PRIORITIZATION OF CRITICALLY UNWELL CHILDREN IN LOW RESOURCE PRIMARY HEALTHCARE CENTRES IN CAPE TOWN, SOUTH AFRICA

by

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DECLARATION

I, Bhakti Hansoti, hereby declare that the work on which this thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university. I authorise the University to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever. I further declare the following:

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The evolution of this thesis and the SCREEN program would not have been possible without the divine grace of God and the following people to whom I am eternally grateful.

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ABSTRACT

Background: Every day, sick children die from time sensitive preventable illnesses. Due to an inadequate number of trained healthcare workers and high volumes of children presenting to Primary Healthcare Centres (PHC), waiting times remain high and often result in significant delays for critically ill children. Delays in the recognition of critically unwell children are a key contributing factor to avoidable childhood mortality in Cape Town, South Africa.

Methodology: A stepped implementation approach was undertaken to develop and evaluate a context-appropriate prioritization tool to identify and expedite the care of critically ill children PHC in Cape Town, South Africa. *Aim 1:* To conduct a systematic review of paediatric triage and prioritization tools for low resource settings in order to evaluate the evidence supporting the use of these tools. *Aim 2:* To perform an exploratory study, to identify barriers to optimal care for critically ill children in the pre-hospital setting in Cape Town, South Africa. *Aim 3:* To develop an implementable context-appropriate tool to identify and expedite the care of critically ill children in PHC in the City of Cape Town, South Africa. *Aim 4:* Evaluate the reliability of this tool compared to established triage tools currently used in this setting. *Aim 5:* Evaluate the impact of implementing this tool, on waiting times for children presenting for care to PHC. *Aim 6:* Evaluate the effectiveness of this tool post real-world implementation in identifying and expediting the care for critically ill children.

Findings: Post real world implementation SCREEN was able to significantly reduce waiting times in PHC for critically ill children. Compared to pre-SCREEN implementation, post-SCREEN the proportion of critically ill children who saw a PN within 10 minutes increased tenfold from 6.4% (pre-SCREEN) to 64% (post-SCREEN) ($p<0.001$). SCREEN is also able to accurately identify critically ill children, in an audit of 827 patient-charts SCREEN had a sensitivity of 94.2% and a specificity of 88.1% when compared to IMCI.

Interpretation: The SCREEN program when implemented in a real-world setting has shown that it can effectively identify and expedite the care of critically ill children in PHC.

Funding: This study is funded by the Fogarty Global Health Fellowship Program (R25 TW009340) and the Thrasher Research Fund Award (# 12783).

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LIST OF ABBREVIATIONS

ANOVA	Analysis of variance
CI	Confidence interval
DH	District Hospital
ED	Emergency department
EMS	Emergency Medicine Services
EN	Enrolled Nurse
ETAT	WHO Emergency Triage and Assessment Tool
EQUATOR	Enhancing the Quality and Transparency of Health Care Research
GRADE	Grading of Recommendations Assessment, Development and Evaluation
HCW	Health Care Workers
HREC	Human Research Ethics Board
IMCI	Integrated Management of Childhood Illnesses
IRB	Institutional Review Board
PEWS	Paediatric Early Warning Score
PICU	Paediatric Intensive Care Unit
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
PSTATS	Paediatric South African Triage Scale
PTCS	Pathways to Care Study
PHC	Primary Healthcare Centres
PN	Professional Nurse
RCWMCH	Red Cross Children's Hospital
SA	South Africa
SCREEN	Sick Children Require Emergency Evaluation Now
UCT	University of Cape Town
UNICEF	United Nations Children's Fund
WHO	World Health Organization

GLOSSARY

Action Research methodology - Action research is either research initiated to solve an immediate problem or a reflective process of progressive problem solving led by individuals working with others in teams or as part of a "community of practice" to improve the way they address issues and solve problems.

Acuity - Acuteness; the level of severity of an illness.

Emergency Medical Services - also known as ambulance services or paramedic services, are dedicated to providing out-of-hospital acute medical care, transport to definitive care, or transport to patients with illnesses and injuries which prevent the patient from transporting themselves.

Enrolled Nurse - Practices under the direction and delegation of a registered nurse or nurse practitioner to deliver nursing care. They are graduates of a two-year nursing program and in the PHC have the specific task of performing basic vital signs, weight assessment, and basic diagnosis using IMCI.

High resource setting – Commonly refers to healthcare settings in developed countries.

Implementation-Effectiveness hybrid study design - An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation. There are three established study designs: (1) testing effects of a clinical intervention on relevant outcomes while observing and gathering information on implementation; (2) dual testing of clinical and implementation interventions/strategies; and (3) testing of an implementation strategy while observing and gathering information on the clinical intervention's impact on relevant outcomes.

Implementation Stages - Conducting stage appropriate activities is necessary for successful change, using this framework in Step 1 ("exploration") informal study allowed us to broadly identify current implementation gaps within the clinic system, in step 2 ("Installation") a locally-informed approach was used to develop the intervention and identify implementation drivers, and in step 3 ("initial implementation") an implementation trial was conducted to refine/adjust the developed intervention further.

Low resource setting - Low-resource settings are typically characterized by a lack of funds to cover health care costs, on individual or societal basis, which leads to one or all of the following: limited access to medication, equipment, supplies, devices.

Low and Middle Income Countries - For the current 2017 fiscal year, low-income economies are defined as those with a GNI per capita, calculated using the World Bank Atlas method, of $1,025 or less in 2015; lower middle-income economies are those with a GNI per capita between $1,026 and $4,035; upper middle-income economies are those with a GNI per capita between $4,036 and $12,475; high-income economies are those with a GNI per capita of $12,476 or more.

Modified Delphi Methodology - The Delphi method is a structured communication technique or method, originally developed as a systematic, interactive forecasting method which relies on a panel of experts. The experts answer questionnaires in two or more rounds in person, the modified Delphi method in this study used a combination of in-depth interviews and focus group discussion to facilitate data capture.

Primary Healthcare Centre - sometimes referred to as public health centres, are city-owned health care facilities in Cape Town, South Africa. They are essentially nurse run clinics. Services includes preventative health maintenance (immunization, growth monitoring, and well-baby checks) as well as acute curative care for specific complaints.

Prioritize – To designate or treat (something) as more important than other things.

Professional Nurse – Also known as a registered nurse, are graduates of a four-year nursing degree and are registered with the South African Nursing Council, they are able to practice without supervision in the PHC.

Queue Marshall – A lay person designated to control the order of individuals that present to the clinic.

Reliability - The degree to which the result of a measurement, calculation, or specification can be depended on to be accurate, in simple terms, describes the repeatability and consistency of a test.

Triage - The assignment of degrees of urgency to wounds or illnesses to decide the order of treatment of a large number of patients or casualties.

Validity - Defines the strength of the final results and whether they can be regarded as accurately describing the real world.

CHAPTER 1: INTRODUCTION

Every day, sick children die from time sensitive preventable illnesses. In 2015, 5.9 million children under the age of five died; of these, over 98% of deaths occurred in Low and Middle Income Countries (LMIC).[1, 2] Most of these deaths (70%) were preventable or treatable by access to simple, affordable interventions.[3] Delays in the identification and treatment of critically ill children have been shown to increase under-five mortality by up to 40%.[4] A study that focused on the quality of hospital care for sick children in LMIC identified that the quality of care delivered to critically unwell children was inadequate, with more than half the children under-treated or inappropriately managed.[5] Adverse factors in case management, including inadequate assessment, inappropriate treatment, and inadequate monitoring occurred in 76% of inpatient children.[5, 6]

The top three causes of death in children globally are pneumonia, diarrhoea and new-born illnesses (Figure 1).[7]

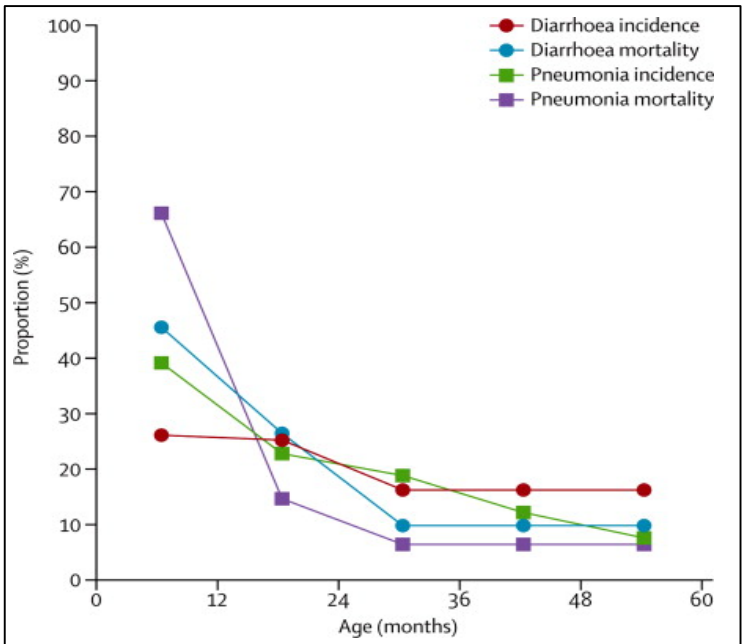

Figure 1. Distribution of cases of, and deaths from, diarrhoea and pneumonia in children aged 0–4[7] years.

These are also the top three presenting complaints of children that present for care in the primary healthcare centres (PHC) setting in low resource settings.[8] Acknowledging the need to identify and treat these conditions within the PHC setting, the World Health Organization (WHO) developed an integrated, assessment and treatment strategy for the out-patient clinical care in low resource settings. The

Integrated Management of Childhood Illnesses (IMCI) was created by the WHO and United Nations Children's Fund (UNICEF) to improve the performance of trained health care workers (HCW) in managing sick children. IMCI is an 80-page booklet that combines lessons from disease specific control programs to develop a syndrome based approach to managing childhood illnesses in primary healthcare settings.[9, 10] Each clinical syndrome has a severity assignment component which determines the treatment strategy necessary for that particular case. IMCI has been implemented in over 100 countries since its inception in 1996.[10]

However, the case management process requires a trained HCW (professional nurse equivalent) and takes between 5-7 minutes to complete. Owing to inadequate numbers of trained HCWs and the large volumes of children presenting to PHC in low resource settings, waiting times for them to be seen remain long, resulting in significant delays for the management of critically ill children.

Targeting delays in the recognition of critically unwell children is the first step to addressing avoidable early childhood mortality.[11] In Cape Town, South Africa (and in many other low resource settings), there is a paucity of tertiary care facilities. Care is funnelled from outpatient centres to district hospitals that refer children tertiary care facilities where paediatric emergency care and critical care experts are available. Furthermore, given the lack of local infrastructure (public transportation, road networks and financial restrictions etc.), the majority of sick children first present to the nearest healthcare facility (most commonly a PHC) for care. [12] Thus, PHC see large volumes of patients daily who present with a variety of urgent and non-urgent conditions. Furthermore, PHC are often staffed by nursing professionals with limited critical care/resuscitation experience. Owing to resource constraints, no formal triage tool is currently used in the primary healthcare setting in Cape Town, even though this is where 90% of health care is delivered. In addition, 20% of the children who present to the PHCs are already critically unwell and warrant immediate referral/transfer to a higher level of care.[12]

PREMISE OF STUDY

This study was born from the initial findings of the "Pathways to Care Study" (PTCS), a 12-month review of cases in the Paediatric Intensive Care Unit (PICU) and Emergency Centre at the Red Cross Children's Hospital (RCWMCH) in Cape Town. The study spanned the public-sector health care services for children in Cape Town, which consist primarily of 109 nurse run clinics, 36 doctor run office hours only community day centres, nine doctor run 24-hour community health centres, eight district and regional hospitals and two tertiary care hospitals.

The objective of the PTCS was to sample a representative population of critically ill children in this Metropolitan area. The study enrolled 282 children, aged <13 years, admitted as emergencies to the PICU at RCWMCH, or who died in the emergency centre at RCWMCH, or died at identified facilities in the Cape Town Metropolitan West area (the main referral region for the RCWMCH). Informed consent from the parents was obtained to conduct a qualitative interview and review the medical charts for the children that were enrolled. Data abstraction, from the medical chart, focused on the pathway of care of these children, medical records from the onset of the illness episode until PICU admission or death were reviewed by the study team. The collected data underwent expert clinical review to identify preventable failures in the care of the children that contributed to unnecessary morbidity and mortality. The key finding of that study was that there was potentially avoidable severity of illness in 185 (74%) of children, and avoidable death prior to PICU admission in 17 of the 30 children (56.7%).[12] Preliminary analyses suggested potential areas for interventions to improve the recognition and management of children with acute illness with in the City of Cape Town Metropole: these are the subject of on-going work in the city.

The overall premise of this thesis was to focus on one of the identified pathways highlighted as a priority area in the PTCS: “Prioritization of critically unwell children (i.e., non-trauma) in non-emergency areas in community-based settings”. Thus the focus of this PhD is to develop a prioritization tool that can aide in the early identification of critically ill children, so that their care can be commenced as early as possible. This will allow critically ill children with acute life-threatening conditions to receive more timely treatment within the PHC setting and permit the prompt transfer of these patients to a higher level of care.

AIM

The overall aim of this thesis was to develop, implement, and evaluate a prioritization tool for Primary Healthcare Clinics (PHCs) in South Africa (SA).

OBJECTIVES

1. To conduct a systematic review of paediatric triage and prioritization tools available to use in low resource settings, in order to evaluate the evidence supporting the use of these tools.
2. To perform an exploratory study, to identify barriers to optimal care for critically ill children in the pre-hospital setting in Cape Town, South Africa.
3. To develop a implementable context-appropriate tool to identify and expedite the care of critically ill children in low resource PHC.

4. Evaluate the reliability of this tool compared to established triage tools currently used in this setting.
5. Evaluate the impact of implementing this tool, on waiting times for children presenting for care to PHC.
6. Evaluated the effectiveness of this tool post real-world implementation in identifying and expediting the care for critically ill children.

ETHICS APPROVAL

The study was approved by the Faculty of Health Sciences Research Ethics Committee, University of Cape Town (UCT HREC 401/2013); and the Johns Hopkins School of Medicine Institutional Review Board (NA_00088758), as well as the City of Cape Town facilities approval committee. (see **Appendix 1 - 4)**

FUNDING

This study was funded by the Fogarty Global Health Fellowship Program (R25 TW009340) and the Thrasher Research Fund Award (# 12783).

REPORTING STRUCTURE

Each of the six objectives were executed as individual studies and are presented in the following chapters. Three chapters include a peer-reviewed publication that reports the methodology and findings from the individual studies relevant to the chapter's objective. The main findings of each study in the chapter as well as the premise for conducting the study are discussed, and the accompanying publication for each of these three chapters is included. This is followed by a detailed discussion of the study, explaining the specific methods, reporting on further unpublished results. Three chapters do not include a peer-peer reviewed publication; here each individual study is presented with a background, methodology, results, discussion and conclusion section. Chapter 8 is the concluding chapter of this thesis and brings together the findings of all the individual studies and presents these in terms of the overall thesis aim, thus concluding the thesis' findings in a single discussion.

CHAPTER 2: REVIEW OF PAEDIATRIC TRIAGE TOOLS

Reference: Hansoti B, Jenson AM, Keefe D, Ramirez SS, Anest T, Twomey M, Lobner K, Kelen G, Wallis L. Reliability and validity of paediatric triage tools evaluated in low resource settings: a systematic review. BMC Paediatrics. DOI: 10.1186/s12887-017-0796-x

MAIN FINDINGS

- There is a paucity of studies evaluating the reliability and validity of triage tools in low resource settings. Furthermore, there is a lack of standardized methodology to evaluate triage tools make comparison across tools difficult.
- The majority of triage tool studies were conducted in tertiary care centres using physicians or trained triage nurses. IMCI was only tool that had reliability and validity studies conducted in a PHC setting.

DECLARATION FROM AUTHOR

The following co-authors contributed to the paper: Dr. Alexander Jenson, Dr. Devin Keefe, Dr. Sarah Stewart de Ramirez, Dr. Trisha Anest, Dr. Michelle Twomey, Ms. Katie Lobner, Prof. Gabor Kelen, and Prof. Lee Wallis.

In the case of Chapter 3, contribution by authors to the work was as follow:

Nature of Contribution:

- BH and LW came up with the original idea; BH and KL designed and executed the search strategy; AJ, DK, TA, MT, SSR and BH all participated in data acquisition, analysis, and interpretation of the data for the work. BH, AJ and DK together drafted the work and all authors contributed to revising it critically for important intellectual content. All authors approved the final published version and agreed 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.

- **Extent of contribution**: BH: 65%; AJ and DK together: 15%; TA, MT, SSR, KL, GK together: 10%; LW: 10%

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Signed: Bhakti Hansoti

DECLARATION BY CO-AUTHORS

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Signed by candidate Signature Removed

Prof. Lee A. Wallis January 29th 2017

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Prof. Ian Maconochie January 29th 2017

INTRODUCTION TO TOPIC

In the PHC setting sick and injured patients can present at any time, and HCW are often faced with more patients than they have resources to deal with; thus, in these settings some form of prioritization for care is required. In emergency care settings, the process of triage is used to prioritise patients into certain acuity categories, which then dictates their place in the queue. The fundamental purpose of triage in a context where, demand exceeds the capacity to meet that demand, is to be able to do the "most for the most". The idea behind triage is to rapidly identifying the sickest patients in the crowd, to ensure timely treatment which will increase the likelihood of survival.

The terms prioritization strategy, triage and screening are often used interchangeably. Triage is a core component of emergency medical care, and is intended to provide a systematized approach to optimize prioritization of care, when there are more patients than providers and/or resources. Modern triage tools often assign patients to one of four or five categories depending on the acuity of the patient and/or the resources required to deliver care.[13, 14] A screening or prioritization tool has a binary outcome separating sick from not sick. The development and refinement of emergency centre (EC) triage tools advanced rapidly in the 1990s, with a variety of systems created, validated, and subsequently implemented in routine practice. Over the past decade, experts in emergency care working in LMICs have begun to either adapt existing triage tools[15, 16] or advance new tools or methods for conducting triage in these settings.[17, 18] Assessing the relative reliability and validity of these new tools and methods is essential for healthcare workers and policy makers, as they seek to improve their triage systems.

MOTIVATION FOR CONDUCTING THE STUDY

Prior to developing a screening or triage tool for use in the PHC setting, it is imperative to develop a wider understanding of the types of triage tools already available for low resource environments, the characteristics of the various triage tools, and the research methodology utilized to evaluate triage tools within this setting.

The objective of this study was to guide the development of a screening tool for the PHC setting in Cape Town. To date eight systematic reviews have evaluated triage tools for high resource environments (Table 1), however, they are limited owing to their lack of inclusion of either paediatric patients or studies conducted in low resource settings.

Table 1: Overview of triage tool systematic reviews to date

Reference	Key Findings	Limitations
Lidal IB, Holte HH, Vist GE. Triage systems for pre-hospital emergency medical services-a systematic review. *Scandinavian journal of trauma, resuscitation and emergency medicine.* 2013 Apr 15;21(1):28.[19]	The search yielded 11,011 unique references, of which 120 had full text review, but none fulfilled the inclusion criteria.	Only pre-hospital emergency medical services
Mirhaghi A, Heydari A, Mazlom R, Ebrahimi M. The reliability of the Canadian Triage and Acuity Scale: meta-analysis. *North American journal of medical sciences.* 2015 Jul 1;7(7):299.[20]	Only 14 studies included, identified that 50% of patients are incorrectly triaged. Furthermore, agreement was lower in paediatric versions.	The Canadian Triage Tool was solely used, which is designed for high resource settings.
Ebrahimi M, Heydari A, Mazlom R, Mirhaghi A. The reliability of the Australasian Triage Scale (ATS): a meta-analysis. World *J Emerg Med*. 2015 Jan 1;6(2):94-9. [21]	Only six studies included. The Pooled coefficient for the ATS was 0.428 (95%CI 0.340–0.509).	Only includes ATS, designed for high resource settings.
Farrohknia N, et al. Emergency department triage scales and their components: a systematic review of the scientific evidence. *Scandinavian journal of trauma, resuscitation and emergency medicine*. 2011 Jun 30;19(1):42.[22]	From 2776 abstracts identified, only 20 articles were included. GRADE criteria was used, 11 articles were low quality, and the remaining 9 as medium quality,	Only studies from high income countries are included in the review.
Christ M, Grossmann F, Winter D, Bingisser R, Platz E. *Modern Triage in the Emergency. emergency.* 2009 Sep(2249).[23]	Overall they conclude that 5-level triage instruments are the gold standard.	A systematic approach was not undertaken
FitzGerald G, Jelinek GA, Scott D, Gerdtz MF. Republished paper: Emergency department triage revisited. *Postgraduate medical journal.* 2010;86(1018):502-8.[24]	Reports significant inconsistencies in triage assessment determining the urgency of any individual patient	A systematic review approach was not undertaken
van Veen M, Moll HA. Reliability and validity of triage systems in paediatric emergency care. *Scandinavian journal of trauma, resuscitation and emergency medicine.* 2009 Aug 27;17(1):38.[25]	This study rated the reliability of the Emergency Severity Index as highest. Exclusively covered paediatric patients.	Only studies from high income countries are included in the review.
Pourasghar F, et al. Kappa agreement of emergency department triage scales; a systematic review and meta-analysis. *Journal of Clinical Research & Governance.* 2014 Oct 25;3(2):124-33.[26]	Five-level scales are more reliable in triaging patients in the emergency department than others (pooled kappa: 0.53, 95% CI (0.48, 0.57)	Only patients >15 years of age.

The abridged review above identified the need to evaluate triage tools in low resource settings. Furthermore, the majority of studies in Table 1 focus on the triage of patients

above the age of 15 years, with only a single study identified that focused on paediatric patients. The undertaking of a systematic review on triage tool evaluation studies conducted in paediatric patients in LMIC is necessary to inform the development and evaluation of a prioritization tool that can be implemented in the PHC setting in Cape Town.

AIM

The aim of this systematic review is to investigate the scientific evidence underlying the use of triage tools to prioritize care for critically ill paediatric patients in healthcare settings in LMIC.

OBJECTIVES

1. To identify triage tools and IMCI evaluation studies conducted in LMIC and determine the core components of these tools and the study setting where they were evaluated.
2. To compare the overall reliability and validity of triage tools and IMCI in low resource settings with a goal to recommend a suitable evaluation strategy for the South African PHC context.

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RESEARCH ARTICLE Open Access

Reliability and validity of pediatric triage tools evaluated in Low resource settings: a systematic review

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Abstract

Background: Despite the high burden of pediatric mortality from preventable conditions in low and middle income countries and the existence of multiple tools to prioritize critically ill children in low-resource settings, no analysis exists of the reliability and validity of these tools in identifying critically ill children in these scenarios.

Methods: The authors performed a systematic search of the peer-reviewed literature published, for studies pertaining to for triage and IMCI in low and middle-income countries in English language, from January 01, 2000 to October 22, 2013. An updated literature search was performed on on July 1, 2015. The databases searched included the Cochrane Library, EMBASE, Medline, PubMed and Web of Science. Only studies that presented data on the reliability and validity evaluations of triage tool were included in this review. Two independent reviewers utilized a data abstraction tool to collect data on demographics, triage tool components and the reliability and validity data and summary findings for each triage tool assessed.

Results: Of the 4,717 studies searched, seven studies evaluating triage tools and 10 studies evaluating IMCI were included. There were wide varieties in method for assessing reliability and validity, with different settings, outcome metrics and statistical methods.

Conclusions: Studies evaluating triage tools for pediatric patients in low and middle income countries are scarce. Furthermore the methodology utilized in the conduct of these studies varies greatly and does not allow for the comparison of tools across study sites.

Background

The global burden of pediatric mortality in low resource settings remains high; 6.3 million children under five years old die worldwide each year. Although under-five mortality has declined from 90 to 43 deaths per 1,000 live births since 1990, improvements have fallen short of Millennium Development Goal (MDG) 4 which called for a two-thirds reduction in mortality worldwide by 2015 [1]. A majority of childhood deaths are attributable to easily treatable, time sensitive illness [2]. It is estimated that as much as 60% of mortality in this population may be reduced by improving access to care [3]. Providing timely access to specialized emergency care has been shown in numerous settings to confer a mortality benefit [4].

Triage is the prioritization of patients, usually to identify the sickest for earliest intervention; it typically consists of a complex decision-making process including clinical discriminators, physiological parameters, or both [5]. Triage has the ability to substantially decrease pediatric mortality and morbidity by providing timely care for critically ill patients [6]. Several validated scales exist; however, much of the triage data is derived from high-income countries [7].

In recent years, there has been a push to develop triage scales specifically tailored to low resource environments in Low and Middle Income Countries (LMICs) [8]; examples include tools such as the Pediatric South African Triage Scale (PSATS) [9] and the WHO Emergency Triage and Treatment Tool (ETAT) [10] among others. In the clinic setting healthcare workers utilize the WHO developed

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and implemented Integrated Management of Childhood Illnesses (IMCI) to identify pediatric patients with time sensitive illness requiring urgent treatment and/or referral [2, 3].

Although not a traditional triage tool, the IMCI is a well studied and widely implemented in both out patient clinic and hospital settings. Therefore, the authors' felt that studies evaluating the IMCI in LMICs warranted specific consideration. It is imperative that healthcare providers and policy makers understand the evidence and generalizability of the evaluation studies of these tools, among others, prior to implementation. This systematic review aims to investigate the scientific evidence underlying the use of acute care triage scales and IMCI for pediatric patients in LMICs.

Methods

Search strategy

The authors performed a systematic search of the peer-reviewed literature published, in English language, from January 01, 2000 to October 22, 2013, with an updated literature search on July 1, 2015. The databases searched included the Cochrane Library, EMBASE, Medline, PubMed and Web of Science.

Two separate searches were conducted. Both searches included search filters for LMICs (Additional file 1: Appendix A). The first search included the Medical Subject Heading (MESH) term "triage", and a separate search was conducted for the Integrated Management of Childhood Illness (IMCI). Income status of the country was defined by World Bank criteria [11]. All applicable controlled vocabularies and keyword terms were searched in all databases. The search was run without any restrictions and two authors screened each result. All studies pertaining to the evaluation of triage tools for pediatric patients (<18 years of age), in an acute care setting (i.e., where undifferentiated patients present for care), were included in the review. We included studies conducted in both hospitals and clinic settings.

Studies were excluded if the described tool was not designed to affect patient treatment or destination (i.e. a trauma score), if the tool was disease specific, or if the article was not available in English. Various study designs were included such as randomized control trials, observational studies and descriptive studies, however case reports or case series (defined as $n < 5$) were, excluded (Additional file 2: Appendix B).

Each study included in the review underwent data abstraction using a data abstraction tool (Additional file 3: Appendix C) by two independent reviewers. We collected data on four elements, (1) the demographics of the study locale, (2) the triage tool components, (3) the reliability data and (4) the validity data and summary findings for each triage tool assessed. Evaluations of the studies, including the risk of bias or an evaluation of quality of the individual study methodology, was not a component of the data abstraction tool for this review.

Outcome variables

Reliability was defined as the assessment of triage tools against other evaluations, either by another health care professional (inter-rater), or a triage tool expert designer/study author (expert opinion). Validity was defined as evaluation of outcomes for triaged patients (admission, ICU admission, referral, death etc.) by triage category. Multiple studies included assessments of "over" and "under" triage, but given the heterogeneity of these definitions [12, 13] and different methods of computing the result across studies [13, 14], these analyses were not included in the review.

Results

The initial search strategy returned 4,717 results, with 2,742 unique articles (Fig. 1). Each title was then assessed for inclusion based on the specific criteria above and was analyzed by two independent reviewers; a third senior author evaluated articles with discordant results.

After the initial title review, 411 abstracts were identified, including triage of both adult and pediatric patients. A total of seven studies evaluating triage tools in pediatric patients and 10 studies evaluating IMCI are included in the review.

Study locale

Seven studies assessed a total of five triage tools in pediatric acute care settings in LMICs. Only one of the tools (ETAT) was evaluated in a low income country (Malawi) [15]. All of the remaining tools were evaluated in middle-income countries, with four tools (PEWS, PSATS, ETAT, ESI) [10, 16–18] exclusively evaluated in upper-middle income countries. Five studies were conducted in tertiary care centers, and one study was conducted in a district hospital setting [10]. Only one study was multi-center, with Twomey et al [18] evaluating PSATS in 5 hospitals and 1 community health center.

IMCI evaluations were exclusively conducted in lower middle-income countries (India, Bolivia, and Vietnam) [19–28]. One of the ten studies was conducted in exclusively outpatient settings [28], five were conducted in hospital EDs [19–22, 26], and four were conducted in both settings as a multi-center evaluation.

Tool components

The tools included for pediatric triage had varying components, and as a result varying levels of complexity (Table 1). The ETAT guidelines involve triage of patients according to emergency and priority signs using an ABCD concept (Airway, Breathing, Circulation/Coma/Convulsion, Dehydration), and rely on clinical discriminators rather than

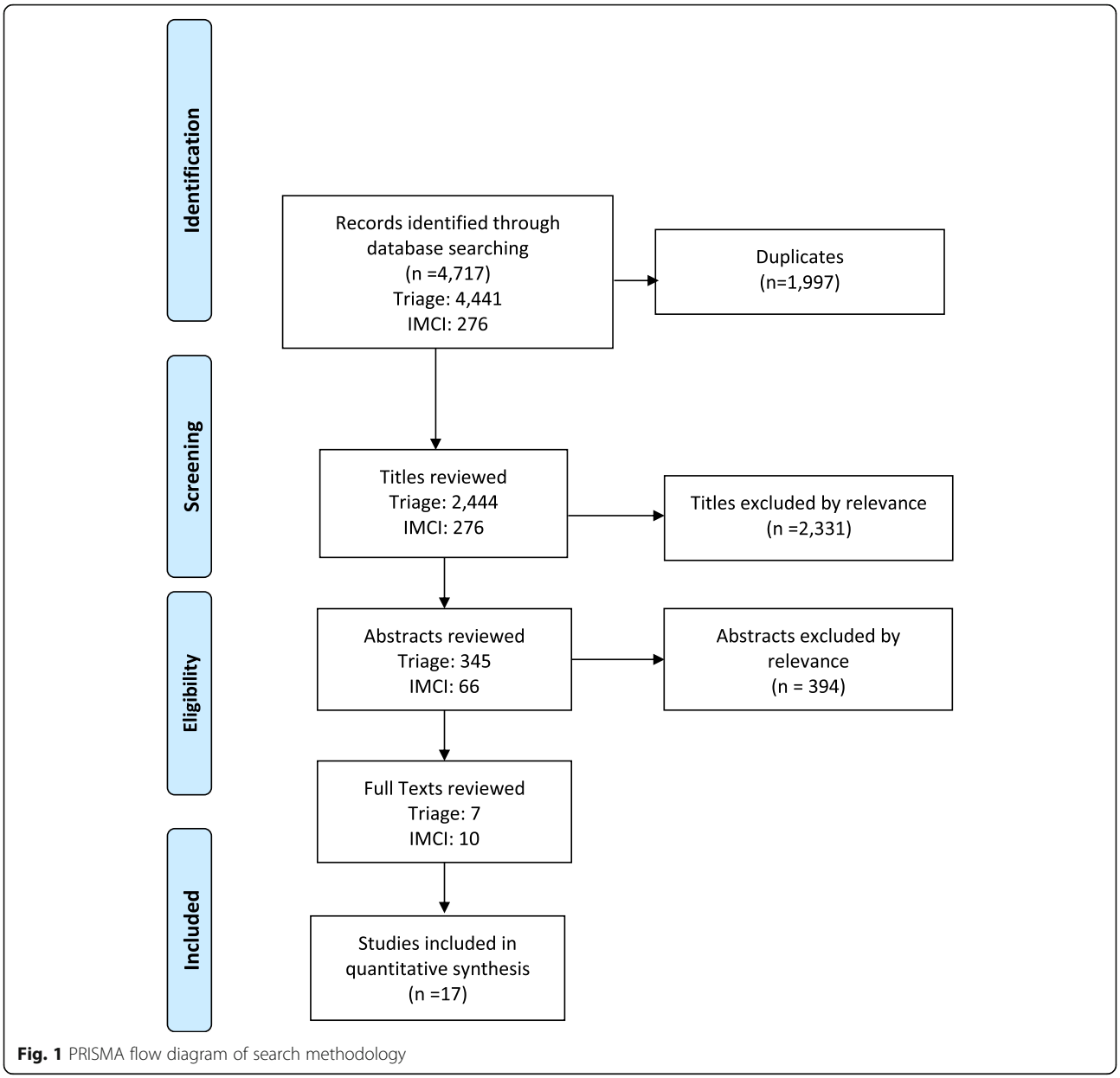

Fig. 1 PRISMA flow diagram of search methodology

Table 1 Overview of study local, study type and triage tool components included in the systematic review

Tool	Studies	Evaluations	Country Setting		Study Locale			Study Type		Tool Components			
			Middle Income	Low Income	Tertiary Hospital	District Hospital	Outpatient Clinic	Reliability	Validity	Vital Signs	Clinical Discriminators	Presenting Complaint	Resources Required
pSATS[a]	2	3	x		x		x		x	x	x	x	
ETAT[b]	2	2	x	x	x	x	x	x	x		x		
ESI	1	2	x		x			x	x	x	x	x	x
PEWS	1	4	x		x			x	x		x		
TOPRS	1	1	x		x				x	x			
IMCI	10	12	x		x	x	x	x	x	x	x	x	

[a]Includes both pSATS and PATS, a modification of SATS with minor changes
[b]Includes both ETAT and abbreviated ETAT

physiologic parameters to stratify sick children [10]. Conversely, the PEWS (Pediatric Early Warning Score) and TOPRS (Temperature, O2 saturation, Pulse, Respiratory rate, Sensorium/Seizures) relies solely on physiologic parameters (vital signs) to predict hospitalization [16, 29]. Some tools combined both physiologic parameters and clinical discriminators such as the Pediatric South African Triage Scale (pSATS) which incorporates the ETAT ABCD emergency signs as well as Triage Early Warning Score (TEWS) physiologic parameters to stratify patients. Lastly, the Emergency Severity Index (ESI) adds further complexity by asking the provider the number of resources that will be required.

IMCI utilizes a syndrome-based approach to target the care of children, and thus uses physiologic and clinical discriminators in evaluating triage category. This is because, although the IMCI strategy does have a prioritization component (so that critically ill children may be transferred to a higher level of care), its stated purpose is to promote curative care in the outpatient setting, and includes algorithms for healthcare workers to direct care for common complaints in a pediatric outpatient settings.

Pediatric triage tools

Reliability

Three studies measured the reliability of three different triage tools (Table 2) [7, 16, 17]. Roberston et al. evaluated ETAT in Malawi and found that nurses have an agreement of 93.8%, assigning the correct triage level, when compared against physician "assessors" observing triage [7]. The ESI evaluation by Jafari-Rouhi et al. utilized blinded re-rating by pediatric emergency medicine physicians to assess nursing performance with an overall kappa of 0.82 [17]. Both studies included real patients with real-time triage evaluations in a clinical setting, and all studies were appropriately blinded to the other provider's assessment. The highest percentage agreement was achieved in the level 1/priority 1 patient group.

Validity

All seven triage studies included some measurement of validity [4, 7, 10, 16–18]. The studies included, tools evaluated, and outcome measures utilized are shown in Table 3.

Two studies analyzed the likelihood of admission by ETAT triage level assigned. Ninety percent of priority 1 (P1 or critically ill) patients were admitted versus 32% of P2 and 4.5% of P3 in one study [7]. Another group published similar percentages with a significant increase in the relative risk of admission in children triaged to level 1 or 2 compared to 3 (RR 2.6; 95% CI 2.2-3.1 in one sample and RR 3.2; 95% CI 2.5-4.1 in another) [10]. Using the pSATS tool, Twomey et al. reported an increase in hospital admission with increasing level of urgency from 4.7% in the lowest triage level to 72.8% of those triaged to level 1 [18]. The area under the ROC curve for predicting overall admission using PEWS was 0.73. PEWS was 100% sensitive and 90.5% specific for predicting ICU admission [16]. In a large study conducted by Mullan et al. analyzed both adult and pediatric (<13 years old) patients using PATS, a modified form of SATS. They demonstrated an increase in hospital admission (20.6–86.7%) and mortality (0–1.4%) when children were assigned a higher acuity score [30, 31].

Using the ESI v.4 in Iran, 100% of patients assigned level 1 by pediatric EM physicians were either admitted to the ICU or died while 0% were admitted to the ward or discharged [17]. Of level 2 patients, 1.2% were admitted to the ICU or died, 29.8% were admitted to the ward, and 69% were discharged. Zero level 3 through 5 patients went to the ICU or died [17]. The TOPRS score was found to have a predictive ability of 81.7% for admission on receiver operating curve analysis with a progressive increase in mortality by increasing score.

IMCI/IMNCI

Reliability

Six of the included studies published Kappa or percent agreement data to quantify the concordance of nurse or health worker IMCI determination with physician diagnosis (Table 4) [19–23, 28]. There was a large variation in the overall Kappa values, from 0.16 to 0.59 [19, 26]. Bhattacharya et al., 2011, reported a syndrome specific kappa and found the highest agreement in the diagnosis of jaundice (0.73) and the lowest agreement in the diagnosis of dehydration (0.19) [21].

Table 2 Included reliability studies of pediatric triage tools

Triage Tool	Author[ref] Year Country (Income level)	Comparison Groups	Volume Patient and Setting Characteristics (Age restrictions)	Results (kappa, percent agreement) by triage level
ETAT	Robertson etal. [7] 2001 Malawi (Low Income)	1. Clinic nurse 2. ED physician	*n* = 2281 Under 5 outpatient clinic (85% <5y/o)	Overall: 94.8% P1: 95.7% P2: 88.0% P3: 96.1%
ESI	Jafari-Rouhi etal. [17] 2013 Iran (Upper Middle Income)	1. Triage nurse to Ped 2. ED physician	*n* = 1104 Emergency department at national teaching hospital (100% <18 y/o)	Kappa 0.82 Overall 87.3% Level 1: 100% Level 2: 93.1% Level 3: 83.4% Level 4: 86.1% Level 5: 84.1%
PEWS	Chaiyakulsil etal. [16] 2015 Thailand (Upper Middle income)	1. Triage nurse 2. Triage nurse	*n* = 1136 ED at large tertiary care hospital	Kappa: 0.75

Table 3 Included validation studies of pediatric triage tools

Outcome	Scale	Author [ref] Year Country (Income)	Site Volume Patient and Setting Characteristics (Age restrictions)	Results (per triage level) [*p* value]	Remarks
Mortality	ESI	Jafari-Rouhi [17] 2013 Iran (Upper Middle Income)	*n* = 1104 ED at national teaching hospital. (100% <18 y/o)	Overall: 0.9% 1: 100% 2: 1.2% 3:0% 4:0% 5: 0%	Outcome was ICU admission or death. ESI performed at patient presentation, not admission.
	TOPRS	Bains 2012 [15] India (Lower-middle Income)	*n* = 777 Teaching hospital with general ED.	Overall: 16.3% TORPS 6: 100% TORPS 5: 80.0% TORPS 4: 66.7% TORPS 3: 60.0% TORPS 2: 38.2% TORPS 1: 12.5% TOPRS 0: 4.4%	All patients were admitted to ED. ROC curve maximal discrimination at 2.5 (sensitivity 79.6%, specificity 74.3%)
	PATS	Mullan 2014 [ ] Botswana (Upper-middle Income)	*n* = 4466 ED at terteriary referral hospital (100% < 13 y/o)	Overall: 0.16% Red: 1.4% Orange: 0.05% Yellow: 0% Green: 0%	Outcome was ICU admission or death. PATS performed at ED presentation. Large study of both adult and pediatric patients with separate analyses.
Admission	ESI	Jafari-Rouhi 2013 [17] Iran (Upper-middle Income)	*n* = 1104 ED at national teaching hospital. (100% <18 y/o)	Overall: 9.4% 1: 0% 2: 29.8% 3: 1.8% 4: 2.0% 5: 0%	Outcome was ED admission or ward admission (does not include ICU admission). Spearman correlation coeficient 0.407.
	Adapted ETAT	Buys 2013 [10] South Africa (Upper-middle Income)	*n* = 407 District hospital with general ED. (100% < 16y/o)	Overall: 24.8% P1: 91.7% P2: 36.9% P3: 10.1%	Second of 2 cohorts (2009), first (2007) immediately following training.
	pSATS	Twomey 2013 [18] South Africa (Upper-middle Income)	*n* = 2014 6 ED centers with varying size/populations. (100% <13 y/o)	Overall: 21.5% 1: 72.8% 2: 29.0% 3: 27.9% 4: 4.7%	Sensitivity 91.0%, Specificity 54.5%. Compared to simply TEWS or clinical discriminator, and improved discrimination.
	ETAT	Robertson 2001 [7] Malawi (Low Income)	*n* = 2281 Under 5 outpatient clinic with referral for admission (85% <5 y/o)	Overall: 14.9% P1: 90.0% P2: 32.0% P3: 4.5%	No follow-up data after admission. Only patients under 5.
	PEWS	Chaiyakulsil 2015 [16] Thailand (Upper-Middle income)	*n* = 1136 ED at large tertiary hospital (100% < 15y/o)	Overall AUC: 0.73 ICU: 0.98 Ward 0.71 PEWS > 1 for admission Sensitivity 77% Specificity 59%	Measured in area under ROC curve, for sensitivity and specificity for admission by PEWS category.
	PATS	Mullan 2014 [ ] Botswana (Upper-middle Income)	*N* = 4466 ED at terteriary referral hospital (100% < 13 y/o)	Overall: 54.5% Red: 86.7% Orange: 66.1% Yellow: 37.6% Green: 20.6%	PATS performed at ED presentation. Large study of both adult and pediatric patients with separate analyses.

Validity

Six studies evaluated the validity of IMCI (Table 5) [19, 20, 24–27]. One study showed an increase in likelihood of admission according to urgency of triage level assigned [19]. Mazzi et al., reported that the sensitivity of individual clinical signs for predicting serious illness requiring hospital management was less than 35% for all signs except fever (65%) [26].

Discussion

Overall, the quantity and quality of evidence to support the effectiveness of any single triage tool for pediatric patients in low resource settings is poor. This is driven by the limited number of studies available; the heterogeneous nature of these studies preventing formal meta-analysis; and the high proportion of studies conducted in urban centers in middle-income countries preventing extrapolation to low resource environments.

Our study identified a research gap in the quality and quantity of studies conducted in urban middle-income countries compared to rural environments in low-income countries, true low resource settings. Only one of the 16 studies were carried out in a low-income country [15] (Table 1). Although it is much more feasible to evaluate triage tools in high resourced district and tertiary care hospitals in middle-income countries (many of which resemble hospitals in high-income countries), these studies are difficult to extrapolate to rural low resource settings, where the need for these tools is greatest. In addition one may hypothesize that the triage tool may alter in their

Table 4 Included Evaluations of Reliability of IMCI/IMNCI

Type of Reliability Evaluation	Author[ref] Year Country (Income level)	Comparison Groups	IMCI Variable Being Assessed	Volume Patient and Setting Characteristics (Age restrictions)	Results (kappa (k), percent agreement (Pa), Sensitivity (Sn), Specificity (Sp)) by triage level
Inter-Rater[a]	Shewade [24] 2013 India (Lower-Middle Income)	1. Health Care Worker 2. Study Investigator	IMCI category	*N* = 128 Community health center (0mos-5 yrs)	Overall k = 0.43 <2mos k = 0.31 >2mos k = 0.44
	Battarachaya [21] 2012 India (Lower-Middle Income)	1. Health Care Worker 2. Physician (IMCI Red/ Yellow)	IMCI Red/Yellow categorization	*n* = 131 Inpatient pediatric hospital (2mos-5 yrs)	Pa = 36% Simple k = 0.16 Weighted k = 0.29
	Battarchaya [20] 2013 India (Lower-Middle Income)	1. Health Care Worker 2. Physician (Diagnosis)	Diagnostic category	*n* = 117 Inpatient pediatric hospital (0-2mos)	Serious Bacterial Infection k = 0.38 Local Bacterial Infection k = 0.20 Jaundice k = 0.73 Dehydration k = 0.19 Unable to Feed k = 0.29
	Battarchaya [19] 2011 India (Lower-Middle Income)	1. Health Care Worker 2. Physician (IMCI Red/ Yellow)	IMCI Red/Yellow categorization	*n* = 117 Inpatient pediatric hospital (0-2mos)	Pa = 56% Simple k = 0.32 Weighted k = 0.41
	Gupta [23] 2000 India (Lower-Middle Income)	1. Health Care Worker 2. Physician	IMCI Categorization	*n* = 129 ED and Outpatient clinics (0-2mos)	Pa = 60%
Gold Standard Comparison[b]	Mazzi [26] 2010 Bolivia (Lower-Middle Income)	1. Triage Nurse 2. ED Physician[a]	IMNCI Red within Diagnostic categories	*n* = 1082 2 pediatric hospital ED (0mos-2mos)	Sn <35% for each sign Sp >85% for all signs
	Battarachaya [20] 2013 India (Lower-Middle Income)	1. ED Nurse 2. Inpatient Physician[a]	IMNCI Red within Diagnostic categories	*n* = 117 Inpatient pediatric hospital (0-2mos)	Serious bacterial infection: 89% Sn, 72% Sp Local Bacterial Infection: 14% Sn, 99% Sp Jaundice: 67% Sn, 99% Sp Dehydration: 25% Sn, 95% Sp Poor feeding: 44% Sn, 87% Sp
	Mittal [27] 2013 India (Lower-Middle Income)	1. Health Care Worker 2. ED Physician[a]	IMCI Red categorization	n = 1043 Outpatient and pediatric ED in tertiary care center (0mos-5 yr)	38.7% diagnostic mismatch in 0-7d age group 24.3% diagnostic mismatch in 7d-2mos age group 19.9% mismatch in 2mos-5 yr
	Cao [22] 2004 Vietnam (Upper-Middle Income)	1. Health Care Worker 2. Physician[a]	IMCI Red categorization	*n* = 859 Inpatient pediatric hospital (2mos-5 yrs)	Severe Illness (IMCI Red) Sn 94.7% Sp 96.1%

[a]Inter-Rater reliability was measured as 2 individuals agreement without weight of importance. It is expressed in percent agreement or kappa statistics
[b]Gold Standard Comparison expresses the ability of triage personnel (workers, nurses) to physicians. It is expressed in sensitivity and specificity

Table 5 Included evaluations of validity by real patient outcomes of IMCI/IMNCI

Outcome	Author [ref] Year Country (Income)	Site Volume Patient and Setting Characteristics (Age restrictions)	Results (per triage level) [*p* value]
Admission	Battarachaya [19] 2012 India (Lower-Middle Income)	*n* = 131 Inpatient pediatric hospital ED (2mos-5 yrs)	Overall: 25% Red: 82% Yellow: 11% Green 5%
Referral to ED	Kaur [24] 2011 India (Lower-Middle Income)	*n* = 419 Outpatient pediatric clinic and ED in tertiary care center (0-2mos)	95% Sn 87% Sp
	Kundra [25] 2008 India (Lower-Middle Income)	*n* = 309 Outpatient pediatric clinic and ED in tertiary care center (2mos-5 yrs)	98% Sn

function in low resource settings given differences in available treatments, training of providers, underlying healthcare system infrastructure and prevalent disease pathologies (i.e., high prevalence of HIV infection and malnutrition for example).

The tools included in this study varied in their construct. ETAT was an example of the use of clinical signs alone, without vital signs or any input of the presenting complaint. Tools based on clinical signs alone have appeal as they can be employed quickly in settings where measuring vital signs may be too time-consuming or impractical [10]. Conversely PEWS and TOPRS allow for a true objective provider assessment, which may be less likely to introduce bias and may be performed by providers with more basic training [16, 29]. Then, tools such as the pSATS and PATS incorporate both clinical and physiologic data. The Pediatric South African Triage Scale (pSATS), incorporates the ETAT ABCD emergency signs as well as Triage Early Warning Score (TEWS) physiologic parameters to stratify patients. Twomey et al. studied the sensitivity of the pSATS tool, suggesting it is a more robust screening modality than either clinical discriminators or TEWS alone. The sensitivity (Sn) and negative predictive value (NPV) of pSATS was higher (91 and 93%, respectively) when compared to clinical discriminators alone (Sn 57 and NPV 86%) or TEWS alone (Sn 75.6 and NPV 89%). Appropriately, children triaged to lowest category were correctly identified as non-urgent. Advocates of these mixed triage scores argue that the addition of vital signs significantly increases the sensitivity for identifying sick children and outweighs the additional time required [18].

Our original intent was to make comparisons between triage tools, and to meta-analyze the reliability and validity of tools in different settings. This was impossible due to the limited number of studies, and variability in study design. Reliability assessments varied in statistical analyses (from kappa statistics to percent agreement [15] to sensitivity/specificity of a binary outcome [22, 26]), and methodology (comparison groups varied between studies, IMCI variable varied in reliability assessments) (Table 1, Table 3). This made formal meta-analysis impossible, and prevented a true global assessment of the reliability of any one triage tool.

A number of studies reported nursing triage to physician triage [17]. However the use of physicians as a gold standard in triage sensitivity does also give cause of concern. In most developed countries, a nursing professional is responsible for triage operations. Given the lack of healthcare provider resources, physicians in triage would be very unusual in LMICs. Therefore, it is unclear if the use of a physician as the gold standard for reliability measurements is appropriate in these studies. All reliability studies did however utilize real patients in their evaluations opposed to written scenarios, and may be the reason for poor reliability data that is reported. In adult patients the many reliability studies use pre fabricated written cases to assess reliability and thus report higher agreement [32, 33].

Validity studies also varied widely, where different methodologies prevented true meta analysis and study limitations hindered the quality of evidence. All validity studies had large sample sizes, ranging from 407 [10] to 4466 [31] participants. However, the methodology varied widely, with some triage applying to patients who were "admitted" to the ED (ie were expected to stay for a period of time) [29], while others were done at initial presentation. A major source of variability was the overall rates of mortality and admission at different locales. The studies measuring admission outcomes differed significantly in their overall admission rates from 9.4% [34] to 55.4% [31]. Overall mortality at the study sites varied from 0.16% [31] to 16.3% [29].

Most studies rely on admission or mortality as a proxy for severity of illness. In low resource health care environments, there are numerous confounders that can impact outcomes including the training of providers, availability of medications and surgical interventions, availability of specialty/critical care, and the ability of patients to pay for treatment. In addition, the lack of follow-up data in any of these studies significantly hinders its effectiveness. For those patients not admitted, there is absolutely no data on mortality or re-presentation in any of the studies featured. Given resource and infrastructure constraints (census, patient records etc.), this is an understandable, but significant, limitation of the research in this field. Furthermore, this oversight is not merely restricted to studies in LMICs but also a limitation of several of the studies in the Farrokhnia review that focuses on high resource settings [5]. A systematic effort is required to overcome this limitation. Funders and investigators need to prioritize prospective evaluations with an emphasis on follow up of all patients that are triaged during the study period opposed to retrospective evaluations that only include admitted patients.

A single study by Molyneaux et al., does warrant special mention [6]. They demonstrated a near 50% reduction in under five-year-old inpatient mortality at a district hospital in Malawi after making improvements in triage, which included formal ETAT training. Although, in its true essence, this study does not evaluate the validity of a triage tool, the authors demonstrated that implementation of a triage system in their clinical environment significantly reduced overall child mortality. This study's validity cannot be appraised, as the authors do not provide specific information on the outcome of patients assigned to various categories. In addition, the pre/post study design is prone to multiple confounders given the many simultaneous changes to the triage system (new hires, better clinician

oversight, new physical plant, etc.). These confounders make quantifying the effects of ETAT alone impossible [6].

In evaluating the evidence supporting IMCI, it is evident that, although numerous, there is insufficient evidence to validate the tool in varied low-resource environments, due to similar problems with heterogeneous study methods and numerous study limitations. Comparing IMCI to other pediatric triage tools, IMCI also addresses aspects of nutrition, immunization, and other important elements of disease prevention and health promotion. Accordingly, many of the IMCI studies considered in this review evaluate patients in an outpatient or clinic setting. Interestingly, the volume of studies evaluating IMCI far outnumber the literature on any of the triage tools, likely due to the 1994 WHO mandate to complete large multi-country evaluations on the training and implementation of IMCI worldwide [35].

Despite the relative plethora of studies validating IMCI, there are significant limitations in study design and locale. First, the IMCI studies are smaller in size, likely representing the relative patient census at the smaller centers in which the studies were conducted. In addition, these studies suffer from a lack of standard method for assessing IMCI reliability, and individual studies present varied methods of comparison, comparison groups, and IMCI variables to be compared (Table 3). This prevents a formal analysis of the overall IMCI reliability between raters.

Additionally, the kappa values for reliability are significantly lower than those reported in the triage tool studies (Table 3). One possible explanation is that IMCI is typically utilized by health care providers with less formal training, while the responsibility of triage in larger centers is often placed on professional nurses with formal schooling. In addition, numerous studies attempt to make validity conclusions based on IMCI performance compared to physician diagnosis as gold standard. In India, Kaur and others demonstrated that the IMNCI adaptation is a sensitive tool (95%) for identifying neonates for referral [25, 36] It is concerning that so many studies opted to use non blinded physician opinion as the gold standard. Diagnostic agreement and decision to admit or refer are generally poor metrics for validation, given that they are inherently biased by the initial triage decision. Of the studies considered in this review, none followed patients to collect outcome data such as treatments required, length of stay, or mortality [20]. Taken cumulatively, all of these limitations prevent a formal analysis of the reliability and validity of IMCI, and thus limit the ability to recommend it for practitioners in low-resource settings.

Limitations

This review only includes studies that were published in the peer-reviewed literature available on databases searched. Second, other tools that may be used to prioritize the care for children in low-resource settings may not be referred to as "triage" tools. Recognizing this, authors performed a separate search for IMCI, but other similar approaches may exist that were not included. Studies not available in English language were not considered in this review. Relevant studies published without translation may have been excluded.

Conclusions

Overall, there is little in the literature studying the performance of triage tools in pediatric patients in low resource settings. The generalizability of these studies is also difficult given the preponderance of studies conducted in urban centers in middle-income countries opposed to true low resource settings. A large number of studies depend on the local physician assessment as a gold standard, which is highly variable and difficult to reproduce across studies. Thus it is difficult to support the use of a single tool based on this systematic review. Despite the methodological concerns evaluating IMCI studies, the ubiquitous use of IMCI as well as the availability of training and implementation though the WHO does support its continued use in outpatient clinic settings where it is currently implemented.

Overall studies evaluating triage tools in this vulnerable population are scarce and generally do not include follow up of lower acuity patients and critically important outcomes data. There is a need to develop and define robust validation methodology that can be prospectively utilized to evaluate triage tools in low resource settings.

Additional files

Additional file 1: Appendix A Search Strategy. (DOCX 24 kb)

Additional file 2: Appendix B. Systematic review inclusion and exclusion criteria. (DOCX 71 kb)

Additional file 3: Appendix C. Triage Tools Data Abstraction. (PDF 126 kb)

Abbreviations

ED: Emergency department; ESI: Emergency severity index; ETAT: Emergency triage and treatment tool; ICU: Intensive care unit; IMCI: Integrated management of childhood Illness; LMIC: Low and middle income countries; MDG: Millennium development goal; NPV: Negative predictive value; PEWS: Pediatric early warning score; PSATS: Pediatric south african triage scale; Sn: Sensitivity; TEWS: Triage early warning score; TOPRS: Temperature, O2 saturation, pulse, respiratory rate, sensorium/seizures; WHO: World health organization

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Availability of data and material

All data generated or analyzed during this study are included in this published article in the Additional files.

Authors' contributions
BH conceptualized and designed the study, participated in article selection, designed the initial manuscript, and edited and approved the final manuscript as submitted. AJ conducted the literature search, participated in article selection, and drafted the initial manuscript. DK drafted the initial manuscript and developed the initial tables. SR, TA, MT participated in article selection and contributed to the writing of the manuscript. GDK and LW conceptualized the study and edited and approved the final manuscript.

Competing interests
The authors have no financial and non-financial competing interests to declare.

Consent for publication
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Ethics approval and consent to participate
Not Applicable.

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DISCUSSION OF STUDY

METHODOLOGY

A three-concept search was developed to conduct the search with (1) low resource settings, (2) triage tools, and (3) paediatric patients. A low resource setting was defined using the income status of the country where the study was conducted (low or middle income country status was assigned using World Bank criteria).[27] The Low and Middle Income Terms were adapted from the Norwegian Cochrane Centre's Developing Country filter (http://epocoslo.cochrane.org/lmic-filters) and Johns Hopkins filters. Both filters are based on the World Bank LMIC country classification. For the triage and paediatrics concept, we added to the "Triage" and "Paediatrics" MESH term in PubMed 'all possible controlled vocabularies and keyword terms i.e., the emergency care and triage filters were started by including applicable MeSH and other controlled vocabularies (e.g. Embase/Emtree), and then adding commonly used keywords/phrases and their variations (singular/plural, British English/American English, etc.). Those filters were run and the results were evaluated for additional relevant controlled vocabularies and keywords. This process was repeated until a high degree of confidence was reached that the most relevant terms have been included. We also searched previously found relevant articles were also scanned for terms. For the second concept "Triage" we added ("triage" OR "emergency severity index" OR "rapid acute physiology score" OR "rapid emergency medicine score") AND ("Emergency Service, Hospital"[mh] OR "Emergency Medicine"[mh] OR "Emergency medicine"[TW] OR "Emergency services"[TW] OR "Emergency department"[TW] OR "Emergency service"[TW] OR "Emergency departments"[TW] OR "ER"[TW] OR "ED"[tw] OR "Emergency room"[TW] OR "Emergency rooms"[TW] OR "Emergency ward"[TW] OR "Emergency Unit"[TW] OR "Trauma Centers"[mh] OR "Trauma Centre"[TW] OR "Trauma Centers"[TW] OR "emergency health service"[tw] OR "emergency health services"[tw] OR "accident and emergency"[tw] OR "accident & emergency"[tw] OR "a&e"[tw] OR "A & E"[tw] OR "Emergency Nursing"[mh]) AND ("score" OR "scores" OR "scoring" OR "scored" OR "rating" OR "rate" OR "rated" OR "index" OR "system" OR "scale"), and for the paediatric concept we used, "Child"[mh] OR "Infant"[mh] OR "Infant, Newborn"[mh] OR "Adolescent"[mh] OR "Child, Preschool"[mh] OR "child"[tiab] OR "infant"[all] OR "adolescent"[all] OR "children"[all] OR "infants"[all] OR "adolescents"[all] OR "paediatric patient"[all] OR "paediatric patients"[all] OR "adolescence"[all] OR "youth"[all] OR "youths"[all] OR "juvenile"[all] OR "childhood"[all] OR "teenager"[all] OR "teenagers"[all] OR "teen"[all] OR "teens"[all] OR "preschool child"[all] OR "neonate"[all] OR "newborn"[all] OR "baby"[all] OR "babies"[all] OR "paediatric"[tiab] OR "paediatrics"[tiab] OR

“paediatric”[tiab] OR “paediatrics”[tiab] OR "toddler"[all] OR "toddlers"[all]). The search was run without any restrictions and the full search strategy including the comprehensive LMIC filter is available in the appendix of the attached manuscript. The search was run though several databases namely, PubMed©, Embase©, Web of Science©, and Scopus©.

The decision to include IMCI required the conduct of a second search in parallel to the one focused on triage tools. Although not a traditional triage tool, IMCI is a well-studied and widely implemented program in both outpatient clinics and hospital settings. This decision was taken after realizing that the initial search for triage tools alone yielded few articles applicable to the low resource PHC setting. In addition, the inclusion of IMCI is an acknowledgement that, despite IMCI not being designed to formally triage patients, the three-level severity assignment “Red/Yellow/Green” is used informally to prioritize those who need emergent transfer or treatment. Therefore, the authors’ felt that studies evaluating the use of IMCI in LMICs warranted specific consideration. The second concept “Triage” was replaced with “Integrated Management of Childhood Illnesses [mh] OR “IMCI” OR “IMCNI”.

The authors strictly adhered to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).[28] PRISMA has been included as one of the tools for assessing the reporting of research within the EQUATOR Network (Enhancing the Quality and Transparency of Health Care Research), an international initiative that seeks to enhance reliability and value of medical research literature by promoting transparent and accurate reporting of research studies.[29] PRISMA is an evidence-based minimum set of items for reporting in systematic reviews and meta-analyses. While PRISMA is not a quality assessment instrument for systematic reviews but it is useful for critical appraisal purposes and allows an objective reproducibility across studies. Furthermore, the 27 item PRISMA checklist guided the research strategy and the PRISMA flow diagram is shown in Figure 2.

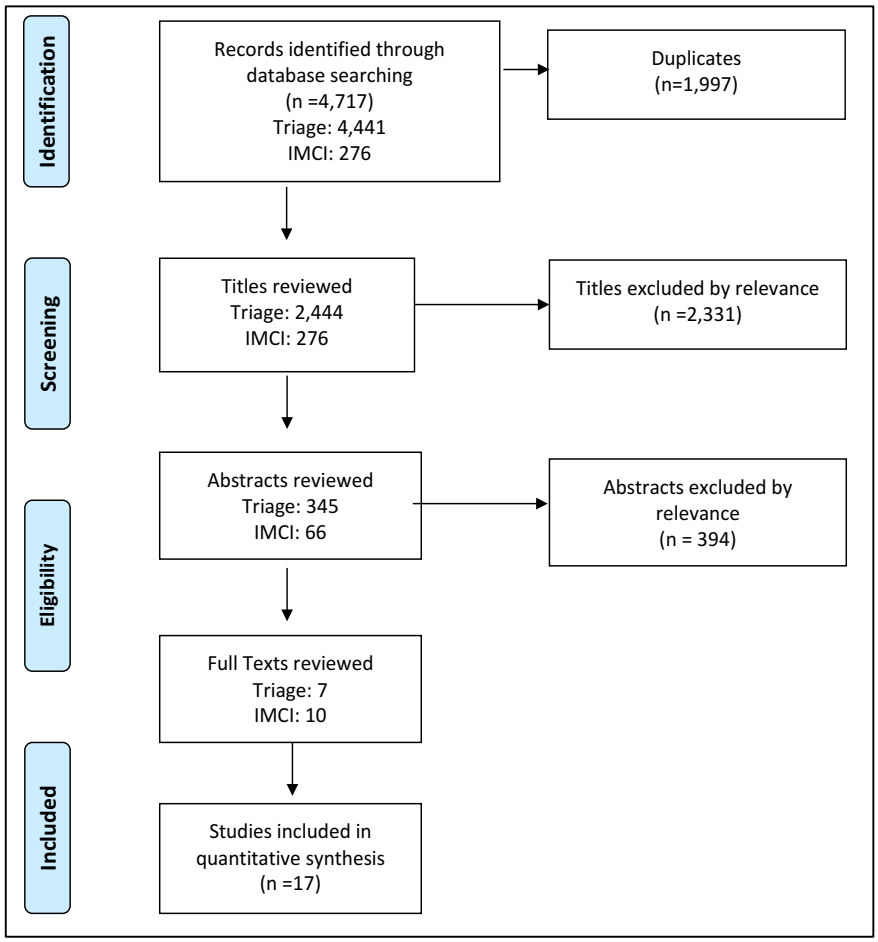

Figure 2: PRISMA flow diagram of search methodology

The data abstraction strategy within this review was purely descriptive. Given the heterogeneous nature of the tools, study designs, and their evaluation methodologies, it was difficult to orchestrate direct comparisons across tools. The initial study design had planned to apply the Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria to the included tools to make an overall recommendation based on the findings of the systematic review.[30] The GRADE approach provides a structured and transparent evaluation of the importance of outcomes of alternative management strategies, acknowledgment of patients and the public values and preferences, and comprehensive criteria for downgrading and upgrading certainty in evidence.[30] This methodology is also similar to that applied by Farrokhnia et al in adult triage tool systematic review.[22] Unfortunately, this review faced two major hurdles in applying the GRADE criteria, 1) most triage tools have fewer than two evaluation studies included in the review and 2) all of the papers included in the review had small sample sizes and inherent flaws in study design meaning that most would be categorized as low or very low quality of evidence.

RESULTS

This systematic review yielded fewer results than anticipated. The search strategy utilized was highly inclusive and developed in collaboration with a librarian. The lack of results yielded in this systematic review may be indicative of the paucity of published literature on this topic. This perhaps speaks to the difficulties of conducting research in LMIC and the lack of published research from LMIC in the international literature. [31, 32]

All the tools evaluated in this study (except for the paediatric early warning score) included a combination of vital signs and clinical discriminators. Not a single tool utilized clinical discriminators alone. The recording of vital signs is time consuming (especially in paediatric patients) and thus can be a hindrance to completion of the complete triage algorithm. Furthermore, there are concerns that the vital signs criteria incorporated in many of the triage tools studies are not evidence-based and are determined using a consensus methodology.[33] In addition, a recent study suggested that the majority of triage decisions (over 90%) are not impacted by the inclusion of vital signs.[34] On the other hand, in low resource settings the task of triage is often given to staff with minimal training (such as nursing students or assistants). [35] The use of clinical discriminators requires some medical knowledge of the terminology and an understanding of the consequences if a patient presents with certain signs. Thus, in low resource settings where there are a lack of trained medical professionals the collection of vital signs may provide a reproducible method that can be implemented by staff with minimal training.[36] Placing this systematic review in to the context of the PHC setting where they see a large volume of patients (100-150 per day) and only a single provider is available to triage the patients, it leads to question whether the collection of vital signs will unnecessarily delay care and lead to long waiting times by impeding patient flow, given that the average patient interaction will take approximately 2-5 minutes.

There were more IMCI evaluation studies than any other triage tool. It was thus surprising to see that the reported reliability of IMCI (kappa 0.20-0.73) was lower than that for other triage tools (kappa 0.75-0.98). However, it is notable that the majority of IMCI studies were conducted in patients by community healthcare workers in PHCs opposed to studies of triage tools which were all conducted in tertiary care hospitals. It is also likely that, given the complex algorithmic nature of IMCI, it is difficult to assess reliability, with IMCI there are multiple permutations that determine the patients final syndrome and acuity, opposed to a simple 4 or 5-point triage scale.

More studies evaluated triage tools using measures of validity opposed to reliability. Most studies relied on admission or mortality as a proxy for the severity of illness in order to conduct validation studies. In low resource health care environments, there are numerous confounders that can impact long term patient outcomes such as mortality, including the training of providers, availability of medications and surgical interventions, availability of specialty/critical care, and the ability of patients/parents/caregivers to pay for treatment. There were fewer validity studies for IMCI; this is anticipated given that these studies were conducted in a PHC setting. In the PHC setting the patient is often cared for at numerous healthcare facilities before reaching a destination facility. Without a formal electronic infrastructure for record keeping and patient tracking it is difficult to conduct follow up studies on these patients once they leave the PHC.

Validity studies also varied widely, and different methodologies prevented meaningful meta-analysis. Furthermore we identified several limitations in study design, such as the exclusion of all patients who are discharged from the healthcare facility, which hindered the quality of evidence. Thus, it was difficult to make comparisons across triage tools and hard to make a recommendation for an overall recommended tool.

LIMITATIONS

This systematic review yielded few results. It may be possible that some evaluation studies of triage tools may have not reached peer-review publication, and thus this study is limited by not expanding the search to the grey literature. Inclusion of a grey literature search strategy could possibly yield implementation reports, which would have been extremely useful in enhancing the scope of this review.

Even though the review provided insight into the spectra of triage tools commonly utilized to identify and prioritize critically ill children in low resource settings and the methodologies used to evaluate them, the study was designed to provide an in depth understanding of the barriers to implementation or the consistency of implementation of the above mention strategies.

CONCLUSION

A critical review of the scientific evidence evaluating triage tools in LMIC yielded few results, many of which were poor quality, and thus the authors were unable to recommend a single “ideal” triage tool for this setting. Building on this in **Chapters 3 and 4,** a qualitative approach will be undertaken to delve in to the barriers to providing adequate care for critically ill children in the pre-hospital setting. The lack of standardized methodology to evaluate triage tools alludes to the challenges ahead when developing and evaluating a new prioritization strategy. It is anticipated that, for

the prioritization tool developed in this thesis, there will be difficulty conducting validity studies based clinical outcomes due to difficulties in patient follow-up after exit from the PHC. Thus the methodology presented in **Chapter 6 and 7**, uses implementation measures to evaluate the developed tool.

CHAPTER 3: QUALITATIVE STUDY OF BARRIERS TO PREHOSPITAL CARE FOR CRITICALLY ILL CHILDREN

BACKGROUND

In South Africa (SA), there are a few tertiary care facilities with specialist paediatric services, that funnel patients from numerous PHCs and district hospitals. In low resource settings, patients with time sensitive illnesses may face delays of hours or even days before reaching the nearest medical facility or provider.[12, 37] Thus, a significant proportion of care is delivered prior to arrival at a definitive care facility. Transportation may be provided by an ambulance, but more often it is provided by laypersons using the handiest means available.[38] Health care before arrival at health facilities may be provided by trained paramedics or by laypersons; quite often, however, no health care is provided.[39] In contrast to systems in high-income countries (HIC), the pre-hospital and emergency medical systems in LMIC are often rudimentary. [40]

Health facility–based subsystems refer to the level within the health care system at which appropriate definitive care is delivered.[37] Capacity at formal health facilities vary immensely across and within countries. In some countries, there is wide spread availability of specialists at the regional/district hospital level, in others (for example, SA district hospitals are staffed with general practitioners or non-specialist doctors). The PHC are staffed with non-physician providers and while they can provide some treatment for conditions such as acute diarrhoea or pneumonia, they do not have the ability to monitor or resuscitate patients, or keep them overnight for observation.

In many health systems, including in SA, most critically ill children will present initially to a non-specialist health facility. A Canadian study looked at how a generalist or a community paediatrician in a lower resourced setting (in terms of staff, equipment, and training) struggled to offer high quality care to critically ill children. Having identified a child as critically ill, they have to attempt to stabilize the child, while dealing with a receiving hospital and ensuring an appropriate ICU bed can be secured, and finally organizing appropriate transport to the higher resourced centre.[41]

In SA, current referral pathways mandate that all children flagged to be transferred to a higher level of care first be taken from the PHC to the next level facility (usually a 24-hour community healthcare centre or district hospital), and thus a child may be transported several times before reaching a definitive care facility.[12] Various triage processes in the pre-hospital subsystem determine which patients receive transportation to which facility, in what time frame, and the level of care necessary during transport. Morbidity and mortality may be increased due to delays in the

identification of critically ill children, and due to delays in arrival to a definitive care facility. In this chapter, we explore the pre-hospital environment further from the healthcare provider perspective.

It was established by the PTCS team, that the pre-hospital setting as whole contributed significantly to increasing childhood mortality and morbidity in the Cape region. [12] The pathway of care for critically ill children in the pre-hospital setting is unclear. [42, 43] It is unknown whether critical delays occur at the clinic level, district hospital level or within the emergency medical transportation services. The purpose of this qualitative study was to hone in on the focused area for interventions to understand the current barriers to providing optimal care for critically ill children in the pre-hospital setting. A similar study was conducted by the PTCS team from the patient/caregiver perspective [42], and thus the focus of this study is on the healthcare providers, support staff, and policy makers who are responsible for care delivery to paediatric patients in the pre-hospital arena in the City of Cape Town.

AIM

To perform an exploratory study to identify barriers to care for critically ill children in the pre-hospital setting in Cape Town, South Africa.

OBJECTIVES

1. Identify the barriers that cause critical delays in the care for critically ill children in the pre-hospital setting in Cape Town.
2. Identify areas for intervention and improvement to mitigate the identified barriers.

METHODOLOGY

In this exploratory study, a qualitative approach was undertaken to conduct in-depth interviews and focus-group discussion with healthcare providers, support staff, and policy makers who are responsible for care delivery to paediatric patients in the pre-hospital arena in the City of Cape Town. In country collaborators (Dr. Peter Hodkinson and Prof. Lee Wallis) were asked to identify key informants and stakeholders along the pathway of care. This included individuals from all levels of facilities i.e., PHC, community healthcare centres, district hospital, tertiary hospitals, and the Emergency Medical Services (EMS) staff. A combination of in-depth individual interviews and focus group discussions, guided by a semi-structured qualitative script were used to conduct the study.

The use of both individual interviews and focus group discussions is known to enhance data richness.[44] Individual interviews are the most widely used data collection strategy in qualitative research. They are typically chosen to gather an in-

depth account of an individual's perceptions, attitudes, thoughts and ideas.[45] The data gathered are highly dependent on how the questions are formulated and thus more vulnerable to interviewer bias.[46] Individual interviews come in a variety of forms i.e., structured versus semi-structured.[45] A more structured approach is easier to replicate and is more time effective, however, this design does not allow for the exploration of new themes or ideas. A completely unstructured approach would require an expertly trained qualitative interviewer with the ability to explore and build on themes in real-time. Our study took a hybrid semi-structured approach, to ensure replicability across all interviews while simultaneously having the ability to explore solutions to concerns raised.

Focus-group discussions on the other hand are designed to explore a particular idea or problem. In this method, the interactions that resulted from discussions between participants allowed for an increased depth of inquiry, while balancing the similarities and differences among the group.[47] The triangulation of both individual interviews and focus group discussion is a recognised qualitative research practice.[48]

The three main reasons for combining these methodologies are: 1) pragmatic reasons, 2) the need to compare and contrast perspectives, and 3) striving towards data completeness and/or confirmation.[44] In this study, some populations, such as the EMS staff, were only willing to meet in a group, opposed to others, such as clinic/hospital physicians, tended to work alone and so could only be interviewed individually. Comparing the EMS/clinic group data to the individual physician perspectives allowed us to re-affirm findings in each group. The focus group methodology also allows us to identify themes early on and assess for thematic saturation as the study progressed.

For this study, de-identified recordings were transcribed to text and two independent reviewers performed blinded content analysis utilising NVIVO© software. There are numerous well-documented qualitative methodologies, all of which have significant overlap. The two most commonly used qualitative approaches are content analysis and thematic analysis (Figure 3).[49] Both content analysis and thematic analysis are more suitable for researchers who wish to employ a relatively low level of interpretation, in contrast to other methodologies such as grounded theory or hermeneutic phenomenology, in which a higher level of interpretive complexity is required and will not be further discussed. The purpose of our study was to describe the current pre-hospital care for critically ill children Cape Town, SA. By using content analysis, it was possible to analyse the data qualitatively and, at the same time, quantify the data. In our study, we used a descriptive approach to code both the data

and their interpretation of quantitative counts of the codes. Conversely, should we have chosen a thematic analysis methodology, our results would have been presented as a purely qualitative, detailed, and nuanced account of data.[50]

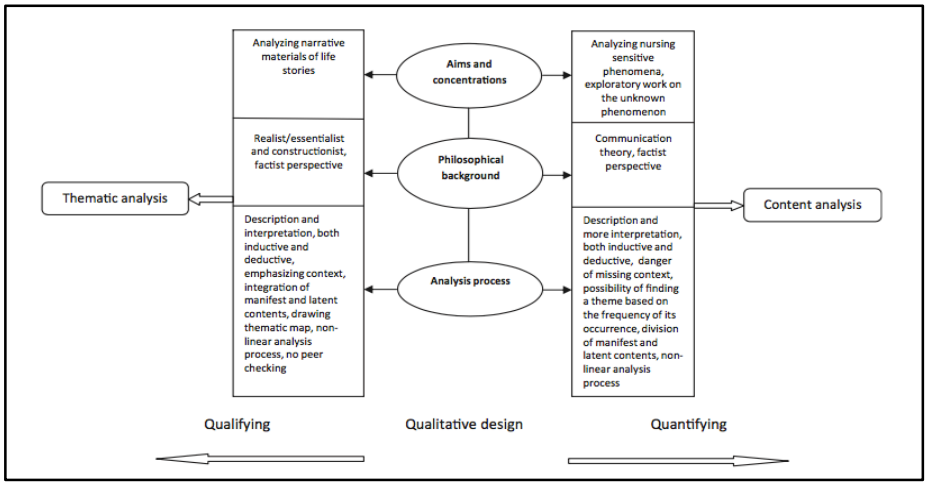

Figure 3. Main characteristics of thematic analysis and qualitative content analysis in the continuum of the qualitative methodology adapted from Vaismoradi et al.[49]

The content analysis methodology consisted of four distinct steps:

(1) Reading for content: Analysis began with data reading until content becomes familiar and emergent themes were noted;

(2) Coding: A list of codes were created based on identified themes and assigned to specific sections of text using NVIVO©, code definitions were documented in a codebook and to ensure inter-coder reliability 10% of data was double-coded;

(3) Data reduction: Once transcripts have been coded, we worked to identify principal sub-themes that may be used to reflect finer distinctions in the data;

(4) Data display: Matrices and tables were used to categorize and display the data to facilitate comparisons, analysis and discussion.

RESULTS

In a single middle income setting, communication barriers were deemed to be the highest priority intervention necessary to improve care delivery. Furthermore, this study identified that there is a paucity of trained healthcare personnel in the clinic setting who can effectively triage paediatric patients. Most commonly, errors in triage were identified as a source of delay for both emergent and transfer calls leading to miscommunication and inappropriate assignments. In addition, many of the healthcare providers interviewed described concerns that families would first wait for the clinic to open and then wait in line to be seen, instead of calling for an ambulance.

Thus, sick children mostly present to a clinic opposed to going directly to higher level of care facility.

DISCUSSION

This study focused on gathering perspective from the view point of healthcare providers, support staff, and policy makers who are responsible for care delivery in the pathway of care for critically ill children. A previous study from the PTCS interviewed caregivers of critically ill children and evaluated their experience. [42] Both studies confirmed that significant and unnecessary delays in the care for critically ill children exist as highlighted by the parent PTCS publication.[12, 43] This study highlighted problems with access to care, and that children were often transferred multiple times as they moved up the levels of care from clinic to district hospital to tertiary referral hospital, leading to delays in access to definitive care. A physician at a tertiary care facility observed,

> *"So the big problem is if the child follows the recommended route of levels of care, so presents to the clinic, then gets sent to the district level hospital, ... those might be three or four steps.... there is no smooth way that they can progress through that, especially being, getting to be assessed, but mainly getting transport and having to sit in the queue. And within sight of the goal, Red Cross Hospital."*

Furthermore, it appears that it is often unclear how/where caregivers should present for care. In the Jones study, a mother states,

> "*After waiting there for my child's turn, I was told that I'm waiting at the wrong place so I had to leave. So I was told to go to 'Trauma'. I wasted a lot of time waiting there whereas I was supposed to go to 'Trauma'*.".[42]

Even within the facilities there seemed to be long delays in receiving care. An EMS manager stated,

> *"(there are) three hour, four hour sometimes delay with the vehicle sitting with a critical patient waiting for a bed, because a lot of the doctors at the hospital,[sic] many times the com centre phones operations, we must go out and make a bed, and it's something we, we can't do. So, we go out, we explain to the doctors, and....you'll stand for three to four hours waiting for the doctor to eventually sign off, and free up the vehicle, which leads to lengthy turnaround times*." Similar a clinic user describes, "*I was not happy about the clinic because when you get there even if your child is an emergency, you must sit down and wait until the sister comes. You cannot quickly rush and go straight 'cause if you do that they shout at you. Also by the hospital it's the same thing.*"[42]

In all healthcare facilities, the delays in caring for critically ill patients are compounded by the numerous administrative process in place. In most facilities, prior to seeing a clinician, caregivers described having to (1) be let in by a security guard (2) see the clerk at reception and open a folder, and (3) wait in a waiting area, with access to the consulting area often controlled by security guards.[42]

Lastly, both studies reported that a significant amount of decision making was dependent on assessments from non-medical personnel. In our study, we identified that, owing to the paucity of trained healthcare professionals available in this region, none of the dispatchers had any previous medical training or experience prior to employment in this role. A communication centre supervisor stated the lack of medically trained dispatchers, as a reason for inaccurate triage of calls, incorrect level of service designation and inappropriate equipment assignments leading to them.

> "*It could be because of the lack of knowledge of the call takers side. Also, they're not prioritising correctly because of their lack of medical knowledge. So they don't know what, the right questions to ask.*"

Similarly, in the clinic setting, owing to the lack of trained healthcare providers, informally, non-medics–security guards, clerks, patients/caregivers–assessed illness severity and determined whether children should be prioritised.[42] This raises concerns that implementing a system that requires medical training or knowledge may penetrated poorly within the current healthcare system due to a large cadre of non-medically trained workers being responsible for decision making. Furthermore, the informal task shifting of "triage" to non-medical personnel may be unavoidable, given the paucity of trained healthcare workers in this region.

LIMITATIONS

This study provided detailed information and a variety of perspectives of a complex system. The utilisation of a single interviewer may introduce bias in the themes identified but our use of two independent coders of the data, who were blinded to the participants, likely minimised it. The purposive sampling of participants was not randomised and may not reflect equally the perspectives of all parts of the system. Also, this is a study of one system, in a singular geographic location and cultural setting, and therefore may not be generalizable to other systems.

CONCLUSION

Overall, the delays in pre-hospital care for critically ill paediatric patients identified in this study were consistent with those previously documented in the literature. The following key findings informed the development of the tool described in **Chapter 4**:

1. Due to the current referral pathway, critically ill children often first present to a PHC setting for care.
2. There is a lack of trained professional staff within the current system.
3. Critically ill children wait for long periods of time at the PHC prior to seeing a healthcare provider.
4. Non-medical staff often take on the role of identifying sick versus non-sick children and prioritizing their care.

In summary, this study supports the notion that a better system may be needed for early identification of seriously ill children at the clinic setting, and that may task shifting this role to up-front staff by providing training in identifying critically ill children may prove to be an effective solution. The outcomes of this small project were accepted and published in the peer reviewed Emergency Medicine Journal (**see Appendix 5**)

CHAPTER 4: DEVELOPMENT OF THE SICK CHILDREN REQUIRE EMERGENCY EVALUATION NOW (SCREEN) PROGRAM

BACKGROUND

Avoidable childhood death is common in low resource settings across the globe, and delays in definitive care remain a key contributor to under-five mortality. Over six million children under five died in 2013, [51] and a large review in the Lancet has demonstrated that up to 70% of these deaths were due to under-treatment or inappropriate management, including a lack of triage. [52] Forty percent of all childhood deaths could have been prevented with timely access to already available definitive care. [53]

In SA, 10% of all children die before the age of five and city-run PHC handle 90% of all paediatric visits. [6,12] In common with other low-resource settings, children with acute life threatening illness in SA often present to the nearest healthcare facilities, in the townships surrounding Cape Town they present to the nearest PHC. The PTCS identified that 57.4% of the critically ill children (medical and trauma) initially presented to a PHC for care and 34.4% were reported to have adverse outcome due to inadequate initial assessment, delays in triage and referral.[12] The group also identified the prioritization of care for critically ill children in community based acute care settings should be a core focus for intervention development. [54] Elsewhere, targeted interventions to improve triage have already been shown to significantly reduce childhood mortality [55, 56].

ORGANIZATIONAL CONTEXT

Primary health care in the City of Cape Town is divided between City and Provincial responsibility. The city of Cape Town health department focuses its efforts on targeted interventions, including child health, maternal and women's health, and HIV/TB care; the remaining healthcare is the responsibility of provincial CHC. All routine paediatric care is the responsibility of city-run PHC. This includes preventative health maintenance (immunization, growth monitoring, and well-baby checks) as well as acute curative care for specific complaints.

The City of Cape Town then divides management of these special programs among eight health sub-districts, each with a different geographic locus (Figure 4). Care for patients in each PHC is coordinated at this level and data are aggregated at the sub-district level to monitor the efficacy of interventions. This was particularly important for this project, as coordination was required with each separate sub-district manager, who then authorized interventions and monitored effectiveness at the PHC level. The PHC are 8-hour facilities (open 0800 – 1600) are mostly run by nursing staff and are

thus designed only for health maintenance of “well” children or children with minor injuries and illnesses. The PHC have limited access to medications, resuscitation resources, and physician support. However, in practice, PHC treat children who have wide range of illness severity. Within each PHC, a Nurse Facility Manager, who is a senior or Professional Nurse (PN), organizes and supervises care (Figure 4). Sick children are attended to by a combination of PNs and Enrolled Nurses (ENs). PNs are graduates of a four-year nursing degree and have received training in IMCI. ENs are graduates of a two-year nursing program and have the specific task of performing basic vital signs, weight assessment, and basic diagnosis using IMCI. Each site has one or two ENs and between one and four PNs at any given time, depending on the patient load of the clinic. The ENs are often the first staff member to assess the patient. Other personnel at PHCs include clerks who oversee and distribute patient charts, pharmacists and pharmacy assistants.

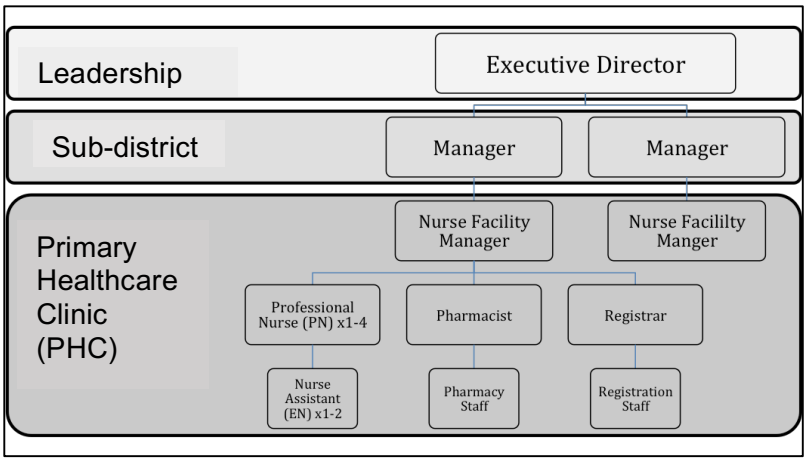

Figure 4: Organizational Structure of City of Cape Town Health System

All nurses in these facilities rely on IMCI to guide the diagnosis and treatment of children under five years old. [10] The goal of IMCI is to improve the performance of healthcare providers through training and support. IMCI combines lessons from disease specific control programs to develop a single efficient and effective syndrome based approach to managing childhood illnesses. [57] IMCI has been widely implemented in over 100 countries since its inception in 1996. [58] The case management process requires a PN equivalent provider and takes several minutes (between 5-7 minutes) to complete. [10]

AIM

To develop a implementable context-appropriate tool to identify and expedite the care of critically ill children in PHC in the City of Cape Town, South Africa.

OBJECTIVES

1. Present the development of the SCREEN program
2. Present the implementation and evaluation strategy for the SCREEN program

METHODOLOGY

A stepped approach was undertaken to develop a PHC-based screening intervention. The initial step was informal study of the PHC setting, followed by in-depth interviews and focus-group discussions with key stakeholders and staff members to develop an intervention, which concluded in pilot implementation using an iterative action research methodology (Figure 5).

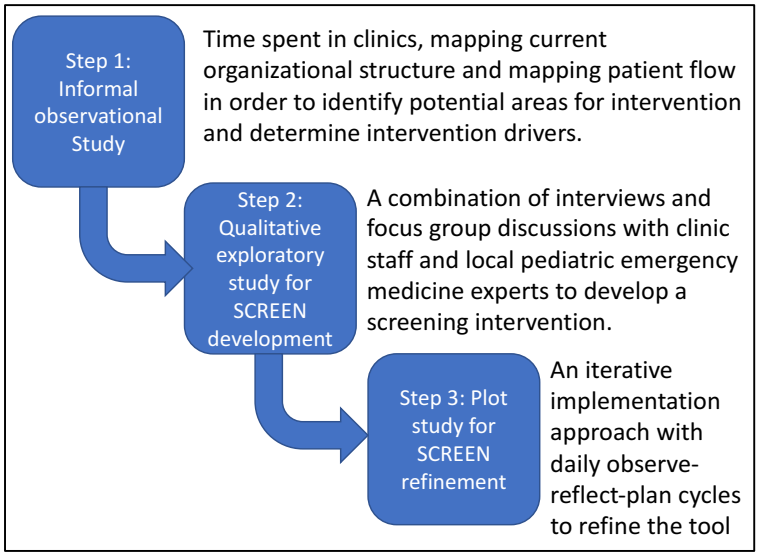

Figure 5: Overview of SCREEN development methodology

The methodologies utilized in SCREEN development form part of the field of implementation science. Over the past decade, there has been growing recognition that scientific discovery and translational research alone will not result in public health gains.(52) For any field, there may be a number of proven clinical interventions; however, the potential for impact is often limited due to poor penetration of the intervention within the healthcare system, lack of resources to uptake the intervention and/or incomplete uptake by individuals/healthcare workers.[59] Implementation Science is the study of factors that influence the full and effective use of innovations in practice. [60] In 2005 the National Implementation Research Network released a monograph that synthesized implementation research across a range of fields and presented five overarching frameworks referred to as the Active Implementation

Frameworks.[14] In this proposal the framework of "Implementation Stages" was utilized to develop a locally-informed PHC-based, screening tool for critically ill children. Conducting stage appropriate activities is necessary for successful change, using this framework in Step 1 ("exploration") informal study allowed us to broadly identify current implementation gaps within the clinic system, in step 2 ("Installation") a locally-informed approach was used to develop the intervention and identify implementation drivers, and in step 3 ("initial implementation") an implementation trial was conducted to refine/adjust the developed intervention further.

RESULTS

INFORMAL OBSERVATIONAL STUDY

The informal observation was conducted in five PHC throughout the City of Cape Town, clinics were chosen by the City of Cape Town executive health management team in order to provide the researcher with a wide variety organizational differences. This observation revealed that the majority of children that attend the PHC (60%), present for scheduled wellness checks and/or preventative care visits. The vast majority of these children are truly well, but occasionally a sick child will come with either a new mother or a caregiver who is not attuned to the child's illness, and the PHC will provide both curative and routine care. Of the remaining 40% of children who present with an acute complaint, 90% are categorized by the professional nurses as IMCI "Green" or "Yellow" (the least sick, with such complaints as rashes, diarrhoea without dehydration, or a viral upper respiratory illness). However, 10% of those who are sick, and 4% of all who present, are IMCI "Red", or critically ill, by the professional nurses' assessment. All of the children wait in the same line for the initial interaction with a healthcare provider. Furthermore, some children leave without even being seen by a EN due to the long waiting times.

The observations are presented in an infographic (Figure 6), which maps the typical flow of a patient through the PHC. South African PHCs operate on a first-come, first-served basis, thus typically parents stand in line with their child long before the clinic opens (between 7:30 and 8:00AM). Each client submits their patient identifying card to the registration desk and sits in the waiting room until they were called by the EN. The wait to see the EN was not dictated by patient acuity, but simply by place in the queue and could be between four and six hours. The EN would weigh the child, gather vital signs and perform a preliminary IMCI evaluation (without formal diagnosis or treatment). The patient would then return to the waiting room to see a PN. This could last up to an additional eight hours. Sometimes, if the patient was recognized as critically ill, they would be ushered to the PN's directly by the EN, however this

practice was not consistent across sites. Given the inadequate number of trained providers, and high volumes of children presenting to PHCs, a large number of children (20-40%) would leave without a PN evaluation, and some without even a basic EN evaluation (10-20%).

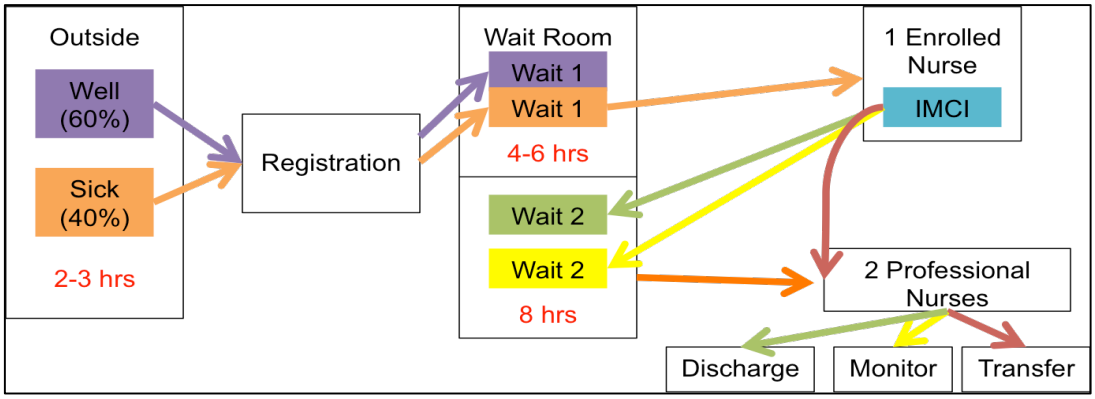

Figure 6: Infographic mapping the flow of children in a typical PHC in Cape Town, South Africa

As is evident from Figure 6, significant bottle-necks exist waiting for the first interaction with a trained healthcare provider. This is because every patient, whether here for immunization or for a sick visit, must visit the EN prior to seeing a PN per citywide protocol. With between 80-100 children visiting some clinics every day and the task of initial evaluation often being left to a single provider, this process is often incomplete and time consuming.

In PHC the expedition of care for critically ill children is at the mercy of ENs and PNs who periodically required query the waiting room to see if any of the children waiting are critically ill. In addition, some clinics had posters commissioned by City of Cape Town that encourage people to immediately seek care if their child showed "danger signs" of critical illness (vomiting everything, poor oral intake, significant diarrhoea, convulsions). These signs are universal to all clinics but lack specific advice for parents on how to expedite care the care of their child, if the child has a "danger sign". Clerical staff had no formal training in identifying critically ill children, but on occasion they would assist if they noticed a lethargic, unconscious, or convulsing child in the waiting room, and taken that child to a PN.

QUALITATIVE EXPLORATORY STUDY

The systematic literature review of paediatric triage in low-resource settings allowed investigators to develop a thorough understanding of the theoretical basis for triage and various evaluation methodologies accepted by the scientific community. [61] This

information was used to design and inform the development of a structured assessment of potential interventions using the modified Delphi technique,[62] a method that has been used in other settings to structure discussions with experts.[63-65] It involves sequential interviews with different experts and stakeholders, with collating of opinions and reformulating of potential interventions between each round of interviews. In this particular model (Figure 7), Dr. Hansoti conducted interviews with South Africa based paediatric emergency medicine experts, staff from the PHCs, and the executive health management team in a serial fashion. This allowed input from experts, implementers and policy makers to develop a cohesive solution that would have a higher likelihood of success.

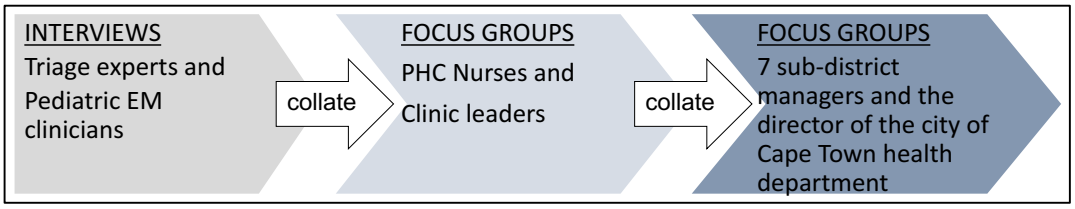

Figure 7: Overview of Modified Expert Delphi Methodology for SCREEN development

From these sequential discussions, it became apparent that a screening tool was necessary to identify critically ill children at the point of entry so that care could be expedited at arrival. In addition to IMCI, the WHO had already developed Emergency Triage Assessment and Treatment Tool (ETAT), which applied the principles of IMCI to an emergency setting with paediatric patients. The local experts believed that would be an appropriate basis for a triage tool in this setting. [66] From the discussions with experts and stakeholders, the importance of an easy to use, dichotomous variable (yes/no) was stressed. The purpose of the tool would be to expedite care for initial PN evaluation. Initial questions were based on the ETAT emergency signs [67] and included oral intake, breathing, or abnormal movements. In addition, questions were added that included the age of the child (given the serious nature of illness in very young children) and if they had recently been to a clinic (as treatment failure is a criterion for referral per IMCI and City of Cape Town policy).

Pilot Study For SCREEN Refinement

After the initial prioritization tool was developed, the tool underwent pilot testing in two clinics in Cape Town. Clerks and ENs were tasked with screening children using this tool prior to registration at the front entrance to the clinic the study staff observed and

solicited feedback from nurses and patients at clinics during this pilot. An Action Research Methodology was used to identify barriers and reflected upon a root cause and potential improvement plans to the tool (Figure 8). [68]

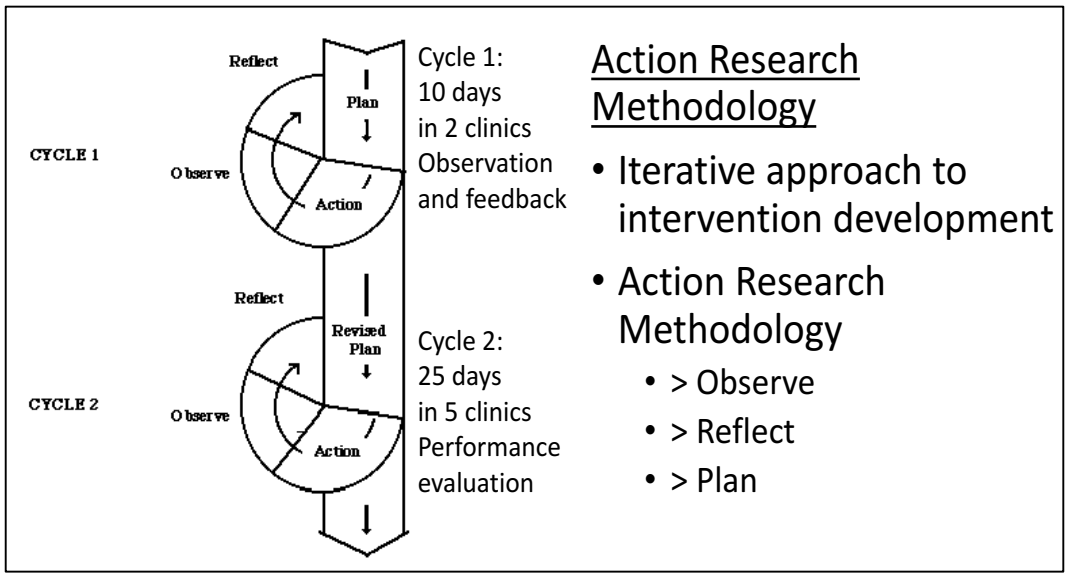

Figure 8: Infographic demonstrating Action Research Methodology for SCREEN refinement

These observed issues included an unclear purpose of the tool and poor understanding of the justification of the tool, a high false negative rate, and practical issues with expediting care for potentially critically ill children. The observed issues were then reflected upon, a root cause was discovered, and changes were made to create a final version of the tool.

A sample of the observe-plan-reflect cycles is presented in Table 2. The initial pilot testing resulted in significant changes to the screening intervention.

Table 2: Overview of findings from pilot study

Observe	Reflect	Plan
Clinic staff unclear as to purpose	Concerns with naming of tool, existing ubiquitous use of the word triage	Introduce the tool to staff as a screening tool i.e., pre-IMCI and pre-triage
Too many children prioritized causing bottle neck with EN	Too many children identified as not breathing normally	Modify inclusion criteria
Inconsistency in understanding clinical discriminators	Likely due to differences in linguistic foundations	Ask IMCI danger signs instead, as better established in the clinic system and easier for staff to communicate with each other
Unclear and inconsistent administration of tool	Over burden staff	Employ dedicated staff for intervention implementation, task shift to non-healthcare providers
Once screened, child continued to wait for long time for EN	Pre-existing culture of first come first serve	SCREN staff to physically hand take the child to a PN and bypass EN assessment
Parents of well children upset that certain children jumped the queue	Triage is not a part of the normal culture of care in PHCs	Announcement by sister every 2 hours to waiting room on why we are going to screen critically ill children

First, the tool was renamed SCREEN – Sick Children Require Emergency Evaluation Now. Due to hesitation over the use of the term “triage” given the professional nurses’ perceived role in formal triage, the purpose of the tool was renamed as “screening”, fitting the name. In addition, the questions were changed to mirror IMCI questions rather than ETAT questions, as this created less confusion in translation and understanding among the clinic staff. Professional nurses had already been using IMCI for diagnosis and management so both health care workers and parents of young children were familiar with IMCI based danger signs. Finally, the team changed the automatic age of inclusion to two months, as this was the age cut off for IMCI (there are separate IMCI tools and danger signs for children under two months of age). This was designed to reduce false negatives and improve specificity. Due to the fact that there was significant resistance by clerical staff to adding screening to their already significant work load, lay healthcare assistants were hired to perform SCREEN questioning at each clinic entrance as “Queue Marshalls” (QMs). Utilizing the national Expanded Public Works Program, unskilled lay workers were hired and trained to implement the SCREEN program. They are paid a salary commensurate with other employees in the program (120 ZAR/$10 per day) and are given short-term

contracts (three to six months) to maximize employment opportunities for impoverished and unemployed individuals in the city. The training of QM was undertaken by the City of Cape Town IMCI training centre, given the significant overlap between the SCREEN tool and the IMCI danger signs. Training include a combination of lectures, videos, and role playing sessions with staff and lasted for one day.

SCREEN PROGRAM

SCREEN asks six simple questions, to all "sick" children that present for care, and is based on the WHO IMCI danger signs. The questions take less than 1 minute to administer and are simple enough to be administered by laypersons (queue marshals) who can be trained in less than one day to rapidly identify critically ill children at the entry point of PHCs, and expedite their care. An overview of the SCREEN program is given in Figure 9.

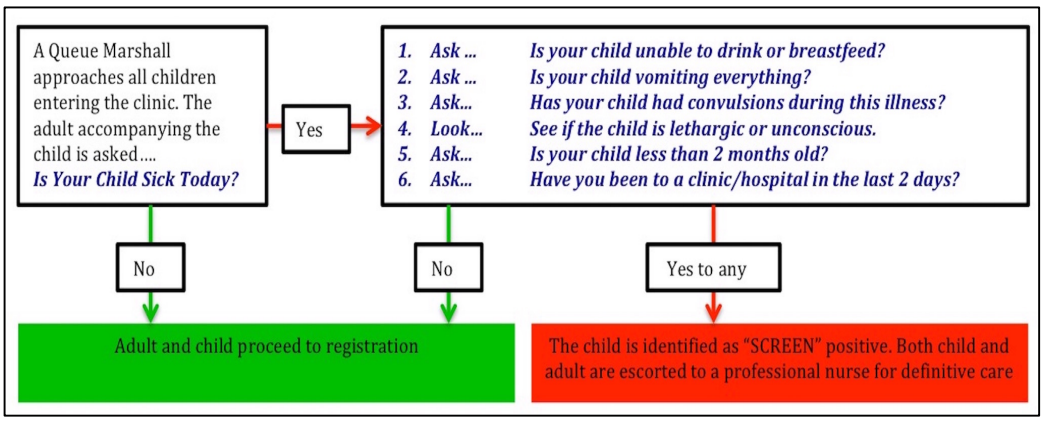

Figure 9: Infographic demonstrating the Sick Children Require Emergency Evaluation Now (SCREEN) program

DISCUSSION

The resulting methodology allowed us to develop and implementation intervention that is designed for the local clinical setting. The systematic review (**Chapter 2),** exploratory study **(Chapter 3)**, and informal observations were critical to defining the contextual framework for intervention development. The modified-Delphi approach starting with experts, then implementers, and ending with policy makers allowed us to develop an intervention that had a high likelihood of acceptance. Despite the significant preparatory work that went into tool development our pilot study still revealed significant barriers to implementation. Active implementation research frameworks advocate the use of implementation stages.[60] Theoretically conducting stage appropriate activities will allow for more successful change. The overall research strategy thus far has followed the implementation stages framework namely:

Exploration (i.e., systematic review, qualitative study and informal observation), Installation (i.e., intervention development) and Initial Implementation (i.e., the pilot study).

Despite well-written guidelines and recommendations, many interventions often fail when poorly implemented. This is because any new intervention seeks to change the overall practice environment and thus often invokes compelling forces of fear of change, inertia, and investment in the status quo, which combine with the inherently difficult/complex work of implementing something new.[69] The initial implementation phase is fragile and can be resource intensive however with support from an implementation team and iterative improvement cycles successful implementation is possible. During the pilot study a small-scale, iterative approach was used to test the intervention. Rapid assessments combined with adaptive refinements permitted flexibility to produce a viable and easily implementable intervention.[69]

LIMITATIONS

While implementation approaches offer investigators a framework with which to develop implementable interventions, the interventions developed are often context specific and less likely to be applicable to a wider audience. The frameworks presented in this thesis use subjective methodology and thus the likelihood of success is highly dependent on the investigator and the rigor with which he or she applies the frameworks utilised.

CHAPTER CONCLUSION

An active implementation research approach was used to successfully develop the SCREEN program. The remainder of this thesis will focus on the evaluation of this intervention within the clinical setting. In **Chapter 5** the study focuses on the clinical effectiveness of the tool in a controlled environment compared to the current standard of care, in **Chapter 6** the study quantifies the impact of SCREEN on patient flow within the organizational context of the clinic and finally in **Chapter 7** concludes the evaluation of the SCREEN program using an effectiveness-implementation hybrid methodology post-real world implementation.

CHAPTER 5: RELIABILITY OF "SCREEN"

Reference: Hansoti B, Hodkinson P, Wallis L. Prioritizing the care of critically ill children in South Africa: How does SCREEN perform against other triage tools? Pediatric Emergency Care. Manuscript ID: PCARE-D-16-00668R2 (Accepted 8th February 2017).

MAIN FINDINGS

- SCREEN has high sensitivity (100%-98.73%; p<0.001) and specificity (64.41%-59.10%; p<0.001) when compared with other validated triage tools.
- SCREEN also has a high negative predictive value approximating 100% in both the primary health care setting and the district hospital setting.

DECLARATION FROM AUTHOR

The following co-authors contributed to the paper: Dr. Peter Hodkinson and Prof. Lee Wallis

In the case of Chapter 3, contribution by authors to the work was as follow:

- **Nature of Contribution:** BH and LW came up with the original idea; BH and LW worked to design the study. BH and PH worked together on data collection. BH, PH and LW together drafted the manuscript and all contributed to revising it critically for important intellectual content. All authors approved the final published version and agreed 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.
- **Extent of contribution**: BH: 75%; PH 10%; LW: 15%

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Signed: Bhakti Hansoti

DECLARATION BY CO-AUTHORS

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data: The raw data and articles are stored on password protected database at Johns Hopkins University, Baltimore, USA. There is no patient data in this study.

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Prof. Lee A. Wallis January 29th 2017

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Prof. Ian Maconochie January 29th 2017

INTRODUCTION TO TOPIC

Screening tests are often used in clinical practice to assess the likelihood that a person has a particular medical condition. The rationale is that, if disease is identified early (before the manifestation of symptoms), then earlier treatment may lead to cure or improved survival or a better quality of life. Screening tools are often laboratory or radiological tests that detect a particular marker of a disease. However, it is important to point out that screening tests are not definitive; while they raise a heightened suspicion of disease, they are not diagnostic. A definitive diagnosis generally requires more extensive, sometimes invasive, and more reliable evaluation.

The central premise of this thesis is that the SCREEN program will identify critically ill children early in their pathway of care, so that they may receive a definitive evaluation by a professional nurse who can administer lifesaving treatment if required. After a screening tool is developed (**Chapter 4)** various characteristics of the tool must be evaluated prior to implementation. In the table below, we apply the WHO "Characteristics of a Screening Test" criteria to the SCREEN program.[70]

Table 3: The WHO Characteristics of a Screening Test applied to the SCREEN program.

Characteristics of a screening test	**SCREEN program**
1. The condition should be an important health problem.	✓
2. There should be a treatment for the condition.	✓
3. Facilities for diagnosis and treatment should be available.	✓
4. There should be a latent stage or asymptomatic stage of the disease.	Does not apply
5. There should be a test for the condition.	✓
6. The test should be acceptable to the population.	To be determined
7. The natural history of the disease should be adequately understood.	✓
8. There should be an agreed policy on who to treat.	✓
9. The total cost of finding a case should be economically balanced in relation to medical expenditure as a whole.	To be determined
10. Case-finding should be a continuous process, not just a 'once and for all' project.	✓
11. Test used should be highly sensitive to determine true cases.	To be determined in Chapter 5

In medical diagnosis, test sensitivity is the ability of a test to correctly identify those with the disease (true positive rate), whereas test specificity is the ability of the test to correctly identify those without the disease (true negative rate). All screening tests should be highly sensitive, given that those with the disease that are missed are unlikely to undergo repeat evaluation or further diagnostic testing. In our study, if a

critically ill child is missed by the SCREEN tool, that child will likely have to sit in the waiting room for hours before seeing a healthcare provider so this would cause further delays in that child's care. Specificity for a screening test is less important feature, however, if too many children are identified as SCREEN positive this may cause a new bottleneck in the system, by an overwhelming number of cases being sent to the PN for evaluation. An ideal screening test for the purpose of this thesis will be highly sensitive and specific.

Two other measures for evaluating screening tools are positive predictive value and negative predictive value. Positive predictive value is the probability that subjects with a positive screening test truly have the disease. Negative predictive value is the probability that subjects with a negative screening test truly don't have the disease. Positive and negative predictive values are influenced by the prevalence of disease in the population that is being tested. If we test the tool in a high prevalence setting, it is more likely that persons who test positive truly have disease than if the test is performed in a population with low prevalence.

Motivation for Conducting The Study

The SCREEN program already meets many of the conditions laid out in the Table 3. The focus of the chapter is to evaluate the last row in the table i.e. the test sensitivity. With that, we also need to measure the specificity, positive predictive value and negative predictive value of the screening tool as well. Prior to implementation, it is important to evaluate if, in a controlled setting, the test is able to perform as designed, i.e., is the test able to identify disease. In Chapter 5, this characteristic of the SCREEN program is evaluated by comparing the performance of the SCREEN tool to the other previously validated triage tools.

Aim

Evaluate the reliability of this tool compared to established triage tools currently used in this setting.

Objectives

- Measure the performance of SCREEN in identifying critically ill children compared to other triage tools currently utilised in the PHC setting
- Compare the positive and negative predictive value of SCREEN in clinical environments that have a high and low prevalence of critically ill children.

COPY OF PUBLISHED PAPER

The following manuscript over the next 20 pages is presented in the form that was accepted for publication by the journal of Paediatric Emergency Care on February 8th 2017.

Manuscript number: PCARE-D-16-00668R2

Pediatric Emergency Care

Prioritizing the care of critically ill children in South Africa: How does SCREEN perform against other triage tools?

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Abstract:	Objective: Childhood mortality remains unacceptably high. In low resource settings children with critical illness often present for care. Current triage strategies are time consuming and require trained healthcare workers. To address this limitation, our team developed a simple subjective tool, SCREEN (Sick Children Require Emergency Evaluation Now), that is easy to administer, to identify critically ill children. This paper presents the development of the SCREEN program, and evaluates its performance when compared to other commonly implemented triage tools in low resource settings. Methods: We measured the sensitivity and specificity of SCREEN, to identify critically ill children, compared to four other previously validated triage tools; the integrated management of childhood illnesses, the Pediatric Early Warning, the Pediatric South African Triage Scale and the WHO Emergency Triage and Treatment Tool. Findings: SCREEN has high sensitivity (100%-98.73%; p<0.001) and specificity (64.41%-50.71%; p<0.001) when compared with other validated triage tools. Conclusion: The SCREEN tool may offer a simple and effective method to identify critically ill children in low resource environments.

Prioritizing the care of critically ill children in South Africa: How does SCREEN perform against other triage tools?

Introduction

For children under five years old, there have been declines in the global mortality rate, and in the total numbers of deaths, from 10.8 million in 2000 to 6.8 million in 2012.[1 2] However, in sub-Saharan Africa, despite some effective interventions, this region has the highest mortality rate at 98 deaths per 1000 live births compared to a rate of 53 deaths per 1000 live births for all developing regions.[3] Care provision in low-resource settings is challenged by fewer or less-trained personnel, a less-developed infrastructure, and limited access to medication, equipment, and supplies, compared to high-resource settings.[4]

Key approaches to reducing childhood mortality through emergency care, are centered on strategies to reduce delays in care that occur because critical illness is not recognized early, [5-7] and improvements in the quality of hospital care for children.[1 8 9]

In common with other low-resource settings, children with acute life threatening illness in South Africa often present to the nearest healthcare facilities - in the townships surrounding Cape Town, they frequently present to primary healthcare centers (PHCs).[7] The PHCs are 8-hour facilities (open 0800 – 1600), run by nursing staff, and designed for routine healthcare of well children or children with minor injuries and illnesses. The PHCs have limited access to medications, resuscitation resources and physician support. In practice, PHCs treat children who have a wide range of illness severity.[10] Furthermore, 10% to 20% of children presenting to PHCs are already sufficiently ill to benefit from referral to definitive care according to the World Health Organization (WHO).[1]

Managing critically ill children is particularly time-sensitive, and delays directly affect outcome.[11 12] To improve the care of critically ill children, the WHO developed a clinical management strategy, the Integrated Management of Childhood Illnesses (IMCI).[13] Since the launch of IMCI in 1996, more than 100 countries have adopted this tool.[2] Multiple studies have shown that IMCI improves the quality of care in healthcare facilities, increases the use of facilities, and increases the percentage of sick children taken to an appropriate health care provider.[14-16] However, IMCI must be administered may trained nursing staff, which are expensive, and often unavailable. Thus a lack of financial resources hampers the scaling up and implementation of IMCI in many settings.[17 18]

Several studies have demonstrated that, despite the universal implementation of IMCI, significant and unnecessary delays in the care for critically ill children exist within the PHC setting in Cape Town, South Africa.[7] The Pathways To Care Study, led by Hodkinson et al, identified that 57.4% of all critically ill children (medical and trauma), initially presented to a PHC for care and 34.4% were reported to have adverse outcome due to inadequate initial assessment, delays in triage and referral.[7] Before being seen by a professional nurse critically ill children wait an average of 2 hours and 45 minutes (CI, 0h:48m- 4h:11m), in a crowded waiting room, among healthy children coming for routine care.[7 19 20] Furthermore, on average over 25% of children in the clinics leave without being seen by a professional nurse.[20]

In collaborating with local healthcare services staff in Cape Town townships, we the need for a better system may be needed for early identification of seriously ill children at the clinic setting, and that task shifting this role to up-front staff by providing training in identifying critically ill children may prove to be an effective solution. Our team developed a simple subjective tool named SCREEN (Sick Children Require Emergency Evaluation Now), which can be implemented by healthcare workers without formal medical/nursing training. The tool was designed to identify critically ill children and eventually improve the prioritization of care for these children in the low-resource townships surrounding Cape

Town. The present paper describes the development of the SCREEN tool, and evaluates its performance against other commonly implemented triage tools.

Methods

SCREEN development

Our team and local staff worked together to develop a prioritization tool to reduce these delays. We identified three groups of stakeholders: (i) healthcare providers at the PHCs, (ii) experts in pediatric emergency and acute care; and (iii) the executive healthcare management team of the Cape Town government. We held focus groups to address the reasons why critically ill children were kept waiting in the current clinic system, the healthcare resources that contributed to the delays, and solutions that would be feasible in the Cape Town PHCs. The solutions suggested were collated and re-presented to the other groups in an iterative fashion until all three groups developed a consensus on the optimal tool. The groups decided that the optimal tool should be simple enough to be administered by lay persons (given that nursing roles in the clinic are often overburdened), the language of the tool should must be consistent with what is used in the current clinic system, and the tool should not require the examination of patients (i.e collection of weight and vital signs) given that this is time consuming and is currently perceived as the biggest contributor to delay in the PHCs.

It was agreed to develop a screening tool derived from the validated WHO IMCI danger signs (already in use in PHCs).[21] In addition to the danger signs we added two further modifiers, 1) if the child is less than 2 months of age as this group is at much higher risk of severe illness and 2) if the child had been seen in clinic/hospital in the last 2 days. SCREEN has seven simple yes/ no questions (Fig. 1), and thus takes less than 1 minute to administer. The goal is to eventually develop a program

so that SCREEN can be utilized by laypersons to screen for critically ill children at the entry point in to the PHCs, and expedite their care.

SCREEN performance: Primary outcome measure, study settings, enrollment criteria, sampling and data collection

No reference standard exists for the definition of "critically ill child". Many studies advocate for the use of "transferred out or died in clinic". In our study, no children died within the clinic and by definition all IMCI children with ICI danger signs are automatically flagged for transfer thus this would have introduced a confounding bias to the results. Thus, in this study we choose defined that the primary outcome of this study was to measure the sensitivity and specificity of SCREEN to identify "critically ill" children. In the clinics healthcare providers use a range of triage tools to define children as "critically ill". In our study we compare SCREEN to four other tools that have been tested and validated for triaging children in low-resource settings.[22] The four tools were chosen by consensus between the primary author (BH) and senior author (LW) a priori: (i) The IMCI guidelines [13] is routinely implemented in all PHCs in the City of Cape Town and is the current standard of care. The IMCI guidelines (which bases severity of illness on symptoms and vital signs) was developed by expert consensus.[5] Given that SCREEN is based on the IMCI danger signs, we anticipate the significant overlap will bias our results and thus other tools are required.[23] (ii) The Pediatric Early Warning Score (PEWS)[24] which uses vital signs only is the most objective tool for comparison, however several studies have shown poor performance of this tool. (iii) The Pediatric South African Triage Scale (PSATS)[25] and (iv) the WHO Early Treatment and Triage Tool (ETAT)[5] both use a combination of vital signs and clinical discriminators, while they both have significant overlap some differences remain. Both have performed well in identifying critically ill children when compared against expert consensus.[26,27] For comparison purposes the gold standard for "critically ill" was

defined as the highest severity category in each of the four validated instruments. The SCREEN tool was deemed positive if the parent answered yes to is your child sick today and said yes to any of the six discriminator questions asked.

The study is set in Cape Town which has 120 primary healthcare clinics and 8 district hospitals (DHs). The City of Cape Town selected five PHCs and two DHs from which to obtain a convenience sample of presenting children. PHCs are intended to provide health maintenance and wellness checks, and thus tend to see a lower proportion of critically ill children than hospital based facilities such as DHs. However, given the lack of transport and access to definitive care in the townships, parents may bring critically ill children to PHCs rather than to DHs.

All children aged 15 years or younger, described by their accompanying adults to be sick on arrival to the healthcare facility and presenting for care during the study period were enrolled in to the study. The age limit of 15 years was chosen because the City of Cape Town classifies “children” as age 15 years or younger. Only children under the age of 5 were included in the IMCI comparison, as IMCI use is restricted to children between the ages of 0 to 5 years.

The purpose of the study was to evaluate the performance of SCREEN using pediatric data prior to implementation. The standard of care is inherently different at PHCs and DHs and thus two different data collection strategies were implemented a schema of which is provided in figure 2. In PHCs we found minimal data to be recorded in the patient chart and thus prospective data collection was necessary to facilitate review. In the DHs nurses routinely perform triage (using PSATS) [22] and thus it was possible to use retrospective chart review. In the PHCs, a member of the research team observed the nursing assistant and patient interactions that occurred during intake in the “weighing

room", and gathered the necessary variables (weight, vital signs and clinical discriminators) to assign a triage category using each of the above-mentioned tools. Each of the 5 clinics was sampled for 5 consecutive days. In the DH we used retrospective chart review to gather the necessary data variables to calculate the triage scores of all children that presented to the hospitals during the study period. In the DH triage is a continuous process that occurs 24 hours throughout the day (the majority of children present in the evenings, nights and weekends). During triage the nurses typically gather a chief complaint, obtain vital signs, ask for clinical discriminators, and assign IMCI danger signs and PSATS score. A limitation in the funding resources of this study prohibited our ability to employ 24 hours a day prospective data collection and thus we opted to for the retrospective chart review methodology. In addition, at the PHC sites a member of the study team was present during data collection and this could introduce bias via a Hawthorne effect.

Assuming a significance level 0.05 (one-sided), power of 80% we will need to enrol 118 critically ill children to demonstrate a sensitivity of 95% +/- 5% (i.e. greater or equal to 90%). Assuming a 12% prevalence of critically ill children based on discussion with City of Cape Town staff, a total of 984 children will need to be enrolled to achieve this significant level. Thus we choose to aim to audit 500 charts in both the PHC and DH arms.

The study staff did not interfere with the care of the children at any of the study sites. The standard of care at both the PHCs and DHs is to ask all accompanying caregivers the IMCI danger signs and the two modifiers. The provider asks the questions as they are written (verbatim) and a yes or no response is recorded. It is important to note that in this pilot study the tool was not implemented by as designed by non-healthcare clinic staff also known locally as queue marshals, rather routine data collected during patient care was used to calculate the SCREEN assessment.

Statistical analysis

The primary outcome measure was the comparison with SCREEN assignment (SCREEN positive is yes to any of the six questions) against triage category assignment via IMCI, PEWS, PSATS, and ETAT (figure 3). Basic descriptive statistics were calculated using SPSS©. The SCREEN score was cross-tabulated against the triage score for each of the four tools in order calculate sensitivity and specificity. A chi-square test was used to determine statistical significance; a threshold of 5% was set a priori.

Funding and institutional review board approval

SCREEN was developed through financial support by a Global Health Fellowship Program (R25 TW009340) the Fogarty International Center of the National Institutes of Health, Bethesda, Maryland, USA. Approval was received from the institutional review boards of the Johns Hopkins University, Baltimore, Maryland, USA (NA_00088758), and from the University of Cape Town, South Africa (HREC 401/2013).

Results

Overall

The study was conducted in the PHCs and DHs from Jan 1st to July 30th 2015, sites were enrolled in a serial fashion, Of the 961 children enrolled in this study, 399 (42%) were identified as SCREEN positive. When compared between health care settings, the proportion of SCREEN positive children was significantly lower in the PHC compared to the DH (26% vs. 56%; $p<0.001$) (Table 1). The proportion of children that were male was significantly lower in the PHC compared to the DH (52% vs. 58%; $p=0.04$). The frequency of positive responses to each of the six individual screening questions varied from 15 – 2% (Table 2). The questions “Vomiting everything”, “Unable to drink or breastfeed”

and “Seen in a clinic/hospital in the last 2 days” had the highest frequency of presentation in SCREEN positive children (15%, 12% and 11% respectively).

Sensitivity and specificity analysis

In the PHC the percentage of children categorized as critically ill ranged from 6.52% (using PEWS) to 1.95% (using ETAT), and in the DH, between 23.83% (using TEWS) to 13.4% (using PSATS). Data from the PHCs and the DHs were pooled to present an aggregate analysis for comparison of the four validated tools and our new SCREEN tool. Of the total of 961 children included in this analysis, 399 were SCREEN-positive and 562 were SCREEN negative (Table 3).

Discussion

SCREEN tool is highly sensitive in identifying “critically ill” children that present to low resource healthcare facilities in South Africa. In low resource settings the number of preventable deaths remains high. The early identification of critically children can save lives, however significant delays remain given the lack of trained healthcare providers to perform triage. SCREEN utilizes six simple questions and provides a quick solution for lay clinic staff to identify critically ill children that require immediate attention.

The SCREEN tool demonstrated the highest sensitivity when compared to IMCI, this is likely attributed to the extensive linguistic overlap between the SCREEN questions and the IMCI danger signs.[25] When comparing the new SCREEN tool to ETAT and PSATS, the new tool also performed extremely well. Both ETAT and PSATS were developed on the ABCD concept of triage.[22 26 27] Triage of patients using ETAT and PSATS involves looking for signs of serious illness or injury. The ETAT triage tool places patients with “emergency signs”, i.e. relate to the Airway-Breathing-

Circulation/Consciousness-Dehydration, in the highest severity category. Those patients with "emergency signs" are equivalent to IMCI red. The Cape Triage Group modified the ETAT tool, by combining it with vital signs, to develop PSATS. Trained nursing professionals, who are in short supply in low resource healthcare settings, are traditionally required to administer triage tools. The high sensitivity of SCREEN may allow for a pre-triage screening in times of high surge when waiting times in the clinical setting are long causing delays to triage.

It is reassuring that even when compared to PEWS, SCREEN has close to 90% sensitivity. This is surprising given SCREEN is a subjective tool relying only on clinical discriminators, while PEWS is an objective tool that relies only on vital signs. This finding is particularly exciting, given that the collection of vital signs in pediatric patients is not only time consuming but can also be difficult to obtain. However it is important to note that the collection of vital signs remains necessary as part of the IMCI pathway and the standard of clinical care. Obviating the need for the collection of vital signs upfront which simply hasten the time to first interaction with a healthcare provider.[20]

Our study did demonstrate a relatively low prevalence of critically ill children in the PHC given that, among the 461 children sampled from the four randomly chosen PHCs, only 17 (4%) were identified as IMCI "red". This percentage is much lower than that in a study in the northern Limpopo and Kazulu-natal townships by Horwood et al. in 2011 [28], who, reported that 108/1,357 (8.0%) children required urgent referral from the PHCs to the district hospital. It was due to the low prevalence of critically ill children in the PHC we repeated the study with a similar sample of children (500) from the DH setting. In this setting the number of children categorized as IMCI red were 68 (14%).

It is estimated that “sick” children account for only 30% of the visits to the PHCs, the remaining 70% usually present for routine health maintenance and vaccinations. In our study, among the “sick” children in the PHC, 119 (26%) were identified as SCREEN positive. This means that almost 8% of patients that present to the clinic will be prioritized, and thus, jump the queue, should SCREEN be implemented. The prioritization of almost one in ten individuals may have a significant impact on patient flow in the clinics. When compared to the other tools, SCREEN had a very low positive predictive value especially in the PHC setting. Thus it is likely that a high number of children who are screened positive and expedited will likely not require urgent treatment. Providing expeditious care to high number of patients may disrupt the current queue system that is in place in all of the PHCs. However, the converse is also true, SCREEN had a very promising negative predictive value (ranging from 0.998 to 1). This implies that the tool can be implemented safely and clinic staff can be confident that no critically ill children will be missed. The impact of SCREEN implementation on waiting times for all patients was measured in a process mapping study.[20] To our surprise, we identified that not only was SCREEN able to reduce waiting times for critical illness children to see a professional nurse (from an average of 2 hours and 45 minute to 1 hour 12 minutes; $p<0.001$), but overall waiting times for well children did not increase and in some case were also reduced.[20] Furthermore, we identified that there was a reduction in the left without being seen rate.

Limitations

This study evaluates the performance of SCREEN against other triage tools, by collecting triage data via direct observation (in the PHCs) or retrospective chart review (in the DHs). The SCREEN tool uses simple language that can be easily translated, and is designed for use by laypersons (i.e. non-healthcare trained individuals). In this pilot study, a member of the research team who had received formal training in IMCI/ETAT/PEWS/PSATS collected the data. We anticipate that in reality there may

be decrease in the sensitivity and specificity when the tool is implemented by a layperson, which may limit the use of the tool. The true clinical effectiveness of the SCREEN algorithm must be determined by measuring the performance of the tool in a real clinic setting by queue marshals. In addition, data from the DHs was retrospectively collected using chart review; real-time evaluation would have been preferential in order to increase diagnostic accuracy. Lastly we were limited in our ability to reach the desired sample size of 984 and stopped short at 961. Our sample strategy at the PHC site (five clinics sampled for 5 days each) did not allow us to enroll the desired 500 patients we required. In addition only 90 children presented with critical illness (using the ETAT definition) compared to the 118 we required in our power analysis.

Conclusions

The SCREEN tool provides a sensitive algorithm by which to identify critically ill children in low resource settings, so that their care can be prioritized to avoid harmful delays. The SCREEN tool uses a subjective algorithm (relying on clinical discriminators), which can be executed by laypersons in less than one minute. We believe that SCREEN offers a scalable and inexpensive method to identify and prioritize critically ill children in under resourced environments. Future study should focus on the clinical effectiveness of the SCREEN program when implemented by laypersons.

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Figure Legends

Figure 1: Schematic representation of the SCREEN algorithm

Figure 2: Patient Flow and Data Collection Strategy at Primary Healthcare Clinics (PHC) and District Hospitals (DH)

Figure 3: Comparison of the definition of ”Critically Ill” used in this study by triage tools

Figure 1: Schematic representation of the SCREEN algorithm

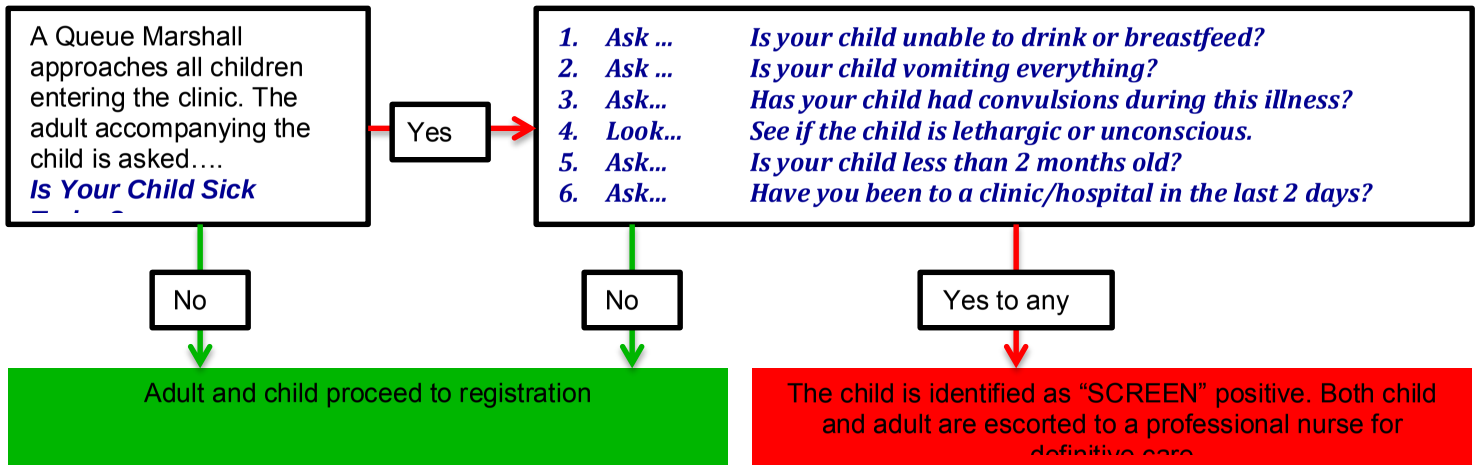


Figure 2: Patient Flow and Data Collection Strategy at Primary Healthcare Clinics (PHC) and District Hospitals (DH).

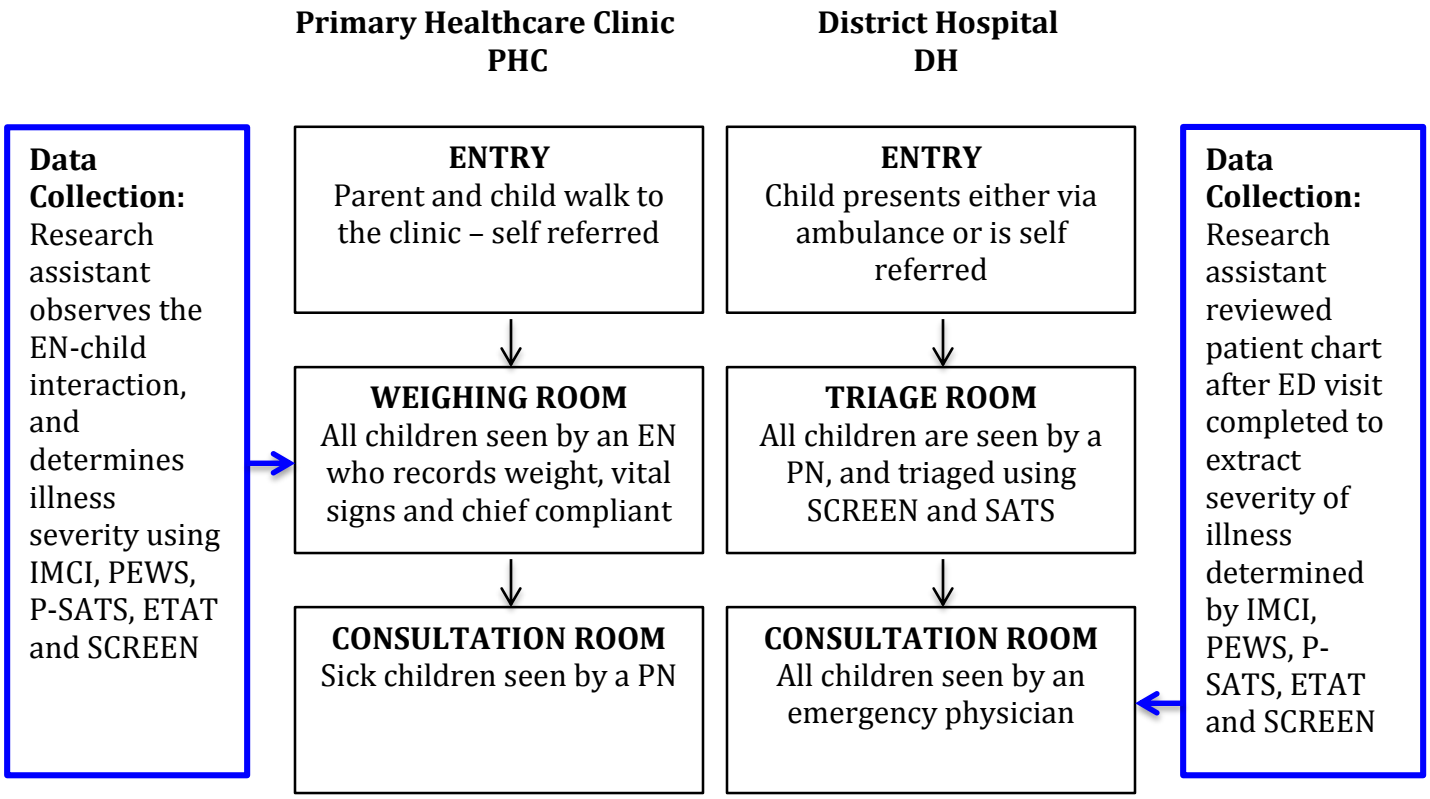


Figure 3

Figure 3: Comparison of the definition of ”Critically Ill” used in this study by triage tools

Triage Tool	SCREEN – Sick Children Require Emergency Evaluation Now	IMCI – Integrated Management of Childhood Illnesses	PEWS – Pediatric Early Warning Score	PSATS – Pediatric South African Triage Score	ETAT – Emergency Triage and Assessment Tool
Definition of “Critically Ill”	Positive to any of the six questions: Is your child unable to drink or breastfeed? /Is your child vomiting everything? /Has your child had convulsions during this illness?/ See if the child is lethargic or unconscious. /Is your child less than 2 months old?/Have you been to a clinic/hospital in the last 2 days?	IMCI "red", indicating severe conditions which need urgent referral to an inpatient facility. It is the highest illness category for the following conditions: acute respiratory infections—including pneumonia; diarrheal diseases, including dehydrating diarrhea, dysentery and persistent diarrhea; meningitis and sepsis; malaria; HIV/AIDS; measles; ear infections; malnutrition; and anemia. Or it is patients that have one of the four IMCI danger signs, “unable to breastfeed, vomiting everything, convulsions and lethargy”	Calculated using age-specific cut offs for heart rate, respiratory rate and systolic blood pressure. In addition to an asessment of O_2 Saturation, Capilary refil, Level of consciousness measured using the Glasgow Coma Scale and Temperature. Each is given a score of 0,1 or 2. A score of > or equal to 8 was deemed as an emergency.	TEWS > than 7 or more, or the presence of an emergency sign: Airway and Breathing (not breathing or reported apnea, obstructed breathing, central cyanosis, severe respiratory distress), Circulation (cold hands +2 or more of the following, weak pulse/capillary refill greater than 3 seconds/lethargic, or uncontrolled bleeding), Active convulsions or immediately post-ictal and not alert, Coma, Dehydration (diarrhea + 2 or more of the following, lethargy/sunken eyes/poor skin turgor), Other (facial/inhalation burn, hypoglycemia, purpuric rash).	The presence of “Emergency Signs” which include one of the following, obstructed or absent breathing, severe respiratory distress, central cyanosis, signs of shock (cold hands, capillary refill time longer than 3 seconds, high heart rate with weak pulse, and low or unmeasurable blood pressure), coma (or seriously reduced level of consciousness), convulsions, signs of severe dehydration in a child with diarrhea (lethargy, sunken eyes, very slow return after pinching the skin or any two of these).

Table 1: Comparison of the children enrolled in study at Primary Healthcare Clinics (PHC) and District Hospitals (DH). Data are numbers, and percent (in parentheses).

	Primary Healthcare Clinics (PHC)	District Hospitals (DH)	Chi-square (degrees of freedom)
Boys	239 (52)	292 (58)	$\chi^2_{3df} = 90.01$ $p < 0.001$
Mean Age in months (IQR)	34 (11-48)	17 (6-40)	
Top 5 chief complaints	"Cough, fever, SOB, vomiting, rash"	"Cough, fever, SOB, vomiting, seizures"	
SCREEN* positive**	119 (26)	280 (56)	$\chi^2_{3df} = 4.17$ $p = 0.04$
Total number of children	461	500	

*SCREEN, Sick Children Require Emergency Evaluation Now; **critically ill

Table 2: Frequency of positive responses to individual SCREEN questions for the 399 SCREEN positive children enrolled. SCREEN positive is defined as the parent/guardian answering "Yes" to at least one of six questions.

Question	**n**	**%**
Q1) Unable to drink or breastfeed?	114	12
Q2) Vomiting everything?	142	15
Q3) Having convulsions?	48	5
Q4) Lethargic/unconscious?	18	2
Q5) Less than 2 months of age?	86	9
Q6) Seen in a clinic/hospital in the last 2 days?	106	11

Table 3: Sensitivity, specificity, PPV and NPV of using SCREEN to identify "critically ill children" compared to four validated triage tools: IMCI, ETAT, P-SATS and PEWS

Site	Reference test and Number (n) triaged to critically ill category	SCREEN Positive (n)	SCREEN Negative (n)	Sens -itivity (%)	Spec -ificity (%)	PPV*	NPV*	Chi-square (degrees of freedom)
Primary Health Care Centers	**Total SCREEN positive and negative in PHC**	**119**	**342**					
	IMCI: RED n = 17	16	1	94.12	76.80	0.134	0.997	
	ETAT: Emergency signs n = 9	8	1	88.89	75.44	0.067	0.998	
	PSATS: Emergency n = 12	11	1	91.67	76.00	0.092	1	
	PEWS: Emergency n = 1	1	0	100	74.35	0.008	1	
District Hospitals	**Total SCREEN positive and negative in DH**	**280**	**220**					
	IMCI: RED n = 68	68	0	100	50.93	0.243	1	
	ETAT: Emergency signs n = 81	81	0	100	52.56	0.289	1	
	PSATS: Emergency n = 67	67	0	100	50.81	0.239	1	
	PEWS: Emergency n = 9	9	0	100	44.81	0.032	1	
Overall	**Total SCREEN positive and negative**	**399**	**562**					
	IMCI: RED n = 85	84	1	98.82	64.04	0.211	0.998	$\chi^2_{3df} = 559$ $p < 0.001$
	ETAT: Emergency signs n = 90	89	1	98.89	64.41	0.223	0.998	$\chi^2_{2df} = 560$ $p < 0.001$
	PSATS: Emergency n = 79	78	1	98.73	63.61	0.195	0.998	$\chi^2_{3df} = 559$ $p < 0.001$
	PEWS: Emergency n = 10	10	0	100	59.10	0.025	1	$\chi^2_{3df} = 559$ $p < 0.001$

* PPV = Positive Predictive Value and NPV=Negative Predictive Value are given to 3 decimal places.

DISCUSSION OF STUDY

METHODOLOGY

Screening and triage are different entities. The WHO Wilson and Junger criteria, describe screening as a central idea where the test is simple and provides early disease detection and treatment is essentially simple.[71] Triage is the process by which one can sort patient in order of priority and does not pertain to a definitive diagnosis, just their likelihood of disease severity and need for emergent treatment.[72]

The assessment of any screening or triage tool will traditionally involve two separate measures, namely reliability and validity. Reliability and validity are two concepts that are important for defining and measuring bias and distortion of the test characteristic compared to reality. Triage/screening tool reliability is defined as the performance of the tool between users, either between health care professionals (inter-rater), between multiple evaluations by the same user (intra-rater), or between a health care professional and a triage tool expert designer/study author (expert opinion). This information is presented as agreement, using Kappa levels. Reliability refers to whether a screening or triage tool gives the same results each time it is used in the same setting with the same type of subjects. Reliability essentially means consistent results. The tools reliability would need to be evaluated once it is implemented by the QM in the clinical setting. This is explored in **Chapter 7,** post real-world implementation.

Validity is likelihood of a test giving accurate or true results, in the case of triage does the triage score accurately predict severity of illness. The outcome validity of triage tool is traditionally defined as the evaluation of the tool in identifying clinical outcomes (i.e., the likelihood of admission, ICU stay, death for patient assigned the highest triage category). In the case of screening tools, however, validity can be measured by comparing the sensitivity and specificity of a tool compared to the current gold standard.[73, 74] Validity refers to the accuracy of measurement i.e., how well the screening tool actually measures the underlying outcome of interest. Validity is not a property of the tool itself, but rather of the interpretation or specific purpose of the tool within a particular setting. In this study the focus of measure is validity within the clinical setting where the tool will likely be implemented i.e., the sensitivity and specificity of the SCREEN tool compared to a goal standard.

The accuracy of any screening tool is best determined by comparing its results with those obtained from a widely accepted reference test or tool.[75] This reference test is also referred to as a gold standard test. The gold standard test should also be widely available, the test results easily reproducible, easily measurable, and clinically

acceptable. The gold standard provides a comparator against which the tool can be measured. The SCREEN tool was designed to identify critically ill children. There are several options that were considered when attempting to identify the gold standard when designing this study, these are presented in Table 4.

Table 4: Possible "Gold Standard tests and outcomes" for critically ill children in primary healthcare clinics

Test or Outcome	Comments
Death (gold standard outcome)	Very few children die within the clinics, most deaths occur prior to arrival, or after leaving the clinic without being seen.
Transfer to a higher level of care	Some children improve after being given emergency treatment and thus may not require transfer to a higher level of care. In some cases, transfer may be thought necessary, but the caregiver refuses transfer or the ambulance does not arrive and these patients would be missed.
Expert opinion	This has been previously used to evaluate the South African Triage Score.(69) This study however, used clinical case vignettes opposed to real patients, which introduces a bias against reproducibility in a clinical setting. (70) Expert opinion can be considered as a theoretical standard.
IMCI category RED	The SCREEN tool was adapted from IMCI, and incorporates the IMCI danger signs in 4 out of the 6 questions. By using IMCI alone, we will introduce a bias of similarity across the two measurements into the study design. In addition, IMCI is not only designed for acute illness but also prioritizes patient with long standing chronic diseases such as malnutrition or HIV. It is also important to note that, in the clinical environment this is the accepted reference standard, all nurses in the clinic utilize IMCI to evaluate if a child is critically ill.
Other triage tool – ETAT, PSATS, and PEWS	Beyond IMCI no further triage is currently implemented in the PHC. However, the WHO Emergency Triage and Assessment Tool (ETAT), the Paediatric South African Triage Score (PSATS), and the Paediatric Early Warning Score (PEWS) have been previously validated in low resource settings to identify critically ill children. They only require collection of vital signs and clinical discriminators and thus are easily implementable.
Lab based tests – lactate etc.	There is no availability of diagnostic testing within the PHC and thus it would not be feasible to collect this data.

In this study, SCREEN was compared to four other tools that have been tested and validated for triaging children in low-resource settings (identified in **Chapter 2)**.[76]

The four tools chosen were:

(i) IMCI, which is routinely implemented in all PHCs in the City of Cape Town and is the current standard of care.[9, 10] The IMCI guidelines (which bases severity of illness on symptoms and vital signs) was developed by expert consensus.[10] Given that

SCREEN is based on the IMCI danger signs, we anticipate the significant overlap will bias our results and thus other tools are required to assess SCREEN in relation to other settings where these tools are used.

(ii) The Paediatric Early Warning Score (PEWS) uses vital signs only and is the most objective (and easily reproducible tool) for comparison, however, several studies have shown poor performance of this tool.[77-79]

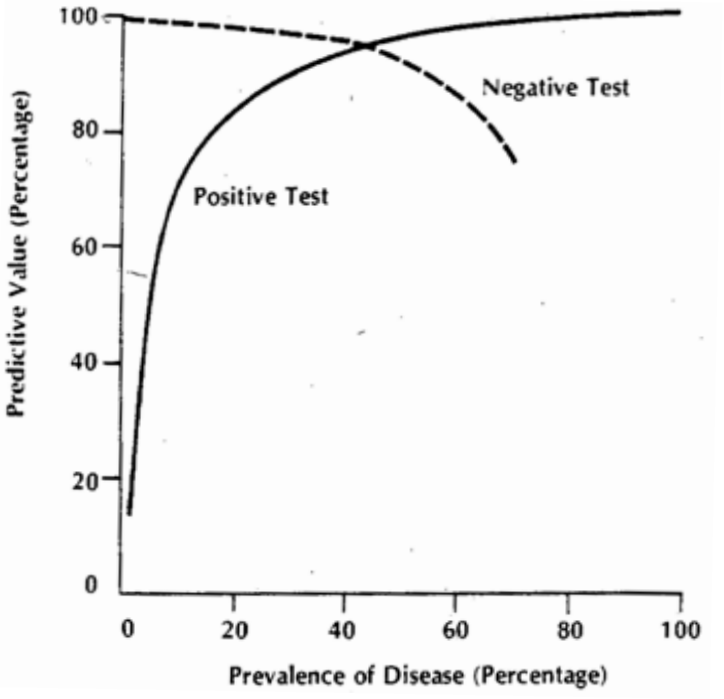
(iii) the Paediatric South African Triage Scale (PSATS)[80]

(iv) the WHO Early Treatment and Triage Tool (ETAT)[10]

Both PSATS and ETAT use a combination of vital signs and clinical discriminators, while they both have significant overlap in data fields they collect, some differences remain. Both have performed well in identifying critically ill children when compared against expert consensus.[11, 80] For comparison purposes, the gold standard outcome for "critically ill" was defined as the highest severity category in each of the four validated instruments. The SCREEN tool was deemed positive if the parent answered yes to 'Is your child sick today and said yes to any of the six discriminator questions asked?'. Data were gathered using real patients opposed to written clinical vignettes to improve the applicability of the findings to the clinical setting.

The outcome measures of interested for this study were determined to be sensitivity, specificity, positive predictive value and negative predictive value. As mentioned above, positive and negative predictive values are influenced by the prevalence of disease in the population that is being tested. Using the same test in a population with higher prevalence increases positive predictive value. Conversely, increased prevalence results in decreased negative predictive value. When considering predictive values of diagnostic or screening tests, the influence of the prevalence of disease therefore has to be considered. To highlight this phenomenon, the Figure 10, taken from Mausner et al. 1974, depicts the relationship between disease prevalence and predictive value in a test with 95% sensitivity and 95% specificity.[81]

Given this finding, it was necessary to evaluate the SCREEN tool in both a high prevalence and low prevalence clinical environment. It is likely that, if SCREEN is effective in identifying critically ill children, it will be widely implemented and thus the outcome measures of positive and negative predictive value should be understood in different prevalence settings. The PHC environment has a relatively low prevalence of critically ill children and thus the study was conducted in both the PHC and the district hospital, wherein the latter setting, there is a relatively higher prevalence of critically ill children.



(From Mausner JS, Kramer S: Mausner and Bahn Epidemiology: An Introductory Text. Philadelphia, WB Saunders, 1985, p. 221.)

Figure 10: Relationship between disease prevalence and predictive value in a test with 95% sensitivity and 85% specificity.[81]

RESULTS

Overall, SCREEN had a high sensitivity (100%-98.73%; p<0.001) and high negative predictive value (1 – 0.997; p<0.001). These are the two most important measures when evaluating any screening tool.

The high sensitivity of the tool was likely, given the six broad questions that were asked to caregivers, which encompass a broad spectrum of disease states. The tool included any child who was less than two months of age, the most vulnerable age group for what adverse clinical outcomes, including this discriminator also likely increases the sensitivity. The high negative predictive value of the SCREEN tool is likely a function of the relatively low prevalence of the critically ill children within, both the PHC (3.69% of children IMCI "Red") and in the DH (13.60% of children IMCI "Red"). The prevalence of critically ill children in PHCs is also much lower than that reported in a study in the northern Limpopo and Kazulu-natal townships in South Africa by Horwood et al. in 2011, which reported that 8.0% children required urgent referral from the PHCs to the district hospital.[82] It is reassuring that, by including children from the district hospital setting, the study was able to evaluate the validity of SCREEN in a high prevalence setting.

The payoff off for a highly sensitive tool is a relatively low specificity. SCREEN had a much lower specificity (ranging from between 64.41%-59.10%; p<0.001 for all 4 triage tools) when compared to the other validated triage tools. To highlight this by looking at SCREEN compared to IMCI, of the 399 children identified as SCREEN positive in our study, only 84 were IMCI "Red". Thus, for every critically ill child who was expedited for higher quality care, another 5 non-critically ill children were also expedited. This was further compounded in a low prevalence setting where, of the 119 SCREEN positive children, only 16 were also IMCI "Red", thus 7.4 children would be expedited for each critically ill child. Since the tool was designed to identify critically ill children, the definition of IMCI "Red" was used to measure sensitivity, and while a significant proportion of children expedited did not meet the definition of critically ill, these children may still be sick (IMICI "Yellow") and thus may still benefit from prompt nursing evaluation. Furthermore IMCI "Red" is a proxy for critical illness and it is likely that this may be coded after the acute condition with which the child presented is resolved. Regardless, the overall concern is that by expediting too many children, the limited resources in a PHC would be overcome. i.e., a secondary bottle neck in the clinic would form, causing a negative impact on the flow of children within the clinics (and may even affect quality of timely care delivery). Lastly a system that introduces more waiting may be unfavourable for clinic staff which will hinder successful implementation. The impact of SCREEN on patient flow is the focus of the process mapping study in the next chapter (**Chapter 7).**

LIMITATIONS

The biggest limitation of this study was that the tool was evaluated when implemented by a medically trained individual. It will be important to see if the characteristics of the tool (sensitivity, specificity, positive and negative predictive values) are still maintained when the tool is implemented by non-medical personnel with minimal training. The PHCs were open for care between 8am and 5pm daily, and thus a prospective data collection strategy was employed. The DHs provide care 24 hours a day, unfortunately, owing to restrictions in funding, it was not possible to employ a 24-hour prospective data collection strategy and thus data were retrospectively collected using chart review, which could introduce bias to the data.

CONCLUSION

The initial evaluation of the SCREEN study is highly promising, given that the tool demonstrated high sensitivity and high negative predictive value for identifying children with critical illness. However, the tool also has low specificity, and thus a high volume of children will be expedited to receiving higher quality of care who are not

critically ill. The impact of the SCREEN program on patient flow in the PHC is evaluated in **Chapter 6.**

CHAPTER 6: IMPACT OF SCREEN ON CLINIC WAITING TIMES

Reference: Hansoti B, Dalwai M, Katz J, Kidd M, Maconochie I, Labrique A, Wallis L. Prioritising the care of critically ill children: a pilot study using SCREEN reduces clinic waiting times. BMJ Global Health. 2016 Jul 1;1(1):e000036.

MAIN FINDINGS

- The SCREEN program resulted in significant reductions in waiting times for children with critical illness to see a professional nurse (2 hours 45 min to 1 hour 12 min; $p<0.001$).
- There was also a statistically significant reduction in the proportion of children who left without being seen by a professional nurse (25.8% to 18.48%; $p<0.001$).

Declaration from author

The following co-authors contributed to the paper: Dr. Mohammed Dalwai, Prof. Joanne Katz, Prof. Martin Kidd, Prof. Ian Maconochie, Dr. Alaine Labrique, and Prof. Lee Wallis.

In the case of Chapter 6, contribution by authors to the work was as follow:

Nature of Contribution: BH and LW came up with the original idea; BH, MD and AL worked to design the data collection methodology for the study. BH and MD worked together on data collection. BH, MJ and JK worked together on the statistical analysis. BH drafted the manuscript and all contributed to revising it critically for important intellectual content. All authors approved the final published version and agreed 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.

Extent of contribution: BH: 65%; MD 10%; JK, MK and AL together 10%; IM 5%; LW: 10%

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Signed: Bhakti Hansoti

DECLARATION BY CO-AUTHORS

The undersigned hereby certify that:

1. The above declaration correctly reflects the nature and extent of the candidate's contribution to this work, and the nature of the contribution of each of the co-authors.
2. They meet the criteria for authorship in that they have participated in the conception, execution, or interpretation, of at least that part of the publication in their field of expertise;
3. They take public responsibility for their part of the publication, except for the responsible author who accepts overall responsibility for the publication;
4. There are no other author of the publication according these criteria;
5. Potential conflicts of interest have been disclosed to (a) granting bodies, (b) the editor or publisher of journals or other publications, and (c) the head of the responsible academic unit; and
6. The original data are stored at the following location and will be held for at least five years from date indicated below

Location of stored data: The raw data and articles are stored on password protected database at Johns Hopkins University, Baltimore, USA. There is no patient data in this study.

Signed by candidate Signature Removed

Prof. Lee A. Wallis January 29th 2017

Signed by candidate Signature Removed

Prof. Ian Maconochie January 29th 2017

INTRODUCTION TO TOPIC

In South African PHC there is no appointment system, and thus patients wait in line to be seen, and when there are too many patients some may be turned away. [12, 42] Patients are treated on a first come first serve bases. A prioritization tool can be used to identify those with time sensitive conditions that need to be seen sooner that the other patients in line. If there is a higher volume of sick patients, who are brought to the front of the queue, the waiting times for those with a lower priority level will become longer. If a new intervention for prioritising when patients should be seen causes confusion and increased waiting times for patients, then it may cause patient dissatisfaction (and potentially nursing/clinical staff dissatisfaction), and thus it is unlikely to be sustained within the clinic system. Thus, it is important to assess the impact of the SCREEN intervention on patient flow in the PHC setting.

MOTIVATION FOR CONDUCTING THE STUDY

The introduction of any new intervention will impact the flow of patients in the clinic setting. This may cause overcrowding, poor patient satisfaction and lead to patients leaving without being seen. While the purpose of a triage or screening intervention is to reduce waiting times for critically ill patients to be seen, this should not be done at a cost, in terms of waiting times, to the remaining patient population. Not only could this potentially cause harm to patients with less severe illness but also may result in patient and provider dissatisfaction and thus will make the intervention un usable. Thus, in evaluating the efficiency of triage systems, researchers have measured patient waiting time or time to treatment as an important variable directly impacting upon patient outcomes.[83-85] Walk-out rate and total length of stay are also frequently evaluated.[86, 87]

AIM

Evaluate the impact of implementing the SCREEN program on waiting times for children presenting for care to PHCs to be seen by clinical staff.

OBJECTIVES

- Evaluate the impact of SCREEN implementation on waiting times for critically ill children defined as IMCI “Red” and on children who are less sick i.e., IMCI “Yellow” or “Green”.
- Evaluate the impact of SCREEN implementation on children who left without being seen in the clinic.

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Prioritising the care of critically ill children: a pilot study using SCREEN reduces clinic waiting times

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ABSTRACT

Objective: In low-resource settings, childhood mortality secondary to delays in triage and treatment remains high. This paper seeks to evaluate the impact of the novel Sick Children Require Emergency Evaluation Now (SCREEN) tool on the waiting times of critically ill children who present for care to primary healthcare clinics in Cape Town, South Africa.

Methods: We used a pre/postevaluation study design to calculate the median waiting times of all children who presented to four randomly chosen clinics for 5 days before, and 5 days after, the implementation of SCREEN.

Findings: The SCREEN programme resulted in statistical and clinically significant reductions in waiting times for children with critical illness to see a professional nurse (2 hours 45 min to 1 hour 12 min; p<0.001). There was also a statistically significant reduction in the proportion of children who left without being seen by a professional nurse (25.8% to 18.48%; p<0.001).

Conclusions: SCREEN is a novel programme that uses readily available laypersons, trained to make a subjective assessment of children arriving at primary healthcare centres, and provides a low cost, simple methodology to prioritise children and reduce waiting times in low-resource healthcare clinics.

Key questions

What is already known about this topic?

- Primary healthcare clinics (PHC) that see large volumes of patients with a wide range of illness severity in low-resource settings.
- Waiting times in PHC remain high due to large volumes of patients and a lack of trained healthcare providers.
- Childhood mortality remains high in PHC in low-resource settings due to delays in the identification and treatment of children with critical illness.

What are the new findings?

- Sick Children Require Emergency Evaluation Now (SCREEN) is a novel tool for low-resource PHC that is quickly implemented by laypersons to identify children with critical illnesses.
- The implementation of SCREEN significantly reduced waiting times for critically ill children.
- SCREEN improved the efficiency of the clinic and had a positive impact on the left without being seen rate.

Recommendations for policy

- SCREEN provides a low cost, easily implementable, simple methodology to prioritise children and reduce waiting times in low-resource healthcare clinics.

INTRODUCTION

Reducing child mortality worldwide remains a challenge.[1] In 2013, 6.3 million children under the age of 5 years died, and it is estimated that 70% of these deaths were due to conditions that can be prevented, or treated, with timely access to simple, affordable interventions.[2] Therefore, it is essential to implement strategies to combat delays in identification and treatment of critically ill children in low-resource settings.

In low income and middle income countries, children with critical illnesses are often initially brought to primary healthcare clinics (PHC) rather than hospitals. Such clinics see numerous patients with a wide range of illness severity.[3] To guide the management of children presenting to the clinic with an acute illness, a cohesive standardised approach is required. To address this need, the WHO and UNICEF collaborated to develop the Integrated Management of Childhood Illnesses (IMCI) approach, which was launched in 1996.[3] The goal of IMCI is to improve the performance of healthcare workers (HCWs), by combining lessons from disease-specific control programmes to develop a single efficient and effective syndrome-based approach.[4] The HCWs use syndrome-centred algorithms to triage children, and deliver care, directed by well-defined management plans based on the child's severity of illness.

Since 1996, IMCI has been widely implemented in over 80 countries.[5] However, there are significant limitations: the case management process requires a trained HCW (professional nurse equivalent), and takes 5–7 min to complete. Owing to an inadequate number of trained HCWs, and large numbers of children presenting to PHC, the waiting times remain long, even after a child has been successfully brought to a facility.[6] For critically ill children, the waiting time of several hours, without evaluation and the initiation of treatment, can be fatal to a child's chance of survival.

A key to reducing under five mortality is to implement a cost-effective programme that promptly identifies critically ill children, prioritises their care and thereby reduces waiting times.[7] Our team worked together with local staff to develop a prioritisation tool to reduce these delays. We identified three groups of stakeholders: (1) healthcare providers at the PHCs, (2) experts in paediatric emergency and acute care; and (3) the executive healthcare management team of the Cape Town government. We developed the algorithm entitled Sick Children Require Emergency Evaluation Now (SCREEN). The screening tool was derived from the validated WHO IMCI danger signs.[4] This new tool was then pilot-studied at a single PHC, and further refined using action research methodology which consisted of cycles of piloting the tool in a single clinic, observing its use, receiving feedback from the nursing staff and adjusting it. SCREEN is administered by laypersons, that is, queue marshals (QM) at the point of entry to a clinic, and uses six simple questions to rapidly identify critically ill children and expedite their care:

1. Ask … Is your child unable to drink or breastfeed?
2. Ask … Is your child vomiting everything?
3. Ask… Has your child had convulsions during this illness?
4. Look…See if the child is lethargic or unconscious.
5. Ask… Is your child <2 months old?
6. Ask… Have you been to a clinic/hospital in the past 2 days?

SCREEN training is provided by the City of Cape Town training division, and consists of a half-day review of IMCI danger signs with a half-day of in-clinic supervised practice.

The key to successful implementation and adoption of a new clinical intervention is the ability to improve individual patient outcomes without disrupting the clinical environment.[8] The SCREEN programme was developed for a complex clinical environment where high volumes of patients, both sick and not sick, routinely present for care. Thus, it was important to determine the impact of SCREEN on waiting times for three groups of children at the PHC: critically ill, those with minor illnesses and healthy children who present for routine healthcare. An intervention for critically ill children (fewer than 10% of patients) that causes delays in the well population (60–70% of patients) would potentially deter patients from attending the clinic.[9] To evaluate the impact of SCREEN on waiting times, we measured the flow of all children who presented to clinics for care pre-SCREEN and post-SCREEN implementation.

METHODS

Study site

This study was conducted from 1 March to 1 September 2014 in PHCs in Cape Town, South Africa. PHCs provide care to all children within their catchment areas. The clinics see both sick children, a small percentage of whom are critically ill, and well children who present for routine immunisations, weighing and nutrition assessments. Clinics normally see patients from 8:00 to 16:00 from Monday to Friday.

Within each PHC, a nurse facility manager, who is a senior professional nurse (PN), organises and supervises care. Sick children are attended to by a combination of PNs and enrolled nurses (ENs). The PNs, graduates of a 4-year nursing degree programme, who have received training in IMCI, complete the formal consultation for each sick child and decide the management plan. In contrast, ENs are graduates of a 2-year nursing degree programme; they collect basic vital signs and perform weight assessment and basic diagnosis using IMCI. Each child must be seen by an EN prior to a PN evaluation. Each clinic has one or two ENs, and one to four PNs at any given time, depending on the patient load of the clinic.

Sampling and study design

In this pilot study, four clinics out of the 120 PHCs in the City of Cape Town were randomly recruited for enrolment in this study. Owing to the heterogeneous nature of the clinics, the unique clinic layout at each site and staffing dynamics, we used a pre/postevaluation study design. Included in the analysis were all children who presented to the clinic for five randomly chosen consecutive days (ie, 1 week), pre and post-SCREEN implementation. The sampling time frame was limited by funding resources.

All four clinics provide care to adults and children. In all clinics, children queued separately and were enrolled prior to entering the clinic, while study coordinators asked parents to put a QR code sticker on each child prior to entry. At all clinics, patients were first scanned at entry into the clinic. Written consent was not required by our protocol. All parents were informed that we were using the QR codes to track the flow of patients; compliance with placing the sticker on the child was given as consent to participate.

Data capture

To ensure accurate capture of data, patient tracking software designed by The Open Medicine Project South Africa (TOMPSA) was created specifically for this study. Each child who presented to the clinic was allocated a randomly generated four-digit number, encoded in a quick response (QR) code sticker that was placed on the

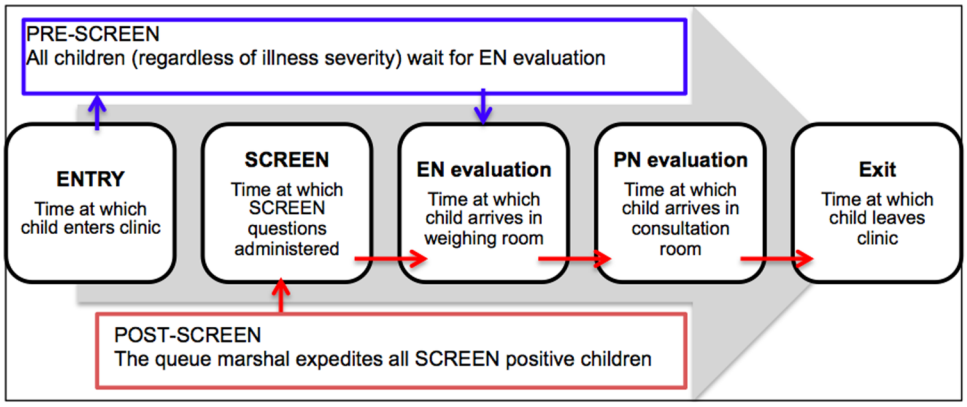

Figure 1 Five patient-tracking interaction points for electronic capture. EN, enrolled nurse; SCREEN, Sick Children Require Emergency Evaluation Now.

child's clothing outside the clinic (before they entered the clinic and joined the waiting line). A QR code is a machine-readable code consisting of an array of black and white squares.

Each member of staff was given an Android smartphone with which to track patient flow. A custom-coded application captured the QR code and transmitted the 'time of scanning' to a website (specifically designed data capture system). If data connectivity was unavailable, the captured data were stored on the phone and uploaded subsequently. Using this system, five time points were recorded: (1) when the child entered the clinic, (2) the time at which SCREEN are asked, (3) was seen by an EN in the weighing room, (4) was seen by a PN in the treatment room and (5) left the clinic (figure 1).

At the time of scanning the QR codes, nurses (time points (3) and (4)) were asked to record the IMCI category (red/yellow/green) to which they considered the child to belong. The IMCI categories (table 1) were used to delineate each child's severity of illness, as this is currently the standard accepted practice in the PHC. For each child, the IMCI category assigned by the PN was used for analysis; if this was unavailable, the EN assigned category was used.

Quality assurance

To ensure that the electronic data collection was accurate, a subset of data was collected manually for comparison. A research assistant interviewed a sample of 10% of patients exiting the clinic (achieved by interviewing all patients who attended the clinic for one of the 5 days during data collection). The adult accompanying the child was asked to recall at what time, and by whom, they were seen in the clinic. This information was compared to the data captured electronically using the QR code system. An encounter was deemed concordant if there was agreement between the electronic and manual data on the hour and who saw the child. A priori, a >90% concordance was decided on as a threshold for inclusion in the analysis. All clinics were able to meet this requirement.

Table 1 IMCI categories and their definitions and implications

Category	Definition	Implication
Red	Critically ill/ life-threatening illness	Transfer immediately for treatment
Yellow	Sick	Treatment and observation in clinic
Green	Well	No active treatment

IMCI, Integrated Management of Childhood Illnesses.

Outcome measures and data analysis

The primary outcome measure was the mean time from entry into the clinic to the first nursing encounter, for each clinic, preintervention and postintervention, for each of the three IMCI categories. We also calculated the mean throughput time (entry to exit). Another key outcome was the number of children who left without being seen (LWBS) by an EN or PN.

Statistical analysis was carried out using two-way analysis of variance with SCREEN (preimplementation and postimplementation) and acuity (IMCI red, yellow, green) as the two factors. Post hoc tests were performed using Fisher's least significant difference testing. The number of children that LWBS pre-SCREEN and post-SCREEN was compared using cross tabulation and χ^2 tests. A 5% significance level was used as the threshold for determining significant differences.

Ethics approval

Verbal consent was requested from all parents to allow their child to be tagged by a QR code, and for the code to be scanned as various healthcare providers saw the child in the clinic.

RESULTS

Overall

A total of 3064 children were enrolled in the study. No severity of illness was assigned for 3% of children as they

left prior to evaluation by a PN or EN. Eighty-five per cent of patients were IMCI green (n=2601), 9.5% yellow (n=288) and 2.5% red (n=81). The remaining 94 patients (3%) left without being assigned a severity category. All IMCI red patients received evaluation from a PN. Eight per cent (23/288) of IMCI yellow patients and 22% (571/2601) of IMCI green patients were seen only by an EN.

A similar number of children presented to all four clinics. Clinic 3 saw the highest volume of children at a total of 778 and clinic 4 saw the lower number of children at 624. The number of SCREEN positive children during the 5-day assessment postimplementation varied from 40 (13%) in clinic 2 to 26 (7%) in clinic 3. In all four clinics, all 'IMCI Red' children were correctly identified as 'SCREEN-positive' (table 2).

Waiting times analysis

Implementation of SCREEN was associated with a significant reduction in the mean time that critically ill (IMCI red) children waited to see an EN and a PN at clinics 2, 3 and 4 (table 3). The greatest reduction in waiting times for these children was at clinic 4, in which the mean wait time to see an EN was reduced from 2 hours 24 min to 20 min, and the mean wait time to see a PN was reduced from 3 hours 13 min to 1 hour 4 min.

Clinic flow

After implementation of SCREEN, there was a statistically significant decrease in the mean amount of time children spent in the clinic, from entry to exit in clinics 1, 3 and 4 (table 3). In contrast, at clinic 2, after implementation of SCREEN, there was a slight—but not statistically significant—increase in the mean amount of time children spent in the clinic.

Left without being seen

After implementation of SCREEN, there was a statistically significant reduction in the proportion of children who LWBS by a PN in clinics 2 and 4 (table 4). There were also decreases in clinics 1 and 3, though these did not reach statistical significance.

Aggregate analysis

Data for all four clinics combined showed that implementation of the SCREEN programme resulted in statistically, and clinically significant, reductions in waiting times for children with critical illness (IMCI Red), and those that required treatment in the clinic (IMCI Yellow) (table 5); there was no impact on the waiting time for well children (IMCI green). There was also a statistically and clinically significant reduction in the proportion of children that LWBS by a PN (table 5). There was no impact of SCREEN on the proportion of children that LWBS by an EN.

DISCUSSION

Waiting times

This pilot study demonstrates that implementation of the SCREEN programme in low-resource primary healthcare clinics can significantly reduce the waiting times for critically ill children. This study enrolled 3064 children at four different clinical sites, and the significant reduction in waiting times, from time of entry to seeing a healthcare provider, was a consistent finding in all four of the clinical sites.

Each clinic provided care to ~350–400 patients per week (75 children per day). Most clinics had only one EN, who was the first point of care for all children, and who was responsible for weighing the child, collecting vital signs and identifying the child as critically ill using IMCI. In this clinic model, the high volumes of children presenting for care, and the time-consuming initial evaluation probably contributed to the long wait times and high LWBS rates. Our new SCREEN programme performed well despite the high patient volumes and lack of qualified healthcare providers in the enrolled clinics. This is most likely due to the design of SCREEN, which task shifts screening to a layperson and requires only a subjective assessment that takes less than a minute per child to complete.

All IMCI Red patients demonstrated significant reductions (over 1 hour) in waiting times for initial healthcare provider evaluation. Critically ill children often present with haemodynamic instability and time-sensitive illness that can be reversed by timely supportive management. In these children, 1 hour can have a large impact on survival and be the difference between life and death.

We had expected that only the care of critically ill children would be expedited (given the sensitivity of SCREEN), and that there may even be a negative impact on waiting times for all other children (IMCI yellow and IMCI green) who presented to the clinic. However, our study showed a decrease in waiting times for all children who presented to the clinic (even those presenting for routine well child checks, vaccinations and deworming). This secondary, and positive, effect is most likely due to the fact that SCREEN streamlined the flow of critically ill children, and thus decreased interruptions to the care of the remaining children. For example, prior to SCREEN, critically ill children would wait in line to be seen (sometimes for hours), until their first interaction with a healthcare provider.[6] Throughout the day, PNs would have to divert their focus to provide life-saving treatment and arrange transfer of care. However, once SCREEN was implemented, most critically ill children would be identified early in the morning, given that over 50% of patients arrive before the clinics open, and their care and transfer could be coordinated by a single PN, thus allowing the remainder of the clinic to continue undisturbed. Anecdotally we observed that multiple critically unwell children were pooled into a single ambulance to be transferred to a higher level of care. In a resource-limited setting, this approach is an efficient

Table 2 Number and percentage of children presenting by IMCI acuity category, at each of four clinics, preimplmentation and postimplementation of SCREEN

	Clinic 1		Clinic 2		Clinic 3		Clinic 4	
Acuity	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**
Red	5	16*	13	13*	5	10*	10	8*
Per cent	1.22	4.01	3.06	4.30	1.13	2.97	3.09	2.74
Yellow	51	27	20	28	36	29	63	32
Per cent	12.44	6.77	4.71	9.27	8.16	8.61	19.44	10.96
Green	354	356	392	274	400	308	251	260
Per cent	86.34	89.22	92.24	90.73	90.71	91.39	77.47	89.04
TOTAL	410	399	425	302	441	337	324	292

*All children were also correctly identified as SCREEN positive by the QM.
IMCI, Integrated Management of Childhood Illnesses; SCREEN, Sick Children Require Emergency Evaluation Now; QM, queue marshals.

Table 3 Median time to evaluation by nursing staff (EN, enrolled nurse; PN, professional nurse) by acuity and clinic, preimplementation and postimplementation of SCREEN

	Clinic 1		Clinic 2		Clinic 3		Clinic 4	
Acuity	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**	**Pre-SCREEN**	**Post-SCREEN**
EN—Red	0:54†	0:31†	1:00	**0:16*** **	1:11	**0:12*** **	2:28	**0:20*** **
PN—Red	2:29†	1:31†	1:29	**0:58****	1:44	**1:09****	3:13	**1:04****
EN—Yellow	1:33	**0:51*** **	0:47	**0:20*** **	1:20	1:13	3:01	**1:27*** **
PN—Yellow	3:25	**2:42****	2:07	2:08	2:07	2:31	4:20	**2:50****
EN—Green	1:43	**1:22*** **	1:05	**0:47*** **	1:55	2:02	2:38	2:29
PN—Green	3:00	**2:41*** **	1:19	1:28	2:54	2:46	3:52	3:49
EXIT	3:19	**3:00*** **	2:05	2:23	3:14	**2:59***	4:41	**4:31***

Bold typeface indicates significance.
Times are given in hrs:mins.
*Statistical significance *p<0.1, **p<0.05, ***p<0.01.
†Decrease in waiting times may not have reached statistical significance secondary to low volume of patients.
SCREEN, Sick Children Require Emergency Evaluation Now.

Table 4 Number and percentage of patients who LWBS, by nursing level and clinic, preimplementation and postimplementation of SCREEN

	Clinic 1		Clinic 2*		Clinic 3		Clinic 4*	
	Pre-SCREEN (%)	**Post-SCREEN (%)**	**Pre-SCREEN (%)**	**Post-SCREEN (%)**	**Pre-SCREEN (%)**	**Post-SCREEN (%)**	**Pre-SCREEN (%)**	**Post-SCREEN (%)**
Enrolled Nurse -EN	17 4.01	21 5.1	8 1.9	7 2.1	17 3.74	15 4.19	33 9.4	20 6.27
Professional Nurse-PN	68 16	55 13.5	17 641	97 30	10 423	72 20	80 23	36 11

*Shows a statistically significant (p<0.05) decrease in the proportion of patients who LWBS by a professional nurse (PN).
LWBS, left without being seen; SCREEN, Sick Children Require Emergency Evaluation Now.

Table 5 Aggregate analysis of waiting times and LWBS counts, by nursing level, pre-SCREEN and post-SCREEN implementation

Waiting times	Acuity*	Pre-SCREEN h:min	Post-SCREEN h:min	p Value
	EN—RED	1:35	**0:20**	**<0.001**
	PN—RED	2:45	**1:12**	**<0.001**
	EN—YELLOW	1:58	**0:59**	**<0.001**
	PN—YELLOW	3:14	**2:29**	**<0.001**
	EN—GREEN	1:45	1:37	0.01
	PN—GREEN	3:00	2:56	0.337
LWBS		Counts, %	Counts, %	
	EN	75, 4.53	63, 4.48	0.948
	PN	428, 25.8	**260, 18.48**	**<0.001**

Bold typeface indicates significance.
*Acuity is determined by IMCI category assigned by the professional nurse (PN); if this is unavailable, enrolled nurse (EN) assignment was used.
IMCI, Integrated Management of Childhood Illnesses; LWBS, left without being seen; SCREEN, Sick Children Require Emergency Evaluation Now.

use of the limited prehospital care teams available to the clinic.

It is also likely that the positive impact of SCREEN on waiting for IMCI yellow and green children may be secondary to the fact that some of these children will have most likely been expedited after incorrectly being categorised as SCREEN positive. In this study, we did not record the proportion of patients identified using SCREEN, merely recording how implementing a screening intervention impacted patient flow.

Unfortunately, despite the significant reduction in waiting times following implementation of SCREEN, the mean waiting times for a PN to see a critically ill child remained disturbingly high (58 min—1 hour 31 min). By definition, these children require immediate life-saving interventions and immediate transfer of care. Many would argue that an hour's wait is still too long.[10 11] Other operational issues continue to contribute to the delay in care for critically ill children. First, despite the QM identifying the child as critically ill, most clinics required that the child be taken to the EN for vital signs, weighing and documentation of chief symptom, prior to being seen by a PN. Second, most PNs would not agree to see a child without their folder; thus, delays in searching for the patient's clinic folder could delay care. Third, despite the QM identifying the child as SCREEN positive, there was sometimes resistance from the ENs and PNs in prioritising children, due to the belief that all children should await their turn, and/or the EN or PN did not trust the assessment of an untrained layperson. These systematic and behavioural issues need to be better defined by an implementation study,[12 13] and could be the basis for further interventions such as providing IMCI training to the lay 'queue marshals' as well so that they may be able to better advocate patients who were SCREEN positive.

Left without being seen

After implementation of SCREEN, the percentage of children who left the clinics without being seen by a healthcare provider decreased at each clinic, with significant decreases at two of the four clinics. The number of patients who did not see a PN pre-SCREEN and post-SCREEN reduced by over 25% (25.8% to 18.48%, respectively). We attribute this improvement to having a clinic representative (the QM) engage the parents early in their child's presentation to the clinic, an action which may have assured them that the clinic was invested in the care of their child. Furthermore, this initial human interaction also allowed parents to ask questions about the system and waiting times, which may have made them more likely to wait for their child's evaluation than in the absence of such information.[14 15]

Clinic 2 had the most significant drop in the LWBS rate; however, we note that this may have resulted in clinic 2 having a slight increase in overall waiting times. This increase was most likely due to the fact that more children were staying to complete a full evaluation (ie, were seen by an EN and PN) before leaving the clinic.

Implementation and future work

This study evaluates a simple intervention in low resource clinics to prioritise care. The current cost to each clinic per QM is averaged at $10–15 per day. The QM workforce is readily available given that no prior qualifications are required for this job. In addition, the training time for QMs is only 1 day. However, when expanded to the City of Cape Town, if one would propose QM coverage in all of the 120 clinics year round, the forecasted cost is in excessive of $350 000 per year. In resource-limited settings, where financial constraints hinder the adoption of most healthcare interventions, this may be cost prohibitive. Anecdotally, in the City of Cape Town, we have found that some of the clinics opted to expand the screening role to security guards and record room staff as opposed to hiring QMs.

Overall, in busy clinics where an additional member of staff is required, this appears be a cost-effective solution that improves patient flow and reduces life-threatening delays in

the care for critically ill children. Our study only evaluates the impact of SCREEN when a dedicated provider uses the tool. Further study is required to evaluate how the flow of children will be impacted if screening is added as a secondary role for security guards and record staff.

Delays in care for critically ill children that exceed over 1 hour are unacceptable and thus must be addressed. SCREEN provides a simple solution to significantly reduce waiting times in the clinic setting by task shifting the role of identification of critically ill patients to laypersons. Large volume scale-up will require further study on how to optimise implementation so that waiting times for critically ill children are <20 min. Currently, the City of Cape Town has adopted the SCREEN tool and QMs as standard of care in all of its high volume clinics.

LIMITATIONS

The biggest challenge with research involving direct observation and performance measurements is the well described 'Hawthorne Effect'. To minimise the incentive for staff to artificially scan/see children quicker than normal, we (1) recruited local study staff and avoided the presence of 'foreign' researchers at the study site, (2) staff were informed that data captured is anonymised, and thus individual performances cannot be ascertained and (3) that the individual's data will not be shared with clinic leadership.

While the novel QR code and Android phone-based patient-tracking system designed for this study allowed the accurate tracking of children in the clinics, there may have been some difficulties in their use. Although all providers were asked to scan the QR codes at the start of their interaction with the child, it is possible that this was forgotten, or was performed inconsistently, thereby biasing the data capture. However, this limitation was addressed by implementing a quality assurance protocol where 10% of clinic attendees were interviewed. We found that during this audit, each of the clinical sites demonstrated a >90% concordance of the electronically collected data compared to self-reporting. Thus, no data were excluded from this study. To retain a normal workflow pattern, by avoiding the interruption caused by scanning the QR codes, a simpler approach may involve the use of radio-frequency identification tags, in which there is electronic capture the instant a patient reaches a specific location. However, this approach was beyond the constraints of the study budget, and would present difficulties in a small, resource poor clinic environment where patients often walk back and forth between several locations.

In addition, staffing variability at each of the clinics is most likely an important confounder for the presented data. Staffing levels varied on a daily basis depending on sick leave, staff's ability to get to work and the number of staff assigned to the paediatric workload. The latter was dependent on the volume of adult patients and if any additional special clinics (TB care, etc) were being run that day. In order to account for the daily variability, each clinic was sampled for 5 consecutive days.

CONCLUSIONS

SCREEN is a novel programme that task shifts the role of identifying and prioritising the care of critically ill children to laypersons using a subjective assessment tool. In our pilot study, the implementation of SCREEN reduced waiting times for all critically ill children, and had a positive impact on the LWBS rates in all clinics. Owing to a paucity of healthcare resources in low-resource settings worldwide, waiting times for critically ill children and downstream mortality remain unacceptably high. SCREEN provides a low cost, simple solution that may be implemented to meet this need. Further evaluation is necessary to inform scale-up and refinement of this novel intervention in clinical settings, beyond South Africa, where sick children present for care.

Handling editor Soumitra Bhuyan

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Contributors BH conceptualised the study, designed the methodology, collected the data, and wrote and edited the manuscript. MD and LW conceptualised the methodology, assisted with data acquisition, and assisted in editing the manuscript. JK and MK made contributions to the analysis and interpretation of data and also to drafting the work or revising it critically for important intellectual content. AL and IM made substantial contributions to the conception of the study and revising the manuscript for intellectual content. All authors made substantial contributions to the study, both to the drafting of the work and its critical revision for important intellectual content; AND have given final approval of the version to be published; AND are in agreement 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.

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Competing interests None declared.

Ethics approval IRB approval was received from the primary authors' home institution, Johns Hopkins University in Baltimore, USA, and the host institution, the University of Cape Town, South Africa.

Provenance and peer review Not commissioned; externally peer reviewed.

Data sharing statement Non-identified data (ie, without protected health information) will be made available in an excel spreadsheet by request to the corresponding author. The following data set is available for all paediatric patients time they entered the clinic, time at which they were seen by an EN/PN, time of treatment and time at which the child exited the clinic.

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Prioritising the care of critically ill children: a pilot study using SCREEN reduces clinic waiting times

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DISCUSSION OF STUDY

METHODOLOGY

A prospective, cross-sectional study was conducted in four PHCs in the City of Cape to evaluate the introduction of SCREEN on patient waiting times. The outcomes measured in this study were the waiting times before and after introduction of SCREEN in the EC.

From **Chapter 3,** it was ascertained that clinics are complex and can see between 100-150 children per day. In addition, while overall dwell time (total time spent in the clinic) is important, it is also necessary to capture the time to initial evaluation by a healthcare professional, nursing student or nursing aid, and the time to nursing evaluation for definitive care. In the clinic setting there are several nurses that play these roles, in addition, roles may switch depending on clinical need as well as the room allocations where nurses see the children. It would not have been possible to capture 100% of children that presented to the clinic using an observation methodology. Furthermore, observation of children and manually recording times would have caused inaccuracies secondary to recording errors, and errors in the accuracy of mechanical clocks available in the clinic.

For this study to ensure accurate capture of data, a patient tracking software, designed by The Open Medicine Project South Africa (TOMPSA©), was created specifically for this study. Each child who presented to the clinic was allocated a randomly generated four-digit number, encoded in a quick response (QR) code sticker that was placed on the child's clothing outside the clinic (before they entered the clinic and joined the waiting line). A QR code is a machine-readable code consisting of an array of black and white squares. Each member of staff was given an Android smart-phone with which to track patient flow. A custom-coded application captured the QR code and transmitted the 'time of scanning' to a website (specifically designed data capture system). If data connectivity was unavailable, the captured data were stored on the phone and uploaded subsequently. The use of an app to capture the time allowed for a reduction in human error, furthermore all phones were synced using a universal clock which decrease errors across capture devices. Using this system, five time points were recorded: (1) when the child entered the clinic, (2) the time at which SCREEN are asked, (3) was seen by an EN in the weighing room, (4) was seen by a PN in the treatment room and (5) left the clinic (Figure 11).

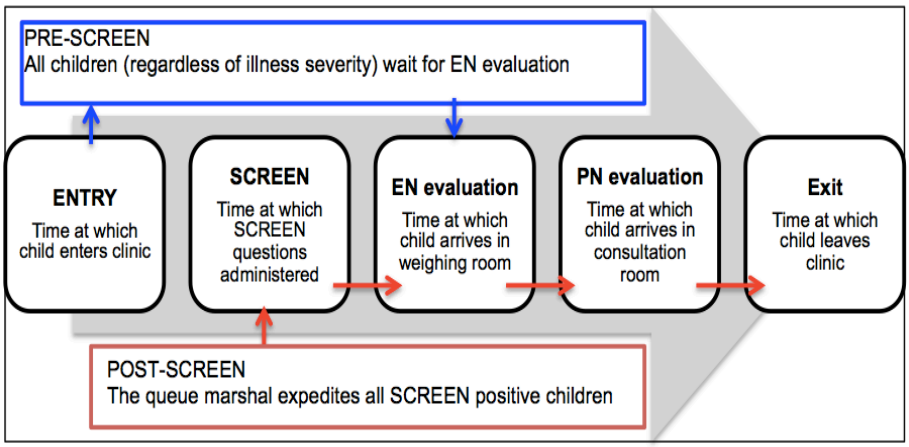

Figure 11: Five patient-tracking interaction points for electronic capture.

At the time of scanning the QR codes, nurses (time points (3) and (4)) were asked to record the IMCI category ("Red"/"Yellow"/"Green") to which they considered the child to belong. The IMCI categories (Table 5) were used to delineate each child's severity of illness, as this is currently the standard accepted practice in the PHC. For each child, the IMCI category assigned by the PN was used for analysis; if this was unavailable, the EN assigned category was used.

Table 5: IMCI categories, their definitions and implications

IMCI Category	Definition	Implication
Red	Critically ill/ life-threatening illness	Transfer immediately for treatment
Yellow	Sick	Treatment and observation in clinic
Green	Well	No active treatment

RESULTS

Reducing the waiting times for critically ill children presenting the clinic is crucial in order to expedite care and provide lifesaving definitive care in a timely manner. Not only did SCREEN implementation reduce waiting times for the IMCI "Red" children but there was a reduction in waiting times for IMCI "Yellow" and "Green" children also that presented to the clinic for care. This is of particular interest as one might have expected an increase in waiting times for these patients. It seems that the introduction of the SCREEN program led to an overall trend in the reduction of waiting times, perhaps by improving the overall efficiency of the clinics. Promisingly, our study also showed a trend toward a decrease in the numbers of left without being seeing in all four clinics. It is likely that this phenomenon was secondary to having a Queue Marshall employed as part of the SCREEN program, leading to patients feeling as they were being seeing and acknowledged, opposed to sitting anonymously in a queue unable to identify how long it would take. Our findings are similar to other

studies that have evaluated the impact of triage intervention on waiting times in other low resource settings.[86, 88] A triage waiting time study in Iran, also showed that the implementation of a triage system also significantly increased patient satisfaction.[88]

Despite the promising statistically and clinically significant reductions in waiting times highlight in the published manuscript, waiting times for critically ill children in the PHC remain unacceptably high. In this study IMCI "Red" children still waited over an hour to see a professional nurse. It is only once the professional nurse is able to evaluate the patient that transport can be arranged to higher-level of care facility. Given the known delays in transport for critically ill children (**Chapter 3)**[12, 42, 89] this one hour delay could translate to delays of several hours downstream.

Anecdotally, we observed several reasons for these delays, 1) professional nurses refused to see patients without their folder being retrieved from the record room, 2) critically ill patients in some clinics having to wait to get their weight recorded prior to seeing a professional nurse, and 3) on occasion, a professional nurse turned the Queue Marshall away as they did not like to be told whom they should see next. All three of this factors were related to operational norms that existed within the current clinic system. Even though we know that the SCREEN program is necessary (**Chapter 4)** and highly effective (**Chapter 5)**, changing the operational norms of a complex clinical setting will require a culture shift and time.

LIMITATIONS

The biggest challenge with research involving direct observation and performance measurements is the well described 'Hawthorne Effect'. To minimise the incentive for staff to artificially scan/see children quicker than normal, we (1) recruited local study staff and avoided the presence of 'foreign' researchers at the study site, (2) staff were informed that data captured is anonymised, and thus individual performances cannot be ascertained and (3) that the individual's data will not be shared with clinic leadership.

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normal workflow pattern, by avoiding the interruption caused by scanning the QR codes, a simpler approach may involve the use of radio-frequency identification tags, in which there is electronic capture the instant a patient reaches a specific location. However, this approach was beyond the constraints of the study budget, and would present difficulties in a small, resource poor clinic environment where patients often walk back and forth between several locations.

CONCLUSION

The pilot implementation of the SCREEN program showed promising results in terms of patient waiting time reduction and left without being seeing numbers. The penultimate chapter (**Chapter 7)** of this thesis will assess if the promising results from **Chapter 5 & 6** are sustained post-real world implementation.

CHAPTER 7: SCREENING SICK CHILDREN: AN IMPLEMENTATION EVALUATION STUDY IN CAPE TOWN, SOUTH AFRICA

BACKGROUND

The Sick Children Require Emergency Evaluation Now (SCREEN) program was developed to rapidly identify critically ill children and to expedite their care. The program uses a six-question screening algorithm derived from the validated WHO IMCI danger signs for all children who report that they are "sick" on arrival. SCREEN is administered by QMs (non-healthcare individuals) recruited from the surrounding community to provide administrative support to the clinic. Given the paucity of trained healthcare professionals in low resource settings, task shifting to QM may prove not only to be cost-effective but also more feasible to implement. There also may be a secondary benefit of building a knowledge base of community champions able to identify the IMCI danger signs. **Chapter 5 and 6** have shown SCREEN to be highly effective in identifying critically ill children and reducing waiting times in the City of Cape Town PHCs.[8] SCREEN was adopted as a city-wide strategy in the autumn of 2014 and has been widely implemented in PHCs via the IMCI training centre.

METHODOLOGY:

This is an effectiveness-implementation hybrid study (Figure 12). Simultaneous testing of the clinical intervention and the implementation strategy will provide a more valid estimate of the clinical effectiveness. An effectiveness-implementation hybrid design is one that takes a dual focus a priori in assessing clinical effectiveness and implementation.[90]

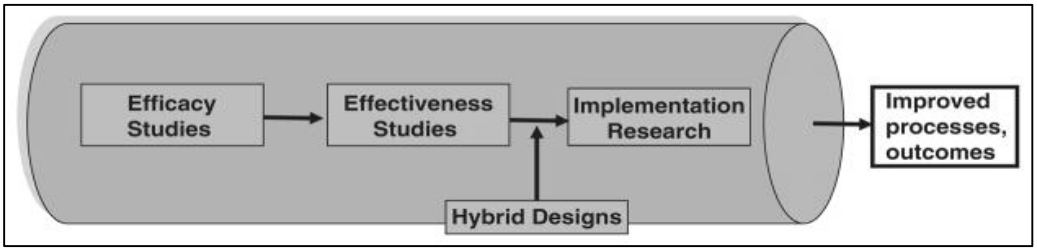

Figure 12: Effectiveness-Implementation Hybrid Designs,
Adapted from Curran et al[90]

To measure clinical effectiveness the primary outcome measure is sensitivity of QM in identifying critically ill children using the screening algorithm. The success of implementation will be measured using an observation methodology. In this study staff observe the adherence of QMs to the SCREEN tool, and waiting times of all children that present to the PHC. The program evaluations were conducted at two different time points, across multiple clinics with multiple QMs. The intention of this

study was to evaluate the effectiveness of the SCREEN program in identifying critically ill children and the impact of the SCREEN program on expediting their care post implementation.

STUDY DESIGN

We conducted an effectiveness-implementation hybrid study[90, 91] , similar to methods used by the WHO to perform multi-country evaluations for IMCI.[92] A 3 prong evaluation strategy was used to evaluate (1) effectiveness, (2) adherence to the SCREEN questions, and (3) impact on timely care delivery (figure 1).

Effectiveness in identifying critically ill children (1) was measured by comparing SCREEN assignment ("Positive"/"Negative") to the IMCI assignment ("Red"/"Yellow or Green"). (2) Adherence was measured by ascertaining how many and which of the SCREEN questions were asked by QMs, and (3) the impact was measured by observing the waiting times to triage and to reach definitive care (i.e. Professional Nurse (PN) evaluation) for critically ill children.

STUDY SETTING AND STUDY POPULATION

The study took place in PHCs in Cape Town, South Africa from January to November 2015. The City of Cape Town Health Management team implemented the SCREEN program, including hiring and training QMs, throughout their PHCs in the autumn of 2014. The QMs are non-health personnel employed from the local community, through the Extended Public Works Program by the South African government. To qualify for employment, a QM must hold at least a high school diploma and be fluent in Xhosa and English. Training is conducted by the City of Cape Town IMCI training centre over a single day and includes lectures, small group activities, and role-playing based on IMCI training manuals that had been adapted for use with the SCREEN algorithm.[93]

Clinics were chosen by a convenience sample that aimed for racial and geographic diversity. Each of the enrolled clinics was sampled for two days and all children who presented for care during those days were enrolled in the study. Consent was waived for effectiveness analysis (due to retrospective chart review) and the direct observation of implementation (due to lack of patient interaction and need for unbiased observation). Verbal consent was obtained from parents prior to administering questionnaires on SCREEN completeness (Figure 1).

DATA COLLECTION, OUTCOMES AND ANALYSIS

We collected data from three sources: (1) chart review to evaluate the clinical effectiveness, (2) parent interviews to assess QM adherence to SCREEN questions and (3) direct observation to gather data on the impact of SCREEN on waiting times for critically ill children. (Figure 13). Data collection occurred in two identical phases (3 months in the spring and 3 months in summer).

	SCREEN Evaluation Constructs		
	Effectiveness	**Implementation Outcomes**	
Objective	(1) Accuracy in identifying critically ill children	(2) Adherence to SCREEN questions by QM	(3) Impact on timely care delivery
Outcome Measures	Sensitivity and specificity of SCREEN category compared to IMCI category assigned	Number of SCREEN questions parents report that the QM administered	Time from entry to SCREEN Time from entry to definitive care (i.e. nursing evaluation) if SCREENed positive
Data Sources	Chart Review	Parent Questionnaire	Direct Observation
Comparison Group	IMCI assignment by PN	N/A	Observation data gathered prior to SCREEN implementation for critically ill children
Consent	Consent waived	Verbal consent	Consent waived

Figure 13: Infographic of SCREEN evaluation methodology

A retrospective chart review of all “sick” children who presented for care was conducted to measure the clinical effectiveness of the screening algorithm when utilized by QM. SCREEN positivity was cross-tabulated against the PN assigned IMCI category (gold standard) in order to calculate the sensitivity and specificity of SCREEN. The gold standard was made binary based on PN assigned IMCI category, with Red as “critically ill”, while Green or Yellow were “not critically ill”. This was cross-tabulated against the QM designation as SCREEN positive or negative. The PN was

not blinded to the QM triage category, given the sequential nature of evaluation within the clinic system.

Parent/accompanying caregiver interviews were conducted to evaluate the QM adherence to the SCREEN tool. All parents/ accompanying caregivers were approached immediately after the QM interaction in a separate waiting room to participate in survey, and each was asked to identify which of the questions they had been asked by the QM at entry. Data was recorded using the Magpi© software on an electronic tablet. The data was presented as the number of questions (out of a possible six questions asked to parents of children with acute illness) that a parent reported being asked by the QM. A summary statistic was created for mothers who reported being asked all six of the questions. ANOVA testing was used to detect inter-clinic variability in QM questioning. Four clinics had incomplete data owing to a software issues, and thus were removed from analysis, leaving a total of 22 clinics sampled in this arm of the study, opposed to 26.

Direct observation was used to gather data on the waiting times of critically ill children to quantify the impact of SCREEN implementation on waiting times. The SCREEN program requires the QM to question all children within 5 minutes of entry to the clinic and, if identified as SCREEN positive, to be taken to a professional nurse within 10 minutes. For each child, we recorded various time points in real-time using a Microsoft Excel© software that allowed us to embed macros that gave us specific time stamps when the cell was selected on an electronic tablet. This allowed us to calculate two times; time from entry to time to SCREEN questionnaire administration, and from entry to seeing a PN for those children who were SCREENed positive. The cumulative proportion of children screened was plotted against time from entry to screening. The proportion screened within five minutes and the median time to screening was plotted against the number of hours since the clinic opened each day. This provided visual information about whether the timeliness of screening changed by time since the clinic opened each day. A similar plot was constructed to show whether the proportion of children seeing a PN within 10 minutes of arrival at the clinic and the median time from arrival to seeing a PN varied by length of time the clinic had been open each day. To evaluate whether the median time to screening and to a PN varied by hours since the clinic had opened each day, a linear regression model was constructed with time to screening as the outcome and clinic ID, day of observation, season of year and time of first child entry.

Finally, a plot of the cumulative proportion of children seeing a PN within 10 minutes prior to implementation of SCREEN[94] and post implementation was constructed. Cox-

regression with time to seeing a PN as the outcome and pre/post implementation as the covariate was used to assess whether there was a statistically significant difference in time to being seen by a PN following SCREEN implementation.

RESULTS:

CLINICAL EFFECTIVENESS

A total of 827 patient charts were audited for this phase of the study (Table 6). Children in phase 1 (from January to March 2015) were slightly older (30.2 vs. 23.1 months), and had higher proportions of IMCI Yellow and Red priorities by professional nurse assessment (34.8% and 5.6% vs. 22.8% and 2.3%, respectively).

Table 6: Characteristics of children included in analysis by phase of study

	Jan-March 2016	**Sept-Nov 2016**	**Total/Overall**
Clinics	13	13	26
Months of Study	Jan-March	Sept-Nov	6 months
N	486	341	827
Age (months) (mean)	30.2	23.1	27.6
Sex (% male)	51.6	45.2	48.9
Temp (C) (mean)	36.5	36.5	36.5
Fever (%)	5.6%	12.0%	8.2%
Below Weight (%) (less than 90% percentile)	5.8%	3.1%	4.8%
SCREEN + (%)	15.6%	15.0%	15.4%
IMCI Green	59.7%	74.8%	65.9%
IMCI Yellow	34.8%	22.8%	29.9
IMCI Red	5.6%	2.3%	4.2%

Overall, QM screening had a sensitivity of 94.2%, a specificity of 88.1%, a positive predictive value of 26.0% and a negative predictive value of 99.7% (Table 7).

Table 7: Clinical effectiveness of SCREEN compared to IMCI assignment

	IMCI "Green/Yellow"	**IMCI "Red"**	**Row Total**
SCREEN positive	698	2	700
SCREEN negative	94	33	127
Column total	792	35	827

IMPLEMENTATION OUTCOME: ADHERENCE

A total of 977 caregivers were interviewed during the study to assess the QM adherence to the SCREEN questionnaire. Of these, 493 reported presenting with a child with a "sick" child and thus were eligible for SCREEN questioning by the QM. Of

the 493 caregivers presenting with a “sick” child only 23% answered “yes” to being asked all of the six SCREEN questions. There was high variability in the number of questions asked by clinic (from 1.5 to 5.4 questions per caregiver, ANOVA p<0.0001). Figure 12 demonstrates an aggregate analysis of all 493 caregivers, and presents the proportion of times each question was asked by the QM. The least asked question (44% of encounters) was “Has your child being seen in a clinic/hospital in the last 2 days?” The most commonly asked question (77%) was, “is your child vomiting everything?”.

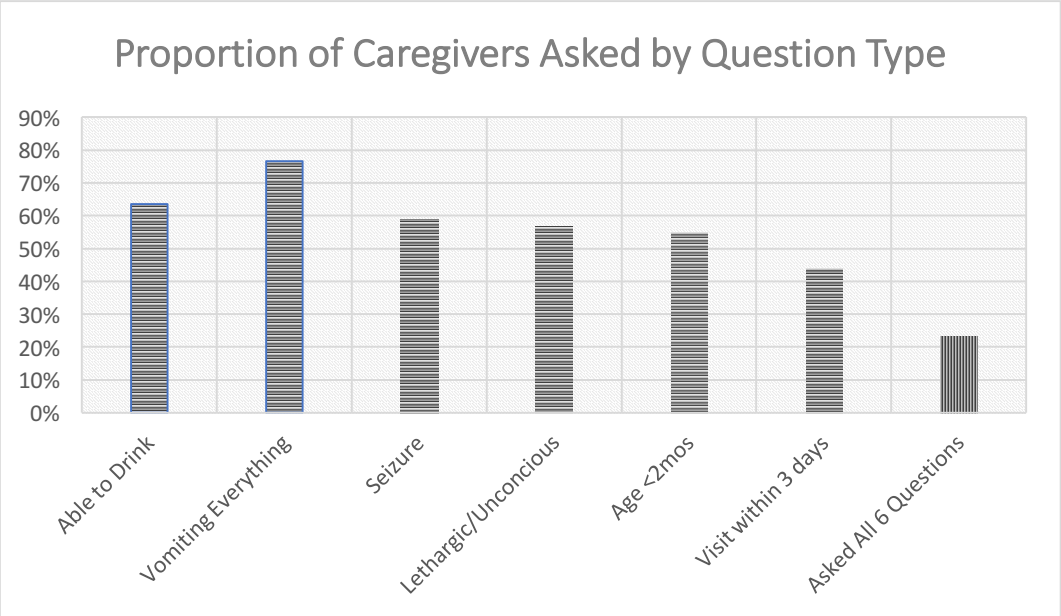

Figure 14: Proportion of questions asked by the QM to caregivers by question type

IMPLEMENTATION OUTCOME: IMPACT

To measure the impact of SCREEN on waiting times, all 3,383 children who presented to the clinics during the study were time-recorded. Of these 3,049 children were approached by a QM (90.1%). Figure 15 shows the median time to screening and cumulative proportion of children screened within 5 minutes by the QMs as the day progressed. Multivariate linear regression confirmed that, as the day progressed, the time prior to QM SCREENing decreased (p<0.001). The time for SCREEN positive children to see a PN was also significantly decreased as the day progressed (p<0.001) (Figure 16). However, across clinics QM performance varied greatly, ranging from 22% to 100% for the proportion of children screened within 5 minutes (ANOVA p<0.0001), and 0% and 100% of SCREEN positive children seeing a PN within 10 minutes (ANOVA p<0.0001).

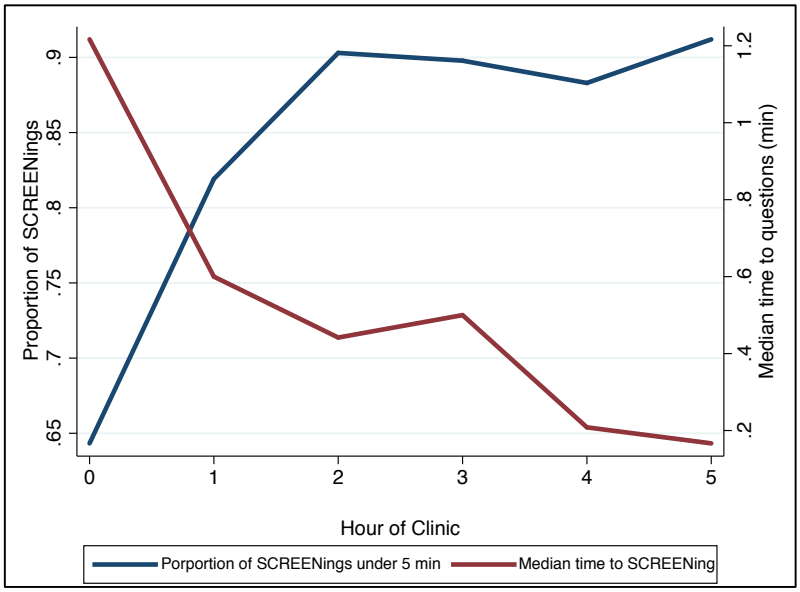

Figure 15: A comparison of median time to screening and the proportion of children screened within 5 minutes of arrival by the number of hours since the clinic opened (for ALL children).

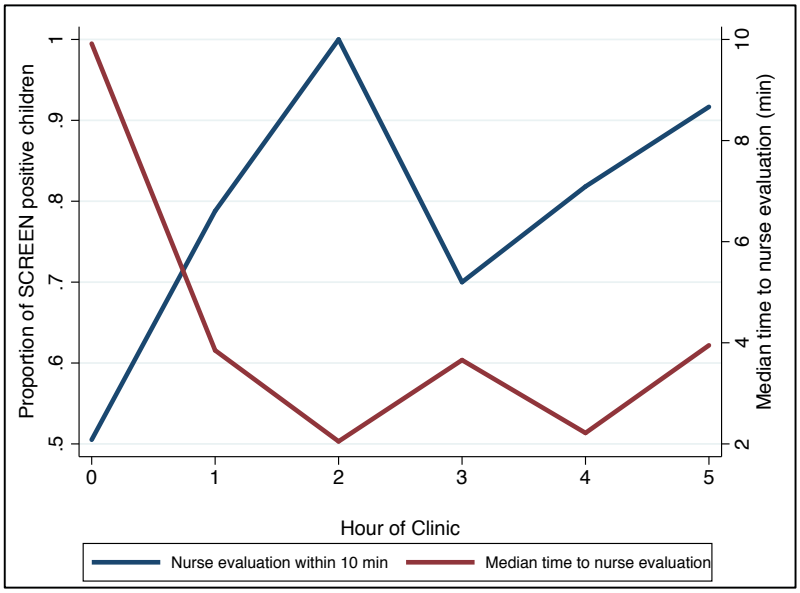

Figure 16: A comparison of the median time to Professional nurse evaluation and the proportion of children seen within 10 minutes of arrival by the number of hours since the clinic opened (for SCREEN positive children only).

Overall, the average time to questioning was 4.7 minutes, with a median of 0.9 minutes, and 73% asked within 5 minutes which is significantly reduced compared to data collected prior to SCREEN implementation (figure 15). The Cox regression coefficient to seeing a PN was 0.13, with a $p<0.0001$. The proportion of critically ill children who saw a PN within 10 minutes increased tenfold from 6.4% (pre-SCREEN) to 64% (post-SCREEN).

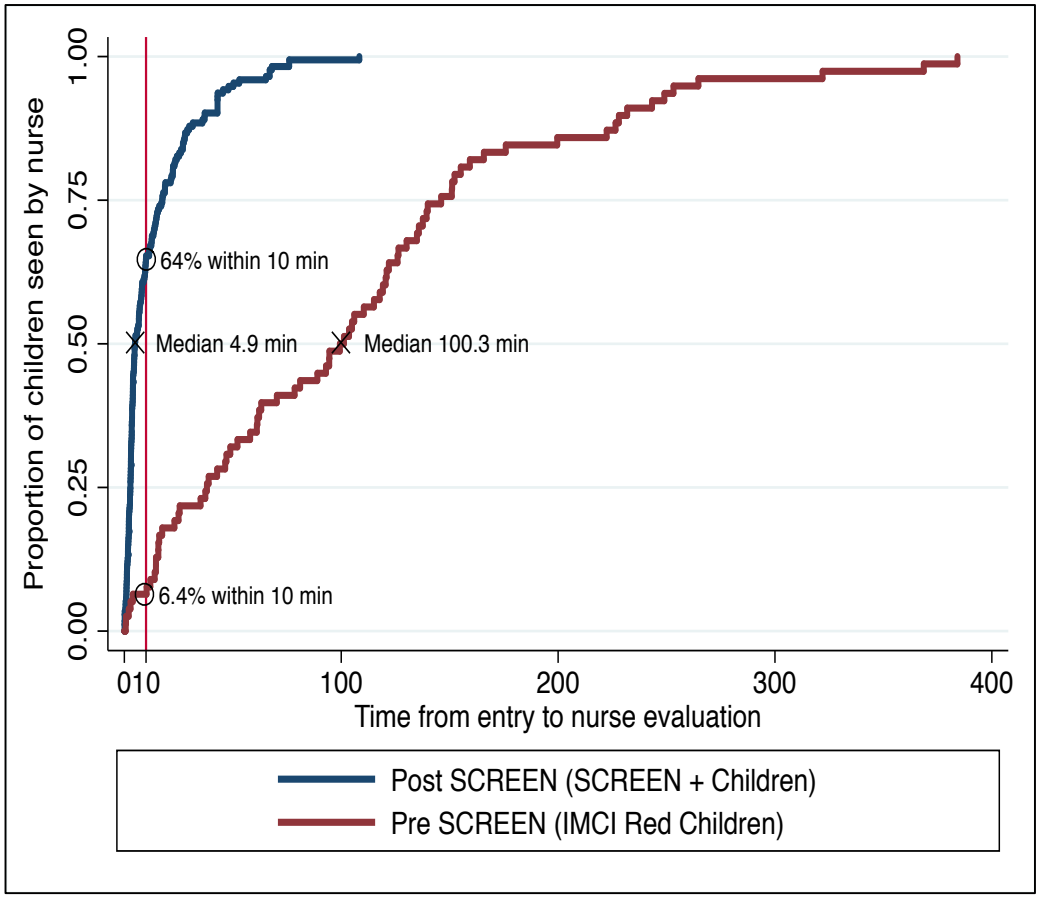

Figure 17: Kaplan Meier survival analysis illustrating the difference between time to nursing evaluation pre-and post-SCREEN Implementation (for critically ill children only).

DISCUSSION:

Interventions can face major obstacles when scaled up.[58, 95] Despite a strong technical basis for the IMCI program, multi-country evaluations have revealed mixed results regarding the success and implementation. [92] Problems with competing commitments, human resources, financing, coordinated program management, and supervision impact the delivery of healthcare interventions. [96,97, 98] Understanding the delivery gaps in implementing the SCREEN program in a real-world environment will inform the dissemination of this innovative program.

This study shows that a simple screening tool for use by laypersons can be successfully implemented in the primary healthcare system to prioritize the care of critically ill children. The proportion of children identified, as critically in our study was 5%, which is significantly higher than what is reported in the HIC literature (1%).[99-101] Despite the low frequency of serious infection, the need to develop a strategy that provides early recognition of a critically ill child is universally accepted. [12, 43, 102, 103] Most work in resource-limited settings has focused on the use of trained HCWs.[12] However, given the paucity of trained healthcare providers and relative low volume of

critically ill children, a simple tool that can be implemented by lay providers offers a more feasible solution.

The SCREEN tool when utilized by QMs had a high sensitivity (94.2%) and negative predictive value (99.7%). This is extremely promising compared to historic reliability studies of IMCI that have demonstrated that the sensitivity of the IMCI tool in identifying serious illness when utilized by HCW can vary from less than 35% [104] to 94.7% [105]. This variability is unsurprising given that there has been vast difference in the reported reliability of IMCI use, with several studies reporting a kappa less than 0.6. [106-108] It appears that the SCREEN tool despite being used by laypersons may have a higher sensitivity in identifying critically ill children compared to the traditional IMCI algorithm utilized by healthcare professionals. It is likely that the simpler algorithm is easier to administer, and is less open to mis-interpretation and thus more effective in the PHC setting. The high sensitivity of SCREEN is, however, mirrored by its lower specificity and poor positive predictive value. This may raise concerns, about large volumes of children being expedited who are not critically ill, and thus increasing the waiting time of children who are not expedited. In our pilot study, we measured the waiting times for all children in the clinic (not just those that were sick), and demonstrated that waiting times were reduced for all children in the clinic. [94] Thus, the benefit from the highly sensitive SCREEN program is not outweighed by consequences in waiting times despite the poor specificity.

Despite training and the linguistic similarities of our tool to identify IMCI danger signs, we found a large variance in the completeness of use of the SCREEN tool. Children who were identified as sick, and thus underwent the SCREEN questions, had an average of only 3.5 of the six questions asked. Studies looking at the adherence of healthcare workers to IMCI danger signs are few, with one paper showing that only 6.6% of healthcare workers asked parents about three or more of these crucial signs in the SA setting. [109] In an observational study in Benin, a median of 1 out of the 4 danger signs were assessed per child. [110] Overall, the evaluation for adherence by QMs was disappointing. We hypothesize that adherence to the SCREEN questions may be poor, as perhaps the QM intuitively/ instinctively only asked certain questions or if a single question was positive, choosing not to ask the remaining questions. Despite poor adherence to the actual questions, the SCREEN tool remained sensitive in identifying sick children. This may speak to the notion that perhaps, the interaction with QM (looking at the child and speaking to the parent) has a more significant impact than the questions themselves. Regardless, we anticipate that adherence may be significantly improved with reinforced training and supervision. [110, 111]

Compared to the pre-intervention study data looking at the flow of children, time analysis demonstrates that SCREEN significantly reduced waiting times. Over the two-year period from the start of the project (that resulted in the SCREEN program development) and the conclusion of this study, the study team met with the City of Cape Town executive health management team to provide real time access to the SCREEN data and discuss strategies for future implementation. This real time access to the pilot studies likely had the biggest impact on the successful implementation of the SCREEN program as it allowed policy makers to see the gaps in the current healthcare system and the benefit of successful interventions. This led to the SCREEN program going from development to implementation in less than year.[94]

LIMITATIONS:

This study was done under real world conditions where it is hard to control for many factors. The use of an effectiveness-implementation hybrid study allowed us to utilize multiple research methods to collect data from different sources to appropriately and accurately capture data about the implementation of SCREEN. Despite the use of a convenience sample of clinics, data was obtained from 26 independent QM groups; by increasing the number of sampling frames we overcame variances in geographic layouts of clinics, clinic management and patient population. Even though this study was conducted in multiple centres in a single city, we anticipate that the results can be widely applied to other low resource PHCs. During the study, the QM, nurses and other clinic staff were aware that the research team was making observations. We anticipate that due to the direct observation methodology utilized in this study, the Hawthorne effect may result in our results being positively skewed. In addition, a proportion of our study relied on the recall of caregivers, while every attempt was made to speak to the caregiver immediately after their interaction with the QM, we anticipate some recall bias.

CONCLUSION:

The SCREEN program, when implemented in a real-world setting, has shown that it can effectively identify critically ill children despite poor adherence to the SCREEN algorithm, and that having a QM at the point of entry in to the PHC results in the timely screening and expedition of care for critically ill children. Future work needs to focus on developing a population-based study that can evaluate the cost effectiveness and long-term sustainability of such an intervention. To understand the true impact of the SCREEN program we need to evaluate if such a program can be successfully scaled up and if that program has an impact on overall childhood mortality in resource limited settings.

CHAPTER 8: CONCLUSION

Avoidable delays in the care of critically ill children in primary healthcare clinics, in Cape Town, South Africa are common. This thesis presents a stepped implementation development and evaluation approach to develop a locally-derived context appropriate tool. In **Chapter 2 and 3** the thesis explores the problem overall. In **Chapter 2** a systematic review methodology is used to identify the availability of exciting tools that can assist with delays in care and their evaluation strategies to inform future study designs. Overall none of the tools available were appropriate for implementation in the PHC setting given their complexity (the use of vital signs and clinical discriminators). The only tool that had been evaluated in the PHC setting was IMCI, however the evaluation studies showed varied results and a lack of consistency in usage. **Chapter 3** sought to gather context appropriate information on the particular difficulties for caring for critically ill children in the pre-hospital setting use a qualitative approach. This study from a healthcare provider perspective reinforced that significant delays particularly in the PHC contribute to overwhelming paediatric mortality in the region and that there is a lack of trained professional nurses to deliver care to all children that present to the PHC. This qualitative study also highlighted that task-shifting of the identification of critically ill children is common informal practice that occurs in many PHCs.

The development of the screening program is the sole focus of **Chapter 4.** In this chapter the framework of “Implementation Stages” was utilized to develop a locally-informed PHC-based, screening tool for critically ill children. The use of an established “Implantation Stages ” guides the conduct of stage-appropriate implementation activities, which are necessary for successful new practices to be used and for organizations and systems to change in order to support new ways of work. A combination of methodologies was necessary to facilitate activities at each implementation stage, for “exploration” an informal observation methodologies was combined with the findings from the two previous chapters, for “installation” a modified Delphi technique was chosen, and lastly for “initial implementation” the study used an action research methodology. The end result was the development of the Sick Children Require Emergency Evaluation Now (SCREEN) program, which utilises 6 simple questions administered by Queue Marshalls to identify critically ill children at point of entry into the clinic and expedite their care.

The remaining chapters focused on evaluating the SCREEN program. In **Chapter 5**, the ability of SCREEN to identify critically ill children is evaluated using a chart review methodology in PHC and district hospitals. Overall, when compared to other widely

accepted triage tool, SCREEN has a high sensitivity (100%-98.73%; p<0.001) and high negative predictive value (1 – 0.997; p<0.001), but a low specificity (64.41 – 59.10%; p<0.001). Given SCREEN high sensitivity this makes an ideal screening tool to assist in the prioritization of critically ill children, however the low specificity raises concerns about causing bottlenecks by expediting the care of too many children. This is then studied in **Chapter 6.** The impact of SCREEN implementation on patient flow in the clinics was measured using a process mapping technique. This methodology permitted the calculation of waiting times for critically ill and non-critically ill children pre-and-post SCREEN implementation. This demonstrated significant reductions (over 1 hour) in waiting times critically ill children. There was also a reduction in the overall waiting times for all children in the clinic and a 30% reduction in the number of children who left the clinic without being evaluated by a professional nurse. The final chapter presents a hybrid implementation-effectiveness study design post real-world implementation to evaluate the SCREEN program. In **Chapter 7** a combination of chart audits (to calculate effectiveness) and implementation observations (to measure adherences and impact) are conducted to evaluate SCREEN. In an audit of 827 patient-charts the QM screening had a sensitivity of 94.2% and a specificity of 88.1% when compared to IMCI. For the 3,383 children who presented to the clinics during the study period the average time to questioning was 4.7 minutes, with a median of 0.9 minutes. When compared to pre-SCREEN implementation, post-SCREEN the proportion of critically ill children who saw a PN within 10 minutes increased tenfold from 6.4% (pre-SCREEN) to 64% (post-SCREEN) (p<0.001).

The SCREEN program is an effective and implementable intervention to prioritize the care for critically ill children in the PHC setting in the City of Cape Town, South Africa. Future research on SCREEN should focus on the cost effectiveness of such a strategy in the South African context and the impact of SCREEN implementation on overall paediatric mortality in the region.

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IMPLEMENTATION AND EVALUATION OF A NOVEL PRIORITIZATION TOOL IN PRIMARY HEALTHCARE CLINICS IN CAPE TOWN, SOUTH AFRICA

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List of Abbreviations

EC	Emergency Centre
ETAT	Emergency Triage Assessment and Treatment
IMCI	Integrated Management of Childhood Illness
JHU	Johns Hopkins University
LMICs	Low and Middle Income Countries
PHCs	Primary Healthcare Centres
PHI	Protected Health Information
PICU	Paediatric Intensive Care Unit
PTCS	Pathways to Care Study
RCWMCH	Red Cross War Memorial Children's Hospital
UCT	University of Cape Town

1. Introduction and Background

1.1. Literature review

Avoidable childhood death is common in countries with limited economic resources. More than 10 million children under the age of 5 die each year (1) and delays in the recognition of critically unwell children is a key contributor to this number. Critical care in resource-limited countries is also often poor.(2) A large review of childhood mortality in the Lancet found that the quality of care delivered to critically unwell children was inadequate with more than half the children under-treated or inappropriately managed.(3) Adverse factors included: lack of triage, inadequate assessment and poor knowledge of treatment guidelines.(4)

A significant burden of diseases in low and middle income countries (LMICs) is caused by time-sensitive illnesses and injuries.(5) However the provision of timely treatment during life-threatening emergencies is not a priority for many health systems in developing countries.

To meet this need the Integrated Management of Childhood Illness Strategy (IMCI) was developed by WHO/UNICEF. IMCI aims to contribute to reducing childhood morbidity and mortality in resource-limited settings. Since 1996 more than 100 countries have adopted IMCI. (6) The IMCI places substantial emphasis on strengthening of triage. Thus as part of IMCI Simplified guidelines for the emergency care of children have been developed to improve the triage and rapid initiation of appropriate emergency treatments for children presenting to hospitals in developing countries.(2) However there have been inherent challenges to implementation of this globally accepted strategy. A survey of all six WHO regions by Goga et al(7), identified among others human resource shortages as a key barrier to global implementation. Several modified triage scales for low resource settings do exist, however most these are supported by limited and often insufficient evidence.(8)

1.2. Motivation for study

South Africa (SA) has an inequitable system of care, with islands of excellence amidst a system with low resources and suboptimal outcomes. In SA, 10% of children die before age 5.(9) The WHO estimates that in sub-Saharan Africa 10-20% of children presenting to primary healthcare centres (PHCs) are already sufficiently ill to benefit from onward referral. Many of

these children present with time dependent critical medical and trauma related illnesses. Barriers to delivering critical care services include lack of triage and inadequate prioritization. (10) Targeted interventions to improve triage and assessment of children have been shown to reduce childhood mortality in resource constraint settings. (11)(12)

1.3. Needs Assessment gathered from Pilot Data

This study is nested within the “Pathways to Care Study” (PTCS), an existing collaboration between Oxford University and the University of Cape Town (UCT). The PTCS is approved by the UCT IRB, and is funded by the Wellcome Trust (WT091107MA). The PTCS performed 12-month review of cases in the PICU/EC at Red Cross Children’s Hospital (RCWMCH) in Cape Town and identified that 30% of admitted cases are potentially avoidable. The study spans the public sector health care services for children in Cape Town, consisting primarily of 109 nurse run clinics, 36 doctor run office hours only community centres (CDCs) and 9 24hr doctor run community health centres (CHCs), 8 district/regional hospitals and two tertiary hospitals with paediatric services including intensive care (PICU).

The objective of this study was to sample a representative population of critically ill children in this Metropolitan area. 282 children aged <13 years admitted as emergencies to the PICU at RCWMCH, or who died in the emergency area at RCWMCH or died at identify facilities in the Cape Town Metropolitan West area (the referral region for the RCWMCH) were enrolled. Informed consent from the parents was sought to enrol the paediatric patients into the study. Data abstraction focused on the pathway of care of these children, from the onset of the illness episode until PICU admission or death. The collected data were used to conduct an expert clinical review of these data in order to identify preventable failures in care contributing to unnecessary morbidity and mortality. An electronic database of all source material and abstracted data enabled a full clinical review of each case to be conducted independently by three clinical reviewers. Data were summarised and reviewed by a clinical fellow, followed by three reviewers (one each from paediatric intensive care, emergency medicine and primary care expert). All four reviewers independently provide: a global assessment of care; an assessment of the avoid ability of the ICU admission; the avoidability of the

death; the avoidability of the severity of the condition on admission. A random 10% of cases are reviewed by an external clinical expert for quality control. Informed consent from the parents was sought to enrol the paediatric patients into the study.

Enrolled cases were 62% male, 15% trauma, and average age of 24 months. Of the 85% medical cases, 80% were aged <1 year. Most live in the Cape Town metropole (93%), with the average distance to the nearest all hours health facility being 10.2 km. The majority of patients came from low socio-economic, high density suburbs. Almost half of the patients live in informal dwellings, with a quarter living in slum "squatter camps". Household monthly income was <R2500 for two thirds of cases and <R1000 for a third. *Diagnosis* Primary diagnosis at PICU admission for medical cases were pneumonia (31%), cardiac pathologies (14%), gastro-enteritis (11%), and sepsis (9%); and for trauma cases overwhelmingly motor vehicle accident related injuries (79%). The "pathway" to care for most cases involved a referral process, with a median of 3 facilities consulted and usually at least one ambulance transfer prior to PICU admission.

Overall outcomes

Expert review of the cases demonstrates that PICU admission was potentially preventable in 30% of cases, and the severity of illness at PICU admission was potentially avoidable in almost 70%. On average only one child a month from each PHC was transferred to PICU. The majority of the critically unwell children in the study (80%) were under the age of one year; the remainder were between the ages of 1-5 years.

Preliminary analyses of the current study suggest the following five main potential areas for the development of interventions to improve the recognition and management of children with acute illness in this region:

A. Introduction of a direct referral pathway for pre-identified high-risk children
B. Prioritization of critical children in non-emergency care areas in community based settings
C. Assessment and resuscitation of critically ill children in in community based settings
D. EMS inter-facility transfer services

E. RCWMCH: Flow management

This study will focus on the second pathway: the Prioritization of critically unwell children (i.e. non-trauma) in non-emergency areas in community-based settings.

1.4. Research question

Can implementing a prioritization tool in low resource PHCs prompt the early identification of critically ill children under the age of one year, decrease the time to treatment/transfer, and decrease overall mortality?

1.5. Objectives of Study

To improve childhood mortality through early identification and prioritization of care to critically ill children through implementation of a prioritisation tool in PHCs in Cape Town in South Africa.

1.6. Aims

1.6.1. To assess the ability of a prioritization tool, that is implemented by nurses, to identify critically ill children under the age of one year who present to PHCs.

1.6.2. To compare time from presentation to treatment (door-to-treatment time) and time from presentation to transfer for definitive treatment (door-to-transfer time) among PHCs that use the prioritization tool to PHCs that do not use the tool.

1.6.3. To compare longitudinal healthcare outcomes of critically ill children under the age of one year that are admitted to the Paediatric Intensive Care Unit (PICU) / emergency care at RCWMCH from PHCs with the prioritization tool to those that do not use the tool.

2. Methods

2.1. Study Overview

Currently no screening/prioritization tool is being utilized in PHCs in Cape Town. A prioritization tool to identify critically ill children under the age of one year, targeted to the resource limitations of PHCs, will be implemented and evaluated. A brief overview is given below.

FORMATIVE PHASE:
1) Formative research on the human resources available at PHCs in Cape Town.
2) Develop a triage tool or modify a previously validated triage tool and training curriculum to match these human resources using consensus methodology from the PTC study team.
3) use LEAN flow / simulation methodology to pre-test the applicability of the tool in PHCs.

IMPLEMENTATION PHASE:
1) Identify PHCs to implement the prioritization tool.
2) Provide training to the nursing staff at PHCs and data collectors.
3) Two week observed implementation phase, to ensure the appropriate use of the tool.

EVALUATION PHASE 1 – SENSITIVITY ANALYSIS
1) 5 randomly chosen PHCs will be recruited for the validation phase.
2) At the PHCs nurse utilization of the prioritization tool will be compare with the parallel use of the tool by the research team (composed of physicians, who have previous training in the management of critically ill children and are certified in NALS/PALs).
3) Ascertain agreement between the nursing staff and the research team.

EVALUATION PHASE 2 – SURVIVAL ANALYSIS
1) 5 PHCs that have implemented the tool will be matched with 5 where the tool will not be implemented. Clinics will be matched by daily volume, nursing capabilities and clinic layout.
2) All children that attend these clinics will be issued a barcode. During their visit arrival time to triage, time to identification as critically ill and time to transfer will be measured.

EVALUATION PHASE 3 – LONGITUDINAL PATIENT OUTCOMES
1) This phase will be an independent case control design, using the random effects model. Children from all PHCs will be included.
2) All children under the age of 1 year presenting to the RCWMCH PICU/EC, will have outcomes measured at the tertiary care center.

2.2. Study Setting

This study is nested within an existing study at the University of Cape Town (UCT), the “Pathways to Care Study” (PTCS), and will utilize the existing infrastructure of the PTCS. This study is a collaborative effort between the University of Cape Town and Oxford University who have contributed epidemiological and project management skills. UCT will lead the study, and will be the sponsor of the study. There are currently 109 nurse-led PHCs enrolled in the study in addition to the RCWMCH PICU and EC.

2.3. Formative Phase

2.3.1. Study design

Simplified guidelines for emergency care of children have been developed to improve the prioritization and rapid initiation of appropriate treatments for children presenting to hospitals in developing countries. In the formative phase we will build on our existing literature review by preforming a systematic review on triage interventions for paediatric patients in low resource settings.

As an example, as part of the WHO Integrated Management of Childhood Illness (IMCI) strategy, ETAT guidelines were developed to improve triage and delivery of timely and appropriate treatment to critically ill children. The ETAT guidelines are based on evidence of significant deficiencies in triage and emergency care. The ETAT tool has been validated in two large trials (in Malawi and Brazil) for use in low resource settings. We will develop and evaluate a prioritization tool similar in principle to ETAT. We will evaluate the strength of the existing supporting evidence along with the applicability to the resources available in PHCs.

Based on our formative research the prioritization tool will be targeted to children under the age of one year. The prioritization tool is likely to incorporate features such as caregiver "gut feeling", gestalt assessment of severity by clinician, patient features (e.g. decreased responsiveness), or duration of illness.

The tool will then be modified using a consensus methodology. Three groups of key informants will be approached. Participants will include doctors and nurses in the clinics and CDCs, CHC staff, EMS staff, RCWMCH staff, the

advisory committee for the current study (which includes managerial representation from the Western Cape Department of Health, City of Cape Town City Health Directorate, UCT and the United Kingdom) and lastly selected experts from outside of Cape Town that deliver emergency care to children in similar low resource settings. The interventions will be modified to take into account feedback from healthcare providers involved in delivering the interventions.

Although we anticipate that a number of the nursing staff will have sufficient fluency in English, we will also translate the tool in to Afrikaans and Xhosa. To ensure integrity in the language of the tool, the tool once translated will be back translated in to English. This process will be repeated until the modified tool is consistent in all languages.

2.3.2 Enrolment and Consent

Participants involved in the consensus process for developing the tool will be invited to participate by the PTC study team. Verbal consent will be sought to audio record key informant interviews and discussion with key stakeholders. Consent scripts are provided in appendix 1.

2.3.2. Timeline

	Aug 1st to October 15th	October 15th to October 25th
Systematic Review	**x**	
Tool development	**x**	
Feedback on developed tool from key stake holders		**x**

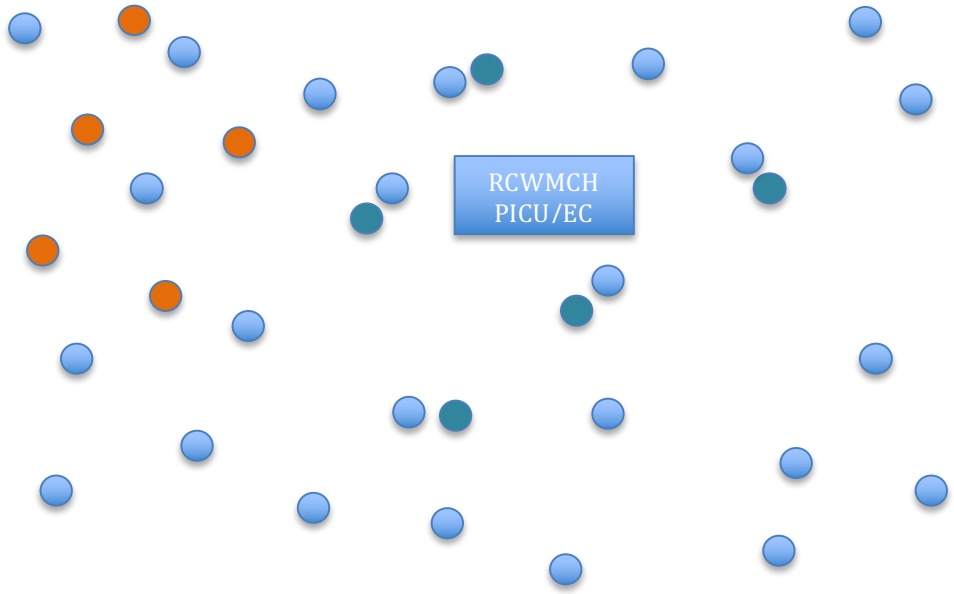
This timeline does not include the existing literature review already performed by the principle investigator on triage interventions. The tool development and the systematic review will be performed by the study investigator remotely, the two weeks allocated for feedback will include focus group discussion with key stake holders in Cape Town.

2.4. Implementation Phase

2.4.1. Study design

The tool will be implemented in 5 selected sites from the 109 nurse-led PHCs currently enrolled in the PTCS. Nurses from the chosen PHCs will be invited to voluntarily participate in the study. The nurses working at PHCs selected for the prioritization tool will receive training to implement the tool and will be compared to 5 PHCs that have not received the intervention. Healthcare providers from selected PHCs will be invited to participate in a training workshop. Training will be conducted using mix media methods such a simulation and class room based didactics.

In the implementation phase PHCs will be selected based on the schematic representation below. Each site that is selected will have a two-week implementation period where independent observers will facilitate the onsite appropriate use of the tool.



Legend:

- Clinic without the prioritization tool
- Clinics implementing the prioritization tool for validation
- Clinics implementing the prioritization tool for survival analysis

In order to overcome practical and ethical consideration a stepped wedge design will be used. Thus eventually all 109 sites will receive the training in the prioritization tool which is ethically important for critical care interventions.

Nursing staff will have the tool available in Afrikaans, Xhosa and English for their reference. However it is likely that the tool will predominantly depend on visual cues only and thus we do not anticipate that language will be a barrier to identifying a child as critically unwell.

2.4.2 Enrolment and Consent

Verbal consent will be sought from nursing staff to participate in training to successfully utilize the tool and implement it in their practice (appendix 2).

2.5. Evaluation Phase 1: Sensitivity Analysis

This phase of the evaluation will assess if tool can successfully identify critically ill children under the age of one year. The research team (including the PI), trained in ETAT, NLS and PALS, will serve as independent evaluators and in parallel to the nurses' score of all children at PHCs using the tool. It is expected that there may be an occasional child who is perceived to be sick by the research team but who the nurses do not prioritize; such children will be brought to the attention of the clinic staff as needing urgent care, but the research team will not be involved in the delivery of that care.

2.5.1. Study design

Cross-sectional study

2.5.2. Study population

PHCs chosen from the PTCS

2.5.3. Sampling

The 5 clinics will be randomly selected from the 109 nurse-led clinics currently enrolled in the PTCS.

2.5.3.1.Inclusion criteria

Clinic staff that voluntarily enroll.

2.5.3.2 Exclusion criteria

Refusal/inability of clinics to utilize the prioritization tool in clinical practice.

2.5.3.3.Sample Size

In line with previous validation studies, approximately 200 children.

2.5.4. Outcome Measures

The number of sick children identified by using the prioritization tool by the investigator and the nursing staff.

2.5.5. Data collection and management

The nursing staff and one of the study investigators will in parallel prioritize children under the age of one year that present to the PHC. They will both independently assess the child using the tool as part of the routine care for the child. Every child will be given a unique numeric code and each will log if the child is identified as critically ill. Both the nurse and study investigator will be blinded to each other's decision.. This data will not be attached to any PHI, or other identifying information. This data will be compiled on a daily basis to assess for percentage agreement in the cohort.

2.5.6. Statistical Analysis

The sensitivity and specificity of prioritization tool in the PHC setting will be calculated. We will also ascertaining percentage agreement between the investigator and nurse based clinic staff will derive a kappa statistic.

2.5.7. Reporting and implementation of results

If the tool is successfully validated in this stage of the study and is proven to be highly sensitive in identifying and prioritizing critically ill children in the PHC setting, then the study will proceed to the next stage. In addition the validation phase of the study will be published in peer-review journals to ensure further dissemination of the tool to a wider audience.

2.5.8. Ethical and Legal Considerations

We anticipate that certain children may present with a severity of illness that is obvious and that necessitates immediate referral and management, these children will be excluded from the study. If a child is found to be critically unwell by the study investigator, given the higher level of training, it will be the duty of the investigator to intervene and ensure that appropriate care is delivered. A log of these children will be kept so that a sensitivity analysis can be performed at a later date.

No protected health information or other identifying information will be collected in this phase of the study. Study participants will be logged using a uniquely generated independent numeric code.

2.5.9. Limitations

Preliminary data suggests that the number of children presenting to the PHCs that are critically unwell may be as few as 10%, thus capturing the number of critically ill children required for successful validation may be difficult. There may also be inherent difficulties in blinding the use of the tool by the study investigator from the nursing staff.

The tool will be available in Afrikaans and Xhosa as well as English. However the investigators will most likely only speak English. Since this is a subjective tool most likely dependent on visual cues only we don't anticipate language as barrier to identifying a critically unwell child. However data forms will be available in all three languages and will be coded use a unique numeric code for each child so as to match the investigator with the nursing staff.

Lastly we anticipate a selection bias as nursing staff will have to voluntarily agree to implement the tool. Thus it is likely that this population will have a greater enthusiasm to implement the tool and thus may be more likely to positively identify critically unwell children correctly using the tool.

2.5.10. Resources

2.5.10.1. Available resources

The 109 nurse led clinics have already been enrolled in to the Pathways to Care study. The division of emergency medicine at UCT will be able to provide space and classroom materials to conduct the training of the staff from the PHCs.

2.5.10.2.Budget

In South African RAND: Per diem for study investigators 250 ZAR/day x 200 days = 50,000 ZAR. Per diem/transport/food for 3 day training 1000 ZAR/nurse x 15 = 15,000 ZAR/

In USD:Per diem for study investigators $25/day x 200 days = $5,000. Per diem/transport/food for 3 day training $100/nurse x 15 = $1,500/

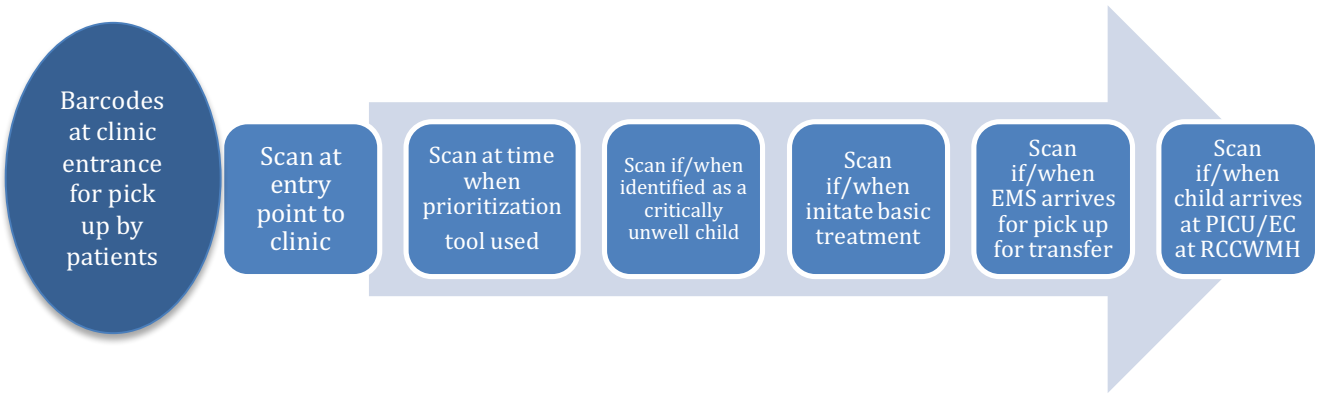
2.5.11. Timeline

	October 25th to November 1st	Nov 1st to 15th	Nov 15th to Jan 15th
Training	**x**		
Implementation		**X**	
Data Collection			**x**

This timeline only includes the implementation phase for the first five clinics enrolled in the first evaluation phase of the study.

2.6. Evaluation Phase 2: Survival Analysis

This phase of the study will compare the time from arrival to prioritization, identification as critically unwell child, treatment and referral in PHCs with the validated prioritization tool to those without. In this phase we will use mobile technology to collect time metrics in an automated fashion from primary health care sites. This phase will only be initiated once the validation phase is completed. In this phase of the study we want to have automated capture of time metrics in the pathways to care. The diagram below illustrates our methodology.



At each time point, the nurse/study personnel will use mobile phones to scan barcodes. We have developed a program to compile the information from each of the mobile phones. Ultimately this information will be compiled into a database; each individual barcode will represent a patient encounter.

2.6.1. Study design

Matched case control study at the clinic level.

2.6.2. Study population

The study population will consist of all PHCs that are enrolled in this phase of the study. The 5 PHCs selected for prioritization tool intervention will be matched to 5 control PHCs by time to a referring hospital, known percentage of critically ill children and level of training of nurses. The nurses working at PHCs selected to implement the prioritization tool will receive training and an observed implementation period. They will be compared to 5 PHCs that have not received the intervention.

2.6.3. Sampling

2.6.3.1 Enrollment and Consent

A total of 10 PHCs will be enrolled in this phase of the study. Enrollment of nursing staff will be voluntary. For PHC level evaluation, verbal consent, for prioritization tool utilization and collection of time metrics, will be obtained from parents that bring their children to the PHCs (appendix 3).

2.6.3.2.Inclusion criteria

Clinics enrolled using the selection criteria, whose nursing staff voluntarily agrees to participate in the study and assist with the measurement of time metrics.

2.6.3.3.Exclusion criteria

Critically ill children that a severely ill and warrant immediate transfer to appropriate care.

2.6.3.4.Sample Size

There is no existing data on screening/referral times in PHCs. Statistical power analysis will be conducted based on preliminary data that will be collected during the formative phase to determine effect size.

2.6.4. Outcome Measures

Time of arrival of child at the PHC to time of prioritization.

Time of arrival to time to identification as critically ill.

Time of arrival of critically ill child to time of rendering basic life support intervention (door-to-treatment time).

Time of arrival of critically ill child to time of transfer to definitive care (door-to-transfer time).

2.6.5. Data collection and management

Time metrics derived by scanning the barcodes will be collected on mobile devices. This information will be compiled to form a database with each unique code tied to several time metrics.

2.6.6. Statistical Analysis

Cox proportional hazards model and Kaplan-Meier Survival Analysis

2.6.7 Reporting and Implementation of results

The results will be distributed to the Western Cape Government and staff at UCT, to utilize in quality assurance. The findings will be delivered to a wider audience through peer-review publication.

2.6.8. Ethical and Legal Considerations

The investigator will play an observational role only in this part of the study. No protected health information or other identifying information will be collected in this phase of the study. Study participants will be tracked using a uniquely generated independent barcode.

2.6.9. Limitations

The use of mobile technology can provide several challenges, it may be difficult to obtain buy in to use this technology, we anticipate issues with compliance, and there may be issues with theft and damage.

2.6.10. Resources

2.6.10.1.Avaliable Resources

The 109 nurse led clinics have already been enrolled in to the Pathways to Care study. The division of emergency medicine at UCT will be able to provide space and classroom materials to conduct the training of the staff from the PHCs.

2.6.10.2.Budget

In South African RAND: Cost of mobile phones (2000 ZAR each) *20 = 40,000 ZAR.

In USD: Cost of mobile phones ($200 each) *20 = $4,000.

2.6.11. Timeline

	Feb 1st	Feb 1st to 15th	Feb 15th to April 15th
Training	**x**		
Implementation		**x**	
Data Collection			**x**

This timeline only includes the implementation phase for the five clinics enrolled in the second evaluation phase of the study.

2.7. Evaluation Phase 3: Patient Outcomes

The prioritization tool that was developed in the first phase of the study is named the "Sick Children Require Evaluation Now" (SCREEN) program. **In September 2014 the City of Cape Town implemented SCREEN in all of the 120 primary healthcare clinics in the Western Cape.** This program couples a simple screening algorithm with readily available human resources to permit active real-time screening, to identify critically ill children at the time of their arrival to a Primary Healthcare Clinic (PHC). The purpose of this phase of the study is to evaluate the effectiveness of the screening algorithm when utilized by laypersons and the implementation of SCREEN in low resource PHCs.

Specific Aims:

SA1: Measure the effectiveness of Queue Marshalls in identifying Critically Ill Children using the screening algorithm in PHCs in Cape Town, South Africa.

SA2: Measure the implementation of the SCREEN program in PHCs, by counting A) number of children asked all seven questions in the algorithm, B) number of children screened within five minutes of arrival and C) number of critically ill children expedited within ten minutes of arrival.

SA3: Perform a qualitative analysis of the barriers and successes impacting the utilization of the screening algorithm and adherence to the SCREEN program.

2.7.1. Study design

This is an effectiveness-implementation hybrid study; a random sample of clinics will be enrolled to evaluate the effectiveness of the screening algorithm and the implementation of the SCREEN program in a real world environment (low resource primary healthcare clinics); a concurrent qualitative study will be conducted to contextualize the barriers and successes to implementation.

2.7.2. Study population

This study will enroll primary healthcare clinics that have received training to implement the SCREEN program by the City of Cape Town Department of Health.

2.7.3. Sampling

2.7.3.1. Enrolment and Consent

Clinical sites will be enrolled under the guidance of City of Cape Town health department executive health management team.

Effectiveness study: Assuming a significance level 0.05 (one-sided), power of 80% we will need to enroll 118 critically ill children to demonstrate a sensitivity of the QM of 95% +/- 5% (i.e. greater or equal to 90%). For these calculations we have assumed that the prevalence of critically ill children will be 10% (base on WHO burden of disease data and preliminary clinic data)[13] a total of 1180 children will need to be screened. A 97% sensitivity was observed when the screening algorithm was implemented by the PI (trained emergency physician) in a study of 967 children, thus a 95% sensitivity was chosen as a target for successful use by the QMs. Ideally we would like the sensitivity to be greater than 99%, however, given the absence of any existing standard and an alternative of no triage, we believe this is acceptable. *Implementation study*: The sample size calculation is based on the assumption that 80% (+/−2%) of QM will A) correctly ask all 7 questions and B) screen children at point of entry. A sample size of 1585 produces a two-sided 95% confidence interval with a width equal to 0.040. Since evaluations are unlikely to be independent, given a single QM may see many patient, an interim analysis will be required to recalculate sample size. To minimize the bias of clusters a random sample of 40 clinics will be chosen and sampled for 2 randomly chosen non-consecutive days, based on current clinical audit data this will yield over 4000 children.

2.7.4. Outcome Measures

(SA1) The number of critically ill children correctly identified by the QM.
(SA2) A) Number of children asked all seven questions, B) Number of children screened at entry (within 5 minutes) by the QM and C) the number of critically ill children expedited (within ten minutes) to nursing care.
(SA3) Focus group discussions (FGD) will be used to highlight barriers and successes in SCREEN implementation until thematic saturation is reached.

2.7.5. Data collection and management

Data will collated onto an excel spreadsheet on a daily basis by the research staff. For (SA1 & SA2) the research assistants will notate on a paper form their observations of the queue marshall. Each child entering the clinic will be a randomly assigned unique identifier. No identifying personal health information will be recorded. For (SA3), after consent is obtained, Queue Marshalls and Nurses from the selected PHCs will be surveyed in a semi-structured manner to determine the failures and successes of SCREEN implementation. Employees will be reminded that involvement in the survey and any information revealed will be de-identified and will not affect employment with the PHC. The surveys will be administered face-to-face in a private setting, and no identifying information will be obtained on each employee from the included PHCs.

2.7.6. Statistical Analysis

Only simple descriptive statistics will be performed.

2.7.7. Reporting and Implementation of results

The results will be distributed to the Western Cape Government and staff at UCT, to utilize in quality assurance. The findings of the study will be delivered to a wider audience through peer-review publication.

2.7.8. Ethical and Legal Considerations

In this section of the study we will be collecting PHI and other identifiable details. Thus informed consent to collect data is essential. We will protect this information, by avoiding the collection of paper records, using a HIPAA compliant secure online database, and limiting access to IRB approved study personnel only. This methodology has already been safely used in the pathways to care study.

2.7.9. Limitations

The ideal study for an intervention evaluation in this setting would be a pre-post cluster randomization study. However, in this case it is not possible as the COCT decided to implement the SCREEN program in all of its 120 clinics, based on anecdotal experience and feedback from clinic staff, which was overwhelming positive. Despite preliminary data supporting the reliability of the screening algorithm and data on the reduction in waiting times, it is imperative that a rigorous evaluation of this program be conducted prior to further roll out. The evaluation methodology chosen (i.e. the use of mystery

shoppers and direct observation) is in keeping with the study design used in many large multi-country evaluations of IMCI conducted by the WHO.[9,10] We believe that this study design is in keeping with current research standards and will also allow direct comparison for future implementation and scale up. The biggest challenge with research involving direct observation is the well-described "Hawthorn effect". This will be minimized in SA1 by the use of "mystery shoppers," and for SA2 by using RAs disguised as clients. It is appreciated that the time of day will likely impact the outcome measures for SA2, thus direct observations will be conducted for two full days at each clinic. We will minimize compliance bias by sampling each clinic for two random days opposed consecutive sampling.

2.7.10. Resources

2.7.10.1. Available Resources

This study will utilize the existing infrastructure of the PTCS. The principle investigators for the PTCS are Prof Lee Wallis and Prof Andrew Argent from RCWMCH at UCT.

2.7.10.2. Budget

Budget and Justification			
Budget Category Totals	**Feb 1st 2015-April 1st 2015**	**Feb 1st 2016-April 1st 2016**	**Total**
Personnel costs (including fringe)	$12499		$12499
Consultant Costs			
Supplies	$251		$251
Travel		$2000	$2000
Patient Care Costs			
Other Expenses	$700		$700
Indirect Costs -Supervising Institution			
Contractual Costs Research Assistants	$9600		$9600
Subtotal by Year	$23000	$2000	$25000
Total for entire proposed project			

2.7.11. Timeline

First data collection phase will be for 3 months Feb 2015-April 2015, this data will be analyzed used to inform implementation strategy and training for QM in August 2015, repeat the study Feb 2016-April 2016.

References:

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10. English M, Esamai F, Wasunna A, Were F, Ogutu B, Wamae A, et al. Assessment of inpatient paediatric care in first referral level hospitals in 13 districts in Kenya. *Lancet*. 2004; 363(9425): 1948-53.

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12. Molyneux E, Ahmad S, Roberston A. Lessons from the Field: Improved triage and emergency care for children reduces inpatient mortality in resource-constrained settings. *Bulletin from the World Health Organisation.* 2006; 84:314-319.

Appendix 1: Oral Consent Script: Formative Phase

Purpose of the study

You are invited to take part in a research study. The purpose of this study is to identify and define barriers to efficient and appropriate prioritization of critically ill children in primary healthcare centers. The goal is to use this information to provide a thorough report of themes identified with recommendations to develop a prioritization tool for critically ill children. We hope to conduct interviews with key stakeholders involved in the triage of critically ill children. You are invited to participate in this study because of your experience with the resource availability in primary health care centers and the care of critically ill children in Cape Town.

Procedures

If you agree to participate, you will be interviewed by one of the study team members. We will collect information from you and from other participants in the study. The interview will be recorded with a digital audio recorder and the interviewer will take notes. The discussion will last approximately 30 minutes and will consist of a structured set of open ended questions to allow in depth responses. The digital recordings will not contain any identifying information and will be coded to protect your confidentiality. No identifying information will be recorded in hand written notes in order to protect your privacy. You may refuse to answer any questions and you may withdraw participation in the study at any time.

Risks and Discomforts

There are no physical risks to participating in the study. You may feel uncomfortably discussing the care of critically ill children and prioritization issues. All information collected will be utilized to strengthen and improve the current healthcare delivery system. The information collected in this study will not be used as ground for reprimand, discrimination, or termination of any staff member. No names or other identifying information will be collected during this study to ensure that all information collected is strictly confidential. One inconvenience of the study is that participation will take approximated 30 minutes of your time.

Benefits

There is no direct benefit to individuals participating in this study. Your participation will assist in identifying barriers to appropriate and efficient prioritization of critically ill

children and the development of targeted interventions to improve and strengthen the EMS system. The results and interventions developed from this study will benefit all children in Cape Town. The entire health care system will benefit from more efficient and appropriate Prioritization.

Voluntary Participation

You do not have to participate in this study. If you choose not to participate, it will not affect your employment or future involvement with the University of Cape Town or your involvement in the Pathways to care study .If you have any questions regarding your rights as a study participant, or you feel that you have not been treated fairly in the course of this study, you may contact the University of Cape Town Institutional Review Board at #-###-###-#### or the Johns Hopkins Institutional Review Board at 1-410-955-3008.

Permission to Proceed

Would you like to participate in an interview as explained above?

Appendix 2: Staff Consent Script for Prioritize Tool Implementation

Purpose of study

To improve the prioritization of critically unwell children in primary health care centers by implementing a prioritization tool.

Your participation in this study and procedures

If you agree to participate in this study, we will ask you to attend a training session at the University of Cape Town, for two days on the effective use of the prioritization tool. We will then ask that you use the tool in your daily practice. Depending on the phase of the study we will collect data in one of the following methods.

1. If your clinic is chosen to participate in the validation phase, a study investigator will triage children alongside. He/she will independently record their triage score for each child. Your triage score and that of the investigator will be collected to look for percentage agreement. In this phase we are seeing if the tool can be successfully used.

2. If your clinic is chosen to participate in the survival analysis phase, we will be recording different time components in the clinic setting. All children that present to the clinic will be issued a barcode, at various time points (arrival, prioritization , identification as critically ill, administering treatment and transfer we will ask you or a study personnel to use mobile phones to scan barcodes. We have developed a program to compile the information from each of the mobile phones. Ultimately this information will be put into a database. Each individual barcode will represent a patient encounter with different times.
3. In the final phase of the study, once trained on the use of the prioritization tool you simply have to use it in your clinical practice.

Why you are being asked to participate

You are being asked to participate in this study because you are working as staff in the primary healthcare centers where would like to evaluate the effectiveness of using a prioritization tool to identify sick children.

Risks and benefits of participating in the study

You may fill uncomfortable with the prioritization tool and implementing it in your practice, to help with this study personnel will be present at the clinic for the first two weeks to help facilitate the transition. By participating in the study you will be providing us with important information on whether the tool can be used successfully to identify and prioritize critically ill children.

Confidentiality

The study staff will keep your personal information confidential. At the clinic level no protected health information or identifying information from the patients will be collected.

Compensation for your participation

To facilitate your participation in the training we will provide reimbursement for transport and a per diem for personal expenses.

Voluntary participation

You are a volunteer. You do not need to participate in this study.

Questions about the study

If you ever have any questions about this study, or in case you have any problem contact University of Cape Town Institutional Review Board at #-###-###-#### or the Johns Hopkins Institutional Review Board at 1-410-955-3008. We would be happy to share a comprehensive research protocol with you if you would like.

What does your agreement to this consent form mean?

If you agree to participate it means you have been informed about the study's purpose, why you were asked to participate, possible benefits and risks. Your agreement means you consent to receiving training on the prioritization tool and will implement it in your practice.

I agree to participate in this study myself by my own free will and am willing to (Check boxes that are accepted);

_____	_____	_____
Date	Name	*Signature of Staff Member*
_____	_____	_____
Date	Print name of Person Obtaining	Signature of Person Obtaining

Give a copy to the participant and keep one copy in the study

Appendix 3: Oral Consent Script: Clinic Level

Purpose of the study

You are invited to take part in a research study. The purpose of this study is to measure the time it takes to see and treat children that present to the clinic.

Procedures

If you agree to participate, you will be ask to pick up a barcode from the entrance. At different points in your child's care we will scan this barcode in. You may refuse to participate by simply not picking up a barcode.

Risks and Discomforts

There are no physical risks to participating in the study. No names or other identifying information will be collected by the mobile phones used to scan the barcode.

Benefits

There is no direct benefit to individuals participating in this study. Your participation will assist in helping us measure the efficiency of the care delivered in the clinics. The entire health care system will benefit from the results of this study.

Voluntary Participation

You do not have to participate in this study. If you choose not to participate, it will not affect the quality of care delivered to your child today.

If you have any questions regarding your rights as a study participant, or you feel that you have not been treated fairly in the course of this study, you may contact the University of Cape Town Institutional Review Board at #-###-###-#### or the Johns Hopkins Institutional Review Board at 1-410-955-3008.

Permission to Proceed

Would you like to participate in an interview as explained above?

By picking up a barcode and offering it to the staff to scan, will imply your consent to participate.

APPENDIX 2: UNIVERISTY OF CAPE TOWN HREC ORIGINAL APPROVAL

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APPENDIX 3: UNIVERSITY OF CAPE TOWN HREC AMENDMENT APPROVAL

Appendix Removed due to Visible Signature

APPENDIX 4: JOHNS HOPKINS IRB APPRORVAL

Monday, November 25, 2013 6:49:13 AM South Africa Standard Time

Subject: eIRB: FYI - Study Approved
Date: Thursday, November 21, 2013 11:19:00 PM South Africa Standard Time
From: JHM eIRB
To: Bhakti Shroff

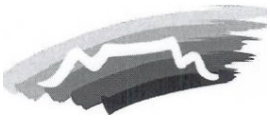
eIRB: **FYI - Do not reply**	**Study Approved**
Study Number:	**NA_00088758**
Study Name:	**Prioritization of critically unwell children in low resource primary centers in Cape Town, South Africa**
PI:	**Bhakti Shroff**
IRB Committee:	**JHM-IRB 2**
Link to Workspace:	**NA_00088758**

The above-referenced eIRB application has been approved by the JHM IRB. Click on the link above to access the application.

QUESTIONS?

Contact: **JHM IRB Office at 410-955-3008**
JHM eIRB Help Desk at jhmeirb@jhmi.edu

APPENDIX 4: CITY OF CAPE TOWN FACILITIES APPROVAL



tilOF CAPE TOWN ISIXEKO SASEKAPA | STAD KAAPSTAO

Civic Centre
12 Hertzog Boulevard
Cape Town 8001
P O Box 296, Cape Town 6000
Ask for: Or G H Visser
Tel: 0214003981
Cell: 0832988718
Fax: 0214214894
E-mail: Helene.visser@capetown.gov.za
Website: http://www.capetown.gov.za
Ref:

Iziko loluntu
12 Hertzog Boulevard
Cape Town 8001
P O Box 298, Cape Town 8000
Cela: Qrll G H Visser
Umnxeba: 0214003981
Cell: 08329887 18
Ifeksi 0214214894

Burgersentrum
Hertzog-boulevard 12
Kaapstad 8001
Posbus 298, Kaapstad 8000
Vra vir: Or G H Visser
Tel 0214003981
Set: 0832988718
Faks: 0214214894

Filename: G:Research\2013\PH odkinson 10378 docx

CITY HEALTH -Specialised Health

2013-11-14

re: Research Request: Implementation and Evaluation of a Novel Prioritization tool in Primary Healthcare Clinics in Cape Town, South Africa (ID NO: 10378)

Dear Dr Hansoti,

Your research for the abovementioned study was approved for the following City Health facilities:

Tygerberg Sub District: Contact People:	Delft South Clinic Mrs M Alexander (Sub District Manager) Tel: (021) 938-8279/084 222 1471 Mrs D Titus (Head: PHC & Programmes) Tel: (021) 938-8281 / 084 308 0596
Khayelitsha Sub District: Contact People	Kuyasa and Matthew Goniwe Clinics Dr V de Azevedo (Sub District Manager) Tel: (021) 360-1258/083 629 3344 Mrs S Patel Abrahams (Head: PHC & Programmes) Tel: (021) 360-1153/ 084 405 6065
Mitchells Plain Sub District: Contact People	Weltevreden Clinic Mrs S Elloker (Sub District Manager) Tel: (021) 391-5012/ 084 222 1478 Mrs N Nqana (Head: PHC & Programmes) Tel: (021) 391-0175/ 084 2221489
Southern Sub District: Contact People	Hout Bay Main Road Clinic Mr M Cupido (Acting: Sub District Manager) Tel: (021) 710-8092/084 2200 145 Mrs B van Niekerk (Head: PHC & Programmes) Tel: (021) 710-9383/ 082 821 7361
Western Sub District: Contact People:	Albow Gardens or Du Noon Clinics (Please confirm which clinic with Mrs Stanley as it will depend on the move from Du Noon into Albow Gardens) Mrs G Sifanelo (Sub District Manager) Tel/Cell: (021) 514-4122 / 084 630 2903 Mrs M Stanley (Head: PHC & Programmes) Tel/Cell: (021) 514-4124 / 072 329 6361

Please note the following:

1. All individual patient information obtained must be kept confidential.

2. Access to the clinics and its patients must be arranged with the relevant Managers such that normal activities are not disrupted.
3. A copy of the final report must be sent to the City Health Head Office, P 0 Box 2815 Cape Town 8001, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (10378). Please use this in any future correspondence with us.

Yours sincerely

Signed by candidate Signature Removed

DR G HVISSER
MANAGER: SPECIALISED HEALTH

cc. Mrs Elloker & Ms Nqana
Dr de Azevedo & Mrs Patel Abrahams
Mrs Cupido & Mrs van Niekerk
Mrs Alexander & Ms Titus
Mrs Sifanelo & Mrs Stanley
Dr K Jennings
Ms J Caldwell

APPENDIX 5: QUALITATIVE STUDY OF BARRIERS TO PREHOSPITAL CARE FOR CRITICALLY ILL CHILDREN

Defining and improving the role of emergency medical services in Cape Town, South Africa

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ABSTRACT

Introduction Low and middle income countries bear a disproportionate burden of paediatric morbidity and mortality. South Africa, a middle income country, has unacceptably high mortality in children less than 5 years of age. Many factors that contribute to the child mortality rate are time sensitive and require efficient access to emergency care. Delays and barriers within the emergency medical services (EMS) system increase paediatric morbidity and mortality from time sensitive illnesses.

Methods This study is a qualitative evaluation of the prehospital care system for paediatric patients in Cape Town, South Africa. A purposive sample of healthcare personnel within and interacting with the EMS system were interviewed. A structured interview form was used to gather data. All interviews were audio recorded and transcribed; two independent reviewers performed blinded content analysis of the transcribed script.

Results 33 structured interviews were conducted over a 4 week period. Eight broad themes were identified during coding, including: access, communication, community education, equipment, infrastructure, staffing, training and triage. Subcategories were used to identify areas for targeted intervention. Overall agreement between the two independent coders was 93.36%, with a κ coefficient of 0.69.

Conclusions The prehospital system is central to delivering time sensitive care for paediatric patients. In a single centre middle income setting, communication barriers between dispatch personnel and medical facilities/EMS personnel were deemed to be a high priority intervention in order to improve care delivery. Other areas for targeted interventions should include broadening the advanced life support provider base and introducing basic medical language in dispatch staff training.

Key messages

What is already known on this subject

- Many illnesses and injuries contributing to child morbidity and mortality are time sensitive, requiring efficient access to emergency care.
- Emergency medical services (EMS) is a key component of healthcare systems, providing prehospital and transfer capabilities necessary for access to life saving interventions.
- The WHO has identified EMS as an area of neglected research.

What this study adds

- Eight barriers to effective EMS care were identified, including: access, communication, community education, equipment, infrastructure, staffing, training and triage.
- Key areas for targeted interventions should include increasing the number of healthcare personnel in the clinics, broadening the advanced life support provider base and introducing basic medical language in dispatch staff training.

INTRODUCTION

Many low and middle income countries (LMIC) will fall short of meeting the fourth Millennium Development Goal (reduce child mortality by two-thirds) (MDG4) this year.[1] While progress towards MDG4 demands essential public health and child care interventions, many of the contributing conditions affecting child mortality in LMICs are time sensitive, requiring access to emergency care.[2–4] A coordinated emergency health system is essential to ensure appropriate and timely interventions to prevent mortality;[5–11] one of the key components is emergency medical services (EMS), a system to provide prehospital and inter-facility transport.[8]

South Africa is a middle income country with persistent health inequity and high infant and child mortality rates (mortality is estimated to be 45 out of 1000 live births for those under 5 years of age).[1] In a recent study which was a key driver to this work, Hodkinson *et al*[10] described a 12 month review of all patients admitted to the paediatric intensive care unit (PICU) at the Red Cross Children's Hospital, Cape Town; they found that 30% of PICU admissions were potentially avoidable. The study team identified that delays within the EMS system and poor prehospital clinical care were key contributors to the morbidity and mortality of critically ill and injured children A survey of LMIC EMS systems identified 22 barriers to prehospital care,[6] and local studies in Gabon and Tanzania have identified barriers to EMS and areas for targets improvement.[11 12] Identifying areas for focused quality improvement interventions can provide significant benefit, both in LMIC and high income settings.[13] Addressing delays and barriers within emergency care is critical to improving the morbidity and mortality of critically ill children in LMIC settings.[14] Given the expansion of EMS systems in LMIC settings, and the importance of EMS in improving outcomes for critically ill and injured children, we undertook a study to identify barriers to care within EMS in Cape Town.[11 12 15–19]

To cite: Anest T, Stewart de Ramirez S, Balhara KS, *et al*. *Emerg Med J* 2016;**33**: 557–561.

METHODS

Study setting

The population of Cape Town is served by Western Cape Government EMS (WCG EMS), a modern prehospital system with sophisticated dispatch and trained personnel. It covers a population of almost 6 million with 248 ambulances and 1588 personnel, of whom only 135 have advanced life support (ALS) training. In 2012, WCG EMS responded to 616 645 calls at its control centres; once connected, the call taker has 90 s to gather information, prioritise and send the call electronically to the dispatcher, who uses the information to assign an appropriate ambulance. Calls are assigned as priority 1 (P1) or 2 (P2). National urban response time targets include 90% of P1 within 15 min, 90% of P2 within 30 min and 100% of all calls within 60 min. At the time of the study, all children under the age of 1 year were automatically categorised as P1. Within the Cape Town metropolitan area there are 90 EMS vehicles on the road in any 24 h period, with 10 equipped and staffed at ALS level. There is a single paediatric flying squad vehicle dedicated solely to paediatric transfers.

Study outline

We undertook a cross sectional qualitative analysis of staff that play a role in the prehospital care of critically ill children in Cape Town. The aim of the study was to identify factors hampering the efficient and appropriate EMS transport of critically ill children. This study focused on four objectives: (1) define factors related to effective communication between EMS personnel, communications centres and healthcare facilities; (2) identify factors impacting the prioritisation of EMS calls; (3) define variables that impact response and transport times; and (4) identify factors that impact assignments of EMS crew, vehicle and equipment.

A purposive sample of healthcare personnel was interviewed over a 4 week period. EMS leaders were assigned to recruit participants to the study. We recruited a minimum of two participants from each step in the prehospital pathway to care, including EMS ground crew personnel, EMS dispatch personnel and each level of facility (clinic, community health centre, hospital). Facility personnel included all personnel interacting with EMS at that facility, which included nurses and physicians. A semi-structured interview template which mirrored the objectives of the study was utilised. Open ended questions included inquiries about the role of EMS, barriers to providing EMS care to critically ill children, factors effecting response and transport time, prioritisation and triage of EMS calls and transfers, and availability of staff, training and equipment. Interviews were conducted until the point of thematic saturation. Thematic saturation was defined as the collection and analysis of data until no new information was obtained.[20]

Analysis

De-identified recordings were transcribed to text and blinded content analysis was performed by two independent reviewers utilising NVIVO software. Eight broad themes were identified; six were later re-coded by the same two independent reviewers to identify subcategories for future targeted intervention. On completion of independent coding, statistical analysis was performed to determine agreement between reviewers; κ coefficients were calculated.

RESULTS

Nine focus groups and 24 individual interviews were conducted during November/December 2013. Dispatch personnel were from the EMS call centre. EMS operational personnel were from two of the four Cape Town EMS stations. Facility personnel were interviewed from each care level, including a clinic, community health centre, district hospital, regional hospital and tertiary receiving facility. Facility personnel included physicians and nurses as utilised at each facility (table 1).

The eight core themes identified by participants included access, communication, community education, equipment, infrastructure, staffing, training and triage. The frequency with which each theme occurred is shown in figure 1. Six themes (communication, equipment, infrastructure, staffing, training and triage) were further divided into subcategories to better understand the barrier and guide intervention. On completion of coding, statistical analysis demonstrated 93.4% agreement between reviewers and an overall κ coefficient of 0.69.

Access

Access to the system as a whole was identified as a barrier, including lack of telephone access and no universal emergency number. Barriers cited included lack of transportation, lack of childcare for other children in the household and restrictive hours of clinic operations.

> "Sometimes they said they didn't have the money to come here, and then you ask why didn't you phone the ambulance? Some they said, we don't know the ambulance number. Some like[sic] they don't have money to phone for the ambulance."
>
> (Nurse, Community Health Centre)

Communication

Communication was repeatedly identified as a barrier by all groups. Facility personnel most frequently identified communication challenges with the dispatch centre, such as difficulty getting through on phone lines, phone lines being cut at facilities, miscommunication regarding the acuity of the patient, level of care being requested and equipment needed for the transfer. A nurse describes a typical interaction with the dispatch centre in the following:

> "I've had one person tell me frankly that he didn't know what I was talking about, and I should just explain to him what I needed, and I was so grateful, because he told me he didn't know. The others I've had incubators pitch up, when I ordered ventilators."
>
> (Nurse, District Hospital)

EMS operational staff identified communication challenges with dispatch most frequently, citing misunderstanding of geography, distance, equipment needed and the level of care required. In contrast, dispatch personnel most frequently cited communication with the community as a challenge, citing difficulty obtaining accurate locations of calls and acuity of patients from the community.

> "The biggest barrier is the lack of communication, and for us inside the communications, it's difficult to get the message across, because the parents are already in such a state when they call, they're frantic, they're panicking and we can't make a clinical decision. Some of the call centre agents have medical background, others don't and we have to try to impart our medical knowledge over to them so they know exactly what questions to ask."
>
> (Communications Centre Manager)

Community education

Community education was cited by operational EMS, dispatch and facility personnel, with emphasis on misunderstanding of the role of EMS and how to navigate the health system. Desire for parent education on how to identify a sick child and what to

Table 1 Detailed attributes of all interviews.

Category	Site	Interview type	Participant details
EMS	Base station one	Group	7 EMS managers
	Base station one	Group	5 EMS ground crew members
	Base station one	Group	4 EMS ground crew members
	Base station two	Group	4 EMS ground crew members
	Base station two	Individual	1 EMS ground crew member
	Base station two	Group	2 EMS ground crew members
	Base station two	Group	2 EMS ground crew members
	Base station two	Individual	1 EMS ground crew
	Base station two	Individual	1 EMS manager
Dispatch	Communications centre	Individual	1 communications manager
	Communications centre	Individual	1 dispatcher and former EMS ground crew
	Communications centre	Individual	1 communications manager
	Communications centre	Individual	1 communications supervisor
	Communications centre	Individual	1 dispatcher
	Communications centre	Individual	1 dispatcher
	Communications centre	Individual	1 dispatcher
Facility	Regional hospital	Individual	1 physician
	Regional hospital	Individual	1 nurse
	District hospital	Individual	1 physician
	District hospital	Individual	1 physician
	District hospital	Individual	1 physician
	District hospital	Individual	1 physician
	Community health centre	Group	2 nurses
	Community health centre	Group	2 nurses
	Clinic	Group	2 nurses
	Clinic	Individual	1 nurse
	Clinic	Individual	1 physician
	Tertiary hospital	Individual	1 physician
	Tertiary hospital	Individual	1 physician
	Tertiary hospital	Individual	1 physician
	Tertiary hospital	Individual	1 physician
	Tertiary hospital	Individual	1 physician and former EMS ground crew
	District hospital	Individual	1 physician

EMS, emergency medical services.

do in an emergency was expressed, with many participants describing concerns that families wait for the clinic to open instead of calling EMS.

> "Once somebody realises that the child is ill, I think there's often a lack of education in terms of how to assess how ill the child is, and what kind of symptoms are significant as opposed to what are not. So, you know, we'll be getting calls at three o'clock in the morning, because the child has a runny nose. But we're not getting calls at three o'clock in the morning because the child is vomiting persistently for days."
>
> (Paramedic)

Equipment

Equipment was thought to be a barrier by all participants, especially EMS equipment. Specific equipment needed included

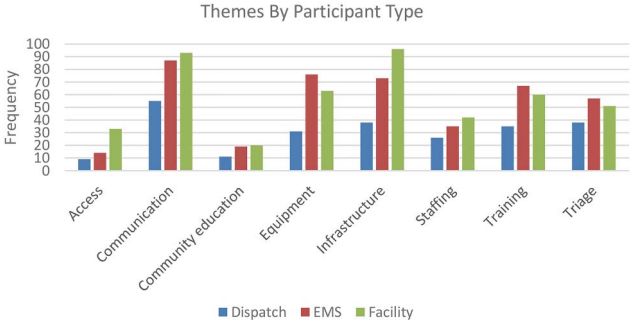

Figure 1 Frequency of themes by participant type. EMS, emergency medical services.

ventilators, IV pumps, pulse oximetry and cardiac monitors, the lack of which restricted ALS personnel's ability to function to the highest level of their training. Lack of paediatric specific equipment was also cited, including incubators, appropriate blood pressure cuffs and ventilators with paediatric settings.

> "We haven't got enough equipment like incubators, ventilators, and then calls is lying for more than an hour[sic], two hours before we can respond. That is a big issue, because if you hear then people say they haven't got that on the vehicle, or even sometimes they don't have oxygen on the vehicle."
>
> (Paramedic)

Infrastructure

Infrastructure was a broad category, requiring sub-coding to better delineate areas for intervention. The three subcategories were civil planning infrastructure, policies and procedures, and telecommunications infrastructure. Civil planning infrastructure barriers included poor roads and housing, with almost no signage to assist in identifying locations in the squatter settlements, and a shortage of hospitals and ambulances for the population requiring care.

> "You see what's happening also here in the Western Cape is our big squatter camps we're having here, and that basically also has a big impact, because when a vehicle moves into a squatter camp they must go look for a number, and it's very difficult to get a number, because you will get number 22 here, then you will think 23 is next door, then 23 is right on the other end."
>
> (Communications Centre Manager)

> "I would say if you want to improve you're probably going to have to either cut the size of the community that we service to a smaller portion, or increase the resources….if you look at how the population[sic] boom in this area, from the last 10 years the resources has not kept up with that. So we've got quite a lot of expertise in EMS, very good systems, and very good people, but the problem there comes with the workload."
>
> (Paramedic)

Policies and procedure barriers were predominantly around inefficient systems. Patients were often transferred multiple times as they moved up the levels of care from clinic to district hospital to tertiary referral hospital, leading to delays in access to definitive care. EMS personnel described lengthy delays at receiving facilities, waiting for a bed to become available for the patient they were transporting, or waiting for a receiving doctor to sign acceptance of the patient.

> "So the big problem is if the child follows the recommended route of levels of care, so presents to the clinic, then gets sent to the district level hospital, ……. those might be three or four

> steps.... there is no smooth way that they can progress through that, especially being, getting to be assessed, but mainly getting transport and having to sit in the queue. And within sight of the goal, Red Cross hospital."
>
> (Physician, Tertiary Referral Centre)

> "(there are) three hour, four hour sometimes delay with the vehicle sitting with a critical patient waiting for a bed, because a lot of the doctors at the hospital,[sic] many times the com centre phones operations, we must go out and make a bed, and it's something we, we can't do. So we go out, we explain to the doctors, and....you'll stand for three to four hours waiting for the doctor to eventually sign off, and free up the vehicle, which leads to lengthy turnaround times."
>
> (EMS Manager)

Telecommunications infrastructure barriers such as the lack of a universal emergency number to reach EMS, lack of phone access in many households and frequently downed phone lines at facilities were identified.

> "Emergency calls are free to any of the call centres. From there, it's actually maybe a lengthy process, because you've first got to get to the one call centre, or will then either re-route you, or take your details and then re-route you to another call centre, okay. And that call centre, if you haven't ended up here, will then transfer you, or take your details and then transfer you here. Or, or just call us and then pass on the details. So your details could actually be third hand. ……..Something that could have made the difference, one little fact that could have made the difference in the child's outcome is lost, and then we grade the child as priority 2 as opposed to a priority 1 call."
>
> (Communications Centre Manager)

Staffing

Staffing challenges were cited by all groups. Lack of ALS EMS personnel was a frequent issue, while facilities also faced staffing challenges, citing physician shortages in clinics as well as hospitals.

> "They need more ambulances, and....I think we have too many of the basics, and not enough of the advanced, because a lot of times the ambulance people will tell you quite frankly that they were the wrong people to go and fetch that child, they know that, everyone knows that, but they were the only people who had wheels, and so go, you do the best you can."
>
> (Physician, Tertiary Referral Centre)

Training

Training barriers were an issue across the system, with the need for additional ALS and paediatric training identified at both EMS and facilities. For dispatch personnel, training barriers included lack of medical training for call takers and dispatchers, leading to subsequent inaccurate triaging of calls, incorrect level of service designation and inappropriate equipment assignments.

> "It could be because of the lack of knowledge of the call takers side. Also they're not prioritising correctly because of their lack of medical knowledge. So they don't know what, the right questions to ask."
>
> (Communications Centre Supervisor)

Triage

Triage barriers were unanimously present, but especially within dispatch. Errors in triage from dispatch were identified as a source of delay for both emergent and transfer calls when the incorrect priority, level of service or equipment was sent to the call. Triage levels were often reported to be discrepant between dispatch, EMS and facilities, leading to miscommunication and inappropriate assignments.

> "The other thing that I also find which is very wrong… is that the minute a person is at a clinic or a day hospital, even though their condition is critical, or serious, it's regarded as a priority 2 call. But what they don't realise is that although there are doctors there, and there are medical staff there, which is like … their perception is they're in a medical facility, therefore they're okay. But the problem is those hospitals are not equipped to handle the problem with that child, or that person. So now because it's a priority 2 they'll send when they've got somebody available. So it can be a 2 to 3 hour delay sometimes. But that 2 to 3 hours for that person is critical."
>
> (Nurse, Clinic)

DISCUSSION

This qualitative study evaluated the prehospital barriers, from onset of illness to arrival at the tertiary care facility, impacting care for critically ill children in Cape Town. We were able to sample key personnel from each step in the prehospital system, define areas for improvement and identify key areas for intervention. Although the focus of the study was paediatric transfers, participants frequently cited barriers to care of all prehospital patients. Although not the intention of this study, much of the data collected applies equally to all prehospital transfers.

Access to care was noted as being limited by geographical location, access to a telephone and access to open clinics. Improved provision of public education on how and when to access EMS may be useful. Access to care is closely linked to increasing staffing, number of clinics and operating hours of clinics available to the communities. In a qualitative study in Gabon, access was also identified as a barrier to use of EMS, due to concern regarding cost, lack of awareness and poor infrastructure, similar to many of the barriers identified in our study.[11] Many of the access barriers are closely linked to infrastructure challenges and mirror the findings of a recent qualitative study in Tanzania, citing the complexity of the health system, complicated and time consuming interfacility transfer policies and procedures, and lack of transportation options.[12]

Communication was the most frequently cited barrier to the care of critically ill children. Miscommunication was frequently cited between EMS personal and dispatchers. Most dispatchers have little medical training and may not understand the medical language utilised by staff and EMS to communicate prioritisation. Providing EMS dispatchers with some medical training may alleviate this barrier.

Research around emergency obstetric care has also explored prehospital barriers. A systematic review of qualitative studies on maternal transport revealed eight major themes: time for transport, transport options, geography, local support, autonomy, culture, finance and ergonomics.[21] A key recommendation was that clearer guidance should be provided to allow prioritisation of cases for emergency transport.[11 12 21] Our study also revealed that errors in triage were key contributors to delays in transport.

This study clearly demonstrates that a multidisciplinary approach is necessary to improve the current EMS system. In their survey of various EMS systems in LMIC, Neilsen *et al* draw similar conclusions. In their survey, 22 different barriers were mentioned by participants, of which infrastructure challenges (lack of funding, organisation and legislation to establish standards) were most prominent.[6] Many publications include funding as a barrier, and although funding was not directly mentioned by our participants, funding impacts many of the barriers cited, such as training, staffing, infrastructure and

equipment.[6 9 15–18 21] There is evidence that investment in EMS in LMIC may be a more cost effective public health intervention than previously thought; a recent study of a new EMS system in rural Uganda calculated the cost of the system at US$89.95 per life saved, when carefully designed to maximise use of already existing infrastructure and resources.[22]

Limitations

This study provided detailed information and a variety of perspectives of a complex system. The use of mixed methods and qualitative research is broadening our understanding of EMS, but it is not without its limitations.[23–25] The utilisation of a single interviewer may introduce bias in the themes identified but our use of two independent coders of the data, who were blinded to the participants, likely minimised it. The purposive sampling of participants was not randomised and may not reflect equally the perspectives of all parts of the system. Also, this is a study of one system, in a singular geographic location and cultural setting, and therefore may not be generalisable to other systems.

CONCLUSION

The barriers to prehospital care of paediatric patients identified in this study are consistent with those previously documented in the literature. Lack of funding will be a significant obstacle to overcoming barriers related to staffing, infrastructure, access and equipment. Key areas for targeted interventions should include increasing the number of healthcare personnel in the clinics, broadening the ALS provider base and introducing basic medical language in dispatch staff training. The biggest barriers for the paediatric population specifically were the lack of paediatric equipment and parent education regarding critical illness and how to access the prehospital system. Solutions that are locally feasible within resource constrained environments must be sought. Strengthening the EMS system for paediatric patients in this setting will require a multidisciplinary approach to increase the clinical capacity of the current system to ensure timely and appropriate prehospital care.

Contributors Each author participated actively and sufficiently in the study design, data acquisition, data analysis, data interpretation and manuscript preparation. All authors have read and approved the submission of the manuscript.

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Notes

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