

Point of Care Testing Compliance

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Learning Objectives

- Identify common compliance issues with POCT programs
- Discuss strategies to improve POCT compliance
- Describe one way to develop a POCT website using Microsoft Word

POCT Management is Complex

- Laboratory
 - One site
 - Limited instrumentation to perform bulk of testing
 - Limited staff, focused on same equipment daily
 - Staff trained in laboratory skills
- POCT
 - Dozens of sites, hundreds of devices and thousands of operators
 - Staff are clinically focused on patient not on equipment
 - Staff do not have laboratory training background

Baystate Health



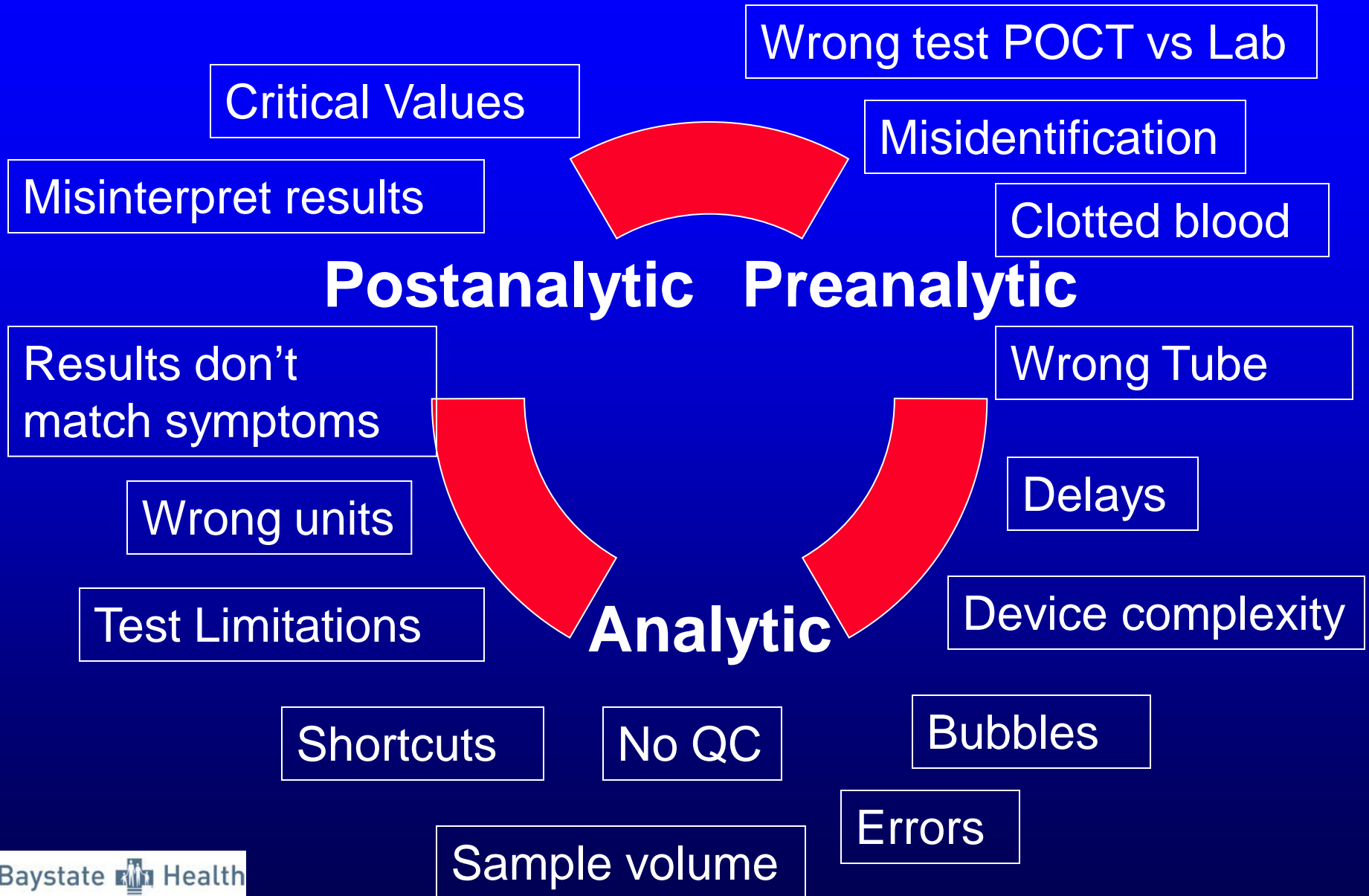
Baystate Health

- Leading provider of healthcare services in Western MA
- 8200 employees, Gross revenues >\$1.1 billion
- Baystate Medical Center - tertiary care
- Hybrid Academic/Private Practice - >1000 physicians
- 615 beds; 3rd largest acute care in NE
 - 4500 employees
 - 40,000 discharges/200,000 inpatient days (4.5 mean LOS)
 - 600,000 ambulatory visits
 - 142,000 emergency visits
- Western Campus Tufts School of Medicine 240 residents
- Franklin (96 beds) and Mary Lane (31 beds) Hospitals

Baystate Health System POCT

<u>METHOD</u>	<u>SITES</u>	<u>DEVICES</u>	<u>OPERATORS</u>
Abbott PCx	46	220	2200
UriSys 1100	5	4	100
Pyloritek	2		15
Quidel Pregnancy	14		80
Quidel Strep	9		50
Hemoccult	2		50
Nitrazine pH	9		50
HIV	2		20
i-Stat-1	10	130	800
DCA2000/Afinion	2	2	10
ITC Signature Elite ACT	7	15	80
ITC ProTime PT	8	20	75
PPM	8		10

Potential Sources of POCT Error



POCT Programs

- Set policy for QA/QC strategies to minimize risk of errors
- Establish quality goals
- Monitor compliance with POCT policies
- Document performance improvement

Performance Indicators

- Successful QC
 - QC documentation
 - Number of errors where wrong QC analyzed
 - QC statistics compared to hospital statistics
 - Percent of QC that fail
 - QC outliers with comment
 - Failed QC with appropriate action (patients not tested)
- Utilization (number of tests/site or device)
 - Tests billed vs tests purchased
 - Single lots of test and QC in use at any time
- Compliance
 - Untrained operators
 - Clerical errors or data entry errors
 - Medical record entry with reference ranges
 - Expired reagents
 - Refrigerator temperature monitored
 - Proficiency testing successful
 - Action plan response to site compliance deficiencies

APTU	1 QC outlier without a comment code.
Cardiac Cath	Ok. ACT pt volume = 223; Liquid QC volume = 36. 4 ACT Liquid QC fails/36 LQC tests = 11% fails.
CICU/PCU	1 QC outlier without a comment code. ID error rate = 1 PCx invalid patient ID/380 total tests = 0.2%.
CSC	1 QC outlier without a comment code.
Daly 4 Inf/Child	ID errors not decreasing: 1 PCx invalid patient ID/76 total tests = 1.3%.
Daly 5A	QC/reagents expired. Manager notified via e-mail 4/11/08. ID error rate = 3 PCx invalid patient ID/1496 total tests = 0.2%.
Daly 6A	Ok. ID error rate = 2 PCx invalid patient ID/1037 total tests = 0.19%.
Daly 6B	ID errors not decreasing: 7 PCx invalid patient ID/2212 total tests = 0.3%.

Common Compliance Issues

- ID errors – the patient ID entered into the glucose meter or other POCT device doesn't match active patient or matches wrong patient on download
- Daily refrigerator monitoring
- Performance and documentation of QC or QC exceptions and corrective actions
- Expired reagents of controls
- Site action plans and follow-up to compliance issues

Improving Compliance

- Self-management
- System Changes
- Communication
- Visibility and POCT representation on unit

Self-Management

- Every person plays a role and has responsibility in patient outcome
- POCT is part of patient care not an ancillary service
- Those involved in patient care have responsibility to perform and maintain POCT
- Promotes mutual respect and individual responsibility
- Philosophy sets lab as resource not dictator

Self-Management

- Lab can't hold everyone's hand, 24 hours a day
- Lab is a resource in setting hospital policy (together with nursing, physicians, etc)
- Lab knows the CLIA requirements and what needs to be done
- Nursing/Clinicians know how the test will be used in patient management
- Mutual trust that this policy will be fulfilled, it is a role of the employee's job
- Nursing not the lab is responsible for discipline when actions not followed.

POCT Policy

- Balance of all disciplines involved
- Remember CLIA'88 and accreditation agency regulations indicate what has to be done not how to do it
- Different nursing units have different workflow and operational aspects that can accommodate the regulations in different ways and still be compliant
- Institutional policies must allow nursing units to implement POCT in ways that fit their work, so policies and procedures must not be so restrictive as to lead to failure and noncompliance

Quality Control

- For many POCT devices, two levels of external liquid QC must be analyzed and documented every 24 hrs of patient testing
- Many ways this can be accomplished
 - Lab can send a MT to perform QC each day
 - Isn't compliant with spirit of law, shared responsibility
 - Units can schedule staff to rotate performance
 - Units can assign to one shift and rotate staff (periodically change shifts – 12 hour days easy to rotate requirement semi-annually)
 - Weekday outpatient clinics only need perform QC when open.
 - Other options possible provided nursing unit meets 2 levels every 24 hr and rotates staff.
- System change to devices with QC lockout features mandate the performance of QC at defined schedule and automatically document that QC was acceptable

Compliance

- When problems occur, often easier to blame an operator than the system for an error
- If we take note of the airline industry, most problems are not the cause of a person, but a weakness in the system that allowed the error to happen in the first place.
- Establish our POCT policies to prevent errors in the first place, and setup controls and monitors around weak steps that can't be engineered out of the testing process (like QC lockouts).

Critical Values

- CLIA and regulatory requirement to contact the ordering physician or clinician who can take action ASAP after critical result
- Some POCT require staff to repeat test or send confirmation to the lab – setup for noncompliance
- Our policy only indicates the various options for staff
 - Repeat the test on same/different device OR
 - Send a confirmatory venous sample to lab OR
 - Treat clinically as result matches clinical symptoms
- Communication doesn't need to be documented IF operator is ordering physician or if nurse who can take action
- All nursing TA's must document critical results like ALL POCT results using the electronic nursing notes in the EMR.
- System integrates critical results into routine operation

Clerical ID Errors

- ID errors – the patient ID entered into the glucose meter or other POCT device doesn't match active patient or matches wrong patient on download
Clerical ID entry errors monitored
- Initial goal 8 years ago was <5% errors, lowered 5 years ago to < 3%
- Blood gas analyzers set up for duplicate data entry to help with clerical errors
- CAP recommended zero tolerance
- Attempted implementing operator 3 strike rule

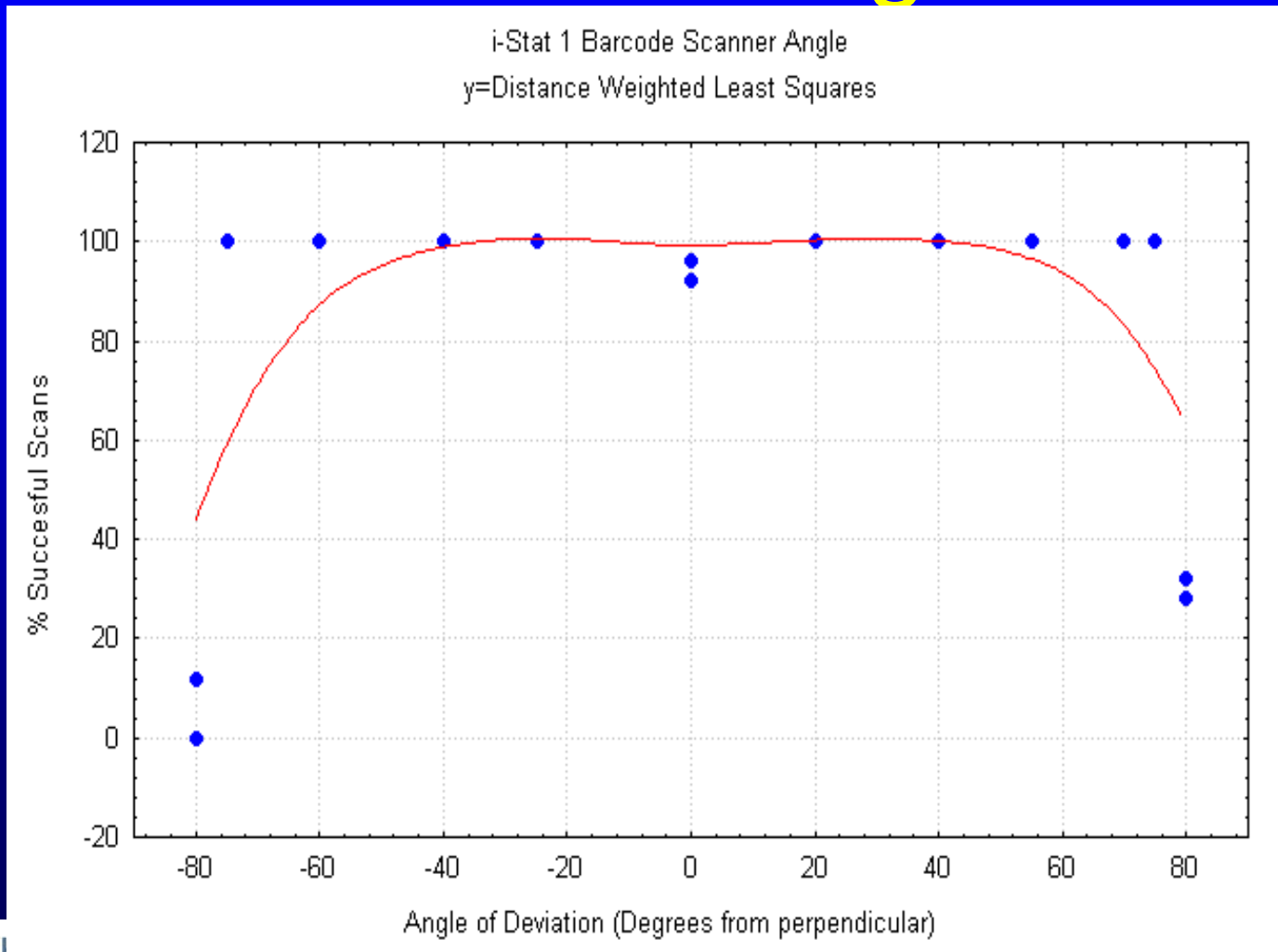
Clerical ID Errors

- Problem was a system problem
- We were requiring a 5 digit operator ID and 9 digit patient account number with every test
- Manual entry of 14 digits is source of errors
- Only means of achieving zero errors -
barcoding

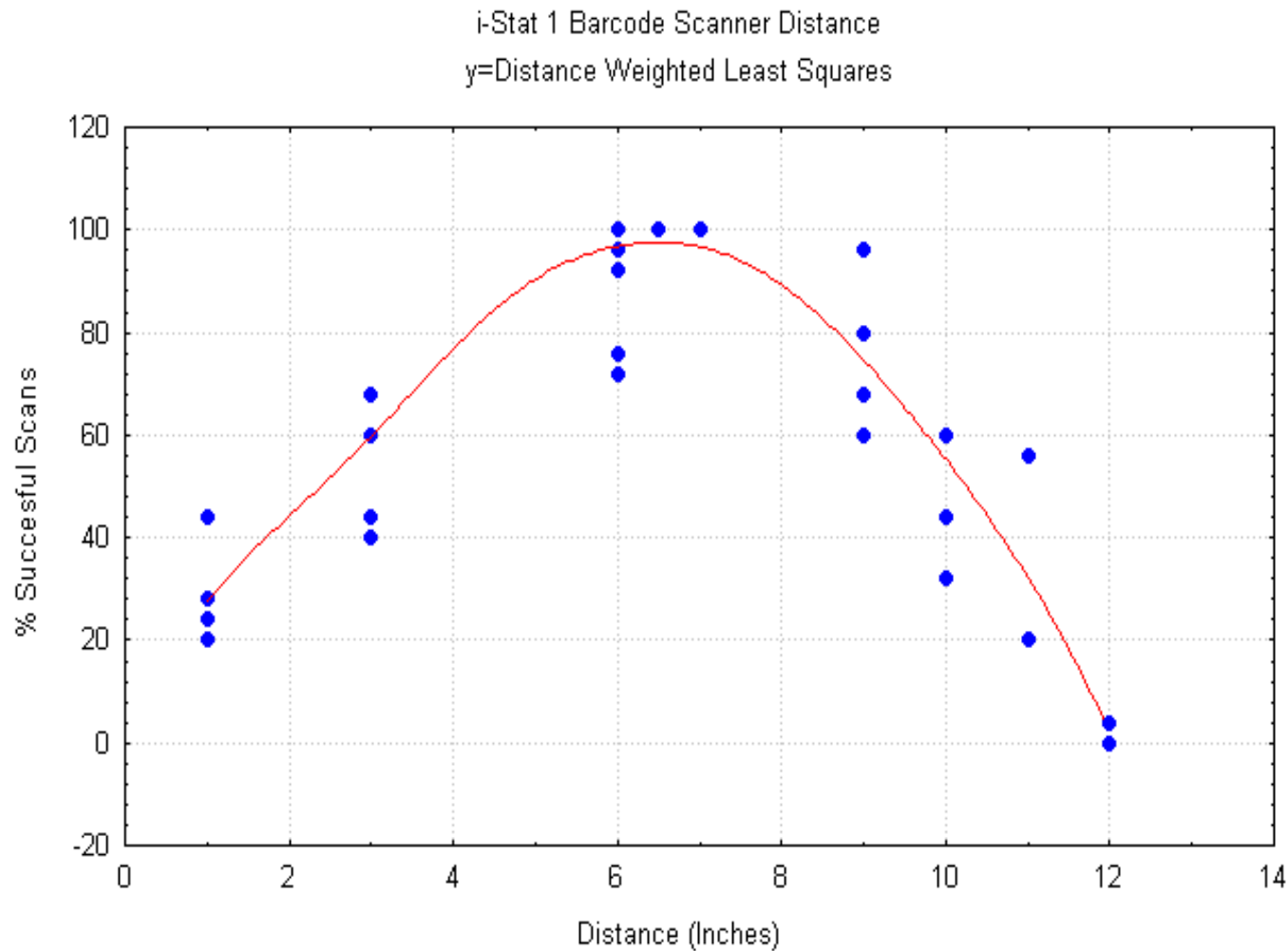
Patient ID Errors

- Barcoding patients reduced frequency of errors, but didn't reach zero errors:
 - Moved to thermal barcoded wristbands (durability)
 - Curved barcodes sometimes not readable
 - Continued manual entry of ID with errors
 - Wrong financial number – outpatient vs inpatient
 - Wrong patient – wristbanded with wrong ID
 - Unreadable - wristbands from other hospitals
 - 911 – testing unregistered patients without follow-up
- Led to continued ID errors (50 – 100 a month)

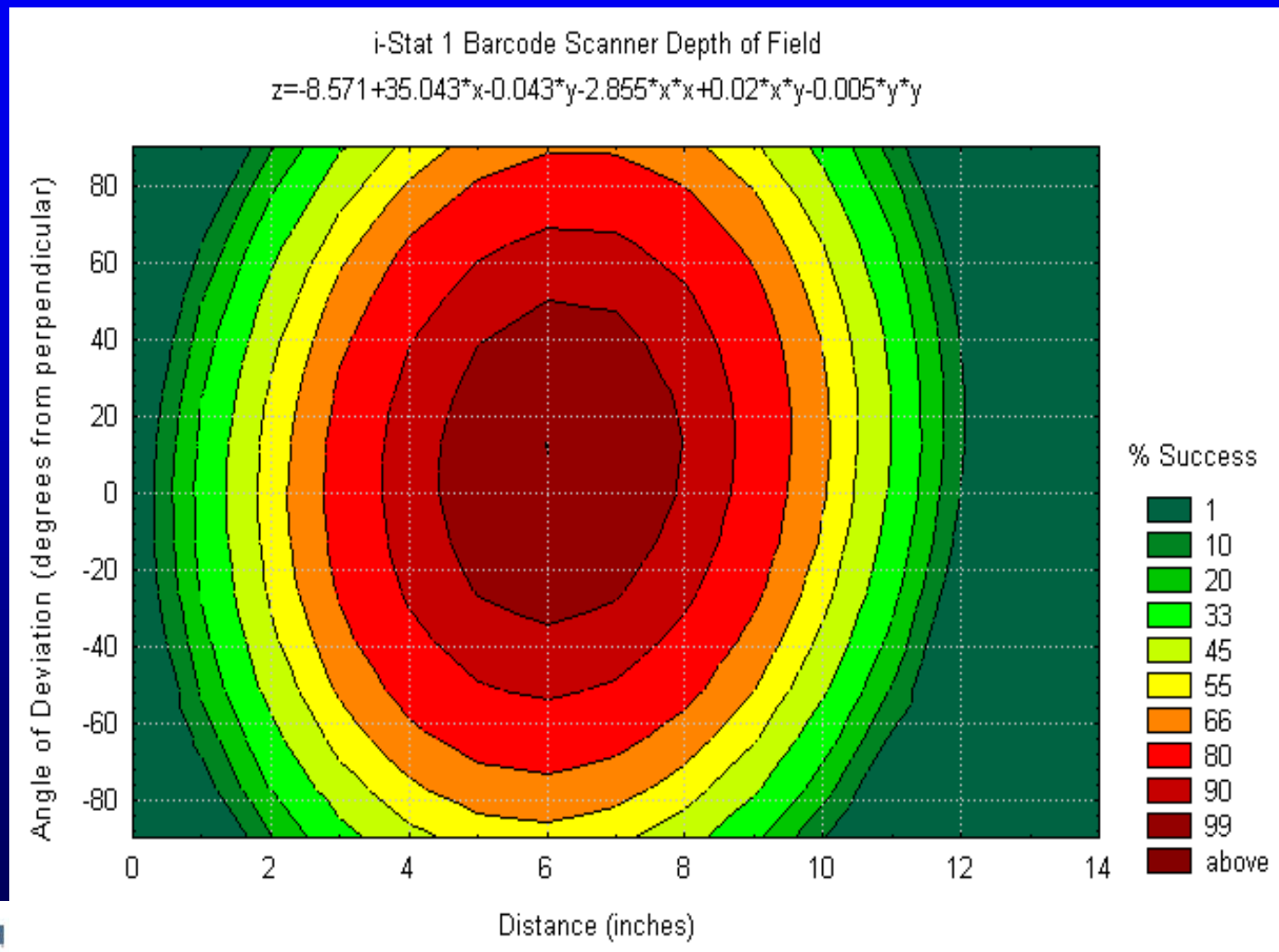
Scanner Angle



Scanner Distance



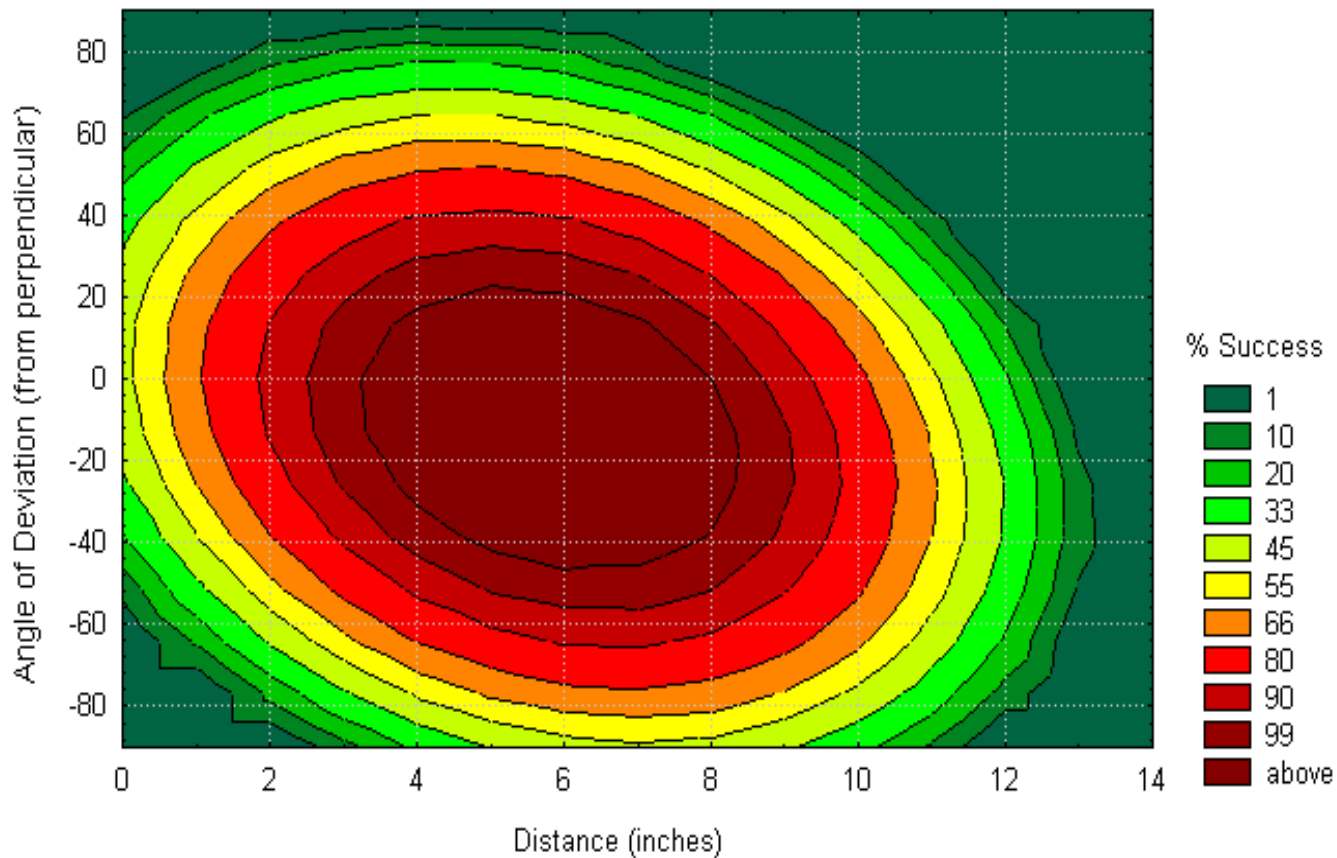
Scanner Depth of Field



Scanner Depth of Field

Abbott PCx Glucose Meter Barcode Scanner Depth of Field

$$z=42.042+24.86*x+0.12*y-2.215*x*x-0.071*x*y-0.012*y*y$$



Bar Code Bands are HERE!!

Tips:

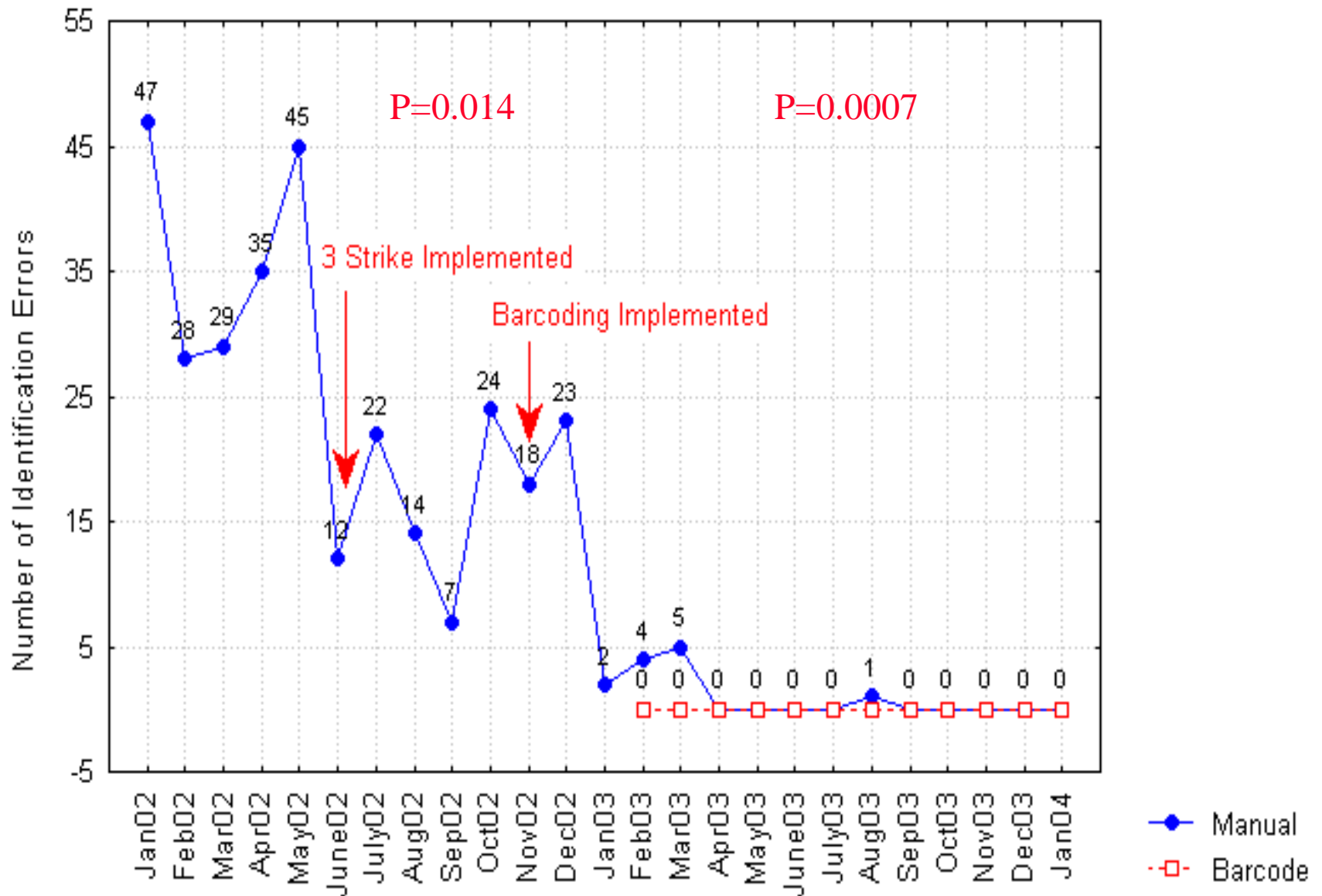
1. Scan 6 inches away.
2. Keep your fingers out of the scan area.



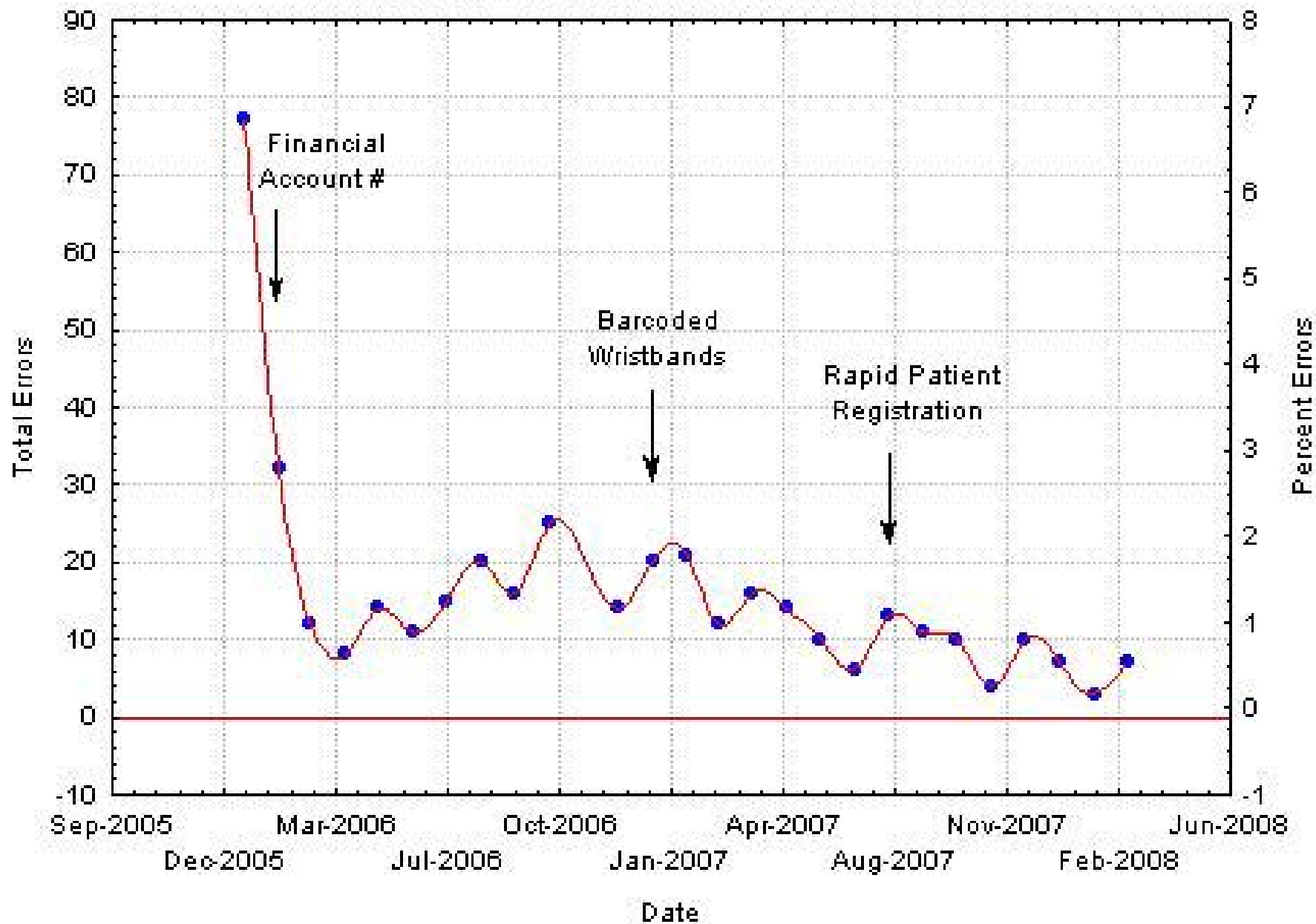
3. When your patients bar code has been accepted the machine will show the # briefly then you will see this screen:



Glucose Meter Identification Errors



Emergency Department Total Glucose Meter ID Errors



Patient ID Errors

- Joint Commission and CAP patient safety require at least 2 unique patient identifiers with each test
- Implemented glucose meter with positive patient ID
- Meter captures patient identifiers from Admissions/Discharge Transfers data
- Active confirmation of barcode scanned financial # by displaying patient name and requiring operator to enter birthdate year
- Positive patient ID has addressed our residual ID errors
 - No more wrong financial #, episode #, wrong pt wristbands or bands from other hospitals
 - Continue to have issues with 911 testing of unregistered patients without follow-up (1 or 2 a month from ED only)

ED Challenges

- POCT staff monthly site inspections
- ED low compliance with key benchmarks
 - Frequent POCT identification errors
 - Missed days for temperature monitoring
 - Outdated reagents/controls
 - Failure to comment failed QC, out of range result communication, etc.
 - Poor follow-up and action plans
 - Leadership claims to be different than other units
- POCT not unique – similar nursing round results

The ED Environment

- Acute care – need for rapid response
- Level 1 trauma center
- High staff turnover and outside coverage
 - Lose administrative continuity
 - Frequent staff reeducation of basics
 - Less ownership than other hospital sites

ED Design Changes

- Two champions of POCT on unit helped motivate staff re: POCT challenges
- This staff provided visibility of POCT on unit and offered ongoing liaison for compliance
- Staff tired of same issues reoccurring month after month
- Collected a team of TA operators
- Redesigned the self-inspection form
 - Delegated tasks
 - Assigned POCT responsibilities to all shifts
 - 4 team leads all responsible wkly compliance

Baystate Health Systems/Emergency Department POCT Site Inspection Report

Signature:

Date:

Glucose	Review OK	Comments or Actions
QC marked with Exp. Date		

The QC bottles are good until manufacturers outdate or for 90 days once opened. There should be one set opened and in the plastic box in the lab room.

Urinalysis	Review OK	Comments or Actions
Reagents dated and not expired?		
Caps tight on the multistix bottles?		
Correct QC on log?		
Correct QC ranges noted on log?		
QC performed each day on all open bottles?		
QC performed when a new bottle is opened?		
QC failures repeated with remedial action plan?		
Daily and weekly maintenance performed on Clinitek 50?		
Temperature chart complete with action taken when out of range?		
Patient results logged? MR # and initials on tape?		
Patient results charted with reference ranges?		

Urine controls are to be kept in the refrigerator. They are good until manufacturers outdate. They are good at room temperature for 30 days.

Each open bottle must have QC done.

Multistix bottles are to be dated and initialed when opened. They are good until manufacturers outdate unless the cap is left too loose or off.

ED Outcomes

- Dramatic shift in compliance observed
- TA ownership of all staff
 - New self-inspection delineated responsibility
 - Defined ownership and job descriptions
 - Enhanced awareness of QC/exp dates/temp
- Staff turnover – planned for continuity
- Enhanced follow-up with action plans
- POCT ID errors down –
 - Staff weren't waiting for pt registration prior to POCT
 - Using downtime 999 codes w/o follow-up in 24hr
 - TA team worked with the ED reg staff to get pts registered and banded faster upon admission
 - Key – a process change led to enhanced outcomes

Concluding Thoughts

- POCT compliance reflects successful optimization of POCT quality
- Compliance requires policies that allow individual flexibility in implementation without being too stringent in enforcing a single view
- Some strategies to improve program compliance include:
 - Promoting self-management and role of each staff in patient care
 - Implementing system changes to compliance issues (rather than blaming the operator)
 - Communication of policies, program goals and expectations
 - Ongoing visibility on the nursing unit through lab visits and POCT contacts on the unit.

POCT as Technology

For a list of all the ways that technology has failed to improve the quality of life, please press three...

Alice Kahn