based on published sources if possible; when data were inadequate or not available, a sensitivity analysis was performed. Only direct costs were tabulated. The analysis presupposed that any vaccinations would take place at age 3 (the most cost-effective age for all policies); incidence rates are the projected results after 27 years of vaccinating. Vaccinating everyone would reduce incidence by 29 percent and decrease the nondiscounted annual cost of diabetes by 18 percent; this policy was preferred to the other 11 on the basis of both incidence and cost. These results were, however, heavily influenced by the cost and efficacy of the vaccine, cost and probability of a vaccine reaction, cost and probability of diabetes, and the discount rate. A decision to vaccinate everyone was preferred to other alternatives for a wide range of vaccine

characteristics. 7 tables, 51 references.

8

TITLE: Multiple Biochemical Blood Testing as a Case-Finding Tool in Ambulatory Medical Patients. Ruttimann, S.; Dreifuss, M.; Clemencon, D.; di Gallo, A.; Dubach, U.C. *The American Journal of Medicine*. 94(2): 141-148. February 1993.

OBJECTIVE: To prospectively assess the yield, disadvantages, and charges associated with routine biomedical testing in a medical outpatient clinic.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-analysis.
Perspective: Health care system.

CONCLUSION: Routine biochemical testing in the university teaching setting was useful in identifying new diagnoses, but the number of newly discovered disorders that required new medical management was small.

RECOMMENDATION: Reducing the number of routine biomedical tests to three — cholesterol, glucose, and alanine aminotransferase measurements — to detect disorders that need treatment may be preferable to ordering large biochemical profiles.

ABSTRACT: The authors assessed the utility of routine biochemical tests in finding new disorders that changed medical management. Patients (n = 493) attending the medical outpatient clinic of the University Hospital in Basel, Switzerland, for the first time during 1989 underwent a 23-test biochemical screen. To differentiate clinically indicated from routine tests, resident physicians were instructed to order only tests required to monitor known or suspected medical conditions, even though the complete profile was performed. Patient charges were $40 for the biochemical profile and $17.60 for each additional visit caused exclusively by abnormal routine tests; charges were counted until diagnosis or patient discharge. Ninety percent of the tests were considered routine; 11.4 percent of these routine tests were abnormal. Four hundred thirty of the 493 patients had new abnormalities diagnosed on the routine tests; further tests were ordered for 10.9 percent of these patients, additional visits were required for 1.4 percent, and new diagnoses were reached for 11.1 percent. A change in management occurred in 5.8 percent (n = 25) of these patients; in all but 4 of these cases the newly detected disorder was hypercholesterolemia, alcoholic liver disease, or diabetes mellitus. These 21 cases could have been detected with cholesterol, glucose, and alanine aminotransferase tests alone. Total charges for all tests were $20,938; total charges for tests considered clinically indicated were $8,256. Additional charges per patient for the detection of the new diagnoses averaged $25.72. Using only the tests relevant to the new diagnoses, per-patient charges would have been reduced 30 percent. Biochemical screening in this setting is feasible and results in acceptable amounts of further testing and additional patient laboratory costs. Prospective studies should be developed to test the utility of reducing

screening to cholesterol, glucose, and alanine aminotransferase tests only. 4 tables, 41 references.

9

TITLE: Screening for Diabetes Mellitus in General Practice Using a Reflectance Meter System: The Islington Diabetes Survey. Forrest, R.D.; Jackson, C.A.; Yudkin, J.S. *Diabetes Research*. 6(3): 119-122. November 1987.

OBJECTIVE: To assess the accuracy of a reflectance meter system in screening for diabetes mellitus in a community-based screening program; to compare the results obtained with the laboratory assessment of blood glucose; and to estimate the costs of screening for diabetes mellitus with this system.

CATEGORY: Secondary intervention.

Type of Study: Population screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The reflectance meter system accurately estimated the prevalence of diabetes mellitus in the study population. Blood glucose concentrations obtained with the reflectance meter were higher than those of the laboratory assay, and confirmatory glucose tolerance tests were needed in a large number of misclassified patients. However, total costs of screening, even with the additional confirmatory glucose tolerance tests, were still significantly lower for the reflectance meter assay.

RECOMMENDATION: The glucose reflectance meter system, along with confirmatory glucose tolerance tests, can provide an acceptable, lower-cost alternative to the autoanalyzer glucose-oxidase method of blood glucose assay for community-based screening for diabetes mellitus.

ABSTRACT: The authors assessed the accuracy and costs of a reflectance meter system for screening for diabetes mellitus and compared the results obtained with laboratory assessment of blood glucose. As a component of the Islington Diabetes Survey, 1,084 randomly selected persons over age 40 were screened with an oral glucose tolerance test after an overnight fast. Two-hour blood glucose was measured using an automated glucose-oxidase method. For 530 persons, blood glucose was also measured using the reflectance meter system. The reflectance meter system gave an acceptable estimate of the prevalence of diabetes mellitus, identifying 14 of the 15 cases found by the glucose-oxidase system, but it did not provide an accurate estimate of the prevalence of impaired glucose tolerance. (Reflectance meter values were higher than glucose-oxidase values in 82 percent of cases.) Costs associated with screening the 530 individuals were calculated at £1,166.00 for the glucose-oxidase method and £358.75 for the reflectance meter. Confirmatory glucose tolerance tests were required in 29 persons on the basis of glucose-oxidase values and in 47 on the basis of reflectance meter values. Total costs for these confirmatory tests were estimated at £1,460.90 for patients initially screened

via glucose-oxidase and £857.95 for those screened by the reflectance meter. Estimated total costs per case of diabetes mellitus identified were £97.39 for the glucose-oxidase method and £ 61.28 for the reflectance meter. The authors conclude that the reflectance meter is an acceptable screening tool for diabetes; it is less costly, it is simpler and easier to use, and it provides results faster than the glucose-oxidase method. 2 figures, 1 table, 16 references.

10

TITLE: Screening for Retinopathy: A Relative Cost-Effectiveness Analysis of Alternative Modalities and Strategies. Sculpher, M.J.; Buxton, M.J.; Ferguson, B.A.; Spiegelhalter, D.J.; Kirby, A.J. *Health Economics*. 1(1): 39-51. April 1992.

OBJECTIVE: To assess the relative cost-effectiveness of various screening strategies for retinopathy associated with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Systematic screening carried out in the general practitioner's office at the same time as routine diabetes care checks can save considerable costs over screening that requires additional visits to a hospital or an optician.

RECOMMENDATION: None.

ABSTRACT: The authors used data from a 1985-1988 English study of the cost-effectiveness of screening for retinopathy to compare various screening options, including single modalities (either ophthalmoscopy or fundus photography), combined approaches, and selective screening. The base study was conducted at three community-based health centers in England; 3,423 patients with diabetes were screened. The authors defined cost-effectiveness as cost per true-positive case detected. Total cost per patient for ophthalmoscopy at the general practitioner's office was £ 20.66; at an optician's office, £ 19.31; for fundus photography, this cost was £ 25.46 at the hospital and £ 14.87 at the general practitioner's office (costs at the general practitioner's office were less if screening was part of a general checkup). The sensitivity of these approaches (in the order just listed) was 0.53, 0.48, 0.40, and 0.58; specificity was 0.91, 0.94, 0.96, and 0.97. Combined approaches (e.g., both ophthalmoscopy and fundus photography at the general practitioner's office) had higher sensitivity but lower specificity. Expected cost per true-positive case detected was £ 784 for ophthalmoscopy (same for general practitioner and optician), £ 1,178 for hospital-based fundus photography, £ 497 for photography at the general practitioner's office, £ 734 for both ophthalmoscopy and photography at the general practitioner's office, and £ 968 for ophthalmoscopy by an optician combined with photography at a general practice. If screening at the general practitioner's office was combined with regular follow-up, these costs dropped to £ 273 for ophthalmoscopy, £ 434 for fundus photography, £ 419 for ophthalmoscopy plus

photography, and £ 914 for photography at the office combined with ophthalmoscopy on the optician's premises. Among the selective screening options, directly referring high-risk patients and not screening those who were low-risk had the lowest cost per true-positive case (£ 168) but only 0.25 sensitivity. Directly referring high-risk patents and providing both ophthalmoscopy and photography at the general practitioner's office had a sensitivity of 0.85 and a cost per true positive of £ 679 (£ 407 if part of a general check-up). 1 figure, 5 tables, 42 references.

11

TITLE: Targeted Screening for Diabetes in Community Chiropody Clinics. Gill, G.V.; Lishman, L.; Kaczmarczyk, E.; Tesfaye, S. *Quarterly Journal of Medicine*. 89:229-232. 1996.

OBJECTIVE: To assess the cost-effectiveness of screening for diabetes in adults attending community podiatry clinics.

CATEGORY: Secondary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Screening was simple and very cost effective, but the diagnostic yield was moderate.

RECOMMENDATION: Screening of a podiatry clinic's population for diabetes cannot be recommended without knowing what percentage of that population is already known to have diabetes.

ABSTRACT: Patients who have known foot problems may have an increased likelihood of having diabetes. In this study, which was based in Liverpool, England, all patients aged 40 to 75 years attending community chiropody (podiatry) clinics who were not previously known to have diabetes were offered postprandial screening for glycosuria. Patients who reported positive results on the self-test were brought to the hospital for a glucose tolerance test. Of 1,058 patients who accepted screening, 11 (1.0 percent) reported positive results; of this group, 4 had diabetes, 2 had impaired glucose tolerance, and 5 had normal glucose tolerance. The cost for each person screened was 11 pence; for each person with a positive urine test, £ 2.06; and for each newly diagnosed patient with diabetes, £ 34.46. No cost was included for staff time in the coordinating hospital chiropody department to respond to the participants. The authors indicate that their slightly disappointing result (0.4 percent new diabetes patients) is probably due to the very high proportion (17.3 percent) of Liverpool chiropody clinic patients already known to have type 2 diabetes. According to the authors, screening of a podiatry clinic's population cannot be recommended without knowing its proportion of already identified diabetes patients. They also observe that a major difficulty with screening for type 2 diabetes is the lack of a sufficiently sensitive and specific test. The authors also point out that handing out rather than mailing the test strips was cost-saving, as was having

the patients telephone in their results. 1 figure, 2 tables, 15 references.

12

TITLE: Value of Serum Glucose Assay as Part of the Biochemical Profile in Screening for Diabetes. Northam, B.E.; Smith, J.H.; Fitzgerald, M.G.; Nattrass, M.; Wright, A.D. *Annals of Clinical Biochemistry*. 19(6): 412-415. November 1982.

OBJECTIVE: To evaluate a system of identifying patients with previously undetected diabetes that begins with a screening assay for serum glucose.

CATEGORY: Secondary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Addition of serum glucose testing for inpatients undergoing other laboratory evaluations is a useful and cost-effective method of screening for diabetes.

RECOMMENDATION: None.

ABSTRACT: The authors report the effectiveness and cost of diabetes screening for adult inpatients at General Hospital in Birmingham, England, during 3 months in 1980. A serum glucose test was added to the routine biochemical profiles of 2,050 patients; 453 had values of 10 mmol/L or higher. After elimination of those known to have diabetes or receiving intravenous glucose, 152 patients underwent capillary blood glucose tests; 71 had elevated values. Ten of these patients were referred to the diabetes clinic, 42 underwent oral glucose tolerance testing, and 19 were lost because of illness, death, or discharge. Fifteen patients were found to have normal glucose tolerance, 11 had impaired glucose tolerance, and for 16, the glucose tolerance test was in the diabetes range (3 of these 16 patients were referred to the diabetes clinic). Retesting as outpatients 3 months later resulted in referral of two of the patients with impaired glucose tolerance and one with apparent diabetes to the diabetes clinic. In all, 16 patients with previously undetected diabetes were identified. Additional costs on an annual basis for direct screening were £ 500 for serum glucose testing (reagent only), £ 320 for 2 blood glucose tests (including labor for sample collection and analysis), and £ 440 for oral glucose tolerance testing, for a total of £ 1,260, or £ 20 per case of diabetes identified (64 cases in a year). If time for staff (other than the clinical staff) to eliminate patients with diabetes and on intravenous glucose was added, the total per case would be doubled. The prevalence of diabetes (0.8 percent of inpatients) may have been underestimated because of losses to follow-up (30 patients), size of dose of glucose for the glucose tolerance testing (50 g rather than 75 g), arbitrary selection of serum glucose concentration required for follow-up, and elimination of patients receiving intravenous glucose. The true prevalence of diabetes was probably 0.8 percent to 3.5 percent. This screening method is cost effective, based on the additional screening cost of only £ 20 per case of diabetes identified. 1 figure, 2 tables, 8 references.Disease Management

13

TITLE: Adherence to Treatment and Social Support in Patients with Non-Insulin Dependant Diabetes. Garay-Sevilla, M.E.; Nava, L.E.; Malacara, J.M.; Huerta, R.; Díaz de León, J.; Mena, A.; Fajardo, M.E. *Journal of Diabetes and Its Complications*. 9(2): 81-86. April-June 1995.

OBJECTIVE: To evaluate factors associated with adherence to diet and medication in patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Adherence to diet was associated with years since diagnosis and greater social support; adherence to medication was associated with greater social support and older age of spouse.

RECOMMENDATION: Further research should be conducted to identify psychological and social factors that influence adherence to diet and medication in patients with type 2 diabetes.

ABSTRACT: The authors studied 200 adults with type 2 diabetes recruited from diabetes support groups at two hospitals in Leon, Mexico. Only about 20 percent of patients invited actually participated in the study. These patients completed validated questionnaires detailing adherence to treatment, social support, lifestyle, family structure, family function, and knowledge of diabetes. Adherence to diet was associated with years since diagnosis ($p = 0.003$) and greater social support ($p = 0.007$); adherence to medication was associated with greater social support ($p = 0.002$) and older age of spouse ($p = 0.016$). Patients with rigid control in their families had lower adherence to medication than patients where families had laissez-faire or flexible control. Evaluation of the psychological and social factors that influence adherence to diet and medication is essential because of their important role in the management of patients with type 2 diabetes. 1 figure, 3 tables, 18 references.

14

TITLE: Analysis of Direct Cost of Standard Compared with Intensive Insulin Treatment of Insulin-Dependent Diabetes Mellitus and Cost of Complications. Stern, Z.; Levy, R. *Acta Diabetologica*. 33(1): 48-52. March 1996.

OBJECTIVE: To compare the direct costs of standard and intensive insulin treatment for type 1 diabetes; to compare these approaches when their impact on complications is considered.

CATEGORY: Secondary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: According to the authors' model, standard insulin therapy was less expensive over a 35-year period than was intensive insulin therapy, whether or not the cost of complications was considered.

RECOMMENDATION: Because of the high direct costs of intensive treatment, guidelines should be developed to better identify, select, and treat those patients for whom such therapy is warranted. Intensive treatment should be aimed particularly at patients with nephropathy.

ABSTRACT: The authors modeled annual treatment costs over a 35-year period for a hypothetical patient who had contracted type 1 diabetes at a young age. Results in the literature, including findings of the Diabetes Control and Complications Trial, were used in the model, as was standard practice in Israel, which follows the recommendations of the American Diabetes Association. Annual direct costs (in 1995 dollars) for standard and intensive insulin treatment were calculated to be $1,184 and $3,329 per patient, respectively. Over a 35-year period, total direct costs per patient were $41,000 and $116,000 for the standard and intensive treatments, respectively, a difference of $75,000. The authors found that intensified treatment lowered complication costs by $53,520 (versus standard treatment). Thus, total direct costs of standard therapy were $329,400, versus $350,980 for the intensified treatment. Assuming a discount rate of 6 percent, it was estimated that the intensive treatment entailed lower complication costs (by $20,900) than the standard treatment, but the total cost of the standard treatment was $132,900, compared with $151,900 for the intensive treatment. 3 tables, 16 references.

15

TITLE: Assessment of the Effect of a Comprehensive Diabetes Management Program on Hospital Admission Rates of Children with Diabetes Mellitus. Drozda, D.J.; Dawson, V.A.; Long, D.J.; Freson, L.S.; Sperling, M.A. *Diabetes Educator*. 16(5): 389-393. September-October 1990.

OBJECTIVE: To determine the impact of a comprehensive diabetes management program on hospitalization parameters in children with diabetes seen at a major pediatric referral center.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Care provided through the diabetes management program is expected to save $342,000 annually in direct health service costs.

RECOMMENDATION: Comparison of data from pediatric hospitals not offering comprehensive diabetes programs would help to assess the impact of such programs.

ABSTRACT: The authors evaluated the impact of a comprehensive diabetes management program initiated in July 1978 on admission of children with diabetes mellitus to Children's Hospital Medical Center in Cincinnati, Ohio. Those in the study had a primary diagnosis of type 1 diabetes; the main reason for admission was diabetic ketoacidosis, hyperglycemia, or hypoglycemia. Admission records from January 1973 through December 1987 were reviewed; comparisons were made of admission parameters for January 1973 to June 1978 (period A) and July 1978 to December 1987 (period B). The program included medical and support services and individualized educational interventions; two telephone hot lines were provided as well. Admissions for type 1 diabetes not associated with diabetic ketoacidosis or other diagnoses rose from 27 percent of all admissions in period A to 37 percent in period B ($p = 0.01$). The proportion of admissions for diabetes that were for diabetic ketoacidosis not associated with other diagnoses decreased from 63 percent in period A to 29 percent in period B ($p = 0.0001$). This positive outcome may have reflected the effect of the education program on patient self-management. Mean length of stay for admissions for diabetic ketoacidosis only decreased from 5.8 days (period A) to 4.6 days (period B) ($p = 0.01$), but the introduction of managed care may have encouraged early discharge. 2 figures, 2 tables, 13 references.

16

TITLE: Audit in General Practice by a Receptionist: A Feasibility Study. Essex, B.; Bate, J. *British Medical Journal*. 302(6776): 573-576. March 9, 1991.

OBJECTIVE: To assess whether a medical practice audit, including care of patients with diabetes, can be performed cost effectively by a practice's receptionist.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The practice audit was performed by the receptionist in a cost-effective

manner.

RECOMMENDATION: Audit by a practice's receptionist should be considered a cost-effective alternative to audit by the physicians themselves.

ABSTRACT: The authors assessed the feasibility and cost-effectiveness of having a medical practice audit performed by a practice receptionist. The practice was composed of 6 physicians in London, England, treating 11,500 patients. A system developed to allow the receptionist to audit medical records was evaluated over a 2-year period. Patients with diabetes were identified from disease registers; most data were derived from patient records. A total of 136 patients with diabetes were identified by the receptionist and their records reviewed. The receptionist provided the practice with a breakdown of the level of care (general practitioner only, hospital only, shared, or unknown). The receptionist notified practice physicians of any patients with diabetes under the care of a general practitioner who had not had an annual review. The receptionist spent about 4 hours weekly performing the audit as part of her general duties at a cost of £ 5.20 per hour (£ 960 per year). Regular supervision of the receptionist the first year lasted about 30 minutes weekly; in the second year, about 30 minutes every 2 weeks. After deduction of reimbursements and tax, the cost came to £ 30 per practice physician per year. This system was extremely cost-effective compared with the costs that would be incurred were physicians to perform the audit themselves. 4 figures, 10 references.

17

TITLE: Bedside Blood Sugar Determinations in the Critically Ill. Newman, R.H. *Heart and Lung*. 17(6 Part 1): 667669. November 1988.

OBJECTIVE: To compare various glucose monitoring systems with standard laboratory testing in terms of accuracy and cost-effectiveness.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Results for a bedside system called the Glucoscan 2000 were highly correlated with hospital laboratory results, but the bedside system took less time (mean: 2.4 minutes versus 2.6 hours) and was significantly less expensive (for 110 determinations, $55 in costs versus $990 in charges).

RECOMMENDATION: Glucose monitoring systems cannot and should not replace laboratory glucose determinations, but they can greatly reduce their frequency and supplement expensive laboratory data. A quality control regimen must be implemented for the selected glucose monitoring device to ensure its accuracy.

ABSTRACT: Intensive care unit patients may have large fluctuations in blood glucose concentration; accurate and timely glucose values must be obtained so that these fluctuations may be stabilized. The author compared three blood glucose monitoring systems (AccuCheck, Glucometer, Glucoscan 2000) with the hospital laboratory; there were no significant differences in results between the systems. In a subsequent 3month study, the Glucoscan 2000 and hospital laboratory performed 110 blood glucose determinations in 41 patients; for the first 50 blood glucose tests, mean completion time was 2.4 minutes for the Glucoscan 2000 and 2.6 hours for the hospital (routine) or 0.5 hours ("stat"). Laboratory charges for 110 laboratory determinations totaled $990, versus Glucoscan costs of $55. The author concludes that blood glucose monitoring systems can be effective for close monitoring of blood glucose in the intensive care unit or elsewhere. The purchase price of the Glucoscan 2000 was $127. 1 figure, 2 tables, 16 references.

18

TITLE: Cardiovascular Morbidity and Mortality in Type 2 Diabetic Patients: A 22 Year Historical Cohort Study in Dutch General Practice. de Grauw, W.J.C.; van de Lisdonk, E.H.; van den Hoogen, H.J.M.; van Weel, C. *Diabetic Medicine*. 12(2): 117122. February 1995.

OBJECTIVE: To assess the impact of cardiovascular morbidity and mortality on patients in general practice with type 2 diabetes over a 22year period.

CATEGORY: Secondary intervention.

Type of Study: Historical cohort.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Patients in general practice with type 2 diabetes were at higher risk of cardiovascular morbidity, mortality from any cause, and cardiovascular mortality than were those without diabetes.

RECOMMENDATION: None.

ABSTRACT: An historical cohort study was performed to measure cardiovascular morbidity and mortality in patients with type 2 diabetes; data were collected from 1967 to 1989 in four Dutch general practices involved in the Continuous Morbidity Registration Nijmegen. A total of 265 patients with type 2 diabetes (112 men, 153 women) who met World Health Organization (WHO) criteria were included in the cohort. The remaining 162 patients who were registered during the study period as diagnosed with diabetes were not included because they did not meet WHO criteria or because of other reasons. At diagnosis, 60 percent of the study cohort were aged 65 or under; mean follow-up was 6.8 years. Compared with a matched control group of persons without diabetes, those with type 2 diabetes had higher cardiovascular morbidity (risk ratio, 1.76; 95 percent confidence interval, 1.34 to 2.30). The risk of mortality was also higher in patients with diabetes than in controls (relative risk, 1.54;

95 percent confidence interval, 1.07 to 2.23). Relative risk of cardiovascular mortality was 2.05 in patients with diabetes (95 percent confidence interval, 1.24 to 3.37). Mortality after 10 years for patients with type 2 diabetes was 36 percent, versus 20 percent for the control group ($p < 0.01$). Cumulative survival rates in the group aged 65 to 74 years were significantly lower ($p < 0.01$) in patients with type 2 diabetes than in controls. 2 figures, 3 tables, 32 references.

19

TITLE: Care of the Diabetic Child in the Community. Farquhar, J.W.; Campbell, M.L. *British Medical Journal*. 281(6254): 1534-1537. December 6, 1980.

OBJECTIVE: To describe community care for children with newly diagnosed type 1 diabetes, and to describe in-hospital care for such children.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Descriptive analysis.
Perspective: Health care system.

CONCLUSION: Admitting children with newly diagnosed diabetes to the hospital, then providing them with a home care team, offers numerous advantages for the children and their parents.

RECOMMENDATION: None.

ABSTRACT: The authors describe experience with children newly diagnosed with diabetes who have been admitted to the Royal Hospital for Sick Children in Edinburgh, Scotland. Admitting to the hospital a child newly diagnosed with diabetes along with one or both parents allows parents to develop trust in the staff, to learn more effectively about their child, and to meet the home care sisters. Staff can obtain an indication of parental ability and stability, and an insulin reaction can be induced safely so that the parent can watch the child's reaction to hypoglycemia. The child is normally discharged within 1 week. Having a home care team enabled the hospital to have an average length of stay of about 4.5 days in 1976, versus the national average of 8 days. The home care team permits reduced readmissions, relieves maternal and school teacher anxiety, and decreases school absences. The home care team continually assesses the home — its organization, finances, presence of alcoholism, stability of the parents and marriage, relationships of parents and children and relationships between children, how procedures are conducted, and the extent to which parents seek further education toward controlling diabetes. The home care team visits the school and briefs staff and the school nurse on symptoms and treatment of hypoglycemia and the needs of the child. The team provides continuing care through phone consultations, visits the home when the children are in school, and obtains spot urine specimens or blood checks if there is a question of diabetic control. To avoid disharmony between the hospital clinic and the primary care and community health services, each important contact with the home care team or the unit staff should be recorded. 4 references.

20

TITLE: A Comparison of Accuracy and Estimated Cost of Methods for Home Blood Glucose Monitoring. Shapiro, B.; Savage, P.J.; Lomatch, D.; Gniadek, T.; Forbes, R.; Mitchell, R.; Hein, K.; Starr, R.; Nutter, M.; Scherdt, B. *Diabetes Care*. 4(3): 396-403. May-June 1981.

OBJECTIVE: To compare the accuracy, convenience, and cost of various methods of home blood glucose monitoring.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: All the capillary blood glucose methods correlated well with laboratory blood glucose measurements and all were more accurate than urine glucose measurements. The Chemstrip bG was the least expensive and easiest method to measure blood glucose concentrations at home.

RECOMMENDATION: None.

ABSTRACT: The authors compared accuracy, convenience, and cost of four products for home blood glucose monitoring. Sixteen patients used Eyetone, Dextrometer, StatTek (all of which used a reflectance meter and a reagent strip), and Chemstrip bG (reagent strip only) twice daily within 1 minute of collection of venous blood for laboratory blood glucose measurement. Urine glucose was measured from collections made before and after blood collection. For laboratory blood glucose concentrations of 48 to 464 mg/dL and 48 to 250 mg/dL, correlation coefficients for Eyetone, Dextrometer, and StatTek reflectance meter readings (by a physician or nurse) and for Chemstrip bG readings by the patient, a nurse, and a physician ranged from 0.90 to 0.95 and from 0.85 to 0.92, respectively ($p < 0.0001$). All home blood glucose monitoring methods except StatTek underestimated blood glucose concentrations between 48 and 250 mg/dL. The correlation coefficient for urine glucose concentrations was 0.74. When Chemstrip bG was reread at intervals over 14 days, glucose readings decreased by 6.8 to 10.1 percent (not clinically significant) in the first 2 days; no further decrease was noted. The coefficient of variation (CV) for repeated readings of the three reflectance meters was 8.9 to 12.0 percent for nurses and 6.7 to 9.0 percent for physicians; the CV for Chemstrip bG was 17.8 and 11.6 percent, respectively. The costs (1980 dollars) per glucose determination (excluding cost of reflectance meter) for Dextrometer, Eyetone, StatTek, and Chemstrip were $0.71 to $1.32, $0.51 to $0.71, $0.72 to $1.01, and $0.53, respectively, and reflectance meters for the first three cost between $339.95 and $395.00. The Chemstrip bG method is easy to use and less expensive than the other systems, and readings can be verified by a physician up to 2 weeks later. 3 figures, 5 tables, 26 references.

21

TITLE: Comparison of Different Models of Diabetes Care on Compliance with Self-Monitoring of Blood Glucose by Memory Glucometer. Hoskins, P.L.; Alford, J.B.; Handelsman, D.J.; Yue, D.K.; Turtle, J.R. *Diabetes Care*. 11(9): 719-724. October 1988.

OBJECTIVE: To evaluate the accuracy of patient-generated records of blood glucose concentrations, and to determine whether the model of diabetes care influences the validity of these patient records.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: There was no difference in validity of reported blood glucose results based on instruction technique, but private health insurance status was associated with greater validity of patient records.

RECOMMENDATION: Health professionals should not assume that patients will follow treatment instructions because they have been fully counseled.

ABSTRACT: The authors evaluated 34 patients with diabetes on their self-monitoring of blood glucose. Participants had been referred to the diabetes center of Royal Prince Alfred Hospital in Camperdown, Australia; 17 had gestational diabetes; 13 had type 2 diabetes; and 4 had type 1 diabetes. Participants were randomized to one of three models of instruction: mutual decision making (emphasized team approach; patient could adjust treatment based on results), didactic (nurse educator would make decisions based on results), and authoritarian (physician would make decisions based on results). Participants performed blood glucose estimations four times daily over 2 weeks using a blood glucose monitor with memory but were not informed of the memory capacity. Blood glucose results recorded in patient logbooks were compared with monitor records. No difference was found in the validity of patients' records by instruction group. The overall proportion of correctly recorded estimations was 86 percent; 70 percent of examinations were actually performed as requested and correctly recorded, and another 16 percent were correctly recorded as not done. Conversely, 30 percent of scheduled examinations were not performed properly or were recorded incorrectly. Compared with patients with type 2 diabetes, patients with gestational diabetes recorded a lower percentage of blood glucose estimations accurately. Private health insurance was one of two predictors of greater validity of blood glucose records (the other was perceived high intelligence). Although there were no direct financial disincentives for compliance with testing, as patients were not required to copay, health insurance status may represent a surrogate socioeconomic indicator. Some patients may have experienced financial or social pressures that act as a barrier to successful completion of diabetes self-care activities. 6 tables, 8 references.

22

TITLE: Continuous Quality Improvement Can Improve Glycemic Control for HMO Patients with Diabetes. O'Connor, P.J.; Rush, W.A.; Peterson, J.; Morben, P.; Cherney, L.; Keogh, C.; Lasch, S. *Archives of Family Medicine*. 5(9): 502-506. October 1996.

OBJECTIVE: To evaluate the impact of a continuous quality improvement (CQI) intervention on glycemic control of patients with diabetes mellitus attending a primary care clinic.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Use of a CQI intervention can improve glycemic control without increasing utilization or charges.

RECOMMENDATION: Health care providers should consider implementing CQI to improve adult diabetes care; several of the strategies developed by the CQI team may be useful for other primary care settings.

ABSTRACT: The authors analyzed the effect of implementing a CQI plan on glycemic control in patients with diabetes. Patients were followed for 18 months at two clinics of a Midwest staff model health maintenance organization. The intervention clinic had 4,100 patients; the comparison clinic, 4,700 patients. The staff at the intervention clinic developed a computerized patient audit system and held monthly 1-hour CQI meetings. The patient audit and review of the process of care led to a modified system using computerized printouts, targeting certain patients for special attention, and authorizing more aggressive outreach by resource nurses. Patients were selected for readiness to undertake behavioral change and given appropriate levels of support. Success of management was based on change in glycosylated hemoglobin (HbA_{1C}) levels. After intervention, in the CQI and comparison clinics, respectively, (HbA_{1C} levels were acceptable, $\leq$ 8 percent) in 51 versus 40 percent of patients, fair (8 to 10 percent) in 37 versus 33 percent, and poor ($\geq$ 10 percent) in 12 percent versus 27 percent ($p = .008$). Intervention clinic patients had significant improvement in HbA_{1C} levels relative to patients at the comparison clinic ($p = .01$). Mean outpatient visits at the intervention and the comparison clinics were 7.86 and 7.40 prior to and 9.08 and 8.96 after initiation of CQI, respectively. Mean charges for outpatient services were $991 and $958 prior to and $1,218 and $1,281 after initiation of CQI, respectively. 1 table, 25 references.

23

TITLE: A Cost-Benefit Analysis of Subcutaneous Insulin Pump Infusion Therapy for Insulin-Dependent Diabetes Mellitus. Turkelson, C.M.; Coates, V. Abstract 195. *Annual Meeting of the International Society for Technology Assessment in Health Care*. 11. 1995.

OBJECTIVE: To compare the costs of subcutaneous insulin pump infusion therapy and conventional therapy for type 1 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Insulin pump therapy may be more cost-beneficial than conventional therapy, but it may take 9 years of treatment for this to be true. How many patients will remain on pump therapy for this long is not known.

RECOMMENDATION: The conclusions of this study and other cost analyses of insulin pump therapy must be treated cautiously.

ABSTRACT: The authors used Markov analysis to compare the costs of insulin pump and conventional therapy. Separate models were used to determine treatment-specific costs associated with diabetic nephropathy, retinopathy, and amputations. When just retinopathy and amputations were considered, insulin pump therapy did not provide as great a cost-benefit as conventional therapy. However, the savings associated with the third complication (diabetic nephropathy) were large enough for a greater cost-benefit to be realized for insulin pump therapy after 9 years of treatment when all three complications were considered simultaneously. The authors note that the proportion of patients who should be given this type of therapy (or any form of intensive therapy) is unknown, as is the effectiveness of this therapy under regular clinical practice conditions.

24

TITLE: Cost-Effectiveness Analyses of the Conversion of Patients with Non-Insulin-Dependent Diabetes Mellitus from Glipizide to Glyburide and of the Accompanying Pharmacy Follow-up Clinic. Law, A.V.; Pathak, D.S.; Segraves, A.M.; Weinstein, C.R.; Arneson, W.H. *Clinical Therapeutics*. 17(5): 977987. September/October 1995.

OBJECTIVE: To retrospectively evaluate the cost effectiveness of converting from glipizide therapy to glyburide therapy and of using a pharmacy follow-up clinic.

CATEGORY: Secondary intervention.

Type of Study: Patient management.

Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The conversion from glipizide to glyburide was cost effective, as was the follow-up clinic. For every 1 percent of patients in the follow-up group who achieved good glycemic control, the Department of Veterans Affairs would spend only $1.01 more per patient on costs related to the follow-up clinic.

RECOMMENDATION: Due to its cost-effectiveness, the conversion from glipizide to glyburide is recommended in practice settings similar to that of the Department of Veterans Affairs. Follow-up clinics are justifiable because they are cost effective and possibly increase patient compliance with the medication regimen or with nondrug factors (e.g., diet, exercise).

ABSTRACT: During a 6month period in 1993, the Department of Veterans Affairs Outpatient Clinic in Columbus, Ohio, converted patients with type 2 diabetes from glipizide to glyburide therapy as a way to reduce costs. For this retrospective study, patients were divided into groups: I included all 730 patients while they were being treated with glipizide; II, 408 patients who converted to glyburide and returned to the follow-up clinic; III, 244 patients who converted to glyburide but did not return to the follow-up clinic (records were missing for the other 78 patients). Cost data were gathered by examining the direct costs (in 1994 dollars) of the conversion and the follow-up clinic. Costs common to all three groups were not included in the analysis. The effectiveness measure was defined as the percentage of patients whose glycemic control was rated as good (i.e., fasting blood glucose 200 mg/dL or less). The authors found that the average mean daily dose for glipizide was 1.82 to 1.85 times that for the glyburide dose. Based on a daily dose of two 10mg tablets of glipizide (Group I) and two 5mg tablets of glyburide (Groups II and III), the cost savings to the Department of Veterans Affairs for the first year after conversion were $104,974.12 for Group II and $132,132.12 for Group III. Although Group III achieved higher cost savings, Group II had a higher percentage of patients who achieved good glycemic control. 5 tables, 14 references.

25

TITLE: Cost-Effectiveness Study of a Lipid-Lowering Therapy in Hyperlipoproteinaemia Type IIb and Type IV (Frederickson). Bergemann, R.; Brandt, A.; Siegrist, W. *PharmacoEconomics*. 3(Supplement 2): 131-139. February 1993.

OBJECTIVE: To conduct a cost-effectiveness analysis of four drugs (acipimox, bezafibrate, fenofibrate, and gemfibrozil) for treating patients with hyperlipoproteinemia types IIb and type IV (according to Frederickson), with and without type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: When hospitalization costs for treating gallstones are taken into account, acipimox is a more cost-effective therapy than the other three drugs.

RECOMMENDATION: None.

ABSTRACT: In this Swiss study, a computer model was developed of hyperlipoproteinemia types IIb and IV and their treatment. The study was based on up to 7 years of therapy; in 10.5 percent to 11.8 percent of patients, according to the model, the therapy was interrupted because of adverse events or inadequate therapeutic effect. Only direct costs were included (for drugs, physician visits, and hospitalizations for coronary vascular disease, coronary artery bypass graft surgery, peripheral arterial occlusive disease, and gallstone operations). Calculations were based on computer-aided medical decision analysis and the Monte Carlo method; the discount rate was 5 percent per year. Results from various epidemiologic and clinical trials were used to compare long-term outcomes. Efficacy studies with long-term endpoints are available for the three fibrate drugs; the authors used various studies to derive estimates for the effects of acipimox. Yearly costs of medication for the four drugs ranged from 434 to 446 Swiss francs. Annual treatment costs with the three fibrate drugs were about 100 Swiss francs more than with acipimox for both kinds of hyperlipoproteinemia, with or without type 2 diabetes. The risk of gallstones with the fibrate drugs was more than three times that for acipimox; this difference, according to the authors, explained the marked differences in the cost of therapy. The authors state that estimated savings with acipimox were conservative because only the cost of the hospital stay was included; additional expenses for diagnosing and treating gallstones as well as for lost productivity were not included. They note that the dosages (mg/day) in the study were specific to Switzerland: 500 for acipimox; 400, bezafibrate; 300, fenofibrate; and 900, gemfibrozil. 1 figure, 7 tables, 1 appendix, 38 references.

26

TITLE: The Costs and Effects of Two Different Lipid Intervention Programmes in Primary Health Care. Tomson, Y.; Johannesson, M.; Åberg, H. *Journal of Internal Medicine*. 237(1): 1317. January 1995.

OBJECTIVE: To compare the costs and effects of two different intervention strategies for the nonpharmacological treatment of hypercholesterolemia.

CATEGORY: Secondary intervention.

Type of Study: Other prospective trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: There was no difference in the effectiveness of the two intervention strategies.

RECOMMENDATION: Of the two strategies, the low-intensity program is preferable from a Cost-effectiveness viewpoint.

ABSTRACT: All persons aged 25 to 54 years who resided in the catchment area of a health center south of Stockholm were invited to a health check; 2,338 were screened for hypercholesterolemia. From a group of 372 persons found to have this disorder, the authors selected men and women with a serum cholesterol in the range of 7.07.8 mmol L-1. Those with hypertension, diabetes mellitus, and ischemic heart disease were excluded. The 92 persons who met all criteria were randomized to low-intensity (n = 45) or moderate-intensity (n = 47) intervention programs. The low-intensity program focused on diet modification; participants were given brochures. The moderate-intensity program, which followed Swedish national guidelines, also focused on diet modification but included more active involvement with the participant's general practitioner and with a dietitian. Both groups were followed for a year and compared with respect to serum cholesterol concentration and treatment costs in Swedish crowns (SEK), using 1993 prices. (Apart from the health care costs, the treatment costs for the patient included the time cost for the visits and travel costs to the health care center.) Both intervention strategies resulted in small decreases (3.3 percent for low intensity, 3.7 percent for moderate intensity) in total cholesterol, with no significant difference between the groups. The total cost per patient in the low-intensity group was SEK 753; in the medium-intensity group, SEK 3,614. The authors estimate that if only 30 percent of the population aged 25 to 54 years in Stockholm county with hypercholesterolemia were discovered by the primary health care system and followed the dietary advice, the net savings with the low-intensity model (versus the moderate-intensity model) would be SEK 93 million. 5 tables, 10 references.

27

TITLE: The Development of Community Orientated Recommendations for Diabetes Care in South Auckland. Wilson, P.; Simmons, D. *New Zealand Medical Journal*. 107(989): 456-459. November 9, 1994.

OBJECTIVE: To describe the development of recommendations for preventing and controlling diabetes and its effects in South Auckland, New Zealand, a community in which diabetes is a major public health priority.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Historical review.
Perspective: Societal.

CONCLUSION: The provision of scientifically derived data, followed by discussion of the data with community representatives and its subsequent dissemination throughout the community, has provided an opportunity to begin controlling diabetes in the South Auckland area.

RECOMMENDATION: Numerous recommendations are set forth in the body of the report.

ABSTRACT: South Auckland, New Zealand, a community with considerable socioeconomic deprivation, has many residents of Maori and Pacific Islander descent, two groups with a disproportionate risk for diabetes. In 1990-1991 the South Auckland Diabetes Survey canvassed all general practitioners and practice nurses in that district on diabetes management and barriers to care. Community experience was obtained from existing diabetes focus groups. Patients and selected general practitioners were interviewed about barriers to care. Additional interviews were conducted with physicians, dietitians, and others involved in diabetes care, and a 54-page preliminary information document was prepared. A 12-member planning group found the document to be too long and technical; a 4-page summary was prepared and distributed to a variety of groups. The next draft followed 12 meetings and extensive community consultation. Sixty-eight recommendations were eventually made on diabetes care, including altering the environment, coordination and standardization, access, cost reduction, diabetes support groups, foot and eye care, diabetes in pregnancy and impaired glucose tolerance, and screening. A cost-outcome evaluation of the plan suggested significant savings in direct health expenditure, and full funding was subsequently recommended. 1 table, 1 figure, 22 references.

28

TITLE: Diabetes in Urban African Americans: III. Management of Type II Diabetes in a Municipal Hospital Setting. Ziemer, D.C.; Goldschmid, M.G.; Musey, V.C.; Domin, W.S.; Thule, P.M.; Gallina, D.L.; Phillips, L.S. *American Journal of Medicine*. 101(1): 25-33. July 1996.

OBJECTIVE: To prospectively study the effectiveness of multidisciplinary, nonphysician, nonpharmacologic management in an urban outpatient setting of a largely African American group of patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Nonpharmacologic, nonphysician management of type 2 diabetes is effective in a socioeconomically disadvantaged population.

RECOMMENDATION: Further study is needed to identify risk factors for patient loss to follow-up.

ABSTRACT: The authors prospectively evaluated care provided to patients with type 2 diabetes in a municipal hospital clinic in Atlanta, Georgia; most study patients were African Americans and socioeconomically disadvantaged. At an initial visit, the diagnosis was confirmed, family history obtained, patient education initiated, and a nurse practitioner or registered nurse assigned for follow-up; obese patients were instructed in a hypocaloric diet. Drug therapy was initiated, adjusted, or eliminated based on fasting plasma glucose levels at each visit. Data were analyzed for 325 patients who returned for follow-up visits at 2, 4, 6, and 12 months. Patients were more likely to return if diagnosed less than 1 year previously, over age 55 years, or female; 80 percent missed at least 1 visit. Compared with initial levels, both fasting plasma glucose and glycosylated hemoglobin improved significantly in the first 2 months ($p < .001$); levels were somewhat higher at 12 months. Initially, 36 percent of obese patients were managed by diet only, 24 percent by sulfonylureas, and 40 percent by insulin. After 2 months, 70 percent were managed by diet alone; at 6 months, 61 percent; and at 12 months, 55 percent. Lean patients had little change in management over the 12 months. Neither weight gain nor loss correlated with metabolic control at 12 months. Keeping appointments correlated with better metabolic control. Average cost per patient visit for physician and staff salaries, rent, utilities, and administrative overhead was $59 (1994 costs). The program was effective for a socioeconomically disadvantaged population, but further study is needed to identify risk factors for patient loss to follow-up. 7 figures, 1 table, 37 references.

29

TITLE: Effect of Value-Added Utilities on Prescription Refill Compliance and Medicaid Health Care Expenditures: A Study of Patients with Non-Insulin Dependant Diabetes Mellitus. Skaer, T.L.; Sclar, D.A.; Markowski, D.J.; Won, J.K. *Journal of Clinical Pharmacy and Therapeutics*. 18(4): 295-299. August 1993.

OBJECTIVE: To determine the effect of mailed prescription-refill reminders, specialized packaging, or a combination of both interventions on prescription refill compliance and health service utilization among patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Mailed prescription refill reminders, specialized packaging, or a combination of both significantly increased patient refill compliance. Patients receiving both interventions also had decreased expenses for physician, laboratory, and hospital services.

RECOMMENDATION: Pharmacy-based value-added utilities should be used more under both public and private health insurance programs.

ABSTRACT: From 10 to 30 percent of patients with type 2 diabetes withdraw from prescribed treatment within 1 year of diagnosis; of the remainder, about 20 percent do not take enough prescribed medication to maintain their blood glucose at satisfactory concentrations. A randomized trial was undertaken to determine the effects of valued-added pharmacy services on the compliance of type 2 patients with prescription refills and their use of health services. The 1-year study included 258 Medicaid beneficiaries with previously untreated type 2 diabetes. Patients lived in South Carolina, were less than 65 years old, had prescriptions to administer 5 mg glyburide twice daily, and were not to have received an alternative sulfonylurea or used insulin after receipt of the initial glyburide prescription. The patients were assigned to one of four groups: a control group (standard pharmacy care), standard pharmacy care plus mailing of a reminder 10 days before the refill date, standard pharmacy care plus unit-of-use packaging, and standard pharmacy care plus both mailed refill reminders and unit-of-use packaging. The medication possession ratio (MPR) was used to compare groups; the MPR is the days' supply of medication obtained by the patient relative to the days in the study period (optimal = 1.00). Dispensing of drugs was authorized in 30-day supplies. Analysis of data after 1 year revealed that patients receiving mailed prescription refill reminders, unit-of-use packaging, or a combination of both achieved a significant ($p < 0.05$) increase in the MPR for sulfonylurea therapy relative to the controls. The MPR for those receiving both interventions was significantly higher than for the groups receiving one intervention. Multivariate regression analysis revealed that patients receiving both interventions had significant ($p < 0.05$) reductions in expenditures for physician, laboratory, and hospital services relative to the control group. 2 tables, 22 references.

30

TITLE: Efficacy of Insulin and Sulfonylurea Combination Therapy in Type II Diabetes. A Meta-Analysis of the Randomized Placebo-Controlled Trials. Johnson, J.L.; Wolf, S.L.; Kabadi, U.M. *Archives of Internal Medicine*. 156(3): 259-264. February 12, 1996.

OBJECTIVE: To evaluate the efficacy of combination therapy with insulin and sulfonylurea in type 2 diabetes by performing a meta-analysis of studies that met strict criteria.

CATEGORY: Secondary intervention.

Type of Study: Formal meta-analysis of randomized clinical trials.
Methodology: Data analysis.
Perspective: Health care system

CONCLUSION: Combination therapy improves glycemic control while lowering daily insulin dosages and without adversely affecting body weight. In developing countries, combination therapy is far less expensive than insulin monotherapy.

RECOMMENDATION: None.

ABSTRACT: Forty-three citations were obtained from a search of the MEDLINE database from January 1980 through March 1982; 16 studies with a total population of 351 participants were analyzed — these studies met strict criteria for study design and outcome measures. The meta-analysis showed that the combination of insulin and sulfonylurea improves metabolic control for periods of at least 16 weeks. This improved metabolic control is achieved despite a decrease in daily insulin dose and does not result in a significant change in body weight. Combination therapy appears to be more expensive than mono-therapy with insulin, as the total monthly cost for combination therapy is about $60 to $85, versus $20 for two daily injections of a total dose of 100 U of intermediate-acting insulin. However, for patients using insulin monotherapy, the costs of insulin administration are higher, more frequent glucose monitoring may increase expense, and more frequent office and emergency department visits may be needed. In addition, money could be saved by substituting a first-generation sulfonylurea such as tolazamide for a second-generation drug. However, second-generation sulfonylureas are dropping in price. In developing countries, the cost of sulfonylureas is minuscule compared with insulin. 7 tables, 61 references.

31

TITLE: Evaluation of a Practice-Based Programme of Health Checks: Financial Cost and Success at Risk Detection. Sacks, G.; Marsden, R. *Journal of the Royal College of General Practitioners*. 39(326): 369-372. September 1989.

OBJECTIVE: To evaluate the efficacy and cost of a screening program for cardiovascular risk factors among patients in a large group practice in Oxford, England.

CATEGORY: Secondary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The screening program increased recording of risk factors but its cost was not fully met by reimbursement for salaries or services.

RECOMMENDATION: To avoid the financial disincentive to general practitioners to provide such preventive medicine programs, salaries for program staff should be completely reimbursed by the government.

ABSTRACT: The authors evaluated the efficacy and cost of a screening program to identify patients at risk for cardiovascular disease in a large suburban group practice in Oxford, England. Costs for the unfunded program were to be recouped through fees generated by referrals for tetanus and polio shots and cervical cytology exams. Of 1,470 patients invited to

participate in the nurse-run health checks, 1,382 (94.0 percent) participated. In this group, 66 cases of previously undiagnosed hypertension and 11 cases of previously undiagnosed diabetes were identified. Just over one-third (34.9 percent) of patients were overweight and 27.0 percent smoked. Total cost of the program was £ 11,785, of which £ 11,510 was for staff salaries. Estimated service fees generated totaled only £ 1,167, which was adjusted to £ 1,342 to reflect patients who had died or left the area. With £ 8,057 of income added to this amount from 70 percent reimbursement of salaries, the screening program operated at a net cost to the practice of £ 2,386, or £ 1.73 per patient. This outcome casts doubt on the results of other studies that have suggested that the costs of government-recommended prevention programs can be fully recouped through item-of-service payments. 1 figure, 2 tables, 14 references.

32

TITLE: The Feasibility of a Potentially "Ideal" System of Integrated Diabetes Care and Education Based on a Day Centre. Day, J.L.; Johnson, P.; Rayman, G.; Walker, R. *Diabetic Medicine*. 5(1): 70-75. January 1988.

OBJECTIVE: To evaluate the feasibility of a new system of clinical and educational care designed to replace traditional diabetes clinics.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The new integrated diabetes care system improved quality of care of patients without incurring major costs.

RECOMMENDATION: None.

ABSTRACT: The authors evaluated a new, integrated diabetes care and education program in Ipswich, England, at a new day facility. Staff from a traditional hospital clinic were reorganized and the role of the specialist nurse changed to providing primary counseling (physicians also provided care in the new center). Clinic hours were revised and a new appointment system created. After 1 year, the new program was found to have provided a pleasant environment for diabetes care and education, largely eliminated excessive waiting time, established continuity in consultation, and made available a more comprehensive and systematized educational program. Mean glycosylated hemoglobin levels of patients did not differ significantly by whether they saw the physician or specialist nurse. These results were achieved without major additional expenses: building maintenance, £ 3,000; nursing staff, £ 2,275; phlebotomist services, £ 300; and receptionist services, £ 2,476. Most costs were within original financial targets. In addition, the British Diabetic Association provided a 3-year support grant of £ 17,129. Capital costs of the new building and equipment (total of £ 88,000) were considered small when spread over the potential lifetime of the building. 6 tables, 12

references.

33

TITLE: Fructosamine or Glycated Haemoglobin as a Measure of Diabetic Control? Allgrove, J.; Cockrill, B.L. *Archives of Disease in Childhood*. 63(4): 418-422. April 1988.

OBJECTIVE: To determine whether measuring fructosamine concentration is a suitable alternative or useful adjunct to the measurement of glycated hemoglobin A1 (HbA_{1C}) in the routine management of children with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: In children with diabetes, fructosamine values were well correlated with HbA_{1C} levels, but only when values outside the normal range were not excluded. Measuring fructosamine is not a direct substitute for assaying HbA_{1C}.

RECOMMENDATION: Use of fructosamine concentration for routine diabetes control monitoring, with HbA_{1C} assayed under select conditions, should be considered a cost-saving alternative to routine HbA_{1C} monitoring.

ABSTRACT: The authors evaluated the potential of measuring fructosamine concentration as an alternative or adjunct to HbA_{1C} measurement in routinely managed children with diabetes. HbA_{1C}, fructosamine, and total proteins were assayed in 61 children with diabetes and 30 normal children. Linear regression analysis showed a highly significant correlation in children with diabetes between HbA_{1C} and fructosamine; however, when values outside the normal range were excluded, the significant relation- ship disappeared. The same results were obtained when HbA_{1C} values were plotted against the fructosamine:protein ratio. In three newly diagnosed patients whose disease was being brought under control, fructosamine concentrations were lower than expected; in one deteriorating patient, values were higher than expected. The authors conclude that fructosamine is not a direct substitute for HbA_{1C}. The routine addition of a fructosamine test to a HbA_{1C} measurement would increase overall costs of assessing diabetic control (by 10 to 15 percent if the reagents are made up in the laboratory) and cannot be justified. Conversely, substituting fructosamine for HbA_{1C} monitoring would provide only small savings in a pediatric clinic and cannot be justified on clinical grounds. Using fructosamine for most routine monitoring, with HbA_{1C} assayed on selected occasions, would reduce overall costs of assessing diabetic control while retaining the

flexibility of having both assays available. 2 tables, 4 figures, 12 references.

34

TITLE: Importance of Outpatient Supervision in the Prognosis of Juvenile Diabetes Mellitus: A Cost/Benefit Analysis. Deckert, T.; Poulsen, J.E.; Larsen, M. *Diabetes Care*. 1(5): 281284. September/October 1978.

OBJECTIVE: To investigate whether outpatient follow-up visits to a subspecialized clinic have a favorable effect on survival of patients with type 1 diabetes, and to evaluate whether the cost of this effort is in reasonable proportion to the benefit obtained.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: A clear relationship was found between the frequency of outpatient visits to a subspecialized clinic and the duration of survival with diabetes. Outpatient supervision in a subspecialized clinic involves relatively little cost compared with the benefit derived.

RECOMMENDATION: None.

ABSTRACT: The study consisted of 180 insulin-treated patients with diabetes (89 females, 91 males) who had been referred for admission to the Steno Memorial Hospital in Denmark before their 15th year of diabetes. Sixteen patients could not be traced after 40 years of diabetes; the others were followed until death or until 40 years of diabetes. Subsequent to the first hospital admission, 77 patients never attended follow-up in the outpatient clinic; the others attended 1 to 145 times in the course of their first 20 years of diabetes. (Only outpatient visits that took place within these first 20 years were included in the authors' analysis.) The aim of the outpatient supervision was to keep the patient symptom free and socially well adapted, to avoid long periods of poor metabolic regulation, to prevent insulin reactions, and to adapt the treatment to intercurrent diseases. The authors found a clear correlation between the number of outpatient visits and the duration of survival with diabetes: patients seen more than 20 times in the outpatient clinic in the course of their first 20 years of diabetes had a longer survival with diabetes (mean, 38.5 years) than patients who did not have outpatient follow-up (mean, 26.6 years); this difference was highly significant ($p = 0.0001$). Those in the first group averaged 4.4 outpatient follow-up visits annually over a 12.5-year period (first visit was at an average of 7.5 years of follow-up). If regular follow-up for these patients produced 11.9 additional years of work, total benefit from years gained working (1976 earnings of an unskilled laborer were used) and hospital admissions eliminated was estimated to be $100,656. In contrast, cost per patient (1976 prices) of running the clinic for 40 years was estimated at $10,468. 1 figure, 1 table, 2 references.

35

TITLE: Inpatient or Outpatient Initiation of Insulin Therapy: Experience and Cost Effective Analysis in a Suboptimal Clinical Setting. Mengistu, M.; Lungi, Y.; Mamo, F. *Tropical and Geographical Medicine*. 43(1-2): 180-183. January-April 1991.

OBJECTIVE: To assess the safety, feasibility, and cost-effectiveness of initiating insulin therapy in an outpatient setting in an area where day-care centers for persons with diabetes do not exist.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Initiation of insulin therapy in the outpatient setting was safe, feasible, and cost effective even though the setting was suboptimal.

RECOMMENDATION: None.

ABSTRACT: The authors report initiation of insulin therapy in a suboptimal clinical setting in Ethiopia for patients with newly diagnosed diabetes mellitus. Between 1985 and 1989, 53 patients with diabetes and no impending or established ketoacidosis began insulin therapy as outpatients. Treatment began on a Monday to allow sufficient working days for patient education. Patients returned to the outpatient clinic for 3 to 4 weekly visits, then were followed every 2 to 3 months. Outpatient costs included clinic staff salaries and taxi fare; examining room rent was excluded as minimal. Results were compared with 51 retrospectively chosen inpatients hospitalized for insulin initiation because of distance from the clinic or existing practice. Inpatient costs included medical and nonmedical staff and the declarable cost of beds, which included food and other utilities. Costs for third-class (n = 46), second-class (n = 4), and first-class (n = 1) beds were 2.2, 12.0, and 30.0 Birr, respectively (2.07 Birr = $1 U.S.). Mean blood glucose levels before and after treatment were 357.9 and 197.6 mg/dl, respectively, for inpatients and 325.4 and 205.8 mg/dl, respectively, for outpatients. Mean weight before and after treatment was 44.8 and 49.1 kg, respectively, for inpatients and 53.3 and 56.4 kg, respectively, for outpatients. Mean insulin dose for inpatients and outpatients was 29.4 ± 14.7 units and 28.7 ± 9.2 units, respectively. Mean duration of hospitalization for inpatients was 24.3 ± 9.2 days. Total cost per outpatient visit was 6.8 Birr; total cost per inpatient day was 24.3 Birr. Total outpatient and inpatient costs were 1,346.2 and 30,115.0 Birr, respectively. The savings realized with outpatient care equaled $14,000 (U.S. dollars). Outpatient initiation of insulin therapy is safe, acceptable, and cost effective. 3 tables, 10 references.

36

TITLE: Insulin Injection Technique Can Be Taught without Hospitalization. Lester, F.T.; Demissie, Y.; Negash, A. *Ethiopian Medical Journal*. 28(4): 191-195. October 1990.

OBJECTIVE: To assess the feasibility of outpatient instruction in insulin injection technique for patients with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Outpatient instruction in insulin injection technique is safe and feasible.

RECOMMENDATION: None.

ABSTRACT: The authors assessed the feasibility of outpatient instruction in insulin injection technique as an alternative to the traditional Ethiopian practice of inpatient instruction for patients with diabetes. A total of 144 patients were instructed in insulin injection technique over a 1-year period at an Addis Ababa hospital; 85 of these patients were instructed while hospitalized and 59 were instructed as outpatients. Patients were instructed in a single group by two nurses; sessions were held 6 days a week. Outpatients needed an average of 4.7 days to learn the technique; an additional 3 to 4 weeks of frequent monitoring was needed to attain control. No severe hypoglycemic reactions were seen among the outpatients. Instruction was unsuccessful for two very symptomatic outpatients. Six to 16 months after the instruction period, 62.7 percent of the outpatients but only 50.6 percent of the inpatients were still attending the clinic. Hospitalization is disruptive and costly and diabetic control achieved there is artificial, i.e., control has not been achieved in the patient's natural environment. 3 tables, 6 references.

37

TITLE: Insulin-Glyburide Combination Therapy for Non-Insulin-Dependent Diabetes Mellitus: A Long-Term Double-Blind, Placebo-Controlled Trial. Casner, P.R. *Clinical Pharmacology and Therapeutics*. 44(5): 594-603. November 1988.

OBJECTIVE: To determine whether the combination of a sulfonylurea agent and insulin can improve glycemic control in patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The combination of a sulfonylurea agent and insulin did not improve glycemic control during the study year, and the extra cost and inconvenience of combination therapy would not make it worthwhile except in a few select patients.

RECOMMENDATION: Providing combination therapy in a pulse form instead of continually may be more effective and may need to be studied; insulin clamp studies are required to address insulin sensitivity.

ABSTRACT: Sixty-four patients with insulin-treated type 2 diabetes were treated with a combination of insulin and oral sulfonylurea therapy or insulin and a placebo in a double-blind controlled trial conducted over 12 months. There were no significant differences between the two groups of patients except for age; the control group was 4.2 years older. In the treatment group, fasting blood glucose concentrations were significantly below those for the control group only at 3 and 4 months. Insulin dose for the treatment group was significantly below the dose for the control group at month 8 only. In comparisons of the two groups, glycohemoglobin values were significantly lower for the control group at months 3 and 6 only; C-peptide levels were significantly higher in the treatment group at 3 and 9 months only. At each visit, placebo or glyburide was titrated to higher doses, with both groups attaining maximal dosage (20 mg/day). Oral glucose tolerance test results did not significantly differ between groups except at 3 months, when the control group's were higher. The treatment group was divided into responders (a fasting blood glucose concentration $\leq$ 140mg/dL on at least 3 visits and a 25 percent reduction in total daily insulin requirements sometime during the study) and nonresponders. Forty-two percent were responders; 29 percent of these responders received a > 50 percent reduction of insulin dose at some time during the study. By the end of the study, the daily insulin dose for responders was about 50 percent lower than that of the control group and non-responders, suggesting that combination therapy may improve insulin sensitivity and enhance insulin secretion. Patients in the treatment group experienced no serious side effects from the combination of insulin and glyburide. Combination therapy may increase the cost of treatment by nearly 50 percent, and its effect appears to be transitory in most patients. Patients most likely to benefit are those who show an increase in C-peptide levels when taking oral hypoglycemics. 6 figures, 2 tables, 41 references.

38

TITLE: Less Expensive, Reliable Blood Glucose Self-Monitoring. Spraul, M.; Sonnenberg, G.E.; Berger, M. *Diabetes Care*. 10(3): 357-359. May-June 1987.

OBJECTIVE: To determine whether splitting test strips for capillary blood glucose self-monitoring will permit reliable measurement of blood glucose levels.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Cutting capillary blood glucose test strips (Chemstrips bG) in half had no effect on the reliability of self-assessment of blood glucose levels and halved the cost of the test.

RECOMMENDATION: All patients should be advised to split their test strips (Chemstrips bG) to reduce the costs of blood glucose self-monitoring.

ABSTRACT: The authors tested the reliability of using split test strips to self-assess blood glucose levels by experimenting with Haemoglukotest 20-800 (Chemstrips bG) test strips. Ten participants (patients and laboratory personnel) who were trained in reading test strips but had never used split test strips were each asked to test blood samples using 10 full-size strips, 10 strips halved mechanically with a splitting device, and 10 strips halved manually with scissors. Results were compared with plasma glucose concentrations measured in a Beckman glucose analyzer. The correlation coefficients (r) values for uncorrected plasma glucose concentrations were 0.95 for full-thickness strips, 0.966 for mechanically split strips, and 0.966 for manually split strips, respectively. The mean absolute deviation from the reference value and standard error (in mg/dl) was 17 ± 2 for full strips, 17 ± 1 for mechanically split strips, and 17 ± 1 for manually split strips. There was no significant difference between the three self tests and the laboratory analyzer by analysis of variance ($p = .98$), variance between participants ($p = .12$), or interrelationship between participants' readings and the three methods ($p = .61$). Test strips reliably monitor blood glucose concentrations, and halving the strips with scissors cuts the cost of monitoring in half without reducing reliability. Patients should be advised to use split test strips to save money. 1 figure, 1 table, 5 references.

39

TITLE: Lifetime Benefits and Costs of Intensive Therapy as Practiced in the Diabetes Control and Complications Trial. The Diabetes Control and Complications Trial Research Group. *Journal of the American Medical Association (JAMA)*. 276(17): 14091415. November 6, 1996.

OBJECTIVE: To examine the costs and benefits of intensive treatment of type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Intensive therapy for those meeting eligibility criteria would improve quality and length of life and represents a good monetary value.

RECOMMENDATION: None.

ABSTRACT: The authors developed a Monte Carlo simulation model to estimate the lifetime benefits and costs of conventional and intensive insulin therapy for patients with type 1 diabetes. The intensive therapy regimen was designed to achieve blood glucose levels as close to the nondiabetic range as possible with three or more daily insulin injections or with treatment with an insulin pump, self-monitoring of blood glucose levels four times daily, and monthly outpatient visits with a multidisciplinary team. Conventional therapy consisted of one or two injections each day, daily self-monitoring, and quarterly visits. Data were collected as part of the Diabetes Control and Complications Trial (DCCT) and supplemented with data from other clinical trials and epidemiologic studies. The authors assumed that approximately 17 percent of the U.S. population with type 1 diabetes (120,000 persons) would qualify for enrollment in the DCCT. They included all direct medical costs for the Cost-effectiveness analysis but did not include direct nonmedical costs (e.g., transportation, lodging) or potential production losses arising from disease related absence from work, long-term disability, or premature death. The costs of conventional and intensive therapy were based on actual resources used in the DCCT. The Monte Carlo model simulated the course of the patient's disease over his or her expected lifetime. The authors found that implementing intensive rather than conventional therapy among the 120,000 persons meeting DCCT criteria would gain 920,000 years of sight, 691,000 years free from end stage renal disease, 678,000 years free from lower extremity amputation, and 611,000 years of life, at an additional cost of $4 billion (1994 U.S. dollars with future costs and effects discounted 3 percent) over the lifetime of the group. The incremental cost per year of life gained was $28,661. The incremental cost per quality-adjusted life-year gained with intensive treatment was $19,987. 2 figures, 4 tables, 49 references.

40

TITLE: Management of Patients with Diabetes by Nurses with Support of Subspecialists. Peters, A.L.; Davidson, M.; Ossorio, R.C. *HMO Practice*. 9(1): 8-13. March 1995.

OBJECTIVE: To describe a program for managing patients with diabetes via diabetes nurses within a health maintenance organization (HMO) system, and to report on the cost-effectiveness of the program.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Patients achieved significant decreases in glycated hemoglobin levels; the program appears to have achieved substantial cost savings by avoiding acute hospitalizations for diabetes in 244 patients.

RECOMMENDATION: None.

ABSTRACT: Staff at the Cedars-Sinai Medical Center in Los Angeles developed a program to manage diabetes patients called the Comprehensive Diabetes Care Service. Diabetes nurse specialists, supervised by diabetologists, provide diabetes and lipid management per protocols. Staffing ratios are one nurse and one staff assistant for each 250 patients with diabetes and one diabetologist for each 1,000 patients. An independent practice association at the hospital with approximately 150 physicians and a capitation contract with 12 HMOs (as of 1986) was persuaded to participate in the diabetes program. The program began in February 1987 with a capitated population of approximately 8,000; in July 1994, that population was approximately 65,000. Actual patients with diabetes followed in the program numbered 236 in January 1990 and 754 in December 1993. A diabetologist sees the patient in conjunction with the nurse initially and annually. The nurse sees the patient quarterly and follows a defined format at each visit. Patients are referred to a dietitian at entry and are seen by an ophthalmologist at their first visit. A computer system was designed to improve patient management. The authors found that glycated hemoglobin levels improved significantly ($p < 0.01$) in a subset of all patients and a subset of compliant patients but not in noncompliant patients. The authors estimated that over a 4-year period (1990 to 1993), 244 patients who would probably have been hospitalized by other physicians at the hospital were not because of the intensive outpatient follow-up available. The authors estimated the potential net cost savings to be $568,721 over the 4 years. 1 figure, 2 tables, 9 references.

41

TITLE: Nursing Case Management: An Innovative Model of Care for Hospitalized Patients with Diabetes. Edelstein, E.L.; Cesta, T.G. *Diabetes Educator*. 19(6): 517-521. November-December 1993.

OBJECTIVE: To evaluate the effect of using a diabetes team with a case management approach to quality of care and length of hospital stay.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Length of hospital stay was reduced for patients with a primary and secondary diagnosis of diabetes whose care was managed by the team. Blood glucose control before discharge was at least fair in more than 98 percent of team patients before discharge.

RECOMMENDATION: None.

ABSTRACT: The authors reported on 160 patients admitted to Beth Israel Medical Center in New York City who did not have private physicians. Eighty-five patients had a principal diagnosis of diabetes; 49, a secondary diagnosis of diabetes; and 26 were antepartum patients admitted for blood glucose control. A team consisting of a case manager, diabetes nurse

educator, diabetologist, and nutritionist managed the care of these patients. Consultations per patient totaled 7.5; average length of stay of the patients with a principal diagnosis of diabetes was 4.14 days, 58 percent lower than the hospital's 1990 average for such patients. For patients with a secondary diagnosis of diabetes, the average length of stay was 14 percent below the 1990 Beth Israel average. The study readmission rate was 7.33 percent within 30 days of discharge, but readmissions were unrelated to diabetes. The team patients had excellent (28.7 percent), good (26.9 percent), or fair (42.7 percent) blood glucose control prior to discharge. 3 figures, 14 references.

42

TITLE: Pointers to Preventing Hyperglycaemic Emergencies in Soweto. Buch, E.; Irwig, L.M.; Huddle, K.R.; Krige, L.P.; Krut, L.H.; Kuyl, J.M. *South African Medical Journal*. 64 (18): 705-709. October 22, 1983.

OBJECTIVE: To analyze emergency hospital admissions for hyperglycemia in Soweto, South Africa, including associated costs; to assess the use of health services by emergency patients before and after hospital admission.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Health service costs for admissions for hyperglycemic emergencies in Soweto were estimated as at least 462,000 rand (South African currency) in 1981; many admissions were preventable, and patient use of health resources and self-monitoring prior to and after admission were inadequate.

RECOMMENDATION: Ambulatory services for patients with diabetes should be developed and upgraded in Soweto, with the following specific considerations: improved patient education, allocation of special staff for hyperglycemic emergencies, establishment of a registry for such emergencies, improved records systems, and application of compliance-improving strategies.

ABSTRACT: The authors reviewed the incidence of admissions for hyperglycemic emergencies during a 2-month period in 1981 at Baragwanath Hospital in Soweto, the associated costs, and the use of health services by patients with diabetes prior to and following admission. Problems related to providing diabetes care are compounded in Soweto by poor socioeconomic conditions. During the study period, 60 patients were admitted for hyperglycemic emergencies; 15 (25 percent) died in the hospital; just 3 of the deaths may have been unrelated to the emergency. Of 56 patients interviewed, 7 percent were previously undiagnosed with diabetes. Average hospital stay was 20 days, and the estimated cost of treating the emergency admissions during the study period was 77,000 rand. Of the 49 patients known to have diabetes prior to admission, only 19 (39 percent) had attended any

health services 3 or more times during the 3 months before admission, and 25 percent had not attended a health service at all. (Three attendances would be the minimum to receive adequate medication.) Of the 36 patients with whom follow-up interviews were conducted 3 months after discharge, 12 (33 percent) had been readmitted. Extrapolating from the study sample, the cost of hyperglycemic emergencies to Soweto's health services was estimated as at least 462,000 rand for 1981. 5 figures, 3 tables, 7 references.

43

TITLE: Precision and Costs of Techniques for Self-Monitoring of Serum Glucose Levels. Chiasson, J.L.; Morrisset, R.; Hamet, P. *Canadian Medical Association Journal*. 130(1): 38-43. January 1984.

OBJECTIVE: To evaluate the accuracy and cost of blood glucose monitoring techniques involving a glucose oxidase reagent strip with or without a reflectance meter.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The techniques evaluated, particularly those involving reflectance meters, compared favorably with standard laboratory methods, were easy to perform, and were less expensive.

RECOMMENDATION: Blood glucose monitoring using a glucose oxidase reagent strip and reflectance meter should be considered a feasible, cost-effective alternative to standard laboratory testing.

ABSTRACT: The authors evaluated the accuracy and cost of seven blood glucose monitoring techniques available for patient self-monitoring; they also examined the correlation between serum glucose concentrations obtained. The blood glucose techniques, which involved a glucose oxidase reagent strip with or without a reflectance meter, were evaluated in more than 100 patients with or without diabetes. Two of the techniques were tested by members of a rotating staff of hospital nurses, all seven by a nurse specifically trained for the task, and four of the seven by the patients themselves. Results were compared with reference values determined by the hexokinase method in a hospital biochemistry laboratory using the Simultaneous Multiple Analysis, Computerized (SMAC) or Autoanalyzer II (AAII) (Technicon Instruments Corporation, Tarrytown, New York) assays. Costs were evaluated via a survey of drugstore prices. Techniques involving a reflectance meter showed excellent correlation with the laboratory reference method ($r2 = 0.85$ to 0.96) for all three types of testers. Correlation with the reference standard was poorer for techniques not involving a reflectance meter ($r2 = 0.69$ to 0.90); correlation improved when the techniques were performed by a specially trained nurse. Reflectance meters ranged in price (Canadian dollars) from $290 to $565. Costs for bottles of 25 reagent strips ranged from $13 to $19.80. Costs

for each determination using the self-monitoring techniques ranged from $0.46 to $0.99; these values were up to three times less expensive than the laboratory methods ($1.86 for the SMAC and $1.04 for the AAII). These blood glucose monitoring techniques, particularly those using a reflectance meter, were reliable, easily performed by patients, and less expensive per determination when compared with laboratory testing. In contrast, the correlation between urine and glucose levels was poor (r2 = 0.21). 4 figures, 12 tables, 19 references.

44

TITLE: Randomized Controlled Multicentre Evaluation of an Education Programme for Insulin-Treated Diabetic Patients: Effects on Metabolic Control, Quality of Life, and Costs of Therapy. de Weerdt, I.; Visser, A.P.; Kok, G.J.; de Weerdt, O.; van der Veen, E.A. *Diabetic Medicine*. 8(4): 338-345. May 1991.

OBJECTIVE: To assess the effect of an education program for insulin-treated patients with diabetes on their metabolic control, quality of life, and costs of therapy.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The education program had no effect on metabolic control, quality of life, and costs of therapy, although the patients significantly increased their level of self-monitoring blood glucose and diabetes knowledge. The authors suggest various reasons for the failure to find effects.

RECOMMENDATION: None.

ABSTRACT: This study was conducted in 15 randomly selected hospitals in The Netherlands. Control patients were taken from 5 hospitals and intervention patients (experimental) from the other 10. In five of the experimental hospitals the program was led by a health care worker; in the other five, by a fellow patient. A total of 625 patients were asked to participate, 558 (89 percent) of whom agreed. Each group had 40 to 50 patients. The patient characteristics of the groups (age, occupational status, duration of diabetes, duration of insulin use, and number of daily injections) did not differ significantly. Patients in the experimental group were evaluated immediately before and after the education program and at 1 and 6 months following the program's conclusion. Patients in the control group were assessed twice (at 6- to 7-month intervals). At each evaluation, participants completed a questionnaire and a blood sample was taken. The effect of the program on metabolic control (glycosylated hemoglobin, serum fructosamine concentration, number and severity of hypoglycemic reactions, and clinical signs of poor control), quality of life (Affect-Balance Scale and subjective social indicators), and costs of therapy (hospitalizations, doctor visits, medication, self-testing, sick days, and cost of education program) was assessed. No significant effect from the education program on any one of these variables could be found,

although there was significant improvement in self-care and diabetes knowledge. This lack of effect could be due to the quality of the education program, short follow-up of the study, the lack of integration of the education program in standard therapy, the lack of follow-up of the education given, or the lack of concurrent changes in diabetes therapy. 4 tables, 30 references.

45

TITLE: A Risk-Benefit Assessment of Conventional versus Intensive Insulin Therapy. Reichard, P. *Drug Safety*. 10(3): 196202. March 1994.

OBJECTIVE: To assess the benefits of intensive insulin therapy for type 1 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Intensified insulin therapy leads to a slowing down or halting of microvascular complications in patients with type 1 diabetes, including those with diabetes of short duration and those with longer term diabetes and nonproliferative retinopathy.

RECOMMENDATION: An intensified treatment program is generally indicated for the majority of adults with type 1 diabetes; such treatment should start before the complications become too advanced.

ABSTRACT: The author explores whether intensified insulin treatment to lower blood glucose concentrations is effective in reducing diabetes complications by addressing five questions: (1) Is there an association between blood glucose concentrations and complications? (2) Is the association causal? (3) Are there any adverse effects of intensified treatment? (4) Is intensified treatment acceptable? and (5) How great could the gains be with general acceptance and execution of the treatment program? By reviewing various studies, most notably the Stockholm Diabetes Intervention Study and the Diabetes Control and Complications Trial, the author finds the following: Lower blood glucose concentrations are associated with reduction of complications affecting the eyes, kidneys, and nerves. Prospective, randomized studies are needed to answer the question of a causal association. The chief adverse effects of intensified insulin treatment are weight gain and an increased frequency of serious hypoglycemic episodes. Intensified treatment is acceptable to patients. The gains are very large, not only for the individual patient, but also for society as a whole. The author speculates that if 400,000 patients were put on an intensive treatment program, 64,000 who would develop nephropathy if conventionally treated would not do so, and 100,000 would not need laser treatment for retinopathy who otherwise would. Implementing an intensified treatment program for type 1 diabetes would bring a significant reduction of serious complications and a gain in terms of patient discomfort and cost. 2 figures, 32 references.

46

TITLE: Utility of Serum Fructosamine as a Measure of Glycemia in Young and Old Diabetic and Non-Diabetic Subjects. Negoro, H.; Morley, J.E.; Rosenthal, M.J. *American Journal of Medicine*. 85(3): 360-364. September 1988.

OBJECTIVE: To determine the utility of a serum fructosamine assay as a measure of glycemia.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Serum fructosamine was comparable to other measures of glycemia.

RECOMMENDATION: Serum fructosamine should be considered superior to measures of other glycosylated proteins because of its automaticity, reproducibility, and lower cost.

ABSTRACT: The authors evaluated the utility of serum fructosamine as a measure of glycemia by comparing it with other standard glycemic indices: glycosylated hemoglobin, glycosylated albumin, and fasting glucose. Participants were 145 adults in six categories, including two groups of healthy persons (aged 22 to 50 and 64 to 86) without diabetes; one group with chronic debilitating illness (aged 60 to 91); otherwise healthy persons in a maintenance methadone program; and two groups (mean ages: 48 and 70 years) of patients with diabetes. Blood samples were collected at 8 a.m. after a 12-hour fast. Serum fructosamine detected glycemia as well as the established tests, and fructosamine concentrations correlated well with serum glycosylated hemoglobin, glycosylated albumin, and fasting glucose. Fructosamine concentrations were not significantly affected by any of a large battery of medications or by large differences in plasma lipid levels. Age did not affect serum fructosamine concentration, which makes this a particularly useful test for older persons with diabetes. Serum fructosamine is also amenable to automated determination and is far simpler and less expensive than assays for glycosylated proteins. The current charge to patients for assays is $6.50 for plasma glucose, $8.00 for fructosamine, $26.00 for glycosylated hemoglobin, and $31.00 for glycosylated albumin. 2 figures, 3 tables, 27 references.

47

TITLE: Variation in Office-Based Quality: A Claims-Based Profile of Care Provided to Medicare Patients with Diabetes. Weiner, J.P.; Parente, S.T.; Garnick, D.W.; Fowles, J.; Lawthers, A.G.; Palmer, R.H. *Journal of the American Medical Association (JAMA)*. 273 (19): 1503-1508. May 17, 1995.

OBJECTIVE: To demonstrate that profiling of claims data can be used as an ongoing method to support ambulatory care quality improvement, to measure the quality of office-based care provided to elderly patients with diabetes, and to identify factors associated with higher or lower conformance to recommended criteria of care.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Claims review.
Perspective: Health care system.

CONCLUSION: The care of elderly patients with diabetes is not meeting nationally recommended guidelines; screening rates are particularly low in rural areas. Examining Medicare claims has great potential for measuring patterns of care.

RECOMMENDATION: Programs should be established to disseminate clinical practice guidelines relevant to primary care of diabetes and further research should be conducted to delineate variations in office practice patterns.

ABSTRACT: The authors assessed the quality of office-based care provided to elderly patients with diabetes. Data were derived from review of all Medicare claims (Parts A and B) in Alabama, Iowa, and Maryland for July 1990 to June 1991 for patients aged 65 years and over. Four services/procedures were identified as quality indicators for diabetes: three (hemoglobin A1c measurement, ophthalmologic exam, and total cholesterol measurement) were to be performed at least annually; the fourth, blood glucose measurement, was identified as a limited-use procedure. Across the three states, only 16.3 percent of patients with diabetes underwent hemoglobin A1c measurement, 45.9 percent received an ophthalmologic exam, and 55.1 percent underwent cholesterol measurement at least once during the year. In contrast, four-fifths (80.5 percent) of patients underwent blood glucose measurement. In almost all instances, practice patterns varied significantly across the three states, even after controlling for practice and patient characteristics. With the exception of ophthalmologic exams, rates of procedures were significantly lower in rural areas. Results demonstrate that elderly patients with diabetes are not receiving optimal care; a large gap exists between national practice guidelines and actual primary care practice. Clinical practice guidelines need to be more widely disseminated. Further research is needed to identify the causes of variation across office practices in order to design quality improvement programs. 3 tables, 38 references.

Nutrition Care

48

TITLE: Cost-Effectiveness of Medical Nutrition Therapy Provided by Dietitians for Persons with Non-Insulin-Dependent Diabetes Mellitus. Franz, M.J.; Splett, P.L.; Monk, A.; Barry, B.; McClain, K.; Weaver, T.; Upham, P.; Bergenstal, R.; Mazze, R.S. *Journal of the American*

Dietetic Association. 95(9): 1018-1024. September 1995.

OBJECTIVE: To report on the cost-effectiveness of nutrition care by practice guidelines for patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The implementation of nutrition guidelines in type 2 diabetes can be met with a reasonable investment of resources and improvement in metabolic control.

RECOMMENDATION: Additional research should be conducted before more intensive nutrition intervention can be recommended as the preferred approach for patients with type 2 diabetes.

ABSTRACT: The authors conducted a cost-effectiveness analysis of 179 adult patients with type 2 diabetes randomized to basic nutrition care (n = 85) or nutrition care following practice guidelines (n = 94). Basic care included just one visit from the dietitian; practice guidelines, three or more. The defined outcome for the cost-effectiveness analysis was the effect of nutrition care on glycemic control at 6 months as measured by changes from baseline in levels of fasting plasma glucose and glycated hemoglobin. Costs were limited to those for direct health care as documented through an accounting approach. The per-patient cost (1993 dollars) of providing basic care was $41.95; the comparable cost for guidelines care was $112.07. Each mg/dL of change in the fasting plasma glucose concentration after 6 months of intervention required an investment of $5.75 in the basic group and $5.84 in the guidelines group. When net costs were considered (per-patient costs minus cost savings due to changes in therapy), the required investments were $5.32 and $4.20 for the basic and guidelines groups, respectively. Changes in medical therapy resulted in a per-patient cost savings over 12 months of $31.49 in the guidelines group and $3.13 in the basic group. Sensitivity analysis showed that the relative cost-effectiveness of guidelines care versus basic care was unchanged by dietitian salary or additional laboratory testing. Results show that nutrition therapy can be provided in a cost-effective manner. Additional information is needed, however, before more intensive nutrition intervention can be recommended as the preferred approach for type 2 patients. 5 tables, 26 references.

49

TITLE: Effects of Diet and Exercise Interventions on Control and Quality of Life in Non-Insulin-Dependent Diabetes. Kaplan, R.M.; Hartwell, S.L.; Wilson, D.K.; Wallace, J.P. *Journal of General Internal Medicine*. 2(4): 220-228. July-August 1987.

OBJECTIVE: To assess the impact of diet and exercise on glycemic control and quality of life in patients with type 2 diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Patients in the diet-plus-exercise group significantly improved their quality of life and significantly decreased their glycosylated hemoglobin (HbA_{1C}) over 18 months.

RECOMMENDATION: Additional studies of nonpharmacologic intervention for patients with type 2 diabetes are needed using larger sample sizes.

ABSTRACT: The authors report a study of 70 volunteers with type 2 diabetes who were randomized to one of four types of nonpharmacologic management: diet, exercise, diet and exercise, or education (control group). All participants were given the same diet (the exchange diet recommended by the American Diabetes Association) and asked to attend 10 consecutive weekly meetings; exercise routines were prescribed individually based on graded exercise tests. The intervention groups underwent behavioral modification sessions that included goal-setting and diet and/or exercise plans. The control group received lectures from a variety of health care specialists but no specific behavior modification plans. After 3 and 6 months, the diet group had significantly greater weight loss than the control group (2.52 kg loss versus a gain of 1.37 kg), but at 18 months, the diet group had regained an average of 1.81 kg. Also at 18 months, the diet-plus-exercise group had reduced its HbA_{1C} levels from 9.18 to 7.70 percent, versus an increase from 8.21 to 8.57 percent for the controls ($p < 0.05$). Changes in HbA_{1C} in the diet-only and exercise-only groups were not significant compared with controls. Over 18 months, quality of life improved for participants in the combined intervention group, improved less markedly for the diet group, remained relatively static in the exercise group, and deteriorated for the control group. Estimated direct cost of the diet-plus-exercise intervention was $1,000 per participant per year; this program yielded 0.092 years of well-being over that obtained by the control group, which was actually less than zero. Thus, the cost of producing a well year was $10,870. 2 figures, 4 tables, 19 references.

50

TITLE: Reliability and Cost of Diabetic Diets. Tunbridge, R.; Wetherill, J.H. *British Medical Journal*. 2(701): 78-80. April 11, 1970.

OBJECTIVE: To ascertain the adherence of patients with diabetes mellitus to the recommended diet, and to calculate the cost of maintaining the recommended diet.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.

Perspective: Health care system.

CONCLUSION: Thirty percent of patients adhered to within 10 percent of their recommended diet. The cost of the recommended diet was higher than the cost of food for the general population.

RECOMMENDATION: None.

ABSTRACT: The authors reported on adherence to prescribed diets for 63 patients attending the diabetes clinic at the General Infirmary in Leeds, England, for a single week in the spring of 1968. Dietary control was satisfactory (90 to 100 percent within guidelines) for 30 percent of patients, tolerable (80 to 89 percent within guidelines) for 38 percent, and "hopeless" (less than 80 percent within guidelines) for 32 percent. Less than one-third of women (n = 35) and men (n = 28) followed satisfactory diets. Adherence was best among participants aged 40 years and under and worst among those aged over 60 years. Dietary control was poorer among participants treated by diet plus oral hypoglycemic agents than in those treated by dietary control with or without insulin; it was poorer among those diagnosed within 10 years than among those diagnosed for more than 10 years. Dietary control was best with diets of 1,201 to 1,999 calories and worst with 1,200 calories or less. Diabetes control was satisfactory (blood glucose between 50 and 200 mg/ml, no ketonuria, weight steady) in 42 percent of patients with satisfactory diets, 33 percent of those with tolerable diets, and 40 percent of those with hopeless diets. The estimated cost per patient per week to follow an ideal diet was 44 shillings and 1 penny, versus 38 shillings, 4 pennies for the general population. Low-income patients continue to have difficulty purchasing the food to maintain a correct diet. 7 tables, 5 references.

51

TITLE: Spin-Off Cost/Benefits of Expanded Nutritional Care. Davidson, J.; Delcher, H.; Englund, A. *Journal of the American Dietetic Association*. 75(3): 250-257. September 1979.

OBJECTIVE: To describe and evaluate an expanded nutrition care program developed in a hospital diabetes unit; to compare projected costs of continuing the preintervention program with actual costs incurred with the expanded intervention.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Over an 8-year period, the expanded nutrition care program saved the hospital $379,988 from reduced use of insulin (1973 to 1978 only) and no use of oral agents and over $3,700,000 from decreased incidence of lower extremity amputations and severe diabetic ketoacidosis. Net savings for the year 1978 were $216,699.

RECOMMENDATION: Registered dietitians should collaborate with physicians and nurses to organize health care teams that will provide expanded nutrition care programs for all Americans who have diabetes.

ABSTRACT: The authors describe the outcome of an expanded nutrition care program developed over an 8-year period (1971-1978) in the Grady Memorial Hospital Diabetes Unit in Atlanta, Georgia; Grady is the primary teaching hospital of the Emory University School of Medicine. Projected costs of continuing the pre-1971 program, which consisted of basic nutrition care with high use of insulin and oral agents, were compared with actual costs of the expanded program. The latter program emphasized short-term fasts, hypocaloric diets, patient education and follow-up, discontinued oral agents, and limited use of insulin. Total costs of the pre-1971 program were estimated at $125,863 per year, including $43,176 for oral agents, $23,723 for insulin, $23,963 for the basic nutrition program, and $35,000 for personnel, facilities, and supplies. Estimated total cost of the expanded nutrition care program for the year 1978 was $615,164, including approximately $500,000 for personnel, facilities, and equipment; $73,391 for expanded nutrition care; and $41,774 for insulin. Despite these increased costs, the hospital had an estimated net savings of $216,699 for that year, as it saved more than $706,000 because of decreased prevalence of severe diabetic ketoacidosis and severe lower extremity amputations. During the 8-year study period, decreased hospitalization for severe diabetic ketoacidosis and lower extremity amputation provided the hospital with gross savings of more than $3.7 million. 2 figures, 9 tables, 15 references.

Educational Programs

52

TITLE: Comparison of Five Glucose Meters for Self-Monitoring of Blood Glucose by Diabetic Patients. Gifford-Jorgensen, R.A.; Borchert, J.; Hassanein, R.; Tilzer, L.; Eaks, G.A.; Moore, W.V. *Diabetes Care*. 9(1): 70-76. January-February 1986.

OBJECTIVE: To compare the accuracy, ease of operation, and cost of five self-monitoring blood glucose meters.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: For four of the five meters, adjusted blood glucose values were not significantly different from laboratory values. Various advantages and disadvantages were found relative to price, calibration, strip utilization, and ease of operation.

RECOMMENDATION: Patient education is absolutely necessary for accurate use of the

blood glucose meters.

ABSTRACT: The authors assessed five kinds of currently marketed meters for home use: Accu-Chek (Bio-Dynamics, Inc.); Glucochek II bG (Medistron/Larken), with Chemstrip bG reagent strips; Glucochek II-Dextro (Medistron/Larken), with Dextrostix reagent strips; two Glucometer (Ames Division, Miles Laboratories) reflectance photometers, with calibration either by fluids or special chips; and Glucoscan II (LifeScan, Inc.). Fasting blood samples were taken from patients (n = 37) at the University of Kansas College of Health Sciences and Hospital and tested immediately on the meters. Blood samples were also taken to the laboratory for serum testing according to the glucose-oxidase method. When unadjusted meter readings of whole blood glucose were plotted against laboratory values, three of the meters had a 35-49 percent inaccuracy rate; for the other two, inaccuracy rates were 65 and 70 percent. After adjustment of the whole blood glucose values to match the serum values, only the Glucochek II-Dextro with Dextrostix reagent strips had significantly different values. (A technical revision by the manufacturers may have changed this meter's performance.) For blood glucose ranges of both 60-180 mg/dL and 181-300 mg/dL, all meters except Glucoscan II were at least 95 percent accurate. For values of 301-400 mg/dL, both the Glucometer (with "CHIP" calibration) and the Glucoscan II were less than 95 percent accurate. Prices approximated $150 for the Accu-Chek and the Glucometers, $140 for the Glucochek models, and $178 for the Glucoscan II; 40**4** to 70**4** for reagent strips. The Glucoscan II and the two Glucochek models were factory calibrated; the other models required periodic recalibration. 7 figures, 3 tables, 32 references.

53

TITLE: Conference Report: Approaches to the Treatment of Type II Diabetes and Developments in Glucose Monitoring and Insulin Administration. Bloomgarden, Z.T. *Diabetes Care*. 19(8): 906-909. August 1996.

OBJECTIVE: To review presentations at conferences held in 1996 concerning treatment of type 2 diabetes and developments in glucose monitoring systems and insulin administration.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Conference summary.
Perspective: Health care system.

CONCLUSION: None.

RECOMMENDATION: None.

ABSTRACT: The author reviews 1996 conference presentations concerning treatment of type 2 diabetes, glucose monitoring, and insulin administration. In 1992, medical costs for diabetes were 12 percent of total health care costs, but only 8 percent of patient visits were to

diabetes specialists. For each 1 percent fall in hemoglobin A1c (HbA_{1C}), development of proliferative retinopathy and nephropathy falls 50 percent. Diet and exercise are effective in controlling blood glucose and in decreasing the risk of developing type 2 diabetes. Elizabeth Barrett-Connor suggested that achieving glycemic control is not a key to decreasing mortality. A speaker on managed care stated that protocol-based care is needed, and that outcomes and costs should be followed. Researchers in England are looking at the effect that controlling blood glucose and hypertension has on outcome for patients with type 2 diabetes. A new study of the effects of obesity and exercise on development of type 2 diabetes is about to start. According to one speaker, Julio Santiago, most self-glucose monitoring is a waste of money. He indicated that an annual investment of $2,000 per patient would decrease mortality substantially in patients with diabetes (supporting data are available). Santiago proposed that therapeutic programs use algorithms based on the HbA_{1C}, the fasting blood glucose value, and the avoidance of hypoglycemia. Another speaker stated that home blood glucose meters are inaccurate, especially at glucose concentrations less than 75 mg/dL. An implantable insulin pump was found to decrease blood glucose and HbA_{1C}, but infections, mechanical failures, and cost were problems. Inhalation, trans-dermal delivery, and sonophoresis are being investigated, as is the use of computer programs for records management and treatment advice. 4 references.

54

TITLE: The Diabetes Education Study: A Controlled Trial of the Effects of Diabetes Patient Education. Mazzuca, S.A.; Moorman, N.H.; Wheeler, M.L.; Norton, J.A.; Fineberg, N.S.; Vinicor, F.; Cohen, S.J.; Clark, C.M. *Diabetes Care*. 9(1): 1-10. January-February 1986.

OBJECTIVE: To assess, in the context of a randomized clinical trial, the impact of an education program for adult patients with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Patients in the intervention education group made lasting changes in skills and self-care behavior and achieved modest improvement in glycemic control.

RECOMMENDATION: More research in similar and different settings is needed to determine whether the patients from this study are truly representative of patients with type 2 diabetes.

ABSTRACT: The authors report the results of the Diabetes Education Study (DIABEDS) developed by the Indiana University School of Medicine. The DIABEDS is a randomized, controlled trial of patient and physician education in managing diabetes. The 532 patients recruited from a clinic population into the study were primarily elderly, female, black, and

obese; 95 percent had type 2 diabetes. Patients could be assigned to intervention groups (patient education, physician plus patient education) or control groups (control group, physician education group). Staff were randomly assigned to care groups. Patients in the intervention groups (n = 263) received interactive instruction over an 8-week period on diabetes and its complications, use of medications, the effects of diet and exercise, foot care, urine testing, and behavior modification; they also received meal plans and menus as well as a home visit. Patients in the control groups (n = 269) received the standard institutional patient education. Patients were assessed at entry into the study and at postintervention periods ranging from 6 to 14 months. Two hundred seventy-five patients took part in postintervention assessment. On most knowledge items, there was little difference between intervention and control groups; intervention patients did better in listing causes of hyperglycemia, knowledge of urine test implications, and knowing the diabetes exchange list system. Intervention patients were significantly better on two of four urine testing skills as well as on food partitioning and/or weighing. In addition, they made more improvement in fasting glucose concentrations, glycosylated hemoglobin, body weight, diastolic and systolic blood pressure, and serum creatinine concentrations. Intervention patients also had statistically better diet compliance and safety habits. 8 tables, 13 references.

55

TITLE: Effect of Diabetes Education on Self-Care Metabolic Control and Emotional Well-Being. Flack, J.R. *Diabetes Care*. 13(10): 1094. October 1990.

OBJECTIVE: To rebut the assertion by Rubin et al. (*Diabetes Care*. 12:673-679. 1989) that educational programs with a few sessions spread over a long time period are probably less effective than a program of 5 consecutive days.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Diabetes education programs that spread the education process over a period of time (up to 6 weeks) may be more effective than five consecutive-day programs.

RECOMMENDATION: Future studies on diabetes programs need to focus on who should teach what, when and how it should be taught, and how to assess outcome.

ABSTRACT: The author questions the contention of Rubin et al. that educational interventions for persons with diabetes that consist of a few sessions spread over a long period will probably be less effective than the 5 consecutive-day program of Rubin et al. A study presented by Beeney et al. (1988) at the 13th International Diabetes Federation meeting compared four diabetes education programs over 3 years. At 12 months after entry, knowledge improvement was independent of the program format. Psychological adjustment was better in patients for whom the program was prolonged for up to 6 weeks. Beeney et al.

concluded that the demonstrated benefits of extended formats must be rationalized with the size and requirements of the population served to determine the most cost-effective program. They noted that shorter programs have higher patient turnover. The author suggests that diabetes education needs more study in terms of who is to teach what, when and how it should be taught, and how to assess a suitable outcome. In a reply, Rubin et al. agree that extended education programs can be effective. They state that the content and time devoted to teaching are the most important factors in a program, but they indicate that the point of diminishing return for the amount of education has not been identified. They recommend that future studies seek to identify the content and format that produce the best results. 6 references.

56

TITLE: Effect of Diabetes Education on Self-Care, Metabolic Control, and Emotional Well-Being. Rubin, R.R.; Peyrot, M.; Saudek, C.D. *Diabetes Care*. 12(10): 673-679. November-December 1989.

OBJECTIVE: To determine whether an intensive comprehensive educational program will improve emotional well-being, self-care practices, and metabolic control in patients with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Prospective trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: An intensive comprehensive educational program improves emotional well-being, self-care practices, and metabolic control, especially in patients whose functional status in these areas is poor.

RECOMMENDATION: Randomized, controlled studies are needed to assess more definitively the effectiveness of diabetes education programs.

ABSTRACT: Participants (n = 165) in this study at the Johns Hopkins Diabetes Center were enrolled in a week-long outpatient diabetes education program designed to improve self-care practices, emotional well-being, and metabolic control. The study population was 70 percent white, mean age was 47.4 ± 16.5 years, and 59 percent had some college education; most participants were overweight. Sixty-three percent were taking insulin, and 62 percent had type 2 diabetes. Disease complications in the study group included neuropathies, retinopathy, vascular complications, and infections. Baseline data were collected on emotional status, self-care behaviors, diabetes knowledge levels, and glycemic control as measured by hemoglobin A1c tests (HbA_{1C}). One hundred twenty-four (75 percent) of the participants completed a 6-month follow-up questionnaire, and 71 (43 percent) had HbA_{1C} tests at 6-month follow-up. At both program end and 6-month follow-up, participants had significantly improved from

baseline on all measures of emotional well-being as well as on knowledge. At 6 months (versus baseline), bingeing was lower ($p < 0.01$), exercise was more frequent ($p < 0.001$), self-monitoring of blood glucose was more frequent ($p < 0.001$), and HbA_{1C} was lower ($p < 0.001$). Program effects were unrelated to demographic or disease characteristics but were strongly related to initial status. On six different measures, participants who entered the program in the worst condition improved the most; those who entered in the best condition improved little, if at all. 1 figure, 3 tables, 28 references.

57

TITLE: The Effectiveness of Diabetes Education for Non-Insulin-Dependent Diabetic Persons. Scott, R.S.; Beaven, D.W.; Stafford, J.M. *Diabetes Educator*. 10(1): 36-39. Spring 1984.

OBJECTIVE: To determine the effectiveness of a patient education program for patients with type 2 diabetes in improving their understanding and management of the disease and their use of hospital and specialist services.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The patient education program did not result in sustained improvement in glycemic control or long-term behavior change.

RECOMMENDATION: The effectiveness of any education program for people with type 2 diabetes should be carefully assessed, as considerable investment of time by health professionals may not result in substantial benefits.

ABSTRACT: This two-part study was carried out at the Christchurch Diabetes Center in New Zealand. In the first part, individuals with type 2 diabetes were referred to a diabetes education program where they were randomly assigned to a treatment ($n = 32$) or control ($n = 28$) group. The treatment group entered an education program immediately, while the control group entered it four weeks later. Researchers assessed participants' knowledge and anxiety levels and glycemic control at the time of referral and 4 weeks later, before the control group had begun the education program. At the latter time, assessment indices (plasma glucose; urinary glucose; glycosylated hemoglobin; and knowledge, anxiety, and depression levels) in the control group showed no significant improvement except for a small increase in the knowledge score ($p < .05$). In the treatment group, knowledge ($p < .001$), plasma glucose ($p < .01$), glycosylated hemoglobin ($p < .1$), and anxiety score ($p < .1$) had all improved, but the urinary glucose score had increased ($p < .05$). Comparison of improvement in the control and treatment groups found significant differences in favor of the treatment group for knowledge, plasma glucose, glycosylated hemoglobin, and anxiety. In the second part of the study, 30

patients received education at referral and 26 patients received education after a 4-week delay. Glycemic control was assessed at referral, at the end of the program, and 4 weeks after the program's completion. In both groups, the mean values for blood glucose and glycosylated hemoglobin were not significantly different 4 weeks after program conclusion from the values at referral. 2 tables, 7 references.

58

TITLE: Effects of Educational Interventions in Diabetes Care: A Meta-Analysis of Findings. Brown, S.A. *Nursing Research*. 37(4): 223-230. July-August 1988.

OBJECTIVE: To assess the effects of educating patients with diabetes on their knowledge, self-care behavior, and metabolic control.

CATEGORY: Secondary intervention.

> **Type of Study:** Formal meta-analysis of randomized controlled trials.
> **Methodology:** Statistical analysis.
> **Perspective:** Health care system.

CONCLUSION: Patient education has positive outcomes in adults with diabetes.

RECOMMENDATION: More research is needed to develop the statistical basis for meta-analysis, and researchers must make data available in a form that permits comparisons with other studies.

ABSTRACT: The author used meta-analysis to explore several issues: What is the magnitude of the effect of patient teaching in adults with diabetes? What outcomes from teaching in this population have been documented in terms of patient knowledge, self-care, and metabolic control? Is there a relationship between outcome effects and various study characteristics (e.g., research design, type of instruction)? Data were derived from published and unpublished sources; studies had to have a control group (n = 27) or a preintervention control phase (n = 20) for comparison of results. Studies had been published between 1954 and 1986 (50 percent after 1982). The studies included 3,605 patients (range: 8 to 373), 236 effect sizes, and 52 pooled effect sizes. (An effect size is the difference between the experimental and control group in standard score form.) The author found that patient teaching appears to enhance patient outcomes in diabetes management; she determined that the weighted mean effect size across all studies was 0.33 (i.e., outcomes that are 0.33 standard deviation units higher than those for the comparison group). The effect of teaching on patient knowledge was moderate to large; on skill performance it was small to low-moderate. There was a small effect of teaching on weight loss and a large effect on dietary compliance. Teaching also had a positive effect on metabolic control. The only study characteristic to be correlated with overall weighted mean effect size was attrition. 3 tables, 59 references.

59

TITLE: Evaluating the Costs and Benefits of Outpatient Diabetes Education and Nutrition Counseling. Kaplan, R.M.; Davis, W.K. *Diabetes Care*. 9(1): 81-86. January-February 1986.

OBJECTIVE: To analyze the studies that supported the resolution of the American Diabetes Association recommending third party payment for outpatient education and nutrition counseling of patients with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: The reports cited by the American Diabetes Association in support of third party reimbursement for outpatient education and nutrition counseling of patients with diabetes do not meet criteria to measure benefits and rarely include the full costs of such programs.

RECOMMENDATION: The first criterion for evaluating education and nutrition counseling should be evidence that they improve health status. Scientifically sound experiments evaluating education of patients with diabetes should be undertaken.

ABSTRACT: The authors analyzed the scientific validity of 13 studies cited by the American Diabetes Association in support of its recommendation for third party coverage of outpatient education and nutrition counseling of patients with diabetes. Only two of the reports mentioned control or comparison groups, and in neither case were the patients randomly assigned to such groups. Only four studies provided health care cost accounting, and two of these studies did not include the intervention costs. Some of the studies seemed to show an increase in costs with intervention. None of the studies included discount analyses and most failed to report net differences in costs. Some studies did not report costs of related services or program implementation costs. In some cases, apparent savings were in fact cost shifting, which may not equate to cost reduction. None of the studies estimated indirect patient costs, such as travel time, changes in diet, and lost work. Only one study reported costs of medications and educational materials. Costs of continuing intervention were not estimated. Attrition was high in the five studies that reported it, and follow-up was nonexistent or not reported in half of the studies. Researchers extrapolated limited results nationwide, and the programs varied widely. None of the reports meets accepted criteria to establish the cause and effect of education intervention. Well-designed experiments are needed to assess the direct and indirect program costs, the savings attributable to the program, and the net program benefits. Costs must be based on all patients who receive service, adequate patient follow-up, and discounted future benefits. 1 table, 23 references.

60

TITLE: Evaluation of a Structured Treatment and Teaching Program for Non-Insulin-

Treated Type II Diabetic Outpatients in Germany after the Nationwide Introduction of Reimbursement Policy for Physicians. Gruesser, M.; Bott, U.; Ellermann, P.; Kronsbein, P.; Joergens, V. *Diabetes Care*. 16(9): 1268-1275. September 1993.

OBJECTIVE: To evaluate the practicability and efficacy of a structured treatment and teaching program for patients with type 2 diabetes in a routine primary care office setting.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The structured treatment and teaching program improved the quality of care, as evidenced by decreased patient weight, less use of oral antidiabetic agents, and improved metabolic control.

RECOMMENDATION: The participating physicians recommended a higher reimbursement rate for providing a structured treatment and patient education program for their type 2 diabetes patients.

ABSTRACT: In 1991, nationwide insurance coverage of a standard treatment and teaching program for outpatients with type 2 diabetes was introduced in Germany. Physicians' fees and the costs of teaching materials were reimbursed. Physicians and office staff were required to complete a training course to obtain reimbursement. The authors interviewed 127 office-based physicians in Hamburg who had completed the training course (42 percent were internists and 58 percent were general practitioners) 12 months after the training, and information was collected on 179 patients who participated in group treatment and teaching programs, which were provided in 17 randomly selected office practices. Of the 127 physicians, 122 (96 percent) rated the training course content as good and useful, 2 reported they learned nothing new, and 3 rated the content as useless or poor. Sixty-one percent of the physicians had implemented at least one treatment and teaching course in their practice at the time of the evaluation (median: 12 months after completing the training course). Information on patients completing the program showed substantial improvements in quality of treatment and self-care practices. The number of patients who tested their urine for glucose at least twice a week rose from 3 percent to 70 percent. Improved dietary habits led to a reduction in body weight, which resulted in decreased use of oral antidiabetic agents and improved metabolic control. The net cost for the program was $35.80 (U.S. dollars) per patient in year 1, with an expected savings of $13.20 per patient per year beginning in year 2. These savings do not include anticipated reductions in the costs associated with treating long-term complications of diabetes. Most of the physicians found reimbursement for offering the program to be either "extremely inadequate"or "inadequate." 1 figure, 4 tables, 40 references.

61

TITLE: Obesity and the U.S. Navy [letter]. Yowell, S.K. *Military Medicine*. 156(12): A10.

December 1991.

OBJECTIVE: To show that the authors of an earlier article (Hoiberg, A.; McNally, M.S. *Military Medicine*. 156(2): 76-82 [abstract 222]) did not provide support for the Health and Physical Readiness Program of the U.S. Navy.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Review of study.
Perspective: Health care system.

CONCLUSION: The referenced authors' support for the Navy's Health and Physical Readiness Program was not justified by their study.

RECOMMENDATION: A weight control program's efficacy, potential benefits, and adverse effects should be examined, as should its cost of screening and monitoring.

ABSTRACT: This letter to the editor offers several criticisms of Hoiberg and McNally's article on overweight patients in the U.S. Navy. The author points out that obesity was not defined in Hoiberg and McNally's article and that data were obtained from sources that did not verify diagnoses. Furthermore, the control group was not age-matched with the obese group. The author also questions diagnoses of gout, hypertension, gallbladder disorders, and diabetes on admissions of obese patients. He points out that admissions for a diagnosis like diabetes are more likely to have obesity mentioned in the workup than are admissions for diagnoses where weight is thought to be irrelevant. Referring to the authors' finding of a high concordance of alcoholism and obesity, the writer notes that during the study period almost all obesity therapy was offered by alcohol rehabilitation staff; a co-diagnosis of alcoholism was often needed to gain admission. Before implementing weight control programs and examining their potential savings in hospitalization, he suggests looking at their efficacy, potential benefit, adverse effects, and the cost of screening and monitoring.

62

TITLE: A Randomized Study of the Effects of a Home Diabetes Education Program. Rettig, B.A.; Shrauger, D.G.; Recker, R.R.; Gallagher, T.F.; Wiltse, H. *Diabetes Care*. 9(2): 173-178. March-April 1986.

OBJECTIVE: To determine the effectiveness of a home-based individualized instruction program in diabetes.

CATEGORY: Secondary intervention.

Type of Study: Randomized clinical trial.
Methodology: Statistical analysis.

Perspective: Health care system.

CONCLUSION: Six months following enrollment, patients in the intervention group (home teaching) had significantly greater knowledge and skill scores than the control group (no teaching). Hospitalization rates, diabetes-related emergency room visits, physician visits, and sick days did not differ significantly by group at 12-month follow-up.

RECOMMENDATION: Because diabetes is a chronic disease, new guidelines for diabetes patient education should incorporate a long-term management plan in conjunction with periodic reinforcement of self-care knowledge and skills.

ABSTRACT: In this Nebraska-based study, home health nurses provided up to 12 educational visits for 193 patients randomly assigned to the intervention group. The 180 patients in the control group, while not receiving home visits, were free to participate in other types of health education. The two groups did not vary in terms of demographic composition, diabetes duration, diabetes type, or previous diabetes education. A survey instrument developed by the Nebraska Diabetes Demonstration Project was used to measure self-care knowledge and skills. At 6-month follow-up, total mean knowledge scores were 60.2 for the intervention group, 51.6 for controls ($p = 0.001$); total mean skill scores were 74.8 for the intervention group and 72.6 for controls, a difference that was statistically significant ($p = 0.04$) but not considered meaningful. At 12-month follow-up, hospitalization rates did not differ by group on any of three types of admission: nondiabetes-related, nonpreventable diabetes-related, and preventable diabetes-related. There was no difference between the groups in mean foot appearance score at 6-month follow-up. The authors warn of possible bias in the selection of study participants, as those who chose to participate may have been more highly motivated than those who did not (about 70 percent of patients who were asked to participate actually did). Such a bias could have resulted in recruiting patients for whom teaching would have added little to present knowledge and skill levels. In addition, persons hospitalized with a diabetes-related condition were more likely to have been identified as eligible to participate than those hospitalized with a condition not overtly related to diabetes. 5 tables, 13 references.

63

TITLE: Reduced Hospital Utilization and Cost Savings Associated with Diabetes Patient Education. Sinnock, P. *Journal of Insurance Medicine*. 18(3): 24-30. Summer 1986.

OBJECTIVE: To review data demonstrating the impact of patient education programs on health care services used by patients with diabetes; to review the system for assuring the quality of such programs and the current status of reimbursement by third party payers for diabetes outpatient education.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Review of studies.

Perspective: Health care system.

CONCLUSION: Diabetes patient education programs can dramatically reduce the physical and economic costs of diabetes.

RECOMMENDATION: The insurance industry and diabetes community should work together to monitor and improve diabetes patient education programs.

ABSTRACT: Numerous studies have demonstrated an association between diabetes patient education and reduction in hospitalizations, resulting in cost savings. A 2-year study of 6,000 persons with diabetes who participated in a patient education program at Los Angeles County Hospital demonstrated a 73 percent decrease in hospitalizations; cost savings over the study period were estimated at $1.8 million. A program at Grady Memorial Hospital in Atlanta showed a 65 percent decrease in admissions for diabetic ketoacidosis and an estimated savings of $3.5 million over 8 years. In Maine, a Centers for Disease Control state-based program demonstrated a 32 percent reduction in hospitalizations among 1,000 participants, with net savings estimated at $293 per participant per year. A 51 percent reduction in hospitalization from diabetic acidosis and infection and a 63 percent reduction in emergency room visits were seen in a Rhode Island program. Estimated cost savings associated with this intervention were $355 per participant per year. The quality of diabetes education programs in the United States has varied, but it is hoped that the implementation of the National Standards for Diabetes Patient Education Programs (National Diabetes Advisory Board 1983) will improve this situation. Blue Cross and/or Blue Shield and selected private insurers reimburse for outpatient education in 14 states, Medicare in 15 states, and Medicaid in 6 states. Several states are considering legislation that would mandate coverage for self-management education programs for diabetes outpatients. 1 figure, 2 tables, 30 references.

64

TITLE: Third Party Reimbursement for Diabetes Mellitus: Outpatient Education: A Year's Progress. Peddicord, M.; Lyons, A.; Tobin, C.; Vinicor, F. *Diabetes Spectrum*. 3(1): 9-12. January-February 1990.

OBJECTIVE: To determine the progress made in obtaining third party reimbursement for outpatient education programs for patients with diabetes.

CATEGORY: Secondary intervention.

Type of Study: Patient management.
Methodology: Survey.
Perspective: Health care system.

CONCLUSION: Between 1986 and 1989, the number of states reporting reimbursement for diabetes outpatient education increased. Medicare reimbursement increased because of a national policy statement from the Health Care Financing Administration (HCFA). An increase in private insurer reimbursement is credited to consumer demand and Medicare

policies. There was little change in Medicaid programs.

RECOMMENDATION: Continued consumer advocacy, emphasis on quality, providing additional cost and cost-savings information, and ongoing exploration of strategies and alternatives are recommended to continue the progress made in reimbursement policies.

ABSTRACT: Reimbursement for outpatient education programs for patients with diabetes is increasing across the United States. Four states have enacted legislation covering reimbursement of these programs. Medicare reimbursement has increased for outpatient education programs because of a national policy statement issued by the HCFA defining Medicare's criteria for reimbursement of prevention, including diabetes education. Private insurers, including HMOs, have shown the greatest increase in third party reimbursement for outpatient education programs, primarily because of consumer demand and Medicare policies. Medicaid programs, which are regulated by the states, have shown the least change toward third party reimbursement. Among many insurers there is an acceptance of education as a part of treatment, and not solely as a preventive measure. Most reimbursed outpatient education programs are either hospital-based or based in rural health clinics. Programs formally recognized by an accrediting or recognition body at the state or national level are more likely to be reimbursed. Concerns regarding reimbursement for outpatient education for patients with diabetes include the fact that only one or two education programs per state currently receive reimbursement, that the prospective payment system is causing more programs to shift from an inpatient to outpatient setting, and that little progress has been made in reimbursement for free-standing education programs. 1 figure, 3 tables, 3 references.

Tertiary Intervention

Eye Care

65

TITLE: Cost Savings Associated with Detection and Treatment of Diabetic Eye Disease. Javitt, J.C. *PharmacoEconomics*. 8 (Supplement 1): 33-39. 1995.

OBJECTIVE: To estimate current and potential savings in the United States and Sweden from screening and treating retinopathy in persons with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: Treatment of retinopathy in patients with diabetes mellitus yields substantial savings of sight years and money.

RECOMMENDATION: Eye care for patients with diabetes must emphasize patient identification, carefully maintained follow-up, and prompt, appropriate treatment.

ABSTRACT: The author describes the use of the PROPHET modeling system, a program designed to model the progression of a chronic, irreversible disease, to estimate savings from recruiting, screening, and treatment programs for diabetic eye disease. Data from cross-sectional and longitudinal studies and clinical trials are used in the model. The analysis derives the costs of screening and treatment from average Medicare charges for 1990; savings as well as costs are expressed in 1990 U.S. dollars using a discount rate of 5 percent. An annual federal expenditure of $14,296 is predicted for blind persons with diabetes under 65 years of age, just $32 (not counting Medicare, Social Security, income tax exemption) for those 65 and over. Based on studies by Klein et al. (1987) in Wisconsin, the implementation rate of eye screening is currently 60 percent. Even at this suboptimal level, screening and treatment for eye disease in patients with diabetes generates annual savings of $350 million to the federal budget and 100,000 person-years of sight. Each additional person (beyond the 60 percent level) enrolled in appropriate screening and treatment is associated with net lifetime savings of $9,571 (type 1 diabetes) or $973 (type 2 diabetes). The Swedish Council on Technology Assessment in Health Care repeated this analysis and found that 60 percent implementation of screening could potentially save 22 million SEK. Their analysis found that savings associated with detection and treatment were 10 times greater than costs. The authors of the present study found that changing the frequency of screening for patients with no or mild background retinopathy from 1 to 2 years does not reduce years of sight saved and reduces screening costs if the sensitivity of eye screening is 80 percent or greater. 3 figures, 43 references.

66

TITLE: Cost-Benefit Analysis of Diabetic Eye Disease. Matz, H.; Falk, M.; Gottinger, W.; Kieselbach, G. *Ophthalmologica*. 210(6): 348-353. 1996.

OBJECTIVE: To compare the costs of blindness caused by diabetes with the costs of screening and treatment of retinopathy associated with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Screening for blindness saves more money than it costs.

RECOMMENDATION: All patients with diabetes should be screened for retinopathy and optimal therapy should be initiated.

ABSTRACT: The authors calculated the cost-benefit of screening and testing of diabetes-

associated eye disease in the state of Tyrol, Austria. Current and new cases of severe retinopathy (proliferative retinopathy or clinically significant macular edema) were calculated to be 2,147 and 252, respectively. Without proper intervention, all 252 persons with incident cases would be expected to go blind within 10 years, vision could be retained in at least one eye in 179 cases with proper treatment, and blindness could be delayed an average of 3 years in patients for whom it is unavoidable. Costs of blindness included disability payments and allowances; exemptions from telephone, television, and radio fees; tax exemptions; financial aid based on reduced earnings and disability; and early retirement pensions. The anticipated costs of blindness were ATS 19 million overall, of which ATS 14.6 million was considered preventable, assuming 100 percent ability to diagnose severe retinopathy and macular edema and 100 percent ability to treat these conditions at an optimal time. Cost was based on 10-year life expectancy at onset of severe retinopathy, duration of blindness ranging from 2.5 to 8.5 years, sex, age, employment status, type of diabetes, and correlation of minimum retirement age with life expectancy. In Tyrol, 16,913 persons would require annual eye examinations (cost: ATS 5,191,445) and 2,147 persons would require examinations 4 times per year (ATS 3,022,547). Laser coagulation or vitrectomy plus examinations would cost the national health care system ATS 8,560,089 and private insurance ATS 2,119,566 (only 17.7 percent of the population has supplemental private insurance). Up to ATS 3.9 million can be saved through adequate screening and treatment to prevent blindness. 1 figure, 5 tables, 25 references.

67

TITLE: Cost-Effective Screening for Retinopathy Using a Nonmydriatic Retinal Camera in a Pre-paid Health-Care Setting. Peters, A.L.; Davidson, M.B.; Ziel, F.H. *Diabetes Care*. 16(8): 1193-1195. August 1993.

OBJECTIVE: To evaluate the effectiveness of a nonmydriatic retinal camera as a screening tool for serious retinopathy.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The nonmydriatic retinal camera was highly sensitive in detecting serious retinopathy.

RECOMMENDATION: The nonmydriatic retinal camera should be considered an easy-to-use, inexpensive component of screening strategies for retinopathy.

ABSTRACT: The authors evaluated the effectiveness of the Canon CR4-45 nonmydriatic retinal camera as a screening tool for retinopathy. Nurse clinicians took retinal photos of the 522 patients in a diabetes program affiliated with a health maintenance organization at their initial and annual visits. The degree of retinopathy as assessed by the reader (a diabetologist) of the retinal photos was compared with results of examinations of the patients by retinal

specialists. These ophthalmologists used direct and indirect ophthalmoscopy as well as slit-lamp biomicroscopy. Sensitivity and specificity values for photo interpretation were based on 189 patients who had gradable photos for both eyes and a retinal examination report available. Comparison of any retinopathy noted by the examination with any retinopathy noted by the reader yielded a sensitivity and specificity of 85 percent and 93 percent, respectively. The reader occasionally missed background retinopathy not requiring treatment. If serious retinopathy was seen on the examination, the reader always noted some retinopathy (sensitivity: 100 percent; specificity: 82 percent). Results show that the nonmydriatic retinal camera, which is easy to use and inexpensive, can be employed as a screening tool for detecting serious retinopathy. The camera might identify more patients at risk for serious retinopathy than routine referral for ophthalmologic screening, for which compliance rates are often poor (74 percent in this study). 1 table, 11 references.

68

TITLE: Cost-Effectiveness of Alternative Methods for Retinopathy Screening. Lairson, D.R.; Pugh, J.A.; Kapadia, A.S.; Lorimor, R.J.; Jacobson, J.; Velez, R. *Diabetes Care*. 15(10): 1369-1377. October 1992.

OBJECTIVE: To compare the cost-effectiveness of four approaches to screening for retinopathy.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Screening with retinal photographs in a primary care setting can be cost effective. Cost per true-positive case was lowest for retinal photography with dilation.

RECOMMENDATION: Screening could be offered as an addition to a routine visit in a primary care clinic or on a separate visit.

ABSTRACT: The four methods of screening for retinopathy compared were (1) 45-degree retinal camera photography taken by a physician assistant or nurse practitioner without pupil dilation (n = 351), (2) the same kind of photography with pupil dilation (n = 351), (3) direct and indirect funduscopic examination (dilated pupils) by an ophthalmologist (n = 347), and (4) direct ophthalmoscopic examination (dilated pupils) by a physician assistant or nurse practitioner (n = 172). All photographs (methods [1] and [2]) were read by an ophthalmologist. Positive retinopathy was considered a level of 40 or greater on the modified Airlie House reference standard. Screening costs were incurred through Veterans Administration and Department of Defense facilities and included staff salaries and fringe benefits; equipment (amortized over expected life); supplies; participants' travel, screening time, and transportation; space; overhead; and reading fees. Interest rates were set at 8.24 percent, based on 1989 long-term government bond rates, and overhead costs were set at 29.7

percent of ambulatory care health system costs. Patient travel costs were assessed through an interview; wages for unemployed patients were calculated at $3.35 per hour. Cost-effectiveness was based on the cost per true-positive test. Sensitivity of methods 1-4, respectively, was 0.61, 0.81, 0.33, and 0.10; specificity was 0.85, 0.96, 0.99, and 0.99. Total cost (health system plus patient) per exam was $70, $74, $48, and $31, respectively. The average cost to the health care system only per case of identified retinopathy was $295 (method 2); $378 (method 1); $390 (method 3); and $794 (method 4). Adding the patient costs did not change these rankings. 1 figure, 4 tables, 22 references.

69

TITLE: Cost-Effectiveness of Alternative Methods for Retinopathy Screening. Wareham, N.J. *Diabetes Care*. 16(5): 844. May 1993.

OBJECTIVE: To point out an issue not raised in an article by Lairson et al. on screening methods for retinopathy (*Diabetes Care*. 15:1369-1377. 1992. Abstract 53) and offer calculations of sensitivity, specificity, and cost per true-positive for the data presented by those authors.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The conclusions of cost-effectiveness drawn by Lairson et al. may not be as strong as presented.

RECOMMENDATION: None.

ABSTRACT: The author notes that Lairson et al. did not account for error in their sensitivity estimates of the four screening tests they compared. He reassesses their data by applying 95 percent confidence intervals to the sensitivity and specificity of screening patients with diabetes for retinopathy by (1) 45-degree retinal photographs without pupil dilation, (2) retinal photography with pupil dilation, (3) ophthalmologist examination, or (4) technician examination. The sensitivity (with upper and lower 95 percent confidence limits) for 1-4 was 0.61 (0.72, 0.50), 0.81 (0.90, 0.72), 0.33 (0.44, 0.22), and 0.07 (0.14, 0), respectively. The specificity for 1-4 was 0.85 (0.89, 0.81), 0.96 (0.99, 0.94), 1.00 (1.00, 0.99), and 0.99 (1.00, 0.97), respectively. System cost per true-positive diagnosis with these approaches (with upper and lower estimates) was $378 ($463, $330), $295 ($331, $265), $390 ($581, $294), and $794 (not given, $379), respectively. Patient cost per true-positive diagnosis was $171 ($209, $144), $139 ($156, $125), $306 ($454, $230), and $1,009 (not given, $481), respectively. Because of the overlap in confidence intervals, the author points out that conclusions in this paper about the cost-effectiveness of these screening methods are weakened. He also points out that sensitivity is a major determinant of the cost-effectiveness of screening for retinopathy and states that including confidence intervals in the estimate of the cost per true-positive case

is critical for making policy decisions. 2 tables, 2 references.

70

TITLE: Cost-Effectiveness of Current Approaches to the Control of Retinopathy in Type I Diabetics. Javitt, J.C.; Canner, J.K.; Sommer, A. *Ophthalmology*. 96(2): 255-264. February 1989.

OBJECTIVE: To estimate the benefits (in terms of preservation of vision) and attendant costs of screening, diagnosis, follow-up, and treatment of retinopathy in patients with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: Screening, diagnosis, follow-up, and treatment of retinopathy in patients with type 1 diabetes resulted in a cost of $966 per person-year of sight saved, which is only 14 percent of the direct cost to the federal government of a year of blindness-related disability.

RECOMMENDATION: The federal government should fund eye care for patients with type 1 diabetes to avoid the higher cost of disability from blindness.

ABSTRACT: The authors used a computer model to analyze the benefits (in terms of preservation of vision) and attendant costs of screening, diagnosis, follow-up, and treatment of retinopathy in patients with juvenile-onset type 1 diabetes. Screening recommendations were taken from the Public Health Committee of the American Academy of Ophthalmology. Current charges for screening and treatment of retinopathy were compared with current federal budgetary expenses for blindness-induced disability under the Social Security Disability program. Incidence, disease progression, and mortality data were drawn from several population-based studies. The computer model, based on a Monte Carlo simulation, was run for a hypothetical cohort of 31,000 patients with type 1 diabetes beginning at age 12.5 years and followed over a 60-year period. Model inputs were based on published reports of cross-sectional and disease incidence studies, clinical trials, and U.S. statistics. The model predicted that by age 60, background retinopathy would have developed in 98 percent of the cohort, macular edema in 42 percent, and proliferative retinopathy in 72 percent. Despite appropriate screening and treatment, ultimately 28 percent of the cohort, according to the model, would suffer severe vision loss. Over the 60 years, costs for ophthalmologic examinations, focal laser treatment, and panretinal photocoagulation were $91.0 million, $26.0 million, and $44.0 million, respectively. A total of 92,700 person-years of sight could be saved at the end of 60 years by the application of screening and panretinal photocoagulation. The cost of screening and panretinal photocoagulation per person-year of sight saved was $966, which is only 14 percent of the direct cost ($6,900) to the federal government of a year of blindness-related disability payments. 8 figures, 2 tables, 35 references.

71

TITLE: Cost-Effectiveness of Detecting and Treating Retinopathy. Javitt, J.C.; Aiello, L.P. *Annals of Internal Medicine*. 124 (1 Part 2): 164-169. January 1, 1996.

OBJECTIVE: To determine from the perspective of health insurers the cost-effectiveness of ophthalmologic screening and treatment to prevent vision loss for patients with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-utility analysis.
Perspective: Health care system.

CONCLUSION: Ophthalmologic screening and treatment of eye disease in patients with diabetes is a highly cost-effective approach to preventing blindness in people with diabetes.

RECOMMENDATION: Implementation of current guidelines regarding eye examinations for people with diabetes should be encouraged.

ABSTRACT: Detection and treatment of diabetic eye disease has been shown to result in cost savings. Prevention of diabetes-related blindness, on a cost-effectiveness basis, ranks above other medical interventions commonly provided. The PROPHET system, based on Monte Carlo simulation, was used to model the progression of proliferative retinopathy. Monte Carlo simulation, which uses random number generation, allows for a simple, probability-based solution of complex disease progression processes over time. Screening and treatment costs were derived from average Medicare charges in 1990, using a discount rate of 5 percent. Previous reports suggest that over 413,200 person-years of sight are currently saved, and over 710,800 person-years of sight could be saved, if all patients with diabetes had appropriate ophthalmologic screening and treatment. The cost of implementing currently recommended guidelines for screening and treatment of retinopathy was calculated to be $1,757 per person-year of sight saved. The cost per quality-adjusted life-year (QALY) associated with detecting and treating diabetic eye disease was found to range from $1,996 per QALY for those with type 1 diabetes to $3,530 per QALY for those with type 2 diabetes who do not require insulin. Overall cost of detecting and treating disease in patients with diabetes was $3,190 per QALY. Despite the high level of efficacy, clinical effectiveness, and cost-effectiveness, screening and treatment for diabetic eye disease are not universally practiced. Recommendations for annual dilated eye examinations of patients with diabetes have now been included in the Health Plan Employer Data and Information Set (HEDIS II) quality guidelines adopted throughout the managed care industry. 1 figure, 4 tables, 55 references.

72

TITLE: Cost-Effectiveness of Strategies for Detecting Retinopathy. Dasbach, E.J.; Fryback, D.G.; Newcomb, P.A.; Klein, R.; Klein, B.E. *Medical Care*. 29(1): 20-39. January 1991.

OBJECTIVE: To evaluate the cost-effectiveness of six different strategies for providing ophthalmologic care to patients with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Screening for retinopathy is generally cost effective in younger-onset patients and in those older-onset patients who take insulin.

RECOMMENDATION: None.

ABSTRACT: The authors used data from the Wisconsin Epidemiologic Study of Retinopathy to create simulation models of the natural progression of retinopathy and the effects of detecting and treating retinopathy on this process. Data were modeled (by the Markov process) for three groups of 1,000 patients: younger-onset patients (under age 30 years at diagnosis) with diabetes for 5 years or more, older-onset patients (age 30 years or over at diagnosis) who required insulin, and older-onset patients who did not take insulin. The six strategies modeled for ophthalmologic care were annual or biannual use of ophthalmoscopy, annual or biannual use of fundus photography through physiologic pupil dilation (the nonmydriatic camera), and annual or biannual use of fundus photography through pharmacologic pupil dilation (mydriatic). Effectiveness was based on sight years saved with intervention. Each strategy was modeled over 10 and 60 years, with costs remaining constant; savings in years and costs were discounted by 5 percent to represent their present value. Except for the older-onset group not taking insulin, net savings for annual or biannual screening by all methods were substantial; for 10 years they ranged from $877,656 to $997,462 in the younger-onset cohort and from $19,043 to $71,986 in the older-onset group taking insulin. The younger-onset group (10-year model) saved more than 200 sight years by any of the strategies; the older-onset groups taking insulin saved 45 to 59 years; and those not taking insulin, 14 to 19 years. Sixty-year results were similar to those for 10 years; an exception was that the younger-onset cohort gained considerably more sight years and cost savings. Annual screening with fundus photography using the mydriatic camera was the most effective of the six screening strategies; however, the gain in effectiveness was small compared with annual screening with the nonmydriatic camera or with an ophthalmoscope. 7 figures, 5 tables, 32 references.

73

TITLE: Cost-Effectiveness of the Screening and Treatment of Retinopathy. What Are the Costs of Underutilization? Fendrick, A.M.; Javitt, J.C.; Chiang, Y.P. *International Journal of*

Technology Assessment in Health Care. 8(4): 694-707. Fall 1992.

OBJECTIVE: To determine whether screening and treating retinopathy is cost effective in Sweden.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Annual photographic screening to detect early signs of retinal disease combined with laser photocoagulation treatment of macular edema and retinopathy leads to improved health outcomes in terms of years of sight saved and also to decreased medical expenditures.

RECOMMENDATION: None.

ABSTRACT: A computer model (PROPHET) was used to simulate the health and economic outcomes of an annual screening program for retinal disease in a group of patients with type 1 diabetes in Sweden. Many Swedish patients with type 1 diabetes do not receive optimal eye care because physicians have inconsistent practice patterns, are inexperienced in performing the eye exam, and lack knowledge of screening recommendations. Screening for retinopathy and macular edema before high-risk lesions become worse is the key to preventing vision loss. The study looked at 750 patients newly diagnosed with diabetes over a 60-year life span. Fundus photography (3 fields per eye) was used as the screening method and photocoagulation (panretinal for proliferative retinopathy and focal retinal for macular edema) was employed to treat eye disease. The model predicted that background retinopathy, a preclinical state, would be present in 98 percent of the patients after 60 years of diabetes. Macular edema and proliferative retinopathy were predicted to occur in more than 50 percent of the patients in that period. The number of person-years of vision preserved by annual screening was closely linked to patient compliance with screening recommendations. The model revealed that with a compliance rate of 70 percent, more than 45,000 screening exams were performed over the 60-year study period and 2,306 years of vision were saved. Without screening and treatment, 6,500 years of sight would be lost. The model showed that with a screening compliance rate of 60 to 100 percent, net savings, including the costs of screening and treatment, would range from $3.7 to $6 million (U.S. dollars). Although the program was costly in the beginning, its net cost decreased over time as the years of sight saved accrued and treatment sessions decreased. Sensitivity analysis was performed to evaluate variables for which there was uncertainty. In this model, screening compliance rates correlated positively with improved clinical and economic outcomes. 5 figures, 3 tables, 64 references.

74

TITLE: Detecting and Treating Retinopathy in Patients with Type I Diabetes Mellitus: A Health Policy Model. Javitt, J.C.; Canner, J.K.; Frank, R.G.; Steinwachs, D.M.; Sommer, A.

Ophthalmology. 97(4): 483-494 (discussion: 494-495). April 1990.

OBJECTIVE: To estimate the medical and economic implications to the federal government of several screening and treatment strategies for retinopathy in patients with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: All five retinopathy screening and treatment strategies resulted in cost savings to the federal government.

RECOMMENDATION: Public health policy must consider the enormous medical and economic benefits that can be realized by detecting and treating diabetic eye disease.

ABSTRACT: The authors used a cost-benefit model to evaluate the average net savings to the federal government of retinopathy screening and treatment in patients with type 1 diabetes. Using a PROPHET simulation system, the authors analyzed outcomes for a hypothetical cohort of 31,000 patients developing the disease at age 12.5 years; these values represent annual incidence and average age of onset for this disorder in the United States. Five screening strategies involving various schedules of dilated ophthalmoscopy with and without full fundus photographs were tested: (1) ophthalmoscopy (with the eyes dilated) every 2 years, (2) annual ophthalmoscopic exam, (3) ophthalmoscopic exam annually for patients with no retinopathy, every 6 months for those with retinopathy, (4) annual ophthalmoscopic exam with full fundus photography, and (5) annual ophthalmoscopic exam with fundus photographs for patients with no retinopathy, an exam and photos every 6 months for those with retinopathy. The discount rate was set at 5 percent; potential savings (in 1986 dollars) were based on the amounts paid by the federal government for blindness-related disability ($6,300 annually in the model). Undiscounted screening and treatment costs for the five strategies varied from $89.2 million to $290.3 million. All of the strategies resulted in substantial net annual savings to the federal government, ranging from $62.1 million to $108.6 million. The model predicted a clear medical and economic advantage for the strategy of dilated ophthalmoscopy performed annually, then semiannually upon diagnosis of retinopathy. This strategy had the second highest government savings (annual ophthalmoscopy only had the highest), but saved several thousand more person-years of sight than annual ophthalmoscopy. Positive returns were seen for all five strategies at discount rates below 10 percent. Screening and treatment were cost-saving if the value of a year of sight saved was $2,500 or more. Little advantage was demonstrated in adding routine fundus photography to screening exams. 3 figures, 8 tables, 41 references.

75

TITLE: Detecting and Treating Retinopathy in Patients with Type I Diabetes Mellitus: Savings Associated with Improved Implementation of Current Guidelines. Javitt, J.C.; Aiello,

L.P.; Bassi, L.J.; Chiang, Y.P.; Canner, J.K. *Ophthalmology*. 98(10): 1565-1573 (discussion: 1574). October 1991.

OBJECTIVE: To estimate the net federal budgetary savings that might be attained with increased enrollment of patients with type 1 diabetes into appropriate ophthalmologic care.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: At current levels of screening and treatment implementation, it is less expensive to provide preventive eye care for patients with type 1 diabetes than to support subsequent disability. Because each 10 percent improvement in implementation over current levels would save $16.5 million annually, significant recruitment efforts could be undertaken without diminishing returns.

RECOMMENDATION: Public education should be expanded so that all possible patients are recruited into appropriate screening strategies, and primary care physicians must be enlisted to identify patients so that strict ophthalmologic follow-up may be instituted.

ABSTRACT: The authors analyzed the net federal budgetary savings achieved under current American Academy of Ophthalmology screening and treatment conditions for retinopathy in patients with type 1 diabetes and estimated savings that might be obtained by increased enrollment of patients into appropriate ophthalmologic care. A PROPHET modeling system, based on Monte Carlo techniques, was used to analyze events and costs. Disease data in the model were derived primarily from reports of cross-sectional studies and clinical trials. Screening and treatment costs were derived from average Medicare charges in 1990. The authors expressed costs and savings in 1990 U.S. dollars with a discount rate of 5 percent. They estimated that 60 percent of patients with type 1 diabetes receive retinopathy treatment and screening that meets American Academy of Ophthalmology guidelines. At this level, 47,374 person-years of sight are salvaged and $101.0 million saved annually. The model predicts that for every additional 10 percent of patients who enter screening, more than 7,966 person-years of sight and $16.5 million in further annual savings would be realized. With 100 percent screening, 79,236 person-years of sight and $167.0 million would be saved annually. Current American Academy of Ophthalmology guidelines recommend initiating retinopathy screening 5 years after diagnosis of type 1 diabetes. The additional annual financial burden of beginning screening upon diagnosis would be $3.03 million. However, the yearly increase in expense would be recovered totally if less than 1 additional patient were recruited to screening from every 56 patients with diabetes. The model predicts a loss of $17.4 million and 5,961 person-years of sight if treatment of retinopathy is delayed 1 year. 8 figures, 3 tables, 41 references.

TITLE: Detection of Sight-Threatening Diabetic Eye Disease. Leese, G.P.; Broadbent, D.M.; Harding, S.P.; Vora, J.P. *Diabetic Medicine*. 13(10): 850-853. October 1996.

OBJECTIVE: To review the feasibility and costs of screening methods to detect asymptomatic eye disease in patients with diabetes in the United Kingdom.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Community-based screening programs employing fundus photography or slit-lamp biomicroscopy may offer a cost-effective alternative to ophthalmological screening for eye diseases in patients with diabetes.

RECOMMENDATION: Formal research-based measurements of the effectiveness of alternative eye disease screening methods are needed, and health services purchasers must be persuaded to implement cost-effective community-based screening programs.

ABSTRACT: The authors review the status of screening for sight-threatening eye disease among patients with diabetes in the United Kingdom and assess the feasibility of alternatives to ophthalmological examinations. Because the number of ophthalmologists in the United Kingdom is not sufficient to allow screening of all patients, other options must be considered. Screening for retinopathy and other eye diseases at hospital-based clinics, at general practice clinics, in optometry practices, and by mobile fundus photography is discussed. The per-patient cost of screening by direct ophthalmoscopy has been estimated at £ 13 when performed by community-based optometrists, £ 15 by general practitioners, and £ 27 by hospital physicians. Costs of fundus photography by a mobile unit have been estimated at between £ 10 and £ 23 per patient versus £ 19 per screen if the camera is maintained within a hospital. When using a mobile van, overall costs per potentially sight-saving treatment have been estimated by other researchers at £ 700 to £ 1,000. Screening by fundus photography has been demonstrated to be more cost effective than ophthalmoscopy because of its greater sensitivity. Screening costs must be evaluated in comparison with the costs of supporting a blind person in the community, which were estimated in 1981 to be £ 3,500 per year. 42 references.

77

TITLE: Evaluation of Argon Laser Treatment of Retinopathy and Its Diffusion in The Netherlands. Vondeling, H. *Health Policy*. 23(12): 97111. January 1993.

OBJECTIVE: To review studies on argon laser treatment for retinopathy, including its cost-effectiveness; to discuss the diffusion of this technology.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: Screening for and treating retinopathy is cost effective.

RECOMMENDATION: None.

ABSTRACT: Clinical trial evidence indicates that immediate argon laser treatment can prevent blindness and stabilize retinopathy for at least 10 years in 70 percent of cases. Drummond et al. (1990) analyzed the U.S. Retinopathy Study and found a net savings from the trial for U.S. society over 22 years of laser photocoagulation of $2,816 million (including $2,585 million in lost production). Another model (Javitt and coworkers), for patients with type 1 diabetes, predicted a cost (in 1986 dollars) of $966 per person-year of vision saved from proliferative retinopathy and $1,118 per person-year of central acuity saved from macular edema; in contrast, average annual federal payments to eligible blind recipients were $6,900. A model of screening practices indicated that the most cost-effective method is dilated ophthalmoscopy performed annually for patients without retinopathy and every 6 months for those with retinopathy. Proper screening of 60 percent of persons with type 1 diabetes would result in annual savings of 47,374 person-years of sight and $101 million. In The Netherlands, the number of argon lasers increased from 10 prior to 1978 to 111 in 1992. Change in clinical practice in The Netherlands could have been implemented more quickly with more active governmental support. Adequate screening for diabetic eye disease is being promoted by the American Academy of Ophthalmology, the U.S. National Eye Institute, the World Health Organization, and the International Diabetes Federation. Further studies are needed to document accurately the cost-effectiveness of screening and early treatment programs. 3 figures, 21 references.

78

TITLE: The Evaluation of Mobile Screening for Retinopathy. Thompson, C.; Leese, G. *Scottish Medical Journal*. 40(1): 5-7. February 1995.

OBJECTIVE: To overview the use of mobile screening for retinopathy.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Mobile retinal cameras, which offer the chance to expand eye screening for retinopathy, particularly to remote and rural areas, should be considered a valuable addition to current methods.

RECOMMENDATION: None.

ABSTRACT: The authors review previous studies on screening for retinopathy in the United Kingdom. The ideal screening program for retinopathy, which has yet to be determined, should be technically accurate, cost effective, and applicable to the whole population. Mobile screening in the community is a possible alternative for patients who do not attend diabetes clinics and may be particularly valuable in remote rural areas, where fewer people attend specialty diabetes clinics or receive a regular ophthalmic examination. In the great majority of cases, mydriatic drops (to increase pupil size) are not required for the retinal cameras used. An evaluation of a rural mobile screening program (in Tayside) for persons with diabetes found that 20 percent of those not attending diabetic clinics had retinopathy, and 6.5 percent needed urgent ophthalmological assessment. It has been estimated that a comprehensive screening program that included detection, referral, treatment, and follow-up would reduce new blindness by 10 percent in persons under 70 years. A recent multicenter study on screening found the cost of diagnosis per true-positive case of sight-threatening retinopathy to be 33 to £ 1,079 when the screener was a general practitioner, £ 497 for a mobile community-based retinal camera, £ 1,546 for a hospital-based retinal camera, £ 1,028 for opticians, and £ 1,033 for hospital physicians. In the Tayside program, the cost to screen a patient was £ 10; the cost per case of newly discovered sight-threatening retinopathy was £ 50. The cost per patient receiving laser therapy for retinopathy was £ 1,000. A screening service's cost-effectiveness depends on the prior probability of detecting significant retinopathy; after the initial impact of the mobile camera it may drop because of the low annual incidence of this problem. The development of a strategy for identifying high-risk groups has been advocated. 24 references.

79

TITLE: Local Survey of Optometrists about Dilated Funduscopic Examinations for Patients with Diabetes: Making Use of Phone Book Yellow-Page Listings. Foster, D.T.; Wylie-Rosett, J.; Walker, E.A. *Diabetes Educator*. 22(6): 605-608. November-December 1996.

OBJECTIVE: To assess the knowledge, attitudes, and practices of optometrists in the Bronx, New York, area related to providing dilated funduscopic examination for patients with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Telephone survey.
Perspective: Health care system.

CONCLUSION: Dilated funduscopic examinations were available at a relatively modest cost in over half of the optometry practices listed in the NYNEX yellow pages for the Bronx.

RECOMMENDATION: Information is needed concerning how to increase education about dilated fundoscopic examinations in medically underserved areas such as the South Bronx. Campaigns to increase the rate of dilated funduscopy among patients with diabetes should consider how optometrists interact with the medical care system to achieve early detection of retinopathy and other diabetes-related eye problems.

ABSTRACT: The authors surveyed optometrists listed in the Bronx, New York, NYNEX yellow pages. Telephone interviews were conducted with 23 of the 31 optometry practices listed. Dilated funduscopic examinations were performed by 13 of the 23 practices. The primary contraindication to performing dilated funduscopy cited by respondents who performed the examination was narrow-angle glaucoma; hypertension was also mentioned as a contraindication (it is not considered one per se, and this problem is frequently associated with diabetes). Estimates by optometrists of the percentage of patients with diabetes who knew of the need for dilated funduscopy examinations ranged from 2 percent in the South Bronx to 25 percent for Westchester County (New York) practices. Billing charges for a general examination ranged from $12 to $55. The billing charge for dilated funduscopy ranged from no additional charge to a $27 extra charge. Of the 23 practices, Medicaid payment for examinations was accepted by 22, credit card by 20, and Medicare by 18. Performing dilated funduscopy could be a recruitment strategy for optometrists and might increase the number of patients who get this examination annually. 2 tables, 12 references.

80

TITLE: Meeting the Challenge of Diabetic Blindness in the 90's. Yeo, K.; Fan, R.; Yong, V. *Singapore Medical Journal*. 34(2): 128-130. April 1993.

OBJECTIVE: To describe a 5-year screening and education program for diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Blindness from retinopathy is largely preventable.

RECOMMENDATION: Institute a nationwide program of screening and treatment for diabetes.

ABSTRACT: The prevalence of diabetes in Singapore is rising, and retinopathy is a leading cause of blindness among Singapore adults. Hospital-based screening efforts in Singapore will

reach only a small percentages of those with diabetes. Most Singapore patients with diabetes are treated in primary-level services (general practitioners, outpatient departments), where direct ophthalmoscopy is widely available. This approach, however, has important technical limitations. Many persons with diabetes do not know that diabetes might cause blindness, and those with good vision are often not motivated to seek a fundal examination. If blindness can be prevented in 10 percent of the people in Singapore who have diabetes, cost savings will be significant. A nationwide screening program for public education in diabetes; training of medical staff, nursing personnel, and volunteers; and providing adequate treatment and follow-up facilities are suggested to reduce blindness from diabetes, with initial screening targeting high-risk groups. As a first step, the authors suggest establishing a centralized screening clinic in a hospital or diabetic center coupled with a mobile screening service. They project that 16,800 patients can be screened the first year, with 10 percent increments each year, for a total of 102,564 patients for 5 years. The cost of these two programs is estimated at $150,000 (Singapore dollars) for the first year, with equipment accounting for the major expenditure in that year. The cost of screening is not excessive and is much below the cost of treating late-stage retinopathy and rehabilitating blind patients. The loss of economically productive persons with diabetes must also be considered. Education can be carried out through mobile exhibits, mass media, talks and seminars, and a diabetes education exhibit in the screening center. Additional laser facilities would have to be made available to treat patients with sight-threatening retinopathy. 8 references.

81

TITLE: Mobile Retinal Photography: A Means of Screening for Retinopathy in Aboriginal Communities. Karagiannis, A.; Newland, H. *Australian and New Zealand Journal of Ophthalmology*. 24(4):333-337. November 1996.

OBJECTIVE: To determine whether interpretable fundus photographs of the eye could be taken by specially trained aboriginal health workers in a mobile screening setting.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Quality review.
Perspective: Health care system.

CONCLUSION: Of the 390 photographs taken of 47 patients known to have diabetes, 371 slides were of sufficient clarity to interpret for retinopathy. However, 158 of the 371 slides were suboptimal.

RECOMMENDATION: Mobile retinal photography carried out by aboriginal health workers as part of routine health visits could be an efficient, practical approach to eye screening of aboriginal diabetes patients living in remote areas and of monitoring patients with existing retinopathy.

ABSTRACT: The prevalence of diabetes in the aboriginal community in Australia is

estimated to be up to 15 percent. Aborigines and Torres Strait Islanders living in remote areas of Australia and New Zealand have limited access to screening services for retinopathy. The investigators describe a pilot study to train aboriginal health workers to take fundus photographs of the eyes of aborigines with diabetes during routine health clinic visits. The health workers received 2 weeks of training from an ophthalmic photographer; 1 week took place on-site in an aboriginal community. The photographer then supervised the health workers on 2 clinic visits in a 6-month period in the community during which the health workers carried out dilated eye examinations in 47 known diabetes patients. The health workers took an average of 8 photographs per patient (range: 4 to 27), for a total of 390 slides. A retinal specialist compared the slides with baseline photographs taken by the ophthalmic photographer at the beginning of each clinic visit and graded them for quality and interpretability. Nineteen slides, representing 11 patients, could not be read; 371 slides were of sufficient quality to detect significant eye disease. The unit cost per photograph was $1.00 (Australian dollars), not including the cost of the equipment, services of the retinal specialist, or mobile screening vehicle. 2 figures, 14 references.

82

TITLE: Ophthalmic Screening for Diabetics: The Importance of Physician-Ophthalmologist Collaboration in the Prevention of Blindness. Chew, S.J.; Hart, P.M.; Ang, B.C.; Lim, A. *Singapore Medical Journal*. 31(1): 26-29. February 1990.

OBJECTIVE: To evaluate the efficacy and cost-effectiveness of a screening program for retinopathy involving the coordination of primary physician and ophthalmologist services.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The screening program accurately identified patients with varying degrees of retinopathy at a reasonable cost.

RECOMMENDATION: Screening for retinopathy based on fundus photography performed by primary care physicians and interpreted by ophthalmologists should be considered an accurate, cost-effective strategy for blindness prevention in patients with diabetes.

ABSTRACT: The screening program, which was offered in Singapore, included Polaroid fundus photography, noncontact tonometry, and blood pressure measurement, with primary care physicians and ophthalmologists equally responsible for patient care. Screening examinations took place at a retinal clinic, and photographs were reviewed and discussed with patients by a retinal specialist. During the first 6 months of the program, 428 patients with known diabetes were screened; retinopathy was detected in 161 eyes (18.8 percent). The prevalence of retinopathy was closely associated with duration of diabetes; age of onset was of lesser importance. Of the 161 eyes with retinopathy, 60 percent exhibited only background

changes; sight-threatening retinopathy was found in 7.6 percent of all cases (59 of 856 eyes). Background retinopathy occurred in 22.5 percent of eyes among patients with type 1 diabetes and 9.7 percent of eyes among patients with type 2 diabetes. Proliferative retinopathy was 10 times more prevalent in the eyes of patients with type 1 than in the eyes of patients with type 2 diabetes. Patients were charged S$6.00 for the screening service, which included the cost of photography. 7 tables, 5 references.

83

TITLE: Opportunities for Cost Reduction in Retinopathy Treatment: Case Study From Mexico. Phillips, M.; del Rio, I.; Quiroz, H. *Bulletin of the Pan American Health Organization*. 28(1): 50-61. March 1994.

OBJECTIVE: To measure the costs of treating eye problems in patients with diabetes, to find out who bears these costs, and to determine how cost reduction could be accomplished.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: The cost of treating eye problems was quite high, and the individual patient bore most of the costs for treatment. Reducing the number of visits could substantially lower the economic impact on patients.

RECOMMENDATION: Further research is needed to clarify the benefits gained by patients who have photocoagulation laser therapy.

ABSTRACT: A randomized study was conducted at the Hospital for the Prevention of Blindness in Mexico City to determine the costs of treating patients with diabetes who had retinopathy. Clinical records of a random sample of 69 patients were used to collect data on demographic and socioeconomic variables, diabetes treatment, initial eye diagnosis, and the amount and type of eye treatment provided by the hospital from 1985 to 1991. The cost of the resources used for each type of treatment provided was determined. Patient interviews provided information about treatment-associated costs incurred by patients and those accompanying them. The average age of patients was 59 years; most were poor and had little formal education. All lacked private health insurance and none was reimbursed for medical care expenses incurred. The cost of treatment per patient over 5 years was $630; the patient and family paid 83 percent of the cost. Fees accounted for 45 percent of patient costs, other direct expenses (e.g., travel and accommodations) made up another 45 percent, and lost income accounted for 10 percent. Suggestions for reducing patient costs without lowering quality of care included shortening waiting time, increasing the strength of laser treatments to decrease number of visits needed, completing more procedures in a single visit, revising the policy on fluoroangiography, and educating patients and at-risk relatives accompanying them about the need for early detection and treatment of eye problems. 5 tables, 13 references.

84

TITLE: Practical Community Screening for Retinopathy Using the Mobile Retinal Camera: Report of a 12 Centre Study. British Diabetic Association Mobile Retinal Screening Group. Also, Population-based Screening for Retinopathy: A Promising Start (Comment). Greenwood, R.H. *Diabetic Medicine*. 13(11):925-926, 946-952. November 1996.

OBJECTIVE: To report the progress of a project involving the use of mobile units equipped with retinal cameras to provide eye screening services to diabetes patients in 12 health districts in the United Kingdom.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The mobile units performed 64,905 screenings; analysis of 42,803 screenings found 2,400 referrals for further evaluation, of which 516 resulted in immediate laser therapy for sight-threatening disease. During subsequent years of this multiyear project, the number of patients referred and those needing laser therapy declined.

RECOMMENDATION: Mobile eye screening programs should be designed to fit the specific needs of each district, retinal photographers should be personable and well trained, and close liaisons with local ophthalmologists should be established.

ABSTRACT: In 1989, the British Diabetic Association initiated a mobile eye screening program designed to reduce morbidity from diabetic eye disease, the leading cause of blindness in working-age adults. Twelve health centers, representing urban and rural areas, participated in the program. The vans were equipped with retinal cameras, and each center was responsible for training an operator/driver, determining how the screening service would be used in the district, and setting up systems for reporting results. Most screenings (76.5 percent) were carried out in primary care settings; the remainder were carried out in hospital-based settings. The average cost per patient screened and per patient treated was £ 13.11 and £ 1,110, respectively. Patient acceptance of the screening process was high, and in 10 of 12 districts financial responsibility for the program has been taken over by hospital trusts or district health authorities. The investigators conclude that the use of mobile vans for retinal screening is cost effective and efficient. An accompanying "Comment" notes that performance standards need to be developed by a central organization such as the British Diabetic Association before the program can be implemented on a wider scale. A table of proposed standards developed by the British Diabetic Association Retinal Screening Group is presented in the original article. The article also includes an appendix listing reports from district units. 7 tables, 1 appendix, 19 references in principal article; 15 references in Comment.

85

TITLE: Preventive Eye Care in People with Diabetes Is Cost-Saving to the Federal Government: Implications for Health Care Reform. Javitt, J.C.; Aiello, L.P.; Chiang, Y.; Ferris, F.L.; Canner, J.K. III; Greenfield, S. *Diabetes Care*. 17(8): 909-917. August 1994.

OBJECTIVE: To estimate savings to the federal government from screening and treatment of retinopathy in patients with type 2 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: Improvement in ophthalmologic screening of patients with type 2 diabetes will reduce vision loss and save money for the federal government.

RECOMMENDATION: Eye care for patients with type 2 diabetes must emphasize patient identification, careful follow-up, and prompt, appropriate treatment.

ABSTRACT: The authors used the PROPHET computer model system to project the incidence and the costs of screening and treatment of eye disease resulting from diabetes. PROPHET is designed to model the course of a chronic, irreversible disease. Incidence data for type 2 diabetes were applied to 1990 Medicare, Social Security Disability Insurance, and Social Security Insurance costs for screening and treatment; a 5 percent discount rate was used. Costs of screening were based on complete dilated eye examinations ($62 each) at diagnosis and every 2, 3, or 4 years or, for those with retinopathy, every 6, 12, 18, or 24 months. Treatment (photocoagulation for both eyes) cost, including fluorescein angiograms, was $1,980. Based on 1988 population figures for the United States, 576,136 patients yearly develop type 2 diabetes. Blindness in patients with diabetes costs the federal government $14,296 annually per patient under age 65; per patient aged 65 and over, federal expenditures are $32 annually (does not include Medicare/Social Security payments or income tax exemption). Screening and treatment for eye disease in patients with type 2 diabetes saves 53,986 person-years of sight at an annual federal budget savings of $247.9 million; these results assume that 60 percent of type 2 patients receive appropriate eye care. For patients with type 2 diabetes controlled by insulin, however, savings would be $1,715 per person, versus $725 for those controlled by other means. Patients with onset prior to age 45 account for 89.1 percent of sight savings and 100 percent of cost savings. With recommended eye care, 112,730 and 94,304 person-years of sight and $624 and $472.1 million would be saved annually in all patients with diabetes and those with type 2 diabetes, respectively. 4 figures, 2 tables, 52 references.

86

TITLE: A Relative Cost-Effectiveness Analysis of Different Methods of Screening for Retinopathy. Sculpher, M.J.; Buxton, M.J.; Ferguson, B.A.; Humphreys, J.E.; Altman, J.F.; Spiegelhalter, D.J.; Kirby, A.J.; Jacob, J.S.; Bacon, H.; Dudbridge, S.B.; Stead, J.W.; Feest, T.G.; Cheng, H.; Franklin, S.L.; Courtney, P.; Talbot, J.F.; Ahmed, R.; Dabbs, T.R. *Diabetic Medicine*. 8(7): 644650. August/September 1991.

OBJECTIVE: To determine the relative cost effectiveness of various screening methods for sight-threatening retinopathy in terms of cost per true-positive case detected.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Cost per true-positive case ranged from £ 633 to £ 1,079 for general practitioners; it was £ 1,033 for a hospital physician; £ 784 for an ophthalmic optician; £ 441 to £ 609 for an ophthalmological clinical assistant; £ 601 to £ 1,546 for a hospital-based camera; and £ 497 to £ 747 for a traveling camera. Except for the ophthalmological clinical assistant (the reference standard), the sensitivity of all screening methods was low (0.35 to 0.67). Relative Cost-effectiveness changes if the screening can take place without requiring an additional patient visit and is strongly related to the relative sensitivity of the screening methods and to the prior probability (prevalence or incidence) of retinopathy in the population with diabetes.

RECOMMENDATION: Approaches to screening, which are discussed in this report, may improve sensitivity without reducing specificity or increasing cost per true-positive case substantially.

ABSTRACT: The authors report on screening for sight-threatening retinopathy of five patient groups (n = 3,318) in three British centers. Patients' fundi were assessed by a primary screener (a hospital physician, a general practitioner, or an ophthalmic optician) using ophthalmoscopy with mydriasis. Additionally, all patients had their fundi photographed by a nonmydriatic fundus camera, and they received an ophthalmoscopic examination with mydriasis by an ophthalmological clinical assistant (the reference standard). The costs per true-positive case for the primary screeners ranged from £ 633 to £ 1,079 (£ 1,033 for the hospital physician), for the clinical assistant from £ 441 to £ 609, and for photography from £ 497 for a camera that is taken to general practices in one center to £ 1,546 for a hospital-based camera. The cost for true-positive case for hospital physicians would drop from £ 1,033 to £ 353 if an additional visit to the hospital were not required. Similarly, if ophthalmoscopy is part of a general assessment by a general practitioner rather than requiring an additional visit, the cost per true-positive case would drop dramatically (to £ 245 to £ 362). Total costs per patient screened by primary screeners ranged from £ 19.31 for ophthalmic opticians to £ 37.77 for hospital physicians. The low sensitivities of primary screeners and of photography (35 to 67 percent) may indicate that none of these methods would be acceptable in routine clinical

practice, despite their relatively high specificities (86 to 98 percent). Alternatives that may improve sensitivity (while avoiding a reduction in specificity or increase in cost per true-positive case detected) include (1) clinical assistant screening of both hospital and community-based patients; (2) use of combined screening strategies (e.g., general practitioner, ophthalmoscopy and fundus photography); and (3) identification of risk factors for retinopathy that could be used, exclusively or in combination with single or joint screening methods, as forms of screening in themselves (e.g., patients with 10+ years of type 1 diabetes could be referred directly to an ophthalmologist without prior screening). 1 figure, 3 tables, 25 references.

87

TITLE: Retinopathy in the West of Scotland: Its Detection and Prevalence, and the Cost-Effectiveness of a Proposed Screening Programme. Foulds, W.S.; McCuish, A.; Barrie, T.; Green, F.; Scobie, I.N.; Ghafour, I.M.; McClure, E.; Barber, J.H. *Health Bulletin*. 41(6): 318-326. November 1983.

OBJECTIVE: To assess the prevalence of retinopathy as diagnosed by ophthalmoscopy in the West of Scotland and to evaluate the financial implications of implementing a screening program for retinopathy in that part of Scotland.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Societal.

CONCLUSION: A projected screening program for retinopathy appeared to be cost savings in terms of costs of patient identification and screening relative to savings associated with the prevention of blindness.

RECOMMENDATION: Universal screening for early detection of serious retinopathy should be performed.

ABSTRACT: The authors assessed the prevalence of retinopathy in the West of Scotland. Based on ophthalmoscopic examination of 1,147 patients with diabetes, the authors estimated the prevalence of retinopathy to be 26 to 35 percent; of serious retinopathy, 9.5 to 11 percent. The potential cost-effectiveness of a proposed screening program involving annual ophthalmoscopic examination of all patients with diabetes in the West of Scotland (population about 2.5 million) was assessed. Projected annual cost associated with physician/ophthalmologist examination plus nurse time was £ 51,800. Total annual cost to identify those patients with serious retinopathy was estimated to be £ 55,300 , or £ 183 per patient with serious retinopathy identified. Total cost per annum of identifying and treating patients at risk for blindness was estimated to be £ 387 per patient treated. Costs associated with identifying and treating a backlog of patients during the first year of the program were estimated to be £ 86 per patient treated. Projected savings in blind welfare services and state

benefits per case of prevented blindness were calculated to be £ 3,575. It is estimated that 60 percent of blindness from retinopathy could be prevented by appropriate laser therapy. Total savings to the state per annum in treating and preventing blindness in such a percentage of at-risk patients were estimated to be £ 193,050. One-time savings associated with treating the backlog of patients with serious retinopathy were estimated to be £ 1.6 million. Appropriate laser therapy was estimated to result in a net savings of £ 135,025 annually based on projected treatment costs and savings for the state associated with blindness prevention. In addition, the 90 patients annually prevented from going blind would be expected to earn £ 4.67 million. 1 table, 10 references.

88

TITLE: Retinopathy — Need and Demand for Photocoagulation and Its Cost-Effectiveness: Evaluation Based on Services in the United Kingdom. Savolainen, E.A.; Lee, Q.P. *Diabetologia*. 23(2): 138-140. August 1982.

OBJECTIVE: To assess both need for photocoagulation and the cost-effectiveness of using this therapy in patients with retinopathy.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Patient care model.
Perspective: Societal.

CONCLUSION: The cost of photocoagulation and follow-up is less than the indirect costs to maintain a blind person for 1 year.

RECOMMENDATION: Criteria for the need for photocoagulation are urgently needed.

ABSTRACT: The authors used published literature from 1962 to 1978 to estimate the number of patients with diabetes needing photocoagulation for retinopathy in two regional Health Authorities in England. They also reviewed case notes (only 141 of 272 sampled were available) from 9 of 10 photocoagulation centers in the region. Interviews were conducted with consultants at the centers, and information on manpower, equipment, and practices with different patient groups was obtained to develop a model for estimating consultant hours and treatments needed per year. It was estimated that 10,608 eyes were in need of photocoagulation, which would require 21,417 consultant hours per year and 14,496 treatments. The estimated number of actual treatments for 1979 was only 3,080. The annual outpatient cost for photocoagulation and follow-up was £ 100 per patient (£ 170 in 1981 to 1982 prices). The cost of maintaining one blind person for 1 year (considering lost earnings and Social Security payments) was estimated to be £ 1,751 (£ 2,871 at the end of 1981). As two of the nine centers in the sample accept patients from outside the regions, these data indicate that fewer than 20 percent of the patient need for photocoagulation was met. Patients may be undiagnosed or diagnosed too late for treatment to be effective. Criteria are needed to guide early detection, adequate treatment, and follow-up of retinopathy in patients with

diabetes. Interested physicians, and possibly paramedical staff, will require training in photocoagulation to meet the need for this service. 1 figure, 1 table, 10 references.

89

TITLE: Screening for Retinopathy in a Clinical Setting: A Comparison of Direct Ophthalmoscopy by Primary Care Physicians with Fundus Photography. Griffith, S.P.; Freeman, W.L.; Shaw, C.J.; Mitchell, W.H.; Olden, C.R.; Figgs, L.D.; Kinyoun, J.L.; Underwood, D.L.; Will, J.C. *Journal of Family Practice*. 37(1): 49-56. July 1993.

OBJECTIVE: To compare the accuracy and cost-effectiveness of two approaches to screening for retinopathy in a clinical setting: (1) ophthalmoscopy by trained primary care physicians followed by referral to ophthalmologists as indicated, and (2) seven-view nonstereoscopic, mydriatic fundal photographs read by general ophthalmologists and retinal specialists.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Dilated ophthalmoscopic screening by primary care physicians followed by referral to an ophthalmologist if indicated was at least as accurate as and more cost effective than nonstereoscopic mydriatic fundus photographs read by ophthalmologists in screening for retinopathy.

RECOMMENDATION: Future studies should measure the absolute sensitivity, specificity, and predictive value of referral decisions for various diabetic retinal screening strategies and should estimate their costs. Similar trials should be conducted in other clinical settings to assess physicians' referral decisions.

ABSTRACT: The two screening strategies were implemented at a rural clinic in Toppenish, Washington, that served more than 400 Native Americans with diabetes. During the 2.5-year study period, 243 clinic visits were recorded; 93 referrals were made, of which 83 were completed. The primary care physicians were first given a 2-hour update about retinopathy and their role as screeners; they were told to refer every patient with marked retinopathy to an ophthalmologist. The "primary physician method" referred all 17 patients ultimately diagnosed with significant retinopathy. Estimated maximum sensitivity in diagnosing retinopathy was 100 percent for primary physicians; for the general ophthalmologists and retinal specialists reading photographs, it was 94 and 100 percent, respectively. Estimated maximum specificity was 93 percent for the primary physician, 82 percent for the general ophthalmologists, and 64 percent for the retinal specialists. Projected costs, including personnel and material costs plus examination charges (according to the American Academy of Ophthalmology), for screening and diagnosing 100 patients by these methods were $3,132 for ophthalmoscopic screening by primary providers, $4,942 to $5,734 for screening by retinal photography, and $8,800 for

referring all patients for full annual examination by an ophthalmologist. Transportation, training, equipment, and other direct or indirect costs were not included. 3 tables, 34 references.

90

TITLE: Screening for Retinopathy in South Africa with 60° Retinal Colour Photography. Joannou, J.; Kalk, W.J.; Mahomed, I.; Ntsepo, S.; Berzin, M.; Joffe, B.I.; Raal, F.J.; Sachs, E.; Van Der Merwe, M.T.; Wing, J.R. *Journal of Internal Medicine*. 239(1): 4347. January 1996.

OBJECTIVE: To assess the use of a 60° mydriatic fundal camera to screen for retinopathy.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Mydriatic retinal photography with a 60° field was more sensitive and diagnostically more accurate than funduscopy by clinic doctors and compared well with screening by an ophthalmologist. Screening for treatable retinopathy by 60° mydriatic retinal photography is likely to be cost effective.

RECOMMENDATION: Both retinae should be screened.

ABSTRACT: Patients attending a diabetes clinic in South Africa were screened for retinopathy by mydriatic fundal photography with a 60° camera. Selected eyes were evaluated by an ophthalmologist. Randomized photographs were assessed through single or two overlapping 45° fields (by masking the slides) and at 60°. The authors found that 92 percent to 94 percent of photographs were diagnostically useful (80 percent were excellent quality), which compares well with nonmydriatic cameras. Compared with an ophthalmologist's assessment, retinal photography had a sensitivity of 93 percent and a specificity of 89 percent for any retinopathy, and 100 percent and 75 percent, respectively, for severe retinopathy. Funduscopy missed 28 percent of affected eyes, compared with only 5.5 percent missed by photography. A single 45° field missed 31 percent and two overlapping 45° fields missed 11 percent of retinopathy as compared with that detected by a 60° field camera. For the 122 eyes assessed at the three field areas, the mean scores increased significantly as the field area increased ($p < 0.0001$ for each comparison). The costs of screening were calculated from the price of film and processing (but not the camera) and from related staff salaries for the first 663 patients screened. The basic expenditure (in U.S. dollars) was determined to be $5.85 per patient screened, $13.55 per patient with retinopathy (n = 286), and $37.03 for each patient referred for formal ophthalmological assessment (n = 103, 15.5 percent). 2 figures, 1 table, 30 references.

91

TITLE: Use of Mobile Screening Unit for Retinopathy in Rural and Urban Areas. Leese, G.P.; Ahmed, S.; Newton, R.W.; Jung, R.T.; Ellingford, A.; Baines, P.; Roxburgh, S.; Coleiro, J. *British Medical Journal*. 306(6871): 187-189. January 16, 1993.

OBJECTIVE: To compare the rate of retinopathy detected by a mobile screening unit equipped with a nonmydriatic Polaroid between rural and urban areas; to identify the cost associated with the service.

CATEGORY: Tertiary intervention.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Mobile eye-screening units seem to be particularly effective at identifying previously unrecognized advanced retinopathy in rural patients with diabetes; these patients were more likely than urban patients to need urgent laser photocoagulation. The cost per patient with mobile eye screening units was relatively low.

RECOMMENDATION: Patients with diabetes living in rural areas are less likely to seek help at hospital clinics and would benefit from an expanded mobile-eye-screening program to detect and treat retinopathy.

ABSTRACT: Researchers compared the effective-ness of screening for retinopathy using mobile eye-screening units in rural versus urban patients with diabetes during 2 years in the Tayside region of Scotland. They estimated that 64 to 77 percent of the population with diabetes was screened: 1,225 urban and 961 rural patients were photographed with a nonmydriatic fundal camera. Rural patients were less likely to attend a hospital clinic than urban patients (46 percent versus 86 percent, $p < 0.001$) and were less likely to be receiving insulin (27 percent versus 34 percent, $p < 0.001$). Advanced retinopathy was greater among rural than urban patients (13 percent versus 7 percent, $p < 0.001$), and more rural patients required urgent laser photocoagulation (1.4 percent versus 0.5 percent, $p < 0.02$). Direct and indirect costs, estimated for screening 1,800 patients a year, included the salary of the ophthalmic photographer; the purchasing and processing of film; and the servicing, running, and depreciation costs of the van and camera. The cost of the screening program per patient was £ 10, which is cheaper than all alternatives. This cost is equivalent to £ 350 per patient with previously unrecognized disease and £ 1,000 per patient receiving laser treatment. These costs are low compared with alternatives and could be further reduced by screening more patients per unit. 5 tables, 23 references.

Renal Care

92

TITLE: Cost Analysis of Kidney-Pancreas and Kidney-Islet Transplant. Lenisa, L.; Castoldi, R.; Socci, C.; Motta, F.; Ferrari, G.; Pozza, G.; Di Carlo, V. *Transplantation Proceedings*. 27 (6): 3061-3064. December 1995.

OBJECTIVE: To compare outcomes and costs for patients with diabetes undergoing kidney-pancreas or kidney-islet cell transplantation.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Costs for kidney-pancreas and kidney-islet cell transplantation were nearly the same. Pancreas grafts had better actuarial survival than islet cell grafts.

RECOMMENDATION: Improvements are needed in isolation and purification techniques for islet cell transplantation, which might lower costs for that approach.

ABSTRACT: The authors report the costs for 51 kidney-pancreas transplants and 21 kidney-islet cell transplants in patients with type 1 diabetes transplanted at an Italian hospital since 1989. Among kidney-islet cell patients, 14 received islet cells after kidney transplantation and 7 received islet cells simultaneously with the kidney. All 72 patients received the same immunosuppression and antimicrobial and vascular thrombosis prophylaxis. Actuarial survival was calculated from life tables. Expenditures were the actual costs incurred for hospitalization from pretransplant evaluation until discharge; kidney-islet cell costs were calculated based on using islets from two pancreases per kidney-islet cell transplant and assuming simultaneous transplantation of islet cells. Actuarial survival at 48 months was 70 and 52 percent for pancreas and islet cell grafts, respectively. Peri-operative mortality, morbidity, and incidence of surgical complications were 1.9 and 5 percent, 54 and 29 percent, and 43 and 4.8 percent for kidney-pancreas and kidney-islet cell, respectively. Total transplantation costs were comparable ($46,085 for kidney-pancreas and $47,550 for kidney-islet cell). Graft retrieval cost $1,400 for kidney-pancreas versus $2,260 for kidney-islet cell; islet cell isolation cost $15,500. Costs for surgery, hospitalization, and immunosuppression were higher for kidney-pancreas than for kidney-islet cell ($5,440 versus $2,580, $30,765 versus $20,790, and $5,640 versus $3,760, respectively). Patients stayed in intensive care a mean of 7 days for kidney-pancreas versus 3 days for kidney-islet cell transplantation and in the medical department a mean of 60 versus 50 days, respectively. Hospitalization represented 67 percent of kidney-pancreas and 44 percent of kidney-islet cell costs; islet cell isolation represented 32 percent of kidney-islet cell costs. The mean length of hospital stay (the major cost for both groups) is likely to be lowered. Improvements in islet cell isolation might decrease costs for kidney-islet cell transplantation. 2 figures, 2 tables, 6 references.

93

TITLE: The Cost of Immunosuppression and Coverage of Immunosuppressive Drugs for Kidney Transplant Recipients Under the Medicare Catastrophic Coverage Act. In: *Cost and Outcome Analysis of Kidney Transplantation: The Implications of Initial Immunosuppressive Protocol and Diabetes (Final Report: Volume I)*. Evans, R.W.; Manninen, D.L.; Thompson, C. Battelle Human Affairs Research Centers, Seattle, Washington. 1989. Chapter 13.

OBJECTIVE: To provide the Health Care Financing Administration with information it needs to quantify the economic consequences of the Medicare Catastrophic Coverage Act of 1988.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: There are likely to be relatively few changes in transplant immunosuppression between 1988 and 1995 that will seriously affect the overall costs of organ transplantation.

RECOMMENDATION: None.

ABSTRACT: The Medicare Catastrophic Coverage Act of 1988 will shield Medicare beneficiaries from excessive hospital, doctor, and outpatient prescription drug bills. In this chapter, the authors project the number of kidney transplant recipients likely to be eligible for Medicare catastrophic coverage through 1995, estimate per-patient annual expenditures for immunosuppressive drugs during the year of transplant and subsequent years, and highlight future developments in the field of transplant immunosuppression. In 1987, there were 39,585 living kidney transplant recipients; for 1995 the authors project totals ranging from 63,910 (base case) to 144,653. The authors note that cyclosporine was approved by the Food and Drug Administration in 1983; for 1990 through 1995 they project that 95 percent of transplants (cadaver or living related donor) will use this drug as a primary immunosuppressive agent. They present cost estimates associated with major immunosuppressive protocols in use in the United States; per the "high" estimate, total first-year costs range from $947 for conventional immunosuppression without antithymocyte globulin to $12,819 for quadruple-drug cyclosporine therapy. Subsequent-year annual costs range from $793 for conventional immunosuppression to $8,227 for triple-drug cyclosporine therapy (U.S. variation); this cost is $6,870 for quadruple-drug cyclosporine therapy. Per the National Task Force on Organ Transplantation (1985), the cost-effectiveness of cyclosporine therapy is believed to exceed that of conventional therapy, but the Task Force assumed that patients on cyclosporine would be converted to conventional therapy within 1 year after transplant. The authors state that triple-drug and quadruple-drug cyclosporine therapy appear to be equally cost effective. 56 tables, 5 figures.

94

TITLE: Cost-Effective Treatment for Diabetic End-Stage Renal Disease: Dialysis, Kidney, or Kidney-Pancreas Transplantation? Lenisa, L.; Castoldi, R.; Socci, C.; Motta, F.; Ferrari, G.; Spotti, D.; Caldara, R.; Secchi, A.; Pozza, G.; Di Carlo, V. *Transplantation Proceedings*. 27 (6): 3108-3113. December 1995.

OBJECTIVE: To compare the survival, morbidity, and cost of hemodialysis, kidney transplantation, and kidney-pancreas transplantation in patients with end-stage renal disease associated with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: In terms of survival rate and financial savings, kidney-pancreas transplantation is the most cost effective of the three treatments.

RECOMMENDATION: None.

ABSTRACT: The authors report survival, morbidity, and cost data for 122 patients with type 1 diabetes treated at San Raffaele Hospital in Milan, Italy. All patients had undergone hemodialysis (HD); in this study, 48 remained on HD, 23 underwent kidney transplantation (K), and 51 had a kidney-pancreas transplant (KP). Survival rates were calculated by life-table methods from the beginning of HD for all patients and from the third month after transplantation for K and KP. To correct for selection bias, survival curves were also calculated from the day of transplantation for the K and KP groups and from 25 months after initiation of HD for the HD group (25 months was the mean duration of dialysis at transplantation for the transplant groups). Expenditures were the actual costs (undiscounted) incurred for hospitalization from pretransplant evaluation until discharge and for consumable materials, depreciation of machinery and buildings, and personnel costs. Actuarial survival 96 months from initial HD for HD, K, and KP was 40 percent, 70 percent, and 87 percent, respectively ($p < .001$ for K and KP compared with HD); 84-month survival from date of transplantation or from 25 months after HD initiation (for the HD group) was 36 percent, 65 percent, and 96 percent, respectively ($p < .001$ for K and KP compared with HD). In KP, there were five kidney transplant failures and one pancreas graft failure; in K, there was one graft failure. Peri-operative mortality was 8.7 percent in K and 1.9 percent in KP. The first year of HD cost $43,150 for 3 treatments per week, monthly assessment, and vascular access. Transplantation costs were $30,090 for K and $46,085 for KP. Surgery, hospitalization, and rejection treatment costs were higher for KP than K. Estimated costs for each year after transplantation were $13,070 for K and $10,880 for KP, which were 32 percent and 27 percent of expected yearly HD costs, respectively. 4 figures, 3 tables, 15 references.

95

TITLE: Cost-Effectiveness Modeling of Simultaneous Pancreas-Kidney Transplantation. Holohan, T.V. *International Journal of Technology Assessment in Health Care*. 12(3): 416-424. Summer 1996.

OBJECTIVE: To compare simultaneous pancreas-kidney transplantation and kidney transplantation plus continued insulin therapy in patients with type 1 diabetes using a cost-effectiveness model.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The model predicted that simultaneous pancreas-kidney transplantation would be less cost effective than a kidney transplant plus continued insulin therapy except for patients with complicated diabetes that was poorly responsive to exogenous insulin and whose costs of maintaining blood glucose control were high. In that scenario, the two interventions were equal in cost-effectiveness.

RECOMMENDATION: These cost-effectiveness analyses should be reviewed periodically as data on pancreas survival after simultaneous pancreas-kidney transplant accumulate and as more comprehensive cost information becomes available.

ABSTRACT: In the authors' cost-effectiveness model, estimated costs for 100 hypothetical recipients of simultaneous pancreas-kidney transplants were compared with those for 100 hypothetical recipients of a kidney transplant only. Cost estimates for transplant procedures and for maintaining blood glucose control in those without a normally functioning pancreas as well as estimates of the quality of life resulting from transplant were considered. Costs were estimated for a 3-year posttransplant period; costs for kidney transplant alone included ongoing expenses of treating hyperglycemia or hypoglycemia. The model assumed no renal graft loss in either group; pancreas graft survival rates were based on United Network for Organ Sharing data. The costs of combined transplant included managing hyperglycemia or hypoglycemia in those patients whose pancreas grafts failed over time. Payment data for the procedures were obtained from the Health Insurance Association of America, the Health Care Financing Administration, and a survey of transplant centers. The cost per quality-adjusted life-year of the two procedures was equivalent only when the annual cost of blood glucose control was in the range of $28,000 to $40,000. Simultaneous pancreas-kidney transplant was therefore likely to be equivalent in cost-effectiveness to kidney transplant plus continued insulin therapy only for those patients whose annual direct costs of blood glucose maintenance were high, in the range of $15,000 to more than $40,000 per year. Average annual direct costs for treating diabetes and its complications have been estimated to be $6,280 by the American Diabetes Association. 1 figure, 4 tables, 65 references.

96

TITLE: Cost-Effectiveness of Screening and Early Treatment of Nephropathy in Patients with Insulin-Dependent Diabetes Mellitus. Siegel, J.E.; Krolewski, A.S.; Warram, J.H.; Weinstein, M.C. *Journal of the American Society of Nephrology*. 3(Suppl 1): S111-S119. October 1992.

OBJECTIVE: To determine the effect of angiotensin-converting enzyme inhibitors (ACEIs) on survival and the cost of using these drugs at an early stage of nephropathy; to determine what kind of intervention program with ACEIs would be appropriate.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Early treatment of type 1 diabetes with ACEIs can be a very cost-effective use of health care resources.

RECOMMENDATION: None.

ABSTRACT: Researchers developed a model to simulate the progression of renal complications in newly diagnosed type 1 diabetes patients to determine the effectiveness of using ACEIs as a treatment modality. Three alternative strategies (programs) were analyzed (versus standard antihypertensive treatment); patients were screened twice annually for renal complications in each. Overt proteinuria, significant microalbuminuria, and microalbuminuria were treatment indicators for ACEIs in programs 1, 2, and 3, respectively. The progression of nephropathy and medical care costs incurred with the new programs were compared with those for standard treatment. Cost-effectiveness was considered the ratio of the net increase in health care costs (discounted by 5 percent per year) to the discounted net improvement in health outcome (life expectancy). With standard treatment, a cohort of 15-year-old patients with type 1 diabetes had a median life expectancy of 44.9 years (undiscounted) and lifetime costs for treatment of $4,706 per person (discounted). Program 1 was used as the baseline to calculate cost-effectiveness ratios because it had lower costs and it improved life expectancy more than standard treatment. Program 1 lifetime costs were $4,643 per person (discounted) and additional life expectancy was 45.1 years (undiscounted), assuming a starting age of 15 years. Values for program 2 were $5,542 and 45.3 years; program 3, $5,927 and 45.5 years. Program 2 offers additional life savings at an additional cost; however, it is not a cost-effective option; the substantial increase in screening and treatment costs from this program is not offset by a sufficient increase in life expectancy. Program 3 had the highest initial costs but avoided twice as many cases of renal failure as program 1; it provided an additional 5 to 8 months of life expectancy (not discounted) and its incremental cost-effectiveness ratio was $7,900 to $16,500 per additional year of life saved. Resources permitting, program 3 would be the preferred choice. 1 figure, 6 tables, 23 references.

97

TITLE: The Costs of Nephropathy in Type II Diabetes. Borch-Johnsen, B. *PharmacoEconomics*. 8(Supplement 1):40-45. 1995.

OBJECTIVE: To discuss the problem of nephropathy in patients with diabetes, including the social cost of this disorder and the economics of prevention.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: Screening, intervention, and treatment for nephropathy is cost effective in type 1 diabetes patients; more research on this issue is needed for type 2 diabetes.

RECOMMENDATION: Future controlled clinical trials on the benefits of screening for diabetic nephropathy should focus on type 2 diabetes patients.

ABSTRACT: The lifetime risk of diabetic nephropathy may be as low as 15 to 25 percent in type 1 diabetes patients. Studies of the natural history of nephropathy in patients with type 2 diabetes are difficult to perform, but research in selected high-risk populations has found incidence patterns to be similar for types 1 and 2 diabetes. Patients with diabetic nephropathy have an increased risk (versus other patients with diabetes) of developing other late diabetic complications (e.g., they have a relative risk of 5-10 for acute myocardial infarction and 2-4 for stroke). Genetic susceptibility appears to be essential for developing nephropathy. Important risk factors for nephropathy among type 2 diabetes patients include young age at diagnosis, familial predisposition, poor metabolic control, hypertension, retinopathy, and microalbuminuria. The author discusses a model for estimating the actual costs of diabetic renal disease in a society; epidemiological data, results of controlled clinical trials, and reliable cost data are needed for the model. Studies of type 1 diabetes patients show the costs of treating end-stage renal failure to be so high that, even for rather expensive screening, intervention, and treatment programs, the benefits exceed the costs; a separate analysis would be needed for type 2 diabetes patients. In white populations in western Europe and North America, most type 2 diabetes patients will die from vascular disease. In nonwhite populations, the incidence of type 2 diabetes in patients below age 50 is much higher than in whites, and these patients will live long enough to develop diabetic nephropathy. Intervention trials targeted at preventing end-stage renal failure in type 2 diabetes patients are urgently needed; studies in Asia, the Pacific Islands, and Latin America (high-risk areas for early-onset type 2 diabetes) should be encouraged. 1 figure, 4 tables, 21 references.

98

TITLE: Economic Analysis of Captopril in the Treatment of Diabetic Nephropathy. Rodby, R.A.; Firth, L.M.; Lewis, E.J.; the Collaborative Study Group. *Diabetes Care*. 19(10): 1051-1061. October 1996.

OBJECTIVE: To determine the long-term impact on health care costs of using captopril therapy in patients with diabetic nephropathy to delay the progression to end-stage renal disease (ESRD) or death.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: The analysis showed that captopril therapy in patients with type 1 or type 2 diabetes and overt nephropathy saves substantial direct costs and reduces health care expenditures for treatment of ESRD.

RECOMMENDATION: None.

ABSTRACT: The authors assessed the long-term impact on health care costs of treating patients with diabetic nephropathy with captopril, an antihypertensive drug. A medical treatment model was developed to compare the costs and benefits of captopril therapy in delaying the progression to ESRD or death. The model was based on data derived from a prospective, double-blind, multicenter clinical trial of captopril in patients with type 1 diabetes and nephropathy. In that model, captopril therapy reduced the risk of both progressive renal insufficiency and the combined endpoint of death, dialysis, and transplantation by about 50 percent. Data for patients with type 2 diabetes were projected from the type 1 study. The model assessed the economic impact of captopril therapy over the projected lifespans of patients in the study (31 years for patients with type 1 diabetes and 12 years for patients with type 2). Projected costs for ESRD included direct costs associated with treatment (dialysis and transplantation), including transportation, and indirect costs related to disability and premature death. Direct and indirect costs were stated in 1994 dollars; both costs and life-years saved were discounted at 5 percent. Direct lifetime cost savings associated with captopril use were $32,550 per patient for those with type 1 diabetes and $9,900 per patient for those with type 2. Indirect per-patient cost savings were $84,390 and $45,730 for those with type 1 and type 2 respectively. These savings included future monies not spent on ESRD treatment because of death of some patients from other causes, such as cardiovascular disease. According to the model, if captopril therapy were initiated in 1995 for patients with either type of diabetes and nephropathy, the aggregate health care costs savings would be $189 million a year for the year 1999 and $475 million a year in 2004; the present value of cumulative health care cost savings over 10 years would be $2.4 billion. 4 figures, 2 tables, 2 appendixes, 66 references.

99

TITLE: Economic Evaluation of the Contribution of Captopril in the Treatment of Diabetic Nephropathy: A Cost-Effectiveness Approach. (Article in French with an English abstract.) Le Pen, C.; Petitjean, P.; Lévy, P.; Hannedouche, T. *Nephrologie*. 17(6): 321-326. 1996.

OBJECTIVE: To evaluate the cost-benefit ratio of the use of captopril to treat nephropathy in patients with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: The use of captopril to treat nephropathy in patients with type 1 diabetes is therapeutically and economically efficacious, especially for patients who require antihypertensive therapy as well.

RECOMMENDATION: None.

ABSTRACT: The authors analyzed the cost benefit of captopril treatment of nephropathy in patients with type 1 diabetes, using previously published data from a randomized, double-blind, clinical trial (Lewis. New England Journal of Medicine 329: 1456-1462. 1993). Patients had been diagnosed at least 7 years previously and had proteinuria greater than 500 mg/24 hours and blood creatinine less than 221 μmol/L at entry. Serum creatinine doubled in 25 of the captopril group (n = 207, 25 mg, 3 times per day for an average of 883 days) and in 43 of the placebo group (n = 202, average of 824 days; $p < 0.007$). The combined death, dialysis, or transplantation events numbered 23 (8 deaths) in the treatment group and 42 (14 deaths) in the placebo group ($p < 0.006$). Costs were calculated based on 1993 French health care costs and on the Lewis data from which the effects of other antihypertensive treatment could not be separated nor costs of screening for admission to the study or follow-up determined. Captopril treatment cost 1,263,017 French francs (FFr) for the cohort (FFr 6,101.53 per patient); other antihypertensives cost (in FFr) 543,271 in the captopril group and 649,832 in the placebo group. In the captopril and placebo groups, hospitalizations cost (in FFr) 630,312.98 and 712,752.14, respectively, and dialysis/transplantation cost (in FFr) 13,842,500 and 20,912,500, respectively. Overall, the cost savings in the captopril group was FFr 5,995,983; a savings of 131 life-years was also realized in the captopril group. If all patients were treated with captopril for nephropathy, the net cost-benefit would be FFr 475 per patient. These savings actually underestimate cost-benefit since they do not include, for instance, the hospitalization costs for vascular access and initiation of dialysis or pretransplant examinations. Further economic benefits from captopril would be expected from a study of longer duration. 5 tables, 10 references.

100

TITLE: Employment, Work Disability, and Income Support Program Participation. In: *A Cost and Outcome Analysis of Kidney Transplantation: The Implications of Initial Immunosuppressive Protocol and Diabetes (Final Report: Volume I)*. Evans, R.W.; Manninen, D.L.; Thompson, C. Battelle Human Affairs Research Centers, Seattle, Washington. 1989. Chapter 8.

OBJECTIVE: To examine the employment and work disability experience of renal transplant patients after their transplant surgery.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Survey.
Perspective: Societal.

CONCLUSION: Kidney transplantation is not very effective in allowing previously disabled dialysis patients to return to the labor force.

RECOMMENDATION: None.

ABSTRACT: In this multicenter observational study (sponsored by the Health Care Financing Administration) of patients who underwent kidney transplantation, questionnaires were used to find out about employment status in the year prior to transplant and at 3, 6, 9, 12, and 15 months after the procedure. Sample sizes frequently differed by analysis. Just over half (50.7 percent) of patients reported they were employed either full time or part time in the year prior to surgery; 3 months after surgery, only 28.7 percent said they were employed. In an analysis by primary renal diagnosis, less than half (43.3 percent) of those whose diagnosis was not diabetes and 33.3 percent of those with a diabetes diagnosis were employed full time before transplant; 23.8 and 20.0 percent, respectively, were employed full time 3 months later. On the issue of ability to work (not employment status), rates for the diabetes and nondiabetes groups were as follows: not able to work for pay, 63.1 percent and 39.1 percent; limited in kind of work, 83.1 percent and 58.6 percent. Three months posttransplant, 43.5 percent of transplant patients were receiving Social Security retirement or disability benefits and 17.8 percent were receiving Supplemental Security Income. More than half (53.8 percent) of patients with a primary renal diagnosis of diabetes were receiving Social Security retirement or disability benefits at that time. Although 97.2 percent of transplant patients said they received assistance (Medicare, State Kidney Program, Medicaid, etc.) in paying for immunosuppressive drugs, 22.8 percent said they had difficulty paying for the drugs. Fifteen months following transplantation, 43.1 percent of patients reported being employed either full or part time, but the number of patients for whom employment status was known was very small (n = 51). 27 tables.

101

TITLE: Hospital Charges. In: *Cost and Outcome Analysis of Kidney Transplantation: The Implications of Initial Immunosuppressive Protocol and Diabetes (Final Report: Volume I)*. Evans, R.W.; Manninen, D.L.; Thompson, C. Battelle Human Affairs Research Centers, Seattle, Washington. 1989. Chapter 12.

OBJECTIVE: To analyze costs of the initial hospital stay and follow-up periods for patients undergoing kidney transplantation.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Kidney transplantation is an expensive procedure.

RECOMMENDATION: None.

ABSTRACT: In this multicenter observational study of kidney transplantation, which was sponsored by the Health Care Financing Administration, the authors analyzed hospital charges rather than costs. The mean charge for the transplant procedure (the initial hospital stay), including professional fees, was $41,046 (range: $18,484 to $727,392); length of stay ranged from 6 to 252 days (n = 396). Patients were compared by whether their primary renal diagnosis was diabetes: Average transplant charges for the nondiabetes group were $41,587; for the diabetes group, they were $39,718. Estimated follow-up hospital charges (not including professional fees) in the first year after transplant were $22,098 for the diabetes group and $12,533 for those without the diabetes diagnosis. Patients with a diabetes diagnosis averaged more follow-up hospital days than other patients in the first four posttransplant periods (each 3 months), with the most pronounced difference in the 6-9-month period (5.8 days versus 1.5 days). For the 24 patients who experienced a graft failure or died between initial hospital discharge and the 3-month checkpoint, hospital charges for this period (excluding professional fees) averaged $31,049. In contrast, for the 346 patients with functioning grafts at 3 months, average charges were $3,835. 13 tables.

102 *(Cross-Reference 161)*

TITLE: Is Screening and Intervention for Microalbuminuria Worthwhile in Patients with Insulin Dependent Diabetes? Borch-Johnsen, K.; Wenzel, H.; Viberti, G.C.; Mogensen, C.E.

British Medical Journal. 306(6894): 1722-1725. June 1993. Correction: 307(6903): 543. August 1993.

OBJECTIVE: To analyze the cost benefit of screening for microalbuminuria and providing antihypertensive treatment for early renal disease indicated by microalbuminuria in patients with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Assuming drug treatment effects (delay in normal progression of microalbuminuria) of 33 percent or 67 percent, median life expectancy increased by 4 or 14 years, respectively, and the need for dialysis or transplantation decreased by 21 percent or 63 percent. Establishing a screening program for microalbuminuria for patients with type 1 diabetes would be economically neutral at a treatment effect of 11 percent and a discount rate of 6 percent.

RECOMMENDATION: A screening program including annual measurement of urinary albumin excretion rate should be implemented to help increase life expectancy and reduce end-stage renal failure, and an intervention program of antihypertensive treatment should also be considered (it is known to be effective in patients with nephropathy, and its effectiveness for microalbuminuria has been suggested by clinical studies).

ABSTRACT: This cost-benefit analysis of the effects of a screening and antihypertensive intervention program for microalbuminuria used a computer simulation of a 30-year program involving an imaginary cohort of 8,000 patients with type 1 diabetes, whose urine was screened annually beginning 5 years after onset of the disease. Objectives were to estimate mortality, incidence of nephropathy, and need for kidney transplantation or dialysis as well as the direct costs and savings associated with preventing or postponing the development of nephropathy. One scenario described the natural progression of the cohort and another the progression of the same cohort with screening and treatment. The economic evaluation was based on direct costs (screening, antihypertensive treatment in patients with microalbuminuria and nephropathy, dialysis, kidney transplantation, and immunosuppressive agents in patients needing transplants). Costs (and savings) were based on 1991 German sickness fund prices and were given in Deutschmarks (DM). A progression rate of 20 percent was assumed for untreated microalbuminuria. Assuming treatment effects (decrease in progression rate) of 33 percent or 67 percent, median life expectancy would increase by 4 or 14 years, respectively; onset of nephropathy, by 6 or 24 years; and the need for kidney transplantation or dialysis by 21 percent or 63 percent, respectively. Costs and savings would balance with a real discount rate of 6 percent a year and an antihypertensive treatment effect of 11 percent or with a real discount rate of 2.5 percent and an 8 percent treatment effect. Savings per patient would range from DM 1,500 (U.S. $800) with a discount rate of 6 percent and a treatment effect of 33 percent to DM 11,000 for a discount rate of 2.5 percent and a 67 percent treatment effect. 4 figures, 3 tables, 35 references.

103

TITLE: Pancreas Transplantation as a Treatment for Diabetes: Indications and Outcome. Sutherland, D.E. *Current Therapy in Endocrinology and Metabolism*. 5: 457-460. 1994.

OBJECTIVE: To review the indications for various pancreas transplantation options and their outcomes and costs.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: It is more expensive to treat diabetes with a pancreas transplant than with insulin injections, but if secondary complications are ameliorated, health care costs over a lifetime may be less than if the recipient remained diabetic. Improved quality of life in patients who have received a pancreas transplant also justifies the cost of the procedure.

RECOMMENDATION: None.

ABSTRACT: The author examines pancreas transplantation in terms of medical and quality of life outcomes as well as costs. Worldwide, more than 4,000 pancreas transplants had been reported by 1992, including 2,600 in the United States. Successful pancreas transplantation may stabilize retinopathy over the long term and significantly improve survival probability in patients with severe nephropathy. Kidney function is adversely affected by immunosuppressive drugs. As long as rejection is prevented, improvement in quality of life for patients with transplanted pancreas and kidneys is dramatic, because both insulin dependence and dialysis are prevented. Patients with only a pancreas transplant must balance the benefit of relief from diabetes with the difficulties of immunosuppression. In a study of 131 patients, 92 percent found immunosuppression was easier to manage than diabetes. Standardized well-being indices showed that 100 percent and 85 percent of patients with successful and failed grafts, respectively, would recommend transplantation. Insurance coverage for kidney transplant is routine but highly variable for pancreas transplantation. Pancreas transplants performed as a solitary procedure at the University of Minnesota cost $65,000 for hospital care plus the cost of immunosuppressive drugs. 27 references.

104

TITLE: Simultaneous Pancreas-Kidney Transplantation (SPK): A Cost-Effectiveness Analysis Model (abstract). Holohan, T.H. *Annual Meeting of the International Society for Technology Assessment in Health Care*. 1996; 12:25.

OBJECTIVE: To compare cost per quality-adjusted life-year (QALY) of simultaneous pancreas-kidney transplantation and kidney transplant only.

CATEGORY: Tertiary intervention.

Type of Study: Epidemiological cohort model.
Methodology: Cost-utility analysis.
Perspective: Health care system.

CONCLUSION: Even though the model's assumptions favored the combined transplant, in terms of cost per QALY the combined transplant was equivalent to a kidney transplant alone only for patients whose annual treatment costs for managing diabetes were quite high ($15,000 to $40,000) or for patients whose quality of life after a simultaneous transplant has been shown to be superior to the quality of life of patients having a kidney transplant alone with continued insulin therapy.

RECOMMENDATION: None.

ABSTRACT: The author describes a model developed to compare costs associated with a combined pancreas-kidney transplant to treat end-stage renal disease in people with type 1 diabetes with that of a kidney transplant alone. The model assumed that improvement in secondary complications (neuropathy, nephropathy, and retinopathy) resulting from a combined transplant remained unproven; that a combined transplant resulted in improved quality of life, although there are few objective data to support this assumption; that no technical failures occurred with the combined transplant; and that there were no renal graft failures. The model accounted for a period of 3 years, the length of time for which graft survival data were available. Benefit was expressed in terms of QALY, and costs included costs or charges related to the transplant operation and those associated with treating hypoglycemia or hyperglycemia in patients getting kidney transplant alone and in patients with pancreas graft failure.

105

TITLE: Therapeutic Interventions in the Progression of Diabetic Nephropathy. Lewis, E.J. *American Journal of Hypertension*. 7 (9 Part 2): 93S95S. September 1994.

OBJECTIVE: To determine whether the drug captopril exerts kidney-protective effects independent of the effects it has on systemic blood pressure.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.

Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: The protection that captopril offers against deterioration in renal function is significantly greater than that attributable to control of blood pressure alone. Captopril is very cost effective compared with other therapies and has no costs associated with life-years gained.

RECOMMENDATION: Treatment with captopril can potentially eliminate high annual treatment costs for dialysis and kidney transplantation in numerous patients.

ABSTRACT: A prospective, double-blind, randomized, placebo-controlled multicenter trial was conducted in 30 clinical centers in the United States and Canada. Captopril (25 mg 3 times daily) was compared with a placebo in 409 patients with overt nephropathy associated with type 1 diabetes (average age, 35; mean duration of diabetes, 22 years). Three quarters of the patients either had hypertension at entry or were already on antihypertensive treatment. In both groups (n = 207, captopril group; n = 202, placebo group), the aim was to maintain blood pressure below set limits using agents other than an angiotensin-converting enzyme (ACE) inhibitor or a calcium antagonist during the median 3year follow-up so that the potential kidney-protective effect of ACE inhibition by captopril could be assessed independently. The primary outcome measure was a doubling of the baseline serum creatinine concentration (among study participants, median time from doubling of serum creatinine to requiring dialysis was 9 months). In the placebo group, 43 of 202 patients doubled their serum creatinine, versus 25 of 207 in the captopril group, which had a risk reduction of 51 percent. The placebo group lost renal function at a rate of nearly 17 percent per year versus 10 percent in the captopril group. The combined endpoint of endstage renal disease or death was reached by nearly twice as many in the placebo group (n = 42, 21 percent) as in the captopril group (n = 23, 11 percent, p = 0.006). Nephroprotective therapy could double the time to dialysis from 3 years in a patient who has routine blood pressure control to 6 years on captopril. An economic model (Rodby R.A. et al., unpublished study) to determine the economic value of treating nephropathy patients with captopril to reduce progression to end-stage renal disease found significant overall cost savings. Projecting figures from this study yields a savings of more than $2.6 billion over 10 years for end-stage renal disease. 2 references.

106

TITLE: Type I Diabetic Nephropathy: Clinical Characteristics and Economic Impact.
Chukwuma, C. *Journal of Diabetes and Its Complications*. 7(1): 15-27. January-March 1993.

OBJECTIVE: To examine the incidence, prevalence, pathogenesis, risk factors, and costs of nephropathy associated with type 1 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.

Perspective: Health care system.

CONCLUSION: Direct medical costs are much higher in diabetes than in other diseases. Type 1 diabetic nephropathy necessitates kidney replacement in many patients. The cost of renal replacement therapy is greater for patients with diabetes.

RECOMMENDATION: The pathogenesis and treatment of type 1 diabetes nephropathy needs to be elucidated to reduce the economic impact of that disorder.

ABSTRACT: The author reviews the incidence, prevalence, pathogenesis, risk factors, and economic impact of diabetic nephropathy in patients with type 1 diabetes. About one-third of type 1 patients develop diabetic nephropathy. Several risk factors, including poor metabolic control, hypertension, and genetic factors are related to its development. End-stage renal disease (ESRD) is a frequent consequence of nephropathy. The incidence of ESRD from diabetic nephropathy increased in the United States from 10 percent in 1973 to 30 percent in 1987. Also in the U.S., Medicare costs in 1982 for ESRD among persons with diabetes were $330 million. These costs appear to be increasing at a rate exceeding $800,000 per year. ESRD therapy is more costly for patients with diabetes than for other causes because of a higher hospitalization rate and poorer treatment outcomes.

Foot Care

107

TITLE: Benefits of Prevention: The Medicare Therapeutic Shoe Demonstration. Wooldridge, J.; Handwerger, S. *Diabetes Spectrum*. 2(6): 390-394. November-December 1989.

OBJECTIVE: To describe the Medicare Therapeutic Shoe Demonstration, a congressionally mandated research initiative into the cost-effectiveness of using Medicare Part B coverage for therapeutic shoes in patients with diabetes mellitus who have severe foot disease.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: None.

RECOMMENDATION: None.

ABSTRACT: In the Medicare Therapeutic Shoe Demonstration, physicians (including podiatrists) in the demonstration states (California, Florida, and New York) are to certify the eligibility of patients with diabetes who have severe foot disease. Patients are to be randomly assigned to receive or not receive Medicare Part B coverage for therapeutic shoes (n = 13,700

patients per group). Cost-effectiveness will be determined by aggregate federal and state costs. If costs for patients who receive the benefit exceed costs for those who do not, it will not be cost effective. Unless the shoe benefit is not cost effective, it will become permanent in 1993. Eligible patients will have a past or present history of callus formation with peripheral neuropathy, foot ulceration, prior amputation of a foot in whole or in part, foot deformity with potential for ulceration, or poor circulation. The legislation limits coverage to one pair of depth-inlay or custom-molded shoes; an authorized shoe supplier will bill Medicare directly, with annual deductible and copayment costs the responsibility of the patient. The demonstration began in August 1989 and will run for 1 to 3 years. 1 table.

108

TITLE: Cost-Effectiveness of Early Digit Amputation in the Patient With Diabetes. Benton, G.S.; Kerstein, M.D. *Surgery, Gynecology and Obstetrics*. 161(6): 523-524. December 1985.

OBJECTIVE: To assess the cost-effectiveness of early versus delayed amputation of the osteomyelitic toe in patients with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Early amputation is the preferred approach for managing osteomyelitis of the toe in patients with diabetes. Oral antibiotic use alone is neither clinically nor cost effective.

RECOMMENDATION: Early surgical intervention and rehabilitation would reduce hospitalizations for foot lesions among patients with diabetes and have beneficial economic effects.

ABSTRACT: The authors report the costs of treating 14 men and 8 women with diabetes who had radiologic confirmation of osteomyelitis of the toe with no systemic sepsis. Cultures confirmed the diagnosis, with Staphylococcus aureus the predominant organism. Patients were initially treated with 2 grams/day of oral cephalosporin. Average length of antibiotic treatment was 108 days for men and 84 days for women. All patients subsequently met minimum criteria for local amputation: (1) Gangrene and infection was localized, (2) patient was free of pain, (3) patient had minimal or no rubor of the toes on dependency, and (4) venous filling was no longer than 20 seconds. All amputations were through the metatarsal phalangeal region. Time to complete healing and rehabilitation after surgery was 15 days (range 9 to 31) for men and 13 days (range 8 to 28) for women. Costs were assessed for antibiotics, local wound care, and mean length of hospitalization and did not reflect days lost from work. Per-patient and total costs for antibiotics were $350 and $7,700, respectively. Per-day and total hospitalization costs were $165 and $2,359, respectively. Postoperative hospitalization averaged 2.6 days, and daily costs of medicine, operating room, laboratory, and ancillary services averaged $350.

The surgeon's fee averaged $250. Oral antibiotic therapy was ineffective and therefore an unnecessary cost. Definitive surgery allows the patient to return to work within 2 weeks of amputation. 5 references.

109

TITLE: Diabetic Foot Care: Financial Implications and Practice Guidelines. Reiber, G. *Diabetes Care*. 15(Supplement 1): S29-S31. March 1992.

OBJECTIVE: To examine the financial implications of foot care in patients with diabetes and to review the implementation of practice guidelines for diabetic foot care.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Diabetic foot problems result in significant morbidity and mortality in the United States. Foot care guidelines are emerging, but their role in reducing foot problems in diabetes is not well defined.

RECOMMENDATION: Studies should be conducted to address the impact of current guidelines for foot care, the cost-effectiveness of both preventive and therapeutic measures, and modes of delivering patient education and foot care.

ABSTRACT: The author examines the available data on the impact of foot problems in patients with diabetes and the status of practice guidelines. Although the actual cost of diabetic foot problems in the United States is under debate, the current data show that diabetic foot problems result in significant morbidity and mortality. A 1986 study estimated that chronic skin ulcers alone accounted for $150 million of the $11.6 billion direct costs of type 2 diabetes in the United States. California hospital discharge data showed an average cost of $20,085 and length of stay of 19.3 days for nontraumatic diabetic amputation in 1987. In fiscal year 1987, Medicare reported 31,120 bills submitted for reimbursement of lower-extremity amputation, with reimbursements averaging $12,230 and length of stay averaging 18.7 days. Average cumulative cost of care for 106 patients (diabetes status unknown) treated at a New England medical center for limb-threatening ischemia was $40,769 for a lower-extremity bypass (average follow-up: 2.2 years) and $40,563 for amputation (average follow-up: 1.8 years). Foot care guidelines for persons with diabetes from several sources are reviewed. The author concludes that these guidelines should be viewed by providers as recommended minimum practice guidelines that should be modified and adapted according to patient pathology, comorbidity, and ability. 20 references.

110

TITLE: Diabetic Foot Ulcers in a Multidisciplinary Setting: An Economic Analysis of Primary Healing and Healing with Amputation. Apelqvist, J.; Ragnarson-Tennvall, G.; Persson, U.; Larsson, J. *Journal of Internal Medicine*. 235(5): 463-471. May 1994.

OBJECTIVE: To perform a cost analysis of healing with and without amputation in patients with diabetes who had foot ulcers.

CATEGORY: Tertiary intervention.

Type of Study: Prospective.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The findings indicate a potential cost savings from preventive, multidisciplinary foot care. Treatment for healing without amputation in a multidisciplinary system was associated with relatively low costs, while amputation was costly, due mainly to multiple and prolonged hospitalization.

RECOMMENDATION: Early and aggressive intervention in the management of foot ulcers is important in keeping treatment costs low. Costs increase dramatically with the severity of the lesion, impaired peripheral circulation, and wound-healing time.

ABSTRACT: A total of 314 consecutively presenting patients with diabetes who had foot ulcers were included in a prospective study. Forty patients died before healing occurred; the remaining 274 were included in a retrospective economic analysis. In this group, 197 patients (72 percent) healed without amputation, and 77 (28 percent) healed after amputation. All patients were treated by a combined foot care team (diabetologist, orthopedic surgeon, diabetes nurse, podiatrist, orthotist) both as inpatients and outpatients and were followed up by the same team until final outcome. Data from the prospective study and from patient records were used to estimate direct costs for inpatient care, antibiotics, surgery, outpatient care, staff attendance, drugs and material for ulcer dressings, and orthopedic appliances. Indirect costs (e.g., loss of production) were not calculated. Costs were calculated in Swedish Krona (SEK) in 1990 prices (SEK 6.0 = about $1 U.S.). Costs related to treatment in years 2 and 3 after diagnosis were discounted by 5 percent to 1990 values. The average direct cost for healing with amputation was SEK 344,000; for patients who healed without amputation, SEK 51,000. Costs for inpatient care accounted for 82 percent of the total average costs for patients with amputation and 37 percent for those who healed without amputation. Topical treatment of ulcers in the outpatient setting comprised 13 percent of the total average cost for patients who underwent amputation; for those who healed without amputation, it made up 45 percent. Costs for medical visits (45 minutes for the first visit, 20 minutes for subsequent visits), antibiotics, and orthopedic appliances were low in relation to total costs. Inpatient stay for those who healed with amputation averaged 76 days; for major amputation, 84 days. The authors state that treating patients with diabetes who have foot ulcers in a multidisciplinary system is associated with a high probability of healing without amputation. 4 tables, 29 references.

111

TITLE: Evaluation of the Costs to Medicare of Covering Therapeutic Shoes for Diabetic Patients. Wooldridge, J.; Moreno, L. *Diabetes Care*. 17(6): 541547. June 1994.

OBJECTIVE: To evaluate the cost to Medicare of a therapeutic shoe benefit for Medicare Part B beneficiaries with severe diabetic foot disease.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: There is no strong evidence that expanding Medicare Part B to cover therapeutic shoes for beneficiaries with severe diabetic foot disease will increase total Medicare costs. The demonstration indicated that lowering the cost of therapeutic shoes through a Medicare benefit would substantially increase ownership and use of such shoes.

RECOMMENDATION: A more orderly approach would have been to determine the conditions for clinical effectiveness of the shoes before assessing their effect on Medicare costs.

ABSTRACT: Congress mandated a demonstration of a therapeutic shoe benefit for Medicare Part B beneficiaries with diabetes. The benefit would be made permanent if it could not be shown that the benefit was not cost effective. The authors implemented a 3year demonstration in New York, Florida, and California in which they sought to enroll 27,500 eligible beneficiaries; only 4,373 applied. Participants were randomly assigned to either a treatment group that received the extra therapeutic shoe coverage or a control group that received standard Medicare coverage. The authors evaluated the Medicare payments and service use for a 12-month period of 3,428 participants (1,711 in the treatment group; 1,717 in the control group) who applied by August 25, 1991, and were randomized by September 30, 1991. Data were collected from the Health Care Financing Administration, the demonstration's enrollment form, and a telephone survey of beneficiaries. A onetailed test of statistical significance assessed the null hypothesis that Medicare payments for the treatment group were ≤ to payments for the control group. Results indicated that cost differences between groups were not statistically significant, although Medicare payments for all services among the treatment group in the first year of the demonstration were 3.8 percent higher ($451) than those for the control group. The lower extremity amputation rate during this period also did not differ significantly (2.6 percent for the treatment group, 1.8 percent for controls). Similarly, during this year, Medicare payments for foot care services were 14.6 percent ($318) higher among the treatment group, but this was also a statistically insignificant difference. At the beginning of the demonstration, 32 percent of both the treatment and control groups owned therapeutic shoes; almost 3 years later, 85 percent of the treatment group used them, versus 55 percent of controls — this difference was statistically significant.

2 tables, 14 references.

112

TITLE: Foot Infections in Diabetic Patients: Decision and Cost-Effectiveness Analyses. Eckman, M.H.; Greenfield, S.; Mackey, W.C.; Wong, J.B.; Kaplan, S.; Sullivan, L.; Dukes, K.; Pauker, S.G. *Journal of the American Medical Association (JAMA)*. 273(9): 712-720. March 1, 1995.

OBJECTIVE: To examine the cost-effectiveness of approaches to the diagnosis and treatment of foot infections and suspected osteomyelitis in patients with type 2 diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Markov modeling.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Noninvasive testing procedures add significant expense to the treatment of patients with type 2 diabetes in whom pedal osteomyelitis is suspected but may result in little improvement in health outcomes.

RECOMMENDATION: For patients with no signs of systemic infection who have adequate perfusion, surgical debridement followed by a 10-week course of culture-guided oral antibiotics may be as effective as and less costly than other strategies.

ABSTRACT: The authors performed a decision and cost-effectiveness analysis of strategies for the diagnosis and treatment of patients with type 2 diabetes who have foot infections and suspected osteomyelitis. Data were drawn from English-language literature by using MEDLINE searches and the bibliographies of selected articles. The base case scenario specified a 56-year-old man with type 2 diabetes for 7 years. Five interventions were assessed following hospitalization for surgical debridement and intravenous antibiotic therapy: (1) treatment for presumed soft-tissue infection, (2) culture-guided empiric treatment for presumed osteomyelitis, (3) 71 combinations of diagnostic tests prior to antibiotic therapy, (4) 71 combinations of tests prior to amputation, and (5) immediate amputation. A Markov state transition model was constructed to analyze decision trees and perform sensitivity analyses. Main outcomes were quality-adjusted life expectancy and average costs (in 1993 dollars). A long course of culture-guided antibiotic therapy was the least expensive strategy, with an average lifetime cost of approximately $30,880; immediate amputation was the most expensive, costing $46,900. Noninvasive testing to select patients for long-term antibiotic therapy cost from $31,000 to $33,750. Sensitivity analysis showed that roentgenography followed by magnetic resonance imaging cost an average of $120 more than empiric therapy, either with no discounting or with cost-discounting of 5 percent, but resulted in no gain in quality-adjusted life expectancy. Results show that noninvasive testing adds expense to the treatment of patients with type 2 diabetes in whom pedal osteomyelitis is suspected but may result in little improvement in health outcomes. A 10-week course of empiric antibiotic

therapy may be as effective as and less costly than other strategies. 2 figures, 5 tables, 83 references.

113

TITLE: long-term Costs for Foot Ulcers in Diabetic Patients in a Multidisciplinary Setting. Apelqvist, J.; Ragnarson-Tennvall, G.; Larsson, J.; Persson, U. *Foot and Ankle International*. 16(7): 388394. July 1995.

OBJECTIVE: To analyze long-term costs for prevention, treatment, home care, and social services in patients with diabetes and foot ulcers.

CATEGORY: Tertiary intervention.

Type of Study: Prospective.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The expected average annual costs per patient during the first 3 years after healing ranged from $5,200 to $11,200 for primarily healed patients and from $14,000 to $32,000 for patients healed with amputation. These findings indicate the potential cost savings of preventive foot care.

RECOMMENDATION: When estimating the costs for diabetic foot ulcers, a short-term perspective is not sufficient. long-term costs are high and are due mainly to the need for increased home care and social services as well as to costs for recurrent ulcers and new amputations.

ABSTRACT: A total of 314 consecutively presenting patients with diabetes and foot ulcers were followed to a final outcome; those who healed were followed for an additional 3 years. Primary healing occurred in 197 patients (72 percent); healing after amputation, in 77 patients (28 percent). The 40 patients who died before healing were excluded from a retrospective economic analysis (n = 274) of costs during 3 years after healing. All patients were treated and followed, both as inpatients and outpatients, by a foot care team consisting of a diabetologist, an orthopedic surgeon, an orthotist, a podiatrist, and a diabetes nurse. Those who healed primarily were further divided according to the presence (n = 56) or absence (n = 141) of critical ischemia. Healing with amputation was divided according to minor (n = 27) or major (n = 50) amputation. Inpatient, outpatient, home care, and social service costs were determined for a period of 3 years after healing of the initial ulcer and were calculated in Swedish Krona in 1990 prices. Costs related to treatment in years 2 and 3 were discounted by 5 percent to equal 1990 values. The expected total present value costs per patient during 3 years of observation for primarily healed patients were $26,700 (U.S. dollars) for those with critical ischemia and $16,100 for those without critical ischemia. These calculations account for the probability of surviving the first and second year of observation. The corresponding figures were $43,100 and $63,100 following minor and major amputation, respectively. The highest costs for inpatient care were found during the first year of follow-up for patients who

had undergone major amputations ($11,900). Similarly, the estimated annual extra costs for social service and home care were higher among patients who healed with major amputation than in other groups. 1 figure, 3 tables, 29 references, 1 appendix.

114

TITLE: Medicare Therapeutic Shoe Demonstration: Report to Congress. Health Care Financing Administration, Baltimore, Maryland. 1990. 85 pp.

OBJECTIVE: To provide a report to Congress on the cost-effectiveness of providing a Medicare Part B benefit for therapeutic shoes.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: It is too early to tell whether the benefit will be cost effective; a demonstration to determine cost-effectiveness is ongoing.

RECOMMENDATION: None.

ABSTRACT: The Omnibus Reconciliation Act of 1987 mandated a demonstration project in which Medicare Part B coverage would be provided for therapeutic shoes. An evaluation was also required to determine whether the benefit would be cost effective and should be introduced as a regular benefit. To be eligible for the demonstration, Medicare beneficiaries with diabetes had to have one or more of five conditions (previous amputation, deformity with potential for ulceration, callus formation or history of callus formation with peripheral neuropathy, a history of foot ulceration, poor circulation) in one or both feet. A priori, to be cost effective the cost to Medicare of therapeutic shoes had to be less than the savings resulting from reduced use of other Medicare-covered services attributable to the program. In the evaluation, costs to Medicare of a group receiving the experimental benefit are being compared with costs for a similar group not receiving the benefit. The authors note that these are insufficient data at this point to indicate whether the benefit is cost effective, and that the demonstration project is ongoing. Thus, they provide background on the demonstration project, present the clinical arguments on coverage, give a legislative history, describe how the demonstration was implemented, and discuss what is known about the population at risk and how their characteristics affect the likelihood that the benefit will be cost effective. In the demonstration project, physicians must certify the eligibility of beneficiaries who meet the clinical criteria and prescribe the therapeutic shoes, which must be provided by suppliers authorized by the Health Care Financing Administration. Early enrollment has been below expectations, and, in the first 4 months, very few primary care practitioners certified patient eligibility or prescribed therapeutic shoes. Plans are under way to increase participation during early 1990 in cooperation with the clinical community. 2 figures, 11 tables, 10 references.

115

TITLE: Medicare Therapeutic Shoes Demonstration: Was the Demonstration Cost Effective? Final Comprehensive Report, Volume I. Wooldridge, J.; Bergeron, J.; Moreno, L.; Thornton, C. Mathematica Policy Research, Inc., Princeton, NJ, June 30, 1993. 261 pp.

OBJECTIVE: To evaluate the cost-effectiveness of the Medicare Therapeutic Shoe Demonstration.

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The hypothesis that the shoe benefit was cost effective could not be rejected statistically. However, because enrollment in the program was below the target level, the authors lacked sufficient precision in their estimates to be sure that if the benefit was not cost effective, they would have correctly identified it as such. (Medicare added a therapeutic shoe benefit [Part B] in May 1993 as a result of the demonstration findings.)

RECOMMENDATION: The authors recommend several changes in the benefit (e.g., provide Medicare coverage for shoe repair) and its procedures as well as regulatory changes.

ABSTRACT: The Medicare Therapeutic Shoe Demonstration (conducted from August 1989 to October 1992) enrolled 4,373 Medicare beneficiaries with diabetes and severe foot disease. Enrollees were randomly assigned to a benefit group (who received Medicare Part B coverage for therapeutic shoes) or a control group (no coverage). The authors refer to two earlier reports on the demonstration: the first (1990) found no evidence that the program was cost saving; the second (1993) found no statistical basis to conclude that costs had increased. In the present report, the authors summarize a more comprehensive evaluation of whether providing the benefit was cost effective (Congress had mandated that the shoe benefit be enacted nationally unless it was shown not to be cost effective). For this report, a null hypothesis was tested to see whether it could be rejected: that under the demonstration, costs were lower than or equal to what they would have been without the intervention. For evaluation purposes, the shoe benefit would not be cost effective if the net cost to Medicare of providing the shoes significantly exceeded zero (i.e., the gross cost of covering the shoes significantly exceeded savings from reduced use of Medicare services that might result if the shoes helped to prevent new foot problems). The authors state that their approach assured a low probability of asserting that costs increased because of the program if they really did not. However, they state that their approach also carried the risk of not concluding that costs truly increased under the new benefit if the increase in cost was small. For the benefit group's first year in the demonstration, the authors found no statistically significant differences from the control group in terms of Medicare payments for all services, for Medicare Part A or Part B services only, or for all foot care services, although in each instance the figure for the

treatment group was higher. Hospital admissions for the two groups were also indistinguishable statistical. 6 figures, 44 tables, 38 references.

116

TITLE: Osteomyelitis in Feet of Diabetics: Clinical Accuracy, Surgical Utility, and Cost-Effectiveness of MR Imaging. Morrison, W.B.; Schweitzer, M.E.; Wapner, K.L.; Hecht, P.J.; Gannon, F.H.; Behm, W.R. *Radiology*. 196(2): 557564. August 1995.

OBJECTIVE: To evaluate the sensitivity, specificity, clinical utility, and Cost-effectiveness of magnetic resonance imaging (MRI) in the diagnosis of osteomyelitis of the foot in patients with diabetes.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: MRI has good sensitivity and specificity for diagnosing osteomyelitis in the feet of patients with diabetes, is competitively priced compared with other imaging methods, and is clinically useful in accurately delineating the extent of osteomyelitis so that limited surgical resection may be achieved.

RECOMMENDATION: Although the common perception of MRI is that it is a high-tech, high-cost modality, in the inpatient setting it may be the best and most cost-effective method of diagnosis.

ABSTRACT: The authors prospectively evaluated 62 MRI studies of the foot in 59 patients to detect the presence and extent of osteomyelitis. The population was divided into patients with diabetes (study group, n = 27 feet) and patients without diabetes (control group, n = 35 feet). MRI was performed with a 1.5T unit and an extremity coil; two orthogonal planes were imaged in each study. Contrast enhancement was used in 53 of the 62 studies. Biopsy (n = 41 feet) and clinical follow-up (n = 62 feet) were used to establish the diagnosis, select treatment, and determine outcome. Patients were followed up for an average of 6 months after treatment. A subgroup of 13 patients who underwent footsparing resection procedures was followed up for an average of 9 months; in every case, there was no recurrent infection at the surgical margin. Good sensitivity (82 percent) and specificity (80 percent) were obtained with MRI in diagnosing osteomyelitis in diabetic feet despite a high frequency of neuropathic osteoarthropathy (33 percent) and peripheral vascular disease (19 percent), both of which can complicate image interpretation. Sensitivity and specificity were higher in the control group (89 percent and 94 percent, respectively), but the differences were not statistically significant. Cost analysis revealed that contrast-enhanced MRI is competitively priced compared with the combination of two scintigraphic methods, one involving three-phase bone scanning and the other, white blood cell scanning. The overall cost of diagnosis, surgical procedures, and hospitalization was slightly lower with contrast-enhanced MRI than with the optimal

(combined) scintigraphic method. 5 figures, 2 tables, 52 references.

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TITLE: Preventing Diabetic Foot Disease: Lessons From the Medicare Therapeutic Shoe Demonstration. Wooldridge, J.; Bergeron, J.; Thornton, C. *American Journal of Public Health*. 86(7): 935-938. July 1996.

OBJECTIVE: To determine why few at-risk patients with diabetes purchased and used therapeutic shoes in the Medicare demonstration program (1989 to 1992).

CATEGORY: Tertiary intervention.

Type of Study: Randomized clinical trial.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Physicians may not recognize the importance of special foot care for patients with diabetes. Only 6 percent of physicians who were notified about the Medicare demonstration ever enrolled any patients.

RECOMMENDATION: Internists and general and family physicians need to receive continuing education on preventive care for foot problems in patients with diabetes. Frequent reminders to physicians about the Medicare shoe benefit might increase the number of participating physicians. A legislative change to allow podiatrists to certify eligibility in the national program would facilitate access.

ABSTRACT: Patients with diabetes often have amputations because of foot ulcers from impaired peripheral sensation, circulatory problems, and poorly controlled blood sugar levels. In May 1993, Medicare added coverage of therapeutic shoes for beneficiaries with diabetes at risk for foot disease after an evaluation did not show that this benefit increased Medicare costs. The patient's physician certified patient eligibility, a physician prescribed the shoes, and an authorized shoe supplier fit and furnished the shoes. The evaluation took place in California, Florida, and New York from August 1989 to October 1992, with few beneficiaries applying in the first 6 months despite a publicity campaign in which 43,000 Medicare beneficiaries who had a relatively recent admission for a diabetes-related foot problem and 56,000 physicians or podiatrists as well as clinics were notified. A second campaign, targeted at physicians, was mounted in response. Enrollment after 37 months totaled 4,373 beneficiaries, far below the target of 27,500. Of this group, 2,183 were randomly assigned to the treatment (coverage) group, 2,190 to the control group (no coverage). Three years after the evaluation began, 85 percent of the treatment group and 55 percent of the control group owned therapeutic shoes. Despite the promise of Medicare coverage, only 71 percent of the treatment group bought therapeutic shoes through the demonstration. Podiatrists enrolled nearly half of the eligible participants; internists and orthopedic surgeons were the next most frequent enrollers. Pedorthists supplied 29 percent of the shoes; podiatrists, 23 percent; and prosthetists, 22 percent. Only 2 percent of the 43,000 Medicare beneficiaries who were

notified of the demonstration subsequently enrolled. Podiatrists reported that many patients resist wearing custom-molded shoes. 2 tables, 8 references.

118

TITLE: A Prospective Evaluation of Transcutaneous Oxygen Measurements in the Management of Diabetic Foot Problems. Ballard, J.L.; Eke, C.C.; Bunt, T.J.; Killeen, J.D. *Journal of Vascular Surgery*. 22(4): 485-492. October 1995.

OBJECTIVE: To determine whether lower extremity transcutaneous measurements of the partial pressure of oxygen can accurately predict the severity of foot ischemia and be used to select appropriate treatment for patients with diabetes and tissue necrosis or ischemic pain at rest.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Mapping of lower-extremity transcutaneous partial pressure of oxygen is an accurate, noninvasive, and relatively inexpensive method to prospectively select appropriate treatment for patients with diabetes and limb-threatening ischemia, and it may obviate the need for arteriography to determine the severity of foot ischemia.

RECOMMENDATION: An absolute transmetatarsal level for the partial pressure of oxygen of 30 mm Hg or greater appears to be an accurate cutoff point for the selection of conservative or operative treatment for almost all diabetic foot problems. However, the conservative management scheme requires diligent patient follow-up. A higher threshold (40 mm Hg) may be required to manage calcaneal gangrene or some very severe nonhealing ulcerations.

ABSTRACT: Thirty-four men and 21 women (ages 34 to 87) with diabetes and ischemic pain at rest or pedal tissue necrosis (representing 66 threatened feet) were prospectively treated from June 1993 to July 1994. Treatment indications included nonhealing ulcer (53 percent), gangrene (38 percent), and rest pain (9 percent). Noninvasive hemodynamic arterial assessment and transcutaneous mapping of the partial pressure of oxygen for the involved limb were obtained before treatment was selected. Patients with trans-metatarsal levels of 30 mm Hg or higher received conservative treatment (e.g., local wound care, debridement, minor foot amputation). If the trans-metatarsal level was less than 30 mm Hg, arteriography was performed. The endpoints for determining treatment success or failure were complete wound healing or relief of ischemic rest pain. Thirty-one of 36 (86 percent) limbs with an initial transmetatarsal level of 30 mm Hg or higher were treated successfully with conservative care, including 11 of 15 feet without a palpable pedal pulse. After revascularization (16 feet) or angioplasty (8 feet), 20 of 24 (83 percent) limbs with initial partial pressure of less than 30 mm Hg achieved a transmetatarsal level greater than 30 mm Hg. An initial or postintervention

transmetatarsal level of 30 mm Hg or greater was more accurate (90 percent, p = 0.001) than a palpable pulse (65 percent, p = 0.009) in predicting ultimate resolution of pedal gangrene, nonhealing ulceration, or ischemic rest pain. The total cost for transmetatarsal mapping of a lower extremity was $93.88 per patient, versus $1,052.73 for a diagnostic lower extremity arteriogram. If absence of pedal pulses had been the indication for arteriography, 45 limbs in this study would have been subjected to this examination, yet only 31 actually required it. The authors also found that conservative management is cost effective compared with revascularization surgery or angioplasty. 3 tables, 17 references.

119

TITLE: Towards Less Amputations in Diabetic Patients: Incidence, Causes, Cost, Treatment, and Prevention — A Review. Larsson, J.; Apelqvist, J. *Acta Orthopaedica Scandinavica*. 66 (2): 181-192. April 1995.

OBJECTIVE: To discuss the problem of lower extremity amputation in patients with diabetes, and to analyze possibilities for reducing the number of such procedures.

CATEGORY: Tertiary intervention.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: A comprehensive system that incorporates regular foot examinations, preventive foot care, protective footwear, education of patients, a multidisciplinary approach to foot ulcers, strict amputation criteria, long-term follow-up after healing, and continuous registration of amputations can reduce major amputation in patients with diabetes.

RECOMMENDATION: None.

ABSTRACT: Foot ulcers are the most common reason for amputation in the patient with diabetes. The most frequent underlying condition is polyneuropathy with sensory, motor, and autonomic disturbances. Most often, the foot ulceration is precipitated by trauma, usually caused by faulty or incorrectly used footwear. Patients with diabetes with a high probability for an amputation include those with polyneuropathy and those with vascular disease without evidence of polyneuropathy. Common indications for amputation in patients with diabetes are gangrene, infection, and nonhealing ulcer. In 1990, the estimated cost of an amputation in the United States (hospital treatment only) was $18,300. When evaluating costs of treatment or other therapeutic strategies, it is important to include the costs of hospitalization and rehabilitation along with outpatient treatment costs until healing. The first step to minimize the risk of amputation is preventing lesions that may develop into gangrene and/or a deep infection. An important regimen is regular inspection of feet and footwear of patients with diabetes during health care visits; however, previous studies have shown this occurs in only 12 to 15 percent of checkups. Patients should have early access to a multi-disciplinary team for examination and treatment, both as inpatients and outpatients. From a long-term perspective,

among patients with diabetes, a minor amputation has a lower risk for a new major amputation. A minor amputation also has a better rehabilitation potential. 8 tables, 117 references.

Diabetes in Pregnancy

Gestational Diabetes

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TITLE: Capillary Blood Glucose Screening for Gestational Diabetes: A Preliminary Investigation. Landon, M.B.; Cembrowski, G.S.; Gabbe, S.G. *American Journal of Obstetrics and Gynecology*. 155(4): 717-721. October 1986.

OBJECTIVE: To evaluate the utility of capillary blood glucose measurement using a reflectance meter as an outpatient screening tool for gestational diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Capillary blood glucose evaluation using a reflectance meter can provide accurate outpatient screening for gestational diabetes with significant cost savings over laboratory plasma assays.

RECOMMENDATION: None.

ABSTRACT: The authors screened 125 consecutive pregnant women in a high-risk practice in a university hospital in Philadelphia, Pennsylvania. All the women underwent a standard 50 g glucose challenge at 26 to 28 gestational weeks. Capillary glucose values obtained with the use of a reflectance meter were highly correlated with plasma venous values obtained by the central laboratory, but mean capillary values were significantly higher (136.35 versus 111.74 mg/dL, $p < 0.001$) with the reflectance meter. The authors found that a capillary value of 160 mg/dL was the optimal reference point; its sensitivity and specificity were 93 percent and 96 percent, respectively, for an abnormal test of venous plasma ($\geq$ 135 mg/dL). Costs of screening 1,000 patients were estimated to be $5,900 for the laboratory plasma study and $1,034 for the capillary reflectance meter assay, with the latter costs including 32 additional glucose tolerance tests at $12 each because of a 3.2 percent false-positive rate. The potential cost savings associated with capillary blood glucose screening combined with its high efficiency make it an economically viable alternative to laboratory plasma assays for the detection of gestational diabetes. 2 figures, 2 tables, 16 references.

121

TITLE: Capillary Glucose Determination in the Screening of Gestational Diabetes. Meriggi, E.; Trossarelli, G.F.; Carta, Q.; Menato, G.; Porta, M.A.; Bordon, R.; Gagliardi, L. *Diabetes Research and Clinical Practice*. 5(1): 55-61. May 19, 1988.

OBJECTIVE: To determine a threshold for glucose challenge test positivity using capillary blood to facilitate use of a reflectance meter in gestational diabetes screening; to verify a plasma glucose threshold for glucose challenge test positivity; and to determine the differences and correlations between glucose values obtained from plasma and capillary blood with a reflectance meter during a glucose challenge test.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: A plasma glucose value of 135 mg/dL and a capillary value of 155 mg/dL represent optimal cutoff points for recommending a diagnostic glucose tolerance test.

RECOMMENDATION: The simplicity, precision, and high efficiency of the reflectance meter make it suitable for screening for gestational diabetes in all pregnant women.

ABSTRACT: Paired capillary-venous blood samples were obtained from 418 pregnant women, aged 25 years or older with or without risk factors, who underwent an oral glucose challenge test (GCT) to screen for gestational diabetes. Plasma glucose was measured by the glucose oxidase method; capillary glucose, by a Reflocheck glucose strip and a Reflocheck reflectance meter (both from Boehringer Mannheim Diagnostic, Inc.). The relationship between capillary and plasma glucose concentrations was investigated to establish a capillary GCT threshold. The receiver operator characteristic curve technique provided a quantitative method for determining cutoff points and the level of efficacy to be expected in detecting gestational diabetes. A plasma glucose value of 135 mg/dL and a capillary value of 155 mg/dL were found to represent optimal cutoff points for recommending the oral glucose tolerance test. Values of various plasma thresholds and those of corresponding capillary thresholds (20 mg/dL higher) were similar in sensitivity, specificity, and predictive values. The differences between mean values of plasma and capillary glucose determinations fasting and 1 hour after glucose load were 10-12 mg/dL and 22-24 mg/dL, respectively. The authors recommend early screening (at 12-16 weeks) in cases with risk factors because one-third of glucose tolerance test positive cases can be diagnosed and treated. These investigators believe the reflectance meter has advantages over laboratory enzymatic techniques in the screening of gestational diabetes. 3 figures, 3 tables, 20 references.

122

TITLE: Clinical Experience with a Screening Program for Gestational Diabetes. Lavin, J.; Barden, T.; Miodovnik, M. *American Journal of Obstetrics and Gynecology*. 141(5): 491-494. November 1981.

OBJECTIVE: To evaluate the cost and effects of a screening program for gestational diabetes in a large population of women attending a prenatal clinic at a university hospital.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The cost per case of gestational diabetes detected was $328.96.

RECOMMENDATION: Cost-benefit analyses should be included in determinations of the sensitivity and specificity of screening tests for gestational diabetes and comparisons of perinatal morbidity and mortality in screened and unscreened populations.

ABSTRACT: The authors determined the cost of screening for gestational diabetes in 2,077 pregnant women without diabetes attending a university prenatal clinic in Cincinnati over a 2-year period. Participants were divided into group 1 (959 women who presented with historical or clinical risk factors for gestational diabetes) and group 2 (1,118 patients without risk factors). Patients in group 1 underwent a glucose challenge test at their initial visit; an oral glucose tolerance test was performed if the glucose challenge test was abnormal. Glucose challenge and glucose tolerance tests were repeated at 28 weeks if the patient had an initially normal glucose challenge test. Group 2 patients underwent a glucose challenge test at 28 to 32 weeks; a glucose tolerance test was performed if the glucose challenge test was abnormal. Direct costs of the screening program were estimated by proration of component costs. The incidence of abnormal glucose challenge test and abnormal glucose tolerance test results was not statistically different for the two groups. Of the total population, 137 participants (6.6 percent) had an abnormal glucose challenge test and 30 participants (1.4 percent) had an abnormal glucose tolerance test. The total estimated cost for the screening program was $9,900, including $5,700 for serum glucose determination, $1,300 for glucose challenge test and glucose tolerance test solutions, and $2,900 for the phlebotomist's salary. The cost per patient screened was $4.75 and the cost per case of gestational diabetes detected was $328.96. These costs are marginally understated. The study confirms the feasibility of routine screening for abnormal carbohydrate metabolism in pregnancy in large populations. 4 tables, 16 references.

123

TITLE: Cost Efficacy of Routine Screening for Diabetes in Pregnancy: 1-h versus 2-h Specimen. Weiner, C.P.; Fraser, M.M.; Burns, J.M.; Schnoor, D.; Herrig, J.; Whitaker, L.A. *Diabetes Care*. 9(3): 255-259. May-June 1986.

OBJECTIVE: To compare the specificity and costs of 1-hour and 2-hour oral glucose challenge testing to screen patients for gestational diabetes mellitus.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The 2-hour glucose challenge testing was more sensitive and cost effective than the 1-hour screening test.

RECOMMENDATION: Screening for gestational diabetes on the basis of past medical history should be abandoned, and all pregnant women should undergo oral glucose challenge screening.

ABSTRACT: This study at the University of Iowa Hospitals and Clinics sought to determine whether the specificity of the glucose challenge test for diabetes screening during pregnancy could be increased by using a 2-hour rather than a 1-hour glucose challenge. Plasma glucose concentrations were measured in 790 women 1 hour after challenge (Trutol, Monoject Scientific, 50 g): all the women were asked to give a 2-hour blood sample; 342 complied. Abnormal 1-hour glucose challenge tests (above 139 mg/dL) prompted standard oral glucose tolerance tests. Costs per glucose challenge test and oral glucose tolerance test were $7.25 and $64.00, respectively. Of 1-hour glucose challenge tests, 24.3 percent were elevated; 2-hour glucose challenge tests exceeded 115 and 117 mg/dL in 20.5 and 16.3 percent of women, respectively. Oral glucose tolerance tests were positive in 10.8 percent of women with an elevated 1-hour glucose challenge test, in 13.0 percent of those with a 2-hour glucose challenge test above 115 mg/dL, and in 16.4 percent of women in which the latter test exceeded 117 mg/dL. All women with abnormal 1-hour glucose challenge tests and positive oral glucose tolerance tests had abnormal ($\geq$ 118 mg/dL) 2-hour glucose challenge tests; 28 women had abnormal 2-hour but normal 1-hour glucose challenge tests. Thirty-four percent fewer oral glucose tolerance tests were needed based on 2-hour (versus 1-hour) glucose challenge tests ($p < .05$), and the cost of identifying a case of gestational diabetes mellitus would have dropped 24 percent (from $866 to $662) if the 2-hour test were used. With risk-factor screening, 77 percent of gestational diabetes mellitus cases would have been missed, and the cost per case would have been $1,805. In a second group (n = 190), the cost per case of gestational diabetes mellitus would have declined by 32 percent if the 2-hour screen had been used. 6 tables, 9 references.

124

TITLE: Cost of Non-Insulin-Dependent Diabetes in Women with a History of Gestational Diabetes: Implications for Prevention. Gregory, K.D.; Kjos, S.L.; Peters, R.K. *Obstetrics and Gynecology*. 81(5 Pt 1): 782-786. May 1993.

OBJECTIVE: To estimate the potential savings in health care costs that would result from primary prevention programs targeted at women with gestational diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Preventive therapy may result in a net savings over 10 years of $32 million to $331 million, depending on the assumed percentage reduction in diabetes incidence.

RECOMMENDATION: A prospective prevention trial should be conducted to evaluate the potential health and cost benefits of ongoing postpartum education and cognitive reinforcement of lifestyle changes adopted during pregnancy in women with gestational diabetes.

ABSTRACT: The authors estimated potential health care cost savings over 10 years from a hypothetical primary prevention program aimed at women with gestational diabetes. An economic model was developed based on a series of assumptions about a national cohort: 3 percent of all live births in 1990 were complicated by gestational diabetes (resulting in 125,370 cases of gestational diabetes); 50 percent of the women with gestational diabetes (62,685) would develop type 2 diabetes; and the rate of progression to diabetes would be constant (6.7 percent) over a 10-year period. Average annual health care costs per case for women with diabetes were estimated at $2,834 (in 1990 dollars), cumulative net costs for caring for all women who developed diabetes over 10 years were estimated at $818 million. Calculations discounted future dollars by 5 percent per year. New costs incurred for preventive counseling and evaluation were estimated at $39.8 million (in 1990 dollars) for the entire cohort over 10 years (these costs included serum glucose determinations and dietary consultations). Net potential savings began to accrue if the prevention program reduced the incidence of diabetes by 5 percent. Estimated net savings for reductions in the incidence of gestational diabetes of 5, 10, 25, and 50 percent were $500,000, $31.9 million, $139.5 million, and $331.4 million, respectively, over 10 years. Various limitations of the analysis are discussed; for example, evidence suggests that conversion to diabetes is not linear, occurring more often in the first 5 years after pregnancy than the second 5 years. For another example, the Latina population has a 6 percent rate of gestational diabetes and a higher rate of disease progression. 3 tables, 17 references.

125

TITLE: Cost-Effective Approach to Office Screening for Gestational Diabetes. Teplick, F.B.; Lindenbaum, C.R.; Cohen, A.W. *Journal of Perinatology*. 10(3): 301-303. September 1990.

OBJECTIVE: To examine the cost-effectiveness of outpatient office screening for gestational diabetes using capillary blood measurements with a reflectance meter.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Use of a glucose reflectance meter offers an accurate, quick, cost-effective approach to glucose screening for gestational diabetes.

RECOMMENDATION: Providers of prenatal care should use screening programs like glucose reflectance meters more readily for gestational diabetes, with the understanding that cutoff values for each meter must be established for each facility.

ABSTRACT: Over a 6-month period, 50 patients were screened for gestational diabetes with a standard 50 g oral glucose load (Glucola) in the nonfasting state at 27 to 28 weeks gestation. One hour later, a capillary blood specimen was evaluated by means of an Accu-Check II (Boehringer-Mannheim, Indianapolis, IN) reflectance meter; a venous sample was evaluated in a hospital laboratory. Any patient with a serum glucose value greater than 130 mg/dL was scheduled for a 3-hour glucose tolerance test. The authors found a significant correlation between capillary blood glucose concentration and laboratory serum values (r = 0.59). Using a reflectance meter cutoff value of greater than 160 mg/dL, the authors did not miss any patients who would have required a 3-hour glucose tolerance test via serum screening. The sensitivity and specificity of this testing method were very good, and its negative predictive value was 100 percent. The authors' findings suggest that by using the glucose reflectance meter, 90 percent of patients can be screened without laboratory studies, resulting in significant savings. In addition to the cost savings, the immediate results (within 2 minutes) obtained by a reflectance meter allow for prompt identification of an abnormal screen and timely scheduling of the 3-hour glucose tolerance test. 1 figure, 1 table, 11 references.

126

TITLE: Cost-Effective Criteria for Glucose Screening. Marquette, G.P.; Klein,V.R.; Repke, J.T.; Niebyl, J.T. *Obstetrics and Gynecology*. 66(2): 181-184. August 1985.

OBJECTIVE: To identify a cost-effective method of screening for gestational diabetes without decreasing sensitivity to a level substantially below that of universal screening.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The cost of screening for gestational diabetes can be reduced without

substantially compromising sensitivity by restricting screening to patients aged 24 years or older and using a glucose screening threshold of 150 mg/dL.

RECOMMENDATION: Studies are needed to analyze the cost of additional days in the hospital caused by maternal or neonatal morbidity secondary to undiagnosed gestational diabetes.

ABSTRACT: The authors conducted a cost-effectiveness analysis of screening criteria for gestational diabetes on 1,012 unselected pregnant women registered at Johns Hopkins Hospital who were between 26 and 30 weeks of gestation. Direct medical costs included glucose tolerance tests and glucose screening. Fasting patients were given a 50 g oral glucose load, followed by a 1-hour plasma glucose test. If the glucose concentration was 130 mg/dL or greater, a 3-hour oral glucose tolerance test was performed. A total of 24 women (2.4 percent) were identified as having gestational diabetes; 21 of the 24 women were aged 24 or older with glucose concentrations of 150 mg/dL or greater on screening. Increasing the glucose screen threshold from 130 to 150 mg/dL with universal screening caused the positive predictive value to increase from 10 percent (24 of 235 patients) to 24 percent (23 of 96). Screening only patients aged 24 years or older and using the 130 mg/dL threshold had a positive predictive value of 14 percent (22 of 153). Increasing the threshold to 150 mg/dL while still screening only women aged 24 or older caused the positive predictive value to increase to 30 percent, with 21 of 24 cases of gestational diabetes identified. The cost of the diagnosis in these latter patients was 40 percent of the cost of diagnosis of universal screening using a 130 mg/dL threshold. 2 figures, 3 tables, 10 references.

127

TITLE: First Prenatal Visit Glucose Screening. Hong, P.L.; Benjamin, F.; Deutsch, S. *American Journal of Perinatology*. 6(4): 433-436. October 1989.

OBJECTIVE: To determine the benefit of early glucose screening for gestational diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Universal screening for gestational diabetes at first prenatal visit detected a significant number of cases that would have been missed if current screening recommendations were followed.

RECOMMENDATION: Universal glucose screening for gestational diabetes at first prenatal visit is recommended; minor increases in cost associated with universal screening may be offset by potential savings from more timely initiation of appropriate antepartum management.

ABSTRACT: The authors evaluated the benefit of glucose screening at first prenatal visit. Nine hundred and ninety-nine new obstetric patients at a New York City hospital who had not been previously diagnosed with diabetes underwent a glucose challenge test at their first prenatal visit, regardless of gestational age. A total of 228 patients had a gestational age (in weeks) of less than 14; 354, 14 to 23; 122, 24 to 28; and 295, greater than 28. Follow-up oral glucose tolerance tests were performed for results of 130 mg/dL or higher. Data were subdivided by patient age in years (under 24, 24 and over, 25 and over, and 30 and over) to allow comparison with other studies and current screening recommendations. Patients under 24 years of age had a lower mean glucose screening value than older patients (106.1 mg/dL versus 117.4 mg/dL, $p < 0.05$), but 13 percent of cases of diagnosed gestational diabetes occurred in this youngest group. One-third of the diagnoses of gestational diabetes were for women screened in week 32 or earlier. Total screening program costs were $7,130 for universal screening, $4,041 for screening patients 25 years and over, and $2,286 for screening patients 30 years and over; costs per diagnosed case of gestational diabetes were $184 (universal), $122 (25 plus), and $120 (30 plus). The slightly greater cost of universal screening for gestational diabetes would be offset by potential savings from more timely initiation of appropriate antepartum management. When the criterion for an abnormal glucose challenge test was changed to ≥ 140 mg/dL, costs per diagnosed case dropped to $115, $106, and $102. 8 tables, 16 references.

128

TITLE: Screening for Gestational Diabetes. Zoller, D.P.; Jurica, J.V.; Gould, S.H.; Weinstein-Mayer, S. *The Journal of the American Board of Family Practice*. 1(2): 98100. April-June 1988.

OBJECTIVE: To determine the validity of screening all pregnant women for gestational diabetes mellitus (GDM); to determine the Cost-effectiveness of such a program.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Universal screening of pregnant women for GDM was found to be simple and cost effective. There was no difference between women with risk factors and those without in rate of abnormal glucose tolerance.

RECOMMENDATION: Because a history of risk factors for diabetes is an insensitive predictor of GDM, it is necessary to screen all pregnant patients; a plasma glucose concentration of 140 mg/dL on the glucose challenge test should be a minimum criterion for proceeding to the glucose tolerance test.

ABSTRACT: Three hundred sixty-three consecutive pregnant patients attending obstetrical

clinics at teaching hospitals of the University of Illinois College of Medicine at Rockford underwent screening for GDM by a glucose challenge test that measured plasma glucose 1 hour after they were fed 50 g of glucose. Most of the women were between 24 and 28 weeks of gestation; their average age was 21.3 years; and 41.9 percent were nulliparous. Those patients with a plasma glucose greater than 140 mg/dL were given a standard 3hour glucose tolerance test using 100 g of oral glucose to confirm GDM. Fifty-two (14.3 percent) of the patients had abnormal glucose challenge tests. The average cost per patient screened was $14.30, and the cost per case of GDM diagnosed was $519. Patients with one or more risk factors (e.g., obesity, family history of diabetes, previous delivery of a macrosomic infant) were compared with those without risk factors; there was no significant difference between the two groups in percentage of abnormal glucose tolerance tests (2.9 percent in the risk factor group; 2.7 percent in the other). The authors concluded that all pregnant patients must be screened in order to identify GDM. They noted that the risks associated with screening are very low and that patients would not be inappropriately treated because of false-positive tests, as all positive glucose challenge tests are followed by a 3hour glucose tolerance test. 1 table, 26 references.

129

TITLE: Screening for Gestational Diabetes: Analysis by Screening Criteria. Reed, B. *Journal of Family Practice*. 19(6): 751-755. December 1984.

OBJECTIVE: To review the appropriateness and cost-effectiveness of a 1-hour, 50 g glucose screening test for gestational diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Screening for gestational diabetes is sensitive and cost effective.

RECOMMENDATION: All pregnant women over age 25 years should be screened for gestational diabetes with a 1-hour, 50 g glucose test.

ABSTRACT: The author examined the cost-effectiveness of various approaches to screening for gestational diabetes. The initial test consisted of measuring the serum glucose level in a pregnant patient 1 hour after ingestion of 50 grams of glucose solution. Five protocol strategies were evaluated: (1) glucose screening test for all patients, with an oral glucose tolerance test for positive results; (2) glucose screening test only for patients with risk factors, with oral glucose tolerance test for positive results; (3) oral glucose tolerance test for patients with risk factors; (4) oral glucose tolerance test for all patients; and (5) glucose screening test for all patients over age 25 years, followed by an oral glucose tolerance test if the result is positive. The costs for utilization of the screening test were calculated using data from O'Sullivan et al. (1973) and current local hospital charges. Costs for the glucose screening test

and the oral glucose tolerance test were assumed to be $10.15 and $24.40, respectively. Cost per case of detected gestational diabetes ranged from $386.11 for screening of all patients over age 25 to $976.00 for an oral glucose tolerance test for all patients. Screening only patients with risk factors for gestational diabetes was not cost effective, costing $683.18 per detected case and missing many cases (60 percent rate of false negatives). Performing an oral glucose tolerance test on all patients was the most accurate means of detecting gestational diabetes (no false negatives) but also the most costly. Screening with the glucose screening test for all pregnant women over age 25 years followed by the oral glucose tolerance test when indicated is the most cost-effective strategy; its false-negative rate in this analysis was 24 percent. 2 tables, 17 references.

130

TITLE: Screening for Gestational Diabetes: An Analysis of Health Benefits and Costs. Everett, W.D. *American Journal of Preventive Medicine*. 5(1): 38-43. January-February 1989.

OBJECTIVE: To determine the health benefits and costs of screening all pregnant women for diabetes at 28 weeks of gestation.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: The most cost-benefit outcome of screening all pregnant women for gestational diabetes would be a decrease in perinatal mortality rates. The cost of preventing cesarean section, death from macrosomia, and certain other outcomes would be so great that a decision to screen should not be based on trying to prevent these events.

RECOMMENDATION: Further research that focuses on decreasing the cost of screening pregnant women for gestational diabetes is needed because available data do not clearly demonstrate a favorable cost-benefit ratio for universal screening.

ABSTRACT: The current recommendation to screen all pregnant mothers for diabetes at 28 weeks of gestation is examined, using known epidemiologic evidence presented in the literature, to determine the cost benefit of averting infant death, macrosomia, cesarean section, birth injury, shoulder dystocia, and maternal death from cesarean section. The author concludes that screening for and treating gestational diabetes may be beneficial, but data are not sufficient to determine the full cost and benefits of universal screening. Most of the benefit would come from a hoped-for decrease in the perinatal mortality rate. Additional benefits such as a decrease in cesarean sections, shoulder dystocia, or birth trauma would have a high cost per case presented. Because of ethical considerations, a study of appropriate size to clarify the issue of decreased perinatal mortality in treated compared with untreated gestational diabetes is unlikely. The Centers for Disease Control recommends that where cost and inconvenience

make universal screening impractical, women with any of the following risk factors should be screened: age 25 years or older, obesity, history of diabetes in a first-degree relative, history of pregnancy with stillbirth or infant weighing over 9 pounds, and history of congenital malformation in a previous child. 1 figure, 4 tables, 21 references.

131

TITLE: Screening for Gestational Diabetes in a High-Risk Population. Massion, C.; O'Connor, P.J.; Gorab, R.; Crabtree, B.F.; Nakamura, R.M.; Coulehan, J.L. *The Journal of Family Practice*. 25(6): 569575. December 1987.

OBJECTIVE: To evaluate the use of the glucose screening test in a well-defined primary care population at high risk for gestational diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: When several variables, including historical factors and the glucose screening test result, were analyzed, only the test result was associated with the risk of gestational diabetes.

RECOMMENDATION: Universal screening for gestational diabetes should be conducted and oral glucose tolerance tests should be performed when 1-hour blood glucose concentrations are ≥ 130 mg/dL.

ABSTRACT: A 50 g glucose load was administered to 181 pregnant, nonfasting Navajo women during routine prenatal care between 28 and 32 weeks of gestation; plasma glucose concentrations were determined 1 hour later. Patients with a plasma glucose concentration of 130 mg/dL or greater were asked to return for a 3hour oral glucose tolerance test to confirm a diagnosis of gestational diabetes. The incidence of gestational diabetes in the study population was 6.1 percent. Incidence of gestational diabetes was 10 percent (2 of 21) in patients whose screening result was 130 to 149 mg/dL; 39 percent (9 of 23) in patients whose screening result was 150 mg/dL or greater. The marginal cost for each case of gestational diabetes detected was $114 for universal screening with the 130 mg/dL as the test cutoff point (181 screening tests and 44 glucose tolerance tests to detect 11 cases of gestational diabetes); for this approach, sensitivity approached 1.00, specificity was 0.80, and positive predictive value was 0.25. For universal screening with a threshold of 150 mg/dL, the marginal cost per case detected was $106 (181 screening tests and 23 glucose tolerance tests to detect 9 cases of gestational diabetes). Sensitivity decreased to 0.81, specificity was 0.58, and positive predictive value was 0.39. The small differences in cost per case of gestational diabetes detected and the increased sensitivity of the universal screening test with the 130 mg/dL threshold suggests this approach is preferable to universal screening with a 150mg/dL threshold or selective screening based on risk factors. This conclusion depends on cost of

screening and diagnostic tests, however. By logistic regression analysis, the glucose test results were associated with risk of gestational diabetes ($p = 0.0004$), but historical risk factors were not. 3 tables, 26 references.

132

TITLE: Screening of High-Risk and General Populations for Gestational Diabetes: Clinical Application and Cost Analysis. Lavin, J.P. *Diabetes*. 34 (Supplement 2): 24-27. June 1985.

OBJECTIVE: To determine the feasibility and investigate the costs of universal screening for abnormal carbohydrate metabolism in pregnancy in a prenatal clinic; to detect the relative prevalence of gestational diabetes among populations defined as high and low risk based on historic and clinical factors.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient screening.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: A significant number of women with gestational diabetes and their offspring will be denied the benefits of improved care if screening is limited to those with a high risk for gestational diabetes. Universal screening costs compare favorably with those incurred for other screening tests for other diseases during pregnancy.

RECOMMENDATION: Greater standardization in protocols, presentation, and interpretation of data will facilitate selection of an optimal protocol for screening for gestational diabetes.

ABSTRACT: Costs and outcomes of screening 2,077 pregnant women for gestational diabetes were analyzed. The women were placed in either high- or low-risk groups, depending on whether they had historic or clinical risk factors (Group 1) or none of these factors (Group 2). Group 1 included 959 women; Group 2 included 1,118 women. All women in Group 2 underwent an initial glucose challenge test between 28 and 32 weeks of gestation, followed by an oral glucose tolerance test if the glucose challenge test was abnormal. Those with an abnormal glucose tolerance test were referred to the Pregnancy Special Care Clinic. Group 1 women underwent a glucose challenge test at their first antepartum visit; those with a normal result or a normal glucose tolerance test after an abnormal glucose challenge test received routine prenatal care until 28 weeks of gestation, when the testing sequence was repeated. Fifty-seven women in Group 1 (5.9 percent) tested positive on the initial glucose challenge test; 14 of these women (25 percent, or 1.5 percent of the total group) also tested positive on the glucose tolerance test. At week 28, 7.2 percent of these women tested positive on the glucose challenge test, but none tested positive on the glucose tolerance test. In Group 2, 6.1 percent of the women had a positive glucose challenge test; 23 percent of these women (1.4 percent of the total group) also tested positive on the glucose tolerance test. Differences between the groups were not statistically significant. In all, 46.7 percent of the cases of

gestational diabetes were identified in women with risk factors, and 53.3 percent were identified in women with no risk factors. The total estimated direct cost for this screening program was $9,869. The cost per patient screening was $4.75 and per case of gestational diabetes detected, $328.96. Results support the concept of greater cost efficiency in universal screening compared with screening only high-risk populations. 3 tables, 25 references.

133

TITLE: Weight Excess Before Pregnancy: Complications and Cost. Galtier-Dereure, F.; Montpeyroux, F.; Boulot, P.; Bringer, J.; Jaffiol, C. *International Journal of Obesity*. 19(7): 443448. July 1995.

OBJECTIVE: To study maternal and fetal complications, course of labor, and overall cost of pregnancy care in relation to prepregnancy weight.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Hypertension, toxemia, gestational diabetes, insulin treatment, urinary tract infections, and macrosomia were positively correlated with maternal excess weight prior to pregnancy. Women who were overweight had longer hospital stays and higher costs than normal-weight women.

RECOMMENDATION: Because even moderate excess weight is a significant risk factor for obstetrical complications, multidisciplinary management before birth is needed to prevent maternal or fetal complications.

ABSTRACT: Data concerning 112 deliveries at a hospital in Montpellier, France, among 89 overweight patients from 1980 to 1993 were reviewed and compared with a control group of 54 normal-weight pregnant patients during the same period. Exclusion criteria were hepatic, cardiac, or renal failure; previous diabetes mellitus; height below 145 cm; and age under 18 years. Patients were placed into four groups according to their pregravid body mass index (BMI = kg/m2): normal weight (control group), 18 to 24.9; moderately overweight, 25 to 29.9; obese, 30 to 34.9; massively obese, 35 or higher. The authors measured the incidence of maternal complications (e.g., hypertension, gestational diabetes), complications of labor (e.g., macrosomia), and duration of hospitalization. Dysfunctional uterine bleeding was more common among obese patients. Hypertensive diseases and glucose tolerance abnormalities were strongly correlated with overweight. The incidence of hypertension increased even in moderately overweight patients ($p = 0.018$). The frequency of gestational diabetes mellitus, insulin-treated gestational diabetes, and toxemic syndrome was higher in the three overweight groups, but it reached statistical significance only for the obese and massively obese. Labor complications among obese women included cephalopelvic disproportion (25 percent), fetal distress (21 percent), and stagnation of induced labor (17 percent). There was a higher

frequency of overall cesarean sections (43 percent versus 9 percent, p = 0.002) and first cesarean sections (33 percent versus 7 percent, p = 0.006) in the massively obese. The mean total duration of hospitalization was correlated with prepregnancy weight. Overall cost (including the postpartum period) was more than three times higher in massively obese than in normal weight patients (p = 0.0001). In the normal-weight group, 9 percent of patients were hospitalized in the antepartum period, versus 33 percent of overweight, 36 percent of obese, and 66 percent of massively obese patients. 1 figure, 4 tables, 22 references.

Pregestational Diabetes

134

TITLE: Cost-Benefit Analysis of Preconception Care for Women with Established Diabetes Mellitus. Elixhauser, A.; Wechsler, J.M.; Kitzmiller, J.L.; Marks, J.S.; Bennert Jr., H.W.; Coustan, D.R.; Gabbe, S.G.; Herman, W.H.; Kaufmann, R.C.; Ogata, E.S.; Sepe, S.J. *Diabetes Care*. 16(8):1146-1157. August 1993.

OBJECTIVE: To determine whether the costs of pre-conception care in women with diabetes are balanced by the savings that result from avoiding complications.

CATEGORY: Diabetes in pregnancy.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Intensive preconception care for women with diabetes followed by prenatal care is cost saving when compared with prenatal care only.

RECOMMENDATION: None.

ABSTRACT: Literature review, consensus development, and questionnaires were used to compare the costs of preconception care plus prenatal care with the costs of prenatal care only for hypothetical groups of 1,000 women each. Preconception care was assumed to require 20 visits; the model specified that only after glycemic control was achieved and maternal health status evaluated would a couple be encouraged to conceive. For the prenatal-care-only group, care was assumed to start at gestational age of 12 weeks. The economic consequences of adverse outcomes of pregnancy included those for the mother (e.g., a stay in the intensive care unit), initial hospitalization for the newborn (costs of congenital anomalies, respiratory distress syndrome, etc.), and subsequent care for the newborn. A cost-benefit analysis (all costs in 1989 dollars) from the perspective of a third party payer was performed in which total

program costs were compared with the dollar value of maternal and neonatal adverse outcomes. Net benefits and a benefit-cost ratio were computed. Net benefits equaled the sum of the costs for prenatal care only and the costs of associated adverse outcomes, minus the sum of the costs of the preconception-plus-prenatal-care program and the associated adverse outcomes. The benefit-cost ratio was calculated by dividing the difference in adverse outcome costs between the programs by the difference in program inputs. The model found that the preconception-care group incurred costs of $11,294 per enrollee and $17,519 per delivery. In contrast, cost per enrollee in the prenatal-care-only program was $12,889 and cost per delivery was $13,843 (the cost was higher in the preconception-care group because more women received medical services without going on to deliver). Rates of adverse outcomes were generally lower for the preconception-care patients. Total costs of adverse outcomes were $9,655,079 in the preconception group and $13,372,792 in the group receiving prenatal care only. Net benefit of the preconception care program was $1720 per enrollee; the benefit-cost ratio was 1.86. 6 tables, 3 appendixes, 44 references.

135

TITLE: Cost-Benefit Analysis of Preconception Care for Women with Established Diabetes Mellitus. Final Report. Elixhauser, A.; Weschler, J.M. Battelle Medical Technology and Policy Research Center, Washington, D.C., 1990.

OBJECTIVE: To analyze and compare costs and benefits of preconception care plus prenatal care versus prenatal care only in preventing adverse fetal and maternal outcomes in women with pre-existing diabetes mellitus.

CATEGORY: Diabetes in pregnancy.

Type of Study: Epidemiological cohort model.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: The program of preconception care plus prenatal care resulted in net savings of $1.7 million; the greatest savings were associated with reduction of adverse outcomes in mothers and infants.

RECOMMENDATION: Third party payers can expect to realize cost savings from reduced maternal and fetal complications in women with pre-existing diabetes by reimbursing for preconception care (including educational and support services provided by allied health care providers) according to standards recommended by the American Diabetes Association.

ABSTRACT: The authors constructed a model, based on literature review, review by an expert panel, and questionnaires, to compare among women with diabetes the costs and

benefits associated with preconception care plus prenatal care with those for prenatal care only. The theoretical study population included 1,000 women in the preconception care program, of whom 785 became pregnant and entered prenatal care; and 1,000 women in the prenatal-care-only program, of whom 900 became pregnant. The preconception component of the program was 17 weeks long and included an initial preconception evaluation and 20 visits for medical evaluation; laboratory tests; and education, dietary, and counseling services. Women in the program were assumed to enter prenatal care six weeks after their last menstrual period. The prenatal-care-only program assumed that all women would have appropriate care and enter the prenatal program at a later stage of pregnancy (10 to 12 weeks after the last menstrual period), that 60 percent would enter the program in less than optimal control and 25 percent would require hospitalization to improve control, and that those in poor control would require more intensive medical and dietary management. Cost-benefit analysis showed that the total costs of care for women in the preconception plus prenatal care group were $11,294,100 (not including nonmedical costs); total costs for women in the prenatal-care-only group were $9,296,900. Costs associated with adverse outcomes totaled $9,655,079 for the first group and $13,372,676 for the second. Total costs for women in the second group were $1,720,397 ($1,720 per woman) higher than total costs for women receiving preconception care, resulting in a cost-benefit ratio of 1.86. 14 tables, 3 figures, 4 appendices, 80 references.

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TITLE: Financial Implications of Implementing Standards of Care for Diabetes and Pregnancy. Elixhauser, A.; Weschler, J.; Kitzmiller, J.; Bennert, H.; Coustan, D.; Gabbe, S.; Herman, W.; Kauffmann, R.; Ogata, E.; Marks, J.; et al. *Diabetes Care*. 15 (Supplement 1): S22-S28. March 1992.

OBJECTIVE: To examine the financial implications of implementing standards of care for pregnancy among women with diabetes.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient management.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Implementing standards of care for pregnancy among women with diabetes will represent a greater use of health care resources for outpatient preconception and prenatal care but can lead to avoided costs for maternal and fetal complications of pregnancy.

RECOMMENDATION: Reimbursement should be provided by third party payers for comprehensive diabetes and pregnancy care to ensure that women with diabetes have access to the care they require to prevent adverse outcomes for themselves and their infants.

ABSTRACT: The authors examine the financial implications of implementing standards of care for pregnancy among women with diabetes. The standards of interest were developed by

the American Diabetes Association and address four main areas of care: preconception care, blood glucose control, frequent visits, and specialized laboratory and diagnostic tests. As these standards did not specify the resources required for preconception and prenatal care, the authors convened a panel of physicians to outline more precise guidelines. The recommendations of the panel were examined for their economic implications. Adherence to these standards may represent additional costs to patients or third party payers for initial outpatient treatment. However, treatment-related costs of adverse outcomes of pregnancy can be enormous, particularly those due to poor maternal glucose control. Corrective surgery for infants with congenital heart malformations secondary to poor glucose control may cost up to $145,000 (1989 dollars) per survivor; lifetime care costs for infants born with severe spina bifida are estimated at $330,000, including both direct and indirect costs. In addition to avoiding costs related to poor fetal outcomes, intensive preconception and prenatal care can help to avoid expensive hospitalizations for maternal complications; hospitalization for a single episode of ketoacidosis averages $4,500. Two recent cost-benefit studies are cited that demonstrate that the savings resulting from avoided adverse pregnancy outcomes in women with diabetes outweigh the added costs of preconception care. Reimbursement of comprehensive diabetes and pregnancy care by third party payers is crucial for ensuring the care necessary to prevent adverse outcomes for these women and their infants. 1 figure, 49 references.

137

TITLE: Prevention: The Cost-Effectiveness of the California Diabetes and Pregnancy Program. Scheffler, R.M.; Feuchtbaum, L.B.; Phibbs, C.S. *American Journal of Public Health*. 82(2): 168-175. February 1992.

OBJECTIVE: To determine the cost-effectiveness of a California program aimed at improving pregnancy outcomes through intensive diabetes management.

CATEGORY: Tertiary intervention.

Type of Study: Retrospective.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: The program significantly reduced hospital charges and length of stay; it returned over $5 for every $1 spent.

RECOMMENDATION: None.

ABSTRACT: The California Diabetes and Pregnancy Program focuses on improving maternal and infant perinatal outcomes in pregnancies complicated by diabetes. Women in the program receive comprehensive preconception and prenatal care, including nutrition, education, and support services. Data for 102 California Diabetes and Pregnancy Program cases were collected from July 1, 1986, to July 30, 1988, from three hospitals with well-established programs, each with a level 3 neonatal intensive care unit. Data for 218 control

cases were collected from five other hospitals, each with at least a level 2 neonatal intensive care unit. The demographic characteristics and health status indicators of mothers and babies at case and control hospitals were similar. Program participants and control cases of the same age, ethnicity, and diabetes classification were randomly matched, yielding a data set of 90 program cases and 90 control cases. In this data set, mean adjusted charges were $15,344 for cases, $21,699 for controls. Mean length of stay (mother and baby combined) was 15.1 days for the program cases, 18.0 days for controls. After adjustment for inflation and differences in hospital charges, for every $1 of program costs, estimated savings were $5.19. The authors' conservative assumptions suggest that actual savings are even larger than their estimates. If 2,598 babies were born to women with overt diabetes in 1990 (as estimated), yearly savings attributable to the California Diabetes and Pregnancy Program would have been $14 million to $19 million. In addition to short-term economic savings, mothers will likely have better future health status, and there should be long-term savings from fewer anomalies and other handicaps. With more normal pregnancies and healthy babies, mothers can stay in the workforce longer and return to work sooner. 6 tables, 27 references.

138

TITLE: Women with Diabetes During Pregnancy: Sociodemographics, Outcomes, and Costs of Care. York, R.; Brown, L.P. *Public Health Nursing*. 12(5): 290-293. October 1995.

OBJECTIVE: To provide sociodemographic, outcome, and cost data for pregnancy through the postpartum period for predominantly low-income women with diabetes who were hospitalized during pregnancy for glucose control.

CATEGORY: Diabetes in pregnancy.

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Women in the study were three times as likely as those in the general Pennsylvania population to deliver low-birthweight infants; mean hospital charges for these infants were $39,787.

RECOMMENDATION: Monies must be targeted to provide a broad spectrum of health care services that will meet the unique needs of low-income, childbearing women with diabetes.

ABSTRACT: The authors evaluated data for 55 women with diabetes who received care at the University of Pennsylvania Medical Center in Philadelphia between August 1988 and December 1992. Fourteen of the women had pregestational diabetes; 41, gestational diabetes. Of the 55 women, 63 percent reported annual family income of under $12,500. Data collection methods included maternal interviews, review of maternal and infant hospital charts, and postpartum telephone interviews. Mean hospital charges for antepartum initial hospitalization for glucose control, evaluation, and education were $4,665 (mean length of

stay: 4.3 days). For women who required rehospitalization for glucose control, mean hospital charges were $6,371 (mean length of stay: 5.9 days). Mean charges for postpartum hospitalization were $7,793 (mean length of stay: 4.3 days). Of the 54 infants born to the study participants, 2 were stillborn and 11 were low birthweight. Mean hospital charges per infant were $12,991; for the low-birthweight infants, $39,787. Compared with Pennsylvania women as a whole, women in this study were twice as likely not to have had first-trimester care (43 percent versus 20.4 percent) and three times more likely to deliver a low-birthweight infant (20 percent versus 7.2 percent). The results provide significant evidence of the complexity of these women's health care needs and the need for monies targeted at addressing these needs. 1 table, 13 references.

The Economics of Diabetes Mellitus

Secondary Intervention

The Economics of Diabetes Mellitus

Tertiary Intervention

The Economics of Diabetes Mellitus

Diabetes in Pregnancy

Direct Medical Costs

Inpatient Care

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TITLE: Amputations in the Surgical Budget. Solomon, C.; van Rij, A.M.; Barnett, R.; Packer, S.G.; Lewis-Barned, N.J. *New Zealand Medical Journal*. 107(973): 78-80. March 9, 1994.

OBJECTIVE: To describe the extent and distribution of inpatient costs for nontraumatic lower limb amputations and to identify areas for cost-saving strategies.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Length of hospital stay was the largest determinant of cost. The need for

long preoperative management and postoperative rehabilitation hospital time might be achieved more economically in less costly settings. Most amputations among patients with diabetes were of the minor type; among patients without diabetes, most were major.

RECOMMENDATION: Greater use of outpatient facilities and providing increased resources for screening, preventive education, podiatry, and early intervention may offer both limb- and cost-saving opportunities. Free flow and integration of clinical and cost information could provide the physician with a more adequate basis for best use of resources.

ABSTRACT: Investigators reviewed data on 134 hospital admissions for nontraumatic lower limb amputations from July 1989 to April 1992 at Otago (New Zealand) Health Board hospitals in order to assess potential cost-saving options. Detailed information on costs, clinical activity, and length of hospital stay was available for analysis. Statistical analysis used the Mann-Whitney U test and the chi-square test. Total in-hospital cost was $1.09 million (New Zealand dollars), with an annual cost of $388,000. The mean cost for general surgical admission was $11,342 (median $21,367), which was significantly higher ($p < 0.001$) than that for orthopedic patients, whose mean cost was $2,318 (median $6,277). General surgical patients, compared with orthopedic patients, required major amputation (above and below the knee) more frequently (46.5 percent versus 10.4 percent) and had concomitant diabetes more frequently (36.0 percent versus 4.2 percent). Of amputations among patients with diabetes, 73.9 percent were minor (forefoot and toe), versus 29.0 percent for nondiabetic patients ($p < 0.005$). For all admissions, ward costs accounted for 55.6 percent of in-hospital costs per admission, making length of stay the most important determinant of admission cost. The long preoperative stay spent to avoid amputation might be decreased by greater use of outpatient facilities for investigation and initial management. The longest portion of hospital stay is for accommodating major amputees until they are fully mobile using an artificial limb; use of less costly facilities outside acute hospital wards may achieve the same ends more economically. 3 figures, 19 references.

140

TITLE: Amputations in the Surgical Budget (letter). Simmons, D.; Thomson, C.; Scott, D. *New Zealand Medical Journal*. 107 (978): 208-209. May 25, 1994.

OBJECTIVE: To report cost findings about patients with diabetes who underwent amputation.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Costs of about $21,000 for the year in which amputation took place were very close to costs reported in a similar study.

RECOMMENDATION: With education on foot care, daily self-inspection of the feet, and effective monitoring and early intervention, at least 50 percent of amputations should be preventable.

ABSTRACT: The authors determined the mean 1-year cost of $20,881 (in 1987 dollars) for treating 20 patients with diabetes during the year of their amputation(s). This figure is close to the figure of $21,439 for a more recent study in Dunedin, New Zealand. The authors point out that using diabetes codes to identify patients with diabetes has been shown to miss 45 percent of these patients. In the present study, many surgical patients with diabetes remained undiagnosed throughout their admissions. The authors found in their own study that 40 percent of patients with diabetes had not had their feet inspected by their diabetes care attendant in the previous 12 months and that 57 percent had poor nail or skin care. The authors suggest that a team approach makes early intervention more likely and state that this would involve close liaison between the diabetes nurse, physician, podiatrist, and preferably a surgical team with skills in vascular surgery and a special interest in the diabetic foot. 6 references.

141

TITLE: The Burden of Diabetes: The Cost of Diabetes Hospitalizations in Wisconsin, 1994. Ford, E.J.; Remington, P.L. *Wisconsin Medical Journal*. 95(3): 168-169. March 1996.

OBJECTIVE: To determine for Wisconsin in 1994 the cost of all hospitalizations in which diabetes was listed as a diagnosis; to analyze these hospitalizations and their costs.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Diabetes cost Wisconsin residents $545 million, or $150 per person, in 1994.

RECOMMENDATION: Efforts should be made to prevent or delay diabetes and to reduce its complications. Interventions that reduce diabetes-related health care costs will benefit all citizens.

ABSTRACT: The state of Wisconsin maintains a database of information on all hospitalizations, including costs. For 1994, hospital discharge data revealed 53,791 admissions in Wisconsin for which diabetes was listed as a primary or secondary diagnosis. Total costs were $545 million; costs of individual admissions ranged from $150 to $1.5 million (median, $6,280; mean, $10,120). For 8 percent (4,234) of admissions, diabetes was listed as the principal diagnosis; the cost of these admissions was $42 million. For the remaining 92

percent, diabetes was listed as a secondary diagnosis. Among these events, costs by principal diagnosis were $208 million for circulatory diseases (38 percent of total costs); $42 million for digestive diseases (8 percent); $35 million for respiratory diseases (6 percent); $32 million for musculoskeletal conditions (6 percent); $30 million for complications of medical care (5 percent); $28 million for neoplasms (5 percent); $21 million for injury and poisoning (4 percent); $16 million for genitourinary conditions (3 percent); and $81 million for all other causes (15 percent). By age, costs were $213 million for persons under age 65 (39 percent), $176 million for those aged 65-74 (32 percent), and $156 million for persons aged 75 and over (29 percent). Medicare was billed for 68 percent of the costs; other government-supported reimbursement, including Medicaid, brought the total supported by taxpayers to over 75 percent. Private insurance accounted for 23 percent. 1 figure, 1 table, 7 references.

142

TITLE: Clinical Features and Health-Care Costs of Diabetic Nephropathy. Narins, B.E.; Narins, R.G. *Diabetes Care*. 11 (10): 833-839. November/December 1988.

OBJECTIVE: To review the natural history, treatment, and costs of treating nephropathy associated with diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Diabetes-associated nephropathy is rapidly becoming the largest cause of renal replacement therapy.

RECOMMENDATION: Further study of the pathogenesis and treatment of diabetes and diabetic nephropathy is needed.

ABSTRACT: The authors review the incidence, course, prognosis, and treatment of diabetes-related nephropathy. Of patients with type 1 diabetes, 40 to 50 percent develop clinically evident renal disease; two-thirds of those who do (30 percent overall) require replacement therapy for end-stage renal disease (ESRD). From 1973 to 1980, the percentage of ESRD attributable to diabetes tripled. ESRD from diabetes is disproportionally common among blacks (versus whites). Microalbuminuria and macroalbuminuria develop 5 to 10 years and 10 to 15 years, respectively, after initial diagnosis of diabetes. Glomerular filtration rate and serum creatinine generally remain constant during the first 10 to 15 years of insulin dependence. ESRD occurs approximately 5 years after persistent proteinuria and azotemia develop. Among patients with type 1 diabetes-related nephropathy, almost two-thirds die from renal failure, 25 to 30 percent from cardiovascular complications, and 5 to 15 percent from other disorders; patients with type 2 diabetes die more frequently from cardiovascular complications. After 5 years, survival is about 75 percent for patients who receive kidney transplants from living related donors, versus 40 to 50 percent for patients who receive other

ESRD therapy. In 1982, average hospital days for patients with diabetes receiving dialysis were 37 percent greater than for ESRD patients without diabetes. In the first post-transplantation year, patients with diabetes averaged 45 percent more days than those without diabetes. Respective annual per capita costs for all patients with ESRD and for patients with diabetic ESRD were $23,833 and $35,616 for hemodialysis, $23,076 and $36,585 for peritoneal dialysis, and $32,075 and $43,010 for kidney transplantation. 6 figures, 30 references.

143

TITLE: The Cost of Hospitalization for the Late Complications of Diabetes in the United States. Jacobs, J.; Sena, M.; Fox, N. *Diabetic Medicine*. 8 (Symposium): S23S29. 1991.

OBJECTIVE: To calculate for U.S. patients with diabetes the risk of hospitalization for late complications (e.g., cardiovascular and kidney disorders).

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: Late complications of diabetes accounted for 2 percent of the total hospital admissions in the United States in 1987. The total cost of treating these complications was estimated at $5.091 billion (cardiovascular, 74 percent; renal diseases, 10 percent; neuropathy, 3.6 percent; ophthalmic disorders, 1.5 percent; and unspecified diseases, 10 percent).

RECOMMENDATION: None.

ABSTRACT: The cost of health care in the United States is usually attributed to a disease according to the primary diagnosis on the patient's medical record. This method underestimates the cost of hospital care for patients with diabetes, which often contributes to a variety of other diseases or complications. The authors used the 1987 National Hospital Discharge Survey to determine hospitalization rates for patients with diabetes and a matched control group; excess hospitalizations and associated costs were attributed to diabetes. Only those hospitalizations with a diagnosis-related group that matched a late complication were included in the analysis. Average cost per day for complications was obtained from the Pracon Med PROs Audit, a Medicare database. For neuropathy, the highest hospitalization rate among persons with diabetes occurred in the 45- to 54-year age group, 6.74 per 1.000; the highest rate for controls (1.80) was in the group 75 years of age and over. Patients with diabetes aged 45 or younger were 46 times as likely to be hospitalized due to neuropathy as those in the control group (95 percent CI, 45.0 to 47.4). Those with diabetes were 21.8 times as likely to be admitted for skin ulcers/gangrene (95 percent CI, 21.6 to 22.0), 15 times as likely for peripheral vascular disease, 10 times as likely for congestive heart failure, and almost 10 times as likely for atherosclerosis. The risk of cerebrovascular accident and heart disease was 6 to 10 times greater for diabetic patients than for controls. Hospitalization from renal

complications was much more common at younger ages for those with diabetes. Late complications of diabetes resulted in nearly 7 million hospital days; inpatient hospitalization costs were estimated to be $5.091 billion. 1 figure, 5 tables, 16 references.

144

TITLE: The Costs of Diabetes-Related Lower Extremity Amputations in the Netherlands. van Houtum, W.H.; Lavery, L.A.; Harkless, L.B. *Diabetic Medicine*. 12(9): 777781. September 1995.

OBJECTIVE: To identify for 1992 the duration of hospitalization for diabetesrelated lower extremity amputations and their associated costs in The Netherlands.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Days in the hospital for lower extremity amputations in the population with diabetes totaled 65,778 (41.8 days per hospitalization); mean cost per hospitalization was £ 10,531.

RECOMMENDATION: The direct cost of prevention strategies for high-risk patients with diabetes should be analyzed to determine the financial impact of the multidisciplinary clinics that provide these preventive services.

ABSTRACT: The authors used 1992 data from the Dutch organization SIG Health Care Information to identify all lower extremity amputations in The Netherlands. Using average costs associated with such amputations obtained from the National Health Tariffs Authority, Netherlands, the authors were able to determine the average cost of hospitalizations. Total direct costs included those associated with hospital stay and the average procedure-specific costs (for surgeon and anesthetist fees and the operating room) for the specific level of amputation. Patient-specific charges were not available. In 1992, there were 1,810 diabetesrelated lower extremity amputations involving 1,575 hospitalizations. The mean hospital stay was 41.8 days, with a mean cost of £ 10,531. The total direct cost associated with hospitalization and surgery for diabetesrelated amputations was £ 16.59 million, and more than 65,000 hospital days were used. Hospital days for amputation among persons without diabetes totaled almost 46,000. Hospital stays in this group were significantly shorter (mean: 31.8 days, $p < 0.001$) than in persons with diabetes. When outcomes were adjusted for age, more multiple amputations were performed in persons with diabetes (13.6 percent) than in those without diabetes (6.6 percent, $p < 0.001$). Indirect costs and costs of continued medical care at rehabilitation centers and other medical facilities were not taken into account in this study, and, thus, the actual costs associated with lower extremity amputations in the population with diabetes were even higher than this study reported. Studies have shown that lower extremity amputations are at least partly preventable with multidisciplinary treatment

programs. 1 figure, 4 tables, 19 references.

145

TITLE: Counting the Cost of Diabetic Hospital Admissions From a Multi-Ethnic Population in Trinidad. Gulliford, M.C.; Ariyanayagam-Baksh, S.M.; Bickram, L.; Picou, D.; Mahabir, D. *Diabetic Medicine*. 12(12): 1077-1085. December 1995.

OBJECTIVE: To measure the impact of diabetes on a major hospital in northern Trinidad and to evaluate the relationship between ethnicity and morbidity from diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Costs of admission for diabetes in the hospital wards surveyed accounted for at least 8 percent of total expenditures at the hospital and 23 percent of bed occupancy.

RECOMMENDATION: Investment in better-quality community care for patients with diabetes would be economically advantageous for countries such as Trinidad and Tobago.

ABSTRACT: Admission records at Port of Spain Hospital in Trinidad were reviewed for all patients with diabetes admitted to any of seven medical wards, five general surgical wards, or two ophthalmology wards over a 26-week period beginning in October 1993. During the study period, 1,722 (13.6 percent) of a total of 12,673 admissions involved patients (n = 1,447) with diabetes. One hundred seventy-eight of these patients had more than one admission; 1,269 had a single admission. Admission rates increased with age and were approximately 40 percent higher in the population of Indian descent than in those of African origin. Diabetes prevalence in the population had a primary influence on admission rates, with level of admissions and morbidity also influenced by accessibility to hospital services and quality of care in the community. Conditions frequently present on admission included disorders of blood glucose control, foot diseases, renal impairment, cardiac failure, angina, and myocardial infarction and stroke. The fatality rate among admissions was 8.9 percent (154 deaths), and the mean length of stay was 4 days. The presence of renal impairment on admission was associated with a fatality rate of 21 percent. The annual number of bed days occupied by persons with diabetes was 26,659, which represented 23 percent of all bed days on the study wards. Annual financial cost for all patients admitted with diabetes was TT$10.7 million, including TT$3.1 million for patients admitted with foot problems, TT$2.5 million for those with glucose control problems, and TT$5.1 million for those with other diagnoses. The mean cost of 1 patient admission with diabetes was TT$3,096. 1 figure, 5 tables, 28 references.

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TITLE: Diabetes - Inpatient Utilisation, Costs and Data Validity: Dunedin 1985-9. Phillips, D.E.; Mann, J.I. *New Zealand Medical Journal*. 105(939): 313-315. August 1992.

OBJECTIVE: To describe the impact of diabetes on public hospital inpatient services in an urban New Zealand 450-bed university teaching hospital from 1985 through 1989.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Admission, bed utilization rates, and associated costs for diabetes rose by factors of 3.2, 3.8, and 2.8, respectively, during the study period. Most utilization increases were accounted for by admissions in which diabetes was a subsidiary diagnosis. At $16,000 (New Zealand dollars) per patient, admissions for diabetic peripheral vascular disease were the most costly.

RECOMMENDATION: Because diabetes consumes many hospital resources in this region, especially for the growing elderly population, alternative options for providing care are needed. Data audits must be performed or restricted to well-defined groups (e.g., diabetes as principal diagnosis only) to achieve an accurate analysis.

ABSTRACT: Hospital discharge data were collected to describe trends in utilization and costs of admissions for diabetes and associated conditions in an urban teaching hospital in New Zealand from 1985 through 1989. A validation study was performed to assess the impact of underreporting or nonreporting and misclassification of diabetes as a discharge diagnosis. Admissions for diabetes-related conditions represented 5 percent of all hospital inpatient costs in 1989, but 45 percent of admissions where diabetes should have been a subsidiary diagnosis were omitted from the discharge data. During the study period, an average 4.6 percent of total hospital bed utilization was for diabetes admissions, 1.9 percent as the principal, and 2.7 percent as the subsidiary diagnosis. Length of stay averaged 12.3 days for admissions with diabetes as the principal diagnosis and 15.4 days for diabetes as a subsidiary diagnosis. The highest daily cost was for diabetic eye disease (90 percent of these costs were for operative treatment of cataracts, 10 per-cent for treatment of retinopathy), and the highest total and mean per-patient costs were for peripheral vascular disease. Annual bed utilization where diabetes was a subsidiary diagnosis rose from 1,580 to 5,972 days during the study period, but utilization days where diabetes was the principal diagnosis declined from 2,036 to 1,860. Macrovascular disease accounted for most admissions and bed utilization when diabetes was the subsidiary diagnosis. Patients with diabetes are surviving to an age where vascular disease becomes common. Admission rates averaged 3/1,000 for the 0 to 44 age group and 60/1,000 for the $\geq$ 75 age group; bed utilization rates were similar, and costs for the two groups rose from $2,400/1,000 to $181,900/1,000. Increased admissions and bed utilization rates are likely due to an increase in available facilities and changes in treatment practices; the validation study suggests that changes in recording practice by doctors is unlikely to be a

major factor. The accuracy of aggregate costs depends on the accuracy of the discharge data, and diabetes has been significantly underreported. 4 tables, 23 references.

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TITLE: Diabetes-Related Hospitalization and Hospital Utilization. Aubert, R.E.; Geiss, L.S.; Ballard, D.J.; Cocanougher, B.; Herman, W.H. In: *Diabetes in America*. 2nd edition. National Diabetes Data Group, ed. National Institute of Diabetes and Digestive and Kidney Diseases. NIH Publication No. 95-1468. 1995: 553-569.

OBJECTIVE: To describe rates and trends for hospitalization of persons with diabetes using data from the National Hospital Discharge Survey (NHDS) and the National Health Interview Survey (NHIS).

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: Persons with diabetes have higher rates of hospitalization than persons without diabetes.

RECOMMENDATION: None.

ABSTRACT: The authors assessed rates and trends of hospitalization for persons with diabetes between 1980 and 1990. Per the NHDS, in 1990, diabetes was listed as a primary or secondary diagnosis for 2.8 million hospitalizations (24.5 million hospital days); the proportion of such hospitalizations for which diabetes was listed as the primary diagnosis declined from 29 percent in 1980 to about 15 percent in 1990. In the latter year, for discharges that listed diabetes, only diseases of the circulatory system exceeded diabetes as a primary diagnosis. Per the 1989 NHIS, among adults with diabetes, 8.3 percent reported multiple hospital admissions and 15.5 percent reported a single admission. In the population aged 18 years and over, persons with diabetes were 3 times more likely than those without diabetes to report hospitalization in the previous year. Women with diabetes were 6 to 18 percent more likely to report being hospitalized than their male counterparts. Reported single and multiple hospitalization rates were proportionally higher with more diabetes-related complications. In 1990, per the NHDS, 89 percent of admissions with diabetes as a listed diagnosis were of patients aged 45 years or older. Hospitalizations that listed diabetic ketoacidosis increased 27 percent from 1980 to 1990 (age adjusted); hospitalizations for lower extremity amputations related to diabetes rose from about 36,000 to about 54,000 during the period. From 1980 to 1990, the average length of stay when diabetes was the primary diagnosis decreased from 10.5 to 7.8 days. The American Diabetes Association estimated costs associated with hospital care for diabetes to be $37.2 billion in 1992; an estimate by Rubin et al. (1994) put the figure at $55 billion. 19 figures, 8 tables, 32 references.

148

TITLE: Diagnosis Related Groups, Resource Utilization, Age, and Outcome for Hospitalized Nephrology Patients. Muñoz, E.; Thies, H.; Maesaka, J.K.; Angus, G.; Goldstein, J.; Wise, L. *American Journal of Kidney Diseases*. 11(6): 481-488. June 1988.

OBJECTIVE: To examine hospital costs and outcome by age of patients for all nephrology diagnosis-related groups at an academic medical center outside New York City.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Nephrology patients with diabetes generated significantly higher hospital costs than nephrology patients without diabetes due to greater resource consumption. Nephrology patients with diabetes generated a mean net loss per admission of $2,353 relative to diagnosis-related group (DRG) payments.

RECOMMENDATION: Reimbursement of nephrology patients with diabetes should be made more equitable under the DRG system.

ABSTRACT: The authors analyzed hospital cost and outcome for 784 adult and pediatric nephrology admissions over a 2-year period at an academic medical center. Seventy-eight of these patients had diabetes mellitus. Hospital costs (excluding physician fees) were calculated by using per-patient charge data and converting charges to costs via the cost-to-charge ratio data used by the hospital. These costs were then compared with DRG reimbursement for all patients using the DRG payment methodology and DRG case-mix index. The 784 nephrology admissions generated approximately $5 million in hospital costs. Patients with diabetes generated significantly higher mean hospital costs, $8,893, than those without diabetes, $6,153 ($p < 0.03$). For nephrology patients overall, those in age groups 55 years and over would have generated losses relative to DRG payment, peaking at a mean loss of $5,343 for patients aged 85 and over. The deficit was due primarily to more expensive care provided to patients 65 and over. Reimbursement under the DRG system should be made more equitable for patients with diabetes. 5 figures, 8 tables, 7 references.

149

TITLE: The First Two Years of Type I Diabetes in Children: Length of the Initial Hospital Stay Affects Costs but not Effectiveness of Care. Simell, T.; Simell, O.; Sintonen, H. *Diabetic Medicine*. 10(9): 855-862. November 1993.

OBJECTIVE: To compare 1-week and 4-week initial hospital stays for children with type 1

diabetes in terms of cost and outcomes during a 2-year follow-up.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective trial.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Total costs for children who had a 4-week initial hospital stay were 1.6-fold higher during the 2-year follow-up, but outcomes for the two groups were similar.

RECOMMENDATION: The main findings from this analysis can be applied to diabetes care centers in Finland and other countries.

ABSTRACT: Sixty-one newly diagnosed children with type 1 diabetes took part in this Finnish study, which was based at two Helsinki hospitals: Children's Hospital, University of Helsinki; and the Avrore City Hospital. Thirty-one children were assigned to the short-term group (1-week initial hospital stay) and 30 children to the long-term group (4-week initial hospital stay). Metabolic control, psychosocial adjustment, and direct and indirect costs of care were compared during the 2-year follow-up. First-month costs accounted for 74 percent of total costs in the long-term group and 59 percent of total costs in the short-term group. The major first-month expenses were for hospital costs (82 percent in the long-term group and 78 percent in the short-term group). The indirect costs of parents' lost work time, traveling costs, children's living expenses at home, and housekeeping and babysitter assistance, although minimal, were substantially higher during the first month in the long-term group. Other direct costs considered during the 2-year follow-up, including outpatient visits, insulin treatment, home monitoring of blood glucose and urine tests, and diabetic diet, did not differ significantly by group. Overall, total costs were 1.6 times greater in the long-term group. The researchers found no significant differences between the two groups in metabolic control, family adjustment to diabetes, psychosocial measures, or satisfaction with patient education during the 2-year follow-up period. They concluded that shortening the average initial hospital stay of children newly diagnosed with diabetes from 23 days to 9 days achieved a savings of 36 percent in costs during the first 2 years of the disease without influencing the metabolic or psychosocial outcome of care. 3 tables, 34 references.

150

TITLE: Hospitalization and Expenditures for the Treatment of General Medical Conditions among the U.S. Diabetic Population in 1991. Ray, N.F.; Thamer, M.; Taylor, T.; Fehrenbach, S.N.; Ratner, R. *Journal of Clinical Endocrinology and Metabolism*. 81 (10): 36713679. October 1996.

OBJECTIVE: To estimate the risk of hospitalization for general medical conditions among patients with diabetes aged 45 years and over; to estimate how much of the cost of these hospitalizations was attributable to diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: Hospitalizations and expenses among patients with diabetes for conditions that are neither acute nor chronic complications of diabetes are greater than hospitalizations and expenses for these conditions among patients without diabetes.

RECOMMENDATION: Additional research is needed to identify medical reasons for increased risk of selected general conditions among patients with diabetes and to identify appropriate interventions for the care of these problems.

ABSTRACT: The authors studied hospitalization for general medical conditions in patients with diabetes aged 45 years and over. Data were derived from the 1991 National Hospital Discharge Survey and the 1987 National Medical Expenditure Survey. Expenditures attributable to diabetes were estimated by multiplying the excess number of inpatient days for persons with diabetes by the mean per-day inpatient cost. Identification of patients with diabetes was based on primary or secondary diagnosis codes for diabetes; general medical conditions were all those not considered to be acute or chronic complications of diabetes. Costs were inflated to 1991 dollars. Mean expenditures per inpatient day per patient with diabetes were $1,673 for those 45 to 64 years old and $1,192 for those 65 and over. Middle-aged persons with diabetes were 60 percent more likely (relative risk, 1.6, 95 percent confidence interval, 1.2-2.0) to be hospitalized for general medical conditions than were persons without diabetes; the greatest relative risks were for peritonitis/intestinal abscess, respiratory failure, liver disease, and male genital disorders. Among the elderly, there was no significant difference between the groups in overall risk of hospitalization for general medical conditions; those with diabetes had elevated risks for liver disease, septicemia, diseases of pulmonary circulation, and various other problems. Middle-aged and elderly persons with diabetes were hospitalized longer than those without diabetes (8.1 versus 6.3 days for Middle-aged and 10.1 versus 8.9 days for elderly patients). Inpatient expenditures attributable to diabetes were $4.12 billion (52.3 percent of this total was for elderly persons). These costs may be understated because they do not account for undiagnosed diabetes among hospitalized patients. 5 tables, 55 references.

151

TITLE: Hospitals Adopt Intensive Programs for Diabetic Patients to Avoid High Inpatient Costs. Conklin, M.S. *Health Care Strategic Management.* 12(6): 1113. June 1994.

OBJECTIVE: To review methods used by some managed care organizations and hospitals to reduce inpatient costs for patients with diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Survey.
Perspective: Health care system.

CONCLUSION: Successful diabetes management programs have reduced inpatient stays by 1 to 2 days.

RECOMMENDATION: None.

ABSTRACT: The author reviews efforts to reduce expensive inpatient care for people with diabetes. According to one national study, $9,493 was expended per patient with diabetes in 1992, of which $5,885 (more than 63 percent) was for inpatient care; corresponding figures for patients without diabetes were $2,604 and $1,222, respectively. The author describes several programs that have been implemented to reduce inpatient costs for diabetes. Kaiser Permanente of Northern California has developed a database for all patients with diabetes (68,000 in May 1994) that will track costs, compliance, and complication rates. Palmyra Medical Centers in Georgia markets an intensive diabetes intervention and prevention plan to employers, which costs $1,000 per patient with diabetes for the first year and $400 per year thereafter; the program is based on the findings of the Diabetes Control and Complications Trial. Control of blood glucose concentrations is stressed, and the program begins with a 2day intensive education program for newly diagnosed patients. Hemoglobin A1c is tested every 3 months, and additional education is provided if concentrations indicate control problems; blood glucose concentrations have decreased in 99 percent of patients. Support groups meet monthly. Rose Medical Center in Denver has reduced the average length of hospitalization by 1 day per patient with diabetes, for a savings of over $500,000, by implementing intensive case management at admission. The hospital uses its computer system to identify patients with diabetes, then involves a member of the diabetes program in the care of the patient. In Macon, Georgia, a similar program at the Medical Center of Central Georgia that emphasizes inpatient education has reduced length of stay by 1.7 days in 3 years. In Louisville, Kentucky, at Saints Mary and Elizabeth Hospital, nurses from all units meet monthly with diabetes nurse educators to discuss diabetes management problems; hospital stays for patients with diabetes have been reduced by 1.92 days in 2 years. 1 figure.

152

TITLE: Operations, Total Hospital Stay and Costs of Critical Leg Ischemia. A Population-Based Longitudinal Outcome Study of 321 Patients. Eneroth, M.; Apelqvist, J.; Troeng, T.; Persson, B.M. *Acta Orthopaedica Scandinavica*. 67(5): 459-465. October 1996.

OBJECTIVE: To estimate costs over time for a population of patients with critical leg ischemia, including many with diabetes mellitus, who underwent surgery in Sweden.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.

Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Mean total costs were $47,000 per patient. Patients with diabetes mellitus more often underwent major amputation, had longer hospital stays, and incurred higher medical costs than those without diabetes.

RECOMMENDATION: None.

ABSTRACT: The authors conducted a longitudinal analysis of costs (in 1996 U.S. dollars) incurred by 321 patients, including 118 with diabetes mellitus, who had surgery for critical leg ischemia in 1987 or 1988 in Malmohus county, Sweden. Surgical procedures, hospitalizations, and hospital treatment costs were assessed from the first procedure until death or for at least six years postoperatively. Only those admissions directly caused by arterial occlusive disease in the lower limbs were included. Admissions to rehabilitation clinics and nursing homes were included, but nursing home stays for those who lived in a nursing home before the surgery and returned to one after the procedure were not. The costs of angiography, implants, intensive care, outpatient care, and orthopedic appliances as well as indirect costs were not included. The initial operation during the inclusion year was a reconstructive vascular procedure for 96 patients, a restorative or other vascular procedure for 111, and a major amputation for 114. Total hospitalization until follow-up in all patients was 37,638 days, of which only 44 percent was in surgical departments. Estimated overall cost for hospital stays was $12.87 million, a mean per-patient cost of $40,103. Overall cost of surgery was estimated to be $2.25 million, a per-patient cost of $7,050. Patients with diabetes had a longer mean total hospital stay (134 versus 108 days, $p = 0.009$) and a higher estimated mean total hospital cost ($52,000 versus $44,000, $p = 0.01$) than patients without diabetes. Both groups had a mean of three operations. Patients with diabetes were more likely than those without diabetes to undergo major amputation as the operation (50 percent versus 27 percent) and more often became bilateral amputees than patients without diabetes (28 percent versus 12 percent). 3 tables, 33 references.

153

TITLE: Patterns of Hospitalization in a Pediatric Diabetes Clinic in Sydney. Sutton, D.L.; Greenacre, P.; Howard, N.J.; Cowell, C.T.; Silink, M. *Diabetes Research and Clinical Practice*. 7(4): 271-276. November 6, 1989.

OBJECTIVE: To ascertain the number of children with diabetes admitted to Children's Hospital in Sydney between 1985 and 1987 and to analyze their admissions.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: For the 351 admissions of 241 children with type 1 diabetes admitted during the period, the median stay was 10 days (12 for newly diagnosed children, 7 for others). Costs for newly diagnosed admissions were projected at $Aust 3,658.00; of other admissions, $Aust 2,681.55.

RECOMMENDATION: Patients' use of existing education and dietary services should be maximized, and additional services should be developed.

ABSTRACT: Medical files were obtained retrospectively on all patients with type 1 diabetes admitted to Children's Hospital from 1985 to 1987. Information was collected on sex, age, number of bed days per admission, and reasons for admission. The direct cost of a bed day and an admission for diabetes in this hospital were calculated using a small sample. Two hundred forty-one children with type 1 diabetes had 351 admissions over the 3 years; 105 stays were for newly diagnosed children. Of these 105 children, 14 (13.3 percent) had additional admissions during this period. Of the 246 admissions for previously diagnosed children, stabilization of high blood glucose was a cause for 145 (59.0 percent); other leading causes were a medical reason (32.5 percent) and education (25.6 percent). The cost of a bed day for a child with diabetes was $Aust 295.00. 3 figures, 1 table, 12 references.

154

TITLE: Precipitants of Hospitalization in Insulin-Dependent Diabetes Mellitus (IDDM): A Statewide Perspective. Fishbein, H.A. *Diabetes Care*. 8 (Supplement 1): 61-S64. September-October 1985.

OBJECTIVE: To describe the epidemiology of precipitants of hospitalization for type 1 diabetes in Rhode Island; to evaluate the effectiveness of outpatient education in reducing hospitalizations for patients with diabetes; and to estimate potential cost savings of the education program.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Poor diabetes control and infection accounted for nearly one-half of all hospital admissions in Rhode Island among patients known to have diabetes. An outpatient education program significantly reduced the incidence of acute hospitalizations among participants and resulted in substantial savings.

RECOMMENDATION: Other investigators may want to consider a registry system for diabetes.

ABSTRACT: The author evaluated the epidemiology of precipitants of hospitalization for type 1 diabetes in Rhode Island and the effectiveness of outpatient education in reducing hospitalizations. A statewide registry of patients with type 1 diabetes was used to identify and characterize the epidemiology of patients admitted to Rhode Island hospitals. Data on precipitating factors were obtained via a review of medical records and physician interviews. During the study period (April 1978 through March 1983), there were 1,344 hospital admissions for type 1 diabetes among 887 persons below age 30. Patients with known diabetes accounted for 1,123 admissions (691 persons). Poor diabetes control (noncompliance with diet/medication) or infection accounted for 54 percent and 44 percent of single and multiple admissions, respectively. Admissions for pregnancy care and for various conditions (e.g., myocardial infarction, stroke) were the next most frequent precipitants of hospitalization. An intensive 10-hour outpatient education program with two follow-up sessions was evaluated in 100 patients; the program reduced the number of hospitalizations by 51 percent. Based on a direct cost for hospitalization of $2,400, the potential savings of the educational intervention for those admitted with known diabetes were estimated at $674,000 (cost of admission x admissions for poor diabetes control or infection x 50 percent for educational effect). The cost of the education program was only about $100 per patient. 2 tables, 1 figure, 10 references.

155

TITLE: Public Cost and Access to Primary Care for Hyperglycemic Emergencies, Clark County, Nevada. Wilson, B.; Sharma, A. *Journal of Community Health*. 20(3): 249-256. June 1995.

OBJECTIVE: To determine the cost and major causes of hospitalizations for emergency admissions for diabetic hyperglycemia at a large public hospital in Clark County, Nevada; to determine the effect of insurance coverage on the availability of primary care providers, hospitalization costs, and precipitators of admissions in the study population.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Uninsured patients accounted for 49 percent of hyperglycemic admissions during the study period. Hospital medications and/or charges were lower for uninsured patients, who were more likely than insured patients to be hospitalized because they lacked access to primary care.

RECOMMENDATION: Public funding or universal insurance coverage and more comprehensive employer-funded insurance programs to provide primary care access for diabetes mellitus management should be evaluated as cost-savings measures in areas with large populations of people with diabetes.

ABSTRACT: The authors evaluated hospital charges and major causes of hospitalization for diabetic ketoacidosis and nonketotic hyperosmolar state, the major acute emergencies of diabetes mellitus, at a large public hospital. Medical insurance coverage associations with availability of primary care and hospitalization charges were also examined. Data were derived from a retrospective search of hospital admissions for diabetic ketoacidosis and nonketotic hyperosmolar state over a 30-month period from 1989-1991. Hospitalization and emergency room charges were compiled from medical records review. Over the study period, 247 admissions for diabetic ketoacidosis and nonketotic hyperosmolar state were identified; uninsured admissions accounted for 49 percent. Only 6 percent of patients in the uninsured group identified a primary care provider, as compared with 85 percent of the insured group. Un-insured patients accounted for a majority of emergency room visits and 52 percent of emergency room charges. However, average hospital charges (exclusive of physician fees) were significantly less in the uninsured group ($4,049) than in the insured group ($7,222). Uninsured patients were much more likely to have been hospitalized because they lacked access to medication and much less likely to be hospitalized because of late complications of diabetes mellitus. These patients had milder acute and chronic disease processes potentially responsive to appropriate out-patient management. 1 figure, 3 tables, 6 references.

156

TITLE: Relative Risk and Economic Consequences of Inpatient Care Among Patients With Renal Failure. Thamer, M.; Ray, N.F.; Fehrenbach, S.N.; Richard, C.; Kimmel, P.L. *Journal of the American Society of Nephrology*. 7(5): 751-762. May 1996.

OBJECTIVE: To identify the leading causes of hospitalization for people with renal failure; to compare the risks of hospitalization associated with these causes and with other chronic progressive diseases; and to quantify total inpatient days, excess length of stay, and associated costs attributable to renal failure.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based cost.
Perspective: Health care system.

CONCLUSION: Chronic renal disease is associated with significant morbidity and medical costs.

RECOMMENDATION: None.

ABSTRACT: The authors studied inpatient care for persons with chronic renal failure, including those with end-stage renal disease as well as those who had not reached that stage, using 1991 data from the Medicare End-Stage Renal Disease program, the National Health Interview Survey, the U.S. Census, and the National Hospital Discharge Survey. If chronic renal failure was the primary discharge diagnosis, all charges were included; a portion of the

charges was included if chronic renal failure was a secondary diagnosis. In 1991, patients with renal failure had 348,962 hospitalizations, of which 64 percent were for either chronic renal failure or 1 of 15 comorbid conditions (e.g., vascular access problems, congestive heart failure). Patients aged 65 years and older accounted for 57.6 percent of these hospitalizations but 63.0 percent of the inpatient days. The renal failure population averaged 1.4 hospitalizations in 1991. Compared with persons without renal failure, the age-adjusted relative risk of hospitalization for persons with renal failure was 10 for all causes, 201.5 for vascular access problems, 32.4 for congestive heart failure, 31.3 for pulmonary edema/respiratory failure, 23.4 for gastrointestinal hemorrhage, 21.7 for diabetes, 19.2 for sepsis/septicemia, 15.6 for electrolyte disorders, 12.4 for hypertension, 10.4 for anemia, and 10.3 for myocardial infarction. Length of stay was significantly longer (mean difference: 0.9 days) than in those without renal failure. Patients with renal failure consumed 1.5 million hospital days, for a total cost of $2.2 billion; of this amount, $291 million was directly for chronic renal failure. Hospitalization for vascular access problems cost $168 million; for congestive heart failure, $142 million. 6 tables, 46 references.

157

TITLE: Resource Utilization in Treatment of Diabetic Ketoacidosis in Adults. May, M.E.; Young, C.; King, J. *American Journal of the Medical Sciences*. 306(5): 287-294. November 1993.

OBJECTIVE: To determine the specific care practices that correlate with decreased hospital stay for adult patients with ketoacidosis related to diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Optimizing hospital care and reducing the incidence of ketoacidosis in women would markedly affect health care costs.

RECOMMENDATION: Future studies of ketoacidosis in adults should focus on criteria for admission to the intensive care unit (ICU), optimum time to move patients out of the ICU, and the etiology and prevention of recurrent ketoacidosis in women.

ABSTRACT: The authors examined the records of 40 women and 25 men with diabetes who were hospitalized a total of 92 times with ketoacidosis (serum glucose greater than 200 mg/dL, positive serum or urine ketones, and evidence of metabolic acidosis). The cases were analyzed by initial level of nursing care (ICU, stepdown, general); the three fatalities were excluded from analysis of the correlates of length of stay or cost. Mean days of hospitalization and total costs (with standard deviations) were 6.3 (5.3) and $12,286 ($12,096) for the ICU group, 4.4 (3.0) and $6,804 ($3,759) for intermediate care, and 6.0 (6.0) and $7,357 ($6,902) for general care. Patients with concurrent infection had significantly longer stays than those

who were culture-negative (9.1 ± 6.8 days versus 4.5 ± 3.2 days). Shorter length of stay was correlated with care by a diabetologist, shorter interval from presentation until time to administration of an intermediate- or long-acting insulin, and time of day of the initial presentation. In-hospital recurrences of ketoacidosis occurred less frequently in patients managed by a diabetologist (30 versus 47 percent of cases) and were correlated with longer hospitalization. Rapid initial correction of hyperglycemia and acidemia did not correlate with reduced resource usage. Level of care did not affect outcome; if all cases were treated at the intermediate level, an overall savings of $2,292 per case would have been realized. The authors conclude that admission to the ICU is indicated for patients with a concurrent diagnosis that would require intensive care (e.g., myocardial infarction) or if the ketoacidosis is grade 4 (the highest grade). They project resource savings of $60 to $90 million yearly from reducing the level of diabetic ketoacidosis in females to the level in males. 4 tables, 33 references.

Oupatient Care (Hospital, Physician, Emergency)

158

TITLE: ACE Inhibition in Diabetic Patients: Economic Implications. Rodby, R.A.; Lewis, E.J. *PharmacoEconomics*. 10(Supplement 4): 315-320. October 10, 1996.

OBJECTIVE: To discuss angiotensin-converting enzyme (ACE) inhibitors, their role in slowing the progression of diabetic nephropathy to end-stage renal disease (ESRD), and their consequent influence on health care expenditures. To project the economic impact of this class of antihypertensive agents on diabetes mellitus.

CATEGORY: Cost of diabetes (direct).

Type of Study: Epidemiological cohort model.
Methodology: Cost-effectiveness analysis.
Perspective: Health care system.

CONCLUSION: Use of captopril, an ACE inhibitor, in patients with diabetes mellitus and overt nephropathy produces substantial cost savings and prolongs life.

RECOMMENDATION: Continuing attention must be given to the cost-effectiveness of all therapies, but a therapy need not save money to be justified.

ABSTRACT: In patients with type 1 diabetes, histological changes from diabetic nephropathy are present within 5 years of diagnosis; overt nephropathy usually occurs after 15 to 25 years of diabetes. Treatment with ACE inhibitors is one of the therapies that appear to influence development and progression of nephropathy in patients with type 1 diabetes in a beneficial way. The authors explore the issue of whether treatment with the ACE inhibitor captopril to delay the onset of renal failure is cost effective. They point out that unless ESRD therapy is avoided altogether for some patients, captopril will not save money. Complete

avoidance of ESRD could occur if captopril halts the progression of diabetic nephropathy entirely in some patients (which has not been shown in overt nephropathy) or if it prevents ESRD long enough for a patient to succumb to another illness first. The authors discuss their medical treatment model of the cost-benefit and cost-effectiveness of captopril therapy in patients with type 1 diabetes and diabetic nephropathy. In the model, patients receive either captopril or placebo and are followed as they progress to ESRD, receive ESRD therapies, and eventually die. Each year, the model predicts costs for the two study groups. In each of the second through 16th years, placebo patients cost more than those receiving captopril. In the 17th and succeeding years, captopril patients cost more than their placebo counterparts. However, the lower cost per captopril patient in the early years more than offsets the higher cost for the captopril group in the later years, resulting in overall cost savings. Captopril prolongs life and simultaneously saves money because progression to ESRD is delayed long enough for some patients taking captopril to die before ESRD develops. The authors' model predicts per-patient savings from using captopril of $7,800 over 5 years, $30,110 over 12 years, and $32,550 over 31 years. 3 figures, 1 table, 11 references.

159

TITLE: Closing the Gap: The Problem of Diabetes Mellitus in the United States. Herman, W.H.; Teutsch, S.M.; Geiss, L.S. *Diabetes Care*. 8 (4): 391-406. July-August 1985.

OBJECTIVE: To review the epidemiology and costs of diabetes and its complications; to discuss methods of reducing the burden of diabetes on the health care system.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: Both type 2 diabetes mellitus and the complications of diabetes are often preventable.

RECOMMENDATION: Continuing to promote public health and *Diabetes Research*, assuring that public health programs follow current standards for diabetes care, and providing third party coverage of educational programs and preventive screening for complications should all be used to reduce the morbidity and mortality of diabetes.

ABSTRACT: The authors review data on diabetes from population-based studies and surveys of the National Center for Health Statistics. Among racial/ethnic groups, the prevalence of type 1 diabetes mellitus is highest in whites, and its peak onset is in children aged 10 to 14 years. The risk of type 2 diabetes increases with age, and the disease is relatively more common among women and nonwhites. The risk of gestational diabetes increases with maternal age. Genetic, familial, and environmental factors; obesity; and inactivity are discussed as risk factors. The prevalence (number of cases) of type 1 diabetes in 1980 was 435,000, and the prevalence of type 2 diabetes was about 5.1 million. Mortality in

1980 from diabetes was estimated at 154 per 100,000 persons in the general population. About 86,000 women develop gestational diabetes annually. The major cause of death in people with type 2 diabetes is cardiovascular disease; the major causes of death for those with type 1 diabetes are renal and cardiovascular diseases. People with diabetes are more than twice as likely to require hospital services as those without diabetes, and in 1977, 15 percent of people in nursing homes had diabetes. In 1980, the direct costs of diabetes were $652 million for physician visits, $6,157 million for hospitalization, $663 million for nursing home care, and $380 million for insulin and hypoglycemic agents. Indirect costs were estimated at $10 billion per year. The authors state that control of obesity, glycemia, and hypertension; patient education; and smoking cessation could annually reduce the prevalence of diabetes or its complications by the following amounts: type 2 diabetes, 293,000; gestational diabetes, 28,000; ketoacidosis, 52,000; congenital malformations, 500; stroke, 19,000; coronary heart disease, 38,000; peripheral vascular disease, 24,000; blindness, 3,500; end-stage renal disease, 2,000; and amputations, 15,000. 23 tables, 105 references.

160

TITLE: Direct Costs of Diabetes Care: A Survey in Ottawa, Ontario 1986. McKendry, J.B. *Canadian Journal of Public Health*. 80 (2): 124-128. March/April 1989.

OBJECTIVE: To determine the annual direct costs of care for patients with diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Of the costs of routine diabetic care, 23.4 percent were for at-home testing; 45.3 percent, treatment supplies; 20.9 percent, physician's services; and 10.4 percent, miscellaneous items. Of direct nonroutine costs, 64.4 percent were for hospital services, 13.9 percent for treatment supplies, 9.6 percent for physician services, and 7.7 percent for testing supplies.

RECOMMENDATION: Periodic cost-of-care surveys, with help from volunteers of the diabetes association, offer an affordable means to monitor utilization trends and costs of supplies and services in caring for patients with diabetes.

ABSTRACT: A total of 205 Ottawa-area patients with diabetes completed questionnaires designed to assess their annual use of equipment, supplies, and professional and institutional services. Average age of respondents was 47.3 years; their average duration of diabetes was 18.3 years. Indirect costs, such as loss of time from work, were not addressed. Direct costs were divided into routine (supplies and equipment for self-treatment and testing and professional services during routine encounters) and nonroutine (nonroutine emergency room and hospital services) categories. The costs of goods and services were estimated using current fee schedules and local pharmacy prices. Methods used for glucose monitoring at

home included blood tests only (64.9 percent), urine tests only (16.6 percent), urine and blood tests (7.8 percent), and no testing (10.7 percent). Annual costs for treatment regimens were as follows: diet only, no cost (4.4 percent); oral medication, $236.40 (9.3 percent); insulin injections, $362.34 (79 percent); and insulin by pump, $1,603.20 (7.3 percent). Assuming six or fewer visits to a family physician or diabetologist, two or less to an ophthalmologist, and no visits to a nephrologist or neurologist, annual costs for physician services were estimated to be $201.47. Annual costs for routine care included 23.4 percent for test supplies, 45.3 percent for treatment supplies, 20.9 percent for physicians' services, and 10.4 percent for miscellaneous items, for a total of $962.01. Nonroutine costs averaged $45.84 for emergency room visits and $1,936.40 for inpatient hospital care. When expressed in terms of routine plus nonroutine cost, hospital care accounted for 64.4 percent; treatment supplies, 13.9 percent; physician services, 9.6 percent; test supplies, 7.7 percent; miscellaneous, 3.4 percent; and emergency care, 1 percent, for a total of $2,944.25. 7 tables, 2 figures.

161(Cross-Reference 102)

TITLE: The Economics of Screening for Microalbuminuria in Patients with Insulin-Dependent Diabetes Mellitus. Borch-Johnsen, K. *PharmacoEconomics*. 5(5): 357-360. May 1994.

OBJECTIVE: To discuss the cost benefit of screening for microalbuminuria followed by antihypertensive treatment of early renal disease indicated by microalbuminuria in patients with type 1 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient screening.
Methodology: Cost-benefit analysis.
Perspective: Health care system.

CONCLUSION: Screening and intervention for microalbuminuria in patients with type 1 diabetes appears to increase life expectancy significantly and improve quality of life for patients while providing considerable savings for health care providers.

RECOMMENDATION: A screening program, including an annual measurement of the urinary albumin excretion rate, should be instituted for all patients with type 1 diabetes.

ABSTRACT: Patients with type 1 diabetes are at risk of developing diabetic nephropathy, a condition in which the urinary albumin excretion rate exceeds 300 mg/day, which can lead to end-stage renal failure, dialysis or kidney transplantation, or death. Patients with microalbuminuria (i.e., a slightly elevated excretion rate of 30 to 300 mg/day) have a much increased risk of developing diabetic nephropathy. The Diabetes Control and Complication Trial Research Group study (1993) showed that metabolic control could reduce the risk of developing microalbuminuria by 39 percent. Intensive antihypertensive treatment may be effective for microalbuminuria and is known to delay the onset of end-stage renal failure if used in early clinical nephropathy. Semiannual screening for microalbuminuria is sufficient for

early detection using albumin assays or less expensive reagent strips. Prevention by metabolic control is possible but costly to maintain. Two studies evaluating screening for microalbuminuria and intervention with antihypertensive drugs showed that the monetary benefits of screening outweighed the costs, even with a limited treatment effect. One study found that reducing the urinary albumin excretion rate from 20 percent to 18 percent annually would result in a net savings because the annual costs per patient for treating end-stage renal failure were very high (dialysis: $35,000 to $55,000; transplantation: $14,000 to $35,000 initially and $7,000 subsequently), compared with screening ($9) and antihypertensive treatment ($350). If, as indicated by recent trials, antihypertensive treatment can reduce the progression of the urinary albumin excretion rate by 33 percent or 67 percent, median life expectancy would increase by 4 or 14 years, and the need for dialysis and transplantation would decrease by 20 percent to 60 percent. 1 table, 25 references.

162

TITLE: "Educating" the Person with Diabetes in an Ambulatory Setting. Travis, L.B. *Texas Medicine*. 88(7): 69-71. July 1992.

OBJECTIVE: To raise questions about the distribution of savings accruing from the transition to the outpatient setting for educating and managing patients with newly diagnosed diabetes; to discuss underwriting the cost of ambulatory education programs.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Outpatient education and management of patients with diabetes results in savings, but these savings are not necessarily returned to the health care system. Health centers themselves under-write the diabetes program.

RECOMMENDATION: None.

ABSTRACT: The author comments on the benefits of outpatient management and education of patients with type 1 diabetes. Increased public awareness of the symptoms of diabetes, earlier detection by the medical profession, and efforts to reduce health care costs have helped to move diabetes education to the outpatient setting. At the Barbara Davis Center in Colorado, 60 percent of patients received all their care as outpatients from 1980 through 1986. In a Texas hospital, the percentage of those receiving only outpatient services increased from 0 to 38 percent in just over 2 years. Outpatient education reduces the disruption of the disease for patients and their families. Although reports of cost savings are no doubt authentic, these savings have not resulted in reduced health insurance premiums or lower taxes. The author reports that outpatient education services at the Children's Diabetes Management Center (University of Texas Medical Branch, Galveston) require, per patient, 2 to 4 hours from the physician, 10 to 12 hours from the nurse educator, and 2 to 4 hours from the

dietitian. Using a conservative estimate of 12 hours of professional time, total costs (salaries, fringe benefits, clinic and laboratory fees, and supplies and education materials) range from $500 to $800 per patient. Private insurance reimburses less than 50 percent of costs, if any. In Texas, diabetes education is not a reimbursable expense; the health care center pays for outpatient education costs. Impediments to outpatient diabetes management and education outside a medical center include the comfort level of practitioners in managing new-onset diabetes, the availability of adequate instructional services, and the cost to practitioners. 5 references.

163

TITLE: Health Insurance and the Financial Impact of IDDM in Families with a Child with IDDM. Songer, T.J.; LaPorte, R.E.; Lave, J.R.; Dorman, J.S.; Becker, D.J. *Diabetes Care* 20 (4):577-584. April 1997.

OBJECTIVE: To examine health insurance experience and out-of-pocket costs of families with and without a child with type 1 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Statistical analysis.
Perspective: Societal.

CONCLUSION: Having a child with diabetes exerts a substantial economic impact on the family.

RECOMMENDATION: The issue of whether limited access to insurance, limited coverage, or high out-of-pocket costs have any long-term health effect on people with diabetes remains to be investigated.

ABSTRACT: The study included 197 families having a child with type 1 diabetes (identified by the Allegheny County [Pennsylvania] IDDM Registry) and 142 control families who did not have such a child. In addition to health insurance issues, three measures of out-of-pocket costs were examined: (1) money spent on health care services and supplies not reimbursed by insurance, (2) reported out-of-pocket costs plus out-of-pocket insurance premiums, and (3) out-of-pocket costs (including insurance premiums) as a share of household income. Out-of-pocket costs were categorized in intervals of $250 up to more than $2,750 (1990 dollars). Case families were older than control families and more likely to be headed by a single parent. About 90 percent of case and control families reported full-year insurance coverage. Case families, however, were more likely to report being denied coverage (8.4 percent versus 1.7 percent for controls, $p = 0.03$). In addition, case families reported significantly higher out-of-pocket expenses ($p < 0.001$), and the median amount of these expenses plus the out-of-pocket costs for insurance premiums was also significantly higher in case families ($1,125 versus $625, $p = 0.03$). The case families spent 5.6 percent of their income on health care, versus 3.1 percent for the control families ($p = 0.004$). The authors note that there is some uncertainty

about the future availability of insurance and care for individuals and families who use health services frequently. 2 figures, 6 tables, 38 references.

164

TITLE: Hospital Costs, Use of Resources, and Dynamics of Death Associated with Diabetes Mellitus. Muñoz, E.; Chalfin, D.; Birnbaum, E.; Goldstein, J.; Cohen, J.; Wise, L. *Southern Medical Journal*. 82 (3): 300-304. March 1989.

OBJECTIVE: To analyze the use of hospital resources for patients with diabetes mellitus admitted to a teaching hospital in a suburb of New York City.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The diagnosis-related group hospital payment system is inequitable for reimbursing the care of patients who die in the hospital from diabetes-related causes.

RECOMMENDATION: Physicians must be advocates for equitable reimbursement and for further study of the economics of patient death in the hospital.

ABSTRACT: The authors analyzed resource use and diagnosis-related group payment for patients with diabetes at an 805-bed teaching hospital outside New York City. Patients had type 1 or type 2 diabetes as a primary or secondary diagnosis. Variables for which nonsurvivors had higher values than survivors included mean age, mean diagnosis-related group weight index (by 5.9 percent), length of stay (by 67.7 percent), number of diagnoses (89.5 percent), procedures (28.2 percent), and severity of illness (56.2 percent); the last value was calculated as the total number of diagnostic codes. Total daily hospital cost was 129.7 percent greater for nonsurvivors; this group generated a $9,910 loss per patient versus a $141 profit for survivors. Nonsurvivors had much higher rates of emergency admission, admission to ICU, and requirements for blood or plasma. The only profitable group of nonsurvivors when these patients were defined by length of stay were those who died within 7 days of admission. All age categories of nonsurvivors except for those aged 25 to 34 years generated financial losses to the hospital. Diabetes-related deaths after a nonemergency admission created a much greater financial risk to the hospital than did such deaths after an emergency admission. 5 tables, 2 figures, 12 references.

165

TITLE: Medical and Financial Implications of Discontinuing a Statewide Free Insulin Program Involving 3,720 People. Nicholas, W.; Watson, R. *Southern Medical Journal*. 82(1): 13-17. January 1989.

OBJECTIVE: To assess the effects of discontinuing a state program that provided free insulin to people with diabetes for almost 20 years.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Discontinuing the program did not affect recipients negatively, as measured by physician or emergency room visits or hospitalizations.

RECOMMENDATION: None.

ABSTRACT: For almost 20 years, the Mississippi State Department of Health provided free insulin to several thousand people with diabetes; the program was discontinued in 1981. The authors hypothesized that discontinuation would adversely affect the people involved. The periods studied were the 18 months before (period 1) and the 18 months after (period 2) discontinuation. Most of the 351 sample patients interviewed were black; the majority were female. Mean age at interview was 58.6 years. Fifty-seven percent had Medicaid or Medicare coverage; 43 percent were uninsured. Mean daily insulin dose, body weight, and blood glucose value did not differ significantly between the study periods, although in period 2 there was a trend among those aged 45 or over for a smaller percentage of patients to have fasting serum glucose values higher than 300 mg/dL. About three-fifths of patients indicated they were not doing without essentials to purchase insulin after program discontinuation. Patients with Medicaid or Medicare coverage had significantly fewer hospitalizations in period 2. For the overall sample, 17 patients were admitted for ketoacidosis in period 1; 7 during period 2. Visits to physicians averaged 8.4 for period 1; 8.9 for period 2. Emergency room visits, which were infrequent, did not differ significantly by period. Diabetes-related hospital admissions decreased from 45.2 to 34.9 per 100 persons, but again the difference was not significant. Using data from the Medicaid Commission and the Mississippi Health Care Commission, the authors extrapolated the decreased hospital admissions to a savings of $85,618 for the sample group as a whole. The small (statistically insignificant) increase in physician visits was projected to cost $2,250. The authors concluded that discontinuing the free insulin program did not have a measurable negative effect on the patients studied. The authors also found that the 3,720 patients who had comprised the complete group of patients receiving free insulin had fewer hospitalizations in period 2, a projected cost savings of $907,404 ($244 per person). A slight increase in physician visits produced a cost increase of $23,846 ($6.40 per person). Overall savings were $883,558 ($237.13 per person). The program had cost the state $550,000 annually. 6 tables, 3 figures, 1 reference.

166

TITLE: An Outpatient-Focused Program for Childhood Diabetes: Design, Implementation, and Effectiveness. Lee, P.D. *Texas Medicine*. 88(7): 64-68. July 1992.

OBJECTIVE: To determine the impact of an outpatient program for management and education of patients with newly diagnosed diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Program evaluation.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Outpatient management and education of patients with new-onset diabetes reduced costs, total days of stay, and length of hospitalizations for diabetes-related problems.

RECOMMENDATION: Third party payers of health care should adjust coverage to encourage more cost-effective health care delivery through outpatient programs for diabetes.

ABSTRACT: The author analyzes the impact of implementing, in mid-1988 at Texas Children's Hospital, outpatient management and education for children with newly diagnosed diabetes mellitus. Patient records from 1985 to 1990 provided comparative data. A pediatric endocrinologist, two nurse educators, a dietitian, and a social worker provided outpatient care; initial sessions usually lasted a total of 8 to 12 hours over 2 to 3 days. Hospitalization for rehydration and initiation of insulin therapy was based on degree of illness rather than specific laboratory criteria; patients entered outpatient care when medically stable. Follow-up visits occurred 1 to 2 weeks and 1 month later. Thirty to 50 new cases of diabetes were seen yearly. Yearly inpatient admissions (1985 to 1990) were 82, 114, 102, 88, 59, and 51; yearly outpatient visits (1986 to 1990) totaled 660, 837, 957, 816, and 964. The proportion of new-onset patients who were never hospitalized increased from 0 to 38 percent between 1987 and 1990. Hospitalizations for new-onset diabetes in 1987 and 1990 totaled 42 and 32, respectively, with an average duration of 5.6 and 4.0 days, respectively ($p < .05$). Readmissions for diabetes-related problems equaled 84 in 1986 and 20 in 1990; average length of stay for these admissions was 4.4 days in 1987 and 2.6 days in 1990 ($p < .05$). An analysis of readmissions from 1989 to 1990 found that none of the readmitted patients had received their initial care as outpatients. Average hospitalization costs (excluding physician, nursing, and dietitian fees) for the last 23 consecutive new-onset patients at the hospital were approximately $1,000 per day. With the outpatient program, average per-patient costs were reduced approximately $100,000 per year, and the average costs of all admissions declined. Outpatient management of new-onset diabetes reduces initial costs and subsequent need for hospitalization. 4 figures, 12 references.

167

TITLE: Resource Utilization and Costs of Care in the Diabetes Control and Complications Trial. The Diabetes Control and Complications Trial Research Group. *Diabetes Care*. 18(11): 1468-1478. November 1995.

OBJECTIVE: To detail the resources used and associated costs of care for patients in the

Diabetes Control and Complications Trial (DCCT).

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Intensive therapy to lower blood glucose concentrations as practiced in the DCCT is associated with a substantial increment in cost.

RECOMMENDATION: The costs of intensive therapy to treat type 1 diabetes should be balanced against the cost savings related to reduction of long-term complications of diabetes.

ABSTRACT: The resources used and associated costs of care of patients in the DCCT are detailed. Researchers calculated resources used for intensive and conventional therapy, including health care professionals' time and services, hospitalizations, outpatient care, and equipment and supplies, as well as for managing the side effects of therapy. Most data were derived from information routinely collected as part of the trial; a questionnaire was used to gather data not available from existing sources. Costs were calculated as the product of the resources used and the unit cost of those resources. The annual cost of intensive therapy with multiple daily insulin injections (approximately $4,000 per year) was $2,300, or 2.4 times, greater than the cost of conventional therapy (approximately $1,700 per year). Most of the difference in cost was attributable to differences in the frequency of outpatient visits and self-monitoring of blood glucose. The annual cost of intensive therapy with continuous subcutaneous insulin infusion (approximately $5,800 per year) was $1,800, or 1.4 times, greater than the cost of intensive therapy with multiple daily insulin injections. The higher expense was due entirely to the cost of the pump and pump-related supplies. The costs ($210 per year) associated with the major side effects of intensive therapy, excessive weight gain and severe hypoglycemia, were three times the cost of treating the side effects of conventional therapy ($70 per year), but as a percentage of the total there was little difference between the groups (5 percent versus 4 percent). The authors point out that costs associated with intensive therapy in the DCCT, which was carried out in academic settings following a research protocol, would probably be higher than the cost of such therapy in the general health care setting. 8 tables, 11 references.

Prescription Drug

168

TITLE: Conversion from Glipizide to Glyburide: A Prospective Cost-Impact Survey. Alexis, G.; Henault, R.; Sparr, H.B. *Clinical Therapeutics* 14(3): 409-417. May-June 1992.

OBJECTIVE: To assess the feasibility and cost of converting patients with type 2 diabetes from glipizide to glyburide.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Conversion of a large number of patients from glipizide to glyburide was found to be feasible and resulted in substantial cost savings.

RECOMMENDATION: None.

ABSTRACT: Researchers studied the cost of converting 211 men with type 2 diabetes from glipizide to glyburide; both are oral hypoglycemic agents. Patients had to be receiving stable doses of glipizide and not require insulin at study entry. Programs were designed to educate both prescribers and patients. Mean patient age was 66.0 ± 8.24 years (range 42 to 82 years). Mean daily glipizide dose at conversion was 18.7 ± 12.32 mg (range 2.5 to 40 mg), and mean duration of glipizide therapy was 8.8 ± 2.07 months (range 4 to 13 months). After conversion, patients were followed for up to 12 months. Mean daily glyburide dose was 8.3 ± 5.68 mg initially and 9.9 ± 6.52 mg at 7 months; mean change in daily dose thereafter was less than 1 mg. The ratio of mean daily dose of glyburide to glipizide was 1:2.3 initially and 1:1.9 at 7 months. Eight patients stopped glyburide and began using insulin; nine patients had insulin added to the glyburide regimen. Daily dose was significantly lower with glyburide than with glipizide in patients analyzed in all six subsets of glipizide dose. The average wholesale price for a 5-mg dose was $0.289 for glipizide and $0.446 for glyburide. The daily costs per patient were $1.08 (glipizide) and $0.88 (glyburide), respectively, and the average annual costs of treatment for all patients were $83,242.43 and $68,010.41, respectively, based on the average wholesale price. Costs based on Veterans Administration discounts were $0.144 versus $0.156 per 5-mg dose, $0.54 versus $0.31 per day per patient, and $41,477.20 versus $23,788.39 per year for all patients, respectively. Conversion from glipizide to glyburide was well tolerated and resulted in substantial cost savings. Potential savings were understated by limiting the study group to the subset of patients who were stabilized on glipizide and had sufficient follow-up data after conversion. 3 figures, 2 tables, 7 references.

169

TITLE: Drug Consumption in Elderly Diabetics. Gram, J.; Damsgaard, E.M. *Diabetes Research and Clinical Practice*. 7(4): 293-298. November 6, 1989.

OBJECTIVE: To compare drug consumption for patients with diabetes versus a control group.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.

Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: More than 80 percent of patients with diabetes used drugs daily, versus 55 percent of controls. Patients with diabetes used more doses of cardiovascular drugs than controls.

RECOMMENDATION: Resources need to be allocated for preventing type 2 diabetes instead of treating its complications.

ABSTRACT: Drug use was studied in 228 patients with diabetes who resided in Fredericia, Denmark; 52 were treated with insulin, 101 with oral hypoglycemic agents, 66 with diet only, and 9 were not treated. An age- and sex-matched control group was selected (n = 223); both groups ranged in age from 60 to 74 years. Information on drug use was obtained through a questionnaire, an interview, and inspection of the drugs. Daily use of prescribed and nonprescribed drugs (antidiabetics excluded) was significantly more common in patients with diabetes (82 percent) than in controls (55.6 percent). The median number of different drugs used by patients with diabetes who took drugs daily was 3.1; the corresponding number for the control group was 2.4. When patients were analyzed by antidiabetic treatment (diet only, insulin, no treatment, oral hypoglycemic agents), no significant differences were found in the percentage who used drugs daily. However, as measured by defined daily dose (DDD), drug use among those taking oral agents was about 20 percent below that of the insulin-treated group and 30 percent under the diet-only group. (Defined daily dose considers the average dose per day when the drug is used for its main indication.) Among daily users, patients with diabetes used 70 percent more DDDs of drug than controls (antidiabetics excluded). The most used drugs (other than antidiabetics) for both patients with diabetes and controls were from the cardiovascular, central nervous system, and musculoskeletal groups. Patients with diabetes in all treatment groups used significantly more DDDs of cardiovascular drugs than controls. Patients treated with oral antidiabetics used significantly fewer DDDs of cardiovascular drugs than the insulin and diet-only groups. The authors previously found in the same study population that patients with diabetes use primary health care services 2 to 3 times as often as controls, have a hospital bed-day occupancy rate 2 to 3 times greater than the general population of the same age, and have an estimated cost of drug therapy more than 2.5 times higher than do controls. 3 tables, 14 references.

170

TITLE: The Economics of Pharmacotherapy for Diabetes Mellitus. Costa, B.; Arroyo, J.; Sabate, A. *PharmacoEconomics*. 11(Supplement 2): 139-158. February 1997.

OBJECTIVE: To review the economics of drug therapy, including insulin treatment, for type 1 and type 2 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.

Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: It is essential to consider individual and social costs of diabetes and to search for reliable indicators of the effectiveness of care for the disease. Educational programs for patients and professionals are the most logical way of rationalizing the use of drugs.

RECOMMENDATION: Prescribers of drug therapy should follow experts' recommendations, even if they do not seem efficient in the short term, as the implications of diabetes must be viewed in the long term.

ABSTRACT: Seventy to 75 percent of patients with type 2 diabetes take oral hypoglycemic agents or antihyperglycemics, 20 to 25 percent take insulin (in some countries these ranges are much different). Among the oral hypoglycemics, sulfonylureas are the most widely used agents; the effectiveness of these drugs decreases progressively, usually 5 to 10 years after initiation. Antihyperglycemic agents cannot cause hypoglycemia. Insulin is essential in type 1 diabetes and may be used in type 2. While expensive, its cost-benefit relationship in type 1 is excellent. Most developed countries have two mechanized systems for delivering insulin: injector pens and preloaded syringes. Self-monitoring devices and glucagon (for hypoglycemic emergencies) are also part of diabetes management. Optimal treatment of type 2 diabetes probably requires diet, exercise, and education initially, with drugs secondary. In obese patients with type 2, an initial trial with antihyperglycemic drugs has been recommended. The authors review prescription trends and drug consumption; in Spain, drug consumption grew 72.6 percent from 1988 to 1994. A study (Rubin, et al. 1994) in the United States concluded that in 1992 drugs and self-monitoring devices accounted for 9 percent of all diabetes mellitus costs. Insulin is not easily available in poorer countries, but it is generally free there. In underdeveloped countries, diabetes-related mortality rates are similar to Western rates 75 years earlier. The authors point out that at present there is no effective drug treatment for specific long-term complications of diabetes, such as retinopathy, neuropathy, and vascular diseases. The authors also state that health education reduces costs of drug therapy. 3 tables, 4 figures, 124 references.

171

TITLE: Hypoglycemic Drugs in the Treatment of Non Insulin Dependent Diabetes Mellitus (NIDDM) in Klong Toey Slum (abstract). Sitthi-amorn, C.; Chiamwongpaet, S. *Abstracts of the International Society for Technology Assessment in Health Care*. 1992:30.

OBJECTIVE: To compare locally produced oral hypoglycemic agents with more expensive imported agents in terms of their efficacy in treating patients with type 2 diabetes living in a slum area in Thailand.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Cost analysis.

Perspective: Health care system.

CONCLUSION: The imported oral hypoglycemic drugs were more effective in lowering blood glucose concentrations than locally produced agents, but at almost double the cost.

RECOMMENDATION: Locally produced oral hypoglycemic agents have a role in the treatment of type 2 diabetes patients living in this area.

ABSTRACT: The researchers randomly selected 67 patients with type 2 diabetes living in a slum area in Thailand who were being treated with imported oral hypoglycemic drugs. The patients were randomized into two groups: one group (n = 34) took locally produced agents for 6 months, then imported agents with the same generic name and dosage for another 6 months. The second group (n = 33) reversed the process. Fasting blood glucose tests and assessments of glycosolated hemoglobin were performed on all patients every 1 to 3 months throughout the 12-month study. Direct medical costs were assessed by the costs of the medication, and direct nonmedical and indirect costs were obtained through interviews. Patients had greater reductions in fasting blood glucose and in glycosolated hemoglobin while on imported drugs. However, the cost to achieve a 1 percent reduction in glycosolated hemoglobin was almost twice as great using imported agents (41.2 Baht for imported drugs versus 22.4 Baht for domestically produced drugs.

172

TITLE: Labour Productivity Effects of Prescribed Medicines for Chronically Ill Workers. Rizzo, J.A.; Abbott, T.A.; Pashko, S. *Health Economics*. 5(3): 249265. May-June 1996.

OBJECTIVE: To estimate the costs and benefits to employers of covering prescription drugs for workers with hypertension, heart disease, type 2 diabetes, or depression.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost-benefit analysis.
Perspective: Societal.

CONCLUSION: The net benefits to employers from covering prescription medicines for these chronic illnesses are substantial.

RECOMMENDATION: None.

ABSTRACT: The authors used data from the 1987 National Medical Expenditure Survey to estimate the costs and benefits of providing prescription coverage for individuals aged 18 to 64 years afflicted with hypertension, heart disease, depression, or type 2 diabetes. Benefits were measured by the extent to which prescription medications decreased productivity losses resulting from employee disability days. Assuming average compliance rates, estimated

average annual days saved from drug treatment were 3.5 for hypertension, 7.3 for heart disease, 9.1 for depression, and 16.1 for diabetes. Employer costs of providing drug benefits were estimated as the difference between total costs of the drugs and patients' out-of-pocket costs. The value of days saved was computed by multiplying days saved by a wage rate of $9.32 per hour (8-hour day assumed) times 1.25 to reflect fringe benefits. With average compliance rates, estimated net benefits per employee (in 1987 dollars) by disease were $286 for hypertension, $633 for heart disease, $822 for depression, and $1,475 for diabetes. When capital costs were included, average net benefits to employers were even greater, ranging from $503 for hypertension to $2,485 for diabetes. Additional benefits could accrue if employees complied fully with their medications. 6 tables, 20 references.

173

TITLE: Medication Cost Savings Associated with Weight Loss for Obese Non-Insulin-Dependent Diabetic Men and Women. Collins, R.W.; Anderson, J.W. *Preventive Medicine*. 24(4): 369-374. July 1995.

OBJECTIVE: To determine the savings in prescription costs associated with a weight loss reduction program in obese patients with type 2 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Significant short- and long-term savings in prescription costs were obtained following a 12-week hypocaloric weight reduction program for obese individuals with type 2 diabetes.

RECOMMENDATION: In deciding upon the most appropriate treatment strategy for patients with type 2 diabetes, careful consideration should be given to the treatment's potential long-term medical and economic benefits.

ABSTRACT: The authors determined the prescription cost savings associated with a weight reduction program in obese patients with type 2 diabetes. Adult patients with a history of type 2 diabetes of more than 1 year and a body mass index of 30-40 kg/m2 were randomized to one of two 800-kcal, 12-week weight loss interventions: five dietary supplements/day with no food (n = 20) or two supplements per day and an evening meal (n = 20). Medication usage was documented upon initiation of the program, after 12 weeks, and 1 year after completion of the diet. Participants' drug profiles were costed through data from local pharmacies; insurance coverage was not taken into account. A refundable fee of $100 (far below usual cost) was paid for the weight loss program. Participants paid $25 weekly (nonrefundable) for dietary supplements. Cost analysis was performed in the 32 patients who took antidiabetes and/or antihypertensive medications. Patients lost an average of 14.8 percent of their pre-diet body weight over the 12-week study period; an average of 58.8 percent of the weight loss was

maintained at the 1-year follow-up. At the beginning of the diet, all antidiabetes medications were reduced by 50 percent, and all diuretics (for hypertension) were discontinued totally. Other antihypertensive medications were decreased in various ways. Prior to the dietary interventions, total monthly prescription costs for all medications and supplies averaged $82.00 per patient, or $984 annually. Average monthly saving in prescription costs per patient was $36.90 at midyear of the follow-up, corresponding to an estimated average cost savings over the year of $442.80 per patient. Average monthly pre-diet cost for antidiabetes and antihypertensive medications was $63.30 at follow-up ($p < 0.001$). After 1 year, average monthly costs for insulin and oral hypoglycemic agents decreased to 59 percent and 88 percent of their pre-diet values, respectively. 1 figure, 1 table, 12 references.

174

TITLE: Oral Hypoglycemic Agents in the Treatment of Type II Diabetes. Tal, A. *American Family Physician*. 48(6): 1089-1095. November 1993.

OBJECTIVE: To review the pharmacologic properties, mechanism of action, therapeutic effects, side effects, drug interactions, and costs associated with first- and second-generation hypoglycemic agents.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: First-generation sulfonylureas are less expensive but less active than second-generation sulfonylureas.

RECOMMENDATION: None.

ABSTRACT: The author reviewed and compared the properties of first- and second-generation oral sulfonylureas used to treat patients with type 2 diabetes. Sulfonylureas provide adequate glycemic control in approximately two-thirds of patients, but about 50 percent of initially responsive patients have inadequate control after 10 years. The average wholesale price per month (1992) for equivalent therapeutic doses of the first-generation drugs tolbutamide, acetohexamide, tolazamide, and chlorpropamide was $14.40, $12.40, $15.00, and $19.20, respectively; their average generic cost per month was $2.70, $11.90, $6.45, and $1.85, respectively. The corresponding average wholesale prices per month for the second-generation drugs glipizide and glyburide were $16.70 and $14.70, respectively. Overall, side effects occur in 3 to 4 percent of patients taking these drugs. Hypoglycemia is the major complication; elderly patients may be at particularly high risk for severe hypoglycemia. Twenty to 30 percent of severe hypoglycemic episodes are related to drug interactions. New types of drugs are undergoing clinical trials. 3 tables, 27 references.

175

TITLE: Use of Health Maintenance Organization Data Bases to Study Pharmacy Resource Usage in Diabetes Mellitus. Glauber, H.S.; Brown, J.B. *Diabetes Care*. 15(7): 870-876. July 1992.

OBJECTIVE: To analyze pharmaceutical drug use by patients with diabetes enrolled in a health maintenance organization (HMO) and estimate its cost.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Patients with diabetes received significantly more medication at a greater total cost than patients without diabetes. Computerized pharmacy databases are useful for studying the epidemiology, patterns of care, and costs of chronic disease.

RECOMMENDATION: None.

ABSTRACT: The authors analyzed data in the Kaiser Permanente Northwest pharmacy database on medication usage by 871 patients with diabetes who were members of the Kaiser plan for the entire year. Patients with diabetes were identified from hospital discharge records, registration in diabetes education programs, referral to specialists in diabetes or diabetes eye care, and prescriptions for products used exclusively by patients with diabetes. Specificity of patient identification was greater than 99 percent; sensitivity was 85 to 90 percent; prevalence of diabetes was 25.4 per 1,000 members. 1,002 patients were randomly selected from the identified group; a total of 131 with no drug insurance were excluded. A control group without diabetes was matched for age, sex, and pharmacy insurance status. Mean number of outpatient visits for patients with and without diabetes was 11.3 and 6.5 and the hospitalization rate was 366 and 105 admissions per year, respectively. Costs were based on 1988 standard values, retail nonmember price, dispensing cost, and overhead. Statistically, a higher percentage of patients with diabetes received cardiovascular, antibiotic, nonsteroidal anti-inflammatory, dermatologic, gastrointestinal, narcotic, vitamin, respiratory, psychoactive, and hypolipidemic medications. Patients with diabetes also received more than twice the number of prescriptions (31.5 vs. 14.4/yr, $p < 0.001$). Annual pharmacy expenses per patient per year were statistically greater for patients with diabetes: $627.93 versus $259.28, $p < .001$. Pharmacy costs accounted for approximately 17 percent of the annual direct cost of care for patients with diabetes. 6 tables, 18 references.

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176

TITLE: The Charges for ESRD Treatment of Diabetics. Smith, D.G.; Harlan, L.C.; Hawthorne, V.M. *Journal of Clinical Epidemiology*. 42(2): 111-118. 1989.

OBJECTIVE: To compare hospital charges for treatment of end-stage renal disease (ESRD) in patients with diabetes and those without diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Treatment charges for ESRD were higher for patients with diabetes than for other patients. The majority of the difference was attributable to higher inpatient hospital charges.

RECOMMENDATION: None.

ABSTRACT: The authors report on charges for treatment of ESRD. Data were from patients with diabetes (n = 243) and without diabetes (n = 903) treated in Michigan in 1982 to 1984, with onset of ESRD from 1981 to 1983. Charges were derived solely from Medicare reimbursement amounts and patient copayments and deductibles. Because Medicare allowable charges do not reflect increased intensity of treatment due to diabetes, use of such charges may lead to an underestimate of the additional costs of treating ESRD in patients with diabetes. The authors adjusted for ESRD treatment modality and differences in patient characteristics. Charges for 12 months (1983) were estimated assuming that average age, sex, race, time since onset of ESRD, and proportion dying were the same for patients with and without diabetes. Overall, patients with diabetes had estimated annual charges of $29,671, significantly higher (by $4,695, $p < 0.01$) than estimated charges for patients without diabetes. Most (84.3 percent) of the total difference in estimated charges was explained by differences in inpatient hospital charges, the remainder by differences in charges for physician services and medical supplies (14.5 percent) and outpatient services (1.2 percent). Estimated charges were similar for the various dialysis modalities for patients with diabetes. However, in the year that a cadaver transplant took place, estimated charges for patients with diabetes were significantly higher than for those without diabetes ($61,493 versus $42,074). 4 tables, 19 references.

177

TITLE: Diabetes and Long-Term Care. Mayfield, J.; Deb, P.; Potter, D. In: *Diabetes in America*. 2nd edition. National Diabetes Data Group, ed. National Institute of Diabetes and Digestive and Kidney Diseases. NIH Publication No. 95-1468. 1995: 571-590.

OBJECTIVE: To present information about nursing home residents with diabetes and compare these persons with residents not known to have diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: In 1987, 18.3 percent of nursing home residents aged 55 years or more were known to have diabetes. Expenditures for residents with known diabetes were about the same as for those not known to have diabetes.

RECOMMENDATION: None.

ABSTRACT: The authors relied heavily on the Institutional Component of the 1987 National Medical Expenditure Survey to develop this report. In 1987, 388,656 persons with diabetes aged 55 years and over resided in nursing facilities; these individuals constituted 98 percent of all nursing facility residents with diabetes. Approximately 18.3 percent of all nursing home residents were known to have diabetes, but the true prevalence may have been much higher. Nursing home residents with diabetes were more likely to be nonwhite and to have a low income than were residents without (i.e., not known to have) diabetes. Total expenditures for 1987 were similar for residents with diabetes and those without ($13,045 versus $13,203). Mean expenditure per day was $57 for both groups. Medicaid's contribution for expenditures of residents with diabetes was $1,226 higher than it was for those without diabetes, which was probably related to the higher rate of Medicaid eligibility in the diabetes population. It is expected that demographic shifts in the United States will result in a dramatic increase in both the proportion and number of persons who will need long-term care over the next several decades. Diabetes care will assume an increasingly important role in nursing facilities. 6 figures, 11 tables, 4 appendices, 68 references.

178

TITLE: Diabetic Ketoacidosis Charges Relative to Medical Charges of Adult Patients with Type 1 Diabetes. Javor, K.A.; Kotsanos, J.G.; McDonald, R.C.; Baron, A.D.; Kesterson, J.G.; Tierney, W.M. *Diabetes Care*. 20(3):349-354. March 1997.

OBJECTIVE: To provide information on direct medical care charges for episodes of diabetic ketoacidosis relative to all direct care charges for adults with type 1 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Diabetic ketoacidosis accounted for more than one-fourth of direct health

care charges for the study patients.

RECOMMENDATION: By designing interventions to reduce recurrent diabetic ketoacidosis episodes in patients with type 1 diabetes, health care organizations could save substantial costs.

ABSTRACT: This study focused on 200 adult patients with type 1 diabetes who had received inpatient or outpatient care at least twice from January 1993 through June 1994 at a facility served by the Regenstrief Medical Record System, which includes Wishard Memorial Hospital in Indianapolis. Of this group, 72 (36.0 percent) experienced at least 1 episode (total: 161) of diabetic ketoacidosis during a 2.5-year observation period that ended in June 1995. All 161 episodes resulted in hospitalization; for 150 (93.2 percent) of these hospitalizations diabetic ketoacidosis was listed as both the primary admission diagnosis and the primary discharge diagnosis. Mean age of the 200 study patients was 43.3 ± 15.3 years; the two study subpopulations (ketoacidosis, no ketoacidosis) did not differ significantly by age, sex, or race. Charges were adjusted to 1995 dollars. Mean charge per ketoacidosis episode was $6,444; mean charge for these episodes was $6,055. The overall charges of $1,037,549 for episodes of diabetic ketoacidosis accounted for 28.1 percent of all direct medical charges for the 200 patients in the study. Mean annual charges per patient by number of ketoacidosis episodes were as follows: none, $4,907; one or more, $13,096; two or more, $21,430; three or more, $29,074; and four or more, $32,872. The authors note that the hospitalization rate for diabetic ketoacidosis and the fraction of costs attributable to that disorder may be higher in their study cohort (predominantly indigent, inner city) than in another population. 4 tables, 26 references.

179

TITLE: Diabetic Ketoacidosis Costs Relative to Medical Costs of Patients with Type 1 Diabetes [abstract]. Javor, K.; Kotsanos, J.; McDonald, R.; Baron, A.; Kesterson, J.; Tierney, W. *AHSR FHSR Annual Meeting Abstract Book*. 1996;13:94.

OBJECTIVE: To determine, among patients with type 1 diabetes, the medical costs of treating episodes of diabetic ketoacidosis relative to the total medical costs of these patients; to assess the medical costs of patients experiencing multiple ketotic episodes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Episodes of diabetic ketoacidosis accounted for one-fourth of medical care expenditures for patients in the study group.

RECOMMENDATION: Interventions that could reduce even modestly the episodes of diabetic ketoacidosis could yield significant cost savings in the health care system.

ABSTRACT: Two hundred twenty-eight patients with type 1 diabetes who had received inpatient or outpatient care at least twice between January 1, 1993, and June 30, 1994, were included in the study. Resources and charges were recorded for hospitalizations, emergency room visits, and outpatient and pharmacy visits. An additional year of information was collected on patients with multiple episodes of diabetic ketoacidosis. Seventy-two (31.6 percent) of the 228 patients experienced 1 or more episodes (total equals 163). Charges for these episodes equaled 25 percent of the medical charges for the study group as a whole. Annual charges per patient were estimated at $7,965 ($13,152 for those experiencing an episode of ketoacidosis, $5,750 for those not experiencing an episode). Twenty-four (10.5 percent) of the study patients experienced multiple (two or more) episodes, which accounted for 56 percent of total medical charges for these patients.

180

TITLE: Digging Out Savings in Diabetes Care: Costing Out Care. Finder, S.F.; Smith, M.D.; McGhan, W.F. *Business and Health*. 14(9):69-70, 72. September 1996.

OBJECTIVE: To provide an overview of diabetes and its complications, to report cost data on the disease, including the cost of various care elements, and to suggest opportunities for controlling costs.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The true opportunity for controlling the costs of diabetes lies in early identification and treatment of this disease.

RECOMMENDATION: Various recommendations are made for controlling costs.

ABSTRACT: The authors present an overview of diabetes, including its prevalence, etiology, and pathology; acute and chronic complications; and a detailed account of costs. Hospitalization of people with diabetes accounts for more than 80 percent of diabetes-related costs. Annual inpatient costs per patient with diabetes average $7,150, compared with $1,220 for a person without diabetes. The corresponding averages for annual outpatient costs are $1,225 and $330. The authors detail expenses for diabetes medications, blood glucose monitoring, laboratory tests, and screening and diagnostic tests for diabetes and related complications. Several opportunities exist for cost savings: (1) workplace screening of employees with one or more risk factors so as to identify and treat the disease early, (2) disease management programs that identify and focus on patients most likely to experience complications, (3) programs that foster improved adherence to diabetes management regimens, (4) programs that demand accountability from health care providers to reduce acute complications associated with poor control, and (5) determining the most cost-effective

options for treatment and glucose monitoring.

181

TITLE: Economic Impact of Diabetes Mellitus in the Elderly. Weinberger, M.; Cowper, P.A.; Kirkman, M.S.; Vinicor, F. *Clinics in Geriatric Medicine*. 6(4): 959-970. November 1990.

OBJECTIVE: To estimate the economic impact of diabetes mellitus among the elderly.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Health care services provided to Americans aged 65 years and older cost an estimated $5.16 billion annually (based on 1987 data), with nearly 80 percent due to hospitalization. The average yearly expenditure per patient with diabetes was estimated to be $4,265, of which $900 was for out-of-pocket expenses.

RECOMMENDATION: Increased vigilance to prevent or delay the incidence of morbidity leading to hospital admissions must be given priority in caring for patients with diabetes. Intensifying outpatient care may offer the opportunity to accomplish this goal.

ABSTRACT: Investigators combined 1987 data on consumer (or third party) prices for hospital stays, nursing home stays, physician visits, laboratory tests, prescriptions, supplies, and self-monitoring tests with estimates of resource use (inpatient, outpatient, and nursing home) attributable to diabetes mellitus to estimate the economic impact of this disease in the elderly. The data were restricted to persons aged 65 and older and to cases of type 2 diabetes. Only direct costs were used and estimates were conservative because many of the data sources excluded people over 74. The authors attributed 400,000 admissions and 3.9 million hospital days to diabetes mellitus or its complications (renal, ophthalmic, neurologic, cardiovascular, and other). Increased length of hospital stay for patients with diabetes who were admitted for other reasons added another 1.5 million patient days. Hospitalization plus inpatient physician visits produced total inpatient expenditures of $4.1 billion (79.7 percent of the expenditures). Nursing home costs totaled $306 million (5.9 percent). Another $742 million (14.4 percent) resulted from outpatient care (office and non-office-based physician visits, laboratory tests, prescriptions, etc.). Total 1987 direct annual expenditures were estimated to be $5.16 billion. Expenses per person (excluding nursing home care) averaged $4,265, about 50 percent higher than age-matched counterparts without diabetes; approximately $900 represented out-of-pocket expenses. Study results suggest that preventing or delaying morbidity leading to hospital admission must take priority in caring for patients with diabetes mellitus. Intensifying outpatient care may offer the opportunity to accomplish this end. 4 tables, 22 references.

182

TITLE: Effect of Third Party Reimbursement on the Utilization of Services and Indices of Diabetes Management among Inner City Diabetic Patients. Nordberg, B.; Barlow, M.; Chalew, S.A. Poster Presentations at the American Diabetes Association, 52d Annual Meeting and Scientific Sessions. San Antonio, Texas. June 20-23, 1992.

OBJECTIVE: To assess the impact of third party reimbursement on the use of health care services by low-income inner-city patients with diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Patients with full or partial reimbursement used health care services more often than patients with no reimbursement benefits.

RECOMMENDATION: None.

ABSTRACT: Low-income adult patients with diabetes (111 women and 56 men) from an inner-city clinic were categorized by their level of medical coverage: full (64), partial (73), or none (30). The patients were followed for 13 months, and data were collected on the number of clinic visits, emergency room visits, hospital admissions, and use of a free daytime hot line, as well as on changes in glycated hemoglobin (HbA_{1C}), blood pressure, and weight, from the beginning to the end of the study. Patients included 141 with type 2 diabetes and 26 with type 1 diabetes. The number of clinic visits, percentage of kept appointments, average number of admissions, and average number of emergency room visits were higher for the full-reimbursement group than for the no-reimbursement group, and older patients in all groups tended to use services more frequently. Use of the free telephone hot line did not differ by reimbursement group. Weight and blood pressure remained the same during the study for all groups, but researchers noted a trend for worsening of HbA_{1C} in the group without third party reimbursement.

183

TITLE: Health Care Expenditures for People with Diabetes Mellitus, 1992. Rubin, R.J.; Altman, W.M.; Mendelson, D.N. *Journal of Clinical Endocrinology and Metabolism*. 78(4): 809A-809F. April 1994.

OBJECTIVE: To estimate the prevalence of diabetes and the health care costs for people with diabetes in the United States, to compare these costs to costs for people without

diabetes, and to estimate the fraction of health care expenditures incurred by people with diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: Health care expenses in 1992 for people with diabetes ranged from 11.9 percent to 14.6 percent of all health care costs, depending on the prevalence estimate used.

RECOMMENDATION: Health care reformers and insurers should promote benefits that will reduce the costs of caring for patients with diabetes.

ABSTRACT: The authors compared health care expenditures for people with diabetes, for those with diabetes confirmed by medical history, and people without diabetes. Health care costs incurred by people with diabetes that may not be related to the disease were included. Data were based on the 1987 National Medical Expenditure Survey and extrapolated to 1992 based on United States Census demographic data and government-derived inflation factors. The estimated prevalence of confirmed diabetes among all ages was 31.1 per 1,000 people, or 7.7 million people. Total U.S. health care expenditures were approximately $720.5 billion, of which approximately $105.2 billion (14.6 percent) was for persons with diabetes, with $85.7 billion (11.9 percent) for persons with confirmed diabetes. Per capita expenditures were significantly higher ($p < .01$) for patients with confirmed diabetes than for those who did not have diabetes for inpatient care ($7,153 versus $1,222), office visits ($1,045 versus $554), outpatient care ($1,225 versus $330), drugs and durable medical equipment ($1,056 versus $201), home health ($438 versus $67), and emergency room care ($131 versus $84). Per capita annual health care expenditures for persons with diabetes were significantly higher ($p < .01$) than for persons without diabetes for all age groups combined and for all age groups aged 35 years and over. Annual expenditures by payer for persons with diabetes and those without diabetes were, respectively, 27 and 13 percent for Medicare, 15 and 10 percent for Medicaid, 9 and 7 percent for other public programs, 20 and 29 percent for employment-based insurance, 19 and 26 percent for other private insurance, and 12 and 15 percent for self-pay. These data confirm the high cost of health care for patients with diabetes. Policies of prevention and more effective management of diabetes are needed to help control these costs. 3 tables, 2 figures, 34 references.

184

TITLE: Medical Expenditures and Insurance Coverage for People with Diabetes: Estimates from the National Medical Care Expenditure Survey. Taylor, A.K. *Diabetes Care*. 10(1): 87-94. January-February 1987.

OBJECTIVE: To provide information on public and private health insurance coverage of patients with diabetes and on health care services and costs for these patients.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Prevalence-based costs.
Perspective: Health care system.

CONCLUSION: Private insurance coverage for persons with diabetes was similar to that for the remainder of the population. However, persons with diabetes used medical care services more frequently and, as a result, had higher average medical expenses.

RECOMMENDATION: None.

ABSTRACT: The author reports data from the 1977 National Medical Care Expenditure Survey on the health insurance coverage, health services usage, and health care expenditures related to diabetes. Approximately 4.5 million Americans had diabetes in 1977. Among persons with diabetes under 65 years old (2.525 million people), approximately 12 percent had no health insurance and 70 percent had private insurance. Uninsured persons tended to be black or Hispanic, and to be poorer and younger, in better health, living in the South and West, and residing outside large cities. Persons covered only by Medicaid tended to be female, black or Hispanic, and in poor health. Almost all persons aged 65 and over were covered by Medicare; 67 percent carried supplemental private insurance; 15 percent also had Medicaid. Persons with diabetes visited doctors more often, were hospitalized more often, had longer hospitalizations, accessed nonphysician services more, and purchased medical equipment and supplies more than other people. Per capita expenses (for those with any expense) for persons with and without diabetes were $1,514 and $548, respectively; over two-thirds of expenses for the former were related to hospital care. Reimbursement was approximately 22 percent out of pocket, 24 percent through private insurance, 32 percent through Medicare, 12 percent through Medicaid, and 10 percent through other sources. Private insurance coverage was comparable in persons with and without diabetes; more persons with diabetes lacked coverage of physician office visits and major medical expenses. Trends in public and private third party coverage of medical costs will have a large impact on persons with diabetes. 7 tables, 10 references.

185

TITLE: Must Diabetes Be a Fatal Disease in Africa? Study of Costs of Treatment. Chale, S.; Swai, A.; Mujinja, P.; McLarty, D. *British Medical Journal*. 304(6836): 1215-1218. May 9, 1992.

OBJECTIVE: To estimate the cost of diagnosing and treating patients with diabetes in the African country of Tanzania.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Of total 1-year outpatient costs, about 32 percent was for insulin, 31 percent to treat complications, and 24 percent to purchase oral hypoglycemic drugs. Estimated costs (U.S. dollars) for inpatients and outpatients combined were about $4 million.

RECOMMENDATION: Because per capita annual income in Tanzania ranges from $160 to $200 and an insulin dependent patient requires $156 per year to purchase insulin, patients must continue to be exempted from paying for these items.

ABSTRACT: Tanzania, a very poor country with health expenditures in 1989 (U.S. dollars) of $2 per person, has one of the lowest rates of diabetes in the world. To estimate costs at the national level, the authors studied two groups of patients seen at Tanzania's largest hospital. Group 1 consisted of 262 consecutive new patients seen at the hospital's diabetic clinic and in the inpatient wards from September 1989 to August 1990. Group 2 included 202 patients first seen in June 1981 to May 1982. Patients in both groups were monitored until October 1990. Costs of insulin, syringes, and other items not purchased by the patient were calculated from 1989 to 1990 prices charged by central medical stores of the government and by estimates from the hospital's budget. Market prices were used for supplies patients had to buy; prices charged by private hospitals were used for treatment and investigations at those institutions. For physician time, the authors assumed 7 minutes per outpatient visit and 10 minutes each day for inpatients; for nurse time, 10 minutes for an outpatient visit and 90 minutes daily for inpatients. Average salary for a physician was assumed to be 30 cents (U.S.) for a working hour; for a nurse, 4 cents. A prevalence of 0.2 percent was assumed for patients aged 15 years or over with diabetes requiring insulin or oral hypoglycemic drugs. For patient groups 1 and 2 combined, annual outpatient costs were $229 for those requiring insulin and $69 for those not requiring insulin. Thirty-two percent of total outpatient costs were for purchasing insulin, 31 percent for treatment of complications, and 24 percent for purchase of oral hypoglycemic drugs. Direct diabetes costs of nearly $4 million represented almost 8 percent of the Tanzania government's health budget. 1 table, 16 references.

186

TITLE: Prospective Reimbursement and Diabetes Mellitus: Impact upon Glycemic Control and Utilization of Health Services. Weinberger, M.; Ault, K.A.; Vinicor, F. *Medical Care*. 26 (1): 77-83. January 1988.

OBJECTIVE: To compare costs of patient care prior to and after implementation of reimbursement based on diagnosis-related groups (DRGs) in patients with type 2 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.

Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Short-term cost-cutting goals have probably been met with reimbursement based on DRGs, but the long-term consequences (e.g., poorer glycemic control) may offset potential cost savings.

RECOMMENDATION: Larger studies that include other diagnostic groups are needed to assess inpatient and outpatient care at other sites.

ABSTRACT: The authors investigated the effect of changing Medicare reimbursement to a method based on DRGs by comparing outcomes for patients with type 2 diabetes who were hospitalized for regulation of glycemia before (n = 53) and after (n = 31) implementation of DRGs. Patients and their health care use were identified from medical records at Wishard Memorial Hospital, a county hospital in Indianapolis, for all admissions in 1981 (pre-DRG) and for 1 year beginning in July 1983 (post-DRG). Primary care was delivered to the patients in a general medicine clinic staffed by Indiana University School of Medicine. Age, sex, and plasma glucose levels at admission for initial glycemic control were similar in the two groups; significantly more pre-DRG patients were black. Post-DRG patients had significantly fewer of several tests: plasma and urine glucose, serum calcium, serum phosphate, SMA-12, routine urinalysis, urine culture, and serum uric acid. Post-DRG patients were relatively less likely to have an education session with a registered nurse (0 versus 21 percent) and a dietitian (71 versus 96 percent); they had significantly fewer rehabilitation medicine consultations (0 versus 25 percent) as well. Hospital stay was significantly shorter in the post-DRG group (5.6 ± 4.7 days versus 8.3 ± 2.7 days; $p < 0.001$). Plasma glucose concentrations at discharge were similar in the two groups. Among patients for whom information was available for the year following initial hospitalization, both blacks and whites in the post-DRG group had significantly more visits to the general medicine clinic than their pre-DRG counterparts. Random plasma glucose concentrations were significantly higher in post-DRG patients. 3 tables, 17 references.

187

TITLE: A RCT of Community Clinic Versus Hospital Outpatient Care in the Treatment of Non Insulin Dependent Diabetes Mellitus (NIDDM): Abstract. Sitthi-amorn, C.; Chaimwongpaet, S. *Abstracts of International Society of Technology Assessment in Health Care*. 1992:7-8.

OBJECTIVE: To determine whether structured community clinic care was as good as routine hospital outpatient treatment in controlling uncomplicated type 2 diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Prospective.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Adherence rates were higher in the clinic, which was also more cost effective.

RECOMMENDATION: The distinguishing features of care in the community clinic should be used to redirect diabetes care in the community.

ABSTRACT: In this study of 132 patients with type 2 diabetes residing in Klong Toey Slum in Thailand, half were randomized to structured community clinic care and half to hospital outpatient care. Patients were stratified by age, sex, and body mass index. Glycosylated hemoglobin, the main outcome measure, was measured at the end of the third, sixth, ninth, and twelfth months. Clinic adherence, treatment compliance, satisfaction, fasting plasma glucose, hospital admission, mortality, and cost of care were also assessed. Patients in the two groups had comparable reductions of fasting plasma glucose and glycosylated hemoglobin; these decreases were significant. The adherence rate for the hospital clinic at 3, 6, 9, and 12 months was 64 percent, 54 percent, 50 percent, and 22 percent, respectively. After 12 months the community clinic adherence rate was 90 percent. Treatment at the community clinic was more cost effective.

188

TITLE: A Simple Economic Evaluation Model for Selecting Diabetes Health Care Strategies. Gagliardino, J.J.; Olivera, E.M.; Barragán, H.; Puppo, R.A. *Diabetic Medicine*. 10(4): 351-354. May 1993.

OBJECTIVE: To compare the cost of providing complete care to patients with diabetes who have no com-plications with costs of treating selected complications.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Providing complete care for patients with uncomplicated diabetes is a better allocation of resources than covering the treatment of complications.

RECOMMENDATION: None.

ABSTRACT: To perform their estimates, the authors surveyed the files of 60 diabetologists from various provinces of Argentina; physicians from both the public and private health sectors were surveyed. Based on survey records, the authors created a standardized patient's record reflecting common physician practice; economic costs were obtained from values published by Argentina's National Insurance Institute. The authors also used hospital inpatient files to create standardized records for treating ketoacidosis and acute myocardial infarction as

well as the amputation of two toes. The authors estimate the annual outpatient cost for treating patients free of chronic complications to be $1,221.47 (U.S. dollars) for those with type 1 diabetes and $330.26 for patients with type 2 diabetes. They estimate the cost to treat one episode of ketoacidosis to be $632.09; of myocardial infarction, $3,415.47; and of amputation of two toes of a lower limb, $1,707.22. Preventing one of these episodes would provide enough funds to cover either the total or partial annual cost of controlling and treating several patients with uncomplicated diabetes. The authors acknowledge the possible weakness of their model's assumption that well-controlled patients would not develop chronic complications. They stress that their preliminary investigation does not seek to offer definitive proof that prevention pays for itself but that it points out that covering health care costs of patients with uncomplicated diabetes would be more efficient than covering the usual treatment of their complications. 3 tables, 20 references.

189

TITLE: Tallying the Cost Of Diabetes. Caruthers, C. *Business and Health*. 14(1A): SR8SR13. January 15, 1996.

OBJECTIVE: To review the problems experienced by the government and employers in assessing the costs of diabetes; to review approaches used by some employers and insurers to reduce costs through preventive programs.

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Assessing the true costs of diabetes is difficult, but more insurers and employers are supporting preventive measures to reduce the costs from diabetes and improve patient quality of life.

RECOMMENDATION: None.

ABSTRACT: The author reviews data on the total cost of diabetes in the United States and the effect of good diabetes management on costs. Costs are difficult to calculate because diabetes involves multiple organ systems, often is not reflected in the primary diagnosis, and results in longer hospitalizations for nondiabetes-related illnesses than those required for patients with the same diagnosis but no diabetes. In a study by Lewis-VHI using data from the 1987 National Medical Expenditure Survey, per capita medical costs were found to be 3.5 times higher for persons with diabetes than for those without diabetes ($9,493 versus $2,604); differences were statistically significant at all ages but were greatest for persons aged 45 to 54 years ($11,000 versus $3,698). This study, which estimated the total cost of diabetes to be $112 billion, used a higher estimate of diabetes prevalence than a 1992 report by the American Diabetes Association, which put the cost of diabetes at $92 billion, and also included all medical charges incurred by persons with diabetes, whether or not they were diabetes-related.

In terms of patient care, the Diabetes Control and Complications Trial proved that comprehensive diabetes management to improve blood glucose control can reduce some complications from diabetes by more than 50 percent. However, most primary care physicians are unable to provide comprehensive diabetes management, and many insurance companies do not provide adequate coverage for such services, including patient education. Although addition of diabetes management programs including diabetes education to health insurance plans may cost employers an estimated $1,100 to $2,500 per year per person with diabetes, comprehensive education programs may reduce hospitalizations by 13 to 74 percent. A study of a diabetes management program found, after 1 year, reductions of 72 percent in hospitalization, 71 percent in emergency unit visits, and 63 percent in lost work days. 4 figures, 2 references.

190

TITLE: Trends in Medicare Reimbursement for End-Stage Renal Disease: 1974-1979. Eggers, P.W. *Health Care Financing Review*. 6(1): 31-38. Fall 1984.

OBJECTIVE: To examine expenditures in the Medicare program for end-stage renal disease (ESRD).

CATEGORY: Cost of diabetes (direct).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Per capita costs to Medicare for reimbursement of ESRD rose at a modest 7 percent per year from 1974 to 1981. Costs for diabetic nephropathy were slightly higher than those for other conditions. Some of this difference can be attributed to the higher mortality rate among diabetic patients.

RECOMMENDATION: None.

ABSTRACT: Reimbursement through Medicare for ESRD rose from $229 million for 16,000 enrollees ($14.3 thousand per capita) in 1974 to $1.471 billion for 64,100 enrollees ($23 thousand per capita) in 1981, a 7 percent increase in per capita reimbursement per year. From 1974 to 1975, total reimbursement increased 58 percent; from 1980 to 1981, just 17.7 percent. Enrollment grew 41.9 percent from 1974 to 1975 but only 10.9 percent from 1980 to 1981. Distribution of reimbursement by type of service was relatively stable over the 7-year period; outpatient ranged from 49.7 to 59.3 percent; inpatient, 25.6 to 29.2 percent; and physician/supplier services, 12.1 to 20.6 percent. Between 1974 and 1979, hospitalization rates and length of stay for inpatient dialysis decreased while per capita reimbursements remained stable. In 1979, reimbursement for dialysis was lowest in persons 65 years of age and older, was slightly higher for women than men, and was nearly the same for whites and blacks; reimbursement for transplant increased with patient age and was slightly higher for blacks. Per-patient dialysis reimbursement in 1979 was $22,770 for patients with diabetic

nephropathy; for other major diagnoses, it ranged from $20,396 to $21,248. Among dialysis patients, reimbursement was 45 percent higher for those who died than for those who survived. The introduction of continuous ambulatory peritoneal dialysis and the drug cyclosporin for immunosuppression in transplant patients could affect program expenditures after the period covered. 10 tables, 9 references.

191

TITLE: Why Do Elderly Diabetics Burden the Health Care System More Than Non-Diabetics? Damsgaard, E.M. *Danish Medical Bulletin*. 36(1): 89-92. February 1989.

OBJECTIVE: To determine why elderly patients with diabetes use the health care system more than elderly patients without diabetes.

CATEGORY: Cost of diabetes (direct).

Type of Study: Patient management.
Methodology: Statistical analysis.
Perspective: Health care system.

CONCLUSION: Elderly patients with diabetes scored higher on subjective symptoms and had a greater frequency of objective findings; they also had more visits to a general practitioner or clinic.

RECOMMENDATION: Some of the cost of treating elderly patients with diabetes may be reduced if these patients are treated more vigorously by diet and oral hypoglycemic agents in general practice, thereby avoiding time-consuming and costly insulin treatment.

ABSTRACT: This Danish study focused on 228 patients with diabetes and 223 sex- and age-matched controls without diabetes; median age for both groups was 68 years. Of the patients with diabetes, 52 were treated with insulin, 101 with oral hypoglycemic agents plus diet, 66 with diet only, and 9 were untreated. The study period was the 12 months preceding the month in which the participant was examined for the screening; data were taken from local and national registers. All participants underwent an examination and responded to a questionnaire covering subjective symptoms during the preceding year, education, and marital status. Visits to a general practitioner or outpatient clinic were made by 93 percent of patients with diabetes and 72.1 percent of controls ($p < 0.0001$). Fifty percent of the control group had two or more visits in a year; 50 percent of the patients with diabetes had seven visits or more. Twenty-six percent of the patients with diabetes and 10 percent of controls had more than 10 visits in a year; 56 percent of patients with diabetes who were treated with insulin had at least 10 visits. The increased number of physician visits by insulin-treated patients may have been due simply to control of insulin treatment; these patients had the same prevalence of subjective symptoms and objective findings (except for retinopathy) as other patients with diabetes. All objective findings were more frequent in patients with diabetes than in controls; hypertension, ischemic heart disease, and nephropathy were the most common objective findings in patients with diabetes. More than half of the visits made by patients treated with insulin were to

hospital clinics; other patients with diabetes made only a few visits to these clinics. 3 figures, 4 tables, 10 references.

Direct and Indirect Costs

192

TITLE: The Burden of Diabetes in North Carolina. Kegler, M.; Lengerich, E.; Norman, M.; Sullivan, L.; Stoodt, G. *North Carolina Medical Journal*. 56(4): 141-144. April 1995.

OBJECTIVE: To assess the true burden of diabetes in North Carolina using prevalence, hospitalization rate, multiple-cause mortality, and economic cost figures.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: The burden of diabetes in North Carolina, as reflected by its listing on death certificates as the underlying cause, is underestimated. The total cost of diabetes in the state in 1990 was estimated to be $1.2 billion, 46 percent attributable to inpatient or outpatient care and 54 percent to indirect costs.

RECOMMENDATION: Regular collection, analysis, and reporting of data about diabetes in North Carolina is needed to enable decision makers to plan for and allocate scarce health resources.

ABSTRACT: The authors applied prevalence, hospitalization rate, multiple-cause mortality, and economic cost data to the calculation of the true burden of diabetes in North Carolina. Prevalence data, based on the Behavioral Risk Factor Surveillance System survey, indicated that 290,000 adult North Carolinians had diabetes (5.8 percent of the total population). Between 1980 and 1989, 41,676 North Carolina decedents had diabetes listed as a contributing cause of death, but it was listed as the underlying cause of death for only 9,771 decedents. Diabetes was mentioned as a diagnosis in 66,067 hospitalizations but as a primary cause for these hospitalizations in only 15 percent of cases. Charges for diabetes-related hospitalizations during 1988 to 1989 totaled $490 million, or $73 per resident. The total cost of diabetes in North Carolina during 1990, however, was estimated at $1.2 billion based on a Centers for Disease Control model. Approximately 46 percent of this total was attributed to inpatient and outpatient care ($574 million). The remaining 54 percent ($664 million) reflected indirect costs, including forgone wages due to short-term morbidity, long-term disability, and death. Because of the large burden of diabetes in North Carolina and the potential to prevent complications from diabetes, regular collection, analysis, and reporting of data about diabetes is needed so that decision makers can accurately plan for and allocate scarce health resources. 4 tables, 15 references.

193

TITLE: The Cost of Diabetes. Gerard, K.; Donaldson, C.; Maynard, A.K. *Diabetic Medicine*. 6(2): 164-170. March 1989.

OBJECTIVE: To estimate the cost of diabetes in England and Wales in 1984, and to outline problems in ascertaining the true costs of diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: The total indirect and direct costs of diabetes in England and Wales ranged from £ 259.5 million to £ 602.5 million, depending on the rate of absenteeism from work.

RECOMMENDATION: The epidemiological base on which the cost of diabetes estimate was based must be improved by using prospective studies with long follow-up periods.

ABSTRACT: The authors estimated both direct and indirect costs of diabetes; direct costs were associated with preventing, detecting, and treating diabetes; indirect costs to lost productivity due to absenteeism, early retirement, and premature mortality. The cost of welfare effects attributable to deterioration in quality of life was not included. Total direct costs were estimated at £ 238.9 million, including £ 74.0 million and £ 86.0 million for inpatient treatment of diabetes as a primary and secondary diagnosis, respectively; £ 22.8 million for outpatient care; and £ 56.1 million for family practitioner services. Lost earnings were estimated at £ 20.6 million. Losses due to absenteeism varied based on the assumed rate of absenteeism relative to the normal population, ranging from £ 0.0 (absenteeism equal to that of the normal population) to £ 343.0 million (absenteeism equivalent to three times that of the normal population). Total costs associated with diabetes ranged from £ 259.5 million to £ 602.5 million. The authors state that existing data are deficient in quality (in particular, no distinction is drawn between patients treated by insulin and those not so treated). More detailed epidemiological data are needed to accurately assess the economic burden of diabetes. To set priorities, economic evaluation (e.g., cost-effectiveness, cost-benefit analysis) rather than cost-of-illness studies, such as this one, is needed. 5 tables, 22 references.

194

TITLE: Cost of Diabetes in France. Triomphe, A.; Flori, Y.A.; Costagliola, D.; Eschwege, E. *Health Policy*. 9(1): 39-48. February 1988.

OBJECTIVE: To determine direct costs for patients with type 1 and type 2 diabetes residing in Paris.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The direct cost for type 1 patients was 19 percent greater than the average direct cost of medical care for France's general population, while the direct cost of the type 2 group was somewhat below the national average.

RECOMMENDATION: None.

ABSTRACT: Of 109 patients studied, 27 had type 1 diabetes and 82 had type 2 diabetes. The type 1 group was 56 percent female and had an average age of 48 years; the type 2 group was 62 percent male and had an average age of 59 years. Mean duration of disease was 10 years for both groups. Costs (for hospitalization, laboratory studies, drugs, visits or consultations, sick leave, and other) for the type 1 group averaged 12,178 French francs (FFr); for the type 2 group, 6,908 FFr. Not including sick leave, mean costs were 7,711 FFr for the type 1 group and 5,892 FFr for the type 2 group, versus mean medical care costs of 6,462 FFr for the general French population. Two areas accounted for most of the non-sick leave costs: drugs (44.7 percent in the type 1 group and 34.3 percent in the type 2 group) and hospitalization (33.9 percent in the type 1 group and 40.1 percent in the type 2 group). In the general French population, drugs accounted for 17.9 percent of costs. The frequency of hospitalization was similar for the type 1 group and the general population. Compared with findings from a 1978 study, hospitalization was higher and visits or consultations lower. 5 tables, 13 references.

195

TITLE: Costs of Diabetes in Texas, 1992. Warner, D.C.; McCandless, R.R.; De Nino, L.A.; Cornell, J.E.; Pugh, J.A.; Marsh, G.M. *Diabetes Care*. 19(12): 1416-1419. December 1996.

OBJECTIVE: To estimate the direct and indirect costs of diabetes in Texas for 1992.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Costs were conservatively estimated at $4.0 billion.

RECOMMENDATION: The databases consulted for this research study could assist state and local planning efforts in diabetes.

ABSTRACT: For this study, several billing databases were searched to find individuals with diabetes or hypoglycemia as a primary or secondary diagnosis. Unique individual identifiers were used to capture all incidents of health care use by persons with the diagnoses identified. For most direct medical costs, the authors relied on third party or provider databases, which included Texas Medicare and Medicaid; selected Veterans Affairs and public hospitals; the state's Department of Health, Rehabilitation Commission, and Commission for the Blind; a commercial pharmaceutical database; and a migrant/community health center. Costs were defined in terms of allowed charges or payments. Three categories of direct costs were estimated — clearly attributable to diabetes, clearly attributable plus probably attributable to diabetes, and all costs for people with diabetes. Survey data were used to estimate private insurance claims and associated out-of-pocket costs. For nursing home costs, the finding of a 1992 American Diabetes Association study on days attributable to diabetes was applied to Texas experience. National Health Interview Survey and U.S. Department of Labor data were used to estimate costs of short- and long-term disability. For the cost of premature mortality, 1992 Texas death records were searched for persons with diagnoses of diabetes or hypoglycemia; present value of lost future productivity was calculated with a discount rate of 3 percent. The authors estimated that $2.4 billion in indirect costs and $1.6 billion in direct costs were clearly or probably attributable to diabetes. Almost half of direct costs were paid by Medicare. 2 tables, 14 references.

196

TITLE: The Cost of Diabetic Foot Problems. Ward, J.D. *PharmacoEconomics*. 8 (Supplement 1):55-57. 1995.

OBJECTIVE: To discuss the prevalence and incidence of diabetic foot problems, their economic cost, and strategies for improvement.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Vigilant identification of those at risk for diabetic foot problems, supported by education, care, and appropriate clinical services, will dramatically lower the incidence of foot ulceration and its associated costs.

RECOMMENDATION: All diabetes clinic services should provide a foot care specialist.

ABSTRACT: Peripheral vascular disease, neuropathy, and social factors are important precursors of foot ulceration and amputation. In 50 percent of cases of the diabetic foot, vascular disease and neuropathy will both be present. The authors report their impression that few patients with diabetes who have foot problems are employed. According to a British study (Robinson et al. 1990), hospital admissions with peripheral vascular disease and neuropathy

accounted for 20.8 percent of total bed days associated with diabetes in a recent period. Estimated total cost for these admissions was £ 12.9 million. According to Caddick et al. (1994), there is a very significant correlation between residing in an economically deprived area and being admitted to the hospital for diabetes; it is 2.5 times more common for those from deprived areas to be admitted. The author of the present article cites studies showing that provision of a foot care specialist reduces the incidence of diabetic foot ulceration and recommends offering a regular session for diabetic foot problems with a team consisting of a physician, diabetes specialist nurse, chiropodist (podiatrist), and orthotist. The author states that there is no reason that the objective included in the St. Vincent Declaration (1990) of reducing amputation in diabetes by 50 percent over 5 years cannot be achieved. In the United Kingdom, local diabetes services advisory groups have been set up in every health district to oversee, organize, and improve the provision of diabetes care. 17 references.

197

TITLE: The Cost of Diabetic Neuropathy. Ward, J.D. *PharmacoEconomics*. 8 (Supplement 1):52-54. 1995.

OBJECTIVE: To discuss diabetic neuropathy and its economic implications.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Health care system.

CONCLUSION: Assuming that up to 20 percent of patients in a diabetic clinic will have neuropathic problems, numb feet, predisposition to ulcers, or impotence, a great deal of time should be spent with such patients (much more than currently available in many clinics).

RECOMMENDATION: Measures of quality of life need to be developed to prove the efficacy of treatments in patients with diabetic neuropathy.

ABSTRACT: No available economic studies actually state the economic price of diabetic neuropathy, a term with no precise definition. The author suggests defining diabetic neuropathy as a state of nerve damage leading to unpleasant symptoms mainly in the distal lower limbs that will lead the patient to consult a physician or the detection of physical signs indicating severely damaged nerves likely to result in clinical problems (diabetic foot ulceration). This definition includes 20 percent of patients; many epidemiological studies quote a prevalence of 28 to 38 percent. The most common syndrome of diabetic neuropathy is chronic sensory neuropathy of insidious onset (83 percent of cases). Autonomic neuropathy is relatively rare. Among men with diabetes aged 55 or over, 50 percent are impotent — the cause is primarily neuropathic, with vascular sclerosis and psychological factors also contributing. Although the role of neuropathic disease in developing foot ulceration is well recognized, the great amount of suffering among those with other forms of neuropathy is not. As a consequence, these other forms of neuropathy are not recognized as costly. 15

references.

198

TITLE: The Cost of Education (Editorial). Siddons, H. *Diabetic Medicine*. 11(3): 239240. April 1994.

OBJECTIVE: To point out the benefit of education for patients with diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Not educating patients with diabetes is very expensive.

RECOMMENDATION: Convince health service authorities that diabetes education is worth the investment.

ABSTRACT: The editorialist points out that the 1993 Diabetes Control and Complications Trial in the United States clearly demonstrated that intensive education and good blood glucose control can improve outcomes for people with diabetes. She notes the conflict between the Diabetes Control and Complications Trial recommendation of 20 minutes of education monthly for each patient with the British Diabetic Association's recommendation of one diabetes nurse per thousand patients. She also points out that nurse specialists are considered expensive and notes that many people are looking to practice nurses to take on this role. Practice nurses, however, are under pressure and their time is often used inappropriately. The editorialist states that it is well documented that education can reduce the cost of complications and hospital admissions for persons with diabetes. She notes that the cost of not educating patients is extremely high — about £ 300 for an overnight stay at the Manchester Royal Infirmary (before treatment) and £ 5,000 for inpatient treatment alone for a below-knee amputation at that institution. The health service is currently driven by financial implications, but this may not be bad. The authorities must be convinced that it is worthwhile to invest in diabetes. 2 references.

199

TITLE: The Cost of Insulin-Dependent Diabetes Mellitus (IDDM) in England and Wales. Gray, A.; Fenn, P.; McGuire, A. *Diabetic Medicine*. 12(12): 1068-1076. December 1995.

OBJECTIVE: To estimate the direct and indirect costs of type 1 diabetes in England and Wales in 1992 using a cost-of-illness approach.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Epidemiological cohort model.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: The estimated direct medical costs related to type 1 diabetes were £ 95.6 million; indirect costs (lost earnings) were estimated at £ 113 million.

RECOMMENDATION: Cost-of-illness studies such as this one should provide a framework for cost-effectiveness analyses to determine appropriate levels of expenditures for diabetes treatment programs.

ABSTRACT: The authors performed a cost-of-illness study of type 1 diabetes in England and Wales in 1992 using an incidence-based approach. The total number of persons with type 1 diabetes in 1992 was estimated at 93,581. Using available information on mortality risk, 2,014 deaths were estimated per year from type 1 diabetes for this imaginary cohort, resulting in an annual loss of 50,993 life-years and 23,691 potential working years. Estimated direct costs were £ 95.6 million; per sensitivity analysis, the range was £ 77 million to £ 113 million, depending on disease incidence. About half (£ 47.3 million) of these costs were those directly attributable to diabetes. Almost half of those costs were associated with routine insulin maintenance, including glucose monitoring and routine outpatient care. The second most important direct expenditure category was renal complications, which accounted for £ 30.2 million. Most of these expenses (£ 26.5 million) were for renal replacement therapy. Vascular complications accounted for nearly 5 percent of direct costs; ophthalmic and neurological complications each accounted for about 1 percent. Costs of social security payments attributable to type 1 diabetes were estimated at £ 11 million annually. Potential earnings losses (discounted at 6 percent per year) due to premature mortality were estimated at £ 113 million annually. 6 tables, 33 references.

200

TITLE: The Cost of Obesity: The US Perspective. Wolf, A.M.; Colditz, G.A. *PharmacoEconomics*. 5 (Supplement 1): 34-37. 1994.

OBJECTIVE: To estimate the economic impact of obesity in the United States by examining the economic costs attributable to obesity for major chronic disorders, including type 2 diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: The estimated direct cost of obesity-associated disease in 1990 was $45.8

billion; the indirect cost was estimated to be $23.0 billion. The cost of type 2 diabetes attributable to obesity was 12.7 billion dollars ($8.835 billion for direct costs and $3.890 billion for indirect costs associated with lost productivity resulting from excess mortality).

RECOMMENDATION: Programs aimed at preventing weight gain in children and adults may help contain rapidly rising health care costs.

ABSTRACT: The authors estimated the economic impact of obesity (body mass index ≥ 27.8 kg/m2 for men or 27.3 kg/m2 for women) in 1990 U.S. dollars. Direct costs were derived from estimates for five major chronic disorders (type 2 diabetes, gallbladder disease, cardiovascular disease, cancer, and musculoskeletal disease) for which obesity increases risk. The authors estimated the percentage of costs attributable to obesity for these disorders to be 57, 30, 19, 2.3, and 10, respectively. For diabetes, direct costs included routine care, cost of complications, and costs from an increased prevalence of other conditions (e.g., peripheral vascular disease, cerebrovascular disease). The authors used a published estimate of the 1980 U.S. health care expenditure for type 2 diabetes as the basis for making the cost estimate for this disorder. They estimated that, for 1990, direct costs for type 2 diabetes that were attributable to obesity were $8.8 billion. Indirect costs in this study were divided by causes: (a) lost productivity as a result of obesity-related illness and (b) excess mortality. The authors estimated that 52.59 million work days were lost in 1988 because of obesity-related disease; they estimated the cost of this lost productivity to be $4.06 billion. They did not, however, allocate this cost to the five diseases studied. Costs of lost productivity from excess mortality for the five diseases were estimated at $18.94 billion, including $3.89 billion for type 2 diabetes.

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TITLE: Costs of Insulin-Dependent Diabetes Mellitus. Simell, T.T.; Sintonen, H.; Hahl, J.; Simell, O.G. *PharmacoEconomics*. 9(1): 24-38. January 1996.

OBJECTIVE: To review the costs to the individual and society of initial treatment, follow-up, and late treatment for type 1 diabetes; to assess the potential for decreasing these costs.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Societal

CONCLUSION: The costs of type 1 diabetes peak at the diagnosis of the disease and again with the development of complications. Intensive patient education, shortened hospitalizations for initial treatment, and maintenance of good metabolic control and mental health are the primary means of containing or reducing costs associated with type 1 diabetes until primary prevention is available.

RECOMMENDATION: None.

ABSTRACT: The authors review the epidemiology and the direct and indirect costs of type 1 diabetes. Their review considers total costs as well as costs associated with three clinical stages: initial treatment, follow-up after initial treatment, and late treatment. The incidence and prevalence of type 1 diabetes vary, with the highest rates occurring in Scandinavia and the lowest rates in the Far East. Costs are difficult to ascertain because there are no prospective or longitudinal studies of the total long-term costs of type 1 diabetes. Available data suggest that the highest costs of type 1 diabetes are associated with initial and late treatment stages of the disease. The mean length of initial hospitalization at the clinical onset of type 1 diabetes ranges from 2 days in the United States to 6 weeks in northern and eastern Europe. A Finnish study found that shortening the initial hospitalization from 23 to 9 days had no effect on patient outcome at 2 years. Costs accumulate slowly after initial treatment; for children with type 1 diabetes in one study, total costs of self-care over a 2-year period were less than the cost of 1 inpatient day at a university hospital. Late-phase treatment is characterized by a rapid increase in costs because of complications, including retinopathy requiring laser treatment; renal disease, requiring dialysis; cardiovascular disease, which is responsible for more than 20 percent of deaths among type 1 patients; and neuropathy, which can lead to amputation. The estimated cost to provide tight metabolic control in type 1 patients in the Diabetes Control and Complications Trial was $3,700 (U.S.) per year, which would increase current control costs by 120 percent. However, the authors assert that the potential long-term personal and economic savings of continuing tight control and reducing complications are enormous. 121 references.

202

TITLE: Costs of Temporary and Permanent Dis-ability Induced by Diabetes. Olivera, E.M.; Duhalde, E.P.; Gagliardino, J.J. *Diabetes Care*. 14 (7): 593596. July 1991.

OBJECTIVE: To evaluate indirect costs of diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Retrospective.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Persons with diabetes but without complications and a control group of persons without diabetes had similar rates of absenteeism and yearly cost. In contrast, the costs of overall absenteeism and permanent disability were much higher in persons with diabetes and chronic complications.

RECOMMENDATION: Secondary prevention of diabetic complications might be an optimal approach to reducing the burden of diabetes.

ABSTRACT: From 1984 to 1986, the cost of temporary disability for patients with diabetes was studied in a group of La Plata University (Argentina) employees (n = 42 for both control

group and group with diabetes); the cost of permanent disability for patients with diabetes was studied in a larger group (n = 2,763) of Buenos Aires government employees. The La Plata University group with diabetes was divided into those without complications (31 percent) and those with chronic complications (69 percent). Complications consisted of macroangiopathy (42 percent peripheral, 22 percent coronary, and 5 percent cerebral), peripheral neuropathy (33 percent), retinopathy (25 percent), and kidney lesions (11 percent). The number and causes of working days lost during the calendar year were determined for each individual. For temporary disability, average days per year lost in patients without complications did not differ significantly from the number for the age- and sex-matched control group. However, patients with chronic complications had a considerably higher rate ($p < 0.05$) of days lost than the control group or patients with diabetes without complications. The costs of permanent disability for the government employees were estimated by calculating the expected number of years to retirement age for each early retiree. Work production loss was discounted at a 6 percent rate. Average work production lost for 115 patients disabled by diabetes was 11 years (n = 115; 48 women, 67 men). At an annual cost of $23,660 (U.S. dollars), the total cost for these employees was $2,720,900. 3 tables, 17 references.

203

TITLE: Diabetes. Vaughan, J.P.; Gilson, L.; Mills, A. In: *Disease Control Priorities in Developing Countries*. Jamison, D.T; Mosley, W.H.; Measham, A.R.; Bobadilla, J.L.; eds. New York: Oxford University Press. 1993. pp. 561-576.

OBJECTIVE: To summarize information for developing countries on the incidence and development over time of diabetes as well as the direct and indirect costs of this disease.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Literature review.
Perspective: Societal.

CONCLUSION: Resource allocation to improve the diagnosis and treatment of diabetes in developing countries needs to be fitted to the public policy and needs of individual countries.

RECOMMENDATION: Further research is needed to assess the incidence and prevalence of type 1 and type 2 diabetes in developing countries, to evaluate possible interventions to prevent type 2 diabetes, and to assess case management and financing strategies.

ABSTRACT: The authors review the epidemiology and economic burden of diabetes worldwide and especially in developing countries. Detection and reporting of new cases of diabetes depends on the availability and use of health care services, or on the result of large-scale population-based surveys. The authors briefly review the evidence for genetic and environmental factors in the development of type 1 and type 2 diabetes. The incidence of type 1 diabetes may be rising, but it is considered a rare disease in most developing countries and the very poor database makes the situation there uncertain. The incidence of type 2 diabetes

has risen in the United States, Singapore, and Taipei, Taiwan; for Africa and Latin America, there are fewer data on incidence of this disease. Poor epidemiologic data and the failure to separate type 2 from type 1 diabetes makes it difficult to determine indirect costs in developing countries. In most of these countries, direct costs for diabetes are likely to be low. Reducing the incidence of new cases requires primary prevention strategies, and reducing complications requires early detection and improved case management. Prevention needs to include modification of behavior, improvement in health services and health education, and government regulation. However, the success of attempts to modify behavior is debated, and improvement in health services is expensive, especially for developing countries. The authors suggest strategies for developing countries based on both incidence of diabetes and income. Further research is needed to assess the incidence and prevalence of type 1 and type 2 diabetes in developing countries, to conduct studies of possible interventions for preventing type 2 diabetes (including broad-based noncommunicable disease control), to assess case management, and to consider financing mechanisms.

204

TITLE: Diabetes Care in a UK Health Region: Activity, Facilities and Costs. Alexander, W.D. South East Thames Diabetes Physicians Group. *Diabetic Medicine*. 5(6): 577-581. September 1988.

OBJECTIVE: To compare facilities and staffing for diabetes care in the Southeast Thames region with recommendations from the Royal College of Physicians and the British Diabetic Association, and to assess the cost of diabetes care for the region.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Total cost of diabetes was estimated at £ 21.6 million per year for the South-east Thames region. Physician staffing, patient education, and an ineffectual system of care have resulted in an unacceptably high hospitalization rate for uncomplicated diabetes and metabolic imbalances.

RECOMMENDATION: Regional and District Health Authorities need to give priority to establishing effective, formal diabetes care strategies.

ABSTRACT: The authors reported facilities and services available to patients with diabetes mellitus in 15 districts of the Southeast Thames Regional Health Authority and estimated the basic hospitalization costs for patients with diabetes based on 1985 Hospital Activity Analysis data. Cost estimates were £ 100 per day for inpatient care and £ 20 per visit for outpatient care, and estimates for insulin, sulphonylurea, and modified diet were £ 165, £ 80, and £ 13 per patient per year, respectively. Using recommendations from the Royal College of Physicians and the British Diabetic Association as a standard, mean deficits (with ranges) in

the number of consultant physicians, consultant sessions per week, and nurse specialists were 0.9 (0 to 2.2), 6.6 (0 to 15), and 3.1 (0.4 to 6.0), respectively. Many districts provided no retinopathy screening, education program, computerized records, secretaries, or diabetes day unit. Of 11,857 hospitalizations for patients with diabetes, 4,185 had diabetes given as the principal cause; mean stay for all cases was 4.4 days. Among stays where diabetes was the principal cause, 76 percent had no mention of complications or were for ketoacidosis or coma, and 7.6 percent were for peripheral circulatory disorders (mean stay of 35.3 days) or neurologic complications. Estimated total out-patient costs were £ 4,489,320 (£ 1,432,000 for visits, £ 1,772,100 for insulin, £ 1,145,600 for sulphonylurea, £ 139,620 for dietary intervention, and £ 3,057,320 for supplies); estimated inpatient costs, £ 17,074,080 (£ 6,026,400 for patients admitted primarily for diabetes). Estimated excess inpatient costs for all patients with diabetes, using hospitalization costs of the whole population as a comparison, were £ 13,460,800. Investment of approximately 11 percent of excess costs would bring staffing to recommended levels and improve chiropody and dietetic services. The authors recommend that all regional and district health authorities adopt a strategic plan for diabetes care. 4 tables, 12 references.

205

TITLE: Diabetes Mellitus in Egypt. Arab, M. *World Health Statistics Quarterly (Rapport Trimestriel de Statistiques Sanitaires Mondiales)*. 45(4): 334-337. 1992.

OBJECTIVE: To report findings from a series of surveys of the epidemiology of diabetes mellitus in Egypt; to discuss the cost of diabetes, its interaction with other health problems, and health care delivery in that country.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: The direct and indirect costs of diabetes mellitus constitute a great burden on the economy of Egypt; a national program cannot provide free care for all Egyptians with diabetes.

RECOMMENDATION: Improvements in health care delivery in Egypt are needed to reduce the morbidity and mortality of diabetes mellitus.

ABSTRACT: The author reports that average prevalence of diabetes mellitus in Egypt is 4.3 percent, with distinct geographical variations. The incidence of type 1 diabetes per 100,000 in children below age 15 was found to be 8.3 in an urban population and 7.6 in a rural population. Socioeconomic factors, including religion, may have an impact on the prevalence of diabetes in Egypt. For example, Islam calls for healthy behaviors, including the limitation of food intake to meet one's real needs and encouragement of exercise. Schistosomiasis, a parasitic disease, affects an estimated 20 million Egyptians; this disorder affects metabolism

and may be reflected as hypoglycemia or hyperglycemia or as insulin resistance or other problems. Total 1990 direct costs for treatment of diabetes were approximately $74.3 million (U.S. dollars). Average monthly costs for medication were $1.12 for oral hypoglycemic agents, $2.44 for insulin, and $2.90 for glucose self-monitoring supplies. Laboratory assays cost $22.20 per year, and private physician fees ranged from $9.00 to $60.00 per year. There are substantial government subsidies for basic medication. The costs of treatment for complications of diabetes were much higher, ranging from $2.90 per month for hypertension to $555.00 per month for advanced nephropathy. Basic hospital costs ranged from $0.88 to $3.80 per day for uncomplicated cases. Indirect costs of diabetes mellitus were estimated at $11.8 million per year for the effects of absenteeism on productivity; indirect costs due to premature death were not estimated. 2 tables, 7 references, French summary.

206

TITLE: Diabetes - The Cost of Illness and the Cost of Control: An Estimate for Sweden 1978. Jonsson, B. *Acta Medica Scandinavica*. 671 (Supplement): 19-27. 1983.

OBJECTIVE: To estimate the economic cost of diabetes mellitus in Sweden in 1978, and to address the question of possible savings from improved metabolic control.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: Total direct and indirect costs for diabetes mellitus in Sweden in 1978 were estimated at 568 million and 749 million SEK, respectively. Management and control costs were estimated at 313 million SEK, while the cost of treatment of complications was estimated to be 1 billion SEK. There are great potential benefits to be expected from improved metabolic control.

RECOMMENDATION: Cost-beneficial improvements in management and control of diabetes should be undertaken to lessen the economic burden of diabetes.

ABSTRACT: For this study, direct costs for inpatients were estimated by multiplying number of hospital bed days for patients with a principal diagnosis of diabetes by average cost per bed day. Outpatient costs were developed from estimates of physician visits; cost estimates took into account differences between general practice and hospital outpatient departments. The cost of drugs was estimated from data on drug sales. Indirect costs were estimated separately for short-term illness, permanent disability, and premature death. Direct costs were estimated at 568 million SEK, including 358 million and 210 million SEK for institutional and noninstitutional care, respectively. Persons aged 65 years and older accounted for more than 50 percent of the direct costs and nearly 66 percent of the institutional costs. Total indirect costs were estimated at 749 million SEK, including 134 million SEK from short-term illness, 438 million SEK from permanent disability, and 176 million SEK from premature mortality.

Lost production due to permanent disability accounted for 60 percent of the indirect costs and one-third of the total costs. Complications were more costly than management or control: The latter costs were estimated at 313 million SEK; estimated costs associated with complications were 1 billion SEK, including 255 million SEK in direct costs and 749 million SEK in indirect costs. Models that estimate potential savings from improved metabolic control are discussed. Simulations show that even with modest assumptions for beneficial outcomes, investment in improved control of diabetes will be cost beneficial. Limiting cases to those with a primary diagnosis of diabetes leads to an underestimate of the economic consequences of this disease. 2 figures, 14 tables, 18 references.

207

TITLE: Direct and Indirect Costs of Cardiovascular and Cerebrovascular Complications of Type II Diabetes. MacLeod, K.M.; Tooke, J.E. *PharmacoEconomics*. 8(Supplement 1): 46-51. 1995.

OBJECTIVE: To review the literature on the economic impact of macrovascular complications on diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: Much of the cost of type 2 diabetes is attributable to accelerated atherosclerosis and macroangiopathy.

RECOMMENDATION: None.

ABSTRACT: The authors review various studies on the economic impact of diabetes. In a U.S. study (Rendell et al. 1993), persons with diabetes accounted for 3.1 percent of the study group but 8.3 percent of overall health care charges. Adjusted odds ratios for various diagnoses for those with diabetes (versus those without) were 3.32 for ischemic heart disease, 3.14 for peripheral vascular disease, 2.83 for hypertension, and 2.26 for cerebrovascular disease. In a Finnish study (Aro et al. 1994), 50.7 percent of those with diabetes and 12.4 percent of a control population were hospitalized annually. In a Danish study of elderly patients (Damsgaard et al. 1987), macro-vascular disorders (cardiac, cerebrovascular, and peripheral vascular disease) accounted for 87.4 percent of bed days used for diabetic complications. In a U.S. study reported in the same year, Jacobs et al. found the risk of acute myocardial infarction and chronic ischemic heart disease to be 8.3 and 7.2 times as great among patients with diabetes as it was in the general population. In that study, which used patient records identified from the 1987 U.S. National Hospital Discharge Survey, cardiovascular complications accounted for 74 percent of hospitalization costs for the treatment of the late complications of diabetes. Huse et al. (1986) found that circulatory disorders (hypertension, ischemic heart disease, and cerebrovascular disease) accounted for

33.3 percent of U.S. direct costs for type 2 disease in 1986. These authors estimated the national economic cost of type 2 diabetes to be $19.8 billion for that year, with macrovascular disease accounting for 47 percent. 1 figure, 4 tables, 17 references.

208

TITLE: Direct and Indirect Costs of Diabetes in Minnesota in 1988. Roesler, J.; Walseth, J.; Bishop, D. Minnesota Department of Health, Minnesota Diabetes Surveillance Project. 18 pp. September 1990.

OBJECTIVE: To assess the total economic burden of diabetes in Minnesota in 1988.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: Diabetes represented a significant economic burden in Minnesota in 1988, with total costs estimated at more than $300 million.

RECOMMENDATION: To reduce the economic burden of diabetes; interventions designed to prevent the complications of diabetes should be expanded.

ABSTRACT: The authors estimated costs in Minnesota for diabetes by applying the cost estimates from a study by the Center for Economic Studies in Medicine for the American Diabetes Association (1988) to the state's population with diabetes. For 1988, the incidence and prevalence of diabetes in Minnesota were estimated at 9,695 and 87,109 cases, respectively. A total of 1,119 deaths were attributed to diabetes. Total direct costs were estimated at $189.4 million. Of this amount, $154.0 million was for hospital-related costs and $11.9 million for nursing home costs; outpatient costs were estimated at $23.5 million. Estimates of components of hospital costs included $30.5 million for diabetes, $75.6 million for its chronic complications, $7.3 million for increased intensity of care, $36.1 million for additional length of stay, and $4.4 million for physician visits to inpatients. Indirect costs were estimated at $112.2 million; those associated with short-term morbidity were estimated at $2.0 million; with long-term disability, $44.6 million. Lost earnings due to premature death were estimated at $65.5 million. Total costs were therefore estimated at $301.5 million, of which direct costs accounted for 62.8 percent and indirect costs, 37.2 percent. 12 tables, 23 references.

209

TITLE: Direct and Indirect Costs of Diabetes in the United States in 1987. Center for Economic Studies in Medicine, Pracon Incorporated. American Diabetes Association, Alexandria, VA. 20 pp. 1988.

OBJECTIVE: To update previous estimates of the incidence and prevalence of diabetes in the United States; to measure health care use for diabetes in 1987 and associated direct costs; and to estimate for that year morbidity and mortality resulting from diabetes and their associated indirect costs.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: Diabetes represents a significant economic burden in the United States, with total economic costs estimated at $20.4 billion for 1987.

RECOMMENDATION: As most of the costs of diabetes are due to its chronic complications, programs designed to increase the early diagnosis and treatment of this disorder and enhance accessibility to care should be expanded with a goal of preventing complications.

ABSTRACT: The authors used the human capital approach of D.P. Rice et al. (1985) to estimate costs associated with diabetes. Data sources for the study included several government surveys: the National Health Interview Survey, National Hospital Discharge Survey, National Nursing Home Survey, and National Ambulatory Medical Care Survey. Prices were specified in 1987 dollars. There were an estimated 6.51 million patients with diabetes in the United States in 1987, and 564,868 cases of diabetes were newly diagnosed during the year. Total costs of diabetes in 1987 were estimated at $20.4 billion. Direct costs, which accounted for 47.1 percent of the total, were composed of $7.9 billion in hospitalization and nursing home expenses and $1.7 billion for outpatient care. Indirect costs, 52.9 percent of the total, were composed of $142 million attributable to short-term morbidity, $3.14 billion attributable to long-term disability, and $7.5 billion associated with premature mortality. 2 exhibits, 12 tables, 33 references, 1 appendix.

210

TITLE: Direct and Indirect Costs of Diabetes in the United States in 1992. Medical Technology and Practice Patterns Institute, Washington, DC. American Diabetes Association, Alexandria, VA. 27 pp. 1993.

OBJECTIVE: To report prevalence and incidence estimates for diabetes; to estimate health care use and expenditures for treating diabetes; and to estimate morbidity and mortality costs as well as associated indirect costs for diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: The total economic cost of diabetes in the United States in 1992 was estimated to be $91.8 billion.

RECOMMENDATION: The economic burden of diabetes may be reduced by programs aimed at increasing the use of preventive and diagnostic services, improving patient education, and increasing access to maintenance therapies and screening for complications.

ABSTRACT: The authors used a prevalence-based and human capital approach to estimate costs associated with diabetes. Data sources used to determine the prevalence of diabetes and the use of health services included the Centers for Disease Control, the National Hospital Discharge Survey, the National Nursing Home Survey, the National Ambulatory Care Survey, and the National Medical Expenditure Survey. Costs were expressed in 1992 dollars. In that year, an estimated 7.2 million persons had diagnosed diabetes. Total costs (direct plus indirect) for diabetes in 1992 were estimated at $91.8 billion. Direct costs accounted for 49.2 percent ($45.2 billion), with hospital, nursing home, and outpatient costs estimated at $37.2, $1.8, and $6.2 billion, respectively. (Outpatient costs included $2.9 billion in hospital outpatient visits, $1.2 billion in prescription drugs, $1.0 billion in physician visits, and $0.5 billion for medical equipment.) Indirect costs, which comprised 50.8 percent ($46.6 billion) of total costs, included $8.5 billion for short-term morbidity, $11.2 billion for long-term morbidity, and $27.0 billion for premature mortality. Persons aged 45 to 64 years accounted for 62.3 percent of total mortality costs (the value of productivity foregone because of diabetes). The authors note that although 40.5 percent of all expenditures for diabetes were attributed to inpatient hospital care, only 0.03 percent of expenditures went toward diet/nutrition counseling and only 1.0 percent to diagnostic testing. They describe several ways in which the direct medical costs were likely to be underestimated in the report. 17 tables, 40 references, 1 appendix.

211

TITLE: Economic Consequences of Diabetes Mellitus in the U.S. in 1997. Alexandria, VA: American Diabetes Association, 1998.

OBJECTIVE: To estimate both direct medical and indirect costs attributable to diabetes and to calculate total and per capita expenditures for people with and without diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: Estimated direct medical and in-direct costs were $44 billion and $54 billion, respectively.

RECOMMENDATION: None.

ABSTRACT: The authors used prevalence-based cost-of-illness methods and data from national health care expenditure surveys to determine costs attributable to diabetes. Direct medical costs were calculated as both the medical expenditures attributable to diabetes (i.e., cost from excess prevalence of both diabetes-related chronic complications [e.g., neurological disease, renal disease] and general medical conditions [e.g., liver disease, respiratory failure, malignant neoplasms] and total cost of all services for people with diabetes). Indirect costs were those related to foregone earnings because of disability and diabetes-attributable mortality. The 1987 National Medical Expenditure Survey was used to estimate mean expenditures for encounters where the primary diagnosis was diabetes; this survey was also used to estimate diabetes prevalence as well as chronic complications and general medical conditions. For 1997, 2.3 million hospital discharges were attributed to diabetes (287.2 per 1,000 people with diabetes). Of an estimated $44.1 billion in direct medical expenditures attributable to diabetes in that year, $27.5 billion was for inpatient care, $10.9 billion for outpatient services and home health care, $5.5 billion for nursing home care, and $0.2 billion for hospice care. Of the total direct expenditures, treating diabetes and its acute metabolic complications accounted for 17.4 percent; chronic complications, 26.8 percent. Of an estimated $54.1 billion in attributable indirect costs, premature mortality accounted for $17.0 billion and disability, $37.1 billion. Total medical expenditures for people with diabetes were estimated at $77.7 billion ($10,071 per capita), versus $540.6 billion ($2,669 per capita) for people without diabetes. 44 references.

212

TITLE: Economic Cost of Diabetes Mellitus: Minnesota, 1988. Minnesota Department of Health. Centers for Disease Control. *Morbidity and Mortality Weekly Report (MMWR)*. 40 (14): 229-231. April 12, 1991.

OBJECTIVE: To describe the economic impact of diabetes mellitus on the state of Minnesota for the year 1988.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: During 1988 in Minnesota, direct and indirect costs for diabetes mellitus approximated $189 million and $112 million, respectively. Chronic complications of diabetes mellitus accounted for more than half of the hospital days and cost more than $75 million.

RECOMMENDATION: To reduce the costs of diabetes mellitus, effort should be directed at preventing its chronic complications.

ABSTRACT: The author summarizes an analysis prepared by the Minnesota Diabetes Surveillance Project that estimated the economic impact of diabetes mellitus on Minnesota in 1988. Prevalence of diabetes mellitus was obtained from a previous population-based study; national sources were used to estimate hospitalizations, physician visits, nursing home stays, laboratory tests, outpatient care, and disability compensation. In 1988, the total cost of diabetes mellitus in the state was $301 million. The direct cost of diabetes mellitus, including diagnosis, treatment, hospitalizations, nursing home care, and outpatient care, was $189 million. Chronic complications accounted for 78,304 hospital days, more than half of total hospital days for diabetes mellitus. Hospitalizations for chronic complications of diabetes mellitus cost more than $75 million, and the indirect cost of diabetes mellitus was calculated at $112 million, with $2 million, $44.6 million, and $65.5 million attributable to short-term morbidity, long-term disability, and mortality, respectively. Prevention of some of the chronic complications of diabetes mellitus should result in a major reduction in its cost. Minnesota has developed a multifaceted plan to reduce the morbidity and disability that result from lower extremity amputations, diabetic eye disease, uncontrolled hypertension, and adverse pregnancy outcomes; the project includes measuring the burden of diabetes mellitus, implementing a statewide plan, and monitoring that plan's impact. 1 table, 10 references.

213

TITLE: The Economic Cost of Obesity: The French Situation. Levy, E.; Levy, P.; Le Pen, C.; Basdevant, A. *International Journal of Obesity* and Related Metabolic Disorders. 19(11): 788-792. November 1995.

OBJECTIVE: To estimate for France the direct and indirect costs of obesity as well as excess mortality from this condition.

CATEGORY: Expert opinion.

CONCLUSION: The economic cost of obesity in France is approximately 2 percent of all health care costs.

RECOMMENDATION: Prospective studies of the costs of obesity are needed that will measure relative risks adjusted for age, sex, socioeconomic conditions, and country-specific epidemiologic data.

ABSTRACT: The authors used a prevalence-based analysis of 1992 data to estimate the direct and indirect costs of obesity in France. Indirect costs were based on lost production due to obesity as indicated by Health Insurance System reimbursements for obesity-related causes. The prevalence of obesity (body mass index 27 Kg/m2 or greater) and morbid obesity (body mass index 30 Kg/m2 or greater) in the population aged 20 to 49 was 16.7 and 6.2 percent, respectively. Direct costs, based on prevalence of obesity and the relative risk of an obese

person contracting a disease, were calculated for obesity, hypertension, myocardial infarction, angina pectoris, stroke, venous thrombosis, type 2 diabetes, hyperlipidemia, gout, osteoarthritis, gall bladder disease, colorectal cancer, breast cancer, genitourinary cancer, and hip fractures (this last disorder was considered cost-saving). The lowest estimates for relative risk were used. Total direct costs were French francs 66 billion or approximately 11 percent of French Health Care System costs, 20 percent of which were for type 2 diabetes health services. Obesity and related diseases accounted for 65, 25, and 10 percent of drug, physician, and laboratory expenditures, respectively. Total indirect costs were FF 575 million, versus FF 3.5 billion from all causes. A savings of FF 190 million was found because of fewer hip fractures. One-year mortality from obesity was 180,000 persons. Total direct costs of obesity amounted to about 2 percent of French Health Care System costs, a finding that accords with results of studies in other western countries. This estimate is conservative, in part because not all obesity-related diseases were included and the lowest values for relative risk were used. Prospective studies of the costs of obesity are needed that will measure relative risks adjusted for age, sex, socioeconomic conditions, and epidemiology for each country. 3 tables, 42 references.

214

TITLE: The Economic Costs of Non-Insulin-Dependent Diabetes Mellitus. Huse, D.; Oster, G.; Kilen, A.; Lacey, M.; Colditz, G. *Journal of the American Medical Association (JAMA)*. 262(19): 2708-2713. November 17, 1989.

OBJECTIVE: To estimate the 1986 costs of morbidity and mortality attributable to type 2 diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: The estimated total economic cost of type 2 diabetes in 1986 was $19.8 billion, including $11.6 billion in health care expenditures and $8.2 billion in foregone productivity. Of type 2 diabetes-related health care expenditures, 59 percent were attributable to diabetes or its complications, and 41 percent to an excess prevalence of related conditions, for the most part circulatory disorders.

RECOMMENDATION: The significance of the public health and clinical problems associated with type 2 diabetes-related conditions must be recognized.

ABSTRACT: The authors estimated the total economic burden of type 2 diabetes using conventional prevalence-based cost-of-illness techniques and data from government surveys. The total economic cost of type 2 diabetes in 1986 was $19.8 billion, including $11.6 billion in health care expenditures and $8.2 billion in foregone productivity due to morbidity or mortality. Approximately $4.8 billion of these health care costs were attributable to treatment

of other diseases, principally circulatory disorders ($3.8 billion) that were attributable to type 2 diabetes. Men younger than 65 years accounted for $7.0 billion in economic costs; women aged 65 years and older, $5.9 billion; men over 65, $3.5 billion; and women under 60, $3.4 billion. Per case, annual health care expenditures attributable to type 2 diabetes ranged from $1,274 among men younger than 65 years to $3,078 among women 65 aged years and older. In addition to the significant economic burden of type 2 diabetes, the human toll of type 2 diabetes was staggering: 144,000 premature deaths were attributable to this disorder in 1986, representing 6.8 percent of all U.S. mortality and a loss of 1,445,000 years of life. This mortality estimate is more than four times greater than the previously reported estimate of 35,000 deaths due to all kinds of diabetes. Of the 144,000 deaths, cardiovascular disease was the cause in 124,000. 3 figures, 5 tables, 33 references.

215

TITLE: Economic Costs of Obesity. Colditz, G.A. *American Journal of Clinical Nutrition.* 55(2 Suppl): 503S-507S. February 1992.

OBJECTIVE: To estimate costs attributable to obesity for type 2 diabetes, hypertension, cardiovascular disease, gall bladder disease, colon cancer, and breast cancer.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: Estimated 1986 costs for the six diseases studied totaled $39.3 billion, representing 5.5 percent of the cost of illness in that year.

RECOMMENDATION: Programs that target weight gain avoidance in middle and older age should be implemented.

ABSTRACT: For this prevalence-based estimate of the economic cost of obesity (a body mass index ≥ 27.8 kg/m2 for men or 27.3 kg/m2 for women), the author includes both direct and indirect costs. A discount rate of 4 percent was applied to indirect costs. The cost for type 2 diabetes included routine care for uncomplicated illness, costs related to morbidity and mortality from complications, and costs from excess prevalence of other diseases (e.g., renal disorders). A published estimate of the 1980 cost of type 2 diabetes was adjusted to 1986; direct costs for the latter year were estimated at $11.6 billion; indirect costs, at $8.2 billion. Using information from the Nurses' Health Study, the author estimated that 57 percent of these costs ($11.3 billion) were attributable to obesity. Total estimated 1986 costs attributable to obesity for the 6 diseases studied were $39.3 billion. If the costs of obesity related to musculoskeletal disorders (about 50 percent of total costs for those problems) were included, another $17 billion would be added to this total. 5 figures, 36 references.

216

TITLE: Economic Evaluations of Type II Diabetes. Leese, B. *PharmacoEconomics*. 8 (Supplement 1): 23-27. 1995.

OBJECTIVE: To discuss the cost-of-illness methodology as an approach to studying the costs of diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: Existing studies highlight the difficulties involved in comparing diabetes costs between countries with different health care systems and the importance of defining the study population and the sources of costs. Relatively few studies make suggestions about how their cost estimates might be used.

RECOMMENDATION: None.

ABSTRACT: Most economic analyses of diabetes mellitus have been descriptive and used a cost-of-illness methodology. Evaluative studies, in contrast, use cost-effectiveness, cost-benefit, or cost-utility methodologies. Cost-of-illness studies bring together three kinds of costs — direct, indirect, and intangible — to measure the economic burden on society of a disease. These studies are usually based on disease prevalence, less often on its incidence. Incidence-based studies, which show where cost savings could be obtained from changes in treatment, are preferable but harder to perform. Direct costs are the easiest of the three kinds of costs to collect, but relevant costs may be excluded, or these costs may be incorrectly estimated or valued inappropriately. Indirect costs, which are the subject of considerable debate, measure the cost to society of illness, disability, and premature mortality. Intangible costs, which are more subjective, have rarely been considered in cost-of-illness studies because of difficulties in assigning costs to factors such as stress, pain, and anxiety. The valuation of life necessary to derive indirect costs is the main area of debate about the cost-of-illness methodology. One way of valuing life is to consider market earnings; here the human capital method is the most widely used approach. However, this method is biased (e.g., toward the unemployed). Willingness to pay is another approach, but it has found little acceptance. The friction method is a third approach, in which only production losses during the period required to replace the sick worker are costed. The most serious criticism of cost-of-illness studies is that they do not indicate where resources should be devoted to a particular disease. The author reviews various studies of the direct costs of type 2 diabetes and notes that most studies of the costs of diabetes have not distinguished between type 1 and type 2. 37 references.

217

TITLE: Economic Impact of Diabetes. Entmacher, P.S.; Sinnock, P.; Bostic, E.; Harris, M.I. In: *Diabetes in America*: National Diabetes Data Group. Chapter 32. U.S. Department of Health and Human Services, 1984.

OBJECTIVE: To review estimates of the direct and indirect costs of diabetes in the United States.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: Diabetes represents a significant economic burden in the United States, with the estimated total cost of diabetes in 1984 equaling $13.75 billion.

RECOMMENDATION: None.

ABSTRACT: The authors discuss the direct and indirect costs of diabetes in the United States. Using the human capital approach of Rice (1966) and data derived from surveys of the National Center for Health Statistics, they estimate that the cost of diabetes rose from $2.6 billion in 1969 to $13.75 billion in 1984. They state that this increase was largely due to inflation and the increasing number of persons with diabetes. In 1984, estimated direct costs for medical and health care services were $7.4 billion; estimated indirect costs attributable to disability were $4.4 billion and $1.9 billion to premature death. An estimated $3.5 billion in direct costs were attributable to care in short-stay hospitals. The increase in total expenditures for diabetes from 1969 to 1984 was proportionate to the rise in overall health care expenditures during that time. The proportion of the total cost of diabetes attributable to direct medical care expenditures rose during the time period from 38 percent to 54 percent; the prevalence of diagnosed diabetes rose from 3.2 million in 1969 to 5.5 million in 1980 (no figures were given for 1984). In a 1977 national survey, 99 percent of persons with diabetes had a direct medical care expense versus 87 percent for those without diabetes. Per capita expenses for persons with diabetes who had an expense were 2.7 times higher than those for persons without diabetes. 8 tables, 2 appendices, 10 references.

218

TITLE: Economic Impact of Diabetes. Javitt, J.C.; Chiang, Y-P. In: *Diabetes in America*: National Diabetes Data Group, 2nd Edition. Chapter 30, 11 pages. 1995.

OBJECTIVE: To review studies of the economic costs of diabetes and examine methodological differences between published analyses.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost of illness.
Perspective: Societal.

CONCLUSION: The economic costs of diabetes are substantial, with estimates of total costs as high as $92 billion per year. However, comparisons between the estimates of this study and others are made difficult by several methodological issues.

RECOMMENDATION: As health care expenses escalate, the cost of treating diabetes should be considered from the perspective of transfer payments and tax losses.

ABSTRACT: The authors review recent published estimates of the economic cost of diabetes in the United States, update and synthesize them, and discuss methodological differences between these studies. Most studies of the economic costs of diabetes conducted in the 1980s used the human capital approach to valuing human life and relied on prevalence-based annual cost estimates. Methodological issues discussed by the authors include the attribution of cost to underlying conditions, valuing human life and health, and estimating volume of medical services; variation in these methodologies makes comparisons between studies difficult. In four 1980 studies, estimates (in 1990 dollars) of the total direct cost of diabetes ranged from $9.3 to $13.8 billion; indirect cost estimates ranged from $7.9 to $15.8 billion. Hospitalization accounted for most of the direct costs in all four studies. The American Diabetes Association published a study for the year 1992 in which it estimated direct medical costs of diabetes and its complications at $45.2 billion and indirect costs due to disability and premature death at $46.6 billion, for a total economic cost of $91.8 billion. This total, more than three times as great as the highest of the four earlier studies described, in part reflects increases in medical care costs above the inflation index used as well as more intensive and expensive technology. Important differences in the methodology of the 1992 analysis were the inclusion of cost components (e.g., home health visits, glucose monitors) not included in other studies, more comprehensive ascertainment of services due to systemic comorbid conditions attributed to diabetes, and morbidity databases that better capture contributing causes of death. The study attributed 344,914 deaths to diabetes in 1992 (80,339 were attributed to the disease in an analysis for 1987). Studies indicate that patients with diabetes use a much higher proportion of medical services and incur much higher expenses than do persons without diabetes 5 tables, 22 references.

219

TITLE: Economic Impact of Type II Diabetes Mellitus. Krosnick, A. *Primary Care: Clinics in Office Practice*. 15(2): 423-432. June 1988.

OBJECTIVE: To document the direct and indirect costs associated with type 2 diabetes in the United States.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Review of studies.
Perspective: Societal.

CONCLUSION: For 1988, total costs associated with type 2 diabetes were estimated at $20 billion: $10.5 billion for direct costs due to diagnosis and treatment and $9.5 billion for indirect costs associated with disability and mortality.

RECOMMENDATION: A concerted national effort is needed to address the morbidity, mortality, and economic burden of type 2 diabetes.

ABSTRACT: The author reviews recent studies of the direct and indirect costs associated with type 2 diabetes in the United States. Type 2 diabetes represents 85 to 90 percent of all diabetes cases; an estimated 50 percent of persons with type 2 diabetes are undiagnosed and/or untreated. In addition, the prevalence of diagnosed type 2 diabetes is rising steadily. In 1983, diabetes accounted for 7.2 percent of all hospitalizations nationally, up from 4.6 percent in 1971. In 1980, patients with diabetes made approximately 13 million to 16 million physician visits and 3 million additional contacts in clinics or emergency rooms or by telephone. Patients with diabetes currently average approximately $1,200 in pharmacy purchases annually, which is 3 to 8 times higher per year than persons without diabetes. Nursing home care for patients with diabetes is estimated to cost between $5 and $6 billion annually; the estimated total cost for hospital care in 1980 was $2.2 to $6.5 billion. Diabetes is the leading cause of blindness for persons aged 20 to 74; the annual cost of blindness due to diabetes is estimated at $75 million for lost income and welfare benefits. 1 table, 16 references.

220

TITLE: Financing the Care of Diabetes Mellitus in the U.S.: Background, Problems, and Challenges. Bran-some, E.D. *Diabetes Care*. 15(Supplement 1): 1-5. March 1992.

OBJECTIVE: To review the concerns of the diabetes community that led to the Second National Conference on Financing the Care of Diabetes Mellitus in the 1990s and to review topics included in that conference.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Commentary.
Methodology: None.
Perspective: Health care system.

CONCLUSION: Papers presented at the conference focused on the demographics of diabetes in the United States, standards of care, economic issues, and related topics.

RECOMMENDATION: None.

ABSTRACT: The author reports that the concerns that led to the conference included inadequate reimbursement for outpatient care interventions, below-standard quality of care of patients with diabetes, and confusion among patients and health care professionals about reimbursement changes. The author reviews the issues of the demographics of diabetes, the economic impact of diabetes, quality care, and reimbursement; he also briefly discusses papers presented at the conference. Approximately 6.6 percent of the population has diabetes. The American Diabetes Association estimated direct costs of diabetes care in 1987 to be about $9.6 billion, of which almost $7 billion was for inpatient care in acute short-stay hospitals. Indirect costs associated with short-term morbidity, long-term disability, and premature mortality were estimated at $10.8 billion. Reimbursement remains inadequate for preventive services and patient education, and there is evidence that limited access to care contributes to premature mortality in young adults with type 1 diabetes. The diabetes community has had difficulty convincing third parties that preventive care is cost effective. Quality assurance is emerging as a concern of accrediting organizations and the Health Care Financing Administration. Reimbursement procedures relevant to managed care programs and the Medicare Revised Fee Schedule are addressed. 2 figures, 3 tables, 12 references.

221

TITLE: The Indirect Costs of Morbidity in Type II Diabetic Patients. Persson, U. *PharmacoEconomics*. 8(Supplement 1):28-32. 1995.

OBJECTIVE: To estimate the indirect costs of type 2 diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Excess indirect costs (value of lost production) averaged $7,000 (US dollars) per person with diabetes.

RECOMMENDATION: Estimates of the economic burden of diabetes must take into account the excess risk of diabetes-related illness, not just the costs of diseases that are related to diabetes.

ABSTRACT: The author reports estimates of indirect costs developed by Olsson et al. (1994). The population of Vetlanda, a town in southern Sweden, served as the study site; the age- and sex-adjusted prevalence of diabetes was 3.0 percent. The records of all diabetes patients aged 20 to 64 years (n = 285) were included (general retirement age in Sweden is 65). Of this group, 139 were treated with insulin (all 86 patients with type 1 and 53 of the 199

patients with type 2). To estimate the excess prevalence of sick days and early retirement in the study population, data for the 285 study patients were compared with data for the town's entire population aged 20 to 64 (including the study patients). The expected number of sick days for the study population was determined by multiplying annual sick days for each sex and age group in the general population by the number of insulin-treated and noninsulin-treated men and women with diabetes. Similar calculations were carried out for permanent disability (premature retirement). The cost of production losses was measured by multiplying lost time by average wages plus social security contributions, in 10-year age and sex groups. In an analysis adjusted by age and sex, insulin-treated men had 75 percent more sick days and insulin-treated women 31 percent had more sick days than expected. Among those not treated by insulin, sick days were near the expected number among women and slightly below expected among men. For subjects aged 40 years and above, the number of permanently disabled individuals was three times higher than expected for diabetic men. The annual per-patient excess cost of lost production due to short-term illness and permanent disability was estimated to be SEK 40,000 (US $7,000). Permanent disability among patients aged 40 to 64 years accounted for 92 percent of these costs. 3 tables, 6 references.

222

TITLE: Profiling Overweight Patients in the U.S. Navy: Health Conditions and Costs. Hoiberg, A.; McNally, M.S. *Military Medicine*. 156(2): 76-82. February 1991.

OBJECTIVE: To identify the health conditions in a sample of Navy men hospitalized in 1974 to 1984; to compare these disorders with those reported in the literature; and to examine obesity-related costs in terms of days hospitalized and career outcomes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Societal.

CONCLUSION: Conditions common among the obese patients included hypertension, alcoholism, and diabetes.

RECOMMENDATION: Assign overweight individuals to a weight reduction program at an early stage of their obesity.

ABSTRACT: Researchers studied 518 enlisted Navy men with a primary diagnosis of obesity and 1,092 Navy men with a secondary or additional diagnosis of obesity who had hospital stays in 1974 to 1984. A 10 percent sample of male Navy patients who had not been diagnosed as obese served as the comparison group. The most common diagnoses in the obese group were hypertension, alcoholism, diabetes mellitus, respiratory system symptoms, and chronic ischemic heart disease. In the comparison group, alcoholism, hernia, personality disorders, internal derangement of joint, and other cellulitis/abscess were the most common. For 20.2 percent of hospital days in the obese group, obesity was listed as the primary

diagnosis. At $200 per day, the cost of treatment over the 11-year period would have been $2,115,000. About 25 percent of separations and retirements in the obese group were attributed to a disability (primarily diabetes mellitus), to chronic ischemic heart disease, or to hypertension. According to the authors, the study supports implementation of weight reduction programs. With stricter adherence to assigning overweight personnel to weight reduction programs, they assert that the Navy Medical Department can expect to reduce costs associated with obesity-related hospitalizations and physical disability separations. 5 tables, 19 references.

223

TITLE: Social and Economic Costs of Diabetes: An Estimate for 1979. Platt, W.G.; Sudovar, S.G. Pracon Incorporated, Washington, D.C. Home Health Care Group, Ames Division, Miles Laboratories, Inc. 20 pp. 1979.

OBJECTIVE: To provide detailed estimates of the direct and indirect costs associated with diabetes mellitus in the United States in 1979.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost-of-illness.
Perspective: Societal.

CONCLUSION: The authors estimated that 8.3 million persons had diabetes in 1979 and that they generated total costs (direct and indirect) of $15.7 billion in that year.

RECOMMENDATION: None.

ABSTRACT: The authors derived cost estimates for 1979 from earlier governmental and commercial statistics. The authors estimated there were 8.26 million persons with diabetes in the United States in 1979, 1.94 million with type 1 diabetes, 2.91 million with type 2 diabetes controlled by medication, 1.62 million with type 2 diabetes controlled by diet, and 1.78 million with undiagnosed diabetes. Total costs generated by these patients were estimated at $15.7 billion. Direct economic costs accounted for 36 percent of this total, with $1.95 billion associated with short-stay hospital and nursing home costs, $3.28 billion associated with noninstitutional costs, and $0.41 billion associated with complications. Indirect costs due to morbidity, mortality, and complications were estimated to be $10.03 billion, 64 percent of total costs. Morbidity (measured in work disruption) accounted for most of the indirect costs. Total costs for the 1.94 million patients with type 1 diabetes were estimated to be $4.8 billion. Direct costs accounted for 37 percent and indirect costs for 63 percent of total costs for these patients, for whom estimated per capita costs were $2,453. 7 figures, 5 tables, 4 appendices, 10 references.

224

TITLE: The SocioEconomic Cost of Diabetic Complications in France. Triomphe, A. *Diabetic Medicine*. 8 Symposium: S30-S32. 1991.

OBJECTIVE: To measure the direct cost of diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: Average per-patient medical costs (in French francs [FFr]) in 1984 were 12,178 for type 1 diabetes and 6,908 for type 2 diabetes.

RECOMMENDATION: None.

ABSTRACT: An evaluation of the direct costs of diabetes was conducted in 1984. One hundred and nine sample patients with diabetes who resided in Paris were assessed; direct costs (e.g., home visits, laboratory tests, drugs, hospitalization, paramedical services) were analyzed. The average value (in FFr) of the total medical services used was 12,178 for patients with type 1 diabetes, 6,908 for patients with type 2 diabetes. Omitting sick leave, the figures were 7,711 for type 1 and 5,892 for type 2 diabetes; the average cost for a sample of the general French population was 6,462. The higher figure for type 1 (versus type 2 diabetes) patients was principally due to higher drug costs among type 1 patients. Hospitalization accounted for 34 percent of medical costs incurred by type 1 patients, 40 percent by type 2 diabetes patients, and 51 percent by patients in the national sample. The costs of diabetic complications were not assessed in this study because they were not well documented. Reports from the United States and Sweden indicate that hospitalization accounted for a relatively higher percentage of medical costs for patients with diabetes in those countries than in this study. 4 tables, 10 references.

225

TITLE: Structure and Costs of Health Care of Diabetic Patients in Finland. Kangas, T.; Aro, S.; Koivisto, V.A.; Salinto, M.; Laakso, M.; Reunanen, A. *Diabetes Care*. 19(5): 494-497. May 1996.

OBJECTIVE: To examine the structure and direct costs of health care for Finnish patients with drug-treated diabetes.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.

Perspective: Health care system.

CONCLUSION: Direct medical costs (including insulin) for these patients accounted for 6 percent of all health care budgets in Finland in 1989 and 13 percent of total inpatient hospital days; direct costs per patient ($3,941) were three times higher than for patients without diabetes ($1,323).

RECOMMENDATION: Treatment strategies for diabetes should emphasize high-quality ambulatory care to improve blood glucose control, thereby reducing both the personal and economic burden of this disease.

ABSTRACT: Outpatient care was evaluated by analyzing 30,266 questionnaires completed by patients with diabetes who obtained their medications through pharmacies during a 7-week period in 1989. Data on hospital inpatient care were derived by linking data from the Hospital Discharge Register covering the years 1987 to 1989 and the Central Drug Register to identification numbers assigned to each Finnish citizen. Analysis of the questionnaires showed that 31 percent of survey respondents were treated by insulin alone, 63 percent by oral medication alone, and 6 percent by a combination of the two. The mean number of physician visits for diabetes among respondents was 3.6. During the study period, patients with diabetes used an average of 1.5 million inpatient hospital days, which represented 13 percent of the total hospital days in Finland. Total direct cost of health care for patients with diabetes averaged $3,941 per year. Of this, 80.8 percent was for hospital inpatient care, 8.8 percent for diabetes medications, 8.0 percent for ambulatory care, 2.1 percent for self-care equipment, and 0.3 percent for medical rehabilitation. The value of self-care was estimated at up to 48,282 working months per year, equivalent to $980 (U.S. dollars) per patient per year; however, this cost was not included in the calculation of ambulatory costs. The direct costs of health care for patients with diabetes represented 5.8 percent of the total health care costs in Finland in 1989 and were three times higher than the average costs of care for patients without diabetes. 1 figure, 1 table, 22 references.

226

TITLE: Systematic Care of Diabetic Patients in One General Practice: How Much Does It Cost? Koperski, M. *British Journal of General Practice*. 42(362): 370-372. September 1992.

OBJECTIVE: To assess the cost of conducting a monthly health promotion session focused on diabetes within a general practice consisting of seven physicians, two trainees, and two nurses.

CATEGORY: Cost of diabetes (direct and indirect).

Type of Study: Economic assessment.
Methodology: Cost analysis.
Perspective: Health care system.

CONCLUSION: The costs of running a diabetic care day in a London general practice were

greater than remuneration.

RECOMMENDATION: An adequate remuneration package for general practitioners could improve care for many patients with diabetes.

ABSTRACT: The author analyzed the direct costs for a London, England, general practice of seven physicians, two trainees, and two nurses for monthly "diabetic days" that emphasized care of patients with diabetes. To calculate the cost of physician time, the number of targeted consultations in 1987 was multiplied by the scheduled consultation time, then divided by the total number of office hours booked for 1 year for a full-time general practitioner. The result was multiplied by £ 31,105, the average net remuneration established by the Doctors and Dentists Review Body in 1989. The hours worked by nurses and clerical staff on diabetic days were divided by the total hours worked per year, then multiplied by their annual salary plus employer's contributions. Without family health service authority reimbursement, costs for 77 patients to make a total of 117 visits on diabetic days were £ 1,340.97 for physicians, £ 1,214.93 for nurses, £ 357.66 for clerical staff, £ 41.32 for 16.8 square meters of building space, £ 45.10 for stationery, and £ 1,465.66 for dietitian and chiropodist consultation, for a total of £ 4,465.66. With family health service authority reimbursement, costs for nurses and clerical staff were reduced to £ 330.01 and £ 97.13, respectively, lowering the total cost to £ 1,854.53. Thus, the cost per patient visit was £ 38.17 to the National Health Service and £ 15.85 to the practice. Diabetic days earn a practice £ 1,080.00 annually (1991 prices) through a health promotion incentive, well below the cost to the practice surveyed. Furthermore, there is no payment for setting up these clinics. The present system encourages low-quality, low-cost care. 1 table, 18 references.

POLICY/POSITION STATEMENTS RELATED TO DIABETES

227

TITLE: American Diabetes Association Annual Meeting 1996: Managed Care and Change in Medicine. Bloomgarden, Z.T. *Diabetes Care*. 19(10): 1169-1173. October 1996.

OBJECTIVE: To review presentations at the 1996 meeting of the American Diabetes Association (ADA) about managed care and changes in health care delivery.

CATEGORY: Policy/position statement.

CONCLUSION: Various presentations at the meeting are discussed.

RECOMMENDATION: None.

ABSTRACT: At the annual meeting of the ADA, the president of the association, Frank Vinicor, asserted that the United States does not perceive diabetes to be high risk (i.e., a

transmissible disorder) or economically important. Edward Wagner, of Group Health of Puget Sound, advocated a population-based approach to diabetes care focused on preventing complications and reaching all patients. He considered it critical to define the subset of patients who need a specialist. Another speaker, Neal Friedman, advocated critical pathways for decision making, which lower inter-physician variability, increase cost efficiency, and improve outcomes. Dr. Friedman recommended using experts from other industries in the quality assurance process, as well as focus groups. He stressed data management and emphasized using the database to improve quality. His clinic in New Mexico uses disease management for the 30 most expensive diseases, which include diabetes. Also at the meeting, the potential adverse impact of managed care practices on diabetes care was addressed. Alan Jacobson, of Boston, raised the possibility that diabetes care may become similar to that of mental health disorders under managed care, with carve-out for-profit specialty companies drastically limiting patient access to specialty care. The subprograms of the Diabetes Control Network, a program that was publicized by both the Pfizer drug company and the ADA, were detailed. This program includes practice guidelines for primary physicians in managed care organizations and a computer program that models future medical costs and potential quality control strategies. Other issues addressed at the meeting included the disproportionately high use of medical resources by patients with diabetes, inadequate and variable reimbursement for preventive and self-management methods, and deficiencies in the current treatment of diabetes, particularly in screening for complications.

228

TITLE: Medicare Supplement Plan Required to Cover Diabetes. *Minnesota Medicine*. 78 (12): 40. December 1995.

OBJECTIVE: To describe a new law governing Medicare supplemental insurance plans.

CATEGORY: Policy/position statement.

CONCLUSION: The law will help the elderly afford preventive testing and management supplies they need for diabetes care.

RECOMMENDATION: Accepted standards of care ought to be covered by insurance policies.

ABSTRACT: Medicare supplemental insurance plans are now required to cover the cost of supplies and equipment necessary to treat diabetes. Previous law required only that health plans cover "all physician-prescribed, medically appropriate and necessary" equipment and supplies used to manage and treat diabetes. The change takes effect for those plans issued or renewed on or after January 1, 1996. In Minnesota, 45 percent of persons diagnosed with diabetes are aged 65 or over. According to the Minnesota chapter of the American Diabetes Association (ADA), the new law will make it easier for the elderly to afford the preventive testing and management supplies they need to control their diabetes and reduce the risk of complications. According to the chair of the government relations committee of the ADA, the new law will greatly improve access to appropriate medical care for the patient with diabetes.

229

TITLE: Budget Trends and Issues Affecting Biomedical Research: A Perspective from the National Institute of Diabetes and Digestive and Kidney Diseases. Gorden, P.; Cyphers, D.F.; Feld, C. *Hepatology*. 18(3): 677-687. September 1993.

OBJECTIVE: To review the federal budget process for research from the perspective of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK).

CATEGORY: Policy/position statement.

CONCLUSION: The federal deficit and debt and associated cost containment and cost management principles will continue to have a major impact on the National Institutes of Health (NIH) budget, limiting the size of research grants.

RECOMMENDATION: None.

ABSTRACT: The authors describe the NIH budget process and review historical developments. In the late 1980s, NIH funding became more constrained, but average grant size continued to rise; the duration of grant awards increased, and the number of applications rose. In response to congressional concerns about rising grant costs and approval rates, the NIH developed the NIH Financial Management Plan (1991). The plan limits the percentage increase in grant size to the rate of inflation, adjusts grant budgets on a case-by-case basis, and limits the length of an award to 4 years. From 1987 to 1993, the NIDDK's appropriation in constant dollars was virtually flat. The institute has become increasingly committed to investigator-initiated research and to the NIH peer review system for making funding decisions based on scientific merit. The NIDDK will need to continue to conceptualize and justify its research portfolio in terms of major cross-cutting categories of interest to the public, the administration, and Congress, such as research in the areas of prevention and women's and minority health. To the extent that the NIDDK can compete successfully for trans-NIH funds, it will increase its own funding and help its constituencies. With limited funding for grants likely to continue, other funding options will be explored: cofunding; smaller, short-term awards; a sliding-scale approach to paying grant costs; cost containment incentives; caps on salaries and other costs; and reducing indirect costs. 6 figures, 2 tables, 6 references.

230

TITLE: CDC Diabetes Control Programs — Overview of Diabetes Patient Education. Alogna, M. The *Diabetes Educator*. 10(4): 32-36, 57. Winter 1985.

OBJECTIVE: To describe the planning process for the development of diabetes patient education programs in state Diabetes Control Programs (DCPs) supported by the Centers for Disease Control (CDC).

CATEGORY: Policy/position statement.

CONCLUSION: Preliminary results from state Diabetes Control Programs show that education interventions have increased knowledge, improved self-management skills, reduced hospitalizations, and lowered costs.

RECOMMENDATION: None.

ABSTRACT: The CDC established its DCP in 20 states in 1977 on the recommendation of the National Commission on Diabetes. The goal of the DCP was to reduce mortality, morbidity, and cost burden from preventable complications of diabetes at the community level. As part of this effort, CDC collected data from participating states on mortality, morbidity, and available resources as well as problems in controlling patients with diabetes and factors contributing to those problems. These data showed a lack of outpatient education programs; in most states, inpatient education was offered at more than 80 percent of hospitals but outpatient education at less than 25 percent. Inspection of Utah programs revealed that smaller hospitals there were less likely to have written teaching plans, formal follow-up of patients, and support groups. An inquiry into education in Ohio found that simple measures such as return demonstration and repetition and preassessments and postassessments were used most frequently. The least-used evaluation methods were monitoring the number of hospital admissions or emergency room visits. The states formed a working group to develop recommendations for quality patient education and process and outcome evaluation. As a result, the CDC developed the CDC-State Patient and Professional Education Guidelines to be used in evaluating existing programs, developing new programs, promoting reimbursement, and providing a guide for program certification. The CDC guide also served as a basis for Patient Education Standards later developed by the National Diabetes Advisory Board. Numerous other materials, manuals, assessment tools, instruments, and standards of care for diabetes care and education have been developed. The author describes diabetes education activities undertaken in the individual states with a DCP. 2 tables, 6 references.

231

TITLE: Coverage of Diabetes Education Programs. Health Care Financing Administration Memorandum dated August 25, 1987. U.S. Department of Health and Human Services, Public Health Service, Health Care Financing Administration, Office of Coverage Policy, Bureau of Eligibility, Reimbursement & Coverage.

OBJECTIVE: To detail Medicare coverage of outpatient diabetes education programs.

CATEGORY: Policy/position statement.

CONCLUSION: Outpatient hospital diabetes education programs located in a hospital or rural health clinic are covered under Part B of the Medicare program. Programs must be closely related to the care and treatment of individual patients.

RECOMMENDATION: Intermediaries for Medicare should be making coverage decisions.

ABSTRACT: In this memorandum, the author, Robert E. Wren of the Health Care Financing Administration, responds to an inquiry from the Regional Administrator in Dallas, Texas, about Medicare coverage of outpatient diabetes education programs. The author notes that Section 801 of the Coverage Issues Manual provides a useful framework for intermediaries in the claims review process. He also states that outpatient hospital education programs may be covered by Medicare if services are ordered by a physician, given by the provider's personnel, supervised by the medical staff, and rendered to registered patients of that provider. The services must be closely related to the care and treatment of the individual patient and must provide essential skills and knowledge that will aid in the patient's active participation in his/her own treatment. In general, patients likely to be suitable for such education efforts would be those newly diagnosed with diabetes, persons with unstable diabetes, and those with longterm diabetes who have current management problems. Long-term patients with stable diabetes would not likely be candidates. Programs should be relatively brief, with entrance by physician referral only. A letter to David C. Warner, Chairman of the Texas Diabetes Council, is appended in which Mr. Wren goes over many of the same points.

232

TITLE: Diabetes Outpatient Education: The Evidence of Cost Savings. American Diabetes Association Task Force on Financing Quality Health Care for Persons with Diabetes. 1986. 4 pp.

OBJECTIVE: To document evidence of cost savings resulting from diabetes education; to report the existence of standards for assuring quality educational programs.

CATEGORY: Policy/position statement.

CONCLUSION: Diabetes education is now recognized as an integral component of treatment that results in cost savings and improved quality of life. The quality of an education program is assured by the existence of certification exams for educators, national standards and criteria for programs, and a recognition process for programs that meet the standards.

RECOMMENDATION: None.

ABSTRACT: This report summarizes reported evidence of cost savings achieved through diabetes outpatient education. Much of the economic cost of diabetes is due to short- and long-term complications. Outpatient education in self-care leads to improved blood glucose control, self-care skills, and adherence to treatment regimens and reduces morbidity and premature mortality associated with diabetes and its complications. A record audit of 78 consecutive community hospital admissions for complications due to diabetes found that 27 percent of these admissions occurred because of a specific educational deficit. Lack of reimbursement is the most significant barrier to the development of outpatient education programs. The American Diabetes Association, American Hospital Association, National

Diabetes Advisory Board, American Public Health Association, and the American Association of Diabetes Educators have all endorsed the concept of patient education as an integral part of diabetes treatment. Many studies on outpatient education show that these programs are clinically and cost effective. National standards for diabetes patient education programs have been developed, and a recognition process has been established for programs meeting the standards. In addition, a certification process for diabetes educators has been implemented. An increasing number of insurers are recognizing diabetes outpatient education as a reimbursable benefit. 2 tables, 23 references.

233

TITLE: Evaluative Approaches to Type II Diabetes. Triomphe, A. *PharmacoEconomics*. 8 (Supplement 1): 58-61. 1995.

OBJECTIVE: To review major methods for evaluating the economic efficiency of diabetes therapy and educational programs.

CATEGORY: Policy/position statement.

CONCLUSION: The economic evaluation of type 2 diabetes could play an important role in making management decisions about the disease. Yet, results of economic analyses should be used cautiously.

RECOMMENDATION: A more consistent application of recent methods of economic evaluations could improve understanding of the economic consequences of type 2 diabetes.

ABSTRACT: The author asserts that there are still very few economic evaluation studies on diabetes, especially type 2 diabetes. Cost-of-illness, the simplest form of economic evaluation, considers costs but not outcomes of therapy. Cost-effectiveness, cost-utility, and cost-benefit analyses are the major methods of evaluating the economic efficacy of diabetes therapy and educational programs. All three methods express costs in monetary terms, but they differ in the way they assess outcomes. In cost-effectiveness analysis, the efficiencies of interventions, treatments, or control programs are compared; and the health outcomes of the interventions are measured in physical units. Cost-utility analysis usually summarizes health outcomes in quality-adjusted life years saved. Cost-benefit analysis places a monetary value on the health outcomes of a program or therapy and can be used to compare the benefits and opportunity costs of a program. The quantity of health obtained is usually valued in terms of work productivity gained, which is generally measured by average wages. An alternative approach is to value life or health with a "willingness to pay" approach. The author notes that prevention programs are commonly held to save money over the long term, but she reports that they generally cost more than they save. She states the economic issue for discussion is not whether prevention saves money but whether it improves health at a reasonable cost. 1 table, 9 references.

234

TITLE: Improving the Financing of Diabetes Care in the 1990s: Recommendations of the 1989 Conference. Bransome, E.D. *Diabetes Care*. 15(Supplement 1): 66-72. March 1992.

OBJECTIVE: To report on the financing problems identified by the 1989 Conference on Financing the Care of Diabetes Mellitus in the 1990s and on the recommendations for action made at the conference.

CATEGORY: Policy/position statement.

CONCLUSION: Major problems evident in the financing of diabetes care include lack of an adequate chronic disease model, inadequate communication between the treatment and reimbursement communities, and absence of data demonstrating the cost-effectiveness of diabetes care.

RECOMMENDATION: Develop a health care delivery model appropriate for diabetes, establish better communication mechanisms between the diabetes and reimbursement communities, and expand the database of information pertinent to diabetes care reimbursement activity.

ABSTRACT: The author reviews problems identified by participants in a conference workshop on the financing of diabetes care as well as their recommendations to address these problems. The prevailing acute disease model is not applicable to diabetes care, which involves ongoing, mostly outpatient services. Communication between reimbursers and the diabetes community is often ineffective, with health care professionals focusing on quality of care and service delivery and insurers on cost containment. A national forum is needed to involve both parties in the reimbursement decision-making process and ensure ongoing communication. Most patients with diabetes do not receive care that meets the current standards established by the American Diabetes Association and the Centers for Disease Control (CDC). Standards of care should be reviewed and updated in a timely fashion and widely disseminated to health care professionals and reimbursers. The diabetes community should work with the Health Care Financing Administration to expand reimbursement for patient education to Medicare beneficiaries. It should also support efforts to include reimbursement costs for patient education in services provided by nonphysicians. Patients are not meaningfully involved in the reimbursement decision-making process. Informed consumers should have input along with health care professionals working to implement standards of care. Insufficient data are available to document the cost-effectiveness of diabetes care. The CDC's database on reimbursement activity should be expanded to include data on program costs, outcomes of various delivery systems, cost-effectiveness and cost-benefit studies, and health care utilization patterns. 7 references, 2 appendixes.

235

TITLE: Medical Technology and Costs of the Medicare Program. Office of Technology Assessment, U.S. Congress, Washington, DC. July 1984. 230 pp.

OBJECTIVE: To review policy mechanisms for limiting or reducing Medicare costs related to technology.

CATEGORY: Policy/position statement.

CONCLUSION: Medicare policies increase the use of medical technologies, and the use of medical technologies significantly affects Medicare costs.

RECOMMENDATION: The authors make several suggestions for restraining the rise in Medicare costs by changing the incentives for adopting and using technology.

ABSTRACT: The authors define medical technologies as the drugs, devices, and medical and surgical procedures used in medical care as well as the organizational and supportive systems in which such care is provided. Medical technology has been a primary cause of the rapid escalation in U.S. health care costs over the past 15 years. Medicare policies affect the adoption and use of medical technologies and, conversely, patterns and levels of use of Medicare technologies significantly affect Medicare costs. In this report, the Congressional Office of Technology Assessment identifies possible areas for changes in Medicare policies that could be used to influence the adoption and use of medical technology and to restrain Medicare costs: coverage policy for specific technologies, methods of payment to hospitals, methods of payment to physicians, and approaches to changing the incentives for adopting and using technology that do not directly involve the Medicare payment system (e.g., alternative delivery systems). Efforts to curb the escalation in Medicare costs and control the diffusion of medical technology have been largely ineffective to date. There are numerous incentives in Medicare's benefit policy to provide too many of some kinds of technologies and too few of others. The authors note Medicare's policy of not explicitly considering cost or cost-effectiveness in making coverage decisions; Medicare also has refrained from limiting coverage of particular technologies to specific institutions or to physicians with specific skills. 29 tables, 3 figures, 5 appendices, 437 references.

236

TITLE: The National Long-Range Plan to Combat Diabetes, 1987. National Diabetes Advisory Board, U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health. Washington, DC, 1987. 76 pp.

OBJECTIVE: To set forth a long-range plan to combat diabetes mellitus that includes research, national goals, the translation of research findings to patient care, a review of accomplishments and future directions, and the role of the private sector.

CATEGORY: Policy/position statement.

CONCLUSION: None.

RECOMMENDATION: Numerous recommendations are set forth in the body of the report.

ABSTRACT: The National Diabetes Advisory Board, whose members (scientists, physicians, other health professionals, members of the general public) are appointed by the Secretary, Department of Health and Human Services, set forth recommendations in research, patient care, and other areas. In research, the Board recommended the development of eight interdisciplinary research programs, a biologic resource bank for studies on diabetes, and an information and data system for *Diabetes Research*. The objective of the interdisciplinary programs is to promote the rapid integration of newly developed methodologies of the basic sciences into diabetes-related research. Various recommendations are made to continue and strengthen current programs: for example, the Board recommended that adequate funds be appropriated to institutes of the National Institutes of Health to support at least 50 percent of approved diabetes-related, competing, individual research grants at budget levels approved by the scientific review committees; it is also recommended that the National Institute of Diabetes and Digestive and Kidney Diseases receive adequate funding to complete the Diabetes Control and Complications Trial as planned. In the section on diabetes goals for the nation, the Board recommended that consensus be reached on treatment guidelines for the diabetes patient without complications and that guidelines for the management of patients with complications be developed. In diabetes translation, the Board recommended that a Diabetes Translation Center be established at the Centers for Disease Control. In the section on the private sector, the Board recommended that this sector increase financial and human participation in *Diabetes Research*.

237

TITLE: National Standards and Review Criteria for Diabetes Patient Education Programs: Quality Assurance for Diabetes Patient Education. National Diabetes Advisory Board. *Diabetes Educator*. 12(3): 286-291. Summer 1986.

OBJECTIVE: To define the standards and review criteria for a diabetes patient education program.

CATEGORY: Policy/position statement.

CONCLUSION: None.

RECOMMENDATION: None.

ABSTRACT: Ten standards developed under the aegis of the National Diabetes Advisory Board and endorsed by the diabetes community are presented. (1) Needs assessment: This activity should guide program management and form the basis for program planning. (2) Planning: The planning process should describe the program's goals and objectives, target audience, setting, referral mechanisms, procedures, and evaluation methods. (3) Program management: The ultimate responsibility should lie with the designated program coordinator. (4) Communications/coordination: A physician should act as liaison between the medical staff

and the program coordinator. (5) Patient access to teaching: Both patients and staff should be routinely informed about self-care programs. (6) Content/curriculum: The individual needs assessment provides the basis for a patient's instructional program. (7) Instructor: Instructors should be skilled professionals with recent experience and training in diabetes and educational principles. (8) Follow-up: Written communication between program staff and primary physicians is essential for identifying the patient's needs. (9) Evaluation: Review should be conducted by an advisory committee made up of at least one of each of the following: physician, nurse (or qualified diabetes health educator), dietitian, consumer, and the patient education program coordinator. (10) Documentation: All information about the patient's educational experience should be documented in the patient's permanent medical or educational record.

238

TITLE: New Approaches to Medical Technology Coverage: Conference Proceedings. Miller, J.E. Health Insurance Association of America. 48 pp. April 1991.

OBJECTIVE: To provide a synopsis of the proceedings of a 1990 conference on medical technology coverage sponsored by the Health Insurance Association of America.

CATEGORY: Policy/position statement.

CONCLUSION: Insurers must try to balance cost control, resource utilization, and quality of care as they make coverage and payment decisions.

RECOMMENDATION: Insurers must develop the will and ability to adapt to pressures for faster and more open coverage processes.

ABSTRACT: The author synopsizes the proceedings of the 1990 conference "New Approaches to Medical Technology Coverage" sponsored by the Health Insurance Association of America. Topics included the ethics of technology assessment, insurance coverage issues and innovative approaches to coverage decisions, law and policy, evaluating the clinical effectiveness of screening tests, designation of qualified centers for specialized services, and methodologies and applications of quality assessment. The controversy surrounding the development and use of medical practice guidelines was debated, with opinions offered by representatives of the medical and insurance communities. The issue of coverage policy relative to a technology's cost-effectiveness was also addressed. Cost-benefit and cost-analysis data were noted to be inadequate in many areas of health care, and it was suggested that such studies be conducted not only by the government but also by companies seeking to market new drugs and technologies.

239

TITLE: Office Visits for Diabetes Mellitus: United States, 1989. Schappert, S.M. *Advance Data from Vital and Health Statistics of the National Center for Health Statistics*; No. 211.

12 pp. March 24, 1992.

OBJECTIVE: To present national estimates of diabetes-related office visits in the United States in 1989.

CATEGORY: Policy/position statement.

CONCLUSION: During the study period, there were an estimated 13.2 million visits to nonfederally-employed, office-based physicians in the United States in which the principal diagnosis was diabetes mellitus.

RECOMMENDATION: None.

ABSTRACT: The author reports on estimates of diabetes-related office visits in the United States for the 12-month period of March 1989 to March 1990. Data were derived from the National Ambulatory Medical Care Survey. During the study period, there were an estimated 13.2 million visits made to nonfederally-employed, office-based physicians at which the principal (first-listed) diagnosis was diabetes mellitus. More than half (57.5 percent) of these visits were made by females, and 86.3 percent were made by persons aged 45 years and older; 79.3 percent of visits were made by white persons. Forty-four percent of visits were made to general or family practice physicians. Internal medicine specialists received 28.7 percent of visits, and ophthalmologists received 6.8 percent. Patients making return visits to the physician for care of their condition accounted for 92.2 percent of the 13.2 million office visits. During the study period, diabetes mellitus was the second- or third-listed diagnosis for an additional 8.7 million office visits. For all office visits in 1989, diabetes mellitus was the seventh most frequently reported principal diagnosis but the fourth most frequently reported morbidity-related principal diagnosis (essential hypertension, otitis media, and acute upper respiratory infections were the first three). Approximately 72 percent of visits with a principal diagnosis of diabetes mellitus included a blood pressure check; other frequently performed diagnostic services on these visits included "other" blood tests, urinalysis, cholesterol measure, and visual acuity examination. Weight reduction was the most frequently reported type of counseling/advice ordered or provided. 3 figures, 18 tables, 7 references, 1 technical note with 3 tables.

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TITLE: Practice Guidelines for Nutrition Care by Dietetics Practitioners for Outpatients with Non-Insulin-Dependent Diabetes Mellitus: Consensus Statement. Franz, M.J. *Journal of the American Dietetic Association*. 92(9): 11361139. September 1992.

OBJECTIVE: To present practice guidelines for nutrition care to dietetic practitioners who treat outpatients with type 2 diabetes.

CATEGORY: Policy/position statement.

CONCLUSION: Nutrition practice guidelines provide a road map for nutrition care that

allows for consistency in the individualized care of people with type 2 diabetes.

RECOMMENDATION: Patients with type 2 diabetes should be referred to a registered dietitian within the first month after diagnosis, with a follow-up visit at two to four weeks and semiannual or annual visits thereafter. Physicians should supply the registered dietitian with information on diagnosis, treatment modalities and response to date, laboratory values, medical clearance or limitations for exercise, and, if appropriate, psychological or economic data.

ABSTRACT: The American Dietetic Association contracted with the International Diabetes Center (IDC) in Minneapolis, Minnesota, to develop, fieldtest, and evaluate nutrition care practice guidelines. This article is the report of an interdisciplinary consensus panel of experts chaired by the IDC's M.J. Franz, which met in Minneapolis in October 1991. The panel was charged with addressing several critical questions: (1) What are realistic outpatient nutrition care practice guidelines for persons with type 2 diabetes? (2) What decisions are the responsibility of the physician? Of the registered dietitian? (3) What are the expected outcomes related to the nutrition practice guidelines? (4) What is usual nutrition care in the United States for persons with type 2 diabetes? The panel concluded that registered dietitians should determine an appropriate diet prescription for the patient and select appropriate educational materials and interventions. It was determined that two-way communication between the physician and the registered dietitian is critical and that medical outcomes should be evaluated to determine the effectiveness and cost of treatment. Implementing therapeutic advice is important for patients, but how patients view their quality of life may be equally important. In evaluating usual nutrition care in the United States for persons with type 2 diabetes, the panel found that initial nutrition information is provided by the physician, nurse, or registered dietitian. Physicians may spend approximately five minutes handing out diet sheets, but they solicit little if any information from patients about convenience or their ability to follow the meal plan. Another frequent option is for the nurse to spend 10 to 20 minutes providing initial nutrition information. In a 1989-1990 physician survey conducted by the National Institute of Diabetes and Digestive and Kidney Diseases, a majority of respondents said they referred patients with type 2 diabetes to registered dietitians, but it is not known how may patients actually see a dietitian. 17 references.

241

TITLE: Practice Guidelines for Nutrition Care by Dietetics Practitioners for Outpatients with Non-Insulin-Dependent Diabetes Mellitus: Methodologies for Field Testing and Cost Effectiveness Analysis. Mazze, R.S.; Franz, M.J.; Monk, A.; Cooper, N.; Barry, B.; Weaver, T.; McClain, K.; Upham, P.; Haugen, D.; Bergenstal, R. *Journal of the American Dietetic Association*. 92(9): 11391142. September 1992.

OBJECTIVE: To describe a clinical study designed to assess the impact of nutrition care on persons with type 2 diabetes.

CATEGORY: Policy/position statement.

CONCLUSION: The study is expected to yield information that will help physicians and dietitians better understand the nature of nutrition care in diabetes management. Designing and implementing the nutrition protocols has already yielded important information, such as a consensus as to what is meant by basic and intensive nutrition care for people with type 2 diabetes.

RECOMMENDATION: This study design may serve as a model for the study of the effectiveness and cost-effectiveness of nutrition care for other diseases and conditions.

ABSTRACT: A 2year clinical study has been designed to test three hypotheses for persons with type 2 diabetes treated in an ambulatory setting with either basic nutrition care or care based on practice guidelines determined by expert consensus. The hypotheses are that nutrition care based on practice guidelines will significantly lower blood glucose levels, will significantly improve abnormal lipid profiles, and will significantly control weight in obese patients; in each case, the change is to be within three months, with a requirement for stabilization or further improvement over the next three months. The study will include 240 patients diagnosed with type 2 diabetes and free of diabetes complications (e.g., nephropathy), who were recruited from ambulatory clinical sites in three states and randomly assigned to either basic nutrition care or care based on the guidelines. The patients will be between the ages of 40 and 70 years, must be able to attend the clinics as required by the protocol, and be willing to follow either the basic or practice guideline care regimen. Patients will be evaluated at study enrollment, at three months, and at six months. Data will be collected for biophysical measures (e.g., blood glucose, body mass index), behavior/education (e.g., compliance, knowledge), and cost. Records will be kept of adverse events (e.g., coma, infections). A cost analysis of the two interventions will document the costs for labor, administrative overhead, supplies, and medications related to direct service delivery and outpatient treatment. Rigorous documentation of effects and careful cost documentation will permit a cost-effectiveness analysis to be performed. 1 figure, 35 references.

242

TITLE: Preventive Health Services for Medicare Beneficiaries: Policy and Research Issues. Washington, DC: Office of Technology Assessment, United States Congress. February 1990. 37 pp.

OBJECTIVE: To examine the process that dictates the coverage and delivery of preventive services for Medicare beneficiaries.

CATEGORY: Policy/position statement.

CONCLUSION: None.

RECOMMENDATION: Consideration should be given to funding extended follow-up periods at some of the sites for federal demonstration projects on the costs and effectiveness of providing preventive health services under Medicare. Effectiveness research should be

targeted to services offering the potential for large impacts on health status or health costs of the elderly.

ABSTRACT: Vaccines for pneumococcal pneumonia and hepatitis B, screening, mammography, and Pap smears are the only preventive services covered by Medicare. The wisdom of excluding preventive services has been questioned by numerous experts and interested groups. The authors point out that some procedures performed for screening purposes (e.g., lower GI endoscopy) may be paid by Medicare as diagnostic procedures, and tertiary preventive services (e.g., hypertension control) may be reimbursable as therapeutic services. In addition, Medicare beneficiaries enrolled in health maintenance organizations or other competitive medical plans may receive extra preventive care. The authors note several reasons why Medicare coverage of a preventive service may not be enough to bring about appropriate use patterns; consumer, physician, and service characteristics may be more important than out-of-pocket costs. The current strategy for adding preventive services is ad hoc and procedure-specific; formulation of a complete strategy requires choices in the unit of payment (individual procedures versus a service package), criteria to govern the coverage decision and standards for evidence (possible criteria include effectiveness, cost-effectiveness, impact on Medicare outlays, and net economic benefits), and locus of responsibility for coverage decisions. The authors discuss several issues relating to the evaluation of evidence on the cost-effectiveness of preventive services for the elderly and note that the Health Care Financing Administration is supporting six demonstration projects whose goals are to assess the costs and effectiveness of providing health services under Medicare. They cite problems (e.g., design and funding) in the studies and predict that the evidence they produce will be limited. Appendices A-D cover acknowledgments, Office of Technology studies in preventive services for the elderly, Medicare preventive services demonstration projects, and recommendations for periodic health examinations in the elderly. 6 tables (1 in main text, 5 in appendices), 4 appendices, 101 references.

243

TITLE: Preventive Services. United States Department of Health and Human Services, Public Health Service, Health Care Financing Administration. In: *State Medicaid Manual*. Part 4: Services. Transmittal No. 41. February 1989. 4 pp.

OBJECTIVE: To provide guidelines on optional coverage of preventive services under Medicaid.

CATEGORY: Policy/position statement.

CONCLUSION: Increased use of preventive services offers the potential for improving individual health and reducing the cost of treating illness and injury.

RECOMMENDATION: States should consider reviewing their Medicaid programs for ways to make a wider range of preventive services available and accessible to their Medicaid beneficiaries.

ABSTRACT: In addition to including preventive care as part of other covered services, each state may cover preventive care as a separate benefit under its Medicaid program. For a Medicaid service to be covered, it must involve direct patient care and be for the express purpose of diagnosing, treating, or preventing (or minimizing the adverse effects of) illness, injury, or other impairments to an individual's physical or mental health. Often, a state may have a wide range of preventive services available, but the services are fragmented among numerous agencies and programs in addition to Medicaid. States interested in initiating or expanding a Medicaid preventive care effort can take a two-pronged approach: (1) Medicaid funding of medically oriented personal preventive services for which federal financial participation is available under Title XIX; and (2) increased coordination between Medicaid and other programs that fund or provide preventive care, including referral to social and environmental programs and services. In evaluating amendments to state plans for providing preventive services, the Health Care Financing Administration requires that the proposed services be preventive and fit within the basic Medicaid medical-remedial framework, be directed at the patient, not be otherwise available without cost, not duplicate other federally funded services, and not entail additional payment for a service that is logically a part of otherwise covered services (e.g., a physician providing preventive counseling). Regarding coordination with other programs, the Medicaid agency can perform a valuable referral function and help to supplement available preventive services by directing beneficiaries to appropriate preventive care (e.g., examinations, immunization and treatment services) available from other sources.

244

TITLE: Public Health Focus: Physical Activity and the Prevention of Coronary Heart Disease. Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report (MMWR)*. 42(35): 669-672. September 10, 1993.

OBJECTIVE: To summarize information on the potential efficacy and cost benefit of promoting physical activity as a way to prevent coronary heart disease.

CATEGORY: Policy/position statement.

CONCLUSION: Educating health professionals and lay persons to implement effective ways of reducing risk factors for coronary heart disease could reduce health care costs substantially.

RECOMMENDATION: Sites that promote physical activity should emphasize participation in a variety of self-directed, moderate-level physical activities with a goal of 30 minutes of participation a day for 5 days a week.

ABSTRACT: Coronary heart disease is the leading cause of mortality in the United States; each year 1.5 million people are diagnosed with this disorder, whose direct and indirect heath care costs are estimated at $47 billion. A 1987 review of 43 epidemiologic studies concluded that moderate to vigorous physical activity reduced coronary heart disease. The risk for coronary heart disease was almost doubled for persons who were physically inactive. Based

on 1989 mortality estimates for coronary heart disease, the extrapolated cost of physical inactivity was $5.7 billion, with elevated serum cholesterol the only risk factor for coronary heart disease having a higher estimated cost. In an analysis using hypothetical cohorts over a 30-year period, physical activity was associated with 78 fewer coronary heart disease events and 1,138 quality-adjusted life-years gained. For each quality-adjusted life-year gained, direct cost equals $1,395 and total costs, $11,313. Worksite-based physical activity programs have been estimated to cost employers $100 to $400 per employee per year, but they return an estimated $513 per employee per year. A Canadian intervention program reduced medical claims $6.85 per year for each dollar invested. Annually, in the United States, 20,000 fewer people would die if half the persons with no leisure-time physical activity engaged in moderate physical activity two to three times per week. Physical activity may prevent coronary heart disease by improving weight control, enhancing glucose tolerance and insulin sensitivity, reducing blood pressure, improving coronary artery blood flow, and augmenting high-density lipoprotein levels. Educating health professionals and lay persons to implement effective ways to reduce risk factors for coronary heart disease could result in substantially reduced health care costs. In addition to worksite programs, physical activity programs have been promoted in the schools, community, physician offices, health clinics, homes, and neighborhoods. 2 tables, 16references.

245

TITLE: Public Health Focus: Prevention of Blind-ness Associated with Retinopathy. Division of Diabetes Translation, National Center for Chronic Disease Prevention and Health Promotion, Centers for Disease Control and Prevention. *Morbidity and Mortality Weekly Report (MMWR)*. 42(10): 191-195. March 19, 1993.

OBJECTIVE: To summarize information on the efficacy and cost-effectiveness of screening for retinopathy.

CATEGORY: Policy/position statement.

CONCLUSION: (from editorial note) Screening for retinopathy is effective for preventing blindness and is cost effective.

RECOMMENDATION: (from editorial note) Improvement must be made in the timeliness of screening, case-finding, and entry into the health care system of persons with diabetes. All persons with diabetes (except those with type 1 diabetes for less than 5 years) should receive an annual dilated eye examination by a trained provider with appropriate referral and treatment.

ABSTRACT: Studies of the efficacy and cost-effectiveness of screening for retinopathy are reviewed. More than 90 percent of persons with type 1 diabetes have some retinopathy 15 years after diagnosis; 90 percent of persons with type 2 diabetes who are treated with insulin have some retinopathy 25 years after diagnosis. Among type 2 patients not treated with insulin, more than 60 percent have some retinopathy after 20 years. Prospective clinical trials have shown that laser photocoagulation therapy is effective in reducing the risk of visual

impairment. Panretinal laser photocoagulation can reduce the risk of severe visual loss by at least 60 percent in some patients with diabetes. An annual eye examination can identify retinopathy early and permit timely treatment to prevent loss of vision and possible blindness; in a retinal study, however, half of diabetes patients had not had a dilated eye examination in the preceding year. Economic evaluations indicate that screening for retinopathy costs less than the cost of 1 person-year of blindness. A study by Dasbach et al. (1991) showed that biannual and annual screening programs for persons with type 1 and type 2 diabetes were cost effective. A study by Javitt et al. (1990) evaluated the cost-effectiveness of different screening protocols for retinopathy in patients with type 1 diabetes; the various strategies were estimated to save $62 million to $109 million and 71,000 to 85,000 sight years annually in the United States. 2 figures, 1 table, 14 references.

246

TITLE: Rediagnosing Health Care: Providers' Perspectives. Shortridge, C.L. *Diabetes Care*. 17(3): 248250. March 1994.

OBJECTIVE: To provide an overview of the Health Security Act unveiled by President Clinton in October 1993 and to discuss the potential health care implications of this plan should it be enacted.

CATEGORY: Policy/position statement.

CONCLUSION: The American Diabetes Association supports health care reform, but the specifics of the Health Security Act give concern to many physicians who treat patients with diabetes.

RECOMMENDATION: As this and other health care plans are circulated through Congress, concerns raised by the medical community (e.g., ease of referral to specialists in the treatment of diabetes, effective preventive services for people with diabetes) must be considered.

ABSTRACT: If passed, President Clinton's 1993 Health Security Act would create a national managed competition system with health alliances, which would be similar to health maintenance organizations and preferred provider organizations. Some physicians fear that this system will hurt private practice, restrict access to specialists, and impair freedom of choice. The Health Security Act establishes a seven member National Health Board that would oversee the health care system, which would be composed of regional or corporate health alliances or state run, single-payer systems. Regardless of which system a state chooses, a comprehensive benefits package will be offered. The American Diabetes Association is committed to ensuring that the plan's basic benefits package includes access to appropriate diabetes treatment and management. Physicians in a health alliance will be paid by the alliance, and those in a single-payer system will be reimbursed by the state. Provider fees will be set by the alliance or by the state. Physicians may choose to join the health alliance or single-payer system in their state or remain outside the system in private practice. The only way patients can access a provider in private practice, however, is to pay for the visit themselves. The plan

will establish programs to retrain some specialists as primary care physicians. The plan will also guarantee that 55 percent of medical students enter residencies in family medicine, general internal medicine, general pediatrics, or obstetrics and gynecology. To further deter specialization, the plan will determine the number of specialty slots nationwide available for enrollment in medical education programs.

247

TITLE: Resource Manual to Help Your Program Meet the National Standards. Teza, S.L.; DeVito, A.V. II; Hiss, R.G. *Diabetes Educator*. 13 Supplement: 210-228. May 1987.

OBJECTIVE: To provide advice on developing or improving diabetes education programs; to give specific suggestions on ways to meet the National Standards for Diabetes Patient Education Programs.

CATEGORY: Policy/position statement.

CONCLUSION: Specific suggestions are provided for establishing, organizing, implementing, and evaluating education programs for patients with diabetes.

RECOMMENDATION: These program suggestions should be considered by diabetes educators in developing and evaluating their patient programs.

ABSTRACT: The authors first discuss needs assessment standards, which involve evaluating the need for diabetes education in the area served by a given institution and the educational needs of persons with diabetes. The planning phase of a diabetes education program is then detailed, including methods of establishing policy, the development and role of an advisory committee, and the steps involved in actual program planning. Program management is then discussed, including the role of the program coordinator, organizational relationships, and budgeting. The fourth section examines communication/coordination, the use of physician liaisons, educational teams, and education records and provides sample education records. The fifth through tenth sections deal with patient access to teaching, content/curriculum, instructors, follow-up, evaluation, and documentation. A glossary of terminology and a collection of abstracts relating to diabetes education programs are included. Also included are the National Standards for Diabetes Patient Education Programs, which were developed under the aegis of the National Diabetes Advisory Board and have been endorsed by the diabetes community. 6 figures, 16 tables, 1 glossary.

248

TITLE: Screening for Diabetes Mellitus. U.S. Preventive Services Task Force. In: *Guide to Clinical Preventive Services: An Assessment of the Effectiveness of 169 Interventions*. Baltimore: Williams & Wilkins. 1989. pp. 95-103.

OBJECTIVE: To assess the appropriateness of screening for diabetes mellitus in the U.S.

population.

CATEGORY: Policy/position statement.

CONCLUSION: Screening for diabetes mellitus has not been proven sufficiently beneficial in nonpregnant, asymptomatic individuals to warrant widespread use.

RECOMMENDATION: An oral glucose tolerance test is recommended for pregnant women between gestational weeks 24 and 28, but routine plasma or urine glucose screening in other asymptomatic persons is not recommended except possibly for people at high risk for diabetes.

ABSTRACT: The authors discussed screening for diabetes mellitus in the population at large. As there are large intra- and interindividual variations in glucose measurements in healthy individuals and those with impaired glucose tolerance or diabetes, complex criteria involving multiple measurements are needed for a definitive diagnosis. Fasting blood glucose is an accurate test, but fasting is inconvenient, and, in some cases, sensitivity has been poor. Postprandial blood glucose is more convenient, but the time limitations for collecting blood makes it difficult to use for screening. The oral glucose tolerance test (GTT) is expensive and inconvenient because of the requirement for multiple venipunctures over several hours. A half-dose oral GTT for pregnant women has 83 percent of the sensitivity and 87 percent of the specificity of the full-dose GTT; for every true positive case of gestational diabetes identified, 5 false positives are found. Urine glucose testing is considered unreliable with a sensitivity of less than 30 percent. Evidence is conflicting about the benefit of early detection and treatment impaired glucose tolerance; most people do not develop diabetes even without treatment. Data on the effect of early glycemia regulation on the subsequent development and progression of complications from diabetes are also conflicting. Studies have shown benefit to mother and child of glycemic control during pregnancy, although the influences of good prenatal care on outcome could not be assessed. An oral GTT is recommended for pregnant women between gestational weeks 24 and 28, but routine plasma or urine glucose screening in other asymptomatic persons is not recommended, except possibly for people at high risk for diabetes. 79 references.

249

TITLE: Source Book of Health Insurance Data 1991. Health Insurance Association of America. Washington, DC. 1991. 135 pp.

OBJECTIVE: To provide a basic reference tool for private health insurance in the United States.

CATEGORY: Policy/position statement.

CONCLUSION: None.

RECOMMENDATION: None.

ABSTRACT: The authors describe the role and function of health insurance (chapter 1) and review the private health insurance industry (chapter 2). Succeeding chapters discuss public health coverage — expenditures and enrollment; medical care costs; health services, resources, and utilization; and disability, morbidity, and mortality. Brief sections cover "health and health care acronyms" and "historical facts." An extensive glossary is included. The report contains tables on a wide variety of topics, including coverage, premiums, health maintenance organization enrollment, Medicare enrollment, national health expenditures, hospital utilization, disability days, and many others. Data in the book were obtained from reports of insurance companies, government agencies, hospital and medical associations, and other health insurance plans. The book has been published annually by the Health Insurance Association of America since 1960. 67 tables.

250

TITLE: Third Party Coverage for Diabetes Education Program. Schwartz, R.; Zaremba M.; Ra, K. *Quarterly Review Bulletin*. 11(7): 213-217. July 1985.

OBJECTIVE: To review the Ambulatory Diabetes Education and Follow-up Program in Maine and its efforts to acquire third party reimbursement.

CATEGORY: Policy/position statement.

CONCLUSION: The Maine Diabetes Control Project has successfully obtained third party reimbursement for a diabetes education program, first as a demonstration project, then on the basis of a study that revealed its economic benefit.

RECOMMENDATION: Health education programs seeking reimbursement are encouraged to keep up with existing literature and Medicare and Medicaid regulations, ensure representation from third party payers, and prepare a cost-benefit analysis.

ABSTRACT: Under an agreement with the Centers for Disease Control, Maine's Department of Human Services developed the Ambulatory Diabetes Education and Follow-up Program by working with area physicians to identify individuals with diabetes, interviewing the patients to assess their level of knowledge and attitudes about diabetes, and enrolling individuals and family/friends into group education classes and individual diet counseling. The curriculum (five classes plus a one-to-one dietary counseling session) covered an introduction to diabetes, testing and hyperglycemia, meal planning, medications and hypoglycemia, and "general factors" such as foot care, smoking, and publications and associations. In 1980, major third party payers agreed to reimburse hospitals or rural health centers in the state for this program if participants were referred by a physician, had an individualized education plan, had records maintained for them, and if the program met state guidelines. A follow-up study for January 1981 through June 1982 found that the number of hospitalizations and length of stay were both reduced 32.2 percent, with a gross savings of $359,835. Participation in the program cost $150 per participant and resulted in a net savings of $293 per patient. Blue Cross-Blue Shield of Maine, Medicare, and Medicaid have continued to reimburse the program, which the

parent Diabetes Control Project oversees to ensure its quality and to keep insurers informed of institutions that are participating. The authors suggest that those seeking third party coverage become familiar with existing literature and with Medicare and Medicaid regulations, solicit representation from third party payers at the project's beginning, prepare a cost-benefit analysis, form a committee of various entities (e.g., Blue Cross-Blue Shield, the hospital association) that might endorse the project's efforts to get reimbursement, and gain and maintain physician support. 2 figures.

251

TITLE: Third Party Reimbursement for Outpatient Diabetes Education and Counseling. American Diabetes Association. *Diabetes Care*. 13 (Supplement 1): S36. January 1990.

OBJECTIVE: To articulate the position of the American Diabetes Association on reimbursement for outpatient education programs for patients with diabetes. (Note: This position statement was superseded by "Third Party Reimbursement for Diabetes Care, Self-Management Education, and Supplies." *Diabetes Care*. 19 (Supplement 1): S48. January 1996.)

CATEGORY: Policy/position statement.

CONCLUSION: Not making outpatient education a covered benefit is a major barrier to its availability and accessibility.

RECOMMENDATION: The American Diabetes Association strongly supports and encourages adequate reimbursement and payment for those outpatient education services for patients with diabetes that meet accepted standards.

ABSTRACT: Complications for patients with diabetes cost about $20 billion in 1987. Many studies have shown that education and self-management programs reduce costs of diabetes. Continuing patient education for self-management is integral to diabetes treatment, and all people with diabetes should have access to affordable patient education. National standards and a quality assurance program are already in place. The major barrier to patient education services is the lack of reimbursement by insurers and health care financing plans. 10 references.

252

TITLE: Worksheet to Estimate Program Costs and Savings. Hunt, C. *Diabetes Educator*. 16 (4): 282283. July-August 1990.

OBJECTIVE: To provide a worksheet that clinicians can use to estimate program costs and net cost savings for diabetes outpatient education programs.

CATEGORY: Policy/position statement.

CONCLUSION: None.

RECOMMENDATION: None.

ABSTRACT: A worksheet used by Pennsylvania diabetes outpatient education programs to assist them in their dialogue with third party payers is presented. According to Barbara Bodnar, diabetes nurse consultant with the Pennsylvania Department of Health, pilot studies have documented a one-third reduction in inpatient hospital usage attributable to diabetes outpatient education programs. The worksheet has three distinct sections: inpatient costs, program costs, and net cost savings (estimated). Users of this worksheet simply input numerical data as outlined in the instructions. Upon reaching the end of the worksheet, users will have an estimate of the net savings to their hospital/clinic from the diabetes outpatient education program. A 30 percent figure is used in the worksheet for the reduction in hospital costs from diabetes patient education.

EXPERT OPINION

253

TITLE: Access to Coverage: Health Insurance for People With Diabetes. Bransome Jr., E.D. *Diabetes Spectrum*. 1(1): 5962. March-April 1988.

OBJECTIVE: To review progress made in health insurance coverage following the 1984 Conference on Financing Quality Health Care for Persons with Diabetes.

CATEGORY: Expert opinion.

CONCLUSION: The diabetes community has made some progress in influencing coverage decisions by the reimbursement community, but much more still needs to be done.

RECOMMENDATION: Since many coverage decisions are made locally, data collection and advocacy are needed at that level. The involvement of government relations, public policy, and advocacy committees of the American Diabetes Association affiliates is needed.

ABSTRACT: The author provides an update of accomplishments and work still to be done in each of the topic areas for the 1984 Conference on Financing Quality Health Care for Persons with Diabetes. He notes that the American Diabetes Association (ADA) estimated that 5 to 8 percent of all persons with diabetes (i.e., 550,000 to 880,000 persons) have no health insurance. He discusses legislation under consideration that would encourage states to establish health insurance risk pools. The author notes that reimbursement for patient education is usually not covered by third parties despite agreement that it is integral to care and evidence that it reduces hospitalizations. He reviews efforts by the diabetes community to justify coverage for outpatient education and notes that the Health Care Financing

Administration (HCFA) issued a memorandum to a regional administrator that outpatient hospital and rural health education should be reimbursed under Part B of Medicare. The author points out that Medicare is still not paying for teaching programs except those based in hospitals or rural health clinics. He reports that the American Diabetes Association has begun discussions with HCFA about covering free-standing programs that are the sole educational programs in a community. The author also notes that preconference surveys found that important durable equipment and supplies were frequently not covered. He reports that the ADA has begun discussions with HCFA about broadening Medicare coverage to all people with diabetes who require insulin. In addition, the Office of Health Technology Assessment is reviewing continuous subcutaneous insulin infusion pumps, whose purchase is not covered by Medicare. 1 figure, 1 table, 9 references.

254

TITLE: Ambulatory Medical Care for Diabetes. Janes, G.R. In: *Diabetes in America*. 2d ed. National Diabetes Data Group, ed. National Institute of Diabetes and Digestive and Kidney Diseases. NIH Publication No. 95-1468. 1995: 541-552.

OBJECTIVE: To review survey data on ambulatory care for persons with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Patients with diabetes account for a disproportionate amount of ambulatory care services.

RECOMMENDATION: None.

ABSTRACT: The author assessed data from the National Health Interview Survey (NHIS); National Ambulatory Medical Care Survey (NAMCS), which samples office-based physicians; and the National Medical Expenditure Survey concerning the impact of diabetes on the ambulatory medical care system. Per the 1990 NHIS, persons with diabetes accessed ambulatory care 96.1 million times, averaging 15.5 visits per person, compared with 5.5 visits per person in the general population. Rates were somewhat higher for women than men and for whites versus blacks. Per the NAMCS for 1981 and 1985, diabetes ranked second (excluding well-baby and pregnancy visits) to hypertension among frequently cited principal diagnoses associated with the patient's primary complaint during return office visits (for 1989 and 1990 it ranked third after these exclusions). Between 1981 and 1990, the number of visits by persons with diabetes to an office-based physician increased 44 percent, versus an increase of 20 percent in the population at large. According to the 1990 NHIS, 96 percent of patients with diabetes indicated that as an inpatient or outpatient they had seen or talked with a physician or an assistant within the past year. Patients with type 2 diabetes saw a physician more frequently than those with type 1 diabetes; frequency of visits increased with age. Per NAMCS, in 1990-1991, only 8 percent of visits by patients with diabetes were made to a specialist in diabetes/endocrinology; in the 1989 NHIS, fewer than 50 percent of patients recalled seeing an ophthalmologist in the previous year, only 21 percent a dietitian/nutritionist, and only 17 percent a podiatrist. Mean length of physician visits (per NAMCS) for diabetes

increased from 15.3 minutes in 1981 to 17.5 minutes in 1990. The percentage of visits paid for by patients decreased from 1985 to 1990, while the percentage paid by Medicare and commercial insurance (other than Blue Cross-Blue Shield) increased. 6 figures, 13 tables, 2 appendices, 12 references.

255

TITLE: Ambulatory Nutrition Care: Adults-Diabetes Mellitus. Disbrow, D.D. VIII. *Journal of the American Dietetic Association*. 89(4):S35-S39. April 1989.

OBJECTIVE: To describe through a literature review the economics, benefits, and costs of diabetes education programs.

CATEGORY: Expert opinion.

CONCLUSION: Evaluations of structured programs to provide diabetes education in outpatient settings have found improved clinical outcomes and cost savings from reduced use of health services.

RECOMMENDATION: The cost of various nutrition services for patients with diabetes is very important information to provide to third party payers; dietitians need to report the costs of services provided.

ABSTRACT: The author summarizes economic, benefit, and cost analyses of diabetes education programs. Reported costs per patient for outpatient diabetes education programs have ranged from $100 to $770. The North Dakota Diabetes Education Program (1982) was found by Blue Cross of North Dakota to be cost-saving; in 1985, Medicare and 18 insurance companies agreed to cover the service. Programs in Maine and Rhode Island and at Grady Memorial Hospital in Atlanta were also found to be cost-saving. A meta-analysis of 47 studies found that diabetes education had a moderate effect on all outcomes examined. The research suggests that opportunities for frequent contact and reinforcing the education principles over a long time have the greatest impact. The author states that there is considerable evidence that large savings in health dollars can be achieved by delivering diabetes education programs in the outpatient setting rather than during hospitalizations, but she points out that the validity of the research results has been questioned. Kaplan and Davis (1986) criticized reports used to support the resolution of the American Diabetes Association for third party reimbursement of outpatient diabetes education and nutrition counseling, finding fault with the study designs, cost analyses, follow-up, and extrapolation of results. 2 tables, 22 references.

256

TITLE: Amputation in the Diabetic Population: Incidence, Causes, Cost, Treatment, and Prevention. Fylling, C.P.; Knighton, D.R. Journal of Enterostomal Therapy.16(6): 247255. November-December 1989.

OBJECTIVE: To summarize the current medical literature on the criteria for nontraumatic amputation and proposed interventions to reduce its incidence.

CATEGORY: Expert opinion.

CONCLUSION: Amputation is a complex problem for the patient, the health care system, and the country.

RECOMMENDATION: Every effort should be made to reduce the incidence of amputation; this can only be achieved by identifying the causative problems and designing interventions to solve those problems.

ABSTRACT: Patients with diabetes or with peripheral vascular disease are primary candidates for amputation. In the United States, there were 118,000 amputations of the lower limb in 1983. The authors found that contralateral amputation is common (e.g., 42 percent of patients in 1 study required an amputation of the other leg within 1 to 3 years of the first amputation). Death frequently occurs soon after an amputation (50 percent died in 3 years in 1 study). The cost of amputation is high (over 50,000 lower extremity amputations in 1985 cost a total of about $500 million for direct medical care, not including rehabilitation). Diabetes mellitus is by far the most common primary indication for lower extremity amputation; ischemia without diabetes ranks second. Amputations should be performed at the lowest level consistent with function (with the intent to maintain or restore the best function with the least loss of tissue). The most frequently cited criteria for amputation are gangrene, infection, and nonhealing ulcers. Modern prevention of amputation in the patient with diabetes includes state-of-the-art noninvasive vascular testing, angiography, distal vascular reconstruction procedures, infection control, total contact casting as appropriate, growth factors to enhance healing, orthopedic shoes, and patient education. 5 tables, 109 references.

257

TITLE: Applying Recent Findings to Clinical Care in Type II Diabetes. Williams, R. *PharmacoEconomics*. 8 (Supplement 1): 80-84. 1995.

OBJECTIVE: To discuss the economics of applying findings from major clinical trials to the care of patients with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: The economic arguments for applying the results of major diabetes studies from the United States and the United Kingdom are compelling in the long term but require considerable short-term investment. This level of investment may be beyond the means of many developing countries.

RECOMMENDATION: None.

ABSTRACT: The economic consequences of diabetes vary in different parts of the world, due to differences in disease burdens (the epidemiologic transition) and differences in who bears the burden of the costs of diabetes (the individual, their families, or society). It has often been argued that advances in diabetes therapy, particularly advances in preventing complications, will reduce the cost of care. The effects of preventive measures on quality of life and on indirect costs, however, are likely to be much greater than on direct costs. Unfortunately, there are wide disparities in estimates of indirect costs and severe methodological difficulties in making these estimates. Application of the Diabetes Control and Complications Trial (DCCT) conducted in the United States and the United Kingdom Prospective Diabetes Study (UKPDS) (a study of the effectiveness of various oral hypoglycemic regimens versus dietary therapy alone in type 2 diabetes) to practice in developing countries will have economic consequences that are largely inconceivable, let alone sustainable. Analysis of the economic consequences of the DCCT, which confirmed the benefit of intensive therapy, found that the benefits of reduced complications outweighed the costs of more intensive treatment in the long term. In the UKPDS, glycemic control was significantly better in the groups treated with insulin or with oral hypoglycemic agents than in those treated with diet alone. Both the DCCT findings and early results of the UKPDS show that "higher tech" solutions are more effective. The economic case for implementing available interventions is usually less convincing for type 2 diabetes than for type 1, in part because the time that persons can remain free of complications is much less with type 2. The capacity for developing countries to make short-term investments is severely limited and will be further taxed as noncommunicable diseases such as diabetes become more prevalent. 2 tables, 15 references.

258

TITLE: Assessing the Costs and Benefits of Medical Research: The Retinopathy Study. Drummond, M.F.; Davies, L.M.; Ferris, F.L. *Social Science and Medicine*. 34(9): 973-981. May 1992.

OBJECTIVE: To develop and test a methodology for assessing the social costs and benefits of medical research. The Retinopathy Study is used as an example.

CATEGORY: Expert opinion.

CONCLUSION: It is possible to develop and test a methodology of assessing the costs and benefits of medical research that does not have the defects of earlier approaches. Using this method, the Retinopathy Study was extremely cost beneficial, with $10.5 million in research costs generating a net savings of $2,816 million to society.

RECOMMENDATION: With some modification, the methodology described can be applied prospectively to assess not only how many resources should be invested in a specific clinical trial but also to determine the payoff from investing resources in promoting the dissemination of results or in changing incentives to encourage the adoption of new, cost-effective clinical practices.

ABSTRACT: The authors retrospectively assessed the costs and benefits of the Retinopathy Study, a major clinical trial funded by the National Eye Institute between 1972 and 1981. The impact of the study, which was a randomized, controlled clinical trial of photocoagulation for severe retinopathy, on clinical practice for both proliferative and nonproliferative retinopathy was examined. Decision analysis was used to assess the expected costs and consequences of laser photocoagulation for persons with proliferative retinopathy in two alternatives: with and without the clinical trial. It was estimated that the trial, which cost $10.5 million, would provide a net savings to society of $2,816 million over 22 years' use of photocoagulation therapy, most of that figure coming from the avoidance of lost production. The government would save $2,249 million; patients, $1,339 million; and third party payers would incur a net cost of $772 million because of an increase in the use of photocoagulation. Even excluding the costs of lost productivity, there would be a net savings of $231 million to society over the same time period. In addition, there would be a net gain to the population of patients with retinopathy of 279,000 vision years. Sensitivity analysis showed the results were most affected by the assumptions about the likely impact of the trial on clinical practice, the effectiveness of the therapy, and the view taken on the relevance of including productivity losses. 2 figures, 4 tables, 25 references.

259

TITLE: Cardiovascular Complications of Diabetes Mellitus: What We Know and What We Need to Know about Their Prevention. Savage, P.J. *Annals of Internal Medicine*. 124 (1 Part 2): 123-126. January 1, 1996.

OBJECTIVE: To review the problem of cardiovascular disease in persons with diabetes. To discuss the questions related to prevention of cardiovascular complications of diabetes that must be addressed by future clinical trials.

CATEGORY: Expert opinion.

CONCLUSION: Persons with diabetes are at substantially increased risk for cardiovascular complications, particularly those related to atherosclerosis.

RECOMMENDATION: Until new clinical trials determine whether optimal glucose concentration normalizes the risk of cardiovascular disease and whether this approach is the most cost-effective intervention, existing guidelines for the control of cardiovascular disease risk factors in patients with diabetes should be strictly followed.

ABSTRACT: The author reviews the existing literature on the etiology of cardiovascular disease in persons with diabetes and discusses future research needs relevant to prevention. Many studies have demonstrated an association between overt diabetes and cardiovascular disease. In developed countries, the risk of cardiovascular disease is increased two- to four-fold among patients with diabetes. Up to 75 percent of deaths among patients with type 2 diabetes in the United States are attributed to ischemic heart disease or other heart and vascular diseases. The cardiovascular complications of diabetes are increasingly important

because of population trends (rapid growth among the elderly and minorities) and because success in reducing microvascular complications will increase the numbers at risk for macrovascular complications. The Diabetes Control and Complications Trial did not establish that the macrovascular complications of diabetes can be reduced by controlling glucose concentrations, and questions about the relationship of hyperglycemia to risk for cardiovascular disease remain unanswered. Because of concern about medical care costs, consideration must be given to issues of relative efficacy, relative cost, and the patient burden from different interventions in developing a cardiovascular disease reduction program effective for most patients with diabetes. As the average patient with diabetes sees a physician less than one hour annually, without a major expansion in care there will be severe limits in the complexity of any program that could be implemented. Key questions to be answered are whether optimal glucose control normalizes the risk of cardiovascular disease and whether controlling glucose concentration is the most cost-effective intervention to prevent cardiovascular complications. 2 tables, 29 references.

260

TITLE: Case Management and Quality of Care for Diabetic Patients. Korn, A. *Diabetes Care*. 15(Supplement 1): 59-61. March 1992.

OBJECTIVE: To describe a clinically sensitive case management process and its impact on quality of care.

CATEGORY: Expert opinion.

CONCLUSION: All patients may benefit from case management if it is accomplished through a peer-driven process.

RECOMMENDATION: None.

ABSTRACT: The author describes the elements of a clinically sensitive case management process and its potential impact on the quality of care of patients with diabetes. Case management, which he also calls managed care, is designed to achieve the best possible clinical outcome for each episode of patient care at a cost that represents the best value to the patient and benefit plan. The overall process must be ongoing and dynamic; a commitment to flexibility is required of payers so that, as feasible, benefits may be matched to clinical need in a sensitive, efficient manner. To achieve the best possible clinical outcome, case management must focus on the medical necessity of services. Interpretation of medical necessity should include a peer review. The value of a given treatment plan must also be evaluated from a financial as well as a clinical perspective. To serve the patient's best interests, the treatment plan should focus on the long-term outcome. But good case management must look at both short- and long-term values; price is only one determinant of cost over time. Clinical criteria are an evolving part of the case management process. Applying appropriateness criteria for specific therapies results in a risk-benefit analysis for a particular patient. Appropriateness criteria are gaining increased acceptance within the provider and payer communities. Case management has the potential to affect the quality of care of patients with diabetes, including

aspects of individual patient treatment plans and laboratory screening procedures, patient compliance monitoring, and hospital utilization. 6 references.

261

TITLE: Clinical Economics: A Guide to the Economic Analysis of Clinical Practices. Eisenberg, J.M. *Journal of the American Medical Association (JAMA)*. 262(20): 28792886. November 24, 1989.

OBJECTIVE: To provide information for clinicians on how economic techniques can be applied to their medical practice to improve decision making about ways to use resources in the hope of improving health.

CATEGORY: Expert opinion.

CONCLUSION: The clinical economic techniques reviewed may help clinicians reach the societal goal of achieving the greatest benefit for the most people.

RECOMMENDATION: None.

ABSTRACT: The author provides a broad overview of the principles of economic analysis and how they can be used to make intelligent choices between alternative uses of resources. These decisions must consider both cost and outcome because there are only limited resources available; tradeoffs and choices are inevitable. The author describes three dimensions of economic analysis applied to medical care: type of analysis (cost identification, cost-effectiveness, and cost benefit), point of view (society, patient, payer, and provider), and type of costs and benefits (direct medical, direct nonmedical, indirect, and intangible). Cost identification simply asks what the cost is; this analysis can guide medical practice only if a service has both lower cost and better or equal outcomes than the alternatives. Cost-effective analysis measures the net cost of offering a service and the outcomes obtained. It does not, however, assess whether outcomes are worth the cost. Cost-benefit analysis forces an explicit decision about whether the cost is worth the benefit. In terms of point of view, the author notes the bias that generally favors medical care for identifiable victims. He also discusses sensitivity analysis, which determines the degree to which uncertainty can influence conclusions about the economic impact of clinical decisions. The principles and methods of clinical economics equip physicians to be more critical users of information about the costs and effects of clinical practice. 4 figures, 2 tables, 44 references.

262

TITLE: A Clinician's Guide to Cost-Effective Analysis. Detsky, A.S.; Naglie, I.G. *Annals of Internal Medicine*. 113(2): 147154. July 15, 1990.

OBJECTIVE: To show how economic analysis can be used to help decision makers set priorities for funding health care programs.

CATEGORY: Expert opinion.

CONCLUSION: Policymakers will be better able to set priorities for funding if their perspective and objectives follow some of the principles of a cost-effectiveness analysis.

RECOMMENDATION: Clinicians should understand cost-effectiveness analysis, even though they do not use it in their clinical practice.

ABSTRACT: The authors examine fundamental ideas about efficiency analysis in health care, which includes cost-effectiveness, cost-benefit, and cost-November/Decemberutility analysis. They provide examples to define cost effectiveness analysis and to show how it can be employed to allocate scarce health care resources across competing uses. Using this technique to set priorities assumes the decision maker has one objective, to maximize net health benefit to a target population from a fixed amount of resources, and that the decision maker values health benefits accruing to all persons in the target population equally. Cost-effectiveness analysis of a health care intervention requires comparing it with alternative methods of dealing with the patients in a given health state (e.g., comparison of drugs for patients with hypertension). The tension between the extra costs of an intervention and the extra clinical benefits brings forth the issue of setting priorities. Ratios of extra costs required to achieve one extra unit of clinical outcome are derived; these may be cost-effectiveness, cost-utility, or cost-benefit ratios. When units of clinical outcome can be measured in direct clinical terms (e.g., premature deaths avoided), cost-effectiveness ratios will be estimated. If clinical outcome units also consider utility or quality of life, cost-utility ratios are estimated. Incremental (marginal) cost-effectiveness or cost-utility ratios can be used to set priorities. The type of economic analysis discussed in this paper has a very limited role for individual clinicians caring for individual patients and is more appropriate for decisions affecting populations. 4 tables, 17 references.

263

TITLE: Cost Concepts for Diabetes Educators: An Introduction. Tobin, C.T. *Diabetes Educator*. 16(6): 456, 459. November-December 1990.

OBJECTIVE: To introduce diabetes educators to decision analysis tools for business that are currently used in the health care setting.

CATEGORY: Expert opinion.

CONCLUSION: Understanding economic analysis and incorporating it into diabetes management practices enables diabetes educators to use cost terminology and analysis correctly, to evaluate the diabetes literature, to develop accurate cost data for individual services, and to enhance the credibility of reimbursement proposals to third party payers.

RECOMMENDATION: It is more practical for health care professionals to learn business language than for policymakers or decision makers to learn the language of education and

diabetes.

ABSTRACT: Lack of third party reimbursement for outpatient education is a common problem for diabetes educators. When developing a proposal to have this service reimbursed, educators must understand the concerns of insurers. The author provides an overview of economic analysis so that diabetes educators can improve their communication with policymakers. She discusses four types of economic analysis: cost identification, cost-effectiveness, cost benefit, and cost utility. Cost identification identifies the lowest cost of available alternatives. Cost-effectiveness provides the least costly alternative to achieve an outcome. Cost benefit determines whether a benefit is worth the cost. Cost utility adjusts outcome for quality and measures costs in dollars (e.g., cost of quality-adjusted life-years). The more diabetes educators know and understand about reimbursement and cost analysis, the more they will be able to activate their policymakers and third party payers and to make more informed decisions affecting their patient population. 1 table, 4 references.

264

TITLE: Cost of Diabetes Care. In: *Clinical Diabetes Mellitus: A Problem-Oriented Approach*. InZwaag, R.V.; Connor, M.; Dickson, H.D.; Runyan, J.W. (eds.) New York, NY: Thieme Medical Publishers. 1991. pp. 717-722.

OBJECTIVE: To discuss direct and indirect costs for patients with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Medical care costs are increasing and will continue to increase, but attempts are being made to change these trends through government regulations, preventive care, and new methods of health care delivery. Hospitalization costs related to the treatment of diabetes complications are a major component of the total cost of diabetes.

RECOMMENDATION: None.

ABSTRACT: The authors define direct costs as those associated with diagnosis and treatment of diabetes, and indirect costs as those associated with loss of productivity from work, disability, and early mortality. The authors discuss direct costs of diagnostic tests, home glucose monitoring (urine and blood tests), and physician visits in 1987. The American Diabetes Association (ADA) reported for that year that 63 percent of persons with diabetes used home urine tests ($.10 per test) and 16 percent used home glucose tests ($.83 per test); of the home-monitoring group, 64 percent tested once a day. National Ambulatory Medical Care Survey data published in 1981 found diabetes ranked second to hypertension for disease-coded physician visits. Diabetes had the highest proportion of return visits (.94), indicating a recurring expense for patients with diabetes. The authors analyze hospitalization data from two Memphis, Tennessee, providers. At the Baptist Memorial Hospital in 1988, circulatory disorders and hyperosmolar coma were the most expensive major complications of diabetes in terms of average length of stay and charge per day. Although average charges per day for most disorders were less for patients with diabetes, total charges were greater because lengths

of stay were longer. Much earlier, the Memphis Chronic Disease Program demonstrated that hospital days can be reduced with a system of decentralized clinics using specially trained nurses as primary care providers. The total charges per patient in that program averaged $611 per year (1977 dollars), in the range of national per capita expenditures for medical care in that period. Blindness, kidney disease, limb amputation, myocardial infarction, and stroke are expensive conditions that also should be considered in the direct costs of diabetes. In 1975, the direct cost of diabetes was estimated at $2.52 billion, and the indirect costs at $2.82 billion. A 1987 report estimated direct costs for the disease of $9.6 billion and indirect costs of $10.8 billion. The authors note that the greatest benefit from prevention programs may derive from educational efforts directed to juvenile patients and pregnant women with diabetes. 4 tables, 15 references.

265

TITLE: Cost-Effectiveness of Diabetes Education. Assal, J-P. *PharmacoEconomics*. 8 (Supplement 1): 68-71. 1995.

OBJECTIVE: To present an argument for diabetes education.

CATEGORY: Expert opinion.

CONCLUSION: Resources spent on patient education lead to substantial savings over the longer term.

RECOMMENDATION: Investment in patient education is needed.

ABSTRACT: A review by Bartlett (1995) showed average savings of $3 to $4 per $1 invested in patient health education. Diabetes education is also cost effective, but many patients do not have adequate access to such a program. In addition, educational programs on diabetes often do not include the poorly motivated or poorly educated, the elderly and isolated, and patients in denial. Physicians and allied health professionals have not been prepared through their education and training to educate their patients. The methodology required to educate patients about diabetes must be based on active learning by health professionals. Initially, education specialists need to supervise the educational programs for these professionals. Major investment in patient education by health care policymakers and administrators appears to be warranted. Without such investment there is little prospect of substantial improvement in the delivery of health education to the population with diabetes. 1 figure, 1 table, 15 references.

266

TITLE: The Cost-Effectiveness of Preventive Care for Diabetes Mellitus. Elixhauser, A. *Diabetes Spectrum*. 2(6): 349-353. November/December 1989.

OBJECTIVE: To summarize the literature on the costs associated with diabetes and to

evaluate the economic aspect of programs for preventing its complications.

CATEGORY: Expert opinion.

CONCLUSION: Most of the programs were found to be effective in reducing morbidity, mortality, and costs associated with diabetes, but the strength of these findings is limited by study deficiencies.

RECOMMENDATION: More accurate assessment of the clinical and economic impact that interventions have on preventing complications of diabetes is needed.

ABSTRACT: The author summarizes the literature on the costs of diabetes and interventions against the disease. Five types of interventions are examined from an economic point of view: primary prevention, screening for gestational diabetes, glucose monitoring, changes in structure of medical care services, and educational or behavioral interventions. The main types of economic evaluation discussed are cost-of-illness studies, cost-benefit analysis (CBA), cost-effectiveness analysis (CEA), and cost-utility analysis (CUA). All of the studies examined in this analysis were deficient in some way, limiting valid conclusions. The cost-of-diabetes studies examined only the primary diagnosis to avoid counting resource use twice, but this approach underestimates costs — diabetes is a secondary diagnosis in 2.5 times as many hospital discharges as it is a primary diagnosis and it is reported as a secondary cause of death 3.5 times more often than as a primary cause. Studies to evaluate the cost-effectiveness of interventions are flawed by weak study design, lack of validation for the methodology used, failure to outline potentially relevant costs and consequences, use of a restricted range of costs, failure to report intervention costs, attributing changes to global measures without ruling out alternative explanations, failure to provide justification that the patient group examined was representative of the larger group with which it was compared, and failure to take into account false-negative screening results. Suggestions for improving the studies include allowance for false-negative screening results, adherence to performance standards (e.g., assessment of nonmedical direct and indirect costs), and adherence to the same research-design criteria governing studies of medical interventions. 3 tables, 49 references.

267

TITLE: The Costs of Diabetes and Its Complications. Leese, B. *Social Science and Medicine*. 35(10): 1303-1310. November 1992.

OBJECTIVE: To review studies of the costs of diabetes and its complications.

CATEGORY: Expert opinion.

CONCLUSION: Major gaps exist in the data on the economics of diabetes, particularly on the indirect costs of the disease and the marginal benefits and costs of investing (e.g., providing funding for prevention and treatment) in diabetes.

RECOMMENDATION: Cost-effectiveness studies must be performed for diabetes

interventions to provide a basis for attempts to reduce the costs of the disease and to ensure that persons with diabetes are treated with efficacy and equity.

ABSTRACT: The author reviews several studies of the costs of diabetes and its complications in order to locate gaps in the data, particularly for the United Kingdom. Results of studies on the economics of diabetes are presented in five categories: direct costs, indirect costs, psychological costs, cost of treatment of complications, and cost-effectiveness. Numerous direct-cost studies are reviewed; in Britain, people with diabetes consume 4 to 5 percent of all health care resources. Few studies have included calculations of indirect costs because of the difficulty in assigning monetary values for such studies (e.g., to time lost from work, early retirement, and premature death). Psychological costs have rarely been considered in economic analyses. Complications are the most important contributors to the costs of diabetes, but lack a great deal of investigation from an economic perspective. Most studies of the economics of diabetes have been conducted in the United States, where health care is provided very differently than in the United Kingdom, making comparisons unreliable. Most studies also lack suitable retrospective data, and needed long-term prospective studies are difficult to set up and expensive to run. The literature lacks evidence on the efficacy and cost-effectiveness of interventions to reduce the burdens of diabetes and its complications. 50 references.

268

TITLE: Diabetes Care in Health Maintenance Organizations. Geffner, D. *Diabetes Care*. 15 (Supplement 1): S44-S50. March 1992.

OBJECTIVE: To review the history of health maintenance organizations (HMOs) and to describe the organization of the CIGNA Health plans of California; to describe how HMOs have dealt with health education, drug prescriptions, cost containment, and other issues.

CATEGORY: Expert opinion.

CONCLUSION: HMOs theoretically offer a system of delivering care that is accessible, affordable, and of good quality to patients with diabetes.

RECOMMENDATION: None.

ABSTRACT: The author reviews the historical development of HMOs and describes developments in managed care. Within CIGNA Health plans of California, provisions for access to care for patients with diabetes are described and details of cost containment practices presented. In both the staff model HMO and at the independent practice association (IPA) model, primary care physicians are responsible for the care of patients with diabetes. Most HMOs provide health education and nutrition counseling and at CIGNA Health plans of California, there is unlimited access (with no copayments) to health education programs. Cost containment is an underlying precept of the HMO model. While fee-for-service plans reward maximum use of resources, in the HMO setting, financial incentives favor conservation of resources. Financial incentives include bonuses to physicians for surpluses and responsibility

and financial risks for deficits. Other administrative constraints in the outpatient setting for the use of services include prior authorization for elective hospitalization and expensive diagnostic and therapeutic procedures, concurrent utilization review, mandatory second opinions, and drug formularies. Nonfinancial measures to improve cost-effectiveness can also improve quality; they include specialized clinics with integrated personnel, easy referral to specialists, exposure to patient education opportunities, and peer review. Studies have shown that HMO patients are less likely to be hospitalized and undergo fewer outpatient procedures and laboratory testing with the same health care outcomes. Whether differences in rates of utilization in the outpatient setting represent overutilization in the fee-for-service system or underutilization in the HMO setting is not known. 62 references.

269

TITLE: Diabetes Guidelines, Outcomes, and Cost-Effectiveness Study: A Protocol, Prototype, and Paradigm. Carey, M. *Journal of the American Dietetic Association*. 95(9): 976-978. September 1995.

OBJECTIVE: To review several articles in the September 1995 issue of the *Journal of the American Dietetic Association* that report the findings of the diabetes guidelines, outcomes, and cost-effectiveness studies.

CATEGORY: Expert opinion.

CONCLUSION: Medical nutrition therapy provided by dietitians to persons with type 2 diabetes is clinically beneficial and cost effective.

RECOMMENDATION: Future challenges include long-term management of diseases using medical nutrition therapy, quality of life, and segmenting study subjects according to variables likely to affect outcomes, such as duration of disease.

ABSTRACT: The author comments on several articles in the referenced journal issue that address practice guidelines for medical nutrition therapy in patients with diabetes. Monk et al. (1995) discussed the development of the guidelines. Following a randomized, controlled clinical trial, Franz et al. (1995) concluded that medical nutrition therapy provided by dietitians significantly improves medical and clinical outcomes and is, therefore, beneficial to persons with type 2 diabetes. A second study by Franz et al. (1995) found that medical nutrition therapy is cost effective for type 2 diabetes. Using fasting plasma glucose levels as the primary indicators and a 6-month time frame, they found that basic nutrition care cost $5.32 per unit of outcome and practice guidelines (expanded) nutrition care cost $4.20 per unit. 23 references.

270

TITLE: Diabetes, Health Insurance, and Health-Care Reform. Herman, W.H.; Dasbach, E.J. *Diabetes Care*. 17(6): 611-613. June 1994.

OBJECTIVE: To outline the health insurance issues that faced patients with diabetes in 1994.

CATEGORY: Expert opinion.

CONCLUSION: The United States needs a new health insurance system. Many persons with diabetes have no health insurance, have inadequate coverage, or receive less than optimum care.

RECOMMENDATION: A new health insurance system should provide coverage that is not employment based, disregards preexisting conditions, is rated on community rather than individual health care usage, and will provide for health education, supplies, equipment, and preventive services.

ABSTRACT: The authors summarize the underlying issues influencing health care reform in 1994 by outlining information from several studies. The authors state that in 1988, 17 percent of children or adolescents under age 18 had no health insurance. For 1989, they report that among persons with diabetes, 13.5 percent of those aged 18 to 64 and 1.2 percent aged 65 and over were not insured. Among people aged 18 to 64, those with diabetes were more likely to have Medicare or Medicaid coverage than those without diabetes. However, fewer than one-half of all people with annual incomes below the federally defined poverty level receive Medicaid benefits, and approximately one-fourth of practicing physicians do not accept Medicaid patients. In 1987, 46 percent of the uninsured population were working adults, 7 percent were nonworking spouses, and 24 percent were children of working adults; 13 percent of those under age 65 were underinsured. A survey in the 1980s revealed that many primary care providers did not adhere to consensus guidelines for care of diabetes. A 1993 report found that fewer than half of all patients with diabetes received annual dilated eye examinations. These data show that the United States needs a better health insurance system that will provide broader and more adequate coverage for patients with diabetes. Coverage should provide for preventive care, health education, and management by a multidisciplinary team. 21 references.

271

TITLE: Diabetes in a Managed Care System. Quickel, K. *Annals of Internal Medicine*. 124(1 Part 2): 160-163. January 1, 1996.

OBJECTIVE: To analyze the effects of managed care strategies on the care of persons with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Managed care programs have the potential to provide excellent care for persons with diabetes if clear evidence is presented to them that costs can be cut and quality improved.

RECOMMENDATION: The diabetes community must work with managed care organizations to develop diabetes care programs that are cost effective and result in improved outcomes.

ABSTRACT: The author provides a general review of managed care, then examines the care of patients with diabetes in that setting. Managed care uses payment incentives, provider designation, coverage policies, and traditional insurance mechanisms. Payment incentives effectively limit use of some services, particularly inpatient hospitalization. While payment incentives have the positive effect of encouraging routine initiation of insulin therapy on an outpatient basis, they may also adversely affect the care of some patients with diabetes who would benefit from hospitalization. There is evidence of deficient knowledge of diabetes among primary care physicians, but no direct studies have compared the quality (by process or outcome) of diabetes care provided by primary care physicians with that given by specialists. Provider designations will likely adversely affect the care of patients with complex diabetes, especially those with type 1 diabetes. However, structured programs provided by managed care programs, such as eye care, may improve some aspects of diabetes care. Acute care needs and the care of documented complications are generally well covered under managed care. Coverage of self-management training and nutrition counseling are inconsistently covered, however. As care of patients with diabetes costs three times as much as care of those without diabetes, managed care programs tend to exclude patients with diabetes. Preexisting condition exclusions by managed care plans may leave persons with diabetes without health insurance for necessary services. 1 table, 35 references.

272

TITLE: Diabetes Mellitus and the St. Vincent Declaration: The Economic Implications. Leese, B. *PharmacoEconomics*. 7(4): 292-307. April 1995.

OBJECTIVE: To examine the social and economic factors that affect diabetes mellitus and how the St. Vincent Declaration (St. Vincent, Italy, 1989) addresses them.

CATEGORY: Expert opinion.

CONCLUSION: The cost of providing more services to people with diabetes is a major barrier to implementing the St. Vincent Declaration.

RECOMMENDATION: None.

ABSTRACT: The St. Vincent Declaration (1989) set forth two general goals and several 5-year targets for improving quality of life and life expectancy for people with diabetes mellitus and reducing the disease's complications. The authors examine social and economic factors affecting diabetes mellitus and how the declaration addresses them. One problem with chronic diseases is that money spent on prevention will not achieve savings for 20-30 years and thus has little appeal for governments. In Britain, type 2 diabetes often remains undiagnosed, and systematic screening in general practice will reveal many undiagnosed cases. A U.S. report

indicates that increasing age, decreasing income, poor education, poor diet, obesity, race, and heredity are risk factors for diabetes. The cost-of-illness approach, including direct, indirect, and psychological costs, can be used for diabetes. Indirect costs include losses in productivity from short-term illness, early retirement, and death before retirement. In general, about 55 percent of total costs are direct and 45 percent are indirect (psychological costs are usually disregarded). A standardized method of collecting data for economic evaluations of the disease does not yet exist. Prevention of diabetes would lead to cost savings and improve quality of life for patients. There have been few cost-effectiveness analyses of diabetes mellitus. Financial considerations are a major barrier to implementing the St. Vincent Declaration. Diagnosing and treating more people with diabetes will add costs, but benefits may not be seen for many years. However, prospects are good for reducing costs of complications in the long term. The authors discuss primary, secondary, and tertiary prevention. With patient compliance, complications would be reduced and costs lowered. The St. Vincent Declaration has been an impetus for further research and refinement of databases, which are essential to effectively monitor improvements in service provision and outcomes. 1 table, 1 figure 104 references.

273

TITLE: Diabetes Patient Education Programs: Quality and Reimbursement. Wheeler, M.L.; Warren-Boulton, E. *Diabetes Care*. 15(Supplement 1): S36-S40. March 1992.

OBJECTIVE: To describe a quality assurance process for diabetes education programs and to evaluate the impact of recognition by the American Diabetes Association (ADA) on reimbursement for these programs.

CATEGORY: Expert opinion.

CONCLUSION: Reimbursement for ADA-recognized education programs is inconsistent and unpredictable.

RECOMMENDATION: Professionals in the diabetes community and third party payers should work together to clarify coding and coverage issues related to the delivery of outpatient education services in all appropriate settings. Programs seeking reimbursement should achieve positive review of quality assurance from an external source. Medicare should reimburse hospital-based programs and extend coverage to alternative programs such as those in the physician's office.

ABSTRACT: The authors detail the components of a quality assurance mechanism for patient education programs in diabetes, including a description of the recognition program of the ADA. Results of a 1990 survey evaluating the impact of ADA recognition on reimbursement are presented. A survey of 120 recognized programs from 40 states showed reimbursement by third party payers to be inconsistent and largely unpredictable. Programs in 17 states showed disparity in Medicare reimbursement coverage, with recognized programs in 9 states showing no Medicare activity at all. Medicaid provided very limited coverage for diabetes education; no recognized programs were reimbursed in 23 states. Blue Cross/Blue

Shield provided no reimbursement for recognized programs in 15 states, and 17 states had inconsistent coverage by these carriers. Further effort is needed to clarify, for both providers and payers, coding and coverage issues related to the delivery of the specific components of acceptable, reimbursable education services. Specific recommendations are made, particularly with reference to Medicare coverage. Diabetes education is provided most effectively and efficiently in the outpatient setting; Medicare should appropriately reimburse hospital-based outpatient education programs as well as education programs in alternative sites. 4 tables, 9 references.

274

TITLE: Diabetic Dyslipidemia: A Case for Aggressive Intervention in the Absence of Clinical Trial and Cost-effectiveness Data. Lewis, G.F. *Canadian Journal of Cardiology*. 11 (Supplement C): 24C-28C. May 1995.

OBJECTIVE: To provide a rationale for aggressively treating dyslipidemia in patients with diabetes in the absence of clinical trials and cost-effectiveness data.

CATEGORY: Expert opinion.

CONCLUSION: The evidence is overwhelming that patients with diabetes have a high rate of coronary artery disease, that traditional risk factors for coronary artery disease operate in diabetes, and that dyslipidemia in people with diabetes is highly prevalent and atherogenic.

RECOMMENDATION: Compelling clinical trial evidence is needed to support treating dyslipidemia in people with diabetes to reduce the incidence of coronary artery disease in the population.

ABSTRACT: People with diabetes have a twofold to fourfold increase in incidence of atherosclerotic cardiovascular disease. Atherosclerotic complications account for up to 80 percent of all deaths for people with diabetes; about 75 percent of these deaths are due to coronary artery disease. In 1992, people with diabetes made up 4.5 percent of the United States population, but they accounted for 14.6 percent of health care expenditures. People with diabetes who do not have complications incur few additional costs versus those without diabetes. Once complications occur, however, individual costs are high. The traditional risk factors for atherosclerotic cardiovascular disease (age, hypertension, left ventricular hypertrophy, hyperlipidemia, and smoking) operate in people with diabetes but do not account for the total increase in atherosclerotic cardiovascular disease; diabetes itself confers an independent additional risk. The most common lipid abnormalities in type 2 diabetes and poorly controlled type 1 diabetes are hypertriglyceridemia and low high-density lipoprotein. Treating dyslipidemia with conservative measures (diet, weight loss, aerobic exercise, improving glycemic control, etc.) and pharmacological management has been effective in correcting lipid levels. The author reports that few trials of lipid-lowering therapy have included patients with diabetes or demonstrated the cost-effectiveness of lipid-lowering therapy in reducing atherosclerotic cardiovascular disease. 1 table, 35 references.

275

TITLE: Economic Costs of Diabetes. Lipsett, L.F. *Pediatric and Adolescent Endocrinology*. 11: 143-148. 1983.

OBJECTIVE: To review estimates of the direct and indirect costs of diabetes in the United States.

CATEGORY: Expert opinion.

CONCLUSION: The economic burden of diabetes is significant, with the total cost of diabetes estimated at $9.7 billion in 1980.

RECOMMENDATION: Indirect costs of diabetes due to morbidity might be reduced through improving the accessibility of health services and creating greater awareness of diabetes complications.

ABSTRACT: The author reviews recent estimates of the direct and indirect costs of diabetes in the United States. The human capital approach (Rice 1966), which has been used by most economists in estimating the economic burden of disease in this country, includes estimates of both direct and indirect costs (time lost from work, losses to the economy from premature mortality). Estimates of the cost of diabetes grew from $2.6 billion in 1969 to $9.7 billion in 1980. In 1969, morbidity accounted for 56 percent of the total economic cost of diabetes and mortality accounted for 43 percent. In 1980, morbidity accounted for over 85 percent of costs and mortality just 15 percent. Siebert (unpublished data) estimated the annual costs per patient for outpatient dialysis, renal transplant, and home dialysis to be $23,088, $19,000, and $12,400, respectively, for patients with diabetes and end-stage renal disease. Patients with diabetes account for one-fourth of entrants into end-stage renal disease programs. In 1973, only 57 percent of adults with diabetes were estimated to have had an eye examination during the preceding 2 years, only 52 percent an electrocardiogram, and only 41 percent a glaucoma test. 1 figure, 1 table, 17 references.

276

TITLE: The Economic Costs of NIDDM. Songer, T.J. *Diabetes-Metabolism Reviews*. 8(4): 389-404. December 1992.

OBJECTIVE: To review basic concepts in health economic research and how they have been applied to issues involving type 2 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: *Health Economics* data provide relevant information for decisions made by governments and health agencies about diabetes.

RECOMMENDATION: Developing a better means of identifying persons with type 2 diabetes could help a great deal to highlight the epidemiologic and economic components of the disease.

ABSTRACT: The author discusses three broad kinds of health economic approaches: descriptive, evaluative, and explanatory. Descriptive approaches include cost-of-illness studies and assessments of patients' costs and concerns. Cost-of-illness studies usually include direct and indirect costs; intangible or psychosocial costs are normally not included. Although the literature on the cost of diabetes is fairly extensive, data specific to type 2 diabetes are uncommon. Costs and concerns of patients include direct payments by individuals for health care or insurance as well as sacrifices (losses) in time; little has been published in this area relative to diabetes. Evaluative approaches include cost-benefit analysis, cost-effectiveness analysis, and cost-utility analysis. Cost-benefit analysis considers monetary cost versus monetary benefits; there is no measure of health gained. Both cost-effectiveness analysis and cost-utility analysis consider monetary cost minus monetary benefit versus health gained (measures for cost-effectiveness analysis include years of life, disability prevented, etc.; for cost-utility analysis the measure is quality-adjusted life-years). Explanatory approaches include examinations of incentives, demand, and supply. Economic incentives might change the price of a healthy or an unhealthy activity, or they might change an individual's knowledge about the consequences of activities. The author suggests including an economic component in the evaluation of intervention programs to prevent type 2 diabetes. He points out that in most scenarios, prevention does not save money. Referencing Weinstein (1990), he states that the economic issue is not whether prevention saves money, but whether prevention improves health at a reasonable cost. 4 figures, 4 tables, 83 references.

277

TITLE: Economic Implications of IGT Intervention: The Case of a "Phantom Alternative"? Gafni, A. *Diabetic Medicine*. 13(3 Suppl 2): S25-S28. March 1996.

OBJECTIVE: To assess whether it is possible to perform an economic evaluation of primary strategies for preventing diabetes in patients with impaired glucose tolerance (IGT) or whether such strategies represent "phantom alternatives" (illusionary choices that look real but are unavailable at the time a decision is made).

CATEGORY: Expert opinion.

CONCLUSION: At present, an economic evaluation of primary prevention strategies cannot be performed, even for the purpose of determining the strategies' technical efficiency.

RECOMMENDATION: Effectiveness-type clinical trials should be designed, based on existing evidence in favor of possible interventions, to test properly the effectiveness of potential primary intervention strategies.

ABSTRACT: The methodologies of economic evaluations of health care interventions are

reviewed and the economic questions to be answered are discussed. Key issues are (1) the identification of the cluster of technically efficient programs for each disease level and (2) the determination of the optimal mix of interventions. The author argues that no comprehensive descriptions have yet been put forward about primary prevention strategies for diabetes. Satisfactory evidence of the effectiveness of existing preventive strategies, their impact on quality of life, or their acceptance by individuals, also is not available. Evidence is also lacking on effective methods for identifying high-risk individuals. The author concludes that, because of these deficiencies, no economic evaluation of primary prevention strategies can be performed. 12 references.

278

TITLE: Emotional Side Effects of Diabetes Educational Program (letter; comment). Conget, J.I.; Esmatjes, E.; Ferrer, J.; De Pablo, J.; Gomis, R. *Diabetes Care*. 13(8): 901-902. August 1990.

OBJECTIVE: To argue that an intensive diabetes educational program can produce severe adverse emotional effects in predisposed patients and to recommend a psychological assessment before program participation.

CATEGORY: Expert opinion.

CONCLUSION: Following their participation in a health education program, patients with chronic diseases and premorbid personalities have exhibited psychological disorders.

RECOMMENDATION: A psychological assessment should be performed before a diabetes education program begins to rule out patients at high risk of developing emotional disorders. Select patients would be given special educational techniques.

ABSTRACT: The authors respond to an article by Rubin et al. (*Diabetes Care*. 12(10): 673-679. 1989) on the effects of diabetes education. They agree with Rubin et al. that an intensive diabetes education program evaluated by those investigators improved the emotional status of participants and that this improvement contributed markedly to improved metabolic control. However, the authors argue that intensive diabetes educational programs can also produce severe adverse emotional effects in predisposed patients. They illustrate their point with the history of a 19-year-old patient who exhibited disturbed behavior following such a program. They recommend a preprogram psychological assessment to rule out patients at high risk for emotional disturbances. They note that psychological disorders have been described in patients with chronic diseases and premorbid personalities after their inclusion in a health education program. In a reply, Rubin et al. argue that the disorder of the patients described by Conget et al. might not have been caused by the educational program. Rather than preprogram assessment, they suggest close monitoring during and after the program. 6 references.

279

TITLE: Estimating the Impact of Total Illness Burden on Patient Outcomes among Patients with Non-Insulin Dependent Diabetes: A Comparison of Three Co-Morbidity Measures (abstract). Greenfield, S.; Sullivan, L.M.; Dukes, K.A.; D'Agostino, R.; Dittus, R.; Wagner, E.; Kaplan, S.H. *AHSR FHSR Annual Meeting Abstract Book*. 12: 85. 1995.

OBJECTIVE: To compare three different measures used to assess total disease burden in patients with type 2 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: The Total Illness Burden Index provided the most accurate assessment of total illness burden. This index may reveal a formerly underestimated disease burden among women and minorities and may decrease distortions in assessing quality of care.

RECOMMENDATION: None.

ABSTRACT: The investigators compared the accuracy of three comorbidity measures in estimating the burden of diabetes in two populations of patients with type 2 diabetes included in the Type II Diabetes Patient Outcome Research Team (PORT) study. One group of patients (n = 1,738) was from the Group Health Center of Puget Sound (Washington state); the other (n = 790), from the Regenstrief Health Center in Indianapolis. The measures were a simple count of diagnoses (NDX), the Charlson Index (CI), which is a weighted measure, and the Total Illness Burden Index (TIBI), an aggregated patient-reported measure of severity scores for each of 15 body systems. The groups differed significantly in terms of race, socioeconomic level, and presence of diabetes complications. Compared with the Puget Sound group, patients from Regenstrief had lower annual incomes, less education, a longer duration of diabetes, more diabetes-related complications, and were more likely to be female and African American. In multivariate models, the authors found that TIBI explained a greater proportion of the variation in PFI10, office visits, and restricted activity days than did the other two measures. Results were not explained by multi-collinearity. Sex was significantly related to the TIBI but not to the CI. Race and income were significantly related to each of the measures.

280

TITLE: Financial Implications of Implementing Standards of Care for Diabetic Eye Disease. Rand, L. *Diabetes Care*. 15(Supplement 1): S32-S35. March 1992.

OBJECTIVE: To review the practical financial implications of implementing published care standards for diabetic eye disease.

CATEGORY: Expert opinion.

CONCLUSION: Several economic factors influence the implementation of guidelines for eye

care for patients with diabetes and will greatly influence how effective these guidelines will be in reducing blindness due to retinopathy.

RECOMMENDATION: Factors affecting the full implementation of eye care standards must be addressed, particularly in terms of prepaid health care organization standards and regional variations in resource availability.

ABSTRACT: The author reviews the financial implications of implementing the American Diabetes Association (ADA) guidelines for retinopathy screening. Broad financial issues related to practice patterns are discussed, and no specific dollar projections on potential cost savings are made. ADA guidelines emphasize the role of the primary physician in coordinating the total health care of persons with diabetes mellitus. The financial implications of physicians' taking this role are enormous, not only because of liability issues, but also because of cost escalations resulting from increased testing and referral. Full implementation of each of the specific ADA guidelines for retinopathy screening will result in increased costs. Implementation of annual ophthalmic exams, for example, is expected to increase the cost of care by at least 30 percent, as only one-half of patients with diabetes currently receive annual care. However, increased costs of care may be offset by decreases in disability payments: a 1990 study showed screening for retinopathy resulted in net annual savings of $62 million to $109 million to the federal government when disability payments were considered. The available guidelines are excellent and their implementation should reduce visual loss from retinopathy. The financial impact of implementing these guidelines, however, both in terms of manpower and dollars, is wide-ranging and will greatly influence how effective they will be in reducing blindness due to retinopathy. Low-cost screening strategies must be developed, particularly for low-risk groups. 15 references.

281

TITLE: The Health Belief Model and Adolescents with Insulin-Dependent Diabetes Mellitus. Bond, G.G.; Aiken, L.S.; Somerville, S.C. *Health Psychology*. 11(3): 190198. 1992.

OBJECTIVE: To test the utility of the health belief model for predicting both behavioral adherence to the diabetic regimen and glycemic control among adolescents with type 1 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Compliance was positively associated with two of three constructs (cues, benefits-costs) of a modified health belief model. Compliance was not significantly related to metabolic control.

RECOMMENDATION: None.

ABSTRACT: Fifty-six adolescents (mean age: 14.2 years) with type 1 diabetes were included in this study; 43 percent were male and 91 percent were white. All participants had type 1 diabetes for at least 1 year (mean: 5.8 years) and were attending school. The study protocol

had four components: (1) a children's self-administered questionnaire that covered the health belief model for diabetes, (2) three telephone interviews on compliance in which the adolescent recalled the day's regimen-related events in sequence, (3) three parent telephone interviews on compliance in which the parent recalled his or her child's regimen-related events, and (4) a glycosylated hemoglobin blood test for each adolescent four to six weeks after completion of the last compliance interview. Because of the small sample size, a measurement model containing the five constructs of the health belief model (susceptibility, severity, costs, benefits, and cues) could not be estimated. Instead, the authors used a benefits-costs construct, a perceived threat construct (severity plus susceptibility), and a construct of perceived cues to action as their model. Benefits refer to a conviction that the preventive regimen is effective, costs are difficulties or barriers in undertaking the regimen, threat is perceived susceptibility combined with viewing the disease as severe (severity), and cues involve willingness to seek help or medical treatment after symptoms (e.g., cold sweats) are experienced. Data obtained from parents about compliance were not used because the parents, in 70 percent of the cases, were unaware of the details of their children's daily routines. The authors found that as a child's age increased, adherence to the exercise, injection, and frequency components of the regimen decreased. Compliance was positively associated with cues to action and with perceived benefits-costs. The greatest compliance was achieved with high benefits-costs and low threat. Glycosylated hemoglobin did not correlate significantly with either age or disease duration. Poor metabolic control was associated with high threat and cues. Better metabolic control was associated with lower carbohydrate consumption. 2 figures, 5 tables, 45 references.

282

TITLE: Health-Insurance Coverage for Adults with Diabetes in the U.S. Population. Harris, M.I.; Cowie, C.C.; Eastman, R. *Diabetes Care*. 17(6): 585-591. June 1994.

OBJECTIVE: To compare health insurance coverage for adults with diabetes with coverage for adults without diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Health care coverage in the United States is similar in adult patients with and without diabetes, but in the 18 to 64 age group, persons with diabetes are more likely to depend on government-funded insurance than those without diabetes.

RECOMMENDATION: None.

ABSTRACT: As part of the 1989 National Health Interview Survey, 2,405 adults with diagnosed diabetes and 20,131 adults with no known diabetes were asked about their health care insurance coverage. Coverage was similar for persons with diabetes and those without diabetes (92.0 versus 86.8 percent). About 600,000 persons with diabetes had no insurance coverage. Among persons under age 65, 26.4 percent of those with diabetes relied on government-funded medical care, compared with 8.3 percent of persons without diabetes; for private health insurance, the proportions were 69.3 percent and 78.6 percent, respectively (p

< .001 for both comparisons). Reasons given by adults with diabetes aged 18 to 64 for not having private insurance included cost; having other coverage; being unable to obtain insurance because of poor health, illness, or age; and unemployment. Among persons aged 65 and over, 69.2 percent of those with diabetes and 79.9 percent of those without diabetes had private insurance ($p < .001$). In this age group, more than half of persons with type 2 diabetes had no coverage for insulin or prescription drugs; only 13.5 percent of those with diabetes of any type had dental coverage. Among younger diabetes patients (aged 18 to 64 years), 23 percent of type 1 patients, about 26 percent of insulin-using type 2 patients, and 32 percent of noninsulin-using type 2 patients had no coverage for prescription medicines. Uninsured diabetes patients under age 65 were more likely than those who were insured to be of minority ethnicity, have less than a high school education, have annual family incomes less than $25,000, report more episodes of hyperglycemia and glycosuria, and have less preventive care. Because government-funded insurance programs provide coverage for 57 percent of adults with diabetes, changes in government health care policies could have a major impact on this patient group. 6 figures, 2 tables, 13 references.

283

TITLE: Insurance Coverage for People with Diabetes: Third Party Reimbursement for Diabetes Education and Technologies. Sinnock, P.; Bauer, D. *Diabetes Dateline*. 4(5): 1-2. September-October 1983.

OBJECTIVE: To discuss the status of insurance reimbursement for outpatient education, new technologies, services, and equipment for persons with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Medicare is the largest insurer of persons with diabetes. Per the Medicare Part A Intermediary Manual, patient education programs appear to be covered, but just five states have obtained Medicare reimbursement for patient education programs.

RECOMMENDATION: More efforts are needed to foster an understanding among third party payers of the potential cost benefits of patient education, technologies, and services for diabetes care.

ABSTRACT: Educational activities can improve the ability of people with diabetes to care for themselves and to comply with medically prescribed treatment protocols, which in turn can lead to a reduction in diabetes morbidity, mortality, and related costs. Medicare is the largest insurer of persons with diabetes; in 1978, it covered 41.3 percent of patients with diabetes aged 20 or over and 95.9 percent of those aged 65 or over. Five states have obtained reimbursement under Medicare for diabetes outpatient education; programs must be therapeutic rather than preventive, provided by a Medicare-certified hospital or rural health center, and have physician referral and involvement. As of September 1983, 11 Blue Cross/Blue Shield plans, 6 commercial insurers, and 1 Medicaid program also reimbursed outpatient diabetes education. There is little uniformity nationwide of coverage for diabetes-related technologies and services among third party payers; of the four major payer groups,

only Medicare has a national office that can serve as an arbitrator. Third party reimbursement of diabetes-related technologies, services, and equipment seems to depend on the type of insurance, the state of residence, and the item or procedure to be covered.

284

TITLE: Intensive Ambulatory Treatment of Insulin-Dependent Diabetes. Felig, P.; Bergman, M. *Annals of Internal Medicine*. 97(2): 225-230. August 1982.

OBJECTIVE: To determine whether an intensive management program should be preferred over a conventional management program in the treatment of type 1 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: In many patients, intensive management is superior to conventional management in terms of lowering blood glucose concentrations and improving the metabolic state. Net savings from intensive management will be substantial if reducing blood glucose is effective in preventing or delaying complications or reducing hospitalization for diabetic ketoacidosis or hypoglycemia.

RECOMMENDATION: Additional observations on safety and efficacy are needed before insulin pump treatment can be considered routine. Prospective studies are needed that compare morbidity and mortality attributable to hypoglycemia during conventional treatment with morbidity and mortality during intensive treatment.

ABSTRACT: The authors reviewed available data on the efficacy of intensive management regimens for type 1 diabetes. Intensive management is defined as self-monitoring of blood glucose (SMBG) and adjusting insulin doses based on this monitoring. In intensive management, insulin is administered in a continuous subcutaneous infusion with portable insulin pumps or given as two or more manual injections per day. Conventional management involves one or two insulin injections daily, urine glucose monitoring by the patient, and blood glucose measurement by the physician during office visits. Opinions on the desired frequency of SMBG differ, but the favored approach is four times daily (before main meals and at bedtime) plus occasionally during the night. Drawbacks of intensive management include possible hypoglycemia, adverse psychological effects due to preoccupation with the care of diabetes, and the need for multiple blood tests and frequent contact with health professionals. In one study, although 34 percent of patients reported fewer hypoglycemic reactions with intensive therapy, 20 percent noted an increase. Additional observations are needed to determine the safety and efficacy of the insulin pump. In the hospital setting, the insulin pump lowers the blood glucose as well as does manually injected insulin; in the outpatient setting, data are less conclusive. Potential adverse effects of the pump include hyperglycemia, hypoglycemia, and cutaneous complications at the needle site. No long-term data are available to determine the effectiveness of intensive therapy in preventing or delaying long-term complications of diabetes. Some studies have shown a progression of eye disease and only a transient reduction of proteinuria with improved blood glucose control. 50 references.

285

TITLE: Intensive Insulin Therapy: Part I. Basic Principles. Hirsch, I.B.; Herter, C.D. *American Family Physician*. 45(5): 2141-2147. May 1992.

OBJECTIVE: To review insulin therapy in patients with type 1 or type 2 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Meticulous glycemic control has beneficial effects on diabetic complications, but neither advanced retinopathy nor advanced nephropathy seems affected by improved glycemic control.

RECOMMENDATION: None.

ABSTRACT: The authors review the basic approach to intensive insulin therapy for both type 1 diabetes and type 2 diabetes: Intensive therapy includes a multicomponent insulin regimen; balancing of food intake, activity, and insulin dosage; daily home blood glucose monitoring; and individualized blood glucose goals but not tight glycemic control. A team approach to therapy is beneficial; teams typically include a physician, a nurse, and a nutritionist but could also include a social worker or a psychologist, an exercise physiologist, a pharmacist, and a physician's assistant or a certified nurse practitioner. The authors provide a table comparing time to onset, time to peak concentration, and duration of effect for different animal and human insulin preparations. Animal insulin is bioavailable for a longer time but is also associated with higher circulating anti-insulin antibodies. Intraindividual variation in absorption of insulin is about 25 percent. Absorption is affected by the site of injection and exercise; premeal insulin injections should be timed based on blood glucose. The incidence and progression of retinopathy and glycosylated hemoglobin are positively associated. However, some patients experience a transient increase in retinopathy progression with improved glycemic control, which is thought to be a consequence of retinal ischemia. Microalbuminuria is reduced with glycemic control, but advanced nephropathy is not affected. Nerve function improves with better glycemic control. Individualized glycemic goals are required because of the risk of developing hypoglycemia following treatment. The relationship between glycemic control and complications from diabetes is under study. 2 tables, 22 references.

286

TITLE: Intensive Insulin Therapy: Part II. Multicomponent Insulin Regimens. Hirsch, I.B.; Herter, C.D. *American Family Physician*. 45(6): 2643-2648. June 1992.

OBJECTIVE: To review optimum regimens for insulin treatment of type 1 and type 2 diabetes.

CATEGORY: Expert opinion.

CONCLUSION: A variety of approaches may be used to provide insulin therapy in patients with diabetes.

RECOMMENDATION: Additional studies are required to investigate combination therapy with insulin and sulfonylureas for patients with type 2 diabetes.

ABSTRACT: The authors review optimal insulin therapy for diabetes mellitus. Twenty-one percent of patients with type 1 diabetes are on once-daily insulin injections, despite their proven inefficiency. Many patients administer short- and intermediate-acting insulin prior to breakfast and supper, which requires that the mid-day meal be precisely timed and which may result in nocturnal hypoglycemia. In these patients, a bedtime snack to eliminate nocturnal hypoglycemia is likely to cause fasting hyperglycemia. Another regimen uses only the short-acting insulin for the suppertime dose, with the intermediate-acting insulin given at bedtime. For individuals with unpredictable schedules, a regimen of short-acting insulin prior to breakfast, lunch, and supper and intermediate-acting insulin with a bedtime snack permits more control. A variation of this regimen uses the same three doses of short-acting insulin with long-acting insulin administered prior to breakfast and supper. Continuous subcutaneous infusion of insulin is also available to maintain basal blood concentrations of insulin. For type 2 diabetes, diet and exercise are the primary treatments, followed, if adequate blood glucose control is not achieved, by sulfonylureas. Up to one-third of patients initially fail to respond adequately to sulfonylureas, and 5 to 10 percent of initial responders later stop responding to the drug; these patients require insulin therapy. Moderate hyperglycemia (fasting blood glucose of 140 to 200 mg/dL) is managed with once-daily injection of intermediate- or long-acting insulin. For severe hyperglycemia (fasting blood glucose greater than 200 mg/dL), at least twice-daily intermediate-acting insulin is required. Using insulin and sulfonylurea in combination remains controversial. 6 figures, 1 table, 13 references.

287

TITLE: Is Glycohemoglobin Testing Useful in Diabetes Mellitus? Lessons from the Diabetes Control and Complications Trial. Goldstein, D.E.; Little, R.R.; Wiedmeyer, H.M.; England, J.D.; Rohlfing, C.L.; Wilke, A.L. *Clinical Chemistry*. 40(8): 1637-1640. August 1994.

OBJECTIVE: To evaluate glycohemoglobin testing in the management of patients with diabetes mellitus as a model of laboratory testing cost analysis.

CATEGORY: Expert opinion.

CONCLUSION: Glycohemoglobin testing in patients with diabetes mellitus provides an objective measure of a patient's risk for developing diabetes complications and may prove cost effective through savings incurred by the prevention of these complications.

RECOMMENDATION: Those involved in medical cost containment must weigh short-term

costs (e.g., laboratory studies) against long-term benefits.

ABSTRACT: The authors discuss testing for glycohemoglobin in patients with diabetes mellitus as a model for determining whether laboratory tests cost or save money. The Diabetes Control and Complications Trial provided strong evidence that glycemic control as assessed by glycohemoglobin testing predicts risk for developing diabetic complications. The authors point out that knowing a patient's glycohemoglobin would help the patient and health provider make changes in treatment that would lower the glycohemoglobin and thereby decrease risks of complications. Larsen et al. (1990) performed a study in which 240 patients with type 1 diabetes were randomly assigned to a treatment group in which glycohemoglobin test results were made known to patients and health providers or to a control group in which these results were not made known. After 12 months, glycohemoglobin values were substantially lower in the treatment group. Data from the Diabetes Control and Complications Trial and Larsen et al. study argue strongly for the routine use of glycohemoglobin testing, but despite widely published recommendations, only about 25 percent of patients with diabetes undergo this testing regularly. The authors argue that the costs of increased glycohemoglobin testing and of other aspects of intensive therapy should be offset by savings in other areas (e.g., laser therapy, kidney dialysis). 24 references.

288

TITLE: Managed Care Approaches to Diabetes Mellitus. Fore, W.W. *Hospital Practice*. 31 (7): 115-117. July 15, 1996.

OBJECTIVE: To review approaches by managed care organizations to the management of diabetes.

CATEGORY: Expert opinion.

CONCLUSION: As more managed care organizations implement prevention programs, information on optimum methods of care and cost reduction should become available.

RECOMMENDATION: None.

ABSTRACT: Most managed care organizations now have insured populations with the same prevalence of diabetes as the general population. Managed care information systems have confirmed that the costs of caring for enrollees with diabetes are four times those for members without diabetes. The author states that 90 percent of managed care patients with diabetes have type 2, which has a mortality of approximately 50 percent from coronary artery disease and stroke. Ninety percent of managed care patients with diabetes have type 2. Implementation of intensive treatment may not realize cost savings for 12 to 16 years, while most managed care organizations have annual budgeting and can expect one-third of their members to change plans annually. Even so, additional resources are being allotted to the care of patients with diabetes. Managed care organizations are initiating various programs to improve outcomes and reduce cost of care, including home or workplace visits from nurses and dietitians, follow-up telephone calls from nurses and educators, and providing telephone

access to a computer system than can advise patients on insulin dosage. It appears that many managed care organizations are focusing on preventing the complications of diabetes. The pharmaceutical industry plans to expand its role in the long-term management of diabetes in the managed care setting. 6 references.

289

TITLE: Medicare Admission Criteria for Diabetes Mellitus in Florida. O'Malley, B.L. *Diabetes Care*. 15(Supplement 1): S54-S58. March 1992.

OBJECTIVE: To document the modification of Medicare hospital admission criteria for diabetes mellitus in Florida and the physician response to the process.

CATEGORY: Expert opinion.

CONCLUSION: Stricter Medicare hospital admission criteria for patients with diabetes mellitus in Florida proved to be unacceptable to diabetologists and endocrinologists, who forced a change to the proposed admission criteria. Adoption of the less strict criteria had little impact on the number of hospital admissions.

RECOMMENDATION: Diabetologists and endocrinologists must be involved in the establishment of acceptable hospital admission criteria.

ABSTRACT: The author details physician response to modifications proposed by the Florida Peer Review Organization in 1986 to the Florida Medicare admission criteria for diabetes mellitus. Peer review organizations, which were mandated by the Tax Equity and Fiscal Responsibility Act of 1982, try to control health care costs. The proposed criterion required the fasting blood glucose to be ≥ 22.4 mM. Endocrinologists and diabetologists in Florida recognized that the revised criteria would have a significant adverse impact on the quality of care of patients with diabetes mellitus. Peer Review Organization council physicians, responding to these inputs from specialists, developed and approved less strict criteria for hospital admission. The introduction of these criteria had no significant impact on the number of patients admitted with a primary diagnosis of diabetes mellitus or its complications; such Medicare admissions totaled 6,954, 6,686, and 6,687 in 1986, 1987, and 1988, respectively. The author also notes that some health care providers erroneously thought that admissions criteria are a standard of care. Instead, he contends, they are minimal criteria to be met before thinking about the need to hospitalize a patient. This case illustrates the importance of the involvement of diabetologists and endocrinologists in establishing acceptable hospital admission criteria on a state-by-state basis. 4 tables, 2 references.

290

TITLE: Meeting the Needs of the Economically Deprived Diabetic. Hopper, S.V. *Nursing Clinics of North America*. 18(4): 813-825. December 1983.

OBJECTIVE: To examine the factors that influence treatment of patients from low-income groups and suggest a plan of intervention.

CATEGORY: Expert opinion.

CONCLUSION: Educating low-income patients with diabetes presents the nurse with special challenges.

RECOMMENDATION: The author's recommended intervention covers teaching strategies, economic realities, health attitudes, diet and nutrition, the social network, and adapting the teaching setting.

ABSTRACT: The author reviews the effect of low economic status on the impact and management of diabetes, using information about low-income participants with diabetes who attended a municipal clinic in St. Louis, Missouri, to illustrate various points. According to a 1978 survey, 74 percent of the clinic's patients were black; the same percentage were female; and most had type 2 diabetes. The author reviews the cost of diabetes, the social network of patients with diabetes, and knowledge and beliefs; she outlines an approach to intervention and presents a case study. Many poor people believe they cannot afford the diabetic diet; this has caused conflict between patient and practitioner. Nurses must acknowledge value differences when negotiating self-care priorities with the low-income patient. In setting forth a proposed lay model for treating diabetes, the author indicates that 28 percent of the clinic patients believed that most of what happened to a person's health was due to chance. A clinic study also found that 14 percent of the patients believed that diabetes was not a lifelong illness. In addition, knowledge of the signs and symptoms of hypoglycemia and hyperglycemia did not guarantee better control. Effective patient education uses communication strategies appropriate to the cultural group. 29 references.

291

TITLE: Money Matters: Should Ability to Pay Ever Be a Consideration in Gaining Access to Transplantation? In: *Cost and Outcome Analysis of Kidney Transplantation: The Implications of Initial Immunosuppressive Protocol and Diabetes (Final Report: Volume I)*, Chapter 16. Evans, R.W.; Manninen, D.L.; and Thompson, C. Battelle Human Affairs Research Centers, Seattle, Washington. 1989.

OBJECTIVE: To discuss whether ability to pay should be a condition for gaining access to transplantation.

CATEGORY: Expert opinion.

CONCLUSION: Ability to pay should never be a consideration in gaining access to transplantation, but in reality such a capability is currently a consideration and will be one in the future.

RECOMMENDATION: Ultimately, society must ask itself what it is willing to pay to avoid making decisions about medical treatment based on ability to pay.

ABSTRACT: The authors note that when coverage of transplant procedures is a consideration, both the uninsured (1987 estimate: 37 million people) and the underinsured (estimate: 26 or 27 million) are at near equal risk of not gaining access to selected transplant procedures when the criterion is ability to pay. Most transplant programs in the United States require assurance of payment, which often takes the form of a direct down payment or prior approval by an insurer. In the immediate future, ability to pay will probably become even more important, but this criterion is a condition of access that characterizes all of medical care in a system such as the one in the United States. The National Task Force on Organ Transplantation (1986) rejected the notion that ability to pay should obstruct access. The authors note that although they continue to support the Task Force's recommendations, the concerns of public and private insurers as well as legislators should be recognized. In deciding which new medical and surgical procedures to cover, insurers have historically asked about its safety, effectiveness, and acceptance within the medical community. Four more contemporary questions that insurers ask are about the procedure's cost; whether it maintains or improves health status in the most cost-effective manner; whether it replaces an older, less efficient procedure; and whether costs will increase as the procedure becomes more routine. In many instances, hospitals lose money on transplants but may benefit indirectly from the visibility that transplant programs create. The authors note that patient discrimination in transplantation may be based not only on ability to pay but also on the payment methodology of the insurer; in this regard, Medicare and Medicaid would be less attractive than private insurance. The public strongly objects to use of an economic criterion for transplantation. The National Task Force concluded that it would be unfair and even exploitative to ask the public to donate organs and the distribute them on the basis of ability to pay. 1 figure, 8 tables.

292

TITLE: New Mexicare. Vall-Spinosa, A. *Archives of Internal Medicine*. 151(8): 1503-1509. August 1991.

OBJECTIVE: To propose a health insurance system for the uninsured in New Mexico that would benefit the patient, provider, businessperson, and state.

CATEGORY: Expert opinion.

CONCLUSION: New Mexicare offers a low-cost system for providing basic medical services to people currently denied health care because they lack health insurance.

RECOMMENDATION: New Mexicare could be a paradigm for an eventual national solution to this country's health care problems.

ABSTRACT: The author, a member of the Department of Medicine at the University of New Mexico School of Medicine, presents a proposal for a public health insurance plan that would

provide access to primary and preventive outpatient health care on a fee-for-service basis for all uninsured citizens of New Mexico. The plan, called New Mexicare, would use annual, globally budgeted monies to pay for inpatient care, which is now unreimbursed for those without insurance. Funding would come from a Health Care Trust Fund, which would help set state health policy, determine New Mexicare benefits, and supervise payments to hospitals, laboratories, and physician specialists. All state health care funds, including Medicaid-matching dollars, would support the fund. New Mexicare would function within the state Medicaid Department and would use the Medicaid primary care network and system, which uses primary care providers as gatekeepers to specialist and hospital services. Premiums for unemployed persons would be subsidized, and premiums for employed persons would be shared between workers and employers, with higher-paid workers assuming a larger share of cost than lower-paid workers. The plan includes provisions for low premiums and nominal copayments. All employers and their workers with no private insurance plan would automatically be covered. The plan's very low cost should be acceptable to all employers and eliminate the need for tax credits or incentives. 12 references.

293

TITLE: Nurses' Perceptions: Issues that Arise in Caring for Patients with Diabetes in a Managed Care Environment (abstract). McDonald, P.E.; Tilley, B.C.; Havstad, S. *AHSR FHSR Annual Meeting Abstract Book*. 1996;13:191.

OBJECTIVE: To examine the role of nurses in the care of patients with diabetes within the Henry Ford Health System, a managed care environment.

CATEGORY: Expert opinion.

CONCLUSION: Constituting the largest segment of health care providers in the country, nurses are in a unique position to facilitate the improvement of health and quality-of-life outcomes for patients with diabetes.

RECOMMENDATION: None.

ABSTRACT: Randomly selected registered nurses from the Henry Ford Health System completed surveys on caring for patients with diabetes. Twenty-six percent of the respondents reported they did not see diabetes patients, a surprising finding given the prevalence of diabetes in the community. Nurses felt they needed more education in caring for patients with diabetes, saw practice guidelines as helpful, believed it was appropriate for a nurse to change treatment regimens, considered primary patient problems to be lack of knowledge and acceptance of diabetes, and believed solutions should focus on educating nurses and reinforcing to patients the need for follow-up care.

294

TITLE: Optometrist Screening for Retinopathy: Evidence and Environment. Mason, J.;

Drummond, M.; Woodward, G. *Ophthalmic & Physiological Optics*. 16(4): 274-285. July 1996.

OBJECTIVE: To examine the role of optometrists in screening for retinopathy and to challenge inappropriate conclusions in the literature about this issue. To consider how screening for retinopathy should be developed in Great Britain.

CATEGORY: Expert opinion.

CONCLUSION: How screening for retinopathy should be conducted is still unresolved.

RECOMMENDATION: Research should be conducted on a variety of issues relative to screening.

ABSTRACT: For the present review, a MEDLINE search was conducted that identified two data sets relating to screening by optometrists that the authors considered to bear directly on screening in the United Kingdom-the Special Medical Development Project (SMDP) and the Frenchay study. In the SMDP, no significant difference in performance of ophthalmoscopy was found among screeners (general practitioners, hospital physicians, and optometrists) in terms of sensitivity. However, test sensitivity was lower than expected for all methods used (Buxton et al. 1991). In another evaluation of SMDP (by Sculpher et al. 1992), screening by opticians (optometrists) alone was, in relative terms, found not to be a competitive option. The authors of the present study express concern with the SMDP study design and subsequent analysis; they find the conclusion that screening strategies based in general practices provide considerable cost savings over those obtained with screening by optometrists to be questionable. The authors note that results of the Frenchay study, in which optometrists were asked to report retinopathy and indicate whether it was sight-threatening, suggest that they performed considerably better in this study than did the optometrists in the SMDP. Two studies (one on the SMDP, one on the Frenchay study) that addressed referral on the basis of need for treatment suggested test sensitivities for optometrist screening of 48 and 87 percent, respectively, with specificities of 94 percent in both. The authors note a study (Ryder et al. 1994) reported in abstract form that found a sensitivity of 100 percent when optometrists performed both mydriatic-assisted photography and ophthalmoscopy. General practitioners and optometrists, because of their numbers, are the main candidates for community screening according to the authors. In their discussion they state that the need to screen for retinopathy is uncontroversial, but the mode of screening is unresolved. They note that the only way to resolve current controversies may be to undertake a more methodologically rigorous comparison of primary screeners. 7 tables, 54 references.

295

TITLE: Pancreas Transplantation for Type I Diabetes Mellitus: Do the Benefits Offset the Risks and Cost? Larsen, J.L.; Duckworth, W.C.; Stratta, R.J. *Postgraduate Medicine*. 96(3): 105-111. September 1, 1994.

OBJECTIVE: To determine whether the benefits of a pancreas transplant to treat type 1

diabetes are worth the risks and cost.

CATEGORY: Expert opinion.

CONCLUSION: Combined pancreas-kidney transplantation is becoming increasingly common and acceptable for treating patients with type 1 diabetes and end-stage renal disease. Patient mortality and kidney graft survival are not significantly different from a kidney transplant alone, and costs are offset by the added benefits to the patient of improved glycemic control without exogenous insulin, better lipid profiles, and improved quality of life.

RECOMMENDATION: None.

ABSTRACT: The authors discuss the current status of pancreas transplantation, either alone or in combination with a kidney transplant, as a treatment for type 1 diabetes. Between 1987 and 1991, the overall 1-year patient survival rate in the United States for all types of pancreas transplants was 91 percent, and the 1-year pancreas graft survival rate was 72 percent. Pancreas transplantation should be considered for all patients with type 1 diabetes and severe nephropathy. At the University of Nebraska, patients with significant nephropathy are considered for a combined transplant, and patients who have had a kidney transplant or those with severe end-organ complications (e.g., proliferative retinopathy) or severely unstable glucose control are considered candidates for pancreas transplants. A comprehensive multidisciplinary evaluation confirms the diagnosis of type 1 diabetes, the patient's ability to undergo major surgery, absence of exclusion criteria, and existence of end-organ complications that would benefit from improved metabolic control. The success rates for solitary and sequential pancreas transplants are not as high as those for combined pancreas-kidney transplants. Improved graft and patient survival rates result from better HLA matching, better organ retrieval with shorter preservation times, better operative techniques, improved ability to predict rejection by renal parameters, and better immunosuppressive regimens. Potential immediate complications include graft rejection, vascular thrombosis, pancreatitis, and infection, while later concerns relate to the effects of immunosuppression and hyperinsulinemia. At most centers, kidney-graft survival and overall mortality rates for combined trans-plants are comparable to those for kidney transplants only. Patients who have had transplants must take immunosuppressive drugs for the remainder of their lives, but they have fewer dietary and activity restrictions and experience a marked improvement in quality of life, with improved glycemic control and potential for rehabilitation. 1 figure, 3 tables, 6 references.

296

TITLE: Patient Education Financing under Medicare. Smith, S.A. *Patient Education and Counseling*. 8(3): 299-309. September 1986.

OBJECTIVE: To provide the history of Medicare reimbursement for preventive services.

CATEGORY: Expert opinion.

CONCLUSION: Medicare payment is currently limited to diagnostic or therapeutic care, with a few exceptions. The Prospective Payment System (PPS) may benefit hospitals, patients, and health education specialists if educators provide good evidence of their own usefulness in decreasing stay and shifting care to the outpatient setting.

RECOMMENDATION: None.

ABSTRACT: In this overview, the author notes that since 1965 Medicare reimbursement has been generally limited to treatment of illness or injury. Two exceptions have been pneumococcal immunization (authorized in 1981) and hepatitis B vaccination (1984), both of them primary prevention. A broad range of secondary prevention clinical/educational services are reimbursable under Part B of Medicare if an individual physician deems them appropriate as part of routine care. The key to assuring Medicare coverage for preventive services lies in presenting the claim to Medicare carriers as necessary to the diagnosis or treatment of a disease or injury. Before the advent of the Diabetes Control Program of the Centers for Disease Control (CDC), Medicare did not pay for outpatient diabetes education. The CDC-sponsored project has succeeded in defining what is allowable under Medicare regulations for patient education as a separately billable item. By 1988, PPS will have replaced retrospective cost reimbursement. Under PPS, certain patient education services could be more attractive to hospitals; solid evidence shows that focusing on ambulatory outpatient diabetes education is profitable because stays can be reduced. As a result of the Tax Equity and Fiscal Responsibility Act of 1982, expanded benefit programs including preventive services are being offered by health maintenance organizations. 16 references.

297

TITLE: Paying for Preventive Care: Moving the Debate Forward. Davis, K.; Bialek, R.; Parkinson, M.; Smith, J.; Vellozzi, C. *American Journal of Preventive Medicine*. 6(4 Supplement): S7-S30. 1990.

OBJECTIVE: To suggest methods of improving the delivery and reimbursement of preventive services.

CATEGORY: Expert opinion.

CONCLUSION: Several strategies need to be adopted to improve payment for and delivery of preventive services, including the modification of health insurance plans to cover preventive services specified by the U.S. Preventive Services Task Force.

RECOMMENDATION: In addition to modification of insurance plans, reimbursement codes need to be modified and more research on preventive services needs to be conducted.

ABSTRACT: The authors discuss primary and secondary preventive care services. They review the Guide to Clinical Preventive Services (1989) developed by the U.S. Preventive Services Task Force, which contains age-, sex-, and risk-specific recommendations for

prevention of illness and death. Both public and private insurers base reimbursement for services and procedures defined with the American Medical Association's Current Procedural Terminology (CPT-4), and CPT-4 codes exist for age-specific preventive services. However, a 1986 survey found that only 35 percent of reporting insurance companies offered preventive care coverage under group contracts. Furthermore, until 1981, no preventive service was covered by Medicare. Use of preventive services is correlated with insurance coverage, and such services are used less than is recommended. The authors consider four methods (a-d) of paying providers for preventive services. They note that (method a) fee-for-service reimbursement is the primary mode of paying for physician services and is most acceptable to physicians, but they point out that overuse is a possibility. A periodic preventive health visit fee (method b), which would involve a specified package of preventive services, would create an incentive to provide appropriate preventive services at appropriate intervals. However, it would have extensive administrative requirements as well as other shortcomings. Capitation payment (method c) may not be seen by capitated organizations as cost-beneficial; many users are transient, and the organization may not believe there will be a long-term benefit from providing preventive services. A preventive services account (method d) would allow patients to decide which preventive services they wanted, but patients might get caught up in current fads; other weaknesses are discussed. The authors make several recommendations: public and private health insurance plans need to be modified and fee-for-service payment for preventive services merits continued consideration, but a periodic preventive health visit fee might be preferable in the longer term. 1 figure, 10 tables, 48 references.

298

TITLE: Payment for Diabetes Care Under the Medicare Fee Schedule. Lasker, R.D. *Diabetes Care*. 15(Supplement 1): S62-S65. March 1992.

OBJECTIVE: To review the problems with payment for diabetes care under the current (pre-1992) Medicare system; to describe the anticipated effects of the Medicare fee schedule on physician reimbursement and on the quality of care of patients with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: The Medicare fee schedule to be phased in beginning January 1992 should more adequately compensate physicians who provide evaluation and management services for patients with diabetes and should improve the quality of care of these patients.

RECOMMENDATION: None.

ABSTRACT: The author describes problems associated with payment for diabetes care under the current (pre-1992) Medicare system and reviews the anticipated impact of the new Medicare fee schedule on physician reimbursement and the quality of care of patients with diabetes. The care of patients with diabetes primarily involves evaluation and management services; the current Medicare payment system, which is based on "customary, prevailing, and reasonable" charges, inadequately compensates physicians for such services, and payments do not correlate well with service resource costs. Payments also vary for the same service,

depending on physician specialty and location of practice. Under the Medicare fee schedule to be implemented in 1992, a fee will be assigned to each patient care service that is proportional to the work and practice costs involved in providing it. Fees for evaluation and management services are expected to increase an average of 28 percent over what they would increase with the current system; Medicare payments to physicians providing primarily evaluation and management services should increase by 17 to 38 percent. Payments for evaluation and management will differ by specialty to reflect differences in time and effort. With more equitable compensation for lengthy and new patient visits, physicians will be encouraged to provide the time-consuming evaluation and management services that patients with diabetes require. Physicians will also have greater financial incentive to obtain advanced training in diabetes management, and specialties such as endocrinology and internal medicine will be more attractive to physicians-in-training. The Medicare fee schedule should improve access to care and the quality of care for patients with diabetes who are beneficiaries of the Medicare program. Note: A footnote to the article indicates that budget cuts and other factors may reduce expected increases in evaluation and management payments. 6 references.

299

TITLE: Perceived Effectiveness, Cost, and Availability of Patient Education Methods and Materials. Funnell, M.M.; Donnelly, M.B.; Anderson, R.M.; Johnson, P.D.; Oh, M.S. *Diabetes Educator*. 18(2): 139-145. March-April 1992.

OBJECTIVE: To determine the efficacy and cost-effectiveness of patient education methods and media.

CATEGORY: Expert opinion.

CONCLUSION: Teaching methods that were used most frequently and given the highest marks for effectiveness received relatively low marks for cost-effectiveness.

RECOMMENDATION: None.

ABSTRACT: A survey about patient education was sent to 816 members of the American Association of Diabetes Educators; there were 325 respondents (40 percent). The educators were asked to rate selected educational materials and methods on their educational and cost-effectiveness. Among educational materials, videotapes, slides/tapes, and booklets received the highest rankings for both measures of effectiveness. Among methods, individual approaches (skill sessions, counseling sessions, content sessions) got the highest marks on educational effectiveness but received relatively low marks on cost-effectiveness. Booklets, videotapes, and books were used by more than four-fifths of respondents; most did not use computer-assisted or programmed instruction. Respondents obtained materials from manufacturing companies (88 percent), developed their own (84 percent), or purchased them from other sources (60 percent). Lack of third party reimbursement and lack of patient motivation were identified most often as major barriers to high-quality patient education. Psychosocial issues (e.g., adjustment, stress) were found to be the areas of greatest need for developing more educational materials, followed by special populations and long-term

complications. The authors point out that the teaching methods that diabetes educators use most frequently and believe to be educationally sound are not considered by this group to be cost effective. 8 tables, 8 references.

300

TITLE: Potential for Reducing Health Care Costs by Public and Patient Education: Summary of Selected Studies. Roccella, E.J. *Public Health Reports*. 91(3): 223-225. May-June 1976.

OBJECTIVE: To review selected studies pertaining to the potential impact of patient education on health care costs.

CATEGORY: Expert opinion.

CONCLUSION: Educational programs that help patients to understand the nature of their illness and what they can do to help themselves have the potential to reduce health care costs.

RECOMMENDATION: Additional, more carefully controlled studies are needed to fully document the impact of patient and public education programs on health care costs.

ABSTRACT: The authors review several studies that document the impact of patient education programs on health care costs. A study by Miller and Goldstein (1972) assessed the effects of a telephone hot line developed by a California clinic for patients with diabetes . Patients could call the hot line for information, medical advice, and prescriptions. An education program on use of the service was designed for clinic patients with diabetes. Over a 2-year period, the incidence of diabetic coma at the clinic was reduced from 300 to 100 cases, and the number of emergency room admissions for patients with diabetes decreased by 50 percent even though the clinic population increased from 4,000 to 6,000. The hot line saved an estimated 2,300 clinic visits for medications alone. This and other studies indicate the potential positive impact of patient education programs on health care costs. More detailed, controlled cost-benefit and cost-effectiveness studies are needed to document the potential cost savings associated with patient education programs. 18 references.

301

TITLE: Psychosocial Challenges for Children with Insulin-Dependent Diabetes Mellitus. Pond, J.S.; Peters, M.L.; Pannell, D.L.; Rogers, C.S. *Diabetes Educator*. 21(4): 297-299. July-August 1995.

OBJECTIVE: To relate the psychosocial stages of child development delineated by Erik Erikson to children with type 1 diabetes; to give suggestions to families and health care providers involved with such children.

CATEGORY: Expert opinion.

CONCLUSION: Key issues in the psychosocial growth of children include the development of trust, autonomy, initiative, and industry. These key issues are particularly important for children with type 1 diabetes.

RECOMMENDATION: Family members and caregivers should try to build trust, autonomy, initiative, and industry at every age.

ABSTRACT: The authors apply the psychosocial stages of childhood delineated by Erik Erikson (1950) to children with type 1 diabetes. They emphasize the first four stages, which include developing a foundational trust or acquiring a mistrust of the world during infancy; developing a sense of autonomy; the conflict of initiative versus guilt (preschool years); and "industry versus inferiority" (at school and home). Chronic illness, such as diabetes, affects a child's progression through the psychosocial stages. Recommendations are made for families and health care providers to help children with their development. During "initiative versus guilt," for example, health care providers can help parents understand that it is normal for children to consider their illness a punishment. Family members and health care providers should try to build trust, autonomy, initiative, and industry at all ages; consistent understanding and support can enhance trust at any stage. Autonomy can be increased by helping children explore and master the environment with as few limitations as appropriate for maintaining health and conforming to social obligations. Initiative can be increased by not allowing type 1 diabetes to be the only focus of the child's life. Helping children with type 1 diabetes to care for themselves and make as many decisions as possible is crucial to maintaining adequate metabolic control. Parents should be encouraged to gradually transfer responsibilities for diabetes care to their children. Children are usually ready to begin injecting insulin at about age 9. 9 references.

302

TITLE: Quality Assurance Issues. Homa-Lowry, J. *Diabetes Care*. 15 (Supplement 1): S51-S53. March 1992.

OBJECTIVE: To document changes since 1965 in health care quality assurance systems and their impact on health care for patients with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Since enactment of the Prospective Payment System for Medicare in 1983, the venue of diabetes care has shifted dramatically from inpatient hospitalization to outpatient care, a setting not subject to significant quality assurance review.

RECOMMENDATION: Standards must be established for patient outcomes and the processes needed to attain them to fully assess the impact of quality assurance system changes on the quality of diabetes care.

ABSTRACT: The author documents changes since the 1965 establishment of Medicare and

Medicaid in health care quality assurance systems and the impact of these changes on the financing of diabetes care. The most significant change to the utilization review and quality assurance processes resulted from the 1983 enactment of Title IV of the Social Security Act, which established the Prospective Payment System for Medicare. With this act, reimbursement was shifted from reasonable costs to a predetermined fixed price per discharge. Prior to the Prospective Payment System, utilization review programs were not very effective in monitoring and limiting resource utilization; the cost reimbursement system rewarded those that used the most resources. The impact of the financial changes of the Prospective Payment System on quality of care is difficult to assess because data on patient outcomes prior to its enactment are not readily available. Hospital admissions for treatment of type 2 or type 1 diabetes as a primary diagnosis declined dramatically from 1981 to 1988, suggesting a significant shift in diabetes care to the outpatient setting. The issue of quality assurance systems in the outpatient treatment venue remains to be addressed, as does the potential impact of case management on patient quality of care. 2 tables, 1 reference.

303

TITLE: Quality-of-Life Evaluation in Diabetes. Eiser, C.; Tooke, J.E. *PharmacoEconomics*. 4(2): 85-91. August 1993.

OBJECTIVE: To review the state of the art in developing quality-of-life scales and to assess their potential value in *Diabetes Research* and clinical practice.

CATEGORY: Expert opinion.

CONCLUSION: Measures of quality of life appear to be most important for assessing the impact of different treatments and procedures.

RECOMMENDATION: Quality-of-life assessments should be integral components of clinical trials of alternative therapies for patients with diabetes and should be part of everyday clinical decisions.

ABSTRACT: The authors review current methods of measuring quality of life, discuss the application of such measures to diabetes, and examine sex differences in self-reports of life quality. Managing diabetes, especially its emphasis on self-care, imposes great demands on patients and their families, and it potentially compromises the attainment of a good quality of life in numerous ways. Two broad approaches are used in quality-of-life assessments: one assumes that quality of life is synonymous with health status; it emphasizes the importance of an individual's absolute level of functioning relative to the general population. A second approach stresses individual differences in how people perceive and appraise situations; in this approach, the individual's perceptions of and satisfaction with level of functioning are central. Diabetes-specific quality-of-life scales are useful in assessing how a specific treatment for diabetes affects individuals and where comparisons across alternative treatments are desired. The most widely quoted instrument is the Diabetes Quality of Life measure developed for the Diabetes Control and Complications Trial (Jacobson et al. 1988). The authors note that quality-of-life measures have most commonly been used to assess the impact of new

treatments, particularly when patients change from syringe injections to multiple pen treatments. They have also been used in assessing the impact of transplants and in studies involving the conversion to insulin in type 2 diabetes. In using these measures, differences in quality of life as a function of age and sex must be considered, especially in evaluating clinical trials. 26 references.

304

TITLE: Rationale for the Hypertension Guidelines for Primary Care in South Africa. Opie, L. H.; Steyn, K. *South African Medical Journal*. 85(12 Part 2): 13251328, 13301331, 13341335. December 1995.

OBJECTIVE: To provide a rationale for the proposed hypertension guidelines for primary care in South Africa.

CATEGORY: Expert opinion.

CONCLUSION: Cost-Effective care should be provided to as many persons with hypertension as possible.

RECOMMENDATION: The guidelines need to be reviewed and adapted regularly as new knowledge becomes available or if their practical application suggests viable alternatives.

ABSTRACT: The authors reviewed the hypertension guidelines proposed by the Hypertension Society of Southern Africa and rationalize their adoption. Aims are to provide practical recommendations that can be followed in the primary care setting and to provide Cost-Effective care for as many hypertensive persons as possible. The guidelines recommend measuring blood pressure with the patient sitting and taking more than one measurement. Per the guidelines, patients with a systolic blood pressure reading of 140 to 169 mm Hg or a diastolic reading of 90 to 99 mm Hg should be provided with education on hypertension and treatment by lifestyle modifications (e.g., proper diet, exercise). The cutoff point for drug treatment is a diastolic blood pressure of 110 to 114 mm Hg or a systolic blood pressure of 170 to 199 mm Hg. For a patient with a diastolic blood pressure of 115 to 129 mm Hg and/or a systolic blood pressure of 200 mm Hg or higher, the blood pressure reading should be repeated after 1 hour's rest; if it is still in this range, the primary care provider should start drug treatment promptly and refer or investigate the patient within 1 week. All patients with diabetes should be referred, and the aim in these patients should be a diastolic pressure of 90 mm Hg and a systolic blood pressure of 140 mm Hg or less. Drug therapy for hypertension is categorized as first-line (e.g., diuretics), second-line (e.g., betablockers, ACE inhibitors), and third-line (e.g., hydralazine). Each line of treatment is progressively more expensive. Practitioners should begin drug treatment with a low-dose diuretic because of its cost-effectiveness and the wide experience with it. 3 tables, 55 references.

305

TITLE: Reimbursement for Diabetes Self-Care Training: The North Carolina Experience. Fore, W.W. *Diabetes Care*. 17(6): 608-610. June 1994.

OBJECTIVE: To determine why diabetes programs in North Carolina were slow to use special codes enacted in 1985 for the reimbursement of training in self-care.

CATEGORY: Expert opinion.

CONCLUSION: The establishment of specific service codes by Blue Cross/Blue Shield of North Carolina did not lead to the use or level of reimbursement anticipated. Other sources of revenue are supporting self-care programs. Just six of nine programs were aware of the codes eight years after enactment, and only four of these six used them to obtain reimbursement from two major North Carolina insurers.

RECOMMENDATION: The team approach to diabetes self-care needs specific billing codes that identify the service as well as reimbursement that will cover the cost of providing it.

ABSTRACT: Providers of health services encounter barriers in obtaining reimbursement for preventive and educational services. In 1985, Blue Cross/Blue Shield (BC/BS) of North Carolina published Guidelines for Reimbursement of Diabetes Self-Care, which acknowledged the team approach in diabetes care and provided three service codes for billing. The guidelines were extended the same year to the State Health Insurance Plan of North Carolina. A 1993 review of the guidelines' effect found that in 1991, insurance benefits were paid for less than 250 patients under either BC/BS's regular business plan or the state plan. Patient volumes were similar in 1992. This minimal activity contrasted with the growth of diabetes programs in North Carolina recognized by the American Diabetes Association from none in the first six months of 1988 to nine in 1992. A 1993 survey of the nine programs found only six to be aware of the codes and only four of these six to be obtaining reimbursement from the insurers noted; the remaining two programs billed under physician or hospital codes in an effort to obtain more revenue. Two of the four programs using the new codes mentioned obstacles to filing or exclusion of coverage. The author notes that Medicare requires diabetes self-care training to be associated with a hospital to be reimbursed under Medicare Part B. He states that the restriction of reimbursement to physicians or hospitals for self-care is not preventing the use of such programs nor decreasing their cost. The author also notes that current payments for self-care training do not cover costs. He calls for adequate compensation of the administrative and teaching effort of physicians. In discussing proposed legislation to extend Medicare reimbursement for self-care training, the author states that the costs of such training are already present in physician and hospital billing and would not be all new funding. 5 references.

306

TITLE: Reimbursement Issues in Diabetes. Sinnock, P.; Bauer, D.W. *Diabetes Care*. 7(3): 291296. May-June 1984.

OBJECTIVE: To review reimbursement issues in outpatient education and in new technologies and services for people with diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Outpatient diabetes education is generally a covered service, but the mechanism to reimburse providers for the service varies from state to state. For diabetes-related technologies or services, there is little uniformity among third party payers.

RECOMMENDATION: The authors make a variety of recommendations to improve problems with reimbursement for education.

ABSTRACT: The authors review coverage under Medicare, Medicaid, Blue Cross/Blue Shield, and private insurance for 20 inpatient diabetes education programs; 15 states have coverage through 1 or more of these sources. Although third party payers recognize the role of patient education, they routinely reimburse only when the education is provided during a hospital stay. Third party reimbursement of diabetesrelated technologies/services and equipment depends on the type of coverage, the state, and the item or procedure covered. Many third party payers do not have stated policies on reimbursement for a particular piece of equipment, or they do not have consistent, well-communicated standards for determining coverage. Based on their review of attempts to obtain third party reimbursement for diabetes outpatient education, the authors assert the following: the language of insurers differs from that of providers, the types of services covered under existing policies are explicitly stated, patience is a virtue in requesting coverage, third party payers usually request that cost-effectiveness be addressed, and requests for reimbursement will be evaluated according to the criteria of the third party payer. To help overcome the problem with reimbursement for education, the authors state that there is a need for rapid dissemination of Medicare policies on outpatient education. They also ask that successes in obtaining coverage be documented and published in national journals. In addition, they request that the minimum standard for patient education developed by the National Diabetes Advisory Board be disseminated to all insurers. They also recommend educating providers about health care finance. 3 tables, 27 references.

307

TITLE: Reins or Fences: A Physician's View of Cost Containment. Grumbach, K.; Bodenheimer, T. *Health Affairs*. 9(4): 120-126. Winter 1990.

OBJECTIVE: To discuss the impact of expenditure targets and utilization review on cost containment and clinical decisions.

CATEGORY: Expert opinion.

CONCLUSION: Global budgeting strategies are preferable to utilization review for cost containment.

RECOMMENDATION: When evaluating cost-containment measures, physicians and policymakers should consider the impact on clinical autonomy.

ABSTRACT: The authors compare the impact of utilization review and global budgetary controls on the professional autonomy of physicians. They define professional autonomy as clinical freedom, which is essentially the ability of the physician to deliver optimum medical care to a patient without restraint from groups with other interests. The authors consider peer review and negotiations with third party payers to set fees as unrelated to professional autonomy. Utilization (not peer) review, however, suffers from uncertainty about what constitutes inappropriate care and has turned American physicians into the most "second-guessed and paperwork-laden physicians in western industrialized democracies." Proposals to expand current utilization review practices into the ambulatory sector are daunting. The utilization review system has promoted a large bureaucracy, which has resulted in administrative costs increasing more than twice as fast as overall health costs from 1980 to 1986. The alternative is expenditure targets, which limit resource usage by particular groups but distance day-to-day clinical decisions from the cost-control process. Expenditure limits let the community of physicians regulate itself rather than relying on outside review, although such limits exert pressure to control the number of physicians relative to the population. Global budgetary strategies allow more clinical freedom for physicians than does utilization review. 18 references.

308

TITLE: Relevance of Postprandial Glycosuria in Survey for Diabetes Mellitus. Tosetti, C.; Brunetti, R.; Evangelisti, A.; Napoli, A. *Minerva Medica*. 87(11): 505-508. November 1996.

OBJECTIVE: To evaluate the measurement of postprandial glycosuria as an approach to selecting adults needing a fuller assessment for possible diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Performing urinalysis measured after a meal rich in carbohydrates and urinalysis following glucose load could be considered simple, inexpensive approaches in people over 50 years old. In those under age 50, fasting glycosuria or clinical criteria, particularly relevant family history, are superior approaches to postprandial urinalysis.

RECOMMENDATION: None.

ABSTRACT: The authors studied 110 adults; 64 had had postprandial glycosuria on a previous screening, and 46 had been referred by general practitioners to the authors' diabetes center in Italy because of risk factors (family history with or without overweight, or overweight plus dyslipidemia). Urine was tested for glucose with the participant in the fasting state, postprandially (after a hyperglycemic meal), and 30, 60, 90, and 120 minutes after 75 g of glucose was ingested. Five criteria (family history of diabetes, relevant family history [at least one first-degree relative with diabetes], overweight, overweight plus diabetic family

history, and overweight plus relevant diabetic family history) were also evaluated retrospectively. Ten of those evaluated (9 percent) were found to have diabetes and 16 (15 percent) to have impaired glucose tolerance. All 10 determined to have diabetes had postprandial glycosuria as well as glycosuria 60 minutes or more after glucose load; thus these tests had 100 percent sensitivity. Only 2 of 10 persons found to have diabetes had fasting glycosuria. The specificity of postprandial glycosuria in younger patients (≤ 50 years old) was 48 percent; in older patients it was 44 percent. Specificities for glycosuria 60 or more minutes after glucose load ranged from 61 to 67 percent in younger patients and from 35 to 48 percent in older patients. The sensitivity of fasting glycosuria was 100 percent for younger adults (specificity equaled 96 percent) but just 11 percent for older adults (specificity equaled 94 percent). All five clinical criteria had 100 percent sensitivity in younger patients (specificity ranged from 37 to 87 percent), but in older patients the sensitivity was 33 percent or less for four of the five criteria. The positive predictive value of postprandial glycosuria was 23 percent for older patients but only 4 percent for younger patients, which the authors attribute to the much higher prevalence of diabetes in the older population. 1 table, 11 references.

309

TITLE: Scientific Rigor of Economic Analyses (letter). Lee, J.T.; Sanchez, L.A. *Annals of Internal Medicine*. 117(2): 172. July 15, 1992.

OBJECTIVE: To supplement the findings of Udvar-helyi et al. that were published in an earlier issue of *Annals of Internal Medicine* with a similar assessment of manuscripts appearing in pharmacy journals.

CATEGORY: Expert opinion.

CONCLUSION: Economic articles in the pharmacy literature reviewed by the authors were often deficient methodologically.

RECOMMENDATION: A multidisciplinary initiative is warranted to educate researchers, practitioners, and third party payers in the essential components of a thorough economic analysis.

ABSTRACT: The authors performed an assessment, using a process similar to that of Udvarhelyi et al., of the methodologic soundness of 65 articles that included economic analyses in six pharmacy journals from 1985 to 1990. The articles were subjected to 10 criteria to assess whether appropriate methodologic techniques were used. Only 3 of the 10 criteria were fulfilled by 50 percent or more of studies evaluated. The authors found deficiencies in identifying all relevant costs and consequences, in discounting, and in performing sensitivity and incremental analyses. The term "cost effective" was misinterpreted in 57 percent of the studies evaluated. The authors found no differences in methodologic soundness by journal or year of publication. 4 references.

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TITLE: Screening for Retinopathy. Singer, D.E.; Nathan, D.M.; Fogel, H.A.; Schachat, A.P. *Annals of Internal Medicine*. 116(8): 660671. April 15, 1992.

OBJECTIVE: To determine appropriate patients, methods, timing, and cost-effectiveness for screening for retinopathy.

CATEGORY: Expert opinion.

CONCLUSION: Cost-effectiveness analyses indicate that widespread screening for retinopathy appears to be good policy.

RECOMMENDATION: Although the current recommendations for retinopathy screening are reasonable, the following changes should be considered to increase efficiency and benefit: (1) reduce the frequency of screening in the initial years after the diagnosis of diabetes in selected patients with type 2 diabetes, and (2) encourage wider use of stereoscopic fundus photography for screening.

ABSTRACT: The authors review the natural history of retinopathy, identify risk factors for its development, review intervention studies defining eye lesions that respond to laser therapy, and review cost-effectiveness analyses and evaluate available screening modalities. Relevant articles were identified by examining prominent review articles and the authors' own files as well as through recommendations from experts at the American Academy of Ophthalmology and a MEDLINE search. Articles on the natural history of retinopathy were limited to large clinical series and formal epidemiologic studies of defined populations; those on the therapeutic effect of photocoagulation and of glycemic control were restricted to randomized trials. For important data variables, individual estimates from multiple studies were presented in the study rather than a single metaanalytic summary estimate. Analysis revealed that photocoagulation therapy can reduce the risk for vision loss due to macular edema or proliferative retinopathy by about 50 percent. The evidence also showed that duration of diabetes is the main risk factor for retinopathy. (The type of diabetes and the severity of baseline retinopathy also influence the onset and progression of retinopathy.) The authors found that standard ophthalmoscopic examination has moderate sensitivity (80 percent in research settings) and specificity (greater than 90 percent for proliferative retinopathy, lower for macular edema), thereby making seven-field stereoscopic photography of the fundus a more accurate method. cost-effectiveness analyses indicate that widespread screening for retinopathy seems to be good health policy. Among patients with type 1 diabetes, the cost of preventing blindness is less than averted disability payments. Screening is far less beneficial for patients with type 2 diabetes but still can be expected to provide additional years of sight efficiently. Cost savings could safely be realized by having patients with type 2 diabetes who do not have retinopathy on initial screening wait 4 years for their next screening, then proceed with annual screening. 3 figures, 2 tables, 74 references.

311

TITLE: Should Persons with Diabetes Be Licensed to Drive Trucks? Risk Management.

Lave, L.B.; Songer, T.J.; LaPorte, R.E. *Risk Analysis*. 13(3): 327-334. June 1993.

OBJECTIVE: To assess whether persons with diabetes mellitus who use insulin should be licensed to drive trucks on interstate highways.

CATEGORY: Expert opinion.

CONCLUSION: The additional risks of licensing insulin-using drivers are well within the currently accepted range of risks for all drivers. The annual costs per driver from additional crashes incurred by insulin-dependent drivers were estimated at $4,800; for such drivers with a history of severe hypoglycemia, $17,900.

RECOMMENDATION: Denying commercial vehicle licenses for persons with a recent history of severe hypoglycemic reactions should be considered because of the large costs potentially incurred by such persons.

ABSTRACT: The Federal Highway Administration has denied commercial motor vehicle licenses to persons who use insulin but is reconsidering this decision; the authors apply risk analysis to this issue. As a group, persons with diabetes who use insulin have almost four times the risk of highway crashes as persons without diabetes. Songer et al. (1993) estimated that mild hypoglycemia would cause an insulin-dependent driver to have an additional 0.00002 crashes each year, on average, while an insulin-using, but not insulin-dependent, person would have an additional 0.00001 crashes per year. Severe hypoglycemia would lead to 0.04 to 0.24 additional crashes per driver, depending on insulin-use status. Additional crashes caused by insulin-using drivers were estimated to cost society at least $3,600 per driver per year. The additional annual costs for insulin-dependent persons were estimated at $4,800; for persons with a history of severe hypoglycemia, $17,900. The authors note that the three- to five-fold increases in risks of a crash (for persons using insulin) are well within tolerable limits for highway risks for type of highway, size of car, and time of day. For example, the safest urban highways are 9.2 times safer than the most dangerous rural highways. The authors also note that 70 percent of states permit insulin-using persons to drive trucks within their states. They contend, however, that the additional social costs due to fatalities, injuries, and property damage associated with allowing persons with a history of severe hypoglycemia to drive exceed currently acceptable levels. 3 figures, 4 tables, 16 references.

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TITLE: Social and Economic Impact on Youth-Onset Diabetes in Japan. Matsushima, M.; Tajima, N.; Agata, T.; Yokoyama, J.; Ikeda, Y.; Isogai, Y. *Diabetes Care*. 16(5): 824-827. May 1993.

OBJECTIVE: To evaluate whether patients in Japan with type 1 diabetes are socially handicapped and to determine the factors associated with their socioeconomic status.

CATEGORY: Expert opinion.

CONCLUSION: Patients with type 1 diabetes experienced discrimination in the job market and had lower average incomes.

RECOMMENDATION: Further studies should be performed to precisely document the social and economic impact of diabetes.

ABSTRACT: The authors used a matched-pair, case-control approach to study patients with type 1 diabetes (onset before 25 years) who had visited a Tokyo clinic. Case patients (n = 35) and controls, all of whom were siblings without diabetes, completed a questionnaire on socioeconomic status and employment. The distribution of educational achievement was similar between the two groups. There was also no significant difference in current employment status, but the controls had higher incomes than patients with diabetes ($p < 0.05$); there was still a difference even when the data from the six patients with work disability from diabetic complications and their control siblings were excluded. While none of the controls had experienced job refusal, seven patients with diabetes had been refused a job. Six of these seven had developed diabetes before obtaining a job and had mentioned their diabetes to job interviewers. Multivariate analysis showed that diabetes status was independently associated with income level. Absenteeism did not differ between patients with diabetes and controls. 3 tables, 10 references.

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TITLE: Statistics, CPT, ICD9, CDM, and Level III Codes: What Are They and How Did I Get This Job? Bourgeois, P. *Diabetes Educator*. 17(5): 349, 351352. September-October 1991.

OBJECTIVE: To provide diabetes educators with an overview of what they can do to reduce the risk of their program being cut financially or eliminated entirely.

CATEGORY: Expert opinion.

CONCLUSION: Diabetes educators must be aware of reimbursement issues and terminology for their patients' sake as well as for their own, or risk losing the diabetes education program entirely.

RECOMMENDATION: Diabetes educators should prepare a mission statement with goals, objectives, and a business plan; meet with administrators to discuss the program; obtain admission statistics on patients with diabetes; learn the coding terminology; prepare charge descriptions; and meet with Medicare/Medicaid intermediaries and private insurers to discuss reimbursement.

ABSTRACT: Acknowledging that education, particularly diabetes education, is one of the first hospital services to be eliminated or cut back, the author encourages diabetes educators to justify the importance of their position to administrators. The author recommends developing a mission statement and 1-year business plan. Diabetes educators should document

their time by activity. The American Diabetes Association's (ADA's) publications Diabetes Outpatient Education: The Evidence of Cost Savings and Third party Reimbursement for Diabetes Outpatient Education: A Manual for Health Care Professionals are recommended. Educators should meet with administrators to discuss the education program, including preparation of charge descriptions and use of various codes (e.g., ICD-9, CPT). They should prepare charge description master codes for procedures using the ADA's manual. They should request an audit of patients admitted with a diabetes-related diagnosis and possibly ask for statistics about patients admitted with a secondary diagnosis of diabetes. These statistics should be available for reimbursement discussions with administration or negotiations with insurance companies. The number of patients admitted with diabetes as a secondary diagnosis is usually three times the number of those admitted with diabetes as a primary diagnosis. The business office should be asked to file insurance claims for patients with diabetes, even briefly, to convince that office it is worthwhile. The memorandum on outpatient diabetes education reimbursement coverage, Hosp 88-08, should be requested from Medicare. Diabetes educators must be aware of reimbursement issues and technology. 5 references.

314

TITLE: Summary Document of Nutrition Intervention in Diabetes. Geppert, J.; Splett, P.L. *Journal of the American Dietetic Association*. 91(11):S27-S30. November 1991.

OBJECTIVE: To describe and assess nutrition interventions in diabetes mellitus.

CATEGORY: Expert opinion.

CONCLUSION: Nutrition is important in managing diabetes and in preventing and treating its complications.

RECOMMENDATION: With other members of the diabetes team, dietitians can help patients improve glycemic control, promote appropriate weight loss, control hypertension, and improve lipid concentrations.

ABSTRACT: Nutrition affects outcomes for diabetes mellitus directly through control of blood glucose and indirectly through therapeutic effects on high blood pressure and obesity. The primary goal of nutritional therapy for this disorder is to promote normal blood concentrations of glucose and lipids. Thirty-three percent of patients who have had type 1 diabetes for more than 15 years and 20 percent of those who have had type 2 diabetes that long will develop nephropathy; restricting protein intake and controlling hypertension are thought to slow progression of renal disease. Blood pressure control, which is important in preventing and treating diabetic nephropathy, retinopathy, and cardiovascular disease, includes weight control and a low-sodium diet. The success of nutrition intervention in promoting normal blood sugar and lipid concentrations is well established. Studies are cited in which diabetes education reduced hospital days by 50 percent (a Rhode Island study reported by Fishbein, 1985) and by 33 percent (Nersesian et al. 1982). Reported per-patient costs for diabetes education programs range from $150 to $250. 1 table, 40 references.

315

TITLE: Where Do We Go From Here? Clark, C., Jr. *Annals of Internal Medicine*. 124 (1 Part 2): 184-186. January 1996.

OBJECTIVE: To review research in care for type 2 diabetes and make recommendations for the care of patients with this disorder.

CATEGORY: Expert opinion.

CONCLUSION: Given the enormous cost of diabetes complications, the benefit of comprehensive management should outweigh the cost relatively quickly.

RECOMMENDATION: Further research is needed to precisely define how comprehensive care will be delivered and to determine who will pay for it.

ABSTRACT: The author assesses care for type 2 diabetes and broadly describes research on the care of patients with that disorder. Comprehensive patient education is an essential component of care; all patients must be made aware of the risks inherent in a diagnosis of type 2 diabetes. Thorough assessment of a patient's risk status is needed, including assessment of retinopathy, nephropathy, and neuropathy. Initial evaluation must also include assessment of cardiovascular disease and risk factors. The applicability of specific glycemic goals to various subsets of patients with type 2 diabetes remains controversial, but any decrease in hemoglobin A1c levels is beneficial. The limitations of diet, exercise, and available oral hypoglycemic therapies are being reduced through the introduction of new therapeutic agents; type 2 diabetes may eventually be controlled with combined oral agents. Ongoing research is evaluating the impact of current therapies on macrovascular and microvascular disease in type 2 diabetes, current diabetes practices and outcomes, and care in both health maintenance organizations and fee-for-service sites. A collaborative model involving the expanded use of nurses, dietitians, diabetes educators, and subspecialist physician consultation for specific complications is the most likely model for diabetes care, particularly within the managed care setting. The question remains, however, of who will pay for comprehensive care. 26 references.

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TITLE: Where Have All the Pennies Gone? The Work of Manchester Medical Audit Advisory Group. Johnson, R. *British Medical Journal*. 309(6947): 92-102. July 9, 1994.

OBJECTIVE: To review the work of the Manchester Medical Audit Advisory Group, including the group's involvement in the Diabetes 2000 project, a multi-practice audit of diabetes.

CATEGORY: Expert opinion.

CONCLUSION: Preliminary results from the second year of the Diabetes 2000 project show indicators of improved care.

RECOMMENDATION: Continuing support for medical audit advisory groups, along with continued evaluation, is justified.

ABSTRACT: The author reviews the work of the Manchester Medical Audit Advisory Group, including the group's involvement in the Diabetes 2000 project, which involves an audit of diabetes care in general practices. The group developed a stepwise audit approach to the management of the disease and produced audit packs that permitted practices to enter the audit regardless of their current level of diabetes management. The project had a target of recruiting 25 practices for the first year; currently, 80 of the 107 Manchester practices are actively participating. In the second complete year of the audit, markers of improved care have been documented. The recorded prevalence of diabetes has increased, as has the recording of monitoring measures such as foot pulse examination and fundoscopy. Project fieldworkers report better practice organization and improved confidence in the care of patients with diabetes. The Manchester group expects to follow patients with diabetes to measure final outcomes, but it is anticipated that many years of follow-up will be required to document the benefits of the audit process. The author points out that the Manchester group's core funding from the family health services authority is less than the annual amount spent by an average general practitioner on drugs. In addition to the core funding, the group has funds from the Department of Health (for Diabetes 2000) and the regional health authority. 5 tables, 16 references.