Finding the Right Tool: Evaluating POCT on the Basis of Outcomes

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Learning Objectives

- Discuss challenges associated with evaluating POCT applications as solutions for clinical operations
- Formulate strategies for critically evaluating a growing number of POCT applications in a clinical environment
- Identify clinical outcomes that may be measured for evaluation of whether POCT applications are meeting a clinical need

Clinical Utility

- POCT is not a “black box” fix; nor is it something to do just because it’s available
- Does the POCT request fix the problem?
  - Will the test allow rule-in or rule-out diagnosis?
  - Why does the central or critical care/satellite lab not meet the need?
  - Can therapy or consultation be initiated based on POCT result?

Clinical Utility

- Faster results does not guarantee improved clinical outcome
- To assess clinical utility, need to evaluate:
  - Reason for ordering test
  - How the result will be utilized for patient care
  - Is POCT method appropriate for patient needs in that particular setting?
- Communication with clinical staff is vital for determination of clinical utility and implementation

Case Study: Whole Blood Testing

- Emergency Department (ED) would like to implement whole blood testing at POC
  - Interested in cardiac markers (cTnI, lactate and Na+/K+)
  - Testing on an ABG instrument
  - Goal: to increase throughput and reduce LOS
- Neonatal Intensive Care Unit (NICU) has similar request, but for a larger menu
  - Large floor plan in the new hospital building, would like a wireless solution
  - Goal: reduce blood draw volume (and transfusions), decrease infection risk, increase patient satisfaction

Important Considerations for Workflow and POCT Implementation

- What are the analytical limitations of the test?
- Who will perform the test?
- Is the infrastructure present to support POCT?
  - Appropriate power, storage, connectivity
- How will the testing be inserted into the current workflow of the providers?
- Will the availability of POCT results be able to solve the clinical challenge presented?
  - Are the expected outcomes realized?

Case Study: Whole Blood Testing (continued)

- ED Testing
  - Several misconceptions: availability of cardiac markers, users wouldn't need training due to automation, K+ results were robust
  - Outcomes studies were discussed, but project was dropped before they began
- NICU Testing
  - Menu and goals for POCT were found to be compatible
  - Determined that testing staff would need to be expanded (RTs → Nursing)
  - Technical evaluation is acceptable; infrastructure will support testing
  - Current phase: bringing in the technology & evaluation of outcomes (discussion phase)

Clinical Chemistry 46:4
543–550 (2000)

Laboratory Management

Clinical Outcomes of Point-of-Care Testing in the Interventional Radiology and Invasive Cardiology Setting

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Background: Point-of-care testing (POCT) can provide rapid test results, but its impact on patient care is not well documented. We investigated the ability of POCT to decrease inpatient and outpatient waiting times for cardiovascular procedures.

Methods: We prospectively studied, over a 7-month period, 216 patients requiring diagnostic laboratory testing for coagulation (prothrombin time/activated partial thromboplastin time) and/or renal function (urea nitrogen, creatinine, sodium, and potassium) before elective invasive cardiac and radiologic procedures. Overall pa-

0.02). For patients needing coagulation testing, wait times improved only when systematic changes were made in workflow (phase 4, 109 ± 41 min; n = 12; P = 0.01).

Conclusions: Although POCT has the potential to provide beneficial patient outcomes, merely moving testing from a central laboratory to the medical unit does not guarantee improved outcomes. Systematic changes in patient management may be required.

CVDL Outcomes Trial

- Prior to therapeutic intervention, patients require coagulation (PT/aPTT) and/or renal function testing (Na/K, BUN/Creat)
- Phase 1 – workflow and patient throughput determined using central lab testing.
- N = 135 patients over 95 days
- Despite arriving 120 minutes early if lab work needed, 44% of results not available prior to scheduled procedure time.
- Average patient wait time was 167 minutes

Clin Chem. 46 (2000) 543.

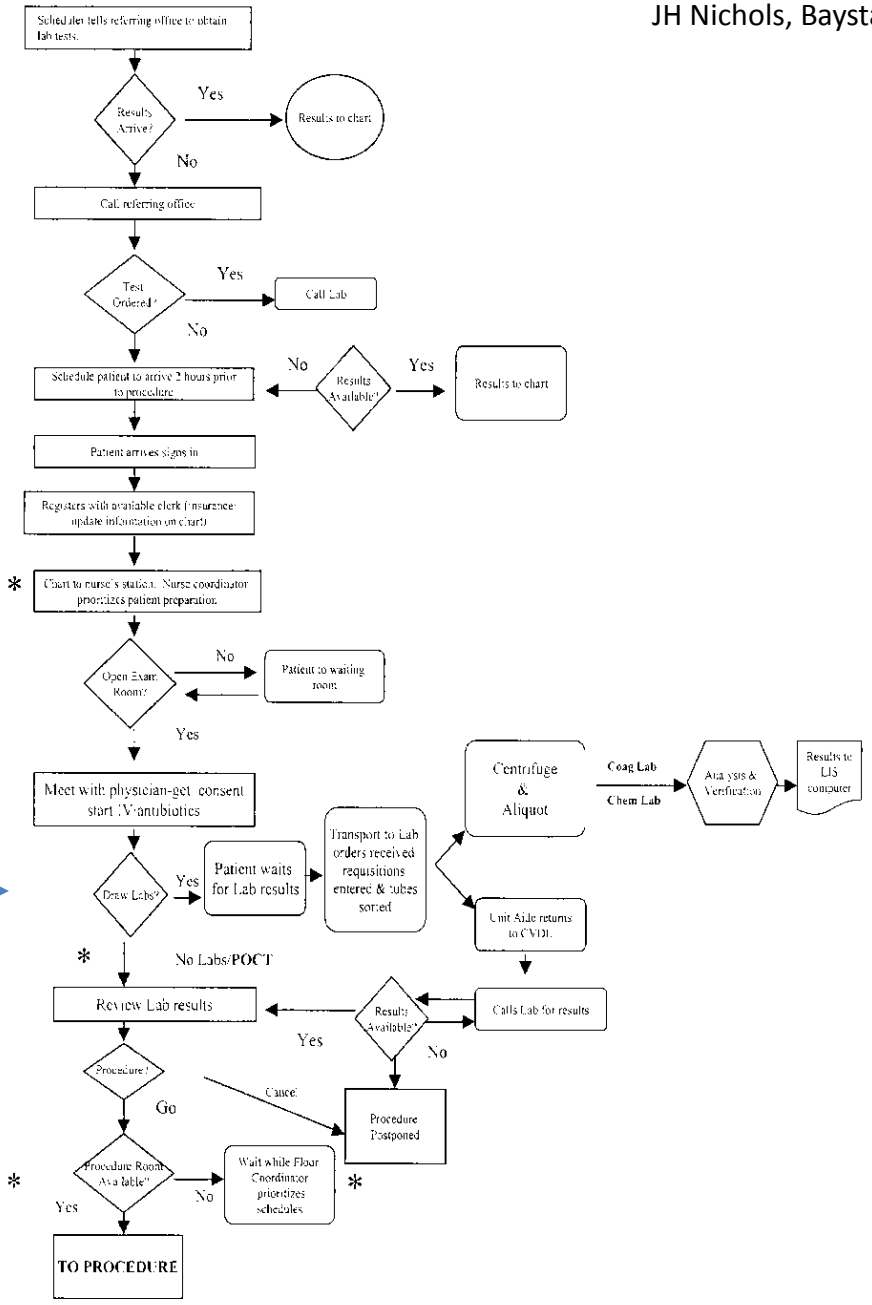

Fig. 2. CVDL patient workflow.

*, steps affected by implementation of POCT and workflow improvement initiatives. *IV*, intravenous drip; *Coag*, coagulation; *Chem*, chemistry; *LIS*, laboratory information system.

JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.

Clin Chem. 46 (2000) 543.

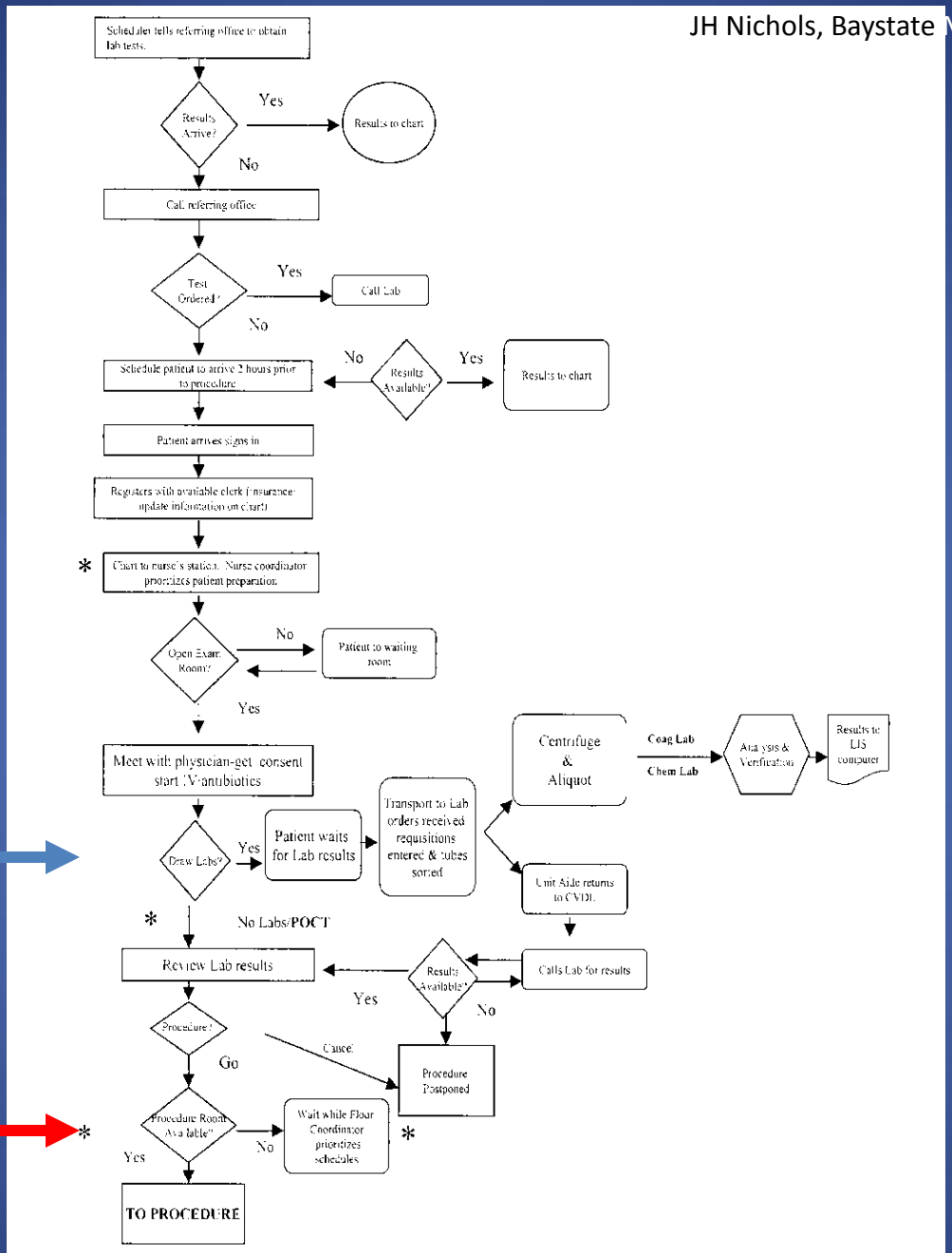

Fig. 2. CVDL patient workflow.

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Clin Chem. 46 (2000) 543.

JHH CVDL Outcomes Trial

- POCT improved wait times over core laboratory, but not significantly.
- Significant changes only occurred after unit workflow reorganized to optimize use of POCT results (implemented communication center between admit and procedure rooms); decreased wait times 63 mins for coag (N=9, p = 0.014) and 47 mins for renal (N=18, p = 0.02)

Clin Chem. 46 (2000) 543.

Changes in Utilization of Intraoperative Laboratory Testing Associated with the Introduction of Point-of-Care Testing Devices in an Academic Department

David B. Wax, MD

David L. Reich, MD

BACKGROUND: Availability of point-of-care testing (POCT) technology may lead to unnecessary testing and expense without improving outcomes. We tested the hypothesis that frequency of intraoperative blood testing (IBT) would increase in association with installation of POCT devices in our surgical suites.

METHODS: We performed a retrospective analysis of 38,115 electronic anesthesia records for cases performed in the 1 yr before and 1 yr after POCT installation. For each case, the frequency of IBT was tabulated and the change in frequency of IBT between the study periods was calculated for individual anesthesiologists, for the department as a whole, and for clusters of anesthetizing locations.

RESULTS: For the department as a whole, there was no significant change between the before and after study periods in the 13% proportion of cases in which IBT was obtained. For cases in which IBT was used, there was no significant increase in the number of IBTs per case.

CONCLUSIONS: We found no significant increase in the overall utilization of IBT associated with POCT presence in noncardiothoracic operating rooms.

(Anesth Analg 2007;105:1711–3)

Anesthesia & Analgesia. 105 (2007) 1171.

Does Availability Lead to Increased Usage?

- Hypothesis: introduction of intra-operative POCT will lead to increased frequency of testing
- Investigation focused only on whole blood testing
- Compared records from 12 months before and after introduction of POCT
- Outcome measure: frequency of intraoperative blood testing (IBT)

Anesthesia & Analgesia. 105 (2007) 1171.

Table 1. Quantity of Intraoperative Blood Tests (IBT) in Noncardiothoracic Anesthesia Cases for Entire Department and in Six Anesthetizing Location Clusters Pre- and Postinstallation of Point-of-Care Testing (POCT) Devices

C	*N*	0 IBT (%)	1 IBT (%)	2 IBT (%)	3 IBT (%)	≥4 IBT (%)	*P*
All	17,972 → 20,143	87.2 → 87.2	6.1 → 5.6	3.3 → 3.4	1.7 → 1.6	1.8 → 2.1	NS
1	1050 → 1182	62.3 → 63.6	19.0 → 17.9	11.0 → 10.3	4.7 → 5.3	3.0 → 2.9	NS
2[a]	2875 → 2897	89.8 → 91.2	3.6 → 3.0	2.8 → 2.8	1.9 → 1.4	2.0 → 1.5	NS
3	3621 → 3479	95.2 → 95.8	3.0 → 2.5	1.0 → 0.9	0.4 → 0.3	0.3 → 0.4	NS
4	3892 → 5580	97.9 → 97.8	1.4 → 1.4	0.5 → 0.5	0.2 → 0.2	0.1 → 0.1	NS
5	3626 → 3817	89.0 → 88.4	6.4 → 6.5	2.9 → 3.2	1.1 → 1.1	0.5 → 0.8	NS
6[a]	2908 → 3188	67.1 → 63.2	13.4 → 13.1	8.2 → 9.6	4.7 → 4.9	6.6 → 9.3	<0.01

C = clusters with predominant surgical subspecialties: 1 = neurosurgery; 2 = otolaryngology, urology; 3 = orthopaedics; 4 = gynecology, ophthalmology, plastics, pediatrics; 5 = general surgery; 6 = vascular, transplantation, hepatobiliary, colorectal.

N = Total number of cases in PRE → POST periods.

IBT = Proportion of all cases that had each # quantity of IBT in PRE → POST periods.

$P = \chi^2$ test for trend. NS = $P \geq 0.05$.

[a] Location clusters in closest proximity to new POCT devices.

Anesthesia & Analgesia. 105 (2007) 1171.

The cost-effectiveness of point of care testing in a general practice setting: results from a randomised controlled trial

Caroline O Laurence*†[1], John R Moss†[2], Nancy E Briggs[3], Justin J Beilby[4] for PoCT Trial Management Group

Abstract

Background: While point of care testing (PoCT) for general practitioners is becoming increasingly popular, few studies have investigated whether it represents value for money. This study aims to assess the relative cost-effectiveness of PoCT in general practice (GP) compared to usual testing practice through a pathology laboratory.

Methods: A cost-effectiveness analysis based on a randomized controlled trial with 4,968 patients followed up for 18 months and fifty-three general practices in urban, rural and remote locations across three states in Australia.

The incremental costs and health outcomes associated with a clinical strategy of PoCT for INR, HbA1c, lipids, and ACR were compared to those from pathology laboratory testing. Costs were expressed in year 2006 Australian dollars. Non-parametric bootstrapping was used to generate 95% confidence intervals.

Results: The point estimate of the total direct costs per patient to the health care sector for PoCT was less for ACR than for pathology laboratory testing, but greater for INR, HbA1c and Lipids, although none of these differences was statistically significant. PoCT led to significant cost savings to patients and their families. When uncertainty around the point estimates was taken into account, the incremental cost-effectiveness ratio (ICER) for PoCT was found to be unfavourable for INR, but somewhat favourable for ACR, while substantial uncertainty still surrounds PoCT for HbA1c and Lipids.

Conclusions: The decision whether to fund PoCT will depend on the price society is willing to pay for achievement of the non-standard intermediate outcome indicator.

Trial registration: Australian New Zealand Clinical Trial Registry ACTRN12605000272695

BMC Health Services Res. 10 (2010) 165.

Is POCT Cost-Effective in a General Setting?

- Randomized controlled trial (N = 4,968) in Australia
  - Patients followed for 18 months
  - Measurements across 53 practices
  - Comparison of POCT with central lab services
  - Focus on INR, ACR (Urine Albumin Creatinine ratio), HbA1c, and lipid testing

- Outcome measure: total direct costs per patient for testing, incremental cost-effectiveness ratio (ICER)
  - ICER = Cost/QALY

BMC Health Services Res. 10 (2010) 165.

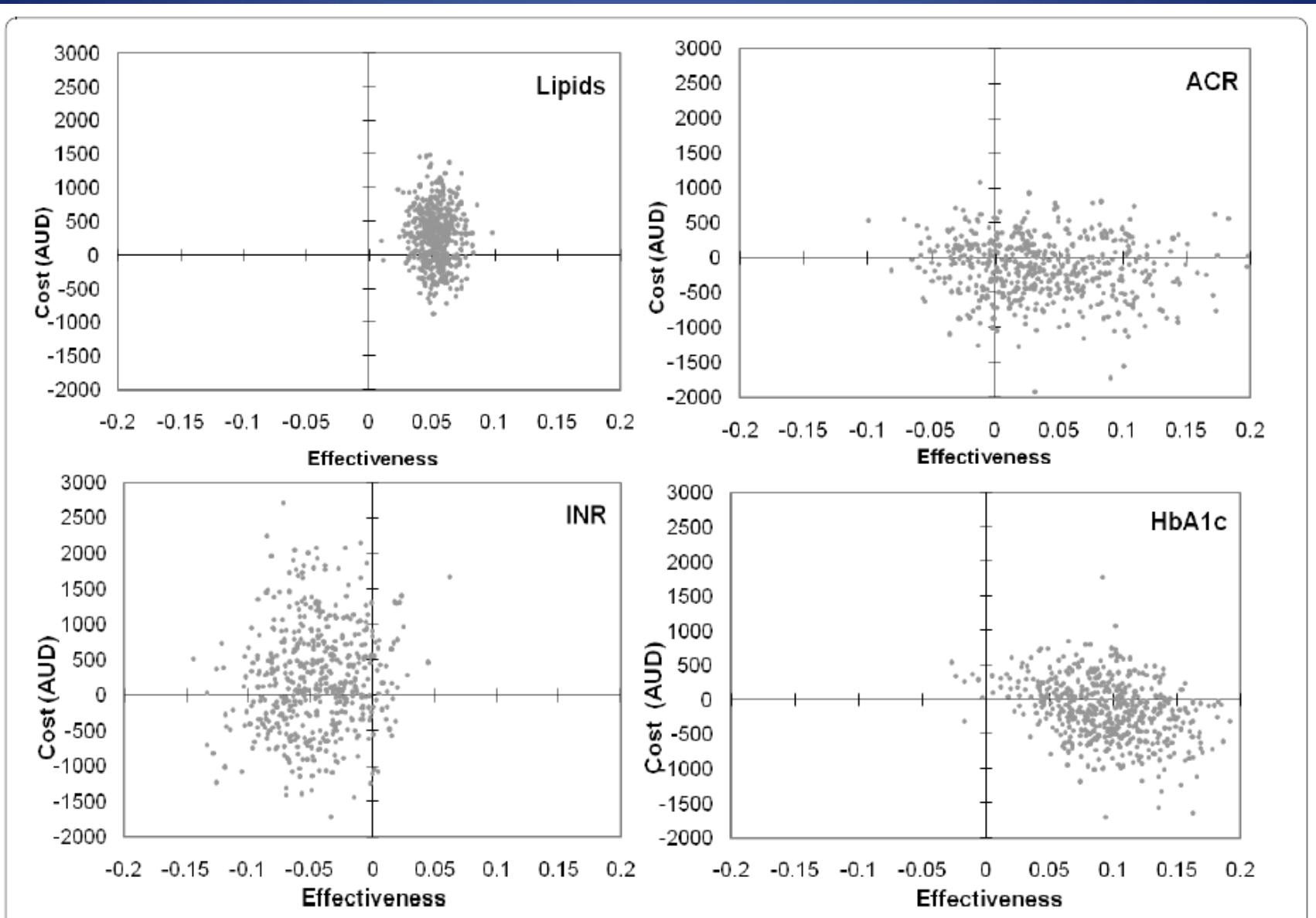

Figure 1 Joint probability distribution of the incremental costs and effects of PoCT for INR, HbA1c, ACR and Lipids.

CLINICAL INVESTIGATION

Impact of Point-of-care Testing in the Emergency Department Evaluation and Treatment of Patients with Suspected Acute Coronary Syndromes

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Acad Emerg Med. 15 (2008) 216.

Does POCT for Cardiac Markers in the ED Improve Patient Outcomes?

- Open-label, randomized, single center trial
  - Focus on cTnI in patients with suspicion of NSTE-ACS in the ED
  - Study subjects randomly allocated to POCT or central lab testing
  - Data analyzed for all study participants, low risk (no chest pain & no ST elevation), and also those deemed 'high-risk' (cTnI > 0.1 ug/mL)
- Outcomes measure: time to anti-ischemic therapy, ED length of stay, clinical outcomes for patients

Acad Emerg Med. 15 (2008) 216.

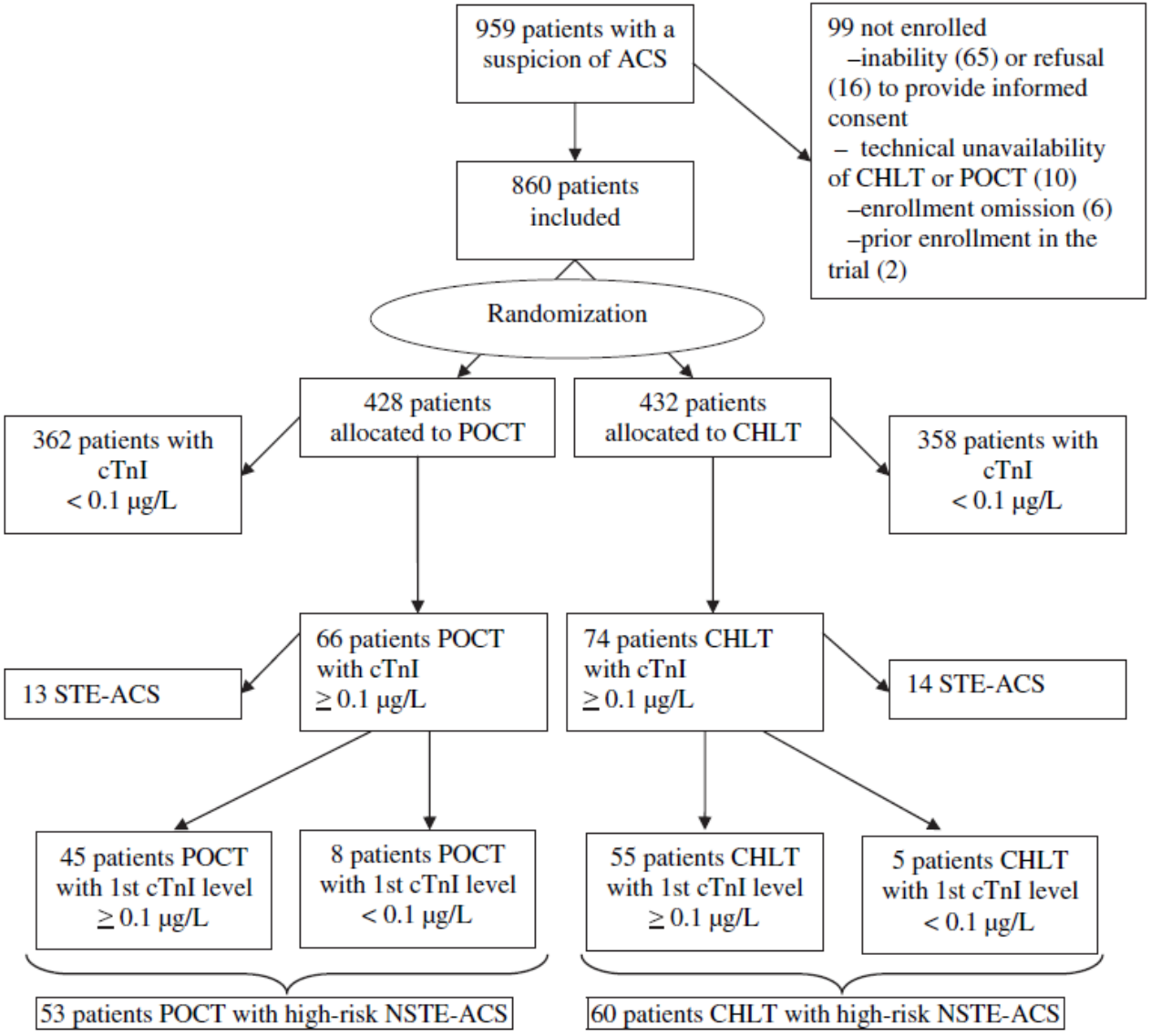

Figure 1. Study participants flow. ACS = acute coronary syndrome; CHLT = central hospital laboratory testing; cTnI = troponin I; NSTE-ACS = non–ST-segment elevation ACS; POCT = point-of-care testing; STE-ACS = ST-segment elevation ACS.

Acad Emerg Med. 15 (2008) 216.

Table 2
Comparisons of Time Lags in Minutes (Median and Interquartile Range [IQR]) between Patients Allocated to the Point-of-care Testing (POCT) or to the Central Hospital Laboratory Testing (CHLT) for Cardiac Troponin

	Overall		
Characteristics	POCT (n = 419)	CHLT n = 414)	p-Value
Time (minutes), median (IQR)			
From presentation to blood sample collection	75 (70–80)	65 (60–70)	0.005
From blood collection to physician notification of first cTnI	38 (35–42)	109 (104–115)	<0.001
From Presentation to AIT	151 (139–162)	198 (187–210)	<0.001
Length of stay at ED (min), median (IQR)	309 (204–411)	307 (229–401)	0.99

Low-suspicion ACS referred to patients presenting no chest pain and non–ST-deviation NSTE-ACS with elevated cTnI.
cTnI = troponin I; ED = emergency department; IQR = interquartile range; NSTE-ACS = non–ST-segment elevation acute coronary syndrome; AIT = anti-ischemic treatment.

Acad Emerg Med. 15 (2008) 216.

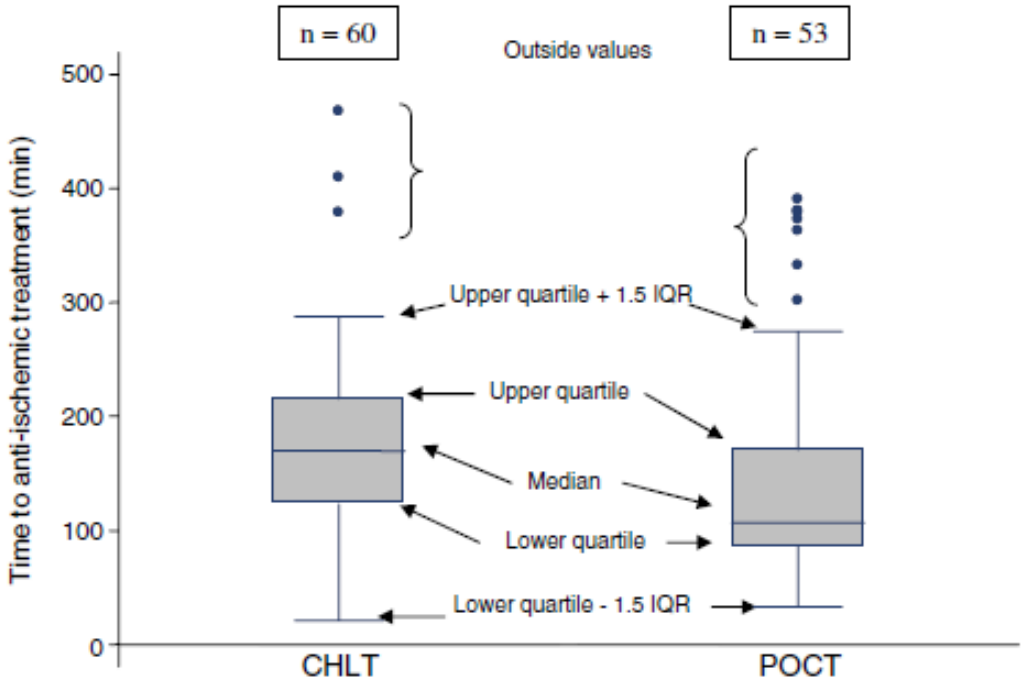

Figure 2. Time to anti-ischemic therapy (TAIT) of the 113 patients with non–ST-segment elevation acute coronary syndrome and elevated troponin I (cTnI; ≥ 0.1 μg/L) allocated to point-of-care testing (POCT) compared to those allocated to central hospital laboratory testing (CHLT) for patients with NSTE-ACS and elevated cTnI. Boxes are delimited by the upper limit (75th percentile) and by the lower limit (25th percentile) of the interquartile range (IQR). The line inside boxes figures the median value of the TAIT. Adjacent lines figure the upper (upper quartile + 1.5 IQR) and the lower (lower quartile – 1.5 IQR) adjacent values, and dots represent outside values.

Acad Emerg Med. 15 (2008) 216.

Administration of Emergency Medicine

IMPROVING PATIENT FLOW IN ACUTE CORONARY SYNDROMES IN THE FACE OF HOSPITAL CROWDING

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J Emerg Med. 2011 Oct 18. [Epub ahead of print].

Does POCT for Cardiac Markers in the ED Improve Patient Outcomes?

- Observational cohort study
  - 6 months pre- and post-implementation of POCT for cardiac markers
  - Focus on cTnI, CK-MB, and myglobin for risk stratification (RACE protocol)
  - 30 day follow-up on study subjects
- Initial Outcomes Measure: telemetry admissions, ED LOS, hospital LOS, and disposition
- 30-day Outcomes Measure: significant cardiac events, repeat ED visits or admission, death

J Emerg Med. 2011 Oct 18. [Epub ahead of print].

Table 1. Patient Characteristics Stratified by Cohort*

	Pre-RACE (n = 676)	Post-implementation (All Patients) (n = 804)	RACE Cohort (n = 396)	Non-RACE Cohort (n = 408)
Age (years)	68	66	62	69
Male	48.8%	47.0%	48.5%	45.6%
White	41.1%	37.4%	28.8%	45.8%
Black	35.5%	38.1%	40.9%	35.5%
Hispanic	18.3%	17.7%	23.2%	12.3%
Admitted	100%	87%	74%	100%
NSTEMI	4.3%	4.5%	4.3%	4.7%
Unstable angina	6.4%	6.8%	7.6%	6.1%
Hospital revisits (30-day)	91/676 (13.5%)	112/804 (13.9%)	44/396 (11.1%)	68/408 (16.7%)
Hospital revisits (chest pain only) (30-day)	22/676 (3.3%)	24/804 (3.0%)	13/396 (3.3%)	11/408 (2.7%)
Cardiovascular events† (30-day)	1/676 (0.1%)	3/804 (0.4%)	1/396 (0.2%)	2/408 (0.5%)
Mortality (30-day)	5.0%	1.9%	1.0%	2.7%

RACE = Rapid Acute Cardiac Evaluation; NSTEMI = non-ST- elevation myocardial infarction.
* The post-implementation cohort was divided into those who received point-of-care testing (RACE cohort) and those who were admitted to Telemetry without point-of-care testing (non-RACE)
† Cardiovascular events include STEMI, NSTEMI, and angiography with cardiac stent placement after index hospital visit.

J Emerg Med. 2011 Oct 18. [Epub ahead of print].

Table 2. Comparison of Time from Triage to MD Evaluation, Disposition, Discharge from the ED (for Admission or to Home), and Discharge from the Hospital in the Pre-RACE, RACE, and Non-RACE Cohorts*

	Pre-RACE (n = 676)	Post-implementation (All Patients) (n = 804)	RACE Cohort (n = 396)	Non-RACE Cohort (n = 408)
Time to MD evaluation (95% CI)	1.8 h (1.7–2.0)	1.7 h (1.4–1.9)	1.9 h (1.6–2.2)	1.5 h (1.3–1.7)
Time to disposition (95% CI)	5.1 h (4.9–5.4)	5.0 h (4.7–5.3)	5.7 h (5.3–6.0)	4.3 h (4.0–4.6)
LOS in the ED (95% CI)	14.0 h (13.4–14.7)	9.6 h (8.5–10.3)	10.3 h (9.0–11.5)	8.6 h (7.8–9.4)
Time to objective cardiac testing (95% CI)	38.7 h (33.7–43.8)	35.7 h (28.7–41.7)	32.8 h (23.5–42.2)	39.2 h (32.3–46.2)
LOS in the hospital (95% CI)	5.3 days (4.8–5.9)	4.3 days (3.5–4.9)	3.5 days (2.5–4.5)	5.0 days (4.3–5.7)

RACE = Rapid Acute Cardiac Evaluation; ED = emergency department; CI = confidence interval; LOS = length of stay.
* Post-implementation results are based on combination of RACE and non-RACE cohorts. Times are reported as means.

J Emerg Med. 2011 Oct 18. [Epub ahead of print].

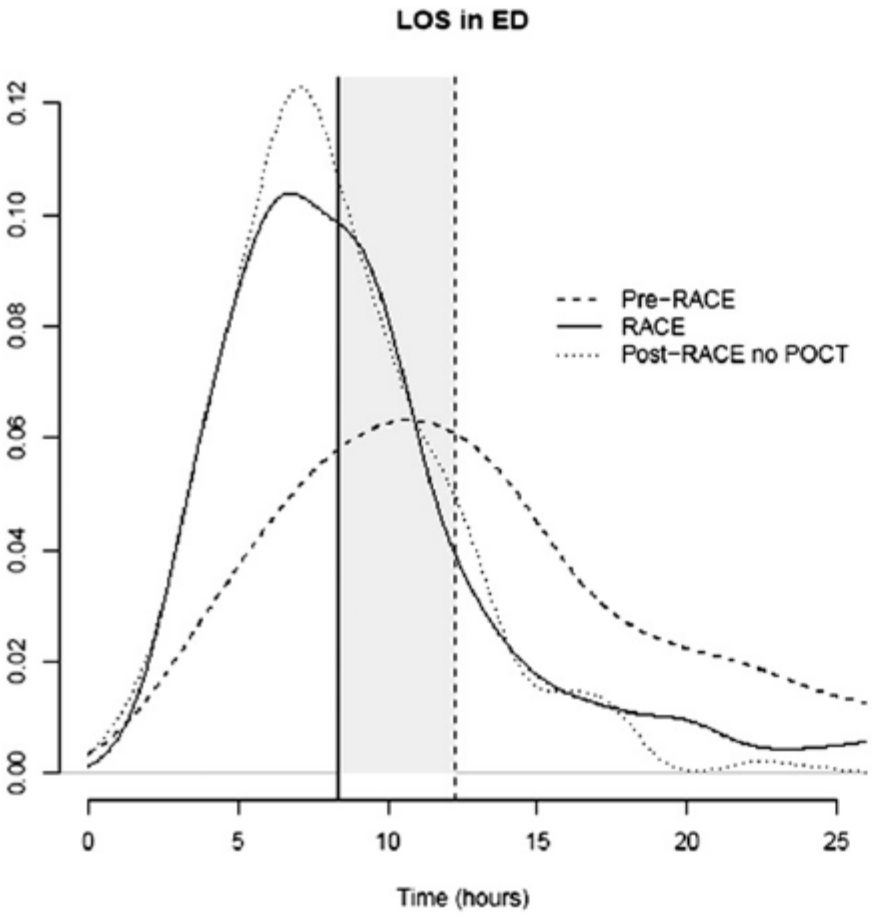

Figure 2. Distribution of length of stay (LOS) in the Emergency Department (ED) utilizing the standard testing of troponin T at 6-h intervals in the pre-Rapid Acute Cardiac Evaluation (RACE) and non-RACE cohorts vs. the accelerated RACE pathway using point-of-care bedside testing (POCT). Median times for the pre-RACE and RACE are indicated by the vertical lines.

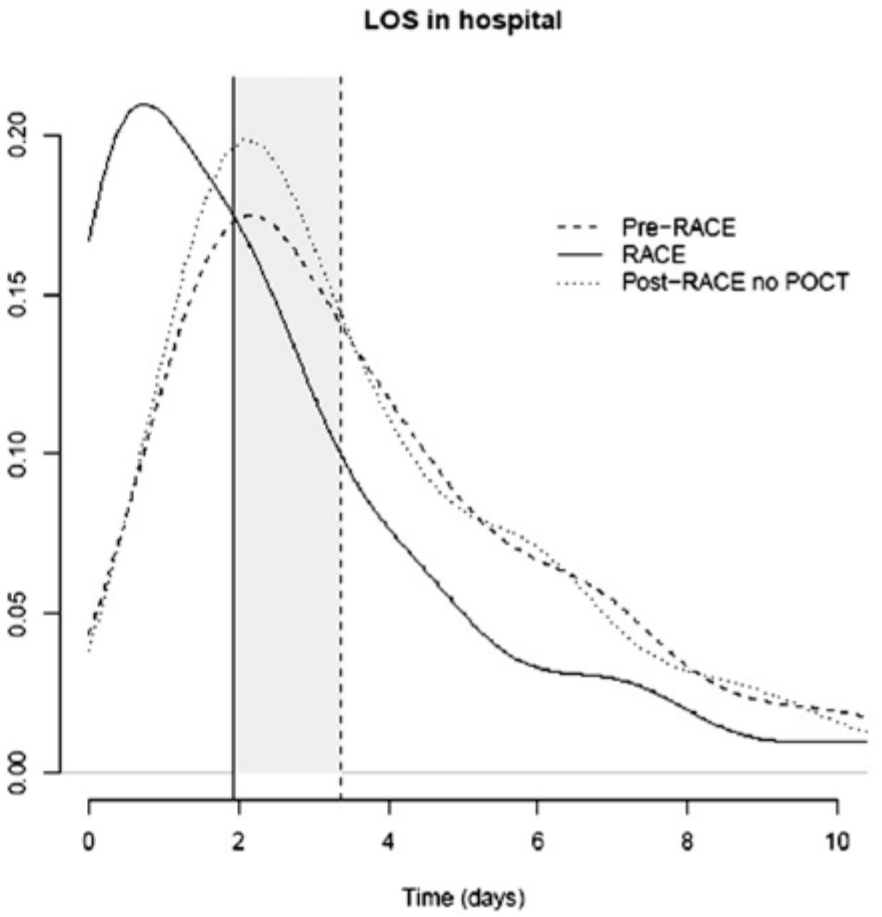

Figure 3. Distribution of hospital length of stay (LOS) utilizing the standard testing of troponin T at 6-h intervals in the pre-Rapid Acute Cardiac Evaluation (RACE) and non-RACE cohorts vs. the accelerated RACE pathway using point-of-care bedside testing (POCT). Median times for the pre-RACE and RACE cohorts are indicated by the vertical lines.

J Emerg Med. 2011 Oct 18. [Epub ahead of print].

The RATPAC (Randomised Assessment of Treatment using Panel Assay of Cardiac markers) trial: a randomised controlled trial of point-of-care cardiac markers in the emergency department

S Goodacre, M Bradburn, P Fitzgerald,
E Cross, P Collinson, A Gray and AS Hall

Health Tech Assess. 15 (2011) 1.

Does POCT for Cardiac Markers in the ED Improve Patient Outcomes?

- Multi-center, open randomized control trial in the UK across 6 acute hospital EDs
  - POCT biomarker panel versus central lab
  - Population: adults presenting to ED with chest pain and suspected AMI (N = 2,263)
  - Biomarkers: cTnI, CK-MB, myoglobin

- Primary Outcome Measure: proportion of patients successfully discharged from ED within 4 hours and suffering no major adverse events over the next 3 months

Health Tech Assess. 15 (2011) 1.

Additional Outcome Measures

- Secondary Outcome Measure: LOS, inpatient days over 3 months, major adverse events

- Economic analysis: estimated mean costs and quality-adjusted life-years (QALY); estimated cost-effectiveness assuming willingness to pay 20K (British pounds) per QALY gained

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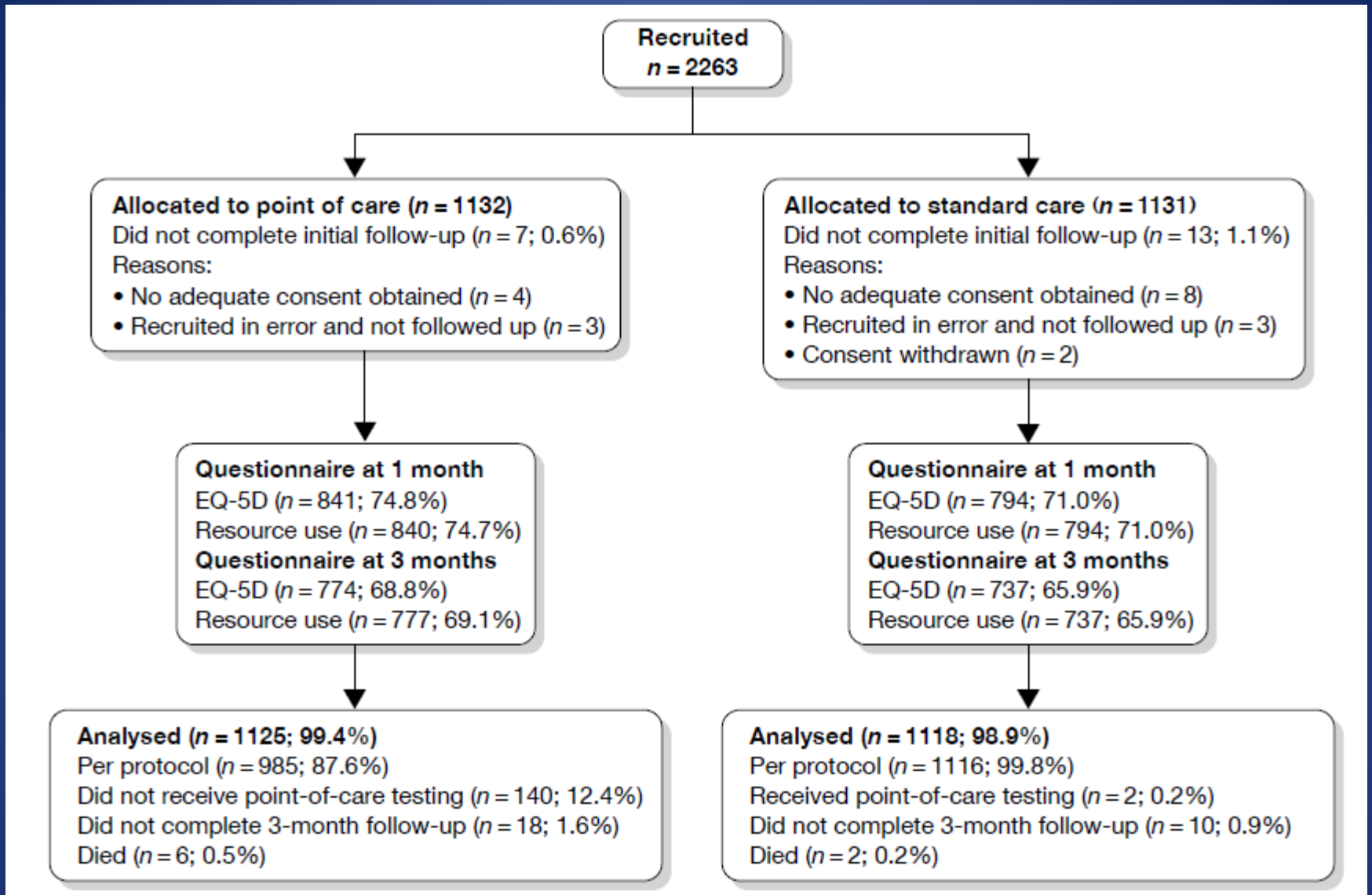

FIGURE 2 CONSORT chart showing flow of patients after recruitment.

Health Tech Assess. 15 (2011) 1.

TABLE 15 Primary outcome: per-protocol analysis

	PoC [*n* (%)]	SC [*n* (%)]	Total [*n* (%)]
Successfully discharged	326 (33)	145 (13)	471 (22)
Not successfully discharged	659 (67)	971 (87)	1630 (78)
Reason for no successful discharge			
In hospital 4 hours after arrival and no decision has been made to discharge	655 (66)	970 (87)	1625 (77)
Initially discharged but re-attended with major adverse event	4 (< 1)	1 (< 1)	5 (< 1)
Discharge success by initial status			
Initially discharged	330 (34)	146 (13)	476 (23)
Not in hospital at 4 hours	292 (30)	133 (12)	425 (20)
In hospital at 4 hours, decision made to discharge	38 (4)	13 (1)	51 (2)

PoC, point of care; SC, standard care.

Health Tech Assess. 15 (2011) 1.

TABLE 30 Major adverse events

	PoC ($n = 1125$) [n (%)]	SC ($n = 1118$) [n (%)]	Total ($n = 2243$) [n (%)]	OR (95% CI)[a]	p-value[a]
Any event	36 (3)	26 (2)	62 (3)	1.31 (0.78 to 2.20)	0.313
Death	6 (1)	2 (< 1)	8 (< 1)	3.4 (0.7 to 17.3)	0.142
Non-fatal AMI	5 (< 1)	5 (< 1)	10 (< 1)	0.9 (0.3 to 3.2)	0.903
Hospitalisation for ACS without AMI	18 (2)	9 (1)	27 (1)	1.8 (0.8 to 4.1)	0.149
Life-threatening arrhythmia	6 (1)	2 (< 1)	8 (< 1)	3.2 (0.6 to 15.9)	0.160
Emergency revascularisation	10 (1)	14 (1)	24 (1)	0.7 (0.3 to 1.5)	0.324

PoC, point of care; SC, standard care.

a Adjusted for age, gender and known CHD.

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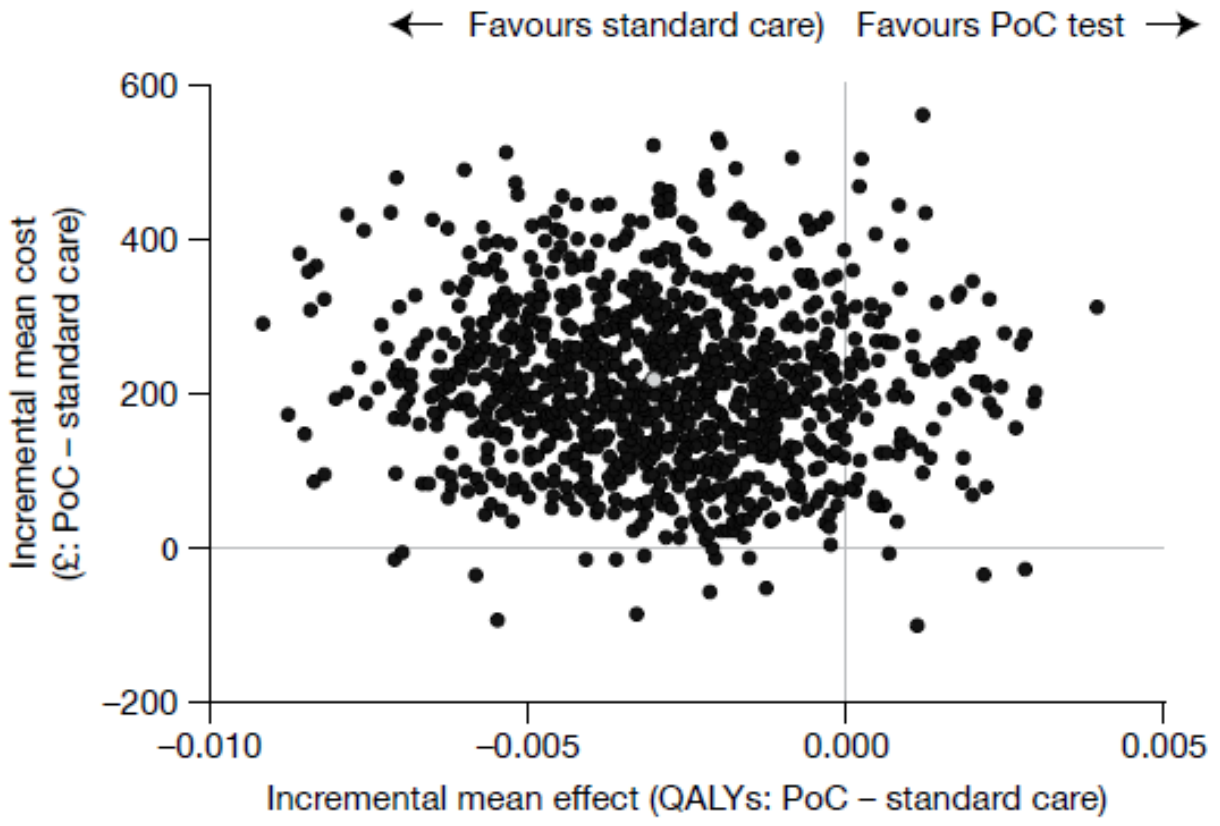

FIGURE 6 Cost-effectiveness plane for point-of-care treatment strategy.

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What Makes a Good Outcomes Study?

- Ideally would like parallel comparison (e.g randomized controlled trial)
  - Often difficult to implement & we must rely on observation cohort (before/after study)
- Define outcome measures during study planning (prior to data collection)
- Well-defined, quantifiable outcomes are preferable
  - Easier to make the case for/against testing with hard data
- Set performance/acceptability criteria prior to beginning of the study
  - What would the results need to show in order to demonstrate 'improved' outcomes?

How Can I Use This Where I Am?

- Most likely an observational study will be what is possible
- Work with clinical team to define the clinical problem – what do they want to accomplish?
- Define outcomes that can measure the level of success relative to the desired goals of the clinical team
- Encourage ownership of the clinical team in the process
- Let the data speak for itself!

QUESTIONS??

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Johns Hopkins Medical Laboratories
Baltimore, Maryland

Point-of-Care Testing
New Test Request Form
(One test request per form)

Date: _____ Department/Unit Requesting Test: _____

Requester's Name: _____ Title: _____

Telephone number / e-mail address: _____

TEST PROCEDURE: _____

Instrument/Kit Name: _____ Manufacturer: _____

A. Test site location(s): _____(Building, Floor, Room Number)

[ ] Inpatients only [ ] Outpatients only [ ] Inpatients and Outpatients [ ] Research Study

B. Hours of operation : _____ Frequency of test performance: _____

C. CLIA Test Complexity: [ ] Waived [ ] Moderately Complex [ ] Highly Complex [ ] PPM

D. Is this service currently available through the central laboratory? [ ] Yes [ ] No

E. What is the desired turnaround time for this test if performed in the central laboratory?

_____

F. Briefly explain why the current central laboratory services do not fulfill your needs?

_____

_____

G. If this test were made available at the point-of-care, how soon would the results be utilized for clinical decision making?

_____

H. Would patient treatment/management decisions be based solely on the point-of-care test results? [ ] Yes [ ] No

Explain: _____

_____

_____

Johns Hopkins Medical Laboratories
Baltimore, Maryland

Point-of-Care Testing
New Test Request Form

I. Estimate the number of point-of-care tests to be performed: _____/day _____/week ____/month

J. What level(s) of staff would be performing this test and how many would need to be trained?

_____

_____

K. Briefly describe what the patient care benefits/outcomes and potential cost savings would be with implementing this point-of-care test. (Please provide evidence, preferably peer-reviewed, of the test's clinical utility)

_____

_____

_____

L. Are funds approved to support the costs associated with this new test request? ? [ ] Yes [ ] No
(Some costs associated with bringing in POCT include quality control, reagents, test validation, training/competency assessment, proficiency testing, oversight, etc.)

M. Please provide cost center/budget number designated for Point-of-Care Testing costs: _____

N. Signatures Required:

Medical Director Signature/ Date: _____

PRINT NAME: _____

Finance Administrator's Signature/ Date: _____

PRINT NAME: _____

Testing Personnel Manager's Signature/Date: _____

PRINT NAME: _____

Date Received: _____ **[ ] Approve [ ] Disapprove**

Director, POCT Program: _____ **Date:** _____

Process Completion Date: _____ **Revision: 11/14/11**