Missed opportunities for immunisation in health facilities in the Western Cape metro

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Part 0: Preamble

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Declaration

I, Nisha Anne Sunny Jacob, hereby declare that the work on which this dissertation/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 empower the university to reproduce for the purpose of research either the whole or any portion of the contents in any manner whatsoever.

Signature 

Date: 29 June 2015

Dedication

I thank the Lord, my God.

I dedicate this work to my parents, Sunny and Lizzie Jacob, my husband, Jithan Koshy, and my daughter, Namitha for their unwavering support, love, encouragement and prayers.

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I wish to thank

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Abstract

Background: Childhood immunisations are a cost effective public health intervention for prevention of infectious diseases. Immunisation coverage, however, is still sub-optimal which may result in disease outbreaks. Immunisation at every contact with a health facility is a strategy developed by the World Health Organization (WHO) in order to improve immunisation coverage.

Objectives: The aim of this study was to estimate the prevalence of missed opportunities for immunisation at different levels of healthcare in the Western Cape and assess factors associated with missed opportunities.

Methods: The study included a health-facility based cross-sectional exit survey of caregivers with children up to 5 years of age, followed by a qualitative exploration of staff attitudes towards immunisation.

Results: The prevalence of missed opportunities for immunisation was 4.6%; 81.3% of caregivers brought Road-To-Health- Booklets (RTHB's) to consultations. Overall, 56.0% of health workers requested to see the RTHB's during consultations. Children attending primary level facilities were significantly more likely to have their RTHB's requested than children attending a tertiary level facility. Lack of training, resources and heavy workloads were the main challenges reported at secondary/tertiary level facilities.

Conclusion: Missed opportunities for immunisation at health facilities in the Western Cape metro were low, most likely due to good immunisation coverage among children accessing health facilities. Increased health worker support, as well as monitoring and discussion of the value and correct use of the RTHB is needed, particularly at secondary/tertiary levels of care, to improve immunisation coverage.

Contents

Part A: Protocol

Summary

Childhood immunisations are an important public health intervention for the prevention of many serious infectious diseases. Immunisation coverage, however, is still sub-optimal in many areas which may result in disease outbreaks, such as the unanticipated measles epidemic in South Africa in 2009/2010. Immunisation at every contact with a health facility is a strategy developed by the World Health Organization (WHO) in order to improve immunisation coverage. The proposed study addresses two aspects of missed opportunities for immunisation. The first aspect of the study is a quantitative cross-sectional study to determine the prevalence of missed opportunities for immunisation and associated factors, using a simple questionnaire and assessment of the Road to Health Booklet (RTHB). The second aspect of the study is a cross-sectional assessment of staff attitudes towards immunisation through semi-structured interviews. The study will be conducted at five health facilities in the Western Cape metro district of the Western Cape, spanning primary, secondary and tertiary levels of care. The specific facilities will be chosen in conjunction with provincial and local municipality mangers. It is hoped that the study findings will be used to improve immunisation coverage, thus contributing to the prevention of various infectious diseases.

Introduction

Background

Childhood immunisations are considered one of the most effective public health interventions, with a significant impact on mortality and morbidity. The Expanded Programme on Immunization (EPI) was initiated by the World Health Organization (WHO) in 1974 with the aim of providing vaccines to all children worldwide[1]. Immunisation programmes contribute significantly to public health and play a crucial role in achieving Millennium Development Goal 4 to reduce child mortality rates by two thirds by 2015, compared to 1990[2]. Despite advances in expanding immunisation coverage globally, coverage is still sub-optimal in many areas. In areas where access to and utilisation of health services is low, every contact with a health facility provides a key opportunity to immunise, particularly as these areas are likely to be at higher risk of vaccine-preventable diseases[3]. In 1983, the approach to immunisation at every opportunity was introduced by the EPI Global Advisory Group[3]. WHO defines a missed opportunity as "any contact with a health service that did not result in an eligible child or woman receiving the needed vaccines.[1,3]" The elimination of these missed opportunities can significantly improve immunisation

coverage, thus reducing the risk of vaccine-preventable disease[3]. In 1984, EPI developed standardised protocols to study missed opportunities which have been in use worldwide to assess and improve immunisation programmes.

Although immunisation coverage figures at health facilities were greater than 95%, the Western Cape experienced a major measles outbreak in 2009/2010. A herd immunity of 95% is required to prevent ongoing measles virus transmission[4, 5]. Low coverage, incorrect vaccine administration, lower vaccine efficacy and host response factors are the main causes of an outbreak of a vaccine-preventable illness in an area with a functional immunisation programme[4]. The 2009/2010 epidemic raised concerns as to the validity of immunisation coverage data. Since coverage indicators are very sensitive to data inaccuracies such as incorrect population estimates, reported data may not be a true reflection of coverage in the population. Without appropriate coverage data, one cannot predict the potential of another epidemic. In addition to improving the quality of coverage data, it is imperative that strategies to improve coverage are strengthened. The Western Cape Department of Health would like to improve the current immunisation programme in order to increase immunisation coverage, and hence prevent mortality and morbidity from vaccine-preventable diseases. One strategy is to identify and improve coverage in areas of low immunisation coverage that were most affected by the last measles epidemic. Additionally, a missed opportunity survey is another strategy to evaluate immunisation practices and identify ways to further improve immunisation coverage.

Summary of Literature Review

The Expanded Programme on Immunisation in South African (EPI-SA) aims to "prevent death and reduce suffering from infections that can be prevented by immunisation of children and women[6]." Table A1 shows the current EPI-SA immunisation schedule. The immunisation schedule is available in the Road to Health Booklet (RTHB), or in the Road to Health Card (RTHC) for children born before 2011, issued to a child's mother at birth or to a subsequent caregiver. The RTHB remains with the child's caregiver and is to be brought with the child for all health care visits, including immunisation visits.

Table A1: EPI-SA Immunisation Schedule 2012

Age of child	Vaccine needed	How and Where is it given?
At birth	OPV(0) Oral Polio Vaccine	Drops by mouth
	BCG Bacillus Calmette Guerin	Intradermally / Right arm
6 weeks	OPV(1) Oral Polio Vaccine	Drops by mouth
	RV (1) Rotavirus Vaccine	Liquid by mouth
	DTaP-IPV//HIB(1) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(1) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(1) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
10 weeks	DTaP-IPV//HIB(2) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(2) Hepatitis B Vaccine	Intramuscularly / Right thigh
14 weeks	RV (2) Rotavirus Vaccine	Liquid by mouth
	DTaP-IPV//HIB(3) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left thigh
	Hep B(3) Hepatitis B Vaccine	Intramuscularly / Right thigh
	PCV(2) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
9 months	Measles Vaccine(1)	Intramuscularly / Left thigh
	PCV(3) Pneumococcal Conjugated Vaccine	Intramuscularly / Right thigh
18 months	DTaP-IPV//HIB(4) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined	Intramuscularly / Left arm
	Measles Vaccine (2)	Intramuscularly / Right arm
6 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm
12 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm

The guidelines from the National Department of Health stress the importance of checking the RTHB at every visit for missed immunisations and the prompt provision of the pending immunisations[6]. The guidelines further stress that if immunisation status is unknown due to missing RTHB and caregiver uncertainty, the eligible doses are to be administered. Contra-indications for immunisation are also detailed in the guidelines.

In 2005, Corrigall et. al conducted a household survey in the Western Cape to assess routine immunisation coverage rates in children aged 12 – 23 months in the Western Cape[7]. Results showed lower coverage rates of 76.8% for vaccines due by 9 months and 53.2% for vaccines due by 18 months[7]. The main reasons for not being immunised were clinic-related factors including missed opportunities (34%) [7]. This reveals the potential of significantly improving immunisation coverage by avoiding missed opportunities.

Missed opportunity survey methodology was developed from 1984, as a way to evaluate immunisation practices and thereby improve immunisation coverage[1,3].

Missed opportunity studies can be broadly classified into two categories:

1. Observational surveys including both population and facility- based surveys
2. Intervention trials e.g. coverage before and after an intervention to reduce missed opportunities[3]

Although the ideal study design for assessing missed opportunities is a population-based cross-sectional study, health facility-based studies provide an easier and more efficient way of measuring missed opportunities[3].

In the 1980's and 1990's, numerous missed opportunity studies were conducted worldwide. In 1991, EPI reviewed all missed opportunity studies published in world literature or reported to WHO[3]. The review reported that missed opportunities were found in all studies, except one, with an overall median of 32% of children and women of childbearing age who were surveyed had missed immunisation opportunities[3]. Missed opportunity surveys conducted in the Western Cape in the 1990's revealed a prevalence of 60-95%[8.9.10]. Category of consulting health worker and type of service (i.e. curative, preventative or integrated service) impacted on whether RTHC's were requested and immunisations given appropriately[9].

The EPI review by Hutchins et. al in 1991 showed the main reasons for missed opportunities were:

- Failure to administer all eligible vaccines simultaneously.
- False contraindications.
- Health worker practices to avoid vaccine wastage.

- Logistical problems such as vaccine shortages [1,3].

In South Africa, numerous studies noted a trend of decreasing availability and requests for and checking of RTHC's with increasing age[8, 10]. It was evident that fewer opportunities for immunisation were missed if immunisation services were available throughout the week, rather than on specific days and times[10].
A few studies conducted in the United Kingdom (UK) and United States of America (USA) has also highlighted staff factors associated with immunisations[11, 12, 13]. Poor knowledge regarding aspects of immunisation such as contra-indications was noted. Views on a hospital's role in providing a preventative service also differed among staff members[11]. Other staff-related factors resulting in missed opportunities included insufficient time and staff not viewing immunisation as a priority or within their scope of practice[11].

Missed opportunity surveys thus serve as an important tool in the evaluation and improvement of immunisation programmes, however there is a clear gap in the literature on missed opportunity studies in the last decade, worldwide and in the South African context.

Motivation for the study

The Western Cape Department of Health is concerned that the province is at risk of another measles epidemic. There are concerns regarding the validity of immunisation coverage data. Immunisation coverage data may not identify areas with low coverage and campaigns may be required to improve coverage. However immunisation of eligible children at every contact with a health facility is an important strategy in improving immunisation coverage, particularly in areas with poor accessibility to health care, and we therefore need to identify the extent of missed opportunities at health care facilities.

Purpose

This study will quantify missed opportunities for immunisation at a variety of health facilities in the province and explore factors associated with missed opportunities, in order to reduce and eliminate missed opportunities. This may, in turn, help in improving immunisation coverage and reducing mortality and morbidity of vaccine-preventable diseases.

Aims and Objectives

Aim:

To estimate the prevalence of missed opportunities for immunisation at different levels of healthcare in the Western Cape and assess factors associated with missed opportunities.

Objectives:

1. To estimate the prevalence of missed opportunities for immunisation at health care facilities in the Western Cape
2. To determine the proportion of children up to 5 years of age visiting selected health care facilities in possession of a Road to Health Booklet
3. To determine factors associated with missed opportunities for immunisation
4. To identify underlying reasons for missed opportunities for immunisation
5. To understand staff attitudes towards immunisation

Methods

Definition of terms

Immunisation – "the creation of immunity usually against a particular disease"[14]

Vaccination – "the introduction into humans of microorganisms that have previously been treated to make them harmless for the purpose of inducing the development of immunity"[14]

Road to Health Card Booklet – A sex-specific 28 page booklet, distributed to all newborns in South Africa, containing a child's medical information, completed by relevant health care workers[15].

Missed opportunity - "any contact with a health service that did not result in an eligible child or woman receiving the needed vaccines"[1,3]

Attitude – "a feeling or way of thinking that affects a person's behaviour"[14]

Caregiver – "a person who gives help and protection to someone" e.g. child [14]

For the purposes of this study, a caregiver is a person responsible for a child during the child's visit at a health care facility.

Primary caregiver –"A caregiver that takes primary responsibility for another person who cannot care fully for themselves."[16]

Study design

This study has two components:

1. The first component is a health-facility based cross-sectional survey to determine the prevalence of missed opportunities for immunisation and associated factors.
2. The second component is a qualitative exploration of staff attitudes towards immunisation using a semi-structured questionnaire.

Population and sampling

The study population is children up to 5 years of age attending health care facilities in the Western Cape metro district. Caregivers of children will act as proxies for measurement purposes.

Purposive sampling will be employed to select study sites. Five sites representative of primary, secondary and tertiary levels of care will be selected, including a local municipality clinic (primary level), community health centre (primary level), one district hospital (secondary level), one regional hospital (secondary level) and one central hospital (tertiary level). Provincial and City of Cape Town managers and other stakeholders will be consulted for selection of sites.

A sample size of 96 per facility was calculated using an anticipated proportion of missed opportunities as 50%, alpha error of 0.05 and absolute precision of 0.1. An anticipated proportion of 50% was used as no recent missed opportunity surveys have been conducted in the Western Cape and earlier studies also show a wide range of prevalence estimates. An anticipated proportion of 50% will thus maximise the sample size for the desired precision. Within each facility, every child/caregiver pair, including outpatients and inpatients, exiting the facility at a designated exit will be invited to participate in the study. An appointed recruiter will recruit participants, direct them to the fieldworker interview and thereafter direct them to the immunisation area if necessary. Only caregivers above the age of 13 will be included in the study. Since some children may attend a health facility with an older sibling or a teenage mother, exclusion of

caregivers under the age of 18 may result in a non-representative sample, biasing the results, hence the age criteria was extended to included caregivers who are above the age of 13 years.

Purposive sampling will be used to select 2- 3 staff members at each of the research health facilities for the staff attitudes component of the study.

Measurement

Questionnaire

The data collection tool for the first component of the study is a simple questionnaire to be administered face-to-face to the caregiver by the fieldworker (Appendix 1). Questionnaires will be piloted and made available in English, Afrikaans and Xhosa. The questionnaire consists of 14 items including demographic information, details of the health visit and brief assessment of the RTHB. Each questionnaire will have an immunisation schedule sheet in order to capture completed and pending immunisations (Appendix 2). In addition to formal training, the fieldworker will be provided with an information sheet on contra-indications to immunisation for easy reference on site (Appendix 3). The administration of a questionnaire will take approximately 8 minutes.

Semi-structured interviews

The second component of the study will make use of semi-structured interviews of selected staff members to better understand staff attitudes towards immunisation and their perceived roles in immunisation (Appendix 6). The interviews will be conducted by the primary researcher shortly after conducting the missed opportunity survey. An interview questionnaire with open-ended questions will be used to direct the discussion and will be employed flexibly, allowing the participant freedom to discuss various issues emerging from the questions. Interviews will be recorded with a digital audio recorder following participant consent. The interview will take approximately 20 minutes.

Site preparation and stakeholder engagement

All relevant Provincial and City of Cape Town health managers will be consulted prior to conducting the study. Formal research approval from both authorities will be obtained prior to conducting the study. Only senior managers at the study sites will be informed of the study so that healthcare worker practices

will not be influenced. This may avoid biasing the results of the missed opportunity survey. Feedback will be provided to Provincial and City of Cape Town management as well as the health facilities where the study was conducted.

Data management and analysis

Data from the missed opportunity survey will be analysed using Stata 12. Numerical variables will be explored using appropriate graphical representations and descriptive statistics, including measures of central tendency and dispersion. Categorical variables will be explored using proportions and two-way frequency tables. Immunisation status will be stratified according to information source viz. RTHB or caregiver history and analysed further within these strata. Multivariate logistic regression will be used to model predictor variables for missed opportunities.

Data from the staff interviews will be recorded using a digital recorder and transcribed. The data will be analysed manuallyby the primary researcher only. Data will be further analysed for emerging themes.

All data will be stored in Microsoft Excel and Microsoft Word on the primary researcher's computer.

Ethical and legal considerations

This research protocol will be submitted to the University of Cape Town Human Research Ethics Committee. Following ethics approval, applications for approval from the Provincial Health and City of Cape Town Research Committees will be submitted. The research follows the ethical standards outlined in the Helsinki Declaration[17] and the National Health Act[18]. The risks to study participants are minimal. It is anticipated that the study may be beneficial to the community and provincial health system, by improving immunisation services.

Participation in this research study will be voluntary. This will be emphasised to all potential participants, caregivers and staff alike. All subjects will be treated with respect and dignity, even if they refuse to participate or answer certain questions. Since the research is of minimal risk with questions similar to that of a routine healthcare consultation, all caregivers above the age of 13 years, personally responsible for a child up to 5 years of age at the health facility, will be included in the study. Caregivers below the age of 18 may be considered a vulnerable population, and care will be taken to ensure that these participants are

treated with the same respect and dignity as all participants. Interviews will take place in a private setting at the health facility. Participants will be briefed on the research process and an information sheet in simple and clear language will be provided or verbally explained, depending on the participant's preference. Participants electing to read the information sheet will be given ample time to read and make an informed decision. The information sheet will broadly outline the purpose and process of the research (Appendix 4 & 7). The consent form and information sheet will be made available in English, Afrikaans and Xhosa. Participants may provide verbal consent if consenting to participate and this will be indicated on the consent form by the fieldworker (Appendix 5 & 8).

Confidentiality and anonymity will be maintained throughout the study. Care will be taken to ensure that participants are not inconvenienced while being interviewed, particularly with respect to time spent during the interview.

Questionnaire administration for the missed opportunity survey will be conducted by a trained fieldworker with appropriate nursing qualifications for administration of immunisations. Furthermore, the fieldworker will have previous experience in child health, and will thus be well versed in assessing Road to Health Booklets. The trained fieldworker will be able to communicate adequately in English, Afrikaans and Xhosa. On completion of the interview, survey participants will be provided with a bar of soap in order to thank them for their time and participation.

Since the study will identify children who have had missed opportunities for immunisation, we are ethically obliged to offer immunisation to these children, as per WHO protocol of immunising at every contact with a health facility. All children thus found to be eligible for immunisation, will be immunised by the trained fieldworker or selected staff member on site in a designated clinical area. For those children requiring immunisation, the benefits of immunisation, procedure for immunising and associated risks will be explained to the caregiver. Only children whose caregivers provide verbal consent for immunisation will be immunised. Any other medical concerns raised at the time of interview will be referred back to the appropriate area at the research health facility or local health facility, depending on the nature of the concern. Any children who experience adverse events following administration of the immunisation will be attended to immediately at the health facility as arranged by the facility managers. Caregivers will be told to return to their local health facility should any delayed adverse events occur after leaving the health facility. Contact details for the local health facilities will be provided for further advice in such situations. The provision of immunisations for those eligible is beneficial to participants as it contributes to disease prevention at an individual and population level and also reduces inconvenience of attending a health

facility again for the pending immunisation. Should needlestick injuries occur, the assigned fieldworker will follow the needlestick injury protocol at the research health facility.

All data from the missed opportunity survey will be captured on the primary researcher's password-protected computer. Completed questionnaires will be stored in a locked cupboard for 2 years, and destroyed on closure of the study. Audio recorded interviews of staff members will be transferred to the primary researcher's password-protected computer and deleted once transcribed. Personal identifiers will be removed from research-related information.

Participants will be reassured that their contributions, including possible criticisms will be treated confidentially with the aim to use all contributions constructively to improve quality of care at the facility. All research findings will be presented to relevant stakeholders, including the research facilities, in a format that is easily understandable by the various audiences.

Validity and reliability

Various sources of bias may influence the study. Selection bias may occur as the study will be conducted during working hours on weekdays. The survey will not include health visits occurring after-hours and on weekends. These times may have more missed opportunities for immunisation due to higher workload and fewer staff members on duty. Response rates will be recorded in order to assess potential non-response bias. Information bias may occur during data collection. Questionnaire items are derived from previous survey questionnaires. The RTHB is a valid data source for immunisation data and demographic information. Immunisation status details obtained from caregiver history may be affected by recall bias. As mentioned above, only facility managers will be informed of the purpose of the study so as not to influence healthcare worker practices. The fieldworker will conduct fieldwork in an area separate from other health workers, close to the exit of the facility. Furthermore, the study will be limited to as few days as possible to achieve the target sample size per facility, in order to limit awareness of the study purpose. Interviews, both of patient caregivers and staff members, may be influenced by social desirability bias. Staff members may portray good attitudes towards immunisation and caregivers without RTHB may report complete immunisations. Researchers will be aware of this and encourage participants to answer questions truthfully by explaining the potential benefits of the study. Only one fieldworker will be used for the missed opportunity survey. This will eliminate inter-observer bias.

Since the study focuses on a small sample of specific sites at different levels of care, the results may not be generalizable to all facilities. The study results may however identify broad issues of concern that may be addressed to improve province-wide immunisation coverage. Furthermore, it may highlight the importance of regular evaluations of immunisation practices at all facilities.

Resources (revised August 2014)

Resource	**Unit Cost/Provider**		**Total**
Stationery	*WCG		
Questionnaire printing	*WCG	500 copies	
Field worker (Professional Nurse)	R182/hour	3 days/site = 15 days	R19 110.00
Recruiter	Employee WCG		
Transport			±R 1 800.00
Gift for participants	R 8.00	500	R 4 000.00
Grand Total			**R 24 910.00**

Logistics

Activity	**Proposed time period**
Obtain UCT Human Research Ethics Committee Approval	May - June 2014
Obtain Provincial and City of Cape Town Research Approval	June 2014
Engage with facility managers and conduct site visits	July 2014
Appoint and train fieldworker and recruiter	July 2014
Fieldwork for missed opportunity survey	August 2014
Staff interviews	August 2014
Data capturing and analysis	September 2014
Report compilation	September 2014

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Part B: Literature Review

Objectives of Literature Review

In order to better understand immunisation programmes and the value of missed opportunity surveys, a literature search was conducted. The main objectives of the literature review were to explore available evidence on the immunisation programme in South Africa, missed opportunity study methodology, use of Road to Health Cards (RTHC) and Booklets (RTHB), global results of missed opportunity surveys as well as staff-related factors associated with immunisation.

Search Strategy

A literature search was conducted during February and March 2014. Literature published in English from 1990 to 2013 was searched using search engines Google Scholar and PubMed.

Keywords used included "Immunisation programme" "Immunisation schedule South Africa" "Missed opportunity immunisation" " "missed opportunity immunisation South Africa" "WHO expanded programme on immunisation" "South Africa Expanded programme on immunisation "EPI missed opportunity" "staff attitudes immunisation" "staff factors immunisation" "health worker attitudes immunisation" "road-to-health card" "road-to-health booklet". Research methods were not taken into account when selecting the papers for review.

In addition to literature published online, publications within the Department of Health were accessed, following discussion with key experts in Child Health within the Provincial Department of Health.

Immunisation programmes in South Africa

The Expanded Programme on Immunization (EPI) was initiated by WHO in 1974 with the aim of providing vaccines to all children worldwide[1, 2]. Since its inception, immunisation programmes have had a significant impact on reducing childhood mortality and morbidity[2]. Immunisation programmes contribute significantly to public health and play a crucial role in achieving Millennium Development Goal 4 to reduce child mortality rates by two thirds by 2015, compared to 1990[3].The South African national policy on immunisation follows that of EPI. The Expanded Programme on Immunisation in South African (EPI-SA) aims to "prevent death and reduce suffering from infections that can be prevented by immunisation of children and women."[4] Table B1 shows the current EPI-SA immunisation schedule. The immunisation schedule is available in the Road to Health Booklet (RTHB), issued to a child's mother at birth or to a

subsequent caregiver. The RTHB remains with the child's caregiver and is to be brought with the child for all health care visits, including immunisation visits. The RTHB serves as the child's immunisation record and also contains other important medical information.

Table B1: EPI-SA Immunisation Schedule 2012

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6 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm
12 years	Td vaccine Tetanus & reduced amount of diphtheria vaccine	Intramuscularly / Left arm

The National Department of Health provides comprehensive guidelines on the administration of immunisations, in order to standardise immunisation practices and address challenges experienced by those administering vaccines[4]. These guidelines stress the importance of checking the RTHB at every visit for missed immunisations and the prompt provision of the pending immunisations. The guidelines further stress that if immunisation status is unknown due to missing RTHB and caregiver uncertainty, the eligible doses are to be administered. Contra-indications for immunisation are also detailed in the guidelines[4]. General contra-indications to immunisation are previous severe hypersensitivity to a vaccine and severe illness. Specific immunisation contra-indications such as non-use of measles vaccine, rotavirus and BCG vaccine in children with symptomatic HIV infection are also described. Other issues addressed in the guidelines include cold chain issues, injection safety, adverse events and immunisation data management[4]. The general EPI policy states that a multidose vial should be opened, even for one child. Furthermore, EPI training materials reinforce this policy, stating that vaccine wastage rates of 25% are expected[4, 5].

In the Western Cape currently, the BCG vaccine is administered from a 20-dose vial, while measles and hepatitis B are administered from 10-dose vials. Pneumococcal, rotavirus and the combined Pentaxim vaccine are administered from single-dose vials. Current guidelines indicate that vaccines requiring reconstitution such as BCG and measles vaccines must be kept at 2-8^{0}C and must be discarded at the end of each immunisation session or at the end of six hours, whichever comes first. In contrast multi-dose vials such as OPV, Td and hepatitis B vaccines from which doses of vaccine have been removed may be used in subsequent immunisation sessions up to a maximum of four weeks provided specific conditions are met such as appropriate cold chain conditions[4].

Immunisation coverage under 1 year is a surveillance indicator which reflects the percentage of children under 1 year of age who have received immunisations[6]. This indicator may be used as a proxy to measure the effectiveness of the immunisation programme and the general functioning of a health system. Coverage indicators of specific immunisations e.g. measles, further reveal population immunity to the disease. This can be used to infer whether disease transmission can be appropriately prevented.
In the Western Cape, overall immunisation coverage rates have dropped over the past few years and an unanticipated measles epidemic occurred in 2009/2010[7]. A herd immunity of 95% is required to prevent ongoing measles virus transmission[8]. Low coverage, incorrect vaccine administration, vaccine efficacy and host response factors are the main causes of an outbreak of a vaccine-preventable illness in an area with a functional immunisation programme[8]. Prior to the 2009/2010 epidemic, however, coverage rates were well over the required 95%, sometimes exceeding 100%[9]. Since coverage indicators are extremely

sensitive to inaccurate numerators and denominators, indicators of greater than 100%, suggest data quality issues[10]. In 2005, Corrigall et. al conducted a household survey in the Western Cape to assess routine immunisation coverage rates in children aged 12 – 23 months in the Western Cape. Results showed lower coverage rates of 76.8% for vaccines due by 9 months and 53.2% for vaccines due by 18 months[11]. These findings revealed that routine data have variable validity, depending on the denominator used and the area from which data are received[12]. Similar findings in various provincial studies stress the importance of improving both immunisation coverage as well as data management[6, 7, 12].

Use of Road-to-Health Documents

The Road-to-Health card (RTHC) system was originally implemented in the Western Cape in the 1970's as a health status record for children[13]. The card underwent several revisions over time and in 2011, the card format was changed to a standardised national booklet, with the introduction of the current comprehensive 28-page RTHB[14]. In addition to immunisation record, the RTHB contains identifying data, details of the mother's antenatal care, birth history, family history, growth monitoring charts, milestone record and medical history as well as infant feeding guidelines and health education. In 2012, Visser et. al evaluated the implementation of the new RTHB and found that the new booklet had successfully replaced the old card in selected areas of the Western Cape[14]. A number of studies in various provinces of South Africa have shown that RTHC's were ineffectively utilised by both caregivers and staff members[13]. These studies are however dated, and no similar studies evaluating the current RTHB were found. Good utilisation of RTHB's requires that caregivers bring the booklets for all healthcare visits, and that all health workers in contact with children assess the cards and update them appropriately. A Cape Town study conducted by Harrison et. al in 1998 assessed staff and caregiver perceptions regarding the RTHC[13]. Most staff members acknowledged the usefulness of the RTHC as an immunisation record, however half of the nurses who participated noted that they were frequently too busy to check the RTHC[13]. Failure to check RTHC's may result in missed opportunities for immunisation as well as other health promotive and disease preventative activities.

A more recent study by Tarwa et. al. in 2007 in Limpopo Province showed that the RTHC was not brought to 48% of consultations, with a perception that RTHC's are only required for well-baby clinic visits, not consultations[15]. This suggests that caregivers with children, who do not access healthcare for routine check-ups such as well-baby clinic visits, will continue to miss opportunities for preventative health interventions despite accessing healthcare facilities for management of illnesses. Although practices on RTHB may vary considerably between provinces and areas within provinces, it is evident

that appropriate use of the RTHB requires education of both caregivers and healthcare workers on the importance of the RTHB. Additionally, strategies on incorporation of RTHB checks within healthcare consultations at busy, under-resourced healthcare facilities should be given consideration.

Missed opportunity study methodology

In the immunisation study by Corrigall et. al, the main reasons for not being immunised were clinic-related factors including missed opportunities (34%)[11]. This reveals the potential of significantly improving immunisation coverage by avoiding missed opportunities. This potential was recognised by the WHO in 1983, and the strategy of immunising at every opportunity was introduced[1, 5]. It was further recognised that contact with health facilities sometimes acted as a source of infection, particularly in areas of poor immunisation coverage, thus highlighting the need for optimising every opportunity for disease prevention through immunisation[5, 16]. Missed opportunity survey methodology was developed from 1984, as a way to evaluate immunisation practices and thereby improve immunisation coverage[1, 5].

Missed opportunity studies can be broadly classified into two categories:

1. Observational surveys including both population and facility- based surveys
2. Intervention trials e.g. coverage before and after an intervention to reduce missed opportunities[5]

The ideal study design for assessing missed opportunities is a population-based cross-sectional study[5]. This may quantify the potential gain in immunisation coverage by avoiding missed opportunities. This design is, however, logistically challenging and costly. Health facility-based studies provide an easier and more efficient way of measuring missed opportunities. A potential source of bias in the health facility-based studies is a change in the usual practices through awareness of the study[16]. Some researchers have emphasised only informing senior management of the purpose of the study, so that usual health worker practices are not duly influenced[16].

Health facility-based missed opportunity survey measurements occur through brief interviews of caregivers in the EPI target group as they exit a health facility[5]. The interview covers a range of questions primarily around the child's immunisation history and reason for attending the health facility as well as reasons for missed opportunities. Following data collection, the total study population is divided into those fully immunised or up-to-date and those in need of at least one vaccine. Those with an incomplete immunisation status are further subdivided into those with and without contraindications to immunisation.

Those eligible for immunisation and without contraindications are further subdivided into those who received some, but not all vaccines and those who did not receive any vaccines[5].

Prevalence of missed opportunities is then calculated as the "number of persons without a true contraindication to immunisation who completed a health care visit and remained not fully immunised or up-to-date for age according to the national immunisation policy, divided by the total number in the study population[5]." This figure reveals the potential gain in immunisation coverage through elimination of missed opportunities, as well as the need to focus strategies to reduce missed opportunities.

Worldwide missed opportunity survey findings

Numerous missed opportunity surveys have been conducted worldwide. With improvements in immunisation coverage and reductions in vaccine-preventable disease mortality, these surveys are used less frequently as a managerial tool. In the 1980's and 1990's, numerous missed opportunity studies were conducted worldwide.

In 1991, EPI reviewed all missed opportunity studies published in world literature or reported to WHO[5]. Of the studies reviewed, 59 were conducted in developing countries and 20 in developed countries. The majority of the studies were based at health facilities. The review reported that missed opportunities were found in all studies, except one, with an overall median of 32% of children and women of childbearing age who were surveyed had missed immunisation opportunities[5]. Despite differences between countries, it was also noted that the opportunity to immunise with measles vaccine or BCG was missed more often than immunisation opportunities for DPT and OPV[5]. In the studies, there were fewer children requiring measles and BCG vaccine and this most likely led to health worker reluctance to waste vaccine vials, thus resulting in more missed opportunities for these specific vaccines.

The findings of this international EPI review may not be a true reflection of current immunisation practices, given the considerable time period since the review was conducted. Most missed opportunity studies were conducted in the 1990's in South Africa. In 1991, Yach et. al studied the extent of missed opportunities for measles immunisation in curative hospitals in the Western Cape[16]. The study covered primary, secondary and tertiary level hospitals. Those with documentation of measles immunisation such as an RTHB met the "strict" definition of immunisation, while those whose immunisation history was obtained from the caregiver met the "lenient" definition of immunisation. Although the overall prevalence of missed opportunities varied significantly between hospitals, 60 – 95% had no documentation of

measles immunisation according to the strict definition. This proportion decreased to 2 – 39%, according to the lenient definition[16]. It was also found that RTHC's were predominantly requested by nurses and 34% of those whose cards had been requested by the health care worker left without evidence of immunisation[16]. The need for including preventative care at curative services in the Western Cape was thus highlighted in this study.

In 1993, Harrison et. al evaluated missed opportunities at primary care facilities, including separate curative and preventative services and integrated services. The study showed that integrated services had fewer missed opportunities than separate services[17]. This study, however, did not stratify children according to reason for visit. This may have been a confounder in the analysis[17,18].

The results from Harrison et. al were echoed in a 1996 study by Bachmann et. al which concluded that separate services have more missed opportunities, with the prevalence as high as 91% in a curative clinic, compared to 12% at an integrated clinic[18].

A more recent study conducted in 2003 in Swaziland showed that 54% of children less than 2 years of age had missed opportunities for immunisation[19]. Such findings indicate that despite improvement in immunisation coverage in developing countries, continual evaluation and improvement is imperative.

Most facility-based missed opportunity surveys focus on outpatient contacts. A study conducted in 2007 in the United Kingdom revealed that at least 20% of inpatients at a paediatric tertiary hospital were not fully immunised[20]. This reveals that missed opportunities span all levels of healthcare and tertiary facilities can play an important role in improving coverage. Similarly, in Australia, a study conducted in 2009 showed a 6% prevalence of missed opportunities for immunisation among children attending emergency departments. In this study, Kaplan-Meier analysis of time to immunisation, revealed a median delay of 77 days until immunisations due were given among those overdue[21]. In developing countries, such a delay may have dire consequences for children in impoverished communities, where communicable diseases are rife and access to healthcare limited. Furthermore, this study showed that those with overdue immunisations were more likely to present to emergency departments multiple times, have life-threatening illnesses and present at tertiary health facilities[21].

Reasons for missed opportunities

In the Western Cape, Corrigall et. al identified various factors for incomplete immunisation status in children. These factors included:

- clinic-related factors
- lack of information
- caregiver inability to attend clinic
- lack of motivation[11]

Of the clinic-related factors, missed opportunities and being told to return at another time were shown to be the most pertinent factors[11]. A similar population-based cross-sectional study conducted in Mozambique found that 28% of children had incomplete immunisation status and 26% of children had experienced a missed opportunity[22]. Accessibility to immunisation sites was identified as the primary reason for incomplete immunisation, and thus eliminating missed opportunities is extremely important.

Missed opportunity surveys can also identify reasons for missed opportunities which may be used to develop interventions to reduce missed opportunities and improve coverage.

The EPI review by Hutchins et. al in 1991 showed the main reasons for missed opportunities were:

- Failure to administer all eligible vaccines simultaneously.
- False contraindications.
- Health worker practices to avoid vaccine wastage.
- Logistical problems such as vaccine shortages [1, 5].

More recently, in 2008, the WHO Strategic Advisory Group of Experts of Immunisation (SAGE) requested information on the "epidemiology of non-vaccination"[2]. In response to this request, a systematic review on published literature from 1999 – 2009 on reasons for under-vaccination and non-vaccination in low and middle income countries was conducted[2]. Missed opportunities were identified as one of the more frequently occurring reasons for under-vaccination across all regions. Reasons for missed opportunities included incorrectly applied contraindications, provision of curative services only and absent vaccination card[2]. These findings were echoed in a review of grey literature on under-vaccination[23].

In South Africa, numerous studies noted a trend of decreasing availability and requests for and checking of RTHC's with increasing age[16, 18]. It was evident that fewer opportunities for immunisation were missed if immunisation services were available throughout the week, rather than on specific days and times[18].

Recommendations to improve immunisation programmes from missed opportunity surveys include health worker education with regular in-service updates on immunisation strategies, the importance of prevention and contra-indications to immunisation[2, 5, 24]. Other recommended strategies to decrease missed opportunities include changes in practices at health facilities, such as locating immunisation services adjacent to consultation rooms, routinely assessing in-patient immunisation status and reducing waiting times for immunisation[25, 26]. Furthermore, logistical issues and concerns such as vaccine wastage can be better addressed through adequate supply of appropriately sized vials of vaccine. The routine use of missed opportunity survey is recommended by the WHO in order to identify and address issues that lead to sub-optimal performance of programmes[1, 5].

Staff factors affecting immunisation

Staff knowledge, attitude and practices contribute to reasons for missed opportunities for immunisation. A qualitative study of mothers in Australia showed that health worker attitudes strongly influence immunisation practices among mothers, often acting as a barrier to immunisation[27]. A missed opportunity survey may be perceived as a means to criticise staff practices, rather than improve the immunisation programme. A better understanding of staff-related factors is therefore needed in order to adequately reduce missed opportunities, while also empowering staff. There is limited literature exploring staff-related factors, particularly in developing countries. A few studies conducted in the United Kingdom (UK) and United States of America (USA) have highlighted staff factors. Walton et. al. noted that health professionals have poor knowledge regarding contraindications to immunisations[20]. Concerns regarding the simultaneous administration of immunisations have also been recognised. Additionally, views on a hospital's role in providing a preventative service differed among staff members[20, 26]. Similarly, an earlier study in 1994, conducted in USA found that physicians who graduated more recently and those in high-risk urban practices were more likely to vaccinate during acute illness visits, provide simultaneous immunisations and favour immunisations in hospital settings[28]. Other staff-related factors resulting in missed opportunities included insufficient time and staff not viewing immunisation as a priority or within their scope of practice[20]. Prislin et. al conducted a few studies assessing psychosocial and practice correlates in missed opportunities for immunisation[29, 30]. They assessed staff factors through a questionnaire on knowledge, attitudes, self-efficacy, vested interests and perceived barriers and practices. They found that health care professionals with higher vested interest in immunisation and more positive attitudes towards having all children fully immunised at every health care contact had significantly lower missed opportunities[29]. Knowledge of immunisations did not correlate significantly with missed opportunities[29]. Although these studies provide some insight into staff factors, they are of limited value in

the South African context with a considerably different health system and staff complement. No studies were found assessing such staff-related factors in developing countries.

Conclusion

Missed opportunity surveys serve as an important tool in the evaluation and improvement of immunisation programmes. There is a clear gap in the literature on missed opportunity studies in the last decade, worldwide and in the South African context. Furthermore, there is growing concern of another measles epidemic in the Western Cape, similar to the unexpected epidemic of 2009/2010 which resulted in 59 measles deaths, of which 43 were children[9]. Given these concerns as well as uncertainty on the validity of immunisation coverage data, a missed opportunity survey may efficiently identify the potential to improve immunisation coverage, as well as recognise reasons for missed opportunities that may be addressed. A health facility-based survey may allow exploration of staff attitudes towards immunisation, an issue minimally addressed in the literature. Reasons for missed opportunities may be understood in more detail, facilitating a more targeted approach in reducing missed opportunities and improving coverage.

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Part C: Publication-ready Manuscript

South African Medical Journal

Missed opportunities for immunisation in health facilities in the Western Cape metro

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Abstract

Background: Childhood immunisations are a cost effective public health intervention for the prevention of infectious diseases. Immunisation coverage, however, is still sub-optimal which may result in disease outbreaks. Immunisation at every contact with a health facility is a strategy developed by the World Health Organization (WHO) in order to improve immunisation coverage.

Objectives: The aim of this study was to estimate the prevalence of missed opportunities for immunisation at different levels of healthcare in the Western Cape and assess factors associated with missed opportunities.

Methods: The study included a health-facility based cross-sectional exit survey of caregivers with children up to 5 years of age, followed by a qualitative exploration of staff attitudes towards immunisation.

Results: The prevalence of missed opportunities for immunisation was 4.6%; 81.3% of caregivers brought Road-To-Health- Booklets (RTHB's) to consultations. Overall, 56.0% of health workers requested to see the RTHB's during consultations. Children attending primary level facilities were significantly more likely to have their RTHB's requested than children attending a tertiary level facility. Lack of training, resources and heavy workloads were the main challenges reported at secondary/tertiary level facilities.

Conclusion: Missed opportunities for immunisation at health facilities in the Western Cape metro were low, most likely due to good immunisation coverage among children accessing health facilities. Increased health worker support, as well as monitoring and discussion of the value and correct use of the RTHB is needed, particularly at secondary/tertiary levels of care, to improve immunisation coverage.

Introduction

The Expanded Programme on Immunization (EPI) initiated by the World Health Organization (WHO) in 1974 aimed to provide vaccines to children worldwide [1]. Despite advances in expanding immunisation services, coverage is still sub-optimal in many areas. Where accessibility and utilisation of health services is low, every contact with a health facility provides an opportunity to immunise, particularly as these children are likely to be at higher risk of vaccine-preventable diseases [2,3]. The EPI Global Advisory Group [2] defines a missed opportunity as 'any contact with a health service that did not result in an eligible child or woman receiving the needed vaccines.' [1,2] The elimination of missed opportunities can significantly improve immunisation coverage, thus reducing the risk of vaccine-preventable diseases [2]. The current immunisation schedule for the Expanded Programme on Immunisation in South Africa (EPI-SA) is in the Road-to-Health-Booklet (RTHB) issued to a child's mother at birth or to a subsequent caregiver.

Although immunisation coverage figures at health facilities were greater than 95%, the Western Cape experienced a major measles outbreak in 2009/2010. Herd immunity of 95% is required to prevent ongoing measles virus transmission [4,5]. Low coverage, incorrect vaccine administration, vaccine efficacy and host response factors are the main causes of an outbreak of a vaccine-preventable illness in an area with a functional immunisation programme. The 2009/2010 epidemic raised concerns as to the validity of immunisation coverage data. Since coverage indicators are very sensitive to data inaccuracies such as incorrect population estimates, reported data may not be a true reflection of coverage in the population. In addition to improving the quality of coverage data, it is imperative that strategies to improve coverage are strengthened. The missed opportunity for immunisation survey was developed in 1984 to evaluate immunisation practices and improve immunisation coverage [1, 3].

In 1991 EPI reviewed all missed opportunity studies published worldwide or reported to WHO [3]. Missed opportunities were found in all studies, except one, with an overall median of 32% of children and women of childbearing age having had missed immunisation opportunities [3]. Reasons for missed opportunities included false contraindications, health worker practices and vaccine shortages. A more recent systematic review by Rainey et. al evaluated reasons for non-vaccination and under-vaccination of children in low and middle income countries. Immunisation system issues including missed opportunities, distance to services and low health worker knowledge were the most frequently observed reasons for under-vaccination[6]. Missed opportunity for immunisation surveys conducted in the Western Cape in the 1990's revealed a prevalence of 60-95%. Category of consulting health worker, age of child, and type of service (i.e. curative, preventative or integrated service) impacted on whether RTHB's were requested and immunisations given appropriately [7,8,9].

A 2005 household survey among children aged 12 – 23 months in the Western Cape, revealed immunisation coverage rates of 76.8% for vaccines due by 9 months and 53.2% for vaccines due by 18 months. The main reasons for not being immunised were clinic-related factors including missed opportunities (34%) [10]. Studies conducted in developed countries have highlighted poor knowledge of EPI, insufficient time and staff not viewing immunisations as a priority or within their scope of practice [11,12,13]. These factors are yet to be explored in developing countries. Few

missed opportunity studies have been conducted in the last decade, worldwide and in South Africa.

Methods

A cross-sectional study design comprising two components was used:

1. Health-facility based cross-sectional survey to determine the prevalence of missed opportunities for immunisation and associated factors.
2. Qualitative exploration of staff attitudes towards immunisation using a semi-structured questionnaire.

The study population was children 0-5 years of age attending health care facilities with a caregiver from 08:00-16:00 on weekdays in the Western Cape metro district.

Purposive sampling was employed to select study sites. Five sites representative of primary, secondary and tertiary levels of care were selected, including a local clinic (Clinic A - primary level), community health centre (CHC B - primary level), one district hospital (Hospital A - secondary level), one regional hospital (Hospital B - secondary level) and one central hospital (Hospital C - tertiary level).

A sample size of 96 per facility was calculated estimating that 50% of opportunities would be missed, with an alpha error of 0.05 and absolute precision of 0.1. A recruiter identified caregiver/child pairs exiting the health facility, including both inpatients and outpatients. Only caregivers above the age of 13 years were included in the study. All caregivers were interviewed by a trained fieldworker. A request for an RTHB during the consultation was used as a proxy indicator that the immunisation status of a child was checked by the health worker.

Logistic regression was used to explore associations between outcomes (immunisations status, request of RTHB and presence of RTHB) and explanatory variables with adjustment for potential confounding variables. A forward selection procedure was applied for model building. The final model was selected by comparison of models using the likelihood ratio test and Akaike's Information Criterion (AIC).

In order to elicit themes regarding staff attitudes towards immunisation, a purposeful sample of two to three staff members at participating health facilities were interviewed by the primary researcher using a semi-structured questionnaire. Data was analysed manually by the primary researcher.

The research protocol was approved by the University of Cape Town Human Research Ethics Committee (HREC: 321/2014). The research followed the ethical standards outlined in the Helsinki Declaration [14] and the National Health Act [15]. The risks to study participants were minimal. Participation in the study was voluntary, and all participants provided written informed consent. All children found to be eligible for immunisation were immunised on site in the designated clinical area. Verbal consent for immunisation was obtained from caregivers.

Results

482 participants were recruited, with an overall respondent rate of 81.1%. Respondent rates varied, ranging from 67.2% at Hospital C to 86.4% at Clinic A.

Descriptive characteristics are summarised in Table 1.

Table 1: Descriptive characteristics of caregiver, child and visit to facility

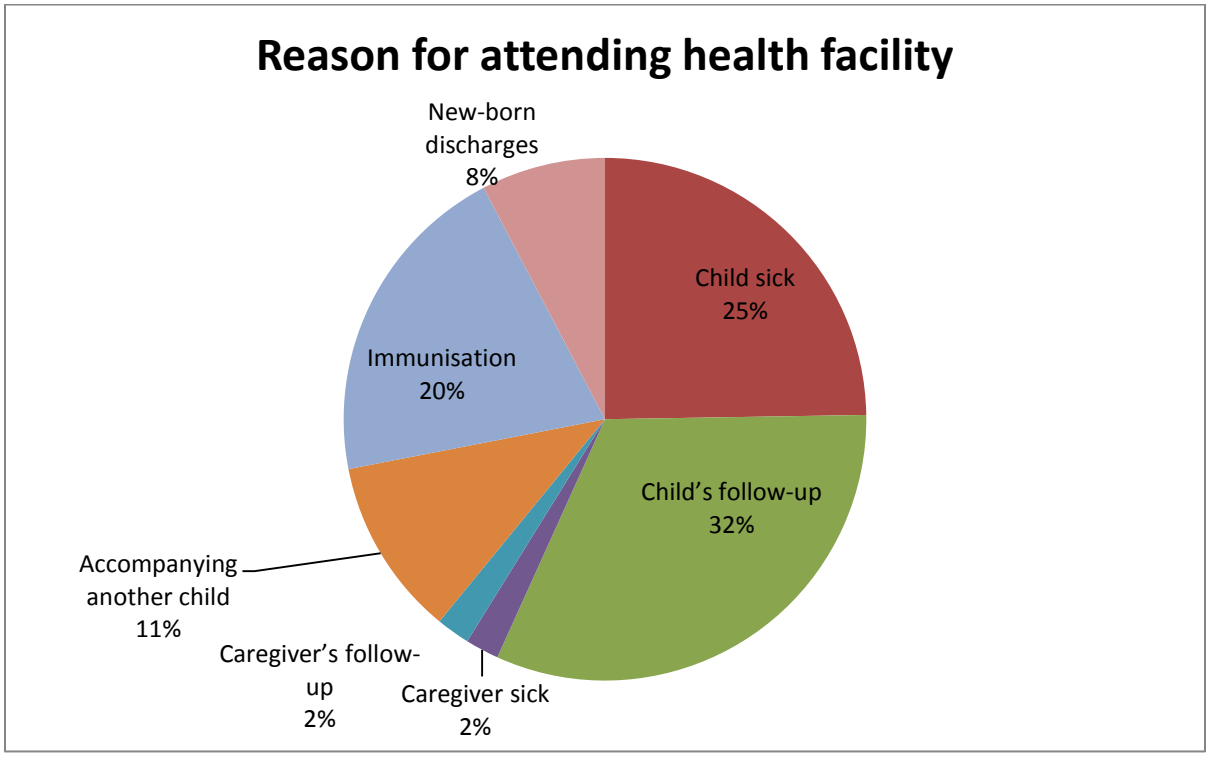
Variable	**Median (range)/ Percentage proportion (95% Confidence interval)**
***N=482 unless specified**	
Age of child in months (median; range)	11 (0 -60)
Age of caregiver in years (median; range)	29 (16 – 70)
Day of week (95% Confidence interval)	
Monday	23.0% (19.2% - 26.8%)
Tuesday	19.1% (15.6% - 22.6%)
Wednesday	17.6% (14.2% - 21.1%)
Thursday	18.7% (15.2% - 22.2%)
Friday	21.6% (17.9% - 25.3%)
Time of day	
09:00 – 11:59	41.8% (37.4% - 46.3%)
12:00 – 13:59	32.3% (28.0% - 36.5%)
14:00 – 16:00	25.9% (21.9% - 29.9%)
Primary caregiver	100%
Specific illness reported by caregiver	21.6% (17.9% - 25.3%)
HIV	1.7% (0.5% - 2.8%)
TB	1.5% (0.4% - 2.5%)
Malnutrition	*0.4% (-0.2% - 1.0%)
Health worker consulted	
Doctor only	39.2% (34.8% - 43.7%)
Nurse only	51.3% (46.8% - 55.8%)
Doctor and nurse	5.7% (3.6% - 7.8%)
Allied health staff only	3.8% (2.1 – 5.5%)
RTHB asked for by health worker	64.9% (60.7% - 69.2%)
RTHB present	81.3% (77.8% - 84.8%)
Vaccines given today	
Yes – all pending vaccines given	17.3% (13.9% – 20.6%)
Yes - some pending vaccines given	2.1% (0.8% - 3.4%)
No	80.7% (77.1% - 84.2%)
Vaccine pending but contraindication to immunisation	

No	4.6% (2.7% - 6.4%)
Yes	*0.2% (-0.2% - 0.6%)
Not applicable (Complete immunisations)	95.2% (93.3% - 97.1%)
Immunisation status – complete by RTHB (n=392)	94.6% (92.4% - 96.9%)
Immunisation status – complete by caregiver report (n = 90)	86.7% (79.5% - 93.8%)
Overall immunisation status	
Complete by caregiver	16.2% (12.9 – 19.5%)
Uncertain by caregiver	2.1% (0.8% - 3.4%)
Complete by RTHB	77.0% (73.2% – 80.7%)
Missed opportunities by RTHB (n=21)	
Incomplete RTHB & checked by health worker	61.9% (39.3% - 84.6%)
Combined overall immunisation status	
Complete (RTHB + Caregiver)	93.2% (90.9% - 95.4%)
Uncertain (Caregiver)	2.1% (0.8% - 3.4%)
Incomplete (RTHB+ Caregiver)	**4.6% (2.6% - 6.4%)**
Incomplete with contraindication	*0.2% (-0.2% - 0.6%)

*Confidence intervals overlapping 0

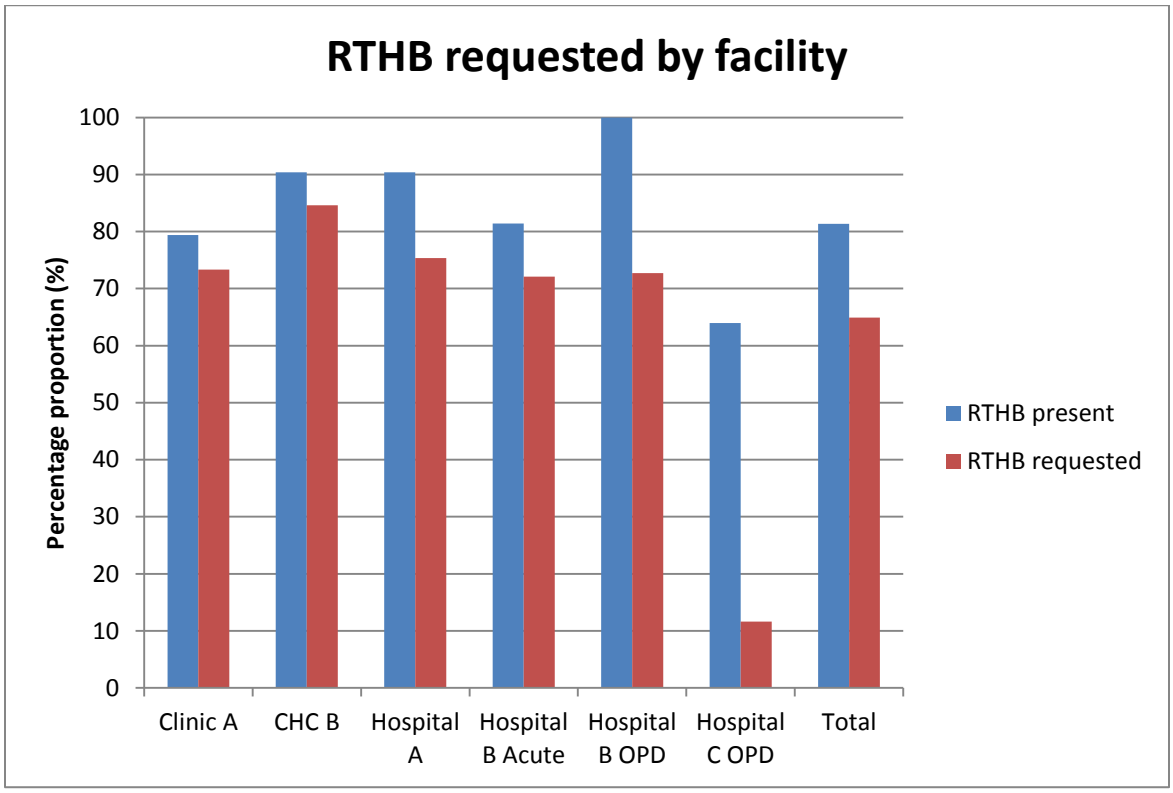
The majority of children who participated in the study attended the facility for a consultation due to illness or for a follow-up consultation (Figure 1). Discharged newborn infants exiting the facility were included but no children discharged following in-patient admission participated in the study.

Figure 1: Reason for attending health facility



81.3% of caregivers had RTHB's present at consultation. During children's consultations, 64.9% of health workers requested the RTHB. This decreased to 56.0% when excluding children who presented specifically for immunisation. There were notable differences between facilities. Only 11.6% of health workers requested to see RTHB's at Hospital C, while greater than 70% of health workers at all other facilities requested the RTHB (Figure 2). 90.0% of patients attending primary level facilities (Clinic A and CHC B) brought RTHB's to the facility. Only 64.0% of patients attending Hospital C, however, brought RTHB's to the facility.

Figure 2: RTHB requested by health worker, by facility



Of the total recruited, 392 children had an RTHB present, of which 5.4% had incomplete immunisations. Among the caregivers of the 90 children who did not have an RTHB present, 13.3% reported that immunisation status was incomplete or uncertain.

Overall, 77.0% of children had complete immunisations by RTHB, 16.2% had complete immunisations according to the caregiver's report and the remaining 6.9% had incomplete immunisation status by RTHB or caregiver report or uncertain immunisation status by caregiver report. Of the 21 children with incomplete immunisations by RTHB, 61.9% had their RTHB's checked on the day, and 61.5% of these children received some, but not all due immunisations on the same day. No facilities experienced vaccine stock-outs during the study period and one child was erroneously identified by the health worker as too sick for immunisation. Only one child had a true contra-indication for immunisation. The overall prevalence of missed opportunities for immunisation according to both RTHB and caregiver reports was 4.6%. This

figure increased to 6.6% when uncertain immunisation status was included. At all facilities, among children with RTHB's, more than 90% of children exiting the facilities had complete immunisations required for age.

When excluding children presenting specifically for immunisation 68.7% of children seen by nurses only had RTHB requested, compared to 49.2% seen by doctors only.

The logistic regression revealed no statistically significant determinants of complete immunisation status. A number of factors associated with health worker requests for RTHB were identified (Table 2).

Table 2: Factors associated with health worker requests for RTHB

Variable	**Odds Ratio**	**p-value**	**95% Confidence Interval**	
RTHB present	34.80	**0.0000**	7.32	165.43
Age (months)	0.97	0.0220	0.95	1.00
Reason for attending (Reference: Child's follow-up)				
Accompanying another child	0.06	**0.0000**	0.01	0.26
Caregiver follow-up	0.09	0.1070	0.00	1.69
Child sick	3.49	**0.0130**	1.30	9.34
Day (Reference: Friday)				
Monday	1.66	0.4030	0.51	5.39
Tuesday	4.03	0.0790	0.85	19.05
Wednesday	15.44	**0.0030**	2.50	95.27
Thursday	11.10	**0.0030**	2.27	54.33
Site (Reference: Hospital C)				
Hospital A	3.26	0.1950	0.54	19.55
CHC B	7.31	**0.0190**	1.39	38.52
Clinic A	17.21	**0.0000**	4.52	65.42
Hospital B Acute	1.46	0.7360	0.16	13.07
Hospital B OPD	5.34	0.1690	0.49	57.97

The model excluded those attending for immunisations and newborns who had been discharged. Similarly, none of the children accompanying a sick caregiver had RTHB's requested, and were also excluded from the model. Those with RTHB present at consultation were 34.8 times more likely to have their RTHB requested by the health worker than those without RTHB's. A child presenting with an acute illness was 3.5 times more likely to have their RTHB requested compared to a child presenting for follow-up. Children presenting to health facilities from

Monday to Thursday were more likely to have RTHB's requested than those presenting on Friday.

Children presenting to Hospital C were least likely to have RTHB's requested. Those seen at Clinic A were 17.2 times more likely to have their RTHB's requested than those seen at Hospital C. Although exploratory analysis revealed that nurses were more likely to request RTHB's than doctors, this factor did not influence the model significantly, most likely due to collinearity with site.

Younger children and those who were sick were significantly more likely to present with an RTHB as shown in Table 3.

Table 3: Factors associated with RTHB present at health facility visit

Variable	**Odds Ratio**	**p-value**	**95% Confidence Interval**	
Reason for attending (Reference: Child's follow-up)				
Accompanying another child	0.08	**0.0000**	0.03	0.20
Caregiver follow-up	0.04	**0.0010**	0.00	0.26
Caregiver sick	0.01	**0.0000**	0.00	0.12
Child sick	3.21	**0.0330**	1.10	9.37
Age (months)	0.96	**0.0000**	0.95	0.98
Site (Reference: Hospital C)				
Hospital A	5.52	0.0560	0.96	31.87
CHC B	2.94	0.2140	0.54	16.14
Clinic A	2.00	0.2120	0.67	5.95
Hospital B Acute	1.29	0.8090	0.16	10.43
Day (Reference: Friday)				
Monday	1.25	0.5890	0.56	2.78
Tuesday	1.74	0.4310	0.44	6.92
Wednesday	1.23	0.8250	0.20	7.54
Thursday	1.21	0.8230	0.22	6.60

Staff attitudes towards immunisation

The majority of the 17 staff members interviewed two weeks after the quantitative component of the study, said they checked the RTHB and viewed it as an important and useful clinical tool. Doctors at tertiary level noted that RTHB's were less likely to be checked among follow-up patients as they are well-known to the hospital and assumed to be up to date with immunisations.

Many felt that a dedicated, well-trained immunisation nurse should be appointed at secondary/tertiary health facilities to prescribe and administer immunisations. The majority of those interviewed identified challenges, which often led to missed immunisations at health facilities (Table 4).

Table 4: Immunisation-related challenges

Vaccine stock-outs
Hospital pharmacies do not stock certain vaccines
Unavailability of vaccines after-hours at all levels of care
Staff shortages and high workloads, particularly among nursing staff
Uncertainties among doctors on dosages and prescription format for immunisations
Pervasive nursing perspective that immunisations are only for primary level facilities
Poor staff training on immunisations, management of adverse events and cold chain management
Staff conflict on appropriate hospital area where immunisations should be allocated
Lack of resources e.g. EPI fridge

Discussion

This study revealed that the prevalence of missed opportunities for immunisation at selected health facilities in the Western Cape metro was low. This is in contrast to earlier studies conducted in the Western Cape which showed notably higher prevalence figures [7,8,9]. The majority of children who presented specifically for immunisations received those immunisations on the day of the study, suggesting good local immunisation coverage among those accessing health facilities. Additionally, the majority of children presenting to hospitals were up to date with immunisations prior to their healthcare visit on the day of participation in the study. However children who do not access routine immunisation services are more likely to become ill and present particularly at secondary and tertiary services. The low percentage of health workers who requested RTHB's at these services indicates that vulnerable children could be missed. Furthermore, request for RTHB's was a proxy indicator for checking immunisation status, although the health worker may have requested the RTHB to check other information.

A large proportion of children with incomplete immunisations had their RTHB's requested on the day and received some, but not all of their immunisations. Although no vaccine stock-outs occurred during the study period and only one correct contraindication to immunisation was elicited, missed opportunities for immunisation may also be influenced by health worker knowledge regarding schedules and contra-indications for immunisation. It appears that false contra-indications to immunisation or concerns regarding simultaneous administration of immunisations contributed to the missed opportunities as seen in similar studies [3].

A number of factors were associated with requests of RTHB by health workers during consultation. Many of these factors have not been addressed in previous studies. Having the RTHB present at consultation had the largest effect. This may indicate that mothers were aware of the need to bring the RTHB at every visit, or that health workers were more likely to request the RTHB if it was visible to them at the consultation. The lower proportions of children with an RTHB present as well as requests for an RTHB at Hospital C suggests that caregivers were aware that RTHB's were less likely to be utilised at facilities such as Hospital C. Hospital C has

more diverse patients attending follow-up services compared to the other facilities and unmeasured contributory factors such as socioeconomic status and level of education may also have contributed. The main differences observed across health facilities were due to the nature of the visit. Secondary/tertiary level outpatient services typically see older children for follow-up purposes. At primary level facilities younger children present for preventive care such as immunisation and management of acute illness. The markedly lower percentage of RTHB's requested at Hospital C OPD is likely due to the fact that these children are known to the doctors. Nevertheless, this reveals that routine documentation of health visits in the RTHB is practiced infrequently. It suggests that the RTHB is viewed as a tool for primary level only, with little relevance to tertiary facilities and that it is not used to ensure good continuity of care across levels of care.

Compared to other days, RTHB's were least likely requested on Mondays and Fridays, after adjustment for site, age of child and reason for attending the health facility. Greater patient load and health worker fatigue may have contributed to this finding.

Children accompanying other children for consultations and those accompanying caregivers for follow-up visits were markedly less likely to have their RTHB requested. Nevertheless, some accompanying children had an RTHB with them. The presence of a child at any health facility is an opportunity for immunisation and health promotion, particularly where access to and utilisation of health care is poor.

A clear distinction was seen in staff attitudes towards immunisation at secondary/tertiary level facilities. Heavy workload, pharmacy stock practice, lack of training and uncertainty regarding immunisation guidelines and practices were cited as reasons for the avoidance of immunisation at hospitals. Clinicians preferred to refer to primary level facilities creating a missed opportunity. Although most clinicians recognised the value of the RTHB in all consultations, many in secondary/tertiary facilities identified the need for a dedicated immunisation nurse who could administer immunisations appropriately and train other clinicians on guidelines and practices. Given the limited literature available on staff attitudes towards immunisation, particularly in developing countries, further research in this area is warranted. Attention should be given to providing vaccinations at all levels of care during both working hours and after hours. Staff training on vaccinations and the value and use of the RTHB is imperative. The appointment of a dedicated immunisation nurse at tertiary level should be considered, as services are highly specialised in such facilities.

Limitations

The poor response rate at hospital C may have introduced selection bias. Non-responders were generally in a hurry and their children may have been less likely to be immunised. Only senior management at facilities was informed about the study, so that practices were not influenced by the study; however, awareness of the study over the study period may have influenced health worker practices. Furthermore, a number of questions in the questionnaire relied on caregiver recall. Social desirability bias may have influenced results, particularly when the RTHB was not presented. Extending the study after working hours would also have explored the prevalence of missed opportunities after hours, when resources, including time and staff, are often limited

further. A household survey to identify missed opportunities would have been more representative but also far more costly.

Conclusion

This study revealed a low prevalence of missed opportunities for immunisation at selected health facilities in the Western Cape metro, most likely due to good local immunisation coverage among children accessing the health facilities. The lower proportion of health workers assessing RTHB's during consultations indicates that missed opportunities may occur if immunisation coverage is poor. Increased health worker support regarding immunisations, as well as monitoring and discussion of the value and correct use of the RTHB, is needed to ensure that opportunities for immunisation are not missed and immunisation coverage is improved.

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Conflict of interest: We declare that we have no conflict of interest

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Part D: Appendices

Appendix 1: Questionnaire (Caregiver)

Questionnaire no:

Site:

Date (dd/mm/yyyy):

Day

Monday	Tuesday	Wednesday	Thursday	Friday

Time:

The Western Cape Department of Health wants to improve child health services in the province. We would like to ask you a few questions about your visit today and have a look at your child's Road to Health Booklet. This will take about 10 minutes of your time. Are you willing to participate?

Screening questions for eligibility:

Age of child:

Age of caregiver:

If child > 5 years and/or caregiver ≤ 13 years, thank the person for their time.

If eligible, read information sheet or provide copy of information for participant to read.

1. **Are you the [child name]'s primary caregiver?**

Yes	No

2. **What is [child name]'s reason for coming to the clinic/hospital today?**

Child sick
Child's follow-up visit
Immunisation
Caregiver sick
Caregiver's follow-up
Accompanying another child
Other (please state)

3. **Does [child name] have any other illnesses?**

HIV
TB
Malnutrition
Other (please state)

4. **Whom did you consult today?**

Doctor
Nurse
Dietician
Physiotherapist
Social worker
Other (please state)

5. **Did the health care worker ask for [child's name] RTHB?**

Yes	No

6. **Do you have [child's name]'s RTHB here?**

Yes	No

If the RTHB is present: *Please could you show me the RTHB*

If RTHB is not present, skip to question 8

7. [1]**Immunisation status**

Complete	Incomplete

If no RTHB is present:

8. [1]Has [child name] received all his/her immunisations needed for this age?

Yes, complete
No, incomplete
I don't know

9. **Did [child name] receive vaccines today?**

Yes - all vaccines due were given

[1] See immunisation schedule

Yes - some vaccines, but not all were given
No

If incomplete immunisation status in question 7 or 8:

10. [2]Are there any contra-indications present?

Yes	No

If yes to question 10:

11. State contra-indication/s:

If RTHC requested(yes to question 6), incomplete immunisation (question 7 or 8) status and no contra-indications (question 10):

12. Do you know why [child's name] was not immunised today?

I don't know
Told to come another day
Told to go to another facility for immunisation
Told that child is too sick for immunisation
Other (please state)

[2] See contra-indication sheet

Appendix 2: Immunisation Schedule

Tick vaccines that have been given and circle pending immunisations for child's current age.

Table D1: Immunisation schedule

Age of child	Vaccine needed
At birth	OPV(0) Oral Polio Vaccine
	BCG Bacillus Calmette Guerin
6 weeks	OPV(1) Oral Polio Vaccine
	RV (1) Rotavirus Vaccine
	DTaP-IPV//HIB(1) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined
	Hep B(1) Hepatitis B Vaccine
	PCV(1) Pneumococcal Conjugated Vaccine
10 weeks	DTaP-IPV//HIB(2) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined
	Hep B(2) Hepatitis B Vaccine
14 weeks	RV (2) Rotavirus Vaccine
	DTaP-IPV//HIB(3) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined
	Hep B(3) Hepatitis B Vaccine
	PCV(2) Pneumococcal Conjugated Vaccine
9 months	Measles Vaccine(1)
	PCV(3) Pneumococcal Conjugated Vaccine
18 months	DTaP-IPV//HIB(4) Diphtheria, Tetanus, acellular Pertussis, Inactivated Polio Vaccine & Haemophilus influenzae type b combined
	Measles Vaccine (2)

Appendix 3: Contra-indications to Immunisation Sheet

(from New EPI Vaccines Guidelines, National Department of Health)

General Contra-indication

- Children who have a known severe hypersensitivity to any component of the vaccine, or who have had a serious allergic reaction to a previous dose of a specific vaccine, should not receive such a vaccine.
- Postpone vaccination if the temperature is **38,5ºC** or above.

Specific Contra-indication

Oral Polio Vaccine (OPV)

- Do not give Oral Polio vaccine to children who are sick with AIDS. Refer for medical opinion.

Bacille Calmette Guerin (BCG)

- Do not give BCG to a child that is **more than12 months old.**
- Do not give BCG vaccine to children who are sick with AIDS.
- If a child is HIV exposed and you seriously fear that the child may be infected with HIV and or the child is sick, do not give BCG at birth. Do PCR at six weeks and give BCG if results are negative.
- Do not give BCG to a newborn if the mother is on anti -TB drugs, this child should be on TB prophylaxis and be followed up for BCG later.

BCG should still be given to HIV exposed children

DTP/Hib, DTaP-IPV//Hib and DTP

- Do not give DTP/Hib, DTaP-IPV//Hib and DTP to a child with epilepsy that is not controlled or when the child is 24 months and above.
- Do not administer DTaP-IPV//Hib when the child is above 24 months.

Pneumococcal Conjugate Vaccine (PCV) (Prevenar®)

- Do not give PCV on the same site with DTaP-IPV//Hib, DPT/Hib and DPT but PCV can be given concurrently with any of these vaccines at different sites.

Measles Vaccine

- Do not give Measles vaccine to children who are sick with AIDS. Refer for medical opinion.

Rotavirus Vaccine (RV) (Rotarix®)g

- Do not give Rotavirus vaccine if a child has history of chronic gastro-intestinal disease or severe diarrhoea. Refer the child for medical opinion.
- Do NOT give the first dose of Rotavirus vaccine if the child is ≥ 24 weeks.
- Do not give the second dose of Rotavirus vaccine if the child is above 24 weeks.

Tetanus and reduced amount of diphtheria Vaccine (Td) (Diftavax®)

- Do not administer Td for children who are below **6 years** of age.

Appendix 4: Information Sheet (Caregiver)

Title of research project: Missed opportunities for immunisation in Western Cape health facilities

Thank you for your interest in this research project. This information sheet gives an outline of the project and your potential involvement, if you are willing to participate.

Who is doing this study?
The Western Cape Department of Health along with the University of Cape Town are doing this study at a few clinics and hospitals in Cape Town.

What is the purpose of the study?
We would like to understand whether children under 5 years who come to clinics or hospitals have had their immunisations on time and whether they are able to catch up on immunisations when they visit the clinic or hospital.

What do I have to do?
The study nurse will ask you a few short questions in your language about your visit to the clinic/hospital, your child's immunisations and general health. The nurse will also have a quick look at your child's Road to Health Booklet. Answering the questions will take approximately 8 minutes. If your child has missed some immunisations for his/her age, the study nurse can give your child the immunisations needed. You will be asked whether the nurse can give the immunisation and if you agree you and your child will be taken to a clinic room for the immunisation. The nurse will explain the procedure to you more and you may ask questions at any time.

Do I have to participate?
No, you do not have to participate in the study if you do not want to. Your participation is voluntary. You may choose not to participate or not to answer certain questions. You may stop answering questions at any time. Your child does not have to be immunised if you do not want to do so, however we would advise that all children who have not completed their immunisations should get their immunisations as soon as possible unless there is specific reason not to immunise.

Will what I say be anonymous/private?
The questions will be asked in a private area. The information you share with us will be kept completely anonymous and confidential – we will not report it with your name, address or any other details. Your information will only be handled by the researchers.

Are there any risks in participating? What do I get from participating?
There are no major risks in participating, although you may spend some of your time to answer questions. There is no payment for participating in the study. If your child has not received his/her immunisations, you will be given the opportunity to get these immunisations at the clinic itself. You do not have to pay for the immunisations. We hope to use this information to improve services for children at clinics and hospitals in the Western Cape. Your community may benefit from this research and the results of the study will be given to your clinic/hospital and the Provincial Department of Health and City Health.

What are the benefits and risks of immunisation?
Immunisations are very important for children to stop them from getting very serious infectious diseases such as measles, polio etc. The government recommends that all children get immunisations as shown in the child's Road to Health Booklet. Some immunisations are given as an injection, and others are given as drops in the mouth. After an immunisation your child may have slight pain where the injection was given, slight redness or bleeding where the injection was given, or a low fever. Very rarely, some children have an allergic reaction to immunisations. If your child has had a reaction to immunisations before, please tell the study nurse. If any reactions happen, the nurse is trained to give medical help to your child with help from other staff at the clinic/hospital. If your child develops any side-effects after you leave the clinic/hospital that you are unsure of or you are concerned about the side-effects, please go to your local clinic as soon as possible *(details provided on site)*.

If I want more information about the study or the study results, who can I contact?
You may ask questions to your interviewer or you may contact Dr Nisha Jacob at 021 483 0886. E-mail nisha.jacob@westerncape.gov.za

If I want more information on my rights as a research participant, who can I contact?

Human Research Ethics Committee, University of Cape Town

E52 Room 24, Old Main Building

Groote Schuur Hospital

Observatory,

Tel: 021 406 6338

Fax 021 406 6338

Appendix 5: Consent Form (Caregiver)

I have understood the information contained in the information sheet. I understand the reason for the research project and what is needed. I have had the opportunity to ask questions and choose to participate in this study. I understand that I will not be disadvantaged if I decide not to participate.

Caregiver signature:
……..

Fieldworker
signature:……

Date:

Immunisation due?:	Yes	No

Consent for immunisation:	Yes	No	Not applicable

If I want more information on my rights as a research participant, who can I contact?

Human Research Ethics Committee, University of Cape Town

E52 Room 24, Old Main Building

Groote Schuur Hospital

Observatory,

Tel: 021 406 6338

Fax 021 406 6338

Appendix 6: Interview questionnaire (Staff)

1. Age
2. Area of work
3. Explain your main areas of focus when consulting a child
4. Do you think it is important to check the RTHB? Explain.
5. What do you mainly check in RTHB and why?
6. Are there any challenges in assessing the RTHB?
7. Who do you think should be responsible for the administration of immunisations?
8. What are your thoughts on administering immunisations at your facility?
9. Do you feel it is necessary to check and update immunisations for all children attending the facility (regardless of the reason for their visit)? Please explain.
10. Are there any challenges in administering immunisations at your facility?
11. Have you had any training regarding immunisations (e.g. schedule, contraindications, administration)? Explain – when, where etc. Do you feel the training is adequate?

Appendix 7: Information Sheet (Staff)

Title of research project: Missed opportunities for immunisation in Western Cape health facilities

Thank you for your interest in this research project. This information sheet provides an outline of the research project and your potential involvement, should you be willing to participate in this study. Please note that your participation is entirely voluntary, thus you are in no way obliged or expected to participate.

This research project is a joint collaboration between the Western Cape Department of Health, City of Cape Town Health and the University of Cape Town.

What is the purpose of the study?
The purpose of the study is to quantify missed opportunities for immunisation at health facilities and better understand factors associated with missed opportunities including staff attitudes towards immunisation.

What do I have to do?
The researcher would like to interview you privately on your thoughts and attitudes towards immunisation. The interview will take approximately 15 – 20 minutes. A digital recorder will be used to record the interview, if you agree to participate. Once the information from the recording is transcribed, the recording will be deleted. The interviews will only take place at a time of your convenience.

Do I have to participate?
No, you do not have to participate in the study if you do not want to. Your participation is voluntary. You are also welcome to inform me if you do not want to answer certain questions during the interview, without providing a reason. Furthermore, you may withdraw from the study at any point.

Risks and benefits

This study has minimal risks. All information discussed at the interview will be kept confidential. Your name will not be used to identify any of the information collected, thus your anonymity will be preserved throughout the study. You will not receive any remuneration for participating. It is hoped that the information from this study will be used to improve child health and immunisation services at your facility and surrounding community, while also addressing staff concerns related to the matter. The study results will be presented to the facility when completed.

If I want more information about the study or the study results, who can I contact?
For further information you may contact Dr Nisha Jacob at 021 483 0886.
E-mail nisha.jacob@westerncape.gov.za

If I want more information on my rights as a research participant, who can I contact?

Human Research Ethics Committee, University of Cape Town

E52 Room 24, Old Main Building

Groote Schuur Hospital

Observatory,

Tel: 021 406 6338

Fax 021 406 6338

Appendix 8: Consent Form (Staff)

I have understood the information contained in the information sheet. I understand the reason for the research project and what is needed. I have had the opportunity to ask questions and choose to participate in this study. I understand that I will not be disadvantaged if I decide not to participate.

Participant signature: ……..

Fieldworker
signature:……

Date:

If I want more information on my rights as a research participant, who can I contact?

Human Research Ethics Committee, University of Cape Town

E52 Room 24, Old Main Building

Groote Schuur Hospital

Observatory,

Tel: 021 406 6338

Fax 021 406 6338

Appendix 9: Ethics Approval Letter

UNIVERSITY OF CAPE TOWN
Faculty of Health Sciences
Human Research Ethics Committee

Room E52-24 Old Main Building
Groote Schuur Hospital
Observatory 7925
Telephone [021] 406 6338 • **Facsimile** [021] 406 6411
Email: shurette.thomas@uct.ac.za
Website: http://www.health.uct.ac.za/fhs/research/humanethics/forms

13 June 2014

HREC REF: 321/2014

Prof D Coetzee
Public Health & Family Medicine
Falmouth Building

Dear Prof Coetzee

PROJECT TITLE: *MISSED OPPORTUNITIES FOR IMMUNISATION IN HEALTH FACILITIES IN THE WESTERN CAPE METROPOLITAN (MMed Candidate – Dr N Jacob)*

Thank you for your response letter to the Faculty of Health Sciences Human Research Ethics Committee received on 11 June 2014.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year until the 30th June 2015

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/fhs/research/humanethics/forms)

We acknowledge that the MMed student, Dr Nisha Jacob is also involved in this study.

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC reference no in all your correspondence.

Yours sincerely

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN ETHICS
Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.

HREC 321/2014

Appendix 10: South African Medical Journal Publication Guidelines

Author Guidelines

Accepted manuscripts that are not in the correct format specified in these guidelines will be returned to the author(s) for correction, and will delay publication.

AUTHORSHIP

Named authors must consent to publication. Authorship should be based on: (i) substantial contribution to conception, design, analysis and interpretation of data; (ii) drafting or critical revision for important intellectual content; or (iii) approval of the version to be published. These conditions must all be met (uniform requirements for manuscripts submitted to biomedical journals; refer to **www.icmje.org**).

CONFLICT OF INTEREST

Authors must declare all sources of support for the research and any association with a product or subject that may constitute conflict of interest.

RESEARCH ETHICS COMMITTEE APPROVAL

Provide evidence of Research Ethics Committee approval of the research where relevant.

PROTECTION OF PATIENT'S RIGHTS TO PRIVACY

Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives informed written consent for publication. The patient should be shown the manuscript to be published. Refer to **www.icmje.org**.

ETHNIC CLASSIFICATION

References to ethnic classification must indicate the rationale for this.

MANUSCRIPTS

Shorter items are more likely to be accepted for publication, owing to space constraints and reader preferences.

Research articles (previously 'Original articles') not exceeding 3 000 words, with up to 6 tables or illustrations, are usually observations or research of relevance to clinical medicine and related fields. *References should be limited to no more than 15.* Please provide a structured abstract not exceeding 250 words, with the following recommended headings: *Background, Objectives, Methods, Results,* and *Conclusion.*

Scientific letters will be considered for publication as shorter ***Research articles***.

Editorials, Opinions, etc. should be about 1000 words and are welcome, but unless invited, will be subjected to the *SAMJ* peer review process.

Review articles are rarely accepted unless invited.

Letters to the editor, for publication, should be about 400 words with only one illustration or table, and must include a correspondence address.

Forum articles must be accompanied by a short description (50 words) of the affiliation details/interests of the author(s). Refer to recent forum articles for guidance. Please provide an accompanying abstract not exceeding 150 words.

Book reviews should be about 400 words and must be accompanied by the publication details of the book.

Obituaries should be about 400 words and may be accompanied by a photograph.

Guidelines must be endorsed by an appropriate body prior to consideration and all conflicts of interest expressed. A structured abstract not exceeding 250 words (recommended sub-headings: *Background, Recommendations, Conclusion*) is required. Sections and sub-sections must be numbered consecutively (e.g. 1. Introduction; 1.1 Definitions; 2. etc.) and summarised in a Table of Contents. References, appendices, figures and tables must be kept to a minumum.

Guidelines exceeding 8 000 words will only be considered for publication as a supplement to the SAMJ*; the costs of which must be covered by sponsorship or advertising. The Editor reserves the right to determine the scheduling of supplements. Understandably, a delay in publication must be anticipated dependent upon editorial workflow.*

MANUSCRIPT PREPARATION

Refer to articles in recent issues for the presentation of headings and subheadings. If in doubt, refer to 'uniform requirements' - **www.icmje.org**. Manuscripts must be provided in **UK English**.

Qualification, affiliation and contact details of ALL authors must be provided in the manuscript and in the online submission process.

Abbreviations should be spelt out when first used and thereafter used consistently, e.g. 'intravenous (IV)' or 'Department of Health (DoH)'.

Scientific measurements must be expressed in SI units except: blood pressure (mmHg) and haemoglobin (g/dl). Litres is denoted with a lowercase 'l' e.g. 'ml' for millilitres). Units should be preceded by a space (except for %), e.g. '40 kg' and '20 cm' but '50%'. Greater/smaller than signs (> and 40 years of age'. The same applies to ± and º, i.e. '35±6' and '19ºC'.

Numbers should be written as grouped per thousand-units, i.e. 4 000, 22 160...

Quotes should be placed in single quotation marks: i.e. The respondent stated: '...' Round **brackets** (parentheses) should be used, as opposed to square brackets, which are reserved for denoting concentrations or insertions in direct quotes.

General formatting The manuscript must be in Microsoft Word or RTF document format. Text must be single-spaced, in 12-point Times New Roman font, and contain no unnecessary formatting (such as text in boxes, with the exception of Tables).

ILLUSTRATIONS AND TABLES

If tables or illustrations submitted have been published elsewhere, the author(s) should provide consent to republication obtained from the copyright holder.

Tables may be embedded in the manuscript file or provided as **'supplementary files'**. They must be numbered in Arabic numerals (1,2,3...) and referred to consecutively in the text (e.g. 'Table 1'). Tables should be constructed carefully and simply for intelligible data representation. Unnecessarily complicated tables are strongly discouraged. Tables must be cell-based (i.e. not constructed with text boxes or tabs), and accompanied by a concise title and column headings. Footnotes must be indicated with consecutive use of the following symbols: * † ‡ § ¶ || then ** †† ‡‡ etc.

Figures must be numbered in Arabic numerals and referred to in the text e.g. '(Fig. 1)'. Figure legends: Fig. 1. 'Title...' All illustrations/figures/graphs must be of **high resolution/quality**: 300 dpi or more is preferable, but images must not be resized to increase resolution. Unformatted and uncompressed images must be attached individually as '**supplementary files**' upon submission (not solely embedded in the accompanying manuscript). TIFF and PNG formats are preferable; JPEG and PDF formats are accepted, but authors must be wary of image compression. Illustrations and graphs prepared in Microsoft Powerpoint or Excel must be accompanied by the original workbook.

REFERENCES

References must be kept to a maximum of 15. Authors must verify references from original sources. *Only complete, correctly formatted reference lists will be accepted.* Reference lists must be generated manually and **not** with the use of reference manager software. Citations should be inserted in the text as superscript numbers between square brackets, e.g. These regulations are endorsed by the World Health Organization,[2] and others.[3,4-6] All references should be listed at the end of the article in numerical order of appearance in the **Vancouver style** (not alphabetical order). Approved abbreviations of journal titles must be used; see the List of Journals in Index Medicus. Names and initials of all authors should be given; if there are more than six authors, the first three names should be given followed by et al. First and last page, volume and issue numbers should be given.

Wherever possible, references must be accompanied by a digital object identifier (DOI) link and PubMed ID (PMID)/PubMed Central ID (PMCID). Authors are encouraged to use the DOI lookup service offered by **CrossRef**.

Journal references: Price NC, Jacobs NN, Roberts DA, et al. Importance of asking about glaucoma. Stat Med 1998;289(1):350-355. [http://dx.doi.org/10.1000/hgjr.182] [PMID: 2764753]

Book references: Jeffcoate N. Principles of Gynaecology. 4th ed. London: Butterworth, 1975:96-101. *Chapter/section in a book:* Weinstein L, Swartz MN. Pathogenic Properties of Invading Microorganisms. In: Sodeman WA jun, Sodeman WA, eds. Pathologic Physiology: Mechanisms of Disease. Philadelphia: WB Saunders, 1974:457-472.

Internet references: World Health Organization. The World Health Report 2002 - Reducing Risks, Promoting Healthy Life. Geneva: World Health Organization, 2002. http://www.who.int/whr/2002 (accessed 16 January 2010).

Other references (e.g. reports) should follow the same format: Author(s). Title. Publisher place: publisher name, year; pages. Cited manuscripts that have been accepted but not yet published can be included as references followed by '(in press)'. Unpublished observations and personal communications in the text must not appear in the reference list. The full name of the source person must be provided for personal communications e.g. '...(Prof. Michael Jones, personal communication)'.

PROOFS

A PDF proof of an article may be sent to the corresponding author before publication to resolve remaining queries. At that stage, **only** typographical changes are permitted; the corresponding author is required, having conferred with his/her co-authors, to reply within 2 working days in order for the article to be published in the issue for which it has been scheduled.

CHANGES OF ADDRESS

Please notify the Editorial Department of any contact detail changes, including email, to facilitate communication.

CPD POINTS

Authors can earn up to 15 CPD CEUs for published articles. Certificates may be requested after publication of the article.

CHARGES

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Please refer to the section on '*Guidelines*' regarding the publication of supplements, where a charge may be applicable.

Submission Preparation Checklist

As part of the submission process, authors are required to check off their submission's compliance with all of the following items, and submissions may be returned to authors that do not adhere to these guidelines.

1. Named authors consent to publication and meet the requirements of authorship as set out by the journal.
2. The submission has not been previously published, nor is it before another journal for consideration.
3. The text complies with the stylistic and bibliographic requirements in **Author Guidelines**.
4. The manuscript is in Microsoft Word or RTF document format. The text is single-spaced, in 12-point Times New Roman font, and contains no unnecessary formatting.
5. Illustrations/figures are high resolution/quality (not compressed) and in an acceptable format (preferably TIFF or PNG). These must be submitted individually as 'supplementary files' (not solely embedded in the manuscript).
6. For illustrations/figures or tables that have been published elsewhere, the author has obtained written consent to republication from the copyright holder.
7. Where possible, references are accompanied by a digital object identifier (DOI) and PubMed ID (PMID)/PubMed Central ID (PMCID).
8. An abstract has been included where applicable.
9. The research was approved by a Research Ethics Committee (if applicable)
10. Any conflict of interest (or competing interests) is indicated by the author(s).

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Appendix 11: Dataset Variables

Table D2: Dataset Variables

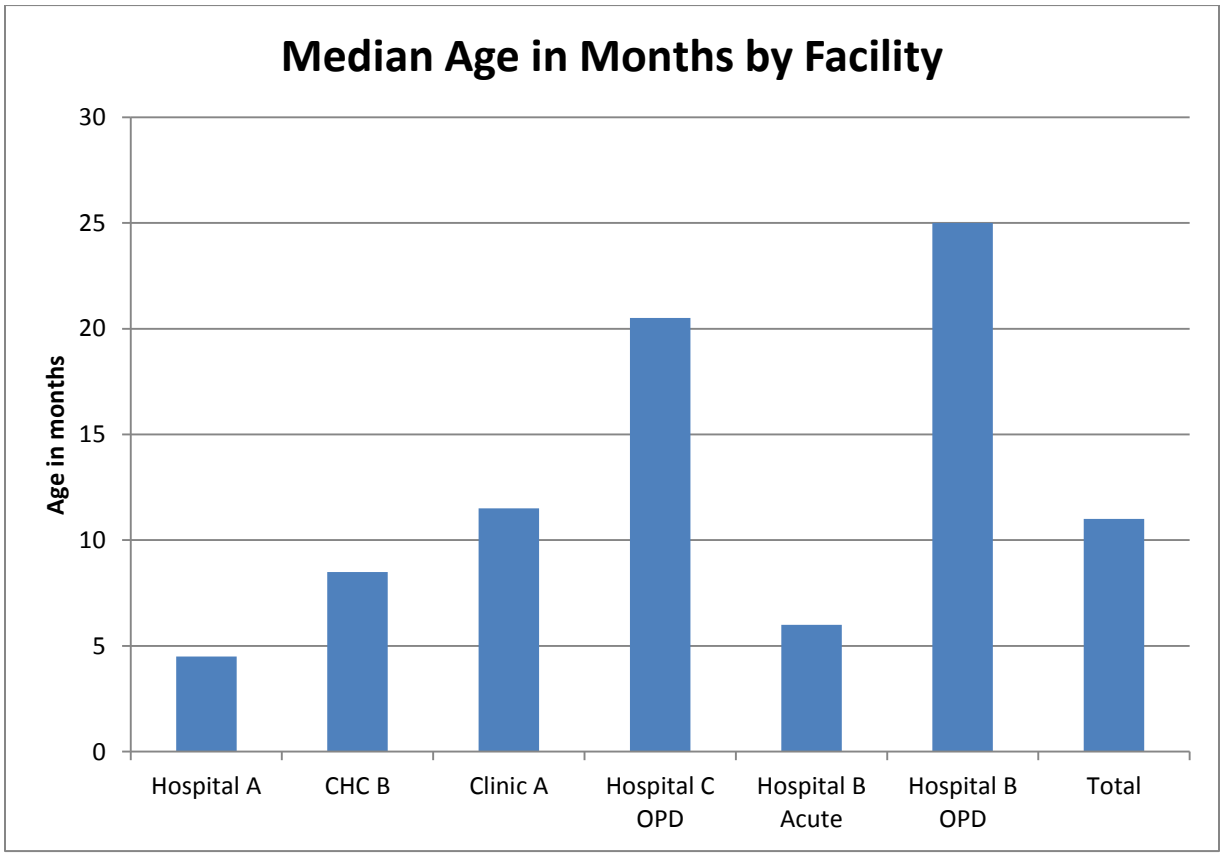
Variable	Description	Code	Type
Site	Survey facility	1 – Hospital A 2 – CHC B 3 – Clinic A 4 – Hospital C 5 – Hospital B Acute 6 – Hospital B OPD	Categorical nominal
Day	Weekday on which survey took place	1 – Friday 2- Monday 3 – Thursday 4 – Tuesday 5 – Wednesday	Categorical nominal
Time	Time at which patient exited facility		Numerical
Time category	Time category at which patient exited facility	1 – 09:00 - 11:59 2 – 12:00 – 13:59 3 – 14:00 – 16:00	Categorical ordinal
Age of child (months)	Age of child in months		Numerical continuous
Age of caregiver (years)	Age of caregiver in years		Numerical continuous
Primary caregiver		Yes/No	Categorical binary
Reason for coming	Reason for attending health facility	1 – Accompanying another child 2 – Caregiver follow-up 3 – Caregiver sick 4 – Child sick 5 – Child follow-up 6 – Immunisation 7 – Newborn discharge	Categorical nominal
Other illness (including HIV,TB, malnutrition)	Other medical conditions	Yes/No	Categorical binary
HIV	HIV according to caregiver history-taking	Yes/No	Categorical binary
TB	TB according to history-taking	Yes/No	Categorical binary
Malnutrition	Malnutrition according to history-taking	Yes/No	Categorical binary
Consult: doctor		Yes/No	Categorical binary
Consult: nurse		Yes/No	Categorical binary
Consultation		1 – Doctor only 2 – Nurse only 3 – Doctor and nurse	

		4 – Allied staff only	
RTHB asked for		Yes/No	Categorical binary
RTHB present		Yes/No	Categorical binary
Immunisation status: RTHB		Yes/No	Categorical binary
Immunisation status: caregiver		0 – Complete 1 – Incomplete/Don't know	Categorical nominal
Missed (Overall immunisation status)		1 – Complete by caregiver 2 – Uncertain by caregiver 3 – Incomplete by caregiver 4 – Incomplete by RTHB 5 – Complete by RTHB	Categorical nominal
Vaccines today		2 – No 3 – Yes all 4 – Yes some	Categorical binary
Contra-indications		1 – No 3- Not applicable – Immunisations complete 4 - Yes	
Reason for missed immunisation		1 – Child too sick 2 –Don't know 3 – Not applicable	Categorical nominal
Time category	Time patient seen	1 – 09:00 – 11:59 2 – 12:00 – 13:59 3 – 14:00 – 16:00	Categorical ordinal
Level	Level of care	0 - Primary 1 – Secondary/tertiary	Categorical binary

Appendix 12: Additional figures of results stratified according to health facility

Since the South African Medical Journal (SAMJ) only allows a maximum of 6 tables or illustrations, additional figures and tables have been included as appendices to provide more detailed analyses. Salient results stratified according to health facility are presented below.

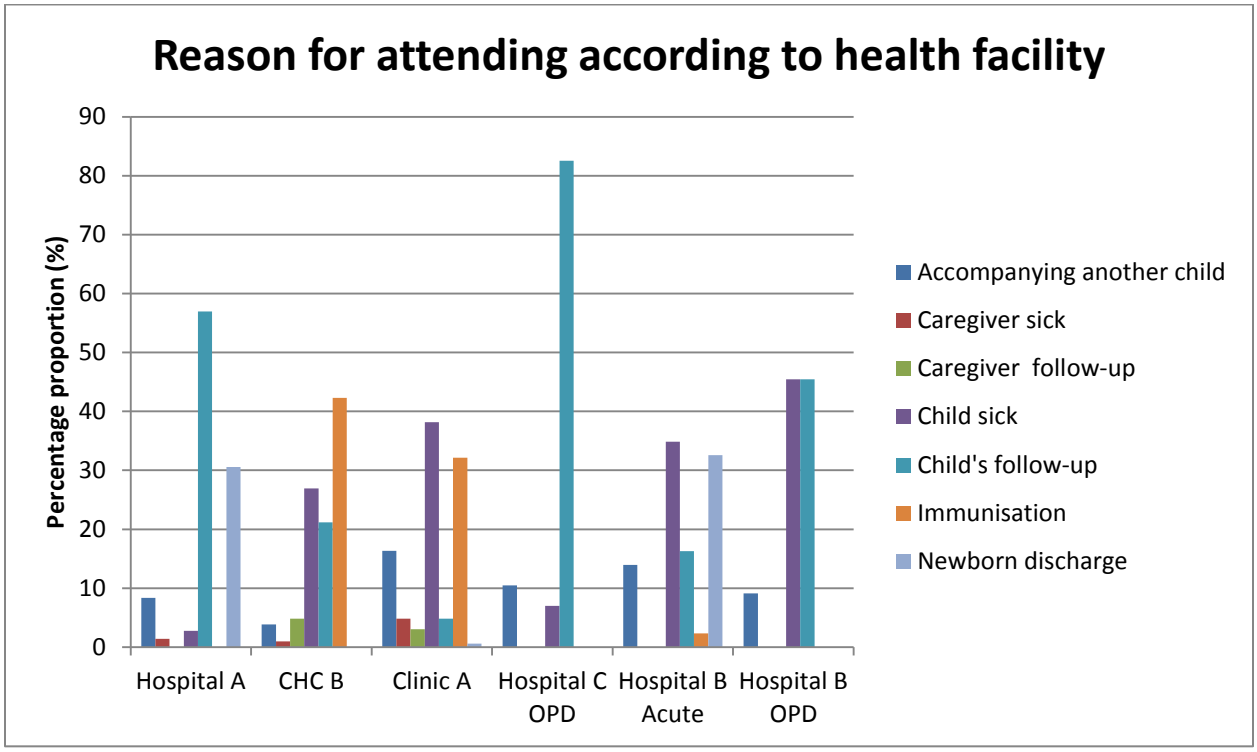
Figure D1: Median age of child in months by health facility



Median age of patients at each facility varied considerably. Patients at Hospital C and Hospital B OPD appear older, while at Hospital A, the median age was much lower.

The notably low median age of children exiting Hospital A and Hospital B Acute area was due to the newborn children exiting the health facilities on discharge, who were also included in the study.

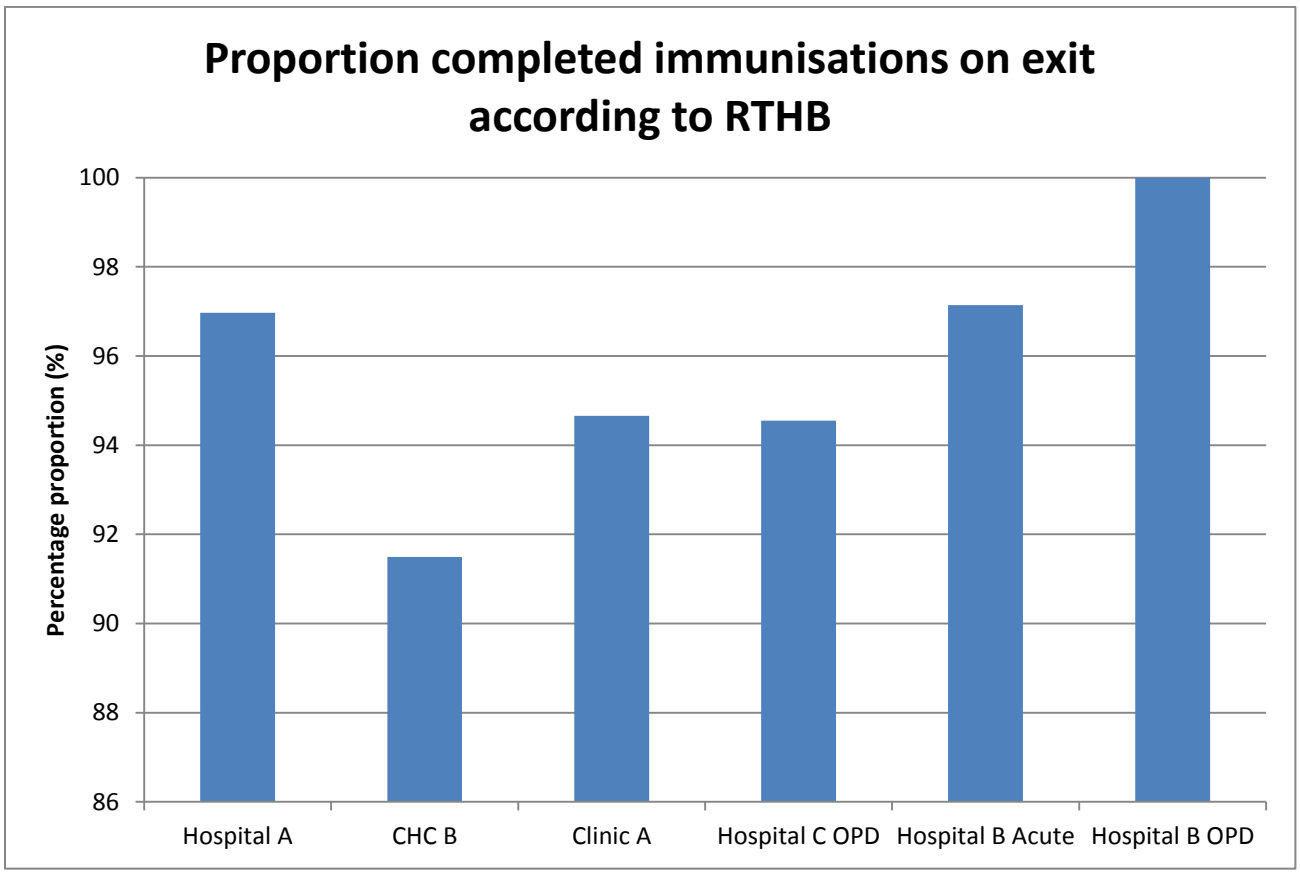
Figure D2: Reason for attending according to health facility



As illustrated in Figure D2, marked differences are seen between primary and secondary level facilities. Most notably, patients seen at Hospital C primarily attended for children's follow-up visits.

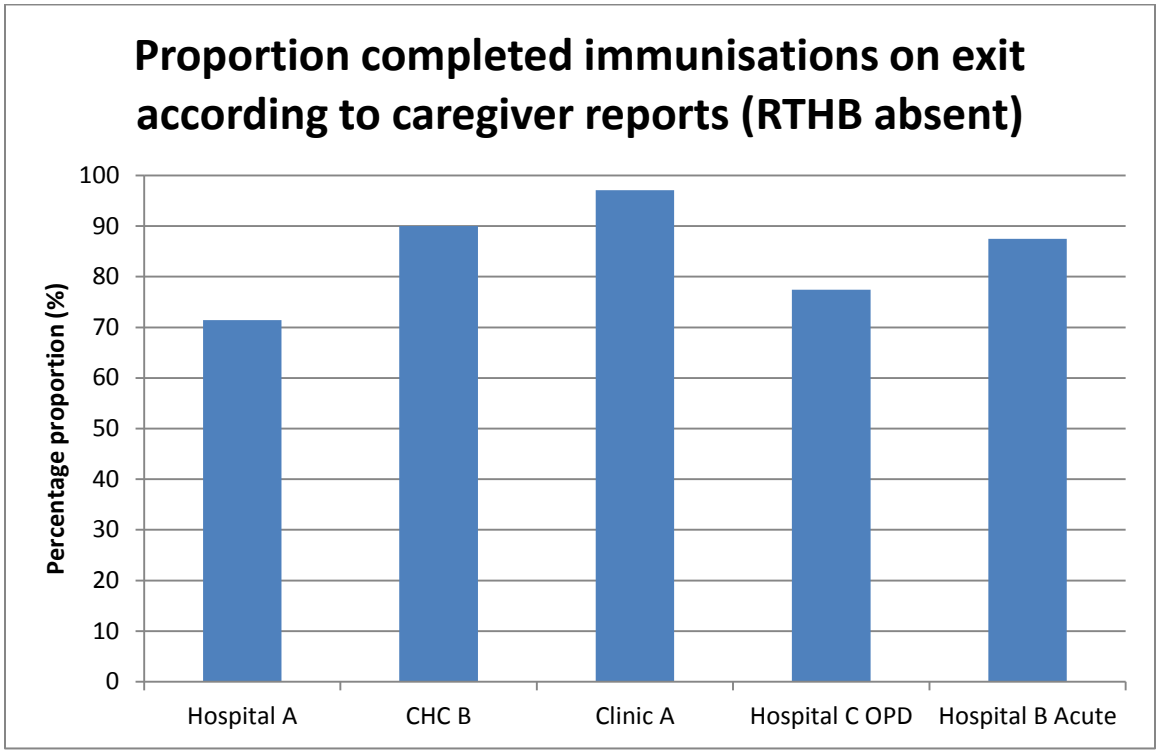
Immunisation status: RTHB

Figure D3: Proportion completed immunisations on exit according to RTHB, by facility



As seen in Figure D3, at all facilities, among children with RTHB's, more than 90% of children exiting the facilities had complete immunisations required for age. All children presenting to the hospitals with RTHB's had completed their immunisations prior to the visit on the day of participation in the study.

Figure D4: Proportion completed immunisations on exit according to caregiver reports, by facility

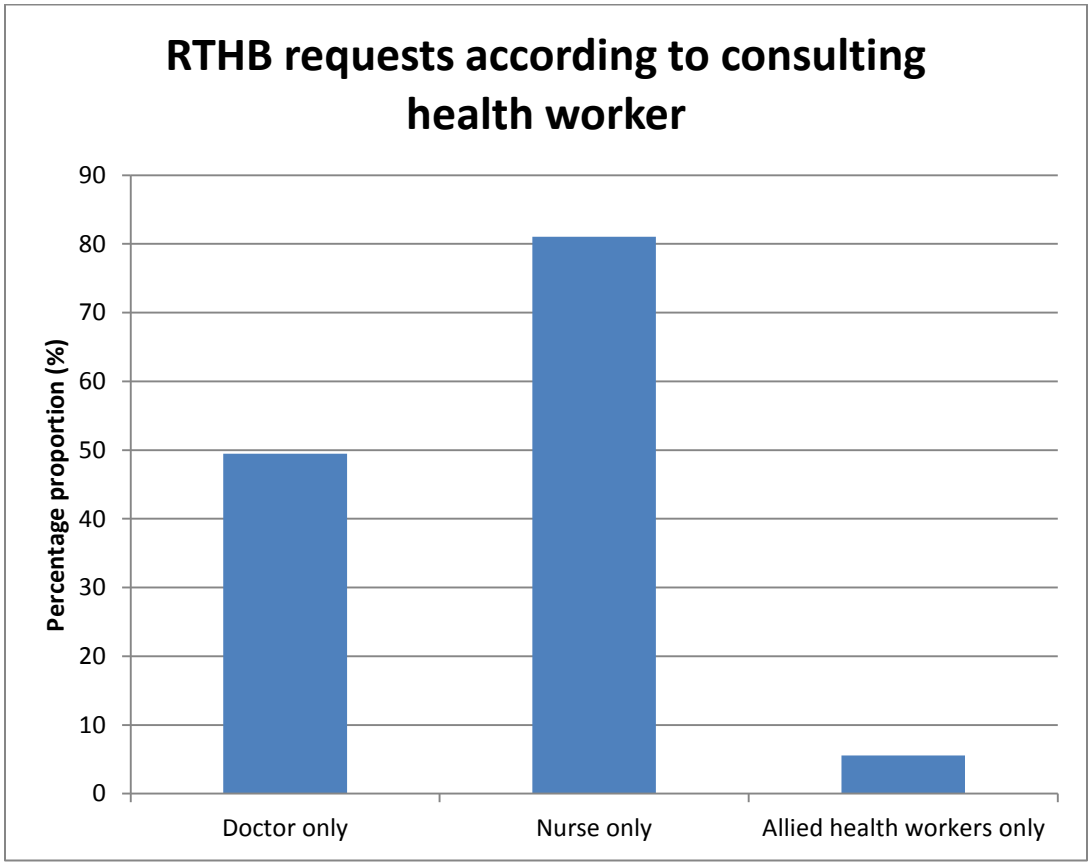


Among those whose RTHB's were absent, caregiver reports of complete immunisation status were highest at Clinic A and lowest at Hospital A.

Appendix 13: Additional figures from bivariate analyses

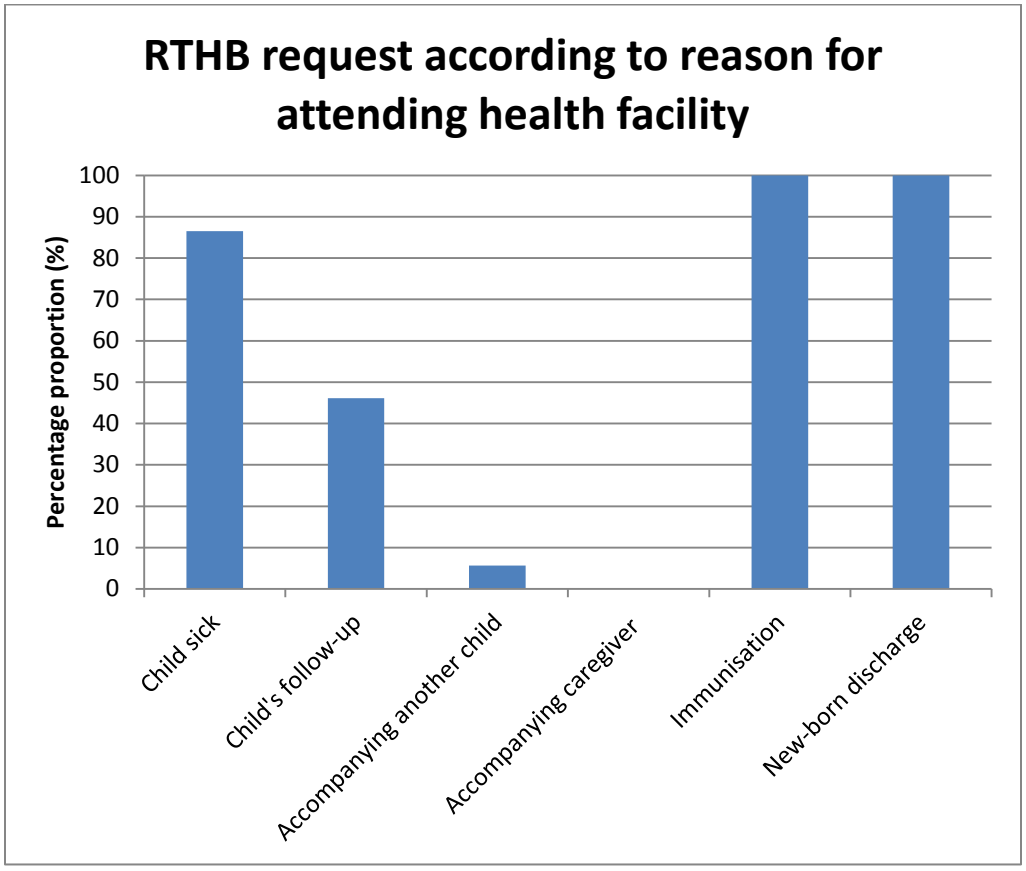
Category of consulting health worker and reason for attending health facility were found to be associated with requests for RTHB during exploratory analyses.

Figure D5: RTHB request according to consulting health worker



81.1% of children seen by nurses only had RTHB requested, compared to 49.5% of children seen by doctors only. When excluding children presenting specifically for immunisation who are routinely seen by nurses, 68.7% of children seen by nurses only had RTHB requested, compared to 49.2% seen by doctors only. Of the 18 patients who were seen by allied health workers, only 1, who consulted a dietician, had RTHB requested. The reason for requesting RTHB is unknown, however dieticians are known to assess growth charts at consultations. It is unknown whether immunisation status was checked.

Figure D6: RTHB requests according to reason for attending health facility



Children attending with acute illness had much higher percentage of requests for RTHB than those attending for follow-up. Children attending for caregiver consultations and those accompanying other children had a very low percentage of RTHB requests. All children attending for immunisations or newborn babies discharged from hospital had RTHB's checked on the day of participation of the study.

Appendix 14: Summary of bivariate analysis

Findings of exploratory bivariate analysis are summarised in Table D3. Statistically significant p-values are highlighted in bold text. Results of the bivariate analysis were used to enhance interpretations of the multivariate analyses.

Table D3: Summary of bivariate analysis

Outcome variable	Explanatory variable	Statistical test	Finding	p-value
Immunisation Status: RTHB	Age	Wilcoxon rank-sum	Complete: Median age= 9 months Incomplete: Median age = 18 months	0.1345
Immunisation Status: RTHB	Caregiver age	Wilcoxon rank-sum	Complete: Median age = 28 years Incomplete: Median age = 31 years	0.0860
Immunisation Status: RTHB	Reason for coming	Fisher's exact		0.683
Immunisation status caregiver	Age	Wilcoxon rank-sum	Complete: Median age= 21 months Incomplete: Median age = 31.5 months	0.8819
Immunisation status caregiver	Caregiver age	Wilcoxon rank-sum	Complete: Median age= 28.5 years Incomplete: Median age = 32 years	0.1910
Immunisation status caregiver	Reason for coming	Fisher's exact		0.617
RTHB requested	Day	Chi-square test	RTHB requested less on Mondays and Fridays compared to other days	**<0.001**
RTHB requested	Time	Chi-square test	Slightly lower requests for RTHB between 09:00 – 12:00	0.285
RTHB requested	Age	Wilcoxon rank-sum	Requested: Median age = 8 months Not requested: Median age = 21 months	**<0.001**

RTHB requested	Caregiver age	Wilcoxon rank-sum	Requested: Median age = 28 years Not requested: Median age = 30 years	**0.0048**
RTHB requested	Reason for coming	Fisher's exact	*See Figure D6*	**<0.001**
RTHB requested	Health worker consulted	Chi-square	*See Figure D5*	**<0.001**
RTHB requested	RTHB present	Chi-square		**<0.001**
RTHB present	Age	Wilcoxon rank sum	Present: Median age = 9 months Absent: Median age = 21.5 months	**<0.001**
RTHB present	Caregiver age	Wilcoxon rank sum	Present: Median age = 28.5 years Absent: Median age = 29 years	0.1321
RTHB present	Reason for coming	Fisher's exact		**<0.001**

Appendix 15: Additional tables from multivariate analyses

The outcome variables for multivariate analysis were:

- Immunisation status according to road-to-health booklet
- Immunisation status according to caregiver
- Road-to-health booklet requested by health worker
- Road-to-health booklet present at consultation

Immunisation status according to RTHB

Although bivariate analysis was inconclusive as no significant associations between variables and immunisation status were observed, a model was built including variables that may affect immunisation status to understand approximate magnitude of effects, as shown in Table D4. No statistically significant associations were found, most likely due to the low prevalence of incomplete immunisation status.

Table D4: Factors affecting immunisation status according to RTHB

Variable	Odds Ratio	p-value	95% Confidence Interval	
Age of caregiver (years)	0.97	0.1960	0.93	1.02
Age of child (months)	0.99	0.5180	0.96	1.02
Reason for attending (Reference: Child sick)				
Accompanying another child	0.66	0.7220	0.07	6.49
Child follow-up	0.58	0.4440	0.15	2.31
Immunisation	0.89	0.8490	0.25	3.10
Site (Reference: Hospital C)				
Hospital A	1.27	0.7990	0.20	8.13
CHC B	0.41	0.2680	0.08	2.00
Clinic A	0.63	0.6040	0.11	3.54
Hospital B Acute	0.78	0.8450	0.07	8.91
Hospital B OPD	1.00			
Other illness	1.07	0.7990	0.62	1.85

Although a notable difference between median age of those with complete and incomplete immunisation status was observed, with younger children more likely to have complete immunisations, the association was not statistically significant due to the small sample.

Those seen at Hospital A were 1.3 times more likely to have complete immunisation status on RTHB than those at Hospital C. Those with a history of other illnesses were 1.1 times more likely to have complete immunisation status on RTHB than those without a history of other illnesses. These associations were also not statistically significant.

Immunisation status: Caregiver report (RTHB absent)

As with immunisation status according to RTHB, no significant associations were identified between the explanatory variables and immunisation status according to caregiver report in bivariate and multivariate analysis, as shown in Table D5.

Table D5: Factors affecting immunisation status according to caregiver

Variable	**Odds Ratio**	**p-value**	**95% Confidence interval**	
Age of child (months)	0.97	0.2560	0.91	1.02
Age of caregiver (years)	1.08	0.0700	0.99	1.17
Reason for attending (Reference: Child sick)				
Accompanying another child	0.93	0.9580	0.06	14.72
Caregiver follow-up	1.00			
Caregiver sick	1.00			
Child follow-up	0.57	0.7140	0.03	11.66
Site (Reference: Hospital C)				
Hospital A	3.35	0.3550	0.26	43.24
CHC B	0.36	0.5200	0.02	7.94
Clinic A	**0.05**	**0.0410**	**0.00**	**0.89**
Hospital B Acute	0.54	0.6800	0.03	10.11
Other illness	0.60	0.2790	0.23	1.52

Among those whose RTHB's were absent, those seen at Hospital A, were 3.4 times more likely to have caregiver-reported complete immunisation status compared to those at Hospital C. This finding was not

statistically significant. Those seen at Clinic A, however, were 0.1 times less likely to have caregiver-reported complete immunisation status compared to those at Hospital C. Given the small sample used for this model, these findings are imprecise, with a very wide confidence interval.

Appendix 16: Descriptive characteristics of staff interviewed

Table D6 summarises the main characteristics of staff interviewed. Since the focus of this component of the study was to elicit themes around staff attitudes towards immunisation, a small sample was purposively selected for primarily qualitative exploration. Percentage proportions and confidence intervals are expected to be large, given the small sample size, and not meaningful given the qualitative focus.

Table D6: Descriptive characteristics of staff interviewed

Variable (n=17)	**No. of participants**
Level of care	
Primary	3
Secondary	9
Tertiary	5
Age (median; range)	36 (26 – 59)
Profession	
Doctor: Medical officer	7
Nurse (Hospital)	7
Nurse (Clinical Nurse Practitioner)	2
Nurse (Clinic immunisation sister)	1
Work Area	
Emergency Unit	4
Paediatrics	13