Today's Featured Speaker

James H. Nichols, Ph.D., DABCC, FACB

is a Professor of Pathology at Tufts University School of Medicine and Medical Director, Clinical Chemistry for Baystate Health in Springfield, MA. Jim received his B.A. in General Biology/Premedicine from Revelle College, University of California at San Diego. He went on to complete a Masters and Doctorate in Biochemistry from the University of Illinois, Urbana-Champaign. Dr. Nichols was a fellow in the Postdoctoral Training Program in Clinical Chemistry at the Mayo Clinic, Rochester, MN.

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Point of Care Testing Compliance

James H. Nichols, PhD, DABCC, FACB

Professor of Pathology

Tufts University School of Medicine

Medical Director, Clinical Chemistry

Baystate Health

james.nichols@baystatehealth.org

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TUFTS UNIVERSITY

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

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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
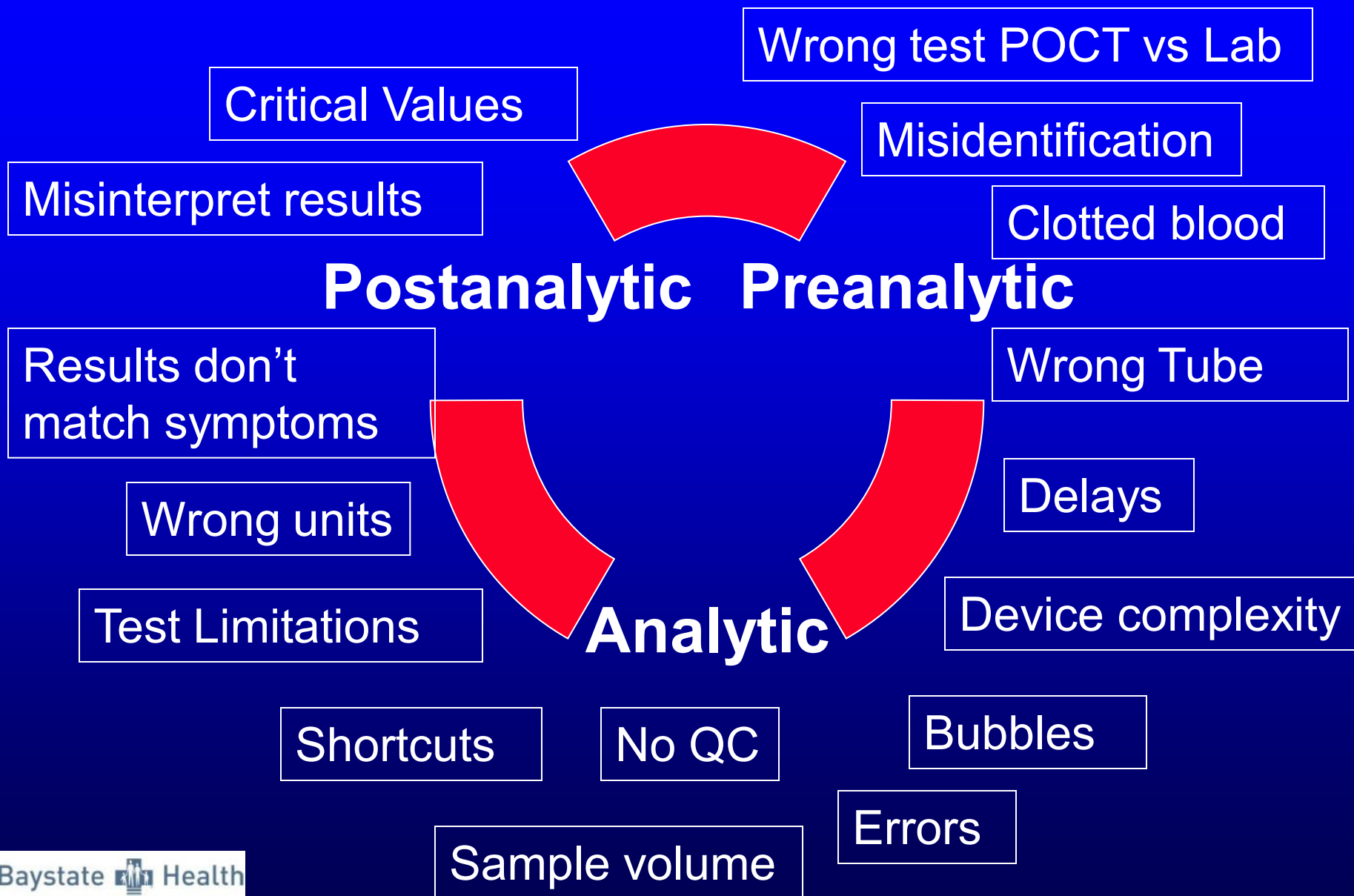 - Staff do not have laboratory training background

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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

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Baystate Health System POCT

METHOD	SITES	DEVICES	OPERATORS
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

Wrong test POCT vs Lab

Critical Values

Misidentification

Misinterpret results

Clotted blood

Postanalytic Preanalytic

Results don't match symptoms

Wrong Tube

Wrong units

Delays

Test Limitations

Device complexity

Analytic

Shortcuts

No QC

Bubbles

Errors

Sample volume

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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

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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%.

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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

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Improving Compliance

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

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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

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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

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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

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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

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Barcoding

- In practice, one of the more challenging projects to implement in an institution:
  - Devices only read specific barcode languages
  - Wristbands vary in durability
  - Ink isn't permanent (thermal vs inkjet)
  - Devices don't require barcode entry!
  - Try to engineer around manual entry by adding special characters or digits to ID
  - These work-arounds lengthen the barcode and increase read failure if barcode not flat on wrist.
  - How to print? Wristbands only or labels that an operator can stick onto device or paper chart? What about neonates?

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Barcoding

- During implementation, operators continued to manually enter patient IDs due to the scanner failing on the 1st attempt

- An investigation was conducted into why scanners fail

- i-Stat scanners failed more frequently than glucose

- Operator interaction with the POCT device was the primary determinant in scanner failure

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Scanner Angle

i-Stat 1 Barcode Scanner Angle

y=Distance Weighted Least Squares

Scanner Distance

i-Stat 1 Barcode Scanner Distance
y=Distance Weighted Least Squares
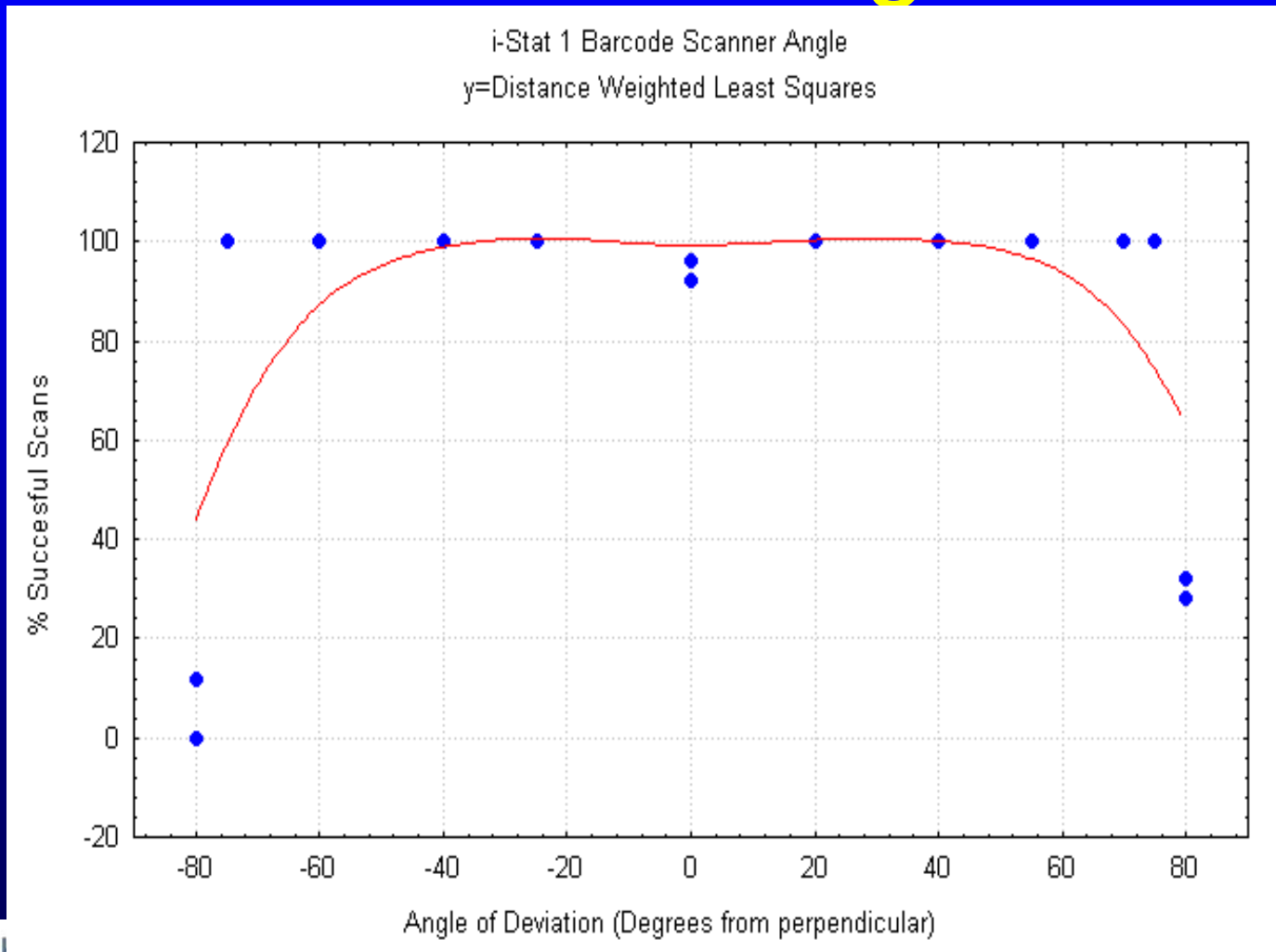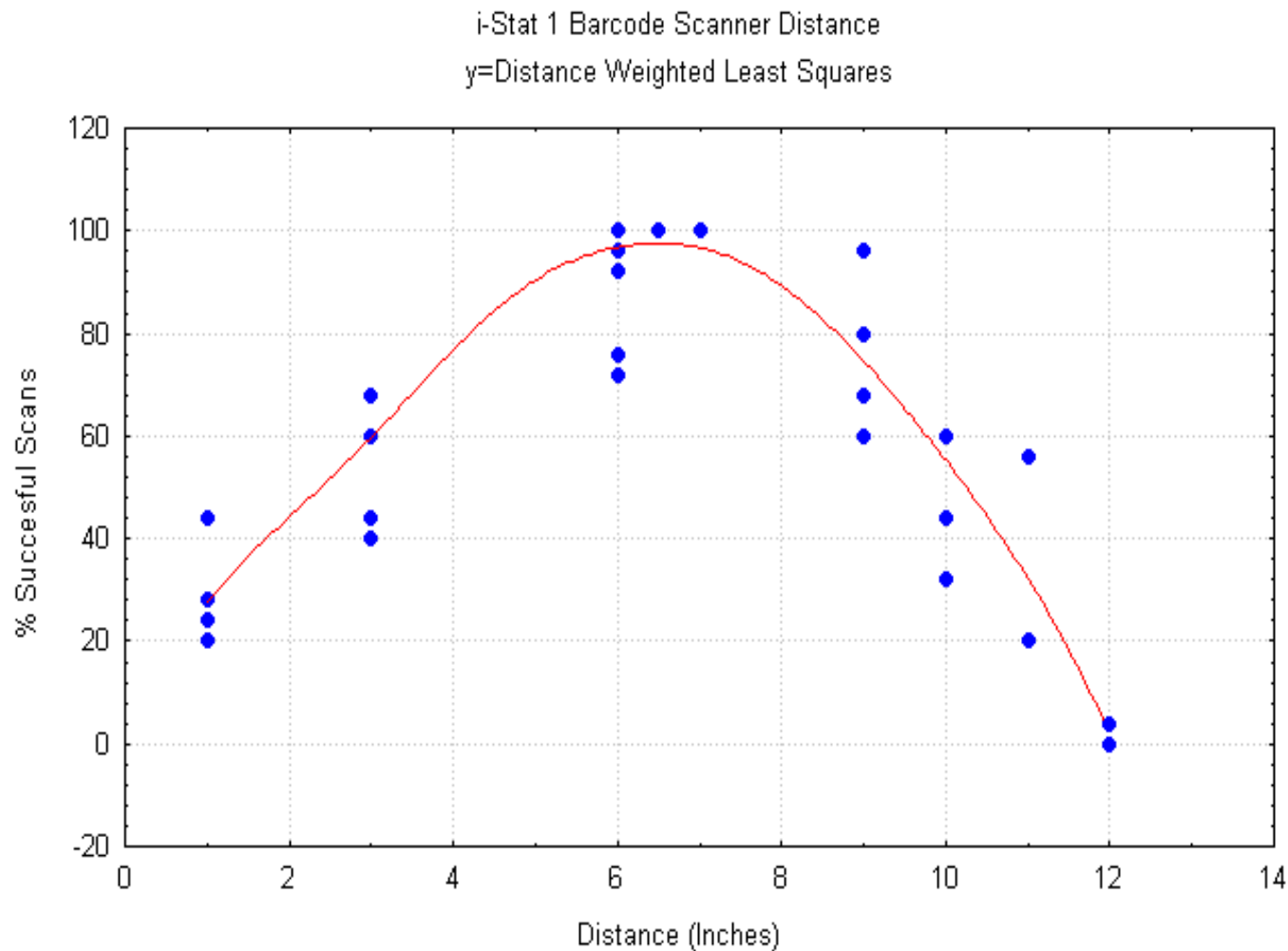
Scanner Depth of Field

i-Stat 1 Barcode Scanner Depth of Field

$$z=-8.571+35.043*x-0.043*y-2.855*x*x+0.02*x*y-0.005*y*y$$

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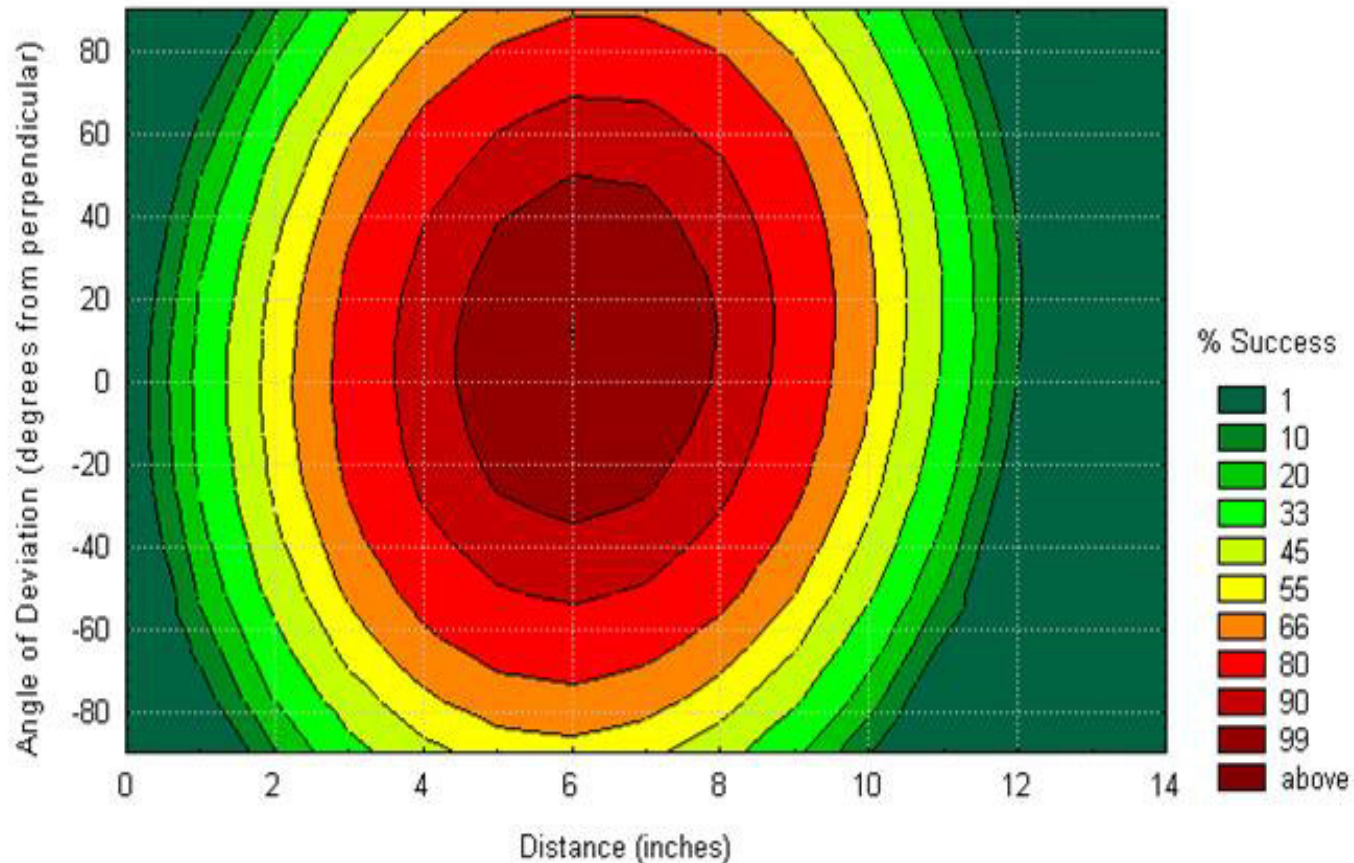
Scanner Depth of Field

Abbott PCx Glucose Meter Barcode Scanner Depth of Field

$z=42.042+24.86*x+0.12*y-2.215*x*x-0.071*x*y-0.012*y*y$
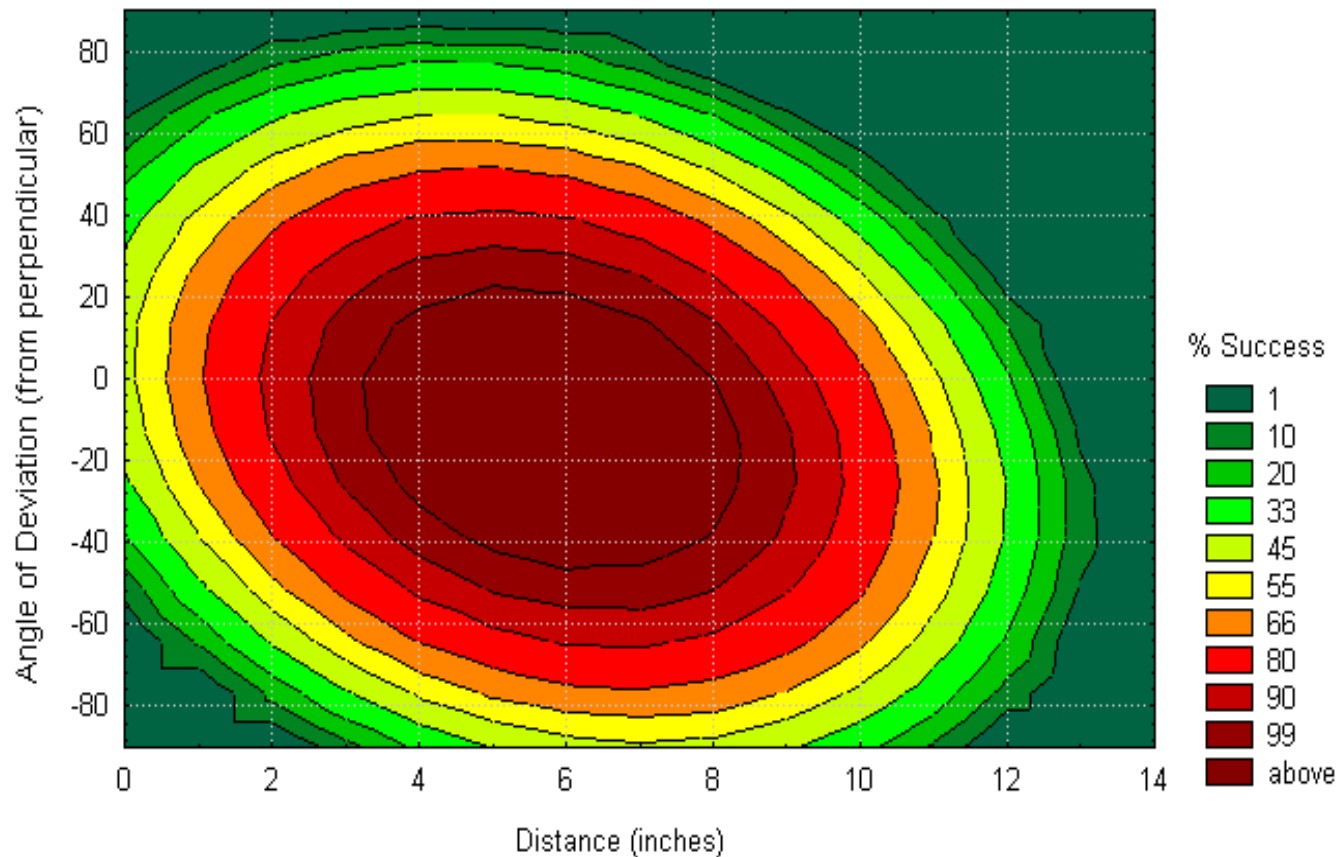
Bar Code Bands are HERE!!

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
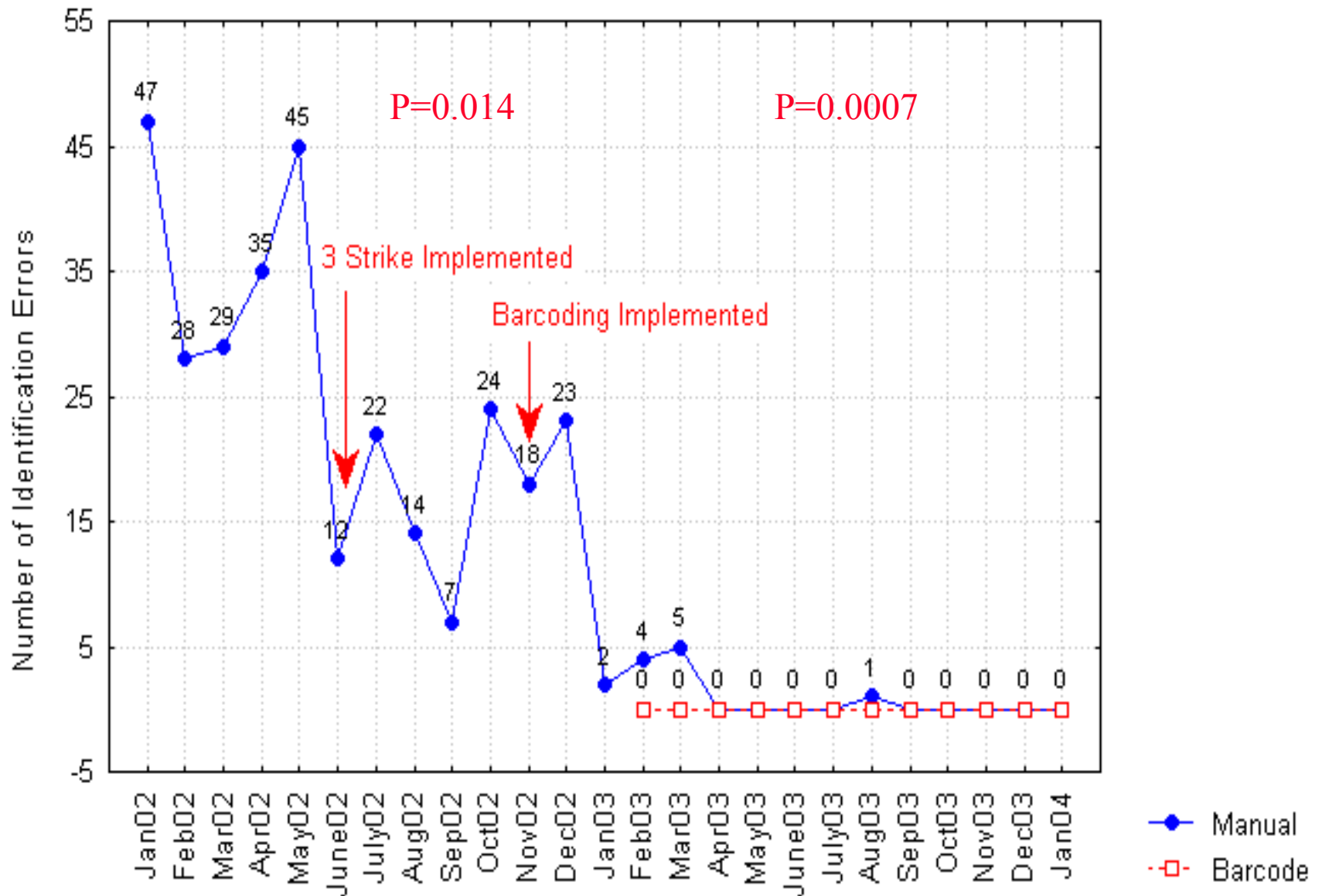
Emergency Department Total Glucose Meter ID Errors

Financial Account #

Barcoded Wristbands

Rapid Patient Registration
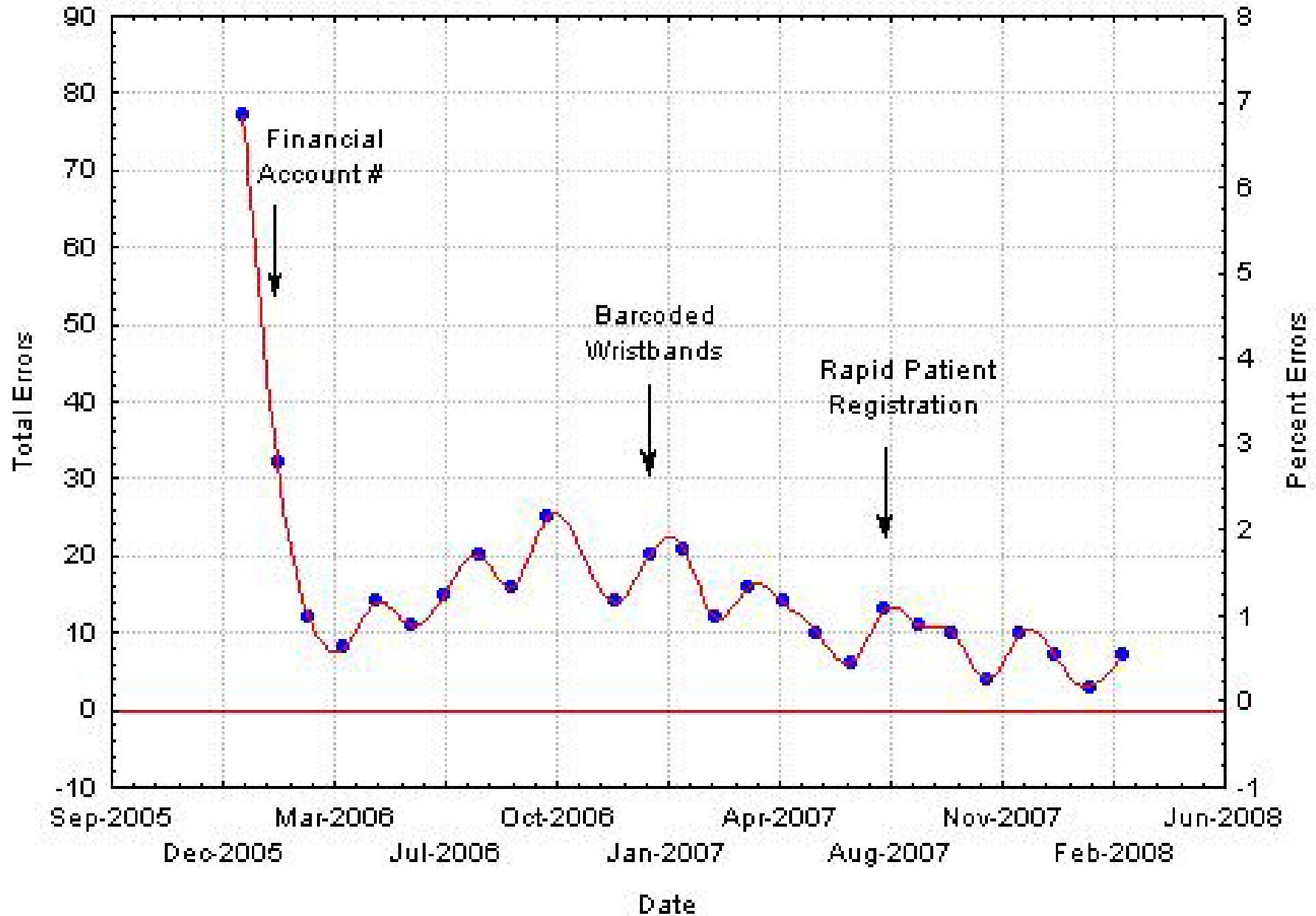
New Glucose Meter

- Implemented new glucose meter, Abbott Xceed Pro
  - Improved barcode scanner – fewer scanning errors
  - Positive patient ID
  - ADT feed, posts patient name when ID scanned or manually entered
  - Must manually confirm ID by entering patient birth date
- Few patient ID errors post implementation
  - Selection of outpatient episode for inpatient care
  - ED downtime "911" codes without follow-up in 24 hr
- Change in system has taken us from >5% ID errors to <5 a month throughout the health system

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Baystate Communication

- POCT website developed with all of the tools necessary to manage POCT

- POCT sites have necessary resources, and have no one to blame but themselves for not succeeding

- Separates the lab from being responsible and in the middle of a nursing care process. Lab is available, nursing is responsible

Building a POCT Website

- Many ways to accomplish
- Use IT resources to design to specification (most institutions don't have staff availability)
- Recruit Lab Information Services staff to build the website (particularly if lab policies and procedures going paperless)
- Build it yourself

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Website Tools

- Website software
  - Website Studio 4.0
  - Adobe Dreamweaver CS4
  - Photon FX Easy Website Pro
  - EZGenerator
  - Web Page Maker
  - Site Spinner
  - WebEasy Professional
  - Flash Website Builder
- Facebook, Twitter, Blogs
- Google free software – Google Page Creator

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POCT Website 101

- I, like most medical professionals have no web experience nor available staff resources from IT to build a site for me

- POCT could budget for resources, but the wait time is long for IT projects and expensive even if we could get budget to build a site

- Build it myself using existing software (Word)

Building a POCT Website

- .html is the universal webpage file extension
- Microsoft word has templates and can walk you through a short tutorial. Once done save the file as an .html rather than .doc
  - Open Microsoft word
  - Load a template
  - Fill in the page content
  - Save the file as .html

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Normal   Times New Roman   12

AutoShapes

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Address | http://office.microsoft.com/en-us/templates/results.aspx?qu=website&av=TPL000 | Go   Links »

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| **Home** | **Products** | **Help and How-to** | **Downloads** | **Clip Art** | **Templates** | **Microsoft Office Live** |

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E-mail newsletter
Templates > Template categories > More categories > E-mails
Version: Word 97 or later
Downloads: 393381
Rating: ★★★★☆ (4167 votes)

Business e-mail newsletter (2-col., uneven, w/hyperlinks)
Templates > Template categories > More categories > E-mails
Version: Word 97 or later
Downloads: 266360
Rating: ★★★★☆ (4841 votes)

Done

Internet

ISSUE | VOLUME | YEAR

Financial focus

ADDRESSING THE NEEDS OF INDIVIDUAL INVESTORS AND PLANTING THE SEEDS FOR A SECURE FUTURE.

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Helping you achieve your financial goals

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Microphone | Tools

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Normal 75% Read

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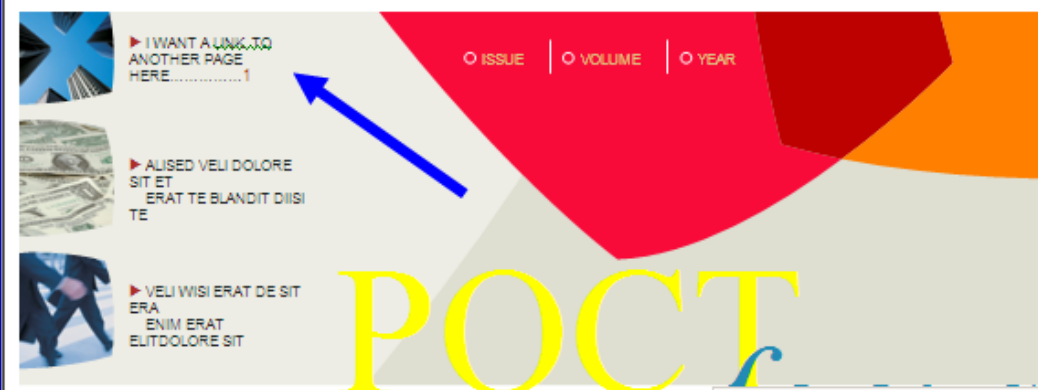► VELI WISI ERAT DE SIT ERA
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POCT

ADDRESSING THE NEEDS OF NURSING STAFF WITHIN OUT HOSPITAL

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Helping you achieve your financial goals

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Link to:

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Look in: Website2

Existing File or Web Page

Current Folder

Doc2_files
POCT
POCT Website Documents
Point of Care Testing
~$Doc2.htm
Doc2.htm

Place in This Document

Browsed Pages

Create New Document

Recent Files

Bookmark...

Target Frame...

E-mail Address

Address: Doc2.htm

OK   Cancel

Draw AutoShapes

Page   Sec   At   Ln   Col   REC TRK EXT OVR English (Uni)

Start | Inbox - Microsoft ... | NYC Webinar 090... | C:\Documents and... | C:\Documents and... | Doc2.htm - Micr... | 2:54 PM

Building a POCT Website

- Basic pages with a few links are easy to build and manage
- As links grow, number of files to manage becomes a challenge
- Updating one page, can lose links tied to that page, so need to check all links on a page after each revision
- This is where the task of maintaining a website becomes resource intensive
- Recommend to keep all files with associated links, pictures, etc. in a separate folder on your hard-drive, the back-up, working copy
- Simple task to copy this folder to the "live" website server

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POCT DYI Website

- Obviously, this is not as professional nor does the website have as many features as a professionally developed site
- Website can be built in a few hours from existing files and educational materials
- Only requires IT assistance to provide space on hospital server and a link to your POCT content

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Baystate Health

eWorkplace Physician

| Applications | Departments | Learning Center | My Baystate | Policies |

Welcome James Nichols   **Home**

Policies

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Advanced

A B C D E F G H I J K L M N O P Q R S T U V W X Y Z

A
Academic Affairs Policies
Acute Stroke Packet
Administrative Policies [BFMC]
Anesthesia [BMC]
Anesthesia [Preadmission Testing]

B
Baystate Medical Practices
Baystate Practice Guidelines
Blood and Body Substance Exposure Protocols [BFMC]

C
Children's Hospital
Clinical Ops Manual [BMC]
Contract Guidelines [BH]
Corporate Policy Manual [BH]
Critical Care

D
Division of Midwifery and Community Health Practice Agreement

E
Employee Guide to Emergency & Disaster Management

Trusted sites

M
Materials Management
Medical Staff Bylaws

N
Nursing Manuals
Nutrition Care Manual
Nutrition Care Manual Addendum

O
OB Policy Manual
Operations Manual [BMLH]

P
Patient Privacy [HIPAA] Policies
Perioperative Services
Physician Billing Office
Point of Care Testing

R
Radionuclide Radiation Safety Policies
Respiratory Protocols
Risk Management Principals for Clinics and Office Practices

S
Stroke Packet for tPA Administration

T
tPA for Ischemic Stroke
Transfusion Manual

W
WETU

X
X-Ray Radiation Safety Policies

Address http://bhsiisvap01/PointOfCare/Website/Point%20of%20Care%20Testing/default.htm

Point of Care Testing

POCT Home

Policies and Procedures

Training

Quality Improvement

POCT Committee

CAP Checklist

POCT Contacts

Back to BHS Intranet

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Point of Care Testing

Last updated: May 26, 2009

Contents

- What's New in POCT?
- The Department of Pathology POCT Staff
- Contact Information

Welcome

Welcome to the   Point-of-Care Testing (POCT) website. This site is designed to provide you the tools to manage your POCT program. Staff will find current policies and procedures, training forms, quality improvement scores for individual sites and guidance to manage their POCT program. Unit POCT contacts, nurse managers and directors are encouraged to visit this site frequently to keep up-to-date with the latest developments affecting their POCT.

Mission

The Point-of-Care Testing program supports the Baystate Health System mission for premier patient care by providing quality, rapid diagnostic testing at the site of patient

Point of Care Testing

POCT Home

Policies and Procedures

Training

Quality Improvement

POCT Committee

CAP Checklist

POCT Contacts

Back to BHS Intranet

Policies and Procedures
Last Updated: May 26, 2009

These are the current Policies and Procedures for POCT with the latest revision date. Hard copies can be printed to update the medical unit POCT Procedure Manuals at least annually.

Calibration AMR Verification for PCx and iSTAT POCT [reviewed 11/5/2008]

HemaPrompt (Fecal Occult Blood) [reviewed 11/5/2008]

Hemochron Signature Elite (ACT-LR/ACT+) [reviewed 10/7/2008]

i-Stat 1 Testing Procedure [updated 12/17/2008]
     i-Stat 1 Glucose Fact Sheet [updated 2/26/2004]
     i-Stat 1 or PCx: Which Glucose is Right for My Patient? [updated 12/02]

Macroscopic Urinalysis Dipstick Chemistrip 10MD [reviewed 6/4/2008]

Macroscopic Urinalysis (UriSys 1100) Chemistrip 10MD [reviewed 6/6/2008]

Macroscopic Urinalysis Visual Dipstick [reviewed 11/5/2008]

pH Paper/Nitrazine Paper [reviewed 10/7/2008]
     pH Paper QC Log [updated 1/2/2003]

Pregnancy (Quidel QuickVue) Urine hCG Test [reviewed 11/5/2008]

Proficiency Testing (POCT) [reviewed 11/5/2008]

Fern Test [reviewed 10/7/2008]

Processing of KOH Preparations [reviewed 10/7/2008]

Identified as a Category I
Task as defined by the
U.S Department of Labor.

Adopted: 6/21/94	Approved by:		Date:
Revised and Effective: 2/4/00; 5/3/01; 3/14/02; 3/27/03; 3/23/04; 5/1/05; 7/6/05; 4/21/06; 9/11/06; 3/5/07; 11/5/07; 12/17/08	Medical Director: James H. Nichols, Ph.D., DABCC, FACB		
Reviewed:	Proofread by: Janet Galvin, MLT, ASCP, POCT		Date:
Reviewed:			
Reviewed:	Prepared (Revised) by: Claudia Chiapuzzi MT, ASCP, POCT		Date:
Reviewed:			

Supercedes: 11/5/07 version

Baystate Medical Center
i-STAT Testing Procedure

I.   **Purpose**
The i-STAT 1 analyzer is intended for use with i-STAT cartridges for in vitro quantification of various analytes in whole blood and with the Abbott MediSense® Precision PCx™ Blood Glucose Test Strip for the in vitro quantification of glucose in whole blood. The system incorporates a comprehensive group of components to perform blood analysis at the point of care. A portable hand-held analyzer, a cartridge with required tests and up to 95 µL of blood will provide quantitative test results for blood gas and chemistry tests within 2 minutes. Glucose results are available from the Precision PCx Blood Glucose Test Strip in as little as 20 seconds on the hand-held analyzer.

II. **Principle**
   a. i-STAT Test Cartridges
       Sodium, potassium, chloride, ionized calcium, pH and pCO_2 are measured by direct ion-selective electrode potentiometry. In the calculation of results for sodium, potassium, chloride and urea, concentration is related to potential through the Nernst equation.

POCT Website Afterthoughts

- Protect your content
  - Use .pdf versions or copy protected word docs
  - Only allow access behind your institutional firewalls
  - Get IS involved in serving your content
  - Becomes important with separate physician offices/hospitals under separate CLIA just adopting your policies

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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

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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

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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

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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

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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.

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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

Baystate ⚕ Health
Springfield, MA 01199