PRIMARY CARE SEMINARS

The REACHE Center

REGIONAL ENHANCEMENT OF AMBULATORY COLLABORATION AND HEALTH EDUCATION

Boise VA Medical Center of Excellence
in Primary Care Education

PRIMARY CARE SEMINARS

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Contributing Authors

C. Scott Smith, MD
Janet Willis, RN
William Weppner, MD, MPH
Melanie Nash, MSN, FNP
Andrew Wilper, MD, MPH
Winslow Gerrish, PhD
Amber Fisher, PharmD
Jared Bernotski, BA
Marcel Roy, MD
Deb Smith, DNP, FNP
Michael Kilfoyle, MD
Hee Yon Sohng, MD
Caroline Rhoads, MD
John Naylor, MD

In memory of Julie Phister, MD
who pioneered an ambulatory curriculum at the Boise VAMC

VA Center of Excellence in Primary Care Education (CoEPCE)

VA Medical Center, Boise, Idaho

in conjunction with

Department of Medicine, University of Washington
School of Nursing, Gonzaga University
School of Pharmacy, Idaho State University
Psychology Service, Boise VA Medical Center
School of Nursing, Northwest Nazarene University

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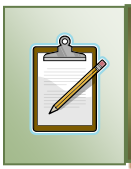
CASE METHOD TEACHING

To ground an abstract approach to illness in practical terms, we have selected several cases to act as the focus of discussion for our classes.

These are real cases from the faculty panels that were "coin tosses, the decision about how to manage the case could have gone either way. They have been written to protect patient confidentiality and to emphasize one particular facet of patient care.

Along with these cases, each module is organized with Core Readings (Module 4 also has some Supplemental Readings) and an associated quiz at the end.



To draw your attention to written and reflective assignments as well as key points, watch for colored boxes and the clipboard symbol.

Also, during the seminars, we will distribute several support materials. These will be primary data articles, several types of review articles, and editorial opinion pieces that may help to support one or another of the clinic choices that you might take.

For some modules, we will divide participants into two groups as part of answering the key question and discussion points at the bottom of the case. One will argue FOR the possible intervention (to screen, to treat with a medication, to affirm a diagnosis, etc.). The other will argue AGAINST the intervention.

The approaches we will advocate are based on our collective experience and represent "85%" solutions; they will help you about 85% of the time. At the end of each module you should ask yourself, "What would I do next if this approach isn't working?"

Module 1 Introduction to Clinic

Something's Gotta Change!

Patient:
Dale—a 36-year-old divorced male, recently back from Afghanistan and separated from the Army, lives alone in Idaho City but wants to move closer to his two children

Figure 1. Dale. Adapted from Flickr, 2009 and UW, n.d..[1,2]

Chief Complaint:
New-patient appointment on the Boise VA Silver Team, needs medication refills

Past Medical History:
Moderate PTSD— SSRI (Zoloft) daily
HTN—Lisinopril 10mg daily
Hyperlipidemia—Simvastatin 40mg daily
Pre-Diabetic—recent fasting BG levels between 110-130, no HgbA1c done

History:

- Dale awaits a compensation/pension appointment—likely 10 weeks out
- Today, has a 1-hour appointment with an intern and a later job interview
- At this visit, a Medical Assistant (MA) completes a comprehensive intake to include VS and applicable reminders—Dale tests positive for depression and alcohol abuse, but denies SI/HI and refuses referral to the Integrated Care Team (ICT) d/t time constraints
- Today's visit takes almost two hours, mostly spent with the intern and waiting while the intern discusses the case with the attending supervisor
- VS: B/P 170/93, HR 88, RR 18, T 98.1, SaO2 98%
- Exam
  - repeat B/P 163/86
  - general: pensive, appropriate, thin
  - finger stick blood sugar 122
  - cardiovascular: regular rate and rhythm, no murmurs
  - neck: supple, no lymphadenopathy, no thyromegaly
  - eyes: extra-occular movememtns intact, pupils equal round to light and accomodation, discs normal, grade 1 nicking and narrowing
  - abdomen: soft, not distended or tender, bowel sounds normal, no hepato-spenomegally
  - extremities: warm, dry, no cyanosis, clubbing, edema

- ✓ **Before class, write down your assessment and plan for this patient.**
- ✓ **Consider ways to improve efficiency and teamwork using the PACT model.**

Module One

Teamwork & Efficiency in Patient Aligned Care Teams

"A medical home is not a physical building but rather an approach to providing comprehensive primary care."

American Academy of Pediatrics

INTRODUCTION

Welcome to the Boise VAMC. When you look back at the end of your training, you will find that most of your learning came from direct patient care and reflection on those experiences.

This module will introduce you to a team concept using components of the Patient-Centered Medical Home (PCMH) and Patient Aligned Care Team (PACT) models, the purpose behind the Primary Care Seminars (PCS), and the structure of the curriculum. It will also provide some basic rules in caring for patients and making clinic visits more efficient and productive.

Figure 2. VA PACT Logo

During training, ambulatory patient care is frequently unfamiliar and uncomfortable. It is characterized by complex interactions, evolution of illness, unpredictability, surprise, and experimentation. In this environment, the most helpful approach is to develop a knowledge base of explanations, listen carefully to the patient's story, and be open to change when standard explanations are not working. In addition, collaborating with an interdisciplinary team will enhance efficient and effective ambulatory care.

To improve this interdisciplinary focus in training and clinical practice, the VA is implementing PACT, which, in turn, is derived from the PCMH concept. Since understanding both PCMH and PACT are so essential to the journey to improved modern primary care practice, our discussion begins there.

First, we will address: What is PCMH? How does it differ from traditional primary care, the "old model?"

PCMH

In response, three main change concepts define PCMH's evolution:

1. A balanced plan for patient-centered care
2. Proactive care
3. Team-based care

Although PCMH has yet to be standardized, these change concepts have stayed consistent. Therefore, we will use them to point out elements of PCMH and show how and why it can succeed as the preferred "new model."

Figure 3. Balanced Plan Icon. Adapted from Wikimedia, n.d.[3.]

First, PCMH clinics are shifting their focus from providers to become most convenient for the patient. As the PCMH name implies, its clinics have **a balanced plan for *patient-centered care*** at their core. Typical clinics, in contrast, have traditionally been structured around providers and staff, with scheduling open only when providers are conveniently available. In such clinics, phone requests or questions are triaged and answered asynchronously, and visits are mostly face-to-face. However, to accomplish the motto of the PCMH, which is, "Do today's work today," providers must become less reliant on traditional, face-to-face visits, and capitalize on forms of communication that are more frequent and beneficial for patients and/or healthcare teams. These forms of communication include telephone visits, same-day access, real-time conversations, secure messaging, team-huddles and other types of provider-provider consults, and group visits.

Moreover, this PCMH change concept features a scale to focus on elements that must be kept in equilibrium. First, acommodating the patient's interests must never overbalance what is truly in the patient's best interest. An optimal, *balanced plan* depends on how well the interdisciplinary team and the patient work together. Notice that below the figure's weighing pans, both sides must nurture certain attributes. On the patient's part, equilibrating requires that they not merely stand as passive recipients of treatments, but take a more active and accountable role in their care.

In the case of the provider, they must fill an almost paternal role in facilitating care decisions that continue the traditional model's emphasis on evidence-based medicine (EBM). At the same time, however, providers must equally calibrate their interpersonal skills to be *patient-focused*. Therefore,

our PCS modules and associated curriculum are designed to be a pivot point for weighing EBM and the interpersonal skills needed as part of a balanced plan. Therefore, our in-class discussions and clinical rotations will focus on developing the perspicacity and sensitivity that enable providers, working as individuals and as part of teams, to communicate their treatment plan in ways that patients will understand and be willing to follow.

The second main difference that makes PCMH an improved model is moving away from provider-driven to ***team-based care.*** However, in order to accomplish this change, individuals will have *to* "work at the top of their license." Traditionally, the provider completes all patient visits, review of labs, and writing of perscriptions, which creates an unnecessary bottleneck in care. Unfortunately, since this system of control has become so ingrained in the old model, it is hard for providers to share these responsibilities. Likewise, it is also hard for others to stretch and take on expanded roles required as part of a team. A fully-functioning PCMH, however, depends on mutual trust between team members, the free flow of information, and sharing of responsibilities. Therefore, our emphasis in the PCS and as a PCMH clinic is on developing new paradigms and practices that "unclog the pipe," through improvements in interdisciplinary teamwork.

Figure 4. Reactive care. Adapted from Graphic River, 2012.[4]

Finally, the third main difference is moving from reactive (always putting out fires) to ***proactive care*** (preventing problems). As with a wildfire, problems facing a modern primary care environment are no less threatening or endemic. While traditional clinics commonly face challenges in getting and maintaining resources, constraints are expected to get worse in the coming years. In particular, an aging population is "turning up the heat" as clinics become increasingly saturated with patients facing chronic diseases.

To respond to these demands, we suggest adapting the US Forest Service's well-known Smokey the Bear campaign to a clinical setting: "Remember. Only you can provide proactive care." No, we don't actually have the badge shown for you to sew on, but we hope that its slogan resonates. Modern providers will likely continue to be "stretched thin," which makes a reactive, fire-hose approach insufficient. Managing resources and adopting more effective preventive practices is becoming increasingly vital. As Klein points out, engaging a multidisciplinary health care team to proactively address chronic disease and behavioral health issues gives the provider more time to offer intensive services to the most clinically complex patients.[5]

PACT

While the PCMH is gaining momemtum amongst practicioners and policy analysts, it should be mentioned that it is still an experimental, evolving intervention. At this early stage of implementation, consensus has not been reached regarding the "design and focus" of public and private sector PCMH programs.[6] However, our purpose is not to present a comparative cross section of features. Instead, we would argue that the VA's version of PCMH, PACT, has grown organically from the three main change concepts discussed previously. Due to this close linkage, the PCS will treat PCMH and PACT as virtually synonymous terms, but our emphasis will be on PACT. In particular, we will examine how PACT embraces the following four educational domains:

1. Shared Decision Making (SDM)
2. Sustained Relationships (SR)
3. Interprofessional Collaboration (IC)
4. Practice Improvement (PI)

Throughout the PCS, we will examine how these domains provide a framework to facilitate development of a patient-centered, interdisciplinary clinical experience. To facilitate recall, we have designed icons for PACT's four domains, which we will refer to throughout the text:

Figure 5. SDM Icon

Patients are most likely to make positive changes when they feel empowered. Therefore, the team and patient should work together to arrive at informed, patient-centered care decisions.

SDM is a formal process in which the interdisciplinary care team:

- Provides evidence-based information
- Explains the pros and cons of different options
- Combines expertise to improve outcomes

Similarly, as part of this process, patients:

- Review evidence-based decision aids to understand the likely outcomes of different treatment options
- Discuss their personal values and priorities with providers relating to proposed treatment options and goals

Ultimately, patients decide how to proceed, in collaboration with and actively supported by their health care team.[5] Building strong teacher-learner, patient-provider, and provider-team relationships are all critical for trust. In an ambulatory learning environment, mentoring and a continuous teacher-learner relationship bolster analysis of health care processes that may take a long time to unfold.

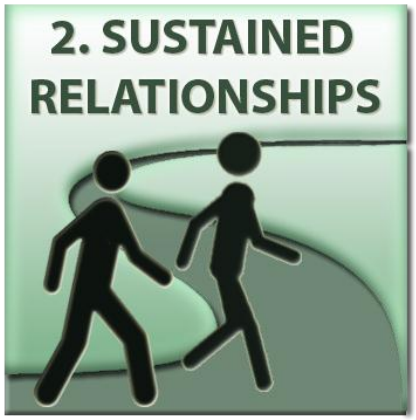


Figure. 6. SR Icon

In the same way, sustained patient-provider relationships establish the foundation for care management and coordination in the PACT model. Providers manage a panel of patients and work with a dedicated team of professionals to deliver efficient, comprehensive care with an emphasis on continuity.

To maintain effectiveness over the long term, the provider-team relationship is also vital and includes coordinated hospitalization/ER follow up, chronic disease management protocols, team huddles, clinic, telephone, and group visits along with warm hand-offs during absences.

Remember that your goal is to avoid care that is provider-centric, episodic, and, as has been mentioned previously, reactive. Much as an illness weakens the body, disconnected care can damage relationships. Therefore, the PCS will provide tools and techniques to help you become a provider who doesn't cause a bottleneck in single-handedly treating patients, but who acts as a team player to maintain all essential relationships in a healthy status. You will learn to

develop a therapeutic plan for sustained relationships that uses clear communication to foster well-organized, coordinated care.

As was mentioned earlier when discussing the change concept of team-based care, coordinating efforts with interdisciplinary team members can make primary care more effective. To emphasize this team dynamic, we designed the REACHE logo below, with its circle framing joined hands, to illustrate how teamwork is needed to place the interests, dignity, and respect of patients at the center of health care delivery.

Figure 7. IC Icon. Adapted from Canstockphoto, 2011.[7]

By the same token, making teamwork more than an abstract representation in your clinical practice will require you to:

- Leverage the unique roles and responsibilities of interprofessional team members to provide comprehensive care
- Embrace the cultural diversity and differences of health care teams
- Assess and address the health care needs of patients

Unfortunately, no one-time shot in the arm has previously or will likely ever produce interprofessional collaboration. Instead, much as winning sports teams depend on frequent practice, you'll achieve success through consistent efforts to foster your team's capacities to cooperate and deliver proactive, safe, timely, efficient, effective, and equitable care.

In this context, you might wonder what collaborative game plans have been shown to enhance outcomes?

First, future PCS sessions will explore how using care coordination, registries, and motivational interviewing have improved chronic disease management.[6] In addition, faculty mentors and clinical experiences will focus on using information technology, health information exchange, and other means that help ensure that patients get the indicated care how, when, and where they need and want it.

Figure 8. PI Icon.

To build your foundation as a high-functioning provider, your experiences at the Boise VAMC will include seminars and projects devoted to quality improvement across disciplines. As a guide for you in this process, you will learn to use evidence-based medicine and clinical decision-support tools. Since continuous quality improvement is a key primary care skill, your faculty will actively encourage and mentor you to accept accountability and engage in performance measurement and process improvement.

PCS LEARNING GOALS

To establish benchmarks for developing and assessing the concepts that are part of PCMH, we have set the following learning goals:

- Understand and apply the four domains of PACT in clinical practice as you:
  - Develop effective models for patients and care teams
  - Manage the clinic visit through adapting communication styles that foster patient trust and confidence
  - Provide evidence-based information using reliable resources
  - Initiate warm hand-offs when appropriate
  - Participate with interdisciplinary team members in quality improvement projects
- Apply dynamic, evolving standards for an interdisciplinary team of providers, that vary by profession and include team-based as well as individual competencies, to deliver effective ongoing patient care.
- Develop a systematic approach that facilitates relevant and comprehensive care to your panel of patients as you:
  - Navigate the internal Computerized Patient Records System (CPRS) and external Idaho Health Data Exchange (IHDE)
  - Order a wide variety of consults and other unique testing as part of comprehensive patient care
  - Provide efficient follow-up of all patient results

PCS STRUCTURE

Primary Care Seminars will occur during intensive two-week ambulatory immersion blocks. These are scheduled six times during the year for each ambulatory cohort (roughly two out out of every eight weeks). Every module has a scenario at the beginning, which will be used to launch in-class discussions. At the end of the modules, you will find a listing for a few "Core Readings" that are essential to understanding the module. Also, an associated written and online quiz below these core readings is designed to:

- Prompt analysis of problems that do not have straightforward answers
- Enhance IC and SDM through drawing out disciplines in primary care teams' unique and overlapping perspectives

To prepare for class sessions, you will also be expected to visit the PCS Moodle site (http://moodle2.boisevacoe.org). On that site, notice that Core Readings and an online quiz for the modules are also available.*

Class sessions include:

- 10-min. to review your individual answers to each module's online, pre-class quiz (assessment and plan, reading, etc.) in order to reach a group consensus
- 20-min. for a pro/con debate about your assessment and treatment plan for Dale and other "scenario" patients (do a test, start a medication, deal with a diagnosis, etc.)
- 1 hour for a mini-lecture and seminar discussion about the module's topic and core readings.

Our classes progress from provider-centric decisions to patient-controlled decisions as seen in the curriculum outline:

Table 1. List of PCS Classes and Themes

Module	Theme	Exemplar
1	Introduction to Clinic	Getting to the heart of the visit Communication styles
2	Screening	Prostate Cancer
3	Asymptomatic Disease	Hypertension
4	Symptomatic Disease	Diabetes
5	Harmful Health Habits	Alcoholism
6	Symptoms as the Disease (Somatization)	Organic Pain Disorders

*Note: Accessing the online resources in Moodle will be discussed during the first session of PCS.

ADAPTING TO THE AMBULATORY CLINIC

Much of your background as a provider has likely been within inpatient settings. To prepare you for outpatient interactions, you should realize how the ambulatory clinic has progressed to the PACT model. Instead of providing reactive, provider-centric face-to-face patient care, this model includes a health care team and non face-to-face patient interactions, such as secure electronic messaging (MyHealtheVet), scheduled phone care, and group visits.

As emphasized in the third change concept, the more traditional office visit is currently seen as a scarce resource that should be managed proactively rather than reactively. To achieve these aims, the PACT model emphasizes a patient-centered approach with coordinated, interdisciplinary management of care.

As an example of the contrasting care and teaching emphases between inpatient wards (traditional) versus ambulatory (traditional plus distinctive), notice one group's findings in the following table:[10]

Table 2. Inpatient Versus Ambulatory Clinic

Traditional	Distinctive
Etiology	Continuity
History	Context
Physical exam	Health education
Laboratory tests	Economics
Therapy	Responsibility

From this table, three differences between inpatient and ambulatory care are worth mentioning: locus of control, the degree of uncertainty, and the time scale involved.

First, *locus of control* examines who has the greater decision-making power. With inpatient care, control is firmly lodged within the healthcare system. However, in the ambulatory clinic, the patient ultimately decides whether they will follow our advice and prescriptions, may have several different health care providers (both traditional and non-traditional), and even chooses when and if they visit us. Giving patients such control requires coordinating care in a more collaborative manner, which many trainees accustomed to inpatient settings find unfamiliar and uncomfortable.

Second, the *degree of uncertainty* involved differs between inpatient wards and the ambulatory clinic. A patient is typically admitted to the ward with a diagnosis followed by a predetermined set of expectations. In the ambulatory clinic, however, the provider is often presented with a symptom rather than a diagnosis. Consequently, problem solving in the ambulatory clinic requires a greater tolerance for initial ambiguity, experimentation, and attention to feedback from the patient and the situation.[11]

Third, the tremendous *time scale* pressures that you will face necessitate greater efficiency in the ambulatory clinic compared to the wards. By the end of the year, you'll have 6-8 scheduled patients per half day of clinic. You will be expected to function as a primary care provider in Boise and experience the shifts to increased uncertainty and more collaboration with an interdisciplinary team of

Figure 9. Boise VA Collage. Adapted from public domain images, iStockphoto, and Flickr[12,13]

healthcare professionals. Panel sizes here are large and continuity with the patient is important. You will be expected to respond to telephone inquiries, medication refill requests, and follow-up test results in a timely manner. It will also be your responsibility to provide a warm hand-off to your attending supervisor during times of transition (before an "away" rotation, annual leave, sick leave, end of year, etc.).

With such demands in mind, remember that Francis M. Peabody's maxim, while written in 1927, still holds true:

> "The treatment of a disease may be entirely impersonal; the care of a patient must be completely personal" and "one of the essential qualities of the clinician is interest in humanity, for the secret of the care of the patient is in caring for the patient."[14]

Along with your technical skill as a clinician, you must never take the human dimension lightly. In an ambulatory setting, you will succeed as a caring provider only as you make a long-term and more personal commitment to the patient than is typical of the inpatient ward.

Like the ambulatory clinic's progression to become more patient centered, the PCS to include your clinical rounds is structured as an immersive environment that builds on your current strengths till you become a provider equipped for the rigors of outpatient care.

PROVIDER-PATIENT COMMUNICATION

While we previously touched on communication under the PCMH change concept of a *balanced plan for patient-centered care*, this section provides more specific strategies for improvement in this area. Researchers have shown that traditional clinic visits are usually provider-centered; patients concerns are commonly ignored; ill-defined complaints are accepted without clarification; and patients' educational needs are frequently not met.[15] Our own research here at the Boise VAMC would agree with these findings.

Figure 10. Provider-Patient Communication. Adapted from nj.gov, n.d.[16]

However, many such issues could be alleviated through improved provider-patient communication. The heart of an efficient office visit starts in the first few minutes during the patient interview in which the provider has two roles to perform. The first is the bio-scientific role of "finding and fixing" (or at least optimizing) the patient's problems, which depends largely on the quality of communication between the provider and the patient.

Similarly, the second caring, supportive role requires effective communication as the provider engages the patient, empathizes, educates, and enlists them in a collaborative management plan.[17]

In both these roles, note what often happens versus what should happen:

What Often Happens

- **Researchers have shown that it takes an average of 18 seconds before the provider interrupts the patient and controls the interview. These interruptions often occur in a closed question format. Furthermore, these controlling interruptions lead to lost data and a longer clinic visit.**
- **Patient care is managed only through face-to-face office visits.**

What Should Happen

- **Visits should generally start with an introduction, an open-ended question about the reason for the visit, and then careful listening for 1-2 minutes, paying attention to nonverbal cues. Remember that "silence is golden."**
- **Stick to the agenda and remind the patient that the end of the visit is near with statements like, "In our last few minutes I want to . . . "**
- **Confront rambling discourse by interrupting politely and refocusing the interview: "Help me understand how that relates to . . . "**
- **Avoid inefficient activities, such as routine physical exams, exhaustive review of systems, and questions that have little or no bearing on the heart of the visit.**
- **Summarize findings and goals of treatment.**
- **Manage patient care with telephone as well as office visits, communication through secure messaging, and/or by group visits.**

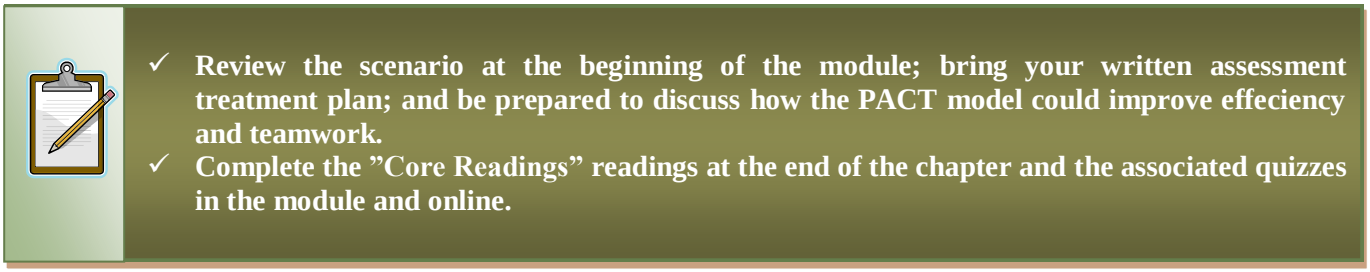
To help you realize "what should happen" as part of provider-patient and other communication, the PCS focus on facilitation, observation, and appraisal. For example, your interactions will be evaluated during clinical rotations as part of the Boise VAMC's Silver Team. Here you'll also become part of an interdisciplinary teamlet consisting of a PCP, nursing staff (clinical associate and RN care manager), administrative staff (clerical associate), pharmacy, and a behavioral health team. The Boise VAMC has been structured with teamlets and other resources for patient care and performance evaluation in an effort to provide the best, most efficient care for your patient.

Your individual success at the Boise VAMC and the success of the PCMH and PACT model depends on clear role negotiation and division of labor. How well you perform and how effectively you enlist other members of the health care team is ultimately up to you.

CONCLUSION

This module has provided an introduction to the need for PCMH as well as its relationship to the PACT model, with its four domains of Shared Decision Making, Sustained Relationships, Interprofessional Collaboration, and Practice Improvement. In later chapters, we will deepen our understanding of these domains through discussing scenarios and readings that examine common clinical and contextual challenges. For example, the next seminar focuses on Shared Decision Making, using the example of PSA testing.

REMEMBER THAT PRIOR TO EACH CLASS YOU MUST:



- ✓ **Review the scenario at the beginning of the module; bring your written assessment treatment plan; and be prepared to discuss how the PACT model could improve effeciency and teamwork.**
- ✓ **Complete the "Core Readings" readings at the end of the chapter and the associated quizzes in the module and online.**

Completing such assignments inside and outside of class are merely the first steps. Ultimately, while this module presents symbols and analysis as signposts to make concepts more tangible, your vitality as a change agent is what will make PCMH and PACT powerful down the road. In joining the Boise Center of Excellence, you've become part of a learning lab that is committed to finding ways to improve primary care education and health outcomes. You'll reach the desired destination of a balanced plan for patient-centered care that is proactive and team-based through your contributions as an individual provider and as part of interdisciplinary teams. As we unite our efforts, we feel confident that the journey to improve outpatient care using the four domains of the PACT model will succeed.

HELPFUL TIPS FOR CLINIC EFFICIENCY

- Learn to communicate effectively with the interdisciplinary staff in clinic. Like a sports team, it only works well when each person does their part toward a common goal.

- Write brief notes, but communicate your thinking, management plan, and goals of treatment. This helps others when they have to care for the patient in your absence, and helps you remember what you intended six months later.

- Develop a standard format for the visit, the note, and the problem list. Avoid cutting and pasting extraneous information from previous notes; all information should be relevant to the upcoming visit.**

- Use a tracking system that identifies pertinent labs, consults, and medication needs that might be out of the "norm. "

- Schedule non face-to-face visits using telephone clinics, secure messaging, and group visits with your patient when a traditional clinic appointment is unnecessary. Frequent, short visits incorporating non face-to-face interactions are more efficient than infrequent appointments that can end up lasting longer than anticipated.

- Check Amion and the "Visual Aid" in the Program Manager frequently to assure accuracy of your clinic schedule—conflicts in schedules need to be addressed at least 30 days in advance.*

**Note: Accessing these resources will be discussed during the first session of PCS.

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MODULE 1 CORE READINGS (available online in Moodle)

- Klein S. The Veterans Health Administration: Implementing patient-centered medical homes in the nation's largest integrated delivery system. Commonwealth Fund Case Study 2011; pub.1537, vol 16:1-19.

- Wagner EH, et al. The changes involved in patient-centered medical home transformation. *Prim Care Clin Office Pract* 2012;39(2):241-259.

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

1. In the case study by Klein, what is the driving force behind the VA's adoption of the PACT model?

2. According to Wagner, et al., what are the key change concepts required to successfully convert to the medical home model?

Module 2 Screening

Questions About Screening: Patient 1

Patient:
Mr. Grey is a 55-year-old man presenting for annual follow up.

Figure 11.. Mr. Grey. Source: adapted from Flickr, 2007.[1]

Problem List:

- Hypertension – well controlled on chlorthal-idone, potassium supplementation
- Impaired Fasting Glucose – patient doing MOVE program to improve activity
- Family history of early CAD & DM – mother had DM & died of MI at age 54; father still alive at 80; no other family history of medical problems

Physical Exam

- Well appearing caucasian male, somewhat overweight, who is pleasant, interactive, and engaged
- Afebrile, BP 132/75, HR 82, RR 12, O_2 98% on RA, Weight 190, BMI 31
- Physical exam including HEENT, cardiovascular, respiratory, abdominal, extremities and skin are within normal limits; prostate exam reveals slightly enlarged prostate without asymmetry, tenderness or nodules.

Clinical Question

After addressing his active medical problems, you discuss preventative care. He asks about "all this news about prostate cancer screening" and wants to know: Is the PSA test a useful test? Is it right for him?

- What do you recommend to him?
- What tools might you use to help him decide if he should do this test?

Questions About Screening: Patient 2

Patient:
Ms. Erby, a 43-year-old female, has recently relocated to your locality for work. She is "interviewing" you as a prospective PCP and has questions regarding your philosphy of care and health maintenance screenings.

Figure 12. Ms. Erby. Adapted from Flickr, 2010.[2]

She had provided basic personal health information. Last PAP 10 months ago, when Mirena IUD placed, mammogram never.

Problem List:

- Menstrual irregularities – thought related to triathelete training, Mirena IUD
- Mild GAD, well controlled on Citalopram 10mg daily
- F Hx: Mother well 66, MGM Dx BrCa age 55, deceased age 80 of "natural causes;" Father: 69 HTN, CAD; Sibs: 1 sister, age 48, well

Physical Exam:

- Well appearing caucasian female, thin, athletic build, animated and engaged
- T 37.C, BP 112/78, HR 55, RR 16, 02 98% RA, Wt 125, BMI18
- PE: deferred as this is an interview

Clinical Question:
After discussing past medical history, you ask Ms. Erby about what is important to her regarding her health. She asks, "What are your recommendations for breast cancer screening in a woman like me?"

She is concerned because a co-worker was recently diagnosed with breast cancer, and she has a remote family history.

- What are your thoughts and recommendations for her?
- What tools might you use to help her decide how to approach breast cancer screening?

Remember that before class, you must:

- ✓ **Complete the Core Readings as well as the in-text and online Quizzes**
- ✓ **Review this module's two scenarios**
- ✓ **Bring your written assessment and treatment plan**
- ✓ **Be prepared to discuss how the PACT model can help to facilitate your decisions**

Module Two

Screening and Preventive Medicine

"There are three kinds of lies: lies, damned lies, and statistics."
Benjamin Disraeli (popularized by Mark Twain)

INTRODUCTION

Few would argue against the need to carefully consider medical evidence when making treatment decisions. However, the evidence is always changing, guidelines are often conflicting, and even when they are clear, how do you apply population-based evidence to an individual patient? Since such questions don't often have simple answers, this module provides some broad strategies that will begin to enhance your skills in evaluating and applying evidence based medicine.

Specifically, our critical discussion in this module centers around the areas of **prevention and screening for disease**. In both these areas, the role of the health professional overlaps between that of a patient advocate and as a guardian of society's increasingly scarce healthcare resources (the "medical commons"). When weighing whether to apply screening or preventive medicine with individual patients, the domains of data acquisition, clinical reasoning, preventive medicine, ethics, and health economics all interact.

To help you make such decisions appropriately, we will highlight two major themes that will be revisited throughout the seminars:

1. Evaluating the **information contained in the primary literature**
2. Applying it to individual patients **based on their values**

Module two places a special emphasis on critically evaluating **health screening proposals**. We will also introduce a few statistical concepts that are crucial to understanding the quality of the information generated by clinical tests. Finally, we will discuss using **Shared Decision Making** when the evidence is less clear on the correct recommendation.

LEARNING GOALS

- Develop an understanding of the differences between ***case finding and population screening***.
- Critically evaluate screening proposals for ***efficacy and appropriateness.***
- Understand ***sensitivity and specificity*** and their role in evaluating the performance of diagnostic tests.
- Become familiar with ***reference sources on preventive health care***, such as the *Guide to Clinical Preventive Services* from the U.S. Preventative Services Task Force or the *Cochrane Collaboration.*
- Develop a qualitative understanding of the ***issues of health care costs and delivery***.
- Discuss ***Shared Decision Making*** to help address "grey areas," in which screening guidelines do not recommend a specific path.

DISEASE SCREENING STRATEGIES

Figure 13. Three Strategies. Source: adapted from FC for IT, 2013.[3]

To begin, the approach to the identification of disease in clinic can be divided into three broad strategies, which are:

1. Case finding
2. Population screening
3. Diagnostic evaluation

The first strategy, ***case finding*****,** uses all available resources in an attempt to identify potential disease in an individual patient, unrelated to any presenting signs or symptoms. Examples of case finding are best represented by comprehensive "executive physicals" or diagnostic modalities such as "full body CT scans." Such procedures emphasize high utilization of resources for a low yield of diagnoses, in a situation where evidence for cost effectiveness and safety may be lacking.

Next, a ***population screening*** strategy is a diagnostic test that is recommended for a predefined, asymptomatic population. It would typically be recommended when diagnostic tests used for screening have been shown to be effective and cost efficient for the population at risk. Population screening differs from case finding in that it trades the chance of not identifying some individuals with preventable conditions against the risks and costs of performing the screening procedure on everyone.

Finally, a ***diagnostic evaluation*** is the use of an appropriate diagnostic test to investigate an individual patient's presenting signs or symptoms. Diagnostic evaluation is heavily emphasized during training, but it differs from prevention strategies, which tend to focus on disease prior to becoming symptomatic.

PREVENTION SCREENING STRATEGIES

Prevention strategies can be further divided into:

1. Primary prevention
2. Secondary prevention

Primary prevention screening is typically designed to identify and treat a target condition before it is clinically evident, such as screening all patients of a certain age for hypercholesterolemia.

Secondary prevention screening aims to identify and treat a contributing factor when another clinical condition has made the likelihood or the impact of treatment greater, such as cholesterol evaluation of patients following a myocardial infarction.

SOCIETAL IMPACTS OF DISEASE AND PREVENTION SCREENING

Figure 14. Costs and Benefits. Adapted from Flickr, 2011.[5]

When deciding whether to conduct screening tests, you should consider the costs and benefits, not only for your individual patients, but in terms of broader impacts. As you no doubt realize, the expense of health care in our society is of increasing concern to patients and policy makers. The United States spends a higher percentage of its gross national product (GNP or GDP for gross domestic product) on health care than any other nation, and the rate is increasing. In 2008, per capita US health spending was $7,681, which accounted for 16% of the GDP.[4] This rate continues to outpace other spending; if it continues, fully one third of the nation's GNP will be spent on healthcare by the year 2030. Even with the full implementation of the Affordable Care Act of 2010, the United States remains one of the few western nations that still does not provide all citizens coverage, and ranks lower than many other developed countries in preventative health services. As a result, many experts and advocacy groups have proposed different solutions to these problems. Most proposals combine some method to extend basic benefits to all Americans coupled with mechanisms to control the rate of rising health care costs.

The reasons that healthcare costs are rising so rapidly are beyond the scope of this module, but clearly provider-directed expenditures play a large role. The costs associated with the tests and treatments that we order can be considerable. Ultimately, our patients and our society will gain if the benefits of these expenditures are worth the costs. In considering the "yield" of your own clinical activities, the following passage by Fuchs from, *No Pain No Gain; Perspectives on Cost Containment,*[6] merits consideration:

> "Examples of defensive medicine and unnecessary care are not hard to find, but they are only part of the problem; there is another category of care that has an even greater impact on expenditures. These are services that do provide some patient benefit, but the value to the patient is less than the cost to society of providing them. 'Low yield' medicine is not 'no yield' medicine . . . It is this kind of medical care that is the most difficult to constrain."

Although there is no agreed upon "threshold" of cost-effectiveness in the US, there is a suggestion that $50,000 per "disability-adjusted life year" gained is acceptable.[7] This amount is said to be based on the cost of life-prolonging dialysis provided for one year, although these costs are changing.

Beyond providing an overview of costs, this module will describe a practical approach to the evaluation of screening proposals. With this approach you will be able to assess a far more important consideration than just "*dollars and cents*," namely determining whether a proposal "*makes sense*" for your clinic population. In the next section, you will also learn a formalized way of examining screening and other clinical procedures as a means to gain insight into facilitating decisions for patients in which guidelines do not offer an explicit recommendation.

EVALUATING SCREENING & PREVENTION PROPOSALS

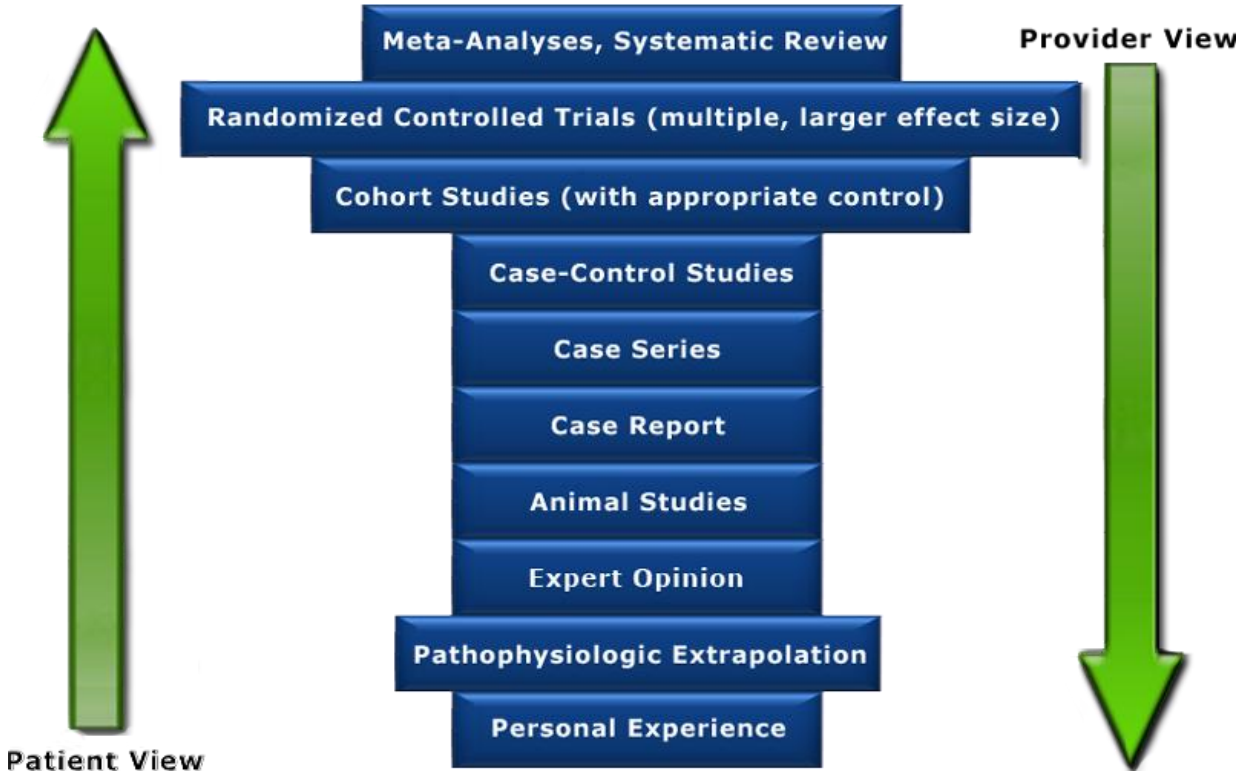
The first step in deciding how to increase our "yield" in disease prevention is to examine the sources from which we get recommendations for our patients. While no one can be expected to master the multitude of studies that are being published on the prevention of disease, making appropriate recommendations requires knowledge of recent primary literature, and an ability to interpret the literature for our own practices. Consequently, we need to develop a strategy that allows us to efficiently screen the literature itself. We can then scrutinize only those studies that appear likely to significantly influence our practice. We will address these techniques in more detail later in the Journal Club module, but some thoughts are worth considering here.

First, no doubt most of us would prefer that all our significant medical questions were addressed in large, randomized, controlled trials. Unfortunately, because of the expense and, at times, ethical difficulty in performing these studies, this ideal is sometimes impossible to attain. And even when these trials are completed, the "correct" course of action may still be unclear! Therefore, we must turn frequently to several other types of evidence to find answers to the problems we face in clinic.

As shown in the figure below, clinical information can be thought of as existing in a hierarchical structure with the randomized, controlled trial at the top and the clinician's personal preference at the bottom. Our discussion will address the "Provider View" before considering the "Patient View."

Providers feel more confident in information derived from study designs near the top of this structure than from those at the bottom. One reason for this confidence is that studies near the top tend to have

Figure. 15. Patient vs. Provider Confidence.



higher internal validities. While both internal and external validities will be defined in greater detail in Module 3, internal validity is a statistical concept that can be thought of as a measure of the degree to which a study's results are due to the intervention being studied. Studies with high internal validities have controlled for confounding variables, and, therefore, the reader can be confident that the results described are due to the intervention performed. Prospective, randomized, controlled trials frequently have high internal validities. Since the clinician's personal preference lacks such controls, we try to lean towards trials with higher internal validity.

However, a high degree of internal validity alone is not sufficient to convince us to alter our practices. An ideal study would possess both a high degree of internal validity as well as a convincing degree of external validity, which is a measure of the degree to which a study's results are applicable to your own clinical practice. For example, a study of a new antihypertensive agent in elderly men, who were smokers with coronary artery disease, might have a high degree of external validity in relation to a VA clinic population. However, the same agent tested in otherwise healthy, non-smoking, young adults would lack such applicability.

In terms of the three disease screening strategies mentioned earlier, we are frequently basing our decisions on evidence near the bottom of the hierarchy when using **case finding**. In such cases, personal preference is heavily relied upon, but the difficulty with this approach is that it doesn't lend itself to a rigorous analysis of the costs and benefits of the clinical activity. Without understanding the risks, costs, and likely benefits of a screening proposal it is difficult to make recommendations for different patients and practice settings.

In the case of the second **population screening** strategy, ideally, proposals would be based on information located near the top of the hierarchy. However, remarkably few randomized, controlled trials are available that *clearly demonstrate* decreased morbidity or mortality for any screening proposals. In part, this inability to show causal decreases is due to the large costs and difficulty in conducting such studies with enough power to detect meaningful differences. The Evidence-Based Medicine module will deal in depth with such studies' strengths and weaknesses, but the next section after *DAMHIT SCRAP* provides a useful, broadly applicable method of analyzing all screening proposals.

Speaking of challenges, it is interesting to note that many patients tend to base their decisions on a hierarchy that is directly *reversed* from the "provider view" discussed previously. In our experience, patients and their caregivers tend to value personal preference, experience, expert opinion, and anecdote from friends and families much more highly than more abstract forms of evidence, such as meta-analyses and systematic reviews. While such tendencies are highly variable, likely based on the patient's health care literacy and education, this reversal of priorities may lead to conflicts related to medical decisions. It is of paramount importance to realize that personal preference and experience will be an important driver in patient decision making, and to factor these drivers into Shared Decision Making. We will address ways to address such potential conflicts in later discussions.

DAMHIT SCRAP

Given our desire to increase "yield" in our clinical activities, how does the clinician decide what is a valid approach to disease prevention and screening? We have developed a structured approach to the evaluation of screening proposals that is helpful in organizing your thinking about screening tests. This approach can be described by the mnemonic, *DAMHIT SCRAP*, as follows:

DAMHIT SCRAP	
Disease:	The disease must be common in the population being screened.
Asymptomatic:	The disease must have an asymptomatic period where treatment would alter the course of the disease.
Morbidity:	The morbidity associated with the disease must be significant.
High Risk:	The identification of a high risk group can greatly affect the efficiency of your screening activities.

Intervention:	An intervention must be available that is acceptable and effective at changing the natural history of the condition.
Test:	The test in the screening procedure must meet the **SCRAP** criteria outlined next.
Sensitivity and specificity:	The sensitivity and specificity must be adequate.
Cost:	The cost and convenience must be reasonable.
Reliability:	The reliability must be high, including accuracy, precision, person to person variability, etc.
Acceptability:	The testing procedure must be acceptable to the patient.
Positive predictive value:	The positive predictive value should be high in the population screened

The application of this mnemonic can help to structure your thinking about screening proposals. To demonstrate, we will now apply the *DAMHIT SCRAP* model to a hypothetical proposal to screen men for the presence of prostate carcinoma with a PSA test:

Screening for prostate cancer, a critical evaluation:	
Disease:	(+) Prostate cancer is the most common cancer (excluding skin cancer) and the second leading cause of death from cancer for men in the U.S.[8] The prevalence by biopsy is at least 15% in men > 62[12] (needle biopsy may under-estimate the prevalence).[9] Prevalence may reach > 90% by age 80.[14] The lifetime risk of dying of prostate cancer is 3.4%.[15]
Asymptomatic:	(+) There is an asymptomatic period during which treatment may work.
Morbidity	(+) The morbidity and mortality to society and individuals are major (29,554 deaths in 2003).[14] However, autopsy and census data suggest that millions of men have latent (but possibly detectable) prostate cancer but may never be symptomatic.[11]
High risk:	(+) Risk increases with age and family history. African-Americans have an increased risk for any given age.[15]
Intervention:	(?) One study purporting to show survival benefits with screening had several methodological flaws.[16] Another recent study showed a moderate decrease in disease-specific and all-cause mortality after 5 years with radical prostatectomy.[17] Only ~5% of these patients entered the study because of PSA screening (most had abnormal exam or symptoms). The surgery patients had double the

	rates of erectile dysfunction (80 vs. 45%) and urinary leakage (49 vs. 21%) but also ¾ the rate of obstructive symptoms (28 vs. 44%), with overall quality of life unchanged.[18] On the other hand, cohort studies have shown that men with low grade prostate cancer have a small chance of dying from the disease even without treatment for 15 or more years.[19,20]
Test:	PSA – See the SCRAP criteria below.
Sensitivity and Specificity**:**	(?) Reported sensitivity of a PSA ≥ 4 range from 29-80%.[10] However, a substantial number of men (~15%) with PSA < 4 will also have cancer.
Cost:	(-) The cost of the test itself is relatively modest. Subsequent work-up is not. Estimates for the cost of mass screening in the U.S. are in the range of $12-$28 billion.[14] The cost to prevent one cancer death based on the ERSPC trial (listed below) is $5.2 million annually (including cost of screening, as well as further diagnostic testing and treatment).[26]
Reliability:	(-) Reliability is modest. Levels can vary more than 10-fold in some men due to sub-clinical prostatitis. Concerns exist regarding over-diagnosis (diagnosing clinically irrelevant disease), length bias (less deadly prostate cancers are more likely to be picked up by PSA screening, making it look as if screened patients live longer) and lead-time bias (less advanced cases of prostate cancer are diagnosed earlier because of PSA criteria, making it seem like patients live longer).
Acceptance:	(?) The blood test is acceptable to most patients. Implications of the test (e.g., treatment and associate complications) are trickier.
Positive predictive value:	(???) If present, this is small – the positive predictive value is reported to be 28-35%.[14] Delving into recent clinical trials (RCTs), two large studies reported somewhat conflicting results regarding the effectiveness of screening; in the US, the PLCO study of 76,000 men indicated that although 22% more prostate cancers were detected using DRE & PSA > 4.0, there was no evidence of mortality benefit at 7 years of follow-up – the impact of this study was limited due to almost 40% cross-over in the control population, and 44% of both groups having PSA prior to the study.[22] The ERSPC study in a European population of 182,000 men aged 50-74 were offered PSA screening on average every 4 years. Using a PSA threshold of 3ng/ml, 8.2% vs. 4.8% men with cancers were identified over a median f/up of 9 years. A statistically significant mortality benefit was identified (RR 0.80, p=0.04); however, the **number needed to screen to identify *one* cancer was 1,410**; of those identified, the **number need to treat with surgery or other intervention was 48 to prevent one death at nine years**.[23] A study from Sweden, including many of the younger patients from ERSPC (n=20,000) indicated a greater reduction in death

	younger patients from ERSPC (n=20,000) indicated a great reduction from prostate cancer in the screened population (RR 0.56, P=0.02), but no decrease in overall death was found in this slightly younger group of men.[27] But even in results from Sweden, conflicting evidence was identified – the most recent large randomized trial, which followed 9,000 men for 20 years, indicated that there is no difference in death between screened and unscreened groups.[28]
Guidelines:	• USPSTF: recommends **against** PSA-based screening for prostate cancer (May 2012) • American Urological Association: "...believes that the prostate-specific antigen test, when used appropriately, provides clinicians with valuable information to aid in the diagnosis and treatment of prostate cancer" (May 2012) • American Cancer Society: "...recommends that men discuss the possible risks and benefits of prostate cancer screening with their doctor..."

As another example of applying *DAMHIT SCRAP*, consider the analysis in the chart below:

Screening for breast cancer, a critical evaluation:	
Disease:	(+) Most common non-skin cancer and second highest mortality cancer in women. Autopsies studies show a 1.3% median prevalence of undiagnosed invasive breast cancer and 8.9% undiagnosed ductal carcinoma in situ.[41] By age 90, lifetime risk of diagnosis is estimated at 13%.[34]
Asymptomatic:	(+) There is an asymptomatic period where treatment may alter course of the disease.
Morbidity	(+) Annually ~230,000 diagnoses of invasive breast cancer. 2012 deaths attributed to breast cancer are estimated at 40,000.[39]
High risk:	(+) Variables that affect risk: age, genetic predisposition, gender, + family Hx, ethnicity, estrogen exposure, Hx of atypical breast Bx, age of menarch, and age at birth of first child. *Gender***:** women 100 times greater than in men. *Age***:** Risk increases with age, 85% of breast cancers are found in women older than 50 years of age. *Risk Assessment Tools*: help clarify/stratify risk groups, but predictive accuracy is modest as not all risk factors have been identified. The Gail Model, a popular risk assessment tool, takes into account risk factors as mentioned above, but has a low PPV of predicting breast cancer for an individual patient;[32,34] see www.cancer.gov/bcrisktool.

Intervention:	(?) Harms from screening includes false positive testing, anxiety specific to fear of breast cancer and breast cancer screening, fear of pain related to procedure. Standard treatment Options: • Surgery: mastectomy, lumpectomy • Sentinel node Bx followed by surgery • Radiation therapy • Chemotherapy • Hormone Therapy[27] Note that the full range of breast cancer treatment options and efficacy of treatment regimens are complex, multifactorial, and beyond the scope of this discussion.
Test:	Unlike prostate cancer screening, many different testing modalities exist, with different types of mammography (film-screen mammography, full-field digital mammography, computer-aided detection mammography, as well as MRI, clinical breast exam, and ultrasound—with varying and less convincing evidence). For this example, we will discuss mammography in general.
Sensitivity and Specificity	(+/- based on population risk) Mammography: 79% sensitivity/90% specificity[39] dependent on breast tissue density and the skill of the radiologist interpreting the imaging. Sensitivity is increased in older women; sensitivity is poor in women younger than age 50 or thin women. False + are more common in younger women. False negative misses 1 in 5 cancers,[39] or 6-46% in younger women or those with fast growing tumors.[34] CISNET modeling for women aged 40 to 49, 746 women need to be screened to prevent one cancer death. 351 women in their 50's and 233 women in their 60's would have to have annual screening over the same time period to prevent one cancer death, respectively.[38]
Cost	(+/-) Typical cost is $80-$120, averaging $120. Cost varies dependent on provider.[36] Out-of-pocket cost for mammogram in Boise: • $21,400 per QALY gained in women 50-69 years old • St Luke's RMC Digital film: $300, + $50 for radiology read • St Alphonsus RMC Digital film $200, + $50 for radiology read (if paid immediately and in full, 25% discounted) Reports indicate that many grants are available to provide services free.

Reliability	≥ Cost per life year gained (QALY)[40] • $21,400 per QALY gained women, 50-69 years old • $105,000 per QALY women, 40-49 years old (+/-) One in ten (11%) of mammograms require additional evaluation; 90% of the biopsied lesions identified by mammography are benign.[35,41] One in three, or 33% of breast cancers detected by screening, mammograms represent over diagnosis (disease that is detected by screening that would not have caused morbidity or mortality if it had not been found).[33] For those who have annual screening for 10 years, 50% will have a false positive.[38] When mammography screening is performed biannually, there is a small, non-statistical increase in the rate of late stage breast cancer.[34]
Acceptance:	(+/-) Mammogram is acceptable to most people. Some report breast discomfort from mechanical compression of breast tissue between plastic and imaging plate.[33]
Positive predictive value:	Population based +PPV of mammogram: • 40-49 years, 6.3% • 50-59 years, 6.8% • 60-69 years, 7.8% PPV of having an abnormal mammogram is 8%, increasing to 14% at 70 years of age.[30,39]
Guidelines:	National mammographic screening guidelines offer differing conclusions: • The United States Preventative Services Task Force (USPSTF) recommends biennial screening starting at age 50, concluding age 74, noting screening prior to age 50 be based on patient preferences and individual context. • The American College of Radiology (ACR) advises all women to start annual mammographic breast cancer screening at age 40. • The American Cancer Society recommends annual mammograms commencing at age 40 and continued indefinitely in a healthy woman. While guidelines are written to incorporate best research into best practice, the lack of recommendation consensus reminds us that differing emphases and individual patient values and preferences make universal applicability difficult.

As you can see, although PSA and early age breast cancer screening has some success at detection and enabling prevention, it fails to meet many of our *SCRAP* criteria, and the evidence leaves a lot to be desired in recommending one specific course of action. Such factors do not mean that obtaining a PSA on older men or a mammography on younger women in your clinic is completely without benefit.

Evaluating the evidence does, however, demonstrate that a policy of screening the entire population may not be cost effective, and that discussions of individual levels of risks and benefits are necessary. Though some groups still exhort us to adopt a broad screening strategy, the most common recommendation is that we make the decision to screen on a patient-by-patient basis and only after a full informed consent discussion with the patient.

REFERENCE SOURCES ON PREVENTIVE HEALTH CARE

What screening practices should you implement? As illustrated with prostate and breast cancer screening, expert groups often disagree on what constitutes appropriate screening policy. Many disease societies and foundations take a very aggressive approach to screening for "their" conditions. At times these recommendations seem at odds with the amount of resources that society can afford to devote to a particular disease. Due to such conflicts, the United States Preventive Services Task Force (USPTF) is one group that critically examines screening proposals.[42] The Cochrane Collaboration performs a similar function[9] (see, for example, their example summaries for prostate cancer and breast cancer screening[10,11]). Such groups' conclusions are sometimes at odds with those issued by disease societies and foundations. In addition to examining such recommendations, we further suggest that you use the *DAMHIT SCRAP* mnemonic to evaluate screening practices in different clinic populations. This approach is also a useful guide to identifying those patients whom an overzealous screening program might harm.

ADDRESSING "GREY AREAS"

For "preference sensitive" decisions such as PSA testing or early age breast cancer screening, where a specific course is not clearly dictated by treatment, we certainly must weigh societal impacts of our choices. At the same time, however, perhaps our most important obligation is to help the patient make the choice that is right for them. As previously mentioned, patients tend to make decisions based on personal preferences and experiences much more than abstract evidence. In contrast, as part of evidence-based practice, we try to do the opposite. Finding a way to bridge these differences can be difficult, but is an example where the "art" meets the "science" of medicine.

In addition to the concepts addressed in this module, you should recognize that sensitivity and specificity as well as positive and negative predictive values are used in many clinical decisions beyond those involved with screening. By the end of your residency or other professional rotations training, you will have a rough idea regarding the prevalence of certain diseases in your clinic population. However, often we don't stop to examine the sensitivity and specificity of the tests that we order and how this oversight affects our decisions. Most of us can think of patients whose diagnosis was missed or delayed by over-reliance on a spurious test result. Ignorance of these concepts can lead to other harm, such as in the AIDS epidemic and subsequent calls for mandatory screening of certain populations, where false positives occurred during a program aimed at population benefit. In addition, there are risks associated with deciding not to screen. As has been mentioned in the case of PSA testing, some may opt to limit its use, but such an action should be carefully considered given the high prevalence of prostate cancer and "retrospective" judgments in men found to be positive.[24]

A Brighter Day Through SDM

Given such "gray areas" as well as high demands on providers, patients, and the economy, what can be done to dispel a potentially cloudy forecast for future healthcare? How can you apply this module's strategies to meet day-to-day, individual patient needs? In such a context, we believe and the evidence supports, that the PACT domain of Shared Decision Making (SDM) can assist you and lead to a brighter day. Therefore, we encourage you, as patient-centered providers, to discuss with your patients and help clarify their values related to treatments or tests, while also informing them of the evidence regarding their options. Using the "Ask-Tell-Ask" approach, as outlined by Gaster, et al. in the Core Readings for this module, can help you to develop an approach to SDM. This approach is useful for all forms of decisions that don't have a clear, evidence-based path; not only in long-term screening decisions, but in other choices, such as for elective surgery or difficult treatment options without clear guidelines. When serving as the patient's primary care provider and/or part of his/her team, you are arguably in the most unobstructed position to facilitate such discussions. In particular, you should use the patient's knowledge and values regarding the risks and benefits of the test to help them frame their decision, as well as their overall morbidity and life expectancy.

In turn, since you serve as a steward of increasingly limited healthcare resources, remember that your team members can be among your greatest assets. Though costs for many procedures may not decrease near term, open communication with your team can help you manage various procedures including screening most effectively. For example, an interdisciplinary team brought together through open communication has greater likelihood of clarifying patient values and of ultimately achieving patient compliance. Moreover, drawing upon SDM tools will help you facilitate such communication. Specifically, there is evidence that SDM tools can improve screening behavior and decision-making related specifically to prostate cancer screening.[27] Such tools, either in written, video, or interactive web-based form should be used to provide patients with relevant information that they can understand, that can elicit their values, and that can then help you, them, and other care team members develop a concrete plan that patients will feel comfortable following and discussing.

CONCLUSION

As healthcare providers, throughout our careers we will need to help patients make important, at times difficult decisions when evidence may fail us. Our efficacy in this endeavor will depend on our ability to interpret the data, effectively use available resources, understand our patients' different perspectives, and thus be able to help them make a decision that is right for them.

SUMMARY OF KEY POINTS

1. Screening is only useful if there is an ***effective treatment***.
2. The main determinants for positive predictive value of most screening tests are the ***disease prevalence*** and the ***test specificity***
3. ***Screening s trategies range in philosophy*** from "the greatest good for the greatest number" (population-based view) to "find all cases and treat them" (individual-based view)

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MODULE 2 CORE READINGS (available online)

- Gaster B, Edwards K, Trinidad SB, et al. Patient-Centered Discussions About Prostate Cancer Screening: A Real-World Approach. *Ann Intern Med* 2010; 153:661-665.
- Woolf SH & Harris R. The Harms of Screening: New Attention to an Old Concern. *JAMA* 2012; 307:565-566.
- Merenstein, D. Winners and Losers. *JAMA* 2004;291:15-16

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

4. How can you begin discussions of treatment options with patients when there is no "obvious" course of action (or when the guidelines are conflicting or changing)?
5. How do you translate the evidence and knowledge you have regarding treatment options into statements that different patients can understand?
6. In the article "Winners and Losers," what do you think the resident should have done differently?
7. Which do you think is worse for our individual patients and our society in general–frequent false positive tests or rare missed diagnoses of diseases?

Module 3

Asymptomatic Disease

”Dislikes Medical Offices”

Patient:
Sarah, a 52-year-old woman

Figure 16. Sarah. Adapted from Flickr, 2011.[1]

Chief Complaint: Hypertension control "so that she can have her root canal dental work done." Her dentist won’t perform the procedure unless she is normotensive. She has had multiple BPs taken, listened to calming tapes in the dental office, and even had "laughing gas" administered in an effort to reduce.

History of Present Illness: Onset of hypertension three years ago and has tried several medications that she judged to be ineffective due to "not feeling any different. " As such, she has not been treated since then. She brings in BPs from the past two weeks with an average of 180/120. She sees no difference in her BPs whether taken at work or at home. She would not be here ("dislikes medical offices") except for a short-term goal of root canal work, as she is in pain and believes the procedure will resolve her pain.

Past Medical History: Hypertension three yearrs ago. Vaginal delivery 33 years ago. No surgeries.

Family History: No siblings. Mother stroke in 70s; father died of MI @ 50. "Grandparents died when I was little."

Current Medications: None except ibuprofen for headaches (#4-6 tabs q 6-8 H)

Medication History: HCTZ – stopped 2/2 due to perceived "sulfa allergy;" metoprolol – stopped 2/2 due to fatigue; lisinopril – "didn’t work."

Allergies: Sulfa – "I don’t remember what happened. I think I might have had a rash."

Habits: Denies tobacco for 10 years; no illicit drug use ever; + ETOH has reduced to 6-8 cans of beer per night.

Adherence: Questionable – stopped two HTN meds on her own; not good about keeping appointments

ROS:
General: + weight gain 10 lbs in past year, + some fatigue, no fever/chills/malaise/noc sweats

- Eyes: no changes in vision, eye pain or discharge
- Throat/Neck: no dysphagia, slight hoarseness, no stiffness or pain
- Lungs: Denies cough, shortness of breath, wheezing, or dyspnea on exertion

- Heart: Denies chest pain or pressure, palpitations, or leg edema
- GI: Rare heartburn, denies nausea, vomiting, diarrhea, or blood in stools
- Neuro: + headache partially relieved by Ibuprofen, denies paresthesias, tremor, weakness, changes in senses

"**News**":

- Nutrition: B = Cheerios with 2% milk and 3 cups of coffee; L = macaroni and cheese with coffee; dinner: meatloaf with green beans and apple pie. "A pot of coffee per day."
- Elimination: No bowel or bladder problems, except up at night to void 2-3 times
- Work: Nurses' Aid at nursing home; works 7:00 AM – 3:00 PM. Fairly satisfied with work.
- Sleep: 11:00 PM – 5:30 AM; "OK" but not fully restorative sleep.

Exam:

VS: 200/120; repeat B/P: 178/110, 90, 16, 98

- General: Anxoius, thin extremities with relative trunkal obesity. NAD, WD, A&O X 3
- HEENT: PERRLA OU, 20/20, no icterus, A:V 1:2 little nicking, no exudate, no hemorrhage no erythema or exudate
- No masses; supple neck; no adenopathy
- Pulmonary: Respirations unlabored, clear breath sounds
- CV: RRR, no murmurs, no bruits at carotid, aorota, renal arteries
- Abdomen: Soft, nontender, not distended, bowel sounds in all four quadrants; no tenderness/guarding/rebound, no hepatosplenomegally, no CVA tenderness
- Extremities: Warm, dry, no edema, thinned skin legs, hairless, shiney foot pulses 1+
- Neuro: cranial nerves II-XII intact, sensation intact to light touch throughout. Reflexes 2+ patellar/Achilles, 5/5 strength upper and lower extremities

- ✓ **Before class, write down your assessment and plan for this patient.**
- ✓ **Also, consider ways to improve efficiency and teamwork using the PACT model.**

Module Three

Individualizing Treatment in Asymptomatic Disease

"It is a boresome disease to try to keep health by following too strict a regimen"
La Rochefoucauld, Maxims (1865)

INTRODUCTION

In the skillset required of systematic, conscientious providers, this module has chosen three areas for development:

1. Assessing the utility of treating common conditions identified by screening
2. Critically assessing intervention trials
3. Incorporating the patient into treatment decisions

You may have learned these skills previously, but this module will function like a repeated calisthenics program, helping to define these areas in greater detail and make you more agile in applying them in your professional routine. In particular, our goal is to enhance your critical thinking abilities to assess research and apply research-based interventions in your patient-centered clinical practice. Hand-in-hand with enhancing these skills, we will also address the PACT principles of Practice Improvement, Interprofessional Collaboration, Shared Decision Making, and Sustained Relationships. Ultimately, mastering these skills and principles with your patients and team will require you to rely on your fund of knowledge as well as your interpersonal, resource management, data acquisition, clinical reasoning, and interview skills.

Throughout the module, the lens that we will use to focus our discussion of asymptomatic disease will be the treatment of hypertension. Such a topic is vital since hypertension is treated to prevent or reduce the future occurrence of cardiovascular disease, by far the leading cause of death in the United States. Moreover, it is common; one quarter of American middle-aged adults have diastolic blood pressures greater than 90 mm Hg. As you have no doubt experienced, it is also a common reason for visits to primary care physicians. Most importantly for your patients' health and your success as a provider, patient adherence with treatment is critical.

Figure 17. Focus on HTN. Adapted from Flickr, 2010.[2]

LEARNING GOALS

Through studying and applying principles from this module, you will:

- Learn how to elicit vital information from the literature as needed for treatment decisions (using "ODSPIRC" and other techniques).
- Be able to come to a scientifically and ethically sound treatment goals using this data and a dialogue with the patient.
- Capitalize on education, behavioral modification techniques, pharmacologic therapy, and your interdisciplinary healthcare team in an appropriate fashion to achieve these treatment goals.
- Understand how the PACT principles of Performance Improvement, Interprofessional Collaboration, Shared Decision Making, and Sustained Relationships relate to the hypertensive case study at the beginning of this module as well as other asymptomatic disease situations.

To guide you in achieving these goals, this module is arranged in the following order:

1. We will address the process to establish treatment goals, including weighing internal and external validity.
2. Then we will explain the ODSPIRC approach to reviewing clinical trials while also outlining significant factors in the treatment of hypertension.
3. After that, we will discuss the concepts of adherence (compliance) with treatment programs and optimizing team management based on PACT principles to achieve the best possible results.

ESTABLISHING THE TREATMENT GOAL

How do we arrive at treatment goals? Many of our practices in treating asymptomatic conditions rely first on identification of a characteristic as a risk, usually by epidemiologic studies, and second on demonstration that alteration of the characteristic can change outcomes. This important second step is often overlooked in our zeal to avoid negative outcomes identified in the first step.

In order to optimize treatment of asymptomatic diseases in our clinic, we must answer three questions:

THREE KEY TREATMENT GOAL QUESTIONS

1. **What evidence is there, on a population basis, that treating the characteristic will improve poor outcomes?**
2. **What are the risks and benefits to an individual patient?**
3. **How does my patient feel about these risks and benefits?**

When faced with a patient who has an asymptomatic condition, we are required to make individual decisions based on data from aggregate analysis, and to modify these decisions based on the patient's evaluation of potential benefits and outcomes.

INTERNAL AND EXTERNAL VALIDITY

As you evaluate intervention trials and work to effectively apply the results to individuals, you must understand the concepts of *internal* and *external validity*.

Internal Validity

Simply stated, *internal validity* is a measure of the degree to which a study's results are due to the intervention being studied. For an experiment to obtain internal validity, it must limit all variables except the one being tested (to the extent possible). Also, it usually relies on a properly designed and executed intervention trial, and the conclusions are often statistically based. However, the challenge is that the group of patients studied may have characteristics that do not match your study's population, such as high compliance, a single disease, etc.

External Validity

External validity, on the other hand, is a measure of the degree to which the results of any study are generalizable to the population as a whole. In other words, it allows the assumption that these results also apply to your individual patients.

Application

Internal and external validity are related much like sensitivity and specificity were in module two, that is, an increase in one usually results in a decrease in the other.

To explain, consider an example. Suppose we design a study to look at the effects of treating hypertension with a new drug. We would select patients for the study who had not had a stroke or coronary disease, as these are the endpoints we wish to change with our treatment. In designing the study, the better that we control the study population, i.e. the higher the internal validity, the more attributable these results are to the chosen intervention(s). However, the more controlled the study population, the less likely that the treatment and outcomes are generalizable to the general population, i.e. the lower the external validity.

In our example, the study shows a major reduction in stroke. When using this result as a basis for treating similar patients in our clinic, we find our patients with pre-existing coronary disease (the vast majority) have increased angina with the new drug. This would be poor external validity, or generalizability of the result to our patient population.

In terms of process for using internal and external validity to establish treatment goals, we:

1. Identify an asymptomatic condition as a risk factor by examining large epidemiologic studies (which have high external validity).

2. Then, we test the hypothesis that modification of that risk factor changes outcome for our study group (which gives us high internal validity).
3. Finally, we apply this information in practice to an individual patient.

How are we able to follow this process?

"ODSPIRC"ing

First, we need a systematic approach to reviewing clinical trials. One that many journals use and which we have adopted is called "ODSPIRC." This approach may be used to see if the patients in the study are similar to your own, if the intervention is do-able in your setting, and if the results are clinically meaningful.

ODSPIRC is:

Objective	Hypothesis being tested.
Design	See levels of evidence in module two.
Setting	What nation, hospital/clinic type, expertise involved.
Patients	Inclusion and exclusion criteria, particularly with respect to other prognostic factors.
Intervention	How well defined? Reproducible?
Results	How do they apply to an individual patient? Do they make sense given the hypothesis?
Conclusions	Clinically significant and do-able?

To see how we might "ODSPIRC" in a single study of interest, let's examine the Medical Research Council (MRC) trial in mild hypertension:[5]

Objective: To assess the effects of treating mild hypertension on stroke, coronary events and deaths due to hypertension.

Design: Prospective, randomized, single-blind, placebo controlled

Setting: Office based practices, United Kingdom

Patients: 17,354 men and women, age 35-64, with DBP 90-109. Not excluded for previous end-organ disease.

Intervention: Bendrofluazide or propranolol

Results:	Start BP	End BP	CVA*	MI*	all CVR deaths*
Placebo	158/98	149/92	2.6	5.5	8.2
Benz.	158/98	135/85	0.8	5.6	6.6

Prop.	158/98	137/87	1.9	4.8	6.7

* events per 1000 patient years

Conclusion: CVA significantly reduced by treatment. Diuretics more effective than beta-blockers, perhaps because BP was lower with them. Coronary events only improved in non-smokers using beta-blockers.

ODSPIRC is not an exercise in "filling in the blanks," but a useful way to help us decide how to answer the patients' question: "Why should I take this medicine anyway?" As a practical example, let's work through the rationale for treatment of mild hypertension.

POPULATION EVIDENCE FOR TREATING MILD HYPERTENSION

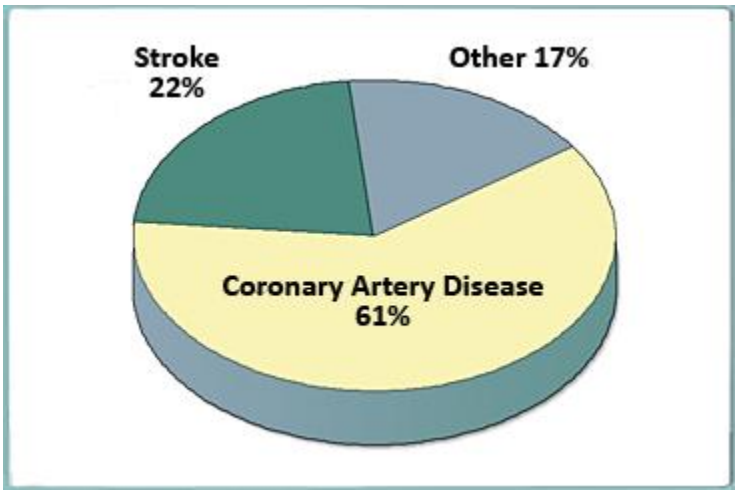


Figure 18. Causes of Cardiovascular Mortality.Adapted from *Lancet*, 1990.[3]

Hypertension was identified as an independent risk factor for cardiovascular disease in a number of studies in the '60s and '70s (especially the Framingham study). From this data, the hypothesis was put forward that reducing blood pressure would prevent or decrease adverse cardiovascular outcomes. As we can see from Figure 1, the outcomes we are most interested in are stroke and coronary artery disease.

To examine the hypothesis that reduction of blood pressure improves outcomes further, we will review the clinical trials. An "ODSPIRC" of the major clinical trials in mild hypertension (diastolic blood pressure 90-105 mm Hg) is included in appendix 1, and you may wish to review this. Basically, the results showed a 35-40% reduction in stroke and a 15-20% reduction in MI using diuretics, beta-blockers, ACE/ARBs, or calcium channel blockers. Given all this data, a national committee decided in 1988 that treatment using a "step care" approach should be started on most individuals at a diastolic blood pressure above 90 mm Hg. Let us see if we come to the same conclusion.

The accompanying figure illustrates that the cost to society will change given the different cut points for defining hypertension as diastolic blood pressure above 90, 95, and 100 mm Hg. With your review of the primary studies and this information, what will you select as a scientifically defensible treatment goal?

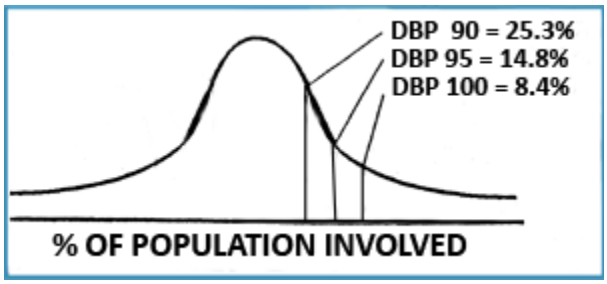


Figure 19. Cut Points for Hypertension. Adapted from *JAMA*, 1979.[4]

RISKS AND BENEFITS IN THE INDIVIDUAL PATIENT

Now, let us look at these studies in a different way. You have a 52-year-old man in your clinic with an average of 10 DBP's of 98 mm Hg. Non-pharmacologic therapy has made no difference.

Should you start medications?

To decide, you might first want to know his other cardiovascular risk factors. These were not specifically taken into account in the trials on mild hypertension (although randomization did seem to even them out—an important point to check in evaluating the trial). Next, what benefits can we expect with treatment? The aggregate of these studies, as we have said, is a 35-40% reduction in stroke (a less likely event), and a 15-20% reduction in coronary disease (the more likely event).

Now, we introduce the concept of **number needed to treat**. In short, this concept addresses the question: *How many people need to be treated to avoid one event*?

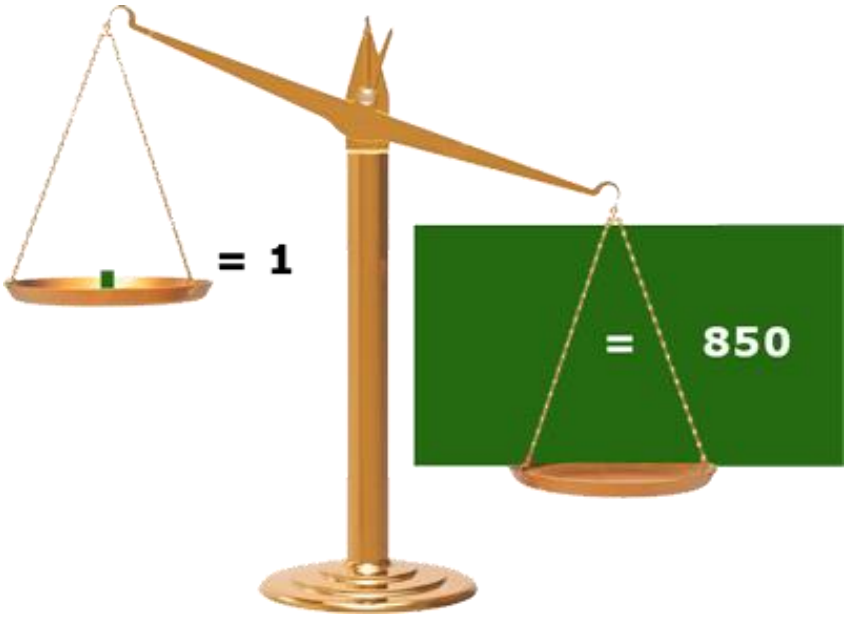


Figure 20. Likelihood of stroke is on the left. Taking a pill to control BP is on the right. What is the weight of each outcome for your patient?

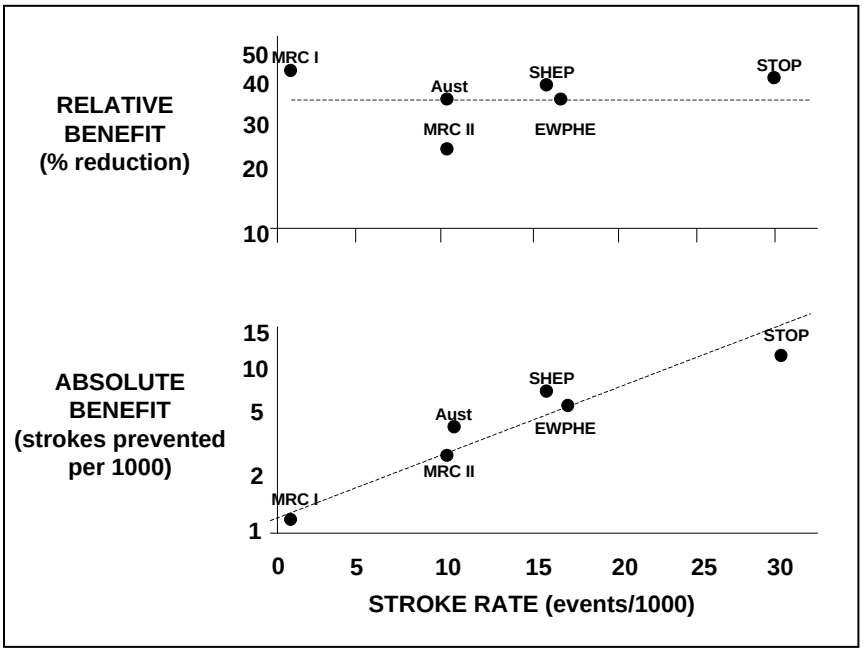
In the case of this gentleman, he falls into the same category as the MRC study patients. We see that 109 patients had strokes in the placebo group (42,504 patients), while 60 patients had strokes in the treated group (42,673 patients). Although this is indeed a 46% reduction in stroke, we also see that there are only 2.6 strokes per 1000 patient-years without treatment. Thus, to prevent one stroke, we would need to treat 850 people for one year. Notice that you need to "read between the lines" of the ODSPIRC data to obtain these facts, which are the most useful to you in clinic.

Remember also that you must present this scientific data to the patient in a way that helps them to understand your rationale. We are often more cognitively based (thinking) than experiential (feeling or seeing), while the patients are often the reverse. As a result, we may need to present data in a visual format that is more easily understood by the patient.

For example, the chart on the following page shows another way of looking at individualizing study results. Here are data from several studies of mild hypertension in the elderly. While the relative benefit of treatment is remarkably similar across studies (about 35-40%, just as in studies of the non-

elderly), the absolute benefit is very dependent on the individual risk. As the risk of stroke goes up, the absolute benefit goes up, and the number needed to treat goes down.

As an illustration, if you had a 65-year-old male patient with mild hypertension, the chart indicates that on average, from treating him for 10 years and achieving average results (decrease of ~10/5 mmHg) we can expect to achieve a 25% reduction in MI, a 40% reduction in stroke, and a 15% reduction in overall mortality.[6]



In evaluating research, remember that population-based trials tell us what works, and how well it works (the potential relative benefit). Then, to apply such research in clinical practice, we need to individualize risk based on family history and co-morbid disease in the patient in front of us. Only then can we accurately assess the risk/benefit ratio in our individual patient.

WHAT ARE THE "BEST" AGENTS TO USE?

Since medications are such an important part of asymptomatic disease treatment, particularly hypertension, this section provides an overview of some relevant studies' outcomes. As of the year 2000, ACE inhibitors, ß-blockers, calcium channel blockers, and diuretics all have efficacy data for "hard" outcomes (mortality, MI, and/or CVA). The ALLHAT trial showed that α-blockers have increased risk of death (primarily from progression of CHF) and that diuretics have the best overall reduction in endpoints (mortality, CVA, CHF) and are inexpensive.[7] Chlorthalidone was the thiazide used in this trial. In the absence of comparative studies, hydrochlorothiazide (HCTZ) was widely adopted as equivalent in the U.S. Chlorthalidone has a longer half-life and is approximately twice as potent as HCTZ.[11] Chlorthalidone was recently recommended as the first line choice over HCTZ for hypertension control in the Current Treatment Guidelines (published by The Medical Letter).[12,13] Thiazides increase insulin resistance, uric acid, and lithium levels; they appear less likely to react with "sulfa" allergies.[11] The Australian NBP2 trial compared ACE inhibitors to diuretics in relatively healthy older people and found a small benefit for ACE inhibitors in combined outcomes and MI (although CVA increased).[12] Finally, some recent studies show benefit of ARB's over atenolol.[13,14] Such a result has rekindled a debate about the pharmacokinetics of atenolol, which don't support its once-a-day dosing. Another letter to the editor outlines the evidence that other ß-blockers may be more effective.[15] Also, recent reviews of ß-blockers suggest that they should not be used as first line agents in older patients without other indications for ß-blockade.[16,17]

HOME OR OFFICE READINGS

Managing blood pressure is easier when the home and office readings coincide, but what should we do when they don't coincide? A recent study showed that patients with elevated office readings but normal home readings ("white coat" hypertension) had about the same risk as those with normal office readings.[18]

ADDRESSING THE PATIENT'S FEELINGS

Are we finished? Have we decided on an appropriate treatment goal for this patient?

Certainly not! We have no idea how the patient feels about this yet. He may have watched Aunt Mabel suffer a debilitating stroke, and be willing to prevent that at any cost. Or possibly, he may think of himself as healthy, and see taking a pill each day as a catastrophe. Such feelings would certainly color his perception of the importance of this pill, and, therefore, are probably information that you will need to gather to help you care for the patient better.

Forrow, et al.[19] have broken down the scientific and ethical parts of this decision process in a similar way. They state that the scientific decision is based upon demonstration that altering the risk factor does indeed alter health, that the results are meaningful at the level of the individual, and that the negative consequences of labeling do not outweigh the positive benefits of treatment. They further state that the ethical part of the decision is based upon the patient and the physician fully understanding the risks and benefits of treatment. While you may not have time to review detailed intervention studies with patients, helping them gain some understanding of treatment's risks and benefits is much more likely to establish a mutually agreed upon goal that is do-able. Given time and other constraints that you face as a provider, consider how you could present such treatment goals to your patient in a way that is meaningful, memorable, and understandable.

Take a Minute to Reflect

You may wish to review the materials on lipids included in the appendix, examine the results, and consider how such results could apply to treatment goals for your individual patients.

"TROUBLESHOOTING" UNMET TREATMENT GOALS

Even goals that were arrived at under ideal circumstances may remain unmet. What can you do? First, review the logic used to arrive at the goal, and make sure that the goal and your analysis are appropriate. Ultimately, you will seek to identify factors that are then generalizable to any unmet treatment goal.

Speaking of more generalizable factors, the article by Anderson, et al.[20] lays out the following five in determining patient compliance:

1. Patient characteristics
2. Prescribed regimen
3. Provider characteristics
4. The provider-patient interaction
5. The illness itself

We have modified these factors and borrowed a tool from the management literature known as cause-and-effect diagrams (also called fishbone diagrams or Ishikawa diagrams). The cause-and-effect diagram based on the Anderson article would look something like the figure below:

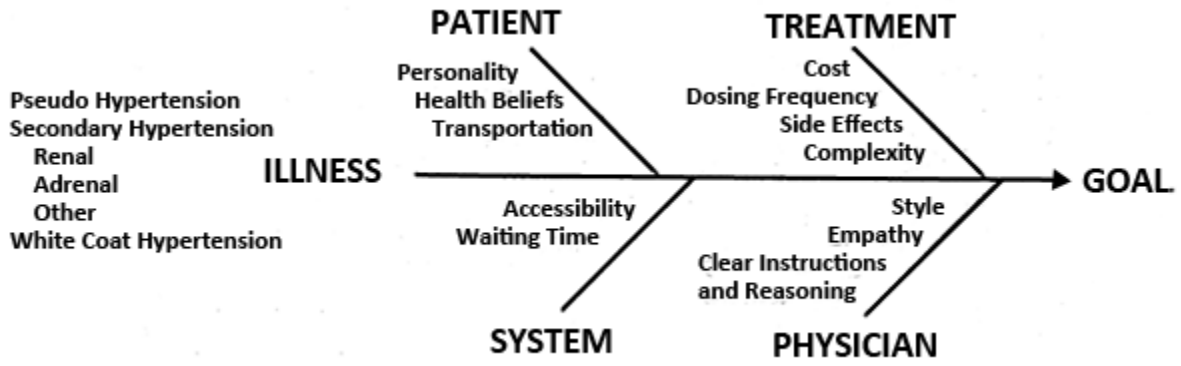


Figure 21. This cause-and-effect diagram shows all of the factors that might lead an unmet treatment goal. The broad categories are factors due to the patient, the physician, the medical care system, the treatment regimen, and the illness itself. Under each of these categories are listed many specific factors that may lead to failure.

Earlier, we included three key questions when establishing a treatment goal with a patient. Also, our discussion has addressed research decisions to ensure that your treatment goals are evidence-based as well as patient-centered. Remember the following as you establish treatment goals and troubleshoot them if unmet:

KEY POINTS OF ESTABLISHING & TROUBLESHOOTING A TREATMENT GOAL

- **Asymptomatic diseases are intermediate variables for serious outcomes (high blood pressure ⇒ stroke and MI). What is the population-based evidence that treating the variable affects the serious outcome?**
- **How is this population-based data modified by the clinical context in the individual patient (e.g., do they smoke, have diabetes or a strong family history of MI)?**
- **Consider the Health Beliefs Model (an individual performs a health behavior based on perceived susceptibility, severity, benefits, and barriers). What are the patient's beliefs and values relative to treatment and outcomes?**
- **How can you help the patient to increase the pros, i.e., their reasons for positive behavioral**

change, and decrease the cons? The TTM Model establishes that ⇑ the pros and ⇓ the cons raises the likelihood of a move from contemplation ⇒ preparation ⇒ action.

- **Use family history to discuss that "genetic susceptibility is not health destiny" and the role of lifestyle and behavioral changes in postponing or preventing disease. How can you involve the family in ways that will maximize the "ripple effect" of behavioral change?**
- **What are the patient's beliefs and values relative to treatment and outcomes?**
- **If treatment goals are not met, what are the provider, system, treatment, and illness characteristics that may be contributing to unmet goals?**

In summary, we have learned how to evaluate population-based studies using ODSPIRC and other techniques. We have learned to apply this to an individual with the "number needed to treat" concept to obtain the desired outcome. Given this data, we arrive at an ethically-sound treatment goal through dialogue with the patient. Finally, if this goal is not met, we have considered a cause-and-effect diagram as one possible method of rethinking and troubleshooting the unmet treatment goal.

PRACTICE IMPROVEMENT

Such a troubleshooting process with individual patients ties into making deliberate and sustained efforts at continuous improvement, which are necessary to maintain high quality healthcare delivery and outcomes. For this reason, PACT includes Practice Improvement as a quintessential principle. Similarly, the Institute of Medicine has envisioned a system that provides the right care to the right people when they need it, and to capture the results for making improvements into a *learning health system*. Creating new, generalizable knowledge should become a necessary and routine aspect of healthcare delivery. Providers today must not only be able to assess and manage the health of individual patients, but also of a panel of patients within the larger context of community and public health. Performance improvement includes activities that measure, compare, evaluate, systematically introduce accepted therapies, share experiences and information, and coordinate these activities among organizations.

The randomized-control trial (RCT) is the gold standard of study design in evidenced-based research. However, evaluation of quality improvement efforts is often better suited to alterative research methodologies. By attempting to control for bias and confounding, RCTs can tell us *if* an intervention changes outcomes, but it cannot tell us *why* or *how*. Performance improvement, therefore, must account for additional variables since it also requires some degree of social change, a non-linear process with multiple component interventions, all acting within a complex social system. Much as an interdisciplinary team approach potentially enhances treatment of asymptomatic and other conditions, adopting assessment techniques borrowed from fields such as engineering and business can help explain the mechanisms and contexts for why an intervention was successful or not.

Specific techniques include using time series analysis, simulations, statistical process control, and qualitative methods like ethnography and anthropology.[22]

In the following table, we compare and contrast the specifics of measurement performed for research purposes as compared to that for learning and process improvement:

From this table, which analyzes purpose, tests, biases, data, and duration, we hope that you will gather a method to break down important factors to consider for analyzing measurement in other areas.

Table 3. Adapted from Institute for Healthcare Improvement.[23]

	Measurement for Research	Measurement for Learning and Process Improvement
Purpose	To discover new knowledge	To bring new knowledge into daily practice
Tests	One large "blind" test	Many sequential, observable tests
Biases	Control for as many biases as possible	Stabilize the biases from test to test
Data	Gather as much data as possible, "just in case"	Gather "just enough" data to learn and complete another cycle
Duration	Can take long periods of time to obtain results	"Small tests of significant changes" accelerates the rate of improvement

Also, as you seek to achieve Practice Improvement, consider a model that has been developed by the Associates in Process Improvement, which lays out a series of questions to define the aims into something that is measurable and time-specific.[27] The diagram on the right shows these questions, which are tested using the Plan-Do-Study-Act cycle. Steps in this cycle include:

1. Identify changes necessary for an improvement intervention (PLAN)
2. Trial the changes (DO)
3. Measure the results (STUDY)
4. implement the changes if successful or perform additional cycles as needed (ACT)

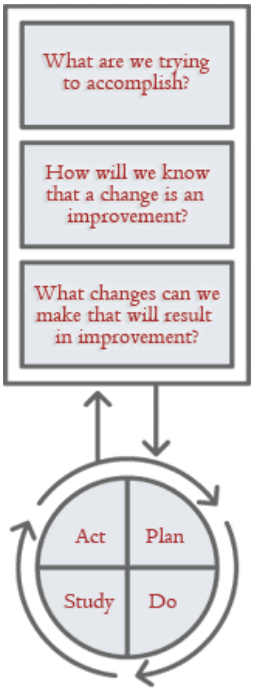


Figure 22. Adapted from API, 2007.[27]

Central to performance improvement is an ability to make changes incrementally and to learn from experience while doing so: *Plan-Do-Study-*

Act. In other words, you will ask the questions shown on the diagram on the right iteratively throughout the cycle. Most importantly, applying these rapid cycle improvement methods as you "test hypotheses" about changing the practice care routine is designed to help you achieve both better performance in the near-term and incremental improvements over time.

Referring back to Sarah, the patient from the scenario at the beginning of this module, how might the challenges of managing her hypertension relate to performance improvement?

In response, regular review of our panel could raise questions such as, "It seems that many of my patients are having trouble maintaining optimal blood pressure control. Why is that? " Such a question may lead us to think about our aim (improving blood pressure control among patients age 50 to 75), then deciding what we can change (the patient may need dietary counseling, closer follow-up with telephone, RN, CCHT, and pharmacy visits), and identifying a measurement of improvement (SBP after three months).

Asking questions and coming up with a specific, measurable action plan is called "The Model for Improvement. " Ultimately, remember that you are not alone in your quest to improve outcomes. Working as part of a collaborative, interdisciplinary team may trigger multiple interventions that could lead to performance improvement.

Among these interventions, do not neglect non-traditional resources (listed below), which are gaining increased emphasis in modern medicine due to their potential to increase efficiency and effectiveness. Here at the Boise VA, non-traditional resources for hypertension management beyond the traditional provider visit include:

- Hypertension registry
- Nurse hypertension protocol follow-up
- Pharmacy hypertension clinic
- Home blood pressure cuffs and monitoring
- CCHT
- Dietician
- Integrated Care Team and mental health counseling
- MOVE program
- MySecureVet.gov

Using such non-traditional resources as well as your interdisciplinary team should become part of your continuous journey to practice improvement. Along this journey, your impact and influence will grow as you balance internal and external validity from pre-existing studies and apply good study design to assess measurable impacts of modifications to practice. Once an intervention is tested it can lead to practice redesign for you as an individual and for your team. Then, if such practice redesign results in higher quality of care for a subset of patients, a new practice pattern can be implemented and monitored on a broader scale.

INTERPROFESSIONAL COLLABORATION

Along with Practice Improvement, you have been introduced to the concept of Interprofessional Collaboration (IC) in previous modules. Also, perhaps you had some classes in school that explained what it means and why it is important. Perhaps you have worked in a clinical setting where various professionals worked together to improve health outcomes for patients.

In this context, it should come as no surprise that a team-wide quality improvement approach has been shown to improve blood pressure control, screening for other "metabolic syndrome" conditions, and exercise prescriptions.[21]

Since IC can lead to such positive outcomes, you may wonder: How does a clinical practice develop an effective team that seamlessly coordinates patient care in a way that provides positive results for patients and staff? How is IC a part of the "Medical Home" concept, and how will it be evident in the Boise VA Center of Excellence? Moreover, you may still question: Why should you be interested in IC, and how is it applicable to the hypertensive case in this module's scenario?

To respond in part, IC is the process by which several healthcare professionals work together to leverage their different areas of expertise and perspectives to meet the needs of populations of patients with chronic disease.[25] Several studies show improvements in outcomes when IC was utilized including pediatrics, geriatrics, oncology, emergency, ICU, and in various chronic diseases.[26] Given the movement toward care in Medical Homes, there are many agencies that offer help for practices to adopt best practices including The Agency for Healthcare Research and Quality (AHRQ). The evidence base supporting IC, although not exhaustive, is building.

Because it shifts decision-making responsibilities to a team of professionals and includes the patient and their family/caregiver rather than resting solely with prescribers, IC constitutes a vital part of the Medical Home. It is a patient-centered concept since good care coordination and effective communication with ALL parties requires multiple professionals and support staff working together toward the good of patients.

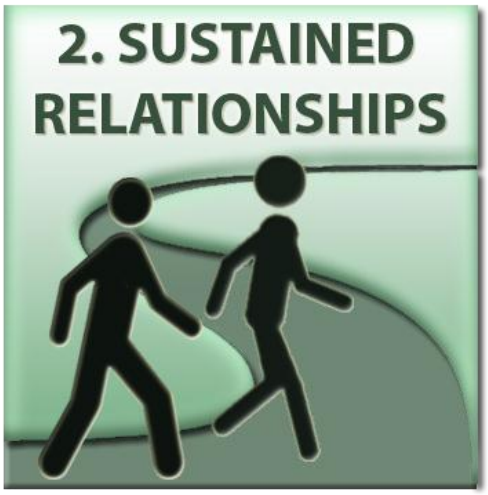
You should notice IC in play every day in the Silver Team. On your team you have physicians, nurse practitioners and RNs, pharmacists, psychologists, dieticians, physical therapists, occupational therapists, and more including various support staff. Each of these has a role with some and perhaps all of your patients. Some are physically present in Silver Team and some are not. Please familiarize yourself with these people and utilize them to improve care.

In the scenario presented at the start of the module, we have a patient who has chronic disease. Perhaps large improvements in her health will be achieved with one or two interventions by the front

line team (MD, NP, RN), but how often is that true in our patient population? It is likely that she will require several interventions over the next few weeks and months and likely many more in the coming years. Over the course of treatment, your team can provide vital assistance to this patient through chronic disease education, self-management education, follow-up on medication effectiveness, dose adjustment, monitoring, and basic support. Many of these activities can be done without an office visit and without directly involving the prescriber.

Remember that IC, like anything worthwhile, needs to be cultivated and practiced. Develop your team early, utilize them daily, and seek to improve over time.

SUSTAINED RELATIONSHIPS



From the similarly important perspective of Sustained Relationships, consider the following points in this module's case study:

- The strongest of the scenario patient, Sarah's, relationships seem to be in her association with work, along with her work ethic. Can we tie we tie success in long term treatment of HTN to work performance, longevity, and/or independence? Will this align us with her goals?

- Once the best alignment is established, team members will maximize treatment by using the same message in working with this patient—e.g., "We recommend this intervention since it will increase your longevity/independence at work. "

Coordinating a similar message as a team should enhance effectiveness, result in improved responses to key patient relationships, and better align our care around patient values.

While you are likely reading individually, as you reflect on this scenario, remember that team-based approaches have been emphasized throughout your training since anything is possible within the context of a relationship. Building and sustaining strong professional relationships with patients and with multidisciplinary team members offers the best chance for optimal effectiveness. In working with chronic diseases, especially those that are asymptomatic. In particular, a relationship based on respect of competence, communication, and trust that you will do what you say you will, is especially important. Ingredients that facilitate this trust, and which you will be encouraged to use at the Boise VA, include coordinated follow-up, team huddles, telephone touch-points, and warm handoffs between multidisciplinary team members and the patient.

CONCLUSION

This module has centered around hypertension studies to highlight best practices for treating asymptomatic disease. After completing the Core Readings, please come to class prepared to discuss your next steps in managing Sarah's hypertension. Specifically, consider the following questions:

- ✓ **What barriers do you perceive in helping her control this asymptomatic disease?**
- ✓ **What non-traditional resources might you leverage within the VA system to help gain adequate blood pressure control?**
- ✓ **Finally, how do you think that Interprofessional Collaboration and Sustained Relationships might pertain to this case?**

While asymptomatic disease presents its own share of complexities, involving the patient and assisting them in achieving treatment goals adds another level of ongoing challenges. While some could feel intimidated, we prefer to view such complexities and challenges as opportunities that make our work as healthcare providers exciting and worthwhile. Similarly, as you apply the research and practical techniques discussed in this module, you will be stretched, no doubt, but you'll also be rewarded as your efforts lead to improve care for individual patients, multidisciplinary teams, and ultimately contribute to broader enhancements of healthcare systems.

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MODULE 3 CORE READINGS (available online in Moodle)

- Forrow L, Wortman SA, Brock DW. Science, Ethics, and the Making of Clinical Decisions. *J Am Med Assoc* 1988;259(21):3161-3167.

- Port S, Derner L, Jennrich R, Walter D, Garfinkel A. Systolic blood pressure and mortality. *Lancet* 2000;355:175-80.

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

1. In the clinical decisions article by Forrow, et al., what are the elements of the scientific basis for treatement and how do they differ from the ethical basis for treatment?
2. In the article by Port, et al., what does the finding of non-linearity in this analysis mean for rational treatment cutoffs and thresholds for action?

APPENDIX 3-1: "ODSPIRC's" OF THE HYPERTENSION TRIALS

In 1967, the first data was published from the V.A. Cooperative trial. It reviewed the treatment of 143 patients with hypertension that had diastolic blood pressure between 115-129 mm Hg. The data clearly showed a benefit to the treatment group with respect to stroke, coronary artery disease, MI, and "hypertensive" complications such as LVH, dissecting aneurysm, and uncontrolled hypertension. Attention then focused on the benefits of treating blood pressure levels lower than this. The **Objective** of all trials was to study the effects of pharmacological intervention with regard to improving morbidity and mortality from cardiovascular disease.

VA Cooperative Trial *JAMA 1970;213:1143-1152*

Design: Randomized, prospective, double-blind, placebo controlled.

Setting: Hospitalized at entry with BP determined after 6 days of bedrest.

Patients: 380 male veterans, avg. age 51, not excluded for end-organ disease. Had to pass a reliability test and had DBP 90–114

Intervention: Step 1 – HCTZ/reserpine, Step 2 – hydralazine.

Results:

	Start BP	End BP	CVA	CAD	CHD	Other	
Placebo	165/105	169/106	20	13	11	12	= 56
Treated	162/104	135/86	5	11	0	6	= 22

Endpoints by DBP	Placebo	Treated	
90–104	21	14	= 35% reduction
105–114	35	8	= 75% reduction
	56	22	

Conclusions:

1. **Treatment significantly improves outcomes for DBP 105-114**
2. **Treatment suggests benefit (NS) for DBP 90-104**
3. **Marked improvement in CVA and CHF**
4. **No significant change in CAD**

HDFP (Hypertension Detection and Follow-up Trial) *JAMA 1979;242:2562-2571*

Design: Randomized, prospective cohort study of stepped care (SC) vs. referred care (RC)

Setting: Multicenter, community-based, U.S.

Patients: 10,940 (7825 with DBP 90-104), 30-69 y.o., not screened for end-organ disease intervention
Step 1 – chlorthalidone -or- triamterene -or- spironalactone
Step 2 – reserpine -or- methyldopa
Step 3 – hydralazine
Goal: reduce DBP by 10 or to 90 mm Hg, whichever is lower

Results:

	Start DBP	End DBP	% at goal	non-CVR death	CVR death	CVA	MI	Other isch.	Other
SC	96	83	64%	109	122	17	30	56	19
RC	96	88	43%	126	165	31	56	51	27

Endpoints by DBP		
	90-94	34% reduction
	95-99	28% reduction
	100-104	19% reduction

Conclusions:

1. **Significant benefit to more rigorous stepped-care approach with greatest benefits at lower DBP levels**
2. **CVA, MI, and HTN complications all significantly reduced**
3. **"Other ischemic heart disease" increased by 9%?**
4. **Treatment benefits markedly diminished in those with pre-existing end-organ disease and those < 50 y.o.**

Oslo Study *Am J Med 1980;69:725-732*

Design: Randomized, prospective, uncontrolled cohort study

Setting: Outpatient clinics, Norway

Patients: 785 men, age 40-49, DBP 90-110, no end-organ disease

Intervention: Step 1- HCTZ, Step 2- methyldopa -or- propranolol

Results:

	Start BP	End BP	coronary events	CVA	hypertensive events
TX	156/97	132/87	20	0	5
C	155/96	153/98	13	7	14

Endpoints by DBP	TX	C	
90-100	5.2%	5.7%	(NS)
> 100	7.6%	16.4%	(p=.06)

Conclusions:

1. **Treatment of DBP > 100 mm Hg has significant benefit for CVA and hypertensive complications**

2. **Treatment has a trend (NS) towards INCREASED cardiac mortality (retrospective analysis found this to be greatest in those with abn. EKG at entry)**
3. **There is no benefit in the 90-99 mm Hg group**

MR. FIT (Multiple Risk Factor Intervention Trial) *JAMA 1982;248:1465-1477*

Design: Randomized, prospective cohort study of special intervention (SI) vs usual care (UC)

Setting: Multicenter, U.S.

Patients: 12,866 high risk men (upper 15% by BP, lipids and smoking status) without clinical evidence of CAD

Intervention: Counseling re: smoking cessation, low fat diet.
Step 1 – HCTZ -or- cholrthalidone
Step 2 – reserpine -or- hydralazine -or- guanethidine

Results:

	DBP	cholesterol	% smoking
SI	99 to 80.5	254 to 236	64 to 32%
UC	99 to 84	253 to 240	64 to 46%

	MI	all CAD	CVA	CHF	Other	CVR risk	Total mortality
SI	38	115	13	0	116	1.79%	4.12%
UC	35	124	11	1	109	1.93%	4.04%

Relative risk:

smoke vs no smoke	70% increase
HTN vs no HTN	37% increase
Chol > 250 vs < 250	14% increase

Endpoints by DBP	SI	UC	
90-94	1.47%	1.02%	
95-99	2.29%	2.25%	
≥ 100	2.08%	2.98%	(33% reduction)

Conclusions:

1. **Trend (NS) toward decreased MI, CVA, CAD when all factors treated aggressively (lack of significance may be due to larger than expected reductions in UC group)**
2. **Smoking has the highest relative risk and greatest benefit when modified**
3. **Tx of HTN only improves mortality above DBP 100 mm Hg**
4. **Tx 95-99 mm Hg shows no benefit**
5. **Tx 90-95 mm Hg actually worsens mortality (retrospective subgroup analysis identified abn. Entry EKG as the group at risk)**

MRC (Medical Research Counsel) Trial *Brit Med J 1985;291:97-104*

Design: Randomized, prospective, single-blind, placebo controlled
Setting: Office-based, Great Britain
Patients: 17,354 men and women, 35-64 y.o., DBP 90-109
Intervention: bendrofluazide -or- propranolol

Results:	Start BP	End BP	CVA	MI	all CAD death	mortality
bendrofluazide	158/98	135/85	1%	9%	10.3%	7.5%
propranolol	158/98	137/87	2.3%	7.6%	10%	6.7%
placebo	158/98	149/92	2.9%	9%	12.3%	8.2%

Conclusions:

1. **CVA significantly reduced by treatment. Effect greater with diuretics (due to greater DBP reduction?). Diuretics worked regardless of smoking status, β-blockers only worked in non-smokers.**
2. **MI only improved by β-blockers in non-smoking men**
3. **NNT was 850/year to prevent one stroke**

European Working Party on High Blood Pressure in the Elderly *Lancet 1986;Sept 13:589-592*

Design: Randomized, prospective, double-blind, placebo controlled
Setting: Multicenter, Europe
Patients: 840 men and women, > 60 y.o., DBP 90-119
Intervention: Step 1- HCTZ/triamterene, Step 2- methyldopa
Results: All CAD events approx. 50% of placebo. CVA similar

Endpoints by DBP	TX	C
90-94	5%	6.4%
95-99	2.8%	6.4%
100-104	4%	7.5%
105-109	2.8%	10%

Conclusions:

1. **SBP slightly better than DBP as predictor in the elderly**
2. **Benefits limited to < 80 y.o., and DBP > 95 mm Hg**
3. **MI significantly improved by Tx**
4. **CVA not changed by Tx.**

SHEP (Systolic Hypertension in the Elderly Program) *JAMA 1991;265:3255-3264*

Design: Randomized, multicenter, double-blind, placebo controlled
Setting: Tertiary care centers, U.S.
Patients: 4736 patients > 60 y.o. with SBP > 160 and DBP < 90
Intervention: Step 1- chlorthalidone, Step 2- atenolol
Results: (event/1000 pt-years)

	end BP	CVA	fatal MI	Other MI	Mortality
C	155/72	8.2	73	26	242
TX	143/68	5.1	59	15	213
	(36% dec., RR 0.64)		(27% dec., RR 0.87)		

Conclusions:

1. **Decline in CVA rate progressive as study went on**
2. **Considerable benefit for Rx systolic HTN in elderly in CVA, MI**
3. **Actual benefit may be greater as there was considerable crossover**

STOP Hypertension (Swedish Trial in Old Persons) *Lancet 1991;338:1281-1284*

Design: Randomized, milticenter, double-blind, placebo controlled
Setting: 116 Health Centers in Sweden
Patients: 1625 70-84 y.o., SBP 180-230 or DBP 105-120
Intervention: Step 1 – atenolol -or- HCTZ/amiloride -or- metoprolol -or- pindolol
Step 2 – add diuretic or β-blocker, whichever not on

Results: (events/1000 pt-years)

	all MI	fatal MI	all CVA	fatal CVA	
	C	16.5	3.5	31.3	7.1
	TX	14.4	3.5	16.8	1.7

Conclusions:

1. **Major benefit to treatment in reduction of fatal and non-fatal CVA**
2. **No difference for MI**

MRC Older Adults *Brit Med J 1992;304:405-412*

Design: Randomized, prospective, single-blind, placebo controlled
Setting: 226 general practices in United Kingdom
Patients: 4396 age 65-74 y.o., SBP 160-209. DBP < 115
Intervention: atenolol -or- HCTZ/amiloride

Results: (events/1000 pt-years)

	end BP	fatal CVA	non-fatal CVA	fatal MI	non-fatal MI
atenolol	157/79	3.3	5.6	8.2	4.5
diuretic	52/82	2.5	4.7	5.2	2.4
placebo	168/87	3.3	7.4	8.6	3.9

Conclusions:

1. **Diuretic group had sig. reduction in CVA (31%), MI (44%) and all CVR events (35%)**
2. **Beta blockers showed no significant reduction in events**

HOT (Hypertension Optimal Treatment) Trial *Lancet 1998;351:1755-1762*

Objectives: Identify ideal target BP, assess whether ASA has additional risk/benefit
Design: PROBE (prospective, randomized, open-label, blinded-endpoints)
Setting: Multicenter, Europe, Canada, U.S.
Patients: 18,790 age 50-80, DBP 100-115
Intervention: Felodipine +/- ASA with 5 additional steps as needed to achieve DBP < 90, DBP < 85 or DBP < 80

Results:

	all MI	all CVA	mortality
DBP < 90	84	94	88
DBP < 85	64	111	194
DBP < 80	61	89	207
	p=.05	NS	NS

	All MI	all CVA	mortality	serious bleeds
ASA 82	146	284	284	129
No ASA	127	148	305	70
	p=.002	NS	NS	

Conclusions:

1. **Intensive lowering of BP is safe and lowers MI incidence**
2. **The event rates are 30% lower than older studies that showed less reduction of BP**
3. **Diabetics showed the greatest gains—a 51% reduction in cardiovascular events**
4. **ASA significantly decreases MI, does not increase CVA, and shows an increase in serious (but not fatal) bleeding complications**

UKPDS (UK Prospective Diabetes Study) 38 & 39 *Brit Med J 1998;317:703-720*

Objective: To determine whether tight control of BP prevents macrovascular and/or microvascular complications in patients with type 2 DM

Design: Randomized, prospective, placebo-controlled trial

Setting: 20 hospital-based clinics in Great Britain

Patients: 1148 patients age 25-65 (mean 56) with BP ≥ 160/90 and DM2

Intervention: atenolol or captopril to achieve BP < 150/85 (tight) or 180/105 (less tight)

Results: (events/1000 pt-years)

	MI	CVA	PVD	microvascular	any DM endpoint	mortality
tight control	18.6	6.5	1.4	12.0	50.9	22.4
loose control	23.5	11.6	2.7	19.2	67.4	27.2
	NS	p=.01	NS	p=.009	p=.005	NS

Non-significant trend favoring atenolol

Conclusions:

1. **Tight blood pressure control trends toward or significantly improves all macrovascular and microvascular outcomes in type 2 diabetes**
2. **When compared with UKPDS 33 & 34 (parts of the same study) it seems that tight blood pressure control has a greater effect than tight sugar control**
3. **There is no significant difference between atenolol and captopril in these data.**

ALLHAT Trial (preliminary) *JAMA 2000;283:1967-1975*

Objectives: Compare the effects of chlorthalidone and doxazosin on CAD death, MI, CVA, CABG, angina and CHF.

Design: Multi-center, randomized, double-blind, placebo controlled

Setting: Multicenter, US and Canada

Patients: 24,335 age > 54, DBP > 90 plus (Hx MI or CVA, LVH, DM2, smoker, low LDL)

Intervention: Doxazosin @ 2,4,8 mg or chlorthalidone 12.5, 25 mg to achieve DBP < 90

Results:

	Mortality	CVA	MI	CHF	(all are events/100)
Chlorthalidone	9.08	3.61	6.3	4.45	
Doxazosin	9.62	4.23	6.26	8.13	
	p=.05	p=.04	p=.71	p<.001	

Conclusions:

1. **Doxazosin shows no benefit relative to chlorthalidone for primary endpoints (fatal CHD or non-fatal MI) or CVA.**
2. **Doxazosin shows increased combined CVD events, especially CHF**
3. **This data, combined with older studies (VA CHF studies) suggest that pure vasodilators such as prazosin or doxazosin may be relatively contraindicated in high-risk, hypertensive patients.**

ALLHAT Trial (final) *JAMA 2002;288:2981-97*

Objectives: Compare the effects of chlorthalidone, amlodipine, and lisinopril on combined endpoint of MI and CHD death.

Design: Multicenter, randomized, double-blind, placebo controlled

Setting: US and Canada

Patients: 33,357 age > 54, DBP > 90 plus (Hx MI/CVA, LVH, DM2, smoker, low HDL)

Intervention: chlorthalidone 12.5, 25 mg; amlodipine 2.5-10; lisinopril 10-40 to achieve DBP < 90 x average 4.9 years

Results:

	Combined	Mortality	CVA	CHF
Chlorthalidone	11.5	17.3	5.6	7.7
amlodipine	11.3	16.8	5.4	10.2
lisinopril	11.4	17.2	6.3	8.7
	p=.81	p=.90	p=.02	p< .001

(events/100 x 6yrs)

Conclusions:

1. **Thiazide-type diuretics are superior in preventing one or more major forms of CVD and are less expensive.**
2. **They should be preferred first step therapy**

CAPPP Trial *Lancet 1999;353:611-616*

Objectives: Compare treatment with captopril to conventional therapy (diuretic, β-blocker)

Design: Multi-center, randomized, open trial with blinded endpoint evaluation

Setting: Multicenter, Sweden

Patients: 10,985 age 25-66, DBP > 100 mmHg

Intervention: Captopril 50 qd (or 25 bid), metoprolol 50-100 qd, HCTZ 25 qd or bendrofluazide 2.5 qd

Results:

	Mortality	CVA	MI
RR (captopril vs conventional)	.77	1.25	96
	p=.09	p=.04	p=.68

Conclusions:

There is no significant difference in endpoints between captopril and conventional first-line therapy (stroke difference probably due to better BP control in previously treated patients randomized to conventional therapy)

Syst-Eur Trial *NEJM 1999:340-384*

Objectives: Evaluate nitrendipine as primary therapy, and to see if it has different effects in diabetics than non-diabetics.

Design: Multi-center, randomized, double-blind, placebo controlled

Setting: Multicenter, Europe

Patients: 4695 patients SBP 160-219, DBP < 95

Intervention: Nitrendipine 10-40 qd, +/- enalapril, HCTZ vs placebo (only 37% nitrendipine alone

Results:	CVR Mortality	CVA	MI	(RR)
Nitrendipine (all)	***.87***	***.62***	***.79***	
(diabetes)	.24	.27	.37	
	p=.02	p=.13	p=.12	

Conclusions:

Nitrendipine therapy is particularly beneficial in older patients with diabetes and isolated systolic hypertension.

HOPE Trial *NEJM 2000:342;145*

Objectives: Test the effects of ramapril on combined MI, CVA, vascular death

Design: Multi-center, randomized, placebo controlled, 2x2 Factorial (w/ Vit E)

Setting: Multicenter, North America and Europe

Patients: 9297 Hx CVD or DM + one other risk (HTN, smoker, μ-albumin, lipids) and Excluded if CHF or EF < 40% or CVR event within 1 month

Intervention: Ramapril 10 mg qd

Results

Combined endpoints Ramapril 14%, Placebo 17.8% (p< .001) NNT =26

Conclusions:

Ramapril protects against MI, CVA, and vascular death in a broad range of high-risk patients without known LV dysfunction or CHF

IDNT *NEJM 2001;345:851-60*

Objectives: Irbesartan, amlodipine, or placebo on combined death, ESRD, creatinine x2

Design: Prospective, randomized, double blind

Setting: Multicenter (Asia, Europe, North America, and South America)

Patients: 1715, 30-70 yo, DM2 + BP > 135/85 + urine protein > 900 mg/24 hrs
Intervention: Irbesartan 300mg qd or amlodipine 10mg qd x 2.6 years
Results: BP reduction similar in irbesartan and amlodipine (19/10). Composite endpoint: adjusted RR irbesartan v placebo 0.8 (.66-.97, p=.03), irbesartan v amlodipine 0.77 (.63-.93, p=.005)

Conclusions:

Irbesartan is protective against progression of diabetic nephropathy independent of reduction in blood pressure

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RENAAL *NEJM 2001;345:861-9*

Objectives: losartan on composite death, ESRD, creatinine x2
Design: Prospective, randomized, double blind
Setting: Multicenter (Asia, Europe, North America, and South America)
Patients: 1513, 31-70 yo, DM2 + urine alb:cr > 300, Cr 1.3-3
Intervention: losartan 50-100mg qd x 3.4 years
Results:

BP reduction losartan 6/4, placebo 3/2. Composite endpoint: Events per 100 pt yrs losartan 15.9, placebo 18.1 (RRR 16%, 2-28, p=.02)

Conclusions:

Losartan is protective against progression of diabetic nephropathy

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AASK *JAMA 2002;288:2421-31*

Objectives: metoprolol/ramapril/amlodipine x usual/tight control on progression and composite death, ESRD, creatinine x2
Design: Randomized, 2x3 factorial design, double blind
Setting: Multicenter US
Patients: 1094, Afriican-American, 18-70 yo, Hx HTN, GFR 20-65 ml/min
Intervention: metoprolol 50-200qd, ramapril 2.5-10 qd, amlodipine 5-10qd to MAP 102-107 or < 92 mmHg x 3-6.4 years
Results:

No difference in achieved BP between the three agents. RRR tight v usual 2% (-22 to 21, p=.85), ramapril v metoprolol 22% (1 to 38, p=.04), metoprolol v amlodipine 20% (-10 to 41, p=.17), and ramipril v amlodipine 38% (14-56, p=.004)

Conclusions:

1. **No additional benefit in slowing progression of renal disease observed with tight BP control**
2. **Ramipril more effective than metoprolol or amlodipine for preventing progression**

LIFE *Lancet 2002;359:995-1003*

Objectives: Losartan vs. atenolol on death, MI, or CVA
Design: Prospective, randomized, double blind
Setting: Multicenter, Europe and US
Patients: 9193, 55-80 yo BP > 160/95 and LVH
Intervention: Losartan 50-100 + diuretic prn, atenolol 50-100 + diuretic prn x 4 years
Results:

BP reduction similar (30/17). Combined endpoints: losartan 23.8/1000 pt yrs, atenolol 27.9/1000 pt yrs RR 0.87 (p=.02); MI RR 1.07 (p=.49), CVA RR 0.75 (p=.001)

Conclusions:

Losartan produces better outcomes than atenolol in hypertensive patients with LVH

Australian NBP2 *NEJM 2003:348:583*

Objectives: ACE vs Diuretic on combined CVR events and death
Design: Prospective, randomized, open label
Setting: Multicenter, Australia
Patients: 6083, 65-84 yo BP > 160/90, no CVR events x 6 mo & creat < 2.5
Intervention: Multiple ACE and diuretics. End of study 58% assigned ACE on it, 62% assigned diuretics on it, CaCB in 22.9% and 24.9%, BB 10.8% and 13.7%, ARB 14% and 12.4%.
Results:

BP reduction similar (26/12). Combined endpoints ACE 56.1/1000 pt yrs, diuretic 59.8/1000 pt yrs RR 0.89 (p=.05); MI RR .68 (p=.04), fatal CVA RR 1.91 (p=.04)

Conclusions:

1. **ACE in older, relatively healthy subjects may produce better composite outcomes than diuretics**
2. **Retrospective subgroups: works better in men, not in women**

Beta-blocker efficacy *CMAJ 2006;174:1737*

Objectives: Beta-blocker effectiveness in patients 46-56 vs. 60-76
Design: Structured review of 21 randomized trials
Setting: N/A
Patients: Total of 137,620 patients
Intervention: Multiple beta-blockers vs. placebo or another agent
Results:

vs. placebo	RRR	NNT	vs. other	RRR	NNT
younger	14%	168	3%	NS	
older	11%	NS	-6%	NNH=179	

Conclusions:

1. **Beta blockers have similar efficacy to other meds in young patients**
2. **Beta blockers no better than placebo in older patients**

Benazepril plus Amlodipine or Hydrochlorothiazide for Hypertension in High-Risk Patients (ACCOMPLISH trial) *NEJM: 2008: 359; 2417-2428*

Objectives: To compare rates of cardiovascular events between groups treated with combination ACE-I + CCB vs. thiazide diuretic+CCB effect on composite end point of cardiovascular event and death from cardiovascular cause.

Design: Randomized, double-blind trial

Setting: US, Sweden, Norway, Denmark and Finland (548 centers)

Patients: 11,506

Intervention: Benazapril+Amlodipine vs. Benazapril+HCTZ among patients with diagnosis of hypertension.

Results:

Mean BP lower (131.6/77.3 vs. 132.5/74.4 mmHg , p<0.001)) and fewer primary outcome events (9.6% vs. 11.8%, ARR=2.2%, NNT=45, RRR 19.6%) in the ACE-I+CCB group. For the secondary end point for death from CV causes, non fatal MI and nonfatal stroke the HR was 0.79 (95% CI 0.67, 0.92) for those in the intervention arm.

Conclusions: Combination Benazapril+Amlodipine outperformed Benazapril+HCTZ when comparing combined cardiovascular endpoints.

Treatment of Hypertension in Patients 80 Years of Age or Older (HYVET trial)

NEJM: 2008: 358; 1887-1898

Objectives: To assess benefits of treating hypertension among those 80 years and older.

Design: Randomized, double-blind trial

Setting: Europe, China, Australasia, Tunesia

Patients: 3,845 patients 80 years and older with SBP 160 mmHg or more

Intervention: Indapamide vs placebo. Added perindopril to achieve target BP of 150/80

Results: At 2 years, mean BP was 15/6 mm Hg lower in the active-treatment arm than in the placebo group, a 30% reduction in fatal or nonfatal stroke (p=.06), 39% reduction in death from stroke (p=.05), 21% reduction in death from any cause (p=.02), 23% reduction in death from cardiovascular cause (p=.06) and a 64% reduction in rate of CHF (p<.001).

Outcome	Treatment Rate	Placebo Rate	RRR	NNT
Stroke	12	18	30	NS
CHF	5.3	15	64	106
CV event	34	51	33	60
All cause mortality	47	60	20	82
Stroke mortality	6.5	11	39	241
CV mortality	24	31	23	NS

Cardiac mortality	6.0	8.4	29	NS

Conclusions: Treating hypertension in those over 80 with indapamide +/- perindopril is beneficial.

The Action to Control Cardiovascular Risk in Diabetes blood pressure trial (ACCORD BP)

NEJM. 2010: 362; 1575-1561

Objectives To assess benefits of targeting normal blood pressure (<120 mm Hg) reduces major cardiovascular events in participants with type 2 diabetes at high risk for cardiovascular events..

Design Randomized trial

Setting United States and Canada

Patients 4,733 type II diabetics, age 40 years and older with CV disease, or 55 and older with anatomic evidence of CVD.

Intervention Target BP <120 vs. usual care.

Results Mean systolic pressure was 119.3 mm Hg in the intensive therapy group, and 133.5 mm Hg in the standard-therapy group.

Table 3: ACCORD BP results[4]:

Endpoints [BP 139.4 ⇨ 133.5 Intensive, 119.3 Standard] Recruitment Jun03-Oct05; followed for an average of 4.7 years	Intensive Tx n=2363 no. of events	(%/yr)	Standard Tx n=2371 no. of events	(%/yr)	ARR/ ARI (%)	NNT Over 4.7yrs	Hazard Ratio (95% CI)	P Value
First occurrence of major CV event non fatal MI or stroke, or death from CV cause	208	(1.87) 8.8% / ~4.7yrs	237	(2.09) 10% / ~4.7yrs	↓1.19	NS	0.88 (0.73-1.06)	0.20
° 1° outcome + revasc. or nonfatal HF	521	(5.1)	551	(5.31)	↓1.19	NS	0.95 (0.84-1.07)	0.40
° major coronary disease event eg. fatal coronary event, nonfatal MI, unstable angina	253	(2.31)	270	(2.41)	↓0.68	NS	0.94 (0.79-1.12)	0.50
° non fatal MI	126	(1.13)	146	(1.28)	↓0.83	NS	0.87 (0.68-1.10)	0.25
° stroke -any	36	(0.32)	62	(0.53)	↓1.09	92	0.59 (0.39-0.89)	0.01
-nonfatal	34	(0.3)	55	(0.47)	↓0.88	114	0.63 (0.41-0.96)	0.03
° death from any cause	150	(1.28)	144	(1.19)	↑0.27	NS	1.07 (0.85-1.35)	0.55
from CV cause	60	(0.52)	58	(0.49)	↑0.09	NS	1.06 (0.74-1.52)	0.74
° fatal or nonfatal HF	83	(0.73)	90	(0.78)	↓0.28	NS	0.94 (0.70-1.26)	0.67

♦ ACCORD BP: showed no significant difference in annual rate of 1° outcome between groups treated with intensive therapy & standard therapy.
The annual rate of stroke, a 2° outcome, was significantly reduced from 0.53% in the standard group to 0.32% in the intensive group. NNT=92 over 4.7yr.
Serious adverse events (SAE) death, life threatening event, disability, hospitalization were more frequent in the intensive tx group: 3.3 vs 1.27%, NNH=50 p= 0.001 over 4.7yr.

Conclusions: In patients with type II diabetes at high risk for cardiovascular events, targeting a systolic blood pressure of less than 120 mm Hg, as compared with less than 140 mm Hg, did not reduce the rate of a composite outcome of fatal and nonfatal major cardiovascular events.

Module 4 Symptomatic Disease

"Sick of Being Sick"

Figure 23. Phil. Adapted from Flickr, 2011.[1]

Patient
Phil, a 58-year-old male veteran, married, two children

Chief Complaint
Med refills

Past Medical History
Hypertension; Diabetes – Type 2—A1c 9.1% (>9% for years); Chronic Back Pain—takes acetaminophen and ibuprofen OTC

History

- Has not been seen on Silver Team for 18 months; former resident was filling rx with 5 refills each
- Resident left 3 months ago and new resident refuses to refill without seeing pt
- Pt gets 20 minute appt slot, and at this visit, the MA does a brief check-in (BP and weight only), but the visit takes 90 minutes since the resident is new (unfamiliar with CPRS), and it takes a while to update his history from the past 18 months. Patient does a lot of talking off-subject, and resident has a difficult time guiding the conversation.

Family History

- Mother alive 88 yrs old – has hypertension. Father died of CVA at 67 yrs old – had diabetes.

Current Medications

- HCTZ 25mg qd; metformin 1000mg BID; OTC ibuprofen and acetaminophen

Medication History

- Glipizide 10mg BID -> patient doesn't remember med (30 day supply filled once 2 yrs ago)
- Metoprolol 25mg twice daily – "I hated that stuff. It made me feel like crap!"

Allergies

- Aspirin

Habits

- Drinks 1-2 beers on weekend nights. Smokes 4 cigarettes per week; wants to quit.
- Drinks sweetened iced tea all day.

Exam

Vitals:

- Weight = 187 lb; BMI = 32.3
- BP = 160/90
- Home blood glucose = patient doesn't bring log. Reports "180-250"

Plan

- Refill metformin
- Start lisinopril 20mg qd and insulin NPH 10 units at bedtime

- Flu shot, pneumovax, TDAP
- Places consults: DM education, ophthalmology, podiatry
- Renal panel, A1c, urine microalbumin, lipid panel, echocardiogram
- RN visit for BP check and insulin start in 2 wks
- Return to clinic in 4 months

Follow-Up (part 1)

- RN visit reveals BP = 160/94 and fingerstick BG = 250
- RN asked about BP med—he took lisinopril but stopped HCTZ because he thought he was supposed to. He also doesn't want to start taking insulin. His back pain is getting worse, and he's asking for something for it.
- RN chart review shows the following notes:
  - Intern: "HTN—start lisinopril today. DM—start NPH"
  - Attending: "The patient was seen, discussed, and examined with the resident physician. I was present for the key portions of the history and exam. Agree with note above. "

- New labs show:
  - A1c = 9.4%
  - Urine microalbumin = 280 mg/dl
  - Glucose 247; BUN 25; Cr 1.2; K 3.5; eGFR 94
  - Lipid panel: TC 295, HDL 30, LDL 158, TG 479

- RN pages the intern, but she is post call and not here
- Original attending cannot remember patient
- RN asks precepting attending to see the pt, and he does the following:
  - Restarts HCTZ, starts simvastatin 20mg qpm, and reschedules to RN visit in 2 wks
  - Refers the patient to pharmacy for insulin/DM teaching

Follow-Up (Part 2)

- The patient misses appointments (they were mailed) for DM education, ophth, and podiatry.

- The patient receives a random satisfaction survey, and he replies: "Get someone to translate for the doctors."

✓ **What would you recommend as part of the PACT team?**
✓ **How will you address the patient's various chronic health conditions?**
✓ **Before class, write down your assessment and plan for this patient.**

KEY QUESTION

Should we aim for tight targets of HbA1c < 7.0, LDL-C < 100, and BP < 130/80?

Group 1	**YES**	**(defend your point of view)**
Group 2	**NO**	**(defend your point of view)**

Module Four

Chronic, Symptomatic Disease

"Patients worry over the beginning of an illness; doctors worry over its end."

Chinese Proverb

INTRODUCTION

Our clinics are rife with patients who live with chronic, symptomatic diseases, such as rheumatoid arthritis, diabetes mellitus, COPD, and Parkinson's Disease. In treating such patients, medical professionals often focus primarily on diseases' purely biomedical aspects. However, patient-centered care also requires attending to cultural aspects of disease since patients experience and attempt to manage their symptoms in a complex psychosocial environment. Your goal in this setting is to promote patient automomy and ability to control symptoms while still balancing quality of life with the burdens of treatment. Also, collaborating with other PACT team members and drawing upon their unique knowledge and negotiation of treatment goals and regimens will enhance effectiveness.

Sound like a tall order? Well, this module is designed to get you started. Using diabetes as an example, we will explore the biological, psychological, and social aspects of chronic disease and then examine how these diverse factors affect disease and symptom management.

LEARNING GOALS

This module focuses on a broader understanding of treating chronic disease beyond the biomedical to also include psychosocial aspects. Specifically, this module will help you:

- Develop an appreciation of the patients' experience of disease, understand the chronic disease perspective of healthcare professionals, and negotiating treatment goals that balance lifestyle and convenience through the process of Shared Decision Making

- Develop a repertoire of strategies for promoting patient self-management of disease by developing strong long-term relationships with your team and with patients.

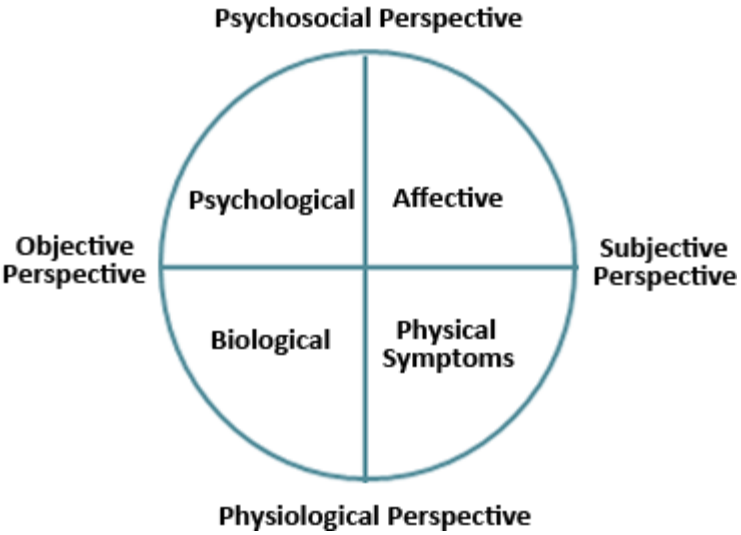
- Understand how to utilize the healthcare team to formulate treatment goals and mutually acceptable treatment regimens for patients and populations by incorporating an interdisciplinary health care team approach.

- Utilize performance measures and evidence-based medicine to improve chronic disease management in your population of patients while maintaining individualized treatment goals.

THE PATIENT'S RESPONSE TO CHRONIC ILLNESS

Shared Decision Making (SDM) is important when working with patients with chronic illness. Your team members will likely have vital knowledge and expertise, and patients and their families' beliefs can and should guide treatment decisions. At the same time, such human interactions are dynamic and potentially complex, so SDM requires skill and flexibility.

To emphasize how responses from both sides impact the provider-patient interaction, the diagram below is useful:



Patients are generally focused on their symptoms and how they feel, and thus govern the right half of the circle. Physicians tend to focus on the objective left half. Most acute problems can be addressed by straightforward juxtaposition of one quarter of the circle with the opposite one. For instance, if the problem is affective, the diagnosis is psychological; if the symptom is physical, the diagnosis is biological.

However, chronic illness, which brings unavoidable changes to a person's life, blurs these distinctions. The patient's symptoms are a daily reminder of losses of health, normal appearance, independence, dignity, financial security, and so forth. Thus, focusing on the objective left half is no longer sufficient for chronic symptoms. Instead, our repertoire of skills must expand to encompass the whole circle and the blend of physical, emotional, spiritual, and social problems.

As you work to encompass the whole circle, remember that coping with loss is a strong factor in symptomatic illness. Therefore, it is a small wonder that many of our interactions with patients have one or more of the responses that Elizabeth Kubler-Ross[2] described in the context of terminal illness, namely denial, anger, bargaining, depression, and acceptance. Other patients develop wonderfully functional coping strategies such as information seeking and problem solving. Still others carry these to a dysfunctional extreme of attention to sources of magical treatments or obsessive behaviors. Keep in mind that *at any given time, patients are doing the best they can with the coping skills they have*

developed. If we react appropriately to patient responses and keep our minds open to strategies for coping with loss, we will be in the best position to help guide a patient to his/her optimal management.

THE CARE TEAM'S RESPONSE TO CHRONIC ILLNESS

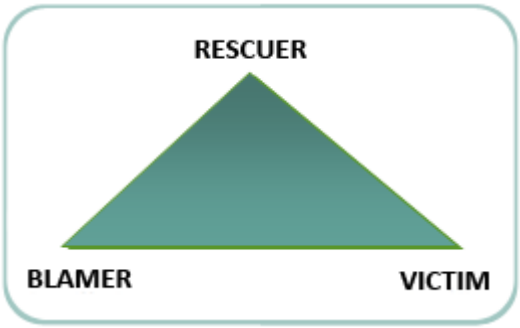
In addition to accounting for patient responses, remember that you bring your own background to the chronic disease state. Whether from personal or family experience or from experience with prior patients with the disease, most of us have developed stereotypes. While stereotypes can be helpful in facilitating correct action, we must be aware of them and their limitations.

Take a Minute to Reflect

- **Consider your feelings about diabetes and the salient memories that you have of it.**
- **What is your image of the "usual" patient?**

AVOIDING DYSFUNCTIONAL RESPONSES

One common set of roles that can lead to dysfunctional responses is shown in the accompanying triangle:



The optimal patient interaction involves behaviors that emphasize NONE of the vertices. Either a dysfunctional patient response or a stereotype can cause the patient or provider to move to one vertex. When that happens, it tends to force the other individual into one of the other vertices, unless positive steps are taken to avoid it. For instance, if a patient stresses how being victimized led to their health problems, we may tend to rescue them by doing more than usual (e.g., extra after-hours appointments). If time passes without any substantive change, there is a risk of us moving to the blamer vertex, since we may feel angry that they are not doing enough to help themselves. Similarly, the patient may move to the blamer vertex, saying, "I'm not getting better; you must be doing the wrong things." We may then move to the victim vertex, and so forth in a counterproductive cycle. Even worse, the more enhanced these attitudes and behaviors, the more dysfunctional the relationship.

To help avoid such pitfalls, the first step is acknowledge that we could easily fall into such behaviors. At the same time, it is an unavoidable reality that we will have negative feelings from time to time. To handle such feelings, in *The Fifteen Minute Hour*,[3] Stuart and Lieberman suggest a few general rules:

- **What am I feeling? (label the emotion)**
- **What do I want? (identify the desired outcome)**

- **What can I do about it? (develop a plan to reach that outcome)**

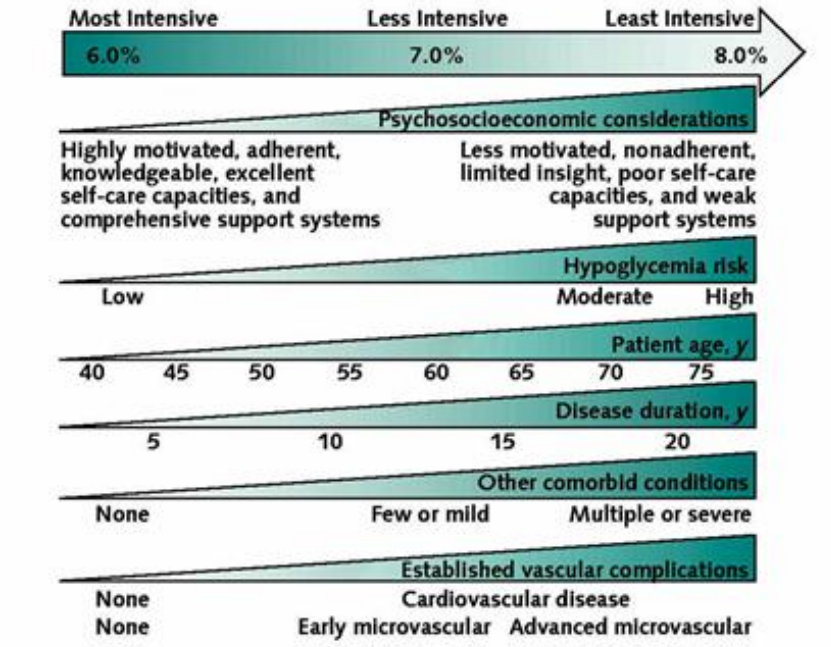
Sometimes the answer to the third question is "nothing." In that case the authors further recommend that you don't take responsibility for things you cannot control. In other words, empathize, but avoid defensively moving to one of the vertices of the triangle.

DEFINING THE "IDEAL" TREATMENT GOAL

As you respond to such questions, remember that one problem with many chronic diseases, and diabetes is a great example, is that our understanding of "good" control can evolve over time based on research data. In the 1920's, our goal was to avoid diabetic ketoacidosis (DKA). By the 1940's, it was to avoid glucosuria. After the DCCT (1993), it was a HgbA1c < 7 for all patients with diabetes. However, recent studies have caused us to moderate our enthusiasm for tight control in some patients with type 2 diabetes. Most recently, ADA guidelines emphasize individualizing A1c goals in DM T2.[16]

As shown in the figure below, we can individualize the ideal treatment goal based on life expectancy, duration of diabetes, and co-morbid conditions.[14] There is a "legacy" effect in both type 1 and type 2 diabetes (early tight control has prolonged benefit). There also appears to be less benefit and possibly increased risk of tight control for patients who have existing vascular disease.

Figure 24. Framework to asssist in determining glycemic treatment targets in patients with type 2 diabetes.



Several major studies support these recommendations, as summarized in the table below, which shows the relationship between HgbA1c and outcomes:[14]

Table 4. Selected Characteristics and Outcomes of the UKPDS, ACCORD Trial, ADVANCE Trial, and VADT

Variable	UKPDS	ACCORD Trial	ADVANCE Trial	VADT	References
Duration of study, *y*	11	3.5	5	5.6	1–4
Goal					1–4
Intensive therapy	FPG <6.0 mmol/L (<108.1 mg/dL)	HbA_{1c} <6.0%	HbA_{1c} ≤6.5%	HbA_{1c} <6.0%	
Standard therapy	FPG <15.0 mmol/L (<270.3 mg/dL)	HbA_{1c}, 7.0%–7.9%	Standard HbA_{1c} values	HbA_{1c}, 8.0%–9.0%	
HbA_{1c} achieved, %					1–4
Intensive therapy	7.0	6.4	6.4	6.9	
Standard therapy	7.9	7.5	7.0	8.5	
Change in achieved HbA_{1c}, %	0.9	1.1	0.6	1.6	1–4
Annual event rates per 100 patients					
Severe hypoglycemia*					1–4
Intensive therapy	0.71†	4.6†	0.56†	12.0†	
Standard therapy	0.20	1.5	0.30	4.0	
Primary outcome‡					1–4
Intensive therapy	4.09†	2.11	3.62†	4.39	
Standard therapy	4.60	2.29	4.00	4.89	
All-cause mortality					5
Intensive therapy	0.13	1.41†	1.86	2.22	
Standard therapy	0.25	1.14	1.99	2.06	
Cardiovascular mortality					5
Intensive therapy	0.53	0.79†	0.95	0.83	
Standard therapy	0.52	0.56	1.08	0.63	
Retinopathy§					1–4, 6
Intensive therapy	0.79†	1.83†	6.0	4.0	
Standard therapy	1.10	2.60	6.3	5.7	
Visual deterioration‖					1–4, 6
Intensive therapy	3.44†	4.84	10.9	3.03	
Standard therapy	4.16	5.05	10.8	3.95	
Neuropathy¶					1–4, 7
Intensive therapy	2.33†	2.51†	8.44	6.86	
Standard therapy	2.77	2.84	8.30	7.14	
Renal failure**					1–4, 7
Intensive therapy	0.08	0.57	0.4	2.0	
Standard therapy	0.08	0.59	0.6	1.8	
Renal failure and retinopathy††					4, 7
Intensive therapy	0.86†	2.35	–	–	
Standard therapy	1.14	2.35			
Microalbuminuria‡‡					1, 3, 4, 7
Intensive therapy	2.13†	3.38†	4.74†	1.73	
Standard therapy	2.82	4.14	5.14	2.35	
Macroalbuminuria‡‡					1, 3, 4, 7
Intensive therapy	0.49†	0.73†	0.58†	0.52†	
Standard therapy	0.72	1.05	0.82	0.91	

ACCORD = Action to Control Cardiovascular Risk in Diabetes; ADVANCE = Action in Diabetes and Vascular Disease: Preterax and Diamicron Modified-release Control Evaluation; FPG = fasting plasma glucose; HbA_{1c} = hemoglobin A_{1c}; UKPDS = United Kingdom Prospective Diabetes Study; VADT = Veterans Affairs Diabetes Trial.
* An episode that requires third-party assistance.
† $P < 0.05$ compared with standard glycemic therapy.
‡ An aggregate end point of any diabetes-related end point (UKPDS); a composite of nonfatal myocardial infarction, nonfatal stroke, and fatal myocardial infarction and stroke (ACCORD); combined microvascular and macrovascular disease (ADVANCE); and time to occurrence of a composite of major cardiovascular events (VADT).
§ Nine-year results (UKPDS), worsening of ≥3 steps in fundus photographs (ACCORD), new or worsening retinopathy (defined as development of proliferative retinopathy, macular edema, or photocoagulation therapy or diabetes-related blindness) (ADVANCE), or progression to proliferative retinopathy (VADT).
‖ Two-line (UKPDS, ADVANCE, and VADT) or 3-line (ACCORD) change in visual acuity.
¶ Nine-year results (UKPDS), loss of sensation to light touch (10-g monofilament) (ACCORD), new or worsening neuropathy (ADVANCE), or peripheral neuropathy (VADT).
** Dialysis or plasma creatinine level >250 μmol/L (>2.8 mg/dL) not related to acute intercurrent illness (UKPDS); initiation of dialysis, end-stage renal disease, renal transplantation, or increase in serum creatinine level to >292 μmol/L (>3.3 mg/dL) in the absence of an acute reversible cause (ACCORD); need for renal replacement therapy or death from renal causes (ADVANCE); or creatinine level >265 μmol/L (>3.0 mg/dL) (VADT).
†† A composite of retinopathy, photocoagulation, vitreous hemorrhage, and fatal or nonfatal renal failure (UKPDS and ACCORD).
‡‡ Nine-year results (UKPDS).

From the referenced figure and table you can see that, generally, new onset, young patients without end-organ disease should receive tighter control, while patients with long standing diabetes, especially if they have evidence of vascular disease, should not.[14]

NEGOTIATING TREATMENT REGIMENS & PATIENT BEHAVIOR

As has been previously mentioned, some patients may be less than cooperative in adhering to provider-prescribed treatments. Especially with such patients, openness and the ability to compromise are essential to achieving the trust and mutual respect that lead to successful therapeutic relationships. For you to successfully negotiate treatment regimens and patient behavior, it may be helpful to consider Emanuel and Emanuel's[3] four models of the provider-patient relationship:

1. In the *paternalistic model*, the provider's job is to make the correct decision; the patient's is to do what he or she is told.
2. In the *informative model*, the provider's job is to present the information clearly and completely, the patient's to make a rational decision based on those data.
3. In the *interpretive model*, not only are data considered but the provider helps the patient explore his or her values, what is more important and less important.
4. In the *deliberative model*, the provider presents information, explores values, and makes a recommendation for what he or she thinks is best for the patient.

Note that each has model a place, depending on the situation.

KEYS TO TREATMENT REGIMENS

Once we have established a relationship with a patient, the work of devising an acceptable treatment regimen begins. This is an important process and you will want to schedule enough time for it. Using understandable language and writing key points down will increase the effectiveness of your communication.

While some patients will jump right into this process, others will be reticent, and you will have to draw them out in order to assemble the information necessary for negotiating the treatment regimen. Remember to ask the patient the following important questions:

THREE KEY QUESTIONS TO BEGIN

1. **Does he/she believe that they have a disease?**
2. **What is their understanding of the disease?**
3. **What aspects of the disease and its consequences concern him/her the most?**

Though we would all like to simultaneously optimize health, functional status, independence, dignity, financial well-being, and a host of other variables, this is usually impossible. Therefore, we must set priorities and make compromises in negotiating treatment goals. For example, a patient with diabetes

who wants the least expensive regimen and tight control must decide which goal is more important and compromise on the other.

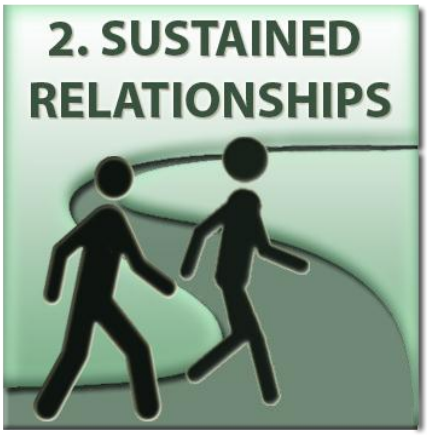
Similarly, before settling on a particular course of action, again, remember to ask other important questions:

FIVE MORE KEY QUESTIONS

1. **Does your patient want to do this?**
2. **Does the plan address both the patient's concerns and yours?**
3. **Does your patient believe that the intervention will work?**
4. **What does your patient see as the costs?**
5. **Does your patient believe that he/she can do it?**

However, even the most carefully thought out regimens will need revisions. For instance, a patient may not be able to adhere to a previously successful regimen because of changes in disease severity, financial status, social support, or any number of other variables. As an additional help, the article by Rosenstock[4] in the Bibliography at the end of the chapter discusses the issues involved in devising regimens and offers practical advice for improving adherence.

PROMOTING PATIENT SELF-MANAGEMENT OF CHRONIC DISEASE



Ultimately, the relationships that you build with your team and with patients will determine how effectively chronic disease is managed. Your team must trust one another to share key knowledge, and you must allow the patient to participate in a way that addresses their needs. Teaching and promoting self-management is a key step in allowing the patient to participate in the team. A carefully devised regimen is necessary but not sufficient for self-management and promotion of optimal health. Also, additional factors such as cognitive ability, personality, and financial resources will affect the level of self-management that a given individual can achieve. Because self-management isn't likely to be taught in a single visit, an investment of time by the healthcare team is essential. The relationship between the patient and members of the team must be based on trust over time.

As healthcare professionals, two areas that we can influence and that correlate most strongly with successful self-management are a sense of self-efficacy and a strong support system.

SELF-EFFICACY

Self-efficacy is the patient's belief that he/she can accomplish the tasks at hand. It requires that the patient have the necessary knowledge and skills to manage his regimen plus a positive attitude to utilize these tools, and that he receive reinforcement when he applies his knowledge and skills successfully. In this context, a few rules could be helpful for us as providers:

Rules to Increase Patients' Self-Efficacy

- **Educate incrementally**
- **Demonstrate successful use of self-management skills**
- **Supervise practice of new skills**
- **Give feedback**

Explanations of these rules are provided below:

- **Educate incrementally**. The information the team gives a patient should be tailored to his particular needs and cognitive ability. Both of these are dynamic, and the type and complexity of the information will change with time. Perhaps most importantly, education should be incremental. Overwhelming a patient with more information than he can assimilate in a single visit can promote feelings of inadequacy and result in a defeatist attitude. In addition, while education must be targeted at specific needs, generalizable information for problem solving is necessary as well.

- **Demonstrate successful use of self-management skills**. The office is a safe environment for practicing and applying new skills. In this safe environment, we can ask patients to use their skills in ways that allow them to successfully manage their symptoms. Following up on this success by assigning the activity as homework promotes ongoing positive experiences with self-management.

- **Supervise practice of new skills**. As with knowledge, skills should be taught incrementally. Your patient should practice all new skills under direct supervision and demonstrate mastery before the next skill is taught. An example might be making sure that your patient can correctly do pursed-lip breathing before showing him how to use that skill to facilitate walking or other exercise.

- **Give feedback**. Linking a patient's actions to the result of those actions provides powerful reinforcement and increases the likelihood that the patient will continue to act in a certain way or to use a particular skill.

A support system, as noted previously, is also critical to successful self-management. Your patient needs a clearly defined treatment plan, as does the care team. Which tasks belong to whom? Is there role overload? We can support our patients by scheduling appointments at intervals which correspond to their level of need, which will change over time. We also support our patients by providing continuity of care,

coordinating care, and by being available as a safety net when they have exhausted their repertoire of self-management skills. While this is an appropriate role for us to play, we need to be wary of falling into the rescuer role discussed previously.

A STRONG SUPPORT SYSTEM

To make patient care coordination as seamless as possible, practice guidelines recommend team-based care, including patient registries and embedded decision support tools. With the shortage of primary care providers, we should look to the existing evidence that supports the use of a multidisciplinary healthcare approach to improve patient care. The following team-based examples promote a strong support system:

- The involvement of psychologists, pharmacists, and nurses to help with continuity of care, education, and to provide valuable feedback to patients has been shown to improve outcomes.
- Group visits are another effective way to help patients manage their own illness.
- A recent study found that even in a well-controlled group of patients with diabetes and hypertension, the combination of a community pharmacist and a nurse-based intervention that empowered patients to take charge of their blood pressure and educated them about dietary and exercise approaches resulted in overall improved blood pressure control.[13]
- Psychologists are also useful in evaluating patient behaviors and helping achieve goals in regard to chronic disease.

Many other studies provide evidence that interprofessional management of chronic disease improves outcomes.

By extension, the patient-centered healthcare team has more important partners, in particular, social support from family, friends, and other people who are grappling with the same disease. At times we will want to actively involve these people by having them join the patient during the office visit or by enlisting their help as necessary. At the same time, It is important that those people whom the patient relies on for support have a positive attitude towards the patient's efforts at self-management. Negative attitudes on the part of family and friends constitute a powerful disincentive to self-management activity. As you work with patients and their support group of family and friends, you should draw upon the wealth of material written by and for patients and their family members which may be helpful in providing ongoing support for self-management.

POPULATION MANAGEMENT

Population management is another area that has increasingly been viewed as an important part of primary care. One group who supports this emphasis, the Agency for Healthcare Research and Quality (AHRQ), defines population management as an approach to care that uses information on a group ("population") of patients within a primary care practice or group of practices ("practice-based") to improve the care and clinical outcomes of patients within that practice. The goals of population management are to help primary care practices engage in preventive care, improve quality of care, and ultimately, to improve health outcomes. Achieving these goals requires infrastructure such as electronic health records and IT support.[16]

According to AHRQ, poulation management can be divided into four domains. The first two domains are as follows:

1. To identify populations of patients by defined criteria
2. To examine characteristics of subpopulations of the patients identified

Again, a collaborative approach is beneficial since multiple team members are skilled in identifying and examining patient populations, including pharmacists and nurses. At the Boise VAMC, examples supporting population management include the Boise VA Lipid Initiative and the Silver Team RN Hypertension Protocol.

APPLYING PERFORMANCE MEASURES & PRACTICE IMPROVEMENT

As discussed earlier, research sometimes gives mixed results. The same is true with the application of performance measures. We need to exercise caution when applying performance measures to every patient to avoid undesirable outcomes. One study shows that following clinical guidelines improves outcomes in Acute Coronary Syndrome,[6] but another shows that strictly adhering to guidelines in older patients with several comorbidities may lead to polypharmacy, drug interactions, and excessive costs.[7] For example, the VA has emphasized keeping patients' HbA1c values less than 7.0. However, despite such a measure, a recent VA-based study[7] which analyzed retrospective longitudinal data for diabetics, found that 1/3 of veterans in the study group had co-existing conditions (major medical problems, such as neurological and/or psychiatric) in which attempting to achieve intensive glycemic control (HbA1c < 7.0) was actually more harmful than beneficial. Similar harmful effects of intensive glycemic control with certain patient populations were seen in the ACCORD trial,[8] and in another recent VA-based study.[9] In ACCORD, poor outcomes were associated with aspirin use, higher beginning HgbA1c, and neuropathy (perhaps markers of longer duration DM and vascular disease).[11]

However, while generic performance-based measures may not be helpful in treating every patient, such measures are an unavoidable part of the modern practice envionment. Returning to the previously mentioned AHRQ population management domains, AHRQ recommends tracking performance measures in domain four, which allows for comparisons with key populations or based on these measures. For example, groups of providers or patients can be compared against each other or to a clinical standard. Through such comparisons, valuable insight can be gained about important clinical patterns, such as incidence of smoking or the need for increased efforts to vaccinate.[16]

Despite pressures that may arise from systems using performance measures, we must not lose sight of what approach may or may not best serve the individual patient at hand. At the same time, the included Practice Improvement graphic shows individuals climbing uphill to represent that the journey is long and the potential pitfalls many.[12] At times, we may experience a tension between the performance we expect of ourselves and what others expect of us. Therefore, we must learn to balance assessments of our performance based on what we can or cannot control. Areas that are beyond our immediate control include the system and patient traits and values. We can influence some degree of patient motivation, but we have more control over developing our personal skills that contribute to overall effectiveness both in performing individual and team-focused healthcare roles. In terms of patient care and practice improvement these myriad, compelling factors are often distilled down to one number, e.g., Hemoglobin A1c. With such complex, systemic factors, however, it is not likely that tensions will be resolved any time soon, nor will the solutions likely be simple. Fortunately, with the use of evidence from recent trials along with the emphasis on individualizing treatment goals, frameworks are being developed that can assist in determining appropriate HbA1c targets for diabetic patients.[14] Most importantly, it is the authors' belief that we should always be guided by the principle of advocating what is best for the patient.

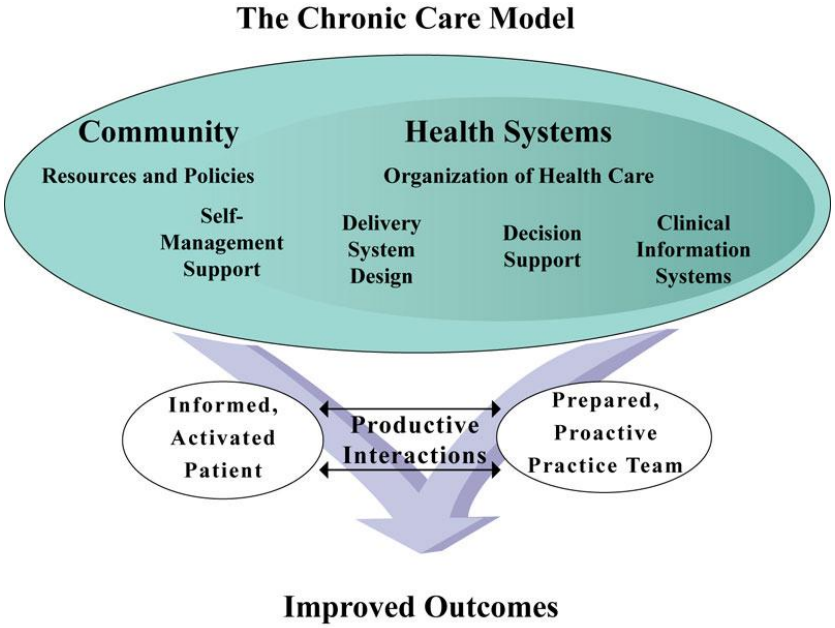


Figure 25. The Chronic Care Model. Developed by the the MacColl Institute, n.d..[15]

To help summarize chronic cares' roles and domains, consider the model that is shown to the left:

Because of our aging population, is it expected that there will be 171 million people living with chronic disease by the year 2030. The Chronic Care Model (CCM) provides an effective way to visualize the system as a whole while identifying potential problem areas as well as pointing to potential solutions.[15] This model emphasizes the central role of patients and their relationship with an effective care team. Further, the CCM illustrates how the community and healthcare system interact to engage the patient and care team in productive ways that improve the likelihood of positive chronic disease outcomes. As a healthcare professional, you should play a role in both the

community and the healthcare system. Specifically, you should involve yourself proactively in areas that include education, clinical decision making, information gathering and sharing, and possibly system design. As you work in these areas to foster collaboration and Shared Decision Making, your patients will benefit from the leadership and expertise that you help facilitate as part of a healthcare team.

CONCLUSION

To review, the main points to remember from this module include:

- Shared Decision Making is a process that will help you gain an appreciation of the patients' experience of disease, understand the chronic disease perspective of healthcare professionals, and negotiate treatment goals that balance lifestyle and convenience.

- Continue to develop a repertoire of strategies for promoting patient self-management of disease by developing sustained relationships with your team and with patients.

- Utilize the health care team to formulate treatment goals and mutually acceptable treatment regimens for patients and populations by incorporating an interdisciplinary healthcare team approach.

- Maintain individualized treatment goals while properly utilizing performance measures and evidence-based medicine to improve chronic disease management in your population of patients.

Phil's case from the scenario at the beginning of the module illustrates the difficulties that symptomatic and chronic disease can present to the patient and the health care team. Ultimately, it is hoped that considering the human as well as biomedical dimensions in handling such a complex patient, together with examining this module's topics, will help build groundwork and motivate you to expand your interpersonal as well as professional preparation to more effectively manage a full range of chronic patients.

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MODULE 4 CORE READINGS (available online in Moodle)

1. Soubhi H, Bayliss E, Fortin M, Hudon C, van den Akker M, Thivierge R, Posel N, Fleiszer D. Learning and Caring in Communities of Practice: Using Relationships and Collective Learning to Improve Primary Care for Patients with Multimorbidity. Ann Fam Med 2010;8:170-177.

2. Wilson T, Holt T. Complexity Science: Complexity and Clinical Care. BMJ 2001;323:685-688.

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

1. According to your interpretation of the Soubhi, et al. article, how do you define your "Community of Practice" (CoP)? What has been your experience working in a CoP? How do you envision using your CoP in caring for Phil?

2. According to Soubhi, et al. ” . . . a community of practice model will require ’maximizing the allocation of clinical responsibility based on clinicians’ knowledge base and training . . . ’” What will you do to ensure that you are maximizing your knowledge base and training as part of a CoP? In what ways can you do to support your interdisciplinary team members in maximizing their roles?

3. Wilson and Holt use diabetes as an example of a complex situation in health care. Although we’re trained to follow clinical guidelines and fulfill performance measures, how might using strictly evidence-based practices fail a patient like Phil? In a case like his, what might you do to resolve uncertainty in diagnosis and/or interventionsl?

4. Consider Figure 2 in "Complexity Science: Complexity and Clinical Care," The Certainty-Agreement diagram by Stacey and Zimmerman. Discuss a previous experience with a case in the Complex Zone. How did you feel during that clinic visit? Did you feel compelled to have certainty in your diagnosis? What did you do to resolve uncertainty? Today, who would you seek for help in a similar situation?

5. When discussing health promotion, Wilson and Holt use the term "shadow systems" as a description of the network of information and relationships that influence patients’ health choices. Consider and discuss a time that you were faced with a patient making health choices that you believed could be harmful. How did you manage the situation? How might you do it differently today? With Phil, what ”attractors” could be used to help him make more positive health choices?

SUPPLEMENTAL READINGS

1. Ohkubo Y, Kishikawa H, Araki E, et al. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. *Diabetes Res Clin Pract* 1995;28:103-117. Often quoted early study on the effects of tight control for Type 2 diabetes.

2. Krolewski AS, Laffel LMB, Krolewski M, Quinn M, Warram JH. Glycosylated hemoglobin and the risk of microalbuminuria in patients with insulin-dependent diabetes mellitus. *NEJM* 1995;332:1251-1255.

3. UK Prospective Diabetes Study (UKPDS) Group. Ten year follow-up of intensive glucose control in type 2 diabetes (UKPDS 33, 10 year data). *NEJM* 2008;359:1577-89.

4. http://www.va.gov/PrimaryCare/pcmh. VA PACT Overview with Resources of interest

5. http://www.pcpcc.net/ Patient Centered Primary Care Collaborative

6. http://www.commonwealthfund.org/Publications/Fund-Reports/2012/Feb/Guiding-Transformation.aspx The Commonwealth Fund Guide on Transformation to PCMH (Full Report may be found here: http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2012/Feb/1582_Wagner_guiding_transformation_patientcentered_med_home_v2.pdf).

7. Emanuel EJ, Emanuel LL. Four Models of the Physician-Patient Relationship. *JAMA* 1992; 267:2221-2226.

APPENDIX 4-1: A SUMMARY OF IMPORTANT DIABETES MANAGEMENT TRIALS

The following is an ODSPIRC summary, which was described in Module 3, of the more important trials concerning diabetes management:

The Diabetes Control and Complications Trial Research Group. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. New Engl J Med 1993;329:977.

O: Relationship between tight control and microvascular complications of diabetes.

D: Randomized, not blinded. Tight control vs. usual care.

S: Multiple tertiary centers in North America.

P: 1441 patients with Type 1 diabetes, ages 13-39, without hypertension, hyperlipidemia, prior diabetes complications, or other severe medical problems. 726 in the primary prevention group had diabetes for 1-5 years. Of the primary treatment group, tight control = 348, conventional = 378.

I: 3 or more injections per day or insulin pump. Self-monitoring QID, clinic visits every month, telephone contact between.

R: Average follow-up was 6.5 years.

	Intensive	Control
Achieved glycohemoglobin	7.0	9.0
Retinopathy	23	91 (76% reduction)
Microalbuminuria	15%	25%
Neuropathy	3%	10%
Macrovascular -	very few events, ? trend favoring tight control.	
Deaths	7	4
Hospitalizations	54	36

Intensive group had 3X the risk of hypoglycemia, increased weight (4.6kg more over 5 years). No difference in DKA.

C: Tight control prevents microvascular complications. The patients entering the study were highly selected and the intervention intensive on the part of both patient and provider. Not blinded. ?Hawthorne effect. In a separate analysis of the data the hypoglycemic events did not seem to influence cognitive ability.

Ohkubo. Intensive insulin therapy prevents the progression of diabetic microvascular complications in Japanese patients with non-insulin-dependent diabetes mellitus: a randomized prospective 6-year study. Diab Res Clin Pract 1995;28:103.

O; Relation between intensive glycemic control and microvascular complications in Type 2 diabetics.

D: Randomized, 6 year study.

S: University metabolic clinic in Japan.

P: 110 patients from the diabetes clinic, already taking one or two daily insulin injections, otherwise no other major diseases. Average age = 49, duration of DM = 8 yrs, BMI = 20 (!).

I: Conventional insulin (CIT)(55) vs. multiple injection therapy (MIT)(55) - intermediate at bedtime, rapidly acting at each meal. Clinic visits in MIT group q 2 wks!!

R: Fasting glucose and HbA1c dropped and stayed low (126 and 7.1) for 6 years.

	MIT	CIT	
Retinopathy	13.4%	38%	(0.007)
Nephropathy	9.6%	30%	(0.005)
Mild hypoglycemia	6	4	

Neuropathy was less with MIT for several physiologic studies. No symptom assessment given.

C: Multiple insulin injections to achieve tight control prevent microvascular complications in Type 2. Best data available until the United Kingdom studies. These patients do not represent the usual United States Type 2 patients. It took intensive intervention to achieve this level of control, although details are not spelled out. Not eligible and eligible but non-participating patients not described. No comment about randomizing smokers. Not blinded.

UKPDS-33. Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes. LANCET 1998;352:837.

O: Effect of tight control of type 2 diabetes on mortality and morbidity.

D: Randomized, open, 1977-1997.

S: Multiple practices in areas of 23 UK hospitals.

P: 3867 newly diagnosed diabetics, ages 25-65. Fasting plasma glucose > 6mmol/L. Baseline: BMI = 27.5, retinopathy = 36%, proteinuria = 2%, and biothesiometer (peripheral sensation) = 11.5%. Other major risk factors for micro- and macrovascular disease matched evenly.

I: 3 month dietary run-in. Conventional Rx aimed at FPG < 15mmol/L (= 270) and without symptoms. Intensive Rx aimed at FPG < 6mmol/L (=108). Rx adjusted in both groups q3mo.

R:

	Intensive	Conventional
Diet alone	12%	58%
Required insulin	38%	16%
Baseline HBA1C	7.09	7.05
End HBA1C	8.1	8.7
Weight gain	5.8 kg	2.7 kg

	Relative risk
Microvascular disease	0.75 (most of this due to decrease in retinal photocoagulation)
MI	0.84
Any diabetes endpoint	0.88
Retinal photocoagulation	0.71

There were no other differences with statistical significance, although there were trends favoring more intense control.

Diabetes mortality	0.90 (CI = 0.77-1.11)
All-cause mortality	0.94 (CI = 0.80-1.10)

Stroke worsened. More hypoglycemic episodes (3%/yr) with intense control. No difference between individual therapies X decreased effect and increased blood pressure with chlorpropamide.

C: Intensive treatment decreases risk of microvascular disease. No effect on macrovascular disease.

UKPDS-34. Effect of intensive blood-glucose control with metformin on complications in overweight patients with type 2 diabetes. LANCET 1998;352:854.

O: Determine the effect of intensive glucose control with metformin.

D: AS above.

S: As above.

P: 1704 patients with weight > 120% of ideal. Baseline BMI = 32. The two groups were not different; there was only slight weight gain with both oral hypoglycemics.

I: Diet alone = 411 patients

Metformin = 342. Start at 850 qd, increase as needed to max of 2550, aim for FPG < 6mmol/L. Could add glibenclamide or insulin as needed.

R:

	Intensive	Conventional	RR	
Any DM endpoint	98	160	0.68	
Diabetes death	28	55	0.58	
All mortality	50	89	0.64	
MI	39	73	0.61	
Microvascular	24	38	0.71	(0.43-1.19)
Baseline HBA1C	7.3	7.1		
End HBA1C	8.3	8.8		
Additional treatment needed:		44%		

In a supplemental study, “The addition of metformin to sulphonylurea was associated with a 96% increased risk of diabetes-related death… also increased the risk of death from any cause (60% increase).”

C: In overweight diabetic patients, metformin decreases the risk of diabetes-related endpoints, and is associated with less weight gain and fewer hypoglycemic attacks. It may be the first line therapy in these patients. The unexpected finding of increased diabetes-related mortality with combination oral hypoglycemic treatment is the first time this has been observed and remains unexplained.

Secondary prevention of macrovascular events in patients with type 2 diabetes in the PROactive Study) PROspective PioglitAzone Clinical Trial In macroVascular Events): a randomized trial. LANCET 2005;366:1279.

O: Does pioglitazone reduce macrovascular morbidity and mortality in patients with type 2 diabetes and previously identified macrovascular disease?

D: Prospective, randomized, blinded, placebo controlled

S: Patients recruited from primary care practices and diabetes and cardiovascular services at hospitals in 19 European countries.

P: 5238 patients with type 2 diabetes, mean age 62, primarily white males, median a1c 7.8, and either prior MI, coronary intervention, ACS, other objective evidence of CAD, CVA or symptomatic PVD.
I: Pioglitazone starting at 15 mg qd for one month, then increased to 30 mg, then 45 mg on subsequent months in addition to subjects' usual medications. Other therapy was increased in both intervention and control subjects to optimize control of other cardiovascular risk factors.
R: Average observation was 34 months. Pioglitazone non-significantly reduced risk of primary composite endpoint of death, MI, CVA, ACS, amputation or revascularization of heart or leg (HR 0.9, CI 0.80-1.02). Predefined secondary endpoint (all-cause mortality, MI or CVA) was statistically improved (HR 0.84). NNT for 3 years to avoid one 1st major cardiovascular event was 48. HDL, TG, a1c, and blood pressure all improved in pioglitazone group.
C: In type 2 diabetics with macrovascular disease, use of pioglitazone for 3 years reduced subsequent macrovascular events, improved metabolic profile and reduced the need to start insulin.

STENO-2 STUDY. Multifactorial intervention and Cardiovascular Disease in Patients with Type 2 Diabetes. NEJM 2003;348:383 and NEJM 2008;358:580.

O: Effects of multifactorial intervention (DM, BP, lipids, smoking, diet, exercise) on overall and CVR mortality.
D: Randomized, open, 1993-2000 (active), 2000-2006 (followed).
S: Steno diabetes center, Denmark.
P: 160 patients with type 2 DM and persistent microalbuminuria.
I: ASA and ACE/ARB in all. Low fat (< 30%) diet; vit C/D/folate/chromium; smoking cessation classes; metformin +/- gliclazide +/- NPH; HCTZ/BB/CaCB; statin/fibrates X 7.8 yrs (followed total of 13.3 yrs)
R:

	Intensive	Conventional
A1c	7.9	9
TC/LDL	159/83	216/126
BP	131/73	146/78
	Relative risk	
Death	0.54	(0.32-0.89, p=.02)
CVR death	0.43	(0.19-0.94, p=.04)
CVR events	0.41	(0.25-0.67, p<.001)
Retinal photocoagulation	0.45	(0.23-0.86, p=.02)

C: Multifactorial treatment reduces all cause and CVR mortality. Based on risk calculator, use of statins and antihypertensive meds had the largest effect.

Should Mitigating Comorbidities Be Considered in Assessing Healthcare Plan Performance in Achieving Optimal Glycemic Control? The American Journal of Managed Care 2007;13:133-140.
O: Does excluding persons with major medical or mental health conditions affect the assessment of healthcare system performance in achieving a HbA1c level of <7.0%?

D: Retrospective longitudinal data analysis
S: Veterans Health Administration; 144 centers
P: 220,922 patients under age 65 with diabetes mellitus.
I: Intensive glycemic control (retrospective study)
R: 75,296 patients were identified as having conditions that would increase risks (or decrease benefits) of intensive glycemic control. The 5 year unadjusted mortalities were assessed in patients who were in the following exclusion groups: major medical and neurological conditions (36% five year mortality), significant mental health conditions (14.9% five year mortality), and 2 or more serious comorbid medical/psychological conditions (16.5% five year mortality). For comparison, the remaining patients in the study were found to have an 8.8% five year unadjusted mortality.
C: One third of veterans under the age of 65 have comorbid conditions that would reduce the benefits or increase the risks of intensive glycemic control. A goal HbA1c of <7.0% should probably not be automatically applied to all diabetic patients, and relevant exclusion criteria should be considered when selecting who may or may not benefit from such therapy.

Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Comorbid Diseases. JAMA 2005;294:716.
O: To evaluate the applicability of clinical practice guidelines to the care of older individuals with several comorbid diseases
Sources: National Health Inventory Survey (most common diseases), National Guideline Clearinghouse (applicable guidelines)
Selection: Hypothetical 79-y.o. woman with COPD, DM2, osteoporosis, HTN, OA
R: Average 12 meds, $5000/year, multiple potential drug interactions
C: Basing pay-for-performance standards on guidelines could lead to inappropriate judgment of the quality care in older patients with multiple co-morbidities and could create perverse incentives for inappropriate care.

Effects of Intensive Glucose Lowering in Type 2 Diabetes (ACCORD). NEJM 2008; 358: 2545-2559.
O: To evaluate if intensive therapy to lower HbA1c reduces cardiovascular events in patients with type 2 DM who have known cardiovascular disease or cardiovascular risk factors.
D: Randomized, not blinded
S: Multiple Clinical Centers in U.S. and Canada
P: 10,251 diabetics with HbA1c of 7.5% or greater who were either between ages 40-79 and had cardiovascular disease or between ages 55-79 and had cardiovascular risk factors. Key exclusion criteria: frequent/serious hypoglycemia, unwillingness to self monitor or take insulin, BMI >45, serum Cr >1.5, or other serious illness.
I: Intensive therapy aimed at lowering HbA1c to <6.0%; Standard therapy aimed to get HbA1c to 7.0%-7.9%.
R: At one year, the mean HbA1c was 6.4% for intensive therapy group, and the mean HbA1c was 7.5% for standard therapy group. The primary outcome (nonfatal MI, nonfatal CVA, or death from cardiovascular cause) occurred in 352 patients in the intensive therapy group, and the primary

outcome occurred in 371 patients in the standard therapy group (hazard ratio, 0.90; 95% CI 0.78-1.04; P=0.16). Concurrently, there were 257 deaths in the intensive therapy group, and 203 patients died in the standard therapy group (hazard ratio, 1.22; 95% CI, 1.01-1.46; P=0.04). Hypoglycemia and weight gain were more frequent in the intensive therapy group (P<0.001).
C: When compared to standard therapy, the utilization of intensive therapy to reduce HbA1c levels increased mortality without a significant reduction in major cardiovascular events in high risk patients with type 2 DM.

Intensive blood glucose control and vascular outcomes in patients with type 2 diabetes (ADVANCE). NEJM 2008; 358: 2560-2572.
O: Evaluate the effect of the addition of gliclizide on a composite endpoint of CVR deat, MI, CVA, and worsening nephropathy (2X creatinine) or retinopathy.
D: Randomized 2X2 factorial design (also studying indapamide vs perindopril)
S: 215 centers in 20 countries
P: 11,140 patients w/type 2 DM > 30 y.o.
I: Usual vs Usual + gliclizide X 5 years

R:	Usual	Usual + gliclizide
A1c	7.48 -> 7.3	7.48->6.5
RR major macro		0.94 (p=.32)
RR major micro		0.86 (p=.01)
RR death		0.93 (p=.28)

C: Compared to standard therapy, adding gliclizide improved A1c and microvascular disease (primarily nephropathy), but not macrovascular disease or death.

10-Year follow-up of intensive glucose control in type 2 diabetes (UKPDS 33). NEJM 2008;359:1577-89.
O: 10-year follow up data of UKPDS 33 (tight vs usual control)
D: Randomized, open, 1977-1997.
S: Multiple practices in areas of 23 UK hospitals.
P: 3867 newly diagnosed diabetics, ages 25-65 (see UKPDS 33 above)
I: Usual vs sulfonylurea-insulin
R: A1c remained better x 1 year, then both groups decreased some during open label.
RRR MI remained about 18% throughout, but significance .052 -> .01
RRR death slowly improved over time 6% -> 17%, significance .44 -> .006
C: Tight treatment early in the course of DM has a "legacy" effect (similar to the "metabolic memory" in type 1 DM). This eventually leads to decreased MI and death.

Glucose Control and Vascular Complications in Veterans with Type 2 Diabetes. NEJM 2009; 360:129-139.
O: To evaluate the effects of intensive glycemic control on cardiovascular events in patients with longstanding type 2 DM.

D: Randomized, open
S: Multiple VA Medical Centers (20 sites)
P: 1791 veterans with longstanding diabetes (mean of 11.5 years since Dx) and poor glycemic control. Exclusion criteria included HbA1c <7.5%, advanced CHF, severe angina, occurrence of cardiovascular event in the past 6 months, life expectancy of <7 years, BMI >40, serum Cr >1.6, and an ALT >3x upper limit of normal.
I: The goal of therapy was an absolute reduction of 1.5% in HbA1c as compared with the standard therapy group.
R: Mean HbA1c was 6.9% in the intensive therapy group; mean HbA1c was 8.4% in the standard therapy group. The primary outcome (first episode of major cardiovascular event) occurred in 264 patients in the standard therapy group and 235 patients in the intensive therapy group (hazard ratio of intensive therapy group, 0.88; 95% CI 0.74-1.05; P=0.14). There was no significant difference in microvascular complications between the intensive therapy group and the standard therapy group. Adverse events (chiefly hypoglycemia) were more prevalent in the intensive therapy group (24.1%) than the standard therapy group (17.6%)
C: Intensive glycemic control in veteran patients with suboptimal control of type 2 DM had no significant effect on the rates of major cardiovascular events, death, or microvascular complications.

Effect of intensive compared with standard glycemia treatment strategies in mortality by baseline subgroup characteristics (ACCORD). Diab Care 2010;33(4):721-7.
O: Identify baseline subgroups from ACCORD that might explain increased all-cause mortality in the tight control group (see ACCORD above for study parameters)
R:

- Usual care group showed a "U-shaped" relationship between achieved A1c and hazard ratio with a nadir at an A1c of ~ 9.2
- Intensive control group had a steady rise in hazards with increasing A1c
- Three characteristics were associated with increased mortality: starting form A1c > 7, neuropathy, and use of ASA (markers for longer duration DM and CVR disease?)

C: Tight control may be dangerous in patients with long-standing DM and vascular disease.

Effects of Combination Lipid Therapy in Type 2 Diabetes Mellitus (ACCORD). NEJM; 362(17):1563-1574
O: Does combination therapy with a statin and a fibrate, when compared with statin monotherapy, reduce the risk of cardiovascular disease in diabetics who are at an increased risk for cardiovascular disease?
R: There were no significant differences between the two study groups with respect to primary and secondary outcomes.
C: The combination of fenofibrate and simvastatin, when compared to simvastatin monotherapy, did not decrease the rate of fatal cardiovascular events, nonfatal MI, or nonfatal stroke.

Effects of Intensive Blood-Pressure Control in Type 2 Diabetes Mellitus (ACCORD). NEJM; 362(17): 1575-1585.

O: Does therapy targeting a normal systolic blood pressure (<120 mm Hg) reduce the risk for significant cardiovascular events in patients with type 2 diabetes who are at an increased risk for cardiovascular events?

R: There was not a significant difference in the 2 study groups (intensive therapy and standard therapy) in the annual rate of the primary composite outcome (nonfatal MI, nonfatal stroke, or death from cardiovascular causes). There was a significantly increased incidence of serious adverse events (attributed to antihypertensive therapy) in the intensive therapy group.

C: Targeting a systolic blood pressure of <120 mm Hg in diabetics did not reduce the rate of fatal and nonfatal major cardiovascular events (composite outcome), and such therapy stands to be harmful as well.

A Randomized Trial of the Effect of Community Pharmacist and Nurse Care on Improving Blood Pressure Management in Patients With Diabetes Mellitus. Arch Intern Med. 2008;168(21):2355-2361

O: Determine the efficacy of community-based multidisciplinary intervention on BP control in patients with diabetes mellitus.

D: Randomized controlled trial

S: 14 community pharmacies in Edmonton and Alberto Canada

P: 227 randomized patients with diabetes and BP >130/80

I: Intervention from a pharmacist and nurse team included a wallet card with recorded BP measures, cardiovascular risk reduction education and counseling, a hypertension education pamphlet, referral to the patient's primary care physician for further assessment or management, a 1-page local opinion leader-endorsed evidence summary sent to the physician reinforcing the guideline recommendations for the treatment of hypertension and diabetes, and 4 follow-up visits throughout 6 months. Control-arm patients received a BP wallet card, a pamphlet on diabetes, general diabetes advise, and usual care by their physician. Primary outcome measure was the derrerence in change in systolic BP between the 2 groups at 6 months.

R: The intervention group had an adjusted mean (SE) greater reduction in systolic BP at 6 months of 5.6 (2.1) mm Hg compared with controls (P=.008)

C: Even in patients who have diabetes and hypertension that are relatively well controlled, a pharmacist and nurse team-based intervention resulted in a clinically important improvement in over-all BP.

Module 5

Harmful Health Habits

"All That Glitters is Not Gold"

History:
Joe is a 68 y.o. retired senior executive. He sees you for hypertension, peptic ulcer disease, and intermittent atrial fibrillation. He returns for routine follow-up and is fairly stable except for some achy pain in his hands and low back.

He has been married for 20 years to his second wife. He was a highly respected CEO of a "Forbes 500" leader. He has three successful children. He quit smoking in 1984. He always has 1-2 Martinis per night, sometimes more, and occasionally 1-2 drinks at lunch with business friends. He also drinks 6-12 beers while watching the ball games each weekend. He denies any legal problems from alcohol. He has cut back, but has never been angry about others' comments, felt guilty, or needed an eye opener.

Review of Systems:
His back occasionally "acts up" and requires some bed rest and opiate pain relievers. A major problem has been poor sleep for several years. He tried Ambien, which his wife's doctor had given her, and it worked wonders for him. He would like some.

Physical Examination:
- Clear lungs
- Cardiac: RRR, no mmr, gallop, rub
- Chest: no gynecomastia
- Back: no CVA tenderness or bruit, no spinal tenderness
- Abd: liver edge palpable and non-tender, span about 11 cm
- Extrem: no edema
- Skin: mild palmar erythema, no spiders or venous prominence

Lab:
- Hematocrit 40% (MCV 98)
- WBC 7,500 w normal diff
- Platelets 60,000
- AST 22 (one episode of elevation to 55 measured two years ago)
- ALT 19 (one episode of elevation to 65 measured two years ago)

KEY QUESTION

Based on the information you have, is Joe suffering from alcoholism?
Group 1 YES (defend your point of view)
Group 2 NO (defend your point of view)

Will you prescribe Ambien?

Module Five

Changing Harmful Health Habits

"Nothing so needs reforming as other people's habits."

Mark Twain

INTRODUCTION

The concept of preventive medicine applies to harmful health habits. These can be defined broadly as habits that have led, or will likely lead, to disease or injury. Examples include not wearing seat belts and unprotected sexual intercourse. In fact, 6 of the top 10 leading causes of death in the U.S. could be dramatically reduced with simple behavior changes.

Figure 26. Monkey on Joe's Back . Adapted from Flickr, 2012 and 2009.[2,3]

We will focus on problematic substance use, since it is one of the most challenging diagnostic and therapeutic problems we face in adult medicine. Tobacco use is the leading preventable cause of death in the United States, causing about 1 in every 5 deaths each year.[1] In 1985 approximately 22% of all deaths among men and 11% among women (360,000 deaths) were attributed to smoking in the United States. Prevalence of smoking has steadily declined since the 1960s; however, the absolute number of smoking-attributable deaths has increased slightly (443,000 in 2004) and is remaining steady due to increased population size among older adults.[1] Also, it is interesting that in 2000 about 70% of smokers reported wanting to quit, a fact that we'll come back to shortly. Alcohol use is related to a huge health burden in the United States; about 10% of deaths are attributed to alcoholism.[5] Research has linked different levels of alcohol consumption to changes in morbidity and mortality risk in more than 60 disease conditions, not to mention acute consequences, disability, and quality of life impact.[5] Those familiar with our veteran population need no introduction to the morbidity and mortality associated with these health habits. Yet, it is often easier for both the health professional and the patient to avoid the issue. Why, and what can be done? Our task is to discover these habits and initiate treatment before diseases take hold.

LEARNING GOALS

Our example is alcohol. While some of the items (e.g., CAGE) are specific to the habit in question, the principles for the most part can be applied to other harmful health habits. During this module we hope that you:

- Learn when to suspect and how to screen for problematic substance use.
- Learn the psychosocial factors involved in alcohol abuse, dependence, and treatment—the patient's and our own.
- Observe common principles involved with behavior change: Engaging, Guiding, Evoking, and Respect for Autonomy.[4]
- Develop the following skills for problem drinking, applied depending on the patient's stage (duration and severity) of the disease and your discipline:
  - Screening – case finding using
    - ✓ AUDIT-C, CAGE
    - ✓ I'D FOLD
  - Making the diagnosis using
    - ✓ explicit criteria
    - ✓ dealing with uncertainty
  - Presenting the diagnosis with a
    - ✓ list of adverse items
    - ✓ non-judgmental statement
  - Recruit to treatment according to
    - ✓ timeliness
    - ✓ knowledge of available resources
  - Fulfilling the primary care role as you
    - ✓ support working a program
    - ✓ avoid enabling
  - Incorporating or assisting in the specialist role, such as
    - ✓ a sobriety program
    - ✓ counseling (CBT?)
    - ✓ pharmacological intervention

SMOKING

We will not dwell a great deal on smoking because the intra- and interpersonal challenges are less for most providers than with alcoholism. However, since smoking so dominates the health scene it deserves some mention.

Psychosocial Factors Involved in Smoking

Most smokers don't deny that they smoke or deny that it is a problem. Most want to quit, but find that sufficient MOTIVATION is lacking. From our frame of reference, most providers have had such poor success getting patients off cigarettes that they don't have the MOTIVATION to spend the extra minutes bringing up the issue again. There are three main obstacles to habit change when motivation is the issue:[7]

- Health beliefs
- Self-efficacy (confidence that you can do it)
- Stress (especially as a cause of relapse)

To begin overcoming these obstacles, ask yourself these questions:

1. Do you think addressing the patient's smoking habit is important enough to take clinic time to do it? (your health belief)
2. Do you think you can succeed? (your self-efficacy)
3. Are you too stressed (e.g. time constraints) to do it? (your stress)

The first step is to ask the patient what they think about tobacco use and their experience with it [*Evoke*]. Many patients have some unusual notions about the effects of cigarettes; for instance, perhaps they believe it helps clear the excess phlegm or that they are not vulnerable to consequences because no one else in the family who smoked had problems. More often, however, they have not linked their smoking with their symptoms. Your therapeutic tools here are education and personalizing the message to this patient's problems. Their motivation will come out of their experiences and beliefs, not yours, so this link is crucial.[4] Keep in mind that the patient's knowledge gap, if present, may not be the major, or only, obstacle to quitting, and scare tactics (threats that their, "lungs are black, rotting out," etc.) generally don't work.

Most patients are so burdened by a string of past failures that they do not believe they have what it takes to quit. Consequently, your acknowledging out loud that it is hard to quit [*Engage*] can relieve considerable guilt. The most important next step is to ask your patient's permission to talk with them briefly about tobacco [*Autonomy*] and optimistically provide tailored information that will allow him or her to have some mastery over the harmful behavior [*Guiding*].

Stress comes from many sources, and solutions are specific to the stress in question. It is best to help your patient develop his or her own plan to deal with the stress. If your patient plans to stop it would be best to pick a quit date for a time when stress levels are relatively low.[7] The Pharmacy Service at the VA sponsors smoking cessation classes that can suggest some solutions to the patient and provide follow-up.

Fortunately, there is a robust group of pharmacological interventions to aid in quitting cigarettes. The VA has nicotine replacement therapy in the form of patches, gum, and lozenges. Bupropion has good data to support its use. Varenicline (Chantix) may have a role in select cases. The VA does not carry, but many patients have opted to use, the electric devices that deliver nicotine only. Costly as they are, these devices are still cheaper than smoking.

The Comprehensive Model of Change

A useful approach to patients who are smoking is the comprehensive model of change, which was enunciated by Prochaska and DiClemente,[8] has become popular. This model outlines five stages of change: pre-contemplation, contemplation, preparation, action, and maintenance. For many, change occurs only after several tries. Thus, a relapse stage creates a cycle that brings a person back to the pre-contemplation or contemplation stage. Our job is to determine what stage a patient is in and then help move the patient to the next stage.

1. In ***pre-contemplation*** the patient has little insight into the need for change. She or he does not consider smoking problematic or are not aware of or minimizes any negative effects. Engaging the patient without judgment and creating a connection between smoking and current or future problems is most useful at this stage. Scolding, berating, or prematurely pressuring change won't help. Families, popular media, legal constraints, and cost, among other factors have moved most patients beyond this stage already.

2. In the ***contemplation*** *stage* the patient is considering quitting, but is weighing the pros and cons. It is most useful here to empathize with the dilemma, identify obstacles, evoke the patient's (not yours) reasons for wanting to change, and possibly suggest strategies to deal with barriers. Asking behavioral health, if available, to talk more with the patient may be helpful at this stage.

3. In the ***preparation*** stage, the patient is considering specifics and planning, including techniques, quit date, aids to quitting, etc. The health provider can help here with encouragement, specific advice, referral to smoking cessation and perhaps prescriptions.

4. In the ***action*** stage reinforcement of progress, empathy, troubleshooting drawbacks, and anticipating problems are all called for.

5. In the ***maintenance*** stage, reinforcement of progress is important as well as facilitating relapse prevention by openly discussing the patient's plans in case of a lapse and encouraging vigilance for triggers or clues of relapse.

IN CASE OF RELAPSE (aka, *The Relapse Stage)*

1. **Normalize the experience**
2. **Ask the patient what they have learned**
3. **Affirm and praise successes**
4. **Ask the patient whether he or she is contemplating trying again for change**
5. **Refer to a behavioral team member or ICT for follow-up and relapse prevention planning**

While the patient pursues the above stages, let us consider our own factors. First, it would be good to keep up with the information about medication and counseling availability and cost, the effects of secondary smoking, and so forth so that you can accurately inform the patient. These aren't beliefs so much as knowledge. Second, be realistic about what you can accomplish. Spontaneous quit rates are less than a few percent. Counseling from a provider increases the quit rate to 8-10% and adding nicotine gum and follow-up can increase the rate to about 20%.[10] One study suggested that the addition of nicotine replacement with bupropion improved quit rates to 35.5%.[11] Third, how can we intervene to benefit the patients without tying up all our time (stress)?

PROBLEMATIC DRINKING

Approach

We have seen that the major problem in quitting smoking is motivation. An alcohol use disorder presents a similar problem, yet its carries with it much stronger psychosocial reactions and stigmas for both patients and providers.[9] Because of the social opprobrium attached to "alcoholism" providers often refrain from insulting the patient with such a label, avoid broaching the subject with their patient, or deny that their patient could be that bad. Given the stress and constraints of the primary care setting, it is often easier to deny the connection between multiple physical, psychic, and social problems and high-risk alcohol use until it is end-stage.[12] Sound familiar? Don't feel bad; we, patients, and society at large all tend to do the same.

Figure 27. Alchollic Fuse. Adapted from Flickr, 2012.[13]

Psychosocial Factors in Alcoholism

There are many factors that can support a patient's denial that his or her drinking is a problem:

- Social attitudes support drinking (see below). How is drinking just beyond tipsy seen in our society? By you? Could Hemingway have been as heroic or creative without alcohol? Many people cannot imagine meaningful social interaction without loosening up a bit.
- Shame and guilt are common emotions; these often vanish under the influence and become magnified during withdrawal.

- Physical symptoms can follow the same course, causing drinking to become a learned response: "When I stop drinking I feel bad; when I resume I feel much better."
- Cognitive deficits induced by alcohol later in the course of the disease can impair understanding of even the most basic reasoning.
- A common form of denial in the VA population is not denial that alcohol is a problem, but rather denial that help is needed to quit and stay sober. A "real man" can control it on his own.

Likewise, another set of factors support our avoidance of the problem:

- Our desire to please the patient and avoid anger is strong. Why are we in the medical field but to help people?
- We are often pessimistic, based on stereotypes derived from previous encounters with end-stage alcoholics.
- We believe that alcoholism is not treatable, or that our job is limited to the severe sequelae.
- We lack knowledge, skills, and confidence to tackle alcoholism, and we fear failure.

The medical community formally recognizes drug dependencies including alcoholism as a disease, with predisposing factors, a constellation of symptoms and signs, an expected course, and a defined treatment.[11] Beyond traditional biomedical criteria, alcoholism is the archetypal bio- (genetics, pharmacologic impact, tolerance, withdrawal), psycho- (motivation, expectancies, attributions, impulsivity, affect, coping), and social- (family, peers, culture, religion, media) disease, with all the attendant complexity. For providers, three components influence ability to help understand/manage alcohol use:

1. your own views of use and treatment
2. the patient's view of use and treatment
3. the interaction of your perspective and your patient's beliefs[7]

One quick way to assess is to apply Brickman's helping and coping model to addictive behaviors. Which quadrant best captures your perspective? Where would your patient place responsibility?[9]

Is the person responsible for changing the addictive behavior?

Is the person responsible for the development of the addictive behavior?

	Yes	No
Yes	Moral Model (War on Drugs) Relapse = crime or lack of willpower	Spiritual Model (AA & 12-steps) Relapse = sin or loss of contact with a higher power
No	Compensatory Model (Cognitive-Behavioral) Relapse = mistake, error, or temporary setback	Disease Model (Heredity & Physiology) Relapse = reactivation of progressive disease

Within these categories there are multiple nuanced views of causality and prognosis, which Rogers and McMillin outline well in Chapter 2 of their book *Don't Help*[15]:

1. Impaired model – Alcoholics are fundamentally impaired to the depth of their souls. It is their nature to drink; they are not remediable. Get them over the acute problem and discharge them from the hospital as quickly as possible. Don't waste your time or resources.

2. Dry moral model – Alcoholics are unwilling or unable to do the right thing. They are so weak of character they cannot stand one drink. Alcohol does the same thing to anyone who uses it; some are just weaker than others.

   They are remediable if they:
   - Recognize their sinfulness
   - Ask for help (forgiveness)
   - Accept punishment - fines, jail, etc. (penance)
   - Rejoin the moral community (salvation)

3. Wet moral model – Alcoholics are too weak to drink the correct way (knowing when to stop). This is US society's and alcoholics' most common model. The patient needs more will power to limit intake; total abstinence is seen as weak-willed. Any relapse to excessive drinking compounds the guilt, which is so discouraging that it can lead to more drinking.

4. Psychoanalytic model – An early experience caused a neurosis which led to alcoholism as the symptom. An addictive personality exists. Treatment must get at the underlying psychopathology.

5. Family interaction model – Alcoholic drinking is simply an implicitly assigned role within the family. A family interaction may have caused, and certainly perpetuates, alcoholism. This explains codependency and enabling behavior.

6. Old medical model – Alcoholism is a self-inflicted illness. Why they drink in the first place is unexplained. Treatment is preoccupied with medical complications, scare tactics, and often a revolving door to the medical ward without connecting to treatment of the alcoholism.

7. New medical model – Alcoholism is a disease with bio-, psycho-, and social components. Alcoholics relapse because they do not know how to stay sober. Treatment: stop or reduce alcohol consumption and find a treatment program to increase knowledge and skill in relapse prevention.

8. Alcoholics Anonymous model – It doesn't matter what caused the alcoholism. Complete sobriety is the ONLY way to recovery.

9. Harm Reduction model – A multidetermined understanding of the etiology, risk, and behavior change associated with addictive behavior. Emphasizes an individual's ability to learn more effective coping strategies and address challenges across a continuum of change behaviors.[13]

It is likely there are more models or mixtures than are mentioned here. Everyone, meaning you, the patient, and your coworkers, all have one or more models that they have incorporated into his or her health beliefs. Disparity between the patient's belief and the practitioner's belief can be a source of conflict. Take a moment to reflect on what your model is. With this background, let us next look at the skills we need, which are: screening – case finding – diagnosis, making the diagnosis, and presenting the diagnosis.

Screening – Case Finding – Diagnosis

How does alcoholism hold up to the DAMHIT-SCRAP screening criteria? Certainly the **D**isease is common. Denial perpetuates the **A**symptomatic period. **M**orbidity and mortality are substantial. The I'D FOLD mnemonic (see below) defines the **Hi**gh-risk group. The **I**ntervention is not limited to symptomatic treatment of medical sequelae, but comprehensive treatment programs that are widely available. Last, there are several commonly used screening **T**ests (the utility of these competing screening tools depends on reliance on a disease versus a harm reduction model) with established sensitivity and specificity data.

The CAGE[17] is the best known, best studied, and the easiest tool for screening:

C: Have you ever felt the need to **C***ut* down your drinking?
A: Have you been **A***nnoyed* when people criticize your drinking?
G: Have you ever felt **G***uilty* about drinking?
E: Have you ever had to take an **E***ye* opener when you got up?

While some prefer to work the CAGE concepts into a stream of conversation, this subtlety can engender stigma reactions and paranoid thoughts ("They are trying to trick me into admitting I am doing something wrong. ") leading to underestimations; the CAGE is best done in a matter-of-fact manner while collecting other basic health behavior information. The CAGE (two or more positive) has a sensitivity of 80-90% and a specificity of 87-95%.

In addition to the CAGE, the AUDIT-C[18] is the World Health Organization- and Veterans Affairs-approved screening tool, whose published performance characteristics are better in women, some minorities, and problem drinkers (as opposed to those who meet criteria for an alcohol use disorder). It asks about drinking in the last year, while the CAGE asks "ever."

1. How often have you had a drink containing alcohol in the past year? Consider a drink to be a bottle of beer, a glass of wine, a wine cooler, or one cocktail or a short of hard liquor (like scotch, gin, or vodka):
   - Never (0 pts)
   - Monthly or less (1 pt)
   - 2-4 times a month (2 pts)

- 2-3 times a week (3 pts)
- 4-5 times a week (4 pts)
- 6 or more days a week (4 pts)

2. How many drinks did you have on a typical day when you were drinking in the past year?
   0 drinks (0 pts)
   - 1-2 drinks (0 pts)
   - 3-4 drinks (1 pt)
   - 5-6 drinks (2 pts)
   - 7-9 drinks (3 pts)
   - 10 or more drinks (4 pts)

3. How often did you have 6 or more drinks (4 or more drinks = gender modification for women) on one occasion in the past year?
   - Never (0 pts)
   - Less than monthly (1 pt)
   - Monthly (2 pts)
   - Weekly (3 pts)
   - Daily or almost daily (4 pts)

The maximum score is 12. A score of 4 or greater in men or 2 or greater in women suggests hazardous drinking or active alcohol abuse or dependence, with sensitivity of 86% and specificity of 72% in men and 85% in women. Positive and negative predictive values depend, of course, on the population screened. The positive threshold is set deliberately low with the idea that further diagnostic data need to be gathered.

In the primary care clinic you are more likely to be case finding or indeed pursuing the diagnosis. For the latter you need an index of suspicion. Recognize that problematic alcohol use presents AS A CAUSE OF many common ambulatory care problems (which actually tend to occur late in the course of the disease):

- Hypertension
- Insomnia
- Dyspepsia
- Somatization (cf. Module 6)
- Anxiety/depression
- Abnormal lab values (MCV, LFTs, etc.)
- Trauma
- Others

As shown, Smith, et al. have developed a useful mnemonic for the spectrum of sequelae from alcoholism, I'D FOLD:[19]

Intrapersonal = anxiety,expression,boredom
Drugs = cigarettes, other drugs of abuse
Family, Friends = marital problems, abuse, unsafe sex
Occupation = absenteeism, job conflict, job loss
Legal = DUI, assault
Diseases = see above

Making the Diagnosis

Positive and negative predictive values and troubles in the I'D FOLD spectrum are, by themselves, insufficient to move further. Assuming the screening does not indicate that the patient is in a high-risk category, but other indicators lead you to believe he or she may be drinking more, the best strategy is to address this discrepancy in a straightforward and nonjudgmental way.

So what is the firm ground of specific diagnostic criteria, i.e., a definition that you can use to determine when to intervene? These are neither clear nor unified. We know that the NIAAA and AMA have identified that men who drink more than 4 drinks per day (or > 14/week) and women who drink more than 3 per day (or > 7/week) are considered at-risk drinkers (3 out of 10 Americans are in this group).[14] We also know the DSM-IV-TR identifies a substance use disorder occurring in either cases of:

1. ABUSE = in the past 12 months your patient's drinking has repeatedly caused at least one of these:
   - risk of bodily harm
   - relationship trouble
   - role failure
   - legal problems

2. DEPENDENCE = in the past 12 months your patient has at least three of these:
   - drank more than wanted
   - failed quit attempts
   - tolerance
   - withdrawal
   - drinking despite problems
   - lots of time in acquiring/imbibing/recovering
   - less time enjoying non-drinking activities

However, some simpler working examples of a definition may be more effective in your clinical practice:

1. Recurrent drinking despite adverse consequences
2. Tolerance or dependence
3. Quantity and frequency of consumption to support both of the previous

And here's an even simpler definition:

1. Continued drinking in the face of significant problems from drinking.

Making the diagnosis is *the* crucial issue with this disease.[12] If you never address the diagnosis when it exists, you will flounder along treating symptoms and not the cause. If you attempt to prematurely push treatment without first establishing a nonjudgmental, but firm diagnosis, the resistance that develops will prevent any progress, and your relationship with the patient can sour. Turned around,

once you make the diagnosis with solid evidence, even if the patient disagrees, your relationship acquires a distinct clarity in this and many other matters as well. With our definition of alcoholism firmly in mind, we can identify patients that have dysfunctional drinking. These patients have minor problems or drink an amount that is worrisome, but otherwise do not meet the definition of alcoholism. They can cut back and control or stop their drinking,[20] where patients with alcoholism may struggle to find a middle ground and fluctuate between binges and abstinence.[21]

Along this continuum you will have to work with your patient to advise what is medically necessary for their health and safety (complete abstinence vs. controlled drinking) while also helping them identify their willingness and personal goals associated with these medical dictates. How will you handle this if their goals go against what is medical necessary for their safety and well-being?

When your clinical data do not distinguish clearly between alcoholism and dysfunctional drinking, it is still useful to:

1. Express concern
2. Urge abstinence
3. Plan observation or further diagnostic evaluation through referral

Even if you feel unsure where your patient fits on the continuum, you can do all these steps while continuing to follow the basic principles of behavior change, namely: Engaging, Evoking, Guiding, and Respect for Autonomy. If your patient expresses a desire to cut-down or quit after hearing your feedback, ask them to see if they can remain abstinent for one month. If they cannot, take it as evidence for you both that they need additional support. A referral to whatever behavioral health resources are available, or having your patient attend an AA meeting, may be helpful or enlightening for your patient as they contemplate their alcohol use, health, and recovery.

When the evidence supports tolerance, dependence, multiple sequelae (I'D FOLD), and so forth, you can make a firm diagnosis of alcohol use disorder with confidence. Above all, only when you are convinced of the diagnosis can you move on to help the patient.

Presenting the Diagnosis

The third skill is presenting the diagnosis. As you follow the principles of behavior change and awareness of stages of change, here are some critical elements:

- First, ask the patient what they think about their alcohol use and their experience with it [*Evoke*].
- Then, ask permission to inform the patient about your concerns [*Autonomy*] and describe to them the alcohol-related problems you see [Guide; see below for tips and tricks].
- Finally, ask for their response and address their concerns [*Engage*].

Figure 28. "addiction." Adapted from Flickr, 2009.[20]

If your patient continues to deny or minimize problematic alcohol use in the face of concrete data (pre-contemplation) you can expect strong denial and resistance, especially if the patient has a moral or spiritual framework associated with their use. This resistance is ok, even expected. It is helpful to think of it as a product of the interaction (not a static characteristic of the patient) that can be defused by gently identifying out loud the primary emotion they are expressing (anger? fear? shame?) and acknowledging it is a hard subject to talk about [Engage].[6] If the patient does not move from pre-contemplation (unlikely in one appointment), at least you have provided your expertise and given guidance while respecting the patient's autonomy and maintaining the relationship. Over time, you may notice differences in your patient's readiness for change and can capitalize on these as they progress.

Additional helpful tips include:

- Be overt. Tentative, half-hearted statements have no role. The most effective nonjudgmental approach is to calmly and confidently present all the evidence in a laundry-list fashion. Emphasize patient complaints that are related to drinking. If the patient interrupts to refute one or more points, keep going; don't debate. (Remember, resistance is not a characteristic of the patient but a product of the relationship.)

  Present your diagnosis in a non-judgmental manner. You are concerned about the patient and his or her well-being; the only way to improve matters is to get at the heart of the problem. How much more productive to compassionately say, "You are drinking more than is medically safe," or "You are struggling with the disease of alcoholism," than to say, "You are an alcoholic." (the patient may hear, " . . . no-good drunk.")

- Don't expect to have your diagnosis accepted the first time. It's ok. On return visits, ask to bring it up again. Evoke from your patient reasons why they might want to change. Relate it to the patient's problems. The SUD treatment community talks of "tilling the soil of change," a process that may take months or years before it sprouts into treatment, controlled use, or abstinence.

- Cajoling, confronting, directing, scolding, scaring, lecturing and generally acting like a frustrated parent is never helpful.

- If the patient declines treatment, you should continue to treat the symptoms as long as you are very clear that the patient is not addressing the real problem. But avoid making the problem worse by prescribing other addictive drugs such as opiates or benzodiazepines.

KEY POINTS

1. **"You are suffering from alcoholism."**
2. **Give a laundry list of findings; ignore interruption**
3. **Expect denial**

Recruiting to Treatment

If the patient remains firmly pre-contemplative, denies that alcohol is a problem and declines to do anything about it, you can agree to disagree. Continue to link symptoms and signs to drinking. Provide empathy, support and information, but don't lecture the patient. If, on the other hand, you or someone else has planted the seed and the patient wants to proceed, you need to be ready to go. Connecting to the proper treatment resources is the next step. You therefore need to be familiar with the resources available in the community and to that patient. This is, of course, entirely context-dependent. Most communities have AA, larger ones have NA. A patient's health insurance may or may not cover treatment for substance abuse.

At the Boise VA some general rules apply:

- The first step in primary care is to coordinate with your team's behavioral health psychologist or with the integrated care team so they can help facilitate engaging and connecting the veteran with treatment.
- With the rare exception of a patient prescribed a chronic stable dose of opiates (or medical-use marijuana, if they live in Oregon), the patient must be willing to commit to sobriety and to no ongoing abuse of controlled substances (street drugs, opiates, benzodiazepines, etc.) while they are in treatment. However, sobriety is not a requirement for treatment at the Boise VA and no veteran will be denied behavioral health services at the Boise VA due to their substance use.
- Early referral, whether from the clinic or inpatient, is encouraged.
- The behavioral health psychologist or someone from the ICT will interview the patient to determine which of the several treatment options (residential, outpatient, AA, etc.) is best. The primary provider does not have to worry about this particular disposition, but can support this effort if they ask him or her to prescribe disulfiram (Antabuse), naltrexone, or similar (acamprosate is the newest, but as yet non-formulary for VA).
- The main effort of treatment is done by our professional counselors and the veteran's program peers.

Primary Care Role

The primary care PACT team has a central role in screening, making, and presenting the early diagnosis, and referring to treatment.[12,21] Two further tasks deserve mention. First, the primary provider should support the treatment effort by asking how the patient's program is going, encouraging commitment to sobriety and continuing to evoke and reinforce the patient's reasons for change. Additionally, discussing and diagnosing lapses, relapses and collapses in the patient's recovery (and helping him or her get back on track) is enormously helpful.

The second ongoing task is to avoid sabotaging the effort. Ignoring obvious signs of relapse, scolding or lecturing, failing to link symptoms (e.g. insomnia) with drinking, and especially prescribing controlled substances (e.g. a benzodiazepine) all enable continued drinking and avoidance of treatment. The treatment community holds that, "a drug is a drug is a drug;" one addictive substance is as bad as another. Someone intent on getting and staying clean and sober must avoid these substances except under the most compelling circumstances.[23] One other note, the research indicates that patients working to quit a primary substance of abuse (e.g., alcohol) have greater success rates quitting tobacco if they do so at the same time. Therefore, if you work with your patient to get them into treatment for addictive behaviors, don't forget to capitalize on the moment to help them kick tobacco!

Specialist Role

The vast majority of patients who suffer from alcoholism will need to engage in treatment (work a program) of some sort.[9] Evidence shows that dysfunctional drinking can be well managed in primary care,[21] but heavy drinkers typically need longer and more intensive specialty treatment.[22,23] Describing the variety of treatment options is beyond this syllabus. Many patients, especially those with dual diagnosis (a major psychiatric diagnosis + a substance use disorder) will struggle mightily with this problem and will need a well-coordinated team, including both primary care and specialty SUD treatment, to stay as healthy as possible.

CONCLUSION

Speaking of health, aerobic exercise may be a meaningful metaphor on which to conclude. Much as the benefits of aerobic exercise can take time before becoming visible, persistence in your efforts to help your patients overcome problematic health habits is likely to be rewarded through a process of delayed gratification. Evidence supports providers' ability to succeed at working with patients to overcome problematic drinking and smoking, but change is rarely linear or unidimensional. For a good, balanced overview of the problem of alcoholism, including a discussion of the three pharmacological therapies in current use, see the article by Saitz.[22] For an equally useful overview of the current addictive behaviors evidence related to alcohol use, early intervention, and relapse prevention in primary care see the article by Marlatt and Witkiewitz.[16] As long as you follow diagnostic and therapeutic approaches like those mentioned in this module, and, most importantly, work together with your patients and team, we feel confident that you can help motivated patients remove the "un" from their unhealthy habits—improving their quality of life while developing your fitness as a patient-centered provider.

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MODULE 5 CORE READINGS (available online in Moodle)

- Smith CS, Kilfoyle M. Recognizing alcohol in ambulatory medicine: the elephant in the waiting room.

- Moyer VA, Screening and behavioral counseling interventions in primary care to reduce alcohol misuse: U.S. Preventive Services Task Force Recommendation Statement. Ann Intern Med (2013). doi:10.7326/0003-4819-159-3-201308060-00652.

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

1. In the paper by Smith and Kilfoyle, which skill is the 'elephant' metaphor used for?

2. According to Moyer and the USPSTF, by whom, how and when should patients be screened for alcoholism in primary care?

Module 6 Symptoms as the Disease (Somatization)

"The Needle or the Haystack?"

History

Earl is a 68-year-old man who wants to see you mid-way through your scheduled clinic. He does not have an appointment, but does have chest pain and wants to talk with you. You saw him two months ago for the first time, when he felt well, looked good, had good vitals, etc. He had a MI in 1999, and then a four-vessel CABG in 2002. Since then he has had five coronary angiograms, three in the last two years, with the most recent one six months ago. All have shown native vessel disease and widely patent grafts. He has been admitted four times for rule-out MI in the last nine months. An exercise test done three months ago was stopped for leg fatigue and dyspnea after 6 minutes. His heart rate was 115 and there were no ST segment changes.

Figure 29. A T-shirt for Earl Adapted from the band, n.d.[1]

He stopped smoking after his MI. His blood pressure has been well controlled with HCTZ and metoprolol. He drinks usually 3-4 beers in the afternoon and 2-3 glasses of wine with dinner.

His chest pain is sub-sternal to left-sided, achy to pressure-like. It comes on at rest and with exertion. It is rarely associated with rapid heart and shortness of breath. It is often, but not always, relieved by nitroglycerin. He had two episodes yesterday, and another in the middle of the night last night. He is concerned he might be having "the big one."

KEY QUESTION

Will you see Earl now (you have all the resources and available in Silver and at the Boise VA)?

Group 1	**YES**	**(defend your point of view)**
Group 2	**NO**	**(defend your point of view)**

Module Six

When Symptoms are the Problem

"Demons are everywhere, and the cursing of them is universal."
Tertullian: *The Testimony of the Christian Soul*, c. 210

INTRODUCTION

In this module we will encounter the troubling set of patients whose complaints of suffering seem far out of proportion to their detectable findings. For these patients, objective medical issues are complicated by subjective beliefs and often further amplified by having a difficult history with multiple medical providers. To mimimize such detrimental outcomes, the provider-patient interaction takes on especial importance. The key to helping these patients is to understand their experience of illness, their explanation of its cause and treatment, and its effects on their self-image, mood, functioning, and hopes.

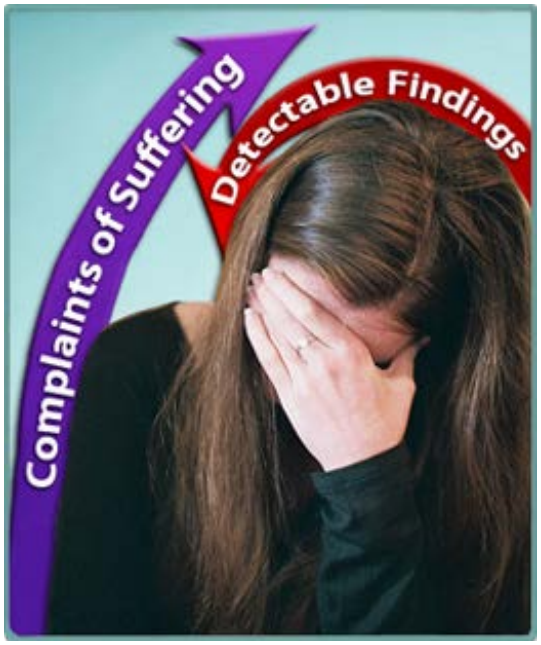


Figure 30. Somatic Patient. Adapted from Flickr, 2008.[2]

While a biomedical, "find it, fix it" approach may work with some other patients, it often proves counterproductive with somatisizers. Instead, your likelihood of success as a provider will improve through addressing the psycho- and social- elements of their condition. At the same time, you have likely experienced that somatisizers often present with, and usually insist that they have, bio- problems.

Therefore, this module emphasizes a biopsychosocial model of illness with a primary focus on the psycho- and -social ends of the spectrum. Similarly, working together to treat the full range of a somatic patient's issues will benefit both the patient and the entire interdisciplinary primary care team.

Ultimately, our goal is to stimuluate discussion in regards to applying and expanding the biopsychosocial model of illness within a patient-aligned care team clinic. During this discussion, we will examine diagnostic and therapeutic approaches to depression, anxiety, true somatization disorders (note the

semantics), and less well-defined symptom presentations such as headache, essential low back pain, irritable bowel syndrome, fibromyalgia, etc.

As a structural overview: 1) we first define somatization; 2) we consider the challenges of identifying somatisizing patients, followed by a four-step process to assist in diagnosis; 3) we discuss recommendations to manage somatic disorders, somatization of true biomedical processes, and chronic use of opiates; and 4) finally, we review relevant PACT principles and leave you with a few "bonus case" examples.

LEARNING GOALS

From this module we hope that you will take away:

- An ability to recognize when somatization might be at play.
- A diagnostic approach that is systematic and just as rigorous as that used with most of the bio- illnesses that are stressed in early training.
- The realization that you, not the lab or X-rays, are the main diagnostic and therapeutic instrument.
- Enhancement of the skills and insight needed to manage these patients artfully and with as little frustration as possible.

SOMATIZATION

What is somatization, and how can you know when it is present? It is "the conversion of mental experiences or states into bodily symptoms."[7] In mental health it is broadly categorized as "somatoform disorders," and it is the expression of psychological distress through physical symptoms. We use the term here to refer to somatization as this broad phenomenon, seen commonly in primary care, with an extensive spectrum of manifestations and severity (see Table 5 on the following page). This "extensive spectrum" is in contradistinction to Somatization Disorder, which is a highly specific DSM-IV-TR diagnostic category with specific criteria. Bodily symptoms with the somatization phenomenon are the same as ones that we commonly see in the clinic, but the symptoms and findings don't fit. As a result, we often respond by assuming the diagnosis has been missed or that we have not tested enough. Often we, and the patients, respond with frustration and anger.

Figure 31. Somatisization Disorder. Adapted from Flickr, 2007.[3]

Such situations and feelings can help us identify criteria for when somatization is present:

TWO MAIN TIP-OFFS WHEN SOMATIZATION IS PRESENT

1. **The lack of traditional fit**
2. **The presence of a strong emotional response by the patient or physician**

At the same time, a further challenge is that somatization can occur not only in patients with normal anatomy and physiology, but also in those with clearly identifiable medical problems – but with findings that do not explain the symptoms.

From your perspective as a provider, why are patients with somatoform disorders so difficult?

- The presentation is confusing.
- It is not a "real" problem.
- The patients are demanding of time and resources.
- They don't get better.[6]

For an interesting discussion of a related issue, of what might be called societal somatization, see Ross's paper on "memes."

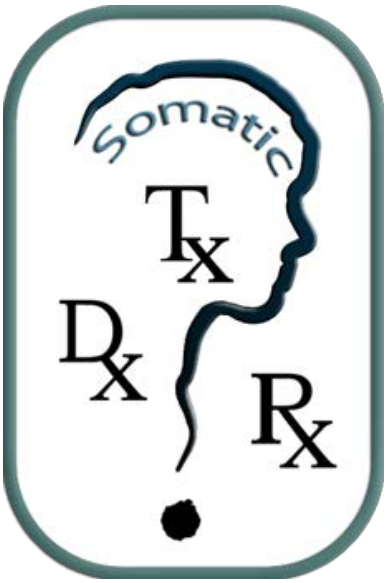


Figure 32.Somatic Questionmark. Adapted from Wikimedia, 2012.[4]

THE DIAGNOSIS OF SOMATIZATION

Now that you have an overview, use the following table as a first step to diagnosing somatization:

TABLE 5. Areas Where Somatization is Found

1. Affective disorders - esp. depression
2. Anxiety (incl. panic disorder)
3. Substance abuse
4. Somatiform disorders
   - Hypochondriasis
   - Conversion
   - Somatization disorder
   - Psychogenic pain
5. Factitial disorders and malingering
6. Psychophysiologic disorders
7. Character (personality) disorders
8. Psychoses
9. Transient emotional stress

That previous table is part of a four-step diagnostic process for somatoform disorders:

4 STEPS OF SOMATIC DIAGNOSIS

1. **Consider Table 01**
2. **"SOAP" the patient**
3. **Analyze the data**
4. **Come to closure**

Step #1 is to consider ALL the diagnoses listed in Table 5.

If your index of suspicion is raised by either: 1) things don't fit, or 2) this is a heartsink patient; then consider applying the points in this module. It would be unusual to determine somatisizing on the first visit. Rather, a pattern develops over several visits, too often after a diagnostic work-up is well under way.

Associated Diseases

DEPRESSION

Depression and anxiety are the two most common causes of somatization. Depression can lead to a disastrous outcome and thus must be considered early. Major depression is an indication for psychiatric referral. Dysthymia (minor depression) tends to be less severe but more common and chronic. The elderly with depression tend to present with greater somatization and less mood change, making the diagnosis more difficult. In general, to treat the somatic complaints, treat the depression.

ANXIETY

Anxiety is second only to substance abuse as a mental disorder in the general population. Anxiety often overlaps with depression, and most frequently presents with physical ailments. Panic disorder should not be missed, because it often progresses to debilitating functional impairment. Something else to be aware of is that a significant number of somatisizing patients in this anxious category have a history of trauma, which may or may not meet diagnostic criteria for PTSD but may be related to their symptoms.

PERSONALITY DISORDERS

Somatization is a common manifestation of several of the personality disorders. We all have our personality traits, which we can emphasize or de-emphasize as the situation demands. However, a trait becomes a disorder when it is used overwhelmingly by a patient, and to his or her harm, which is what can happen with.somatization. These disorders are rare but are also some of the most troublesome. The uninitiated will deem these patients "crazy" and will try to refer to psychiatry. Yet a person's personality cannot change with psychotherapy, medication, or any other means.

Therefore, the management of these patients involves our (including the system's) adaptation of our behavior to meet their individual needs and to allow proper medical care to unfold. When somatic illness is in question, this is the province of primary care. A brief listing of the personality disorders and their characteristics with suggested management points for each group follows[9]:

- **Eccentric Group**
  - Paranoid – guarded, question routine inquiries
  - Schizoid – loners
  - Schizotypal – odd behavior, peculiar beliefs, social isolation

  Management:
  1. Meticulous honesty, keep it simple, humor may be misinterpreted.
  2. Composure, even if you are startled by marked eccentricity.
  3. Concern for patient's well-being and privacy.

- **Dramatic Group**
  - Borderline – borders on depression, instability in mood and interpersonal relationships. Others are all good or all bad => staff splitting. Often will agitate to see how much they can get away with. The prototype is a 2- or 3-year-old child.
  - Histrionic – attention-seeking, excessive emotionality.
  - Narcissistic – self-importance, intolerant of criticism. The concepts of even distribution and waiting your turn make no sense to these patients.
  - Antisocial – irresponsible behavior, agitating or malingering for gain.

  Management:
  1. Minimize interpersonal wrangling, and therefore the personality's impact on medical care.
  2. Clear and even-handed rules of behavior.
  3. Criticize behavior that departs from the rules or is harmful, not the person or personality.
  4. Short-term, symptom-based treatment.

- **Anxious Group**
  - Avoidant – lonely, depressed, often comfortable with physicians only.
  - Dependent – enduring of abuse, sensitive to criticism, prone to symptoms just before doctor leaves for vacation.
  - Passive-aggressive – dependent, lacking self-confidence.
  - Obsessive-compulsive – hypochondriacal, showing little affect.

  Management:
  1. Minimize interpersonal wrangling, and therefore the personality's impact on medical care.
  2. Management of dependency by clear rules of behavior.
  3. Clear and even-handed rules of behavior.
  4. Management of dependency by clear rules of behavior
  5. Criticize behavior that departs from the rules or is harmful, not the person or personality.
  6. Short-term, symptom-based treatment.

Step #2 is to SOAP the patient and gather more data.

Elicit the patient's attributions with these key questions as described by the acronym *SOAP*:

S: What does he/she think happened? (usually this comes out spontaneously)
O: What is his/her understanding of signs, lab, and X-ray results?
A: What is his/her understanding of etiology, pathophysiology, prognosis?
P: What are his/her future expectations?

Since sometimes the answers are surprising (cf. above; heredity protects against smoking problems), use the following guidelines to draw out important information:

- Ask about significant psychosocial stress.
- Determine the patient's coping methods and support systems.
- Assess the current level of function, such as ADLs, sex life, recreation, work, and interpersonal relations.

Step #3 is to analyze the data. It is more important to evaluate correctly than quickly.

PERTINENT POSITIVES: A specific DSM IV diagnosis may be present from Table 5. If so, there may be specific therapy, and referral to specialty services is often appropriate. Nevertheless, continued monitoring of the physiologic symptoms by the primary care provider through early treatment and ongoing support through primary care behavioral health is also necessary. There may be physiologic syndromes present as well, such as irritable bowel syndrome or fibromyalgia.

PERTINENT NEGATIVES: These come from thorough, well-considered workup and observation over time.

Step #4 is coming to closure.

The last step in the diagnostic journey is deciding that the somatization phenomenon is indeed present and coming to closure. This is difficult, for two reasons. First, there is no X-ray, lab test, or physical finding that seals the diagnosis. Instead, there is only the recognition of a pattern of behavior and findings that fits. Those with a strong biomedical model background find this disconcerting. Second, somatization can, and often does, accompany biomedical illness. These patients are seldom otherwise well. Deciding which disease is driving which symptoms is difficult. Yet if we pursue the above diagnostic journey—i.e. pay attention to cues, elicit patient attributions, analyze positive and negative evidence, diagnose associated diseases, and recognize the pattern—we can come to firm closure.

TREATMENT & MANAGEMENT OF SOMATIZATION

Even as the diagnostic process unfolds keep treatment in mind. There is a risk of facilitating/reinforcing maladaptive illness behaviors. Some guidelines are:

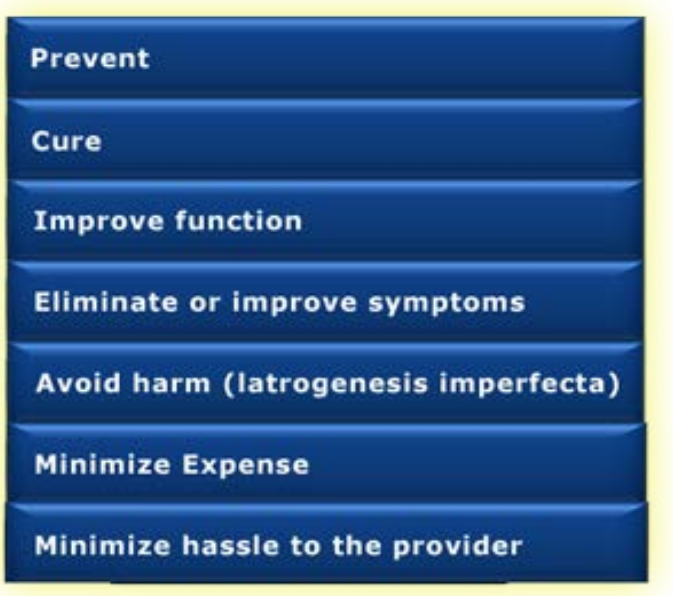
1. Test in a careful, stepwise fashion
2. Minimize repeat testing
3. Be discriminate in referrals
4. Avoid unnecessary prescribing

While treatment is the goal with any condition, management may also be a useful term to describe how to handle somatoform disorders that often lack quick fixes. To help you in this process of dealing with somatization, there are several tools that are most useful:

- *LEGITIMIZE SYMPTOMS*. Assuring patients that the provider believes in their symptoms and that he or she will not try to talk them out of it is critical. Give permission but not encouragement for symptoms. Adopt "an unusual therapeutic stance in which you tolerate the patient's requirement that the condition be viewed primarily as a physical one, while believing that psychological factors are of foremost importance."[6] While often we speculate openly with other patients about diagnostic possibilities, here it is important to:

  - Be slow to make a diagnosis; have firm evidence before even speculating on a diagnosis.
  - Use neutral, descriptive labeling.
  - Monitor symptoms carefully and regularly.

- *NEGOTIATE GOALS*. There is a tacit hierarchy of goals in medicine that is roughly as follows:

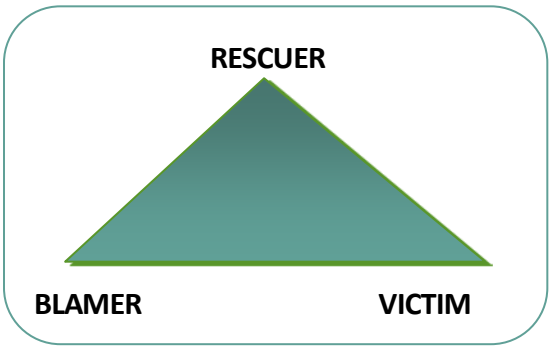


Notice that these goals are not numbered since not everyone agrees on their order. The real problem comes when the patient and provider have different goals. The tool is to *make this disparity explicit* and *negotiate a goal*, with all that the term, "negotiation," implies (statement of positions, persuasion, trials, compromise, as well as perhaps third party involvement, etc.).

- *Schedule REGULAR VISITS*. Make them time contingent rather than symptom contingent. Thus, illness behavior will not be reinforced, and you can focus on coping behaviors and the patient's overall functional status.

- *Address CONFLICT explicitly*. Point out areas where you know or suspect that your ideas differ from the patient's. These should probably not include ideas about etiology ("It's all in your head" and "You're a neurotic" are not productive), but often include disagreements about disability, invasive tests, or surgery.

- *Recognize TROUBLESOME EMOTIONS* (patient's and providers'). Suffering, hostility, and dependency are common (cf. rescuer-blamer-victim triangle). As above, commenting when these emotions are blocking progress is helpful. For the provider, having a knowledgeable, impartial friend to discuss these with can be help you deal with the difficulty.



- *REFER appropriately*. Have specific questions for the consultant. Be careful whom you ask. The vast majority of somatisizers need a conservative primary care physician to manage their symptoms. You can expect a mental health specialist to help with emotions, but not often with chest pain, abdominal pain, etc. Conversely, a med/surg subspecialist will often pursue his or her diagnostic algorithm to the end before concluding, "It is not in my province." This balance between pursuit and restraint is the crux of primary care. It brings to mind Dr. Peabody's statement, " . . . the secret of the care of the patient is in caring for the patient."[10]

- *Sometimes, JUST SAY NO*. Setting limits is difficult for many of us for several reason, such as: conflict avoidance, inherent desire to be of service, degree of doubt about the diagnosis or treatment, or threat to the therapeutic relationship. These patients may bring all these to the fore. Yet saying no is often the best treatment, if done diplomatically, firmly, and without pejorative intent. From an ethical perspective, a competent patient has the right to refuse any recommendation at any time, regardless of what we think of that decision. In addition, they have the right to expect the best treatment that is appropriate. They do not have the right to demand any test or treatment that is not appropriate, and we have no obligation to provide it. This is the border, albeit sometimes gray, where limits need to be set.

As a summary of main ideas for managing patients with somatoform disorders, consider the list on the following page:

KEY POINTS OF MANAGEMENT

1. **Legitimize symptoms**
2. **Negotiate goals**
3. **Schedule regular visits**
4. **Address conflict openly**
5. **Recognize strong emotions**
6. **Refer appropriately**
7. **Set limits**

PACT and Somatization

As those listed keys to management demonstrate, a well-coordinated PACT clinic can offer comprehensive care to a patient struggling with these difficulties while also relieving the stress providers might experience in more traditional clinical settings. Obviously, when identifying, diagnosing, and managing somatization, Shared Decision Making (SDM) skills need to be highly refined. To facilitate SDM, fluid Interprofessional Collaboration within the clinic is essential. In a poorly coordinated clinic, a patient's experience means that they: get mixed messages from different staff and providers; may experience multiple (redundant) tests and appointments; and, as a result, spiral into worse confusion about their own beliefs and understandings of their medical concerns. In contrast, having well-coordinated care management across all levels of the patient's experience in the clinic visit, along with ready access to behavioral health and pharmacy, means that providers and patients are more likely to come to an understanding of treatment decisions and outcomes. Ultimately, this balance can help sustain the patients relationship with the clinic, offer them better care, and decrease unnecessary medical costs and frustrations.

SOMATIZATION AND CHRONIC USE OF OPIATES

Perhaps *the* most contentious issue in primary care is the use of opiates in a patient with chronic pain not due to terminal illness, i.e. chronic, non-malignant pain. You will see these patients in clinic. Some will be your most difficult management cases, especially those where there is a question of somatization. One school of thought is that opiates are contraindicated in this condition, regardless of the patient's condition. Most providers take a softer stance than that, but struggle with the particular place of opiates.

For most pathological conditions there is a spectrum of severity. An example is chronic back pain. At one end of the spectrum are those with severe degenerative changes on X-ray, where the pathology is not in question but functional status is. At the other end are those with no discernible pathology who are incapacitated by the pain.

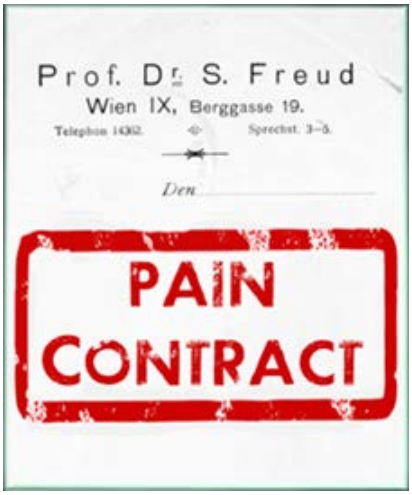
How far does one test in these patients? Do negative tests indicate absence of biological pathology? Does this imply, ipso facto, somatization? Where along this spectrum or in which patients, if any, should opiate therapy come into play?

Unfortunately, limited data is available to help with these questions. Therefore, in addition to consulting with other members of your interdisciplinary team, it is often helpful to consider the pros and cons of opiate therapy for any given patient. Depending on the situation, each factor will weigh differently when making a decision:

Table 6. Pros & cons of opiate therapy.

	Pros	Cons
Physical	Decrease pain	Medication dependence
	Avoid side effects and other meds, e.g., NSAIDS	Opiate side effects (constipation, sedation, etc)
Emotional	May allow focus outside of self	May worsen depression
Social	Fewer doctor/patient hassles	More *system* hassles
Spiritual	Increased meaningful function	*Avoidance* – prevent needed psychological work

Similarly, when you find yourself struggling with the issue of opiates in chronic pain, we recommend that you "walk through" the previously described diagnostic method with a few modifications:



1. Consider the elements in Table 5
2. Get the patient's take on the situation (SOAP)
3. Come to closure
4. Use the appropriate therapeutic tools
5. Consider the balance of good and harm that would likely come from opiates

While somatic disorders have become a speciality within pain clinics and psychology, they have traditionally been managed in primary care, and a full range of primary care providers will continue to treat patients

contending with varying degrees and types of chronic pain. Should you decide to prescribe opiates, make a specific agreement with the patient about amounts, refills, expected benefits, modest doses, criteria for stopping them, etc., i.e. a pain contract. For further considerations on this important issue, the articles by Marcus[11] and Parran[12] are particularly helpful.

CONCLUSION

Managing patients who are high-somatisizers pulls from the full bag of knowledge and tricks available in a primary care clinic. While it may be a somewhat imprecise science, your skills in managing discrepancies between *psyche* and *soma* can definitely be improved. Somatization may never be your favorite clinical issue, but you and your patients will benefit if you using the ideas in this module as your framework to plan out respectful and thoughtful management strategies.. Hopefully raising your awareness of these subtleties will lead to fewer "heartsink" patient interactions in your clinic and point you towards more rewarding, patient-centered, whole-person care.

What Often Happens

Find it, Fix it **approach reinforces maladaptive illness behaviors and beliefs in patient → emotional entanglement ensues in provider/patient relationship → dysfunctional patterns increase → treatment is reactive and negatively reinforcing for providers (*if I give them this they'll go away for a while…*) → relationship is lost, patient or provider is fired, everyone is frustrated . . .**

What Should Happen

Contributing psychosocial factors are identified early and incorporated into management in nonjudgmental and validating ways → team-based treatment allows for necessary balance in visit frequency, needs assessments, etc. → emotional and psychological processes become as central to treatment as biomedical pathology → important medical concerns are addressed and treated, patients' needs are identified and met, relationship is sustained, frustration for all parties is minimized . . .

BONUS CASE EXAMPLES

Now, for extra credit in the upcoming PCS discussions, what are the diagnoses for the following two cases (true cases, with some details altered)?

Case 1. You see a 34-year-old man in clinic for chest pain and palpitations. He has come to you in the past only with relatively minor problems. One month ago you saw his 67 yo father, a 3 pack-per-day smoker for years, for chest pain. The father exercised for 9 minutes on the Bruce protocol without ST changes and stopped due to dyspnea. Three days later he died suddenly. A post-mortem showed several coronary lesions of 95% or greater.

The son smoked until about six years prior. He drinks alcohol only rarely. A recent total cholesterol was 176. He is thin, does not exercise much, and is employed full-time as a mechanic. He is married with three children. An EKG, chest film, and usual labs are all normal. He goes 13 minutes on an exercise test. Trials of nitroglycerin, ibuprofen, and propranolol do not help. A cardiologist does another exercise test, again about 13 minutes without findings. Several times the patient comes to the emergency room with chest pain and palpitations, but symptoms resolve before evaluation. Another exercise test shows a shorter duration of exercise but no other changes. Fatigue sets in. He sleeps in his car in the hospital parking lot three times in anticipation of symptoms with the idea of catching the symptoms on an EKG (pre-event monitor era), but does not get them. He loses his job due to poor performance. His wife is thinking about leaving him.

Case 2. A 46-year-old man drops into your clinic demanding to be seen for new chest pain. He is a smoker, has borderline hypertension, has degenerative arthritis for which he takes chronic opiates, and gets little physical activity. He went to the Emergency Room for this pain last night, but "it was just a kid" who saw him, and all he did was an EKG, CXR, and some blood work. He prescribed nitro, metoprolol, and a statin, but the patient wants to talk this over with you, "a real doctor," before filling the prescriptions. He said the patient HAD to see his regular doctor right away for a definitive workup. The patient has booked out his time this afternoon to be free to visit with you.

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MODULE 6 CORE READINGS (available online in Moodle)

- Bass C, Benjamin S. The management of chronic somatization. *Br J Psychiatry* (1993);162:472-80.
- Ross SE. "Memes" as infectious agents in psychosomatic illness. *Ann Intern Med* 1999;131:867-871.

CORE READINGS QUIZ

As you do the core readings, focus on the questions below. Please bring your responses to class. Also, once you have finished the readings, complete the brief online quiz.

1. In the article by Bass and Benjamin, what behavior help to an either or/ mind-body dualism?
2. According to Ross, "memes" are like viruses in which ways?

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