

Assessment of Best Practices for Standardized Quality Assurance Activities in Pathology and Laboratory Medicine

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Project Principal Investigator:

Dana Marie Grzybicki MD, PhD

Overview

- Project Purposes and Objectives
- Major Project Activities
- Basic Project Methods
- Project Findings & Preliminary Assessments

Purposes

- To assess the usefulness of currently widely measured and reported laboratory quality assurance (QA) measures as valid laboratory performance measures, based on their measurable significant impact on clinically relevant outcome measures (e.g., clinical management decision-making, healthcare costs, patient care outcomes).
- To identify any specific structure or process factors related to the examined QA measures that may represent best practices, based on their association with high and clinically relevant performance

Objectives

- To evaluate the effectiveness of six (6) QA measures representing indicators from each of the three major phases of laboratory testing (pre-analytic, analytic, and post-analytic) in multiple laboratory practice settings, based on multiple levels of evidence, including an examination of their demonstrable linkage to clinically relevant outcome measures
- Since little to no clinically relevant, linked outcome information was available to use as evidence for the project assessments, to identify and collect appropriate outcomes information for each of the 6 measures as needed.

Objectives

- To summarize the findings for each of the QA metrics obtained from project activities and previously published relevant evidence obtained through comprehensive literature reviews in individual QA measure reports for review and assessment by expert consultants
- To disseminate final assessments for each of the project QA metrics, including the input obtained through expert consultation, by preparation and publication of project-based scientific manuscripts in high-impact peer-reviewed publications

Major Activities

- Identify 6 QA measures for examination
- Determine potential appropriate, clinically relevant linked outcome measures for each of the 6 QA measures
- Generate project data collection tools for both laboratory and clinical information for each QA measure
- Recruit volunteer laboratories to share QA and clinical information

Major Activities

- Collect and analyze multi-institutional data
- Formulate preliminary metric assessments
- Prepare metric summary reports
- Distribute project summary reports for expert consultation
- Complete QA metric assessments and disseminate project findings

Basic Methods

- **Design:** Retrospective review of existing data from multiple volunteer laboratories
- **Data Sources:** QA logs, LIS, clinical electronic records (e.g., MARS), hard copy patient charts, institutional administrative databases, freely accessible CMS reimbursement databases
- **Data Collected:** Limited data set

Project QA metrics

- **Pre-analytic:** Specimen Identification Errors and Deficiencies; Blood Culture Contamination Rate
- **Analytic:** Turnaround time; Gynecologic Cytologic-Histologic Non-correlation/Discrepancy Rate
- **Post-analytic:** K+ Critical Value Reporting
- **Point-of-Care Testing:** POC Glucose Accuracy

Project Collaborators

- **Henry Ford Hospital, Detroit, MI** (Large community teaching hospital; urban)
- **University of Iowa Hospitals and Clinics, Iowa City, IA** (University based medical center; rural)
- **Emory University/Crawford-Long Hospital, Atlanta, GA** (University associated community hospital; urban)
- **Kaiser Permanente, South San Francisco Hospital, South San Francisco, CA** (HMO; urban)
- **Eden Medical Center, Castro Valley, CA** (Small community hospital owned by Sutter Health System; suburban). Two-pathologist practice without an electronic LIS

Basic Project Findings & Preliminary Assessments

Gynecologic Cytologic-Histologic
Non-correlations/discrepancies

Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Five (5) laboratories shared qualitative data regarding how they perform this QA process at their institutions
- Four (4) laboratories shared quantitative information obtained through retrospective review of existing laboratory and medical records (Years 2002 and 2003).

Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Major qualitative information about how laboratories perform the correlation process was recorded: 1) relationship to real-time specimen examination 2) time interval utilized for identification of specimen pairs to examine for potential discrepancies, 3) specimen Pap test diagnoses to include in the process, 4) laboratory personnel assigned to perform the process, 4) correlation process information documented, 5) how information was used for CQI

Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Major quantitative descriptive laboratory data recorded or calculated:
- 1) original and review diagnoses for both discrepant case specimens, 2) specific type of tissue specimen(s) associated with each discrepant case, 4) proportion of non-correlating/discrepant cases of all correlating cytology and histology specimens examined, 5) proportion of discrepant cases representing false negative and false positive errors, 6) basic cause for errors (sample factors or interpretation).

Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Major clinical data elements recorded for discrepant cases:
- Patient age, previous history of cervical disease
- First clinical management procedure(s) performed after clinician receipt of discrepant diagnostic information
- Morbidity (if any) associated with procedure(s)
- Interval of time between receipt of discrepant information and next procedure(s)
- Patient harm assessment (no harm, near miss, minimal, minor, moderate, severe).

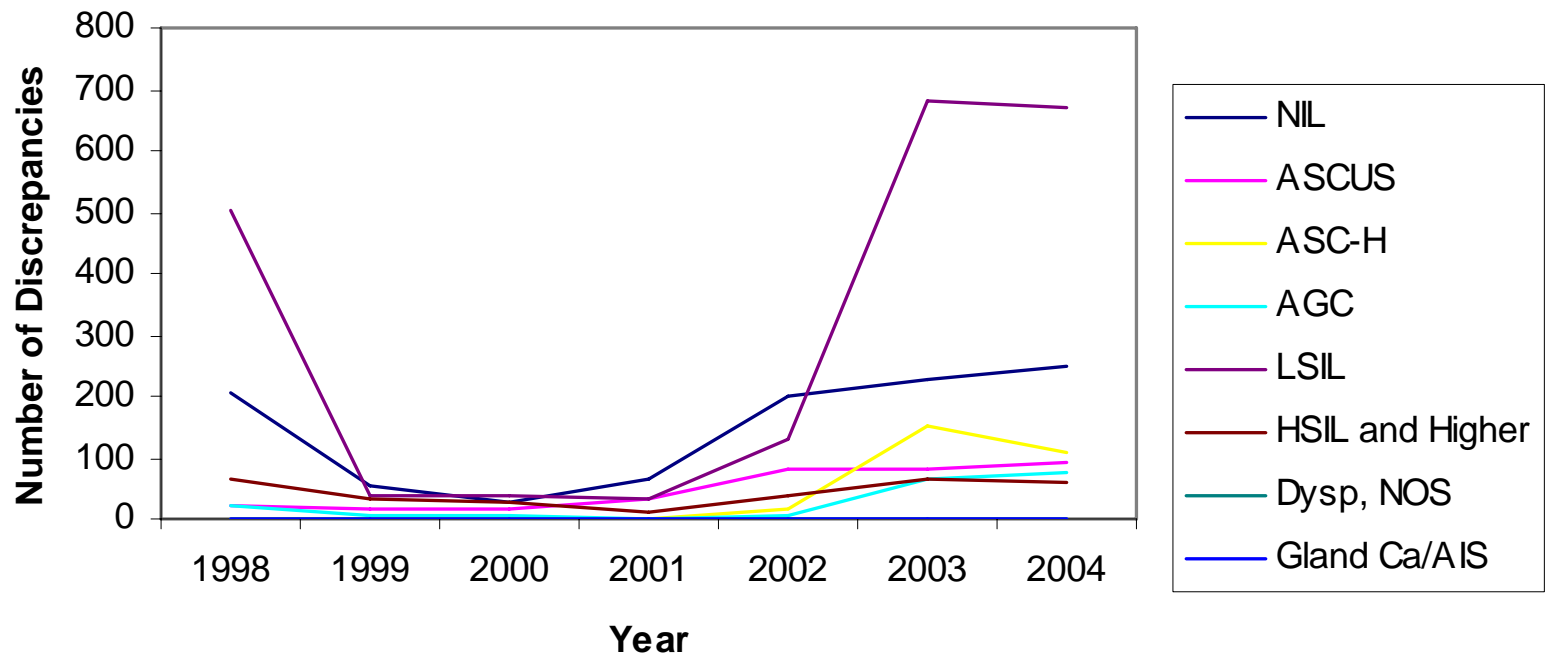
Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Major findings:
- A high level of inter-institutional variability existed for this QA process at essentially all steps.
- Individual institutional proportions of reported discrepancies were highly variable, but generally ranged from 5-10% of all correlating specimen pairs.
- The majority of discrepant cases at all institutions were false negative Pap tests deemed to be due to sample factors (60-100%).
- None of the institutions used their regularly collected and recorded correlation data for CQI purposes.

Gynecologic Cytologic-Histologic Non-correlations/discrepancies

- Institutional assessments of patient harm associated with discrepancies were highly variable, even when using a standardized severity score rubric.
- The majority of identified patient harm was minimal or mild and consisted of delays in diagnosis and the need to undergo potentially unnecessary and/or more frequent screening Pap tests.
- The least amount of patient harm occurred at the institution performing real-time correlations.

Original Pap Diagnosis



Surgical Diagnosis	Cyto Diagnosis LSIL	
	Year 1	Year 2
Unsatisfactory	0	10
Negative	14	666
CIN I	0	1
CIN II/CIN III	20	0
Glandular Ca	0	2
Squamous Cell CA	2	0
Other	0	0
Total	36	679

Cytologic-Histologic Correlation Data

Preliminary Assessment

- Due to the high level of variability associated with every step in this QA process as well as the dependence of the results of this process on many and highly variable pre-pre-analytic and pre-analytic variables, discrepancy rates or other measures obtained through the process of gynecologic cytologic-histologic correlation are not feasible candidates as laboratory performance measures.

Cytologic-Histologic Correlation Data Preliminary Assessment

- However, performance of this process is highly valuable for revealing problems and errors in institutional cervical cancer screening programs in both pre-analytic and analytic phases of the screening process that significantly impact clinically relevant outcome measures (e.g., inappropriate patient management with associated increased costs). Effective use of this data for CQI purposes can lead to decreased discrepancy rates and patient harm.

Basic Project Findings & Preliminary Assessments

Blood Culture Contamination Rates

Blood Culture Contamination Rate

- Multiple previously published studies have shown that institutional blood culture contamination rates are linearly correlated with healthcare costs. Clinicians receiving blood culture reports positive for bacterial growth tend to respond, in most cases, by ordering the administration of IV antibiotics to the patient, regardless of whether the growth likely represents skin flora contamination.

“Contaminant blood cultures and resource utilization. The true consequences of false-positive results.”

Bates DW, Goldman L, Lee TH. JAMA 1991 Department of Medicine, Brigham and Women's Hospital, Boston, Mass 02115.

To determine whether contaminant blood cultures increase resource utilization, we studied charge and length of stay data for episodes in which blood cultures were obtained from hospitalized adults. Compared with 1097 negative episodes, 94 false-positive episodes were associated with increased subsequent length of stay (median, 12.5 vs 8 days) and subsequent total charges (median, \$13,116 vs \$8731), pharmacy charges (median, \$1456 vs \$798), and laboratory charges (median, \$2057 vs \$1426). In multivariate analyses, contaminants were independently correlated with 20% and 39% increases in total subsequent laboratory charges and intravenous antibiotic charges, respectively. Thus, the true costs of contaminants may greatly exceed those of the test itself. Identifying patients at very low risk of bacteremia and attention to sterile technique may reduce costs by decreasing the frequency of contaminants.

Blood Culture Contamination Rates

- Factors shown to be important for decreasing contamination rates are:
 - 1) blood collections performed by dedicated phlebotomists
 - 2) blood collections performed via peripheral venous sites rather than through indwelling catheters of any kind
 - 3) skin decontamination prior to blood collection with specific decontaminants.

Blood Culture Contamination Rates

- Despite good evidence for how laboratories can decrease their contamination rates, it appears that many laboratories do not adhere to published recommendations for most likely multiple but unclear reasons.

Blood Culture Contamination Rate

- Purpose: To confirm previously published findings at a single hospital in a large academic institution, where blood culture collection is performed by both nursing staff and dedicated phlebotomists and the type of personnel performing each blood collection is routinely recorded for QA purposes.

Methods

- A four (4) year retrospective review was performed of microbiology laboratory QA records regarding blood cultures.
- Cultures previously determined to most likely represent contamination were labeled “contaminant”. Contamination status, as well as the personnel type drawing the culture and other relevant variables were recorded for each culture.
- Rates were calculated as:
- $\text{total \# contaminated cultures} / \text{total \# cultures drawn}$

Month	Total Drawn	Total Contam	Contam Rate (%)	Total RN Drawn	Total Phlebot Drawn	Total RN Contam Rate (%)	Total Phlebot Contam Rate (%)	Comment
7/2002	1405	20	1.4	18/20	2/20	2.6	0.3	
8/2002	1658	25	1.7	19/25	6/25	2.3	0.7	
9/2002	1743	29	1.7	28/29	1/29	3.2	0.1	
10/2002	1779	29	1.6	24/29	5/29	2.7	0.6	
11/2002	1676	29	1.7	26/29	3/29	3.1	0.4	
12/2002	1834	30	1.6	24/30	6/30	2.6	0.7	
1/2003	1835	36	2.0	32/36	4/36	3.5	0.4	
2/2003	1722	34	2.0	31/34	2/34	3.6	0.2	1 collector unknown
3/2003	2052	35	1.7	29/35	6/35	2.8	0.6	
4/2003	1714	34	2.0	27/34	7/34	3.2	0.8	
5/2003	1579	31	2.0	27/31	4/31	3.4	0.5	
6/2003	1809	36	2.0	30/36	3/36	3.3	0.3	3 collectors unknown
7/2003	1818	46	2.5	42/46	4/46	4.6	0.4	
8/2003	1760	46	2.6	42/46	4/46	4.8	0.5	
9/2003	1757	45	2.6	42/45	3/35	4.8	0.3	

Month	Total Drawn	Total Contam	Contam Rate (%)	Total RN Drawn	Total Phlebot Drawn	Total RN Contam Rate (%)	Total Phlebot Contam Rate (%)	Comment
7/2005	1641	49	2.99	46/49	3/49	3.91	0.65	
8/2005	1531	45	2.94	41/45	4/45	3.74	0.92	
9/2005	1828	50	2.74	44/50	6/50	3.36	1.16	
10/2005	1772	46	2.60	41/46	4/46	3.22	0.80	1 Collector Unknown
11/2005	1535	38	2.48	37/38	1/38	3.36	0.23	
12/2005	1639	23	1.40	22/23	1/23	1.87	0.22	
1/2006	1638	49	2.99	47/49	2/49	4.00	0.43	
2/2006	1738	42	2.42	37/42	4/42	2.97	0.81	
3/2006	1732	36	2.01	33/36	3/36	2.66	0.61	
4/2006	1863	46	2.47	43/46	3/46	3.22	0.59	
5/2006	1846	51	2.76	46/51	5/51	3.48	0.96	
6/2006	1695	48	2.83	47/48	1/48	3.87	0.21	

Blood Culture Contamination Rate: Distribution by Unit

Unit	7/02	8/02	9/02	10/02	11/02	12/02	1/03	2/03	3/03	4/03	5/03	6/03	7/03	8/03	9/03	10/03	TOTAL	RATE (%)
CTA			1							1			1		1		4	1.4%
CTB		1		2	1	1	1	1						1		2	10	2.0%
CTC																1	1	0.2%
MICU	2	2	6	1	4	3	2	3	3	3	3	8	4	3	4	8	59	6.0%
NICU	1	1	2	3	2	3	3	1	3	1	2	1	3	5	1		32	4.4%
WCCA				1			3	2	1	3	1	2	1		2	2	18	3.3%
WCCB	3	1	3	1	5	1	3	1	2	2		4	3	1	3	1	34	7.0%
3Main												1	2	1	1		5	0.8%
4Main	1	3	2	1		1	1	1			1						11	1.2%
5Main							1										1	0.2%
6Main				2	2	1	1	3				1	3	2	1	1	17	1.1%
7Main	1	3	3	1	2	1	2		4	1		2		1	2	3	26	0.8%
3 PAV	1			1						1	2			2	1	2	10	1.2%
4 PAV	2	1				1				4		1	1	1			11	2.0%
6 PAV																1	1	3.6%
5West	1	2	1									1	1				6	1.0%
6West		2					1	1			1		1	2			8	0.9%
7West		1	3	2	4	4		1			4	3	8	2	4	5	41	1.4%
3East							1	1		1			2	3			8	0.8%
4East								2						3	1		6	0.7%
ER	2	2	4	5	3	4	7	9	13	6	8	4	15	15	18	11	126	1.8%
OP	2											1					3	1.4%
PCI			1	1	1	4	1	2	1		3		2		3		19	2.5%
OHA			1				2				1	1	2	1			8	1.6%
Dialysis																1	1	N.D.

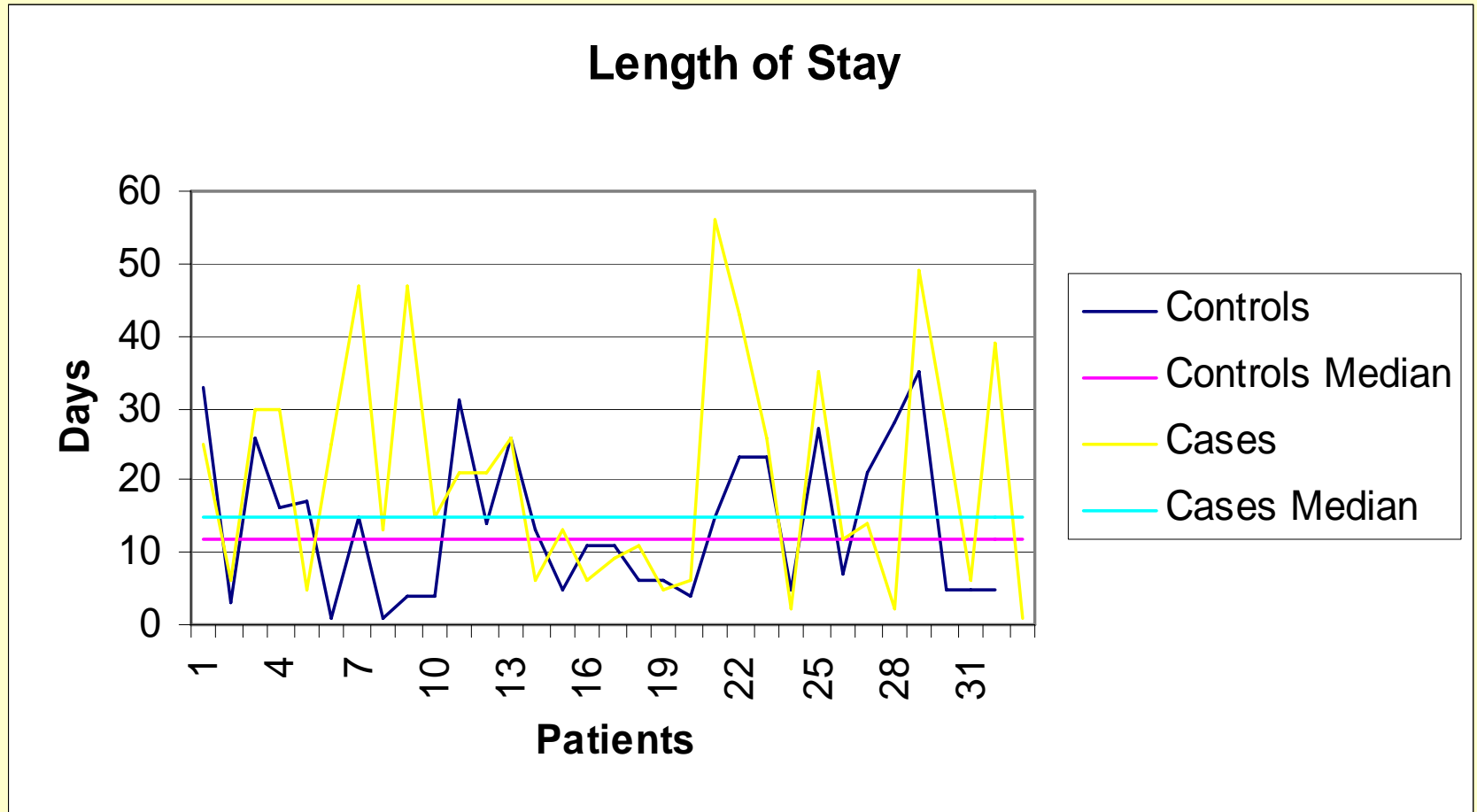
Blood Culture Economic Data

- Matched samples of hospital inpatients (n = 66) with blood cultures drawn in September, 2004 on the floors was examined in more detail.
- Patients were matched for age and primary discharge DRG.
- The controls (n = 33) were patients with negative blood cultures; the cases were patients with contaminated blood cultures per the Hospital laboratory criteria for assignment of contamination (i.e., only one of multiple cultures positive for one or more normal skin flora).

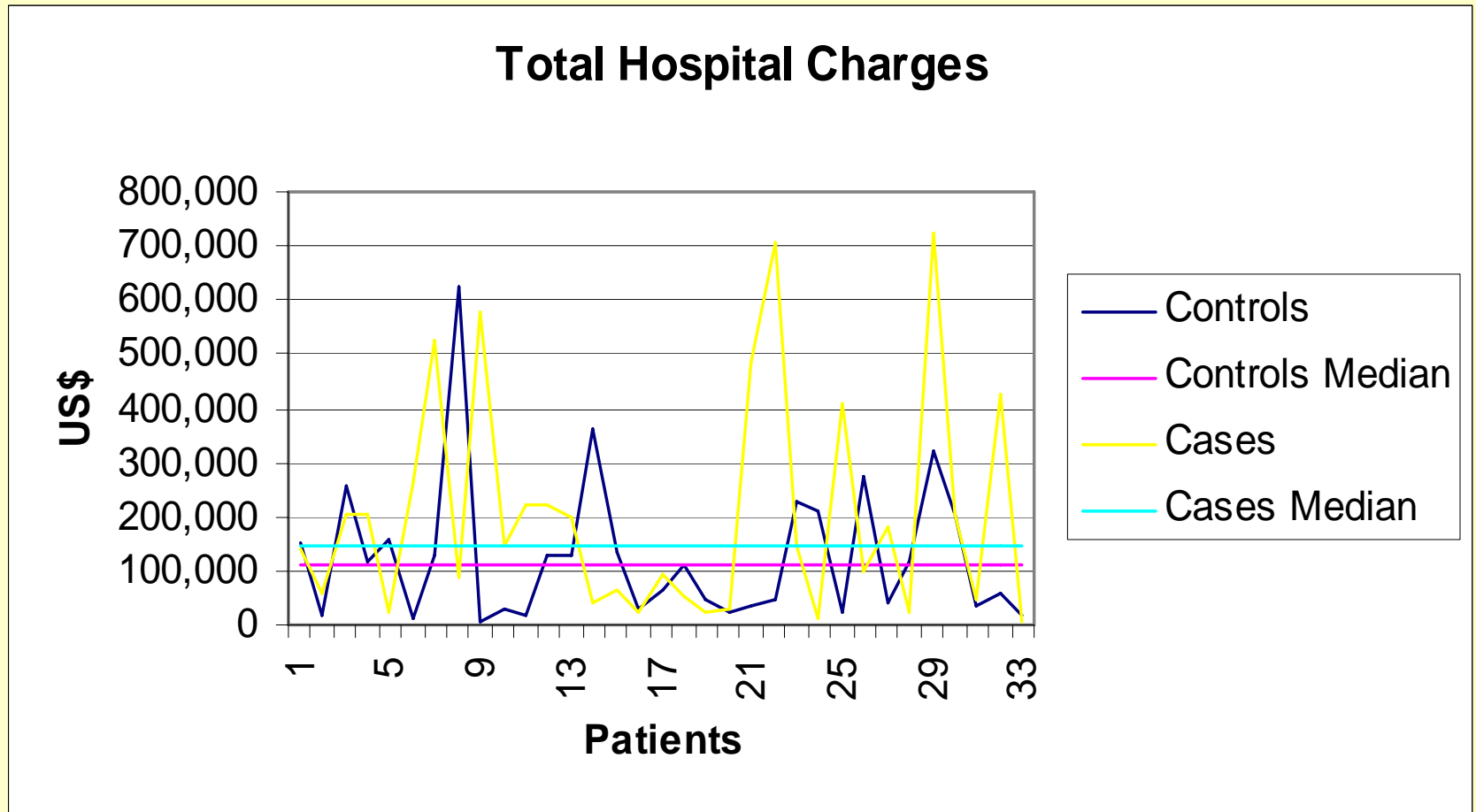
Blood Culture Economic Data

- The Hospital Corporate Database was utilized as the source of cost data.
- LOS, total hospital charges, total laboratory charges, and total pharmacy charges were recorded for each of the case and control patients, and the median values for each of the measures was calculated.

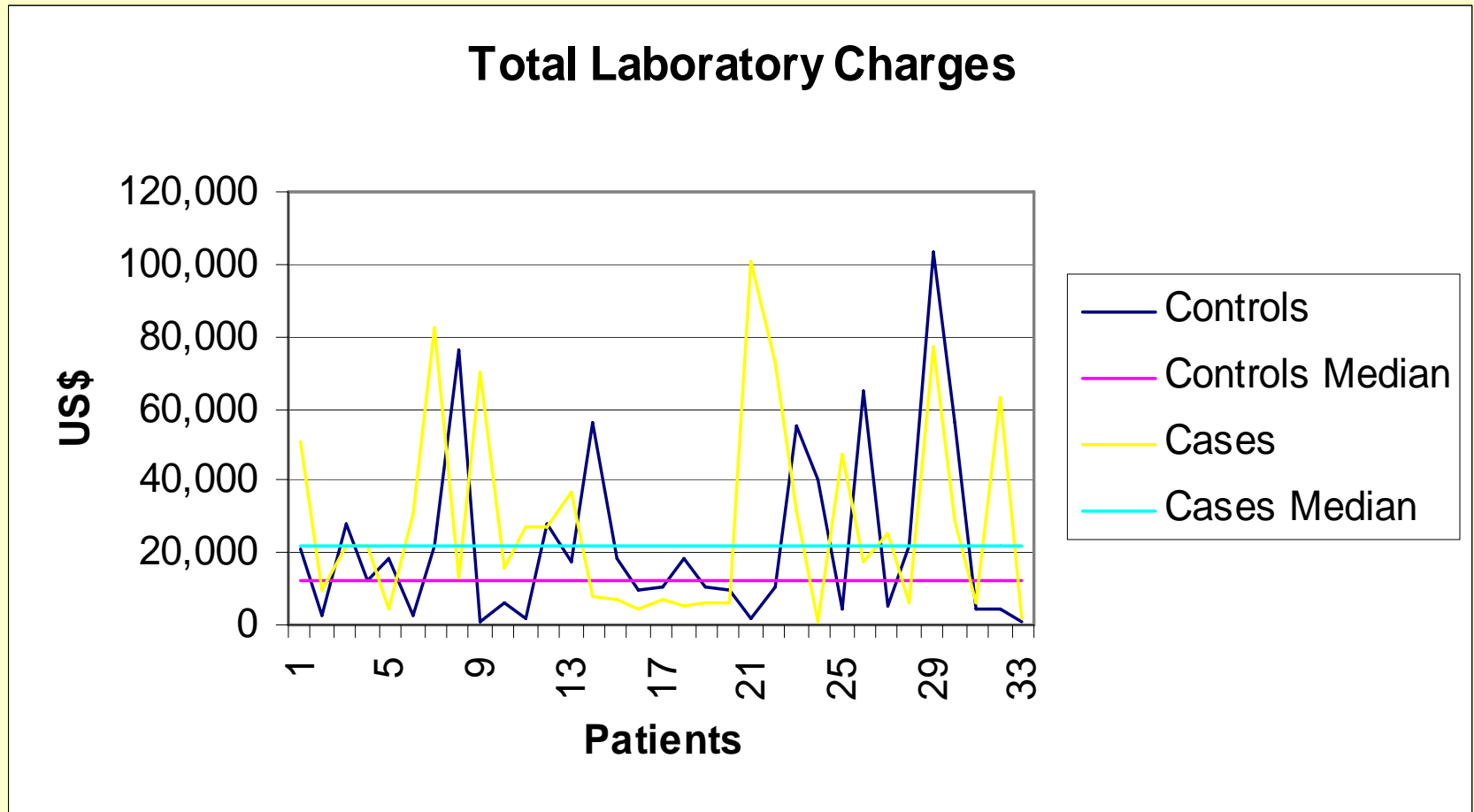
Comparison of LOS



Comparison of Total Hospital Charges

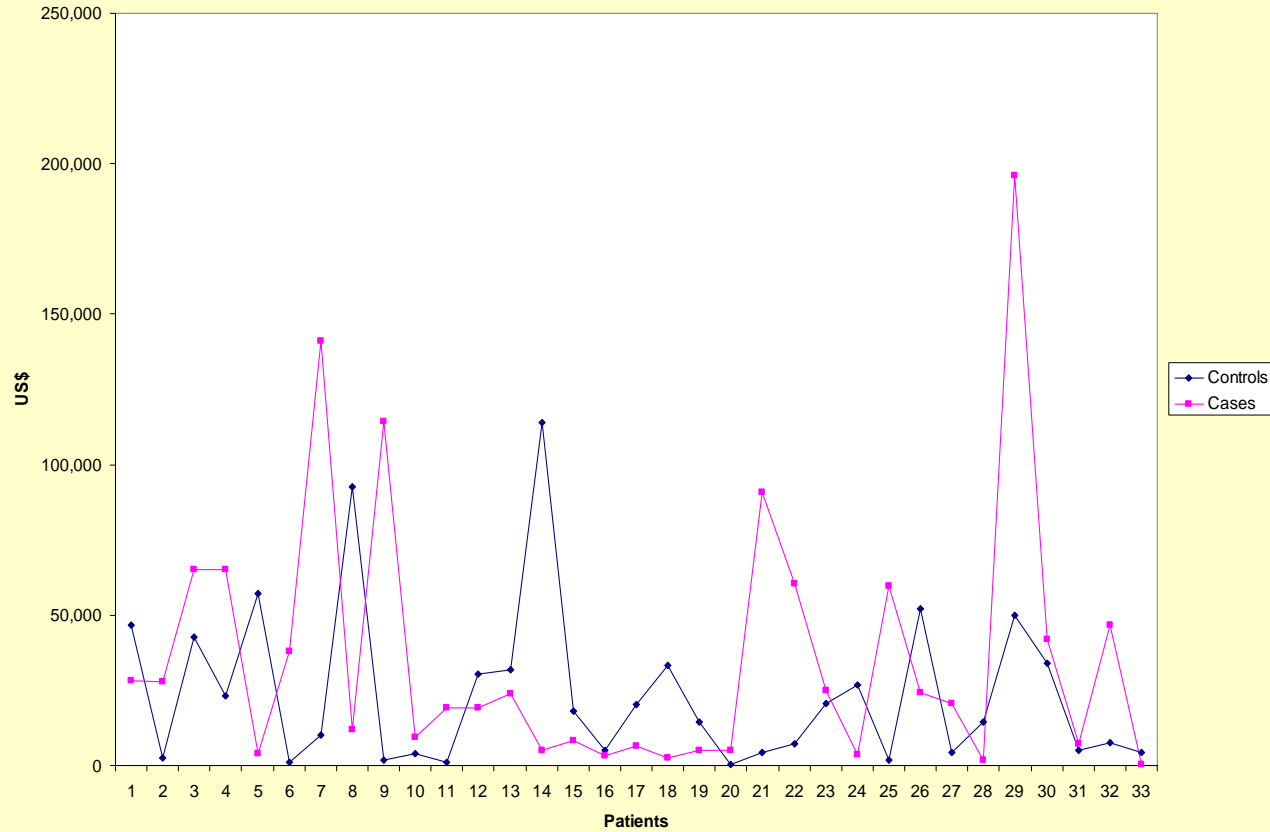


Comparison of Total Laboratory Charges



Comparison of Total Pharmacy Charges

Total Pharmacy Charges



Clinical Outcomes of Patients With Contaminated Blood Cultures

- Retrospective chart reviews were performed on a total of 60 patients: 30 controls (positive but not contaminated) and 30 cases (positive and deemed contaminated).
- Approximately 95% of all patients received IV broad spectrum antibiotics for longer than 3 days post-culture.
- Factors associated with lack of culture contamination: dedicated phlebotomist performed peripheral venipuncture, culture was obtained from a patient not located in an intensive care unit, blood was not obtained through aspiration from an indwelling catheter.

Blood Culture Contamination Rate Assessment

- Institutional results obtained in this project confirm previously published findings showing contamination of cultures is linked to negative institutional and patient outcomes.
- A significant factor affecting contamination rate is the type of personnel drawing the culture, which is dependent on organizational administrative decision-making.
- Based on the existence of consistent evidence linking contamination rates with measureable outcome metrics and the identification of actionable factors related to low contamination rates, blood culture contamination rate appears to be a good candidate laboratory performance measure.

Basic Project Findings & Preliminary Assessments

Specimen Identification Errors & Deficiencies

The major factor underlying all types of sentinel events is

Failure to Communicate

Joint Commission Data

Sentinel Event Frequencies

January 1, 1995 – May 31, 2006

- Wrong-site surgery 13.0%
- Delay in treatment 7.5%

One Root Cause For These Frequent Sentinel Events

- **Hand-offs of Misidentified or Deficiently Identified Surgical Specimens to Surgical Pathology Laboratories**
- **Misidentification:** Inaccurate or missing identification of patient specimen container or conflicting identification information on specimen container and requisition
- **Identification Deficiencies:** Misidentifications or lack of clinically important information on container and/or requisition necessary for optimum processing and examination of specimen (e.g., specimen date and time of collection).

Types of Harm Caused by Specimen Identification Errors

(incident reports, anecdotal evidence)

- Wrong site surgery
- Delays in diagnosis
- Inappropriate diagnostic or therapeutic procedures (appear to be rare)
- Unnecessary laboratory resource utilization associated with resolving error (tissue DNA testing)
- Inefficient laboratory workflow

Current State: Lack of Detailed Evidence Relating to Specimen Identification Errors & Deficiencies

- Surgical practice: No aggregated data measurement
- Surgical Pathology Practice: Aggregated data collected and descriptively analyzed primarily through the College of American Pathologists (CAP) QA Q-probes program
- Q-probes data critically limited by lack of standardized error definitions and data collection methods as well as sampling bias; **Reported error ranges are 1-6% of all accessioned specimens.**
- No detailed, systematically collected and analyzed information regarding specific types of identification errors or their impact on laboratories, clinical practices, or patients.

Method I

- Retrospective review (12 months) of anatomic pathology laboratory QA records: self-report of physician and non-physician health professionals
- Standardized error data collection form utilized
- Review performed at three(3) different anatomic pathology hospital-based laboratories

Method II

- A project, non-clinical staff member performed prospective direct observation as the error detection method.
- Direct observation was performed for three (3) separate 7-day periods of time by the same observer.

Key Variables

- Variables were recorded as either present or absent
- Presence of variables was recorded for both specimen container and requisition
- Patient full name, patient 2nd identifier, provider name, date and time of collection, brief description of specimen
- Additional variables on requisition: patient location, pertinent clinical information/history
- Additional information: mismatch, specimen rejection

Data Analysis

- Mean and median weekly frequencies and rates of deficiencies were calculated
- Inter-laboratory rates were compared, as well as intra-laboratory frequencies and rates using the two different methods of error detection

Results

	QA Reported	Direct Observation
Total # of cases accessioned	564	492
Total # of cases with errors	6	309
Total # of errors	7	377
error rate	1.1%	62.8%
errors/case	1.2	1.2

Results: Containers

	QA Reported	Direct Observation
2 nd Identification	0	82 (17%)
Date/time	0	20 (4.0%)
Brief description	0	4 (10%)
Mismatch	0	1 (0.2%)

Results:Requisitions

	QA Reported	Direct Observation
Physician name	2 (0.4%)	7(1.4%)
Date/time	0	6 (1.2%)
Brief description	0	137(29%)
Clinical information	0	76 (15%)

Impact of Identification Errors: Mean Turnaround Times

	Clinical Information Given	No Clinical Information Given
GU specimens	2.74 d	3.74 d
Bone/Soft Tissue	4.10 d	4.90 d

Specimen Identification Errors & Deficiencies Assessment

- Specimen identification errors currently are underreported as a result of laboratory staff self-reporting
- Direct observation by a non-participant observer reveals many more errors
- Based on current information, most of these errors result in near miss events due to laboratory staff work-arounds
- More information is needed to completely characterize the nature, extent, and clinical impact of specimen identification errors & deficiencies in both anatomic and clinical pathology laboratories before meaningful decision-making regarding its usefulness as a performance measure can be made.

Summary of Findings and Preliminary Assessment for TAT

- TAT for a targeted sample of surgical specimen types processed routinely (prostate core biopsies, breast core biopsies, partial or complete thyroidectomy, colorectal therapeutic resections for malignancy, lung biopsies) did not significantly impact time to treatment or LOS, even after performing outlier analysis.
- Immediate diagnostic information (TAT = minutes) did significantly impact time to treatment for patients having core biopsies at the one institution where routine touch preps of cores were performed.
- More data is needed for this metric; however, laboratory provision of immediate TAT where feasible and cost effective may be an effective performance measure.

Summary of Findings for Communication of K⁺ Critical Values

- At the institution examined, close to 100% of K⁺ critical values were being communicated by telephone to the patient's hospital location.
- Communication of critical values was followed in approximately 50% of cases by a change in patient management – something was done as a result of the communication. The other half of the communicated critical values were on patients for which the critical value was expected clinically, and the appropriate therapy was already scheduled (e.g. dialysis for patients with ESRD).
- A number of abnormal but not critical values were also phoned to patient hospital locations, most of which were followed by repeat testing. A small percentage of these repeat tests that were normal (2%) were performed prior to the regularly scheduled draw times for that patient, possibly representing unnecessary repeat tests.

Summary of Assessment for Communication of K+ Critical Values

- Although these findings need to be confirmed, there does not appear to be a significant quality gap in the communication of K+ critical values, significantly decreasing the usefulness of this metric as a laboratory performance measure.
- However, our findings also reveal potential inefficiencies in the current process that present an opportunity for further study and quality improvement.

Summary of POC Glucose Accuracy Findings and Preliminary Assessment

- At the one institution examined to date, 40-60% of the POC glucose measurements performed in both inpatient and outpatient settings were $> 20\%$ different from the laboratory value measured on a venous sample drawn < 30 minutes from the time the POC glucose was performed.
- The POC glucose measurements are being used for patient management.
- Additional qualitative and quantitative data is required before a valid and meaningful assessment of this metric may be performed.

Future Study and Discussion Questions

- Our results regarding surgical pathology TAT support the idea that when diagnostic information is made available to clinicians rapidly, a positive effect on patient management can occur. For which specimen types may immediate interpretation be feasible and cost-effective? Does a decreased time to treatment translate to improved patient outcomes? Are there process improvements in communication of results that would decrease TAT and improve clinical outcomes?

Future Study and Discussion Questions

- Although communication of K⁺ critical values appears to take place appropriately in the majority of cases, a large amount of inefficiency may remain in the system due to laboratory communication of critical values that are not clinically critical. What process changes could be made that would result in more specific communication of critical results and increase its potential usefulness as a laboratory performance measure?

Future Study and Discussion Questions

- What is (are) the best clinical outcome measures to examine with POC glucose results to test its usefulness as a laboratory performance measure?
- Potential examples: specific clinical management changes made in response to measured values, intra-operative glucose management needs, patient HgbA1c