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Assessing and addressing missed opportunities for vaccination in Cape Town through a collaborative quality improvement approach

Submitted in fulfilment of the requirements for the degree of Doctor of Philosophy (PhD) in Public Health (Epidemiology and Biostatistics)

by

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Declaration

I Chukwudi Arnest Nnaji declare that the entirety of the work contained in this thesis is my own, original work which is being submitted for the degree of Doctor of Philosophy (PhD) in Public Health (Epidemiology and Biostatistics) at the University of the Cape Town. This work has not been submitted for any other degree or examination at this or any other university or institution. I authorise the University of Cape Town to reproduce for the purpose of research either the whole or any portion of the contents.

Signature: Date: 01 December 2023

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Acknowledgements

"Sowing in the sunshine, sowing in the shadows,

Fearing neither clouds nor winter's chilling breeze;

By and by the harvest, and the labour ended,

We shall come rejoicing, bringing in the sheaves".

- Bringing in the sheaves – Knowles Shaw (1874)

I am profoundly grateful to God for the unfailing grace and strength that saw me through this PhD journey, from its inception to completion – indeed, for the grace to sow and rejoice in the end, bringing in the sheaves at harvest time.

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Dedication

I dedicate this thesis to my son Naeto Nnaji, whose birth came at a time I needed to finish up the PhD and whose need of early parental time and care served as additional stimulus for completing this phase of my life. I also dedicate this thesis to every child out there across the world – for inspiring this and other current efforts at improving access to life-saving immunisation services in the pursuit of a much better, healthier and fairer world.

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Thesis structure and content

The structure, content and chapter titles of this thesis are as follows:

Chapter 1: Introduction, study rationale, aim and objectives.

Chapter 2: Literature review and overview of research methodology.

Chapter 3: Missed opportunities for vaccination and associated factors among children attending primary health care facilities in Cape Town, South Africa: a pre-intervention multilevel analysis (focusing on the first research objective/component study).

Chapter 4: Contextualising missed opportunities for vaccination among children in Cape Town, South Africa: a theory-informed qualitative study in primary care settings in Cape Town, South Africa (focusing on the second and third research objectives/component studies).

Chapter 5: Evaluation of a quality improvement intervention to address missed opportunities for vaccination among children in primary health care settings in Cape Town (focusing on the fourth research objective/component study).

Chapter 6: Identifying contextual barriers and facilitators of a quality improvement intervention implemented to address missed opportunities for vaccination among children in Cape Town, South Africa: a mixed methods post-implementation evaluation (focusing on the fifth research objective/component study).

Chapter 7: Integrated discussion, conclusions and personal reflections.

List of publications

Publication with full citation	Associated thesis chapter
Nnaji CA, Wiysonge CS, Lesosky M, Mahomed H, Ndwandwe D. COVID-19 and the Gaping Wounds of South Africa's Suboptimal Immunisation Coverage: An Implementation Research Imperative for Assessing and Addressing Missed Opportunities for Vaccination. Vaccines (Basel). 2021 Jun 23;9(7):691. DOI: 10.3390/vaccines9070691.	Chapters 1 and 2
Nnaji CA, Wiysonge CS, Adamu AA, Lesosky M, Mahomed H, Ndwandwe D. Missed Opportunities for Vaccination and Associated Factors among Children Attending Primary Health Care Facilities in Cape Town, South Africa: A Pre-Intervention Multilevel Analysis. Vaccines (Basel). 2022 May 16;10(5):785. DOI: 10.3390/vaccines10050785.	Chapter 3
Nnaji CA, Wiysonge CS, Cooper S, Mayeye A, Luphondo L, Mabuya T, Kalui N, Lesosky M, Ndwandwe D. Contextualising missed opportunities for children's vaccination: A theory-informed qualitative study in primary care settings in Cape Town, South Africa. Hum Vaccin Immunother. 2023 Dec 31;19(1):2162771. DOI: 10.1080/21645515.2022.2162771.	Chapter 4

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List of abbreviations and acronyms

Abbreviations/ Acronyms	Full meaning
CFIR	Consolidated Framework for Implementation Research
CoCT	City of Cape Town
COM-B	Capability, opportunity and motivation model of behaviour
DOH	Department of Health
DTaP-IPV-Hib-HepB	Hexavalent vaccine containing Diphtheria, Tetanus, Pertussis, injectable Polio, Haemophilus influenzae b and Hepatitis B antigens
EPI	Expanded Programme on Immunisation
EPI-SA	Expanded Programme on Immunisation of South Africa
GTO	Getting To Outcomes
GVAP	Global Vaccine Action Plan
HREC	Human Research Ethical Committee, of the University of Cape Town
IA2030	Immunisation Agenda 2030
ITSA	Interrupted time series analysis
MOV	Missed Opportunities for Vaccination
PDSA	Plan Do Study Act
PHC	Primary Health Care
RtHB	Road to Health Booklet
QI	Quality Improvement
TDF	Theoretical Domains Framework
UHC	Universal Health Coverage
WHO	World Health Organization

Abstract

Background: While significant investments and efforts have been made to promote universal access to immunisation services in South Africa, current evidence shows substantial coverage gaps across the country. Missed opportunities for vaccination (MOV) have been recognised as a major contributor to sub-optimal immunisation coverage globally. The overall aim of the research and its component studies was to assess and address MOV in primary health care (PHC) settings in Cape Town. To achieve this overarching goal, the research sought to address five specific objectives. It started with quantitative and qualitative assessments of the magnitude and multi-dimensional factors associated with MOV among children aged 0-23 months attending PHC facilities in the Cape Town Metro Health District. The goal of that formative assessment was to help inform the design, implementation and evaluation of contextually appropriate quality improvement interventions targeted at reducing MOV in participating PHC facilities. In addition, the research sought to contribute important evidence on the feasibility, effectiveness and sustainability of quality improvement interventions in addressing MOV in PHC contexts. Study rationale, supporting literature and specific objectives are described in detail in **Chapters 1-2**.

Methods: The research used a mixed-methods approach, incorporating data from both quantitative and theory-informed qualitative studies. To address the five specific objectives, the research had five component studies. The first study involved a quantitative assessment of the magnitude of MOV and associated factors (**Chapter 3**), consolidated with two qualitative studies to provide deeper understanding and contextualisation of the first study's quantitative findings from the perspectives of caregivers and health workers (**Chapter 4**). These were followed by a non-randomised controlled study to evaluate the effectiveness of the package of quality improvement strategies implemented in participating health facilities (**Chapter 5**) and a post-intervention mixed-methods evaluation of the factors facilitating or hindering the successful implementation of quality improvement interventions (**Chapter 6**). Study design, methodological considerations and conceptual underpinnings are described in detail in various study chapters (**Chapters 3-6**). Strengths and limitations of each study design are also discussed in their respective chapters, as are their implications for further research.

Results: The first component study (**reported and discussed in detail in Chapter 3**) involved a quantitative study that aimed to assess the prevalence and determinants of MOV in PHC settings in Cape Town. It found a prevalence of 14% and identified individual and health system factors associated with MOV. The second study (**reported and discussed in Chapter 4)** used a qualitative design (focus group discussions with caregivers) to explore the factors that may influence MOV among children in the study setting. Similarly, the third study (**reported also in Chapter 4)** employed another qualitative design (in-depth interviews) to explore the factors that may influence MOV from the perspectives of healthcare workers. Both qualitative studies provided important contextual insights that complemented and enhanced understanding of the findings from the quantitative MOV assessment. In the fourth component study (**reported and discussed in Chapter 5)**, findings from the quantitative and qualitative baseline assessments were used to design and evaluate a package of facility-level quality improvement interventions. From the evaluation using a non-randomised controlled design, we found that implementing contextually appropriate quality improvement strategies was feasible and effective at reducing MOV occurrence in participating PHC facilities. In the final study, we used a mixed-methods evaluation design to conduct a post-implementation evaluation of the quality improvement intervention. From that, we were able to identify the quality improvement implementation facilitators and barriers and how they influenced participants' experiences and perceptions of implementation outcomes, the understanding of which is important for informing the adaptation and sustainability of future MOV-targeted quality improvement strategies.

Conclusion

Overall, the research has demonstrated that there was a substantial burden of MOV among children in Cape Town. It has also provided some scientifically robust evidence on the feasibility, effectiveness and adaptability of a facility-level quality improvement intervention for addressing MOV in primary health care contexts in Cape Town and similar contexts. Implications of study findings for policy, practice and further research have been discussed with specific recommendations in various study chapters (**Chapters 3-6**) and consolidated in the integrated discussion in the final chapter (**Chapter 7**).

Chapter 1: Introduction

About this chapter

This chapter provides an introductory overview of current global, regional and national childhood immunisation coverage trends, with a specific focus on South Africa. It introduces the concepts of missed opportunities for vaccination and quality improvement. In addition, it sets the stage for this thesis by outlining the rationale, primary aim, specific objectives and corresponding research questions of the PhD research.

1.1 Background

Immunisation has been recognised as one of the greatest advances in public health.[1,2] It is seen as a highly cost-effective way of preventing diseases, yielding significant cost-savings for governments, individuals and their families through the aversion of illnesses and the loss of human productivity that often arises as a result of being ill.[3] The full benefits of vaccination go beyond the direct prevention of disease. The benefits extend across the entire life-course of vaccinated persons and their communities; helping to stabilise health systems while promoting health and fostering human development.[1] To harness the proven direct and indirect benefits of immunisation globally, the World Health Organization (WHO) launched the Expanded Programme on Immunisation (EPI) in 1974, as the first ever global health effort to promote universal access to immunisation for all children across the world.[4] Through the EPI's routine childhood immunisation programme, billions of vaccine doses have been administered to protect children around the world to date.[5] This improved access to immunisation at population-level has helped to avert approximately 3 million child deaths every year from vaccine-preventable diseases like tetanus, measles and diphtheria.[6-8] These are in addition to the enormous societal and economic benefits by averting catastrophic health expenditures and yielding morbidity-related productivity gains.[9]

Despite substantial global immunisation coverage progress made since the inception of the EPI, progress made with expanding immunisation coverage has slowed in many countries.[10] In many countries, particularly in sub-Saharan Africa, immunisation coverage failed to reach the Global Vaccine Action Plan (GVAP) targets in 2020, with a substantial proportion of children remaining unvaccinated against major childhood killer diseases.[10,11] Of the estimated millions of infants who do not have access to life-saving vaccines, the majority reside in the sub-Saharan African region, including South Africa (SA).[12,13] Fulfilling the visions of the EPI requires reaching and sustaining optimal immunisation coverage, to reach all people, particularly children.[10]

1.2 Childhood immunisation in SA

Routine immunisation services in SA are provided free of charge through the Expanded Programme on Immunisation of South Africa (EPI-SA), mainly by primary health care (PHC)

facilities at the district level.[14] In May 2012, SA joined other WHO member states to endorse the Global Vaccine Action Plan (GVAP).[11] The vision of the GVAP was that of a world in which all individuals and communities enjoy lives free from vaccine-preventable diseases, with a global recommendation for countries to reach 90% or higher national coverage for the vaccines in their routine immunisation schedule by the year 2020.[10,11]

Like several other low- and middle-income countries (LMICs), SA faces a daunting task in efforts to boost its national immunisation coverage to globally recommended standards, even as socioeconomic inequalities remain prevalent in SA decades after the end of the apartheid era.[15] Immunisation coverage data of children in the first year of life show that SA did not achieve the GVAP goals by the target year of 2020.[14] Recent estimates suggest that immunisation coverage remains below the globally accepted optimal level of 90% across all routine childhood vaccine doses in SA.[16] **Table 1.1** outlines immunisation coverage estimates as proportions of fully vaccinated children from a recent national immunisation coverage survey.[17] An additional challenge was posed by the coronavirus disease 2019 (COVID-19) pandemic, which disrupted immunisation services across the world.[18]

Table 1.1. Provincial immunisation coverage estimates for fully vaccinated children at 12 and 18 months*

Province	Proportion fully vaccinated with all 14 doses at 18 months (95% confidence interval)
Eastern Cape	75.4% (72.1% - 76.0%)
Free State	76.7% (73.8% - 79.9%)
Gauteng	81.4% (80.2% - 82.5%)
Kwazulu-Natal	74.3% (73.1% - 75.5%)
Limpopo	70.5% (69.0% - 72.8%)
Mpumalanga	73.9% (71.0% -76.4%)
North West	75.2% (72.7% - 77.8%)
Northern Cape	81.6% (76.6% - 85.1%)
Western Cape	80.9% (77.9% - 83.9%)
National	**76.8% (75.4% - 78.2%)**

***Based on findings from the 2019 national immunisation coverage survey

Suboptimal immunisation coverage among children in SA has been attributed to several factors. These include rural residence, lack of awareness of the immunisation schedule by the parents or caregivers, non-attendance of antenatal care during pregnancy, as well as health workers'

inadequate immunisation training and heavy workloads.[19-21] Other factors include vaccine stock-outs, poor communication among stakeholders (including insufficient advocacy and insufficient social mobilisation) and weak collaboration between the public and private health sectors.[5,22]

Functionally, the National Department of Health (NDOH) formulates policies, procedures and guidelines to support routine immunisation service implementation across the country through the EPI-SA.[14,21] In line with evolving disease burden priorities, the routine childhood immunisation schedule had been revised at various times. The most recent revision was in 2015, with changes in measles vaccine schedules from 9 and 18 months to 6 and 12 months for the first and second doses, respectively.[23,24] **Table 1.2** illustrates SA's current childhood immunisation schedule:

Table 1.2. Current routine childhood immunisation schedule in SA

Age	**Vaccine offered**
Birth	BCG, OPV (0)
6 Weeks	OPV (1), RV (1), DTaP-IPV-Hib-HepB (1), PCV (1)
10 Weeks	DTaP-IPV-HIB-HepB (2)
14 Weeks	RV (2), DTaP-IPV-Hib-HepB (3), PCV (2)
6 months	Measles (1)
9 Months	PCV (3)
12 months	Measles (2)
18 Months	DTaP-IPV-Hib-HepB (4)
6 years	Td (1)
9 years	HPV (1), HPV (2) (2 doses, 6 months apart)*
12 years	Td (2)

BCG = Bacille Calmette Guerin, DTaP-IPV-Hib-HepB = hexavalent vaccine (containing diphtheria, tetanus, pertussis, inactivated polio, *Haemophilus influenzae* type b and hepatitis B vaccines), HPV = human papillomavirus vaccine, OPV = oral polio vaccine, PCV = pneumococcal conjugate vaccine, RV = rotavirus vaccine, Td = tetanus and reduced dose diphtheria vaccine.
*HPV vaccine is given as part of the school health programme rather than the EPI-SA

1.3 Missed opportunities for vaccination (MOV)

Since 1983, the WHO has recommended the provision of immunisation services at every opportunity and contact with the health system as a strategy to improve immunisation coverage.[25] However, there is evidence that a significant proportion of children who are eligible for vaccination may already have had contacts with the health system for preventive or curative services, but did not receive vaccination during those contacts.[25] Such contacts constitute the occurrence of missed opportunities for vaccination (MOV) - defined as "any contact with health services by a child (or adult) who is eligible for vaccination (unvaccinated, partially vaccinated, or not up-to-date, and free of contraindications to vaccination), which does not result in the individual receiving all the vaccine doses for which he or she is eligible."[13] MOV can occur in two settings; during a visit to a health facility for immunisation and other preventive care services, or during a visit to the health facility for curative or other non-preventive services.[13] MOVs are a major cause of suboptimal immunisation coverage among children.[26] Across sub-Saharan Africa, there is wide variation of the burden of MOV, ranging from as high as 89% in Gabon to as low as 16% in Swaziland.[26] Factors found to be associated with MOV include child's age, birth order, number of under-five children in the household, maternal age, household wealth index, maternal level of education, media access and neighbourhood socio-economic disadvantage.[26-30]

1.4 Quality improvement (QI)

Over the years, quality improvement (QI) approaches have been increasingly used in health care to improve health outcomes.[31,32] Quality improvement has been defined in many ways.[33,34] Notably, it is defined by WHO's Quality and Policy Strategy Manual as "a change in process in a health-care system, service, or supplier to increase the likelihood of optimal clinical quality of care measured by positive health outcomes for individuals and populations".[35] Most commonly, QI has been used to improve maternal and child health, and adherence to clinical practice guidelines.[32,36] The QI approach typically relies on the collaborative efforts of stakeholders to create and implement change ideas that can result in the desired outcome.[37] It involves an iterative process of implementing interventions and the continuous evaluation of process and

outcomes, with a reflection on facilitators and barriers of the change process.[38] Several quality improvement methodologies exist and have been applied in various contexts.[39] There has been a significant growth in the use of QI approaches in routine immunisation service delivery settings, with emerging evidence on their applicability in the context of MOV.[31,36]

1.5 Statement of the problem

Millions of children remain incompletely vaccinated or unvaccinated across LMICs.[11,14] In particular, SA has been in the spotlight concerning its stalling immunisation coverage. Immunisation coverage currently remains below the globally accepted levels, with less than 90% of children across all provinces being fully vaccinated with all 14 doses at 18 months (**Table 1.1**) according to a recent national immunisation coverage survey.[17] Underlying this is the fact that socioeconomic and health inequalities have continued to be a huge problem, despite the end of apartheid over two decades ago.[15] The inequalities are evident in the uneven access to health care services such as immunisation, despite the country's substantial investments and efforts at ensuring universal access to routine childhood immunisation.[40]

Vaccines can prevent diseases only if they reach the target population in need. The 2009/2010 measles outbreak across SA and more recent outbreaks in some provinces including the Western Cape, raised concerns about the suboptimal levels of immunisation coverage across provinces, districts and communities.[20,24] An additional challenge is posed by the COVID-19 pandemic, which has disrupted immunisation services while undermining immunisation coverage progress globally.[18] Adequate and equitable access to immunisation is important, not only for the attainment of global immunisation coverage targets, but also those of the Universal Health Coverage (UHC) agenda and Goal 3 of Sustainable Development Goals (SDGs) by 2030.[41,42]

While there is growing evidence that MOV constitutes a major burden globally and across sub-Saharan Africa,[26-30] not much is known about the burden and determinants of MOV in SA. Although a 2015 cross-sectional study conducted across selected health facilities in Cape Town found a low MOV prevalence of 5% among children aged 0 – 5 years, the magnitude of the burden remains uncertain.[20] The study was likely to have underestimated the prevalence of MOV by

sampling children up to 5 years of age, who are much older than the 23-month age cut-off recommended by the WHO MOV strategy. Given that children should have received the last dose of the primary series vaccine by 18 months of age in SA, a child who is currently 5 years old who missed the 4th dose of hexavalent vaccine at 18 months would have had more than 3 years to catch-up, thus less likely to remain unvaccinated at the current age, compared with another child who is currently aged 23 months. The study found inadequate immunisation training and knowledge among health care providers, as well as heavy workloads, as the main factors associated with MOV. A preliminary analysis of the latest SA Demographic and Health Survey (SADHS) data shows an MOV prevalence of 36% in the Western Cape Province.[43] The study identified individual-level factors such as maternal attendance of antenatal care during pregnancy and geographical factors such as province of residence as significant determinants of MOV.

1.6 Novelty and public health significance

The value which vaccines deliver today in SA remains far below the substantial benefits they can offer.[5] While there have been significant investments and efforts at ensuring universal access to immunisation services in SA, it is evident that in some districts and many neighbourhoods, there are eligible children who are missing out on this very critical health intervention.[14,21] How much of this gap is due to MOV remains uncertain. The mechanism and contextual factors associated with MOV in SA are less certain, as are the role and effectiveness of quality improvement interventions for addressing the problem.

There has been an increasing impetus to conduct MOV assessments, to better understand the magnitude and determinants of MOV at global, national and sub-national levels.[44-46] In 2016, the Strategic Advisory Group of Experts on immunisation (SAGE), based on evidence showing global MOV prevalence to be 32%, recommended the prioritisation of MOV assessments as a global health agenda.[46] While there is currently limited evidence around the structural and contextual factors responsible for MOV in different contexts, research efforts in this area have increased in recent years. As a result, there is an increasing body of evidence on the prevalence of MOV and

its associated factors over the last decade, including in African and other LMIC contexts.[26,44,45,47-49] To date, however, there remain enormous gaps in what is known. Particularly, very little evidence exists on the burden and determinants of MOV in SA.[20] Much less certain is the evidence on the role and effectiveness of interventions for addressing MOV, with very little evidence on these in Africa, and none in SA.[50]

Understanding the magnitude and enablers of MOV is important for policy and practice as it will provide valuable research evidence to inform the adoption of context-appropriate interventions for strengthening immunisation programmes. Such understanding has become even more important for guiding efforts aimed at undoing the proven adverse impact of the COVID-19 pandemic on routine immunisation services.[18] It will help inform the institution of locally-responsive immunisation strategies and interventions, to optimise immunisation access and coverage. Therefore, this study will have local and national policy and practice implications in SA and Africa in general. It will inform strategies for ensuring efficient immunisation service delivery, while fostering equitable and improved immunisation coverage towards the attainment of the post-2020 GVAP targets, UHC agenda and health-related Sustainable Development Goals (SDGs).[52-54]

While a few studies have assessed the burden of MOV in the SA context,[20,51] this will be the first study in SA to estimate the burden and associated factors of MOV, while also implementing and evaluating the effectiveness of a quality improvement intervention to address the burden. Additionally, because this study will be conducted in PHC facilities across various sub-districts in Cape Town, it can help unravel geographical differences in the burden and determinants of MOV across the sub-districts in Cape Town. This is important to understand why opportunities are being missed and how socioeconomic disparities affect MOV and immunisation access in a post-apartheid national context of lingering socioeconomic inequalities. Such findings will help to inform policies and interventions that can address equity gaps in immunisation access.

The MOV burden assessment will employ a mixed-methods approach. It will use a stratified sampling technique, a multilevel quantitative design and appropriate statistical methods for analysing the data. These will be integrated with qualitative methods that are appropriate for

exploring the factors and contextual mechanisms of MOV. Interpretation of the findings will be guided by pre-defined conceptual frameworks. The implementation and evaluation of the quality improvement remedial intervention will be founded on an empirically-sound and evidence-based implementation research framework.

Overall, the pragmatic study design employed in this research can quantify the burden of MOV with contextual precision, while demonstrating the impact of the implemented quality improvement intervention for reducing the burden. It will contribute important evidence for strengthening immunisation-related policy and practice through the use of multifaceted approaches to address MOV and improve immunisation coverage. In addition, the study is in line with the quality improvement mandates of the National Core Standards and Ideal Clinic initiatives in SA.[52,53] Furthermore, the real-world setting of this research has practical and contextual implications, allowing the direct applicability of findings and recommendations for improving routine immunisation coverage at facility, provincial and national levels. In the short to medium term, findings will provide health facility-level change ideas and strategies that can be sustained beyond the study period in the selected facilities. In the long term, the interventions can be potentially scaled up across other PHC facilities in the province and beyond.

1.7 Research questions and objectives

1.7.1 Research question

Do MOVs among children aged 0 – 23 months constitute a significant burden in Cape Town, and how can quality improvement help to address the problem?

1.7.1.1 Specific research questions

1. What is the magnitude of the burden of MOV, and what are the factors associated with it among children aged 0 – 23 months in Cape Town's PHC facilities?

2. Based on the experiences and perspectives of caregivers, what are the contextual determinants and mechanisms of MOV among children aged 0 – 23 months who attend PHC facilities in Cape Town?

3. Based on the experiences and perspectives of health facility staff, what are structural factors and mechanisms of MOV among children aged 0 – 23 months who attend PHC facilities in Cape Town?
4. Can a quality improvement intervention reduce the occurrence of MOV among children aged 0 – 23 months attending PHC facilities in Cape Town?
5. What are the enablers and barriers to the implementation of a quality improvement intervention to address MOV among children aged 0 – 23 months attending PHC facilities in Cape Town?

1.7.2 Research aim

To investigate the burden and factors associated with MOV among children aged 0 – 23 months in Cape Town, and how a quality improvement approach can be used to address the burden.

1.7.3 Specific objectives

1. To determine the magnitude of MOV occurences and assess factors associated with MOV among children aged 0 – 23 months attending PHC facilities in Cape Town.
2. To describe the contextual mechanisms of MOV from the experiences and perspectives of caregivers of children aged 0 – 23 months attending PHC facilities in Cape Town.
3. To describe the structural factors and mechanisms of MOV from the experiences and perspectives of health facility staff of PHC facilities in Cape Town.
4. To implement and evaluate a quality improvement intervention for addressing MOV among children aged 0 – 23 months attending PHC facilities in Cape Town.
5. To describe the enablers and barriers to implementing a facility-based quality improvement intervention to address MOV in PHC facilities in Cape Town.

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Chapter 2: Literature review and overview of research methods

About this chapter

This chapter provides a comprehensive overview of the current evidence on the burden and determinants of missed opportunities for vaccination and the role of quality improvement in the context of health services and routine immunisation in particular. It also explores the potential role of quality improvement in addressing missed opportunities for vaccination. Furthermore, it outlines the methodological approaches used in this PhD research as they relate to the broad aim and five specific objectives and research questions defined in the previous chapter. A publication related to this chapter is accessible via: https://doi.org/10.3390/vaccines9070691; with full citation as follows:

Nnaji CA, Wiysonge CS, Lesosky M, Mahomed H, Ndwandwe D. COVID-19 and the Gaping Wounds of South Africa's Suboptimal Immunisation Coverage: An Implementation Research Imperative for Assessing and Addressing Missed Opportunities for Vaccination. Vaccines (Basel). 2021 Jun 23;9(7):691. DOI: 10.3390/vaccines9070691.

2.1 Global, regional and national burdens of missed opportunities for vaccination

South Africa (SA), like other low-and-middle-income countries, grapples with the daunting challenges of suboptimal immunisation coverage at both national and subnational levels.[1] Socioeconomic and health inequities persist in the country, nearly three decades following the end of apartheid.[2] Such inequities manifest in the unequal access to health care services such as routine childhood immunisation, despite substantial investments and efforts at ensuring universal access to immunisation.[3] Currently, about 3 out of every 10 children in the country are not fully immunised, and the country remains behind in terms of actualising the global immunisation coverage targets.[4,5]

Missed opportunities for vaccination (MOV) are widely recognised as a contributor to low immunisation coverage, with a systematic review estimating its global prevalence to be 32% among children who visited a health facility.[6] In LMICs, the pooled MOV prevalence was 32.2%, but widely varied across countries.[7] In sub-Saharan Africa, the prevalence ranges from as high as 89% in Gabon to as low as 16% in Swaziland.[8,9] Moderately high MOV prevalence estimates have been reported in places like Nigeria (17% to 39.1%)[10-12] and Chad (51%).[13] A 2015 cross-sectional study conducted across selected health facilities in Cape Town, SA, found a low MOV prevalence of 5% among children.[14] However, the study assessed MOV in children aged 0 – 5 years, including children older than the conventional 0 - 23 months birth cohort specified by the WHO's MOV assessment strategy.[13,15] Inclusion of children up to 5 years of age may have led to an underestimation of the burden, as older children were likely to have had time to catch up with missed vaccine doses.

2.2 Factors associated with MOV

Individual-level factors found to be associated with MOV include child's age, birth order, number of under-five children in the household, maternal age, household income, maternal level of education, attendance of antenatal care and media access.[8,16-19] Neighbourhood-level and contextual determinants have also been reported, including socio-economic disadvantage (a composite measure of literacy, unemployment, rurality and poverty levels).[8,9] Other factors like

the reason for children's health facility visit (such as a healthy child accompanying an ill caregiver to the clinic), health facility proximity, health facility travel time and the number of vaccinators available were found to be associated with MOV.[9,12] MOVs also depend on specific vaccine antigens. A study done in Nigeria found MOV to be highest for inactivated polio vaccine (IPV) and measles vaccine, compared with others.[12] In SA, inadequate immunisation training and knowledge among health care providers, as well as heavy workloads, were found to be associated with MOV.[14]

2.3 Current approaches to assessing and addressing MOV

Different methodologies have been used to assess MOV in many contexts.[13,20-28] In response to the need for a standard MOV assessment strategy as parts of efforts at bolstering global immunisation coverage rate, the WHO developed an updated global methodology for countries to assess and address MOV.[29] The methodology was adopted by the WHO in 2016.[30] This strategy involves the systematic analysis of the burden of MOV using appropriate methods and tools.[29] It also involves the implementation of innovative and context-specific interventions to improve vaccination coverage, while utilising existing routine immunisation delivery systems.[30,31] Specifically, the MOV strategy seeks to answer three important questions: what is the burden of MOV, what are the reasons for the missed opportunities, and what can be done to address these?[31] By addressing MOV as an intermediate outcome, the ultimate goal is to improve immunisation coverage.[32]

The feasibility and effectiveness of the MOV strategies depend on prevailing contextual and structural factors, including the functionality of existing health systems and the appropriateness of the strategy within specific contexts.[33] Deficiencies in basic facility-level resources such as improper health records management, inadequate cold chain facilities or low human resource capacity can undermine the impact of the strategy in mitigating MOV.[33,34] For example, due to inadequate human resource resulting in long waiting time, a caregiver may consider the cost of waiting for immunisation services as exceeding that of possible illness in the future.[35] Therefore, there is a need to integrate MOV strategies into broader health systems strengthening frameworks that address such contextual and structural issues.[36]

2.4 Quality improvement and its role in the context of health services

Quality improvement (QI) was originally used in industrial settings to improve systems and processes for optimal efficiency and outputs. It involves the implementation of a tailored change intervention with an iterative and continuous outcome and process measurement, and systematically tracking progress towards the targeted outcome.[37] Quality improvement has become a commonly used approach for addressing service delivery gaps in healthcare contexts.[37] The Institute of Medicine (IOM) defined 6 distinct dimensions of quality: effectiveness, equity, patient-centeredness, timeliness, efficiency and safety.[38] Quality improvement methods have increasingly been used for addressing patient, provider, and systems related problems in health care settings.[39] The approach relies on the collaborative efforts of diverse stakeholders to develop and implement change ideas that can result in improved system outcomes.[39] It involves an iterative process of implementing change interventions or change ideas, as well as the continuous evaluation of processes and outcomes, with a reflection on facilitators and barriers of the change process.[40]

There are different QI models and methodologies.[41-43] While the scientific principles behind these different models are conceptually similar, the choice of which method to apply depends on the type of change needed, as well as the context in which change is needed. For example, the Six sigma framework is a commonly used QI model for correcting defects within systems.[44] The framework consists of the Define Measure Analyse Improve and Control (DMAIC) and Define Measure Analyse Design and Verify (DMADV) models.[44] Another type of QI framework is the Lean method, which is useful for reducing wastes within systems.[44]

A more commonly used QI model in health care is the Plan-Do-Study-Act/Plan-Do-Check-Act (PDSA/PDCA) model.[45] It focuses on reducing gaps in process performance using an experimental approach, involving a sequential identification and selection of small changes that are then tested in multiple PDSA/PDCA cycles. Typically, PDSA cycles involve planning change, testing change ideas, monitoring the effect of change ideas, and reflecting on ways to modify change ideas and associated factors for better outcomes.[45] A similar framework known as the Model for Improvement (MFI) method builds on the PDCA/PDSA model in implementing, evaluating and

improving process effectiveness and efficiency in health care and other fields.[46] This framework seeks to answer three fundamental questions: *what are we trying to accomplish, how will we know that a change is an improvement and what changes can we make that will result in improvement.*[47] The MFI approach has demonstrated some success in health care but not without its shortcomings. One major criticism is the model's lack of tools to guide implementation in the "Do" step of the PDSA cycle.[48] To address this limitation, the Getting To Outcomes (GTO) model was developed. The GTO model incorporates a multi-step comprehensive QI approach, including the use of PDSA cycles. It involves an iterative and more comprehensive process of planning, implementation, evaluation, continuous QI and sustainability.[48]

Quality improvement approaches have been used across diverse health care settings, such as disease diagnostics and treatment, maternal and child health and infection control.[49-52] Within the SA health system, the National Department of Health frames QI as involving activities or processes that are designed to improve the acceptability, efficiency and effectiveness of service delivery and contribute to better health outcomes as an ongoing and continuous process.[53] It is also prioritised as a key element in the implementation of the National Core Standards.[54] In the WHO's health systems strengthening framework, quality was identified as an important element for attaining improved health outcomes, including equity and efficiency.[55]

There is however currently a dearth of literature on the implementation and effectiveness of QI strategies in the context of MOV at global, regional and national levels.[56] The limited evidence available however suggests that QI can be used to implement change ideas targeted at vaccine demand- and supply-side factors, as well as health facility-level and other structural factors associated with MOV.[56] Available evidence also demonstrates that health facility workers were capable of co-designing and implementing QI change ideas that were tailored to their local context. It also showed how a context-appropriate QI programme can be used to improve immunisation service delivery in primary health care (PHC) settings.[56,57]

While QI has a lot of promises for addressing health system gaps at various levels, it is noteworthy to acknowledge a fundamental limitation of its use in the context of MOV. Although QI interventions can help mitigate vaccine demand/supply-side and health facility-level structural

enablers of MOV, they may have limited impact on broader structural and social determinants of MOV that are over and above those mediated by facility-level dynamics. As such, for optimal outcomes, MOV interventions need to be effectively integrated into broader health strategies that can comprehensively address individual, contextual and structural barriers to immunisation access.

2.5 Research conceptual framework and overview of research methods

2.5.1 Conceptual framework

This doctoral research employed a mixed-methods approach, integrating both quantitative and qualitative methods. In line with the five specific objectives earlier highlighted, there were five distinct but complementary component studies. A consolidated conceptual framework (see **Figure 2.1**) was developed based on existing literature, to demonstrate the relationship between the identified individual (child and parent/caregiver) and health facility-level factors, and MOV.[7] It was also based on the current MOV strategy of the WHO that uses a mixed-methods approach to triangulate quantitative and qualitative data from a broad range of sources including caregivers, health workers and health facility managers.[13] This strategy aims to answer three important questions: (1) how many opportunities are being missed, (2) why are these opportunities being missed, and (3) what can be done to reduce the missed opportunities? The framework illustrates the multilevel and multidimensional nature of factors associated with MOV, and shows the hierarchical pathways and dynamics leading to outcomes that can result from implementing a QI programme using PDSA cycles. As earlier highlighted, PDSA cycles typically involve planning change, testing change ideas, monitoring the effect of change ideas, and reflecting on ways to modify change ideas and associated dynamics to improve outcomes.[45] The conceptual framework's theory of change highlights the links between identified individual-level and facility-level factors and MOV, and how PDSA QI processes can result in the targeted goal of reducing MOV.[58]

The ultimate goal of reducing MOV is to increase immunisation coverage. This is a long term outcome that requires ample time to evaluate. As such, the time-frame of this doctoral research

cannot allow for the assessment of this ultimate goal. Nevertheless, the conceptual framework accounts for this potential long term impact of the implemented QI intervention on immunisation coverage rate within the study context.

Figure 2.1 below illustrates the consolidated conceptual framework for this research:

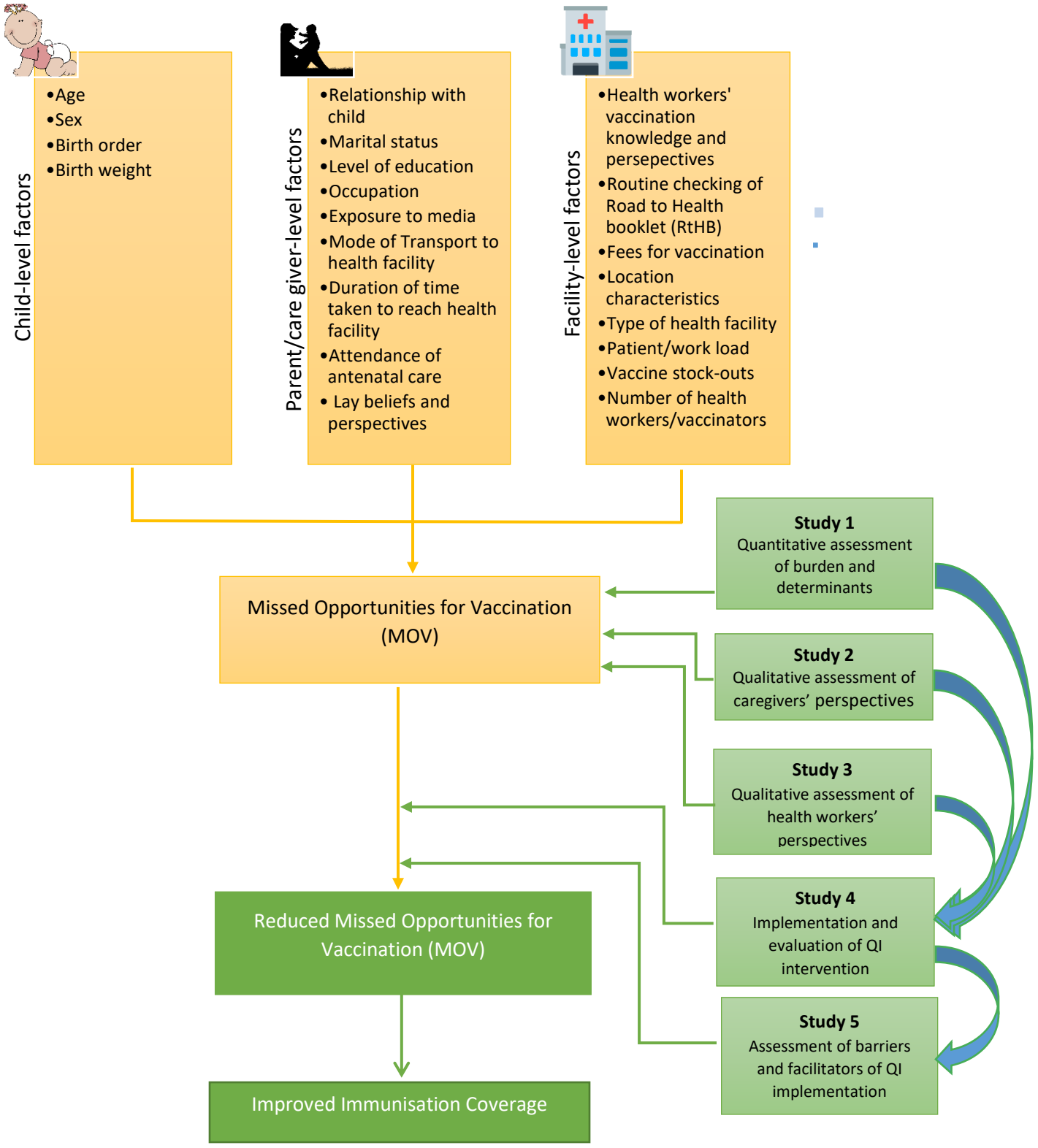

Figure 2.1. A conceptual framework illustrating the relationship between individual- and facility-level factors of MOV and the role of quality improvement.

2.5.2. Overview of research objectives and corresponding component studies

The sub-section summarises the design and methodology of the five component studies. Each study will be described in more detail later in their respective chapters.

2.5.2.1 Study 1

Objective: To determine the magnitude of MOV occurrences and assess factors associated with MOV among children aged 0 – 23 months attending PHC facilities in Cape Town.

Study design: A cross sectional, multi-level analytical study design was used for this objective. Hierarchical quantitative data were collected at two levels (child and caregiver as level 1, and facility as level 2). The multi-level analytical approach was to account for potential clustering of both facility-level and contextual characteristics that may be associated with MOV.

Study participants: Caregivers of children aged 0 – 23 months attending PHC facilities in the Cape Town Metro for any type of health service on the day of assessment were included in this study. To be eligible for inclusion, the child must have been brought to the PHC facility by a caregiver aged 18 years or older. If a caregiver visited the hospital with two or more children, the youngest child's data were primarily collected for the study. This was to avoid overrepresentation of primary respondents (parents/caregivers).

Sampling and data collection approach: Participating health facilities were selected using a modified one-stage cluster sampling approach. Each selected PHC facility was considered as a cluster, from which eligible and consenting caregivers with a child aged 0 - 23 months were enrolled in the study until cluster sample size was reached. Data were collected through exit interviews using an interviewer administered structured questionnaire. This questionnaire was adapted from the WHO tool for assessing MOV in health care settings.[31] Outcome variable (MOV) was defined based on the World Health Organization (WHO) definition as a binary variable of whether or not a 0 – 23 month-old child had any contact with a PHC facility but remained unvaccinated to any vaccine doses for which the child was eligible.[29] Explanatory variables were

grouped at two levels. **Level 1 included individual c**hild-related and caregiver related factors. **Level 2 included h**ealth facility-related factors

Data analysis: Multilevel binomial logistic regression models were fitted using the Markov Chain Monte Carlo (MCMC) method.[59] The models were used to explore individual and contextual factors associated with MOV, with children aged 0 – 23 months at Level 1, nested within PHC facilities (Level 2).

2.5.2.2 Study 2

Objective: To determine the contextual mechanisms of MOV from the experiences and perspectives of caregivers of children aged 0 – 23 months attending PHC facilities in Cape Town.

Study design: An exploratory qualitative phenomenology design involving focus group discussions (FGDs).

Study participants: Caregivers of children aged 0 – 23 months attending PHC facilities in the Cape Town Metro Health District for any type of health service on the day of the assessment. To be eligible for inclusion in this study, the child must have been brought to the facility by a parent/caregiver aged 18 years or older.

Sampling and data collection: Parents or caregivers of children aged 0 – 23 months attending PHC facilities were purposively selected. Qualitative data were collected using focus group discussions with participating caregivers. Discussions were guided by a semi-structured question guide from the WHO tool for assessing MOV in health care settings.[31]

Data analysis: A thematic template analysis approach was used for coding and organising transcribed data segments for analysis.[60] A codebook was used to specify factors identified from the discussion and identify emerging themes inductively.[61] A second codebook was developed based on the 14 domains of the theoretical domains framework (TDF).[62] The themes identified in the first codebook were deductively matched to the corresponding TDF domain, and ultimately interpreted using the capability, opportunity and motivation model of behaviour (COM-B).[63]

2.5.2.3 Study 3

Objective: To determine structural factors of MOV from the experiences and perspectives of staff of PHC facilities in Cape Town.

Study design: Qualitative design using in-depth interviews involving in-depth interviews

Study participants: Staff and facility managers of PHC facilities in the Cape Town Metro Health District.

Sampling and data collection: Health workers and facility managers of PHC facilities were purposively selected. In-depth qualitative interviews were conducted with a purposively selected group of health workers. Interviews were guided by a semi-structured question guide from the WHO tool for assessing MOV in health care settings.[31]

Data analysis: Same thematic template analysis approach as described for Study 2 above.

2.5.2.4 Study 4

Objective: To Design, implement and evaluate a QI programme for addressing MOV among children aged 0 – 23 months attending PHC facilities in Cape Town.

Study design: This study was based on a plausibility evaluation design to determine the effect of the implemented QI intervention on MOV, and to demonstrate that any effect observed was plausibly due to the intervention rather than external or confounding factors.[64] Two PHC facilities implemented the QI intervention, while two other facilities served as control.

Implementation phase: The GTO model was used to guide the design and implementation of the QI intervention by stakeholders in the two intervention facilities. The intervention was implemented in two Plan-Do-Study-Act (PDSA) cycles.[65]

Evaluation phase: The evaluation involved a non-randomised controlled study using an interrupted time-series analysis (ITSA) approach to compare changes in the outcomes of interest between intervention and control arms as well as between pre-intervention and intervention periods of the study.

Data analysis: ITSA was conducted by fitting Newey ordinary least-squares (OLS) regression models to produce regression coefficients of weekly MOV trends, with their corresponding standard errors, p values and 95% confidence intervals Cis).[66] Models were used to compare

weekly MOV trends and other relevant outcomes between intervention and control arms of the study, while controlling for pre-implementation (baseline) and seasonal trends during the intervention period.

2.5.2.5 Study 5

Objective: To describe the enablers and barriers of implementing a facility-based quality improvement intervention to address MOV in PHC facilities in Cape Town.

Study design: A mixed-methods post-evaluation evaluation using a theory-informed implementation research design. This was conducted after the implementation of the second QI PDSA cycle.

Study participants*:* Health care staff of the two PHC facilities where quality improvement was implemented and evaluated.

Sampling and data collection: For the quantitative aspect of the study, a self-administered, structured questionnaire was used to collect data from PHC facility staff. The questionnaire consisted of a rating scale developed based on the five domains of the consolidated framework for implementation research (CFIR) guidance: characteristics of the intervention, inner setting, outer setting, characteristics of individuals, and implementation process.[67] The qualitative component involved In-depth interviews conducted with PHC facility staff members who of the participated in QI implementation. A semi-structured interview guide based also on the five domains of the CFIR was used to elicit responses from the participants.

Data analysis: For the quantitative aspect, an exploratory factor analysis was conducted to explore the factor structure of the rating tool. Median scores with their corresponding interquartile ranges (IQR) were calculated for each item across CFIR domains. Similarly, domain-level median scores with their corresponding IQRs were calculated for each domain. For the qualitative aspect, a template analysis approach was used for coding and organisation of data for analysis. The first codebook included broad and refined themes inductively developed based on the transcripts of the interviews, while the second codebook consisted of domains of the CFIR framework. Qualitative and quantitative findings were integrated across the five CFIR domains, by presenting median scores (with IQRs) and corresponding illustrative quotes under each item and domain.

2.6 Overview of data management

Data were collected using password-protected REDCap-enabled mobile tablets. Data quality assured using appropriate quality checks. All data collected were anonymised. Quantitative data were stored in a secured database accessible only to the principal investigator. After data collection, the data files were exported as CSV files from REDCap to Stata 14.2 for analysis. Audio recordings and transcripts were stored securely in password-protected devices and files accessible only to the lead researcher, and were securely deleted once transcription was finalised and verified for accuracy. All personal identifiers were removed from the interview and discussion transcripts before analysis. All recordings were deleted upon completion of the study.

2.7 Ethical considerations

Ethics clearance for this study was obtained from Human Research Ethical Committee (HREC) of the University of Cape Town (Reference number: HREC 579/2020). Signed informed consent was obtained from all study participants before data collection. It was explained to all study participants that participation was entirely voluntary and that they can withdraw their participation any time without any prejudice. Field data collectors were required to sign a research confidentiality agreement before the commencement of data collection.

Informed Consent Process: The content of the consent form was clearly explained to potential study participants by trained research assistants fluent in both English and local languages (Afrikaans and isiXhosa). Additional information, explanation and clarification was made whenever sought by potential participants or their interpreters, and when necessary simpler explanation was made to make the information as understandable as possible.

Privacy & Confidentiality Protection: Data were collected using password-protected REDCap-enabled mobile tablets. Data collected were stored on a secured database accessible only to the lead research team members. All personal identifiers were removed from the interview and discussion transcripts before analysis. All recordings were deleted upon completion of the study. Privacy and confidentiality were maintained during the informed consent process, as well as in the other aspects of the research.

Autonomy and Respect for Persons: Participants were provided with full disclosure of what participation in the study entails, its nature, objectives, benefits and risks, before they are asked to decide on granting or declining informed consent to participate. The decision to participate was entirely voluntary and even after granting informed consent, participants were at liberty to withdraw their participation at any stage of the study without consequences. In addition, the research did not pose any risks other than loss of earnings during the time taken to participate in the study, so it was not a perverse incentive that can be construed as coercion to participate.

Beneficence and Non-Maleficence: At the individual level, this study provided an opportunity, not only to identify children eligible for vaccination but not fully vaccinated at the time of the study, but to refer them immediately (on same-day) for catch-up vaccination at the respective health facilities before leaving. This was directly beneficial to research participants. Parents and caregivers of such children were provided with useful vaccine and related health information to parents and caregivers on the importance of timely vaccination, and why immediate catch-up vaccination was needed. In addition, this research provided an opportunity for the participants (caregivers and health care providers) to learn more about the benefits of vaccination and raise their awareness of MOV and factors associated with it. At the population level, the findings of the study can help inform public health policies and interventions towards the identification and reduction of the burden of MOV, which can ultimately lead to improved immunisation coverage and prevention of vaccine-preventable disease outbreaks.

While this research aimed to maximise the benefits for participants, while minimising the risk of harm (physical, psychological, social, legal or economic), there was a possibility of unintended harm. Such inadvertent risk of harm was however minimal, as the probability and magnitude of harm anticipated was no greater than the harm or discomfort encountered when seeking routine health services. Such harms might include the time cost of responding to exit interviews, focus group discussions and in-depth interviews. Minimising risk of breaches to privacy and confidentiality was through maintenance of participant's anonymity and securing assess to the collected data. Through the conduct of this research, we had anticipated that there might be a risk, however minimal, of social harms such as the realisation of social deprivation and its psychological impacts during the exit interviews and focus group discussions. Had there been

such incidents, we would have immediately reported the ethics committee and instituted a plan to follow-up with those participants.

Justice: The research aimed to generate information regarding the prevalence and associated factors of MOV among children, as well as innovative ways of addressing the problem. This knowledge was used to inform more effective intervention and/or the improvement of current immunisation service delivery framework. In compliance with the Declaration of Helsinki (2008). To ensure fairness, QI teams in intervention PHC facilities were encouraged to share their experiences and lessons learnt from the QI programme implementation and evaluation with those that did not have the chance to implement the QI intervention.

2.8 COVID-19 contingency plans

All data collection and research activities were conducted in accordance with contingency plans established as part of the research protocol, in line with existing COVID-19 protocols. Data collection was conducted in-person with adequate adherence to physical distancing measures and appropriate use of Personal Protective Equipment (PPE). For research site and data collection visits, research team members and data collectors were provided with the appropriate face masks or face shields/visors and alcohol-based hand disinfectants in line with the Western Cape Government Guidelines for PPE use during the COVID-19 pandemic.[68] Before the commencement of research site visits and data collection, data collectors underwent orientation and training on infection prevention and control (IPC) best practices and precautionary measures for conducting human subject research in infectious disease outbreak settings. This training was in accordance with the National Department of Health's COVID-19 Disease Infection Prevention and Control Guidelines.[69]

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Chapter 3: A pre-intervention multilevel assessment of missed opportunities for vaccination and associated factors among children in primary health care facilities in Cape Town, South Africa

About this chapter

This chapter reports findings from the first component study, based on the first specific objective of this doctoral research. The study was a quantitative assessment of the magnitude and determinants of missed opportunities for vaccination (MOV) among children attending primary health care facilities in Cape Town. It forms part of a mixed-methods pre-intervention, baseline assessment, findings of which were used to inform the design and implementation of a collaborative quality improvement programme to reduce the identified burden of childhood MOV in the study setting as reported in subsequent chapters. A publication related to this chapter is accessible via: https://doi.org/10.3390/vaccines10050785; with full citation as follows:

Nnaji CA, Wiysonge CS, Adamu AA, Lesosky M, Mahomed H, Ndwandwe D. Missed Opportunities for Vaccination and Associated Factors among Children Attending Primary Health Care Facilities in Cape Town, South Africa: A Pre-Intervention Multilevel Analysis. Vaccines (Basel). 2022 May 16;10(5):785. DOI: 10.3390/vaccines10050785.

Abstract

Background: While evidence increasingly points to the role of missed opportunities for vaccination (MOV) as a major contributor to suboptimal immunisation coverage globally, less is known about the magnitude and determinants of MOV in the South African context. This study aimed to assess the magnitude of MOV and associated factors among children aged 0 – 23 months attending primary health care (PHC) facilities in Cape Town.

Methods: The study was a pre-intervention baseline assessment involving a quantitative cross-sectional design. It used multilevel binomial logistic regression modelling to explore individual (child and caregiver) and contextual factors associated with MOV, with children aged 0 – 23 months at Level 1, nested within PHC facilities (Level 2). Bayesian Markov Chain Monte Carlo (MCMC) methods were used to fit the models. measures of association were reported as odds ratios (ORs) with their 95% credible intervals (CrIs).

Results: A total of 674 child-caregiver pairs participated in the study. The prevalence of MOV among children aged 0 – 23 months attending the participating PHC facilities was 14.1%, ranging from 9.1% to 18.9% across sub-districts in Cape Town. Antigen/dose-specific prevalence of MOV was highest for the second dose of measles vaccine (9.5%), while being lowest for the first dose of rotavirus vaccine (0.6%). Highers odds of MOV were observed among children whose caregivers had lower educational attainment, compared with those whose caregivers were more educated (Odds ratio [OR] = 3.53, 95% credible interval [CrI]: 1.13 - 11.03). Conversely, the odds of MOV occurrence were lower among children of caregivers who had recent exposure to immunisation messages (OR = 0.46, 95%CrI: 0.25 - 0.87), those in households where there was shared immunisation decision-making by both parents (OR = 0.21, 95%CrI: 0.07 - 0.62) and those attending PHC facilities with larger staff numbers (OR = 0.18, 95%CrI: 0.06 - 0.61).

Conclusion: The study shows the substantial magnitude of MOV during children's contact with PHC facilities in Cape Town and the multilevel nature of individual and contextual factors underlying it. The study identifies practical entry points for conceptualising quality improvement strategies capable of addressing MOV in the study setting and similar contexts.

3.1 Introduction

Immunisation has been recognised as one of the most impactful public health interventions, having been deemed a highly cost-effective means of preventing diseases, morbidity, mortality and disability.[1-3] Since the launch of the Expanded Programme on Immunisation (EPI) in 1974, over 100 million children are vaccinated every year across the world, helping to avert millions of child mortality from vaccine-preventable diseases.[4-6] Immunisation has also been proven to have indirect benefits beyond disease beyond prevention, including societal and economic benefits through the aversion of catastrophic health expenditures and the loss of human productivity due to ill-health.[7,8]

Notwithstanding the substantial progress made in expanding immunisation access globally since the inception of the EPI, evidence suggests that progress has slowed globally, as many countries continue to struggle to reach children in need.[9] In particular, South Africa (SA) faces a daunting challenge in current efforts to increase national immunisation coverage, in spite of the country's significant investments in the national immunisation programme over the past decade.[10,11] According to recent World Health Organization (WHO) and United Nations Children's Fund (UNICEF) estimates, national immunisation coverage has remained lower than the globally accepted standards of >90% across all vaccines in SA's routine immunisation schedule.[10] Compounding the coverage gaps are the adverse effects of the COVID-19 pandemic's disruption of essential health services, including routine immunisation.[12-15] Suboptimal immunisation coverage among children in SA has been linked to both individual-level factors like low socioeconomic status and low immunisation awareness, as well as health system-level issues like a lack of human resources, gaps in health workers' immunisation training, and vaccine stock-outs, among others.[16-19]

The WHO has recognised missed opportunities for vaccination (MOV) as a major contributor to sub-optimal immunisation coverage globally.[20,21] To accelerate immunisation coverage progress, the WHO recommends the provision of immunisation services to individuals at every contact with the health system.[20] The WHO thus defines a missed opportunity for vaccination as "any contact with health services by an individual who is eligible for vaccination (unvaccinated or not up-to-date, and free of contraindications to vaccination), which does not result in the individual receiving all the vaccine doses for which s/he is eligible".[22] The prevalence of MOV varies widely across countries, with an average of 32.2% in low- and

middle-income countries (LMICs).[23] In sub-Saharan Africa, the prevalence ranges from 89% in Gabon to 16% in Swaziland.[24,25]

Missed opportunities typically occur during children's contact with health facilities, either for vaccination or non-vaccination services.[22] Common reasons for MOV occurrence include the inability of health workers to screen children's immunisation status to identify if children are up to date with age-eligible vaccine doses during health facility encounters; perceived contraindications to vaccination on the part of providers and parents; vaccine shortages; and rigid clinic schedules that separate immunisation from other health services.[22] Individual-level factors found to be associated with MOV include child's age and birth order; maternal age, level of education, media access and attendance of antenatal; and household income.[24,26-29] Contextual and health system factors such as caregiver perception of vaccination, area of residence, proximity of health facility and availability of health workers/vaccinators have also been found to be associated with MOV.[25,30,31]

To enhance understanding of the burden and enablers of MOV, there have been increasing efforts to assess MOV as a public health priority globally.[32-34] Research efforts in this area have particularly grown over the last decade, including in African and other LMIC contexts.[24,25,30,32,33,35] However, little is known about the extent of MOV and underlying determinants in the SA context.[16,36] Initial findings from our secondary analysis of the 2016 South African Demographic and Health Survey (SADHS) data suggested a significant burden of MOV in SA, with estimated national prevalence of 42% among children aged 12-23 months and provincial prevalence of 36% in the Western Cape.[37] The study identified individual-level factors such as maternal attendance of antenatal care during pregnancy and geographical factors such as province of residence to be significantly associated with MOV.

The current study employed standard MOV assessment methods to assess the magnitude of MOV and associated factors among children aged 0 – 23 months attending public PHC clinics in Cape Town. This study is part of a comprehensive baseline assessment involvement both quantitative and qualitative methods, findings of which will help to inform the design and implementation of a facility-level quality improvement intervention to address MOV in PHC settings. Findings will help to identify practical quality improvement strategies and interventions that can be scaled up across districts, provinces and nationally for strengthening

immunisation service delivery and closing current coverage gaps in Cape Town and SA in general.[38]

3.2 Methodology

3.2.1 Study design

A cross-sectional study design was used to quantify the burden of MOV and assess associated factors across individual (child and caregiver) and contextual (subdistrict and facility) levels. To determine the factors associated with MOV at the various levels, multilevel regression modelling methods were used to analyse the data given the hierarchical nature of the data, while helping to account for potential clustering of individual-level characteristics within health facilities. It is considered more appropriate for hierarchical data than conventional regression modelling, which can lead to underestimated coefficients and overstated coefficient significance.

3.2.2 Study Setting

This study was conducted in PHC clinics across five health subdistricts within the Cape Town Metropole. Cape Town is one of the largest municipalities in SA.[39] The Cape Town Metro Health district has 8 legislated sub-districts serving a population of 4.1 million persons.[40] There are 152 PHC facilities, 102 of which are managed by the City of Cape Town (local government) to supplement PHC services provided by the provincial government.[40] Routine immunisation services in Cape Town, like elsewhere in SA, are funded through the Expanded Programme on Immunisation of South Africa (EPI-SA) and are provided free of charge mainly through the clinics and other primary-level health facilities.[41] The current routine immunisation schedule for children in SA is outlined in **Table 3.1**.

Table 3.1. Current routine childhood immunisation schedule in SA

Age	Vaccine offered
Birth	BCG, OPV (0)
6 Weeks	OPV (1), RV (1), DTaP-IPV-Hib-HepB (1), PCV (1)
10 Weeks	DTaP-IPV-HIB-HepB (2)
14 Weeks	RV (2), DTaP-IPV-Hib-HepB (3), PCV (2)
6 months	Measles (1)
9 Months	PCV (3)
12 months	Measles (2)
18 Months	DTaP-IPV-Hib-HepB (4)
6 years	Td (1)
9 years	HPV (1), HPV (2) (2 doses, 6 months apart)*
12 years	Td (2)

BCG = Bacille Calmette Guerin, DTaP-IPV-Hib-HepB = hexavalent vaccine (containing diphtheria, tetanus, pertussis, inactivated polio, *Haemophilus influenzae* type b and hepatitis B vaccines), HPV = human papillomavirus vaccine, OPV = oral polio vaccine, PCV = pneumococcal conjugate vaccine, RV = rotavirus vaccine, Td = tetanus and reduced dose diphtheria vaccine.
*HPV vaccine is given as part of the school health programme rather than the EPI-SA

3.2.3 Study participants

The study involved caregivers whose children aged 0 – 23 months attended PHC clinics in Cape Town for any type of health service on the day of assessment. To be eligible for inclusion in the study, children had to be brought to the PHC facility by an adult caregiver (aged at least 18 years). If a caregiver visited the facility with two or more children, data was collected for the youngest child to avoid overrepresentation of caregivers with multiple children in the study sample.

3.2.4 Sample size estimation

According to the WHO MOV assessment methodology, the required sample size is a minimum of 600 child-caregiver pairs are requirement .[22,32] For this study, a minimum of 630

respondents was determined based on assumed MOV prevalence of 30% (on the basis of evidence from a previous systematic review that found the prevalence to be 32% in low-and-middle income countries[23]). Sample size estimation was also based on an alpha level of 0.05 (95% confidence interval), a margin of error of 5%, non-response rate of 20% and a design effect of 1.5.[23,42,43] A design effect adjustment was made to account for the clustering of respondents' characteristics within health facilities, given the hierarchical nature of the sampling technique used.

3.2.5 Sampling

A modified one-stage cluster random sampling method was used to select five health sub-districts from the eight subtracts in the Cape Metro health District. From the selected sub-districts, 11 PHC clinics were sampled using convenience sampling based on institutional approval. Each selected PHC facility served as a sampling cluster, from which all eligible and consenting caregivers with a child aged 0 - 23 months were enrolled into the study consecutively until study sample size was reached.

3.2.6 Data collection

Study data were collected through exit interviews using a structured, interviewer-administered questionnaire (see appendices) administered electronically on University of Cape Town's Research Electronic Data Capture (REDCap) platform using mobile devices.[44] The questionnaire was adapted from the WHO MOV assessment tool.[45] It was pre-tested before the commencement of data collection. The questionnaire has six sections relating to the child; parent/caregiver; the use of the Road to Health Booklet (RtHB) for checking vaccination status and information on vaccines administered; current visit; quality of vaccination service; and reasons for vaccination.

Exit interviews were conducted by trained research assistants fluent in English and local languages (Afrikaans and IsiXhosa). On each day of data collection, research assistants positioned themselves at the facilities' main exits. They approached caregivers accompanied by children as they exited the facility, provided details about the research and asked if they were willing to participate in the study. Consenting caregivers were then taken to private

rooms or space within the clinic premises where the study questionnaire was administered to them.

3.2.7 Variables

Outcome or dependent variable: MOV was defined based on the WHO definition as a binary variable of whether or not a 0 – 23 month-old child had any contact with a PHC facility on the day of data collection but remained incompletely by one or more vaccine doses for which the child was eligible.[22] Children's date of birth and date of assessment were used to determine if a child was up to date with immunisation based on the current SA national childhood immunisation schedule (**Table 3.1**), and if not, which vaccine doses had been missed. Children who were fully immunised for age and free of contraindications at the time of interview were categorised as not having MOV, while others were deemed to have experienced MOV.

Independent variables: These were stratified along across two levels:

- **Level 1 variables (individual-level): i**ncluded factors relating to the child (such as age of child, sex of child, birth order and birth weight) and those relating to the caregiver (such as caregiver relationship with child, marital status, mothers' attendance of antenatal care, level of education, employment status, mode of transport to health facility, duration of transport to health facility, exposure to media and awareness of childhood immunisation)

- **Level 2 variables (health facility-level):** included factors relating to the health facility or broader health system factors such as, facility size, location, number of staff, patient volume, number of vaccinators, vaccine availability or stockouts and how immunisation services are structured.

3.2.8 Data analysis

Continuous data like age were expressed as mean and standard deviations, while categorical data were expressed as frequencies and percentages. Due to the hierarchical nature of the data collected, a multilevel analytical approach was employed.[46] As an extension of generalised linear models, multilevel models help to address clustering of data by generating cluster-specific random effects.[47] For this study, a two-level binomial logistic regression modelling approach was adopted due to the binary nature of the outcome variable (MOV), with individual (child and parent/caregiver-related) factors at level 1, nested within PHC

clinics (at level 2). Four models were fitted; Model 1 was an empty (null) model with no explanatory variable; Model 2 contained only individual-level (child and caregiver) factors; Model 3 contained only facility-level factors; while Model 4 (full model) controlled for both individual and facility-level factors.

The Bayesian Markov Chain Monte Carlo (MCMC) approach was used to fit the models.[48,49] In this method, a Markov chain generates successive samples of parameters from their posterior distributions.[48,49] In this study, the MCMC model estimation settings were specified to achieve a burn-in period of 10,000 iterations followed by a monitoring period of 5000 iterations. From the posterior estimates, results of fixed effects (measures of association) were reported as odds ratios (ORs) with their corresponding 95% credible intervals (CrIs). For the random effects, variance, intraclass correlation coefficients (ICC) and median odds ratios (MOR) were measured to quantify the attributable influence of health facility-level factors on the outcome of interest. In the regard, ICC represents the percentage of the total variance in the odds of MOV attributable to the context (PHC facility), serving as a measure of clustering of the odds of MOV in the same PHC facility. Relatedly, MOR reflects the total variance in the probability of MOV that was attributable to PHC facilities on the odds ratio scale. The deviance information criterion (DIC) was used to assess model goodness of fit, with lower DIC indicating improved model fit.[48] Variance inflation factor (VIF) was used to assess multi-collinearity among explanatory variables. Multilevel analysis was performed using MLwiN version 3.01 and Stata 14.2, using the *runmlwin* command.[50,51]

3.2.9 Ethical considerations

Ethics clearance for this study was obtained from Human Research Ethical Committee (HREC) of the University of Cape Town (Reference number: HREC 579/2020; see appendices). In addition, institutional approval was granted by the Western Cape Provincial Department of Health (Reference number: WC_2021_01_016) and the City of Cape Town Department of Health (Reference number: 9365); copies of both documents are available as appendices. Signed informed consent was obtained from all study participants before data collection (see appendices for informed consent form). All study participants were made aware that they were at liberty to opt out from the study at any point without consequences. All data collected

are anonymous and were stored securely in a password-protected database accessible only to the research team.

3.3 Results

3.3.1 Participants' characteristics

A total of 674 children aged 0 – 23 months and their caregivers participated in the study, enrolled in 11 PHC clinics across five health sub-districts in Cape Town. The mean age (±SD) of the children was 7.5 (± 1.2) months. Most (92.5%) of the caregivers were mothers, with mean age of 29.3 (± 6.9) years. Immunisation visits accounted for the majority (79.3%) of children's health facility visits, while non-immunisation visits accounted for about a fifth (20%) of clinic encounters. Nearly all (99. 6%) of parents/caregivers brought their children's Road to Health Booklets (RtHB) to the clinic on the day of survey. **Table 3.2** presents the characteristics of study participants by socio-demographic and health facility characteristics.

3.3.2 Facility characteristics

All participating PHC facilities provided immunisation services either on a daily basis (that is, every day) or on most days. Health workers routinely asked to see children's RtHB (on 98.2% of the encounters). In terms of staff capacity, the majority (62.8%) of the health facilities had less than 50 health workers. Immunisation waiting time was 30 minutes or longer in 70.0% of the facilities. About a fifth (22.4%) of the facilities experienced vaccine stockouts in the past three months, while a small minority (5.7%) experienced vaccine cold-chain disruption in the past three months. Less than half (49.2%) of caregivers felt they were provided with sufficient information on the vaccines being administered to their children during immunisation encounters. Less than a fifth (16.8%) of caregivers received information on possible side effects of vaccines administered to their children.

3.3.3 Prevalence of MOV

Upon exclusion of children who were up to date and free of contraindications at the time of exit interview (110) and those with incomplete records (4), the remaining 561 children were included as denominator for estimating the prevalence of MOV and further analysis. Of these, 79 (14.1%) experienced MOV in at least one eligible vaccine dose. Variations in the prevalence

of MOV were observed across a number of individual- and facility-level variables. **Figure 3.1** below illustrates the estimation of MOV prevalence.

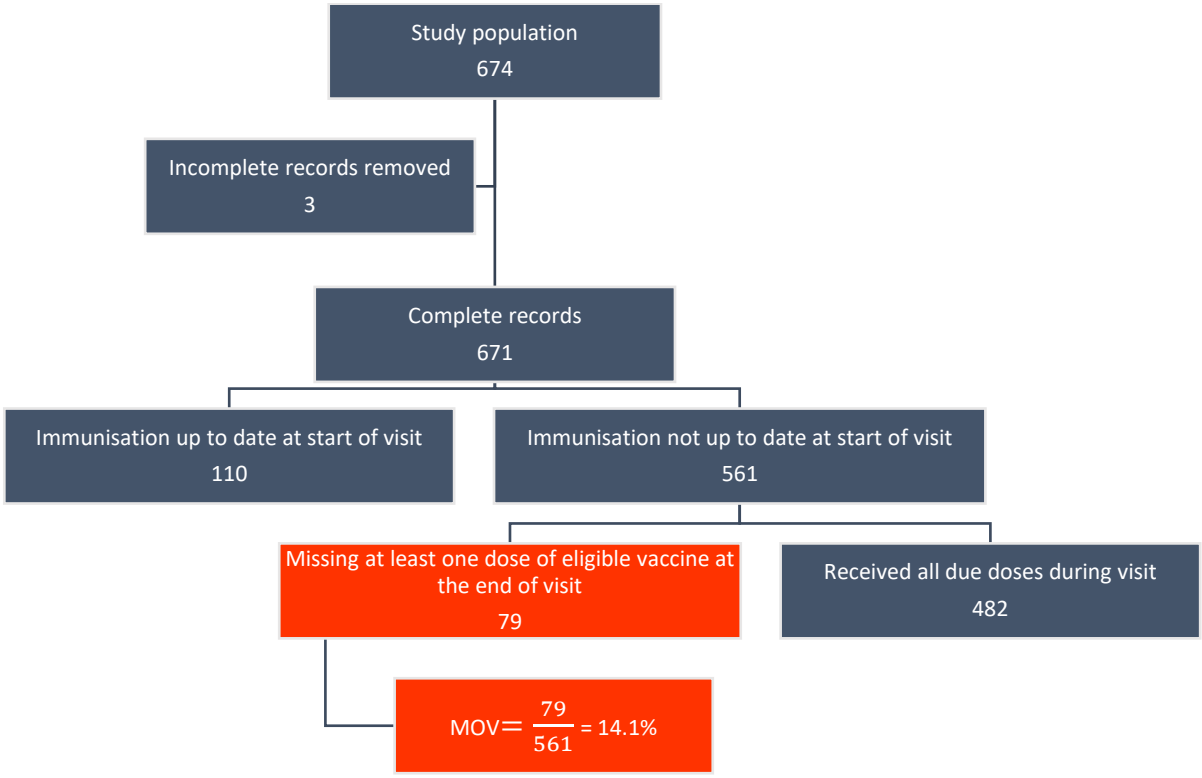

Figure 3.1. Flowchart of MOV prevalence estimation among children aged 0 – 23 months in Cape Town

As shown in **Table 3.2**, MOV prevalence ranged from 9.1% in Western health sub-district to 18.9% in Khayelitsha sub-district. The prevalence of MOV was higher among children whose mothers did not attend antenatal care during pregnancy (50.0%); whose caregivers had low (primary) level of education (26.9%); who were in the health facilities for non-vaccination services (20.4%); whose primary caregivers did not receive any immunisation message in the last three months (19.6%); and those whose caregivers walked to the health facility (i.e. did not have own transport) (17.1%).

Table 3.2. Prevalence of missed opportunities for vaccination among children aged 0 – 23 months attending primary healthcare facilities in Cape Town

Variables	**Number of children (%)**	**MOV prevalence (%)**	**p-value[#]**
All children	561	79 (14.1)	
Sub-district			
Southern	99 (17.8)	9 (9.1)	0.346
Western	38 (6.8)	5 (13.2)	
Tygerberg	240 (43.2)	32 (13.3)	

M/Plain	89 (16.0)	15 (16..9)	
Khayelitsha	90 (16.2)	17 (18.9)	
Facility-level factors			
Facility type			
Community health centre	269 (48.4)	36 (13.4)	0.671
Clinic	287 (51.6)	42 (14.6)	
Facility ownership			
Province	213 (38.2)	29 (13.6)	0.902
City	345 (61.8)	49 (14.4)	
Vaccine stockout in the past 3 months			
Yes	125 (22.4)	17 (13.6)	0.883
No	432 (77.6)	61 (14.1)	
Vaccine cold-chain challenges in the past months			
Yes	32 (5.7)	2 (6.3)	0.194
No	526 (94.3)	76 (14.5)	
Number of health workers			
Less than 50	349 (62.8)	56 (16,1)	0.075
50 or more	207 (37.2)	10 (10.63)	
Immunisation waiting time			
Less than 30 minutes	147 (30.4)	14 (9.5)	0.070
30 minutes or longer	336 (69.6)	51 (15.1)	
Child-level factors			
Age of child	Mean (SD): 7.5 (1.2) months		
0 – 11 months	420 (75.3)	62 (14.8)	0.148
12 – 23 months	138 (24.7)	16 (11.6)	
Sex of child			
Female	280 (49.9)	33 (11.8)	0.148
Male	281 (50.1)	45 (16.0)	
Birth order			
1st – 3rd order	501 (89.3)	67 (13.4)	0.294
4th + order	60 (10.7)	11 (18.3)	
Birth weight			
Large	141 (25.4)	23 (16.3)	
Average	351 (63.2)	47 (13.9)	0.556
Small	63 (11.4)	7 (11.1)	
Reason for visit			
Vaccination	445 (79.3)	55 (12.4)	0.038
Non-vaccination	116 (20.7)	23 (19.8)	
Time of visit			
Morning	342 (61.7)	48 (14.0)	0.970
Afternoon	212 (38.3)	30 (14.2)	
Caregiver-level factors			
Caregiver age	Mean (SD): 29.3 (6.9) years		
18 – 24 years	153 (27.4)	24 (15.7)	0.764

25 – 34 years	281 (50.4)	38 (13.5)	
35+ years	124 (22.2)	16 (12.9)	
Level of education			
Primary	26 (4.6)	7 (26.9)	0.049
Post-primary	535 (95.4)	71 (13.3)	
Relationship to child			
Mother	519 (92.5)	71 (13.7)	0.591
Other relation	42 (7.3)	7 (16.7)	
Marital status			
Not Married	369 (65.8)	56 (15.2)	0.227
Married	192 (34.2)	22 (11.5)	
Maternal antenatal care			
Attended	546	75 (13.7)	0.034
Never attended	6	3 (50.0)	
Employment status			
Employed	138 (30.0)	19 (13.8)	0.958
Unemployed	423 (70.0)	59 (14.0)	
Means of transport			
Own vehicle	61 (11.0)	3 (4.9)	0.027
Public transport	178 (32.0)	21 (11.8)	
Walk	318 (57.0)	54 (17.0)	
Child immunisation message in the last 3mo			
Yes	341 (61.3)	36 (10.6)	0.003
No	215 (38.7)	42 (19.5)	
Child immunisation decision-making			
Both parents	117 (20.1)	10 (8.6)	0.060
Not both parents	444 (79.1)	65 (15.3)	

[#] $\chi 2$ test for difference [*]p-value <0.05

3.3.4 Antigen/dose-specific MOV prevalence

Occurrence of MOV was most common for the second dose of measles vaccine (9.5%), fourth dose of the hexavalent vaccine; containing diphtheria, tetanus, pertussis, inactivated polio, *Haemophilus influenzae* type b and hepatitis B antigens (DTaP-IPV-Hib-HepB) (8.5%) and second dose of oral polio vaccine (OPV) (6.5%). It was lowest for the first dose of pneumococcal conjugate vaccine (PCV) (1.0%), first dose of rotavirus vaccine (RV) (0.6%) and first dose of DTaP-IPV-Hib-HepB (0.6%). Additional results on antigen/dose-specific MOV prevalence are presented in **Table 3.3**.

Table 3.3. Antigen/dose-specific missed opportunities for vaccination among children aged 0 – 23 months in Cape Town

Age of eligibility	Vaccine antigen (dose)	Number eligible	MOV (%)
	All doses	561	79 (14.1)
Birth	BCG	555	9 (1.6)
	OPV (0)	555	15 (2.7)
6 weeks	OPV (1)	520	34 (6.5)
	RV (1)	520	3 (0.6)
	DTaP-IPV-Hib-HepB (1)	520	3 (0.6)
	PCV (1)	520	5 (1.0)
10 weeks	DTaP-IPV-Hib-HepB (2)	439	6 (1.4)
14 weeks	RV (2)	381	14 (3.7)
	PCV (2)	381	12 (3.2)
	DTaP-IPV-Hib-HepB (3)	381	10 (2.6)
6 months	Measles (1)	287	12 (4.2)
9 months	PCV (3)	205	6 (2.9)
12 months	Measles (2)	137	13 (9.5)
18 months	DTaP-IPV-Hib-HepB (4)	59	5 (8.5)

BCG = Bacille Calmette Guerin, DTaP-IPV-Hib-HepB = hexavalent vaccine (containing diphtheria, tetanus, pertussis, inactivated polio, *Haemophilus influenzae* type b and hepatitis B vaccines), HPV = human papillomavirus vaccine, OPV = oral polio vaccine, PCV = pneumococcal conjugate vaccine, RV = rotavirus vaccine,

3.3.5 Measures of association (Fixed effects)

Table 3.4 shows the results of the four multilevel binomial logistic regression models to explore individual and contextual factors associated with MOV. In the fully adjusted model (Model 4), after controlling for the effects of individual (child and caregiver) and contextual (facility) level factors; caregiver level of education, recent receipt of immunisation messages by caregivers, shared immunisation decision-making by both parents and facility staff capacity were significantly associated with MOV. Children whose caregivers had only primary level of education had higher odds of MOV than those whose caregivers were more highly educated (OR = 3.53, 95%CrI: 1.13 - 11.03). Conversely, the odds of MOV were lower among children whose caregivers received immunisation messages in the past three months (OR = 0.46, 95%CrI: 0.25 - 0.87), compared with those whose caregivers had no recent exposure to immunisation messages. Likewise, children from homes in which there was shared decision-making about children's immunisation between both parents were less likely to experience MOV, relative to those from home with no shared parental immunisation decision-making (OR = 0.21, 95%CrI: 0.07 - 0.62). Another notable finding was that children attending health facilities with higher staff numbers (50 or more personnel) experienced MOV to a lesser extent, compared with those attending facilities with fewer staff (OR = 0.18, 95%CrI: 0.06 - 0.61).

2.3.6. Measures of variations (Random effects)

As shown in **Table 3.4**, in Model 1 (unconditional model), there was substantial variation in the odds of MOV across facilities (variance = 0.49, 95%CrI: 0.20 - 1.15). Based on the intra-facility correlation coefficient, 12.85% of the variance in the odds of MOV could be attributed to facility-level factors. Results of the median odds ratio (MOR) were also suggested the substantial influence of facility-level factors on children's odds of experiencing MOV. From the full model (Model 4), it was estimated that if a child moved to another facility with a higher probability of MOV, that child would experience a 2.03-fold increase in odds of MOV. The DIC values for Models 1, 2,3 and 4 were 445.87, 365.26, 447.38 and 366.17, respectively.

Table 3.4. Results of multilevel modelling showing **f**actors associated with missed opportunities for vaccination among children aged 0 – 23 months in PHC facilities in Cape Town

	Model 1[a] OR (95% CrI)	Model 2[b] OR (95% CrI)	Model 3[c] OR (95% CrI)	Model 4[d] OR (95% CrI)
INDIVIDUAL LEVEL FACTORS				
Age of child				
• 0 – 11 months		ref		ref
• 12 – 23 months		0.58 (0.27 -1.25)		0.61 (0.28 -1.35)
Sex of child				
• Male		ref		ref
• Female		0.63 (0.35 -1.14)		0.70 (0.39 -1.28)
Birth order				
• 1st – 3rd order		ref		ref
• 4th + order		1.83 (0.71 -4.74)		2.05 (0.79 -5.35)
Birth weight				
• Average		ref		ref
• Non-average		0.89 (0.58 -1.37)		0.74 (0.47 -1.16)
Reason for visit				
• Non-vaccination		ref		ref
• Vaccination		0.55 (0.61 -2.11)		0.69 (0.27 -1.76)
Time of visit				
• Morning		Ref		Ref
• Afternoon		1.13 (0.61 -2.11)		1.10 (0.58 -2.07)
CAREGIVER-LEVEL FACTORS				
Maternal age				
• 18 – 24 years		ref		ref

• 25+ years		0.73 (0.45 -1.16)		0.69 (0.43 -1.11)
•				
Maternal education				
• Post-primary		ref		ref
• Primary		3.03 (1.00 -9.2)		3.53 (1.13 -11.03)
Marital status				
• Not Married		ref		ref
• Married		0.92 (0.45 -1.86)		1.03 (0.50 -2.14)
Maternal antenatal care				
• No				
• Yes		0.51 (0.95 -2.70)		0.57 (0.11 -3.01)
Maternal employment				
• Employed		ref		ref
• Unemployed		1.29 (0.65 -2.57)		1.33 (0.66 -2.68)
Means of transport to facility				
• Own vehicle		ref		ref
• Public transport		1.49 (0.89 -2.50)		1.51 (0.88 -2.60)
Child immunisation message in the last 3 months				
• No		ref		ref
• Yes		0.45 (0.25 -0.84)		0.46 (0.25 -0.87)
Child immunisation decision-making				
• Other		ref		ref
• Both parents		0.28 (0.10 -0.80)		0.21 (0.07 -0.62)
FACILITY-LEVEL FACTORS				
Facility type				
• Clinic			ref	ref
• CHC			0.71 (0.31 -1.62)	0.72 (0.27 -1.94)

Facility ownership				
• Province			ref	ref
• City			1.95 (1.18 -3.23)	1.71 (0.90 -3.24)
Vaccine cold Chain disruption in last 3 months				
• No			ref	ref
• Yes			0.57 (0.12 -2.72)	0.18 (0.02 -1.71)
Vaccine stockout in the last 3 months				
• No			ref	ref
• Yes			1.35 (0.42 -4.30)	1.73 (0.42 -7.16)
Number of health workers				
• Fewer than 50			ref	ref
• 50 or more			0.33 (0.02 -0.13)	0.18 (0.06 -0.61)
Random-effect estimates				
Variance (95%CrI)	0.49 (0.20 - 1.15)	0.49 (0.18 - 1.34)	0.15 (0.01- 11.42)	0.54 (0.01 – 4.27)
ICC (%)	12.85	12.87	4.46	14.27
MOR (%)	1.94	1.94	1.45	2.03
Model fit statistics				
DIC	445.87	365.26	447.38	366.17

[a]Model 1 – empty null model, without any explanatory variables (unconditional model)

[b]Model 2 – adjusted for only individual-level (child and caregiver) factors

[c]Model 3 – adjusted for only contextual (facility) level factors

[e]Model 4 – full model, adjusted for individual- and facility-level factors

OR – odds ratio, CrI – credible interval, MOR – median odds ratio, DIC – Bayesian Deviance Information Criteria

;

3.4 Discussion

3.4.1 Summary of main findings

The prevalence of MOV was found to be 14.1% among children in the participating PHC facilities, ranging from 9.1% to 18.9% across sub-districts in Cape Town. In terms of specific vaccine antigens and doses, MOV occurrences were most common for the second dose of measles vaccine (9.5%), while being lowest for the first dose of rotavirus vaccine (0.6%) and first dose of DTaP-IPV-Hib-HepB vaccine (0.6%). Occurrence of MOV was observed to be higher among children whose mothers did not attend antenatal care during pregnancy (50.0%); those whose caregivers had lower (primary) level of education (26.9%); those attending the health facilities for non-vaccination services on the day of data collection (20.4%); those whose primary caregivers did not receive any immunisation message in the last three months (19.6%); and those whose caregivers walked to the health facility or did not have own transport) (17.1%). After controlling for the effects of individual, facility and contextual level covariates in the full multilevel regression model, factors such as caregiver level of education, recent exposure to immunisation messages, shared immunisation decision-making between both parents and facility staff capacity (number of staff) were found to be independently associated with the odds MOV among children during PHC facility encounters. These reflect the multilevel nature of the factors influencing the occurrence of MOV among children making contact with the health system in the study context.

3.4.2 Implications of study findings for immunisation practice and quality improvement

Although the level of MOV prevalence found in this study is relatively lower than those reported in previous studies conducted in other African and LMIC settings[23,32,35], it is nonetheless of substantial magnitude capable of undermining current efforts to improve immunisation coverage among children in Cape Town and SA in general. It is worthy of note that the prevalence observed in the current study is lower than the Western Cape province-wide prevalence of 36% found in our previous study using a national dataset[37], while higher than the 5% reported by another study in Cape Town.[16] It could be that these differences in observed prevalence are due to methodological difference, as the previous studies were based on data sources, MOV definitions, evaluation settings and time-frames different from those of the current study. Notwithstanding, the level of prevalence seen in the current study is likely to more accurately reflect the current trend in MOV occurrence in Cape Town, having

been based on standardised MOV assessment methods and more recent. Results thus represent a substantial burden of MOV that warrants attention and remedial efforts as part of broader measures to boost routine immunisation coverage among children in the Cape Town metropole and SA in general.

While many caregivers reported that health workers had asked to see their children's Road to Health Booklets (RtHB), we found that health workers did not always screen the booklets for children's immunisation status at every facility encounter. Interventions targeted at fostering routine immunisation status screening at all clinic encounters can quickly identify children with missed vaccine doses. It is thus important that health facilities and staff are equipped with the appropriate training, tools, standard operating procedures and resources to enhance their capacity for routine screening of children's immunisation status and the provision of catch-up vaccination to eligible children. This could involve strategies such as placement of reminder tags or stickers on children's RtHBs at the point of registration, prominent display of posters with MOV information in waiting rooms and routine supervision to improve RtHB screening compliance.

The study found that MOV prevalence varied by antigens and dose, being highest for the second dose of measles and the fourth dose of the DTaP-IPV-Hib-HepB vaccines. This suggests that immunisation status screening may be especially important for vaccines administered later in the immunisation schedule, which seem to have higher probabilities of MOV according to the current and previous research.[32] Well targeted facility-based immunisation and health messaging can help to raise caregivers' awareness and knowledge of the importance of completing immunisation series for all vaccines, and the consequences of not doing so, such as with the risk of measles outbreak when a significant proportion of the population are not vaccinated or incompletely vaccinated against measles. To ensure synergy between vaccination and other services, all health workers, including immunisation and non-immunisation personnel, must be able to correctly screen children's immunisation status and eligibility at all service delivery points. This is especially critical for mitigating the occurrence of MOV in children accessing non-immunisation services, as the likelihood of MOV may be higher in such settings.

Our study suggests that human resource constraints may be a determinant of MOV, with missed opportunities occurring more frequently among children attending facilities with

fewer staff, compared with those attending facilities with higher staff numbers. This is consistent with evidence from previous studies indicating that inadequate staffing is a major contributor to MOV occurrences.[52,53] Facilities with inadequate staff are less likely to screen children's immunisation status at every facility encounter, may have less capacity to administer immunisation on non-immunisation days and are more likely to experience long immunisation waiting times, all of which can ultimately contribute to MOV.[53,54] In settings of staff shortages, health facilities may consider leveraging non-clinical staff (such as administrative staff and security personnel) to assist with non-clinical aspects of immunisation services, such as instituting an immunisation status screening system at the point of entry or first registration. Another strategy could be an exit-screening system instituted to identify children with incomplete vaccination status as they exit the health facility and have them referred immediately to receive missed vaccine doses. These can help to alleviate some of the pressure on clinical staff of health facilities struggling with the challenge of under-staffing.

The finding that MOV was associated with caregivers' recent exposure to Immunisation messages was consistent with reports of previous studies.[55,56] There is substantial evidence that immunisation-themed health messages targeted at parents can increase not only their knowledge and intention to vaccinate children; but also children's vaccination uptake and immunisation coverage.[55,56] Such interventions, when tailored to the target audience's needs such as in local and cultural appropriate languages, may be effective particularly for addressing enablers of MOV like caregiver low level of education as found in this study. Facility-based immunisation education interventions can be delivered through health talks in waiting rooms; antenatal and postnatal clinic sessions. They can also be community-based, delivered as part of health campaigns, or through support groups.

Another notable finding was the role of shared parental immunisation decision-making as a determinant of MOV. Similar to findings from other studies, our study points to the importance of shared parenting responsibility regarding children's health.[57,58] The effectiveness of interventions aimed at promoting joint decision-making by parents regarding their children's health and immunisation has been described. One of such intervention was aimed at fostering the involvement of fathers as co-decision makers with mothers. It improved immunisation rates, the percentage of parents intending to vaccinate their

infants.[58] Moreover, to maximise the impact of such interventions, it is important to address existing parental or caregiver information gaps such as identified in our study, to effectively share parental immunisation decision-making for reducing MOV. To make informed decisions on behalf of their child, it is vital that parents have access to essential information on the vaccines being administered, health benefits, risks of possible adverse events following immunisation and what to do in the event of an adverse effect.

In line with the global MOV assessment strategy adopted by the WHO, which seeks to answer three important questions: "what is the burden of MOV, what are the reasons for the missed opportunities, and what can be done to address these?", this study constitutes an initial step in the broader MOV strategy.[45] It offers important quantitative baseline findings and pre-intervention lessons for informing evidence-based and locally appropriate interventions to reduce identified burden of MOV. The findings underscore the need to implement practical and context-specific interventions to reduce MOV burden, with the ultimate aim of contributing to improved immunisation coverage by leveraging existing routine immunisation delivery systems.[45,59] The study identifies practical entry points for conceptualising quality improvement strategies capable of addressing MOV in the study setting and similar contexts Specifically, we identified significant opportunities to improve immunisation service delivery through quality improvement strategies such as strengthening routine immunisation status checks, addressing understaffing through workplace adaptations, boosting caregivers' immunisation awareness through targeted messaging, updating health workers' knowledge of immunisation catch-up and contraindication policies, and ensuring adequate supply of vaccines and other essential immunisation commodities.

3.4.3 Implications of study findings for broader policy and practice

While much of the burden of MOV will be amenable to facility-level quality improvement strategies, broader immunisation programme and health system stakeholders also have an important role to play, particularly in addressing the structural factors underlying MOV. First, health and EPI policy makers need to consider policies to enhance the efficient use of home-based records such as the RtHBs for screening children's immunisation status at every contact with the health system. This is achievable through strengthening immunisation programme and primary health care policy frameworks and reinforming in-service staff training to strengthen health workers' competences in the screening of home-based records, update

their knowledge of correct contraindications to immunisation and improve their awareness of catch-up immunisation policies. Furthermore, health facilities need to have the capacity to immediately administer catch-up immunisation whenever an incompletely vaccinated child has been identified and is free of any valid contraindication, irrespective of the reason for the child's healthcare visit. Similarly, it is important to update health workers' awareness of multi-dose vial policies to address common concerns of vaccine wastage if children are vaccinated outside of the dedicated immunisation days or sessions. Moreover, efforts to harmonise the documentation of children's immunisation and other health records in RtHBs across provincial and sub-national health systems can help enhance the utility of RtHBs for immunisation status screening by health workers in settings like Cape Town that receive a substantial number of migrants from other provinces.

The issue of human resource constraints, identified as a likely enabler of MOV in this study, also requires due attention. Health system and immunisation programme authorities at all levels must make necessary efforts to provide health facilities with sufficient supply of human and material resources required to function optimally. This can be achieved through regular performance review to identify and address human resource gaps in a timely manner. In addition to boosting staff capacity where that is feasible, it is also important to optimise the knowledge and capacity of existing staff. For example, gaps in the knowledge of indications for, and valid contraindications to immunisation, which have been identified as contributing factors to MOV, can be addressed through regular staff training and re-training.[32] Where it is not feasible to increase staffing due to resource constraints, efforts should be made to retain existing immunisation workforce, such as through the use of incentives and supportive workplace strategies to enhance staff retention. Furthermore, immunisation service delivery could be restructured to leverage the use of available non-clinical staff. This could be through task-shifting strategies like the training of non-clinical facility-based staff and community health workers to perform routine immunisation status checks.

We found that low educational attainment was associated with higher odds of MOV. This is consistent with findings from previous studies that children of parents or caregivers with low level of education are more likely to experience MOV.[24,25,30] Given that educational attainment is a reflection of socioeconomic status, this finding also implies, consistent with previous evidence, that children from socioeconomically disadvantaged backgrounds may be

more likely to experience MOV.[24,25,30] These, therefore, underscore the role of system-wide efforts to address the underlying social determinants of health. In addition, specific measures such as locally adapted health education and immunisation messaging, tailored to the needs of the targeted population, may help to overcome barriers posed by factors such as low literacy and other socioeconomic determinants.

Notably, the proven adverse impact of the COVID-19 pandemic on health services have posed further constraints on immunisation service delivery globally, with SA being no exception.[12] While the national government recommended that immunisation services continue uninterrupted during the lockdown period, it is clear from available evidence that the pandemic has had negative effects on essential health services across SA, including routine childhood immunisation.[13-15] Thus, assessing MOV to identify children who might have been missed during the pandemic, has become the more imperative for mitigating the pandemic's deleterious impact on national immunisation coverage.[21,60] That can help to ensure that every encounter a child has with the health system is an opportunity to identify those who are incompletely vaccinated for immediate catch-up immunisation. Such efforts can be integrated into existing strategic plans for strengthening national PHC systems and immunisation programme.[61,62] Overall, PHC and immunisation programme managers and policy makers have a crucial role to play to ensure the integration of MOV assessments into routine quality improvement plans for monitoring, tracking and improving immunisation service delivery at the facility and above-facility levels.

3.4.4 Study strengths, limitations and implications for future research

Notwithstanding its strengths, our study and its methodological approach are not without limitations. Due to the cross-sectional nature of this assessment, it is difficult to infer any causal link between the occurrence of MOV and the factors found to be associated with it. However, there has been consistent evidence across a wide array of previous MOV assessment studies that these factors are strongly associated with MOV. [23,32,35] Another limitation arising from the cross-sectional design of the study is the potential for recall and social desirability biases. These were, nevertheless, minimised by using children's RtHBs to validate caregiver's reports of children's immunisation status. This study involved children aged 0 – 23 months sampled exclusively from publicly funded primary care facilities in an urban context. This limits the generalisability of study findings and their implications to

populations and settings different from those of this study. Nonetheless, this age-group restriction is consistent with current global standards for assessing MOV.[22] Moreover, like elsewhere in South Africa, the majority of the population in Cape Town rely on public clinics for immunisation services, with the private health sector covering only about 20% of the population.[41] This lessens the potential for selection bias in the study. Lastly, some health workers might have been aware of the MOV assessment and might have modified their immunisation practices during the assessment period. As such, it is possible that this study underestimated the magnitude of MOV to an extent. However, only district managers were made aware of the specific outcome of interest (MOV), while facility-level staff were informed of the broader aim of the research (i.e., to understand children's immunisation status and factors influencing it). Besides, the use of exit interviews and the conduct of interviews away from main areas of the clinics might have minimised the likelihood of health workers modifying their immunisation practices to influence the outcome of the assessment.

3.4.5 Implications for future research

The research gaps implied from the above-mentioned limitations present opportunities that future MOV research may consider. First, further research in this direction can assess MOV at a national level to provide more representative and generalisable estimates of MOV prevalence and determinants of MOV. Given the focus of the current study on public PHC facilities located in an urbanised metropolitan setting, there remain questions regarding the burden and factors associated with MOV in higher level (secondary and tertiary) health care settings, as well as in facilities in the private sector and those in rural or less urbanised communities. These need to be explored through wider assessments involving facilities across all care levels and both sectors, spanning both rural and urban settings. It would also be valuable for future studies to assess MOV in non-facility settings, such as mobile clinics and community health outreaches, where the burden of MOV may be more substantial. The use of qualitative and quantitative methods in understanding the magnitude and determinants of MOV cannot be overemphasised. Hence, mixed-methods MOV assessment designs (as utilised in this research) are especially useful for understanding the extent of MOV and the enabling factors from quantitative and qualitative data. Lastly, to enhance the uptake of assessment findings for improving routine immunisation and facility practice, it is necessary

that MOV assessment and remedial efforts are integrated into facility-based or health system-wide implementation research initiatives.

3.5. Conclusions

The study demonstrates the substantial magnitude of MOV during children's contact with PHC facilities in Cape Town and the multilevel nature of individual and contextual factors underlying it. Findings underscore the need for MOV remedial measures to target not only enabling factors at the individual level, but also seek to address broader socioeconomic and health system factors. The study, thus, identifies practical entry points for conceptualising and deploying quality improvement strategies capable of addressing MOV in the study setting and similar contexts.

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Chapter 4: A theory-informed qualitative assessment of missed opportunities for vaccination among children in primary care settings in Cape Town, South Africa

About this chapter

This chapter reports findings from the second and third component studies (based on the second and third specific objectives) of this doctoral research. The studies form the qualitative component of a mixed-methods, pre-intervention baseline assessment of missed opportunities for vaccination (MOV), findings of which helped to complement and contextualise the quantitative findings reported in the previous chapter. More importantly, the qualitative findings reported in this chapter helped to inform the design and implementation of facility-level quality improvement strategies implemented to reduce MOV in primary care settings in Cape Town as reported in the next chapter. A publication related to this chapter is accessible via: https://doi.org/10.1080/21645515.2022.2162771; with the following full citation:

Nnaji CA, Wiysonge CS, Cooper S, Mayeye A, Luphondo L, Mabuya T, Kalui N, Lesosky M, Ndwandwe D. Contextualising missed opportunities for children's vaccination: A theory-informed qualitative study in primary care settings in Cape Town, South Africa. Hum Vaccin Immunother. 2023 Dec 31;19(1):2162771. DOI: 10.1080/21645515.2022.2162771.

Abstract

Background: Missed opportunities for vaccination (MOV) have been identified as a major contributor to low immunisation coverage among children. As part of a mixed-methods pre-implementation baseline MOV assessment, this study aimed to explore factors influencing the occurrence of MOV from the perspectives of health facility workers and caregivers of children aged 0 – 23 months attending primary health care (PHC) facilities in Cape Town, South Africa. The aim of the assessment was to help inform the design and implementation of a contextually appropriate facility-based quality improvement intervention targeted at reducing MOV in PHC settings.

Method: This study involved an exploratory qualitative phenomenology design using focus group discussions (FGD) with caregivers of children aged 0 – 23 months and in-depth interviews of facility managers of participating PHC facilities in Cape Town. Interviews and FGD sessions were facilitated by members of the researcher team who are fluent in English and local languages (Afrikaans and IsiXhosa). Each session was audio recorded and transcribed verbatim for analysis. Quotes in languages other than English were translated to English and back-translated for accuracy. A thematic template analysis approach integrating the theoretical domains framework (TDF) and the capability, opportunity and motivation model of behaviour (COM-B) model was used for coding, analysis and interpretation of the data. The COM-B model was used to translate findings from the TDF matrix into distinct MOV enabling factors in a way that can inform the design of a facility-level quality improvement intervention capable of addressing MOV in PHC facility settings.

Results: Three FGD sessions (each involving of 5-8 caregivers) and five in-depth interviews involving facility managers were conducted. Findings are presented based on the three constructs of the COM-B model. The capability construct comprised caregivers' knowledge and capacity to access and utilise immunisation services for their child when in contact with a health facility. Factors identified under this construct were caregivers' knowledge of the importance of immunisation and their attitude and behaviour towards children's immunisation services. The opportunity construct comprised health system-related factors likely to influence whether or not children receive the vaccines they need during health facility encounters. These factors included the organisation of immunisation services; long waiting time; vaccine stock out; understaffing; attitude and behaviour of health workers; and health

workers' capability to identify and administer catch-up vaccination to children who are incompletely. The motivation construct consisted of personal and external factors that can boost or hinder caregivers' intrinsic motivation to immunise children during health facility visits. These included personal optimism about immunisation, fear of vaccine-preventable diseases and concerns about the safety of vaccines.

Conclusion: The study identified important caregiver-, health worker- and health system-related factors that can influence immunisation outcomes and MOV occurrence among children in PHC settings in Cape Town. These findings offer useful contextual insights for informing the adoption of local quality improvement strategies targeted at reducing the occurrence of MOV in PHC settings.

4.1 Introduction

Available evidence points to the substantial gaps in immunisation coverage across South Africa (SA), despite significant investments and efforts made over the past decade to ensure universal access to immunisation services.[1,2] Recent estimates suggest that immunisation coverage remains below the globally accepted optimal level of 90% across all routine childhood vaccine doses in SA.[3] Suboptimal immunisation coverage among children in SA has been attributed to several factors. At the individual level, these include factors such as low awareness of the importance of immunisation and low socioeconomic status; while at the health system level, they include factors such as human resource shortage, health workers' immunisation training gaps, and vaccine stock-outs, among others.[2,4-6]

Recognising that missed opportunities for vaccination (MOV) are a major contributor to sub-optimal immunisation coverage globally, the World Health Organization (WHO) recommends the provision of immunisation services to eligible individuals at every contact with the health system.[7,8] As defined by the WHO, a missed opportunity for vaccination refers to "any contact with health services by an individual who is eligible for vaccination (unvaccinated or not up-to-date, and free of contraindications to vaccination), which does not result in the individual receiving all the vaccine doses for which s/he is eligible".[9] Levels of MOV occurrence vary widely across countries, with an average of 32.2% in low- and middle-income countries (LMICs).[10] Factors commonly associated with MOV occurrence include the failure of health providers to screen patients for eligible vaccine doses; perceived contraindications to vaccination on the part of providers or parents; vaccine shortages; and the non-integration of vaccination services with curative and other healthcare services.[11]

Since 2016, there has been an increasing impetus to conduct MOV assessments, to more accurately quantify the magnitude of MOV and better understand its determinants at global, national and sub-national levels.[12-14] Consequently, research efforts in this direction have increased in recent years, with an increasing body of evidence on the prevalence of MOV and its associated factors across the world over the last decade, including in African and other LMIC contexts.[12,13,15-18] However, despite this growth in the global evidence base, little is known about the burden and determining factors of MOV in the SA context.[4]

Understanding the magnitude and contextual enablers of MOV has important implications for policy and practice. It will provide the empirical evidence needed to enable immunisation programmes and immunisation service providers to consider the use of context-appropriate interventions for tackling the problem, while strengthening immunisation service delivery. In particular, understanding the burden and enablers of MOV can help inform the conceptualisation and deployment of evidence-based and locally responsive MOV-targeted strategies and interventions, to optimise immunisation access. Furthermore, such understanding has become even more important for guiding efforts aimed at remedying the proven adverse impact of the COVID-19 pandemic on routine immunisation services.[8,19]

As part of a mixed-methods baseline assessment, this study aimed to qualitatively explore the individual, health system and contextual factors associated with MOV from the perspectives of health care providers and caregivers of children aged 0 – 23 months attending primary health care (PHC) facilities in Cape Town. The ultimate goal of the assessment was to help inform the design and implementation of a contextually appropriate quality improvement intervention targeted at addressing MOV in participating PHC settings. From the quantitative component of the pre-implementation baseline assessment (reported in Chapter 3), we found an average MOV prevalence of 14.1%, ranging from 9.1% to 18.9% across sub-districts in Cape Town.[20] In addition to quantifying the extent of MOV occurrence, the study found several individual and contextual factors to be associated with MOV. However, the quantitative nature of these findings does not allow for a deeper understanding of the underlying and contextual factors influencing those findings. To complement and add meanings to those quantitative findings, we therefore conducted qualitative explorations of enabling and hindering factors of MOV using a theory-informed approach, from the perspectives of key immunisation stakeholders like caregivers and health workers in PHC settings in Cape Town.

4.2 Methods

4.2.1 Study design

Here, we used a theory-informed, exploratory qualitative phenomenology design involving focus group discussions (FGD) with caregivers of children aged 0 – 23 months attending PHC

facilities and in-depth interviews (IDI) of PHC facility managers. The theoretical framework underlying the design is described below.

4.2.2 Theoretical framework

The theory-informed approach employed in this study integrated the theoretical domains framework (TDF) and capability, opportunity and motivation model of behaviour (COM-B) model in coding, analysis and interpretation of the data. The TDF is a widely used integrative framework in qualitative research for exploring the factors that influence an outcome or construct of interest. The framework consists of 14 distinct but interrelated domains, namely: knowledge; skills; social or professional role and identity; beliefs about capabilities; optimism; beliefs about consequence; reinforcement; intention; goals; memory, attention or decision processes; environmental context and resources; social influence; emotions and behavioural regulations.[21] While the TDF can help explore contextual factors influencing a specific outcome or construct like MOV, it has limited utility in the translation of identified factors to actionable plans and recommendations, such as for addressing MOV. To achieve this, the capability, opportunity and motivation – behaviour (COM-B) model was proposed to enable the translation of TDF findings into practical MOV-targeted recommendations and strategies.[22] The COM-B model is a Behaviour Change Wheel (BCW) approach useful for establishing a broad range of physical, psychological and external (contextual) mechanisms that can influence behaviour.[22,23]

In relation to MOV, the capability construct of the COM-B model can be conceptualised to include caregiver's capacity to access and utilise immunisation services for their child when in contact with a health facility. It corresponds to the TDF domains of knowledge; skills; memory, and attention or decision process. The opportunity construct entails contextual factors, such as health system, social and environmental factors, that are external to caregivers but are capable of influencing caregivers' perceptions, motivation or intention to immunise their children when in contact with health facilities. This corresponds to the TDF domains of environmental context and resources, and social influence. The motivation construct compromises caregivers' own cognitive processes that motivate or hinder behaviour towards immunisation. It corresponds to the TDF domains of social or professional role and identity; beliefs about capabilities; optimism; beliefs about consequence; reinforcement; intention; goals; and emotions and behavioural regulations. In the context of

MOV, these allow for a systematic selection of interventions based on the various factors identified from qualitative analysis. **Figure 4.1** below illustrates the relationship between the TDF and COM-B model in the context of MOV assessment and interventions.

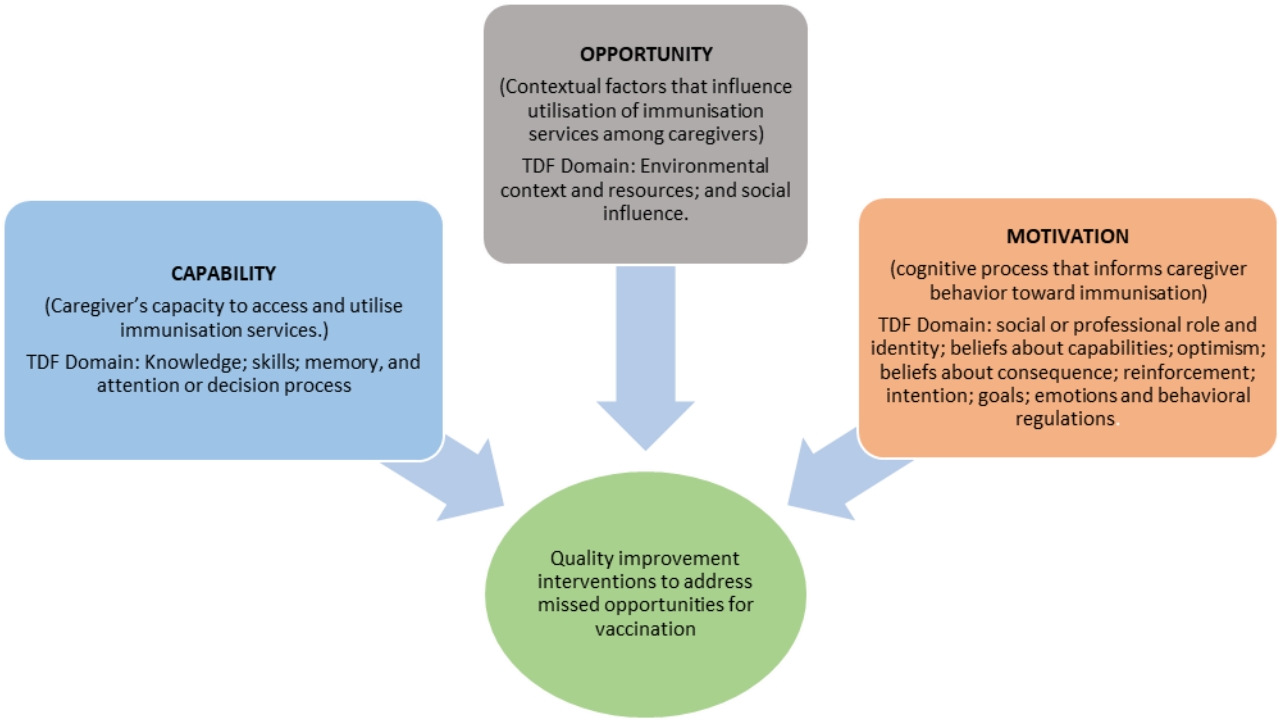

Figure 4.1. The interrelationship between the TDF and COM-B model in the context of MOV

4.2.3 Study setting

With a population of about 4 million, Cape Town is one of SA's largest municipalities.[24] Most of the city's PHC facilities are managed by the City's health department.[25] These facilities provide routine immunisation services funded through the Expanded Programme on Immunisation of South Africa (EPI-SA).[1,26] Further details of the study settings are described in earlier chapters.

4.2.4 Sampling strategy

A total of eleven PHC facilities in the Cape Town Metro Health District participated in the study (the same set of facilities that participated in quantitative study reported in the previous chapter). In-depth interview participants were selected from five of the facilities. To be eligible, they had to be current managers of the facility, should have been working there for

a least a year at the time of the interview and willing to participate in the interview. For the FGD component, participants were caregivers of children aged 0 – 23 months who were aged 18 years or above attending any of the participating facilities, and resident in the catchment area of that facility. Potential In-depth interview and FGD participants were approached by members of the research team at the clinics and informed about the research. Those who were interested and consented to participate were enrolled into the study. In all, three FGD sessions (each consisting of 5-8 caregivers) and five in-depth interviews were conducted.

4.2.5 Data collection

In-depth interviews and FGD sessions were facilitated by two members of the research team who were experienced and trained in qualitative data collection, and fluent in both English and local languages (Afrikaans and isiXhosa). Sessions were conducted using a semi-structured question for the in-depth interviews and discussion guide for the FGD, both of which were adapted from the WHO's caregiver FGD and health worker in-depth interviews guides (see appendices)[9] The data collection guides explored participants' experiences, and perception in relation to immunisation, MOV and ways to reduce MOV. Discussions allowed participants to emphasise what they considered as important and to allow further probes into unanticipated topics emerging from participants' responses. All sessions were recorded using an audio recorder and transcribed verbatim. Local language quotes in the transcripts were translated to English by a professional translator, and then back-translation to the original language to ensure translation accuracy and to check that meanings were not lost in translation.

To supplement audio recordings, one of the two facilitators jotted notes, reflections and captured non-verbal gestures like respondents' facial expressions and nods. Focus group sessions lasted 45 minutes to an hour, while in-depth interviews lasted 30 – 45 minutes. All FGD sessions and in-depth interviews were held in private rooms. Consent to participate was re-confirmed at the start of each session. Upon initial coding and thematic analysis of audio recordings to keep track of emergent themes, it was decided that saturation had been reached at the third FGD and fourth in-depth interview session.

4.2.6 Reflexivity

As the research team consisted of individuals who were knowledgeable and passionate about immunisation, reflexivity was important to minimise the likelihood of researchers' knowledge and sub-conscious bias influencing their positionality throughout the research process, including how they asked questions and how they reacted to or interpreted participants' responses.[27] Before commencement of data collection, the research team engaged in reflexivity by collectively reflecting on expectations and assumptions within the context of the research in one of the training sessions. During data collection, the research team engaged further in reflexivity by jotting notes about participants' comments and non-verbal gestures that may add more meanings to responses. Furthermore, reflexivity was applied during coding and analysis of data, by continually reflecting and maintaining mindfulness of personal and professional positionality in the analysis and interpretation of collected data.

4.2.7 Data analysis

A thematic template analysis approach was used for coding and organising transcribed data segments for analysis and interpretation.[28] That allowed for flexibility and contextual adaptability of thematic analysis.[29] Two codebooks were developed. In the first codebook, emerging themes were identified inductively from transcripts, with illustrative quotes organised under each theme.[30] The second codebook was based on the 14 domains of the TDF. Themes identified in the first codebook were deductively adapted and matched to the corresponding domains of the TDF in the second codebook.[31] To enhance the accuracy and consistency of the analysis, the codes generated were verified independently against the raw data. To avoid overlapping codes, only the most relevant ones in the first codebook were matched to a corresponding TDF domain in the second codebook. Lastly, factors in each TDF domain were subsequently mapped to the corresponding domain of the capability, opportunity and motivation model of behaviour (COM-B).[22] The study was conducted in the pre-implementation phase of a quality improvement (QI) programme to reduce MOV in PHC facilities in Cape Town. Thus, the COM-B model was used to translate the findings in a way that can inform the conceptualisation and deployment of facility-level quality improvement strategies capable of addressing the enablers of MOV and reducing the occurrence of missed opportunities in PHC facility settings. This study was reported in accordance with the Standards for Reporting Qualitative Research (SRQR).[32]

4.2.8 Ethical considerations

Ethics clearance for this study was obtained as noted in previous chapters; from the Human Research Ethical Committee (HREC) of the University of Cape Town (Reference number: HREC 579/2020; see appendices). Institutional approval was granted by the Western Cape Provincial Department of Health (Reference number: WC_2021_01_016) and the City of Cape Town Department of Health (Reference number: 9365); copies of both documents are available as appendices. Signed informed consent was obtained from all study participants before data collection (see appendices for informed consent form). All study participants were made aware that they were at liberty to opt out from the study at any point without consequences. All data collected are anonymous and were stored securely in a password-protected database accessible only to the research team.

4.3 Results

Three FGD sessions were conducted, each consisting of 5-8 primary caregivers of children aged 0-23 who attended any of the 11 participating PHC clinics for any health service during the study period. Participants were women, aged 20 – 42 years and resident in the Cape Town. Five in-depth interviews were conducted, four of which involved female health facility managers, while one involved a male manager. They were aged between 35 and 48 years and have had 10 – 15 years of experience working as healthcare professionals. In-depth interview participants were staff and managers of their respective health facilities, with both administrative and clinical duties at the time of data collection.

Findings from the FGD sessions and in-depth interviews are presented in the following sessions under the three constructs of the COM-B model (capability, opportunity and motivation) with references to their corresponding TDF domains.

4.3.1 Capability construct

This construct of the COM-B model comprises caregivers' knowledge and capacity to access and utilise immunisation services for children when in contact with a health facility. It corresponds to TDF domains of the knowledge; skills; intention; memory, and attention or decision process. Findings are organised under the following emergent sub-themes:

4.3.1.1 *Caregivers' knowledge of the importance of immunisation*

Many caregivers demonstrated good knowledge of the importance of immunisation. When asked what they thought were the ways by which common childhood illness could be prevented, many of the caregivers correctly identified immunisation as one of such ways. For example, one caregiver responded:

"Immunisation is very important as it helps and prevents diseases…I could say that it prevents something that has not occurred from occurring. So it is compulsory for people to always get immunisation all the time" – FGD 1, P1**.**

Another caregiver opined:

"*When a child has been immunised, this protects them*"– FGD 1, P2.

In addition to knowing the importance of immunisation, some caregivers also demonstrated good knowledge of vaccine preventable diseases:

"I feel it's very important for the kid to have the immunisation, it can prevent our kids from a lot of sickness like TB, poliomyelitis, like all those things" – FGD 2, P8.

However, there were instances when caregivers' responses reflected significant gaps in their knowledge of childhood immunisation. For example:

"*I am a grandmother to my child so I don't have much knowledge…I don't even know what I have brought the child for this time around*" **–** FGD 1, P3.

This trend was corroborated by facility staff in the in-depth interviews, with most of them expressing concerns about the low level of immunisation awareness and knowledge of some caregivers:

"*I'm telling you a lot of parents don't know what the children is getting and they don't know what it is for*" – IDI P2.

Another in-depth interview participant shared a similar experience:

"*To be honest with you there is still that level of not knowing or not understanding what is actually happening, what is the certain vaccine for"* – IDI P3.

4.3.1.2 Caregivers' attitude and behaviour towards children's immunisation services

Positive attitudes towards children's immunisation emerged from caregivers' perspectives. Some caregivers narrated how they took personal responsibility and made conscious efforts to get their children immunised, such as by setting immunisation appointment reminders:

"*For me, I set reminders on my phone, like write that on a particular date is the next appointment. Also I paste a paper on my wardrobe for both my children as well as for their appointment dates*" – FGD 1, P2.

Other emergent positive attitudes and practices included safe-keeping of home-based immunisation records documented in the Road to health booklets (RtHB), as expressed by a parent:

"*It is important for a parent to keep the child's book safe and if it happens that you lose it, try by all means to get it again because you won't know those dates without having that book with you. When you have the book, you can track that now the child will go for this particular injection and all*" – FGD 1, P2.

Moreover, some caregivers expressed their positive attitudes towards children's immunisation by asserting that they could spare a day off work; or ask a neighbour to take their children for immunisation if they are unable to get a day off work:

"*The parent must have a mindset of 'As I am working today, the child must go for their immunisation'. You can even ask someone to take your child on your behalf while you work as the parent, but the child should not miss their vaccination date due to you saying you are going to work as the parent*" – FGD2, P2.

Conversely, many negative attitudes were also reported, one of the most common of which included caregivers' late arrival for their children's immunisation appointments:

"*I also wish that the parents could stop arriving late at the clinic*" – FGD 3, P4.

Another common attitude that came up during the discussions was the impatience of caregivers to wait for their children to be immunised, particularly during busy clinic days with longer waiting times:

"There are parents that are impatient and won't be able to stand in the queues - like myself - because I can't go to the clinic at 06:00 am and then leave at 5:00 pm just waiting for an injection. So there needs to be a way in the clinics to ensure that parents don't spend the whole day in the clinic. To not overbook people on certain days as well as ensure that there is enough stuff" – FGD1, P1.

There were also reports by facility staff of caregivers being unwilling to allow clinic staff vaccinate their children, owing to personal reasons, notably misperceived concerns about vaccine safety. One facility staff noted:

"If that mother doesn't want that child vaccinated then what do I do? Because you cannot give a child immunisation without mommies consent, because it becomes a problem" – IDI P2.

Another facility staff added:

"They think we're giving the child a virus so the child is [going to] get the, the, the measles - especially the measles" – IDI P4

4.3.2 Opportunity construct

This construct of the COM-B model comprises factors that are external to caregivers which influence whether or not children attending PHC facilities receive recommended vaccine doses during healthcare encounters. It corresponds to the TDF domains of environmental context and resources, and emotion. At the PHC facility level, it comprises the organisation of immunisation services, as well as health workers' attitudes, behaviours and capability to identify and administer missing immunisation doses to children when in contact with a health facility.

4.3.2.1 *Immunisation services in clinics*

Perceptions of facility managers regarding immunisation services provided by their facilities were mostly positive. For example, while immunisation services are routinely provided on an appointment basis, there appeared be to efforts by health facilities to get children immunised at every clinic encounter from facility staff's responses:

"*So it doesn't mean that we're strict on only the children that has appointments that we give the immunisations. If we notice that this child is coming for something else, but this child didn't get maybe the measles injection then we'll give it that same day*".– IDI P1.

"We have immunisation register, we have appointment system...but we don't depend that much on that schedule like for catch up" – IDI P4.

According to some facility staff, their facilities make efforts to immunise children at every clinic visit even when children have not been given an immunisation appointment, notwithstanding human resource shortages:

"*Even if there's just one sister, we can't defer immunisations. We must give that child […] even if the child comes 9, 3 o'clock for measles injection, we must open that vial"* – IDI P1.

These efforts were reinforced by health facilities' compliance with existing vaccine multi-dose vial policies, as described by one facility staff:

"*Ten children can get a measles vial, but there's a policy, there's a policy in the City of Cape Town where it states that even if you have to open a vial for one child at 10 to 4, you do that*" – IDI P4.

There were also some indications of the integration of immunisation services with other routine primary health care services:

"*We have an integrated approach, a holistic approach to care. Let's say if the child is coming with the mommy who is coming for postnatal [sic: care] and the child happens to be 6 weeks, that sister in that [sic: postnatal] room…does immunisations. Her room is equipped. She's got a cooler box, she's got vaccinations in there, she's attending to the mom, the baby must be sorted there as well"* – IDI P5.

Likewise, a facility staff from another PHC facility hinted on the facility-wide mainstreaming of vaccination and immunisation services:

"*I'm trying to involve everybody so that one cannot work in that corner and the other one works in that corner everybody should know about the vaccination."* – IDI P3

The nature of immunisation services provided at the clinics elicited intense concerns among caregivers. On a positive note, some caregivers expressed their satisfaction with the quality of immunisation services they received:

"*Yeah, and they do everything well*" – FGD2, P1.

Similarly, another caregiver noted:

"*I am happy with my own clinic, they are giving the best service and they don't [sic: waste] time to help the children. I'm happy with their service*" – FGD2, P6.

Conversely, there were negative concerns and dissatisfactions expressed among caregivers about the quality of immunisation services provided by the clinics. These concerns are presented under the following themes:

4.3.2.2 *Attitude of health facility staff*

One of the most commonly raised concerns among caregivers was the unfriendly attitude of clinic staff:

"*Also you find that on the other hand the parents get shouted at. So I wish they could try and work hand-in-hand with the mothers so that the mothers are not intimidated by the nurses, feeling free to always go back to the clinic whenever they need help*" – FGD1, P2.

"*Another thing is that the nurses become rude once you miss the date and even when you tell them that your job does now allow you to attend the appointments, they tell you that, that is not their problem. What I wish to complain about is that even if the parent has missed the appointment date the child should be cared for. The child should get the immunisation. The child should never leave the clinic without their immunisation as there is nothing as important as immunisation*" – FGD1, P7.

Caregivers also conveyed concerns about clinic staff not communicating effectively with them, leaving some parents unaware of reasons for their children's clinic appointments or making some uncomfortable to ask questions about their children's immunisation schedules:

"*The nurses never explain to the parents the reason why the parent must bring the child for the appointment date*" – FGD1, P3.

"*Also you are normally scared to communicate with the nurses as they are often rude to the patients*" – FGD1, P4.

"Many people are scared to ask because they fear that the nurse will be rude, so the nurses need to explain to the mothers with patients as some of the mothers are slow learners" – FGD 1, P3.

Reports of unpleasant attitudes of PHC staff were corroborated during the IDI. For example, one facility staff admitted:

"Sometimes - like I say - we as nurses we aren't really friendly. Sometimes not approachable. It's the truth" – IDI, P4.

4.3.2.3 *Long waiting time*

Dissatisfaction about long queues and long waiting times during immunisation sessions was commonly voiced by caregivers:

"You get there and sit the whole day without getting anything" – FGD 1, P1.

"You have an appointment at 10. You leave at home around to 10 because you know that it takes you 15 minutes to go to the clinic. You get there and wait. At 10 you pass at the reception and leave your child's card and sit down. 10 passes by and you're still sitting there" – FGD2, P7.

One parent gave a hint of how long (in duration) waiting times could be for caregivers:

"Around 10:45 am when you take your child for the 11:00 am appointment you find that the clinic cards for the 8:00 am appointments have not been fetched from the parents. So when are you going to leave the clinic if they haven't started with the 8:00 am appointments at 11:00 am?" – FGD2, P6.

Long waiting time was particularly concerning for caregivers who have to go to work:

"There are cases where they say that from Monday to Thursday we are seeing children. When going there on Friday maybe that's the only day you got an off-day from work, you go the clinic and they tell you that they can't see you so you will need to come back some other day. So they need to prioritise the availability of the clinic. At any given time or day immunisation should be available for parents" – FGD1, P1.

This was corroborated by a clinic staff:

"The other day the lady they said Mr, when are you attending to us because at 9 o'clock I need to be at work. But I said my dear look here your queue, it's a long queue" – IDI P2.

4.3.2.4 *Vaccine availability*

Some caregivers and facility staff expressed concerns about vaccine stockouts, although this issue was not raised by the majority of participants. This was acknowledged by a facility staff in one of the in-depth interviews:

"*There is a stockout of one of the immunisations and that happens very seldom but there has been incidences yeah where there was stock, stockouts*" – IDI P5.

In some cases, caregivers described being asked to procure immunisation services from local pharmacies. One caregiver narrated:

"*At the clinics I wish they could ensure that they have stock because they sometimes send us to Clicks and when you go to Clicks you find out that the injection is R400*" – FGD 1, P1.

4.3.2.5 *Staff shortages*

Human resource shortages were almost unanimously pointed out as a major concern by caregivers and health workers alike. There were reports of children being sent home without vaccination in some of such cases:

"*At my clinic there is a shortage of staff since 2018 so they always book a small number of kids on the system that they cannot attend to in a day ending up having to send the parents back home. So I think this is the reason why some children miss their injections"* – FGD 1, P6.

"*One of the nurses once said that I won't attend the one that the child never came for, I will only do the one that they came for today*" – FGD 1, P1.

"*And the staff, because they sometimes say 'No, we only have two nurses', so those with their cards with them still must return home*" – FGD 1, P5.

Similarly, facility staff noted the impact of staff shortages:

"*You find here at the facility the professional nurse, I must say, it's given a lot of work. You must do the admin; you must see the sick children, you understand"* – IDI P2.

4.3.2.6 *Use of Road to health booklets (RtHB)*

Views of both caregivers and facility managers were mostly positive regarding their perceived importance of RtHBs for documenting and tracking children's health status, including immunisation status screening during clinic visits. Most caregivers take their children's RtHBs

with them during clinic visits. When asked the importance of the booklet, caregivers had these to say:

"*When you look at the card, the ages for a child's immunisation are stipulated*" – FGD1, P4.

"*Once you lose that book you won't know the injections that the child has already taken, and you will forget the written dates for the other appointments as you can't keep them by heart*" – FGD1, P4.

"*I can also add that it is important that the nurses look at the child's book and follow the dates, starting from the previous ones to ensure that the child's injections go as needed*" – FGD1, P5.

When asked about how frequently they checked children's RtHBs for immunisation status and missing vaccine doses, the majority of the health facility staff responded that they routinely did that. However, there were hints that this was not always the case, as one clinic staff admitted:

"*To be honest neh[sic], I am somebody [chuckles] what always check on the immunisation chart. It is[…]I can't say for the next person*" – IDI P1

Staff shortages and excessive workloads were cited as some of the reasons why facility staff do not check the RtHBs:

"*I always check. Personally I always check. But the next person, [...]They're working so under pressure, neh[sic], they have like 40, 50 clients siting outside and maybe that client is coming for sick – neh[sic] the child's maybe coming for sick, but they won't take note of the immunisation. They will focus only on that because their time is so limited*" – IDI P1

4.3.2.7 *Health workers' knowledge and perception about contra-indications to vaccination*

When asked to mention valid contraindications to vaccination, facility staff commonly identified fever as one:

"*So the only reason we won't vaccinate a child if the child has a fever - obviously 38 and above. That's the only time, and then we'll obviously tell the mom maybe in the two days' time we will tell the mommy to come back and then we'll vaccinate if the child's fever has settled then we will catch up on that. But that's the only reason; if the child has a fever of 38 and above*" – IDI P1

"*The only time, we have to it, we are actually forced, we making sure that every child that comes inside, if the child has been sick for instance if the child has had a high temperature more than, 38 and above we don't immunise that child*" – IDI P3.

Acute childhood illnesses were also commonly mentioned as a contraindication:
"*So even if the child comes in - the child is not sick; he's coming for vaccination neh[sic] - we will give that child the immunisation*" – IDI P4.

4.3.2.9 *Information on immunisation and communication of adverse events following immunisation*

According to many caregivers, they were often not given information on immunisation and possible adverse effects during immunisation sessions: Caregivers shared their experiences on these:

"*They don't even teach you anything. You just sit there whilst they are busy with your baby. They never explain to you what they are doing, especially when you are a mother for the first time*" – FGD1, P1.

"*The nurses never explain to the parents the reason why the parent must bring the child for the appointment date. Also openness with the nurse at the clinic so that as the mother you can freely ask*" – FGD1, P3.

"*But the problem is they just inject the baby and you don't know what the injection is for, you understand. You know it's the baby's injection, but what is the injection for or what it protects the child from, you don't know*" – FGD2, P1.

As a result of not being informed about the possible adverse events following immunisation, some caregivers reported not knowing what to do when an adverse event occurs following immunisation:

"*The baby can have fever after the vaccination. They give to my baby the immunisation. After one hour, two hour my baby was okay, and after three hours I said 'No, no I must check my baby'. I touched him, he had a fever. I went to the clinic and they said "You didn't know, you were supposed to give him Panado", but no one told me. No one explained*" – FGD2, P3.

4.3.3 Motivation construct

This third construct of the COM-B model comprises personal and external (sociocultural) factors that may boost or hinder caregivers' intrinsic motivation to immunise children during health facility visits. It corresponds to TDF domains of beliefs about capabilities; optimism; beliefs about consequence; reinforcement; intention; goals; and behavioural regulations. The factors identified here include optimism about immunisation, knowledge of the importance of vaccines, fear of vaccine-preventable diseases and concerns about adverse events following immunisation.

4.3.3.1 *Perceptions about common childhood diseases and the role of immunisation*

The fear of children becoming sick with vaccine-preventable illnesses was a major motivating factor for caregivers' decision to immunise children. This underlying perception is that children who are immunised tend to be healthier than those who are not. Some caregivers shared their experiences and opinions on this:

"*I find that when they immunise the child, the child is protected from falling ill all the time. For example, with other children you will see that they are full of sores, but my children are fine as I take them regularly to the clinic*" – FGD1 P2.

"[…] so since I used to travel back and forth between Cape Town and the Eastern Cape, so I realised that my child missed the measles injection, so when the child was approaching 2 years the child fell ill with measles and when they looked they saw that the child had missed the measles injection" – FGD1 P3.

4.3.3.2 Perceptions, beliefs and sociocultural influences

Some sociocultural factors capable of influencing caregiver's decision to immunise a child when visiting a health facility emerged from the FGDs. Notably, some caregivers mentioned the positive role of health support groups:

"*We do attend the groups. They teach us about everything as well as remind us that the child needs to attend their immunisation appointments. So getting this information from these groups helps us a lot now*" – FGD4 P1.

The influence of social media was also highlighted:

"*When you have opened that Facebook page, you get some advice from the other mothers*" – FGD3 P3.

However, caregivers suggested that prevailing socio-cultural practices and beliefs exist that frequently dissuade them from allowing their children to be immunised. These included misperceptions and rumours that a child can become sick from immunisation:

"*There are rumours and theories that once a child is immunised, they end up getting sick*" – FGD2 P1.

"Where I stay, no one cares about immunisation. It is probably 5% out of 100% that go for immunisation because they give each other wrong information. They tell each other lies that when you take your child for immunisation the child will get sick. As a result, their children are always not well' – FGD1 P6.

4.3.3.3 *Perceptions of vaccine safety*

Fear of adverse events following immunisation emerged as one of the factors potentially undermining caregivers' motivation to immunise children. In addition to common side effects such as fever, caregivers also cited some implausible effects such as tumours:

"*I wish they can explain the side effects of immunisation because I realised that with the one injected here, after some time it changes to become a pimple and so I Googled it and then realised that it was normal, but it was becoming a tumour*" – FGD1 P1.

A major enabling factor of such misconceptions include gaps in knowledge of adverse events following immunisation and clinic staff not informing caregivers about them:

"*I also agree that we should be taught by the clinic that after a certain vaccine there will be side effects so that we are not shocked when these things happen*" – FGD1, P5.

It also seemed that these misperceptions persisted despite efforts by health facility staff to educate caregivers – as expressed by a facility staff in one of the in-depth interviews:

"*We always explain to the parents "It's not a live virus, it's a dead - polio is dead that we're giving. It's just […] to build immunity. They think we're giving the child a virus so the child is [going to] get the, the, the measles - especially the measles*" – IDI P4

4.4 Discussion

4.4.1 Summary of main findings

Using a theory-informed, exploratory qualitative method, this study examined the perspectives of key stakeholders like caregivers and health facility staff, with the aim of

identifying factors that can influence MOV occurrences and children's immunisation outcomes during health facility encounters. Various quality improvement opportunities for addressing MOV while improving immunisation service delivery in PHC settings were identified. These factors were mapped along the thematic domains of the TDF. The COM-B model was then used to interpret factors in each TDF domain in a way that can inform the design of a facility-level quality improvement intervention capable of targeting identified enabling factors for addressing MOV in PHC facility settings. Importantly, the study complements and provides contextual insights for understanding the quantitative findings reported in the previous chapter, and as published.[20]

4.4.2 Implications of study findings for immunisation practice and quality improvement

In the capability construct of the COM-B model, several factors that can influence MOV were identified in this study. While some caregivers were knowledgeable of the importance of immunisation, substantial knowledge gaps were glaring, however, from the response of some of the caregivers themselves and corroborated by health staff in the in-depth interviews. Caregivers' attitude and behaviour towards children's immunisation services that may contribute to MOV include late arrival for children's immunisation appointments or not being patient when there is longer than expected waiting time to have children vaccinated before leaving the health facility. Consistent with the findings by previous studies in Nigeria and Timor-Leste, these factors can contribute to children not receiving age-eligible immunisation during healthcare encounters, thereby constituting common drivers of MOV.[17,33]

For any PHC-level intervention to address MOV effectively, these capability issues warrant due attention. Strategies for addressing caregivers' immunisation knowledge gaps and attitudinal factors include facility-level efforts aimed at improving both caregiver awareness and understanding of the benefits of vaccines and possible adverse events following immunisation. We found that caregivers repeatedly expressed the desire and willingness to be informed and learn about their children's immunisation. This is an important opportunity for quality improvement initiatives to consider for intensifying immunisation messaging and communication. There is substantial evidence that immunisation-themed health education interventions, when tailored to the target audience's needs such as in local languages, can increase caregivers' immunisation knowledge and intention to vaccinate.[34,35] Such interventions can be delivered at the facility level through health talks during immunisation

sessions, and non-immunisation areas such as waiting rooms; antenatal and postnatal clinics; and displaying posters and charts with information about immunisation in prominent areas of PHC facilities.

In the opportunity construct of the COM-B model, the study found factors relating to the organisation of immunisation services, availability of immunisation resources as well as health workers' attitudes, behaviours and ability to identify children who are not up to date with the vaccines they are eligible for during PHC encounters. These factors are external to caregivers but can strongly influence whether or not children attending PHC facilities receive recommended vaccine doses during health facility contacts. These findings substantiate those from our earlier quantitative assessment reported in previous chapter showing that long waiting time and understaffing are common PHC facility-level challenges than can contribute to MOV occurrences.[20] Other factors such as the unfriendly attitude of health workers and vaccine stock-outs can interact with caregivers capability and attitude towards children's immunisation. For example, long immunisation waiting time can discourage caregivers and make them impatient to wait for children to be vaccinated during facility visits for both immunisation and non-immunisation reasons. Likewise, caregivers not arriving early for immunisation appointments can provoke or reinforce unfriendly attitudes of health workers towards them. These go to show the inter-relationship between individual and health system factors, and how one can reinforce the other in the context of MOV. Even if vaccines are available in a public primary health care facility, its utilisation for children can still be influenced by contextual factors that are external to their caregiver, which can be social or environmental.

It was also evident that health facility staff did not always screen RtHBs for children's immunisation status. This could itself be a consequence of other factors such as staff shortages and non-integration of immunisation services with other routine PHC services.[12,36] It is thus important that health facilities establish formal policy and practice for routine RtHB screening and immunisation status checks at every health service encounter. This will require creating an enabling environment for all health facility staff, including immunisation and non-immunisation personnel to be able to correctly screen children's immunisation status and identify opportunities for administering catch-up vaccine doses at all service delivery points. Additionally, efforts are also needed to encourage caregivers to retain and bring children's RtHBs to every health service encounter to aid immunisation status checks.

There were indications of health workers' knowledge gaps, particularly in terms of national immunisation policies and guidelines and valid contraindications to immunisation. Notably, the common perception among health workers that fever is an absolute contraindication to immunisation warrants due attention. Previous studies assessing MOV had similar findings.[12,13,33] PHC authorities and immunisation should explore strategies for improving health worker knowledge and competences on vaccine eligibility, co-administration, valid contraindications and policies for opening multi-dose vials and catch-up of delayed vaccinations. This can be achieved through training and retraining to raise awareness about immunisation among health workers; such knowledge is expected to have a positive spill-over effect to caregivers.[37] Also important is the re-organisation of PHC services such that immunisation services are well integrated with other routine PHC services. To ensure effective integration, vaccines and other immunisation supplies need to be made available at non-immunisation service delivery points. This is especially crucial for mitigating MOV occurrences in children accessing non-immunisation services, as the likelihood of MOV may be higher in such settings.[12,18,20]

Another key finding of this study has to do with vaccine availability. While vaccine stockouts were uncommon from the perspectives of the caregivers and health workers, some participants expressed particular concerns about them. In some cases, caregivers were asked to procure immunisation services from local pharmacies. Cost is a widely recognised barrier to accessing health services, including immunisation[36,38] As such, is it imperative that these supply-side constraints are taken into account when planning and implementing remedial measures against MOV.

In the motivation construct of the COM-B model, the study identified several personal and external factors that may enhance or undermine caregivers' motivation to immunise their children during health facility encounters. Notably, the fear of children becoming sick with vaccine-preventable illnesses was a major motivating factor. The awareness and beliefs about the consequences of vaccine-preventable diseases can reinforce motivation and positive behaviour toward immunisation.[39,40] However, the fear of side effects emerged as one of the factors potentially undermining caregivers' motivation for immunisation. Studies have shown that concerns around vaccine safety, founded or unfounded can influence caregivers' behaviour and reduce their motivation to immunise children.[41,42] In addition to common side

effects such as fever, caregivers also cited some implausible effects such as tumours. A major enabling factor of such misconceptions include gaps in knowledge of adverse effects following immunisation and the health workers not informing caregivers about side effects. Strategies for addressing these include those aimed at reinforcing immunisation education; improving health workers' communication of possible adverse events to caregivers; initiating personal conversations with caregivers with particular safety concerns or misperception to allay fears and dispel myths; and using more motivated and knowledgeable caregivers as local influencers to boost other caregivers' attitude and perceptions towards immunisation at the PHC facility level.

Table 4.1 outlines the key MOV-related issues mapped under the three constructs of the COM-B model and corresponding TDF domains; and illustrative quality improvement strategies targeted at each issue.

Table 4.1. Integrated COM-B and TDF matrix of factors associated with MOV and their implications for PHC-level quality improvement

COM-B construct	TDF Domain	Key issues identified	Examples of quality improvement strategies
Capability	Knowledge	Low levels of immunisation awareness and knowledge among caregivers	• Reinforce immunisation education and information; • Displaying posters and charts with information about immunisation prominently in the facilities and consulting rooms.
	Intention	Caregivers arriving late for immunisation appointments	• Use of punctual and more motivated caregivers as local (facility-level) influencers to boost other caregivers' attitude towards punctuality to immunisation clinics.
	Intention	Caregivers' impatience to wait for children for children to be immunised	• Improve immunisation appointment systems to minimising waiting time; • Creating additional immunisation service delivery points.
Opportunity	Environmental context and resources	Non-screening of road to health booklets (RtHB)	• Placement of reminder tags or stickers on children's RtHBs at the point of registration; • Prominent display of posters with MOV infotmation in waiting areas and consulting rooms; • Routine supervision to improve RtHB screening compliance.
	Knowledge	Health workers' uncertainty about valid contra-indications to immunisation	• Re-training on valid contra-indications; • Placing posters/charts with information on valid contraindication at immunisation service delivery points.

	Environmental context and resources	Non-integration of immunisation services with other primary care services	• Facility-wide training of staff of all departments/ units on the importance of immunisation and sensitisation on MOV; • Procuring additional cold boxes to facilitate immunisation at other service delivery points.
	Environmental context and resources	Concerns about vaccine wastage if multi-dose vaccine vials are opened to vaccinate a few numbers of children	• Re-training health workers on open existing multi-dose vial policies.
	Environmental context and resources	Long waiting time	• Improve immunisation appointment systems to minimising waiting time; • Creating additional immunisation service delivery points.
	Emotion	Attitude of health facility staff	• Provide training and improve supervision on professional healthcare conduct
	Knowledge	Non-communication of information on immunisation and communication of adverse events following immunisation	• Provide information on immunisation and likely adverse events during immunisation sessions.
Motivation	Optimism; Intention; Beliefs about capabilities	Perceptions about common childhood diseases and the role of immunisation	• Reinforce messaging on the benefits of childhood immunisation, such as in waiting rooms or during consultation
	Beliefs about consequences;	Concerns and misperceptions of vaccine safety	• Improve health workers' communication of possible adverse events to caregivers;

	Social influence		• Intensify immunisation education and information; where possible this can be tailored and targeted to specific caregivers; • Initiate personal conversations with caregivers with particular safety concerns or misconception to allay fears and dispel myths; • Engage motivated and knowledgeable caregivers as local (facility-level) influencers to boost other caregivers' attitude and perceptions towards immunisation.

COM-B = capability, opportunity, motivation-behaviour; TDF = theoretic domains framework

4.4.3 Study strengths, limitations and implications for future research

The theory-informed design of this study allowed for a theoretically sound exploration of the factors associated with MOV from the diverse perspectives of caregivers and health workers. It also enabled the understanding of the interrelationships of these factors in the context of MOV and broader immunisation service delivery outcomes at the PHC level. The study, however, has some notable limitations. As with other qualitative designs, the purposive sampling and small number of participants have implications for the generalisability of the findings and recommendations beyond the study context. Notwithstanding this fundamental limitation, it is important to note that the primary goal of the study was not to quantify the underlying factors shaping MOV occurrences, but to provide contextual insights for understanding the quantitative findings reported in the previous chapter. There is, therefor, merit in the study's ability to achieve this goal, particularly by helping to identify practical considerations for informing the development and deployment of locally suitable quality improvement initiatives that can help to target and address MOV in PHC contexts.

As with other qualitative studies of this nature, there are potentials for social desirability bias in this study. This was however mitigated by assuring participants of their anonymity and the confidentiality of their responses. Lastly, it is also important to acknowledge that the study's convenience sampling, its focus on caregivers of children aged 0 – 23 months and health workers in public PHC facilities in an urban setting; and the fact that only female caregivers participated in the study, all limit the generalisability of study findings and their implications to older children, male caregivers, non-PHC healthcare facilities and rural settings. However, the focus on children aged 0 – 23 months is consistent with global MOV assessment standards.[9] The participation of only female caregivers may also reflect the gendered nature of healthcare seeking in the study context. Moreover, the majority of the children in the study setting rely on public PHC clinics for immunisation, making the caregivers and health staff in these settings key stakeholders whose perspectives are more likely to be reflective of the realities and lived experiences regarding MOV among children in the study setting.

The above-mentioned limitations therefore highlight the need for future qualitative and mixed-methods MOV assessments to involve gender-diverse samples of participants. It will be valuable for further research in this direction to be conducted in health facilities across all care levels, in both public and private healthcare sectors and encompassing both rural and urban settings. Future studies should also consider assessing MOV in non-facility settings

where children make contact with health services; such as mobile clinics and community health outreaches, where the burden of MOV may be more substantial.

4.5 Conclusion

As an integral component of a mixed-methods MOV assessment, this qualitative study identified important caregiver, provider and health system-related factors, which are likely to influence MOV occurrences and immunisation outcomes among children in PHC settings in Cape Town. The findings, mapped under the three constructs of the COM-B model and corresponding TDF domains, offer useful practical and contextual insights for informing the deployment of PHC-level quality improvement strategies for tackling MOV and ultimately improving immunisation coverage at the population level.

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Chapter 5: Evaluation of a quality improvement intervention to address missed opportunities for vaccination among children in primary health care settings in Cape Town

About this chapter

Accumulated evidence and insights from the quantitative and qualitative baseline assessments of the burden of missed opportunities for vaccination (MOV) and associated factors, as reported in the previous chapters, were used to inform the design and implementation of a facility-level quality improvement intervention targeted at addressing MOV in selected PHC facilities in Cape Town. This chapter reports findings from the fourth component study (based on the fourth specific objective) of this doctoral research. The study aimed to evaluate the effectiveness of the quality improvement intervention implemented in terms of MOV reduction and other key evaluation outcomes.

Abstract

Background: Evidence from previous studies points to the substantial level of missed opportunities for vaccination (MOV) and the multi-dimensional factors associated with MOV. Based on insights from the evidence, a facility-level quality improvement intervention was designed and implemented, targeted at reducing MOV among children in selected PHC facilities in Cape Town. The aim of this study was to evaluate the quality improvement intervention, to determine its effect in terms of MOV burden reduction and other key evaluation outcomes.

Methods: This study was based on a plausibility evaluation design to determine the effect of quality improvement intervention on MOV and other outcomes, and to demonstrate that any effect observed is plausibly due the intervention rather than external or confounding factors. The evaluation involved a non-randomised controlled study using an interrupted time-series analysis (ITSA) approach to compare changes in the outcomes of interest between intervention and control arms, while controlling for baseline MOV differences between the two study arms, facility-level time-varying factors, and seasonal trends.

Results: A total of 1058 child-caregiver pairs participated in the study across the four participating PHC facilities; 351 in the two intervention PHC facilities and 707 in the two control PHC facilities. In the intervention PHC facilities, the percentage of children whose immunisation status was screened during PHC facility encounters per week ranged from 92.2% to 95.1% before the quality improvement intervention, followed by a gradual increase in the intervention period, reaching 100% by the last week of the evaluation period. In the control PHC facilities, weekly immunisation status screening rate ranged from 87.4% to 96.9% in the pre-intervention period. This trend was maintained in the intervention period, ranging from 84.9% to 94.6% with no significant difference compared with the pre-intervention period. There was a significantly higher baseline MOV prevalence in the intervention facilities, than in the control facilities; with a difference of 6.38% (95% CI = 3.77, 8.98; $p<0.001$). Weekly trends in MOV prevalence remained stable during the pre-implementation period in both arms of the study. After controlling for differences in baseline MOV prevalence between the two study arms and facility-level time-varying covariates, there was a significant reduction in weekly MOV prevalence among children in the intervention facilities compared with those in the control facilities; with a reduction of 1.52% per week (95% CI = -2.69, -0.34; $p <0.05$).

Notwithstanding the significantly higher prevalence of MOV in the intervention facilities at baseline, they had a significantly lower MOV prevalence than the control facilities by the last week of evaluation, with a difference of -7.65% (95% CI = -9.20, -4.40; p <0.001). The quality improvement intervention did not appear to adversely impact or increase the waiting time for other PHC services.

Conclusion: This study has shown that health facility workers are capable of conceptualising, implementing and adapting a wide range of quality improvement strategies suitable for their local contexts. Findings from the evaluation suggest that evidence based and contextually appropriate quality improvement interventions can be effective for tackling MOV and improving immunisation service delivery outcomes in PHC settings, without adversely impacting other healthcare services at the facility level.

5.1 Introduction

Immunisation is recognised as one of the most impactful public health interventions.[1,2] It is considered a highly cost-effective means of preventing diseases and associated deaths, while yielding significant cost-savings for governments and individuals through the aversion of ill-health, mortality and long-term disability.[3] Immunisation coverage among children remains suboptimal at national and subnational levels in South Africa (SA), despite decades of efforts to improve access.[4] There is clear evidence that the country did not reach the Global Vaccine Action Plan (GVAP) target of ensuring 90% national coverage for primary series vaccines by 2020.[4-6] Moreover, findings from the recent national immunisation coverage survey shows that 76.8% of children are fully immunised at 18 months of age, much lower than current globally recommended coverage targets.[7]

South Africa's suboptimal immunisation coverage can be attributed to several factors at the individual, health system and social levels. Previous studies found that health system factors, such as poor attitudes and behaviour of healthcare workers, vaccine stock-outs, and gaps in vaccine knowledge among healthcare workers were a major driver of missed vaccination among children.[8,9] Such health system-related factors contribute to the burden of missed opportunities for vaccination (MOV), which is defined by the World Health Organization (WHO) as any contact with health services by an individual who is eligible for vaccination, which does not result in the individual receiving all the vaccine doses for which s/he is eligible.[10] Missed opportunities for vaccination have been shown to be a contributor to low immunisation coverage globally, with a systematic review estimating its global prevalence to be 32% among children who visited health care facilities.[11]

Individual-level factors found to be associated with MOV include child's age, birth order, number of under-five children in the household, maternal age, household income, maternal level of education, attendance of antenatal care and media access.[12-26] Contextual determinants have also been reported, including socio-economic disadvantage (a composite measure of literacy, unemployment, rurality and poverty levels).[13,27] Other factors like the reason for children's health facility visit (such as a healthy child accompanying an ill caregiver to the clinic), health facility proximity, health facility travel time and the number of vaccinators available were found to be associated with MOV.

To accelerate and sustain immunisation coverage progress, the WHO recommended the mitigation of MOV to ensure the provision of immunisation services at every contact with the health system.[11] To achieve this, the WHO recommended that greater attention be paid to assessing the burden and determinants of MOV; and instituting remedial measures to address the problem. Understanding the burden and contextual enablers of MOV is important for policy and practice as it will provide valuable research evidence to enable policy makers and facility managers to consider context-appropriate interventions for address the MOV and strengthening routine immunisation service delivery. It is also important for guiding efforts aimed at undoing the proven adverse impact of the COVID-19 pandemic on routine immunisation services.[31,32]

Quality improvement (QI) approaches have been used across diverse health care settings, such as disease diagnostics and treatment, maternal and child health and infection control.[33-36] There is however currently a dearth of literature on the implementation and effectiveness of quality improvement strategies in the context of MOV.[37] The limited evidence available however suggests that quality improvement can be used to implement change ideas targeted at vaccine demand- and supply-side factors, as well as health facility-level and other structural factors associated with MOV.[37,38] There is also evidence that key stakeholders like frontline health workers were capable of co-designing and implementing quality improvement strategies tailored to their local context.[37,38]

Following the mixed-methods baseline assessment of the burden of MOV and associated factors among children aged 0 – 23 months attending PHC facilities in Cape Town reported in the previous chapters, accumulated evidence from those assessments were used to inform the design and implementation of a facility-level quality improvement intervention aimed at addressing MOV in PHC settings. From the quantitative component of the pre-implementation baseline assessment, we found an average MOV prevalence of 14.1%, ranging from 9.1% to 18.9% across sub-districts in Cape Town.[8] Using a theory-informed approach, the qualitative component of the formative assessment identified important individual, contextual and health system factors that may influence the occurrence of MOV from the perspectives of key immunisation stakeholders like caregivers and PHC facility staff.[39] Therefore, this study aimed to evaluate the quality improvement intervention

implemented in terms of MOV reduction and other key outcomes in selected PHC facilities in Cape Town.

5.2 Methodology

5.2.1 Study design

This study was based on a plausibility evaluation design to determine the effect of the implemented quality improvement intervention on MOV, and to demonstrate that any effect observed is plausibly due the intervention rather than external or confounding factors.[40] The evaluation involved a non-randomised controlled study using an interrupted time-series analysis (ITSA) approach to compare changes in MOV prevalence and other outcomes of interest between intervention and control arms, while controlling for systematic and time-varying differences between the two study arms.

5.2.2 Study setting

The Western Cape is one of the nine provinces in SA.[41] Cape Town is the biggest metropolitan area in the province with a population of approximately 4 million persons.[42] Primary health care services like immunisation are provided through the city's 152 PHC facilities, 102 of which are managed by the City of Cape Town (local government) to augment PHC services provided by provincial facilities.[42] Routine immunisation services in SA are funded through the Expanded Programme on Immunisation of SA (EPI-SA) and provided free of charge primarily through PHC facilities, including those in Cape Town.[4] While the Western Cape is relatively better resourced health system and health outcomes than other provinces, immunisation coverage remains lower than optimal levels, with as much as 36.1% of children in the province being incompletely immunised.[43]

5.2.3 Study population

Caregivers of children aged 0 – 23 months attending PHC facilities in the Cape Town Metro for any type of health service on the day of assessment were included in this study. To be eligible for inclusion, the child must have been brought to the PHC facility by an adult caregiver (aged ≥18 years). If a caregiver visited the hospital with two or more children, the youngest child's data was primarily collected to avoid overrepresentation of caregivers with multiple children.

5.2.4 Sampling

The four participating facilities (two intervention and two control facilities) in this study were sampled from the 11 PHC facilities involved in the baseline assessment and formative phase of the research project. The criteria for eligibility for selection as an intervention facility included having the capacity to deliver a quality improvement intervention, such as by having existing facility-level quality improvement initiatives, and willingness to participate in the study. Based on the criteria and the recommendation of City of Cape Town Department of Health, four PHC facilities were selected to participate in the study; two of which implemented the quality improvement intervention while the other two served as control. For the study to be powered at 80% for a single parameter (change in level of MOV), 40 data points are required an alpha level of significance set at 0.05 to detect an effect size of a 25% change in MOV prevalence following the quality improvement intervention.[48]

5.2.5 Quality improvement implementation

The implementation phase of this study adopted the getting to outcome (GTO) quality improvement model to plan and guide the intervention.[44] This model comprises an iterative process involving 10 steps, from assessing quality improvement needs to evaluating and sustaining quality improvement. Specifically, it involves systematic planning, implementation of programmes, evaluation, and considerations for sustainability.[44] The 10 steps were adapted for use in the two intervention PHC facilities (**Figure 5.1**). The intervention was implemented over two Plan-Do-Study-Act (PDSA) cycles, each lasting a period of four weeks.[45] The first PDSA cycle occurred in April 2022 while the second PDSA cycle occurred in May 2022 Efforts were made to integrate the PDSA cycles into existing facility- and district-level primary health care and immunisation quality improvement plans.

There was an initial pre-implementation stakeholders' engagement to involve them in the agenda setting and goal sharing, while soliciting their support and participation during the implementation, evaluation and post-evaluation phases. The City of Cape Town Department of Health was engaged to get buy-in, determine which facilities to participate in the study and make initial operational planning. The City Health Department eventually recommended four clinics (two for intervention and two for control) based on discussion and considerations of eligibility mentioned earlier.

Next, quality improvement teams (QI teams) were constituted in each intervention facility. In both facilities, individuals were selected to be QI team members based on several considerations, including current role, level of involvement in immunisation services, previous experience participating similar facility-level initiatives to improve service delivery and availability to participate in QI tasks. Team selection was coordinated by facility managers. The final QI teams comprised 3 - 5 facility staff including facility managers, head of immunisation units, head of outpatient units, and vaccinators (where these were specially designated). Once constituted, the research team (led by the PhD candidate) met with facility-level QI teams in both intervention PHC facilities to clarify the purpose of the intervention and evaluation.

Following that, a one-day workshop on MOV and quality improvement was conducted to further sensitise QI teams on the current evidence on MOV (including local findings on MOV prevalence and associated factors from baseline assessments) and quality improvement approaches in the context of routine immunisation. The quality improvement model proposed by the Institute for Healthcare Improvement (IHI) was used to guide the selection of QI activities and strategies.[46] In addition, insights from the WHO's MOV planning guide and updated methodology were used to guide the selection of quality improvement activities.[29] In that workshop, key MOV findings from the baseline assessment as well as evidence-based interventions capable of reducing MOV were discussed with QI teams. This was to allow QI teams inform their chosen change ideas with currently available evidence, including the adaptation and creation of novel change ideas tailored to their local contexts.[47] The workshop culminated in the adoption of potentially useful quality improvements by QI teams of the two intervention PHC facilities.

Following the workshop and review of baseline MOV findings, QI team members met to clarify roles, assign responsibilities, and examine individual capacities to implement the identified change ideas. Each team identified current facility-level immunisation service delivery gaps and needs. Based on identified gaps and needs, the QI teams defined overarching aims, set specific targets (e.g. by what proportion should the magnitude of MOV be reduced and by when?) and decided on a final list of quality improvement activities and strategies necessary to achieve set goals. QI teams discussed the appropriateness and feasibility of identified

change ideas within their specific facility and catchment community contexts, taking into account the facility's capacity and community's acceptability of change. There was facility-wide communication of quality improvement goals and plans by each QI team, as well as facility-level step-down QI training and capacity building facilitated by QI teams in the intervention PHC facilities.

Table 5.1 below illustrates examples of quality improvement activities adopted and implemented in the intervention PHC facilities. They included: error proofing (placement of reminder tags on children's health cards), workplace adaptations (display of posters and charts with information about MOV in waiting areas and consulting room, conducting daily routine immunisation, deployment of additional cold boxes to facilitate immunisation at other service delivery points), and advocacy (initiate phone conversation with fathers of children that refuse vaccines). Selected change ideas were implemented using two PDSA cycles, each lasting a period of four weeks. The second PDSA cycle served as an opportunity to review and apply learnings from the first cycle to improve implementation outcomes in the second cycle. To ensure adequate supervision and optimal implementation, there were weekly facility-based QI team meetings and supportive supervision led by facility managers, and periodic monitoring and supervision visits by district and municipal health departments in line with existing quality improvement strategies and plans.

Table 5.1. Examples of facility-level quality improvement activities and ideas implemented to reduce MOV in the intervention PHC facilities in Cape Town

Key issues identified	**Examples of quality improvement strategies**
Low levels of immunisation awareness and knowledge among caregivers	• Reinforcing immunisation information and education; • Displaying posters and charts with information about immunisation prominently in the facilities and consulting rooms.
Caregivers arriving late for immunisation appointments	• Use of punctual and more motivated caregivers as local (facility-level) influencers to boost other caregivers' attitude towards punctuality to immunisation clinics.

Caregivers' impatience to wait for children for children to be immunised	• Improving immunisation appointment systems to minimising waiting time; • Creating additional immunisation service delivery points.
Non-screening of road to health booklets (RtHB)	• Use of reminder tags on children's RtHBs at the point of registration; • Display of posters/charts with MOV messages in waiting areas and consulting rooms; • Use of electronic immunisation appointment and reminder systems to identify children who are incompletely vaccinated at the point of registration during clinic visits; • Routine supervision to improve RtHB screening compliance.
Health workers' uncertainty about valid contra-indications to immunisation	• Re-training on valid contra-indications; • Placing posters/charts with information on valid contraindication at immunisation service delivery points.
Non-integration of immunisation services with other primary care services	• Facility-wide training of staff of all departments/ units on the importance of immunisation and sensitisation on MOV; • Procuring additional cold boxes to facilitate immunisation at other service delivery points.
Concerns about vaccine wastage if multi-dose vaccine vials are opened to vaccinate a few numbers of children	• Re-training health workers on open existing multi-dose vial policies.
Long waiting time	• Improving immunisation appointment systems to minimising waiting time; • Creating additional immunisation service delivery points.
Attitude of health facility staff	• Providing training and improve supervision on professional healthcare conduct
Non-communication of information on immunisation and communication of adverse events following immunisation	• Providing information on immunisation and likely adverse events during immunisation sessions.

Perceptions about common childhood diseases and the role of immunisation	• Reinforcing messaging on the benefits of childhood immunisation, such as in waiting rooms or during consultation
Concerns and misperceptions of vaccine safety	• Improving health workers' communication of possible adverse events to caregivers; • Intensifying immunisation education and information; where possible this can be tailored and targeted to specific caregivers; • Initiating personal conversations with caregivers with particular safety concerns or misconception to allay fears and dispel myths; • Engaging motivated and knowledgeable caregivers as local (facility-level) influencers to boost other caregivers' attitude and perceptions towards immunisation.

Figure 5.1 below summarises the integration of GTO steps and phases of the PDSA cycles

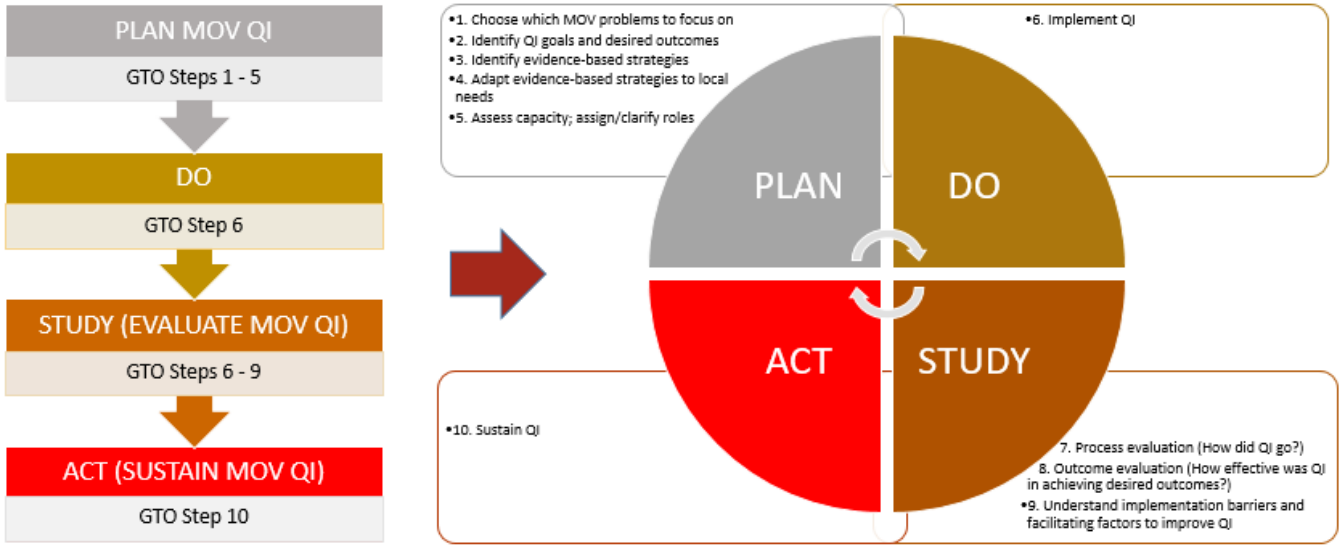

Figure 5.1. GTO quality improvement framework and steps

5.2.6 Quality improvement evaluation

Evaluation design

The evaluation involved comparisons of weekly trends of MOV prevalence and other outcomes of interest between intervention and control arms as well as between pre-

intervention and intervention periods of the study. The entire study period was 11 weeks long. The first three weeks represented the pre-implementation evaluation period, involving the evaluation of baseline data collected in Study 1 (initial phase of the research project). The intervention evaluation period consisted of eight weeks. Evaluation during the intervention period formed the integral 'Study' part of the two PDSA quality improvement implementation cycles as described earlier, with the first four weeks (in April 2022) coinciding with the first PDSA cycle, while the remaining four weeks (in May 2022) coincided with the second PDSA cycle). Evaluation findings were reviewed by QI teams on a weekly basis. Overall, findings from the first PDSA cycle (first four weeks of quality improvement intervention) helped to inform the planning and improve implementation outcomes in the second PDSA cycle.

5.2.7 Data collection

Data collection process and tool

Data used for evaluation were collected using repeated cross-sectional exit surveys of caregivers of children aged 0 -23 months. Data collected during the baseline study (that is Study 1) was used for the pre-intervention evaluation. Data were collected on a daily basis and concurrently in both intervention and control facilities. A standardised semi-structured questionnaire slightly adapted from the version used in Study 1 (See Appendix) was used for data collection. The original questionnaire was adapted from the WHO tool for assessing MOV in health care settings.[29] The survey questionnaire was administered electronically using the Research Electronic Data Capture (REDCap) tool hosted at the University of Cape Town[49] by trained research assistants who were fluent in English, Afrikaans and IsiXhosa. The questionnaire had 6 sections relating to the child; parent/caregiver; use of the Road to Health Booklet (RtHB) for checking vaccination status and information on vaccine administered; current visit; quality of the vaccination service; and reasons for vaccination. Data collectors positioned themselves at the main exits of each health facility, approached caregivers accompanied by children as they were exiting the facility and asked if they were willing to participate in the study.

Evaluation indicators and study variables

Primary evaluation outcome/indicator was defined in **Table 5.2** and as follows:

- **Prevalence of MOV for one or more vaccine doses/antigens:** This was the main evaluation outcome variable/indicator, defined as the proportion of children aged 0 – 23 months visiting a PHC facility per week, who remained unvaccinated or partially-vaccinated despite contact with the PHC facility and free of any contraindication to the missed vaccine doses. MOV was defined based on the WHO definition as a binary variable of whether or not a 0 – 23 month-old child had any contact with a PHC facility but remained unvaccinated to any vaccine doses for which the child was eligible.[10]

Secondary evaluation outcome indicators included the following:

- **RtHBs screening rate:** The proportion of children aged 0 – 23 months visiting a PHC facility per week, whose RtHBs were screened by a health worker during PHC facility visits. This was a process evaluation measure/indicator.
- **Mean patient waiting time:** The mean waiting time for non-vaccination services among caregivers of children aged 0 – 23 months who visited a PHC facility in a given period. This was used as a balancing outcome to monitor the impact of the quality improvement intervention on other routine (non-vaccination) PHC services.

Explanatory variables included sociodemographic factors such as age of child, sex of child, birth order and birth weight) and caregiver related factors (such as caregiver relationship with child, marital status, mothers' attendance of antenatal care, level of education, employment status, mode of transport to health facility, duration of transport to health facility, and recent exposure to immunisation messages). Health facility-level factors included characteristics such as facility type, number of staff, patient volume, vaccine availability and immunisation scheduling.

Table 5.2. Quality Improvement evaluation measures/indicators

QI Measure/Indicator	Evaluation type	Unit	Numerator (N) and denominator (D)	Frequency of evaluation
RtHB screening rate	Process evaluation	Proportion (%)	N: Number of children aged 0–23 months whose RtHBs were screened by a health worker during PHC facility visits in a given period. D: Total number of children aged 0–23 months who visited a PHC facility in a given period.	Weekly

Prevalence of MOV for one or more vaccine doses/antigens.	Outcome evaluation	Proportion (%)	N: Number of children aged 0 – 23 months who remained unvaccinated or partially-vaccinated despite contact with the PHC facility and free contraindications to the missed vaccine doses. D: Total number of children aged 0 – 23 months who visited a PHC facility in a given period.	Weekly
Mean patient waiting time	Balancing outcome evaluation	Minutes	Mean waiting time for non-vaccination services among caregivers of children aged 0 – 23 months who visited a PHC facility in a given period.	Weekly

5.2.8 Data analysis

Continuous variables like were expressed as mean and standard deviations, while categorical variables were expressed as frequencies and percentages. Pearson's Chi-square statistic was used to compare the distribution of individual and facility-level characteristics between intervention and control arms of the study. Due to the time-varying nature of the data collected, an interrupted time-series analysis (ITSA) approach was used to evaluate the intervention. An interrupted time-series analysis (ITSA) offers a quasi-experimental research design with a considerable degree of internal validity.[50,51]

In this study, ITSA was conducted by fitting Newey ordinary least-squares (OLS) regression models to produce regression coefficients of weekly MOV trends representing the mean change in weekly MOV prevalence over a time period, with their corresponding standard errors, p values and 95% confidence intervals CIs. Newey-West standard errors were used to handle autocorrelation in addition to possible heteroscedasticity with one lag.[50] Single-group ITSA regression models were fitted to compare weekly changes and trends of MOV and other outcomes before and during the intervention period in each individual participating PHC facility. Multiple-group ITSA models were specified to compare MOV trends between the intervention and control facilities, while controlling for systematic and time-varying differences between the two study arms, such as differences in baseline prevalence of MOV and facility patient volume. Statistical significance was considered at p value <0.05. Data

analysis will be conducted using Stata 14.2,[52] and reported in accordance with the Standard for Quality Improvement Reporting Excellence SQUIRE 2.0 guideline.[53]

5.2.9 Ethical considerations

Ethical clearance for this study was obtained from the Human Research Ethical Committee (HREC) of the University of Cape Town (Reference number: HREC 579/2020; attached as Appendix). In addition to this, the institutional approval was granted by the Western Cape Provincial Department of Health (Reference number: WC_2021_01_016) and the City of Cape Town Department of Health (Reference number: 9365); both attached as Appendices. Signed informed consent was obtained from all study participants before data collection. It was explained to all study participants that they could, as a matter of personal choice, opt out from the study at any point without consequences. All data collected are anonymous and securely stored in a password-protected database accessible only to the research team.

5.3. Results

5.3.1 Characteristics of participating PHC facilities

All four participating PHC facilities had designated immunisation service delivery points and none of them had experienced any vaccine stock out in the three months prior to the study. Other facility characteristics are described in **Table 5.3** below.

Table 5.3. Characteristics of participating health facilities

Characteristics	**Healthcare facilities**			
	Intervention		**Control**	
	Facility A	**Facility B**	**Facility C**	**Facility D**
Type/level of care	PHC facility	PHC facility	PHC facility	PHC facility
Facility ownership	Municipal	Municipal	Municipal	Municipal
Designated immunisation service delivery point	Yes	Yes	Yes	Yes
Vaccine stock-out in the past three months	No	No	No	No
Vaccine cold-chain challenges in the past three months	No	No	No	No
Number of healthcare staff	27	16	18	25
Average weekly patient load	112	168	188	366

5.3.2 Individual participants' characteristics

Table 5.4 describes and compares participants' sociodemographic characteristics between intervention and control facilities. A total of 1058 child-caregiver pairs participated in the study across the four participating PHC facilities. Of these, 351 (33.2%) were enrolled in the intervention PHC facilities while a greater proportion; 707 (66.8%) were enrolled in the control facilities. The mean age (±SD) did not differ significantly between children in the intervention and control arms (7.8 [1.2] months and 8.0 [1.3] months, respectively; p = 0.223). Similarly, there was no significant difference in mean age between caregivers in the intervention and control arms (29.3 [6.9] and 27.2 [9.7], respectively; p = 0.175). With the exception of children's birth weight and caregivers' marital status, the distributions of other child and caregiver characteristics were fairly balanced between intervention and control arms of the study (**Table 5.4)**.

Table 5.4. Participants' characteristics compared between intervention and control arms of the study

Variables	**Intervention facilities N (%)**	**Control facilities N (%)**	**p value[#]**
All children (1058)	351 (33.2)	707 (66.8)	
Child-level factors			
Age of child (months)	Mean (SD): 7.8 (1.2)	Mean (SD): 8.0 (1.3)	0.223
0 – 11 months	234 (66.9)	500 (70.8)	
12 – 23 months	116 (33.1)	206 (29.2)	0.188
Sex of child			
Female	166 (47.6)	370 (52.3)	
Male	183 (52.4)	337 (47.7)	0.145
Birth order			
1st – 3rd order	316 (90.0)	652 (92.2)	
4th + order	35 (10.0)	55 (7.8)	0.229
Birth weight			
Large	89 (25.5)	72 (10.3)	
Average	216 (61.9)	607 (86.6)	
Small	44 (12.6)	22 (3.1)	<0.001
Reason for health facility visit			
Vaccination	212 (60.4)	483 (68.3)	
Non-vaccination	139 (39.6)	224 (31.7)	0.071
Caregiver-related factors			
Caregiver age (years)	Mean (SD): 29.3 (6.9)	Mean (SD): 27.2 (5.7)	0.175
18 – 24 years	86 (24.6)	169 (23.9)	

25 – 34 years	175 (50.0)	386 (54.6)	
35+ years	89 (25.4)	151 (21.5)	0.365
Level of education			
Primary	36 (10.5)	63 (8.9)	
Post-primary	307 (89.5)	641 (91.1)	0.166
Relationship to child			
Mother	325 (92.6)	658 (93.0)	
Other relation	26 (7.4)	49 (7.0)	0.591
Marital status			
Not Married	129 (36.8)	430 (60.8)	
Married	222 (63.2)	277 (39.2)	<0.001
Maternal antenatal care			
Attended	346 (98.9)	699 (99.0))	
Never attended	4 (1.1)	7 (1.0)	0.879
Employment status			
Employed	87 (25.0)	211 (30.5)	
Unemployed	261 (75.0)	482 (69.5)	0.067

$\chi 2$ test for comparison of proportions

5.3.3 Process evaluation

Weekly trends of the percentage of children whose RtHBs were screened by healthcare workers during PHC facility encounters) are shown in **Figure 5.2**. In the intervention PHC facilities, weekly immunisation status screening rate ranged from 92.2% to 95.1% before the quality improvement intervention (Week 1 – 3), followed by a gradual increase in the intervention period, reaching 100% by the last week of the evaluation period (Week 11). In the control PHC facilities, on the other hand, weekly immunisation status screening rate ranged from 87.4% to 96.9% in the pre-intervention period. This trend was maintained in the intervention period, ranging from 84.9% to 94.6% with no significant difference compared with the pre-intervention period ($p = 0.665$). Notably, the immunisation screening rate did not reach 100% at any point during the evaluation period in the control facilities while it did so in the intervention facilities.

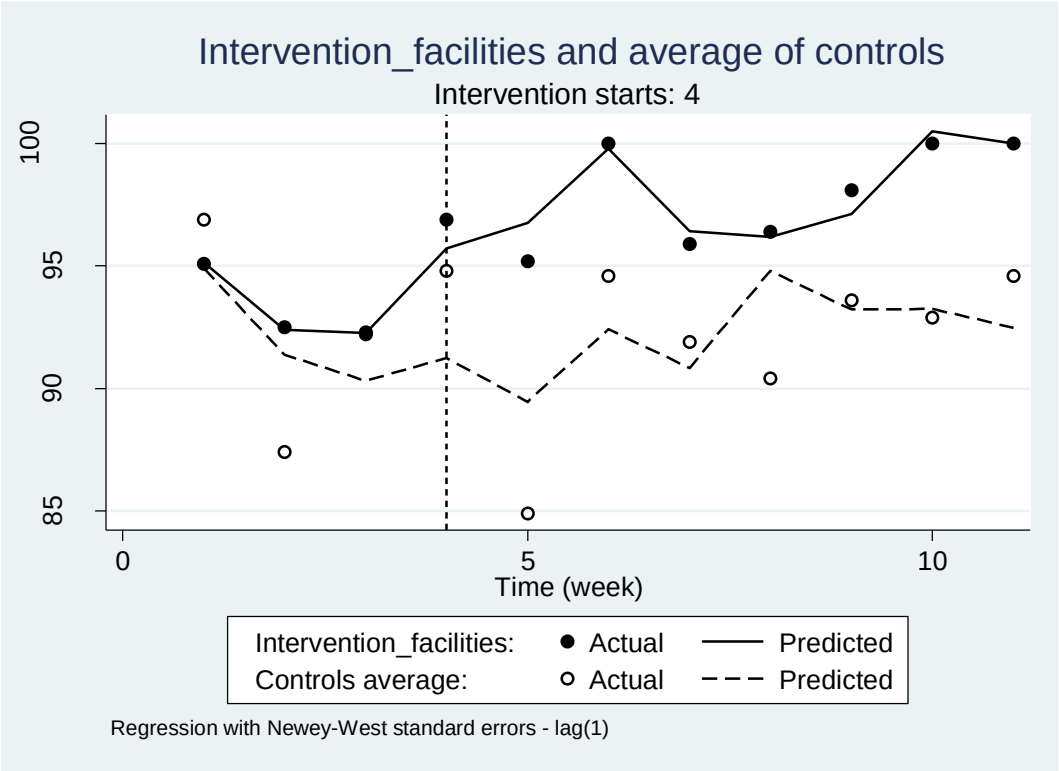

Figure 5.2. Weekly trends of children's immunisation status screening rate (Week 4 marks the commencement of the quality improvement intervention).

5.3.4 Outcome evaluation

5.3.4.1 Weekly trends of MOV prevalence across participating health facilities

Results from the ITSA regression models of weekly MOV trends across participating PHC facilities are shown in **Table 5.5**, with Newey coefficients representing changes in weekly MOV prevalence and their associated 95% CIs. In Facility A (one of the two intervention facilities), baseline MOV prevalence was 18.33% (95% CI = 17.49, 19.17), with a significant decline to 7.65% (95% CI = 4.40, 9.20; p<0.001) by the end of the post-intervention evaluation period. MOV levels remained stable with no significant changes in the weeks prior to the intervention (<-0.01% [95% CI = -1.20e-14, 0.70]; p = *0.999*). In the first week of the intervention (Week 4), a significant decrease in MOV prevalence was observed, reducing by 5.20% (95% CI = -10.26, - 0.13; p <0.05). Overall, there was a significant decrease in the weekly MOV levels of -1.09% per week (95% CI = -2.17, - 0.01; p<0.05) during the intervention period, relative to the pre-intervention trend. Notably, there was an observable increase in MOV the last two weeks of evaluation in this facility, which might have resulted from a combination of factors as will explored later in the discussion section. Weekly trends of MOV prevalence in Facility A are shown in **Figure 5.3a**.

In the second intervention facility (Facility B), the MOV prevalence was 17.75% (95% CI = 17.12, 18.38) at baseline, with a significant reduction to 0.00% (p<0.001) by the last week of post-intervention evaluation. MOV prevalence trends remained stable [no significant change] in the weeks prior to the intervention (-0.25% [95% CI = -0.77, 0.27]; p = *0.296*). In the first week of the intervention, MOV prevalence decreased by -3.33%, though this decline was not statistically significant (95% CI = -7.56, 0.89; p = 0.104). However, this was followed by a significant decrease in weekly MOV levels of -1.49% (95% CI = -2.42, - 0.56; p<0.05) per week on average in the intervention period, relative to the pre-intervention trend). **Figure 5.3b** illustrates weekly trends of MOV prevalence in Facility B.

In contrast, changes in weekly MOV trends in the two control facilities (C and D) were unremarkable, with no significant changes across pre-intervention and intervention periods as evident in the Newey coefficients and their corresponding 95% CIs and p values in **Table 5.5.** As visually illustrated in **Figures 5.3c** and **5.3d**, there were no substantial differences in weekly MOV levels between pre-intervention and intervention periods in both control facilities, in comparison with the declining trends observed in the intervention facilities (A and B).

Table 5.5 ITSA regression model estimates of weekly MOV trends across participating PHC facilities in Cape Town

	Intervention facilities				Control facilities			
	Facility A		Facility B		Facility C		Facility D	
Outcome measures	**Newey Coefficient (95% CI)**	**p value**	**Coefficient (95% CI)**	**p value**	**Coefficient (95% CI)**	**p value**	**Coefficient (95% CI)**	**p value**
Baseline MOV prevalence (%)	18.33 (17.49, 19.17)		17.75 (17.12, 18.38)		7.75 (7.12, 8.38)		16.50 (14.48, 19.51)	
Mean weekly % change in MOV prevalence in the pre-intervention period	<-0.01 (-1.20e-14, 0.70)	0.999	-0.25 (-0.77, 0.27)	0.296	-0.24 (-0.76, 0.26)	0.282	-1.01 (-3.76, 1.10)	0.300
% change in MOV prevalence in the first week of intervention	-5.20 (-10.26, -0.13)	0.046	-3.33 (-2.42, 0.13)	0.104	-0.01 (-3.95, 3.94)	0.996	-2.3 (-9.14, 4.54)	0.453
Mean weekly % change in MOV prevalence in intervention period relative to the pre-intervention period	-1.09 (-2.17, -0.01)	0.048	-1.49 (-2.42, -0.56)	0.007	0.21 (-0.62 , 1.05)	0.565	1.21 (-0.91, 3.34)	0.220
Endline MOV prevalence (%)	7.65% (4.40, 9.20)	<0.001	0.00% (0.00, 0.00)	<0.001	7.65 (6.80, 8.45)	0.900	11.01 (9.85, 13.70)	0.060

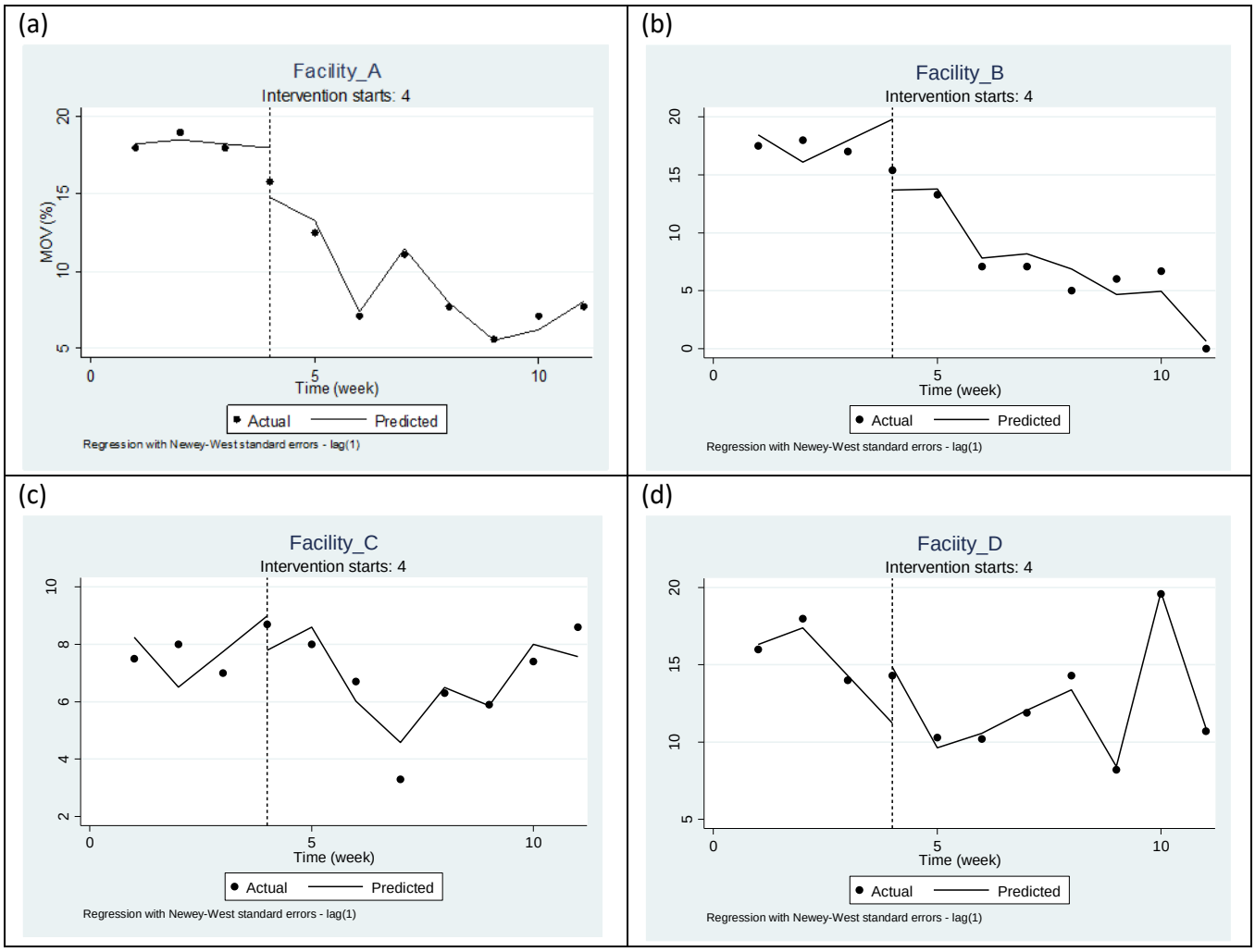

Figure 5.3: Weekly MOV prevalence trends across participating primary health care facilities in Cape Town: Intervention facilities (A and B) and control facilities (C and D)

5.3.4.2 Overall measure of effectiveness of the quality improvement interventions

Table 5.6 presents adjusted Newey coefficients, their associated 95% CI and other results from the comparative ITSA regression model of weekly MOV trends and mean differences in weekly MOV trends between the two study arms. Given the notable differences in baseline MOV prevalence and patient volume between the intervention and control facilities, these factors were adjusted for in the model.

While there was a statistically significant difference in baseline MOV prevalence between children in the intervention and control facilities; 6.38% (95% CI = 3.77, 8.98; p<0.001), both remained stable and there was no difference in weekly trends in MOV prevalence during the pre-implementation period between the two study arms; -0.17% (95% CI = -0.89, 0.86; p =

0.966). After controlling for differences in baseline MOV prevalence between the two study arms and facility-level covariates, there was a significant reduction in weekly MOV prevalence in children in the intervention facilities compared with those in the control facilities, with a 1.52% reduction per week (95% CI = 0.34, 2.69; p <0.05). Notably, while children in the intervention facilities had a significantly higher prevalence of MOV than those in the control facilities at baseline (with a difference of 6.38 [95% CI = 3.77, 8.98]; p<0.001), they had a significantly lower MOV prevalence following the quality improvement intervention (with a difference of -7.65 [95% CI = -9.20, -4.40]; p <0.001). Weekly trends of MOV prevalence in intervention and control facilities are graphically illustrated in **Figure 5.4**.

Table 5.6. ITSA regression model estimates of weekly MOV trends in the intervention facilities compared with the control facilities in Cape Town

Outcome measures	**Coefficient (95% CI)**	**p value**
Difference in baseline MOV prevalence (%) between children in the intervention and control facilities	6.38 (3.77, 8.98)	<0.001
Mean difference in weekly MOV prevalence (%) in the pre-intervention period between children in the intervention and control facilities	-0.02 (-0.89, 0.86)	0.966
Mean difference in weekly MOV prevalence (%) in the first week of intervention between children in the intervention and control facilities	-3.17 (-8.82, 2.49)	0.248
Mean difference in weekly MOV prevalence (%) between children in the intervention and control facilities over the evaluation period	-1.52 (-2.69, - 0.34)	0.016
Difference in endline MOV prevalence (%) between children in the intervention and control facilities	-7.65 (-9.20, -4.40,)	<0.001

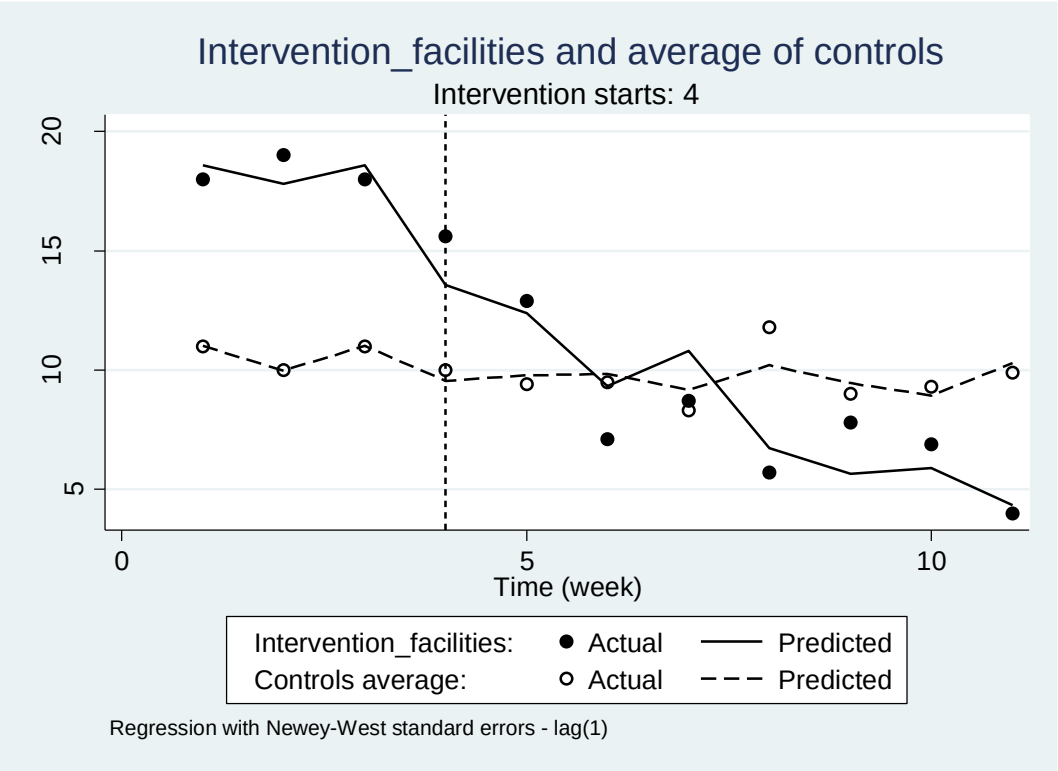

Figure 5.4. Weekly MOV prevalence trends compared between intervention and control health facilities

5.3.5. Balancing measure

Weekly trends in mean patient waiting time (minutes) were used as balancing measures to monitor the impact of the quality improvement intervention on other routine health services provided by participating facilities. This was to ensure that quality improvement implementation did not adversely impact or increase the waiting time for other PHC services. As illustrated in **Figure 5.5**, the weekly mean waiting time of children in the intervention facilities maintained similar trends across pre-intervention and intervention periods. Though increasing slightly in the first week of intervention (Week 4) from 93.3 minutes in the previous week to 120.2 minutes, it stabilised to about the pre-intervention levels in the subsequent weeks of the intervention period ($p = 0.502$).

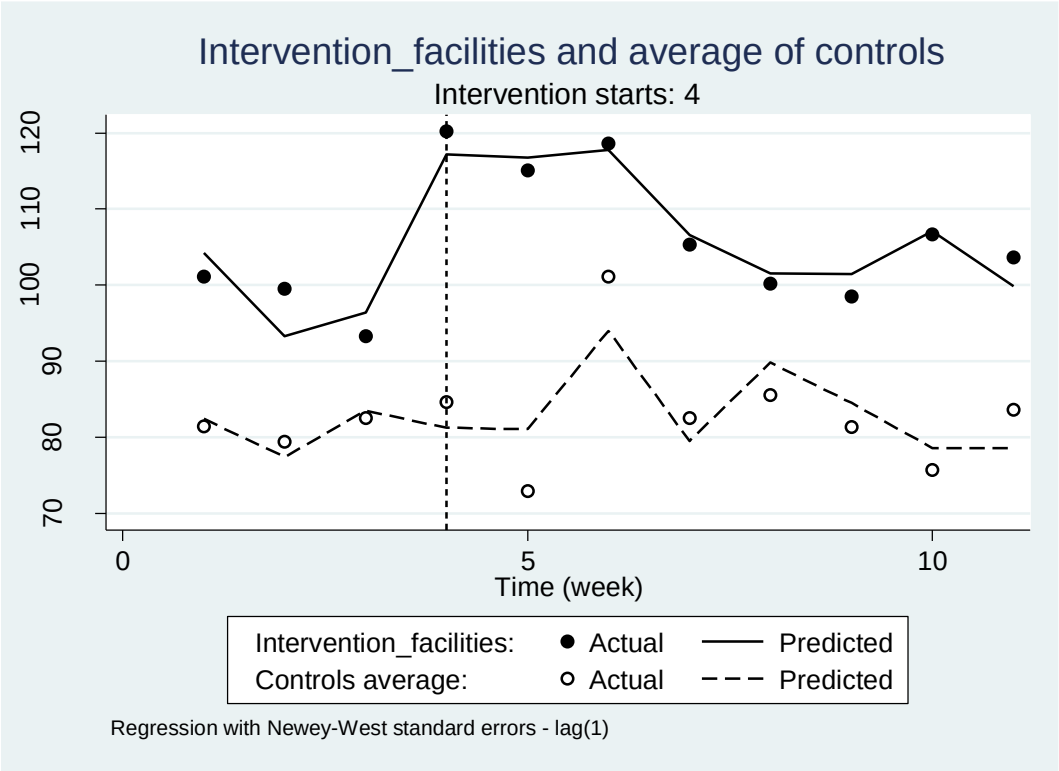

Figure 5.5. Weekly trends of mean patient waiting time (minutes) as balancing measures to monitor the impact of the quality improvement intervention on other routine health services.

5.4 Discussion

5.4.1 Summary of key findings

This study aimed to evaluate a quality improvement intervention implemented to address MOV among children younger than two years attending PHC facilities in Cape Town. Using a quasi-experimental evaluation design, this study has demonstrated that local implementing actors like health workers are capable of conceptualising, developing and adapting a range of quality improvement strategies suitable for their local contexts. There was a significant reduction in weekly MOV prevalence in among children in the intervention facilities compared with those in the control facilities; declining at a rate of 1.52% per week (95% CI = -2.69, -0.34; p <0.05). There was no evidence that the quality improvement intervention adversely affected other PHC services in terms of waiting time. Overall, findings from this evaluation also demonstrate that well planned and contextually tailored quality improvement interventions can help reduce the burden of MOV and improve childhood immunisation service delivery in PHC settings. The findings have important implications for policy, practice and future research as discussed in the following sections.

5.4.2 Implications for policy and practice

The study lends import support to current global efforts to increase immunisation coverage through MOV assessment and reduction in healthcare settings.[28,29] Such efforts include the systematic analysis of the burden of MOV using appropriate methods and tools, as employed by the baseline assessments of this PhD research (as reported in chapters 3 and 4), as well as the implementation and evaluation of context-specific interventions to mitigate the burden of MOV, as reported in this chapter. Particularly, the findings provide a useful evidence base for current and future efforts to expand immunisation coverage and improve quality of primary health care services among children in SA, including the National Core Standards and Ideal Clinic initiative.[54,55]

The study shows that simple and low-cost quality improvement strategies like improving the screening of children's immunisation status with home-based records like the RtHBs during healthcare encounters, can be highly effective for reducing MOV occurrences and increasing the likelihood that children receive recommended vaccines during healthcare visits. Routine screening of children's immunisation status at every healthcare encounter enables health workers identify those children who are not fully immunised for age during that visit and link them to immunisation services. This study also illustrates the important role of technology in driving quality improvement efforts, as seen with the use of electronic reminder and prompt systems for improving immunisation status screening in the participating facilities. Facilities were able to leverage existing electronic immunisation appointment and reminder systems to identify children who were incompletely vaccinated at the point of registration during clinic visits. This in combination with screening of RtHBs was the most commonly adopted quality improvement strategy in the intervention facilities, supporting the current body of evidence on the feasibility and usefulness of technology to support healthcare quality improvement implementation in resource-limited settings.[56]

Evidence from the literature consistently shows that active local-level engagement is important for boosting stakeholders' participation, ownership and ultimately the successful implementation of quality improvement initiatives.[57,58] Involving local health system actors to play critical roles in planning and implementing interventions have many benefits. It can promote deeper awareness and understanding of the problem, while nudging stronger commitment and ownership of the intervention. Moreover, health system stakeholders like frontline health workers are likely to be more knowledgeable of the range of strategies best

suited for their setting. For example, the selection of specific quality improvement strategies and assignment of roles within quality improvement teams in the present study involved a careful consideration of current infrastructure and human resource capacity. Consistent with that, we found that adaptation of strategies to the local context, such as the use of optimised immunisation status screening and the integration of immunisation services with other routine PHC services, helped to enhance the feasibility and effectiveness of quality improvement in the study context.

The need for quality improvement interventions to be informed by local evidence has been recognised as a vital step to optimising health service delivery and improving health outcomes.[59,60] In this study, facility-level QI teams and district–level PHC managers were involved in weekly review of MOV trends against targeted outcomes to track performance, identify gaps and assess needs for improving implementation outcomes. For quality improvement to be effective in health care, it is vital to provide regular feedback to implementing stakeholders on the performance and current implementation gaps.[61] Such feedback is important for improving and sustaining quality improvement outcomes.[56,62]

Remarkably, there was an observable increase in MOV in the last two weeks of evaluation in one of the intervention facilities, which might have been due to several factors, such as health workers being overwhelmed by additional workload due to the quality improvement, which could in turn lead to de-motivation or de-prioritisation of the quality improvement activities. Other possible reasons for this trend could include factors relating to the intervention itself, including inadequate quality improvement planning and supervision; shortage of vaccines and other immunisation commodities; and staff shortages in the affected weeks. The success of any quality improvement intervention depends on prevailing contextual and structural factors, including the functionality of existing health systems and the appropriateness of the strategy within specific contexts.[63] Ultimately, the adequacy of resources to meet quality improvement needs is an important determinant of the impact of the intervention.[63,64] The relatively better outcomes in the second intervention facility may also reflect differences in human and overall capacity and the level of QI team commitment between both facilities. These are consistent with the findings from previous studies.[38] While these are not surprising given the real world setting of the study, these findings have important implications for the feasibility and sustainability of quality improvement interventions. They underscore the need

for ensuring adequate resources and the use of locally appropriate quality improvement strategies to maximise intended quality improvement outcomes.[65]

Another notable finding from this evaluation was that the quality improvement intervention did not adversely impact waiting time for other routine primary health care services in the facilities that implemented the intervention. This implies that attention and resources can be channelled to addressing problems such as MOV, without undermining other services. Strategies such as integrating quality improvement activities into existing quality improvement plans, as was the case in both intervention facilities, can help to enhance the compatibility of quality improvement strategies with other routine facility level workflow.

5.4.3 Study strengths and limitations

The plausibility evaluation design and the ITSA statistical approach used in this study offer a quasi-experimental design with a high degree of internal validity, for comparing MOV trends between the intervention and control facilities, while controlling for systematic and time-varying differences between the two study arms.[50,51] This quasi-experimental design helped to demonstrate the effects seen were plausibly due the intervention. Notwithstanding these strengths, this study has notable limitations. One major limitation was the non-random assignment of facilities to study arms. Randomisation was not feasible due to practical considerations such as ensuring that intervention facilities had the capacity to implement quality improvement initiatives. This might have introduced systematic differences between facilities in the two study arms as it possible that the effect seen is in part due to the intervention facilities being relatively better resourced than those in the control arm. However, we believe that much of these differences were controlled for in the ITSA models by adjusting for baseline and time-varying differences between intervention and control arms of the study.

Given the unblinded nature of the study and the likely interaction of staff of intervention and control facilities during municipal or provincial health meeting, it was possible that a spillover effect occurred to an extent, which could mean an underestimation of the effectiveness of implemented quality improvement interventions. Due to the lower-than-expected number of participants sampled per day across facilities, evaluation was done using analyses of data on a weekly, rather than on a daily basis as planned initially. This reduced the number of data

points used in the ITSA analysis with implications for the statistical power of the study and the precision of estimates of evaluation outcomes.

Stakeholders were actively involved in the planning and execution of the quality improvement intervention. This stakeholder-led approach helped to nudge a deep sense of ownership and participation.[58] The quality improvement strategies were selected by health facility workers, who adapted the strategies to their local context. Moreover, the real-world setting of this research has practical and contextual implications, allowing the direct applicability of findings and recommendations for improving routine immunisation coverage at facility level in the study context, while offering useful lessons and insights for implementing quality improvement in similar settings. However, the awareness of the evaluation by staff of the intervention facilities, which might have influenced their behaviour, poses an additional limitation.

Furthermore, while facility-level quality improvement has a lot of promises for addressing health system gaps at various levels, there is a fundamental limitation of its use in the context of MOV. Although quality improvement interventions can help mitigate vaccine demand/supply-side and facility-level structural determinants of MOV, they may have limited impact on broader structural and social determinants of MOV beyond those occurring at the facility-level. As such, for optimal outcomes, MOV interventions need to be effectively integrated into broader health strategies that can comprehensively address individual, contextual and structural enablers of MOV.

5.4.4 Implications for future research

Considering the above limitations, it is imperative that future quality improvement evaluation studies in the context of MOV consider several methodological improvements. First, further research in this direction can use a randomised study design to control for any systematic differences between the intervention and control study arms that is not due to the quality improvement intervention itself. There is also a need to ensure that future evaluations have a larger sample size per time point and longer follow-up period. Given the focus of the current study on public PHC facilities located within urbanised metropolitan sub-districts, there remains unanswered questions regarding the MOV and the role of quality improvement in secondary and tertiary care settings, as well as in facilities in the private and rural sectors in

SA. These need to be explored through wider assessments involving facilities across all care levels and both sectors, spanning both rural and urban settings. It would also be valuable for future studies to assess and address MOV in non-facility settings, such as mobile clinics and community health outreaches, where the burden of MOV may be more substantial. To enhance the uptake of assessment findings for improving routine immunisation and facility practice, such research efforts should be embedded as part of integrated MOV assessment and remedial implementation research initiatives.

5.5. Conclusion

This study demonstrates that local implementation actors like health workers are capable of conceptualising, implementing and adapting a wide range of quality improvement strategies suitable for their local contexts. Findings from the evaluation suggest that evidence based and contextually appropriate quality improvement interventions can help reduce the burden of MOV and improve immunisation service delivery outcomes in health facility settings, without adversely impacting other services at the facility level.

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Chapter 6: Implementation barriers and facilitators of a quality improvement intervention to address missed opportunities for vaccination among children in Cape Town, South Africa: a mixed methods post-intervention evaluation

About this chapter

This chapter presents findings of the fifth and final component study (based on the fifth specific objective) of this doctoral research. The study followed the implementation of a facility-level quality improvement intervention targeted at reducing missed opportunities for vaccination (MOV) in selected primary health care facilities in Cape Town. It used a mixed-methods post-implementation evaluation approach, with the aim of aiding understanding of the implementation context, identify facilitators and barriers to implementation success, while highlighting learnings for improving and sustaining further quality improvement initiatives in the study setting and similar contexts.

Abstract

Background: This study followed the implementation of a facility-level quality improvement intervention targeted at reducing missed opportunities for vaccination (MOV) among children aged 0-23 months in two primary health care (PHC) facilities in Cape Town. Through the lens of the consolidated framework for implementation research (CFIR), it aimed to explore individual and contextual barriers and facilitators of the quality improvement implementation. The ultimate goal was to aid understanding of the implementation context while highlighting lessons for improving and sustaining the quality improvement initiative.

Method: This study involved a mixed-methods post-intervention evaluation design. Quantitative data were collected using a self-administered, Likert rating tool, while qualitative data collection was guided by an interview guide. Study participants in both components included health workers of the two PHC facilities that implemented the MOV-targeted quality improvement intervention. From the 5-point Likert scale, median scores with their corresponding interquartile ranges (IQR) were calculated for each CFIR domain and for each item across domains. Qualitative were analysed based on themes corresponding with CFIR domains. A thematic synthesis approach was used to consolidate quantitative and qualitative findings.

Result: A total of 28 health workers participated in this study with a mean age (standard deviation) of 37.6 (7.25) years, most (82.14%) of whom were female. Domain-level median scores (IQR) were high; 4 (4-4) in each of the intervention characteristics, inner setting, individual characteristics, and implementation process domains. The score was, however, relatively lower in the outer setting domain; 3 (3-4). In the intervention characteristics domain, most respondents agreed that the quality improvement strategies were locally developed by health workers from their PHC facility; that they were fully involved in choosing the quality improvement ideas; and that they believed the intervention would reduce MOV and improve the performance of their facility's immunisation service. In the inner setting domain, most respondents agreed that staff of their PHC facility received adequate peer support and supervision; and that it was easy to relate with members of the quality improvement team. They however agreed to a lesser extent that they had enough staff to implement the quality improvement intervention. In the characteristics of individuals domain, there was also popular agreement among respondents that they felt ready and confident to

participate in the quality improvement intervention; that they were familiar with the quality improvement strategies before implementation began; and that they considered themselves an important stakeholder for reducing MOV in their health facility. In the intervention process domain, most respondents agreed that there was adequate planning and preparation before the quality improvement commenced in their health facility; that there were adequate communication and involvement of stakeholders in planning and implementing the intervention; and that there was a feedback mechanism for monitoring progress and sharing experiences. Respondents agreed to a lesser extent in the outer setting domain, especially when asked if they believed quality improvement was successful in other places; and if they received incentives or reward for participating in the intervention. Language barrier arising from the multicultural setting of the communities served by the health facilities was perceived by some respondents as a challenging factor in this domain. Most were, however, in agreement that they considered MOV to be a significant problem in their community.

Conclusion: From its quantitative and qualitative findings, this study highlights important factors hindering or facilitating quality improvement implementation success. Findings underscore the importance of conducting post-implementation evaluation to aid understanding of implementation context for improving and sustaining quality improvement efforts.

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6.1 Introduction

With the growing momentum to assess and address missed opportunities for vaccination (MOV), considering early evidence indicating a concerning level of MOV with global prevalence of MOV prevalence of 32%, the World Health Organization (WHO) in 2016 recommended the prioritisation of MOV assessments as a public health strategy.[1-3] Consequently, there has been an increasing body of evidence on the prevalence of MOV and associated factors over the last decade, including in African and other LMIC contexts.[1,2,4-7] To date, however, there remain enormous gaps in what is known about MOV, particularly in South Africa (SA).[8] Evidence on the role and effectiveness of interventions for addressing MOV remains even more sparse globally.[9]

Quality improvement approaches have been used across diverse health care settings, such as disease diagnostics and treatment, maternal and child health and infection control.[10-13] There is, however, currently a dearth of literature on the feasibility and effectiveness of quality improvement strategies in the context of MOV.[14] Limited evidence available suggests that quality improvement initiatives can be used to operationalise remedial measures targeted at vaccine demand- and supply-side factors, as well as health facility-level and other structural factors associated with MOV.[9,14] Available evidence also demonstrates that frontline health workers can initiate and implement quality improvement interventions tailored to their local context and capacity.[9,14]

Like any other intervention, the success or failure of quality improvement interventions can be influenced by various factors.[12,15] These may include factors related to individual implementers and stakeholders such as frontline health care workers and health care users; and those that are structural in nature, such as health facility resource capacity. Understanding how these factors influence quality improvement implementation outcomes is important for gaining insights on how best to adapt implementation strategies to improve or sustain subsequent quality improvement efforts. Several implementation research approaches have been proposed to aid the assessment of factors that enhance or hinder implementation outcomes, including conceptual and theoretical frameworks for guiding implementation research and evaluation.[16,17] The Consolidated framework for implementation research (CFIR) is one of the most commonly used implementation research frameworks.[16,17] It is a validated conceptual framework that is widely used for evaluating the

implementation process of complex and contextually innovative interventions across multiple implementation domains.[16]

This study, through the lens of the CFIR, explored the implementation context of PHC facilities that implemented the quality improvement intervention implemented to address MOV among children attending primary health care facilities in Cape Town. The specific aim was to understand the facilitators and barriers to quality improvement implementation using both qualitative and quantitative data. The study followed the implementation of a facility-level quality improvement intervention targeted at reducing MOV in two PHC facilities in Cape Town. The quality improvement intervention was informed by our mixed-methods baseline assessment of the burden of MOV and associated factors among children aged 0 – 23 months attending PHC facilities in Cape Town, the results of which have been published.[18,19] The ultimate goal of this study was to understand the facilitators and barriers to quality improvement implementation using both qualitative and quantitative data. The ultimate goal of this study was to enable the identification of barriers that need to be addressed and facilitators to be leveraged for improving and sustaining current and future quality improvement efforts.

6.2 Methods

6.2.1 Study design and theoretical framework

This study involved a mixed-methods post-intervention evaluation design. The use of a mixed methods design helped to foster a better and more holistic understanding of implementation outcomes using insights from both quantitative and qualitative data. The quantitative component involved the collection of quantitative insights regarding the quality improvement intervention from PHC facility staff using a rating tool. On the other hand, the qualitative component involved an exploratory qualitative research design using in-depth interviews to explore the opinions and perspectives of PHC facility staff regarding the quality improvement intervention.

The CFIR was adopted as the theoretical framework to guide the collection and synthesis of both data types.[17] The framework has five domains: characteristics of the innovation (intervention), inner setting, outer setting, characteristics of individuals, and implementation process.[17] The framework is comprehensive as it encompasses a wide array of

implementation domains and sub-domains, making it suitable for assessing implementation context from multi-dimensional perspectives.[17]

In the context of the current study and the quality improvement intervention implemented to reduce MOV in PHC settings, the CFIR domain of intervention characteristics included features of the quality improvement intervention. The outer setting domain encompassed features of the external environment in which the implementation setting was nested. The inner setting domain reflected factors relating to the PHC setting where the quality improvement intervention was implemented. The individual characteristics domain included features of implementing actors, such as PHC workers and members of the quality improvement teams; while the implementation process domain referred to activities, strategies and processes that unfolded during the quality improvement implementation.

6.2.2 Study setting

The Western Cape is one of the nine provinces in SA.[20] Cape Town is the biggest metropolitan area in the province with a population of approximately 4 million persons.[21] Primary health care services like immunisation are provided through the city's 152 PHC facilities, 102 of which are managed by the City of Cape Town (local government) to augment PHC services provided by provincial facilities.[21] Like elsewhere in SA, routine immunisation services in Cape Town are funded through the Expanded Programme on Immunisation of SA (EPI-SA) and provided free of charge primarily through the PHC facilities.[22] While the Western Cape is relatively better resourced health system and health outcomes than other provinces, immunisation coverage remains lower than optimal levels, with as much as 36.1% of children in the province being incompletely immunised.[23]

6.2.3 Study population and sampling

Participants were PHC facility staff sampled from the two PHC facilities that implemented the quality improvement intervention. In the quantitative component of the study, participants included all facility staff who participated in the quality improvement activities. Invitation to participate in the quantitative study was extended to all current health workers in the participating PHC facilities. These included staff of all service delivery points including outpatient department, immunisation, maternity, pharmacy, laboratory, among others. To be eligible to participate in the qualitative in-depth interviews, participants had to currently hold managerial roles in either of the two facilities, participated in the quality improvement

intervention and willing to participate in the interview. Potential participants were approached by members of the research team at the clinics and informed about the research. Those who consented to participate were enrolled into the study.

6.2.4 Summary of the quality improvement intervention

The quality improvement strategies implemented were co-designed by quality improvement teams in both implementing PHC facilities and implemented using two plan-do-study-act (PDSA) cycles.[24] The first PDSA cycle occurred in April 2022 while the second PDSA cycle occurred the following month in May 2022. There was an initial pre-implementation stakeholders' engagement to involve them in the agenda-setting and goal sharing, while soliciting their support and participation. Next, quality improvement teams were constituted in each intervention facility, comprising of 3 - 5 facility staff. Efforts were made to integrate the chosen quality improvement strategies into existing facility-level and municipal PHC and immunisation quality improvement plans. Although members of the community were not directly involved as members of QI teams, their voices and insights regarding perceived immunisation service delivery gaps and quality improvement needs, solicited through the qualitative baseline assessment (**reported in Chapter 4**) helped to inform the quality improvement strategies adopted in each intervention facility.

A workshop on MOV and quality improvement was conducted to further sensitise quality improvement teams on the current evidence on MOV (including local findings on MOV prevalence and associated factors from baseline assessment) and quality improvement best practices in the context of routine immunisation. Following the workshop and the review of baseline MOV findings, facility quality improvement teams met to identify gaps and needs; clarify roles and assign responsibilities, while taking into account their facility's capacity and relevance of the selected strategies to the local context.

Examples of quality improvement strategies adopted included: error proofing (placing reminder tags on children's cards), workspace adaptation (such as displaying posters with immunisation messages in waiting areas and consulting rooms, conducting daily routine immunisation, and deployment of additional cold boxes to facilitate immunisation at other service delivery points), and advocacy (such as appealing to caregivers who were unwilling to stay in long queues to have their children immunised before leaving the clinic). Selected

change ideas were implemented using two PDSA cycles, each lasting a period of four weeks. The second PDSA cycle served as an opportunity to review and apply learnings from the first cycle to improve implementation outcomes in the second cycle. To ensure adequate supervision and optimal implementation, there were weekly facility-based quality improvement meetings to review progress and share lessons, periodic monitoring and supervision visits by municipal health managers in line with existing quality improvement strategies.

6.2.5 Data collection process

Quantitative data collection: a self-administered, structured questionnaire was used to collect data from PHC facility staff (See Appendix). The rating scale was adapted from a tool developed based on the CFIR guidance.[25] The questionnaire consisted of two sections: the first section related to data on participants' sociodemographic and professional characteristics, while the second section consisted of a rating tool to collect the health worker's rating of the quality improvement process. The rating was based on a 5-point Likert scale (with 1 representing strong disagreement, and 5 representing strong agreement). The tool captured the five domains of the CFIR namely; intervention (innovation) characteristics, inner setting, outer setting, characteristics of individuals, and implementation process (12). Rating items/questions were developed for each domain; eight items under intervention characteristics; four under outer setting; 12 under inner setting; four under characteristics of individuals; and six under implementation process domain. Data were collected using mobile tablets through questionnaires deployed on the Research Electronic Data Capture (REDCap) platform.[26] To maximise participation, the research assistants returned to each facility the following day to collect questionnaires from health workers who could not complete theirs on the first day.

Qualitative data collection tool: A pre-tested semi-structured interview guide adapted from a previous study[25] was used to elicit responses from in-depth interview participants. The interview guide explored the perspectives of health worker who played key roles in implementing the quality improvement intervention in their facilities. The interviews were conducted face-to-face in private offices or rooms within the participating facilities, with each session lasting about 45 minutes to one hour. Interviews were conducted in the afternoon to

avoid interrupting service delivery. All interviews were recorded using a portable digital audio recorder and transcribed verbatim. Local language texts in the transcripts were translated to English by a professional translator and back-translated from English to the original language to ensure accuracy of translation and that meanings were not lost in translation
Both qualitative and quantitative data were collected in the period 27 June to 30 June 2022.

6.2.6 Data analysis

Quantitative analysis: To test the internal validity and reliability of the Likert rating tool used to collect quantitative data, the reliability coefficient of the items in each domain was calculated using Cronbach's alpha.[27] Exploratory factor analysis was conducted to explore the factor structure of the questionnaire using the polychoric correlation matrix. Eigen values of greater than 1 and the pattern of factor loading on each item were used to assess which factors to retain.[28] An orthogonal varimax rotation was used to ensure that the items are consistent with each other and factors are uncorrelated.[29] The Bartlett test of sphericity and Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy were calculated for all items in each domain. A KMO value over 0.5 was indicative of sampling adequacy,[30] while a significance level for the Bartlett's test below 0.05 was indicative of substantial correlation in the data.[31] Median scores with their corresponding interquartile ranges (IQR) were calculated for each item across CFIR domains. Similarly, domain-level median scores with their corresponding IQRs were calculated for each of five CFIR domains. Quantitative analysis was conducted using Stata 14.2.[32]

Qualitative data analysis: A thematic template analysis approach was used for coding and organising transcribed data segments for analysis.[33] This method allowed for flexibility and contextual adaptability of analysis across relevant themes.[34] Two codebooks were developed. In the first codebook, emerging themes relating to factors that affected the implementation of the quality improvement intervention were identified inductively from the transcripts, with illustrative quotations organised under each theme.[35] In the second codebook, thematic codes in the first codebook were deductively mapped to the five CFIR domains. To enhance accuracy and consistency of the analysis, codes generated were independently verified against the raw data by the lead researcher. To avoid overlapping codes, only the most

relevant codes were matched to a corresponding CFIR domain. Qualitative findings were reported in accordance with the Standards for Reporting Qualitative Research (SRQR).[36]

Consolidation of quantitative and qualitative findings: A consolidation of findings table was used to organise and integrate qualitative and quantitative findings across the five CFIR domains, by presenting median scores (with IQRs) and example illustrative quotes under each item and domain.

6.2.7 Ethical considerations

Ethical clearance for this study was obtained from Human Research Ethical Committee (HREC) of the University of Cape Town (Reference number: HREC 579/2020) (see Appendix). In addition, institutional approval was granted by the Western Cape Provincial Department of Health (Reference number: WC_2021_01_016) and the City of Cape Town Department of Health (Reference number: 9365); both attached as Appendices. Signed informed consent was obtained from all study participants before data collection. It was explained to all study participants that they could, as a matter of personal choice, opt out from the study at any point without consequences. All data collected were anonymous and securely stored in a password-protected database accessible only to the research team.

6.3 Results

6.3.1 Quantitative findings

Characteristics of participants

A total of 28 health workers participated in this study with a mean age (standard deviation) was 37.6 (7.25), most (82.14%) of whom were female and about two-thirds having post-secondary qualifications. The most common cadre represented were nurses (53.57%) and community health workers (14.29%). **Table 6.1** provides more detail on the characteristics of participants.

Table 6.1: Characteristics of participant health workers in two facilities that implemented the quality improvement intervention in Cape Town

Variables	**Frequency (%)**
Age group (in years): Mean (SD) = 37.6 (7.25)	

25 - 39	18 (64.29)
35 - 52	10 (35.71)
Sex	
Male	5 (17.86)
Female	23 (82.14)
Level of education	
Primary education only	3 (11.11)
Secondary education	6 (22.22)
Post-secondary education	18 (66.7)
Cadre of health worker	
Community health worker	4 (14.29)
Nurse	15 (53.57)
Pharmacy assistant	2 (7.14)
Pharmacist	1 (3.57)
Others	6 (21.43)

Results of exploratory factor analysis

Factor analysis yielded satisfactory factor loading of most items on constructs corresponding to the five CFIR domains, with the total variance explained by the retained factors being >50%. The Cronbach's alpha values for each of the five domains; intervention characteristics, outer setting, inner setting, individual characteristics and implementation process, were 0.680, 0.657, 0.620, 0.702 and 0.692, respectively. These reflect an acceptable level (>0.500) of internal consistency in each domain. Results of KMO tests of sampling adequacy and Bartlett tests of sphericity were generally satisfactory across the five domains (Table 6.2).

Results of quality improvement rating by participants

Domain-level median scores (IQR) were high in most domains; 4 (4-4) in each of the intervention characteristics, inner setting, individual characteristics and implementation process domains. The score was, however, relatively lower, in the outer setting domain; 3 (3-4). Median scores for items within each domain were consistent with domain-level scores in most cases, with outer setting item scores being relatively lower compared with items in the other four domains.

In the intervention characteristics domain, most respondents agreed that the quality improvement strategies were locally developed by staff of their PHC facility; that they were fully involved in choosing the quality improvement ideas; and that they believed that the

intervention would reduce MOV and improve the performance of their facility's immunisation service.

In the inner setting domain, most respondents agreed that staff of the facility were well motivated; and that it was easy to relate with members of the quality improvement team. They, however, agreed to a lesser extent that they had enough healthcare staff to implement the quality improvement intervention. Similarly, they agreed less that they received any incentives or reward for participating in the quality improvement intervention.

In the characteristics of individuals domain, there was also popular agreement among respondents that they felt ready and confident to participate in the quality improvement intervention; that they were familiar with the quality improvement strategies before implementation began; and that they considered themselves an important stakeholder for reducing MOV in their health facility.

In the intervention process domain, most respondents were in agreement that there was adequate planning and preparation before the quality improvement commenced in their health facility; there was a quality improvement team charged with coordinating the quality improvement implementation; there were adequate communication and involvement stakeholders in planning and implementation of the quality improvement; that there was involvement and participation of municipal health managers; and that there was a feedback mechanism for monitoring progress and sharing experiences.

Respondents agreed to a lesser extent in the outer setting domain; especially when asked if they believed quality improvement was successful in other places; and if they thought their facility would be rewarded by the municipal department of health if they reduced the occurrence of MOV and improve performance of their immunisation service. Language barrier arising from the multicultural setting of the communities served by the health facilities was perceived by some respondents as a challenging factor in this domain. Most respondents were, however, in agreement that they considered missed opportunities for vaccination to be a very important problem in their community.

Table 6.2 presents median scores and their corresponding interquartile ranges (IQR) for each item within CFIR domains. It also shows domain-level median scores with their corresponding IQRs, along with their alpha values and estimates of KMO test of sampling adequacy and Bartlett test of sphericity.

Table 6.2: CFIR domain-level and item-specific scores with associated statistics

CFIR Domain and items	Median score (IQR)
1. Intervention characteristics *Cronbach's alpha: 0.680* KMO test of sampling adequacy: 0.595 *Bartlett test of sphericity: 0.013*	**4 (4 - 4)**
1.1 The QI strategies were locally developed by stakeholders from this health facility.	4 (4 - 4)
1.2 Health workers from this facility were fully involved in choosing the change ideas to be tested.	4 (4 - 4)
1.3 I believe that the QI strategies would help to reduce missed opportunities for vaccination and improve the performance of our immunisation service.	4 (4 – 4.5)
1.4 The QI intervention is better than other types of interventions for reducing missed opportunities for vaccination and improving performance of immunisation systems.	4 (3 - 4)
1.5 I consider the QI approach to be very flexible.	4 (4 - 4)
1.6 I consider this QI initiative to be very simple to implement.	4 (4 - 4)
1.7 I am very happy with the way the change ideas were delivered in cycles.	4 (4 - 4)
1.8 I consider QI approach to be an inexpensive strategy for addressing missed opportunities for vaccination in primary health care setting.	4 (4 - 4)
2. Outer setting *Cronbach's alpha: 0.657* KMO test of sampling adequacy: 0.505 *Bartlett test of sphericity: 0.005*	**3 (3 - 4)**
2.1 I consider missed opportunities for vaccination to be a very important problem in our community.	4 (3 - 4)
2.2 This primary healthcare facility is a key immunisation service delivery centre in this community.	4 (4 – 4)
2.3 I was interested in using QI approach because I heard it has been successful in other places.	3 (3 - 4)
2.4 Our facility will be rewarded by the City or provincial department of health if we reduce missed opportunities for vaccination and improve the performance of our immunisation clinic.	3 (2 - 4)
3. Inner setting *Cronbach's alpha: 0.620* KMO test of sampling adequacy: 0.573 *Bartlett test of sphericity: 0.025*	**4 (4 - 4)**
3.1 There are enough healthcare workers in this facility.	3 (3 - 4)
3.2 There is a health worker dedicated to managing the immunisation clinic.	4 (4 - 5)
3.3 Immunisation services are provided daily in this facility.	4 (4 – 4.5)

3.4 There was a social media group to keep everyone informed about meetings and key activities regarding the QI intervention.	4 (4 - 4)
3.5 It was easy to relate with all the members of the QI team.	4 (4 - 4.5)
3.6 I will receive a financial reward for using QI to reduce missed opportunities for vaccination and improving immunisation services in this clinic.	3 (3 - 4)
3.7 I will get a promotion for QI to reduce missed opportunities for vaccination and improve immunisation services in this clinic.	4 (4 – 4.5)
3.8 It is easy to implement new ideas like QI in this primary healthcare facility.	4 (4 - 4)
3.9 Parent and caregivers consider this QI initiative to be very valuable and important.	4 (4 - 4)
3.10 There was a good support system in place to seek more information about the QI initiatives.	4 (4 - 4)
The QI team were very committed.	4 (4 – 4.5)
There was easy access to information about the QI initiatives that were implemented.	4 (4 - 4)
4. Characteristics of individuals *Cronbach's alpha: 0.702* KMO test of sampling adequacy: 0.585 *Bartlett test of sphericity: 0.016*	**4 (4 - 4)**
4.1 I was confident in myself during the implementation of the QI initiatives in my facility.	4 (4 - 4)
4.2 I was familiar with the QI strategies before implementation began.	4 (3.5 - 4)
4.3 I consider myself an important stakeholder for reducing missed opportunities for vaccination in this health facility.	4 (4 - 4)
4.4 I was highly motivated and competent to implement QI initiatives this health facility.	4 (4 - 4)
5. Intervention process *Cronbach's alpha: 0.692* KMO test of sampling adequacy: 0.662 *Bartlett test of sphericity: 0.022*	**4 (4 - 4)**
5.1 There was adequate planning and preparation before implementation of the QI ideas commenced in this health facility.	4 (4 - 4)
5.2 There was adequate involvement of parents and caregivers as well as health workers in this facility in planning and implementation of the quality improvement initiatives.	4 (4 - 4)
5.3 There was involvement and participation from district and municipal health managers.	4 (3.5 - 4)
5.4 There was a QI team tasked with the monitoring the change ideas.	4 (4 - 4)
5.5 There was an external person who provided support and direction for this QI initiative.	4 (4 - 4)
5.6 There was a good feedback mechanism for displaying progress and sharing experiences.	4 (4 - 4)

*IQR = Interquartile Range *CFIR = Consolidated Framework for Implementation Research

6.3.2 Qualitative findings

Six in-depth interviews were conducted (three in each participating clinic). Respondents were either facility managers or had leadership roles in their facility's quality improvement teams. Their mean age was 38.50 years (standard deviation: 8.40); four of them were female while two were male. The qualitative findings are discussed under the five domains of the CFIR.

Intervention characteristics

Innovation Source

This sub-domain explores respondents' perceptions about whether the quality improvement intervention originated externally or internally.

While it was widely acknowledged that the idea of implementing the quality improvement intervention to address MOV originated externally from the municipal health department in partnership with the PhD research team, respondents reported that the quality improvement strategies were developed internally at the facility level, and incorporated into existing quality improvement initiatives.

"We heard from City of Cape Town and also from our manager. The manager [was] the one who introduced that it was from the city of Cape Town Head office" – FA2

"So, we sat together and we developed a quality improvement plan" - FB3

"Everything we did, we initiated" – FB1

"Everything we did, we initiated" - FA3

When asked if they understood the rationale behind the quality improvement intervention and what informed it, some health workers mentioned that findings from the baseline quality improvement assessment study necessitated the intervention.

"I think the first change that we made was when we got our first feedback about our performance and immunisation" - FA1

Other respondents were of the opinion that the intervention was born out of a need to improve their PHC facilities' responsiveness to the health of their communities, as part of efforts to address current service delivery gaps, including immunisation services.

"[The QI] was initiated to improve our health system and health in the community and by combating the gaps or improving immunisation" - FA3

Ease, adaptability and flexibility of implementation

This sub-domain is concerned with the extent to which the quality intervention was easy or difficult to implement, as well as the extent to which it could be adapted and tailored to meet local needs.

Many of the respondents were of the view that the quality improvement initiative was well suited for their context while allowing for flexibility and ease of implementation Allowing diverse options and inputs from facility staff came up as a common reason why respondents believed there was flexibility in the quality improvement implementation. The team work approach to the quality improvement implementation was also commonly viewed by respondents as promoting the ease of implementation:

"*Everybody gave the input on how we can do things different, and if it didn't work, we have a facility meeting then we would say OK, let's change it a little bit more and then we would try another strategy"* – FA1

"I think it was flexible, especially for clients working and we just all work together and we exchange ideas as long as the outcome is successful" – FB1

There were, however, concerns that the intervention could have been adapted better to the local context to overcome the challenges of language barriers'

"But the language barrier is a big issue, so I think if we can work on that, getting translators, because we really have a problem with mommies who don't understand English" – FA2

"If maybe we can get more information leaflets and posters in different languages" – FA3

Relative advantage of quality improvement

This sub-domain explores respondents' perception of the advantage of implementing the quality improvement intervention relative to previous or alternative solutions.

Across the participating health facilities, respondents were of the opinion that their experience with the current quality improvement intervention was better than previous

immunisation service improvement initiatives. One of the reasons cited was the facility-level focus of the intervention, as opposed to being at the community-level which was perceived was less easy to implement.

"Because normally we would go outside the facility to [look for children who missed their appointments], but then [in this intervention] children are actually sitting in the facility" - FB1

Another advantage mentioned was that the quality improvement quality improvement implementation leveraged technology.

"You know with technology, a lot of things improve. Because we're also making use of technology, not just…writing down things on papers" – FA1

The low cost of implementation was another aspect of the quality improvement initiative deemed as advantageous by respondents:

"So, it's basically things we already had in place, except for the printout" - FA1

"Yeah, but the materials were enough" – FB1

Inner setting

Readiness for Implementation

This subdomain examines the tangible and immediate indicators of organisational readiness for implementing quality improvement.

Respondents acknowledged the availability of resources required for implementation, such as work spaces, computers; vaccine and other immunisation supplies and in-service training;

"Then we first had to make sure that all the facets of implementation are in place, like from the reception, right through to the clinicians"- FA1

"*So I did some in-service training and on-the-spot training as well"* - FB3

However, a recurring issue was the inadequacy of staff:

"*The workload that came with it [was much], because we are short-staffed. So I have to divide myself and go full time"*- FA2

"We unfortunately do have a limited staff capacity" - FA1

Organisational culture, leadership, cohesion and implementation climate

This sub-domain encompasses norms and values of health facilities, including the commitment, involvement, and accountability of facility leadership regarding the quality improvement implementation and the general level of cohesion and receptivity towards the quality improvement intervention.

There were generally strong indications of a culture of responsiveness to serving the health needs of target communities. For example, there was a common sense of collectiveness and goal sharing, including in the screening of children's immunisation status using road-to-health booklets.

"So, one of the key things that we do with the road to health book is, every single clinician starting from the prep room is responsible for checking the immunisation portion on the road to health book" FA1

"We had to ensure that the role of all staff members adhered to the quality improvement plan" - FB3

A strong sense of cohesion was expressed, particularly relating participation and goal-sharing among facility staff members.

"So, each staff member had an equal input. They could raise their concerns. They could make suggestions" – FB2

"If there's any tweaks that we need to make, we would normally do that as a collaborative in the facility" – PA1

"Because it was a collective decision, so nothing that is done in this facility is done unilaterally" – PA1

In terms of leadership, respondents had generally positive perceptions of the leadership style in their facilities, with particular references to clear communication and supportive supervision.

"So, our manager at a meeting with us informed us that we're going to start the quality improvement program and she briefed us on how we are going to do it" – FB1

"If the one certain person did not fill in the capturing form and we see the trend, it's that person that might need some more supervision' – FB3

"Our manager actually personally went through the files. She took all the folders to her office and she went through everything to make sure that we recorded correctly" –FB2

Respondents also expressed satisfaction with how the leadership climate in their facility helped to foster cohesion, a sense of belonging and a shared purpose towards the quality improvement intervention.

"*So everybody was basically involved in the facility"* – FB1

"Yeah, our manager did support us and we actually support one another" – FB1

Outer setting

Needs and resources of those served by the organisation

This sub-domain entails the extent to which the needs of communities served by the health facilities, as well as barriers and facilitators to meet those needs, are understood and prioritised in the quality improvement implementation.

Respondents expressed concerns over the immunisation service delivery challenges they encountered within the communities they serve. One notable challenge acknowledged by most of the respondents was about parents defaulting their children's immunisation appointments, which most the respondents thought provided a strong rationale for the quality improvement intervention.

"Because we always missed children, we have noted that children will come maybe up to 14 weeks and then stop coming" – FB3

"*After they received the sixth month doses, they don't come for the ninth month and then they come for the 18th month vaccines or they don't come at all"* -FA2

"Babies have been defaulting because mothers couldn't bring them." – FA3

The cosmopolitan and socio-culturally diverse characteristics of the communities came up in the respondents' responses, although some acknowledged this as a challenge:

"*And that is still a problem is whether we've got a very vast community, people from all nationalities"* – FB1

"We had all the different languages, and that is really a problem" – FA2

External policy & Incentives

This sub-domain includes external strategies to spread innovations including participation incentives, performance-based rewards.

Although respondents expressed strong motivation for participating in the quality improvement intervention, some of them did not think that they would be rewarded by the municipal health department for participating, notwithstanding the additional workload and responsibilities arising from the quality improvement intervention.

"We don't have the money [to reward participation], but it gets easier with training and support" - FB2

Characteristics of individuals

Knowledge and beliefs about the innovation

This sub-domain relates to individuals' attitudes towards and value placed on quality improvement, as well as implementers' familiarity with evidence and principles related to the intervention.

Participants' view on the quality improvement intervention was generally positive, with most of them acknowledging the intervention was an important part of their role and that it was important for improving immunisation services and overall performance. Some of the specific benefits highlighted included reductions in number of immunisation defaulters and increases in number of children immunised daily.

"I believe the quality improvement is very important" - FB2

"For me, quality improvement is part of my job, so yes, it is important" - FA1

"*Especially as a facility manager, because every indicator or every service that you're providing that is not reaching the ultimate goals of the organisation, we have to implement the quality improvement project as this is just one of them and immunisation is extremely important in the sense of Security for health wise for the child"*- FA1

"It helps us to improve the regular visit and also the follow up of appointments as well. - FB2

"It has helped a lot, because there was an increase in the number of catch up immunisation for those who missed" - FA2

Self-efficacy

This sub-domain encompasses individual belief in their own capabilities to execute courses of action to achieve implementation goals.

Despite the additional workload and responsibilities that came with implementing the quality improvement strategies, respondents were generally well motivated and felt capable of participating in the programme and contributing to it effectively. One was of the view that quality improvement was part of their roles, while another expressed willingness to sacrifice break time to complete assigned quality improvement tasks.

"I enjoyed it because it's part of my job and we don't want anybody to miss opportunities" - FB2

"You have to push sometimes sacrifice the tea break" - FA2

Implementation process

Planning

This sub-domain involves the degree to which the quality improvement intervention was planned in advance.

Here, there were indications that staff in both intervention facilities were informed well in advance and had ample time to plan the quality improvement. Respondents also alluded to the collective nature of the planning and the clarity of roles assigned to individual staff members.

"We discussed it first and there were plans on how were are going to do it" - FA1

"We always need input and we plan what we decide" - FB1

"So everybody had a chance to give the input" - FB1

"Because everybody knows exactly what the role they play" - FAB3

Engagement

This sub-domain involves the engagement of appropriate individuals in the implementation through a combined strategy of social marketing, education, role modeling and other similar activities.

The presence of facility-level champions was identified as a major driver of engagement in the quality improvement implementation. Respondents, some of whom were themselves champions who played vital roles in the implementation, had mostly positive experiences in how staff were engaged and supported during the implementation process.

"*Our in-charge, she was also a champion. She was sort of championing this thing and then with colleagues"* – FB1

"If there's a new service that we need to render, we do everything ourselves unless it is something that requires training for which we will provide training" - FB2

Reflection and evaluation

This sub-domain encompasses how implementation actors tracked the progress and quality of implementation and how they used the results to inform further implementation decision-making.

The review of weekly performance against set targets was commonly practiced and was seen a motivating factor. Positive results of MOV starting to decline after the initiation of the intervention helped to reinforce confidence and belief in the usefulness of the quality improvement measures and increased motivation to persist with implementation.

"So I must say he was our manager was very pleased because we all worked on that. So we previously we didn't reach that target but with this, we actually reached our targets. We could see the difference. And yeah, there is a change" -FA2

"So for me it was fun just to see how one little change can impact the Community in such a broad manner" - FA1

"The feedback we received showed that the interventions that we are putting in place is assisting because in the beginning there was a peak (of missed opportunities for vaccination" – FB1

There were specific mentions of MOV prevalence statistics tracked as part a key indicator of quality improvement performance.

"Well, the feedback had really showed that the little changes we made assisted us to take missed opportunities down below 10%" – FB3

"It improved the stats and our coverage and we are progressing" -FA1

"A lot because there was an increase in the number of catch up immunisation to those who missed" - FB3

"So where I could see that the quality improvement project was working was the fact that at the end of the month [we saw the decline in MOV]" - FA3

"*But at the end of the day, to see it on paper and seeing that graph go from the roof down to the floor, it really it's a motivator*" – FA1

6.3.3 Integrated findings

As shown in **Table 6.3**, quantitative findings were corroborated by quantitative findings in many instances. Consistent with the higher domain-level median scores in the domains of intervention characteristics, inner setting, individual characteristics and implementation process, respondents in the qualitative interviews tended to express positive views relating to these domains. These included perspectives that the quality improvement strategies were locally developed by stakeholders from participating health facilities, that facility staff were fully involved in choosing the quality improvement ideas and that they were well motivated to participate in the quality improvement intervention. Conversely, qualitative findings tended to be less positive or negative for CFIR items with lower median scores, such as items relating to human resource inadequacy and lack of incentives

Table 6.3: Integrated findings with illustrative quotes and quality improvement rating scores across CFIR domains

CFIR Domain and items	Median score (IQR)	Illustrative quotes
1. Intervention characteristics	**4 (4 - 4)**	
The quality improvement strategies (interventions) were locally developed by stakeholders from this health facility.	4 (4 - 4)	*"So, we sat together and we developed a quality improvement plan" - FB3* *"Everything we did, we initiated"* – FB1
Health workers from this facility were fully involved in choosing the change ideas to be tested.	4 (4 - 4)	"*Everybody gave the input on how we can do things different, and if it didn't work that...we have a facility meeting then we would say OK, let's change it a little bit more and then we would try another strategy"* – FA1
I consider quality improvement approach to be very flexible.	4 (4 - 4)	*"I think it was flexible, especially for clients working. We just all work together and we exchange ideas and that, and it doesn't mean That as long as the outcome is successful"* – FB1
2. Outer setting	**3 (3 - 4)**	
I consider missed opportunities for vaccination to be a very important problem in our community.	4 (3 - 4)	*"Because we always missing children, we have noted that children will come maybe up to 14 weeks and then stop coming*" – FB3 "*After they received the sixth month doses, they don't come for the ninth month and then they come for the 18th month vaccines or they don't come at all"* -FA2
Our facility will be rewarded by the City or provincial department of health if we reduce missed opportunities for vaccination and improve the performance of our immunisation clinic.	3 (2 - 4)	*"We don't have the money [to reward participation], but it gets easier with training and support*". FB2
3. Inner setting	**4 (4 - 4)**	

There are enough healthcare workers in this facility.	3 (3 - 4)	"*The workload that came with it [was much]…because we are short-staffed. So I have to divide myself and go full time"*- FA2 *"We unfortunately do have a limited staff capacity"* - FA1
There was a good support system in place to seek more information about the quality improvement initiatives.	4 (4 - 4)	*"So each staff member, the other health workers, had an equal input. They could raise their concerns. They could make suggestions"* – FB2 *"Yeah, our manager did support us and we actually support one another"* – FB1
4. Characteristics of individuals	**4 (4 - 4)**	
I was highly motivated and competent to implement quality improvement initiatives this health facility.	4 (4 - 4)	*"I enjoyed it because it's part of my job and we don't want anybody to miss opportunities" - FB2* *"You have to push sometimes sacrifice the tea break" - FA2*
5. Intervention process	**4 (4 - 4)**	
There were adequate planning and preparation before implementation of the quality improvement ideas commenced in this health facility.	4 (4 - 4)	*"We discussed it first and there were plans on how were are going to do it"* - FA1 *"So everybody had a chance to give the input"* - FB1
There was a good feedback mechanism for displaying progress and sharing experiences.	4 (4 - 4)	*"The feedback we received showed that the interventions that we are putting in place is assisting because in the beginning there was a peak (of missed opportunities for vaccination"* – FB1

*PHC = Primary Health Care *IQR = Interquartile Range *CFIR = Consolidated Framework for Implementation Research

6.4 Discussion

6.4.1 Summary of key findings

Using a mixed-methods post-intervention evaluation design through the lens of the consolidated framework for implementation research (CFIR), this study explored individual and contextual barriers and facilitators of quality improvement interventions in primary health care settings in Cape Town. Its ultimate goal was to aid the understanding of the implementation context while highlighting lessons for improving and sustaining the quality improvement initiative. Overall, factors related to the inherent characteristics of the quality improvement intervention, inner setting of the primary health care facilities implementing the intervention, characteristics of individual implementers and implementation processes were perceived as factors facilitating implementation outcomes. However, notable factors related to the outer setting; the broader societal and health system context within the intervention health facilities were situated, were perceived as barriers to implementation success. The implications of specific findings are discussed in the following section.

6.4.2 Implications for policy and practice

This study demonstrates the feasibility and perceived effectiveness of facility-level quality improvement strategies. Consistent with previous evidence, it shows that that frontline health workers are capable of initiating, implementing and evaluating quality improvement interventions tailored to their local context.[9,14] This study also demonstrates the feasibility of embedding post-intervention evaluation in quality improvement plans, with the aim of generating critical evidence on the factors influencing the performance of quality improvement using both qualitative and quantitative data, which can inform rapid adaptation of implementation strategies for enhance intervention performance and sustainability.[37]

In the intervention characteristics domain, most respondents in the quantitative assessment agreed that the quality improvement strategies were locally developed by stakeholders from their health facility, that they were fully involved in choosing the quality improvement ideas. This was collaborated by qualitative responses by participants in the in-depth interviews. Engaging implementers like frontline health workers in the conceptualisation phase, and making them key decision makers in the planning of implemented quality improvement initiatives, had numerous advantages. First, it facilitated their understanding of the rationale

for the intervention and buy-in. Moreover, being key health system stakeholders makes health workers more knowledgeable of the range of strategies best suited for their setting. These included the selection of specific quality improvement strategies and assignment of roles within quality improvement teams. Such factors have been found to enhance the feasibility and effectiveness of quality improvement interventions.[25,38] Another notable finding in this domain was respondents' perceptions of the ease, adaptability and flexibility of implementation, reflecting the extent to which it could be adapted, tailored to meet local needs. Most of the health workers agreed that the quality improvement initiative was flexible, fairly easy to implement and well suited for their context. These might themselves have been positively influenced by the involvement of facility staff in the initiation and planning of the intervention.

In the inner setting domain, most respondents agreed that staff of the facility received adequate peer-support and supportive supervision. These served as sources of motivation, which we found to have evoked strong passion, participation and commitment to the intervention, underscoring the importance of peer and supervision support for fostering stakeholder engagement and participation in quality improvement activities and processes.[38] Although most of the health workers agreed that they received adequate support during the quality improvement implementation, they agreed to a lesser degree that they had enough healthcare staff to implement the quality improvement intervention. The challenge of inadequate human resources is not uncommon in healthcare settings in low- and middle-income settings like that of the present study. That, coupled with the lack of incentives and rewards as found in this study may undermine intervention outcomes.[39] Other inner setting characteristics such as having adequate vaccine and cold chain supplies are equally important for the success of immunisation service quality improvement interventions, without which the mere motivation of implementer will not be enough to ensure the achievement of desired quality improvement outcomes.[25,39]

In the characteristics of individuals domain, factors such as self-efficacy (belief in own capabilities to execute courses of action to achieve intended goals) and confidence in the quality improvement intervention were identified as having positive influences on implementation outcomes. There was popular agreement among respondents that they felt ready and confident to participate in the quality improvement intervention, that they were

familiar with the quality improvement strategies before implementation began and that they considered themselves an important stakeholder for reducing missed opportunities for vaccination in their health facility. These intrinsic motivating factors have been shown to be important for nurturing a conducive implementation climate[38,39], and are particularly important to counterbalance the likely negative effects of the absence of incentives and rewards as was the case in the study setting.

A lower degree of agreement was expressed in the outer setting domain relative to other domains, and this was corroborated by qualitative findings from in-depth interviews. Notably, respondents commonly expressed concerns with the lack of incentives for participating in the quality improvement or for reducing MOV and improving immunisation services in their facilities. One of the key strategies for boosting motivation and productivity of frontline health workforce is through the introduction and use of incentives.[40,41] This is more so in the context of quality improvement with additional tasks to health workers' routine roles. Although it has been argued that incentives, including financial and non-financial ones, do not necessarily translate to increased motivation and productivity, it is reasonable for incentives to be considered as much as feasible in the implementation of quality improvement interventions for optimal outcomes.[40,41] This would require a good understanding of the implementation context and consultation with all relevant stakeholders to determine of most suitable approach to incentivising quality improvement stakeholder engagement, participation and performance.[40] The language barrier posed by the cosmopolitan and multicultural feature of the communities served by health facilities, which was identified as an implementation hindering factor also warrants due attention. It is thus vital that efforts are made to adapt quality improvement interventions to such contextual characteristics, particularly in socio-culturally diverse urban areas like the City of Cape Town.

In the intervention process domain, a notable finding was that common agreement by respondents that there was adequate planning and preparation for the quality improvement intervention commenced in their health facility; and that there were adequate communication and involvement stakeholders in planning and implementation of the quality improvement. Such factors have been shown to be vital to the success of quality improvement interventions.[25,38] Another remarkable finding in this domain was how implementation actors tracked the progress and quality of implementation and how they used the feedback from such evaluation to shape further implementation experiences and decision-making. The

review of weekly performance against set targets was commonly practiced and was seen a motivating factor. Positive results of MOV starting to decline after the initiation of the intervention helped to strengthen health workers' confidence in the quality improvement intervention while motivation their further participation. This is consistent with findings from previous studies, underscoring the importance of regular monitoring and assessment of quality improvement outcomes and the use of feedback and insights gained from such assessments to improve quality improvement performance and sustainability in the short and longer terms.[25,39]

6.4.3 Study strengths, limitations and implications for future research

This study has several strengths. This study employed a mixed-methods evaluation design, which enabled the integration of quantitative and qualitative data for deeper and more holistic understanding of quality improvement implementation outcomes. The use of a conceptually sound theory-informed framework to guide collection, analysis and synthesis of both quantitative and quality data was another source of strength that enhanced the robustness of study findings. Notable limitations included the limited sample size arising from the limited number of staff in the two participating PHC facilities. Although study sample size was representative of both facilities and adequate for useful descriptive analyses, further quantitative analyses were constrained by limited sample size. While findings may be representative of the study setting, they may not be generalisable to other settings. However, as a post-implementation evaluation, the purpose of evaluation to identify facility-level factors influencing implementation outcomes and to highlight learnings with which to enhance future quality improvement efforts in the study setting, some of which may be potentially useful in other settings. Furthermore, social desirability bias may have influenced results as the rating tool collected self-reported data. These limitations provide opportunities for future evaluations, such as by considering larger sample sizes and further quantitative analyses to quantify the relationships between implementation factors and implementation outcomes.

6.5 Conclusion

The study has highlighted important factors hindering or facilitating quality improvement implementation success, Findings underscore the importance of conducting post-implementation evaluation to aid understanding of implementation context for improving and sustaining quality improvement efforts.

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Chapter 7: Integrated discussion, conclusions and personal reflections

About this chapter

This final chapter provides an integrated discussion of findings from the five component studies (reported in Chapters 3 – 6) in relation to their respective objectives, while highlighting the implications of study findings; methodological strengths and limitations; and overall conclusions of the PhD research. In addition, this chapter shares personal reflections on my experiences, insights gained, and lessons learnt through my PhD journey.

7.1 Discussion of main findings

It is well recognised that immunisation is one of the most beneficial public health interventions.[1,2] While significant investments and efforts have been made to improve access to routine immunisation services in South Africa, coverage remains sub-optimal across districts and provinces. According to the recent national immunisation coverage survey, less than 80% of children are fully immunised at 18 months of age, falling short of current globally recommended coverage targets.[3]

Missed opportunities for vaccination (MOV) have been recognised as a major contributor to sub-optimal immunisation coverage globally. This doctoral research hypothesised that there was a substantial burden of MOV in South Africa, and Cape Town in particular. It therefore used a mixed-methods approach, incorporating data from both quantitative and theory-informed qualitative studies to answer five specific research question and their corresponding objectives, through five distinct but complementary component studies.

Table 7.1 reflects the contributions made by each component study with references to their methodological design and main findings. In the following sections, implications of study findings are discussed, while notable study strength and limitations are highlighted.

Table 7.1. Consolidated findings from component research studies.

Objective	Thesis chapter	Study design	Main findings
To assess the magnitude of the burden and factors associated with MOV among children aged 0 – 23 months attending PHC facilities in Cape Town.	Chapter 3	A pre-intervention baseline assessment using multilevel binomial logistic regression models to explore individual and contextual factors associated with MOV.	• MOV prevalence was 14.1%, ranging from 9.1% to 18.9% across sub-districts in Cape Town. • Dose-specific MOV prevalence was highest for the second dose of measles vaccine (9.5%) and lowest for the first dose of rotavirus vaccine (0.6%). • The occurrence of MOV was associated with specific individual (caregiver) and facility-level factors.
To explore the contextual mechanisms of MOV from the experiences and perspectives of caregivers of children aged 0 – 23 months attending PHC facilities in Cape Town	Chapter 4	An exploratory qualitative phenomenology design involving focus group discussions (FGD) with selected caregivers. A thematic template analysis approach integrating the theoretical domains framework (TDF) and the capability, opportunity and motivation model of behaviour (COM-B) model was used for coding, analysis and of the data.	• Health workers' knowledge, capability and motivation can influence children's immunisation outcomes and MOV occurrence. • Caregivers' experiences and perception of health facility workers, immunisation services and the health system in general can facilitate or hinder children's uptake of immunisation services during health care encounters.

To explore structural factors and mechanisms of MOV from the experiences and perspectives of health facility staff of PHC facilities in Cape Town	Chapter 4	A qualitative phenomenology design involving in-depth interviews of PHC facility managers within the Cape Town Metro Health District. A thematic template analysis approach integrating the theoretical domains framework (TDF) and (COM-B) model was used for coding, analysis and of the data.	• Health system factors, such as inadequate staffing, routine immunisation scheduling, health service structuring, vaccine availability, training needs and clarity of catch-up immunisation and other relevant immunisation policies are important factors that can influence caregivers' experiences and perception of immunization and children's utilisation of immunisation services during health facility contacts.
To implement and evaluate a quality improvement intervention for addressing MOV among children aged 0 – 23 months attending PHC facilities in Cape Town	Chapter 5	A plausibility evaluation design involving a non-randomised controlled study and interrupted time-series analysis (ITSA), to determine the effect of quality improvement intervention on MOV and other outcomes.	• Weekly MOV occurrence reduced significantly among children in the facilities that implemented quality improvement compared with those in the control facilities; with a mean reduction of 1.5% per week. • Local implementers like health workers are capable of initiating and implementing a range of quality improvement strategies suitable for addressing MOV in their local contexts. • Well conceptualised and contextually appropriate quality improvement interventions can help reduce the burden of MOV and

			improve immunisation service delivery outcomes, without adversely impacting other routine services at the facility level.
To explore the enablers and barriers to implementing a facility-based quality improvement intervention to address MOV in PHC facilities in Cape Town	Chapter 6	A mixed-methods post-intervention evaluation design. Quantitative evaluation involved the use a self-administered, Likert-based rating tool; while qualitative data collection involved in-depth interviews of key facility-level quality improvement stakeholders (PHC facility staff). Quantitative and qualitative data were analysed through the lens of the consolidated framework for implementation research (CFIR).	• The feasibility and effectiveness of a quality improvement intervention can be facilitated by factors relating to the intervention characteristics (e.g., the quality improvement strategies being locally developed with the involvement of health workers who implement them; inner setting of the implementation context (e.g., ensuring adequate peer support and supervision); characteristics of individuals (e.g. health workers feeling ready and confident to participate in the quality improvement intervention; the intervention process (e.g. having a feedback mechanism for monitoring progress and sharing experiences). • Impediments to quality improvement implementation success may include facility-level constraints such as staff shortages; and the lack of incentives or reward for participating in quality improvement initiatives.

The first component study (**Chapter 3**) involved a quantitative assessment of the magnitude and determinants of MOV occurrence in primary health care (PHC) settings in Cape Town. It found a prevalence of 14% among children attending participating PHC facilities in Cape Town, ranging from 9.1% to 18.9% across sub-districts. Dose-specific prevalence of MOV was observed to be highest for the second dose of measles vaccine (9.5%). In addition, the study identified a range of individual, community-level and health system factors associated with MOV, including caregiver level of education, receipt of immunisation messages, shared parental immunisation decision-making and staff capacity of health facilities. While the magnitude of MOV prevalence found in this study is relatively lower than the prevalence reported in previous studies conducted in other low and middle-income (LMIC) and African settings[4-6], it is of substantial extent that, if left unaddressed, may undermine current efforts to improve immunisation coverage among children in Cape Town and SA in general.[7,8]

To contextualise the quantitative findings from the first component study, the second study (**Chapter 4**) used a theory-informed qualitative design (focus group discussions with caregivers) to explore factors that may influence MOV among children in the study setting. Similarly, the third study (**reported also in Chapter 4**) employed another theory-informed qualitative design (involving in-depth interviews of health care workers) to explore factors that may influence MOV from the perspectives of healthcare service providers. From both qualitative studies, it was found that health workers' knowledge, capability and motivation can influence children's immunisation outcomes and MOV occurrence; and that caregivers' experiences and perception of health facility workers, immunisation services and the health system in general can facilitate or hinder the uptake of immunisation services during children's health facility encounters. It was also evident that health system factors, such as staffing, routine immunisation scheduling, routine service structuring, vaccine availability and clarity of catch-up immunisation policies are important factors that can determine caregivers' experiences and perception and children's utilisation of immunisation of immunisation services during health facility contacts. Overall, both qualitative component studies provided important contextual insights to complement and better understand the findings from the quantitative baseline MOV assessment study.

The ultimate goal of the above-mentioned baseline studies was to help inform the design, implementation, evaluation and adaptation of a contextually appropriate quality

improvement intervention aimed at addressing MOV in participating PHC settings. Hence, in the fourth component study (**Chapter 5**), findings from the baseline assessments were used to design, implement and evaluate a facility-level quality improvement intervention aimed at reducing MOV occurrence in selected PHC facilities in Cape Town. From the evaluation, we found that implementing contextually appropriate quality improvement strategies can help reduce MOV in PHC settings. Weekly MOV occurrence reduced significantly among children in the facilities that implemented quality improvement compared with those in the control facilities; with a mean reduction of 1.5% per week. The study demonstrated that frontline health workers are capable of initiating and implementing a range of quality improvement strategies suitable for addressing MOV in their local contexts. It lends important evidence to current knowledge and understanding of the role of quality improvement interventions in reducing the burden of MOV and improving immunisation service delivery outcomes, without adversely impacting other routine services at the facility level.

Like any other intervention, the success or failure of quality improvement interventions can be influenced by various factors.[9,10] These may include factors related to individual implementers and stakeholders such as frontline health care workers and health care users; and those that are structural in nature, such as health facility resource capacity. Understanding how these factors influence quality improvement implementation outcomes is important for gaining insights on how best to adapt implementation strategies to improve or sustain subsequent quality improvement efforts. Hence, the final study (**Chapter 6**) sought to identify facilitators and barriers to the quality improvement implementation success using a mixed-methods evaluation design. From that, we were able to identify the dynamics of implementation facilitators and barriers and how they influenced implementation outcomes, the understanding of which is important for informing the adaptation and sustainability of future quality improvement efforts. It was evident from the evaluation that quality improvement success can be facilitated by factors relating to the intervention characteristics (e.g., the quality improvement strategies being locally developed with the involvement of health workers who implement them; inner setting of the implementation context (e.g., ensuring adequate peer support and supervision); characteristics of individuals (e.g. health workers feeling ready and confident to participate in the quality improvement intervention; the intervention process (e.g. having a feedback mechanism for monitoring progress and

sharing experiences). Conversely, impediments to implementation success could include factors related to facility-level constraints such as staff shortages; and the lack of incentives for motivating participation in quality improvement initiatives.

Overall, this doctoral research makes an important contribution to current global efforts aimed to increase immunisation coverage through MOV assessment and reduction in healthcare settings.[11,12] The research has demonstrated that there is a substantial burden of MOV among children in PHC settings in Cape Town. It also provides scientifically robust evidence on the feasibility, effectiveness and sustainability of a facility-based quality improvement intervention for addressing MOV in Cape Town and similar contexts. Important implications of research findings for policy, practice and future research have been discussed in greater detail in the respective study-chapters, and are highlighted below.

7.2 Implications for policy and practice, with recommendations

Findings from this research provide useful evidence for current and future efforts to expand immunisation coverage and improve quality of PHC services among children in SA.[13,14] The study shows that simple and low-cost quality improvement strategies such as improving the screening of children's immunisation status, routine screening of home-based records like the Road to Health Booklet (RtHBs) during healthcare encounters, can effectively reduce the likelihood of MOV. Findings that the quality improvement intervention did not adversely impact waiting time for other routine services imply that attention and resources can be channelled to addressing problems such as MOV, without undermining other services. Strategies such as integrating quality improvement activities into existing quality improvement plans, as was the case in the intervention facilities, can help to enhance the compatibility of quality improvement strategies with other routine services.

Post-intervention evaluation findings show that active local-level engagement is important for boosting stakeholders' participation, ownership and ultimately the successful implementation of quality improvement initiatives. It is, therefore, imperative for future MOV-targeted quality improvement plans to involve local health system actors to play critical roles in planning and implementing interventions, especially as they are likely to be more knowledgeable of the range of strategies best suited for their local settings. This can help promote deeper awareness and understanding of the problem among local-level

implementing actors, while nudging stronger commitment and ownership of the intervention among them.[15,16] Finding from the evaluation also illustrate the important role of technology as a catalyst for driving quality improvement efforts, supporting the current evidence on the feasibility and utility of technology to support healthcare quality improvement in resource-limited settings.[17]

It is vital to have feedback mechanisms for monitoring progress and sharing experiences.[18,19] For quality improvement to be effective in health care, it is imperative to evaluate performance and provide regular feedback to implementing stakeholders on progress and implementation gaps.[20] Such feedback is important for improving and sustaining quality improvement outcomes.[17,21] Remarkably, there was an observable increase in MOV the last two weeks of evaluation in one of the intervention facilities, which might have been due to several factors, including that health workers were overwhelmed by additional workload of the quality improvement and existing issues of staff shortages as found in the post-intervention evaluation. These could in turn lead to de-motivation or de-prioritisation of the quality improvement activities by implanting actors. While this finding is not surprising given the real world setting of the study, it has important implications for the feasibility and sustainability of quality improvement interventions in routine healthcare settings. Furthermore, they underscore the need for further quality improvement efforts to ensure the availability of adequate resources and sustained motivation of facility-level implementers to maximise and sustain intended quality improvement outcomes.[22]

7.3 Study strengths and limitations

This research has several notable strengths. The mixed-methods approach to the baseline MOV assessments (**Chapters 3 and 4**) allowed for a deep and holistic understanding of the magnitude and determinants of MOV from quantitative and qualitative data sources. The employment of multi-level analysis in the quantitative assessment and the theory-informed analyses of qualitative baseline data are methodological merits of this research. The pragmatic and real-world design of the intervention evaluation (**Chapter 5**) offers a quasi-experimental research design with a high degree of internal validity, for comparing MOV trends between the intervention and control facilities, while controlling for the confounding

effect of time-varying differences between the two study arms.[23,24] This quasi-experimental design helped to demonstrate that the effects seen were plausibly due the intervention. The post-intervention evaluation study (**Chapter 6**) employed a mixed-methods evaluation design, which enabled the integration of quantitative and qualitative data for deeper and more holistic understanding of the facilitators and barriers of quality improvement implementation success. The use of a conceptually sound, theory-informed implementation research framework to guide collection, analysis and synthesis of both quantitative and quality data was another notable strength of this research.

Notwithstanding these strengths, the research is not without limitations. The focus of the baseline MOV assessment studies (**Chapters 3 and 4**) on public PHC facilities located within urbanised metropolitan settings may limit the generalisability of study findings in other healthcare settings, such as secondary and tertiary facilities. Another notable limitation was the non-random assignment of facilities to study arms, as well as the limited sample size and follow-up period of the intervention evaluation period (**Chapter 5**), with implications for the statistical power and the precision of estimates of evaluation outcomes. There were also sample size limitations in the quantitative component of post-intervention evaluation (**Chapter 6**). Lastly, while facility-level quality improvement may help to address health system gaps at various levels, it may have limited impact on broader MOV determinants beyond those occurring at the facility-level. As such, for more better and more sustainable implementation outcomes, MOV interventions need to be effectively integrated into broader health system strategies that can comprehensively address individual, contextual and structural enablers of MOV.

7.4 Implications for future research

Given the focus of this research on assessing and addressing MOV baseline in urban public PHC facilities, future research in this direction should consider facilities across all care levels in both private and private healthcare sectors in both rural and urban settings. It would also be valuable for future studies to assess MOV in non-facility settings, such as mobile clinics and community health outreaches, where the likelihood of MOV may be more substantial.

Considering the limitations of the quality improvement evaluation design, it is imperative that future evaluation studies in the context of MOV should consider a number of methodological

improvements. Such improvements could include the use of a randomised study design to control for differences between the intervention and control study arms that is not due to the quality improvement intervention itself. There is also a need to ensure that future evaluations have a larger sample size per time point and longer follow-up period to provide richer data point for investigating intervention effectiveness and sustainability. To enhance the uptake of assessment findings for improving routine immunisation and facility practice, such research efforts should be embedded as part of routine quality improvement and implementation research initiatives.

7.5 Conclusions

Overall, this research has demonstrated that there is a substantial burden of MOV among children in Cape Town. It has also provided some scientifically robust evidence on the feasibility, effectiveness and adaptability of facility-based quality improvement interventions for addressing MOV in PHC contexts in Cape Town and similar contexts. Study findings have important implications for policy, practice and future research in the SA and similar LMIC contexts, as have been highlighted in this and previous chapters.

7.6 Personal reflections

"An opportunity is like a train on the move. Once its doors have closed, it's gone. But do stick around, another one will surely be on its way; carrying with it better opportunities."

— Naide P Obiang

In many ways, my PhD journey – every phase of it – was characterised by learnings and realisations. In retrospect, as with many other PhD candidates I guess, I never quite realised the significance of my research and its immediate and potential importance until near the end of the journey, when all the puzzle pieces (more aptly, data points) began to fall in place. Why did the 'aha moment' take so long to realise? It certainly wasn't due to a lack of expectation from the outset, that the PhD will make significant and tangible scientific contributions – I had an abundance of expectations. Nor was it because I did not fully appreciate the rationale for investing valuable resources into the aspirations of advancing current knowledge and understanding of the extent, nature and solvability of childhood immunisation barriers like

missed opportunities for vaccination. Instead, it was the constant thought with uncertainties of how things could go right or wrong along the way, that would keep the 'aha moment' at bay until the twilight of the PhD.

Can I have good quality data? Can my analytical methods go as designed? Will I have the support and resources needed to pull through the various component studies? Will the findings make sense in empirically and practically meaningful ways? In fact, can I finish this PhD? Such were the questions that came up endlessly to cast shadows of uncertainties over any sense of optimism and motivation to soldier on. Those were enough to drown any assurance that I was going to complete the PhD research as planned, much less actualising its aspirations of contributing new and robust evidence to what is known about immunisation missed opportunities and how to tackle them. Somewhat, serendipitously, a moment of reckoning ensued in the final phase of my research, leaving behind a lasting impression that the PhD has not fallen short of its intentions to not only create knowledge, but has also provided insights and learnings from implementing and evaluating real-world remedial measures capable of tackling a crucial and globally significant public health issue like MOV.

It thus feels fulfilling to have helped to make these important contributions to current global and local efforts to understand and address immunisation coverage gaps, of which missed opportunities for vaccinating children are a major driver. My PhD has answered, using theoretically and conceptually sound methods, the three critical questions prioritised in the global MOV strategy established by the WHO in 2016: what is the burden of MOV, what are the reasons for the missed opportunities, and what can be done to address these? Hence, the culmination of my PhD research is a comprehensive body of work capable of enriching and catalysing ongoing efforts to revitalise immunisation programmes, particularly in the aftermath of the COVID-19 pandemic and its deleterious effects on routine immunisation and other essential services.

The journey was not without its challenges, and those challenges presented with them many opportunities to learn, gain new perspectives and come to vital realisations. It was during the planning phase of the research that the COVID-19 pandemic began. As a result, data collection was delayed by about a year due to lock down and movement restrictions put in place at the time as public health strategies to mitigate spread. With early evidence beginning to show the disruptive impact of the pandemic on immunisation and other vital health services, I

realised how it had become the more important to prioritise efforts to address MOV as part of efforts to undo the impact of the pandemic and accelerate immunisation coverage efforts in the post-pandemic rea. That realisation motivated our correspondence piece published in the Lancet, in which we drew attention to the role of tackling MOV as imperative for attaining the ambitious goals of the newly launched Immunisation Agenda 2030 (IA2030).[25]

As the pandemic began to ease globally, and movement restrictions were relaxed nationally in South Africa, we commenced data collection with adaptations made to navigate the challenges of field work and recruitment of research participants in the wake of a devasting global COVID-19 outbreak. Thanks to the unwavering enthusiasm and motivation of our research team, we learnt and moved fast; utilising the data collection window of opportunities we had as no one was certain if there would be another wave of COVID-19 infections that could warrant another lock down. From that experience, I was able to learn how to adapt and conduct research in operationally challenging settings without jeopardising the quality of the research and actualisation of planned goals.

The sheer number of health facilities in which we were to recruit research participants at such difficult time made field work the more daunting. Yet, I found particularly motivating the passion with which research participants (caregivers, frontline health workers, health managers and administrators) received our invitations to participate – all thanks to our vibrant and enthusiastic team of field workers whose astuteness in participant enrolment made this daunting mission an eventual accomplishment. Another interesting consequence of the pandemic was how COVID-19 vaccine mandates stirred both curiosity and scepticism across the world. In our experience interacting with caregivers, we learnt how to rather frame missed opportunities for vaccination as ‘missed opportunities for immunisation’, given the sensitivity of the word ‘vaccines’ at the time. This strengthened my understanding of the importance of timely adaptions of public health research messaging and participant engagement in ways that are culturally sensitive, appropriate and at the same time, fit for purpose in such delicate circumstances.

Analysing the data collected from the various studies and making sense of the findings came with many realisations too numerous to mention. Notably, it was interesting to see the many consistencies and parallels between results from quantitative and qualitative studies, such as the caregiver and health system factors associated with children’s MOV occurrences. This

reinforced my perception of the vital role of mixed-methods research designs and data triangulation as necessary empirical approaches to a more accurate and holistic understanding of phenomena of interests. One of the most intriguing findings of the research was the remarkable increase in MOV the last two weeks of evaluation in one of the intervention facilities. Of course, it might have been due to several factors, which including demotivation of health workers or the overwhelming effect of additional workload of the quality improvement in the face of competing priorities – as evident from the post-intervention evaluation findings. Could it have been due to the intervention itself? - I thought to myself. Whatever the reasons were, there was an important lesson to learn, in that the success of any intervention depends ultimately on prevailing contextual and structural factors that could enable or hinder success, such as the functionality of existing health systems, availability of supportive resources and the appropriateness of the intervention within the target context.

On a final note, I am incredibly proud of what my team and I have achieved with the PhD and feel much indebted to everyone who lent a hand to this accomplishment. I owe an eternal debt of gratitude to my supervision team for supporting and enabling me to lead the various aspects of this work – from study design to stakeholder and collaborator engagement; field work planning and coordination; statistical and qualitative data analyses; as well as interpretation, reporting and dissemination of study findings and recommendations. I look forward to utilising the knowledge and insights gained in my next endeavours, and to using the research output to inspire further efforts at stemming the tide of missed opportunities for vaccination and improving immunisation coverage among children the world over.

In the thoughtful and apt words of Naide Obiang, quoted in the beginning of this reflection piece, an opportunity is like a train on the move. Once its doors have closed, it's gone. But if one sticks around long enough (with preparedness), there will be other, perhaps even better, opportunities. I hope that I have not missed any opportunity to make my four-year journey through the labyrinths of PhD more worthwhile. If I have missed any such opportunity, alas, there may never be another PhD opportunity. Luckily, though, there will be many more opportunities to make the most of the learning, insights and realisations gained in future endeavours. Afterall, life is but a moving train of opportunities – and suffice to say, c*arpe diem*.

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Appendices

Appendix 1: University of Cape Town Human Research Ethics Committee (HREC) approval letter

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

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20 November 2020

HREC REF: 579/2020

Prof C Wiysonge
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Dear Prof Wiysonge

PROJECT TITLE: ASSESING AND ADDRESSING MISSED OPPORTUNITIES FOR VACCINATION IN CAPE TOWN THROUGH A COLLABORATIVE QUALITY IMPROVEMENT APPROACH-PHD CANDIDATE-DR CHUKWUDI NNAJI

Thank you for your response letter addressing the issues raised by the Faculty of Health Sciences Human Research Ethics Committee (HREC).

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

This approval is subject to strict adherence to the HREC recommendations regarding research involving human participants during COVID -19, dated 17 March 2020 & 06 July 2020.

Approval is granted for one year until the 30 November 2021.

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)

The HREC acknowledge that the student: Dr Chukwudi Nnaji will also be involved in this study.

Please quote the HREC REF in all your correspondence.

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

Please note that for all studies approved by the HREC, the principal investigator **must** obtain appropriate institutional approval, where necessary, before the research may occur.

Yours sincerely Signed by candidate

PROFESSOR M BLOCKMAN
CHAIRPERSON, FHS HUMAN RESEARCH ETHICS COMMITTEE

Federal Wide Assurance Number: FWA00001637.
Institutional Review Board (IRB) number: IRB00001938
NHREC-registration number: REC-210208-007

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 Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use: Good Clinical Practice (ICH GCP), South African Good Clinical Practice Guidelines (DoH 2006), based on the Association of the British Pharmaceutical Industry Guidelines (ABPI), and Declaration of Helsinki (2013) guidelines. The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

HREC/REF-579/2020sa

Appendix 2: City of Cape Town Health Department approval

CITY OF CAPE TOWN
ISIXEKO SASEKAPA
STAD KAAPSTAD

CITY HEALTH

Dr Natacha Berkowitz
Epidemiologist: City Health

T: 021 400 6864 F: 021 421 4894
E: Natacha.Berkowitz@capetown.gov.za

Ref: 28095 2021-05-11

RE: Assessing and addressing missed opportunities for vaccination in Cape Town through a collaborative quality improvement approach

Dear Dr Chukwudi Nnaji

Your research request has been approved as per your protocol phases 1-3. **The implementation study described needs to be created and discussed with programme managers prior to implementation. Once created the intervention must be presented to HMT for approval.** Please refer to the subsequent pages for the approval of any facilities or focus areas requested. Approval comments on any proposed impact on City Health resources are also provided.

Eastern & Khayelitsha:

Contact Person: Prof Vera Scott (Area East Manager)

Tel/Cell: 021 360 1258/082 308 8059

Email: Vera.scott@capetown.gov.za

Northern & Western:

Contact Person: Dr Andile Zimba (Area North Manager)

Tel/Cell: 021 980 1230/084 627 2425

Email: Andile.Zimba@capetown.gov.za

Tygerberg & Klipfontein:

Contact Person: Mr Ruberto Isaaks (Area Central Manager)

Tel/Cell: 021 444 0893/078 565 7607

Email: Ruberto.Isaaks@capetown.gov.za

Mitchells Plain & Southern:

Contact Person: Mrs Soraya Elloker (Area South Manager)

Tel/Cell: 021 400 3983/084 222 1478

Email: Soraya.Elloker@capetown.gov.za

Facilities

Area	Subdistrict	Facilities		
Area East	Khayelitsha	**Facility name**	**Interaction start date**	**Interaction end date**
		Matthew Goniwe CDC	2021-05-10	2021-12-31
		Nolungile Clinic	2021-05-10	2021-12-31
Area South	Mitchells Plain	**Facility name**	**Interaction start date**	**Interaction end date**
		Weltevreden Valley Clinic	2021-05-10	2021-12-31
		Eastridge Clinic	2021-05-10	2021-12-31
Area South	Southern	**Facility name**	**Interaction start date**	**Interaction end date**
		Claremont Clinic	2021-05-10	2021-12-31
		Masiphumelele Clinic	2021-05-10	2021-12-31
		Ocean View CDC	2021-05-10	2021-12-31
Area Central	Tygerberg	**Facility name**	**Interaction start date**	**Interaction end date**
		Parow Clinic	2021-05-10	2021-12-31
		Elsies River Clinic	2021-05-10	2021-12-31
Area North	Western	**Facility name**	**Interaction start date**	**Interaction end date**
		Langa Clinic	2021-05-10	2021-12-31
		Protea Park Clinic	2021-05-10	2021-12-31

Please note

- If a requested facility does not appear in the list above, its interation request has been rejected and the reason for the rejection can be viewed in the link below
- Approval comments for facilities may exist. These comments can be viewed in the link below.

https://web1.capetown.gov.za/web1/mars/ProjectFacility/Read/0/9365

Impacted resources

Impacted resource	Decision	Comment
Space	Rejected	No space will be guaranteed for research purposes

Please note the following:

1. All individual patient information obtained must be kept confidential.
2. Access to the clinic and its patients must be arranged with the relevant Manager such that normal activities are not disrupted.
3. A copy of the final report must be uploaded to https://web1.capetown.gov.za/web1/mars/ProjectClosure/UploadReport/0/9365, within 6 months of its completion and feedback must also be given to the clinics involved.
4. Your project has been given an ID Number (9365). Please use this in any future correspondence with us.
5. No monetary incentives to be paid to clients on the City Health premises
6. If this research gives rise to a publication , please submit a draft before publication for City Health comment and include a disclaimer in the publication that "the research findings and recommendations do not represent an official view of the City of Cape Town "

Thank you for your co-operation and please contact me if you require any further information or assistance.

Kind Regards
Dr Natacha Berkowitz Epidemiologist: City Health

Appendix 3: Western Cape Provincial Department of Health approval letter

Western Cape Government
Health

STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 0866: fax: +27 21 483 6058
5th Floor, Norton Rose House,, 8 Riebeek Street, Cape Town, 8001
www.capegateway.gov.za)

REFERENCE: WC_202101_016
ENQUIRIES: Dr Sabela Petros

University of Cape Town
Anzio Road
Observatory
Cape Town
7925

For attention: Dr Chukwudi Nnaji, Prof Charles Wiysonge

Re: Assessing and addressing missed opportunities for vaccination in Cape Town through a collaborative quality improvement approach

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.
Please contact the following people to assist you with any further enquiries in accessing the following sites:

Bishop Lavis CDC	**Dr Mumtaz Abbas**	**021 927 1147**

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final feedback (**annexure 9**) within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. In the event where the research project goes beyond the *estimated completion* date which was submitted, researchers are expected to complete and submit a progress report (**Annexure 8**) to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
4. The reference number above should be quoted in all future correspondence.

Yours sincerely

Signed by candidate

DR M MOODLEY
DIRECTOR: HEALTH IMPACT ASSESSMENT
DATE:
CC

Dr Melvin Moodley
Director: Health Impact Assessment
04 MAY 2021

WC_202101_016

Ashleigh Levendall <Ashleigh.Levendall@westerncape.gov.za>
Fri 2021/07/09 17:07
To: Chukwudi Nnaji <NNJCHU001@myuct.ac.za>

Dear Researcher

I hope this email finds you well.

Please be informed that Mfuleni has approved your research request. The Facility Manager would appreciate the study coordinator /facilitator to call or communicate with them regarding start date and other logistics.

Mfuleni CDC- Mr Mzwamadoda Gaji: 021 350 0801

Please note that you will be issued with an approval letter soon.

Kind regards
Ashleigh

Ms Ashleigh Levendall
Admin Clerk
Directorate : Health Impact Assessment
Western Cape Government : Health

Address : 5th Floor, 8 Riebeek Street, Cape Town
Tel: (021) 483 9319
Fax: (021) 483 6058
Email : Ashleigh.Levendall@westerncape.gov.za
Website : www.westerncape.gov.za

Appendix 4: MOV assessment tool - exit interview questionnaire (Chapter 3)

Respondent ID_____

Date of interview _____

Name of interviewer_____

HEALTH FACILITY CHARACTERISTICS

1. Name of health facility_____
2. Name of sub-district _____
3. Type of health facility 1] Comprehensive health centre 2] Clinic
4. Facility ownership 1] Provincial 2] City of Cape Town 3] Others (Specify) _____
5. Total number of health workers _____
6. Average number of patients seen _____
7. Is there a designated vaccinator primarily stationed in vaccination clinic? 1] Yes 2] No
8. Does the facility have designated immunization days 1] Yes 2] No
9. Has there been vaccine cold-chain and storage challenge in this facility in the past 3 months, such as prolonged electricity outage, bad refrigerators, lack of cold boxes etc? 1] Yes 2] No
10. Any vaccine stock-out in the past 3 months? 1] Yes 2] No

SECTION A: CHILD DATA

1. Date of birth _____
2. Age (in months) _____
3. Sex 1] Male 2] Female
4. Birth order 1] First 2] Second 3] Third 4] Others (specify)
5. Birth weight (in Kg) _____
6. Why did you bring the child to this health facility today? (Do not read out options) 1] For medical consultation (child is sick) 2] For vaccination 3] Growth and Development Check-up 4] Child is only accompanying (not for treatment/vaccination) 5] Hospitalization (Child was admitted or still on admission) 6] Others (Please specify)

SECTION B: PARENT/CAREGIVER DATA

7. Age _____
8. Sex 1] Male 2] Female
9. Marital status 1] Single 2] Married 3] Separated 4] Divorced
10. What is your relationship with the child? 1] Mother 2] Father 3] Grandparent 4] Uncle 5] Aunt 6] Brother 7] Sister 8] Mother in law 9] Others (please specify)
11. Did mother attend antenatal care during index child's pregnancy? (If father or other caregivers, do you know if mother attended antenatal care during index child's pregnancy 1] Yes 2] No
12. Level of formal education 1] No formal education 2] Did not complete primary education 3] Completed primary education only 4] Completed secondary education only 5] Post-secondary education
13. Are you currently employed? 1] Yes 2] No
14. If employed, what is your monthly income 1] Less than R10 000 2]R10 000 to R30 000 3] Above R30 0000
15. By what means of transportation do you usually use to come to this facility? 1] Walk 2] Own transport 3] Public transport 4] Others (please specify)
16. How long does it take you to get to this health facility from your home? _____Hours _____ Minutes
17. What is the estimate cost of transportation to this place? _____
18. Have you heard, seen any message on vaccination in the last 3 months? 1] Yes 2] No
19. If yes, where? 1] Radio 2] Television 3] Newspaper 4] Health facility 5] Telephone message 6] Facebook or Internet 7] Children's school 9] Mosque 10] Church 11] During home visit by health workers 12] Community meetings 13] Others (Please specify)
20. Do you feel you know the vaccines your child needs? 1] Yes 2] No 3] Not sure
21. If yes, do you feel that you know when the vaccines should be given? 1] Yes 2] No 3] Not sure
22. Has this child ever been vaccinated? 1] Yes 2] No
23. If no, why not? 1] The necessary vaccines or supplies were not available 2] I am not in favor of vaccination 3] My husband/the decision maker is not in favour of

vaccination 4] I have not visited the health facility on a vaccination day 5] I did not know that the child was eligible to be vaccinated 6] Others (Please specify)

24. Have you ever requested vaccination services for this child and child didn't get vaccinated? 1] Yes 2] No

25. If yes, why was child not vaccinated? 1] The health worker said it couldn't be done because the child was sick 2] There were no vaccines or there were no syringes or some other supply needed for vaccination 3] it was not a vaccination day 4] The vaccination area was closed 5] The person in charge of vaccination was not there 6] There would have been a long wait 7] We didn't have the Road to Health booklet (RtHB) with us 8] The hours for vaccination are limited 9] Others (Please specify)

26. In your home who makes the decision to vaccinate? 1] Father 2] Mother 3] Other relatives 4] Consensus of father and mother 5] Others (Specify) _____

SECTION C: USE OF ROAD TO HEALTH BOOKLET (RtHB) AND INFORMATION ON VACCINES ADMINISTERED

27. Does your child have a Road to Health booklet (RtHB)? 1] Yes, and I have it with me 2] Yes, but I do not have it with me 2] No

28. If no, why don't you have a Road to Health booklet (RtHB)? 1] I lost it 2] I have never been given one 3] I don't know 4] Others (Please specify)

29. Why do you not have the Road to Health booklet (RtHB) or temporary vaccination documents with you today? 1] It is at the school/day care center 2] I left it at home because I forgot to bring it 3] I left it at home because I didn't know it was important to bring along 4] I lost it 5] The care has been damaged 6] I have never been given one 7] Because vaccination was not the reason for this visit 8] Others (Please specify)

30. What vaccines has the child received to date? (Obtain information only from Road to Health booklet (RtHB), vaccination register, or other temporary vaccination documents)

Name of Vaccine (Antigen)/Dose	Date of administration

31. Based on the above information and the EPI schedule (refer to the SA EPI schedule), are there vaccines/doses the child is eligible for by age that the child is yet to receive? 1] Yes 2] No
32. Have you ever lost the Road to Health booklet (RtHB)? 1] Yes 2] No
33. If yes, did you encounter difficulty getting it replaced? 1] Yes 2] No
34. Could you tell me what purpose the Road to Health booklet (RtHB) serves? 1] Don't know 2] To know what vaccines the child has had and which are missing 3] Overall health record and growth monitoring 4] Record and remind for return visit dates 5] Birth certificate and/or identification 6] Others (Specify)

SECTION D: TODAY'S VISIT

35. What day of the week is today? 1] Week day 2] Weekend (Saturday or Sunday)
36. Time of the visit 1] Morning 8:01 am – 12 noon 2] Afternoon (12:01pm to 5:59pm) 3] After hours (6:00pm – 8:00am)
37. During today's visit, did the health worker ask you for the child's Road to Health booklet (RtHB)? 1] Yes 2] No
38. If no, did they ask for the vaccination status of the child? 1] Yes 2] No
39. Was your child vaccinated here today? 1] Yes 2] No
40. If no, why? 1] The health worker said that the child was not eligible for vaccination today. 2] The health workers who saw us did not tell me about vaccinating the child 3] The health worker said that the child could not be vaccinated because s/he was sick 4] The last time the child was vaccinated s/he got sick or had a reaction 5] My religion does not permit vaccination or I don't believe in vaccines 6] Vaccination was not the purpose of this visit 7] The child is already fully vaccinated for his/her age 8] I don't trust the health workers or vaccines in this health facility 9] I forgot to take my child to the vaccination area 10] I didn't have time today to wait for vaccination 11] There were no vaccines in the health facility today 12] There were no syringes or other vaccination supplies 13] Today is not a vaccination day in this health facility 14] The vaccination area was closed 15] The person in charge of vaccination was not there 16] There would have been a long wait 17] The staff treated us badly 18] Other (please specify)

41. If you were advised by a health worker during a clinic visit that your child is missing one or more vaccine doses, and the health worker offers to vaccinate the child with the missed doses, will you refuse? 1] Yes 2] No

SECTION E: QUALITY OF VACCINATION SERVICES

Instruction: Complete this section only if the child received vaccination today

42. How long did you wait for your child to be vaccinated? _____ Hours _____Minutes

43. Did were you informed what vaccines the child was given? 1] Yes 2] No

44. Today, were you informed the date for the child's next vaccination appointment? 1] Yes 2] No

45. Today, were you given details of the next vaccination appointment? 1] Yes 2] No

46. Did you receive information today on the reactions or side effects that can occur following vaccinations? 1] Yes 2] No

47. If yes, what were you told? 1] Pain at injection sites 2] Fever 3] Rash4] Diarrhea 5] Vomiting 6] Others (Please specify)

48. Did you receive information today on what you should do if the child has reactions or side effect to the vaccines? 1] Yes 2] No

49. Are you satisfied with the services provided today? 1] Yes 2] No

50. If yes, why? 1] Immediate attention 2] Friendly treatment by staff 3] No charge for services 4] The necessary vaccines and supplies were available 5] Others (Specify)

51. If no, why? 1] Had to wait a long time 2] The staff was discourteous 3] The language that the health worker use is not clear 4] They did not explain what vaccines they had given the child 5] The necessary vaccines and supplies were not available 6] Others (Specify)

SECTION F: REASONS TO VACCINATE CHILDREN

52. Could you tell me the purpose of vaccines? (Multiple responses allowed) 1] To prevent diseases 2] So children will grow up healthy 3] To cure diseases 4] They don't do any good 5] Not sure what they are for 6] Other (Please specify)

53. Do you think your child could get these diseases if you don't vaccinate him/her? 1] Yes 2] No 3] Don't know

54. What suggestions do you have to improve vaccination services? 1] There should be more vaccination personnel 2] There should be less waiting time 3] Hours and days when vaccinations are available should not be limited 4] Road to Health

booklet (RtHB) should remain free 5] The treatment of the public and of the children being vaccinated should be friendlier 6] The health center should always have vaccines 7] The should provide information on the vaccines that are being given, on the diseases that they prevent, and on the reactions that they produce. 8] More outreach services 9] None 10] Don't know 11] Others (Please specify)

Appendix 5: Informed consent form; quantitative MOV baseline assessment (Chapter 3)

Good Day Sir/Madam.

My name is (mention name of data collector)_____. I am a researcher from the, University of Cape Town, South Africa. Our research aims to understand the reasons why some children make contact with the health facility and do not receive the immunization that they require.

As a caregiver of a child who is less than 2 years old, I would like to invite you to participate in this study because your response is important. Before you decide to take part, you need to understand why this research is being conducted and what would be required of you. Therefore, take your time to read this informed consent form. Please ask any question if anything is not clear or you would like further information about any aspect of the study.

The information from this study will help increase our understanding of the how many children are missed in the health facility and the kind of measures that can be taken to reduce it.

The surveys/interview will take about 40 minutes, and focus group discussion will take about one hour. It is confidential and anonymous. This is guaranteed by not needing to indicate your name while being interviewed. If you decide to take part in this study, be assured that your participation is voluntary, and you are free to withdraw at any time without giving any reason. There are no risk, penalty or loss of benefits whether you participate or not.

I, _____ consent and volunteer to participate in a research aimed as assessing the impact of quality improvement collaborative on reducing missed opportunity for vaccination in the Cape Town Metro Health district, Western Cape, South Africa. The study is being conducted by Chukwudi Nnaji; a doctoral researcher from the Division of Epidemiology and Biostatistics at the School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, South Africa.

I confirm that:

1. I was provided with an information sheet that explained what the study is about I have read and understood the information about the study as provided in the information sheet.
2. I have been given the opportunity to ask questions about the project and my participation.
3. I understand that I will not be paid for participating in the study.

4. I understand that I can withdraw at any time without giving reasons and there will be no risks or penalty for withdrawing
5. It has been clearly explained to me that the research is confidential and anonymous. i.e. and what I say will not be linked to me as a person and that the information will only be used for this research purpose and not shared with other people that are not part of this research team.
6. It has been clearly explained to me that information from this research may be used in a thesis report, publications or presentations.
7. I understand that mobile tablet devices will be used in the collection of data.

Participant

_____	_____	_____
Name	Signature/Thumb Print	Place and date

If you have any concerns or questions regarding any aspect of this study or wish to obtain a copy of the results of the survey, please contact me on;

Name: Chukwudi Nnaji
Tel: 0717210476
Email: nnjchu001@myuct.ac.za

For any concern or questions regarding participants' rights and ethical conduct of research, please contact the **Health Research Ethics Committee, Faculty of Health Sciences, University of Cape Town**. Room G50 Old Building. Groote Schuur Hospital, Observatory 7925, Cape Town. **Tel: 0214066626 Email: hrec-enquiries@uct.c.za**

Appendix 6: Qualitative MOV assessment tool (focus group discussion) guide (Chapter 4)

Introduction:

- Hello everyone. My name is [*Name*] and I will be facilitating the discussion this afternoon.
- This is my colleague [*Name*]. S/he will be taking notes and helping me in this interview.
- Thank you so much for taking the time to be part of our interviews.
- We will be discussing childhood immunization and we are interested in exploring the factors such as societal, community and health system factors influencing children's immunization in this community, from your perspectives as parents/caregivers.
- The information you provide will be anonymous and will be treated as confidential.
- If at any point you do not want to continue participating in this discussion, you are free to do so.
- The information discussed today will help us to understand what can be done to improve childhood immunization programmes in this community and Cape Town in general.
- We would like to record this discussion. Even though we will be taking notes, we are not able to write everything down and want to be able to go back and listen to any information we might have missed. All notes and the recording will be kept safely and securely.
- Is everyone okay with recording this conversation? (Confirm that all participants consent)
- We ask that you please take turns while speaking and do not interrupt anyone. We are interested in what all of you have to say, so please be respectful of each other's opinions.
- This discussion will last about 45 minutes.
- Before we begin, does anyone have any questions?

Opening questions:

1**. What are some health problems that affect children in this community?**

2. **How can children be protected from being affected by these health problems/diseases?**

    - *Probe: If immunization is not mentioned, ask: What about immunization?*

Childhood immunization services

3. How does the community feel about childhood immunization?

4**. What can you tell us about the childhood immunization services in this community?**

- *Probe for levels of satisfaction with the immunization services they receive from clinics, ask: What is good and what is not so good about the immunization services?*
- *Probe for reasons for their satisfaction or dissatisfaction, ask: Why?*

5**. In your opinion, what are some of the ways these immunization services can be improved?**

Compliance with immunization schedule

6. In South Africa, as you may be familiar with, the national programme sets an immunization schedule. **How would you describe compliance with immunization schedules in this community?**

7. Many children do NOT receive all their recommended vaccines on time. What are some of the reasons children do NOT receive all their vaccines at the right time?

8. What will be your suggestion for helping children to receive all their recommended vaccines according to the schedule?

Missed opportunities for vaccination

9. In some cases, children who visit health facilities, for different reasons, still do not get all the needed vaccines. Such cases are called missed opportunities for vaccination. **In your opinion, what are some reasons some health workers may not be willing or able to give children all their recommended vaccines on time, when they visit the clinic/hospital?**

a**.** *Probe for reasons relating to parents not bringing children's RtHBs to clinic or health workers not checking children's RtHB for immunization status, eligible or missed doses*

10. Some children receive some, but not all the vaccines they need. **In your opinion, what are some of the reasons mothers/caregivers may not be willing or able to ensure that their children receive all their recommended vaccines on time when they visit the clinic?**

11. **What are the ways you can recommend for ensuring that children receive all their recommended vaccines on time whenever they have the opportunity of visiting a clinic/ hospital for any reasons?**

Closing question

12. **What additional suggestions/ideas would you like to share at this time? Anything else to add?**

Remember to close on a positive message about immunization and reducing missed opportunities for vaccination.

Appendix 7: Qualitative MOV assessment tool (in-depth interview) guide (Chapter 4)

In-depth Interview Guides

Introduction:

- Good day. My name is [*Name*] and I will be facilitating the discussion this afternoon.
- This is my colleague [*Name*]. S/he will be taking notes and helping me in this interview.
- Thank you so much for taking the time to be part of our interviews.
- We will be discussing childhood immunization and we are interested in exploring the factors such as societal, community and health system factors influencing children's immunization in this community, from your perspectives as a healthcare provider and facility manager.
- The information you provide will be anonymous and will be treated as confidential.
- If at any point you do not want to continue participating in this discussion, you are free to do so.
- The information discussed today will help us to understand what can be done to improve childhood immunization programmes in this community and Cape Town in general.
- We would like to record this discussion. Even though we will be taking notes, we are not able to write everything down and want to be able to go back and listen to any information we might have missed. All notes and the recording will be kept safely and securely.
- Are you okay with recording this conversation? (Confirm that all participants consent)
- This discussion will last about 45 minutes.
- Before we begin, do you have any questions?

Opening questions:

1. What are some of the health problems that affect children you see at this facility?

2. How do you think children can be protected from being affected by these health problems/diseases?

- *(Probe for individual health workers' roles; If vaccination is not mentioned, ask: What about vaccination?)*

Childhood immunization services

3. What can you tell us about children's immunization services in this health facility?

a. Probe for levels of satisfaction among parents/caregivers with the immunization services they are providing

b. Probe for perceptions regarding the immunization programme among different groups including health workers.

4. What are some the challenges to delivering immunization services at this health facility?

a. probe for challenges like unavailability of vaccines, staff shortage, unavailability of other commodities like needles and syringes, cold-chain supplies, load shedding etc.

5. In your opinion, what are some of the ways immunization services can be improved?

a. probe for solutions to challenges mentioned in

Compliance with immunization schedule

6. In South Africa, as you are aware, the national programme sets an immunization schedule. **How would you describe compliance with the immunization schedules in this community?**

a. Probe for proportion of children that receive all their recommended vaccines on time

b. Probe for reasons why some of the children DO NOT receive all their vaccines at the appropriate time (probe health system reasons/factors)

7. Research has shown that there are circumstances when children who come to health facilities are not vaccinated. **Can you tell me the circumstances when you, or other staff, would not vaccinate a child in this clinic?**

a. Probe for contraindications: over age, vial doses, vaccination days, no vaccines, etc.

8. What are your suggestions for helping children to catch up with their vaccinations, if needed?

Missed opportunities for vaccination

9. Some children who may not be up-to-date on their vaccinations may visit a health facility for a variety of reasons (immunization, nutrition, treatment of other ailments, accompanying an adult to the clinic/hospital) and may leave without receiving any immunizations. **What is your experience with such children at this health facility?**

a. Probe: How do you think missed opportunities can be reduced? (at parental and clinic levels)

10. **What strategies, if any, can the department of health employ to improve the number of children receiving all of their recommended vaccinations on time and reduce missed opportunities?**

a. Probe for ideas or strategies that departmental of health can employ

11. **In your opinion, what are the possible barriers to implementing any of these interventions**

to reduce missed opportunities?

a. Probe for possible solutions to any barriers that have been mentioned

Closing question

12. What additional suggestions/ideas would you like to share at this time? Anything else to add?

Appendix 8: Informed consent form; focus group discussion and in-depth interview participants (Chapter 4)

Good Day Sir/Madam.

My name is(mention name of data collector)_____. I am a researcher from the University of Cape Town. Our research aims to understand the factors such as societal, community and health system factors influencing children's immunization in this community.

As a healthcare worker in your facility, I would like to invite you to participate in this study because your response is important. Before you decide to take part, you need to understand why this research is being conducted and what would be required of you. Therefore, take your time to read this informed consent form. Please ask any question if anything is not clear or you would like further information about any aspect of the study.

The information from this study will help increase our understanding of the implementation process of quality improvement programmes in primary health care setting.

The survey will take about 20 minutes, and key informant interview will take about one hour. All information that is collected will be kept confidential and anonymous. This is guaranteed by not needing to indicate your name while being interviewed. If you decide to take part in this study, be assured that your participation is voluntary, and you are free to withdraw at any time without giving any reason. There are no risks, penalty or loss of benefits whether you participate or not.

I, _____ consent and volunteer to participate in a research aimed as assessing the impact of quality improvement collaborative on reducing missed opportunity for vaccination in the Cape Town Metro Health district, Western Cape, South Africa. The study is being conducted by Chukwudi Nnaji; a doctoral researcher from the Division of Epidemiology and Biostatistics at the School of Public Health and Family Medicine, Faculty of Health Sciences, University of Cape Town, South Africa.

I confirm that:

1. I was provided with an information sheet that explained what the study is about I have read and understood the information about the study as provided in the information sheet.
2. I have been given the opportunity to ask questions about the project and my participation.
3. I understand that I can withdraw at any time without giving reasons and there are will be no risks or penalty for withdrawing
4. It has been clearly explained to me that the research is confidential and anonymous. i.e. and what I say will not be linked to me as a person and that the information will

only be used for this research purpose and not shared with other people that are not part of this research team.

5. It has been clearly explained to me that information from this research may be used in a thesis report, publications or presentations.
6. I understand that mobile tablet devices will be used in the collection of data.
7. I understand the during the interview, my voice will be recorded.

Participant

_____	_____	_____
Name	Signature/Thumb Print	Place and date

If you have any concerns or questions regarding any aspect of this study or wish to obtain a copy of the results of the survey, please kindly contact me on;

Name: Chukwudi Nnaji
Tel: 0717210476 Email: nnjchu001@myuct.ac.za

For any concern or questions regarding participants' rights and ethical conduct of research, please contact the **Health Research Ethics Committee, Faculty of Health Sciences, University of Cape Town**. Room G50 Old Building. Groote Schuur Hospital, Observatory 7925, Cape Town.
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Appendix 9: Quality improvement MOV evaluation tool - exit interview questionnaire (Chapter 5)

Respondent ID_____

Date of interview (DD/MM/YYYY) _____

Week of interview 1] Week 1 2] Week 2 3] Week 3 4] Week 4 5] Week 5 6] Week 6 7] Week 7 8] Week 8 9] Week 9 10] Week 10 11] Week 11 12] Week 12

Name of interviewer _____

HEALTH FACILITY CHARACTERISTICS

11. Name of health facility_____
12. Sub-district _____
13. Type of health facility 1] Comprehensive health centre 2] Health clinic 3] Health post 4] Dispensary
14. Facility ownership 1] Provincial 2] City of Cape Town 3] Others (Specify, e.g. private, faith-based etc) _____
15. Total number of health workers in facility _____
16. Average daily number of patients seen _____
17. Is there a designated vaccination space in the facility? 1] Yes 2] No
18. Does the facility have designated immunization days? 1] Yes 2] No
19. Has there been vaccine cold-chain and storage challenge in this facility in the past 3 months, such as prolonged electricity outage, bad refrigerators, lack of cold boxes etc? 1] Yes 2] No
20. Any vaccine stock-out in the past 3 months? 1] Yes 2] No

SECTION A: CHILD DATA

55. Date of birth _____
56. Age in months (note: child must be <24 months) _____
57. Sex 1] Male 2] Female
58. Birth order 1] First 2] Second 3] Third 4] Others (specify) _____
59. Birth weight (in Kg) _____

60. Why did you bring the child to this health facility today? (Do not read out options) 1] For medical consultation (child is sick) 2] For vaccination 3] Growth and Development Check-up 4] Child is only accompanying (not for treatment/vaccination) 5] Hospitalization (Child was admitted or still on admission) 6] Others (Please specify) _____

SECTION B: PARENT/CAREGIVER DATA

61. Age (DD/MM/YYYY) _____

62. Sex 1] Male 2] Female

63. Marital status 1] Single 2] Married 3] Separated 4] Divorced

64. What is your relationship with the child? 1] Mother 2] Father 3] Grandparent 4] Uncle/Aunt 5] Brother/sister 6] Others (please specify) _____

65. Did mother attend antenatal care during child's pregnancy? (If father or other caregivers, do you know if mother attended antenatal care during index child's pregnancy 1] Yes 2] No 2] I am not sure

66. Level of formal education 1] No formal education 2] Did not complete primary education 3] Completed primary education only 4] Completed secondary education only 5] Post-secondary education

67. Are you currently employed? Branching logic: If no, skip to question 15

68. If yes, what is your occupation? 1] Professional, technical or managerial 2] Sales and services 3] Domestic service 4] Agriculture 5] Farming 6] Unskilled labour 7] Self-employed 8] Others (please specify) _____

69. By what means of transportation do you usually use to come to this facility? 1] Walk 2] Own transport 3] Public transport 4] Others (please specify) _____

70. How long does it take you to get to this health facility from your home? _____Hours _____ Minutes

71. What is the estimated cost of transportation to this facility and back? 1] Less than R50 2] R50 to R99 3] R100 to R199 3] R200 or more

72. Have you heard or seen any message on vaccination in the last one month? 1] Yes 2] No Branching logic: If no, skip to question 20

73. If yes, where? 1] Radio 2] Television 3] Newspaper 4] Health facility 5] Telephone message 6] Facebook or Internet 7] Children's school 9] Place of worship 11] During home visit by health workers 12] Community meetings 13] Others (Please specify) _____

74. Do you feel you know the vaccines your child needs? 1] Yes 2] No 3] Not sure Branching logic: If no, skip to question 22

75. If yes, do you feel that you know when the vaccines should be given? 1] Yes 2] No 3] Not sure

76. Has this child ever been vaccinated? 1] Yes 2] No Branching logic: If yes, skip to question 24

77. If no, why not? 1] The necessary vaccines or supplies were not available 2] I am not in favor of vaccination 3] My husband/the decision maker is not in favour of vaccination 4] I have not visited the health facility on a vaccination day 5] I did not know that the child was eligible to be vaccinated 6] Others (Please specify) _____

78. Have you ever requested vaccination services for this child and child didn't get vaccinated? 1] Yes 2] No Branching logic: If no, skip to question 26

79. If yes, why was child not vaccinated? 1] The health worker said it couldn't be done because the child was sick 2] There were no vaccines or there were no syringes or some other supply needed for vaccination 3] it was not a vaccination day 4] The vaccination area was closed 5] The person in charge of vaccination was not there 6] There would have been a long wait 7] We didn't have the Road to Health booklet (RtHB) with us 8] The hours for vaccination are limited 9] Others (Please specify) _____

80. In your home who makes the decision to vaccinate? 1] Father 2] Mother 3] Other relatives 4] Consensus of father and mother 5] Others (Specify) _____

SECTION C: USE OF ROAD TO HEALTH BOOKLET (RtHB) AND INFORMATION ON VACCINES ADMINISTERED

81. Does your child have a Road to Health booklet (RtHB)? 1] Yes, and I have it with me 2] Yes, but I do not have it with me 2] No Branching logic: If 'Yes, but I do not have it with me', skip to question 29; If 'Yes, and I have it with me', skip to question 30

82. If no, why don't you have a Road to Health booklet (RtHB)? 1] I lost it 2] I have never been given one 3] I don't know 4] Others (Please specify) _____ Skip to question 30

83. If 'yes, but I do not have it with me', could you tell us why you do not have the Road to Health booklet (RtHB) or temporary vaccination documents with you today? 1] It is at the school/day care center 2] I left it at home because I forgot to bring it 3] I left it at home because I didn't know it was important to bring along 4] I lost it 5] The care has been damaged 6] I have never been given one 7] Because vaccination was not the reason for this visit 8] Others (Please specify) _____

84. What vaccines has the child received to date? (Obtain information only from Road to Health booklet (RtHB). If RtHB is not with the caregiver at the time of interview, obtain vaccination status information from health facility vaccination register (to do this, complete a health facility register follow-up Form and assure caregivers that this information will only be used to track child's vaccination records in the health facility register)

Fill out the following table. Remember to take pictures of all the relevant pages on the RtHB or facility vaccination register (in cases of absent/missing RtHB)

Age	**Vaccines**	**Administered**	**Date Administered**
Birth	BCG,	[Yes [No [Not sure	
Birth	OPV (0)	[Yes [No [Not sure	
6 Weeks	OPV (1)	[Yes [No [Not sure	
6 Weeks	RV (1)	[Yes [No [Not sure	
6 Weeks	DTaP-IPV-Hib-HepB (1)	[Yes [No [Not sure	
6 Weeks	PCV (1)	[Yes [No [Not sure	
10 Weeks	DTaP-IPV-HIB-HepB (2)	[Yes [No [Not sure	
14 Weeks	DTaP-IPV-Hib-HepB (3)	[Yes [No [Not sure	
14 Weeks	RV (2)	[Yes [No [Not sure	
14 Weeks	PCV (2)	[Yes [No [Not sure	
6 months	Measles (1)	[Yes [No [Not sure	
9 Months	PCV (3)	[Yes [No [Not sure	
12 months	Measles (2)	[Yes [No [Not sure	
18 Months	DTaP-IPV-Hib-HepB (4)	[Yes [No [Not sure	

BCG = Bacille Calmette Guerin, DTaP-IPV-Hib-HepB = Hexavalent Vaccine (containing Diphtheria, Tetanus, Pertussis, injectable Polio, Haemophilus influenzae b and Hepatitis B vaccines), HPV = Human Papilloma Virus vaccine, OPV = Oral Polio Vaccine, PCV = Pneumococcal Conjugate Vaccine, RV = Rotavirus vaccine, Td = Tetanus and reduced dose diphtheria vaccine

85. Based on the above information and the EPI schedule (refer to SA EPI schedule), are there vaccines/doses the child is eligible for by age, that the child is yet to receive? 1] Yes 2] No

86. Have you ever lost the Road to Health booklet (RtHB)? 1] Yes 2] No
Branching logic: If no, skip to question 34

87. If yes, did you encounter difficulty getting it replaced? 1] Yes 2] No

88. Could you tell me what purpose the Road to Health booklet (RtHB) serves? 1] Don't know 2] To know what vaccines the child has had and which are missing 3] Overall health record and growth monitoring 4] Record and remind for return visit dates 5] Birth certificate and/or identification 6] Others (Specify) _____

SECTION D: TODAY'S VISIT

89. What day of the week is today? 1] Week day 2] Weekend (Saturday or Sunday)

90. Time of the visit 1] Morning 8:01 am – 12 noon 2] Afternoon (12:01pm to 5:59pm) 3] After hours (6:00pm – 8:00am)

91. During today's visit, did the health worker ask you for the child's Road to Health booklet (RtHB)? 1] Yes 2] No Branching logic: If yes, skip to question 39

92. Did the health workers ask for the vaccination status of the child? 1] Yes 2] No

93. Was your child vaccinated here today? 1] Yes 2] No Branching logic: If yes, skip to question 42

94. If no, why? 1] The health worker said that the child was not eligible for vaccination today. 2] The health workers who saw us did not tell me about vaccinating the child 3] The health worker said that the child could not be vaccinated because s/he was sick 4] The last time the child was vaccinated s/he got sick or had a reaction 5] My religion does not permit vaccination or I don't believe in vaccines 6] Vaccination was not the purpose of this visit 7] The child is already fully vaccinated for his/her age 8] I don't trust the health workers or vaccines in this health facility 9] I forgot to take my child to the vaccination area 10] I didn't have time today to wait for vaccination 11] There were no vaccines in the health facility today 12] There were no syringes or other vaccination supplies 13] Today is not a vaccination day in this health facility 14] The vaccination area was closed 15] The person in charge of vaccination was not there 16] There would have been a long wait 17] The staff treated us badly 18] Other (please specify) _____

95. If your child was eligible for vaccination but was not vaccinated today, did the health worker refer you to or inform you about where you can receive the missing vaccine doses? 1] Yes 2] No

SECTION E: QUALITY OF VACCINATION SERVICES

Instruction: Complete this section only if the child received vaccination today

96. How long did you wait for your child to be vaccinated? _____ Hours _____Minutes

97. Did they tell you today what vaccines they gave the child? 1] Yes 2] No

98. Today, did they tell you the date for the child's next vaccination appointment? 1] Yes 2] No

99. Today, were you given details of the next vaccination appointment? 1] Yes 2] No

100. Did you receive information today on the reactions or side effects that can occur following vaccinations? 1] Yes 2] No Branching logic, if no skip to question 49

101. If yes, what were you told? 1] Pain at injection sites 2] Fever 3] Rash4] Diarrhea 5] Vomiting 6] Others (Please specify) _____

102. Did you receive information today on what you should do if the child has reactions or side effect to the vaccines? 1] Yes 2] No

103. Are you satisfied with the services provided today? 1] Yes 2] No Branching logic, if no skip to question 51

104. If yes, why? (SELECT THE MOST MPORTANT REASON) 1] Immediate attention 2] Friendly treatment by staff3] No charge for services 4] The necessary vaccines and supplies were available 5] Others (Specify) _____ Branching logic, skip to question 52

105. If no, why? (SELECT THE MOST MPORTANT REASON) 1] Had to wait a long time 2] The staff was discourteous 3] The language that the health worker use is not clear 4] They did not explain what vaccines they had given the child 5] The necessary vaccines and supplies were not available 6] Others (Specify) _____

SECTION F: REASONS TO VACCINATE CHILDREN

106. Could you tell me the purpose of vaccines? (Multiple responses allowed) 1] To prevent diseases 2] So children will grow up healthy 3] To cure diseases 4] They don't do any good 5] Not sure what they are for 6] Other (Please specify) _____

107. Do you think your child could get these diseases if you don't vaccinate him/her? 1] Yes 2] No 3] Don't know

108. What suggestions do you have to improve vaccination services? 1] There should be more vaccination personnel 2] There should be less waiting time 3] Hours and days when vaccinations are available should not be limited 4] Road to Health booklet (RtHB) should remain free 5] The treatment of the public and of the children being vaccinated should be friendlier 6] The health center

should always have vaccines 7] The should provide information on the vaccines that are being given, on the diseases that they prevent, and on the reactions that they produce. 8] More outreach services 9] None 10] Don't know 11] Others (Please specify) _____

Interviewer's remarks_____

Appendix 10: Quality improvement rating tool (Chapter 6)

SECTION A: BACKGROUND INFORMATION

Age _____

Sex 1] Male 2] Female

Level of Education 1] No formal education 2] Primary education only 3] Secondary education 3] Post-secondary education

Cadre of health worker 1] Community health worker 2] Nurse 3] Pharmacist 4] Medical doctor 6] Others

SECTION B: EVALUATION OF COMMUNITY QI

INNOVATION/INTERVENTION CHARACTERISTICS DOMAIN

The quality improvement strategies (interventions) were locally developed by stakeholders from this health facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

Health workers from this facility were fully involved in the choosing the change ideas to be tested

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I trusted that this quality improvement initiative would reduce missed opportunities for vaccination and improve the performance of our immunization service

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

This quality improvement approach is better than other types of interventions for reducing missed opportunities for vaccination and improving performance of immunization systems

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I consider quality improvement approach to be very flexible

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I consider these quality improvement initiatives to be very simple to implement

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I am very happy with the way the change ideas were delivered in cycles

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I consider quality improvement approach to be an inexpensive strategy for reducing missed opportunities for vaccination in primary health care setting

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

OUTER SETTING DOMAIN

I consider missed opportunities for vaccination to be a very important problem in our health facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

This primary health care facility is a key immunization service delivery centre in this community

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I was interested in using quality improvement approach because I heard it has been successful in other places

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

Our facility will be rewarded by the city or provincial departments of health if we reduce missed opportunities for vaccination and improve the performance of our immunization clinic

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

INNER SETTING DOMAIN

There are enough healthcare workers in this facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There is a health worker dedicated to managing the immunization clinic

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

Immunization services are provided daily in this facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was a social media group to keep everyone informed about meetings and key activities regarding quality improvement

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

It was easy to relate with all the members of the quality improvement team

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I will receive a financial reward for using quality improvement to reduce missed opportunities for vaccination and improving immunization services in this clinic

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I will get a promotion for quality improvement to reduce missed opportunities for vaccination and improve immunization services in this clinic

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

It is easy to implement new ideas like quality improvement in this primary health care facility

Mothers and caregivers consider this quality improvement initiative to be very valuable and important

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was a good support system in place to seek more information about the quality improvement initiatives

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

The quality improvement team were very committed

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

The was easy access to information about the quality improvement initiatives that were implemented

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

CHARACTERISTICS OF INDIVIDUALS DOMAIN

I was confident in myself during the implementation of the quality improvement initiatives in my community

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I was very familiar with the quality improvement strategies before implementation began

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I consider myself an important stakeholder for reducing missed opportunities for vaccination in this health facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

I was highly motivated and competent to implement quality improvement initiatives this health facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

INTERVENTION PROCESS DOMAIN

There was adequate planning and preparation before implementation of the quality improvement ideas commenced in this health facility

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was adequate involvement of mothers and caregivers as well as health workers in this facility in planning and implementation of the quality improvement initiatives

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was involvement and participation from city or provincial health department officials

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was a quality improvement team charged with the monitoring the change ideas

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was an external person who provided support and direction for this quality improvement initiative

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

There was a good feedback mechanism for displaying progress and sharing experiences

1] Strongly disagree 2] Disagree 3] Neutral 4] Agree 5] Strongly agree

Appendix 11: Post-intervention quality improvement evaluation in-depth interview guide (Chapter 6)

INTRODUCTION

1. Please describe your role in this health facility
2. What was your role in this quality improvement initiative?
3. What specific function did you play during implementation of this quality improvement initiative

DESCRIPTION OF IMPLEMENTATION

Describe how the QI initiative was implemented in your health facility. Please specify dates of the key activities that were implemented (if you can remember).

What kind of interventions were implemented in this facility? How were they implemented?

What kind of materials were used for the intervention? Where they enough?

Who implemented the interventions? Tell me what you know about them.

PRE-IMPLEMENTATION EXPERIENCES

Tell me how the QI intervention started. How did your facility become involved? How were you engaged to participate in the QI intervention?

What did you see that showed whether this QI initiative would work? Did you know about QI before this initiative started? How was this initiative better than other interventions you've participated in?

To what extent did other health workers buy-in to this QI initiative? Do you think this kind of initiative is important? Tell me more about how it has benefited this facility. To what extent has it served its purpose? Tell me more about how you think it served a purpose?

IMPLEMENTATION EXPERIENCES

Describe your experiences during the implementation of this QI initiative. What kind of support did you get? Tell me about the problems you experienced? What were the facilitators you experienced?

Describe your planning process for implementation of this QI initiative? How did you keep track of the tasks that needed to be done?

What kind of support did you get during the implementation of this QI initiative?

Were the activities flexible? How?

OVERALL EXPERIENCE

Did you enjoy participating in this QI initiative? Tell me why.

Level of endorsement

How successful do you think this QI initiative was? What do you mean by success? *Define your success. Rate the success of this initiative on a scale of 0 – 10. Would you want to continue implementing this QI initiative? What would it take to continue this initiative in this facility? Would you recommend a similar QI initiative to other facilities? What are your suggestions for improving this QI initiative?