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Goldstein, Lara Nicole

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AN ASSESSMENT OF THE TIME-SAVING AND ECONOMIC IMPACT OF UPFRONT, POINT-OF-CARE TESTING IN THE EMERGENCY DEPARTMENT

Lara Nicole Goldstein

9600504A

Original published work submitted to the Faculty of Health Sciences, University of the Witwatersrand, in fulfilment of the requirements of the degree of **Doctor of Medicine**

Johannesburg, 2020

DECLARATION

Candidate's contribution to articles and agreement of co-authors

I, Lara Nicole Goldstein, student number 9600504A, declare that this thesis is my own unaided work. It is being submitted for the Degree of Doctor of Medicine at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University. I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong. I confirm that ALL the work submitted is my own unaided work except where I have explicitly indicated otherwise. I have followed the required conventions in referencing the thoughts and ideas of others. I understand that the University of the Witwatersrand may take disciplinary action against me if there is a belief that this is not my own unaided work or that I have failed to acknowledge the source of the ideas or words in my writing.

CANDIDATE – Lara Nicole Goldstein



Signature of Candidate

24th day of November 2020, Johannesburg

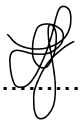
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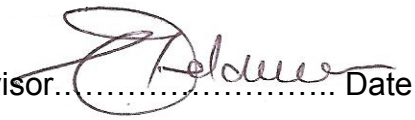
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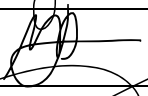
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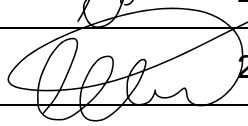
Article 1: Goldstein LN, Wells M, Vincent-Lambert C. A Randomized Controlled Trial to Assess the Impact of Upfront Point-of-Care Testing on Emergency Department Treatment Time. Am J Clin Pathol. 2018;150(3):224-234.

Authors	Name	Signature	Date
1st author	Lara Nicole Goldstein		24 November 2020
2nd author	Mike Wells		24 November 2020
3rd author	Craig Vincent-Lambert		24 November 2020

Article 2: Goldstein LN, Wells M, Vincent-Lambert C. The cost-effectiveness of upfront point-of-care testing in the emergency department: a secondary analysis of a randomised, controlled trial. Scand J Trauma Resusc Emerg Med. 2019;27(1):110.

Authors	Name	Signature	Date
1st author	Lara Nicole Goldstein		24 November 2020
2nd author	Mike Wells		24 November 2020
3rd author	Craig Vincent-Lambert		24 November 2020

Article 3: Goldstein LN, Wells M, Vincent-Lambert C. The cost of time: A randomised, controlled trial to assess the economic impact of upfront, point-of-care blood tests in the Emergency Centre. Afr J Emerg Med. 2019;9(2):57-63.

Authors	Name	Signature	Date
1st author	Lara Nicole Goldstein		24 November 2020
2nd author	Mike Wells		24 November 2020
3rd author	Craig Vincent-Lambert		24 November 2020

Article 4: Goldstein LN, Wells M, Vincent-Lambert C. Doctors' perceptions of the impact of upfront point-of-care testing in the emergency department. PLoS One. 2018;13(12):e0208655.

Authors	Name	Signature	Date
1st author	Lara Nicole Goldstein		24 November 2020
2nd author	Mike Wells		24 November 2020
3rd author	Craig Vincent-Lambert		24 November 2020

DEDICATION

This thesis is dedicated to the love of my life, my husband, Mike.

He makes everything worthwhile!

PRESENTATIONS ARISING FROM THIS STUDY

International Conferences

Conference	6th EMSSA Emergency Medicine Society of South Africa
Title of Presentation	An assessment of the impact of upfront, early point-of-care testing on disposition times in an Emergency Department EPOC-BEX-ED
Date	3-5 October 2017
Location	Sun City, South Africa

Local Conferences

Conference	Annual Gauteng Laboratory and Blood Services Conferences
Title of Presentation	The impact of point-of-care testing on the Emergency Department
Date	20 September 2019
Location	Johannesburg, South Africa

PUBLICATIONS ARISING FROM THIS STUDY

1. Goldstein LN, Wells M, Vincent-Lambert C. A Randomized Controlled Trial to Assess the Impact of Upfront Point-of-Care Testing on Emergency Department Treatment Time. Am J Clin Pathol. 2018;150(3):224-234.

2. Goldstein LN, Wells M, Vincent-Lambert C. The cost-effectiveness of upfront point-of-care testing in the emergency department: a secondary analysis of a randomised, controlled trial. Scand J Trauma Resusc Emerg Med. 2019;27(1):110.

3. Goldstein LN, Wells M, Vincent-Lambert C. The cost of time: A randomised, controlled trial to assess the economic impact of upfront, point-of-care blood tests in the Emergency Centre. Afr J Emerg Med. 2019;9(2):57-63.

4. Goldstein LN, Wells M, Vincent-Lambert C. Doctors' perceptions of the impact of upfront point-of-care testing in the emergency department. PLoS One. 2018;13(12):e0208655.

ABSTRACT

The Emergency Department (ED) is an environment that is perpetually “on the edge of chaos”. Despite this, the optimal functioning of the ED and the ability to provide timeous care, is critical to saving lives and preventing patient morbidity.

Delivering *upfront* point-of-care (POC) testing within an ED – performing diagnostic tests at or near the location of the patient prior to patients receiving their initial doctor evaluation, has the potential to expedite patient throughput and thus save time and possibly money.

The aim of this research was to compare and assess the traditional patient flow pathway of the ED to a modified pathway that made use of *upfront* POC tests (blood tests, ECG and/or LODOX®) in various permutations. The studies evaluated whether the modified pathway had beneficial effect on treatment times and costs, and evaluated doctor perceptions of its implementation.

Two separate studies were conducted in order to assess the impact of *upfront* POC testing in the ED – a prospective, randomised, controlled trial, and a survey. The trial had three separate components to evaluate the effects of *upfront* POC on treatment times; the potential economic benefit for EDs in low- and middle-income countries (LMIC) and overall cost-effectiveness. The survey assessed doctors’ perceptions and acceptance of the system changes and the potential barriers to implementing *upfront* POC testing.

The inclusion criteria were patients presenting to the ED with common medical complaints such as chest pain, abdominal pain, and generalised body pain and weakness. The *upfront* POC intervention implemented novel testing during the non-value-added time that patients spend waiting to see doctors. The results of these investigations were available to doctors to use in their subsequent patient consultations, potentially facilitating quicker disposition decisions.

The results from the study demonstrated that the implementation of *upfront* POC testing in the ED saved time. The economic analysis demonstrated that its implementation could be cost-effective and also potentially beneficial in LMICs. The

doctors surveyed were strongly supportive of the *upfront* POC system. This suggests that the *upfront* POC testing could be well-received if adopted in clinical practice.

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- My godmother and "ancient aunt", Dr Desré Kramer – for making me sound good.
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I gratefully acknowledge the support of Mxolisi Ncube from Abbott Point-of-Care, South Africa as well as the dedication of my research assistant, Helen de Vos.

The randomised, controlled trial would not have been successful without the support of both the medical and allied staff in the Emergency Department at Helen Joseph Hospital.

Finally, I would like to express my sincere thanks to the following companies: -

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Abbott Diagnostics, Johannesburg, South Africa	who provided the CEL-DYN Emerald 22 Benchtop Hematology System and consumables.
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NOMENCLATURE AND ABBREVIATIONS

NOMENCLATURE

Abbott i-STAT system	The i-STAT system consists of a handheld POC blood analyzer and single-use i-STAT test cartridges (i-STAT; Abbott Point of Care, Princeton, NJ).
Acuity	*Acuity* refers to the patient-related "overall severity or seriousness of illness" as utilised in the Emergency Medicine literature and Emergency Department setting.
Boarding time	The time that a patient remains in the ED after the decision to admit has been made but before the patient has been transferred out of the ED.
Disposition	The end-point of all ED patient visits – either the patient is discharged home or the patient is admitted into the hospital for inpatient care.
Front-end time	The time from patient arrival at the hospital ED to the time when their comprehensive evaluation by a doctor begins. It includes triage as well as the administrative requirements of registering the patient at the hospital.
Laboratory turnaround time	The time from when a specimen is received in the laboratory to the time when the result is available.
Point-of-care	Medical diagnostic testing at or near the point of care i.e. at the time and place of patient care and not in the laboratory or radiology department.
South African Triage Scale (SATS)	The scoring system used in South African EDs for determining patients' priority for treatment based on the severity of their condition.
Therapeutic turnaround time	The measured time from when the blood test is ordered until the time the test is interpreted and subsequently actioned by the treating doctor.
Treatment time	Measured from the time a patient is initially assessed by a doctor to the time they have a disposition decision made.
Turnaround time	The time interval from the time of submission of a process to the time of the completion of the process.

ABBREVIATIONS

ACS	Acute Coronary Syndrome
β-HCG	Beta Human Chorionic Gonadotropin
CBC	Complete Blood Count – equivalent to an FBC
CEAC	Cost-Effectiveness Acceptability Curve
CG4+	The CG4+ i-STAT cartridge analyses lactate, pH, partial pressure carbon dioxide, partial pressure of oxygen, total carbon dioxide, bicarbonate, base excess, and oxygen saturation within 2 minutes
Chem8+	The CHEM8+ i-STAT cartridge analyses sodium, potassium, chloride, total carbon dioxide, ionised calcium, glucose, urea, creatinine, haematocrit, haemoglobin, and the anion gap within 2 minutes
CRP	C-reactive protein
λ	Funder's willingness to pay
DKA	Diabetic ketoacidosis
ECG	Electrocardiogram
ED	Emergency Department
FBC	Full Blood Count
HIV	Human Immunodeficiency Virus
ICER	Incremental Cost-Effectiveness Ratio
IFEM	International Federation for Emergency Medicine
INR	International Normalised Ratio
i-STAT	i-STAT point-of-care system
LMIC	Low- and Middle-Income Country
LODOX®	Low Dose X-ray
LOS	Length of Stay
PACS	Picture Archiving and Communication System
PaLM	Pathology and Laboratory Medicine
POC	Point-of-care
SA	South Africa
SATS	South African Triage Scale
TAT	Turn Around Time
U&E	Urea and Electrolytes
USA	United States of America
WCC	White Cell Count
WHO	World Health Organization

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INTRODUCTION AND LITERATURE REVIEW

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1 INTRODUCTION

This chapter will set the scene for the thesis. It will start with a general overview of Emergency Department (ED) functionality. This starts with the triage process and follows the patient journey through the ED. The impact of various special investigations on the patient flow will be highlighted – both the utility thereof and conversely their ability to hinder efficient patient processing. Approaches to ED efficiency will be discussed with respect to "optimising the system" and ultimately it will culminate on point-of-care (POC) testing.

The ED within the hospital has a constant influx of critically ill and injured patients 24 hours a day. It is the gateway into the hospital and is often the main portal of entry for patients into the healthcare system. In order to provide access to medical care for everyone who presents to the hospital – i.e. treating anyone, with any condition, at any time – each patient's acuity[1] requires assessment, and their needs are then prioritised according to the severity of their illness or injury [1]. This is done via a triage system. The emergency queue in the ED is therefore non-linear; "first come, first served" does not apply. The most severely ill or injured patients receive immediate attention whereas everyone else has to wait to various degrees for their turn, subsequent assessment and treatment [2]. While triage tells us the order that we should be assessing patients in order to expedite certain patients' emergency management, triage does not help with the efficiency of flow for the patients that are waiting to be seen.

Despite setting ideal time frames and the best efforts of the ED staff, the system can become overwhelmed. The mismatch between supply and demand leads to delays in patients receiving care and increases in the time that patients spend in the ED. This can happen during the surge of a mass casualty disaster scenario or even on a so-called "normal" day in the ED.

[1] *Acuity*
As utilised in the Emergency Medicine literature and Emergency Department setting, *acuity* refers to the patient-related "overall severity or seriousness of illness" [1].

According to the International Federation for Emergency Medicine (IFEM), patients everywhere in the world have the right to expect the following in the ED: the right personnel; the right environment; the right decision-making; the right processes; the right results; the right approach; the right system; and the right support [3]. ***Time*** is the foundation of the above quality indicators and a fundamental domain for improving healthcare in the 21st century according to the Institute of Medicine's framework from the United States of America [3-5].

1.1 The Functionality of the Emergency Department

The ED does not function in isolation. It is part of an emergency care system framework that starts in the pre-hospital setting and ends at patient disposition whether to their home or to become an inpatient [6]. This is demonstrated in Figure 1.1 from the World Health Organization (WHO).

Similar to the assertions by IFEM and the Institute of Medicine regarding the quality of emergency care and the fundamental rights and expectations of the patient, the WHO has also highlighted the need to provide "timely care for the acutely ill and injured" patient [3, 4, 7]. At the 72nd World Health Assembly in May 2019 in Geneva, Switzerland, an emphasis was given to "**timeliness**" as "an essential component of quality healthcare", and that "mortality and long-term disability could be prevented by patients having access to emergency care" [7]. This is depicted graphically in Figure 1.2.

The pre-hospital and post-ED time frames shown in Figure 1.2 are beyond the scope of the present research. However, the "Time to Provider" and "Length of Stay" are pivotal measurements of **timeliness** in the ED. The "Length of Stay" is one of the key challenges that the present research addressed.

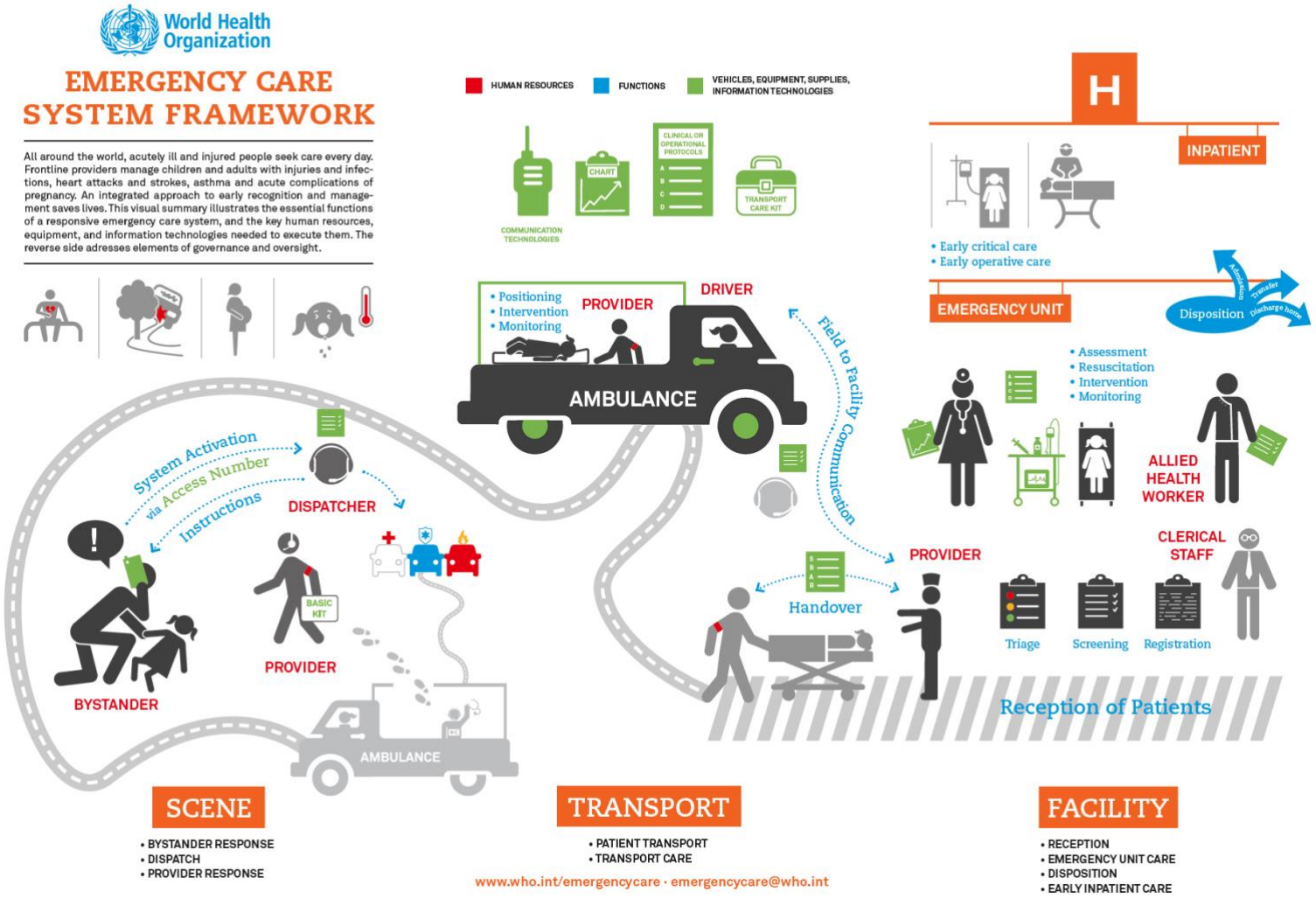


Figure 1.1 Infographic depicting the normal patient flow through the ED from pre-hospital “scene” to disposition [6]. Used with permission – Creative Commons licence CC BY-NC-SA 3.0 IGO.

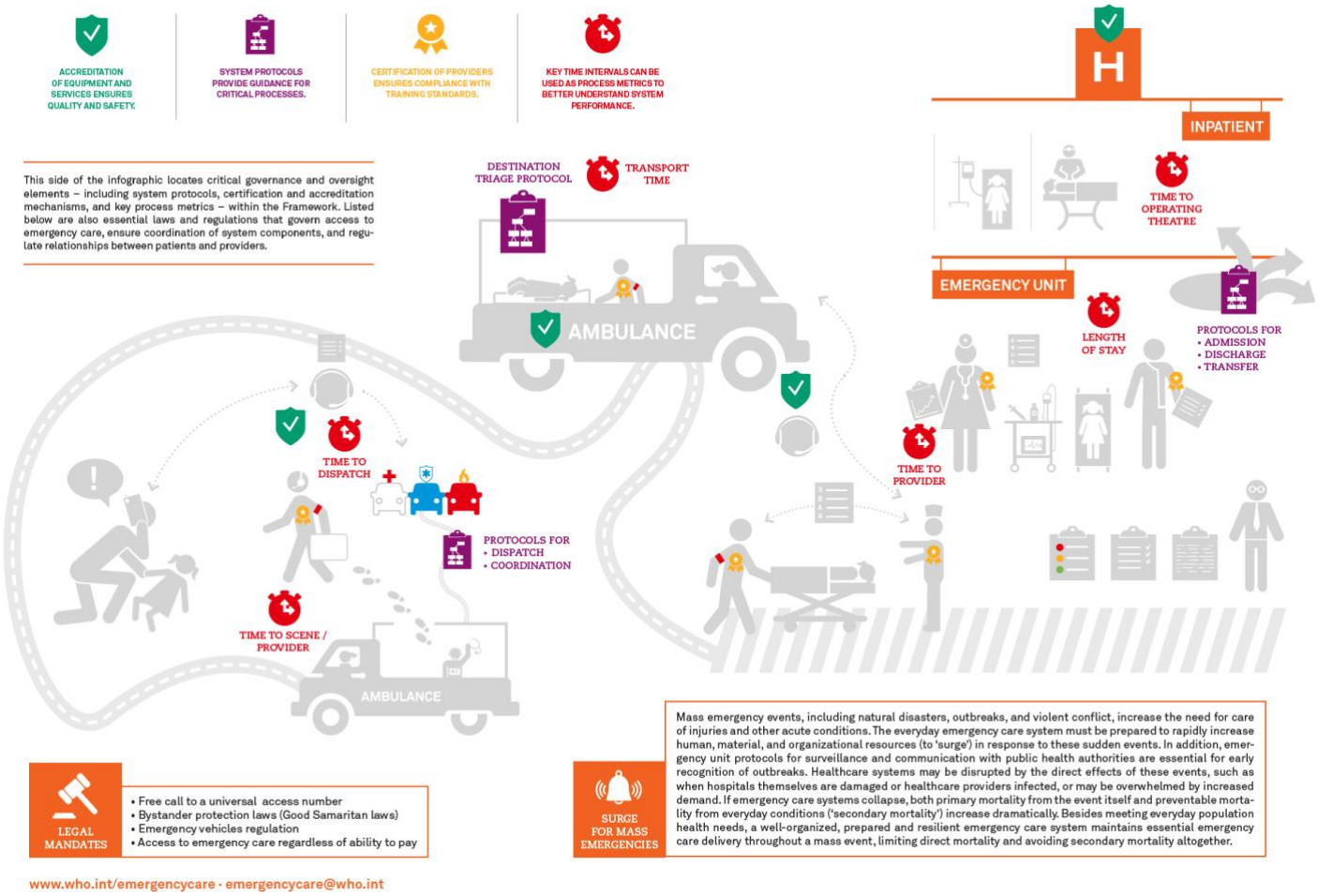


Figure 1.2 Infographic from the WHO emphasizing **time** (represented by a red clock symbol) as a key focus for quality healthcare at various stages in the emergency care pathway [6]. The "Length of Stay" is one of the key challenges that this dissertation addressed. Used with permission – Creative Commons licence CC BY-NC-SA 3.0 IGO.

1.2 Normal Patient Flow in the Emergency Department

The normal flow of patients in the ED starts with their arrival at the hospital. The patients are then triaged. Triage is the process whereby patients are assessed and classified in order to risk stratify them and prioritise their care according to need [8]. In South African EDs, triage is commonly performed using the South African Triage Scale [9]. In order to determine the score, each patient has their vital signs measured to determine if there is any physiological derangement as well as having so-called "discriminators" applied. The discriminators act as a safety net for when a patient's vital signs may be within the normal range, but they require urgent medical care, nonetheless. An example of this would be a previously healthy, young person who has sustained a traumatic injury. They may be bleeding uncontrollably but have stable vital signs at presentation because of their physiological reserve. If treatment is delayed, this patient may decompensate and potentially suffer negative sequelae as a result [8]. Once the patient's score has been calculated according to the South African Triage Scale, they are assigned a colour based on their acuity. If a patient is triaged red, they should be seen immediately. If they are triaged orange, they ideally should be seen within ten minutes of their arrival. Patient's triaged yellow should be seen within one hour and patients triaged green within four hours of their arrival at the ED [9].

Registration (i.e. opening a file or the method whereby a patient's records becomes part of the hospital documentation system), varies from hospital to hospital. It may occur before, during or after the triage process.

Irrespective of triage category, the patient's next step in their pathway through the ED is to be evaluated by a doctor. The one major difference is time – when they will be seen by the doctor. Although the time that a patient waits to be seen by the doctor is determined by their triage category (the time frame referred to by the South African Triage Scale), the suggested goal for when they should be seen is often not achieved. In the reality of everyday ED practice, actual patient waiting times are commonly longer than the guidelines stipulate depending on the current patient load of the ED [10].

Based on my experience as the head of an ED in a public sector hospital and experience working in a number of other hospitals, a conceptual framework for the

traditional flow of patient evaluation and investigation in the ED can be presented as Figure 1.3.

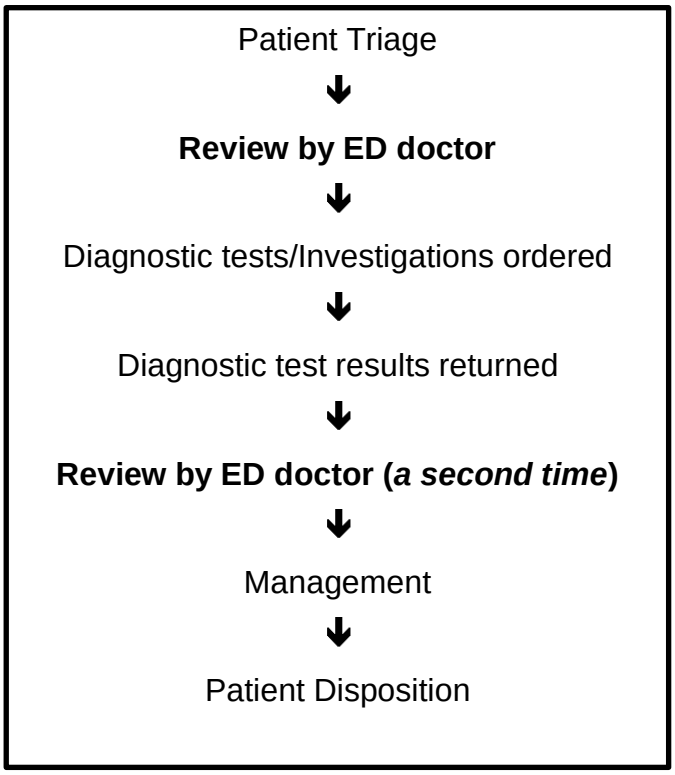


Figure 1.3 Traditional order of patient evaluation and investigation in the ED

The conceptual framework above has also been graphed as a linear correlation as demonstrated in Figure 1.4.

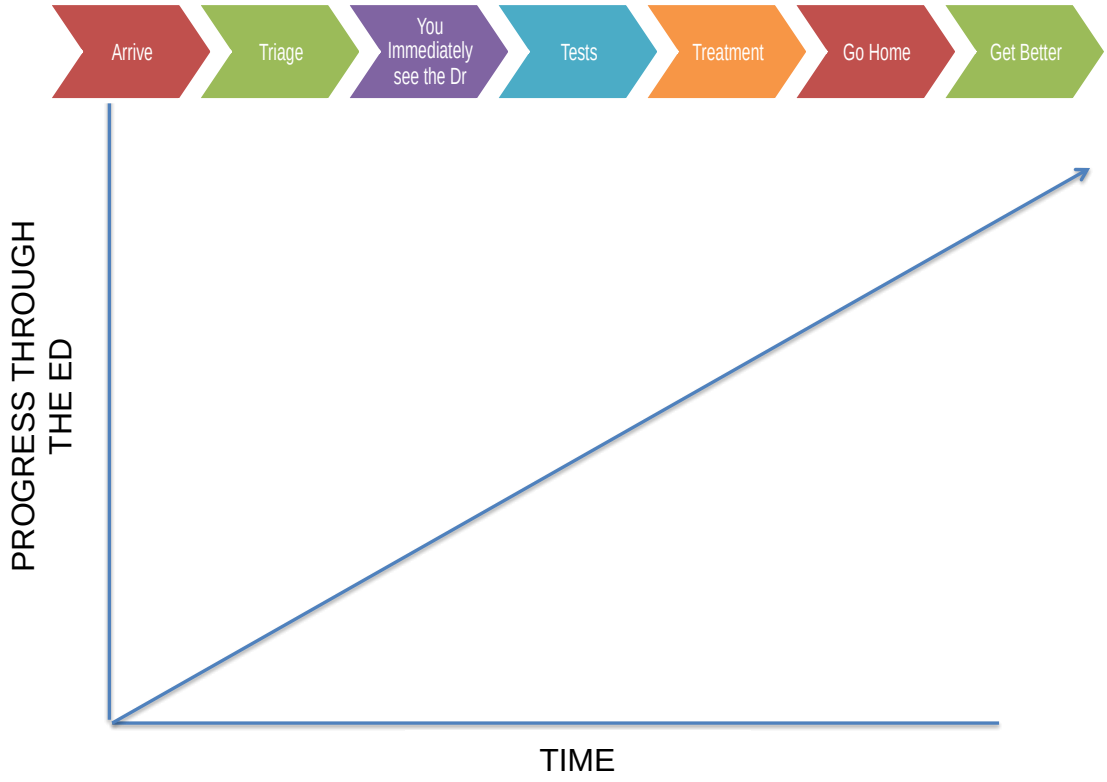


Figure 1.4 The perceived normal ED patient flow
Figure used with permission and courtesy of Mande Toubkin – Netcare Emergency Departments Quality Focus Areas

Usually *after* the initial evaluation of the patient by the doctor, doctors perform or order diagnostic tests or special investigations to assist with the patient's ultimate management and final disposition [11]. Unless a patient's presenting complaint is simple and can be diagnosed and addressed at the time of consultation (for example, a contact dermatitis), the doctor will usually request special investigations or order diagnostic tests to confirm or refute a suspected diagnosis so as to assist with the patient's management and final disposition. These can include blood tests, x-rays and electrocardiograms (ECGs). Patients (and doctors) then have to wait for the results of these investigations before a disposition decision can be made. The patients' ultimate disposition (i.e. whether discharged home or admitted for inpatient care) is thus contingent upon the results of these investigations. The waiting for test results is often a major contributing factor to the delay in final patient disposition.

The patient journey through the ED is therefore not linear. Figure 1.5 is more representative of the actual patient journey.

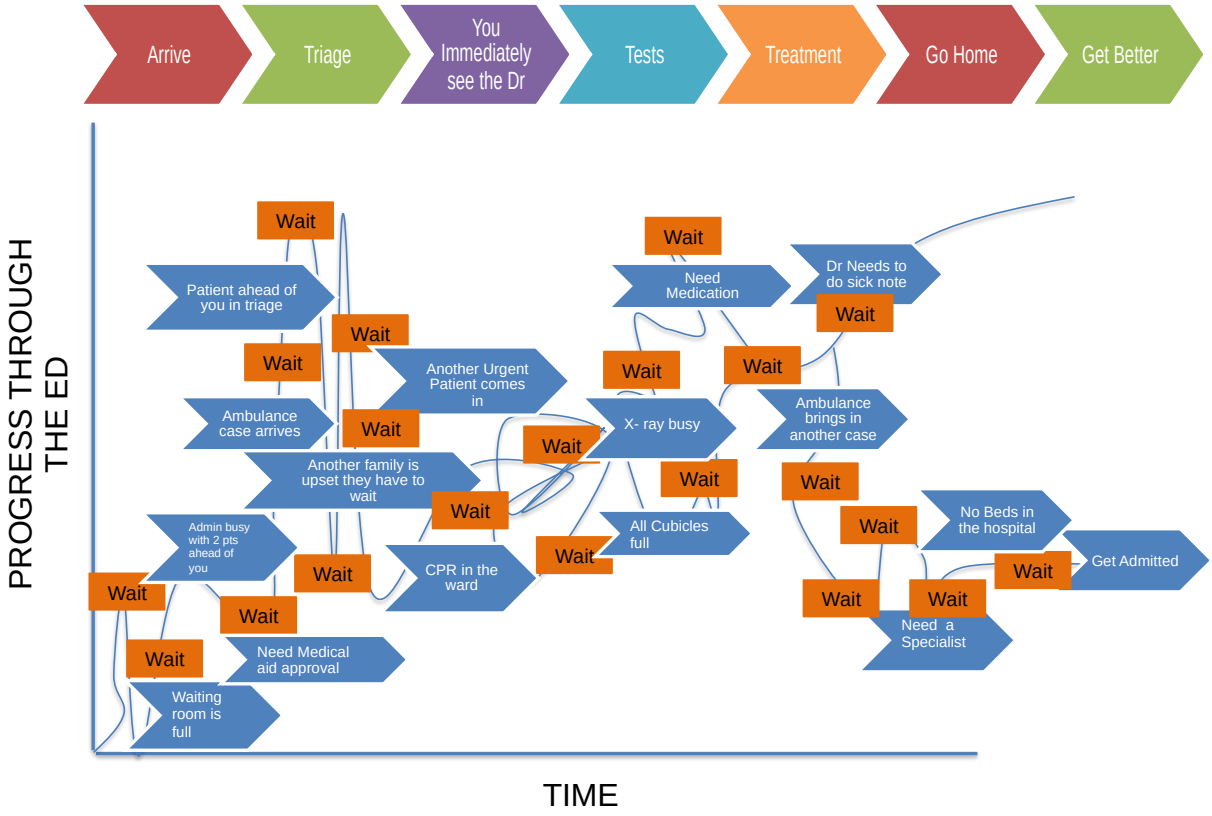


Figure 1.5 A more realistic “normal” ED patient flow

Figure used with permission and courtesy of Mande Toubkin – Netcare Emergency Departments Quality Focus Areas

The concept of *waiting* is inextricably intertwined with the ED and its functionality. Figure 1.6 is a flow chart that I use to illustrate and highlight where the waiting may occur in the patients journey through the ED.

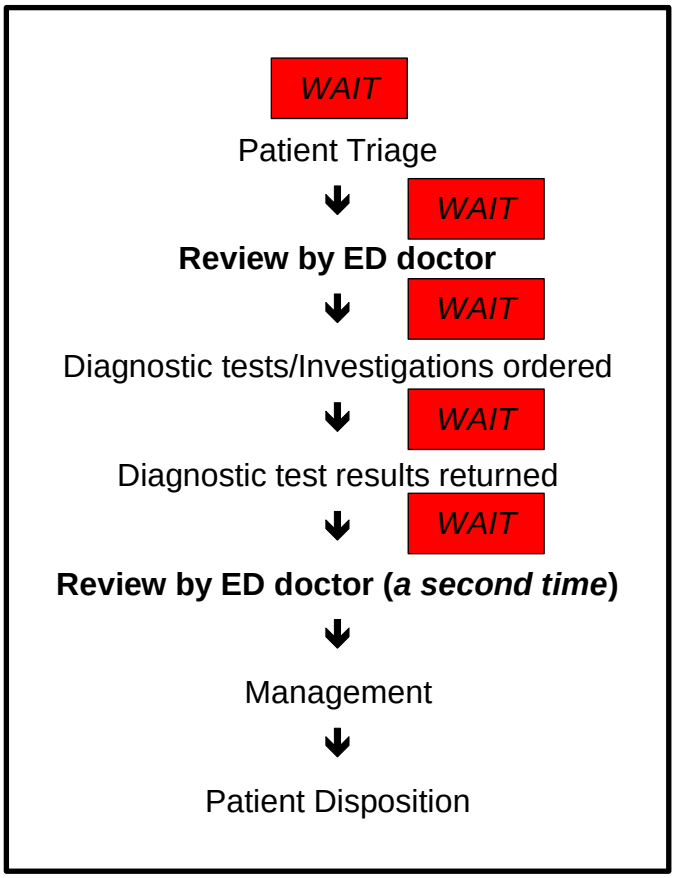


Figure 1.6 Traditional order of patient evaluation and investigation in the ED with *waiting* periods highlighted

1.3 Special Investigations in the Emergency Department

Although integral to a patient's evaluation, the time to receiving results from special investigations can be a major impediment to patient throughput. A study conducted by Doupe *et al.*, in Canada found that 45-78% of a patients' total ED waiting time occurs before the doctor makes a disposition decision, and 30-60% of their ED visit is spent waiting for the results of special investigations in order to facilitate the disposition decision [12]. Finding solutions that could expedite the time to obtaining the results of special investigations could potentially make a positive impact on the time patients spend waiting.

1.3.1 Blood tests

Waiting for laboratory blood test results, in particular, can be the “rate-limiting step for many patients in the ED” [13]. The dominant approximation is that one third of patients presenting to the ED require laboratory tests [14, 15]. However, there are some studies that reveal that over 60% of all ED visits require laboratory work [16]. In a district hospital in Uganda, laboratory tests were used for 85% of ED patients although more than half of these tests were related to testing for malaria [17].

Definitions regarding the classification of the turnaround times for the results of these investigations vary in the literature and tend to refer only to laboratory tests (and not other investigations such as x-rays and ECGs) [18, 19]. The “total testing time” describes the process from the time the blood test is ordered until the time the test is interpreted and subsequently actioned, colloquially called “brain-to-brain turnaround time” [18]. This includes the time taken to collect or perform the test (pre-analytical time) and the time to process the test (analytical time). It also includes the time taken for the doctor to acknowledge the results of the test once the result is ready (post-analytical time). The post-analytical time may be inadvertently extended when doctors have not been informed and are therefore unaware that the results are ready [20].

Many laboratories, however, restrict their definitions of turnaround time to only the time the specimens spend in the laboratory [18]. This type of discrepancy exacerbates the divergence of expectations between the laboratory and the clinician; ED doctors commonly express dissatisfaction about laboratory turnaround times being slower than they desire, leading to unintended patient delays [18, 19].

Service level agreements and expectations for laboratory turnaround times in South Africa can differ between types of facilities (academic vs district vs primary healthcare), between State and private institutions, as well as between laboratory service providers (e.g. National Health Laboratory Service vs one of the private laboratory companies).

A number of institutions have published guidelines for laboratory turnaround times. They vary widely. For example, according to the Essential Laboratory List (the South African handbook developed to enhance appropriate laboratory utilisation and

support the standardisation of clinic-laboratory processes), a full blood count performed at primary healthcare facilities in South Africa should have an estimated turnaround time of 24 hours via the National Health Laboratory Service [21]. Public sector academic institutions may have better turnaround times. For example, a full blood count performed at a mixed tertiary and quaternary academic hospital in Kwazulu-Natal, South Africa has a stipulated turnaround time of less than or equal to four hours [22]. In the private pathology services sector in South Africa, one of the key selling points is result turnaround times. The median time for a full blood count result from most large, private pathology practices is approximately 30 minutes [23].

South African laboratory turnaround times are comparable to those of other countries. In some high-income countries, the turnaround times for commonly ordered laboratory tests ranges from 70 to 150 minutes [24, 25]. These protracted times are not isolated to high-income countries. In a systematic review and meta-analysis of ED wait times in Iran (a low- and middle-income country (LMIC)), the mean waiting time from performance of laboratory tests to receiving tests results was 94 ± 33.9 minutes [26]. In a paediatric ED in Pakistan (an LMIC), in the 16% of patients that stayed in the ED for more than 4 hours, the majority were waiting for the results of blood tests (which look the laboratory 4 to 6 hours to generate) in order for the doctor to decide whether the patients were to be admitted to the hospital or discharged [27].

1.3.2 X-rays

The sicker the patient, the more likely they are to require a diagnostic test in the ED [12]. X-rays are ordered commonly for patients in the ED. A recent study in Winnipeg, Canada, that evaluated ED throughput factors, found that an x-ray was performed in 36.2% of ED visits, with a median evaluation time of 41 minutes (with an inter-quartile range of 20 to 81 minutes) [12]. This is echoed in a study from Virginia in the United States of America (USA), where 40% of ED visits involved radiologic investigations [16]. In a small cohort in Ireland, radiological tests were ordered for 55.4% of the patients [28].

In Iran, the turnaround time from radiology referral to results was 34.4 ± 2.9 minutes [26]. The definition of x-ray readiness is variable. It can mean that the x-ray has been performed by the radiographer and an image has been processed. The treating

doctor could then interpret the x-ray. Alternately, the x-ray may only be considered "ready" once a radiologist has interpreted the image. The added layer of a radiologist interpreting the image potentially leads to further delays for the patient. Even though several radiology guidelines state that ED-requested radiological investigations should have a maximum turnaround time of 15-30 minutes, this is not commonly the case [26, 29].

One of the ways that has been suggested to tackle this time-consuming process has been for nurses to order the x-ray examinations from the triage area. Although it is speculated to lead to shorter waiting times and ED length of stay, to date, the evidence to support this concept is limited [30].

1.3.3 Electrocardiogram

ECGs are commonly used in clinical medicine as a POC test to evaluate the heart in various contexts. ECGs are a relatively inexpensive diagnostic test that can provide useful information about a patient in a variety of different situations. It is also a common screening test for cardiac abnormalities. Although generally quick to perform in isolation, the time taken from decision to perform an ECG to processing the result and interpreting the ECG, can be lengthy. This process took on average 32.2 ± 7 minutes in a study from an Iranian ED [26].

1.4 Hindrances to Efficiency in the Emergency Department

There are a number of hindrances that have been identified as leading to inefficiencies in the ED. This literature review will focus on the two main hindrances that have been identified as most problematic: overcrowding in the ED due to a deficiency of resources to meet the needs of demand, and delays due to the length of time it takes to process investigations and tests to help with diagnosis. The latter is the focus of this dissertation, however since overcrowding in the ED is so endemic, it will be covered first. Delays due to patient registration and administration will also be discussed.

1.4.1 Emergency Department overcrowding, access block and exit block

Overcrowding, "access block" and "exit block" occurs in EDs in high-income countries and low- and middle-income countries alike, to various extents. ED overcrowding is defined by the American College of Emergency Physicians and the Emergency

Nurses Association as a situation in which the identified need for emergency services surpasses the available resources in the ED, in the hospital, or both [31]. ED overcrowding, resulting in “access block”, is the leading safety concern in EDs in high-income countries [32]. The problem, however, is prevalent in all healthcare systems irrespective of a country’s size or wealth. An analysis of ED and hospital overcrowding has clearly demonstrated that overcrowding is a reflection of a mismatch between a healthcare system’s ability to supply resources with the ever-increasing demand on those resources [27].

Overcrowding in the hospital results in patients from the ED, who have been admitted to the hospital, being unable to access hospital beds. This is known as “exit block”. The resulting impact of that is the prolonged boarding of patients in the ED. These boarding inpatients therefore occupy an ED stretcher or room that could potentially be used for the next incoming patient to the ED [32]. Even in the Netherlands where Dutch policy makers do not perceive ED overcrowding to be a problem, managers of their EDs report overcrowding a few times every week [33].

1.4.2 Delays in patient registration and administration

The “front-end” processing of patients who arrive at the ED varies between institutions. “Front-end” processing typically includes the registration of that patient in the record-keeping system of that institution [34]. Whether it is automated, manual or computer-performed, whether it is performed before, during, or after triage, the registration process is yet another place in the process where patients may be required to wait in a queue in the ED.

1.4.3 Waiting for the results of special investigations

While making improvements that lead to the optimisation of the patient disposition and admission processes are integral to patients’ access to appropriate healthcare, improving how quickly diagnostic tests are performed will also lead to significant improvements in patient flow [12].

In Ireland, Ryan et al. found that patients who had radiological tests or blood tests were more than four times more likely to spend more than four hours in the ED than those not undergoing additional tests [28]. Patients spent longer in that Irish ED as

they were waiting for the results of those special investigations. This wait hinders patient flow and ED efficiency.

1.5 Negative Sequelae from Reduced Emergency Department Efficiency

A full ED leading to overcrowding and access block is one thing; however, the implications are, in fact, more widespread. Reduced ED efficiency has effects which extend beyond the ED itself – including, but not limited to – the diversion of ambulances, patients leaving the ED without being seen, as well as prolonging patients' in-hospital lengths of stay.

1.5.1 Ambulance diversion

When an ED closes its doors to incoming ambulances because it does not have the capacity to take on any more patients, this is called ambulance diversion [35]. The diverted ambulances are then expected to drive to the next closest ED. This diversion increases the time taken for the patient to reach an ED, potentially delaying ambulance turnaround, increasing both short- and long-term patient mortality rates by up to 10% and incurring added medical costs from the increased need for more intensive treatment that may otherwise not have been necessary if a patient was seen in a more timely fashion and potential complications due to the delay were avoided [35].

In the province of Gauteng in South Africa, the process of "ambulance diversion" from public sector hospitals is initiated at the hospital level by the superintendent or hospital manager on call [36]. The superintendent speaks to the managing medical officer for Gauteng, who then either agrees to or denies an ambulance diversion for that hospital. Generally, the permission for diversion is for a limited time period – usually a maximum of 4 hours at a time. Pre-hospital emergency medical service providers are then informed via short message service that a hospital is "on divert". Theoretically, no ambulances are then meant to arrive at that hospital during that time period. However, there is commonly a breakdown in communication, or disregard of the diversion, or a decision is made that a critical patient will potentially will not survive a diverted trip to an alternate institution, and the patient arrives at the hospital ED anyway. Ambulance diversion also does not apply to patients who arrive via their own transportation. This can further aggravate an already overwhelmed system.

1.5.2 Leave without being seen

The “leave without being seen” rate is an ED operational metric that can be used as an outcome measure when evaluating the effects of an intervention. Patients who have to wait for protracted periods in the ED have an increased likelihood that they will leave the ED prior to being seen by a doctor [34, 37]. Although generally a small percentage of the total ED patient visits (ranging from <1% but up to 15% of patient visits), leaving the ED without being seen places patients at risk of poorer clinical outcomes [27, 37]. This may have ramifications for the patients’ health and well-being, as well as medico-legal consequences for the hospital and the staff [27].

1.5.3 Morbidity, mortality and prolonged in-hospital length of stay

Inpatients who are obliged to board in the ED due to overcrowding in the hospital are known to have delays to their definitive treatment and worse outcomes than patients who are admitted to hospital wards timeously [32, 34]. Patients admitted to hospital during high hospital occupancy periods, and therefore ED overcrowding periods, have higher morbidity and mortality rates than those who are admitted when the hospital is less crowded. These patients have an increase in their total hospital length of stay, an increase in their hospital costs and are at increased risk of dying [38]. This is because there are delays in the patient receiving their initial treatment, subsequent treatment doses, as well as delays in obtaining definitive investigations.

1.5.4 Decreased patient satisfaction

Patient satisfaction is strongly linked to their perceived timeliness of care. The wait time to be treated by a doctor has the strongest association with satisfaction [34, 39]. Those patients who wait the least amount of time, have the highest satisfaction; with each passing hour spent in the ED, satisfaction declines [13]. Prolonged patient wait times are associated with increased patient complaints [34]. Patient dissatisfaction is also associated with an increased likelihood of the patient leaving the ED without being seen [37].

1.5.5 Decreased staff satisfaction and productivity

The negative ramifications of reduced ED efficiency and subsequent ED crowding are not only linked to patient dissatisfaction, but it also leads to decreased staff satisfaction and productivity [34]. Patients boarding in the ED place an increased burden on ED staff, especially the nurses, who are often busy seeing new and

potentially more unstable patients, as well as having to look after the boarding patients [40]. Compromises in patient care due to ED overcrowding can also negatively impact staff morale [28]. Conversely, employee satisfaction is a definite catalyst to improving patient care as well as patient satisfaction [41].

1.6 Process Strategies to Improve Patient Flow and Efficiency in the Emergency Department

EDs worldwide are constantly looking for ways to decrease patient overcrowding and waiting times [20, 42]. Three major factors interact to affect patient flow and efficiency in the ED. These factors are input, throughput and output factors [43].

This section will summarise some of the initiatives that have been studied in order to improve patient flow in the ED. This includes placing a senior doctor in the triage area; having a fast track and/or rapid review area; utilising triage protocols; standing orders; directly placing the patient in an examination bed on arrival as well as using push notifications for diagnostic test results.

1.6.1 Consultant/senior doctor in triage

The placement of a senior doctor in the triage area has been tried as a strategy to expedite patient throughput [34, 42, 44]. Their function is to perform an initial assessment and potentially initiate testing and treatment of the patient. Their consultation may even lead to the patient being discharged from the ED altogether. There are numerous weaknesses with this method, however. Firstly, a doctor in triage takes a doctor off the ED floor. In addition, the studies that have evaluated this concept were only done at certain times of day and never addressed the quality nor quantity of care provided by those triage doctors [34].

1.6.2 Fast track

A “fast track” concept was initiated in the USA in the 1990s. A separate area is created in the ED in which lower acuity patients are seen in the ED in order to expedite patient care and reduce waiting times [31, 34, 42]. Patients directed to fast track should be able to be managed without special investigations, and hence, the fast track area is generally staffed by senior nurses rather than doctors [30].

1.6.3 Rapid review

The fast track concept has now been taken to the next level of expedited patient care. Recently, Anderson *et al.*, conducted a “rapid assessment zone” pilot study in Massachusetts, USA [45]. They implemented this pilot study to assess whether this method could optimise patient throughput and streamline workflow in the ED by prioritising timely patient evaluation and treatment. In this model, triage of the ambulant patients is even eliminated in order to save time. While the results from the pilot study appeared promising due to the timesaving, there was no reporting of potential negative sequelae from those patients who had missed diagnoses or had experienced delayed care as a result of this intervention.

1.6.4 Triage protocols and standing orders

Certain protocols have been attempted in the triage area that have aimed at early management of certain common patient presentations. These protocols include the administration of medication for pain and initiating antibiotics for pneumonia [34, 46].

Standing orders are usually medical orders for special investigations that have been developed for use in the triage area for certain patient conditions or medical complaints [47]. These orders are traditionally doctor-based; however, nurses can execute the orders if they are following the pre-specified protocols. Commonly; however, these orders are only effected if there are delays in a patient being assessed or at the discretion of the nurse, as opposed to it being instituted irrespective of the patient’s waiting time. This being said, even with inconsistent application, research by Retezar *et al*., in Maryland, USA, found that standing orders can reduce ED patient overall treatment times [47].

The implementation and effectiveness of these triage protocols and standing orders have had mixed results with notable under- and over-ordering of tests as well as deviation from practice guidelines [34]. Standing orders are usually completed in the so-called “non-value-added” period for the patient’s ED visit i.e. during the time when the patient is waiting to be assessed by the doctor [47].

1.6.5 Direct-to-room/immediate bedding

Another mechanism that has been tried in order to improve front-end processing in the ED, is the concept of “immediate bedding”. Patients are placed in a bed in the ED

without undergoing formal triage or registration [39]. This bypass, however, may lead to patients either having a delay in the measurement of their vital signs or, in fact, not having any vital signs taken at all during their ED visit with the associated negative sequalae of that omission [39].

1.6.6 Diagnostic test results push notifications

Doctors working in the ED are generally managing multiple patients simultaneously. They commonly are not tracking the progress of individual patient's special investigation results but are rather becoming aware of them erratically and inconsistently. This delay in realisation that the results are available may contribute to increased laboratory turnaround times [48]. Push notifications to the doctors' smart phone or smart watch are now being used as a method to alert the doctor that a result is ready. This can potentially decrease the time to further decision-making due to timely notification of the result readiness [20, 48]. These interventions have thus far only shortened the time to disposition decisions but not the overall ED length of stay [48]. The major disadvantage of this system lies in its interruption of the doctor's attention with a resultant potential increase in the risk of medical errors [49].

Another process that has the potential to significantly reduce wait times, shorten ED length of stay, and therefore improve patient throughput, is point-of-care testing. Since POC is the focus of this research, the following section will outline the literature on previous work that has explored this process' efficacy.

1.7 Point-of-Care Testing

POC testing usually refers to the performance of laboratory diagnostic tests outside the central laboratory at or near the location of the patient which can potentially be at the patient's bedside [50]. The concept can be applied to other forms of special investigations that are performed at or near the patient's point of care, such as x-rays that are performed in the ED as opposed the radiology department. Due to the provision of rapid results, POC testing has been suggested for use in the ED in order to shorten ED length of stay, improve timeous patient discharge, and therefore increase patient throughput [50].

1.7.1 POC test availability in the Emergency Department

Special investigations are generally performed on patients in order to confirm a diagnosis. These can include blood tests, ECGs and x-rays. Table 1.1 depicts some of the traditional diagnostic tests together with their available POC equivalents.

Table 1.1 Traditional diagnostic test examples and their point-of-care equivalents

Diagnostic Test / Investigation	Point-of-Care equivalent
Full Blood Count (FBC)	Complete Blood Count (CBC)
Urea and Electrolytes (U&E)	i-STAT Chem8+
Blood Gas	i-STAT CG4+
Troponin I	Radiometer AQT90 FLEX Troponin I
D-dimer	Radiometer AQT90 FLEX D-dimer
ECG	ECG
X-ray	LODOX®

ECG electrocardiogram; i-STAT i-STAT POC tests (i-STAT, Abbott Point of Care, Princeton, NJ, USA); LODOX® Low-Dose X-ray; Radiometer AQT90 FLEX analyzer (Radiometer Medical ApS, Brønshøj, Denmark)

Other well-known and commonly utilised POC tests include urine test strips or dipsticks to perform urinalysis and pregnancy testing, as well as finger-prick blood sampling to determine blood glucose or cholesterol levels. Ultrasound, as a point-of-care modality, has been used in the ED since the early 1990s [51].

1.7.1.1 Point-of-care blood tests

Instead of sending blood specimens to the laboratory for analysis, POC blood testing refers to selected tests which can be performed in the ED and provide immediate on-site results and thus have the potential to expedite patient management decisions. One of the most commonly used and indispensable tools has been the POC blood gas analyser. With many indications for the use of blood gas analysis in the ED, arterial and/or venous blood gas measurements can be performed and used to guide the medical care of critically ill and injured patients in the ED [52]. POC blood testing has been shown to be accurate and assist in expediting patient management by decreasing the turnaround time for results [11, 30, 53]. The move to the use of POC testing in a paediatric ED in Pakistan was ratified, despite the additional cost, after it

was found that the results of routine blood tests for patients in their ED took 4 to 6 hours which was an unacceptably long turnaround time [27].

1.7.1.2 Point-of-care x-ray

LOw DOse X-ray (LODOX®) has been marketed as a quick and easy radiological screening tool for trauma patients [54]. It is the radiological equivalent of a POC blood test, providing a full body x-ray within 19 seconds. It is much quicker, and exposes the patient to less radiation, than a standard radiograph [55]. LODOX® has previously been evaluated in trauma patients as a screening tool [56]. LODOX® has also been used as an adjunct diagnostic modality in forensic medicine [57]. A recent study in Switzerland evaluated LODOX® for patient with urolithiasis, but to date, its application as a tool for patients with medical pathologies in the ED has not been fully explored [56, 58].

1.7.1.3 Point-of-care electrocardiogram

ECGs are commonly used in clinical medicine as a POC test to evaluate the heart. It is a relatively inexpensive diagnostic test that can provide useful information about a patient in a variety of different situations including as a screening test for cardiac abnormalities.

1.8 Point-of-Care Test Utilisation in the Emergency Department

POC testing has become a focus area for investigation as EDs look for ways to cope with overcrowding and reduce waiting times [30]. POC tests have be employed via two main methods: using POC tests in place of laboratory tests or using POC tests as a means of secondary triage.

Supplementary Table 1 in Appendix 4 summarises all the literature regarding POC utilisation in the ED up to the present time excluding the publications from this thesis. The majority of the studies have compared the utilisation of POC in place of standard laboratory blood tests. Studies which only looked at the accuracy of the POC tests were excluded.

1.8.1 Point-of-care tests instead of laboratory tests

POC testing in the ED has been found to be a quicker alternative to getting blood results than the performance of standard laboratory testing [24]. The quicker

turnaround time of POC blood test results has the potential to reduce ED length of stay and reduce overcrowding [24, 25]. POC blood tests have been used within both the context of the standard ED patient journey, as well as a supplement early in a patient's journey, as initiated by an experienced clinician in triage [11]. POC testing is also being used in EDs in order to achieve quality targets for certain patient groups. A good example of this is patients presenting with chest pain receiving a POC troponin blood test on their arrival in the ED [59].

1.8.2 Point-of-care tests as a safety net – "secondary triage"

Although it is standard practice to triage patients when they arrive at the ED in order to rank their illness severity and guide the acuity of intervention required, it is not an infallible process. Patients may be under- or over-triaged [9]. Over-triage results in unnecessarily assigning resources to a patient, while under-triage could mean a patient with an occult, but severe, condition may have their treatment wrongly delayed, resulting in potential morbidity or mortality. Rates of both over- and under-triage have been measured as ranging from as low as 4.3% to as high as 22% [9].

POC tests have been suggested as a way to enhance the accuracy of triage risk-stratification as well as to provide a safety net to prevent negative sequelae from mis-triage [60, 61]. A small study in Saudi Arabia conducted in 2018 found that POC blood tests performed for certain patient complaints after triage changed the triage level in 13% of patients. Unfortunately, they did not report on the initial triage accuracy of those patients [60]. Moreover, that reported finding is comparable to the findings and limitations noted in a similar study in Pennsylvania, USA, which only resulted in expedited care for 6% of the enrolled patients [61]. Despite the limited reported effects, the triage nurses in both studies subjectively felt the POC intervention to be helpful.

1.9 Point-of-Care Testing Utilisation in South Africa

1.9.1 Point-of-care testing in South African healthcare

To date, POC test usage in South Africa (SA) has largely been limited in application to testing for communicable diseases such as human immunodeficiency virus (HIV) and tuberculosis, and for non-communicable diseases such as diabetes [62, 63]. Consequently, the South African literature on the topic has been limited.

Current and ongoing research has mainly focussed on the use of POC testing for HIV and tuberculosis in expediting patient treatment regimens [64-66]. These studies have looked at the utilisation of POC devices for the timely diagnosis of tuberculosis using the Xpert MTB/RIF (Xpert; Cepheid, Sunnyvale CA, USA) molecular diagnosis technique. These POC tests have been performed to avoid the delays of central laboratory-based testing which is associated with patient loss to follow-up and further delays in initiating tuberculosis treatment [65]. Studies have also examined the use of POC blood testing for the rapid diagnosis of HIV and early, same-day, initiation of anti-retroviral therapy, as well as POC CD4 cell counts, in order to improve uptake of isoniazid preventive therapy amongst patients with HIV [66, 67]. Some studies have looked at the feasibility of initiating HIV testing in the ED in SA [68, 69].

1.9.2 Point-of-care in South African Emergency Departments

HIV-related testing has been the only POC research that has been executed in South African EDs to date [70]. Hence, there is no published literature on the use of non-HIV-related POC in the ED in SA. The research reported in this thesis on POC testing in the ED is the first of its kind in SA.

Emergency Medicine is a young speciality in South Africa having only being government-gazetted in 2004 [71]. With only 149 registered emergency medicine specialists in SA, not all EDs are staffed by specialists [72]. This makes it difficult to comment on what is generally done in the emergency areas of hospitals in SA. Whereas the performance of blood gas analysis is commonplace, even in EDs where there are no specialists, the use of the different POC modalities is variable and hospital- and ED-dependent, and at this point in time, has not undergone empirical testing. This makes research into the utility of POC in SA imperative.

1.10 Barriers to the Implementation of Point-Of-Care Testing

New advances in medicine are commonly received with dual feelings of excitement and hesitation. There are the early adopters who view technologies favourably and then those who view them with more scepticism and delay implementing them into their practice. The advent of POC testing as a medical innovation was no different. Although positively received by some, it was met with trepidation by others. POC was

perceived as an intervention that was too expensive with further concerns over quality assurance and associated staff and operational issues [73, 74].

1.10.1 Cost

Even with the recent drive in healthcare now being towards a more patient-centred approach, any intervention's value-for-money and cost-effectiveness needs to be included in the analysis of potential benefit [73].

The majority of economic evaluations of POC testing have been from observational studies looking at isolated incidences where a POC test has been used. For example, the effects of POC testing utilised for home blood glucose self-monitoring for the individual patient as opposed to the financial effects of the implementation of POC tests on the diabetic community overall [73]. The biggest fault of these studies has been that the tests are taken at their face-value cost, as opposed to their impact on the outcomes of the patients [73].

The cost-effectiveness of POC testing in the ED has been evaluated in a few isolated patient populations. Unfortunately, these studies have been limited by their small populations, examining only limited outcomes rather than taking into consideration the time saved or improved patient outcomes. This was illustrated by Whitney *et al*., who looked at the application of POC in a paediatric ED in Connecticut, USA, in children with acute gastroenteritis [75]. They showed significant cost-savings in the POC evaluation of electrolytes in this patient population; however, the study only enrolled 225 patients [75].

Interestingly, when it comes to outcome measures used to evaluate the effectiveness of a POC intervention on improving patient flow in the ED, the most common outcome measures evaluated are waiting times and ED length of stay. Only a few studies report on the effects on patient safety and evaluate the cost implications [30, 75-77].

In Sydney, Australia, Asha *et al*., evaluated the cost-effectiveness of exchanging laboratory blood tests for POC tests in the ED. They found only small improvements in disposition time. The authors calculated that using POC tests in their ED required an additional AUS$113 per patient more than if the patient had had traditional

diagnostic tests. This additional amount of money only saved an hour of time [77]. They went on to further evaluate patient medical outcomes in a sub-study looking at patients with suspected acute coronary syndrome [76]. However, this sub-study was only designed to evaluate whether the POC troponin that was used was equivalent to the laboratory troponin as opposed to any ultimate patient outcomes from the intervention [76].

1.10.2 End-user adoption and change management

Successful institution of change in an organisation is partially reliant upon active engagement with the end-user [78]. The satisfaction of the staff (or end-user) with a new intervention can lead to its success or failure when the intervention is implemented [59]. Their perception of the intervention as adding value contributes to this acceptance [59]. If the concerns and expectations of the staff are not addressed, the introduction of a novel operational method, no matter how potentially time-, money- or life-saving, will be seen as disruptive and will be received unfavourably [79].

In the limited formal assessments of staff satisfaction that have been done regarding POC in the ED, POC tests have been favourably received by both doctors and nurses. They have reported a decrease in result turnaround times and improved patient flow cited as the important advantages [59, 80]. Anecdotal reporting of “overwhelming enthusiasm and satisfaction” for POC in the ED have also been published [81].

1.10.3 Quality assurance and accuracy

The so-called barriers relating to quality assurance and accuracy of POC devices apply mainly to POC blood tests. It appears that “beauty is in the eye of the beholder” [82] as opinions regarding quality assurance and POC test accuracy vary widely. These differences emanate depending on whether the opinion is being given from the perspective of the laboratory or the perspective of the end-user.

Laboratory-based literature commonly adopts a more pessimistic slant to non-laboratory personnel performing POC test analyses [74, 83]. This is probably related to a “turf war” – with laboratory personnel deeming non-laboratory clinical staff to have limited training and experience when performing blood test analyses. There is

also a penchant to presume that clinical staff are less likely to comply with the required documentation as well as quality control measures [83]. As with all testing processes, attention to maintaining the quality and integrity of the testing system is vital, which includes following manufacturer guidelines with regards to maintenance and quality control.

There has also previously been scepticism regarding the accuracy of POC blood tests compared to results that originate from the laboratory [74, 84]. As there are numerous POC devices available on the market and a variety of different tests that are on offer, amalgamating them together and saying that they are all inaccurate is a misrepresentation. They range in size, portability, costs as well as functionality – some requiring lots of end-user input and others requiring very little.

The i-STAT® Portable Clinical Analyzer and cartridge system has been studied in a variety of different clinical settings. It has demonstrated the ability to provide rapid and reliable results comparable to formal laboratory measurements [13, 53]. The i-STAT system has high to excellent correlation with laboratory tests in ED and intensive care studies that have compared them [84-86].

In order for POC testing to be instituted permanently into the ED, operational guidelines would need to be in place to assure continued quality and accuracy of the results. This relates to education and training of staff, proper use and storage of devices and consumables, performance and documentation of Quality Control tests if indicated and proper sanitation of the machine for infection control [83]. These processes are not complicated.

The accuracy of usage of a POC device has been shown in non-medical, non-healthcare lay users who have had the appropriate training. This was even demonstrated in a study from the intensive care from a large, academic hospital in Johannesburg, South Africa, comparing lay-person usage to trained laboratory professionals [87]. They concluded that quality assurance and accuracy of the POC tests could be maintained by non-laboratory personnel.

1.10.4 Over-testing

At the turn of the third millennium when POC testing was in its infancy, Crook suggested that the ease of availability of POC tests could lead to increased inappropriate testing [88].

A doctor's decision to order a diagnostic test involves weighing the potential benefit of the test against the discomfort to the patient as well as the cost and inconvenience of waiting for the result [89]. Ease of availability of POC is purported to be a caveat to using it since it could potentially predispose patients to unnecessary testing as well as increasing associated expenses [74]. The reduced inconvenience of POC testing with its associated decrease in turnaround time for results may lead to increased test ordering – so-called over-testing [89]. This theory is potentially negated by the fact that if over-testing due to POC test implementation did occur, then patient length of stay in the ED would conversely be prolonged instead of shortened because patients who would have otherwise not have had blood tests would receive them. This misuse would lead to delays [89]. These theories of over-testing are all contingent on the POC tests being readily available and utilised in place of laboratory tests and not for select patient populations.

Over-testing is a concern with laboratory testing too and not just POC. In the study by Retezar *et al.*, laboratory testing was done using standing orders (i.e. in a protocolised fashion for certain patients). The control patients, in that study, who had not received the standing order tests, commonly went on to receive similar investigations via the standard route nonetheless [47].

Over-testing was acknowledged as a small risk by Begaz *et al.*, in their study looking at the waiting room initiation of laboratory testing [90]. They believed, however, that "the benefits to the patients far outweighed any negatives" that may have resulted from over-testing [90, 91]. Neither study utilised POC.

1.11 The Knowledge Gap

1.11.1 Summary of Knowledge of Point-of-Care in the Emergency Department

The ED is a melting pot of patient complaints, random non-linear arrival of patients as well as space and time constraints. This is compounded by the inability of patients being able to be admitted to the hospital due to lack of bed space leading to ED overcrowding and access block. ED overcrowding is bad for the patients, the staff and the hospital. Various ways are being sought to deal with the input, throughput and output of patients in order to expedite patient processing while not compromising patient care and safety. Decreasing the non-value-added time that patients spend in the ED may be a method of achieving this goal. This non-value-added time is essentially the time that patients spend waiting – waiting for the results of special investigations constitutes a large amount of this time.

One-third to half of all patients presenting to the ED will need a special investigation in order to determine their ultimate disposition from the ED. POC testing has been advocated as a means to decrease turnaround time for test results. Its usage has been implemented mainly as an alternative to laboratory tests and has had varying success.

Protocolised usage of POC tests has also been met with unreliable results; however, these POC tests have only ever been used for specific disease pathologies, for example, acute coronary syndrome, as opposed to a more general usage for the so-called undifferentiated patient presenting to the ED with chest pain of undetermined origin. To date, POC tests have also mainly been limited to blood and urine tests, and there has been not exploration of the effects of POC x-ray interventions for non-trauma patients.

Direct costing comparisons of the POC tests to standard tests has also been a rate-limiting factor in their general adoption. Funders have incorrectly looked at the face-value figures of the POC tests compared to the standard tests. There is also scant evidence of the utilisation of POC in low- and middle-income countries. In particular, there have been no studies that have ever looked at non-HIV-related POC testing in the ED in South Africa specifically. The research that will be discussed in this dissertation will go some way to fill this gap in the body of knowledge.

1.11.2 Gaps in our knowledge of Point-of-Care in the Emergency Department

Having presented the literature to date on the issues facing EDs, and having proposed some potential solutions, it is obvious that this is still a relatively unexplored area of research. There are multiple areas that still need to be investigated to determine evidence-based solutions in order to help make life-enhancing decisions for the care of patients in the ED. A few of these potential research questions are:-

- Could POC tests be performed *upfront* in the ED to reduce ED treatment time i.e. performed prior to doctor evaluation?
- Could the known efficiency of POC blood tests be applied to the novel usage of a POC x-ray (LODOX®) for non-trauma patients?
- If POC tests performed *upfront* could reduce treatment times, which tests would be the most effective?
- Would protocolising POC test usage *upfront* potentially save time by taking away the decision process for performing the special investigations at a later stage in the patients ED journey?
- Would protocolising *upfront* ED POC testing be able to be applicable to a variety of common ED patient medical complaints?
- Would it be useful to implement *upfront* POC testing for patients presenting with abdominal pain, chest pain, generalised body pain and weakness and psychiatric symptoms?
- Would choosing commonly used tests that patients would most likely receive if they presented to the ED under normal circumstances be generalisable?
- Could special investigations be performed in a patient's non-value-added waiting time and therefore demonstrate timesaving?
- Could having the test results available when a doctor first assesses a patient mean that the doctor did not need to see the patient a second time during their ED visit?
- If the *upfront* POC tests were found to be timesaving, would the implementation of a new patient flow be acceptable to the end-user and ultimately adopted?
- If the *upfront* POC tests were found to be timesaving, would the funders agree to pay for it?

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CHAPTER 2

AIMS, OBJECTIVES AND METHODOLOGY

2.1 Aim

The aim of the research which is included in this thesis was to compare and assess the traditional patient flow pathway that was in use in the ED to a modified pathway that made use of *upfront*, POC tests (blood tests, ECG and/or LODOX®) in various permutations. This was to see if an enhanced workflow pathway had any potentially beneficial effect on costs and treatment times. It was also necessary to evaluate doctor perceptions of its implementation in the ED.

2.2 Objectives

The objectives of this research were

1. To describe the current treatment times in the ED to have a control baseline.
2. To assess the effects of protocols for POC testing for different patient presenting complaints.
3. To assess the effect of implementing *upfront* POC tests (blood tests, ECGs and LODOX®) – in the ED with regards to treatment times – individually and in various permutations.
4. To assess the potential cost implications of implementing *upfront* POC tests (blood tests, ECGs and LODOX®) in the ED.
5. To assess the perceptions and response by the doctors to changes in ED patient flow from using *upfront* POC tests.

2.3 Methodology

There were two separate studies conducted in order to assess the impact of *upfront* POC testing in the ED – a clinical trial and a survey.

The trial was an investigator-initiated, composite-structured, prospective, randomised, controlled trial. It was structured into three separate components in order to evaluate each aspect of the impact of implementing POC in the ED and

therefore allow achievement of the above objectives. These were published in three separate papers, which specifically addressed:

1. The impact of implementation of *upfront* point-of-care testing in the ED on treatment times
2. The economic impact of *upfront* point-of-care testing in the ED in low- and middle-income countries – a secondary analysis
3. The overall cost-effectiveness of *upfront* point-of-care testing in the ED – a secondary analysis

In addition to this, once the trial was completed, a questionnaire-based study was conducted in order to study the effects of system changes and therefore the feasibility of implementation by the evaluation of its acceptability amongst them. This was published in a separate paper.

The methodology for the individual studies is described in the individual publications in chapters 4 to 7.

CHAPTER 3
ORGANISATION OF THE THESIS

There are five main Sections in this thesis followed by the Appendices.

The chapters which contain the individual research articles each have a preface in order to provide context for the articles amidst the current literature. The chapter-specific references are included at the end of each individual chapter.

3.1 Section 1

3.1.1 Introductory chapters

This section contains the preliminary chapters for the thesis.

Chapter 1	Introduction and literature review
Chapter 2	Aims, objectives and methodology
Chapter 3	Organisation of the thesis

3.2 Section 2

3.2.1 The impact of upfront point-of-care testing in the Emergency Department on treatment time

This section contains the research dealing with the timesaving aspect of the prospective, randomised, controlled trial evaluating *upfront* POC testing in the ED.

Chapter 4	A randomised controlled trial to assess the impact of *upfront* point-of-care testing on emergency department treatment time

3.3 Section 3

3.3.1 The cost-effectiveness of *upfront* point-of-care testing in the emergency department

This section contains the evaluation of the money-saving aspect of the prospective, randomised, controlled trial evaluating *upfront* POC testing in the ED using secondary analyses of the financial data.

Chapter 5	The cost-effectiveness of upfront point-of-care testing in the emergency department: a randomised, controlled trial
Chapter 6	The cost of time: A randomised, controlled trial to assess the economic impact of upfront point-of-care blood tests in the emergency department

3.4 Section 4

3.4.1 Doctors' Perceptions of *Upfront* Point-of-Care Testing in the Emergency Department

This section contains the evaluation of the staff aspect regarding the effects of system changes when implementing *upfront* POC testing in the ED.

Chapter 7	Doctors' perceptions of the impact of *upfront* point-of-care testing in the emergency department

3.5 Section 5

3.5.1 Final Discussion, Conclusions and Recommendations

The final discussion, recommendations and suggested future research and overall conclusions chapters complete the thesis.

Chapter 8	Final Discussion
Chapter 9	Conclusions and Recommendations

3.6. Section 6

3.6.1 Appendices

The contents of the appendices are presented below.

Appendix 1	MD Proposal
Appendix 2	Ethics clearance documents
Appendix 3	Plagiarism screening report
Appendix 4	Supplementary Table 1
Appendix 5	Journal permissions

SECTION 2

The impact of upfront POC testing in the ED on treatment time

CHAPTER 4
A RANDOMISED CONTROLLED TRIAL TO ASSESS THE IMPACT OF UPFRONT POINT-OF-CARE TESTING ON EMERGENCY DEPARTMENT TREATMENT TIME

Goldstein LN, Wells M, Vincent-Lambert C. A Randomized Controlled Trial to Assess the Impact of Upfront Point-of-Care Testing on Emergency Department Treatment Time. Am J Clin Pathol. 2018;150(3):224-234.

4.1 Background

Time is an ever-present concern in the ED. How long have the patients been waiting in the queue to be seen? How long will it take to get important decision-changing results? How long before we can repeat the troponin on this patient to safely exclude acute coronary syndrome? How long before the surgeon will take this patient to theatre for his acute abdomen? When will the radiologist report on that urgent CT scan be ready? How long will this sick patient wait in the ED to get a bed in the ward? When will this shift end?

Time is a precious ED commodity and providing ways in which time could be saved can potentially have a positive impact on patients, doctors, other staff members and hospitals alike.

POC tests may be the means by which to save time in the ED. To date, however, the optimum way to implement and integrate POC testing into the ED to derive the most benefit is yet to be established. POC blood tests have been tried in triage, or in place of laboratory tests in the traditional ED flow with varying success. There is limited research involving non-blood POC tests. POC x-rays have only ever been considered for trauma patients. No studies have previously looked at performing the tests upfront prior to doctor evaluation nor have they assessed whether the same combination of POC tests can be applied to different patient symptom complaints effectively. Furthermore, there have been few previous evaluations of the value of

POC testing in LMIC. None have been previously undertaken specifically for ED use in South Africa.

Various time frames exist in the patient journey through the ED which can potentially be targeted for improvement. These are laid out in Figure 4.1.

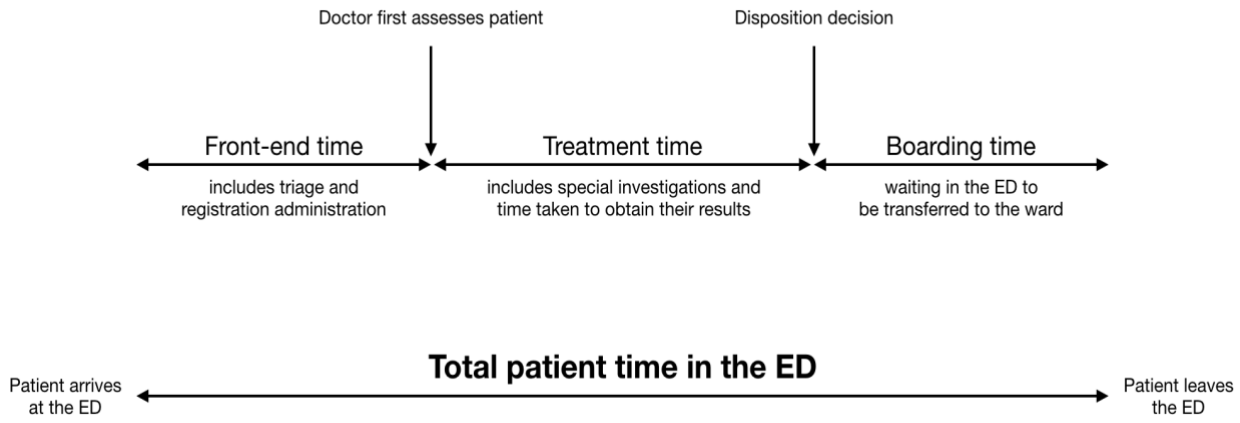


Figure 4.1 Time frames for the patient's journey through the ED. The disposition decision is either to admit the patient to the hospital or discharge the patient from the ED.

Front-end time includes the time from patient arrival at the hospital ED to the time when their comprehensive evaluation by a doctor begins [1]. It includes triage as well as the administrative requirements. Treatment time is measured from the time a patient is initially assessed by a doctor to the time they have a disposition decision made. The classification of the time between the patient's disposition decision and them leaving the ED depends on whether the patient is admitted or discharged. If the patient is discharged, this time is generally not measured, and the disposition decision time is accepted as the time the patient left the ED. If the patient is admitted, the time that a patient remains in the ED after the decision to admit has been made but before being transferred out of the ED is called the boarding time.

Special investigations are generally performed during the treatment time portion of the patient's journey.

4.3 Purpose of the Study

The purpose of this study was to compare the traditional patient flow pathway that was in use in the ED to a modified pathway that made use of *upfront* POC tests (blood tests, ECG and/or LODOX®) in various permutations. This was done in order to assess if *upfront* POC tests had any potentially beneficial effect on reducing patient treatment times and thus expediting the disposition decision.

Whilst POC blood tests had shown promise in decreasing patient treatment times in the ED in previous studies, there had not been any studies evaluating their usage in the ways considered in this study.

The objectives of this study were as follows: -

- To evaluate upfront POC blood tests in the ED and to also assess the utility of ECG and x-ray as POC tests.
- To evaluate the different POC tests alone as well as in various combinations in order to assess which tests or test combinations could potentially be most effective.
- To evaluate the institution of protocolised usage of the POC tests in order to determine which common patient symptom groups (abdominal pain, chest pain, generalised body pain or weakness and psychiatric symptoms) could benefit most from the POC tests.
- To assess whether the non-value-added time that patients spent waiting to see the doctor could be used to perform these tests, *upfront*, in order to enhance timesaving and decrease patients' treatment time and overall length of stay in the ED.

4.4 Major Findings of the Study

- All the POC individual tests and test combinations, except an isolated ECG or an isolated x-ray, reduced patient treatment times by more than 20% (the *a priori* defined minimum clinically significant outcome measure).

- The benefit was seen when this standardised testing was applied to three common medical patient symptom groups: abdominal pain, chest pain and

generalised body pain or weakness. There was no benefit shown in the psychiatric symptom patient group.

- Although showing a clinical timesaving benefit of 35 minutes on average, patients who received the i-STAT tests alone or the i-STAT tests combined with an ECG only, did not show a statistically significant timesaving benefit compared to the control group i.e. the timesaving was not reduced by more than the *a priori* defined minimum 20% threshold. This was due to the stringent threshold adopted in this study.

- The POC tests could be performed in the non-value-added time that the patients spent waiting to be seen by the doctor.

- More patients could be evaluated and disposed of within one hour if they received any test combination compared to the control group. Disposition from the ED within one hour being an alternative perspective to an absolute reduction in treatment time overall.

- Comparison of patients in the control group who received a blood gas analysis (a POC test already available in the ED) compared to equivalent patients in the study who received upfront, i-STAT tests, still showed that the upfront tests outperformed those done during the patient consultation.

4.5 This Study in the Context of the Thesis

This study provided the starting point for this research by assessing whether there was a reduction in treatment time if patients received assorted upfront, POC tests in various permutations in the ED.

It provided confirmation of a key outcome measure in ED throughput evaluation – timesaving. Clinically significant timesaving extended across all POC tests and test combinations except when ECG and x-ray were used on their own. Although this was a promising finding, it did not come without a cost. Direct comparison of the costs between the standardised tests versus the POC equivalents showed a cost of

US$2.54 more per patient for the POC equivalent tests. This study did not address whether there was cost-effectiveness in the time saved – cost-effectiveness will be dealt with in Section 3, Chapters 5 and 6.

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A Randomized Controlled Trial to Assess the Impact of Upfront Point-of-Care Testing on Emergency Department Treatment Time

Lara Goldstein, MMed, FCEM(SA),[1,2] *Mike Wells, MSc, FCEM(SA),*[2] *and Craig Vincent-Lambert, PhD, HPE*[2]

From the [1]Division of Emergency Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa; and [2]Department of Emergency Medical Care, Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa.

Key Words: Point-of-care testing; Point-of-care systems; Emergency department

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ABSTRACT

Objectives: *To compare standard emergency department (ED) workflow to a protocolized pathway using upfront point-of-care (POC) tests performed prior to doctor evaluation to determine if this could produce a significant reduction in treatment time.*

Methods: *We performed a prospective, randomized, controlled trial. Patients were randomized to receive the standard of care or one of the enhanced workflow pathways with POC tests.*

Results: *There were 1,044 patients enrolled. All workflows, except electrocardiogram and low-dose x-ray (LODOX), exceeded the outcome measure (20% reduction in treatment time). It was significantly shorter compared with the control workflow if the patient received any (i-STAT + CBC)–containing workflows (*P = *.0001,* P = *.020,* P = *.0009,* P = *.011), as well as the i-STAT + LODOX workflows (*P = *.0001,* P = *.034).*

Conclusions: *The full benefit of POC testing can be realized if it is implemented prior to doctor evaluation, as part of a standardized procedure in the ED. This allows for a more rapid availability of investigation results subsequently leading to decreased treatment times.*

As with everything in the emergency department (ED), time is of the essence, and waiting for the results of special investigations should not be a rate-limiting factor for patient throughput. Various bottlenecks exist in the ED with regard to input, throughput, and output of patients, which can lead to overcrowding. This can precipitate adverse outcomes, including impaired access to, as well as reduced quality of, emergency care.[1,2] Delays in the turnaround time to obtain the results of special investigations can contribute to this exit block.[3,4]

Traditionally, blood tests and other special investigations such as electrocardiograms (ECGs) and radiologic investigations (plain x-rays) take place after the doctor has clinically evaluated the patient. Patients (and doctors) then have to wait for the results of these tests before a decision can be made regarding the need for further investigations and the patient's final disposition. Point-of-care (POC) testing has been suggested as a throughput intervention to aid in decreasing ED overcrowding.[2,4,5] POC blood testing refers to selected tests that can be performed in the ED at the bedside and provide immediate, on-site results that can potentially expedite patient management decisions.[6] Similarly, low-dose x-ray (LODOX) is the radiologic equivalent of a POC blood test, providing a full body x-ray within 19 seconds. LODOX has been evaluated in trauma patients, but its application as a diagnostic tool for nontrauma patients in the ED has not been investigated previously.[7]

While POC tests have been shown to decrease result turnaround times, there has been mixed evidence for their usefulness in the ED.[1,4,8-10] The utility of POC tests has only previously been evaluated when obtained *after* the

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patient has interacted with a doctor or nurse. The use of POC tests before a doctor has seen the patient has not been explored before.

The aim of this study was to compare the standard workflow pathway in the ED to a modified, protocolized pathway that made use of upfront POC tests (blood tests, ECG, and/or LODOX) performed prior to doctor evaluation to determine if this could produce a significant reduction in treatment time in the ED.

Materials and Methods

Study Design and Setting

This was an investigator-initiated, prospective, randomized, controlled trial that took place in a tertiary, academic hospital ED in a metropolitan area of Johannesburg, South Africa. The ED sees approximately 65,000 patients annually. Most patients have nontraumatic pathologies (approximately 70%), and the rest are trauma related. Pediatric as well as obstetric and gynecology patients are mainly seen at the nearby sister hospital.

Permission to conduct the study was granted by the Research Ethics Committee of the Faculty of Health Sciences of the University of Johannesburg (REC-01-185-2016), the Human Research Ethics Committee of the University of the Witwatersrand (M171086), and South African National Health Research Ethics Committee (DOH-27-0117-5628), and it was registered as a clinical trial with the South African National Health Research Database (GP_2017RP57_655) as well as with clinicaltrials.gov (NCT03102216). Written informed consent was obtained for all patients. In patients in whom consent could not be obtained (eg, psychiatric patients), consent was obtained from the patient's relative at the time of the patient's presentation to the ED. The patient was then followed up in the ward by the research doctor/research assistant to obtain delayed consent once the patient was competent.

Selection of Participants

All consenting adult patients older than 18 years who had one of the symptom groups below, presented to the ED during weekdays, did not require immediate resuscitation, and were not pregnant were eligible for inclusion in the study.

Presenting symptom groups:

- Abdominal/epigastric/stomach pain/vomiting ("abdominal symptoms")
- Psychosis/aggression/hallucinations/overdose ("psychiatric")
- Shortness of breath/dyspnea/cough/chest pain/syncope ("chest symptoms")
- Generalized body pain or weakness ("GBP/GBW")

Patients were then randomized into one of the 12 workflow pathways **Figure 1**. The block randomization was done prior to study commencement using an online randomization tool (www.randomizer.org). Each data collection sheet set was then placed upside-down in the order generated in an individual symptom box. The research doctor/research assistant took the next data collection sheet in the order supplied, after the patient had signed consent.

To ascertain whether an individual POC test or a certain combination of POC tests provided the most benefit with regard to time saving, patients in each symptom group were randomized to receive either the standard workflow pathway (the control pathway) or one of the enhanced workflow pathways with one, two, three, or four POC tests in various combinations (see Figure 1).

In the control workflow pathway, after patients were triaged, they were seen by a doctor. Diagnostic tests and investigations that were clinically indicated were then ordered by the doctor. Diagnostic blood tests were performed in the on-site hospital laboratory according to standard procedures, x-rays were performed in the radiology department, and if the patient required a blood gas analysis to be done, this was performed by the doctor on one of two blood gas analyzers available in the ED (Cobas B 221 POC system [Roche Diagnostics, Basel, Switzerland] or ABL800 Flex [Radiometer, Copenhagen, Denmark]).

Once the results of those tests were ready, the doctor then reviewed the patient a second time with all the results. The decision for patient disposition was then made.

In the enhanced workflow pathways, if the doctor deemed it necessary to perform additional investigations over and above the POC tests, those tests were performed as clinically indicated according to standard procedures. The patient was reviewed once the additional results were available.

Patient throughput time in the ED can be divided into front-end/administrative time (patient time of arrival to doctor evaluation) and treatment time (time from doctor evaluation to disposition).[11] The administrative time consists of opening a file and registering on the hospital system. All patients go through the same process. However, on some days, the administrative process can be substantially longer than on other days. This would change the wait times for the patients prior to them presenting to

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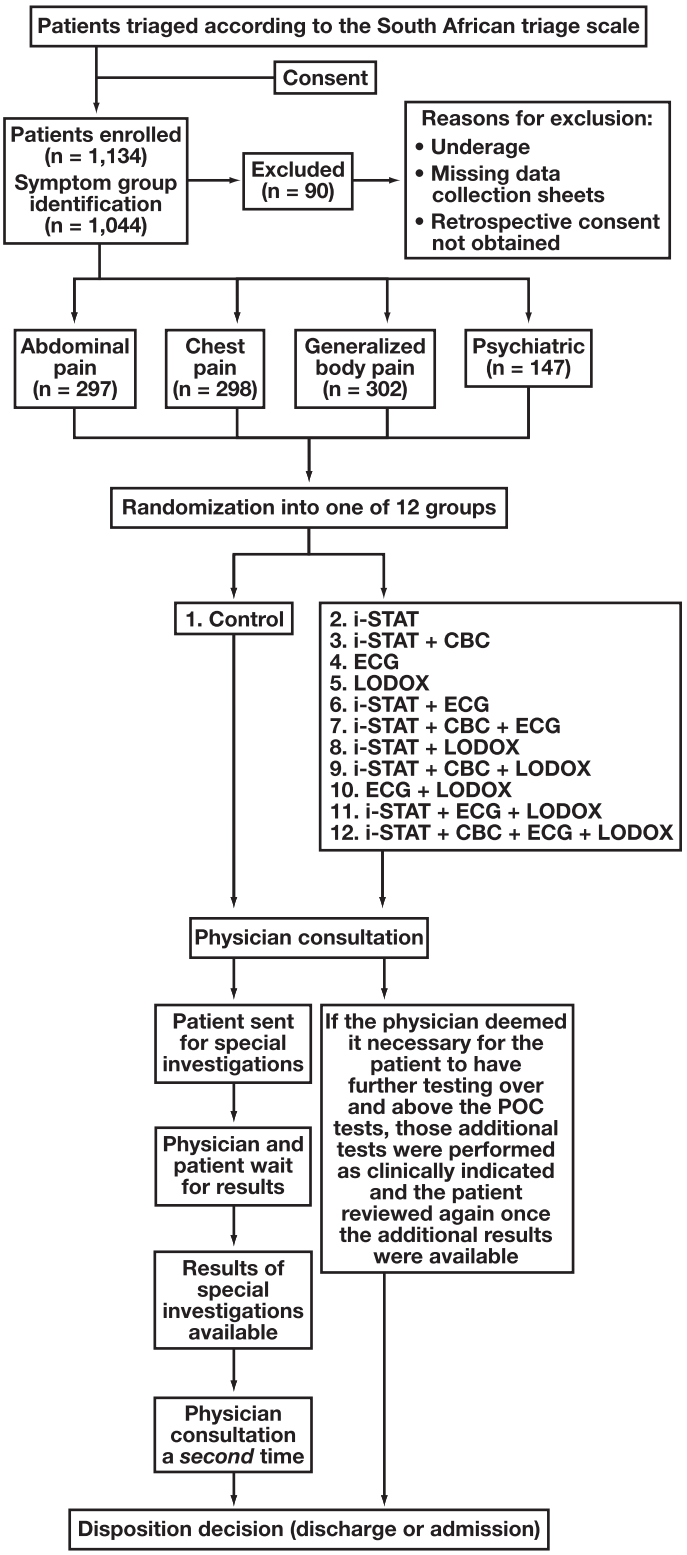


Figure 1 Flowchart showing randomization and data collection procedure. ECG, electrocardiogram; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray; POC, point of care.

the doctor and would confound the time measurements overall. To remove the confounders that the administrative time could have had on the utility of POC testing, we assessed only the treatment time in this study.

In each group, treatment time was measured from the time the doctor first saw the patient until the disposition decision was made. The disposition time was chosen rather than the time the patient actually left the ED because exit

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block or other factors could delay the patients' departure from the ED. This would confound rather than enhance the data.

For the particular symptom groups that were included in the study, patients were not subjected to any form of investigation or testing that they would not most likely have received in any case by following the standard (control) workflow pathway. The only difference for the enhanced workflow groups is that the tests were performed at the POC in the ED *prior* to the patient seeing the ED doctor for the first time.

Interventions

Abbott Point of Care i-STAT System

The i-STAT system consists of a handheld POC blood analyzer and single-use i-STAT test cartridges (i-STAT; Abbott Point of Care, Princeton, NJ). The CHEM8+ (sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, urea, creatinine, hematocrit, hemoglobin, and anion gap) (2 minutes), prothrombin time/international normalized ratio (2 minutes), CG4+ (lactate, pH, partial pressure carbon dioxide, partial pressure of oxygen, total carbon dioxide, bicarbonate, base excess and oxygen saturation) (2 minutes), and troponin I (10 minutes) i-STAT cartridges were used. These tests were run concurrently.

Quality controls were performed on each batch of cartridges to ensure correct target values, calibration verification, and ranges for the i-STAT cartridges as per the manufacturer's guidelines.

Abbott CEL-DYN Emerald 22 Benchtop Hematology System

The only category of blood investigation not covered by the i-STAT system was with regard to the assessment of infection. To this end, the CEL-DYN Emerald 22 benchtop hematology system (Abbott Diagnostics, Johannesburg, South Africa), which is capable of providing a POC CBC as well as a WBC differential count, was used. Processing time was 90 seconds.

Quality controls were performed daily on this machine as per the manufacturer's guidelines.

ECG

Philips (Amsterdam, the Netherlands) Pagewriter TC30 ECG machines were used to obtain the ECGs, which were obtained according to standard procedures and the equipment used as per the manufacturer's guidelines. A standard 12-lead ECG as well as a right-sided (V1R-V6R) and posterior (V7-V9) ECG were performed on all patients randomized to receive "an ECG."

LODOX

A radiographer performed the LODOX radiographs (chest and abdomen, anteroposterior and lateral) on a LODOX Xmplar-dr (Lodox Systems, Johannesburg, South Africa). The radiation exposure was approximately 339 μGy per patient vs a standard chest and abdomen radiograph of approximately 5,200 μGy.[12]

Synchronized Clocks

Synchronized clocks are normal time-of-day displaying clocks that are calibrated through satellite GPS that is built into the unit. These units do not require time setting, as they automatically correct their time on a minute-to-minute basis through GPS signal received. These clocks were in all the areas of the ED where times were recorded.

Measurements

The sample size estimation was based on the determination of the effect of workflow pathways within each symptom group. This required a two-way analysis of variance. Based on the detection of at least a medium effect size ($f = 0.25$ or a 20% difference in times between groups) with 80% power at the 5% significance level, a sample size of 1,116 was required.

The data collection procedure is shown in the flowchart in Figure 1. All times were recorded by the doctors in the ED on a data collection sheet, which was appended to each patient's file.

All POC testing was performed in a private cubicle within the ED where the LODOX machine was located. All other testing was done as per standard procedure for standard workflow within the ED.

Costs of Investigations

Prices for the control pathway investigations were obtained from the relevant hospital departments. Costs for the POC tests were based on standard ED usage. Capital costs of equipment as well as maintenance were taken as being included in the prices of all tests.

Outcomes

The main outcome measure for this study was treatment time, defined as the time from initial contact between doctor and patient to the time of his or her disposition decision. Previous studies have used statistical significance over clinical significance and shown a reduction in treatment time (or equivalent time saving) ranging from 9% to 18%.[4,13] We decided that in order for the tests to be considered worthwhile from a time-saving perspective, they would need to demonstrate a clinically meaningful

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decrease in treatment time. For this reason, we rounded up the time-saving threshold reported in previous studies to 20%. A 20% reduction in treatment time with the enhanced workflow pathways compared with the control pathway was therefore considered clinically significant.

Statistical Analysis

The effect of workflow (within each symptom group) and symptom group (within each workflow) on the outcome (treatment time), controlling for the covariates (time of day of arrival at triage, number of patients seen on that day, number of patients enrolled between 8 AM and 4 PM on that day, and triage category), was determined by a general linear model with treatment time as the dependent variable and the independent variables of workflow, symptom group, their interaction, and each of the covariates and their two-way interactions with workflow and symptom group (excluding the two-way interactions with triage category since not all combinations of triage category and [workflow, symptom group] were covered in the study). A log transformation of the dependent variable was used to meet the assumptions of the general linear model. This was due to the right skewness of time data. All two-factor interactions, including that between workflow and symptom group, were removed from the model since they were not significant. Post hoc tests were carried out using the Tukey-Kramer adjustment for multiple comparisons.

The effect of decision (admission/discharge), workflow, and symptom group on treatment time, controlling for the covariates (as above), was also determined by a general linear model.

A general linear model was used to compare treatment time for the first and last 30 patients of the study within the GBP symptom group, controlling for workflow and the workflow-group (first or last) interaction.

The effect of whether a patient had a blood gas analysis and if symptom group had an effect on the treatment time, controlling for the above covariates, was determined by a general linear model.

Data analysis was carried out using SAS (version 9.4 for Windows; SAS Institute, Cary, NC). The 5% significance level was used throughout.

Results

Enrollment of 1,134 patients took place between February 13, 2017, and June 29, 2017. Figure 1 summarizes the distribution of patients between the four symptom groups. All workflow groups had a minimum of 24 patients per workflow per symptom group except the psychiatric group. Interim analysis showed that the outcomes for the psychiatric group were very different from the other symptom groups. For that reason, only the control, i-STAT, and i-STAT + CBC workflows were enrolled in this subgroup until completion. The total sample population was therefore 1,044 patients. Ninety patients were excluded due to being underage, missing data collection sheets, or retrospective consent not obtained.

Patient Characteristics

A comparison of patient characteristics based on workflow allocation is tabulated in Table 1.

Treatment Times

The treatment time for the psychiatric group (22 minutes; interquartile range [IQR], 17-29) was significantly shorter compared with the other three symptom groups: abdominal pain, 44 minutes (IQR, 36-54; $P < .0001$); chest pain, 42 minutes (IQR, 34-51; $P < .0001$); and GBP/GBW, 38 minutes (IQR, 31-47; $P = .0002$).

Figure 2 shows the mean treatment times based on the various workflow permutations across all symptom groups.

The treatment time was significantly shorter compared with the control workflow if the patient received an ECG + LODOX ($P = .031$), any (i-STAT + CBC)–containing workflows (i-STAT + CBC, $P = .0001$; i-STAT + CBC + ECG, $P = .020$; i-STAT + CBC + ECG + LODOX, $P = .0009$; and i-STAT + CBC + LODOX, $P = .011$), and the i-STAT + LODOX workflows (i-STAT + ECG + LODOX, $P = .0001$ and i-STAT + LODOX, $P = .034$).

The treatment time was also significantly longer for ECG alone compared with i-STAT + CBC ($P = .028$) and i-STAT + ECG + LODOX ($P = .021$), as well as being significantly longer for LODOX alone compared with i-STAT + CBC ($P = .024$) and i-STAT + ECG + LODOX ($P = .017$).

Treatment Time Saving

Table 2 demonstrates the number of patients who could be treated in less than 1 hour and those who took more than 2 hours by symptom group and by workflow permutation.

Time Taken for POC Testing

The different permutations of POC tests averaged between 4 and 23 minutes to obtain depending on the test combination. Figure 3 displays the mean time taken to perform the tests. Some tests could be performed concurrently while others had to be performed sequentially.

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Table 1
Patient Characteristics Based on Workflow Allocation

Characteristic	Control	i-STAT	i-STAT CBC	ECG	LODOX	i-STAT ECG	i-STAT CBC ECG	i-STAT LODOX	i-STAT CBC LODOX	ECG LODOX	i-STAT ECG LODOX	i-STAT CBC ECG LODOX	*P* Value for Between-Group Test
Age, median (IQR), y	45.7 (34.2-61.7)	45.2 (31.6-59.3)	44.2 (33.3-68.0)	44 (33.9-61.0)	41.6 (33.0-55.5)	41.9 (33.3-56.6)	40.7 (27.3-60.9)	42.1 (29.9-60.8)	37.1 (30.0-55.1)	44.9 (35.0-60.5)	39.5 (30.0-61.3)	41.3 (31.5-55.6)	.65
Sex: males, No. (%)	46 (45.5)	44 (43.1)	45 (45.9)	40 (46.0)	35 (40.2)	30 (38.0)	35 (44.3)	27 (34.2)	30 (35.3)	36 (43.9)	48 (57.1)	44 (54.3)	.11
Triage category, No. (%)													
Orange	41 (40.6)	36 (35.3)	31 (31.6)	30 (34.5)	26 (29.9)	19 (24.1)	27 (34.2)	22 (27.8)	29 (34.1)	22 (26.8)	26 (31.0)	27 (33.3)	.30
Yellow	59 (58.4)	62 (60.8)	64 (65.3)	54 (62.1)	61 (70.1)	59 (74.7)	50 (63.3)	55 (69.6)	56 (65.9)	60 (73.2)	58 (69.0)	50 (61.7)	
Green	1 (1.0)	4 (3.9)	3 (3.1)	3 (3.4)	0 (0.0)	1 (1.3)	2 (2.5)	2 (2.5)	0 (0.0)	0 (0.0)	0 (0.0)	4 (4.9)	
Admitted,[a] No. (%)	43 (51.2)	41 (48.2)	47 (56.0)	38 (46.9)	41 (48.8)	31 (41.9)	44 (57.1)	37 (48.1)	35 (44.3)	44 (56.4)	43 (55.1)	42 (55.3)	.62
Discharged,[a] No. (%)	41 (48.8)	44 (51.8)	37 (44.0)	43 (53.1)	43 (51.2)	43 (58.1)	33 (42.9)	40 (51.9)	44 (55.7)	34 (43.6)	35 (44.9)	34 (44.7)	

ECG, electrocardiogram; IQR, interquartile range; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray.
[a]Of all patients, 8.2% were referred to another speciality (ie, neither admitted nor discharged) as their disposition plan.

Factors Affecting Arrival Time to Doctor Assessment

Patients waited on average between 57 and 152 minutes to see the doctor after arrival in the ED. The effect of arrival time on waiting time was significant ($P = .013$), controlling for the other variables in the model. Post hoc tests showed that the estimated time from patient arrival to doctor assessment was significantly shorter if the patient arrived between 7 AM and 11 AM compared with later in the day, but there were no significant differences in waiting times between the different workflows.

Effect of Discharge vs Admission

There were no significant differences in treatment time between patients who were ultimately admitted or discharged *within* particular workflows or between admission and discharge *within* particular symptom groups ($P = .091$).

Assessment for Consistency

There was no significant difference in treatment times between patients who were enrolled at the beginning of the study compared with those who were enrolled at the end.

Comparison Between Patients Who Had a Blood Gas Analysis Performed by the Doctor on the ED Blood Gas Analyzers vs Those Assigned to an Equivalent i-STAT–Containing Workflow

The association between ED blood gas analysis and treatment time was significant ($P = .002$). The treatment time was significantly longer for those patients who had a blood gas (BG) analysis (49 minutes; 95% confidence interval [CI], 34-70) than for those who did not (23 minutes; 95% CI, 15-34).

For each pair of workflows except BG + ECG vs i-STAT + ECG (which was only marginally significant), the treatment time was significantly longer for all workflows with a BG than for the corresponding workflows with i-STAT **Figure 4**.

Costs of Investigations

Costs for the individual investigations are listed in **Table 3**. The ECG costs were the same for both the control and intervention groups. POC equivalent tests cost US$2.54 more per patient than standard control investigations.

Discussion

It has been said that "time heals all wounds," but in the ED, we do not have the privilege of an endless amount of it. Not only do we have to deliver time-critical

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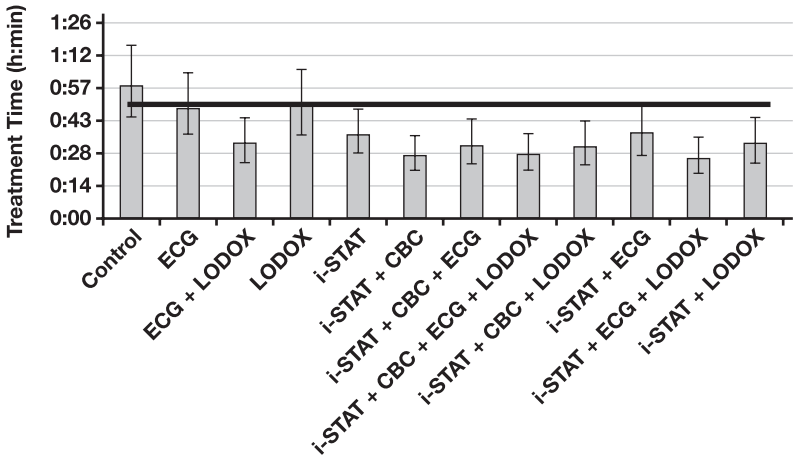


Figure 2 Mean treatment times for the different workflow permutations across all symptom groups. All workflow permutations, except ECG alone and LODOX alone, significantly exceeded the primary outcome measure of a 20% reduction in treatment time (indicated by the thick horizontal black line). ECG, electrocardiogram; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray.

Table 2
Time to Disposition Within 1 Hour and Greater Than 2 Hours

Allocated Workflow	Symptom Group	No. (%) of Patients With Treatment Time ≤1 Hour	No. (%) of Patients With Treatment Time >2 Hours
All	All	666 (63.9)	227 (21.8)
All	Generalized body pain or weakness	195 (64.6)	67 (22.2)
All	Abdominal symptoms	163 (54.6)	90 (30.3)
All	Chest symptoms	181 (60.9)	57 (19.2)
All	Psychiatric	127 (87.0)	13 (8.9)
Control	All	45 (45)	36 (36)
i-STAT	All	68 (67)	23 (23)
i-STAT CBC	All	68 (69)	13 (13)
ECG	All	48 (55)	22 (25)
LODOX	All	48 (55)	23 (26)
i-STAT ECG	All	43 (55)	16 (21)
i-STAT CBC ECG	All	52 (66)	15 (19)
i-STAT LODOX	All	48 (61)	18 (23)
i-STAT CBC LODOX	All	60 (71)	17 (20)
ECG LODOX	All	57 (70)	17 (21)
i-STAT ECG LODOX	All	67 (80)	11 (13)
i-STAT CBC ECG LODOX	All	62 (77)	16 (20)

ECG, electrocardiogram; IQR, interquartile range; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray.

interventions but we also need to deal with the consequences of patient overcrowding.

This is the first study to have assessed the impact of upfront POC testing on treatment times. It is also the first study to have included LODOX as a POC investigation. Since previous studies have not evaluated the utility of POC in this way, it has limited our ability to compare our findings with those of other studies.

Patient Characteristics

In this randomized, controlled trial, the beneficial effects of early POC testing were proven in three common medical patient symptoms groups: abdominal pain, chest pain, and generalized body pain/weakness. As the psychiatric patients who sought treatment from the ED were mostly triaged orange (ie, were generally seen within 10 minutes of arrival the ED), there was no extra benefit in adding early POC testing to their workup pathway.

Treatment Times and Treatment Time Saving

There was statistically and clinically significant time saving in all the symptom groups if the patients had ECG + LODOX, any (i-STAT + CBC)–containing workflows, or any of the four i-STAT + LODOX workflows

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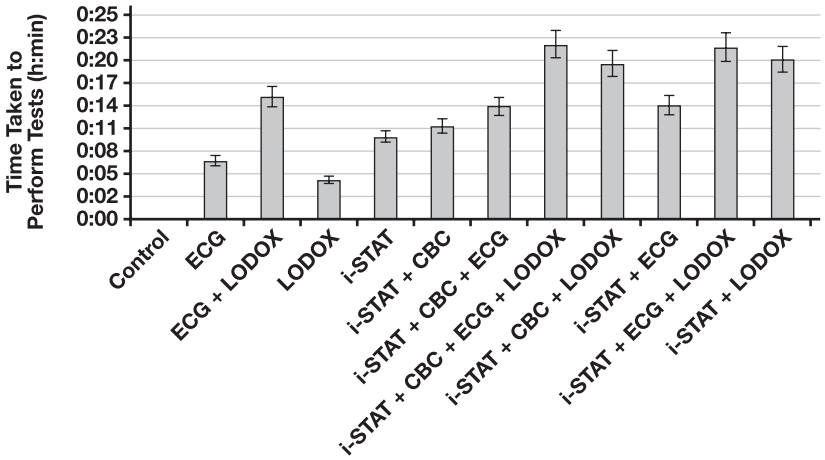


Figure 3 Mean time taken to perform the point-of-care tests. ECG, electrocardiogram; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray.

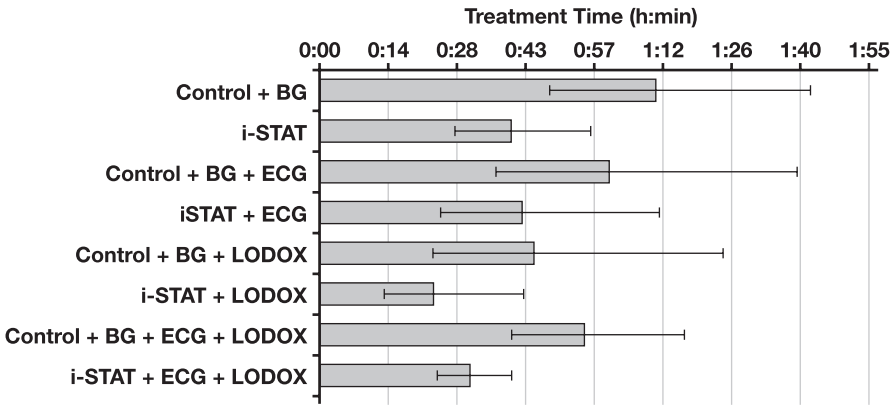


Figure 4 Treatment times for blood gas (BG) vs equivalent i-STAT–containing permutations. ECG, electrocardiogram; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray.

applied. Conversely, although i-STAT alone and the i-STAT + ECG groups tended toward time saving clinically (ie, exceeding the stipulated outcome measure of a 20% reduction in time compared with the control workflow), they did not show a statistically significant amount of time saved overall. In a previous study of a cohort of patients with chest pain who completed a full battery of standing order tests prior to doctor evaluation, Hwang et al[13] showed a similar statistically significant treatment time decrease of 26 minutes (16.9% reduction compared with control).

In general, it is considered that two-thirds of a patient's entire length of stay in the ED is related to waiting for special investigation results such as blood tests, ECGs, and radiographs.[14] If these tests, with their respective results, could be obtained prior to the doctor's initial evaluation of the patient without extending the patient's total time in the ED, then a substantial amount of time could be saved.

Not only does POC testing have the potential to decrease the therapeutic turnaround or so-called vein-to-brain time (ie, the time from ordering the test to the doctor being aware of the result), but it also ensures that the doctor remains focused on the clinical decision that the results are meant to support.[15,16] Furthermore, once the doctor loses contact with a patient who gets sent for investigations, the delay to awareness of the results being ready can be magnified by the myriad distractions and interruptions present within the ED and other critical care settings.[17]

Blood Tests

Thirty percent of discharged patients and 47.2% of patients overall seeking treatment from the ED require laboratory tests.[14,18] Laboratory testing can be the "rate-limiting step for many patients in the ED."[6,19] In an ED operational simulation study, throughput correlated directly with laboratory result turnaround time.[20]

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Table 3
Cost Comparisons Between Control Pathway Diagnostic Tests and Investigations and Their Point-of-Care Equivalents

Diagnostic Test (Laboratory)/Investigation	Cost, US$	Point-of-Care Equivalent	Cost, US$
CBC	4.57	CBC (CELDYN Emerald 22)	2.33
Urea and electrolytes	13.62	Chem8 (i-STAT)	16.15
Troponin I	13.31	Troponin I (i-STAT)	18.89
PT/INR	3.73	PT/INR (i-STAT)	10.62
Blood gas	4.27	CG4+ (i-STAT)	11.46
X-ray	121.58	LODOX	104.17
Total	161.08	Total	163.62

ECG, electrocardiogram; i-STAT, i-STAT point-of-care tests; LODOX, low-dose x-ray; PT/INR, prothrombin time/international normalized ratio.

Gardner et al,[21] who looked at factors influencing patient ED length of stay, demonstrated that any blood test increased length of stay by 35.4 to 40.1 minutes, and Yoon et al[14] demonstrated that laboratory testing added 126 minutes to patient length of stay. In our study, all patients in an i-STAT–containing permutation benefited from a decrease in their treatment time.

ECG

Gardner et al[21] found that ECGs added 4.2 minutes to ED length of stay in patients who were discharged from the ED but saved 2.7 minutes for those patients who were admitted. Our findings tended to the same conclusions where the time saving produced by the provision of an ECG alone did not achieve the primary outcome measure of a 20% reduction in treatment time.

Radiography

X-rays are also time-consuming.[1] Gardner et al[21] showed that length of stay increased by 5 to 15 minutes for any x-ray, and Yoon et al[14] reported that x-rays added 60 minutes in their study. In our study, LODOX alone took only 4.5 minutes on average to perform. Although it did not exceed the 20% reduction in treatment time when used alone, it did contribute to time saving when combined with the other tests.

Standing Orders vs Upfront POC Testing and "Overtesting"

The concept of standing orders is not new. Various tests are currently implemented as per protocol for specific presenting complaints. These orders, however, are actioned only if the ED is full, they have not made use of POC devices, and they have had variable uptake by the nursing staff, resulting in both under- and overtesting.[12,22]

There is no evidence to suggest that standing orders and the ease and availability of POC testing would lead to overtesting.[23-25] In the randomized controlled trial by Begaz et al,[26] which looked at whether screening and initiating diagnostic studies in the waiting room on patients with abdominal pain reduced time spent in the ED, there was a very small overtesting rate. In a study evaluating standing orders specifically, those patients who received the full gamut of tests had a 16% reduction in their mean treatment times and 98% of the patients who did not receive the standing orders went on to receive similar investigations once they were seen, which nullifies the hypothesis that advance protocolized testing leads to "overtesting."[22]

Time Taken for Upfront POC Testing

The premise behind upfront POC is that the tests are performed during the "front-end" part of the patient's ED journey (ie, during a "non-value-added period") while the patient is waiting for the doctor.[22] The longest time to get all the POC results in this study was on average 23 minutes, which was much shorter than the average 57 to 152 minutes in which the patient waited to see the doctor. This makes the patient's time economically spent.

Assessment for Consistency

There was no evidence of a Hawthorne-type effect. Treatment times were not significantly different between patients enrolled at the beginning compared with the end of the 4-month study period.

Comparison of Patients Who Had a Blood Gas Performed by the Doctor on the ED Blood Gas Analyzers vs Those Assigned to an Equivalent i-STAT-Containing Workflow

Blood gas analysis is a common, quick POC adjunct used in the ED. Despite its convenience and efficiency, it too caused delays in patient disposition. This may be due to an extra step in cognition required to decide whether the test is required as well as the time taken to perform the test itself and then interpret the results. Alternately, this may be due to the patients being sicker, but the effect of triage category was accounted for in the statistical analysis. The upfront, i-STAT blood tests outperformed blood

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gas analyzer POC testing with regard to decreasing treatment times.

Barriers to the Adoption of POC Testing in the ED

Although not assessed in this study, various barriers have previously been described regarding the implementation of POC testing in the ED. The main obstacles include quality assurance issues regarding calibration as well as analytical reliability and potential higher costs per test for POC in comparison to centralized laboratory testing.[6,27] The accuracy of POC tests is now generally considered equivalent to tests performed in a central laboratory.[6,28] Quality control procedures are specific to each POC device and should be performed as per manufacturer's guidelines. Actual costs from previous studies have been varied, with some reporting increased costs and others showing an overall reduction in costs.[29,30] Some of the nonfiscal "cost savings" should perhaps be evaluated in future cost-effectiveness studies—decreased patient complaints due to excess waiting, increased staff satisfaction, and fewer patients leaving the ED without being seen.

Utility of POC in the ED

In prior studies, there has been mixed evidence for the utility of POC testing in the ED. However, these have previously only been applied *after* the patient has interacted with a health care practitioner.[1,4,8-10] This has confounded the ability to demonstrate their usefulness for a variety of reasons. A health care provider (commonly a senior doctor or nurse) was required to make a decision regarding the tests required for each individual patient. This takes staff members out of the "seeing patients" circulation and redirects them, leading to potential increases in time required to ultimately assess the patient.

The tests chosen were also not "complete" (eg, the POC tests used by Lee-Lewandrowski et al[4] only included glucose, urine β-human chorionic gonadotropin, urine dipsticks, creatine kinase MB isoenzyme, and troponin)—that is, more tests were needed to make a patient disposition decision.

In addition, these studies only considered the POC route for blood tests. Laboratory tests are not the only "bottleneck" in the system—radiology and ECG delays can also lead to increased treatment times.[1,14,21]

POC testing has also only previously been shown to be of benefit in specific groups (eg, acute coronary syndrome, where up to 25% of the ED workload patients require a cardiac marker).[24] This study demonstrated the benefit of POC testing across a variety of common ED patient presentation symptom groups.

Limitations

This study was performed in a single center, making extrapolation of the results to other EDs difficult. While the impact on the treatment time was evaluated, there was no assessment of the effect on patient morbidity and mortality. Although staff were not blinded to which patients received the upfront POC tests as opposed to the control pathway, there was no evidence of a Hawthorne-type effect. Times, however, were recorded by the doctors themselves and not an impartial observer, which could have been a potential source of error. Cost comparisons were not a primary outcome measure of this study. The total cost calculation was based on the likelihood that the patients in the control pathway received the same tests as an equivalent patient in the POC intervention pathway. Analysis regarding individual patient requirements for testing was not performed separately—this potentially could have led to overtesting. Previous studies have shown this not to be likely.

Conclusions

As Gandalf in J. R. R. Tolkien's *Fellowship of the Ring* said, "All we have to decide is what to do with the time that is given us."

In order for the full benefit of POC testing to be realized, its implementation needs to be prior to doctor evaluation, as part of a standardized procedure in the ED. This takes advantage of the fast vein-to-brain time as well as the timeous delivery of other adjunct testing results to decrease treatment time.

Corresponding author: Lara Goldstein, Postnet Suite 429, Private Bag X1510, Glenvista 2058, South Africa; drg666@gmail.com

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SECTION 3

The cost-effectiveness of upfront POC testing in the ED

CHAPTER 5
THE COST-EFFECTIVENESS OF UPFRONT POINT-OF-CARE TESTING IN THE EMERGENCY DEPARTMENT: A SECONDARY ANALYSIS OF A RANDOMISED, CONTROLLED TRIAL

Goldstein LN, Wells M, Vincent-Lambert C. The cost-effectiveness of upfront point-of-care testing in the emergency department: a secondary analysis of a randomised, controlled trial. Scand J Trauma Resusc Emerg Med. 2019;27(1):110.

5.1 Background

"There is no such thing as a free lunch" is at "the core of economics" according to Campbell McConnell [1]. So while it was shown in Chapter 4 that upfront, POC testing in the ED has promise with regards to saving time by decreasing treatment time, the very next question that funders would ask is "What does it cost?" [2].

The challenge with the introduction of POC testing is commonly related to funders' fixation on the cost of a test. A direct comparison of POC with a laboratory equivalent test almost always shows that the POC test is more expensive [3, 4]. However, it is more complex than just a direct face-value comparison. The cost per test unit is only a portion of the overall picture. Other factors such as staffing costs, time consequences and intangible effects such as patient satisfaction all need to be included in the assessment of the cost of POC testing.

Sometimes, it is not just the funders that are interested in costing. There may be cost implications to the laboratory who might have a drop in their revenue if POC testing replaces traditional testing. Conflicting viewpoints emanate from whether the analyses are performed from the point of view of the laboratory or from the end-user in the ED [5]. Studies from the laboratory perspective are frequently negative towards the use of POC as opposed to traditional laboratory-based analyses [6]. While the end-users, for example doctors in the ED, are more focussed on the added potential

benefits of increasing patient throughput when using POC testing and therefore view it more favourably [7].

Thus, a more robust, scientific approach to the cost question is required in the form of a formal economic analysis.

The main types of economic analyses that can be utilised for healthcare-based applications and have been used in POC research are [4] :-

- Cost-minimisation analysis
- Cost-utility analysis
- Cost-effectiveness analysis
- Cost-benefit analysis

Cost-effectiveness analyses are commonly combined with cost-benefit analyses [4].

5.1.1 Cost-minimisation analysis

Cost-minimisation analysis is based on the assumption that there is no outcome difference between the technologies being compared i.e. they are compared based on their face-value direct costs alone [4]. This was a common problem with the original POC testing costing studies. Comparisons were limited to average costs per test without taking into account the changing costs to the ED or the hospital. For example, if POC tests replace laboratory tests then there will be a reduction in laboratory costs because fewer tests will be submitted to the laboratory [2]. This economic analysis methodology also misses the point when the technologies being compared are not equal in their performance and do have other positive outcome benefits. Schilling translated the time saved by POC in the ED to savings in staffing costs [7]. He used the direct costs of the POC tests (which were, in fact, cheaper than laboratory tests in his study) but then offset the staffing costs from the time saved from the POC tests [7]. However, even taking the reduction in laboratory costs and staff costs into account, cost-minimisation analysis is still inadequate as, in essence, this is still a direct, face-value comparison of costs of POC with traditional testing.

5.1.2 Cost-utility analysis

Cost-utility analysis considers the effect of the various interventions on a number of outcomes including life expectancy and quality of adjusted life year (QALY) effects [4]. In a randomised, controlled trial assessing the effects of POC tests for patients with suspected myocardial infarction, Fitzgerald *et al*. evaluated the cost-utility of POC in the ED for patients with chest pain. The cost-utility was evaluated as part of their entire healthcare costs including hospital admission, discharge and follow-up [8]. POC testing, in this study, resulted in lower general inpatient costs, reduced hospital admissions for patients with suspected myocardial infarction but higher ED, coronary care and cardiac intervention costs. The authors thought that this occurred due to the POC troponin test being performed earlier than the standard laboratory test and having a lower diagnostic threshold. This meant that more tests were positive and therefore those patients had higher admission rates to the coronary care unit and more cardiac interventions performed. Despite similar QALY between the POC and standard groups, the authors acknowledge that there may have been unmeasured potential benefits to these patients that were never analysed [8].

5.1.3 Combined cost-effectiveness and cost-benefit analyses

A cost-effectiveness analysis compares interventions by using the cost required to produce an additional unit of a pre-defined outcome. A cost-benefit analysis converts the effectiveness into monetary terms known as the “funders’ willingness to pay” (generally abbreviated as λ) [4]. In the only other randomised controlled trial to evaluate cost-effectiveness for POC use in the ED, Asha *et al*. exchanged traditional laboratory tests for POC tests in their ED. This was for patients suspected of having non-ST-elevation acute coronary syndrome (ACS) (the “ACS group”) and a so-called “general group” of patients who were thought to only need blood tests from an available POC selection (creatinine, electrolytes, glucose, calcium, haemoglobin, troponin-T, D-dimer, β-HCG and INR) [9]. If the “general group” of patients needed tests outside of the POC availability, they were excluded. Their trial showed that if the funder was willing to pay an extra AUS$120 per patient, then POC implementation as per their design would result in a likely treatment time saving of one hour per patient (time saved to disposition decision was their pre-determined outcome) [9].

5.2 Limitations of Economic Analyses

Cost-effectiveness and cost-benefit analyses aim to quantify and graphically represent the uncertainty associated with the economic evaluation of healthcare interventions [10]. Although these techniques have been widely adopted, there are important limitations to note in their usage [10]. Cost-effectiveness acceptability curves (derived from cost-benefit analyses of cost-effectiveness planes) are meant only to be a guide for decision-makers and funders to determine cost effectiveness [11].

Various assumptions are made in order for certain of the analyses to be calculated. Incremental Cost-Effectiveness Ratios (ICER) evaluate at what cost incremental effects of an intervention are seen [11]. When these analyses are done as part of a randomised controlled trial, there is an inherent “uncertainty” as the costing figures are estimates [11]. Costs will commonly also have a skewed distribution e.g. a few patients will have high costs and many patients may have little or no costs. The analysis, however, uses *average* incremental costs. The effects are therefore also analysed as *average* effects on the population leading to that element of so-called “uncertainty” [11].

The *average* incremental costs and the *average* effects translate into a single point for each intervention on the Cost-Effectiveness Plane derived from the ICER calculations as can be seen in the example in Figure 5.1. Point A is more costly but more effective in the north-east quadrant and Points B and C are both less costly and more effective interventions in the south-east *dominant* quadrant.

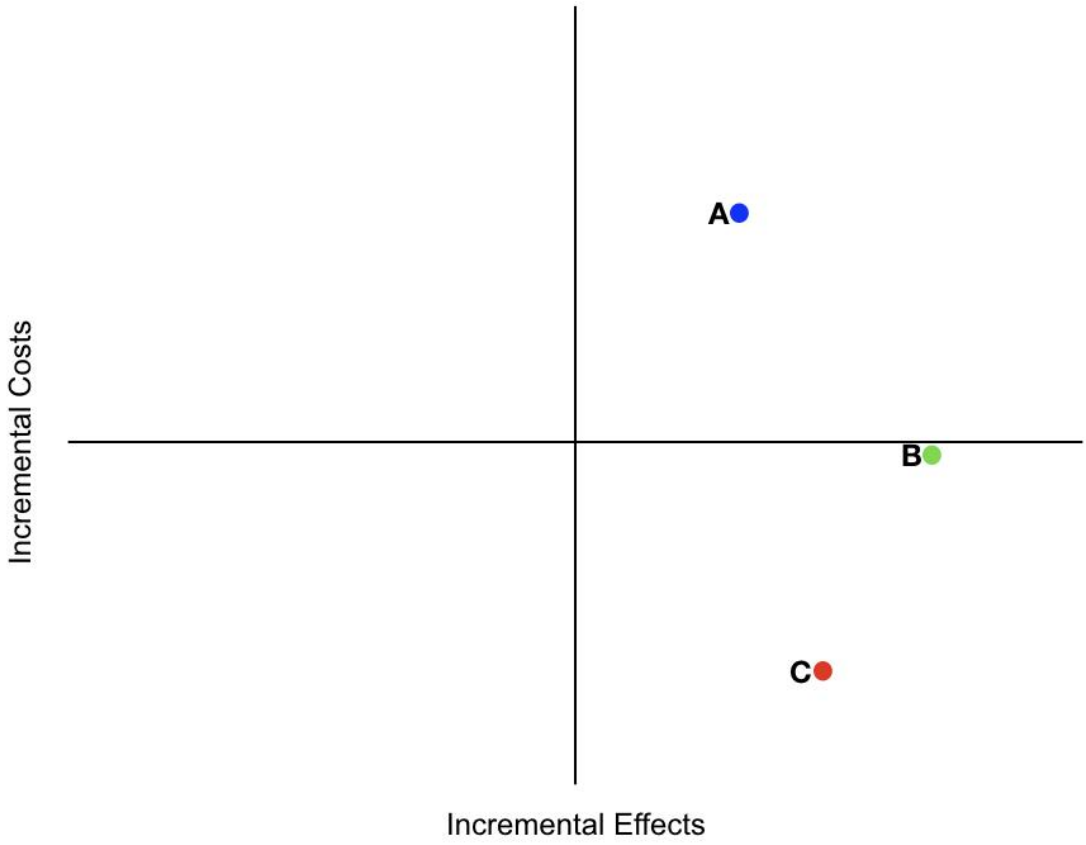


Figure 5.1 The Cost-Effectiveness Plane for 3 hypothetical interventions A, B and C. In the north-east quadrant is Point A (blue dot) which is more costly but also more effective. The south-east *dominant* quadrant contains both Point B (green dot) and Point C (red dot). These interventions would be both less costly and more effective interventions.

While there is minimal “uncertainty” regarding the cost-effectiveness of interventions A and C, there is a likelihood that some patients within group B may have fallen into the north-east quadrant which is “more costly and more effective”. This is graphically represented in Figure 5.2 based on scenarios illustrated by Fenwick *et al* [10]. This spread of all the participants in group B within the ellipse crosses over into the north-east quadrant. This makes the actual cost-effectiveness of group B less likely. It

would therefore be better to convert the ICER into a cost-effectiveness acceptability curve in order to assess the potential benefit.

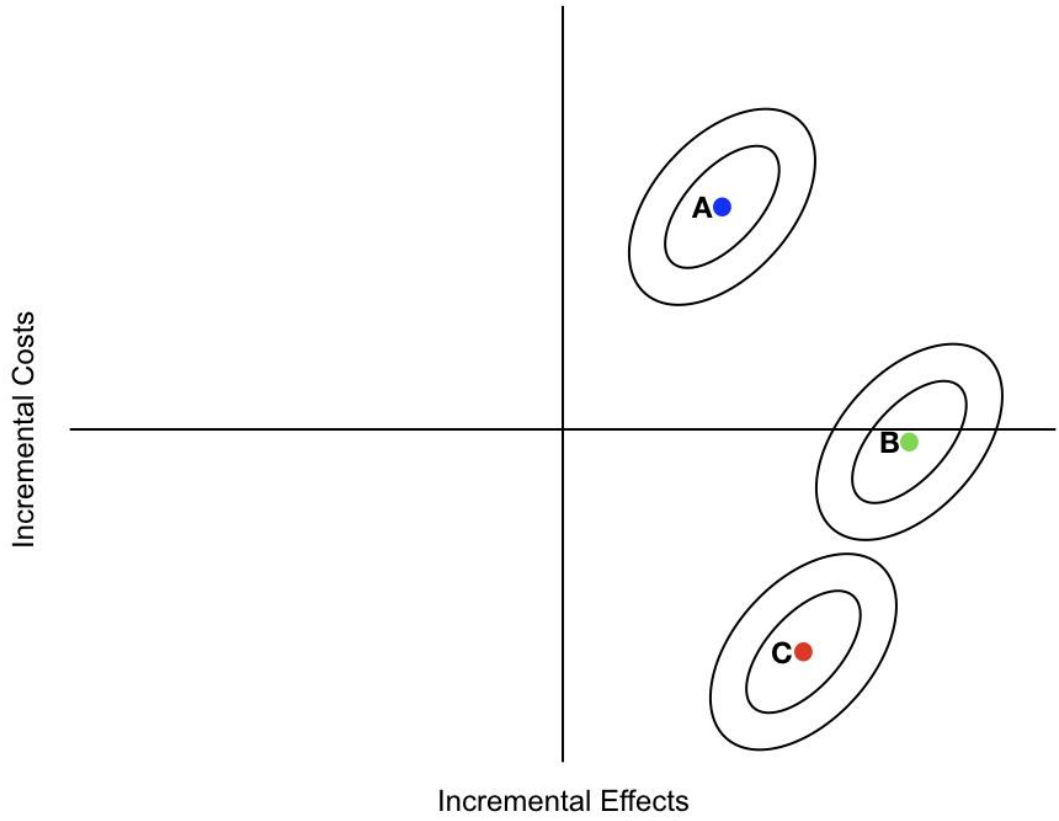


Figure 5.2 The Cost-Effectiveness Plane showing the hypothetical distribution of all the patients in each intervention group. It can be seen that some patients in group B crossed over into the north-east quadrant as demonstrated by the ellipse.

An alternate way of representing the uncertainty of the ICER is to use the Cost-Effectiveness Acceptability Curve (CEAC) [11]. By using a pre-determined maximum amount for a "funder's willingness to pay" (λ), the analysis is then done to determine the probability that the cost-effectiveness will hold [11].

So, while the graphic representation and robust economic analyses appear incontrovertible, there are inherent flaws to, and assumptions made in, their construction.

5.3 Purpose of the Study

The purpose of this study was to assess the cost-effectiveness of implementing a novel combination of *upfront* POC tests (blood tests, ECG and/or LODOX®) in the ED. Chapter 4 showed that this modification to the traditional ED patient processing

pathway saved time – but could it save money? Or, at what price could timesaving be achieved?

The majority of previous POC studies from the ED have focussed only on certain outcomes e.g. decreased ED length of stay without reporting or considering the cost of implementation thereof. None of the POC studies that reported economic analyses ever analysed the different POC tests separately in order to assess from which tests produced the most benefit.

The objective primary of this study was to evaluate the cost-effectiveness of each of the POC tests individually and in their various combinations to determine whether there would be economic benefit from their implementation. The secondary objective was to determine whether the costs would potentially be within a funder's willingness to pay.

5.4 Major Findings of the Study

- A face-value comparison of the traditional tests to their POC equivalents showed a surprising cost-saving if all the tests were performed on all patients. However, not all patients presenting to an ED will receive tests, or if they do receive tests, not all patients will receive the same type or number of tests.

- As per the original data, the "psychiatric group" was excluded from the economic analysis due to the vast difference in needs compared to the other patient groups.

- Almost 79% of patients in the control group had a blood test or a blood gas analysis performed. Twenty-four percent of patients only had a blood gas analysis performed in the control group. Sixty-four percent of control patients had an ECG performed and 58.7% had an x-ray done.

- LODOX®-containing permutations were all "more costly" but were "more effective" from a timesaving perspective. The radiological component formed the bulk of the diagnostic test costs in all the LODOX®-containing permutations. This led to additional cost without significant timesaving to counterbalance it. Despite LODOX® being more inexpensive than a standard

x-ray, there was an additional cost per patient as all patients in the LODOX®-containing permutations received an x-ray compared to only 58.7% of the control group. Use of LODOX® should probably only be instituted after an admission decision is made in order to avoid over-testing and unnecessary radiation exposure for the patient.

- If an additional cost of US$50 was acceptable to the funder, then all the permutations that did not include LODOX® were essentially 100% cost effective and were found in the “less costly and more effective” quadrant of the cost-effectiveness plane.

- The incidence of acute coronary syndrome-related chest pain was very low in our ED. Although troponin is generally useful for patients with suspected ACS as well as a raised troponin having an association with worse short-term patient outcomes, it was excluded from this economic analysis as it would have resulted in over-testing with no added benefit to the patient.

- Similarly, blanket INR usage as was included and reported in the first publication, was excluded from the economic analysis as it too would have resulted in unnecessary patient testing.

5.5 This Study in the Context of the Thesis

This study provided an economic analysis for this research. It was crucial to explore cost implications of instituting *upfront* POC tests in the ED as well as determining which POC tests could provide the most benefit. Just because there was time saving, did not automatically mean that it would be translated into money saving.

This research provided confirmation of the financial benefit of saving time in the ED with *upfront* POC testing – it had the potential to save money. This was clearly evident in all POC test combinations that did not include a LODOX® radiological investigation. Although effective in saving time, LODOX®-containing permutations came at a further cost (financial, over-testing and additional radiation exposure) even though the actual cost of a LODOX® was less than a standard x-ray. The most economical POC test combination was the i-STAT+CBC which saved the most

money per patient. This study did not address the fact that not all hospitals have a LODOX® machine, and in LMIC, there are many hospitals that may not even have a laboratory or an ECG machine on premises. The cost-effectiveness of only implementing *upfront* POC blood tests in the ED will therefore be dealt with in Chapter 6.

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ORIGINAL RESEARCH Open Access

The cost-effectiveness of upfront point-of-care testing in the emergency department: a secondary analysis of a randomised, controlled trial

Lara Nicole Goldstein[1,2*], Mike Wells[2] and Craig Vincent-Lambert[2]

Abstract

Background: Time-saving is constantly sought after in the Emergency Department (ED), and Point-of-Care (POC) testing has been shown to be an effective time-saving intervention. However, when direct costs are compared, these tests commonly appear to be cost-prohibitive. Economic viability may become apparent when the time-saving is translated into financial benefits from staffing, time- and cost-saving. The purpose of this study was to evaluate the cost-effectiveness of diagnostic investigations utilised prior to medical contact for ED patients with common medical complaints.

Methods: This was a secondary analysis of data from a prospective, randomised, controlled trial in order to assess the cost-effectiveness of upfront, POC testing. Eleven combinations of POC equivalents of commonly-used special investigations (blood tests (i-STAT and complete blood count (CBC)), electrocardiograms (ECGs) and x-rays (LODOX® (Low Dose X-ray)) were evaluated compared to the standard ED pathway with traditional diagnostic tests. The economic viability of each permutation was assessed using the Incremental Cost Effectiveness Ratio and Cost-Effectiveness Acceptability Curves. Expenses related to the POC test implementation were compared to the control group while taking staffing costs and time-saving into account.

Results: There were 897 medical patients randomised to receive various combinations of POC tests. The most cost-effective combination was the i-STAT+CBC permutation which, based on the time saving, would ultimately save money if implemented. All LODOX®-containing permutations were costlier but still saved time. Non-LODOX® permutations were virtually 100% cost-effective if an additional cost of US$50 per patient was considered acceptable. Higher staffing costs would make using POC testing even more economical.

Conclusions: In certain combinations, upfront, POC testing is more cost-effective than standard diagnostic testing for common ED undifferentiated medical presentations – the most economical POC test combination being the i-STAT + CBC. Upfront POC testing in the ED has the potential to not only save time but also to save money.

Trial registration: ClinicalTrials.gov: NCT03102216.

Keywords: Point-of-care systems, Point-of-care testing, Emergency department, Economic analysis

* Correspondence: drg666@gmail.com
[1]Division of Emergency Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa
[2]Department of Emergency Medical Care, Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa

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Introduction

Point-of-Care (POC) tests – diagnostic tests that are performed at or near the patient's bedside – have been touted as potential time-saving interventions to decrease waiting times in the Emergency Department (ED) [1–3]. These tests can decrease the turnaround time of special investigations thereby reducing delays which can cause prolonged patient times in the ED [2, 4]. While these POC time-savers are mostly reported in the literature as being cost-prohibitive to implement when their direct costs are compared to the traditional diagnostic testing, the POC system costs have conversely also been reported as being less expensive than central laboratory costs in other studies [2, 5–7]. Recouping the personnel costs from the time that is saved, however, may paradoxically mean that the more expensive POC tests have financial benefit and therefore become an economically viable option [2, 5]. The improved overall processing of the patient as a result of the reduced turnaround times, more rapid diagnosis and disposition could potentially allow for fewer staff members to manage the same number of patients in the same time as using a conventional system [2, 5, 8]. This would be an important potential consideration when planning and optimising ED staffing.

Conventionally, special investigations such as blood tests, electrocardiograms (ECGs) and radiological investigations take place after an ED doctor has evaluated a patient. Both the patient and the doctor then need to wait for the results of these tests before the doctor can make a disposition decision for the patient. When conventional testing is replaced with POC tests performed upfront prior to doctor assessment, significant time-saving has been demonstrated – this was our randomised, controlled trial that provided the data on which this secondary analysis is based [9]. Whether the time-saving from this intervention could translate into money-saving is important to determine. This information would be useful for policy- and decision-makers with regards to deciding whether to implement upfront, POC testing in their EDs.

The aim of this study was to evaluate the cost-effectiveness of common diagnostic investigations, in the form of POC tests, performed prior to doctor assessment, for patients presenting to the ED as a secondary analysis of data obtained from our randomised controlled trial [9].

Methods

Study design and setting

This was a secondary analysis of data from an investigator-initiated prospective, randomised, controlled trial. The original trial evaluated the time-saving potential of upfront, POC tests in the ED [9]. This secondary analysis was conducted in order to assess the cost-effectiveness of the upfront POC testing. The trial was conducted in the ED of a tertiary, academic hospital in a metropolitan area of Johannesburg, South Africa. The ED sees approximately 65,000 patients annually. The hospital is a government-funded, public sector hospital serving a region with a population of approximately one million medium- to low-income people.

The study took place between 13 February and 29 June 2017.

Permission to conduct the study was granted by the Research Ethics Committee of the Faculty of Health Sciences of the University of Johannesburg (REC-01-185-2016); the Human Research Ethics Committee of the University of the Witwatersrand (M171086); South African National Health Research Ethics Council (DOH-27-0117-5628); and was registered as a clinical trial with the South African National Health Research Database (GP_2017RP57_655) as well as with clinicaltrials.gov (NCT03102216). Written informed consent was obtained from all patients. Patients were not paid for their participation in this study nor did they incur any expenses related to the study.

Selection of participants

During weekdays, all adult patients older than 18 years who presented to the ED with various common medical symptoms were eligible for inclusion in the study. The medical symptom groups included were typical of the so-called undifferentiated patient that may present to the ED viz.

- "abdominal group" – patients who presented with any form of abdominal pain and/or vomiting
- "chest group" – patients who presented with dyspnoea, chest pain, cough and/or syncope
- "generalized body pain/weakness group" – patients who presented with generalized body pain and/or weakness
- "psychiatric group" –patients who presented with psychosis, aggression, hallucinations and/or having taken a drug overdose

Patients who required immediate resuscitation or who were pregnant were not considered for inclusion.

Figure 1 demonstrates the methodology followed in the study, showing the normal ED pathway compared to the eleven POC pathways utilised during the study period.

Block randomisation was done prior to study commencement using www.randomizer.org – an online randomisation tool. Randomisation was independent of the nature of the patient presentation. Symptom categories were represented equally in each POC block and all twelve test pathways were assigned to each of the above

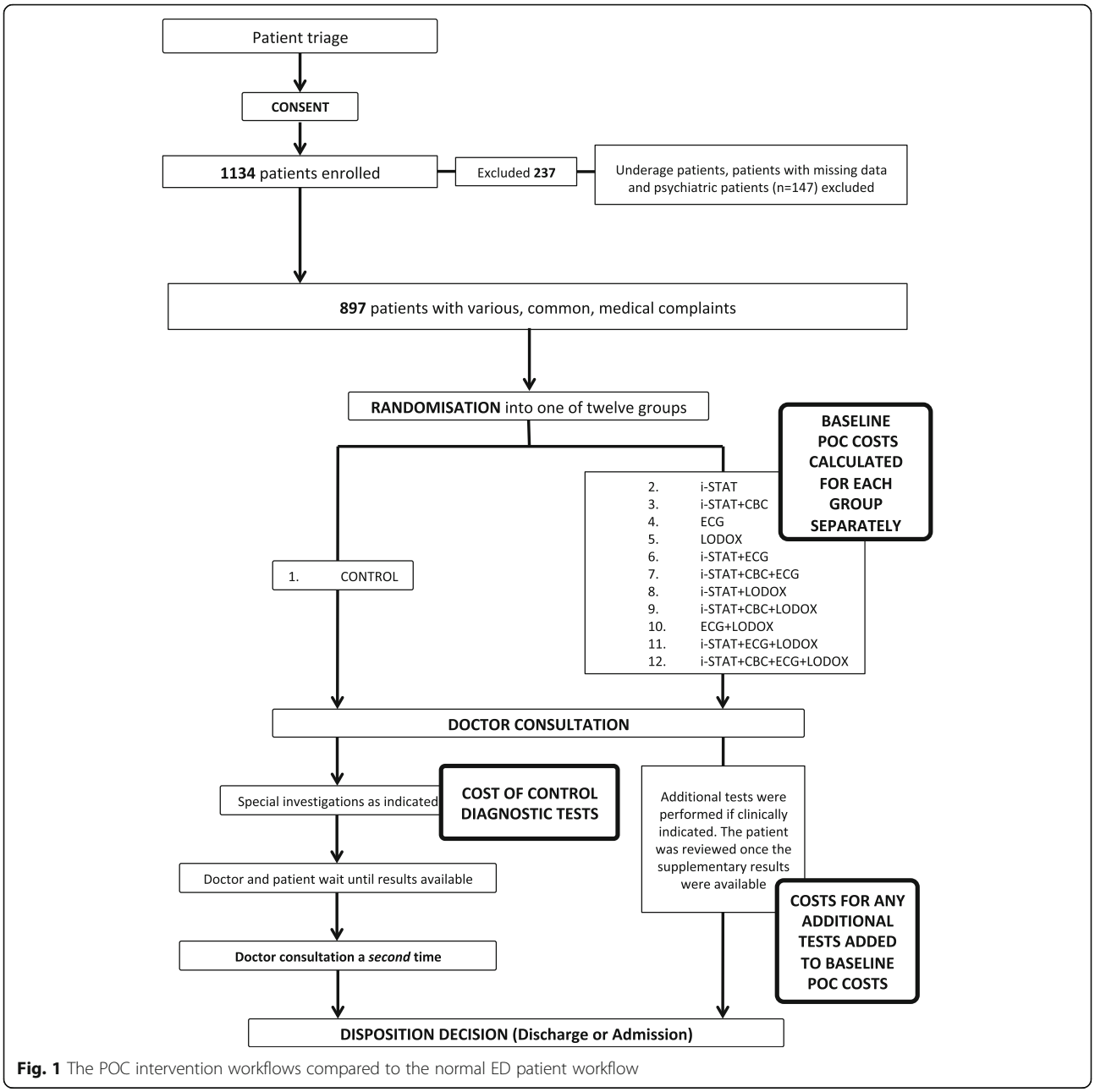


Fig. 1 The POC intervention workflows compared to the normal ED patient workflow

symptoms groups (Fig. 1). Based on the block randomisation, data collection sheet sets were placed upside-down in the order generated. After the patient signed consent, either the research doctor or the research assistant took the next data collection sheet in the order supplied.

The patients were randomised to receive either the normal ED workflow pathway (i.e. the control) or one of the other eleven intervention POC pathways with various combinations of one, two, three or four POC tests (see Fig. 1). This was done in order to ascertain whether any particular individual POC test or if certain combinations of POC tests could provide the most benefit.

In the control pathway, after triage, consent and randomisation, a doctor evaluated the patient. If diagnostic tests were required, they were ordered as indicated. All blood tests were performed according to standard procedures in the on-site hospital laboratory and if the patient required a blood gas analysis, the doctor would perform this on one of two blood gas analysers available in the ED (Cobas B 221 POC system, Roche Diagnostics or ABL800 Flex, Radiometer). X-rays were performed in the radiology

department and the ED staff performed ECGs as required.

The doctor would review the patient a second time once the results of the diagnostic tests were available. This was followed by the disposition decision.

In the enhanced, intervention POC pathways, if the doctor deemed additional investigations over and above the POC tests necessary, those tests were then performed according to the ED standard procedures. Once the additional results were subsequently available, the patients were reviewed.

Patients were not subjected to any form of diagnostic investigation that they would not most likely have received by following the control pathway for each particular symptom group. The main difference between the control workflow pathway and the enhanced, intervention POC workflow permutations was that the tests were performed in the ED at the so-called point-of-care *prior* to the patient seeing the doctor for the first time.

Patient throughput time in the ED consists of administrative time and treatment time [10]. Table 1 contains the definitions, possible confounders and solutions employed in this study to overcome them in order to accurately evaluate the effects of the POC tests on patient time in the ED and therefore the impact on the cost-effectiveness.

POC tests

The POC equivalents of commonly used special investigations in the ED were chosen – details are provided in Table 2. The POC testing was performed in a private cubicle where the LODOX® (LOw-DOse X-ray) machine was located within the ED. All other testing was done as per standard procedure in the ED. Details of the direct cost comparisons of the diagnostic tests and their POC equivalents are depicted in Table 2.

POC costs

Costs for the POC blood tests were obtained from the supplier. Capital and maintenance costs of equipment were included in the prices of all tests whether POC or control diagnostic tests therefore no indirect costs were added. Discounting was not applied. Prices for the control pathway investigations were obtained from the hospital laboratory (blood tests) and radiology department (X-rays/LODOX®). The cost of the ECG was equivalent in both pathways.

When comparing the costs of the intervention permutations to the control group, the costs were calculated as follows:

Control group

All tests as ordered by the doctors were included e.g. if the doctor ordered an ECG and a blood gas, only the costs of those two tests were included for that particular patient.

Intervention POC permutation groups

The costs of the POC tests specific to the group PLUS any additional tests that were ordered by the doctors were included in the total cost e.g. If the doctor ordered an x-ray for a patient who was in the i-STAT + CBC group, the cost of the x-ray was then added to the total cost for that patient.

Staffing costs

The cost calculations were performed as per Schilling's recommendation [5]. Staffing was considered as evenly distributed throughout the year and calculated using doctor and nursing costs only. Using this method, the cost of one minute of ED staffing was calculated to be US$5.37, which is equivalent to US$0.75 per patient per minute in our ED.

Sample size calculation

The sample size estimation was based on the determination of the effect of workflow pathways within each symptom group that were initially analysed. This required a two-way Analysis of Variance (ANOVA). Based on the detection of at least a medium effect size (f = 0.25 or a 20% difference in times between groups) with 80% power at the 5% significance level, a sample size of 864 patients was required.

Table 1 Time frame definitions in the ED

Administrative time	Treatment time
Time from patient arrival to doctor evaluation	Time from doctor evaluation to disposition decision
All patients go through the same process of opening a file and registering on the hospital system in our ED.	After a disposition decision is made, the patient may or may not timeously leave the ED.
The administrative process can be substantially longer on some days than on other days. This would change the wait-times for the patients prior to them presenting to the doctor and would confound the time measurements overall and therefore impact on the cost analysis.	Exit block may lead to a delay in the patient leaving the ED even if a timeous disposition decision is made.
Only treatment time was evaluated.	The disposition decision time was utilised.

Table 2 POC tests employed and cost comparisons between the control pathway tests and their POC equivalents

Abbott Point-of-Care i-STAT® System

The i-STAT System utilises single-use i-STAT test cartridges (i-STAT, Abbott Point of Care, Princeton, NJ, USA) with a handheld POC blood analyser. The CHEM8+ (sodium, potassium, chloride, total carbon dioxide, ionised calcium, glucose, urea, creatinine, haematocrit, haemoglobin and anion gap) and CG4+ (Lactate; pH; partial pressure carbon dioxide (PCO_2); partial pressure of oxygen (PO_2); total carbon dioxide; bicarbonate; base excess and oxygen saturation) were performed on venous blood specimens.

Abbott CEL-DYN Emerald 22 benchtop haematology system

The CEL-DYN Emerald 22 benchtop haematology system was used. It is capable of providing a POC Complete/Full Blood Count as well as a white blood cell differential count.

ECG

Philips Pagewriter TC30 ECG machines were utilised to obtain the ECGs. All patients randomised to receive an ECG received a standard 12-lead ECG as well as a right-sided (V1R-V6R) and posterior (V7-V9) ECG. The cost of the ECG was the same in both the control and the intervention groups.

LODOX®

A Lodox Xmplar-dr was used by a radiographer to perform the LODOX® (LOw-DOse X-ray) radiographs (chest and abdomen, antero-posterior and lateral). The radiation exposure was approximately 339uGy per patient versus a standard chest and abdomen radiograph of approximately 5200uGy [11]. LODOX® is the radiological equivalent of a POC test as it can provide a full body X-ray within 19 s without the patient leaving the ED. Its utility in trauma patients is reasonably well-known but its use as a diagnostic tool for non-trauma patients in the ED has not been evaluated previously [12].

Diagnostic tests	*Cost*	*Point-of-Care equivalent*	*Cost*
Complete Blood Count	4.57	CBC (CEL-DYN Emerald 22)	2.33
Urea, Creatinine, Electrolytes Blood Gas	17.89	i-STAT Chem8 CG4+	27.61
X-ray	121.58	LODOX®	104.17
TOTAL	$ 144.04[a]	TOTAL	$ 134.11[a]

$ Costs shown in US dollars for each individual test
CBC Complete Blood Count, *ECG* electrocardiogram, *i-STAT* i-STAT POC tests, *LODOX®* Low-dose x-ray
[a]The direct comparison of net costs for testing between the groups if the costs of the tests alone are shown in isolation at face value i.e. what the cost would be for a patient who received all the standard diagnostic tests compared to a patient who received all the POC tests. It would cost $9.93 less to have all the POC tests. This does not include the costs of other tests that might be ordered (e.g. serum amylase or lipase tests)

Outcomes

Treatment time was the main outcome measure for assessing the effectiveness of POC interventions. A difference in treatment time of 20% was considered to be clinically significant – this is higher than that utilised in previous studies (9–18%) [2, 9].

The main outcome measure for the cost-effectiveness of upfront, POC tests was the incremental cost effectiveness ratio (ICER).

The ICER was expressed as

$$\mathrm{ICER} = \mathrm{C1} - \mathrm{C2}/\mathrm{E1} - \mathrm{E2}$$

where C1 and E1 are the cost and effect (time) in the intervention group and C2 and E2 are the cost and effect in the control group [13].

Statistical analysis

A cost-effectiveness plane was constructed by plotting the effects on the horizontal axis and costs on the vertical axis. Further analysis utilised a non-parametric bootstrapping model. This model used the observed data for each permutation which was inserted into an excel template supplied by Barton et al [14]. For each bootstrap sample, the mean incremental costs and effects were calculated and repeated 1000 times. Incremental cost-effectiveness acceptability curves were then calculated from the bootstrap data across a range of increasing potentially acceptable costs. This analysis excluded the effects of potential cost-saving related to staffing expenses.

Data analysis was carried out using SAS (version 9.4 for Windows). The 5% significance level was used for all statistical analyses.

Results

There were 1134 patients enrolled in the trial. Consecutive patients were included during the patient enrolment periods – there was no patient selection. Five patients refused to participate in the study. After exclusions, 1044 patients were randomised. Figure 1 summarises the patient flow.

During data collection for the primary study, the outcomes in the "psychiatric group" ($n = 147$) were found to be very different from the other three symptom groups in an interim analysis. The psychiatric patients were seen almost immediately in most cases based on their "orange" triage scores and commonly only needed a single investigation viz. a blood gas analysis. From an ED-throughput perspective it was already functioning optimally and the extra testing was not required. Their data was therefore excluded as it would have skewed the results from both a time- and cost perspective. Therefore, 897 patients were included in the analysis.

Ten patients presented to the ED on more than one occasion during the study period and agreed to be enrolled a second time. They were treated no differently from patients who were seen for the first time. They all signed a new consent form and were randomised yet again. Their inclusion was therefore unlikely to have influenced the study outcomes.

Patient characteristics

A comparison of patient characteristics based on workflow allocation is tabulated in Table 3. There were no significant differences in age, triage category or

Table 3 Patient characteristics based on the twelve workflow allocations

	CONTROL	i-STAT	i-STAT CBC	ECG	LODOX	i-STAT ECG	i-STAT CBC ECG	i-STAT LODOX	i-STAT CBC LODOX	ECG LODOX	i-STAT ECG LODOX	i-STAT CBC ECG LODOX	*p*-value for between group test
N	75	75	74	77	75	74	76	74	77	73	74	73	
Age median (IQR)	45.7 (34.2; 61.7)	45.2 (31.6; 59.3)	44.2 (33.3; 68.0)	44 (33.9; 61.0)	41.6 (33.0; 55.5)	41.9 (33.3; 56.6)	40.7 (27.3; 60.9)	42.1 (29.9; 60.8)	37.1 (30.0; 55.1)	44.9 (35.0; 60.5)	39.5 (30.0; 61.3)	41.3 (31.5; 55.6)	0.65
Sex: Males (%)	30 (40.0)	30 (40.0)	29 (39.2)	36 (46.8)	30 (40.0)	27 (36.5)	35 (46.1)	18 (32.4)	28 (36.4)	31 (42.5)	42 (56.8)	37 (50.7)	0.11
Triage category													0.30
N (%)													
Orange[c]	22 (29.3)	18 (24.0)	11 (15.1)	22 (28.6)	15 20.0)	16 (21.6)	24 (31.6)	18 (24.3)	22 (28.6)	14 (19.2)	18 (24.3)	21 (28.8)	
Yellow[c]	52 (69.3)	54 (72.0)	59 (80.8)	52 (67.5)	60 (80.0)	57 (77.0)	50 (65.8)	54 (73.0)	55 (71.4)	59 (80.8)	56 (75.7)	48 (65.8)	
Green[c]	1 (1.3)	3 (4.0)	3 (4.1)	3 (3.9)	0 (0.0)	1 (1.4)	2 (2.6)	2 (2.7)	0 (0.0)	0 (0.0)	0 (0.0)	4 (5.5)	
Admitted[a] [b] N(%)	32 (42.7)	32 (42.7)	40 (54.1)	34 (44.2)	34 (45.3)	29 (39.2)	42 (56.0)	35 (47.3)	32 (41.6)	39 (53.4)	40 (54.1)	39 (53.4)	0.62
Discharged[a] N(%)	38 (50.7)	41 (54.7)	33 (44.6)	43 (55.8)	41 (54.7)	42 (56.8)	33 (44.0)	39 (52.7)	44 (57.1)	33 (45.2)	34 (45.9)	34 (46.6)	

CBC Complete Blood Count, *ECG* Electrocardiogram, *IQR* inter-quartile range, *i-STAT* i-STAT POC tests, *LODOX*® Low-dose x-ray
[a]8.2% of all patients were referred to another speciality as their disposition plan (i.e. neither admitted nor discharged)
[b]The overall admission rate for this ED is usually 30–35%. This includes all patient presentations e.g. trauma, general surgery, orthopaedics, otorhinolaryngology etc. The medical subgroup of patients typically has a higher admission rate than other patients
[c]Target times for the patients in each triage acuity category are Orange (to be seen within 10 min of ED arrival), Yellow (to be seen within 1 h of ED arrival) and Green (to be seen within 4 h of ED arrival)

disposition between the patients enrolled into the control or POC intervention groups.

Treatment times

A 20% reduction in treatment time was exceeded by all POC workflow permutations, except ECG alone and LODOX® alone groups.

With regards to disposition decision, there were no significant differences in treatment times between patients who were ultimately admitted or discharged within particular workflows, or between admission and discharge within particular symptom groups ($p = 0.091$).

Time taken for POC testing and patient waiting times

The patient waiting time to see a doctor after arrival in the ED was on average between 57 and 152 min. It took between 4 and 23 min to obtain the results of the POC tests. This included the time taken for phlebotomy, specimen processing and results printing for the i-STAT and CBC permutations. The blood tests could generally be performed concurrently, however, the LODOX® and ECGs had to be performed sequentially.

Investigation utilisation in the control pathway

There were 78.7% (59/75) patients in the control group who had blood tests and/or a blood gas analysis. Twenty-four per cent (36/75) had a blood gas analysis only. X-rays were performed in 58.7% (44/75) of patients and 64% (48/75) had ECGs performed.

Costs of investigations

Table 2 lists the costs for the individual investigations. Overall, POC equivalent tests cost US $9.93 less than the standard control investigations if all the tests were performed in a patient.

The time-saving and costs for each workflow is presented in Table 4.

Cost effectiveness analysis

Figure 2 exhibits the Cost Effectiveness Plane (2A), which is a graphical representation of the cost effectiveness analysis as well as the cost-effectiveness acceptability curve (2B).

LODOX®-containing permutations (dashed lines) and non-LODOX®-containing pathways (solid lines) are demonstrated using different values for funder willingness-to-pay (λ). Non-LODOX® permutations were virtually 100% cost-effective if an additional cost of US$50 per patient was considered acceptable.

Table 4 Costs and time-saving analysis ranked according to net additional cost per patient

	Total Average Group Cost[a] (US$ pp)	Difference between costs of POC tests and control (US$ pp)	Time Saved – Difference between control group time and POC group time (min)	Staffing costs saved (US$ pp)	ICER - Incremental Cost Effectiveness Ratio (US$ / min)	Net additional cost per patient in POC group (US$ pp)
CONTROL	81.86	–	–	–	–	–
i-STAT + CBC	82.86	1.00	31	23.21	0.03	−22.21
ECG ONLY	75.96	−5.90	9	6.74	−0.65	−12.63
i-STAT + CBC + ECG	90.73	8.87	26	19.47	0.34	−10.60
i-STAT	92.59	10.73	21	15.72	0.51	−4.99
i-STAT + ECG	95.36	13.50	21	15.72	0.64	−2.22
ECG + LODOX	127.48	45.62	25	18.72	1.82	26.90
i-STAT + ECG + LODOX	143.11	61.25	32	23.96	1.91	37.29
ALL POC TESTS	144.10	62.24	31	23.21	2.01	39.03
i-STAT + LODOX	142.56	60.70	25	18.72	2.43	41.98
i-STAT + CBC + LODOX	146.74	64.88	27	20.22	2.40	44.67
LODOX ONLY	142.09	60.23	9	6.74	6.69	53.49

$ Costs shown in US dollars for each permutation

A negative number indicates a lower cost with the POC test permutation than traditional diagnostic testing

CBC Complete Blood Count, *ECG* electrocardiogram, *ICER* incremental cost effectiveness ratio, *i-STAT* i-STAT POC tests, *LODOX®* Low-dose x-ray, *pp* per patient

[a]These are the average total actual costs that were incurred for the patients in each permutation. In the Control group, the only tests that were included were those selected by the doctors as they saw fit. In other groups, the average costs appear to be higher than would be expected as extra diagnostic tests may have been performed in those groups over and above those which were assigned (e.g. additional blood tests such as serum amylase or lipase). This principle extends across each of the groups

Discussion

Saving time is an ever-present goal in the ED. However, for upfront POC testing to be viable in the ED, the time-saving benefit needs to be weighed against the cost.

Costs of investigations and cost effectiveness analysis

Variations have been reported with respect to the net cost of POC testing [5, 8, 13]. In Sweden, POC was found to be substantially cheaper than the costs of similar tests performed in a laboratory [5]. In Australia, however, test costs were higher in the POC group [6]. Costs have previously been calculated using the direct differences between that of the POC tests and the laboratory costs without taking the expense of personnel into account [8]. The cost of staffing needs to be taken into account as decreases in test turnaround time could be translated into savings in staffing due to an improved overall processing of the patient from decreased turnaround times as well as quicker diagnosis and ultimately more rapid patient disposition [2, 5, 8].

In our study, direct head-to-head cost comparison between the POC tests compared to standard laboratory and radiological expenses in our study surprisingly showed a saving of US$9.93 if all the tests had been performed on all patients compared to using standard diagnostic tests. This was mainly as a result of the lower cost of the LODOX® compared to the x-ray and the lower

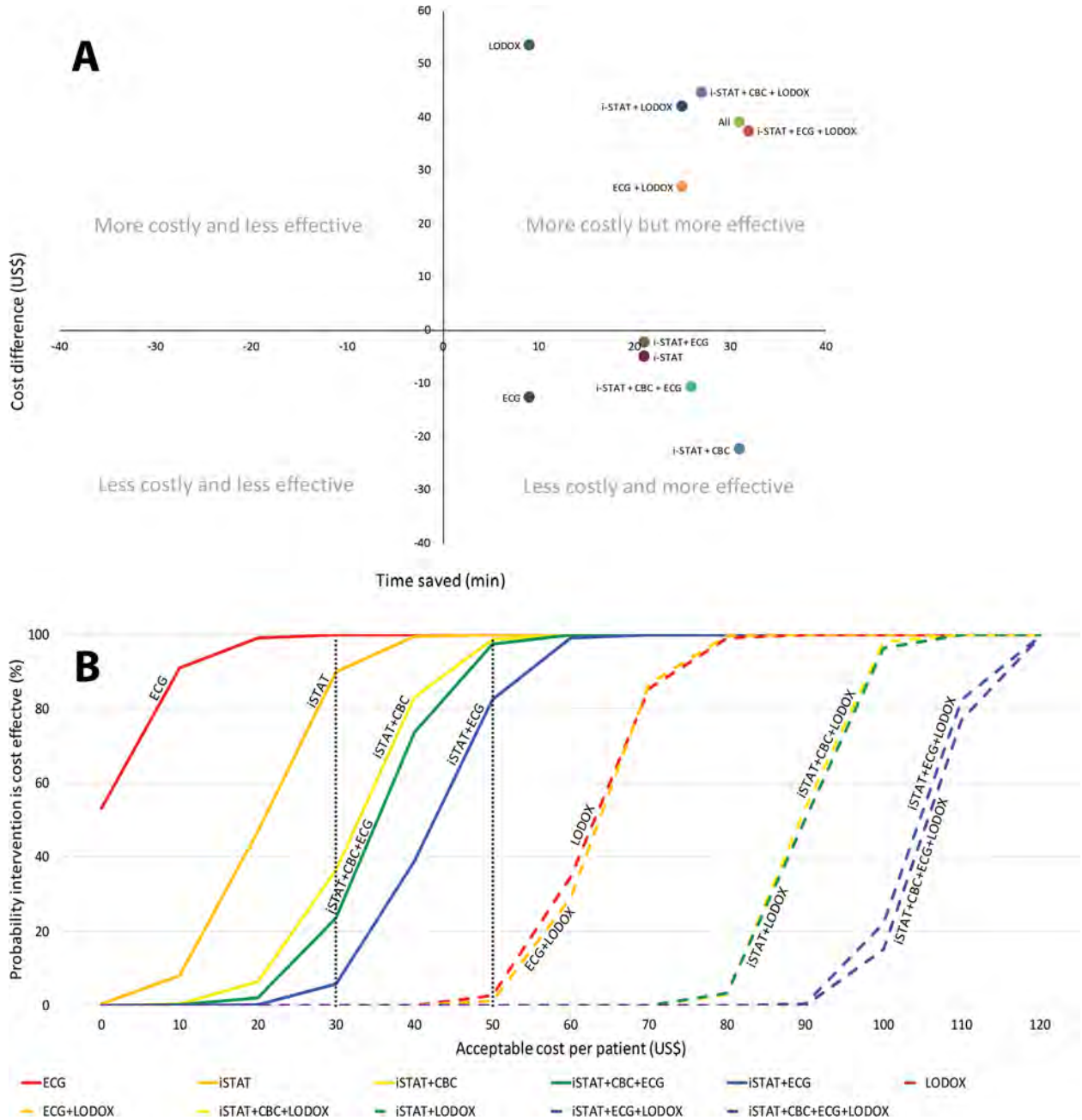


Fig. 2 a Cost Effectiveness Plane. Permutations in the south-east quadrant were less costly and more effective (also referred to as *dominant*) [13]. Permutations in the north-east quadrant were still more effective but were also costlier. **b** Cost-Effectiveness Acceptability Curve. Cost-effectiveness acceptability curves for each of the permutations. The proportion of the bootstrap datapoints achieving cost-effectiveness at each increment of potentially acceptable cost is shown. Permutations which included LODOX® are shown with dashed lines. The dotted lines represent two potential willingness-to-pay thresholds. For example, at US$50, virtually all the non-LODOX® permutations have a high probability of being cost-effective. On the other hand, at a willingness-to-pay threshold of US$30, only the iSTAT and the ECG permutations have a high probability of being cost-effective. This graph allows the funder to weigh the relative cost of each of the permutations against their known effectiveness. CBC Complete Blood Count, ECG electrocardiogram, i-STAT i-STAT POC tests, LODOX® Low-dose x-ray

cost of the POC CBC compared to the laboratory CBC. Although this comparison of total costs appeared promising, it was necessary to look at the cost-effectiveness of the individual permutations.

When evaluating the cost:benefit ratio for POC testing, it is essential to include the disbursements on staffing. The time a doctor spends with the patient has a cost – if this time can be decreased with POC testing then the

cost of the doctor needs to be included in the cost-effectiveness evaluation [2, 5, 8]. When personnel costs and time-saving were both considered, the net additional savings increased further, with the true benefit of certain test combinations being highlighted.

In Fig. 2, it can be seen that all LODOX®-containing permutations fell into the north-east "more costly but more effective" quadrant. X-ray and LODOX® costs formed the bulk of the expenses related to the diagnostic testing combinations making all the LODOX®-containing options more costly. LODOX® therefore added substantially to the cost, without much additional time-saving. Also, only 58.7% of the control group had an x-ray performed while 100% of the participants in the respective LODOX® permutations received an x-ray. This lead to an overall additional comparative cost per patient compared to the control group despite LODOX® being more inexpensive than a standard x-ray. The addition of a LODOX® in a protocolised fashion may need to be re-evaluated and may perhaps be more valuable if introduced only after an admission decision is made. Indiscriminate use of LODOX® on all patients irrespective of whether they require hospital admission would lead to over-testing and unnecessary radiation exposure even if it is relatively low-dose radiation. Some patients also received a formal x-ray in addition to their LODOX® which increased costs and so was a confounder for the LODOX®-containing groups overall.

While the ECG only group was cost-effective because of a direct saving of US$5.90 per patient, the lack of significant time-saving makes it ineffectual to assist with ED throughput.

The most cost-effective combination, which ultimately would save money based on the time-saving, was the i-STAT + CBC permutation. It was second in time-saving to i-STAT + ECG + LODOX® by one minute and equivalent in saving time to the combination where the patients had all the tests performed. The latter two permutations would require additional spending in order for them to be implemented. With one-third of patients having laboratory testing in general in the ED, the i-STAT + CBC option would fulfil the dual purpose of demand and cost-effectiveness [15, 16].

The impact of staffing costs

Staffing costs play a significant role in the calculation of cost effectiveness. In a Swedish ED, Schilling showed a significantly higher cost saving than in our study. This was largely due to their higher cost of staffing (US$24.08/min versus our US$5.37/min) [5]. A higher staffing cost would mean that time saved using POC testing is ultimately even more economical. The time-saving could potentially also be used to offset staffing costs. There may be an opportunity to reduce staffing levels based on reduced treatment times offered by the POC tests. Optimisation of patient processing means that the costs of staffing need to be taken into consideration [5].

Value for money – cost-effectiveness acceptability

Permutations in the north-east quadrant of the cost-effectiveness plane were more effective than the control but were also costlier. The determination of whether an intervention offers "good" value for money depends on the funder's willingness to pay (λ) [17]. The range of potential amounts that the funder may be considering are displayed on the x-axis of the cost-effectiveness acceptability curve and can be judged according to the relative probability that an intervention will be cost-effective shown on the y-axis. Figure 2B demonstrates this concept with the majority of the permutations still most likely to be cost-effective at a willingness to pay threshold of US$50, except for those permutations containing LODOX®.

Non-LODOX® permutations were virtually 100% cost-effective if an additional cost of US$50 per patient was considered acceptable by funders.

This model has been used in previous studies on healthcare cost-effectiveness [13, 14, 17]. It is tool that allows decision-makers to balance up costs against non-quantifiable benefits. For example, a reduced waiting time might not have any direct cost implications, but will increase patient satisfaction. A funder might be willing to pay a small additional amount for this but not a large amount. This tool therefore allows the potential funder to better balance the benefits and costs. It also allows the funder to balance quantifiable costs e.g. the decision whether to close a diagnostic laboratory at night in favour of utilising POC tests.

Waiting times and special investigation use in the ED

Waiting for the results of special investigation such as blood tests, ECGs and radiographs commonly takes two-thirds of a patient's entire ED length of stay [15]. A substantial amount of time could potentially be saved if these test results were available prior to the doctor's initial evaluation of the patient. In this study, waiting for results of the intervention POC tests was concurrent with the patients' wait to be seen by a doctor (minimum waiting time 57 min). This meant that the time taken to perform the POC tests (maximum 23 min) did not cause any significant delays for the patients as it took place during non-valued added time when the patients were waiting to see the doctor.

In Yoon's analysis of factors increasing length of stay in the ED in Canada, 38.4% of patients had laboratory tests and 44% underwent some form of X-ray imaging.

These interventions were associated with longer lengths of stay [15]. In the USA, Gardner et al. found that 33% of patients had laboratory investigations (increasing length of stay by 35.4 to 40.1 min) and 36% had x-rays (increased by 5 to 15 min) [18]. Thirty per cent of discharged patients in a Finnish study by Kankaanpää et al. needed laboratory testing [19]. The laboratory usage in our control group of 30% (excluding patients who had blood gas analyses alone) is similar to the utilisation in these other EDs. The x-ray utilisation rate was higher, however. This may have been due to the higher admission rate at our hospital of 42.7% (versus 11% in the Gardner study) as all patients admitted to the internal medicine service receive an x-ray.

All patients in an i-STAT-containing subgroup in our study showed a decreased treatment time. Although the performance of a LODOX® scan took only on average four and a half minutes, time-saving was only achieved when it was combined with other POC tests. This was similar to the time-saving gained by the performance of an upfront ECG. Gardner et al. found that ECGs only saved time (2.7 min) in those patients who were admitted but added time in patients who were ultimately discharged [18]. In our study, there was no difference in the number of tests performed regardless of disposition decision i.e. whether a patient was ultimately admitted to the hospital or discharged.

Standing orders versus upfront POC testing and "over-testing"

In the ED, standing orders have been shown to improve patient throughput by reducing disposition time by up to 16.9% [20]. However, these orders are usually only actioned if the ED is full; have had variable uptake by the nursing staff resulting in both over- and under-testing and have not made use of POC devices [16, 20]. Over-testing is frequently quoted as a danger when standing orders are in place or when POC testing is made easily available. There is, however, no evidence to support this [16, 21–23]. In Retezar's study evaluating triage standing orders, those patients who received the full gamut of tests had a 16% reduction in their mean treatment times. The hypothesis that upfront, protocolised testing leads to over-testing is nullified by her study findings where 98 % of the patients who did not receive the standing orders went on to receive similar investigations once they were seen by a doctor [24]. The cost of POC usage would therefore be unlikely to be exaggerated compared to standard diagnostic test utilisation. In our study, over-testing was possible in the patients who were ultimately admitted to the internal medicine service. Blood tests are commonly performed as a courtesy for those patients even if the results do not impact on the ED disposition decision. These were extra standard blood tests and not POC tests.

Other potential cost implications

Besides these direct costs, there is also the potential for further cost-saving that may be possible by reducing admission rates. In Fitzgerald et al's RATPAC trial, which focussed on patients with chest pain in suspected myocardial infarction, POC testing was associated with higher ED costs but lower general inpatient costs [7].

Other non-fiscal "cost savings" should also be evaluated in future POC cost-effectiveness analyses. Although we did not collect data on the patient experience, we acknowledge that their input would have been useful as part of the overall impact of the intervention. The very low refusal rate may have suggested that patients favoured this system, but no direct data were collected.

The doctors' perceptions of the effectiveness and appropriateness of the upfront POC testing were evaluated as part of this study. They were strongly supportive of the intervention [25].

Further possible positive effects which need to be quantified include the beneficial knock-on effects of decreases in patient complaints due to excess waiting times, increases in staff satisfaction, and the potential for fewer patients leaving the ED without being seen. This will require future investigation.

Patient sub-groups that could benefit from upfront POC testing

Although the symptom groups originally included in the study characterised typical categories of undifferentiated patients that present to the ED, interim analysis highlighted that the "psychiatric group" was already functioning optimally based on their high acuity triage scores as well as the limited special investigations that they required for safe patient disposition. The use of upfront POC testing in this group of patients would therefore have no time- or cost benefit. Upfront testing appeared to be most appropriate for the undifferentiated medical patient and the ultimate cost-effectiveness in any ED would depend on the case mix presenting to that ED.

Hospital admission rates and patient acuity

There was no difference between the patients who were admitted to the hospital (sicker patients) compared to those who were discharged from the ED (less ill patients). Both groups of patients benefited from the upfront testing. The overall percentage of patients admitted from the ED was higher than the usual admission rate of the ED of 30–35% (Table 3). These higher admission rates are likely related to the fact that only medical patients were included who, in general, are

more ill than the non-medical patient population. They are also the patient group that would potentially benefit most from upfront POC testing. Therefore, it is unlikely that the high level of significant illness was an important source of bias in this study. There was a range of triage categories within each group (not significantly different) that further suggests that this was not an important bias. Furthermore, upfront POC testing is not suggested to be used in *all* patients presenting to the ED. Clearly some patients would not benefit (e.g. *minor* orthopaedic injuries), but it would be best applied to patients with undifferentiated medical presentations. This does mean, however, that EDs that see very few sick patients would benefit less from upfront POC testing.

Limitations

This single-centre study evaluated the impact of POC on the treatment time but there was no data collected nor assessment of the effect on patient outcome and potential adverse effects of universal testing. However, in previous POC studies, there has been no evidence to support the theory of over-testing [16, 21–23]. The patient medical complaints were heterogeneous. Whilst they were common symptoms in our ED, they may not be representative of other EDs. This was notable with regards to the low incidence of acute coronary syndrome-related chest pain. POC troponin was originally included as one of the i-STAT tests used in our study. Although troponin has been shown to be useful for patients with chest pain or suspected acute coronary syndrome in the ED as well as the presence of raised troponin levels having an association with worse short-term clinical outcomes, we ultimately excluded it for the cost-effectiveness analysis as there would be no benefit for our ED population and would have resulted in over-testing [26, 27]. Similarly, the indiscriminate use of D-dimer testing in this heterogenous population without employing pre-test probability scoring could potentially have been harmful and could also have resulted in over-testing. Therefore D-dimer testing was not included in the upfront testing. As the ED doctors were not blinded to which patients received the upfront POC tests, a Hawthorne-type effect was considered, but there was no evidence to support it. However, as the doctors themselves were recording all the times (and not an impartial observer), this could have been a potential source of error. Due to the funding of allied hospital staff being managed separately, staffing costs were calculated using doctor and nursing costs only. The costs related to x-rays and LODOX® were based on the standard prices charged per patient per investigation as opposed to calculations based on the equipment amortisation costs. The different setup costs of a laboratory and of a POC system were also not taken into account. The performance of "admission tests" for the internal medicine service may have also confounded the diagnostic test utilisation. This may have lead to duplication of tests if the patient was admitted.

Conclusion

POC testing in the ED was more cost-effective, in certain combinations, than standard diagnostic tests when utilised upfront for patients with undifferentiated common medical complaints in non-resuscitation triage categories. The most economical POC test combination was i-STAT + CBC, which not only saved time, but, also saved the most money per patient. Besides these direct costs, there is also the potential for further cost-saving that may be possible by reducing hospital admission rates as well as the other non-fiscal "cost savings". These should be evaluated in future POC cost-effectiveness analyses.

Abbreviations

ANOVA: Analysis of Variance; CBC: Complete Blood Count; CG4+: i-STAT test which includes Lactate; pH; partial pressure carbon dioxide (PCO_2); partial pressure of oxygen (PO_2); total carbon dioxide; bicarbonate; base excess and oxygen saturation; CHEM8+: i-STAT test which includes sodium, potassium, chloride, total carbon dioxide, ionised calcium, glucose, urea, creatinine, haematocrit, haemoglobin and anion gap; ECG: Electrocardiogram; ED: Emergency Department; ICER: incremental cost effectiveness ratio; IQR: inter-quartile range; i-STAT: i-STAT system point-of-care tests; λ: funder willingness-to-pay; LODOX®: Low-dose x-ray; POC: Point-of-Care; pp: per patient

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Authors' contributions

LG conceptualized the study, designed the trial and obtained research funding. CVL assisted with research funding and University approval. LG supervised the conduct of the trial and data collection. LG and MW were involved in the statistical analysis and interpretation of data. LG drafted the initial version of the manuscript. All authors revised, edited and contributed substantially to the critical revision of the manuscript. Final approval of the version to be published is made by all authors who agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. LG takes responsibility for the paper as a whole.

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Availability of data and materials

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate

Permission to conduct the study was granted by the Research Ethics Committee of the Faculty of Health Sciences of the University of Johannesburg (REC-01-185-2016); the Human Research Ethics Committee of the University of the Witwatersrand (M171086); South African National Health

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Consent for publication
Not applicable.

Competing interests
The authors declare that they have no competing interests.

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CHAPTER 6
THE COST OF TIME: A RANDOMISED, CONTROLLED TRIAL TO ASSESS THE ECONOMIC IMPACT OF UPFRONT, POINT-OF-CARE BLOOD TESTS IN THE EMERGENCY CENTRE

Goldstein LN, Wells M, Vincent-Lambert C. The cost of time: A randomised, controlled trial to assess the economic impact of upfront, point-of-care blood tests in the Emergency Centre. Afr J Emerg Med. 2019;9(2):57-63.

6.1 Background

The WHO has acknowledged that diagnostic tests play a pivotal role in improving the health of people worldwide [1]. Pathology and Laboratory Medicine (PaLM) is one of the keys to strengthening a healthcare system and enabling the provision of universal health coverage [2]. The desperate need for PaLM in LMICs, in particular, was highlighted in *The Lancet* series of publications in 2018 on this topic [3-5]. Commissions have been created to evaluate the evidence and establish the most clinical- and cost-effective approaches to diagnostic testing. Forty percent of countries in Africa either already have a plan to incorporate diagnostic testing into their system or are working on instituting one [1, 2].

Although PaLM refers to Pathology *and* Laboratory Medicine, the diagnostic test focus of the abovementioned commissions is on pathology testing – specifically their role in the diagnosis and management of communicable diseases such as HIV, tuberculosis and malaria [1-6]. POC pathology testing, in this arena, is seen as having a substantial role in LMIC [5]. It is acknowledged that a proviso to the institution of POC testing in LMIC is ensuring that economic analyses are done in order to determine when the use of these tests would be most affordable, cost-effective and therefore an appropriate addition in a resource-limited setting [4].

Considering the detrimental effects that communicable diseases play in LMIC (twenty-one percent of deaths in LMIC compared to 2% of deaths in high-income countries), it is an unsurprising target for healthcare improvement [3]. However, focus is now shifting and expanding to include non-communicable diseases particularly cardiovascular disease, cancer and diabetes which are leading causes of global disease burden and mortality [3]. Yet, one must not forget that laboratory testing forms a common and significant part of the management of ill and injured patients that present to the ED on a daily basis [7]. Therefore, ways to assist in the delivery of timely and affordable emergency care utilising POC blood tests in LMIC should also be sought.

6.2 Purpose of the Study

With access to traditional diagnostic services such as PaLM and radiology being beyond the reach of many patients in LMIC, alternative options need to be pursued for accurate diagnosis and treatment [6]. Could the concept of *upfront* POC blood testing alone be an economically viable option for EDs in LMICs?

This study was a secondary analysis of the data from the original randomised controlled trial. However, only the *upfront* POC blood test groups were evaluated – the additional x-rays and ECGs were not included in the analysis, as might be fitting in a resource-limited setting.

The objective of this study was to assess the cost-effectiveness of implementing *upfront* POC blood tests only (i-STAT alone or i-STAT + CBC) in the ED. The data in Chapter 5 showed that various combinations of the POC tests evaluated could potentially be cost-effective with the i-STAT + CBC permutation showing the most promise. What would happen if the additional x-rays and ECGs were excluded? Could the POC blood test cost-effectiveness be extrapolated to the LMIC ED?

6.3 Major Findings of the Study

- Both POC blood test groups reduced patient treatment time by more than the *a priori* defined minimum clinically significant outcome measure of 20%. The i-STAT alone, however, did not show statistically significant timesaving compared to the control group.

- The additional costs calculated in the i-STAT only group were related to the extra blood tests that were ordered from the laboratory over-and-above the i-STAT tests that the patients already had had. This resulted in less time saved compared to the control patients (due to waiting for laboratory test results) as well as increased costs incurred in this group.

- The large timesaving in the i-STAT + CBC group together with the added cost-saving on staff, translated its implementation into overall cost savings despite the face-value additional cost of those POC tests of US$7.48 per patient.

- Similar to the overall economic analysis presented in Chapter 5, the i-STAT + CBC group was both timesaving and cost effective. If implemented, this would likely end up saving US$14.96 per patient. This is depicted in the summary shown in Figure 6.1.

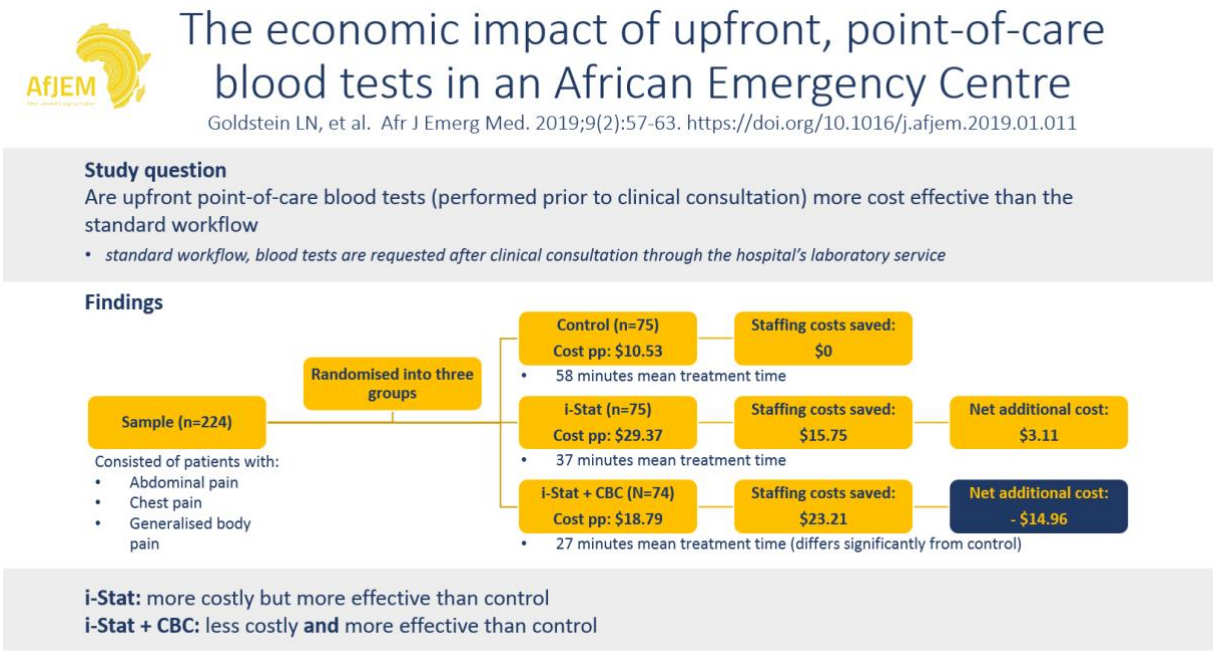


Figure 6.1 Summary of the findings of this study [8]

6.4 This Study in the Context of the Thesis

This study confirmed that *upfront* POC blood tests alone could be cost-effective to implement in a LMIC ED. While both interventions saved time, the potential money-saving from the implementation of the i-STAT + CBC permutation was more notable. This may have been due to the combination of blood tests being more complete than

just having the results of the i-STAT alone. The CBC provides information regarding the patient's haemoglobin, platelets and white cell count with a differential count. This addition can assist in the evaluation of the patient with a potential infective cause for their presentation as the i-STAT alone only provides a haemoglobin and calculated haematocrit result. This would be useful in LMIC with the high incidence of communicable diseases.

This study did not address the process of change management that would be required when implementing a new manner of coordinating patient throughput in the ED. If key stakeholders, such as the doctors working in the ED, do not support the change then there is a risk of not achieving the objectives of the implementation of *upfront* POC testing [9]. Chapter 7 addresses this concept by evaluating the doctors' perceptions of *upfront* POC testing in the ED.

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ORIGINAL ARTICLE

The cost of time: A randomised, controlled trial to assess the economic impact of upfront, point-of-care blood tests in the Emergency Centre

Lara Nicole Goldstein[a,b,*], Mike Wells[b], Craig Vincent-Lambert[b]

[a] Division of Emergency Medicine, Faculty of Health Sciences, University of the Witwatersrand, 7 York Rd, Parktown, Johannesburg 2193, South Africa
[b] Department of Emergency Medical Care, Faculty of Health Sciences, University of Johannesburg, 55 Beit St, Doornfontein, Johannesburg 2028, South Africa

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ABSTRACT

Introduction: Time and cost constraints abound in the Emergency Centre (EC). These resource-constraints are further magnified in low- and middle-income countries (LMIC). Almost half of all patients presenting to the EC require laboratory tests. Unfortunately, access to laboratory services in LMIC is commonly inadequate. Point-of-Care (POC) tests may assist to avert this shortcoming. The aims of this study were to evaluate the cost effectiveness of upfront POC blood tests performed prior to doctor assessment compared to the standard EC workflow.
Methods: A secondary analysis was performed on data from a prospective, randomised, controlled trial where patients with abdominal/chest symptoms or generalised body pain/weakness followed either the normal EC workflow pathway or one of two enhanced workflow pathways with POC tests (i-STAT with and without a complete blood count (CBC)) prior to doctor evaluation. The incremental cost effectiveness ratio (ICER) was used to perform the cost effectiveness analysis.
Results: There were 248 patients enrolled in the study. The use of the two upfront, POC test pathways significantly exceeded the primary outcome measure of a 20% reduction in treatment time. In the i-STAT + CBC group, the 31 min. time-saving translated into cost-saving of US$14.96 per patient (IECR 0.27) whereas the 21 min. time-saving in the i-STAT only group only had an additional net cost of US$3.11 per patient (IECR 0.90).
Conclusion: Upfront, POC blood tests can be utilised in the resource-constrained EC to manage patients more efficiently by saving time. This time-saving can, in fact, be more cost effective than traditional EC workflow making it an economically viable option for implementation in LMIC.

African Relevance

- Access to laboratory services in LMIC is commonly inadequate
- Point-of-Care (POC) blood tests may be a possible solution
- Upfront, POC tests are time-saving and can be cost-effective

Introduction

Time is a valuable commodity in the Emergency Centre (EC). From the institution of time-critical interventions to targets applied to the time a doctor can spend with patients – The staff in the EC are constantly competing against the clock.

Almost half of all patients presenting to the EC require laboratory tests [1,2]. Unfortunately, access to laboratory services in low- and middle-income countries (LMIC) is commonly insufficient [3]. Point-of-Care (POC) testing (near-patient or bedside diagnostic testing that occurs outside the laboratory) is a potential solution to this problem but it has shown both positive and negative results with regards to time- and cost-saving when instituted in ECs worldwide [4–10]. There are various POC blood test options available which have been shown to have equivalent accuracy to formal laboratory testing [10,11]. The convenience and time-saving associated with these bedside tests usually comes at a cost, however, as POC tests are commonly more expensive than traditional laboratory tests [8,9,12].

Traditionally, in the EC, blood tests are performed after a doctor has assessed the patient. The use of protocolised testing prior to doctor review has been evaluated previously in the form of standing orders. These standing orders, however, have not utilised POC devices or have only been instituted when the EC is full. There has also been inconsistent uptake by staff with resultant inappropriate testing [13,14]. Significant time-saving has recently been shown with upfront, POC testing performed prior to the patient being assessed by the doctor in

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* Corresponding author.
E-mail address: drg666@gmail.com (L.N. Goldstein).

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the EC [15].

The aim of this study was to evaluate the cost-effectiveness of upfront POC blood tests performed prior to doctor assessment compared to the standard EC workflow.

Methods

A secondary analysis was performed on data from an investigator-initiated, prospective, randomised, controlled trial that evaluated the cost-effectiveness of upfront, POC tests in the EC. It took place in a tertiary, academic hospital EC in Johannesburg, South Africa. The EC has an annual census of approximately 65 000 patients, the majority of whom (70%) have non-traumatic pathologies.

Although the original randomised, controlled trial evaluated multiple POC tests, this secondary analysis will focus on the cost implications when only POC blood testing is utilised. In LMIC ECs, blood tests would be the easiest POC test to implement and the one with the least capital outlay (versus purchasing ECG machines or a LODOX® (LOw DOse X-ray) machine).

The Research Ethics Committee of the Faculty of Health Sciences of the University of Johannesburg (REC-01-185-2016); the Human Research Ethics Committee of the University of the Witwatersrand (M171086) and the South African National Health Research Ethics Council (DOH-27-0117-5628) all granted permission to conduct the study. Registration as a clinical trial was through with the South African National Health Research Database (GP_2017RP57_655) and with clinicaltrials.gov (NCT03102216). All patients provided written informed consent.

A convenience sample of adult, non-pregnant patients, older than 18 years of age, who presented to EC during weekdays qualified for inclusion. Patients requiring immediate resuscitation were not included.

Patients with “abdominal complaints”, “chest complaints”, “generalised body pain/weakness” and “psychiatric complaints” were approached for participation. “Abdominal complaints” included abdominal pain and/or nausea and vomiting. “Chest complaints” included dyspnoea, chest pain, syncope and/or cough. “Psychiatric complaints” included patients with hallucinations, aggression, psychosis or who had taken an overdose.

Each patient was randomised into a workflow pathway as detailed in Fig. 1. Prior to the commencement of the study, block randomisation of the three workflow pathways (viz. Control, i-STAT and i-STAT + CBC) took place using an online randomisation tool (www.randomizer.org). Three cardboard boxes (one for each symptom group) each had blocks of data collection sheets placed upside-down in them in the order generated by the randomiser. After consent and enrolment, the research doctor/research assistant took the next available data collection sheet from the appropriate symptom box.

In the control group, a doctor would see the patient after the triage process. The doctor then ordered diagnostic tests that they considered to be clinically indicated. The requested blood tests were performed in the hospital laboratory that was on-site. This was done according to standard procedures. If the doctor required a blood gas analysis to be performed on the patient, s/he would perform the procedure and process the specimen on one of two blood gas analysers that were present in the EC (Cobas B 221 POC system, Roche Diagnostics or ABL800 Flex, Radiometer). The doctor would then need to wait to review the patient a second time once the test results were available after which a patient disposition decision was made.

In the two enhanced workflow groups, the patient had the POC blood tests immediately after triage and was then seen by a doctor. If the doctor deemed extra investigations necessary in addition to the POC tests, then those tests were performed as per the standard procedures. The POC enhanced workflow patients would then also be reviewed a second time (like the control group) once the results of the additional tests were ready.

The time taken for patient throughput in the EC consists of both administrative and treatment times [16]. The administrative time is the time from patient arrival to the time of doctor evaluation. In our hospital, it is the time where the patient is registered in the hospital computer system and a file is opened. This process is a prerequisite for all patients. The time taken for patient registration can, however, vary from day-to-day and hour-to-hour. In order to avoid the potential confounding effect this would have on an intervention, only the treatment time was used as the comparator. Treatment time is the time taken from doctor evaluation until the time the decision for the patient’s disposition has been made. Decision disposition time was chosen rather than the time the patient physically departed the EC due to extrinsic factors such as exit block confounding the impact. The original study focused on the time-saving aspect of the POC interventions [15].

The POC tests that were evaluated are shown in Table 1.

The POC blood tests were performed in the EC within a private cubicle. Standard EC procedure was followed for all other diagnostic testing. The time data obtained from the original study was utilised [15]. The costs of the diagnostic tests incurred in the control group were compared to the i-STAT and i-STAT + CBC groups.

The on-site hospital laboratory provided the prices for the control pathway investigations. The i-STAT and CBC costs were obtained from their actual EC usage prices. All test costs were considered to be inclusive of capital and maintenance costs of equipment.

Staffing cost calculations were performed as suggested by Schilling [8]. They were calculated using doctor and nursing costs only with staffing considered to be distributed evenly during the year: Staffing cost per minute (US$/minute) = Total EC staffing cost/Total minutes per annum

The mean time between two patient arrivals was calculated under the assumption of a statistically constant flow to the EC based on 65 000 annual visits (8.09 minutes between new patient arrivals). The average length of stay was calculated using the time for the control population. The average number of patients in the ED requiring attention was the average length of stay divided by the mean time between two new patient arrivals. The staffing cost per patient minute was then based on this time.

The cost-effectiveness of upfront, POC tests was the main outcome measure of this study. The incremental cost effectiveness ratio (ICER) expressed as: ICER = (C1 − C2)/(E1 − E2), was used to perform the cost effectiveness analysis. In this formula, C1 and E1 are the cost and effect (treatment time) of the intervention group and C2 and E2 are the cost and effect of the control group [9].

The statistical analysis of the time component of the study can be found in detail in the supplementary appendix. Data analysis was carried out using SAS (version 9.4 for Windows). The 5% significance level was used throughout.

Results

Enrolment of 248 patients took place between 13 February and 29 June 2017. An interim analysis during data collection in the primary study showed that the outcomes for the “psychiatric complaints” group were very different from the other three symptom groups. Based on their triage scores, the psychiatric patients were seen almost immediately in most cases and commonly only needed a blood gas analysis to be performed. It was therefore a group that was already “functioning at optimum” from an EC throughput perspective and the extra testing was not required. Their inclusion would have skewed the data unnecessarily. Fig. 1 summarises the three symptom groups’ patient distribution. A comparison of patient characteristics is in Table 2.

Fig. 2 shows the mean treatment times across the three workflow permutations when all the symptom groups are combined. The treatment time was significantly shorter compared to the control workflow if the patient received an i-STAT + CBC ($p = 0.0001$).

The primary outcome in the time study (a 20% reduction in

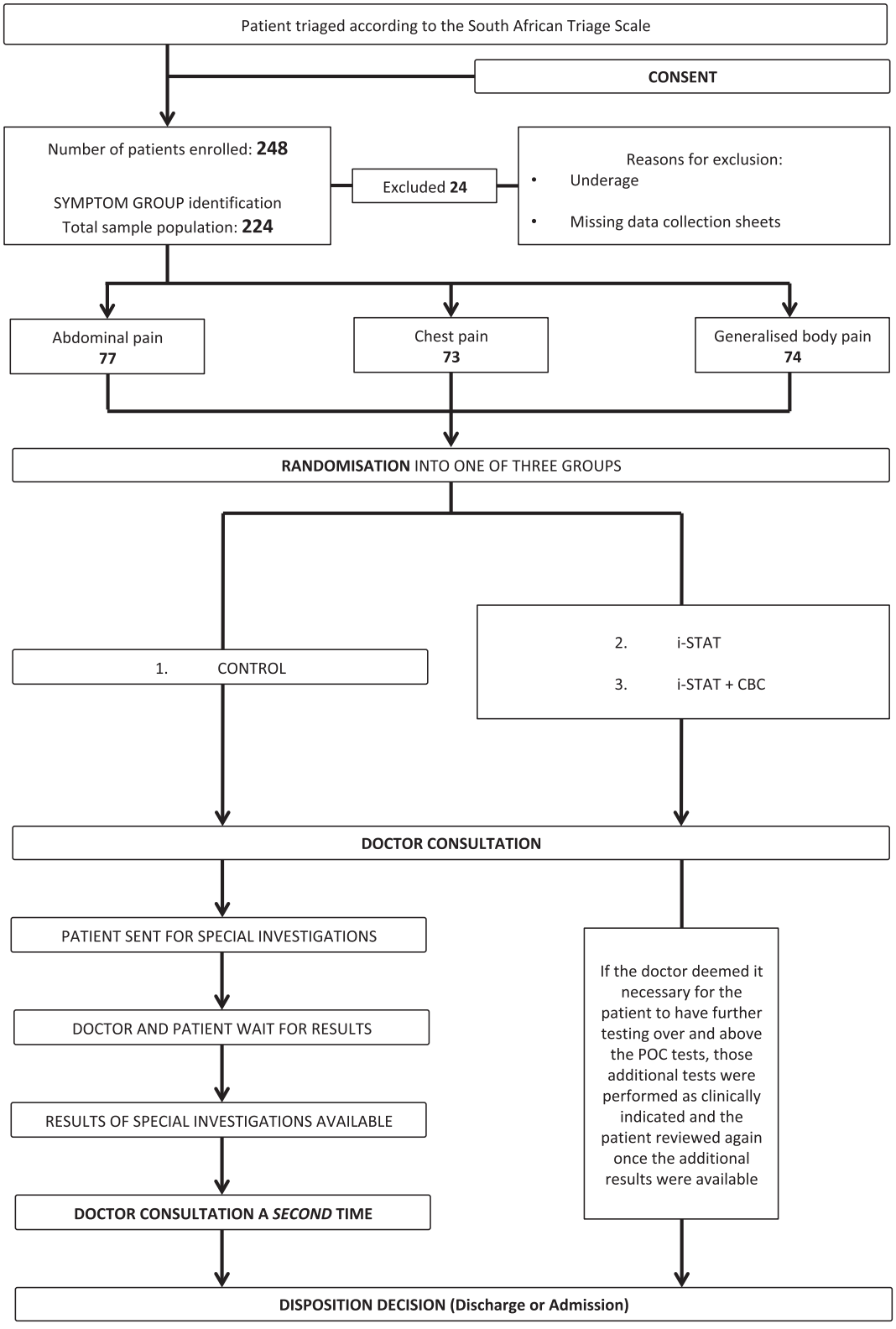


Fig. 1. Flow chart showing randomisation and data collection procedure.

treatment time indicated by the horizontal red line) was significantly exceeded in both POC intervention groups.

It took between 9 and 12 min. to obtain the results of the POC tests. This included the time taken for phlebotomy as well as specimen processing and results printing. The tests could generally be performed

The individual investigation costs are tabulated in Table 1. If all the tests were performed in any patient, the POC equivalent tests would cost US$7.48 more per patient.

The average treatment time for the control patients was 58 mins. Based on this value, there would have been 7.2 patients in the EC at any given time (this excludes patients waiting for disposition).

One minute of EC staffing cost US$5.37, which is equivalent to US

Table 1
POC blood tests employed and the costs of the control pathway blood tests and their POC equivalents.

Abbott Point-of-Care i-STAT® System			
The i-STAT System (i-STAT, Abbott Point of Care, Princeton, NJ, USA) consists of single-use i-STAT test cartridges placed into a handheld POC blood analyser. The CHEM8 + (sodium, potassium, chloride, total carbon dioxide, ionised calcium, glucose, urea, creatinine, haematocrit, haemoglobin and anion gap) and CG4 + (Lactate; pH; partial pressure carbon dioxide (PCO_2); partial pressure of oxygen (PO_2); total carbon dioxide; bicarbonate; base excess and oxygen saturation) i-STAT cartridges were utilised. Venous blood specimens were phlebotomised			
Abbott CEL-DYN Emerald 22 benchtop haematology system			
A POC Complete/Full Blood Count (which included a differential white blood cell count) was provided by the CEL-DYN Emerald 22 benchtop haematology system			
Lab blood tests	Cost	Point-of-Care equivalent	Cost
Complete Blood Count	4.57	CBC (CEL-DYN Emerald 22)	2.33
Electrolytes, Urea, Creatinine	13.62	Chem8 (i-STAT)	16.15
Blood Gas Analysis	4.27	CG4 + (i-STAT)	11.46
TOTAL	$ 22.46	TOTAL	$ 29.94

$, Costs shown in US dollars; CBC, Complete Blood Count; i-STAT, i-STAT POC test

Table 2
Patient characteristics.

Sample variables	CONTROL	i-STAT	i-STAT CBC	p-value for between group test
Age median (IQR)	50.6 (39.4; 66.9)	48.1 (34.8; 61.2)	49.5 (36.1; 68.4)	0.74
Sex: Males (%)	30 (40.0)	30 (40.0)	29 (39.2)	0.96
Triage category N (%)				
Orange*	22 (29.3)	18 (24.0)	11 (14.9)	0.43
Yellow*	52 (69.3)	54 (72.0)	60 (81.1)	0.43
Green*	1 (1.3)	3 (4.0)	3 (4.1)	0.43
Admitted§ N (%)	32 (42.7)	32 (42.7)	40 (54.1)	0.46
Discharged§ N (%)	38 (50.7)	41 (54.7)	33 (44.6)	

§, 8.2% of all patients were neither admitted nor discharged but rather referred to another speciality to be seen in the EC; *, Target times for the patients in each triage acuity category according to the South African Triage Scale: Orange – to be seen within 10 minutes of EC arrival, Yellow – to be seen within 1 hour of EC arrival, Green – to be seen within 4 h of EC arrival

$0.75 per patient per minute. The control and intervention time-saving and costs are presented in Table 3.

The cost effectiveness analysis is graphically presented in a Cost Effectiveness Plane in Fig. 3.

Discussion

Saving time is a common goal in emergency medicine and LMIC resource-constrained ECs are no different. Sometimes we can be surprised when things that we think will come at a higher cost actually end up being cost-effective. While upfront POC testing has been shown to improve treatment times, it was essential to assess whether it could be an economically viable model for use in limited-resource settings [15].

No significant differences existed between the patients in the control or POC intervention groups. This was irrespective of age, sex, triage category and disposition decision.

Both the i-STAT only and i-STAT + CBC groups demonstrated clinically significant time-saving across the three symptom groups [15]. The use of i-STAT alone, however, did not reach statistically significant time-saving compared to the control group. This may be accounted for by the heterogeneity of and within the symptom groups included in this study e.g. “chest symptoms” versus “abdominal symptoms” versus “generalised body pain and weakness” and “chest symptoms” ranging from cough to syncope. The time-saving from the institution of POC tests for isolated “chest pain” and isolated “abdominal pain” has previously been demonstrated [17,18].

The utilisation of blood tests in order to make a disposition decision is commonplace in the EC [1,2]. It is, however, also a “rate-limiting step for many patients” [10,19]. In Yoon’s study, blood testing added 126 minutes to the patient’s length of stay [1]. EC patient length of stay was increased by 35.4–40.1 mins if they received any blood test in Gardner’s evaluation of factors influencing patient EC length of stay [20]. In our study, all patients in the intervention POC groups had a decrease in their treatment time.

The ability to perform the intervention POC tests concurrently and the quick result turnaround time meant that the time taken to perform them did not cause any significant delays for the patient to be assessed by the doctor. Waiting for results was concurrent with the wait to be seen.

Waiting for the results of special investigations including blood tests comprises two-thirds of a patient’s entire EC length of stay [1]. By performing the POC tests during the time that would normally be spent waiting to see the doctor, a considerable amount of time could be saved in the patient’s overall time in the EC.

Frequently quoted barriers to the adoption of POC testing in the EC

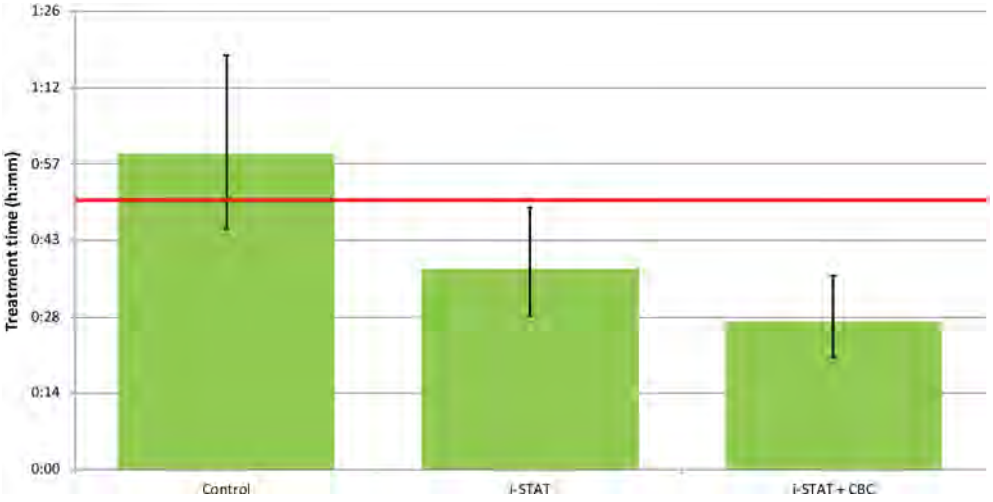


Fig. 2. Mean treatment times for the control and POC workflow permutations (combined symptom groups).

Table 3
Costs and time-saving analysis.

Variable	Total Cost (US$ pp)	Difference between costs of POC tests and control (US$ pp)	Time Saved – Difference between control group time and POC group time (min)	Staffing costs saved (US$ pp)	IECR - Incremental Cost Effectiveness Ratio (US$ / min)	Net additional cost per patient in POC group (US$ pp)
Control	10.53	–	–	–	–	–
i-STAT	29.37	18.84	21	15.72	0.90	3.11
i-STAT + CBC	18.79	8.26	31	23.21	0.27	−14.96

CBC, Complete Blood Count; i-STAT, i-STAT POC tests; pp, per patient.

include quality assurance, reliability of results and higher per test costs for POC compared to centralised laboratory testing [10,12]. There are various POC blood test options available which have been shown to have equivalent accuracy to formal laboratory testing [10,11]. Each POC device has their own quality control procedure that should be performed as per manufacturer's guidelines. Ease of availability leading to over-testing is a further barrier commonly cited with regards to POC testing. It has, however, been shown not to be factor when formally evaluated [15,18].

Previous studies have reported variations in the actual costs of implementing POC testing. Some have reported increased costs and others showed an overall reduction in costs [8,9].

A face value comparison of the direct costs of implementation of POC tests in our EC compared to standard laboratory referral meant an additional cost of US$7.48 per patient. This, however, needed to be offset against the time-saving offered from the upfront, POC tests, hence the cost effectiveness analysis.

When the effects of the costs for staffing as well as the time-saving were considered, the result was a net additional cost of only US$3.11 if the patient received an i-STAT and a saving of US$14.96 if the patient received an i-STAT as well as a CBC. The relatively lower cost of the POC CBC compared to the laboratory CBC together with the additional 10 minute time-saving contributed to this overall cost saving.

Schilling's study on the economic impact of POC testing in a Swedish EC showed a significantly higher cost saving compared to our study. This was mainly due to the lower cost of POC tests in their setting as well as their higher cost of staffing (US$24.08/min versus our US $5.37/min) [8].

The RATPAC Trial for chest pain in suspected myocardial infarction in the EC showed that POC was associated with higher EC costs but lower inpatient costs for that group of patients [21]. Our study looked at the economic impact of POC in the EC only – Further cost saving from lowering inpatient admission rates and therefore costs may be further benefit that will need to be studied.

The impact of non-fiscal "cost savings" should perhaps be evaluated in future POC cost-effectiveness analyses. The decrease in patient complaints due to excess waiting times, the increase in staff satisfaction, and the potential for fewer patients leaving the EC without being seen are positive effects which need to be quantified.

Four barriers have been identified in implementing good quality pathology and laboratory medicine in LMIC: insufficient human resources, shortage of education and training, inadequate infrastructure, and insufficient quality, standards, and accreditation [3]. From the emergency medicine perspective, POC tests are simple, quick and relatively affordable (compared to the costs of opening and running a laboratory) option that can be used in the LMIC resource-constrained environment in order to safely and timeously make our disposition decisions. The unit cost per test of POC is larger than that of the laboratory due to the loss of the economy of scale offered by automation [9]. Nonetheless, the rapidity of result availability and time-saving of POC has the potential advantage of overcoming the four barriers faced by LMIC.

This was a single centre study. Patient outcome effects such as morbidity and mortality were not assessed and could be a focus for future POC studies. Even though the EC doctors were not blinded to control versus intervention patients, a Hawthorne-type effect was not evident. Time recording could have been a hypothetical source of error as the doctors themselves documented these. The use of synchronised clocks throughout the EC would have helped to ameliorate this but does not negate the human factor. Staffing costs were calculated using doctor and nursing costs only due to the funding of allied hospital staff being managed separately. There was no analysis performed for over-testing, however, previous studies have shown that this is not likely. As patient enrolment only took place during weekdays and not on weekends or at night, the possibility of selection bias exists. Patient inflow at night is usually less than during the day which would make it a confounder for

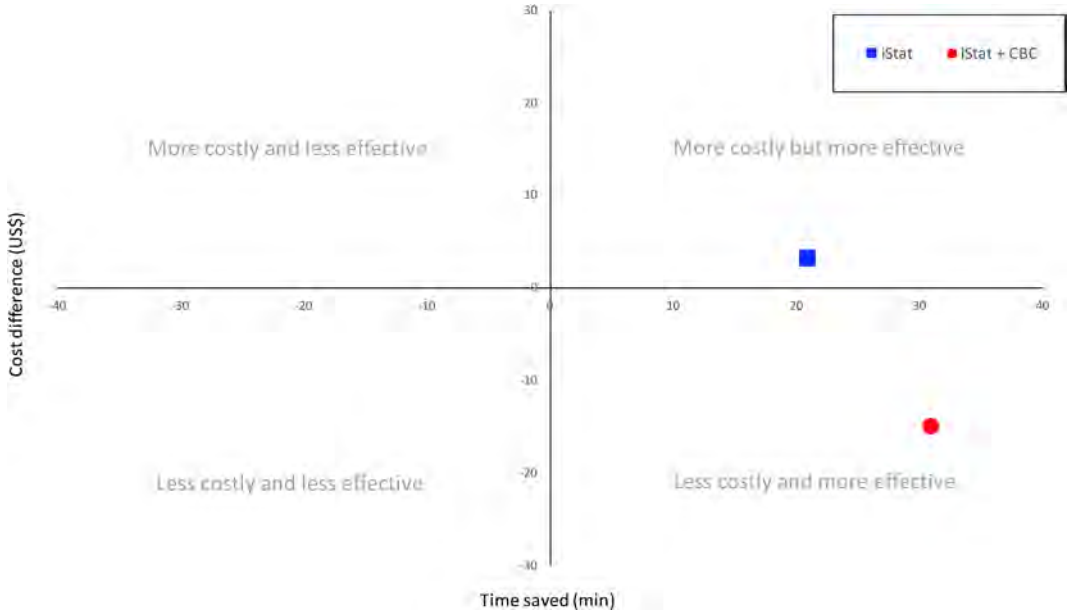


Fig. 3. Cost effectiveness plane.

comparison purposes. Weekend EC attendance also varies substantially depending on the time of month. At times, the EC is even busier than on weekdays, which may have shown the POC interventions to be even more beneficial. Inclusion of weekends would therefore have potentially confounded the results.

Conclusion

The institution of upfront, POC tests in the EC for patients presenting with chest, abdominal or generalised body pain complaints can save time. The utility of these tests mean we can manage patients more efficiently as well as being cost-effective even in a LMIC resource-constrained environment.

Funding support

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Dissemination of results

Dissemination will occur in the form of publications and academic presentation.

Author contribution

Authors contributed as follow to the conception or design of the work; the acquisition, analysis, or interpretation of data for the work; and drafting the work or revising it critically for important intellectual content: LG, MW and CL each contributed 33%. All authors approved the version to be published and agreed to be accountable for all aspects of the work.

Conflicts of interest

Profs Lara Goldstein, Mike Wells and Craig Lambert are editors of the African Journal of Emergency Medicine. Profs Goldstein, Wells and Lambert were not involved in the editorial workflow for this manuscript. The African Journal of Emergency Medicine applies a double blinded process for all manuscript peer reviews. The authors declared no further conflict of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.afjem.2019.01.011.

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SECTION 4

Doctors' perceptions of upfront POC testing in the ED

CHAPTER 7
DOCTORS' PERCEPTIONS OF THE IMPACT OF UPFRONT POINT-OF-CARE TESTING IN THE EMERGENCY DEPARTMENT

Goldstein LN, Wells M, Vincent-Lambert C. Doctors' perceptions of the impact of *upfront* point-of-care testing in the emergency department. PLoS One. 2018;13(12):e0208655.

7.1 Background

"Change is inevitable in healthcare" [1]. People, however, tend to prefer things that have been around longer. This applies equally to the practice of clinical medicine. The way that we have always performed a task or a method that has existed longer is usually evaluated more favourably by people [2, 3]. It is human nature to resist change as it interferes with people's autonomy and causes a sense of uncertainty [4]. This can be one of the reasons why 40-80% of change efforts in healthcare fail [5].

The ED is a chaotic environment exposing the staff to many stressors [6]. Communication, collaborative decision processes and staff buy-in are vital components to successfully implementing change in this environment [7, 8]. The opportunity for staff to give feedback and collaborate in the potential change process is critical to ensure its successful adoption [6, 7].

When staff satisfaction regarding POC testing in the ED has previously been evaluated, high rates of overall satisfaction have been demonstrated [9-11]. In a non-ED setting in Uganda, however, end-users expressed dissatisfaction with the use and performance of POC tests for communicable diseases such as HIV, syphilis and malaria [12]. Although they acknowledged that the POC testing was important for clinical decision-making in their environment and strengthened their health system overall, there were some limitations. Some of the perceived downfalls were related to inadequate training of end-users, old infections being falsely reported as active and

doubts regarding accuracy. This raises concern that the full potential of POC testing in a LMIC country may be inhibited [12].

The implementation of a new intervention, however beneficial it may be, is a big change. Change can only occur if there is buy-in from the people who will ultimately be making use of the intervention – in this instance, the doctors [7]. The evaluation of the doctors' opinions of the intervention is therefore crucial before implementation can occur.

7.2 Purpose of the Study

The purpose of this study was to assess doctors' perceptions of POC testing when they are utilised *upfront* prior to doctor evaluation. This was done in order to identify whether staff acceptance may be barrier to its potential implementation. The data for this study was collected immediately after the original randomised, controlled trial was completed.

7.3 Major Findings of the Study

- The doctors surveyed were very satisfied and all of them would want *upfront* POC testing to be available permanently in the ED.

- They all found it helpful to assess patients who already had test results available.

- According to the doctors, the most helpful individual test was the i-STAT and the least helpful was the LODOX®.

- Even though they were not aware of the study results at the time of the survey, the majority of doctors thought that a higher cost of POC testing would be worth the time that it saved.

- There was no association between the satisfaction score of the doctors with various POC test permutations and the permutation's treatment time-saving. This may have been because having the results of tests lessened the uncertainty around the undifferentiated ED patient.

7.4 This Study in the Context of the Thesis

The ED is a complex system. The most important components of this complex system are the people who make it work [6]. The present study revealed that the people in this system would be receptive to the institution of *upfront* POC testing in the ED. The majority of the doctors working in the ED felt very satisfied with the POC test availability and they found it helpful to assess patients who already had test results available.

These findings strongly suggested that the attitude of the doctors would not be a barrier to the implementation of *upfront* POC testing in the ED.

The institution of *upfront* POC testing in the ED can be seen to be very similar to the well-known pay-off line from Nashua, "Saving you time. Saving you money. Putting you first." [13]. Chapter 4 addressed the timesaving, Chapters 5 and 6 addressed potential money-saving of all the tests as well as just the impact of POC blood tests in a LMIC setting. And Chapter 7 focused on the staff perceptions – putting them first.

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PLOS ONE

RESEARCH ARTICLE

Doctors' perceptions of the impact of upfront point-of-care testing in the emergency department

Lara Nicole Goldstein[1,2]*, **Mike Wells**[2], **Craig Vincent-Lambert**[2]

1 Division of Emergency Medicine, Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa, **2** Department of Emergency Medical Care, Faculty of Health Sciences, University of Johannesburg, Johannesburg, South Africa

* drg666@gmail.com

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Abstract

Objectives

Special investigations (e.g. blood tests, electrocardiograms, x-rays) play an integral role in patient management in the emergency department (ED). Having results immediately available prior to assessing a patient may lead to improved efficiency. This could be instituted by utilizing point-of-care (POC) testing with an alternative ED workflow, but the implementation would be dependent on acceptance by the end-users. The aim of this study was to assess doctors' perceptions of POC testing in the ED when the normal treatment pathway was modified to use upfront POC tests performed prior to doctor evaluation in an effort to decrease treatment times.

Methods

A prospective, randomized, controlled trial was performed in the ED where medical patients received either the normal ED workflow pathway or one of the enhanced workflow pathways with POC tests in various combinations prior to doctor evaluation. At the end of the study period, doctors were invited to participate in an anonymous survey to gauge their opinions on the implementation of the early POC testing.

Results

Overall, the doctors surveyed were very satisfied with use of upfront POC in the ED. One hundred per cent of the 28 doctors surveyed found it helpful to assess patients who already had test results available and would want it to be permanently available. Normalized satisfaction scores were more favorable for combinations of 3 or more tests (0.7–1.0) as opposed to combinations with 2 or less tests (0.3–0.7). There was a preference for combinations that included comprehensive blood results.

Conclusion

The implementation of workflow changes to assist doctors in the ED can potentially make them more productive. End-user buy-in is essential in order for the change to be successful.

x-rays. Philips SA loaned us 2 ECG machines for the duration of the data collection.

Competing interests: The authors have declared that no competing interests exist.

Upfront, protocolised, POC testing is a low-input, high-yield intervention that decreased treatment time and satisfied doctors.

Introduction

Time-pressure is ever-present in the emergency department (ED). The need to deliver timeous, quality care and to deal optimally with critically ill and injured patients leads to a hazardous, high density of decision-making [1]. Ways to increase efficiency of ED operations may lead to decreased physician cognitive burden, decreased treatment times and decreased overcrowding, thus having a positive impact on patient care [2].

Laboratory testing and x-rays can be time-consuming, rate-limiting steps for many patients in the ED [3–5]. When doctors have the results of these investigations immediately available when initially assessing a patient, it can decrease treatment times and improve efficiency in the ED [6].

Changes in ED functionality and processes can have an impact on patient flow. However, if an intervention is to be effective, it needs to perform (i.e. deliver efficiency) as well as be supported by the staff who will be using it. Changes will only be effective if they are embraced and adopted by the medical personnel [1]. Successful implementation of a novel system is difficult without acceptance from the end-user.

Until recently, the benefit of Point-of-Care (POC) tests in the ED has only been evaluated *after* the patient has interacted with a doctor or nurse. Protocolised usage of POC tests based on symptom presentation before doctor assessment has just been explored; with promising results [6]. The substantial and significant time-saving produced by this innovation warrants further investigation into identifying barriers to its potential implementation.

The aim of this study was to assess doctors' perceptions of POC testing when the traditional ED workflow pathway was modified to make use of upfront, POC tests (blood tests, electrocardiograms (ECGs) and/or LODOX (LOw DOse X-ray)) performed prior to doctor evaluation in an effort to decrease treatment times.

Materials and methods

Study design and setting

An investigator-initiated, prospective, randomized, controlled trial assessing the utility of upfront, POC tests was conducted in the ED between 13 February and 29 June 2017. Fig 1 demonstrates how the normal ED patient workflow compared to the POC intervention workflows during the randomized, controlled trial period [6]. The annual census for this ED is 65 000 patients. During the final two weeks of patient enrolment (15–29 June 2017), the doctors were invited to participate in a survey to gauge their opinions on the performance and utility of the early POC testing. All doctors working in the ED during this study were eligible for inclusion. There were no exclusion criteria.

Permission to conduct the study was granted by the Research Ethics Committee of the Faculty of Health Sciences of the University of BLINDED (REC-01-185-2016 and REC-01-51-2017); the Human Research Ethics Committee of the University of the BLINDED (M171086) as well as the BLINDED National Health Research Ethics Committee (DOH-BLINDED). Written informed consent was obtained from all doctors who participated in the survey. The randomized controlled trial was registered with clinicaltrials.gov (NCT BLINDED).

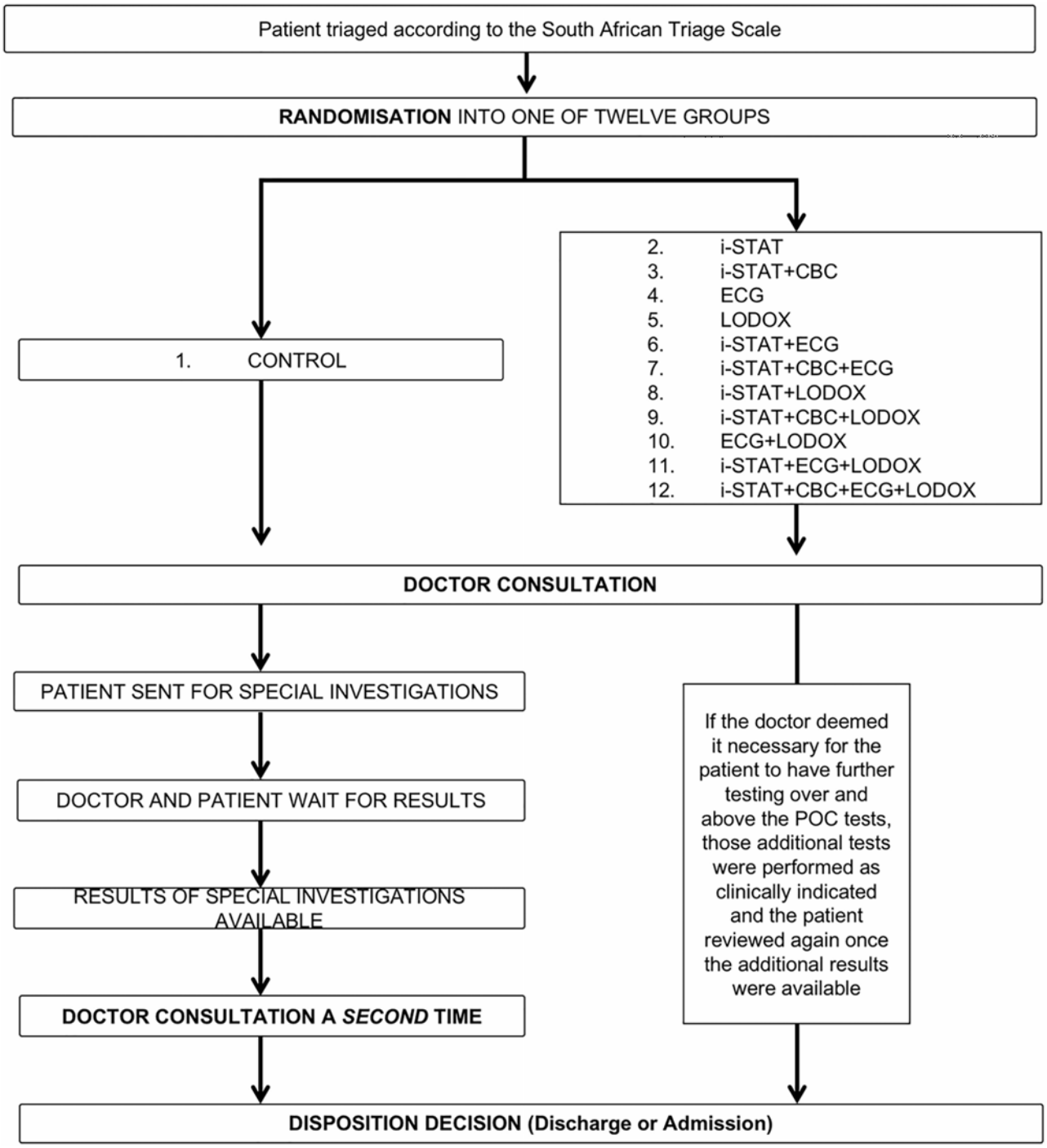


Fig 1. The normal ED patient workflow compared to the POC intervention workflows during the randomized controlled trial period. CBC—Complete Blood Count, ECG—electrocardiogram, i-STAT—i-STAT POC tests, LODOX—LOw-DOse X-ray.

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Study questionnaire

An anonymous survey regarding the impact of POC tests on clinical care in the ED was distributed (S1 File). The purpose of the questionnaire was to investigate user perceptions based on their experiences with the POC test results. It was designed to explore their opinions on the

Table 1. POC equipment and tests evaluated in the study.

Abbott Point-of-Care i-STAT System
The i-STAT System consists of a handheld POC blood analyzer and single-use i-STAT test cartridges (i-STAT, Abbott Point of Care, Princeton, NJ, USA). The CHEM8 + (sodium, potassium, chloride, total carbon dioxide, ionized calcium, glucose, urea, creatinine, hematocrit, hemoglobin and anion gap), PT/INR (prothrombin time and international normalized ratio), CG4+ (Lactate; pH; partial pressure carbon dioxide (PCO_2); partial pressure of oxygen (PO_2); total carbon dioxide; bicarbonate; base excess and oxygen saturation) and Troponin I i-STAT cartridges were utilised on all patients. A venous blood specimen was drawn for this purpose.
Abbott CEL-DYN Emerald 22 benchtop hematology system
The CEL-DYN Emerald 22 benchtop hematology system, capable of providing a POC Complete/Full Blood Count (CBC) as well as a white blood cell differential count, was used.
ECG
Philips Pagewriter TC30 ECG machines were utilised to obtain the electrocardiograms. A standard 12-lead ECG as well as a right-sided (V1R-V6R) and posterior (V7-V9) ECG were performed on all patients randomized to receive an "ECG".
LODOX
A radiographer performed the LODOX (LOw-DOse X-ray) radiographs (chest and abdomen, antero-posterior and lateral) on a Lodox Xmplar-dr. The radiation exposure was approximately 339uGy per patient versus a standard chest and abdomen radiograph of approximately 5200uGy [7].

https://doi.org/10.1371/journal.pone.0208655.t001

operational impact of the tests with regards to time-saving for patients triaged yellow (those to be seen within 1 hour of ED arrival) and orange (those to be seen within 10 minutes of ED arrival) according to the South African Triage Scale as well as for them to rank the individual as well as various combinations of test results that were available during the study.

The POC tests that were evaluated are shown in Table 1.

Statistical analysis

The data were analyzed descriptively, with proportions represented by percentages.

To determine the satisfaction score from the respondents' ranking of the test combinations, seven points were allocated to the most highly-ranked test combination, six points to the next test combination, and so on for each respondent (n = 24). The final satisfaction score was obtained by adding the point allocation from each respondent for each test combination (a maximum score would have been 168). Respondents who did not rank all items (or who did not follow the instructions) were excluded (n = 4).

Due to the small number of doctors, the likert scale was condensed to 3 levels i.e. strongly agree and agree were combined to "(strongly) agree" and strongly disagree and disagree were combined to "(strongly) disagree".

Data analysis was carried out using SAS (version 9.4 for Windows). The 5% significance level was used.

Results

Response rate

The doctors working in the ED ranged in experience from 2 to 5 post-graduate years i.e. medical officer and registrar level. In order to maintain the anonymity offered by the survey, demographic details of the respondents were not sought. There was a 93% response rate– 28/30 eligible doctors completed the survey.

Overall, the doctors surveyed were very satisfied with use of POC in the ED and would want it to be permanently available (Fig 2).

The normalized satisfaction scores for the individual tests from most to least helpful were i-STAT (1.00); ECG (0.84); CBC (0.48) and LODOX (0.43).

The doctors' opinion regarding the perceived time-saving of the separate tests amongst patients triaged yellow (to be seen within 1 hour of ED arrival) and orange (to be seen within 10 minutes of ED arrival) in the ED are shown in Fig 3.

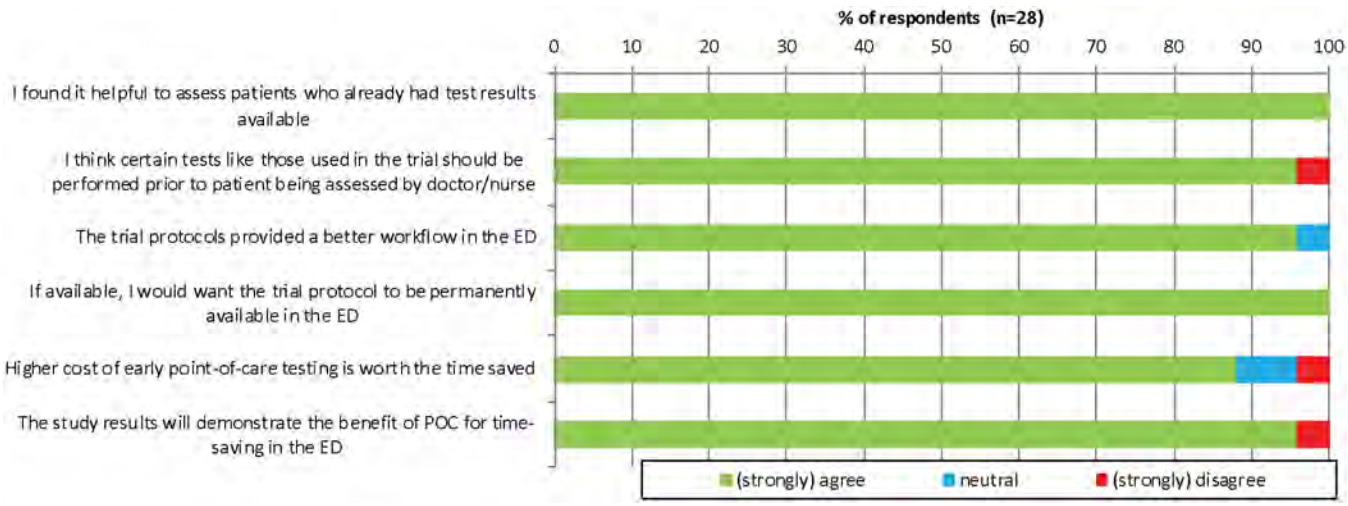


Fig 2. Bar chart of doctors' likert scale responses to POC testing in the ED.

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Fig 4 highlights the doctors perceptions of benefit and satisfaction with the various POC test combinations compared to actual treatment time effects. There was no association between time-saving benefit for the patients and doctors' satisfaction.

Discussion

The challenges of working in the ED abound [1]. There is a need to deliver time-critical interventions in an environment where time is elusive and diagnostic uncertainty is pervasive. This makes the exploration of ways to safely expedite patient throughput a priority. However, without the support of these methods by the end-user, implementation is less likely to be successful.

The main outcome measure for the POC study was a decrease in treatment time [6]. The use of upfront POC tests did result in a substantial and significant reduction in treatment times. While decreased treatment times can impact patient satisfaction positively, it can also improve staff satisfaction [4].

Necessity of special investigations in the ED

As part of the diagnostic workup in the ED, many patients undergo special investigations such as blood tests, ECGs and radiological examinations [8]. These adjunctive tests have a two-fold role—they assist the doctor in confirming or refuting a particular diagnostic hypothesis as well as aiding in the assessment of severity of illness which in the ED is critical to make the disposition decision regarding admission or discharge. Without the delay of waiting for results, the doctors may have preferred having all the information needed to make a diagnosis (history, clinical examination, special investigations) for the patient available at once in order to make the disposition decision quicker and potentially easier. The results could allow rapid identification of patients needing admission thereby avoiding the need for further investigations to take place in the ED.

Doctors' attitudes

Similar to the findings in other studies, utilization of POC testing in this study was favorably received by the doctors who felt that its use was associated with expedited care and improved

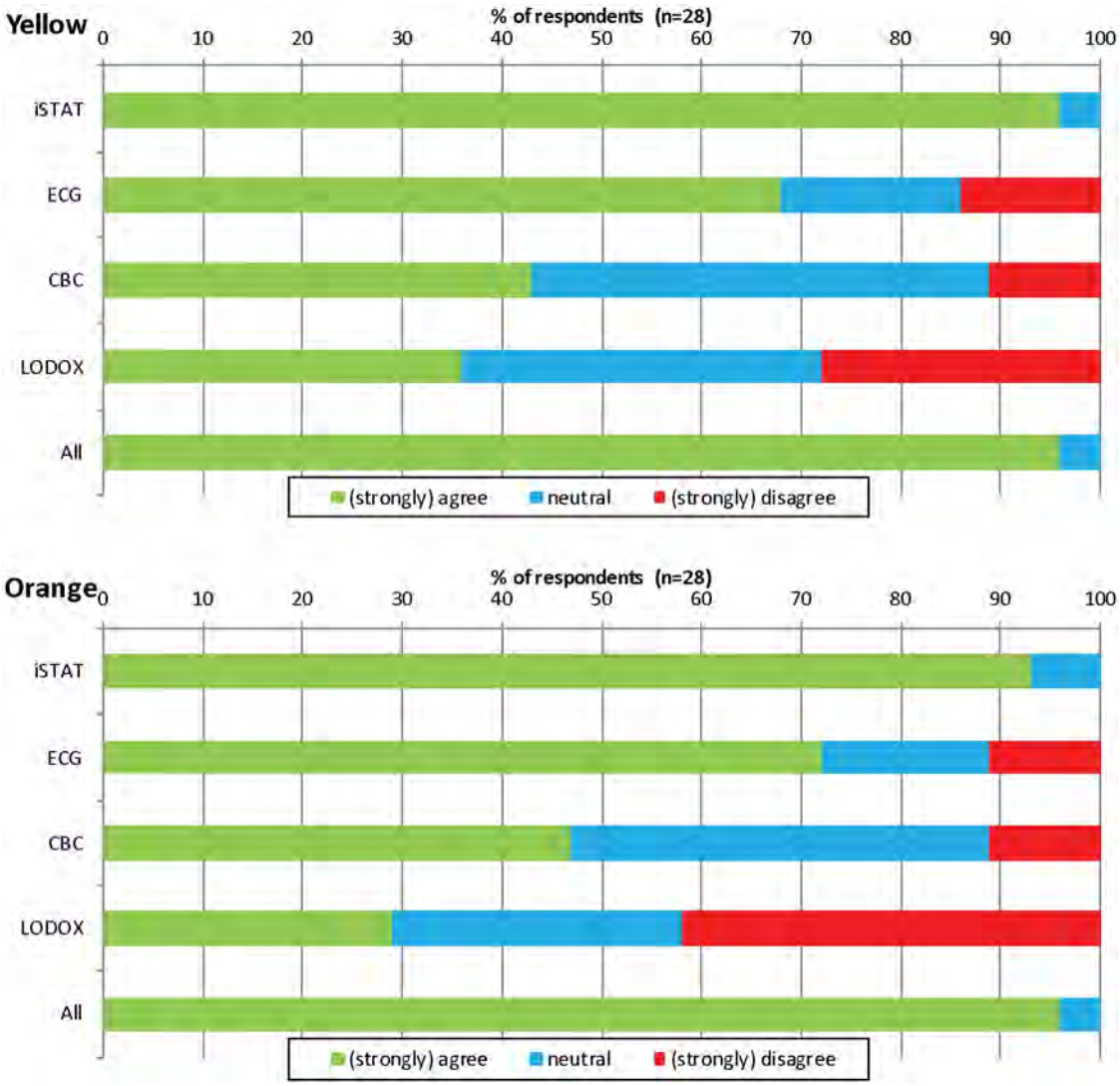


Fig 3. Doctors' opinion on the time-saving of individual POC tests for patients triaged yellow and orange according to the South African Triage Scale. CBC—Complete Blood Count, ECG—electrocardiogram, i-STAT—i-STAT POC tests, LODOX—Low-dose x-ray.

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patient flow [2, 9]. The doctors uniformly wanted the POC testing protocol to be implemented in the ED permanently. Their perception of time-saving extended across patients triaged both yellow and orange. They had a preference for test combinations that included comprehensive blood results i.e. i-STAT combined with CBC (Complete Blood Count). When the individual "helpfulness" of the tests was evaluated, the i-STAT alone (which included the 4 tests described in Table 1) was ranked the highest. This may indicate the doctors' inclination towards more tangible results that require little interpretation compared to the more subjective interpretation associated with either ECGs or x-rays. Blood results may also guide management more definitively. Unless a disorder like an ST-elevation myocardial infarction is diagnosed on ECG or a pneumothorax is diagnosed on x-ray, these modalities are rarely diagnosis clinchers but rather adjuncts.

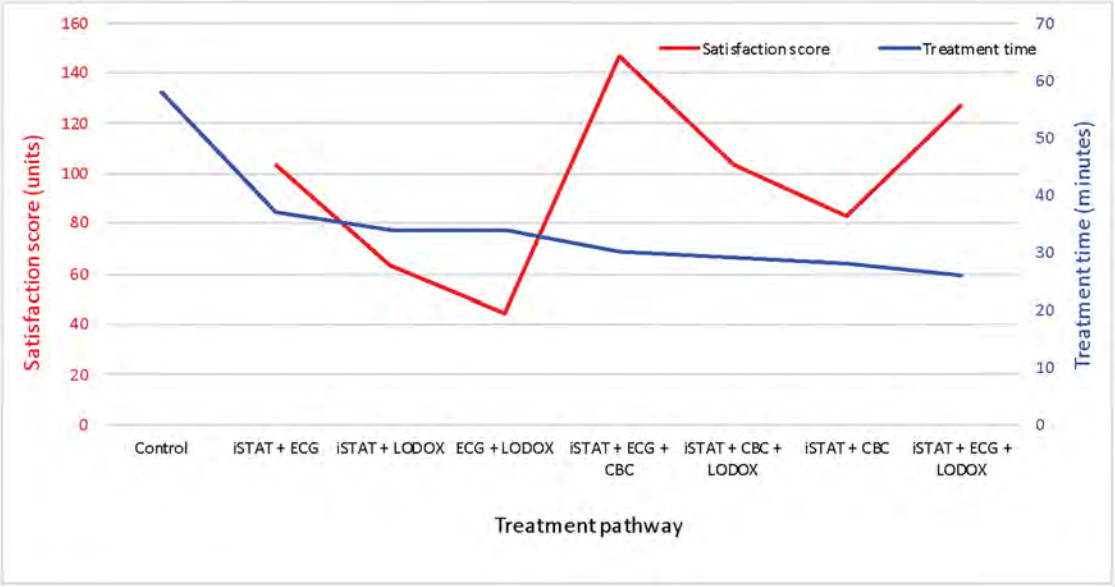


Fig 4. Doctors' satisfaction with the various POC workflow options compared to treatment time benefits. Actual treatment time for each workflow pathway is indicated in minutes. CBC—Complete Blood Count, ECG—electrocardiogram, i-STAT—i-STAT POC tests, LODOX—Low-dose x-ray.

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Association between attitude and actual outcomes

The lack of association between the satisfaction of the doctors and the actual treatment time benefits of the POC tests was intriguing. Again, having the results immediately available may have fulfilled their preference for irrefutable evidence to confirm a diagnostic hypothesis in an effort to take the uncertainty out of their undifferentiated ED patient. The decrease in treatment time may not have been their primary criterion for liking the POC tests, but rather the POC test ease of availability.

Barriers to innovation implementation

Cost. The costs of POC tests are frequently higher than conventional testing [6, 10]. This was accordingly alluded to in the survey. The possibility of higher costs of the POC tests was a concern and did slightly decrease the doctors' positivity towards the benefits of the implementation of POC testing. Contrary to this, the test-for-test direct cost comparison discovered in the post-hoc analysis of the costs involved in the POC study surprisingly demonstrated that there was very little cost difference between the POC tests and the traditional options [6]. Similar to risk-benefit ratios, cost considerations do impact decision-making when new system modifications are proposed. Cost of POC may not be the implementation-limiting factor it was originally perceived to be, however.

Change management. The survey results, although subjective, are an important part of ensuring the success of a POC protocol in the ED [2]. If the end-user is not happy with the system; its implementation is likely to be difficult. Even the best and most innovative ideas can fail if the participants do not support it. Successful diffusion of quality improvement projects requires leadership and a culture conducive to accepting the change [11]. This change can only work if it takes root in people of the organization [1, 12].

Limitations

Limitations of this study include that it was performed in a single center making extrapolation of the results to other EDs problematic. There was no assessment of unnecessary testing; although the findings of previous studies have suggested that this was not likely [13, 14]. There was also no assessment of whether upfront POC testing affected patient outcomes.

Conclusion

According to Richard Branson, "Happy employees equal happy customers" [15]. Likewise, the implementation of systems to assist employees (and ultimately assist our patients) can potentially make them more productive. Upfront, protocolized, POC testing is a low-input, high-yield intervention that not only benefited the patients but also satisfied the doctors.

Supporting information

S1 File. Survey questionnaire on POC testing in the ED.
(PDF)

S2 File. Excel spreadsheet of raw data.
(XLSX)

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Author Contributions

Conceptualization: Lara Nicole Goldstein.

Data curation: Lara Nicole Goldstein.

Formal analysis: Lara Nicole Goldstein, Mike Wells.

Funding acquisition: Lara Nicole Goldstein, Craig Vincent-Lambert.

Investigation: Lara Nicole Goldstein.

Methodology: Lara Nicole Goldstein.

Project administration: Lara Nicole Goldstein.

Resources: Lara Nicole Goldstein, Craig Vincent-Lambert.

Software: Lara Nicole Goldstein.

Supervision: Lara Nicole Goldstein.

Validation: Lara Nicole Goldstein.

Visualization: Lara Nicole Goldstein.

Writing – original draft: Lara Nicole Goldstein.

Writing – review & editing: Lara Nicole Goldstein, Mike Wells, Craig Vincent-Lambert.

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CORRECTION

Correction: Doctors' perceptions of the impact of upfront point-of-care testing in the emergency department

The *PLOS ONE* Staff

Several institution names were omitted during peer review and were not replaced before publication. The second paragraph under sub-heading "Study design and setting" in the Materials and methods section should read: Permission to conduct the study was granted by the Research Ethics Committee of the Faculty of Health Sciences of the University of Johannesburg (REC-01-185-2016 and REC-01-51-2017); the Human Research Ethics Committee of the University of the Witwatersrand (M171086) as well as the South African National Health Research Ethics Committee (DOH-27-0117-5628). Written informed consent was obtained from all doctors who participated in the survey. The randomized controlled trial was registered with clinicaltrials.gov (NCT03102216).

Reference 6 was omitted from the article. Reference 6 should read: Goldstein LN, Wells M, Vincent-Lambert C. A randomized controlled trial to assess the impact of upfront point-of-care testing on emergency department treatment time. Am J Clin Path. 2018; 150(3):224–234. doi: 10.1093/ajcp/aqy042

The publisher apologizes for these errors.

Reference

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SECTION 5

Final Discussion
Conclusions
Recommendations

CHAPTER 8

FINAL DISCUSSION

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8.1 INTRODUCTION

The ED is an environment that is permanently “on the edge of chaos” [1]. Despite the unpredictable nature of the ED, its optimal functionality and the provision of timeous care is critical to saving lives as well as preventing patient morbidity.

This chapter will integrate the findings from each of the studies and discuss them in the context of previous literature in the field of POC in the ED. This starts with a review of the research aim and study objectives followed by a summary of the key research findings. The significance of how *upfront* POC testing differed from traditional diagnostic testing in the ED and the ways in which this research was unique will then be focussed upon. The relative negative findings emanating from the studies and their effects will then be considered. The major themes of timesaving, money-saving and doctor perceptions of *upfront* POC testing in the ED are then individually addressed as to their implications; potential applications as well as their pertinent limitations.

8.1.1 Achieving the Research Aim and Objectives

The focus of this research was to explore *upfront* POC testing as a way to improve the efficiency of the ED by improving patient flow. The aim of this research was to compare and assess the traditional patient flow pathway that was in use in the ED to a modified pathway that made use of *upfront*, POC tests (blood tests, ECG and/or LODOX®) in various permutations to see if this had any potentially beneficial effect on treatment times and costs. It was also intended to evaluate doctor perceptions of its implementation in the ED.

The aims of this research were addressed via two separate studies that were conducted in order to assess the impact of *upfront*, POC testing in the ED: i) a randomised, controlled trial, and ii) a survey. The objectives of the studies were to evaluate whether there would be timesaving, money-saving (overall as well as specifically for a low- and middle-income countries) as well as to evaluate the acceptability amongst doctors for *upfront*, POC testing in the ED.

The findings from the randomised, controlled trial demonstrated that the *upfront* POC testing could save both time and money in an ED. The *upfront* POC testing allowed for quicker decision-making by the doctor which was potentially beneficial for the

patients. The doctors reported that *upfront,* POC testing improved their workload and efficiency. These findings have been published within four publications [2-5].

8.1.2 Summary of Key Research Findings

The findings in this thesis can be summarised as follows:

- POC tests utilised *upfront* in the ED can save time. This applies when comprehensive blood tests (i-STAT+CBC) are used in isolation or when various combinations of blood tests, ECG and LODOX® POC tests are utilised in various combinations. The only tests that do not save time are isolated ECG or isolated LODOX® POC tests.

- The timesaving benefit was found in three common medical symptoms groups: abdominal pain, chest pain and generalised body pain and weakness.

- POC tests can be performed in the non-value-added time that patients spend in the ED without disrupting the flow of patients.

- Patients had a higher likelihood of completing their ED journey in less than one hour of treatment time if they received a POC test.

- *Upfront* POC tests outperformed the same POC tests that were performed at a later stage of the patient's ED evaluation i.e. it saved time to perform the tests prior to doctor evaluation.

- Some POC tests performed *upfront* in the ED can save money. All LODOX®-containing permutations were "more costly" even though they were "more effective" from a timesaving perspective.

- If an additional cost of US$50 was acceptable to the funder, then all the permutations that did not include LODOX® were essentially 100% cost effective.

- Instituted alone, *upfront* comprehensive POC blood tests (i-STAT + CBC) can be cost-effective if instituted in a resource-restricted environment such as LMICs – and even feasibly result in cost savings.

- Doctors are satisfied when *upfront* POC tests are used in the ED and would want them to be available permanently. This strongly suggests that they would, therefore, not be a barrier should the system be implemented.

- Satisfied doctors lead to satisfied patients. It is plausible that this link means that the implementation of *upfront* POC tests in the ED will improve patient satisfaction.

8.1.3 How the application of *upfront* POC testing compared to traditional diagnostic testing in the ED

There are several ways in which this research was unique. The application of the POC testing in the ED in this study was distinctive from what has been tried and reported previously in other settings. These included the fact that: i) POC tests were used *upfront*; ii) the POC tests were protocolised and instituted based on patients' presenting symptoms without prior doctor assessment; and iii) the POC tests included more than just POC blood tests. This meant that what was trialled in this study cannot be directly compared with other studies. Only components of the research can be contrasted to what other researchers have done previously both locally and internationally.

8.1.3.1 Upfront POC testing

In the present study, the POC tests were separate from the triage process and were instituted without additional input from senior medical personnel. Although previous studies have attempted to utilise POC testing early in the patients' journey through the ED, POC testing has never been done in the *upfront* manner as instituted in this present study.

Previously, POC testing has been tried in the form of a safety net for secondary triage purposes, as a supplement to triage when a senior clinician ordered it on a case-by-case basis or as part of standing orders when delays in patient care were

predicted [6-8]. These innate differences undermine any direct comparisons with the existing literature since the *upfront* testing concept was distinctive.

8.1.3.2 Protocolised POC testing

The institution of protocolised POC testing, as applied in this research, was distinct as all the POC tests were implemented based on patient symptomatology as opposed to healthcare provider opinion of whether the patient required a specific investigation. Previous studies on the utilisation of POC testing early in the patient's ED journey have required the input of a staff member to initiate POC test usage i.e. either a nurse or doctor needed to use their discretion and make the decision to institute the POC testing [7, 8]. Protocolisation of the testing meant that an extra potential time-consuming step of decision-making was removed from the process. This meant there was no further delay or deterrent to POC test implementation.

The choice of tests was also fixed in order to limit delays. Time may have been saved by removing these decision steps. This is evidenced by the significant timesaving that occurred for patients who were assigned to an i-STAT-containing pathway compared to those who had a blood gas analysis performed by the doctor in the ED in an equivalent control pathway which was reported in Chapter 4 [2].

This research leads one to conjecture that tailoring the POC tests to even more patient presentations may produce further time- and/or cost-savings. It is also conceivable that by narrowing the focus of each of the permutations e.g. focusing on dyspnoea only and not all chest symptoms, extra timesaving would be possible. These changes would need to be balanced against the risks of complicating the system excessively. If there are too many protocols or too many variables to be considered in each protocol, then the ease and speed of the protocolisation disappears. This would potentially make the *upfront* testing cumbersome and possibly lead to, once again, a reversal to ED inefficiency.

8.1.3.3 Usage of LODOX® as a POC test for medical patients

The present research was the first to use LODOX® for patients with medical complaints.

Prior research has examined LODOX® trauma usage focussing on the full body anteroposterior view only. This is different to the views that were taken for the patients with medical complaints in this study. The anteroposterior as well as lateral views of the patients' chests and abdomens were executed. Although LODOX® testing is an investigation that is generally quick to perform (a full anteroposterior body x-ray can be completed within 19 seconds [9]), this time does not take into account the time it takes to place the patient on the machine, enter their details into the system, perform the scan and then assist the patient off the machine. In addition, the inclusion of a lateral LODOX® view, which was utilised in this study, meant extra time was required in order to rotate the x-ray tube 90 degrees to take the lateral image and then rotate the tube back again in order to disembark the patients from the machine. That being said, the average time to conduct the LODOX® x-rays in this study overall was 4.5 minutes. This truncated time to perform both a chest and abdominal x-ray still makes this a potential timesaving POC investigation.

8.1.3.4 Various POC test permutation combinations were assessed for efficacy

This research evaluated the impact of exchanging laboratory or traditional diagnostic tests with POC tests. The majority of prior POC studies have evaluated the use of POC similarly. These prior ED POC studies were summarised and presented in Table 1.2. These previous studies evaluating POC tests in the ED have, however, either focussed on the impact of a single modality i.e. replacing all laboratory tests with only POC blood tests, or they utilised different POC tests selectively for different patients, e.g. urine dipstick for some patients and finger-prick blood glucose for others [10, 11].

This study, in comparison with the previous POC research, analysed the effects of various permutations of POC tests and how they would apply to patients with differing pathologies. This was done to assess which combination of tests, if any, would have the most benefit. The POC concept was extended beyond just a blood or urine test to include the ECG as well as the LODOX®. These tests were then applied

in various combinations as opposed to previous POC studies which applied them in isolated instances.

8.1.3.5 Non-HIV-based POC testing in South Africa

This study was the first of its kind for non-HIV-based POC testing in EDs in SA.

8.1.4 Relevant Negative Findings which Emerged from this Research

The premise behind the institution of the *upfront* POC testing was that the patients in each group would not be subjected to any tests that they most likely would not have received by following the normal pathway in the ED.

Nevertheless, the major negative findings in this study were:

- No need was found for *upfront* POC testing to be instituted on patients with psychiatric presentations;
- Neither ECG alone nor LODOX® alone led to significant timesaving.

8.1.4.1 Psychiatric patient group

An interim analysis of the data in the present study resulted in a number of relevant outcomes:

i) the time outcomes were very different for the psychiatric group compared to the other medical symptom groups;

ii) the diagnostic test utilisation in the psychiatric patient control group was very different; patients in the psychiatric cohort received less tests than the other symptoms groups – mainly having blood tests performed;

iii) the treatment times for psychiatric patients were essentially already efficient.

The main concern for doctors working in the ED with regards to psychiatric patients is determining whether delirium is the cause for their psychiatric presentation. Various policies and guidelines exist that suggest the workup required for these patients [12, 13].

Psychiatric presentations to the ED are common. At Helen Joseph Hospital, where the study was conducted, almost 2% of ED presentations are for mental health disorders [14]. This is similar to the findings for emergency psychiatric presentations at G.F. Jooste Hospital in Cape Town [12]. According to the Centers for Disease

Control in the USA, approximately 10% of all ED patients present with a psychiatric illness [13]. The psychiatric cohort of patients was included for this reason.

In the Helen Joseph Hospital ED, where the present study was conducted, a protocol was put in place in 2015 regarding the approach to the patient with “acute psychosis” [15]. If a patient was known to have psychiatric pathology, and there was no evidence of organic pathology, then a blood gas analysis is to be performed and if this result was normal then the patient is to be referred to the psychiatric service. If the patient came to the ED as an index presentation, then a full workup is indicated, and the patient is to be referred to either the internal medicine or surgical services.

Anecdotally, it was thought that despite the protocol, many patients were still receiving unnecessary blanket testing. As enumerated above, this was not the case.

POC testing is therefore not recommended for this group of patients due to no apparent time advantage.

8.1.4.2 ECG alone and LODOX® alone permutations

Patients that were assigned to the ECG only and LODOX® only groups did not meet the threshold of a 20% reduction in treatment time. However, when they were combined together both with and without POC blood tests; they were found to save time.

The lack of timesaving associated with the ECG only and LODOX® only groups may potentially be accounted for by each of their intrinsic, limited ability to diagnose disease.

ECGs and x-rays are low sensitivity, high specificity diagnostic tests, in general [16, 17]. For example, the diagnostic yield for a chest x-ray is low in patients who do not have any clinical manifestations of a cardiopulmonary disease [17]. Moreover, although an ECG is synonymous with cardiac pathology, the specificity for diagnosing an ST-segment elevation myocardial infarction, one of the tests we rely on the ECG the most for, for example, is 97% and the sensitivity is 68% [16]. Thus, individually, these tests are unlikely to make a timesaving impact on ED patient

throughput as they may not deliver the certainty of a diagnosis in order to expedite patient disposition.

ECGs and x-rays also rely on the doctor's individual skill and ability to interpret each modality in order to utilise them for patient management decisions. A computer printout with a patient's blood results potentially provides the doctor with more diagnostic certainty than an x-ray or ECG. A blood test result that is digitally printed with a reference range may help to quell the doctor's uncertainty regarding the undifferentiated ED patient. Hence, when ECGs and LODOX® results were combined with the POC blood test results, timesaving was demonstrated.

The lack of timesaving associated with the ECG only and LODOX® only groups could also have been accounted for by the doctors' preference for the additional security offered by blood test results [18]. This blood test result preference may also be related to the lack of confidence and insecurity associated with their clinical examination as well as an inclination towards, and increased reliance on, the tangible results of investigations [19].

8.1.5 Summary of the Introduction

The outcomes of the studies have been reviewed within this thesis in regard to how the findings have addressed the objectives of the research, and have contributed to the general body of knowledge on POC testing in the ED.

Similar to the famous, almost 50-year old tagline for the Nashua company, the impact of *upfront* POC testing in the ED can succinctly be summarised as

"Saving you time. Saving you money. Putting you first." [20]

8.2 SAVING YOU TIME

The ED performs an important safety-net function for the community at all times. It must therefore be readily accessible and provide timely, high-quality care [21]. As one of the doyens of Emergency Medicine, Professor Brian Zink said in his book on the history of Emergency Medicine, the ED is for “Anyone, Anything, Anytime” [22].

According to the International Federation for Emergency Medicine (IFEM) as well as the Institute of Medicine’s framework for improving healthcare in the 21st century, ***time*** is a fundamental domain and a foundational indicator of quality in the ED [21, 23, 24]. The Institute of Medicine’s Committee on Quality of Health Care in America has additionally stated that healthcare should be safe, effective, patient-centred, efficient, equitable and ***timely*** [23]. The “timely” domain asserts that waiting should be reduced in order to prevent harmful delays for “both those who receive and those who give care” [23].

Saving time was therefore the fundamental enquiry of the first study in this thesis. In keeping with the Institute of Medicine’s “timely domain”, the timesaving needed to apply to “both those who received and those who gave care” [23]. This means that the benefits of the timesaving from *upfront*, POC in the ED should apply to both the patients as well as the healthcare providers.

8.2.1 Major Findings of the Study on Evaluating Timesaving

The implementation of *upfront*, protocolised POC testing in the ED, that was examined in this study, was a novel method conceived to improve patient flow and efficiency. It successfully saved time across most of the POC test groups that were evaluated.

The major findings in the study evaluating timesaving were: -

- POC tests utilised *upfront* in the ED can save time – waiting for diagnostic test results does not need to be a rate-limiting step in the ED.

- The timesaving benefit was found in three common medical symptoms groups: abdominal pain, chest pain and generalised body pain and weakness.

- POC tests can be performed in the non-value-added time that patients spend in the ED without disrupting the flow of patients.

8.2.1.1 Upfront POC tests can save time

The timesaving objective was achieved by all the POC test combinations as well as the individual POC tests except if the patient only had an ECG or only had a LODOX® POC test performed.

8.2.1.1.1 Blood tests

Blood test utilisation in the present research was even higher than that which has been previously reported in the literature, with 78.7% of patients in the control group having had blood tests or a blood gas analysis. However, it is important to note that the control group was limited to medical patients only and the estimates of laboratory test usage from previous studies included *all* patients who presented to the ED; for example, a patient with an isolated ulnar fracture generally would not have blood tests performed but would have been included in the denominator when calculating utilisation in those studies.

Depending on the ED patient mix, previous research has found that one third to two thirds of patients will require laboratory tests [25-27]. The acuity of the patients and the type of presentation has a direct impact on whether blood tests will be ordered – the sicker the patient, the higher the likelihood of them requiring blood tests [28].

All permutations of combinations of POC tests showed timesaving capability. Of the permutations that were not part of a combination, only POC blood tests on their own proved to be timesaving. Even this finding, however, had a proviso. Timesaving with the i-STAT alone did not reach the 20% reduction in treatment time benchmark. This may have been because of a missing link in that permutation – a marker for infection. Although there was a calculated haemoglobin/haematocrit value and a serum lactate incorporated in the i-STAT results, there were no other haematological parameters or infective biomarkers such as a white cell count or a C-reactive protein (CRP) value. This may be the reason for the i-STAT only group just missing the target timesaving reduction benchmark by 4 minutes compared to the control group.

POC test combinations with a marker for infection may be particularly relevant for patients presenting with possible infectious diseases. Diseases of infectious origin constitute varying percentages of ED presentations depending on the country. In Spain, infections constitute 5-17% of hospital emergency presentations. In the USA, infections constitute up to 21% of ED cases and in LMIC countries, such as Nicaragua or Mexico, 30-40% of presentations [29]. An ED study from a district hospital in Kwazulu-Natal, South Africa, found an infection presentation rate of 19% in their retrospective record review [30].

The use of POC CRP as a marker for infection in the ED has mainly been studied in the paediatric population [31-34]. In the 2011 study from Mogensen *et al.* (an adult POC study utilising CRP) it was found that having the CRP result saved almost 3 hours in the time to confirmation of an acute bacterial infection [35]. However, if the patient did not have an infection, the POC CRP result had no impact on ED length of stay.

It is possible that the infectious aetiology rate was higher in the present research due to the patient presentations that were chosen, viz. chest pain, abdominal pain and generalised body pain and weakness. In the South African ED study by Ndadane and Maharaj, the most common sites were lower respiratory tract infections, acute gastroenteritis, meningitis, soft tissue and urinary tract infections [30]. Patients with those infections commonly present with chest pain, abdominal pain and/or generalised body pain and weakness. This is similar to a Spanish study from 2000, where 10.4% of emergency presentations were attributed to infectious aetiologies, the majority of those were either respiratory or urinary tract in origin [36].
A separate biomarker to evaluate for infection was, therefore, potentially needed in this present study in order for the doctor to make their disposition decision. This need for an infection biomarker could account for the i-STAT+CBC permutation having had quicker treatment times compared to the i-STAT only group. It is likely that the white cell count and platelet levels, which were contained in the CBC results, acted as a surrogate marker for infection.

In the study by Nijman *et al*., in the Netherlands, in a paediatric ED, it was found that having a POC CRP result decreased total ED length of stay by 30 minutes in febrile children [33]. They postulated that having a CRP result would negate the requirement

for a CBC too. The benefits of a CRP over a CBC would need to be studied further to confirm or refute this; however, both appear to aid in timesaving in the ED.

Although the i-STAT system, can provide a serum lactate level result, this biomarker is more useful for patients with severe sepsis and septic shock as opposed to non-life-threatening infections [37]. The incidence of sepsis and septic shock in the ED is quite low [37]. In a South African district hospital sepsis study from Kwazulu-Natal, the sepsis rate was only 4.4% of all infectious diseases presentations and 0.8% of all ED patient presentations [30]. CRP, while still not a perfect choice, would probably be a more suitable biomarker than a serum lactate level for a presumptive diagnosis of infection in the ED [37]. This again probably accounts for the i-STAT group in the current study faring worse than the i-STAT + CBC group despite the i-STAT containing a lactate result.

Timesaving from implementing POC blood tests in place of laboratory blood tests is dependent on the following: -

- The time frame measured to assess impact

When the time measured (such as treatment time which was used in this study) assesses factors that are within the EDs control, it is a better indicator of effectiveness. This is demonstrated in a 2018 POC study from New York. In a study by Singer *et al.*, there was a significant treatment time saving of 54 minutes between POC and laboratory tests [38]. This was even better than the 31 minutes saved in the current research. However, there was no difference in the patients' ultimate total length of stay. There is no control over when the patient physically leaves the ED – especially if there is hospital access block.

- Hospital admission rates

The average overall ED admission rate for Helen Joseph Hospital is 30%. This is comparable to the worldwide admission rates from average EDs which range from 15% to 35%. Studies with higher hospital admission rates have shown no difference from the institution of POC in their ED length of stay. In Kendall's 1998 study in the UK, the admission rate was 85% [39]. This study is often quoted to support the lack of benefit of POC in the ED, but the abnormally high admission rate makes extrapolation to lack of timesaving in other environments untenable.

- Pre-existing infrastructure

EDs that already have quick laboratory turnaround times are less likely to have timesaving demonstrated by the implementation of POC testing. In EDs that have access to pneumatic chute systems for specimens to be taken directly to the laboratory, for example, blood testing may not be a rate-limiting step in their patient processing and so POC may not demonstrate timesaving in that setting [39, 40].

8.2.1.1.2 X-rays

The x-ray utilisation in the control group (58.7%) in this research was even higher than in prior studies. Previous research has found that approximately one third to one half of patients presenting to the ED will receive an x-ray [25, 28, 41]. Comparatively, the higher x-ray utilisation in this research is likely related to the following two confounders: 1) a higher admission rate in this patient cohort; and 2) it being standard practice at the study hospital for x-rays to be ordered on all medical patients requiring hospital admission.

Patients with medical complaints are commonly sicker than non-medical ED patients. Medical patients were the chosen to be the main patient groups included in this study (chest pain, abdominal pain and generalised body pain and weakness). The higher acuity associated with medical patients meant that there was a higher admission rate for these patients (54.8%) compared to the average overall ED admission rate (30%). The higher admission rate likely contributed to the higher x-ray utilisation compared to prior studies.

The other confounder, which may have resulted in the higher x-ray utilisation, is the standard practice for all patients admitted to the internal medicine service at the study hospital to receive a chest x-ray. The internal medicine service did not have access to the LODOX® images. The PACS (picture archiving and communication system) for radiological imaging was not installed in the medical wards at the time of the trial. This meant that admitted patients needed to receive a standard x-ray before going to the admission ward in order for the internal medicine service to access the patients' radiological investigations.

Obtaining x-rays are known to increase waiting times in the ED [25, 28]. However, when x-ray usage was combined with POC blood testing in the ED in Helsinki, Finland, in 2018, it was found that patients were discharged an hour and 22 minutes sooner than those who had POC tests alone (only saving 55 minutes) [42]. Including the LODOX® as a POC test was therefore likely, and ultimately did, positively impact timesaving in the current research.

That being said, although the average time to conduct the LODOX® x-rays in this study was only 4.5 minutes, all LODOX®-containing permutations did not uniformly save time. Despite the short turnaround time for an x-ray result, the LODOX® tests were only timesaving when they were performed together with one or more of the other POC tests, i.e. an ECG or a POC blood test. This lack of effect on its own was elaborated upon previously under the discussion of negative findings from the study.

8.2.1.1.3 ECGs

ECGs are commonly carried out in the ED for both cardiac and non-cardiac pathologies [43]. This ED ECG utilisation is echoed in the 64% percent of patients who had an ECG performed in the control group of the present research study. This usage, however, is much higher in comparison to other studies that have been done.

Early primary care utilisation of ECGs is quoted as being 2.6% of all outpatients in the USA [44]. A study looking at ECG use in outpatients amongst 10 internal medicine group practices, demonstrated an overall usage rate of 4.4%, with inter-group variability ranging from 0.5%–8.6% [44]. An ED-based study conducted in London by Lui *et al*., in 2014, found that 9.9% of all ED patients had an ECG recorded [43].

The appreciably higher ECG rate in the present study is likely due to the patient selection that was included in the present study – patients with undifferentiated chest pain, abdominal pain and generalised body pain and weakness. Similar to the requirement for x-rays, these patient groups are more likely to require an ECG compared to the average ED patient. This is confirmed in the Liu *et al*., findings where patients who had chest pain, syncope, palpitations, dyspnoea, collapse, drug overdoses or who were feeling “generally unwell”, received the bulk of the ECG investigations in the ED [43].

An ECG, as a POC test, has never been studied in the context of ED flow optimisation. This study demonstrated that the ECG would only be a timesaving modality if it was combined with another POC test.

8.2.1.2 Timesaving in common medical symptom groups

In this study, timesaving was evident amongst three common medical patient symptoms groups: abdominal pain, chest pain and generalised body pain or weakness. All these patient groups had a shorter ED treatment time. More patients could also be evaluated and have a disposition decision within one hour if they received any POC tests *upfront* compared to those who were in the control group.

Timesaving in the ED related to POC implementation has had mixed success in other studies. The decreased turnaround time for POC results does not appear to translate into equivalent decreases in ED treatment time and length of stay.

As can be seen from Table 1.2, POC in the ED has been tried in different patient populations at various points in the ED process.

In this study, the decreased treatment time was evident whether the patient was admitted or discharged. In studies including similar patient populations to the present study, POC has only shown timesaving benefit in those patients who were ultimately discharged from the ED or demonstrated no time benefit at all [26, 42, 45, 46]. There are a few potential reasons for these inconsistencies in POC successfully leading to timesaving: -

- The categories of patients where POC was utilised were too broad for meaningful comparison.

For example, in the study by Singer *et al.*, they included trauma patients (where POC blood testing is generally not useful [47]) who were evaluated together with patients with renal failure [46]. There was no significant reduction in ED length of stay demonstrated in their overall patient population. The potential benefits in one patient category were likely negated by the lack of benefits in others. This was not, however, evaluated by the authors.

- The POC test that was evaluated only impacted decision-making if the result was positive.

The is shown in a study from New York in 2003 where POC urine pregnancy testing was compared to the laboratory urine pregnancy testing. There was only a decrease in ED length of stay if patients had a positive pregnancy test – otherwise there was no difference [48].

- The POC tests were only implemented in certain situations

Some studies have only instituted the usage of the POC tests when the ED was busy and expected waiting times were thought to be protracted [38, 49]. This makes meaningful comparison of results in different settings difficult.

- POC tests were not uniformly adopted in the so-called POC groups for comparison against laboratory times

In some studies, patients in the “POC only” groups were still having laboratory tests performed as well [40, 46, 50]. This potentially confounded the time benefits that those patients may have had from POC as the time measured would then be dependent on the laboratory time.

- Not taking post-analytical time into account

In the study by Ryan *et al*., from 2009, the post-analytical time, i.e. the time between laboratory result readiness and the doctor becoming aware of the result, was used. This artificially lowered the overall processing time for the laboratory which lead to no difference being found when it was compared to POC [50].

- Other timesaving interventions were being evaluated at the same time as POC

The current research evaluated the impact of each of the different POC interventions separately. When multiple process changes are implemented simultaneously, it is difficult to determine which intervention is responsible for change and to what extent. Prior POC studies have instituted multiple potential timesaving processes together with POC testing. This has led to the inability to attribute benefit to the POC testing itself or establish whether benefit was due to one of the other simultaneous interventions [7, 51, 52].

- Equating opinion with fact

In many of the original studies on POC in the ED, POC testing was evaluated retrospectively using interviews on the hypothetical utility a POC test may have had should the test have been performed and the result have been made available [53, 54].

- If POC blood testing was not the rate-limiting step in the ED flow processes, then implementation of POC did not show benefit [39].

- The use of differing or non-specific endpoints – patient disposition versus when the patient left the ED [35, 42].

- Majority of the studies were before & after or prospective, observational studies as opposed to randomised, controlled trials.

The implementation of POC in the current study was done in such a way as to attenuate some of the aforementioned studies' faults.

8.2.1.3 POC tests can be performed in non-value-added time successfully

In the present randomised, controlled trial, the *upfront* POC diagnostic tests were performed in the patients' so-called "non-value-added" time i.e. the time in the ED that they would have spent waiting to be seen by the doctor. The results were also ready within this "non-value-added" waiting time making them immediately available to the doctor during their consultation with the patient with no added delays. This efficient use of waiting time potentially contributed to the overall timesaving of the *upfront* POC tests along with the decreased turnaround time for the results. The time taken waiting for special investigation analysis would, therefore, have been removed from the equation.

It is problematic to contrast this finding with prior POC studies as the time in which the POC tests were implemented in the patient ED pathway was different. The closest timeframe to the "*upfront*" timing used in this study has been in studies where POC was used in triage. When POC has been used in triage, it was either implemented together with additional senior staffing, such as a doctor, or it was done in order to assess if the POC result affected the triage process [6, 7, 55].

In 2014, in the UK, when POC was implemented in triage together with an additional doctor, Jarvis *et al*., noted that the ED length of stay was decreased by 53 minutes [7]. This was unsurprising as putting a senior healthcare provider in triage has previously been shown to decrease waiting times [56]. Furthermore, inclusion of a senior healthcare provider's opinion together with POC testing has been shown to decrease ED length of stay in studies in both Finland and Australia [10, 26]. The big advantage of *upfront* POC testing, as applied in this research, is that an extra senior healthcare provider is not required in order to benefit from the provision of early POC testing.

The benefit of the innovation of the *upfront* timing of the POC tests used in this study was further highlighted in the sub-analysis within the first part of this research. The treatment time for patients who had had a blood gas analysis performed by the doctor on the ED blood gas analysers was compared to those patients who had been assigned to an equivalent *upfront* i-STAT–containing workflow. The *upfront* POC test groups outperformed the equivalent control patient groups who received a POC test during their consultation even if the same tests were ultimately chosen. The use of the tests *upfront* in the non-value-added time is what resulted in the timesaving.

8.2.2 Measures of Improved Emergency Department Efficiency

Improvements in timesaving may lead to improved efficiency in the ED. Positive sequelae from this could mean a decrease in patients leaving the ED without being seen; decreases in patient morbidity and mortality; and shortened in-hospital length of stay.

8.2.2.1 Decreased leave without being seen rate

Although the "leave without being seen" data was not specifically collected in this present study, it is unlikely that it would have been a significant finding. This is because the patients that leave the ED without being seen are generally of a lower triage acuity level i.e. patients triaged green [57]. The patient maladies (chest pain, abdominal pain and generalised body pain and weakness) evaluated in this study are generally associated with higher patient acuity. There were 0-4 low-acuity patients (those triaged green) in each workflow permutation. This means that the "leave without being seen rate" in this patient population would have been an unhelpful

metric to have measured based on the small number of patients that would have been included.

8.2.2.2 Morbidity, mortality and in-hospital length of stay

A limitation of this research was that there was no assessment of the patients' ultimate outcomes. Data collection for each patient was terminated after the disposition decision was made. The main aim of this research was to compare the effects of *upfront* POC testing on treatment time in order to improve ED functionality. The sample size calculation was performed to determine the effects on treatment time and not patient outcomes. Whilst determination of the effects on the patients' clinical outcomes would have been a useful addition to this research, it would have required a considerably larger sample size to have sufficient statistical power to answer this question [58]. This was a preliminary study. Future studies could potentially explore this important aspect.

ED overcrowding is known to be associated with increased inpatient mortality as well as prolonged hospital length of stay [59]. The majority of the patient outcome studies have been performed comparing patient boarding times (as opposed to treatment times) to inpatient morbidity and mortality [60-65]. In other words, they looked at the outcomes of patients who were admitted to hospital but had a prolonged stay after disposition decision as opposed to assessing the outcomes compared to the treatment time.

In recent literature, two studies performed in Europe (in Norway and the Netherlands) showed no association between prolonged length of stay in the ED with treatment times and mortality [66, 67]. The authors in both these retrospective studies have acknowledged that the Norway and the Netherlands healthcare systems are quite distinct in that ED overcrowding is not considered to be a major problem.

The ED in the Norway study only sees approximately 21 000 patients per annum because of the strict gatekeeping by general practitioners in their system. They also have a much higher admission rate of 84% than this study or any other ED study admission rate [66]. Interestingly, they found a lower probability of patients being admitted to the hospital if they had a prolonged ED length of stay. They attributed

lower hospitalisation to the time spent on patient work-up with more time spent on diagnostic testing.

The Dutch contingent found that there was an increase in patient treatment times when their ED was more crowded. Although patient mortality did not increase during those time periods of crowding, they did concede that there may have been a negative impact on patient satisfaction, admission duration of stay as well as other patient outcomes which they did not measure [67].

The impact of *upfront*, POC testing in the ED on subsequent patient morbidity, mortality and hospital length of stay requires further specific study.

8.3 SAVING YOU MONEY

"Everything comes at a price. Everything in your life. The question you have to ask yourself is, what price are you willing to pay?" [68]. This apt quote from Paullina Simons' romance novel, The Summer Garden, applies to *upfront* POC testing in the ED too.

8.3.1 Major Findings Evaluating Overall Costs for POC

Surprisingly, in this study, a face-value comparison of the costs of the traditional tests to their POC counterparts found that the POC tests were, in fact, more economical than traditional test prices. However, not all patients presenting to the ED will receive special investigations, or if they do receive tests, not all patients will receive the same type or number of tests. A face-value comparison, as previously discussed, is not constructive.

Institution of *upfront*, protocolised testing meant that all patients would receive all the tests as per the protocol. The cost-effectiveness of the impact of this blanket testing was therefore evaluated.

The major cost implications elucidated from this research were:

- Instituted alone, *upfront* comprehensive POC blood tests can be cost effective.

- Some POC test combinations performed *upfront* in the ED can save money. All LODOX®-containing permutations were “more costly” even though they were “more effective” from a timesaving perspective.

- If an additional cost of US$50 was acceptable to the funder, then all the permutations that did not include LODOX® were essentially 100% cost effective.

8.3.1.1 POC blood tests only

The cost-effectiveness of *upfront*, POC blood tests were evaluated for their impact in isolation as the access to diagnostic services in LMIC is commonly limited [69]. The research found that the i-STAT + CBC combination was the most cost-effective option which, if implemented, would likely result in a cost-saving of US$14.96 per patient. This is a crucial finding for LMIC where the costs to set up a laboratory *de novo* may be out of reach both financially and geographically.

There are no LMIC POC cost-effectiveness studies to compare these findings to.

In Australia, Asha *et al*., found that an extra AUS$113 would need to be paid per patient in order to save only one hour of time [10]. In Sweden, however, POC saved US$111 per patient – but direct costs were used in this comparison [70].

This research was therefore the start of analysing POC cost-effectiveness in the ED in LMIC.

8.3.1.2 POC tests with and without LODOX® and funder willingness-to-pay

The findings from the current study highlighted that although LODOX®-containing permutations were “more effective” from a timesaving perspective, they were all “more costly” despite the cost of LODOX® image being more inexpensive than a standard x-ray. This reinforces the non-utility of face-value cost comparisons. The radiological component formed the bulk of the diagnostic test costs in all the LODOX®-containing permutations. This led to additional cost without additional timesaving to counterbalance it. The conclusion from the findings are that if LODOX®-containing permutations are to be instituted, the funder will need to

evaluate whether the tangible time benefits and intangible patient benefits are sufficiently counter-balanced by the need to pay an extra US$50 per patient.

A contributing factor towards the lack of cost-effectiveness of including LODOX® as a POC test was ironically related to the protocolised usage. Every ED patient obviously did not ultimately need an x-ray of the chest and abdomen in order to make a disposition decision. This led to the increased costs for all the LODOX®-containing permutations. An alternate implementation of LODOX®, such as after a disposition decision is made, may be the key to its cost-effective usage in the ED.

Cost-effectiveness is ultimately determined by the funders' willingness-to-pay. In Australia, AUS$113 was considered too much money to save only an hour of time in the ED whereas in this research, perhaps US$50 may still be acceptable depending on who will ultimately be paying for the tests [10]. If admission costs were included in this study (as was done by Whitney *et al.*) this could also have potentially increase the acceptability of paying more by the funder [71]. Further research, with inclusion of admission costs, would be required to answer these questions.

8.3.2 How the Cost-Effectiveness of *Upfront* POC Testing Compared to Traditional Diagnostic Testing in the ED

Direct comparison between this research and other previous POC ED study results from a cost perspective is again difficult. Firstly, the novelty of the *upfront*, protocolised POC application in this study means a head-to-head comparison with other studies is not possible. Secondly, there is a scarcity of ED cost-effectiveness POC studies that have been published.

The best approach to performing cost comparisons is to conduct cost-effectiveness and cost-benefit analyses [72]. Ideally, these should be done utilising prospectively collected data from a randomised, controlled trial [46, 73]. In the past 20 years, there have not been many randomised, controlled trials conducted using POC testing in the ED as can be seen in Table 1.2 [10, 35, 50, 74-80]. Only three of these studies evaluated true cost-effectiveness [10, 71, 81].

A study by Whitney *et al*., in a paediatric ED in the USA, assessed cost-effectiveness of POC testing for managing children with acute gastroenteritis. The cost of the POC

tests were balanced against the admission costs. They found savings for the group of patients who received POC tests in the ED [71].

Cost-effectiveness was not demonstrated in a 2014 study conducted in Australia by Asha *et al* [10]. The Australian study only demonstrated small timesavings which translated into increased costs if POC was adopted in their environment [10].

The UK-based, multi-centre Randomised Assessment of Treatment using Panel Assay of Cardiac Markers (RATPAC) study for POC usage in acute coronary syndrome showed standard care to be more cost-effective than POC [81].

The current study certainly showed POC blood tests to be cost effective. The cost-effectiveness of the combination of POC tests, however, would be up to the finder to decide.

8.3.3 Cost-saving Possibilities not yet Evaluated

There are other fiscal, as well as non-fiscal, savings, which may be possible based on the findings from this research on *upfront* POC testing. These can be divided into:
i) LODOX®-related;
ii) staffing-related;
iii) other cost-saving implications.

8.3.3.1 Potential cost-saving utilisation of LODOX®

Although cost-saving was not demonstrated in the LODOX®-containing permutations, there may be potential cost benefits if an alternative usage of the LODOX® for medical patients is considered. For example, if the internal medicine service requests a chest x-ray as a precondition for all patients admitted to their service, and a LODOX® is performed instead of a traditional x-ray, there will be a cost-saving based on face-value prices – a cost-effectiveness analysis would not be needed to prove this. Performing the LODOX® *after* the disposition decision is made could, therefore, potentially save money.

Other preconditions for this system to be cost-effective would be a functioning hospital-wide PACS system, as well as proof of diagnostic equivalence between the two radiological tests, in order to make the change acceptable to the end-user.

LODOX® has thus far only been used as a screening test as opposed to as a diagnostic test [82].

8.3.3.2 Savings on staffing costs

The foundation of the calculation of cost-effectiveness of POC is the cost of staffing the ED. Incorporating *upfront* POC testing into the ED creates the potential to save time. When doctors save time by spending less time with each patient, this potentially provides the opportunity for EDs to reduce the overall number of doctors (and possibly nurses) required in the ED. The higher the cost of staff, the more economical the POC testing potentially becomes. Usage of POC tests would also mean that there should be less laboratory utilisation. This may mean that less laboratory staff would need to be employed leading to further savings in that area.

8.3.3.3 Other cost-saving implications

8.3.3.3.1 Inpatient costs

Although there was no difference between diagnostic test utilisation in patients that were admitted or discharged from the ED in the present study, changes in admission rates and the costs of inpatient care were not evaluated. The effect of *upfront*, POC testing on the costs of admitted patients still needs to be evaluated. In the RATPAC trial (conducted in the UK in 2011), which looked at patients presenting to the ED with suspected myocardial infarction, patients who received POC tests and who were admitted to the hospital, had lower inpatient costs than those who had traditional diagnostic tests [81]. Those POC test patients did, however, have increased costs if they were admitted to the coronary intensive care, as well as having further costs related to coronary interventions.

Cost-savings were also evident for paediatric patients admitted with acute gastroenteritis who had had POC tests done in the ED [71].

These cost-saving trends for patients who are admitted to the hospital after receiving POC tests may hold promise for *upfront* POC implementation in the ED leading to inpatient cost savings. Further research into this facet is still required.

8.3.3.1.2 Patient satisfaction costs

Patient satisfaction was not evaluated in this study but may also have cost implications.

Improvements in patient waiting times and increased efficiency of patient throughput processing in the ED may save costs by potentially increasing patient satisfaction [83, 84]. Increased patient satisfaction leads to decreases in patient complaints [85]. Complaints themselves have costs – the cost of the time of the personnel required to deal with the complaints as well as the expanded costs (financial and psychological) if the complaint leads to a malpractice lawsuit [85]. Decreases in complaints and increases in patient satisfaction may mean less costs to the organisation implementing the *upfront* POC tests.

Improved patient satisfaction is also linked to healthcare organisation loyalty [85]. If increased patient satisfaction from decreased waiting times due to POC is applied to the private hospital sector in South Africa, for example, timesaving would not only lead to cost-saving, but also to potentially improving profits as patients would be more likely to remain loyal to the hospitals with EDs who are the most efficient.

Additional research would be required to ascertain the validity of these speculations.

8.4 PUTTING YOU FIRST

Sigmund Freud said, “When making a decision of (minor) importance, I have always found it advantageous to consider all the pros and cons…” [86]. The implementation of POC is no different. Both the benefits and the barriers need to be addressed if positive outcomes are the goal. While the financial implications play a considerable role, one also needs to consider the human element related to instituting *upfront* POC in the ED. This includes the acceptability to staff as well as the impact on patient considerations. There has been saving of time, there has been saving of money, and so, it is time for “putting you first”.

8.4.1 Major Findings of the Study Evaluating the Doctors' Perceptions of *Upfront* POC Testing in the ED

The doctors were very satisfied with the functionality of *upfront* POC testing in the ED and all of them wanted it to be available permanently. They found it helpful to assess patients who already had the results of diagnostic tests available. They found the i-STAT most helpful and the LODOX® the least helpful individual tests. There was no association between the doctors' satisfaction with the various tests and the tests' impact on timesaving.

8.4.1.1 Staff considerations

The doctors all responded positively towards the implementation of *upfront* POC testing in the ED in this research. This is similar to the favourable response towards POC tests when they have replaced laboratory test usage in EDs elsewhere [11, 46].

A hospital's performance is strongly linked to its relationship with its employees and their level of engagement [87]. There is a direct correlation between the job satisfaction of the healthcare employee and the quality of the patient care they render. This increase is quality of patient care is also intimately linked to patient satisfaction [88].

One of the keys to maintaining staff satisfaction is employee participation in decision-making processes [88]. Communication is pivotal to instituting change management [89]. Lack of staff satisfaction with the implementation of a novel intervention can lead to its failure irrespective of its ability to save time, money or patient lives [90, 91]. It was therefore essential to assess the doctors' perceptions to the institution of *upfront* POC tests in the ED.

Without knowing the outcomes of the study i.e. whether it could save time in the ED or not, the doctors all wanted *upfront* POC testing to become permanently available in the ED. This may be to help quell their uncertainty that is associated with the undifferentiated ED patient [3, 18].

Their positive response towards the *upfront* POC testing protocol is reassuring in that their buy-in would be obtained to ultimately implement the change in the ED successfully.

8.4.1.2 Patient considerations

A limitation of this research was the lack of direct assessment of patient benefit. There was no assessment of the patient experience nor was there any measurement of patient outcomes. That being said, as discussed previously, patient satisfaction is inextricably linked to staff satisfaction [88]. The institution of *upfront* POC tests in the ED satisfied the doctors, its institution would hopefully therefore lead to increased patient satisfaction too.

Prior ED POC studies have also not evaluated patient satisfaction specifically. POC tests have been shown to improve patients' satisfaction in the general practitioner outpatient setting, however [92]. Better patient satisfaction is also one of the top criteria for doctors in the outpatient setting to prefer using POC tests too [92].

The Abbott POC website says that the i-STAT system "can help minimise wait times and (ED) length of stay leading to an enhanced patient-care experience and improved patient satisfaction" [93]. These tenets can be applied to all POC tests in the ED, not just the i-STAT system, in their enhancement of patient satisfaction.

The General Household Survey conducted by Statistics South Africa in 2010 revealed that 88.5% of the 95 918 participants were "somewhat or very satisfied" with their most recent healthcare visit [94]. Patients who had not experienced problems with their visit such as a "long wait time" were more likely to report satisfaction with their visit to the healthcare provider [94]. This too was found in earlier surveys conducted by the South African Department of Health where the main reason for patient dissatisfaction with both private and public sector hospitals was "long waiting times" [95]. If waiting times in the ED can be reduced by the implementation of *upfront* POC testing, this could potentially lead to improved patient satisfaction in the South African setting.

IFEM suggested patient-centredness could be assessed in the ED by monitoring a patient complaint system as well as measuring left-without-being-seen rates [24].

These patient-centred outcome measures require further exploration if *upfront* POC testing is instituted in the ED.

8.5 STRENGTHS AND POTENTIAL LIMITATIONS

Like any research, the work presented in this thesis has both strengths and potential limitations. The strength of this research has hopefully been well-explored, demonstrated, and analysed. The main study was a prospective, randomised, controlled trial with adequate sample size to achieve power. This study design eliminated potential selection bias in assessing the impact of *upfront* POC testing.

The application of POC testing in the ED was both pragmatic as well as the first study of its kind to assess the utility of non-HIV-related *upfront* POC testing in SA. Each of the various permutations of the study were evaluated separately as well as in different combinations in order to assess which test/s would potentially be most beneficial.

Moreover, this was the first study in this field to protocolise POC testing in an *upfront* manner. It was also the first study to evaluate the use of LODOX® as a POC test and the first to evaluate the use of LODOX® for patients with medical complaints.

The cost-effectiveness of the intervention was evaluated using optimal economic analyses. This means that the outcomes published could be trusted to be accurate and appropriate for wider applications taking into account the need to adapt any research findings to unique contexts.

Finally, the research included an evaluation of doctor satisfaction. The results from this analysis were positive. This result was critical in determining that the implementation of the intervention is feasible from a human resources perspective.

However, it is important to also identify, address and examine the potential limitations of the studies. These limitations have been explicated within each of the four publications that make up the body of this thesis. This section will summarise and synthesise these limitations that have been previously identified.

Some of the identified limitations are inherent in the study design, in the available metrics upon which the calculations were made and are due to the limitations imposed upon the study having been conducted in an ED where certain expectations existed for patients who were to be admitted to the hospital.

The studies included in this thesis were performed in a single ED. The complexity of the ED in which the study was conducted mitigates against it being regarded as a simple case-study with the inherent limitations of a case study design. However, all research findings require adaptation to a different context, and this is no different. Each ED is unique in itself with unique limitations and processes. Therefore, the results may not be generalisable to other institutions, to other regions of SA or to other countries.

Even though there was no evidence of a Hawthorne-type effect, staff were not blinded to which patients received the *upfront* POC tests. Although staff realised that the processes were being recorded and timed and that the adapted ED processes were being evaluated, it was not a particularly unusual evaluation situation. This ED is part of a training hospital, and research is conducted within the ED and the rest of the hospital on an ongoing basis, as a regular feature of work.

All times were recorded by the doctors themselves rather an impartial observer. This may have led to some inaccuracies. There was also the possibility for human error when the doctors recorded those times. However, this potential limitation was recognised, and synchronised clocks were utilised in all areas of the ED where times were recorded.

The cost calculations were limited by the availability of costing data within the study hospital. The costing calculations were based on the likelihood that the patients in the control pathway received the same tests as an equivalent patient in the POC intervention pathway. Staffing costs were calculated using only doctor and nursing costs because the funding of allied hospital staff is managed separately in the study hospital. The cost calculations are not necessarily similar to other EDs. In order to accurately evaluate the cost benefits of applying *upfront* POC treatments in other environments, there will probably need to be individualized site analyses.

At the patient-level analysis of limitations, although doctor satisfaction was evaluated, patient satisfaction was not stringently evaluated. However, anecdotally, the patients who were asked said they appreciated the attention they received during extended wait times.

A potential further piece of research for this study should be an analysis regarding individual patient requirements for testing. Due to a limitation of resources, this was not performed in this analysis. This combined with the potential duplication of blood tests and x-rays for patients admitted to the internal medicine service, could have led to over-testing of individual patients. Conversely, the duplication of blood tests and x-rays for the admitted patients could have led to biased results against the usage of *upfront* POC testing from both a time- and cost-saving perspective. This possible duplication and potential over-testing may mean that the cost and time benefits that were found in this study may not be a true reflection of just how beneficial *upfront* POC testing could be.

Finally, yet another potential piece of future research that has been identified by this study, which would significantly build upon the findings of this study, would be an evaluation of the impact of the *upfront* POC tests on patient morbidity and mortality. This follow up of individual patients would be an expensive piece of research in both time and resources, but an evaluation of these long-term patient health outcomes would certainly make a major contribution to the field.

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CHAPTER 9
CONCLUSIONS AND RECOMMENDATIONS

9.1 INTEGRATED CONCLUSIONS

The aim of this research was to compare and assess the traditional ED patient flow pathway to a new modified pathway. This new pathway made use of *upfront*, POC tests (blood tests, ECG and/or LODOX®) in various permutations. This modified approach was evaluated to see whether the process could reduce treatment times and costs, and whether doctors would perceive its implementation in the ED as positive.

The intervention used the non-value-added time that patients spend waiting to see doctors to implement novel *upfront* POC testing to perform common diagnostic investigations. The results of these POC investigations were used by the doctors to in their subsequent patient consultations, facilitating quicker disposition decisions. Patients presenting to the ED with common medical complaints such as chest pain, abdominal pain, and generalised body pain and weakness were included.

The findings of the study demonstrated that the implementation of *upfront* POC testing in the ED saved time. Saving time, however, may potentially not be viewed positively if it was not economically viable. It was therefore necessary to perform a number of economic analyses in order to assess whether the timesaving would translate into money-saving, as well as determine the funders' willingness-to-pay for the more intangible costs.

The economic analysis of *upfront* POC testing demonstrated that its implementation in the ED could be cost effective. This was especially evident amongst patients assigned to the comprehensive blood tests (i-STAT + CBC) group. This was the most cost-effective permutation which was found to potentially even save money. The implementation of *upfront* POC blood tests can also be beneficial in the LMIC.

Including LODOX® *upfront* as part of the POC bundle did not save time if it was utilised on its own. In combination with other POC tests, having a LODOX® result did

save time. Despite this timesaving, LODOX® usage in a protocolised fashion was not cost effective.

Another important part of this study was assessing how doctors perceived the implementation of a different way of processing patients in the ED. A positive evaluation on the part of doctors was deemed to be an indispensable key to the change management process. Discovering that the doctors were satisfied with the *upfront* POC system and that they were in favour of it being instituted full-time was strongly suggestive that implementation of the *upfront* POC testing would be successful. Satisfied doctors are likely to create satisfied patients. However, since patient satisfaction was not evaluated in this study, further research into this part of the *upfront* POC puzzle, as well as recommendations for future research will be discussed in the next section.

9.2 RECOMMENDATIONS AND FURTHER RESEARCH

9.2.1 Recommendations

The following recommendations are based on the findings presented in this thesis.

- When instituting POC testing in the ED, strongly consider performing the tests *upfront* prior to doctor evaluation in order to gain the most time benefit.

- In LMIC or resource-constrained environments consider only implementing POC blood tests alone or POC blood tests together with ECGs.

- If a LODOX® machine is available, unlike in trauma patients, its use for medical patients should be only *after* an admission decision is made. This applies if the internal medicine service requests that all patients needing admission require a chest x-ray to be performed. This could then potentially make the test economical.

- There is no benefit to performing routine isolated ECG or LODOX® investigations.

- Do not apply *upfront* POC testing to psychiatric patients who have psychosis, aggression, hallucinations or drug overdose as there is no time or cost advantage.

- Assess the choice of i-STAT blood tests based on your ED patient population. Do not, for example, include Troponin I if there is a low prevalence of acute coronary syndrome in your patient census.

9.2.2 Future Research

POC can play a significant role in optimising the throughput of the ED and expediting the patients' ED journey.

Future research in the field should include the following:

- What are the effects of *upfront* POC testing on admission costs?

- How does *upfront* POC testing impact patient outcomes?
    - Does quicker disposition have any effect on in-hospital length of stay?
    - Does quicker disposition improve outcomes for sicker patients e.g. admission to ICU sooner?

- How does *upfront* POC testing affect patient satisfaction?
    - Do quicker treatment times enhance the patient's ED experience?

- Should *upfront* POC testing only be performed when the ED is busy? If so, what is the breaking point for its initiation?

- Which other patient groups/presentations can benefit from *upfront* POC testing?

- Is LODOX® of an acceptable standard to replace all standard x-rays in the ED for non-trauma patients?

- Are there other POC tests that can be beneficial *upfront* in the ED?

- Point-of-care ultrasound?
- Other blood tests?

SECTION 6
Appendices

APPENDIX 1
MD Proposal

AN ASSESSMENT OF THE TIME-SAVING AND ECONOMIC IMPACT OF UPFRONT, POINT-OF-CARE TESTING IN THE EMERGENCY DEPARTMENT

Lara Nicole Goldstein

9600504A

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The Proposal

SUPERVISOR

Professor Charles Feldman

MBBCh, PhD, DSc

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1. LITERATURE REVIEW

1.1 Introduction

The Emergency Department (ED) has a constant influx of critically ill and injured patients 24 hours a day. EDs worldwide are constantly looking for ways to decrease patient over-crowding and waiting times. Suggested solutions have included the hiring of additional personnel, creating observation units, ambulance diversion and triage (Hoot & Aronsky, 2008). Some have even tried to improve patient flow by placing a senior consultant in the triage area (Terris *et al*, 2004). Point-of-care (POC) testing has become a focus area for enquiry as EDs look for ways to cope with over-crowding and reduce waiting times (Oredsson *et al*, 2011).

1.2 What is POC testing?

POC testing usually refers to the performance of laboratory diagnostic tests outside the central laboratory at or near the location of the patient. (Rooney & Schilling, 2014). The concept can be applied to other forms of special investigations that are performed at or near the patient's point of care e.g. radiographs (x-rays) that are performed in the ED as opposed the radiology department.

1.3 What POC test options are available in the ED?

Special investigations are generally performed on patients in order to confirm or refute a diagnosis. These can include blood tests, electrocardiograms (ECGs) and x-rays. Table 1 depicts some of the traditional diagnostic tests together with their available point-of-care equivalents.

Table 1 Traditional diagnostic tests and their point-of-care equivalents

Diagnostic Test / Investigation	Point-of-Care equivalent
Full Blood Count (FBC)	Complete Blood Count (CBC)
Urea and Electrolytes (U&E)	Chem8
Blood Gas	CG4+
ECG	ECG
X-ray	LODOX®

1.3.1 Blood tests

Thirty per cent of discharged patients and 47.2% of patients overall presenting to the ED require lab tests (Kankaanpää *et al*, 2016; Yoon *et al*, 2016). Laboratory testing can be the “rate-limiting step for many patients in the ED” (Fermann & Suyama, 2002; Mogensen *et al*, 2011).

Instead of sending blood specimens to the laboratory for analysis, POC blood testing refers to selected tests which can be performed in the ED and provide immediate on-site results and thus have the potential to expedite patient management decisions. POC blood testing has been shown to be accurate and assist in expediting patient management by decreasing the turnaround time for results (Jarvis *et al*, 2014; Stotler & Kratz, 2013).

1.3.2 X-rays

Low dose x-ray (LODOX®) has been marketed as a quick and easy radiological screening tool for trauma patients (Whiley *et al*, 2013). It is the radiological equivalent of a POC blood test providing a full body x-ray within 19 seconds. LODOX® has been evaluated in trauma patients previously but its application as a screening tool for non-trauma patients in the ED has not been properly investigated thus far. It is much quicker and exposes the patient to less radiation than a standard radiograph.

1.3.3 Electrocardiograms

ECGs are commonly used in clinical medicine as a POC test to evaluate the heart. It is a relatively inexpensive diagnostic test that can provide useful information about a patient in a variety of different situations. It is also a common screening test.

1.4 Patient flow in the ED

The traditional flow for patient evaluation and investigation in the ED is shown in Figure 1. Special investigations such as blood tests, x-rays and ECGs are requested and usually performed *after* the doctor has evaluated the patient (Jarvis *et al*, 2014). Patients (and doctors) then have to wait for the results of these investigations before a disposition decision is made. The patients' ultimate disposition (i.e. whether discharged home or admitted for inpatient care) is thus contingent upon the results of these investigations.

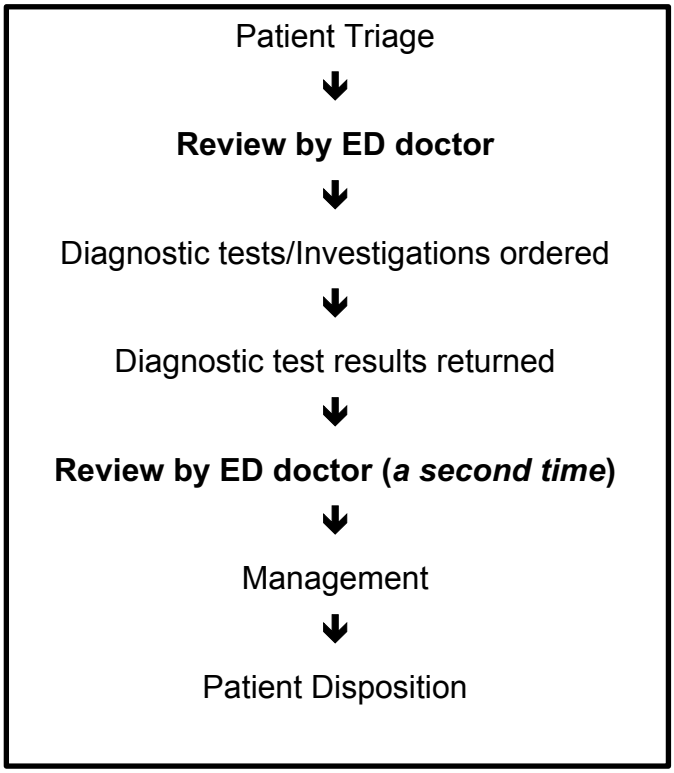


Figure 1 Traditional order of patient evaluation and investigation in the ED

1.5 How is POC testing currently utilised in the ED?

POC testing has been studied in EDs worldwide in the form of "standing orders" as well as utilised in place of traditional laboratory testing. Its use has had variable success (Jarvis *et al*, 2014, Lee-Lewandrowski *et al*, 2003, Oredsson *et* al, 2011; Retezar R *et al*, 2011). Standing orders are medical orders that have been developed for particular types of patient conditions that nursing staff can use to carry out specific diagnostic tests in advance of doctor evaluation (Retezar R *et al*, 2011). ED utilisation of POC testing to date has been reactive i.e. only implemented in response

to a busy ED as opposed to being a standard procedure for all patients. Alternately, the POC tests have been utilised in place of the traditional laboratory tests but still within the traditional order of ED patient evaluation (Lewandrowski *et al*, 2003, Oredsson *et* al, 2011).

1.6 How is POC testing currently utilised in South Africa?

To date, research on POC testing in South Africa has focussed on HIV, diabetes, tuberculosis and sexually transmitted diseases (Mashamba-Thompson *et al,* 2018, Motta *et al,* 2017, Page-Shipp *et al*, 2018, Rosen *et al,* 2016, Stevens *et al*, 2017).

There are no studies on the utilisation of POC testing in the ED in South Africa.

1.7 How to improve patient flow In the ED

By performing commonly utilised special investigations *prior* to initial doctor evaluation in the ED, there is the potential to expedite patient throughput and therefore save time. Figure 2 shows an innovative, alternative proposed order for patient evaluation and the utilisation of POC investigations *upfront* in the ED. The concept of implementing the different POC tests *upfront* in the ED i.e. *prior* to doctor-patient consultation, whether separately or in combination, is novel and has not been previously evaluated in South Africa or internationally. At the time the ED doctor first evaluates the patient, the results of the investigations are already immediately available and could potentially accelerate the patient disposition process.

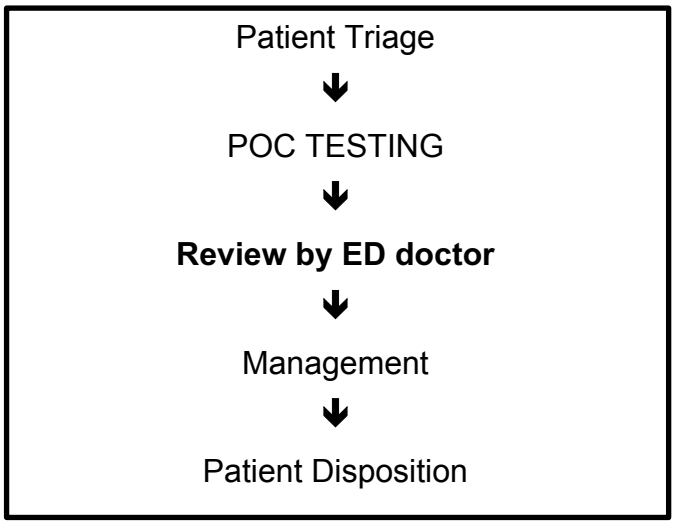


Figure 2 Proposed order for patient evaluation and the utilisation of *upfront* POC investigations in the ED.

1.8 Barriers to implementation

1.8.1 Cost-effectiveness

Using these POC time-savers commonly appears to be cost-prohibitive to implement when their direct costs are compared to traditional diagnostic testing. Recouping the personnel costs from the time saved, however, may ultimately lead to financial benefit and economic viability (Schilling *et al*, 2014). This may be even more important in low- and middle-income countries where access to laboratory services is commonly inadequate (Wilson *et al*, 2018).

1.8.2 End-user adoption

An additional imperative part of ensuring the success of a new POC protocol in the ED is to evaluate the likelihood of its adoption by the end-user. Even the best and most innovative of ideas can fail if the participants do not support it (Greilich *et al*, 2018).

2. HYPOTHESIS, AIMS, OBJECTIVES

2.1 Hypothesis to be tested

Increased waiting times are the unfortunate sequelae of ED functionality. Methods to decrease the negative effects on patient management are constantly being sought. POC testing in the form of blood tests, ECGs and low-dose x-rays performed *prior* to the patient being evaluated by the doctor (and the results being made available to the doctor immediately) may be a time- and cost-saving modality to improve ED patient throughput.

2.2 Aim

The aim of this research was to compare and assess the traditional patient flow pathway that was in use in the ED to a modified pathway that made use of *upfront*, POC tests (blood tests, ECG and/or LODOX®)) in various permutations to see if this had any potentially beneficial effect on costs and treatment times as well as to evaluate doctor perceptions of its implementation in the ED.

2.3 Objectives

1. To describe the current treatment and patient flow times in the ED.
2. To assess the application of protocols for POC testing for different patient presenting complaints.
3. To assess the effect of implementing upfront POC tests (blood tests, ECGs and LODOX®) in the ED with regards to treatment times individually and in various permutations for patient disposition.
4. To assess the effect of implementing upfront POC tests (blood tests, ECGs and LODOX®) in the ED with regards to cost implications.
5. To assess the perceptions and response by the doctors to changes in ED patient flow.

3. METHODOLOGY

3.1 Study design

There were two separate studies conducted in order to assess the impact of upfront, POC testing in the ED – a trial and a survey.

The trial was an investigator-initiated, composite-structured, prospective, randomised, controlled trial. It was structured into three separate components in order to evaluate each aspect of the impact of implementing POC in the ED and therefore allow achievement of the above objectives. These were published in separate papers, which specifically addressed: -

1. The impact of implementation on treatment times
2. The economic impact in low- and middle-income countries
3. The overall cost-effectiveness

In addition to this, once the trial was completed, the ED doctors were invited to participate in a survey in order to study the effects of system changes and therefore the feasibility of implementation by the evaluation of its acceptability amongst them. This was published in a separate paper.

4. RESULTS

4.1 Results of the thesis as they appeared in publications

The publications emanating from this composite, structured, randomised, controlled trial and survey served to evaluate different aspects of the impact of implementing POC in the ED.

1. Time effects
2. Cost effectiveness in low- and middle-income countries
3. Overall economic impact
4. Staff impact and uptake

1. Goldstein LN, Wells M, Vincent-Lambert C. (2018) A randomized controlled trial to assess the impact of upfront point-of-care testing on emergency department treatment time. *American Journal of Clinical Pathology* 150(3): 224–234.

This article highlighted the potential utility of POC testing performed in a protocolised fashion, prior to doctor evaluation, in decreasing treatment times in the ED. It was the first to have assessed the impact of upfront POC testing on treatment times and the first to have included LODOX® as a POC investigation for non-trauma patients.

2. Goldstein LN, Wells M, Vincent-Lambert C. (2019) The cost of time: A randomised, controlled trial to assess the economic impact of upfront, point-of-care blood tests in the emergency centre. *African Journal of Emergency Medicine* 9 (2): 57-63.

“There is no such thing as a free lunch”. Although the implementation of the upfront POC tests showed time-saving, could this be applied to low- and middle-income countries where such resources may not be readily available? This article featured the potential cost-effectiveness and utility of upfront POC blood testing alone if implemented in the ED in low- and middle-income countries.

3. Goldstein LN, Wells M, Vincent-Lambert C. The cost-effectiveness of upfront point-of-care testing in the emergency department: a randomised, controlled trial
(under review)

When direct costs of POC tests are compared to standard testing pathways, these tests commonly appear to be cost-prohibitive. Economic viability may become apparent when the time-saving is translated into financial benefits from staffing, time- and cost-saving. This piece of the randomised, controlled trial focused on the potential overall cost-effectiveness of POC testing in the ED.

4. Goldstein LN, Wells M, Vincent-Lambert C. (2018) Doctors' perceptions of the impact of upfront point-of-care testing in the emergency department. *PLOS One* 13;13(12):e0208655.

Successful implementation of a novel method of patient assessment and flow in the ED is difficult without acceptance from the end-user. This article highlighted the potential to improve doctor productivity in the ED by utilising upfront POC testing. Whilst preliminary evaluation of the POC tests demonstrated their value in time-saving, subjective input from the doctors who would actually utilise the system was crucial. It is a big change to move from conventional medical practice to upfront testing. Its impact on the staff that uses it needed to be evaluated.

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APPENDIX 2
Ethics clearance

R14/49 Dr Lara Goldstein

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)

CLEARANCE CERTIFICATE NO. M171086

NAME: (Principal Investigator)	Dr Lara Goldstein
DEPARTMENT:	Emergency Medicine Helen Joseph Hospital
PROJECT TITLE:	An Assessment of the Impact of Enhanced Workflow Patterns Associated with front, Early Point-of-Care Testing on Costs, Waiting and Dispostion Times in an Emergency Department
DATE CONSIDERED:	Adhoc
DECISION:	Approved unconditionally
CONDITIONS:	
SUPERVISOR:	
APPROVED BY:	Professor P. Cleaton-Jones, Chairperson, HREC (Medical)
DATE OF APPROVAL:	10/11/2017

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and **ONE COPY** returned to the Research Office Secretary on the 3rd floor, Phillip Tobias Building, Parktown, University of the Witwatersrand. I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated, from the research protocol as approved, I/we undertake to resubmit to the Committee. **I agree to submit a yearly progress report**. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. in this case, the study was initially review October and will therefore be due in the month of October each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES

APPENDIX 3
Plagiarism screening report

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Nahal Beik, Kimberly Terry. "Improving Glucose Management with Point-of-Care Testing in the Emergency Department", Current Emergency and Hospital Medicine Reports, 2014

APPENDIX 4

Supplementary Table 1

Supplementary Table 1 POC studies that have been performed in the ED from 1994 – 2020

Studies are ordered chronologically from newest to oldest. The table excludes the research presented in this thesis.
The POC tests are blood tests unless otherwise specified. Times are reported as *medians* unless otherwise specified.

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Baumer-Mouradian [1] (2019) Wisconsin, USA	66 000 Paediatric ED	Prospective, Interventional	783	*i-STAT, Abbott POC* CG4+ (capillary blood)	Lab vs POC Process change	Suspected DKA	LOS (defined as time from patient arrival to disposition) *Overall* No difference *Discharged* Lab 206min POC 186min (p=0.009) DKA determination time (time to HCO_3 result) Lab 86min POC 26min Intravenous line placement usage decreased Lab 85% POC 36%	10% reduction in LOS is an intermediate goal relative to other studies When they moved POC testing to the triage area, times improved.
McCoy [2] (2019) New Jersey, USA	70 000	Prospective, observational	539	*GEM Premier 4000* pH, pCO_2, pO_2, Na^+, K^+, Cl^-, HCO_3, glucose, lactate, Hct, Hb, oxyHb, metHb, carboxyHb, total bilirubin, deoxyHb	Lab vs POC	All patients requiring laboratory testing	Lab TAT used (time from when the specimen is received to when the result was available) *mean* Lab CBC 30.9min Lab Chemistry 55.2min POC 3.5min	During ED high volume periods Peak volumes did not stress either lab or POC option therefore a time motion study was performed “POC faster than lab even during ED high volume situations”
Abualenain [3] (2018) Jeddah, Saudi Arabia	66 000	Prospective, observational	94	*i-STAT, Abbott POC* β-HCG CG4+ CHEM8+ TnI WBC	POC in Triage Process change	Chest or epigastric pain; SOB; generalised weakness; abdo pain; syncope; missed dialysis; GI bleeding; suspected sepsis	Up-triage (7.4%) Down-triage (5.3%) Pt brought into ED (11.7%) 30 patients (32%) left without being seen Nurse perceptions - favourably received (useful)	Substantial methodological limitation Accuracy of triage not checked Different tests according to different presenting symptoms WBC is not available on the i-STAT platform – unclear how this parameter was obtained

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Kankaanpää [4] (2018) Helsinki, Finland	61 000	Prospective, observational	1111 Lab 951 POC 160	*Alere Afinion™ AS100 Analyzer* CRP *i-STAT, Abbott POC* CG4+ CHEM8+ *PocH-100i, Roche* CBC	Lab vs POC	Non-ambulatory patients who required blood tests	LOS (arrival to left ED) *Discharged* Lab 5h52min POC 4h57min (p=0.012) (if no imaging e.g. x-rays) Lab 7h10min POC 5h48min (p=0.010) (with radiological imaging) *Admission* No difference in LOS	Not possible to identify when patient ready for discharge so used time patient left ED 70% of patients had radiological imaging Patients who had both lab and POC tests were excluded from the study (648 pts)
Li [5] (2018) New South Wales, Australia	Multi-centre Rural EDs	Before & After Retrospective	Before 2092 After 338	*Specific systems not disclosed* U&E, LFT, Ca^{2+}, glucose, blood gases, lipids, INR, cardiac markers, endocrinology, diabetes screening, urinalysis	Lab vs POC Rural EDs	Pts with a "circulatory system illness"	LOS (arrival to discharge) Lab 134min POC 123min **(p=0.07)** Proportion of patients discharged within 4 hours increased from 82.2% to 86.8% (p<0.0001)	Substantial methodological limitation Vague diagnosis "circulatory system illness" Less than one-third of data available for analysis in POC group
Pines [6] (2018) Louisiana, USA	30 000	Before & After Retrospective, observational	Before 24 705 After 22 694	*i-STAT, Abbott POC* CHEM8+ TnI	Lab vs POC	All patients who needed a TnI or CHEM8+ blood test	TAT (arrival to test result) POC CHEM8+ 22.6min decrease in time to result POC TnI 21.1min decrease in time to result (p<0.001) LOS (Not specified) No difference Staff perceptions interview - favourably received	"…because most patients still received central laboratory orders in addition to POC, we did not believe that there would be an effect on patient's overall LOS" LOS benefits also confounded by other interventions that were implemented e.g. nurse practitioner program instituted

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Singer [7] (2018) New York, USA	110 000	Prospective, observational, case-controlled	Control 52 POC 52	*i-STAT, Abbott POC* CG4+ CG8+ INR TnI *Beckman Coulter Icon* Urinalysis and urine pregnancy	POC in Triage Process change	chest pain; generalised weakness; GI bleeding; missed dialysis; suspected infection; ♀ with abdo pain ages 18-45yrs; patients >65yrs with abdo pain or syncope	LOS (arrival to disposition) Lab 8.5h POC 7.6h (p=0.015) Up-triage for 3 pts (5.8%) Staff perceptions - favourably received	Diverse inclusion criteria – different tests for different patient presentations “Protocolised” and instituted at triage but only if busy i.e. waiting time thought to be >1h
Dahm [8] (2017) New South Wales, Australia	Multi-centre	Prospective Interviews	14	Not disclosed	Lab vs POC	Patient outcomes Clinical Practice Pathology Governance Cost	Staff perceptions based on the interview - favourably received	Rural and remote EDs Small sample size
Pines [9] (2017) District of Columbia, USA	3 sites	Simulation study	468 cases	Not disclosed “POC test results”	POC in Triage	chest pain or SOB, ≥ 40yrs; suspected sepsis; weakness ≥ 55yrs; abdo pain, ♀≤ 40yrs; abdominal pain, ≥ 55yrs; syncope, ♀≤ 40 yrs; syncope, ≥ 40 yrs; suspected hyperglycaemia; suspected ethanol intoxication; suspected stroke; missed dialysis; GI bleeding	No POC result 42.3% prioritised Abnormal POC result 71.6% prioritised Normal POC result 32.7% prioritised Abnormal POC result Up-triage 32.5% Normal POC result Down-triage 18.6%	468 simulated case scenarios presented to 39 triage nurses Nurses had to choose between 2 pts with the same triage score as to who would be “prioritised” for the next available ED bed when POC results were and were not available Abnormal TnI and lactate most useful

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Kankaanpää [10] (2016) Helsinki, Finland	57 000	Prospective, observational	1.Control 439 2. POC 86 3. POC with EAT 343	*Alere Afinion™ AS100 Analyzer* CRP *Cobas b 123 POC System* Na^+, K^+, glucose *Cobas h 232 POC system* D-dimer *PocH-100i, Roche* CBC *Reflotron Plus system* creatinine ALP, ALT, total bilirubin, amylase	Lab vs POC Process change 3 phases 1. Control 2. POC 3. POC with early assessment team (EAT)	Patients who required blood tests (within the available POC spectrum)	LOS (registration to discharge) 1. 3h51min 2. 3h22min (p=0.000) 3. 3h05min (p=0.033) LOS for patients who had no lab tests performed also decreased by 16min (p=0.000)	Similar to Jarvis *et al.* [11] Admission rate 35% Included only ambulatory non-sick patients who would be discharged (33% of total ED patients) 30% of pts who were discharged, needed lab tests Most of the ED patients needing lab tests had their analysis done in the lab (18-29% of patients in all phases) i.e. the POC spectrum was not sufficient
Whitney [12] (2016) Connecticut, USA	28 000 Paediatric ED	RCT [13] Secondary analysis	225	*i-STAT, Abbott POC* "7 cartridge" CG4+ CHEM8+	Lab vs POC	Children with gastroenteritis	Economic analysis Direct costs Lab US$11.54 POC US$ 8.59 Cost-saving US$303.30 per patient	9-year delay between RCT publication and economic analysis Admission rate Lab 43% POC 31% Compared cost for hospital LOS
Asha [14] (2015) Sydney, Australia	65 000	RCT [15] Secondary analysis	452	*AQT-90 Flex, Radiometer Medical ApS* TnT	Lab vs POC	Suspected ACS	Primary outcome (death cardiac arrest, MI, revascularisation procedure – No difference	Wide CI due to small sample size may have under-estimated negative sequelae
Beynon [16] (2015) Heidelberg, Germany	Pre-hospital	Prospective with retrospective application questionnaire	103	*CoaguChek XS, Roche* INR	Lab vs POC Pre-hospital (POC) vs in-hospital (lab)	If venepuncture performed by pre-hospital doctor	Time gained from POC 69min Utility in 30% of patients	Most useful in neurological patients Utility determined by a questionnaire after the patient was admitted to hospital

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Ivaska [17] (2015) Turku, Finland	70 000 Paediatric ED	Prospective, observational	168	*Alere Afinion™ AS100 Analyzer* CRP *Hemocue* WBC (capillary blood)	Lab vs POC	Pyrexial children	Informal evaluation of staff, patient and parental perceptions - favourably received Staff reported that POC facilitated pt flow and decreased LOS	Pre-term infants Howell-Jolly bodies misread as WBC by POC machine – rare Specimens not taken at the same time – up to a delay of 4 hours LOS was not formally evaluated
Singer [18] (2015) New York, USA	90 000	Before & After	Before 1405 After 377	*i-STAT, Abbott POC* BNP CG4+ (lactate) CHEM8+ INR TnI	Lab vs POC Pneumatic system (lab)	chest pain; any bleeding; stroke; renal failure; suspected sepsis; suspected heart failure or SOB; trauma; any need for intravenous contrast for a CT scan	LOS (Triage to disposition) Overall LOS Lab 291min POC 294min **(p=0.84)** Contrast CT completion Lab 177min POC 96min (p=0.004) Staff perceptions survey - favourably received	Critically ill patients POC not adopted uniformly – POC usage was at the doctor's discretion Benefitted pts who had a CT scan Incremental cost presented as US$3113.28 per annum Cost savings not calculated or estimated Staffing costs not included
Nijman [19] (2015) Rotterdam, Netherlands	9 000 [20] Paediatric ED	Prospective, observational	Before 286 After 728	*Alere Afinion™ AS100 Analyzer* CRP	Lab vs POC	Pyrexial children	LOS (registration to discharge) Lab 178 min POC 148 min (p<0.001) Direct cost Lab €1 POC €5	"CRP outperforms WBC … may save money by doing a CRP because then an FBC unlikely to add diagnostic value"

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Asha [15] (2014) Sydney, Australia	65 000	RCT	811	*ABL-800 FLEX blood-gas* and *AQT-90 Flex, Radiometer Medical Aps* Creatinine, β-HCG, Na^+, K^+, Cl^-, HCO_3, glucose, Ca^{2+}, Hb, TnT, D-dimer *Roche CoaguChek XS-PRO* INR	Lab vs POC	1. Suspected ACS 2. Patients who required blood tests (within the available POC spectrum)	LOS (time to disposition decision) *mean* Overall Lab 3.5h POC 3.24h (p=0.04) Incremental cost-effectiveness ratio Additional AUS$113/pt for 1h of timesaving	Heterogeneous patients – No benefit when groups analysed separately Times reduced more (by 19.1%) in the sub-group of patients enrolled by a senior doctor
Jarvis [11] (2014) UK	65 000	Prospective, observational	Before 3835 After 787	*i-STAT, Abbott POC* CG4+ CHEM8+ *Sysmex XS 1000i haematology analyser* FBC	POC in triage Process change	All ED patients except those with minor injuries	LOS (time to disposition decision) Lab 129min POC 76min (p<0.0001)	Addition of a doctor together with nurse in triage implemented at the same time as POC Not all patients had blood tests performed
Kokko [21] (2014) Tampere, Finland	6 000 Paediatric ED	Retrospective chart review	166	*Alere Afinion™ AS100 Analyzer* CRP *Hemocue* WBC	Lab vs POC	Children with infections	LOS (not specified) Lab + other* 201.5min POC only 147.5min (p<0.001) *Discharged* Lab + other* 179.5min POC only 142.5min (p=0.003)	POC cost 41.5% of the lab cost Comparison of direct costs *other included treatment or other investigations e.g. x-rays or additional blood tests
Schilling [22] (2014) Linköping, Sweden	40 000	Prospective, Observational	41	*i-STAT, Abbott POC* CG4+ CHEM8+ TnI	Lab vs POC	Patients who needed lab tests	TAT (time to test result) *Mean* difference between POC and Lab 48.5min (±28.67min) Costs saved when taking timesaving into account US$168.75/pt	Substantial methodological limitation Economic analysis Direct cost comparison POC tests US$33/pt Lab tests US$111/pt

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Gilkar [23] (2013) UK	100 000	Before & After	Before 229 After 217	*Sysmex XS 1000i haematology analyser* FBC *i-STAT, Abbott POC* "U&E" not specified	Lab vs POC Process change	Patients who only had POC tests	TAT (time to result ready) Lab 60min POC 23min LOS (arrival to discharge) Lab 208min POC 167min	Integrated the POC results into the main hospital network "a financial estimate was carried out … the cost of a FBC…was close to that for the lab... the U&E was more expensive than the lab equivalent"
Jang [24] (2013) Seoul, Korea	54 000	RCT	10 244	*Piccolo Xpress Chemistry Analyzer* and *Comprehensive Metabolic Reagent Discs, Abaxis* total protein, albumin, ALP, AST, ALT, BUN, Ca^{2+}, Cl^{-}, creatinine, K^{+}, Na^{+}, glucose, bilirubin, total CO_2	Lab vs POC	Patients who required a comprehensive metabolic panel of blood tests (LFT and U&E)	LOS (arrival to discharge) Lab 372min [IQR 217 – 1 150] POC 350min [IQR 206 – 1 002] TAT (for blood test results) Lab 55min (±22) *mean* POC 12min (±5)	Very wide IQR for both lab and POC groups Difficult to determine a clear benefit for POC because of the long times in the ED
Koehler [25] (2013) Colorado, USA	105 000	Before & After	Before 24 After 177	*i-STAT, Abbott POC* TnI	Lab vs POC	Suspected ACS	Door-to-troponin result *mean* Lab 105min POC 51min (p<0.000) LOS (arrival to discharge) Lab 290min POC 255min **(p=0.082)** Staff perceptions survey - favourably received	TAT (troponin result ready) *mean* Lab 30min POC 11min The ED protocol for chest pain changed at the same time the study was conducted. CK-MB and myoglobin were removed from the evaluation of patients with chest pain. This may have affected the *Before* comparator

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Soremekun [26] (2013) Pennsylvania, USA	60 000	Prospective, Observational	300	*i-STAT, Abbott POC* BNP CG4+ (lactate) CHEM8+ TnI	POC in triage Process change	chest pain or SOB, ≥ 40yrs; suspected infection ≥ 18yrs; older patients (>65yrs) with nontraumatic complaints Instituted at triage when increased waiting times expected	Change management (14%) – 4% up- triage – 10% down-triage 16% increased concern 6% brought into ED for rapid doctor evaluation Nurse survey "…POC results helpful in 56% of the patients"	Substantial methodological limitation Varied test choice according to patient presentation Did not assess triage accuracy prior to assessing whether the change management related to POC was appropriate Limited objective evidence of benefit
Meek [27] (2012) Melbourne, Australia	47 000	Before & After Quasi-experimental	Before 413 After 258	*Triage MeterPro and Triage profiler, Alere* CK-MB Myoglobin TnI	Lab vs POC Process change	Suspected ACS	LOS (not specified) *Admission* (%pt LOS<8h) Lab 733.5min (18.7%) POC 609.5min (28.8%) (p=0.0007) *Discharge* (%pt LOS<4h) Lab 545min (0.8%) POC 297min (28.6%) (p<0.0001) Cost-savings due to ED LOS reduction (direct costs) Staff perceptions - favourably received	Substantial methodological limitation Different treatment protocols between groups made interpretation of POC advantage difficult 3 TnI tests performed in order to rule-out ACS – 3rd test only performed in high-risk patients Lab Arrival, 6h, 10h POC Arrival, 2h, 6h
Birkhahn [28] (2012) New York, USA	70 000	Before & After	Before 676 After 804 Lab 408 POC 396	*Triage MeterPlus, Biosite* CK-MB Myoglobin TnI	Lab vs POC Process change	Suspected ACS	LOS (total time in the ED) *mean* Lab 14h POC 10.3h (p=0.008) After Lab + process 8.6h Admissions decreased from 113 to 80 pts per month with POC (p<0.00001)	Simultaneously instituted a rapid acute cardiac evaluation pathway which included POC Only approximately half of patients enrolled after the process change had a POC TnI performed too.

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Birkhahn [29] (2011) New York, USA	70 000	Prospective, Observational	151	*Triage MeterPlus, Biosite* CK-MB Myoglobin TnI	Lab vs POC	Suspected ACS At presentation (lab and POC) Then 2h (POC) Or 6h (lab)	TAT (to 2nd troponin result) Lab 660min POC 270min (p<0.0001) Economic analysis Cost-effectiveness – direct costs – incremental cost Costs US$7.40 for each hour of patient care saved	Substantial methodological limitation Difference between lab and POC processes Repeat lab blood tests done at 6h and POC blood tests done at 2h
Bradburn [30] (2011) UK	Multi-centre RATPAC	RCT *Emergency Medicine Journal*	2243	*Siemens Stratus CS analyser* CK-MB Myoglobin TnI	Lab vs POC Process change 90min rule-out instead of 12h rule-out which was the standard of care	Suspected ACS	Economic analysis Cost-effectiveness – direct cost comparison Inter-hospital variation	The effect of POC testing varied significantly between hospitals
Fitzgerald [31] (2011) UK	Multi-centre RATPAC	RCT *Academic Emergency Medicine Journal*	2 243	*Siemens Stratus CS analyser* CK-MB Myoglobin TnI	Lab vs POC Process change 90min rule-out instead of 12h rule-out which was the standard of care	Suspected ACS	Economic analysis Higher ED, intensive care and cardiac care interventions in POC group Incremental cost QALY Standard care (lab) more cost-effective	Included costs of staff and tests but did not adjust staff cost for time saved in the ED Looked at length of in-hospital stay
Goodacre [32] (2011) UK	Multi-centre RATPAC	RCT *Health Technology Assessment Journal*	2 243	*Siemens Stratus CS analyser* CK-MB Myoglobin TnI	Lab vs POC Process change 90min rule-out instead of 12h rule-out which was the standard of care	Suspected ACS	Economic analysis As per findings in *Heart* and *Academic Emergency Medicine journals* POC was GBP211/pt more expensive than the lab Patients in POC group rated care favourably	Reduce the need for hospital admission Unlikely to be cost-effective Changed troponin diagnostic threshold for admission during the study period

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Goodacre [33] (2011) UK	Multi-centre RATPAC	RCT *Heart Journal*	2 243	*Siemens Stratus CS analyser* CK-MB Myoglobin TnI	Lab vs POC Process change 90min rule-out instead of 12h rule-out which was the standard of care	Suspected ACS	Effect of POC on discharge from ED Use of intensive care and cardiac treatments Subsequent re-attendance at and/or re-admission to hospital and major adverse events	Reduced the need for hospital admission Increase in coronary care admissions in POC group Very low adverse event rate Changed troponin diagnostic threshold for admission during the study period
Lee [34] (2011) Seoul, Korea	Multi-centre	RCT	2 323	*Piccolo Xpress Chemistry Analyzer* and *Comprehensive Metabolic Reagent Discs, Abaxis* protein, ALP, AST, albumin, ALT, BUN, Ca^{2+}, total CO_2, Cl^-, creatinine, K^+, Na^+, bilirubin, glucose	Lab vs POC	Patients who required chemistry lab tests	Door-to-clinical decision time Lab 85min POC 46min (p<0.0001) TAT Lab 55min POC 14min (p<0.0001)	Door to decision time, not necessarily patient *disposition* Distribution of clinical decisions in POC cohort 52.8% disposition 38.5% treatment 11.4% additional laboratory tests 29.0% additional radiologic tests 24.9% referral
Mogensen [35] (2011) Kolding Sygehus, Denmark	9 000	RCT	222	*AQT-90 Flex, Radiometer Medical ApS* CRP D-dimer TnI	Lab vs POC	Suspected DVT Suspected ACS Acute appendicitis (AA) Acute Bacterial Infection (ABI)	Blood sample to clinical decision time DVT, ACS, AA No difference ABI confirmed Lab 7h33min POC 4h38min (p=0.009) If no ABI, no time difference	Substantial methodological limitation Different tests for different pathologies Endpoints nebulous Suspected ACS required 3 troponin tests. Second and third troponins performed at the lab not POC

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Walter [36] (2011) Homburg, Germany	Not disclosed	Prospective, Observational Historical controls	200	*Hemochron Junior, ITC* INR *PocH-100i, Roche* CBC *Reflotron Plus system* GGT, amylase, glucose	Lab vs POC Pneumatic system (lab)	Stroke patients	Door-to-therapy decision time *mean* Lab 84min (±26) POC 40min (±24) (p<0.001) TAT Lab 51min (±15) POC 11.7min (±5.1) (p<0.001)	Abnormal POC test meant waiting for formal lab result POC done in the CT scanner suite and not the ED
Loten [37] (2010) Newcastle, Australia	Multi-centre	RCT	912	*i-STAT, Abbott POC* TnI	Lab vs POC	Suspected ACS	LOS (arrival to "physical departure" from ED) Lab 7.2h POC 6.4h **(p=0.063)** 48min difference Only 45.4% of patients in the POC group received a POC TnI Per-protocol analysis of POC and lab showed no significant difference	Substantial methodological limitation The doctors did not use the POC machine in the week assigned to POC – and if they did – they waited for the lab test for confirmation Selection bias – POC done for patients less likely to need hospitalisation 91% of POC TnI were discharged 70% of both methods used were discharged 67% of lab TnI patients discharged
Lee-Lewandrowski [38] (2009) Massachusetts, USA	84 000	Before & After	Before 252 After 211	*Biosite Triage, Biosite* D-dimer	Lab vs POC Stat Lab	Suspected VTE	TAT (blood draw to result) Lab 120min POC 25min LOS (not specified) Lab 6.2h POC 5.88h (p=0.026)	13.8% decrease in admission rate 7.3% increase in discharge from ED 6.4% increase in patients admitted for observation only (p=0.005) Availability of the POC test may have influenced disposition decisions (based on above findings) 6% increase in ED visits during study period

Author (year) Location	**ED census**	**Study design**	**No of patients**	**Which POC tests?** *company* italicized	**Methodology**	**Pathology**	**Outcome Measure Main Findings**	**Comments / Limitations**
Rizos [39] (2009) Heidelberg, Germany	Not disclosed	Prospective, Observational	48	*Coaguchek XS, Roche* INR	Lab vs POC	Stroke patients	Time to INR result *Mean* time gain 28min with POC	INR result as a pre-requisite for thrombolysis
Ryan [40] (2009) USA	Multi-centre	RCT	2 000	*i-STAT, Abbott POC* TnI	Lab vs POC	Suspected ACS	LOS (time to disposition) *Admission* Lab 5.50h POC 5.35h *Discharge* Lab 4.62h POC 4.50h	Variable results depending on the centre – LOS was decreased in the POC arm at site 3. Admission rate 72.15% TnI taken at presentation, 90min, 180min and 360min If patients need to have all the blood tests – it would only be the effects of the final test that have any impact
Lewandrowski [41] (2008) Massachusetts, USA	79 000	Before & After	Before 197 After 286	*Biosite Triage, Biosite* Rapid drugs of abuse testing system	Lab vs POC Urine Stat lab	Drugs of abuse	TAT (time collected to results available) *mean* Lab 108min POC 33min LOS (not specified) *median* Lab 8h POC 7h (p=0.0017)	Brief economic analysis utilising direct costs. "POC option is cost-effective" if "the 0.65 beds that were made available for new patients is worth the $92 122 per year in incremental cost to the laboratory"
Renaud [42] (2008) Paris, France	43 000	RCT	860	*Stratus CS System* TnI	Lab vs POC	Suspected ACS	Time to anti-ischaemic treatment (TAIT) Lab 198min POC 151min (p<0.001) LOS Lab 307min POC 309min **(p=0.99)**	Patients who required a second TnI were analysed separately TAIT still significantly different but LOS not significantly different between lab and POC

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Singer [43] (2008) New York, USA	75 000	Before & After	Before 3869 After 4018	*BeckmanCoulter* CBC *Clinitek* dipstick urinalysis *i-STAT, Abbott POC* TnI *Nova StatProfile, Nova Biomedical* Na^+, K^+, Cl^-, HCO_3, BUN, glucose, creatinine, Ca^{2+} *Quidel* β-HCG	Lab vs POC Process change Stat lab within the central lab Pneumatic system (lab)	Patients who required lab tests	LOS (triage to left ED) *Overall* Lab 298min POC 262min (p<0.001) *Admission* Lab 468min POC 406min (p<0.001) *Discharged* Lab 234min POC 205min (p<0.001)	Admission rate 19.6-20.6% Confounder – Hired extra staff
Hsiao [13] (2007) Connecticut, USA	28 000 Paediatric ED	RCT	225	*i-STAT, Abbott POC* CG4+ CHEM8+	Lab vs POC	Children who were not critically ill *and* required lab tests that the POC device was capable of performing	LOS (total time in ED) Lab 224min POC 185.5min (p<0.001) TAT Lab 70min POC 5min	Admission rate 36.9%
Singer [44] (2005) New York, USA	75 000	Before & After	Before 232 After 134	*Stratus, Dade Behring Inc.* TnI	Lab vs POC	Suspected ACS	LOS (triage until left ED) Lab 7.1h POC 5.2h TAT Lab 83min POC 14.8min	Only looked at admitted patients

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Lee-Lewandrowski [45] (2003) Massachusetts, USA	70 000	Before & After	369	*Abbott Medisense PCX system* Glucose *Bayer Clinitek 50* Urine dipstick *Fisher Scientific* β-HCG *Spectral Diagnostics* CK-MB TnI	Lab vs POC Process change Stat Lab with POC testing	Patients who needed glucose, urine dipstick, β-HCG, cardiac markers	LOS (time to disposition) *Mean* Lab 389min POC 347min (p=0.006) TAT (lab arrival to result) Lab 59.5min POC 8min Staff perceptions - favourably received	Dedicated personnel for stat lab Admission rate 43.9% No change with POC glucose – compared U&E combined with glucose *before* to glucose only *after* therefore results were not comparable and removed from the analysis
Plerhoples [46] (2003) New York, USA	68 000	Before & After Retrospective analysis	Before 991 After 1 103	*Icon II HCG, Beckman-Coulter Inc.* β-HCG	Lab vs POC Urine	Patients who needed a pregnancy test	LOS (triage to disposition) *Mean* LOS difference With β-HCG 50.85min No β-HCG 36.8min **(p=0.33)** Test utilisation decreased with POC availability. Staff perceptions - favourably received	Substantial methodological limitation ED volume of patients rose by 6% and overall LOS for all patients increased during study period LOS only decreased if patient had abdo pain and positive β-HCG High expectations for improvement in LOS – they wanted to detect a 70min difference in median LOS
Kendall [47] (1999) Bristol, UK	50 000	RCT [48]	1 728	*i-STAT, Abbott POC* 6+ EG6+ G3+	Lab vs POC	Patients who required lab tests	Economic analysis Replacement of Lab with POC will reduce costs Supplementary use will increase costs	Non-fiscal benefits reported e.g. earlier decision-making

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Murray [49] (1999) Winnipeg, Canada	41 000	RCT	180	*NOVA 16 CRT™ and the Spectral™ Cardiac STATus™* creatinine, glucose, Na^+, K^+, Cl^-, total CO_2, BUN, Hct, CK-MB, myoglobin	Lab vs POC	Only enrolled patients that were suitable to have POC tests	LOS (triage to disposition) Lab 4h22min POC 3h28min (p=0.02) *Admitted* Lab 6h07min POC 4h46min (**p=0.25**) *Discharged* Lab 4h17min POC 3h05min (p<0.001)	75% of patients were discharged from the ED The authors acknowledged that "a more accurate representation of the time saved with (POC) might have been demonstrated if LOS had been defined as the time from admission to the ED to the time of decision-making" as opposed to the time the patient was transferred out of the ED.
van Heyningen [50] (1999) Liverpool, UK	Not disclosed	Prospective, Observational *Letter to the Editor*	513 Lab 383 POC 130	*NOVA 14 whole blood electrolyte analyser* Not specified	Lab vs POC Process change Lab evaluated with and without pneumatic system	Patients who required lab tests	TAT Lab 58min Lab (pneumatic) 49min POC 5min (p<0.05) LOS (total waiting time) Lab 212min Lab (pneumatic) 258min POC 219min	Substantial methodological limitation Not a full research manuscript Confounders: Reduced ward bed availability Delays associated with other investigations (e.g. x-rays) Direct costs were similar
Kendall [48] (1998) Bristol, UK	50 000	RCT	1 728	*i-STAT, Abbott POC* 6+ EG6+ G3+	Lab vs POC Pneumatic system (lab)	Patients who required lab tests	LOS (total time in ED) *mean* Lab 188min POC 193min **(p=0.30)** Time to decision improved 74min earlier (p<0.0001) (haematological tests) 86min earlier (p<0.0001) (chemistry tests) 21 min earlier **(p=0.09)** (ABG)	Substantial methodological limitation Utility based on doctor opinion in interview conducted after disposition Admission rate 85% Pneumatic chute system was quick "…the availability of blood test results is not the rate limiting step for these patients…"

Author (year) Location	ED census	Study design	No of patients	Which POC tests? *company* italicized	Methodology	Pathology	Outcome Measure Main Findings	Comments / Limitations
Parvin [51] (1996) Missouri, USA	60 000 (calculated based on 15 000 visits in 13-week study period)	Before & After Three periods: Control Experimental Control	Before 2918 After 2067	*i-STAT, Abbott POC* EC6+	Lab vs POC Pneumatic system (lab)	Patients who required at least one of the chemistry lab tests	LOS (triage to discharge) Lab 201min POC 209min POC *and* lab 1631 patients 212min POC only 91 patients 164min	Substantial methodological limitation Vast majority (1631/1722) of the POC group had at least one lab test performed therefore they were not a true POC group. Their LOS would reflect the TAT of the lab Admission rate 55-56% No difference in LOS if the patient was admitted or discharged
Sands [52] (1995) California, USA	38 000	Prospective, observational	960	*i-STAT, Abbott POC* EC6+	Lab vs POC	Patients who required at least one of the chemistry lab tests	TAT (lab arrival to result) *Mean* "potential" timesaving Na^+, K^+, Cl^- 43min Glucose, BUN 44min Hct 31min	Substantial methodological limitation Utility based on doctor opinion in interview conducted after disposition Staff blinded to POC results Collected times retrospectively Result affected disposition decision or treatment in 17.3% patients based on doctor opinion
Tsai [53] (1994) Pennsylvania, USA	Not reported	Prospective, observational Time-motion	210	*i-STAT, Abbott POC* EC6+	Lab vs POC Pneumatic system (lab)	Patients who required at least one of the chemistry or CBC lab tests	TAT (time to result available) *mean* POC 8min Lab 59min Therapeutic TAT 1h25min Direct costs comparison POC from $14.37 to $16.67 Lab $11.14+$9.48 = $20.62	Substantial methodological limitation Utility based on doctor opinion in interview conducted after disposition Staff blinded to POC results 19% patients "earlier therapeutic action" based on doctor opinion Decision to admit based on blood test results in 28.1% of cases based on doctor opinion

Abbreviations used in Supplementary Table 1

♀	female
♂	male
6+	an i-STAT cartridge that analyses Na^+, K^+, Cl^-, glucose, urea, Hct and Hb (aka EC6+)
AA	acute appendicitis
Abdo	abdominal
ABG	arterial blood gas
ABI	acute bacterial infection
ACS	acute coronary syndrome
ALP	alkaline phosphatase
ALT	alanine aminotransferase
AST	aspartate aminotransferase
β-HCG	beta human chorionic gonadotropin
BNP	brain natriuretic peptide
BUN	blood urea nitrogen (aka urea)
Ca^{2+}	calcium
CBC	complete blood count (aka FBC)
CG4+	an i-STAT cartridge that analyses lactate, pH, partial pressure of carbon dioxide, partial pressure of oxygen, total carbon dioxide, HCO_3, base excess, and oxygen saturation
CG8+	an i-STAT cartridge that analyses pH, partial pressure of carbon dioxide, partial pressure of oxygen, total carbon dioxide, HCO_3, base excess, oxygen saturation, Na^+, K^+, ionised Ca^{2+}, glucose, Hct and Hb
CHEM8+	an i-STAT cartridge that analyses Na^+, K^+, Cl^-, total carbon dioxide, ionised Ca^{2+}, glucose, urea, creatinine, Hct, Hb and the anion gap
Cl^-	chloride
CI	confidence interval
CK	creatine kinase
CK-MB	creatine kinase, myocardial bound isoenzyme
CO_2	carbon dioxide
CRP	c-reactive protein
DKA	diabetic ketoacidosis
DVT	deep vein thrombosis
EAT	early assessment team
EC6+	an i-STAT cartridge that analyses Na^+, K^+, Cl^-, glucose, urea, Hct and Hb (aka 6+)
ED	emergency department
EG6+	an i-STAT cartridge that analyses Na^+, K^+, pH, partial pressure of carbon dioxide, partial pressure of oxygen, total carbon dioxide, HCO_3, base excess and oxygen saturation
FBC	Full blood count (aka CBC)
G3+	an i-STAT cartridge that analyses pH, partial pressure of carbon dioxide, partial pressure of oxygen, total carbon dioxide, HCO_3, base excess and oxygen saturation
GGT	gamma glutamyltransferase
GI	gastrointestinal
h	hour
Hb	haemoglobin
HCO_3	bicarbonate
Hct	haematocrit
INR	international normalised ratio
IQR	inter-quartile range
i-STAT	i-STAT point-of-care system
K^+	potassium
Lab	laboratory
LFT	liver function tests
LOS	length of stay in the ED unless otherwise specified
MI	myocardial infarction
min	minute
Na^+	sodium
p	p-value – not significant if **bold (i.e. p≥0.05)**
pCO_2	partial pressure carbon dioxide
pH	percentage hydrogen
pO_2	partial pressure of oxygen
POC	point-of-care
pt/s	patient/s
QALY	quality-adjusted life-year
RATPAC	randomized assessment of treatment using panel assay of cardiac markers trial
RCT	randomised, controlled trial
SOB	shortness of breath
Stat lab	A smaller laboratory, usually found within the ED, capable of performing an abbreviated battery of laboratory tests
TAIT	time to anti-ischaemic treatment
TAT	turnaround time
TnI	Troponin I
TnT	Troponin T
U&E	urea (aka BUN) and electrolytes
UK	United Kingdom
USA	United States of America
VTE	venous thromboembolism
WBC	white blood cell count
yrs	years

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