

POCT in the Emergency Department: How can you save lives if you have inaccurate information?

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Learning Objectives

- Explain why POCT results in the ED must be of the highest quality
- Explain how a risk management assessment process can guide development and prioritization of processes needed to assure accurate Emergency Department (ED) POCT results

POCT in the ED – Lecture outline

- Background - POCT experiences with two EDs
 - “A Tale of Two Cities”
 - San Francisco General Hospital (SFGH)
 - Alameda County Medical Center/Highland General Hospital (ACMC/HGH)
 - “Two tales in One City”
 - ACMC/HGH
 - Case controlled studies
- Recommendations for quality POCT in the ED
 - Applied risk management

Why do you need POCT in the ED?

- Rapid and correct intervention for clinical conditions diagnosable with a lab test
- Highest quality test result required
 - Test result must always be correct, because
 - Action will be taken immediately based on test result, and
 - If incorrect action taken based on incorrect test result
 - Potential adverse effect on patient (harm)

Important things to remember

- All laboratory testing under the oversight of the Laboratory Director
 - JCAHO “single standard of care”
 - Independent lab license for ED irrelevant
 - Laboratory Director personally responsible if testing non-compliant
 - Medical license - ≤ 2 year suspension from directing any laboratory
 - Monetary penalties if fraud an issue
 - Penalties can be levied ($\leq 3x$ charges)

Important things to remember

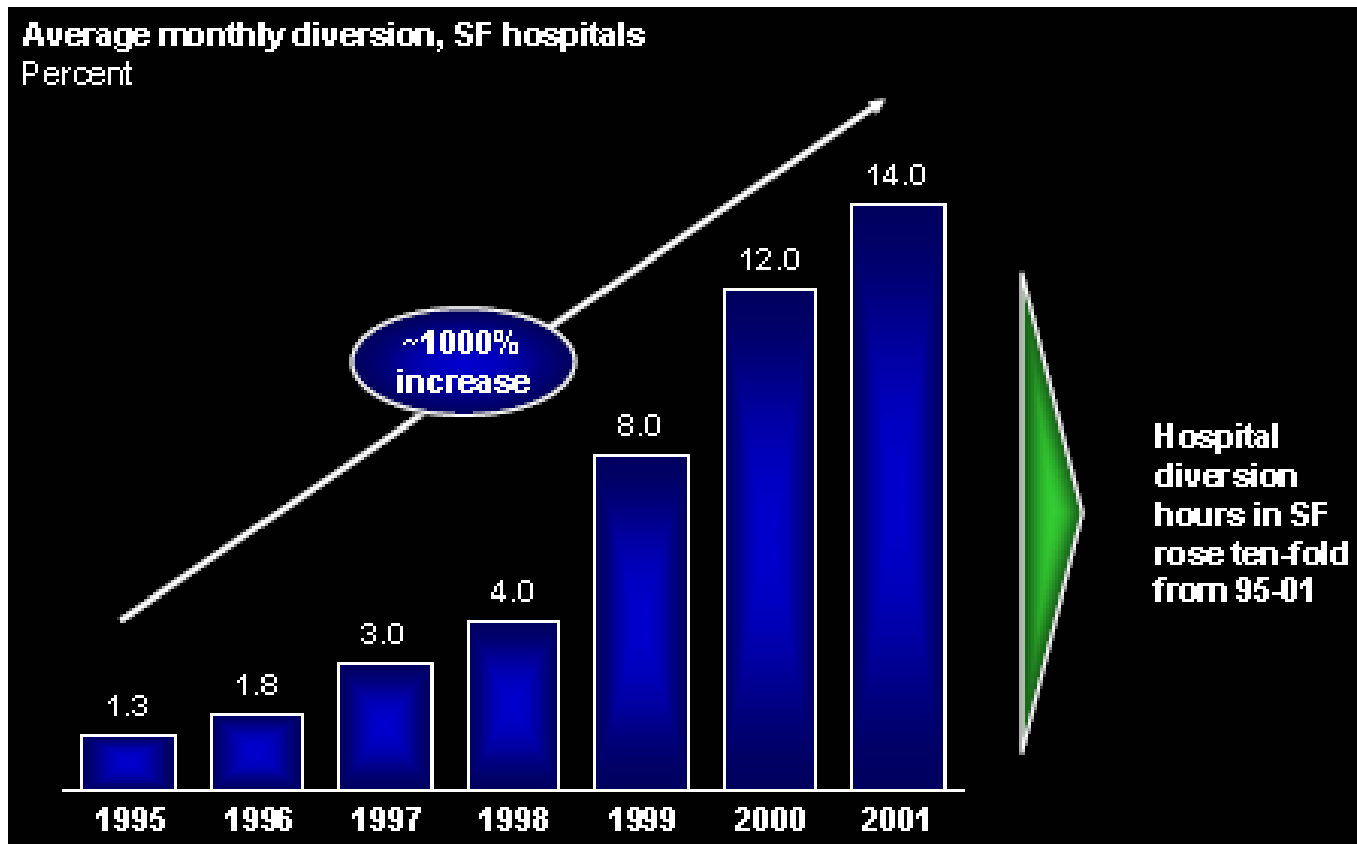
- Laboratory regulations apply anytime a lab test is performed, regardless of where the is performed
 - JCAHO
 - CLIA '88/CLIA '03
 - State law (California, NY, etc.)
- Most clinicians unfamiliar with laboratory regulations
- “Regulations” counter to ED “culture of speed”

A Tale of Two Cities

- SFGH – 2002
 - 24/7 “stat” lab embedded within the ED
 - ABGs, UAs, urine pregnancy, CBCs, misc.
 - All else performed upstairs (one floor above)
 - Pneumatic tube stations throughout the ED
 - Still not fast enough
 - 2002 – request by ED to have POCT
 - Glucose (automated device)
 - UA dipstick (manual test)
 - Urine pregnancy (manual test)

A Tale of Two Cities

- Backdrop to SFGH ED's POCT request



<http://www.sfgov.org/site/uploadedfiles/firecomm/Meetings/supporting/2004/McMillanPresentation.pdf>

Accessed 06/02/07

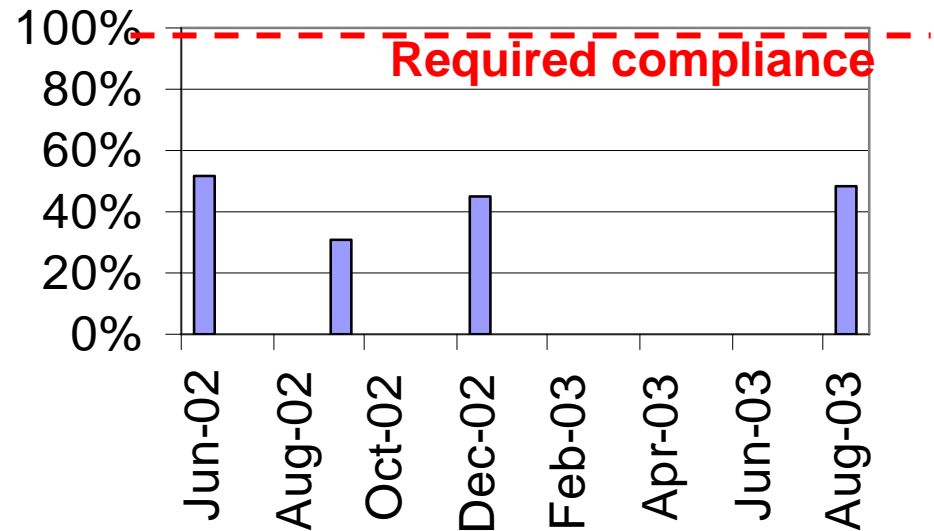
A Tale of Two Cities

- Lab requirements for ED POCT
- Answer each of these four questions for each POCT performed
 - Who did the test?
 - Who was tested?
 - What was the result?
 - What action was taken based on the result?
- 100% compliance required

A Tale of Two Cities

- SFGH ED Glucose POCT
 - Automated device
 - Automatically
 - Captures patient ID
 - Captures tester ID
 - Captures result
 - Can capture action
 - QC “lockout” feature
- No documentation at all available for the manual tests (urine dipstick, urine pregnancy) to assess compliance

- SFGH ED glucose POCT
 - Actual % compliance



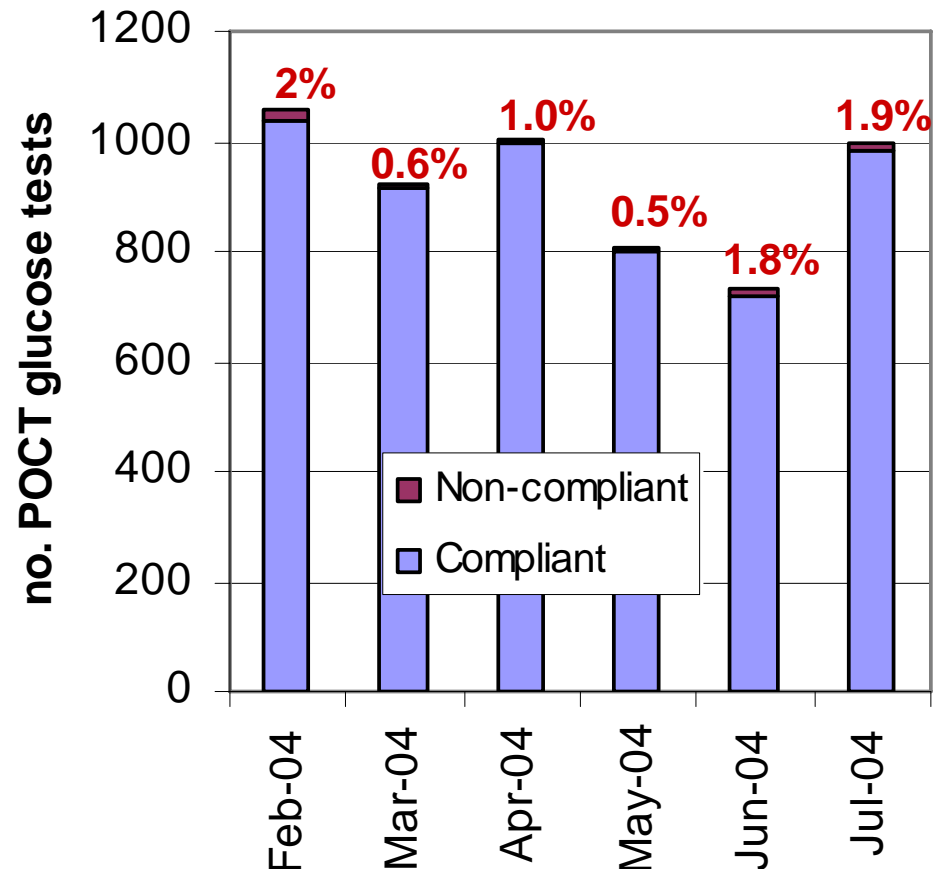
- August 25, 2003 – all POCT in the SFGH ED stopped

A Tale of Two Cities

- Many meetings with many people
- December 1, 2003
 - ED submitted POCT plan of correction
 - requested reinstatement of only POCT glucose
 - Many changes implemented to assure future compliance

A Tale of Two Cities

- Key changes
 - Testers “barcoded”
 - Daily review of all POCT results to identify and improve areas of non-compliance
 - Establishing the system to identify patients who were tested before registered (triage)
 - Nursing accepted responsibility and took leadership



Success!

Two Tales in One City

- July 1, 2005 - Valerie changes jobs
- ACMC/HGH Lab issues –
 - no POCT coordinator
 - Last POCT coordinator left ~2003
 - Lack of hospitalwide coordinated approach to POCT
- POCT coordinator assigned February 2006
 - RN position
 - Nursing Education budget
 - Direct report to Laboratory Director
 - Office outside Laboratory Director's office

(This is why Valerie cannot change jobs again – she doesn't have the energy to bring yet another POCT program into compliance.)

Two Tales in One City

- ACMC/HGH ED – POCT as of 07/01/05
 - Automated, interfaced, with QC lockout
 - Glucose*
 - ABGs
 - Electrolytes

} in control (sorta)
 - Manual
 - Urine pregnancy
 - Urine dipstick
 - Fecal occult blood

} Uh oh

 - Rapid HIV antibody → in tight control (!!!!)

*California phlebotomy regulations, effective 04/09/06, invoked major changes – CNAs no longer allowed to test; RNs had to assume testing

Two Tales in One City

- Issues with automated POCT
 - Glucose meters – 5 issued to ED, only 2 can be found at any one time
 - Strategy – lab “turns off” the missing glucose meters and they quickly surface
 - i-STATs
 - Values are used for “screening”
 - Any abnormality verified with specimen sent to the laboratory

Two Tales in One City

- ED POCT dipstick urinalysis
 - non-compliant for the entire 5 years during which POCT UA had been performed
 - Valerie’s perspective: “This is like deja vu all over again.”
 - Yogi Berra (1925 -)

ED UA non-compliance

- POCT UA “violations”:
 - Unable to find documentation of successful color blindness testing for POCT personnel
 - QC not performed daily as required
 - QC results documented were implausible
 - Repeated glucose QC values of 200 mg/dL reported
 - Only values of 100, 250, 500, 1000, 2000 mg/dL possible
 - ?small print on interpretive guide and aging workforce?
 - Patient testing performed when ED POCT was “suspended”
 - QC reagent required reconstitution
 - Distilled water required
 - Tap water used → ***“last straw”***

Two Tales in One City

- Urine dipstick analysis stopped 02/10/06
- Major impact on ED Urgent Care center
 - Average patient length of stay ~10-15 minutes when POCT UA dipstick performed
 - UTIs: common diagnosis and treatment
- Major impact on Clinical Laboratory
 - Expectation of rapid turnaround time (minutes) for results for urines submitted from the ED
 - Transportation issues for Urgent Care area
 - No pneumatic tube access
 - Most urines had dipstick abnormalities requiring urine sediment microscopic exams
 - At that time, results for UA not released until dipstick and microscopic exams complete

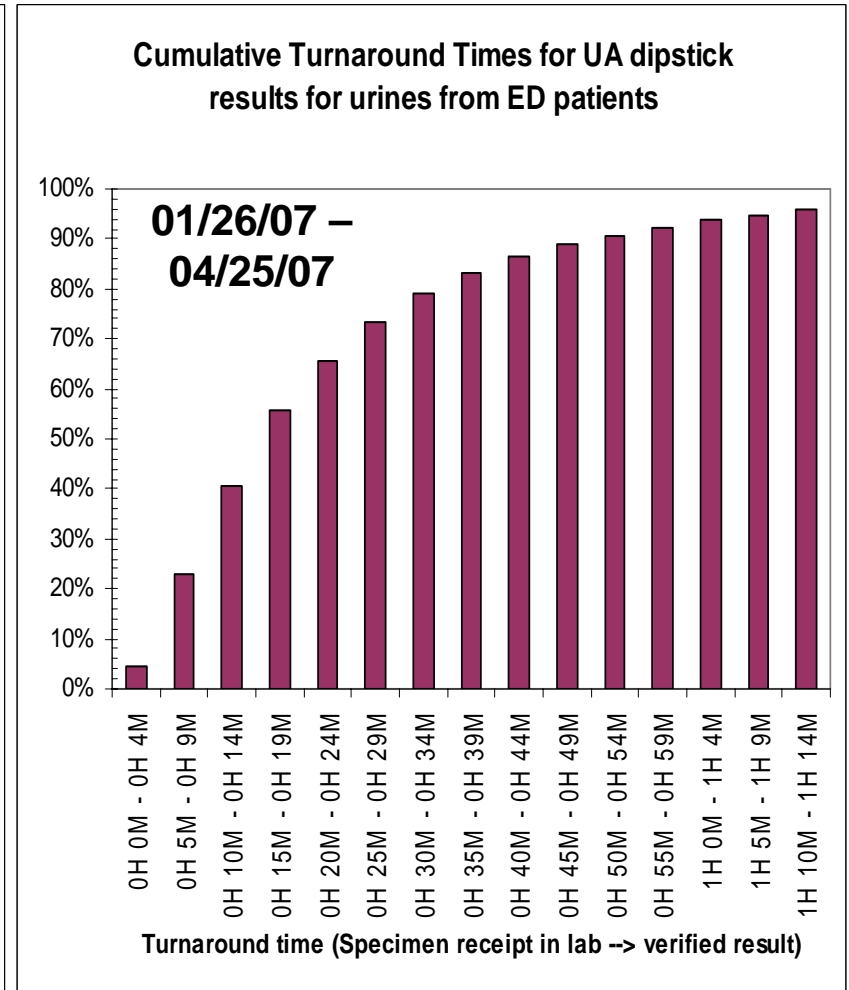
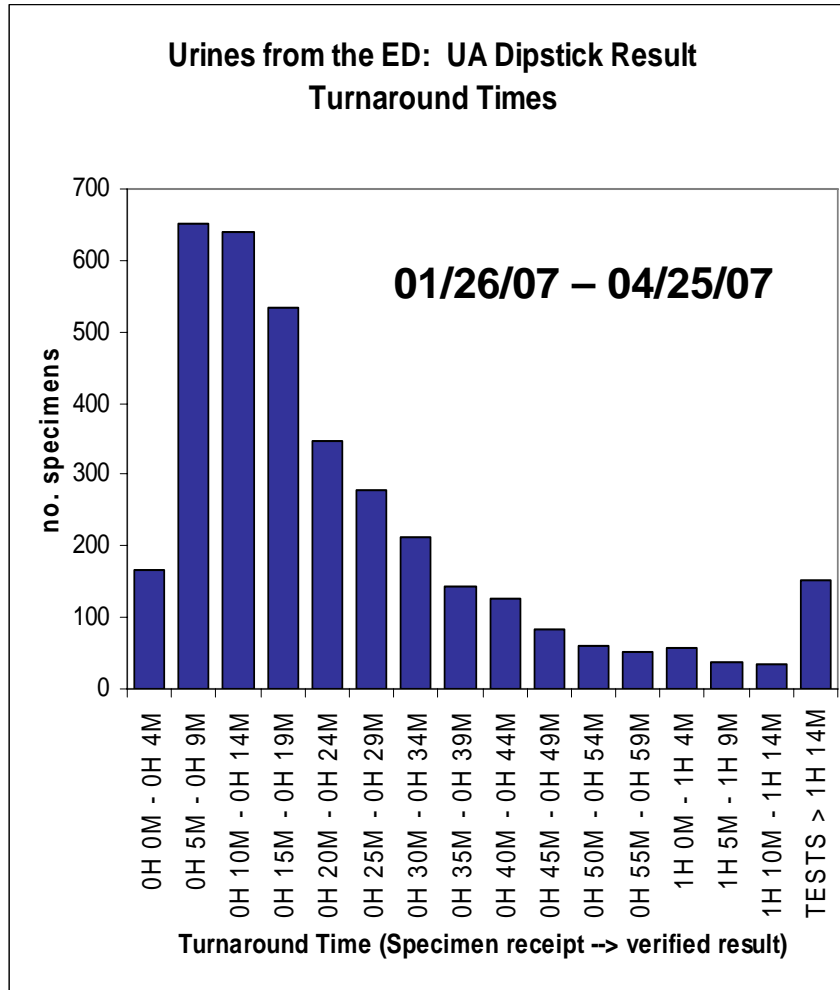
Two Tales in One City

- Evolution of laboratory performed UAs for the ED
 - Reconfiguration of the LIS to release the dipstick result while the reflex urine sediment microscopic exam was pending
 - Recognition of LIS-EMR interface problems for reflex testing
 - “lockout” occurs when test result is submitted at same time reflex test is being ordered
 - Preferentially affects CBCs and UAs
 - Test results not visible in EMR until “lockout” cleared
 - IS only group able to clear “lockouts” – staffed M-Th only
 - Lab soon to implement procedure to clear “lockouts” 24/7

Two Tales in One City

- Increased 24/7 staffing on the urine bench
 - Ironically achieved with no additional personnel
 - Coincident implementation of new Hematology analyzers
 - Improved automated WBC differentials
 - Less CLS time required for peripheral smear microscopic reviews \pm WBC differentials
 - Same CLSs covers UA/coag/blood bank benches (generalists)
 - Able to absorb additional UA workload

Two Tales in One City



Will UA be restored to the ED?

- “No” for now
 - Current UA automation lacks
 - “lockout” features
 - Interface capability
 - Even if automation has “lockout” features, UA dipsticks can still be evaluated manually → ED personnel can still circumvent POCT system controls and requirements
 - Await technological advances (lockout, interface) then reconsider

Two Tales in One City

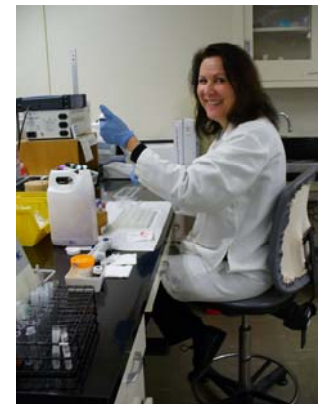
- Issues with other manual POCT
 - Urine pregnancy
 - Fecal occult blood
- Implemented patient test logs
 - Requirement to record
 - Date/time of testing
 - Who did the test
 - Who was tested
 - Internal control results
 - Room temperature at time of testing
 - Test result
- Test logs reviewed monthly by POCT coordinator
 - Corrective actions must be submitted for non-compliant performance
 - Nursing Leadership is actively engaged
- Future directions
 - Fecal Occult blood (that pesky “developer in the pocket” issue)
 - Immunodiagnostic method to be introduced Fall 2007
 - Developing must occurred in the laboratory
 - ?Manual input of POCT results by ED into EMR

Two Tales in One City

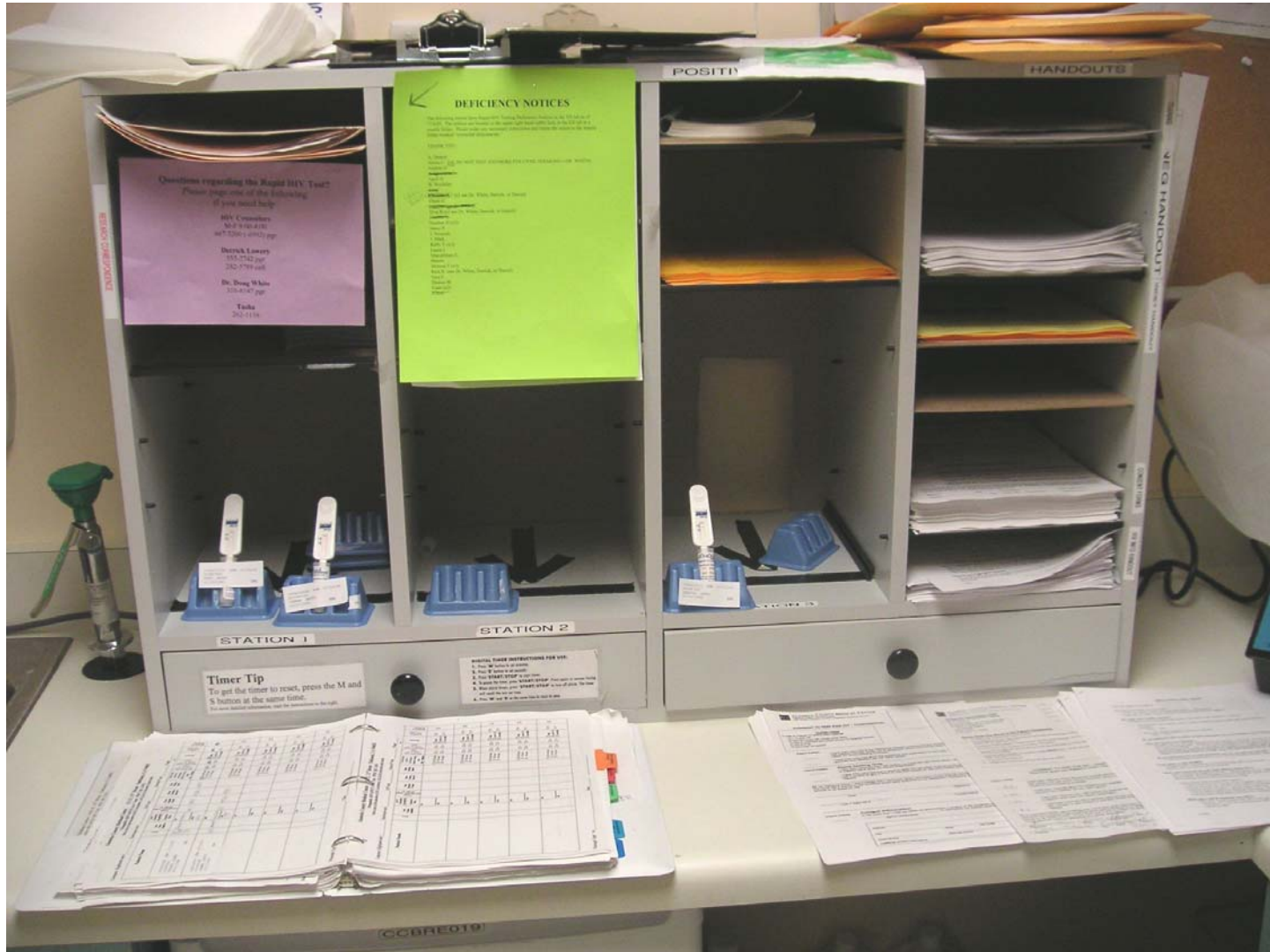
- Rapid HIV antibody POCT in the ED –
- ***A model of POCT excellence***
 - Same environment as other ED POCTs
 - Same personnel as other ED POCTs
 - 120+ nurses
 - Physicians
 - Yet POCT documentation is impeccable and all POCT elements fully compliant

ACMC Rapid HIV Ab POCT

- Best POCT practice – rapid HIV Ab testing in the ACMC ED
 - Funding: CDC “Demonstration project”
- Personnel costs:
 - Site manager: Doug White, MD
 - 0.3 FTE
 - Research Associate
 - 0.33 FTE
 - Lab liaison: Anne Gonsalves, CLS
 - 0.025 FTE
 - Test personnel: ~120 RNs; ?FTE
 - Location: Emergency Department



Emergency Department “Lab”



Emergency Department HIV POC Monthly Review – July 2006
(Response 09/05/06)

CONTROLS:

Deficiency – 7/6/06: Control interpreted 41 minutes. Provider Reed, PA-C, notified of interpretation outside of 40-minute window. I have observed provider accurately perform controls on three separate occasions since deficiency noted.

Deficiency – 7/30/06: Provider incorrectly documented negative control. Error deemed clerical after discussion with provider Paulinetti, PA-C. Provider re-educated.

Deficiency – 7/31/06: Provider incorrectly documented negative control. Error deemed clerical after discussion with provider Kelly, PA-C. Provider re-educated.

Further intervention to improve compliance and accuracy: I will review log and explain importance of clear and conscientious documentation at the next PA-C staff meeting.

TESTING LOG:

Deficiency – 7/5/06: No deficiency apparent upon secondary review by ED personnel. Confirmatory testing was in fact performed.

Deficiency - 7/11/06: No deficiency apparent upon secondary review by ED personnel, lab review misinterpreted start time as 20:04 when in fact it was 20:24.

Deficiency – 7/24/06: Time interpreted >40 minutes. Deficiency notification completed, awaiting reply from RN Cheng. RN Cheng temporarily suspended from performing rapid HIV testing until competency demonstrated. Addendum: a confirmatory HIV test was performed on patient and is concordant with rapid test results.

Deficiency – 7/30/06: Time interpreted 19 minutes. Result changed to invalid. Deficiency notification completed, awaiting reply from RN Raydeen W.

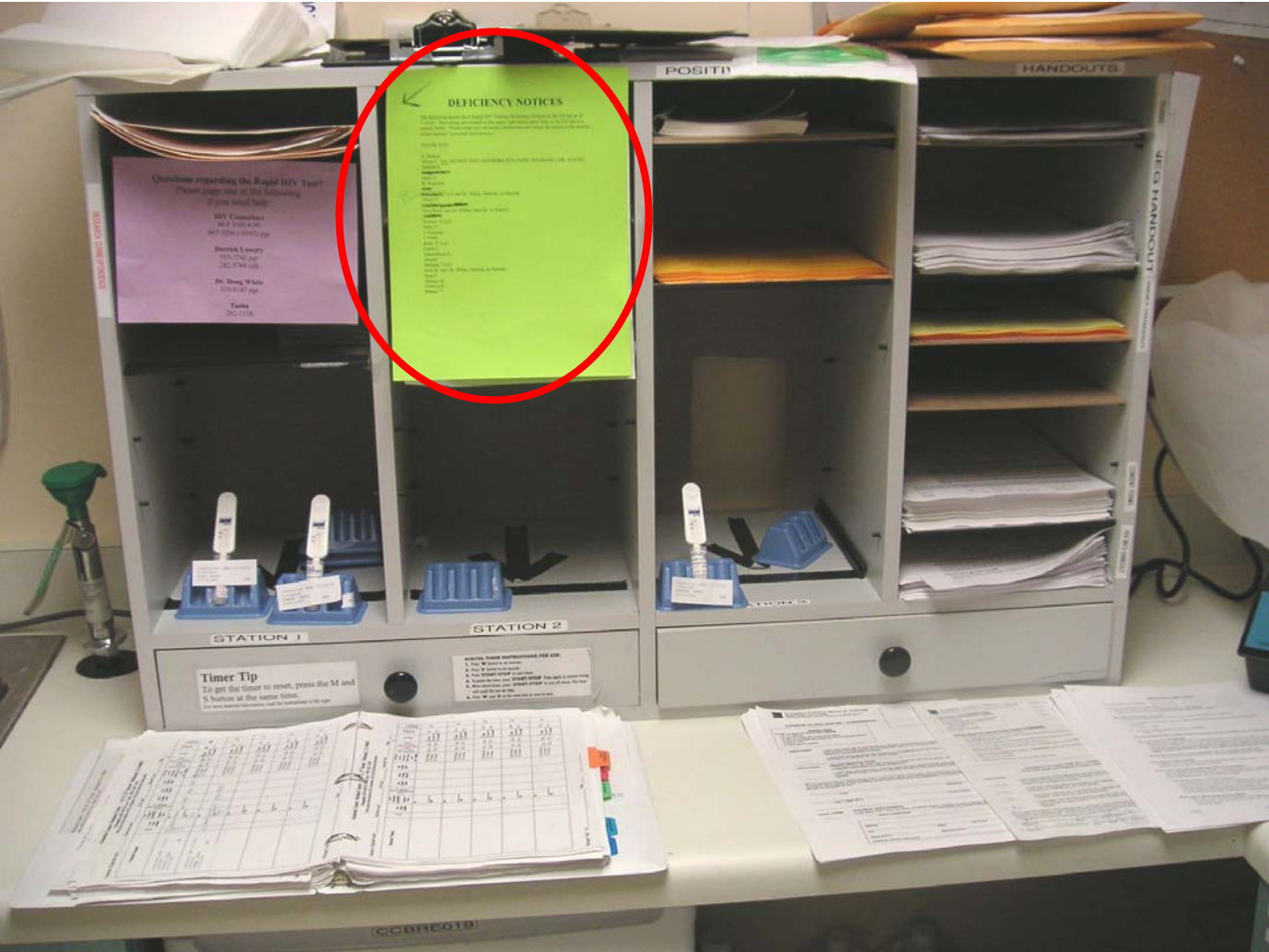
Thanks,

Douglas White, MD
(510) 535-7439

**Deficiencies
identified by
Anne
Gonsalves,
CLS**

**Timely
corrective
responses
by Doug
White, MD**

Public humiliation works



ACMC Rapid HIV Ab POCT

- CDC funding renewed
 - Triple testing has commenced
 - Two additional rapid HIV Ab tests to “confirm” initial rapid HIV Ab preliminary positive result
 - Testing likely to be limited to 4-7 trained testers
- Laboratory fully supportive

Two Tales in One City

- Valerie's conclusions
 - Best practice POCT can occur in the ED
 - Key to success – **PEOPLE**
 - Leadership from within the ED
 - ED staff actively engaged
 - nursing
 - Incentive (e.g., CDC funding and requirements)
 - Motivation (testing under Lab's license, therefore requirement to be compliant with Lab regs)
 - No question of “who's in charge” – Lab Director

POCT - People

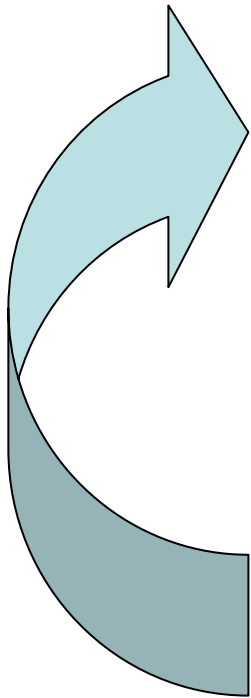
- The biggest factor to POCT success
- Ideal POCT site manager
 - Detail oriented
 - Compulsive
 - Perfectionists
 - Obeys “rules” from the Lab
 - Motivates test personnel to follow “rules”
 - Keeps the Lab Director happy

BIZARRO Piraro



Compliant POCT prioritization

- Apply Risk Management principles

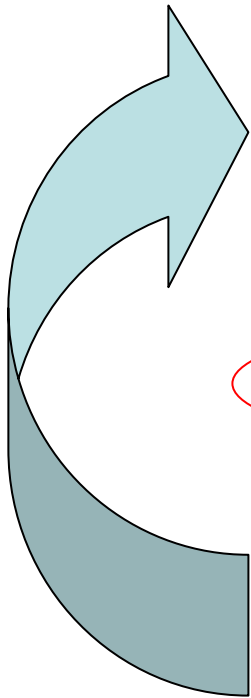


- Hazard identification
 - Risk analysis
 - Risk evaluation
 - Risk control
 - Risk monitoring
- } Risk assessment
- } Risk Management

ISO 14971:2000

Compliant POCT prioritization

- Apply Risk Management principles



- Hazard identification
 - Risk analysis
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ISO 14971:2000

Risk Evaluation

Severity of harm

	<i>Negligible</i>	<i>Minor</i>	<i>Serious</i>	<i>Critical</i>	<i>Catastrophic</i>
<i>Frequent</i>	<i>not ok</i>	<i>not ok</i>	<i>not ok</i>	<i>not ok</i>	<i>not ok</i>
<i>Probable</i>	ok	<i>not ok</i>	<i>not ok</i>	<i>not ok</i>	<i>not ok</i>
<i>Occasional</i>	ok	ok	ok	<i>not ok</i>	<i>not ok</i>
<i>Remote</i>	ok	ok	ok	ok	<i>not ok</i>
<i>Inconceivable</i>	ok	ok	ok	ok	ok

Probability

- Frequent – once/week
- Probably – once/month
- Occasional – once/year
- Remote – once/every few years
- Inconceivable – should never happen (once/career)

ISO 14971

Risk Evaluation

Severity of harm

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- “not ok” risks
 - Must reduce to an acceptable level
- “ok” risks
 - Considered negligible
 - No further attention required
 - Reduce to as low a level as possible

ISO 14971

versus

Example

- ED POCT Urine Pregnancy Testing
 - False positive result – assume pregnant, treat as if pregnant, restricted use of teratogenic Rx
 - Imaging
 - Medications
 - Minimal to no risk to fetus
 - Possible risk to mom if less effective Rx used

	<i>Negligible</i>	<i>Minor</i>	<i>Serious</i>	<i>Critical</i>	<i>Catastrophic</i>
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Example

- ED POCT Urine Pregnancy Testing
 - False negative result – assume not pregnant, no restriction on using teratogenic Rx
 - **Greater and serious (?critical ?catastrophic) risk to fetus**
 - **Not OK**

	<i>Negligible</i>	<i>Minor</i>	<i>Serious</i>	<i>Critical</i>	<i>Catastrophic</i>
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Example

- Urine Pregnancy Testing Risk Mitigation
 - Implement external liquid controls for every day of patient testing (can be “surrogate” - performed by laboratory for same lot of reagents in use in the laboratory)
 - Assure proper storage of supplies at POCT site
 - Daily room temperature monitoring and recording
 - Correct lot number (QC'd by Laboratory)
 - Assure ongoing competency of POCT staff
 - Documentation of successful initial training
 - Documentation of successful competency
 - Initial, 6 months later, one year later, and annually thereafter
 - External proficiency testing to monitor performance

Example

- Fecal Occult Blood in the ED
 - Why is this needed as POCT?
 - What rapid clinical action is dependent on this result?
- Occult blood is really a test for preventative health in the primary care setting
 - Screening for colon cancer
 - 3 specimens over 3 days
- Excuse to keep FOBT in the ED – “Trauma”
 - Trauma’s usual triggers for clinical action
 - Bright red blood (not occult)

Example

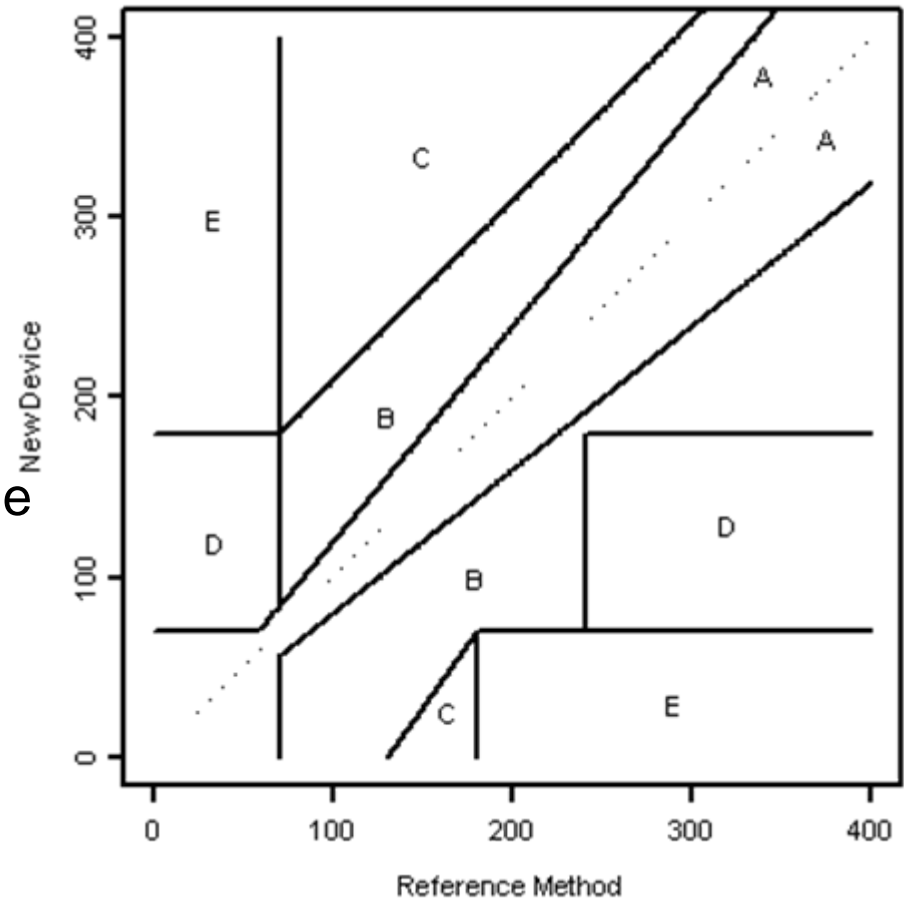
- Fecal Occult Blood

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- How often does it fail? Inconceivable
- How serious is the risk of an incorrect result (positive or negative)? Negligible to none.
- Valerie's advice: Don't lose any sleep over this.

Example

- Glucose
 - Incorrect high value
 - Unnecessary insulin
 - Incorrect low value
 - Unnecessary glucose
 - Clarke's error grid
 - Risk relative to magnitude of error
 - A & B regions – ho hum
 - C – uh oh
 - D, E – critical or catastrophic



Example

	<i>Negligible</i>	<i>Minor</i>	<i>Serious</i>	<i>Critical</i>	<i>Catastrophic</i>
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- How frequently do POCT glucose errors occur?
 - Match values obtained from specimens obtained temporally close to when POCT glucose performed
 - Are our ED colleagues aware of the imprecision of glucose meters?

Glucose Meter Precision

- 2007 CAP WBG-A Proficiency Test surveys
 - 4 meters most commonly used by CAP participants
 - 3 manufacturers – “A, A1, B, C”
 - mean glucose values (mg/dL)

<i>Sample #</i>	<i>A</i>	<i>A1</i>	<i>B</i>	<i>C</i>
<i>WBG-01</i>	436	391	452	372
<i>WBG-02</i>	67	63	80	44
<i>WBG-03</i>	94	89	107	69
<i>WBG-04</i>	363	338	405	306
<i>WBG-05</i>	155	146	162	117

ACMC Glucose Meter Precision

- Same manufacturer's meter
- ~600+ testing personnel (mostly RNs)
- Each meter calibrated twice annually

<i>Sample #</i>	<i>Mean value (mg/dL)</i>	<i>Range</i>
<i>WBG-01</i>	452	415 – 498
<i>WBG-02</i>	84	76 – 93
<i>WBG-03</i>	112	103 – 124
<i>WBG-04</i>	412	378 – 469
<i>WBG-05</i>	168	146 - 193

Learning Objectives

- Explain why POCT results in the ED must be of the highest quality
- Explain how a risk management assessment process can guide development and prioritization of processes needed to assure accurate Emergency Department (ED) POCT results