

Study Title: Impact from point of care devices on emergency department patient processing times compared to central laboratory testing of blood samples: a randomised controlled trial and cost-effectiveness analysis.

Corresponding author:

Dr Stephen Asha,

stephen.asha@sesiahs.health.nsw.gov.au

c/o Emergency Department, St George Hospital, Gray St, Kogarah, 2217, NSW, Australia.

(Phone) +61 2 91131650, (Fax) +61 2 91133946

Study Investigators:

Stephen Edward Asha, MBBS, FACEM

Emergency Department, St George Hospital, Sydney, NSW, Australia

Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia

Adam Chiu Fat Chan, MBBS, FACEM

Emergency Department, St George Hospital, Sydney, NSW, Australia

Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia

Elizabeth Walter, BN, GradCert(Emergency Nursing)

Emergency Department, St George Hospital, Sydney, NSW, Australia

Patrick J Kelly, BMath(Hons), PhD

Sydney School of Public Health, University of Sydney, Sydney, NSW, Australia

Rachael L Morton, MScMed(Clin Epi), PhD

Sydney School of Public Health, University of Sydney, Sydney, NSW, Australia

Allan Ajami, BN, GradDip(project management)

Emergency Department, St George Hospital, Sydney, NSW, Australia

A/Prof Roger Denis Wilson, FRCPA, FRACMA

South Eastern Area Laboratory Services, NSW Health Pathology, Sydney, NSW, Australia

Faculty of Medicine, University of New South Wales, Sydney, NSW, Australia

Daniel Honneyman, MbChB

Emergency Department, St George Hospital, Sydney, NSW, Australia

Keywords: Randomized Controlled Trials as Topic; Point-of-Care Systems; Time Factors; Emergency Service, Hospital; Length of Stay; Cost-Benefit Analysis

Word count: 3290

ABSTRACT

Objective: To determine if time to disposition decisions for emergency department(ED) patients can be reduced when blood tests are processed using point-of-care(POC) devices; to conduct a cost-effectiveness analysis of POC compared to laboratory testing.

Methods: This randomised trial enrolled adults suspected of an acute coronary syndrome(ACS) or presenting with conditions considered to only require blood tests available by POC. Participants were randomised to have blood tests processed by POC or laboratory. Outcomes measured were time to disposition decision and ED length-of-stay(LOS). The cost-effectiveness analysis calculated total and mean costs per ED presentation, as well as total and mean benefits in time saved to disposition decision.

Results: There were 410 POC participants and 401 controls. The mean times to a disposition decision for POC versus controls was 3.24 hours and 3.50 hours respectively, a difference of 7.6%(95%CI 0.4%–14.3%, p=0.04) and 4.32 and 4.52 hours respectively for EDLOS, a difference of 4.4%(95%CI -2.7%–11.0%, p=0.21). Improved processing time was greatest for participants enrolled by senior staff with a reduction in time to disposition decision of 19.1%(95%CI 7.3%–29.4%, p<0.01) and EDLOS of 15.6%(95%CI 4.9%–25.2%, p=0.01). Mean pathology costs were \$12 higher in the POC group (95%CI \$7-18) and the incremental cost-effectiveness ratio was \$113 per hour saved in time to disposition decision for POC compared to standard laboratory testing.

Conclusions: Small improvements in disposition decision time were achieved with POC testing, for a moderate increase in cost. Greatest benefit may be achieved when POC is targeted to senior medical staff.

INTRODUCTION

Reducing the time that patients stay in the Emergency Department (ED) is a desirable goal to reduce over-crowding, improve patient flow, improve patient satisfaction and reduce morbidity and mortality.¹⁻⁵ Australian EDs also must comply with the recently introduced National Emergency Access Target of 4 hours for completion of ED management.⁶ Point-of-care(POC) testing, defined as laboratory testing in or near a patient location with rapid availability of test results, has the potential to reduce ED length-of-stay(LOS) through short turn-around times allowing clinical decisions to be made earlier.

The literature has conflicting results and it is not clear if POC testing can achieve the benefits of faster decision making and shorter ED LOS. A before/after study design⁷ using POC troponin testing for acute coronary syndromes(ACS) demonstrated shorter ED LOS and time to admission decisions, a quasi-randomised trial⁸ was only able to demonstrate a trend to shorter ED LOS, while two randomised trials failed to demonstrate a benefit.⁹⁻¹⁰ In studies of POC testing using machines that perform a variety of blood tests, two before/after studies demonstrated shorter ED LOS¹¹⁻¹² while a third did not,¹³ a small randomised trial found a shorter ED LOS,¹⁴ but a large randomised trial was unable to demonstrate a difference in ED LOS, hospital LOS, admission rates or mortality.¹⁵ None of these studies have assessed cost-effectiveness of POC devices in the ED.

In this study we tested the hypothesis that the short turn-around times of POC devices would translate to improved patient processing times. The primary aim of this study was to determine if the time to make an admission or discharge decision (hereafter referred to as a disposition decision) could be reduced with common blood tests being available by POC testing in the ED. Secondary aims were to investigate improvements in processing times on several patient subgroups, and to perform a cost-effectiveness analysis of POC compared to central laboratory testing from an Australian health system perspective.

METHODS

Study design and Setting

This study was an open, parallel arm, randomised trial conducted in the ED of a tertiary referral and level 1 trauma centre located in Sydney, New South Wales, Australia, over a six month period from December 2011 to May 2012. The ED has approximately 65,000 presentations a year, and pathology services are available 24 hours a day. Permission for the study was granted by the South Eastern Sydney and Illawarra Area Health Service (central network) Human Research Ethics Committee and registered with the Australia and New Zealand Clinical Trials Registry (ANZCTR #12611001228976). Funding for this study was provided by a grant from the NSW Department of Health (Ministerial Taskforce on Emergency Care “Taking the pressure of public hospitals” project grants 2011/12) and from the study hospital.

Selection of participants

Patients presenting to the ED were eligible for the study if they were ≥ 18 years of age, and fulfilled the requirements for either of the following two groups. The first group (ACS group) were patients suspected of having an ACS. Those with acute ST-elevation myocardial infarction were excluded. The second group (general group) were patients whom the enrolling staff member thought would only need blood tests from the selection available by POC to complete assessment and management. The POC blood tests available were creatinine, electrolytes, glucose, calcium, haemoglobin, Troponin T, D-Dimer, beta-HCG, and INR. The POC devices used were the Radiometer ABL-800 FLEX blood-gas analyser, Radiometer AQT-90 FLEX, and the Roche CoaguChek XS-PRO. Patients who presented more than once to the ED within the study period could be re-enrolled.

Participants were enrolled by nurses, nurse-practitioners and doctors from intern to consultant level. Nurses could enrol participants as it is routine practice in this ED for nurses to ‘fast-track’ blood tests for patients waiting to be seen by a doctor. Study recruitment was driven by regular education and updates at staff meetings, and regular encouragement by the research staff in the department.

Method of randomisation

The requirement for obtaining individual patient consent was waived by the ethics committee. Participants meeting the inclusion/exclusion criteria were randomly allocated by opening sequentially numbered, sealed, opaque envelopes which contained the study allocation. Randomisation was stratified according to clinical group (ACS or general). To ensure balanced numbers of participants in each arm of the study block randomisation was used, with blocks of variable size to prevent prediction of the allocation sequence in this non-blinded study. The randomisation sequence was created using a computerised random number generator.

Interventions

For participants allocated to the intervention, in the general group all blood tests were processed in the ED using the POC devices. For participants in the ACS group, only the troponin was processed using the POC device, and other blood tests if required were sent to the central laboratory for processing. This was because we considered troponin to be the critical blood test for making a disposition decision in patients with an ACS, while other tests often are requested for ‘baseline’ measurement and infrequently influence management and disposition. Turn-around times for the POC devices (time from specimen insertion into the POC device to availability of the result) ranged from 2 minutes to 22 minutes.

For participants allocated to the control arm of the study (ACS and general groups) all blood tests were sent to the central hospital pathology service for processing. Turn-around times for

laboratory tests (time from sending a specimen to the laboratory to availability of the result) usually take between 30 minutes and 2 hours.

Following this initial set of testing any additional pathology required was performed in the central laboratory.

Outcome measures

The primary outcome was the time from ED arrival to disposition decision. This was chosen as the primary outcome (rather than ED LOS) as delays in accessing in-patient ward beds and ultimate transfer out of ED may mask a benefit in patient processing time.

The secondary outcomes were ED LOS for the whole study population; time to disposition decision and ED LOS for the following subgroups: diagnostic group (ACS or general), disposition (discharged home, admitted to the ward, admitted to the Emergency Medicine Unit which is an ED short stay ward), seniority of enrolling staff. A cost-effectiveness analysis of POC testing compared to central laboratory testing was conducted.

All outcomes measured were pre-specified with the exception of seniority of enrolling staff which was the only exploratory subgroup analysis performed.

Methods and Measurements

The staff member enrolling a participant entered diagnostic information on a data collection form. For those in the general group this was the provisional diagnosis, while those in the ACS group were stratified to a low, intermediate or high risk category. Demographic data and times for the primary and secondary outcomes were obtained from the ED computer management system in which the times of all significant events in the patient journey are entered. The time of admission decision was defined as the time that the clinician notified the nurse in charge to book a bed following patient acceptance by an admitting team. For patients sent home, the discharge decision time was the departure ready time as entered by the

clinician into the ED computer management system. This was often the same as the departure time but may be earlier for patients awaiting transportation home.

Analysis

The required sample size was determined using the mean and standard deviation of the disposition decision time for the study population estimated from a pilot study conducted over 2 months prior to the start of the randomised trial. Clinicians completed a survey for each adult patient seen to identify patients fulfilling inclusion/exclusion criteria. Disposition decision times were obtained from the ED computer management system. We considered a 15% reduction in disposition decision time to be the minimum clinically important reduction. Using a power of 80% and an α -level of 0.05, 450 participants were needed. We required this study to be powered for subgroup analysis, in particular the ACS group. The pilot study demonstrated the ACS group and the whole study group to have a similar mean and standard deviation, so we determined to stop the study once 450 participants had been enrolled in the ACS group.

The primary analysis was by intention-to-treat. The outcome measures of time to disposition decision and ED LOS were positively skewed. Therefore, the data were first transformed to a normal distribution by taking the natural logarithm and the analysis was conducted by comparing the means of the natural logarithm of these outcomes using linear regression. The differences in time between study groups are presented as percentage reductions in the means of the logarithmically transformed data, while the average times presented are the geometric means, which are the means of the logarithmically transformed data back-transformed using the exponential. A random effect model was included to adjust for repeated presentations over the period of the study. This analysis was conducted in Stata 12(StataCorp LP, Texas, USA).

Economic evaluation

The cost-effectiveness analysis calculated total and mean costs per ED presentation, as well as total and mean benefits in time saved to disposition decision. All pathology and radiology tests from the time of arrival to the time of disposition decision were obtained from the pathology and radiology databases respectively. Direct unit costs from the pathology service provider and hospital casemix data were obtained for each pathology and radiology diagnostic test. Indirect costs for capital equipment (i.e. POC analysers) were calculated using the equivalent annual cost method.¹⁶ A weighted average clinical staff time for POC and laboratory test processing was derived from a time-in-motion study with 25 consecutive ED presentations. The differences between costs in the two groups, and the 95% confidence intervals were then calculated. Volumes of resources and costs are reported as mean values with standard deviations and as mean differences with 95% confidence intervals. Discounting was not applied. The arithmetic mean of the disposition decision time (rather than the geometric mean as described above) was used in the calculation of an incremental cost-effectiveness ratio (ICER) for POC compared to central laboratory testing, as this is the standard methodology used for economic evaluations. The ICER was calculated using the following formula: $(\text{mean cost of POC} - \text{mean cost of control}) / (\text{mean effect of POC} - \text{mean effect of control})$. Non-parametric bootstrapping was employed for a 95% confidence interval around the ICER. The economic analysis was conducted in Excel 2007 (Microsoft, USA).

RESULTS

Characteristics of study subjects

There were 881 presentations enrolled. Sixty six enrolment forms were not returned preventing identification of the participant. Two participants were excluded as they were enrolled in both arms of the study for the same presentation. This left 811 presentations available for the intention-to-treat analysis. There were 410 presentations randomised to POC

and 401 to the control arm of the study (Figure 1). Nineteen participants presented and were enrolled more than once during the study: 17 participants had two observations, one participant had three observations, and one participant had five observations. The trial was balanced with respect to baseline characteristics (Table 1).

Main results

For the primary outcome, POC testing reduced the time to a disposition decision from a mean of 3.50 hours to 3.24 hours, a difference of 0.26 hours or 7.6% (95%CI 0.4%–14.3%, $p=0.04$), with trends toward shorter decision making times in all subgroups analysed (table 2). There was a reduction in ED LOS of 4.4%, from 4.52 to 4.32 hours. This difference was not statistically significant (95%CI -2.7%–11.0%, $p=0.21$). There were trends toward shorter ED LOS in all but one of the subgroups analysed (Table 3). The improvement in patient processing times were greatest for those patients enrolled by senior staff (consultants and registrars), with a reduction in the time to a disposition decision of 19.1% (95%CI 7.3%–29.4%, $p<0.01$) and ED LOS of 15.6% (95%CI 4.9%–25.2%, $p=0.01$). Testing for interaction was performed to determine if there was evidence that the effect of the intervention on processing time depended on the seniority of the enrolling staff (test for interaction $p=0.06$ and $p=0.21$ for disposition decision time and ED LOS respectively).

Economic outcomes

The calculation of the ICER was based on the arithmetic mean time to a disposition decision (rather than the geometric mean presented in the main results). This was 3.78 hours in the POC group and 3.99 hours for the control group, a difference of 0.21 hours (13 minutes) in favour of POC testing.

Resource utilisation

Table 4 shows the utilisation of health-care resources per ED presentation according to the study group allocation. The number of pathology, radiology and cardiology tests per

presentation did not significantly differ between the groups. The ED staff time for hands-on pathology processing was significantly shorter in the POC group compared to the control group (1.34 minutes, 95%CI 1.22–1.46).

Health-care costs

Health-care costs per ED presentation are also reported in Table 4. For pathology costs, there was no significant difference in the mean volume of tests; however the mean cost per patient was \$12 higher in the POC group, (95% CI \$7-\$18). The overall health-care costs per ED presentation were \$174+/- \$157 in the POC group and \$150+/- \$129 in the control group, a net difference of \$24 (95%CI \$4–\$44) in favour of the control group.

Cost-effectiveness

The point estimate of the incremental cost-effectiveness ratio (ICER) was \$113 per hour saved in time to a disposition decision for POC compared to standard laboratory testing. Figure 2 shows a cost-effectiveness plane with a plot of the bootstrap replicates of per-presentation incremental costs and incremental hours saved. Seventy percent of replicates were in the north-east quadrant of the plane, showing that in the majority of cases POC had both higher costs and higher effects (i.e saved time) compared to the control group.

Figure 3 shows a cost-effectiveness acceptability curve of POC testing at different willingness to pay levels for one hour of time saved to disposition decision. This curve indicates the probability that an intervention is cost-effective compared to its alternative, given the data, for a range of values up to a maximum acceptable ceiling ratio. If the Australian health system were willing to pay \$120 or higher in order to save one hour of time in the ED then our data suggests POC testing has an 80% probability of being cost-effective.

DISCUSSION

In this randomised trial we were able to demonstrate a small reduction in the time to reach a disposition decision and in the ED LOS amongst participants randomised to POC testing. While the improvement in the primary outcome was statistically significant, we had pre-specified that we considered the minimum clinically important reduction to be 15%. In the subgroup analysis, there were trends toward small improvements in processing times with the exception of participants enrolled by senior staff where the outcomes were considerably better and exceeded our minimum clinically important reduction.

There are a number of reasons why only modest improvements were demonstrated. Physicians seeing several patients simultaneously may have got caught up in clinical care delaying action on an available result. Participants enrolled by nurses were having tests ‘fast-tracked’ prior to being seen by a doctor, so the benefit of POC testing may have been nullified by prolonged waiting times. Possibly the most important factor was that a junior doctor’s ability to make decisions could be influenced more by the time taken to obtain a history, examination and consultation with a senior rather than the turn-around time of a test. As the majority of patients were enrolled by junior doctors this would have had a strong influence towards a null effect. This is supported by the subgroup analysis of processing times according to the seniority of the clinician. Contrary to what would be expected, processing of POC specimens did not add an extra time burden to ED staff as demonstrated by the time-in-motion studies. The reason for this is that specimens for the central laboratory required a computer generated request form, with time consumed through logging on, entering required tests, electronic signatures and printing.

These are important findings for departments considering the implementation of POC devices, particularly for tertiary EDs with large numbers of junior staff, and laboratory services available 24 hours a day. Our results would indicate that in such a setting only small benefits could be expected. However, if the use was targeted to senior staff with the

experience and ability to make rapid decisions, clinically relevant benefits can be realised. It is also important to emphasise the importance of system improvements to ensure flow of patients out of the ED as any improvements in efficiency within the ED will be quickly lost, an effect echoed in our results with smaller improvements seen in ED LOS compared to a disposition decision.

Despite these modest improvements in processing time, the increased cost of POC testing to the Australian health care system is relatively small for the benefit of an hour saved in disposition decisions. To put our price of \$113 into perspective, Australian EDs are funded based on their activity, with this ED allocated \$505 per patient treated.¹⁷ Participants enrolled in this study had an average LOS of approximately 4.5 hours. At face value this would equate to \$112 per patient per hour of their stay, which would suggest that POC testing is a cost neutral intervention if time saved in decision making translated to time saved in the ED.

Previous research in this area has had mixed results, although if only randomised studies are considered all but one has failed to demonstrate a benefit from POC devices.^{9-10, 14-15} In contrast, this study has demonstrated small benefits and importantly has identified a niche amongst senior clinicians for the rational use of POC devices. As far as we are aware our study is the first to evaluate the cost-effectiveness of POC devices in the ED.

Limitations

This study was not blinded. This study was assessing patient processing times and as POC testing involves the ED staff in sample processing it is important that all normal procedures that would occur with usual use of POC devices be preserved. As such it was not possible to blind staff to the study allocation. Staff behaviour may, however, be influenced by the knowledge of study allocation which could introduce systematic bias.

Another potential source of bias was the loss of 7% of enrolment forms, without which the participant that was enrolled could not be identified. If this was a random event this would be

unlikely to introduce bias, but if there was a systematic reason such as staff discarding the form if they received a particular allocation, this could introduce important bias. Given the similar proportion of missing forms in each arm of the study and the balance in baseline characteristics, this is likely to have been a random event.

There may also be inaccuracies in the measurement of the processing times as this relied on staff entering the time on the computer management system. When staff were diverted by more urgent priorities the time recorded may have been longer.

The generalisability of results from single centre study is always a concern as the patients or conditions unique to a particular institution may reduce the relevance when extrapolated to other sites. However, the patient population targeted by this study tended to be of lower acuity, with single system problems commonly seen in all EDs, and so our results should be relevant to a broad range of ED environments.

With regards to the economic evaluation, the cost-effectiveness results may be limited in their generalisability to tertiary EDs supported by pathology services with similar costs.

Conclusion

To conclude, small improvements in time to a disposition decision were achieved with the use of POC testing in the ED. Despite the modest benefits, POC testing devices within the ED may be a cost effective intervention. The greatest benefit from POC testing may be achieved when the use of POC devices is targeted to senior medical staff.

Figure 1: Participants

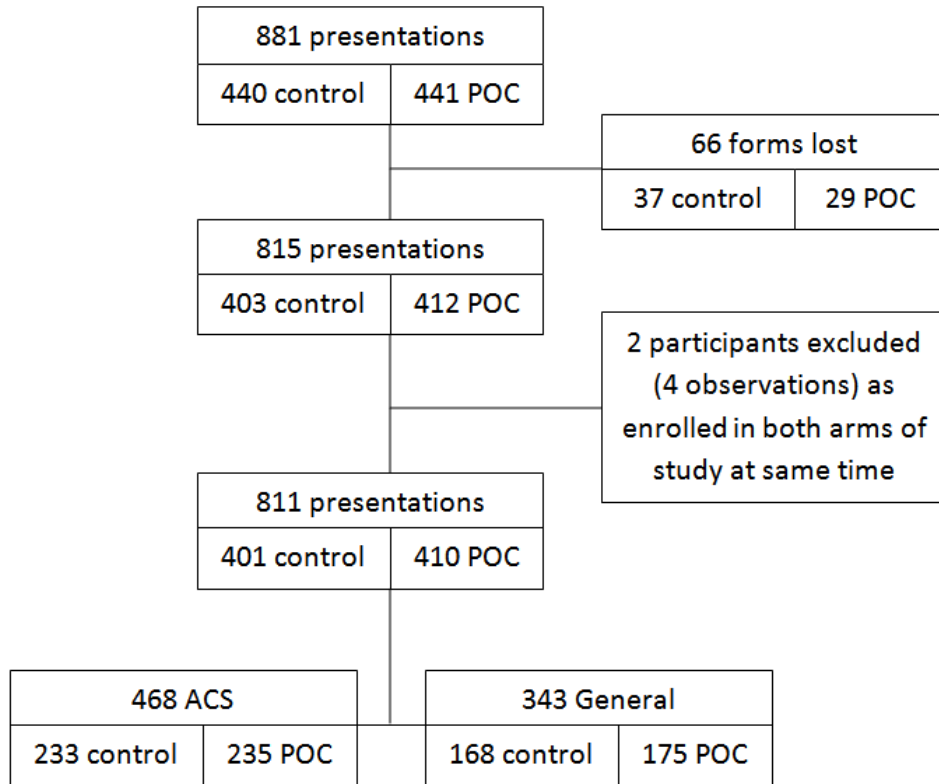


Table 1: Baseline characteristics by randomization group

Characteristic	Control (n=401)		POC (n=410)	
	Mean or n	(SD or %)	Mean or n	(SD or %)
Age	57.8	(20.4)	57.7	(20.1)
Sex				
Female	223	(56)	219	(55)
Male	178	(44)	191	(46)
Arrival mode				
Private Car	247	(62)	264	(63)
Ambulance	152	(38)	144	(37)
Police	2	(1)	2	(<1)
Enrolling Staff				
Consultant	36	(9)	48	(10)
Registrar	77	(19)	83	(20)
Medical Officer (Junior, Career, Senior Resident)	205	(51)	194	(49)
Nurse (Registered or Practitioner)	83	(21)	85	(21)
Australasia Triage scale				
1	1	(<1)	1	(<1)
2	207	(52)	215	(52)
3	127	(32)	103	(28)
4	63	(16)	83	(18)
5	3	(1)	8	(1)
Insurance				
Yes	157	(39)	157	(39)
No	238	(59)	252	(60)
Missing	6	(2)	1	(1)
Diagnosis category				
ACS group	233	(58)	235	(58)
<i>Low risk</i>	77	(19)	65	(18)
<i>Intermediate risk</i>	103	(26)	119	(27)
<i>High risk</i>	33	(8)	41	(9)
<i>ACS risk stratification not specified</i>	20	(5)	10	(4)
General group	168	(42)	175	(42)
<i>Non-cardiac chest pain</i>	19	(5)	21	(5)
<i>Bleeding (nose/GI/respiratory/urine/wound)</i>	18	(4)	16	(4)
<i>PV bleeding in pregnancy</i>	25	(6)	28	(7)
<i>Trauma/falls/head injury</i>	15	(4)	12	(3)
<i>Syncope/vertigo/dizziness</i>	13	(3)	17	(4)
<i>Palpitations/arrhythmia</i>	11	(3)	7	(2)
<i>Abdominal /flank pain</i>	10	(2)	15	(3)
<i>Gastroenteritis/dehydration</i>	9	(2)	7	(2)
<i>Vomiting</i>	8	(2)	11	(2)
<i>Anaemia</i>	3	(1)	9	(1)
<i>Other</i>	37	(9)	32	(9)
Laboratory troponin in ACS subgroup (n = 458†)				
≤ 14ng/L*	171	(75)	175	(76)
> 14ng/L	58	(25)	54	(24)

† Ten presentations had missing laboratory troponin; * Reference range for a negative troponin is ≤ 14ng/L

Table 2: Time from arrival to disposition decision

	Geometric mean (hours)		% reduction (95% CI)	P-value
	Control	POC		
Overall	3.50	3.24	7.6 (0.4, 14.3)	0.04
Diagnostic group				<i>0.86[†]</i>
ACS	3.43	3.15	8.2 (-0.9, 16.5)	0.08
General	3.61	3.36	6.9 (-5.2, 17.6)	0.25
Disposition				<i>0.60[†]</i>
Discharge home	3.68	3.50	4.9 (-5.9, 14.5)	0.36
Admit to ward	3.66	3.22	12.1 (-0.8, 23.3)	0.06
Admit to EMU	2.94	2.81	4.4 (-11.1, 17.8)	0.56
Enrolling staff				<i>0.06[†]</i>
Consultant or registrar	3.63	2.94	19.1 (7.3, 29.4)	<0.01
Junior medical officer	3.54	3.51	0.9 (-9.6, 10.4)	0.85
Nurse	3.24	3.12	3.8 (-15.7, 20.1)	0.68

[†] testing for an interaction between treatment and subgroup

Table 3: Length of Stay in the Emergency Department

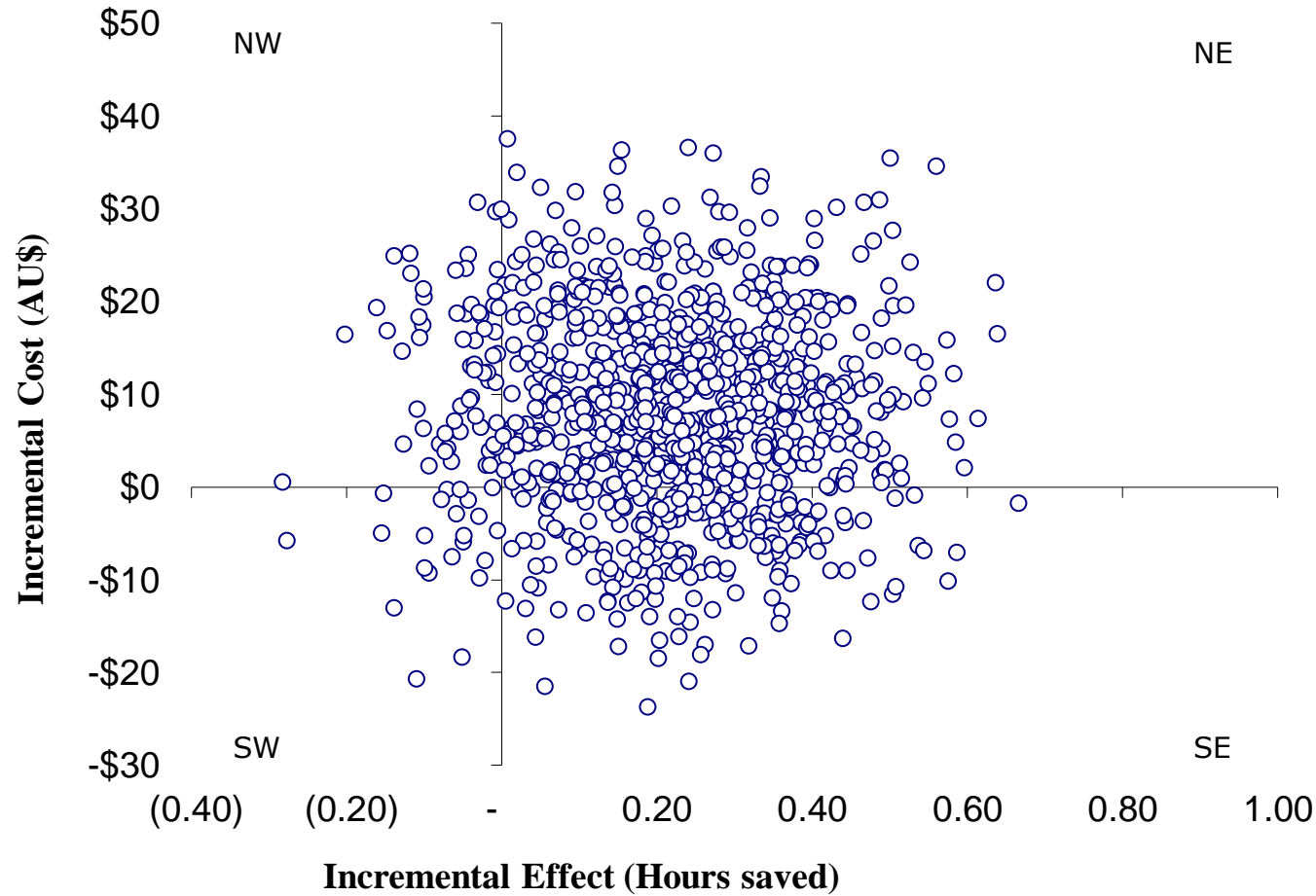
	Geometric mean (hours)		% reduction (95% CI)	P-value
	Control	POC		
Overall	4.52	4.32	4.4 (-2.7, 11.0)	0.21
Diagnostic category				<i>0.70[†]</i>
ACS	4.65	4.50	3.1 (-5.5, 10.9)	0.47
General	4.34	4.09	5.7 (-6.6, 16.6)	0.35
Disposition				<i>0.62[†]</i>
Discharge	4.15	3.78	8.9 (-0.9, 17.7)	0.08
Admit to ward	5.86	5.52	5.8 (-5.6, 16.0)	0.31
Admit to EMU	3.59	3.49	2.8 (-11.2, 15.1)	0.68
Enrolling staff				<i>0.21[†]</i>
Consultant or registrar	4.96	4.19	15.6 (4.9, 25.2)	0.01
Junior medical officer	4.51	4.59	-1.7 (-12.4, 7.9)	0.74
Nurse	4.31	3.70	14.1 (-1.6, 27.5)	0.08

[†] testing for an interaction between treatment and subgroup

Table 4. Mean use of health-care resources and mean total health-care costs per presentation for time to decision according to random allocation

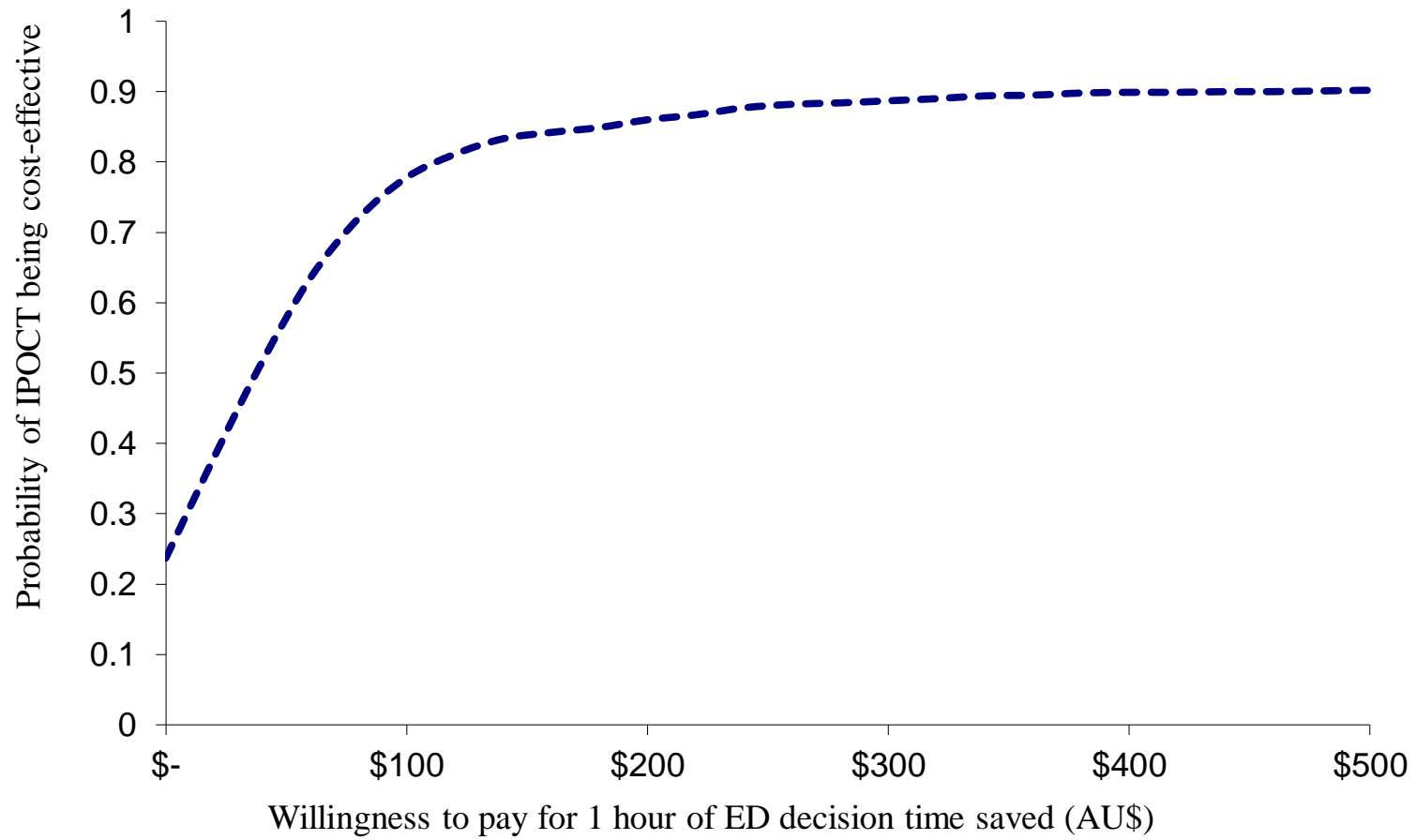
Item	POC (n=410)		Control (n=401)		Difference	
	Mean (SD)		Mean (SD)		Mean (95% CI)	
	Volume	Cost (\$)	Volume	Cost (\$)	Volume	Cost (\$)
Pathology tests	4.41 (2.59)	84 (35)	4.38 (2.08)	72 (41)	0.03 (-0.30, 0.36)	12 (7, 18)
Radiology tests	0.76 (0.71)	85 (145)	0.77 (0.59)	75 (119)	-0.01 (-0.10, 0.08)	10 (-8, 28)
Cardiology tests	0.02 (0.13)	4 (32)	0.01 (0.09)	1 (17)	0.01 (-0.01, 0.03)	3 (-1, 7)
ED staff time pathology (mins)	1.28 (0.78)	1 (0.1)	2.63 (0.92)	2 (0.1)	-1.34 (-1.46, -1.22)	-1 (-1, -1)
Total cost		174 (157)		150 (129)		24 (4, 44)

Figure 2: Cost-effectiveness plane showing 1000 bootstrap replicates of incremental cost per hour saved (time to disposition decision) for POC vs central laboratory testing



NE= north-east quadrant where interventions are more expensive, but more effective. SE= south-east quadrant where interventions are less expensive and more effective. SW= south west quadrant where interventions are less expensive but less effective. NW= north-west quadrant where interventions are more expensive and less effective.

Figure 3: Cost effectiveness acceptability curve for POC at different willingness to pay levels



Competing Interests

None

Funding

Funding for this study was provided by a grant from the NSW Department of Health (Ministerial Taskforce on Emergency Care “Taking the pressure of public hospitals” project grants 2011/12) and from the St George Hospital.

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