mHEALTH INTERVENTIONS TO IMPROVE MEASLES VACCINATION COVERAGE AND TIMELINESS: AN ASSESSMENT OF THE IMMEDIATE AND LONG-TERM IMPACT ON VACCINE-SEEKING IN RURAL KENYA

by

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Abstract

Vaccine-preventable diseases cause considerable childhood morbidity and mortality in low- and middle-income countries (LMICs). To inform scaled use of mobile phone-based interventions (mHealth) to improve pediatric vaccination uptake in LMICs, we evaluated the following:

i. Using current evidence, do short message service (SMS) reminders improve vaccination uptake?
ii. Can SMS reminders with *unconditional* mobile money (mMoney) incentives improve first-dose measles-containing vaccine (MCV1) uptake?
iii. What is the impact of temporary SMS reminders and mMoney incentives on long-term vaccine-seeking?

We conducted:

1) A systematic review and meta-analysis of the impact of SMS reminders on pediatric vaccination uptake.

2) A randomized controlled trial in Kenya to assess the impact of SMS reminders with or without *unconditional* mMoney incentives on MCV1 uptake (the M-SIMI study). Participants received no interventions (Control), SMS reminders alone, or SMS reminders plus 150 Kenya Shillings (SMS+150KES).

3) A post-trial follow-up study (the MSBC study) in Kenya to assess vaccine-seeking after withdrawal of SMS reminders and incentives among former M-SIMU study participants.[1]

Systematic review and meta-analysis (11 studies): SMS reminders significantly improved third-dose diphtheria, tetanus and pertussis (DTP3) timeliness but not DTP3 uptake and full vaccination by age 12 months. Insufficient number of studies precluded meta-analysis for MCVs.

M-SIMI study (N= 455): Compared to Control infants, MCV1 coverage within four weeks of the recommended age was significantly higher among SMS+150KES infants but not among SMS only infants. Neither intervention significantly improved MCV1 coverage by age 12 months.

MSBC study (N= 218): Withdrawal of SMS reminders and incentives was associated with statistically insignificant decreases in MCV1-seeking for subsequent children (SC) and statistically significant decreases in MCV2-seeking for some former M-SIMU children. Decreased MCV1-seeking translated to lower-than-expected coverage among SC of former M-SIMU intervention caregivers compared to Control SC.

[1] Gibson DG, Ochieng B, Kagucia EW, et al. Mobile phone-delivered reminders and incentives to improve childhood immunisation coverage and timeliness in Kenya (M-SIMU): a cluster randomised controlled trial. *Lancet Glob Heal*. 2017;5(4):e428-e438.

SMS reminders can increase vaccination uptake. *Unconditional* incentives may have no added effect on MCV1 uptake over SMS reminders alone. Withdrawal of SMS reminders and incentives could reduce measles vaccine-seeking.

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Table of contents

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List of Tables

List of Figures

List of Appendices

Abbreviations and acronyms

AFRO	World Health Organization (WHO) Africa Regional Office
ANC	Antenatal care
BCG	Bacillus Calmette–Guérin vaccine
CCT	Conditional cash transfer
CDC	Centers for Disease Control and Prevention
CDI	County Development Index
CHV	Community Health Volunteer; analogous to a community health worker
CI	Confidence Interval
CI	Community Interviewer
CFR	Case fatality ratio
DHS	Demographic and Health Survey
DID	Difference-in-differences
DTP	Diphtheria, tetanus and pertussis antigens-containing vaccine
DTP3, DTP2, DTP1	3, 2 or 1 doses of DTP vaccine, respectively
EPI	Expanded Programme on Immunisation
ERC	Ethical Review Committee
EURO	WHO Europe Regional Office
FIC	Fully immunization coverage
GDP	Gross domestic product
GNI	Gross national income
HBM	Health behavior model
HDSS	Health and Demographic Surveillance System
HFR	Health Facility Recorder
Hib	*Hemophilus influenzae* type b
HIV	Human immunodeficiency virus
IMCI	Integrated Management of Childhood Illnesses
KEMRI	Kenya Medical Research Institute
KEPI	Kenya Expanded Programme on Immunisation
KES	Kenya Shilling
LMIC	Low- and middle-income countries
MCH	Maternal and child health

MCV	Measles-containing vaccine
MCV1	First dose of MCV
MCV2	Second dose of MCV
mHealth	Mobile-Health
mMoney	Mobile-Money
MoH	Ministry of Health
MR Initiative	Measles and Rubella Initiative
MSBC	M-SIMU subsequent born child(ren). The MSBC study refers to a planned study to assess vaccination coverage among children who were born to M-SIMU study caregivers following the child that was enrolled in the M-SIMU study i.e., MSBC.
M-SIMI	Mobile and Scalable Innovations for Measles Immunization. The M-SIMI study refers to a randomized controlled trial in Siaya County, Kenya to evaluate the impact of text message reminders with or without a small, unconditional monetary incentive on vaccination coverage and timeliness. The study began in December 2016 and is ongoing as of April 2017
M-SIMU	Mobile solutions for immunization. The M-SIMU study refers to a cluster randomized controlled trial conducted in rural Siaya County, Kenya in 2013-2015 to evaluate the impact of text message reminders with or without small, conditional monetary incentives on vaccination coverage and timeliness
PCV	Pneumococcal conjugate vaccine
Penta	Pentavalent vaccine; formulation used in Kenya contains DTP, Hepatitis B and Hib vaccines
Penta3, Penta2, Penta 1	3, 2 or 1 doses of pentavalent vaccine, respectively
RCT	Randomized controlled trial
RD	Risk difference
RI	Routine immunization
RR	Risk Ratio
SC	Subsequent child(ren)
SEARO	WHO South East Asia Regional Office
SIA	Supplemental immunization activity
SMS	Short message service
SSA	Sub-Saharan Africa
TT	Tetanus toxoid
U5MR	Under 5 mortality rate
UCT	Unconditional cash transfer
USD	United States Dollar

VPD	Vaccine-preventable disease
VR	Village reporter
WHA	World Health Assembly
WHO	World Health Organization

CHAPTER 1: INTRODUCTION

1.1. Project rationale

Vaccines continue to contribute towards reductions in mortality and morbidity globally. Annually, vaccines prevent up to three million global child deaths.[1] Vaccination against smallpox was crucial for elimination of smallpox in 1980; prior to its eradication, smallpox caused an estimated 300 million total deaths and hundreds of millions illnesses globally.[2] Vaccines against polio - a disease targeted for eradication - are estimated to avert 8 million deaths world-wide between 1988 and 2035.[3] Measles-containing vaccines (MCVs) have averted 20.4 million measles deaths globally between 2000 and 2016.[4] Vaccine-associated gains have been observed across high- and low-resource settings. In the US, vaccines averted an estimated 26 million cases of illness between 2001 and 2011.[5] In Gavi-supported low- and middle-income countries (LMICs), use of 10 vaccines is expected to avert 20 million deaths and 500 million illnesses in 2001-2020. Beyond avoiding death and disease, vaccines can avert substantial costs associated with mortality and illness, for example, vaccines are projected to save an estimated $820 billion in Gavi-supported LMICs between 2001 and 2020.[6] Furthermore, vaccines can alleviate poverty resulting from catastrophic health expenditures,[7] increase educational attainment[8,9] and avert cognitive impairment caused by vaccine-preventable illnesses.[10,11] Moreover, vaccines can contribute towards achievement of the Sustainable Development Goals (SDGs) by promoting good health and well-being, reducing poverty and increasing the likelihood of high educational attainment, among other benefits.[12–15]

The 2011-2020 Global Vaccine Action Plan (GVAP) offers a roadmap towards realizing the full public health value of vaccination.[16] However, global progress towards achieving the 2020 targets of the GVAP is unsatisfactory, with only one target – introduction of a new vaccine in

each LMIC – having been met.[17] Certification of polio eradication by 2018 is unattainable as the African (AFRO) and Eastern Mediterranean (EMRO) regions of the World Health Organization (WHO) are not yet certified polio-free and at best, would achieve certification in 2019 and 2021, respectively.[18] In 2018, only the WHO Americas region has eliminated measles out five WHO regions targeted to eliminate measles by 2020. In addition, as of 2016 (the last year with a published global review of measles control progress), none of the countries in AFRO or in EMRO had eliminated measles.[4] Of 194 member states providing national 2016 third dose diphtheria, tetanus and pertussis (DTP3) vaccination coverage data to WHO, 68 had <90% coverage, yet 90% and 80% national coverage and district-level coverage, respectively, are expected by 2020.[19]

In 2016, 96% of LMIC inhabitants and 75% of people living in Africa owned a mobile telephone.[20] An even larger percentage of LMIC inhabitants have access to a mobile phone as phone sharing is prevalent in these settings.[21,22] Vaccination reminders and incentives can increase demand for vaccination.[23–26] High levels of mobile phone access afford an opportunity to reach more people with mobile phone-based vaccination reminders and incentives compared to reminders and incentives delivered via traditional avenues. Of studies assessing the impact of demand-side mobile-phone based interventions (mHealth) to improve vaccination uptake in LMICs,[27–29] the Mobile Solutions for Immunization (M-SIMU) study – a cluster randomized controlled trial conducted in rural western Kenya in 2013 to 2015 – was novel in that it assessed the impact of two mHealth interventions i.e., SMS reminders alone or when coupled with small conditional mobile-money (mMoney) incentives, on vaccination coverage and timeliness. The M-SIMU study found that SMS reminders coupled with the larger of two conditional mMoney

incentives significantly improved first dose MCV (MCV1) coverage from 84% to 90% by age 12 months (coverage endpoint). In assessment of the timeliness endpoint, SMS reminders with or without conditional mMoney incentives significantly increased the proportion of children receiving MCV1 within two weeks of the recommended age within the Kenya Expanded Programme on Immunization (KEPI) by as much as 21% while SMS reminders coupled with the larger of two conditional mMoney incentives significantly improved DTP3 timely coverage by 9%.[30] The implication of findings from the M-SIMU study is that SMS reminders with or without small incentives can be used to reduce the proportion of children susceptible to disease by increasing vaccination timeliness and that these interventions can be used to increase vaccination coverage even among 'last-mile' populations who have relatively high, though sub-optimal, vaccination coverage.

Findings from the M-SIMU study present a case for implementing SMS reminders with or without incentives, at scale so as to improve vaccination uptake. However, stakeholders in LMICs may have scientific and technical concerns. First, there is no information on the summary effect of SMS reminders on vaccination in LMICs. Current summary effect estimates are from predominantly high-income settings[23] and current systematic and scoping reviews focused on LMICs have performed only qualitative syntheses.[27–29] Second, the M-SIMU study demonstrated an added effect of conditional incentives over SMS reminders alone but the use of conditional incentives requires near real-time verification of vaccination status, which in most LMICs is impossible due to the lack of centralized, accurate electronic vaccination records. Third, the long-term impact of SMS reminders alone or when coupled with conditional monetary incentives on vaccine-seeking is not known. Specifically, might SMS reminders and/or incentives cause a

negative rebound in vaccine-seeking behavior when withdrawn? Or might their impact be sustained such that families who received SMS reminders and/or incentives are more likely to vaccinate subsequent children, even in the absence of reminders/incentives? This dissertation aims to provide rigorous evidence to inform at scale implementation of SMS reminders alone or in combination with small monetary incentives for improvement of vaccination uptake in LMICs.

1.2. Specific aims

Aim 1. To assess the pooled quantitative effect of SMS reminders on vaccination coverage and timeliness in low- and middle-income countries.

To assess this aim, we conducted a systematic review and meta-analysis of the effect of SMS reminders on pediatric vaccination coverage and timeliness in LMICs. As mentioned previously, currently no meta-analysis of the effect of SMS reminders on vaccination coverage or timeliness in LMICs has been performed.

Aim 2. To evaluate if SMS reminders, with or without an *unconditional* mobile-money incentive, can significantly increase the proportion of children receiving MCV1 by age 10 months as compared to control arm children in rural Siaya County, Kenya.

This aim was assessed using data from a randomized controlled study, the Mobile and Scalable Innovations for Measles Immunization (M-SIMI) study. The M-SIMI study was conducted between 2016 and 2017 in the same setting as the M-SIMU trial. Whereas the SMS reminders

coupled with *conditional* incentives were shown to improve MCV1 uptake in the M-SIMU study,[30] the impact of SMS reminders coupled with *unconditional* incentives has not been previously evaluated. Unlike *conditional* incentives, *unconditional* incentives do not require real-time verification of vaccination status and thus could present a scalable intervention by eliminating the need for employing staff to verify infants' vaccination status in real time. Measles vaccination was used to illustrate the potential impact of SMS reminders with or without *unconditional* incentives on vaccine uptake.

Aim 3. To assess whether MCV1 timeliness and coverage significantly differ between subsequent born children of M-SIMU caregivers in rural Siaya County, Kenya who received SMS reminders alone or coupled with small mobile-money incentives compared to children of Control M-SIMU caregivers who did not receive any interventions.

This aim was assessed using data from the M-SIMU Subsequent Born Children (MSBC) study. A post-trial follow-up study, the MSBC study conducted a vaccination survey among children born to M-SIMU caregivers after their participation in the M-SIMU study so as to allow comparison of vaccine-seeking among M-SIMU caregivers after SMS reminders and monetary incentives were withdrawn, compared to during the M-SIMU study. The MSBC study was conducted in 2017 in the same area where the M-SIMU study was conducted. Measles vaccine-seeking was the illustrative case used to demonstrate the potential long-term impact of SMS reminders with or without conditional incentives.

1.3. Thesis organization

Chapter 1 describes the rationale of the dissertation project and outlines the specific aims of the dissertation.

Chapter 2 is a compilation of relevant background information. It describes measles disease, global measles prevention and control efforts as well as supply- and demand-side barriers to MCV uptake. It also includes a review of the literature on the use of non-SMS reminders and incentives to improve vaccination coverage in LMICs. In addition, it provides a detailed review of the M-SIMU study and a description of the study setting. The M-SIMU study was conducted prior to the commencement of this dissertation but is relevant as it is the precursor to both the M-SIMI (Aim 2) and MSBC (Aim 3) studies. Finally, Chapter 2 also describes the research setting wherein the M-SIMI, MSBC and M-SIMU trials were conducted.

Chapters 3-5 describe the methods and findings from analyses of the specific aims. Specifically, Chapter 3 presents the systematic review and meta-analysis of the impact of SMS reminders on vaccination coverage and timeliness in LMICs. Chapter 4 presents the analysis of the impact of SMS reminders with or without unconditional mMoney incentives on MCV1 uptake (the M-SIMI study) while Chapter 5 describes the analysis of differences in MCV1 uptake among children subsequently born to M-SIMU intervention caregivers compared to control caregivers (the MSBC study).

Chapter 6 presents a summary of the findings from the specific aims and a contemplation of the implication of these findings to measles control programs and to vaccination programs in general. Chapter 6 also discusses the strengths and limitations of the analyses and recommendations for future studies.

In Chapter 7 (Appendices), readers can find supplementary documents.

1.4. Chapter 1 References

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CHAPTER 2: BACKGROUND AND LITERATURE REVIEW

2.1. Introduction

Measles remains a major cause of morbidity and mortality. Despite substantial reductions in measles mortality and morbidity since 2000, there were an estimated 89,780 global measles deaths and approximately 132,000 measles cases (likely an underestimate) reported to the World Health Organization (WHO) in 2016. All but 1,880 of global measles deaths occurred in the Africa (AFRO), South-East Asia (SEARO) and Eastern Mediterranean (EMRO) regions of the WHO.[1] At the same time, most measles deaths occur in children <5 years old.[2] Vaccination is key for measles prevention yet 21 million children worldwide did not receive first dose measles-containing vaccine (MCV1) in 2016. Of those 21 million, 18 million children lived in AFRO, SEARO and EMRO. Third dose of diphtheria, tetanus and pertussis (DTP3) vaccine coverage in these regions points to suboptimal routine immunization performance. In 2016, regional DTP3 coverage was 74%, 80% and 88% in AFRO, SEARO and EMRO, respectively.[3] Well-functioning routine immunization systems are expected to achieve DTP3 coverage of ≥90% nationally and ≥80% at the district level.[4]

Barriers at the health system level (supply-side) and at the health service user level (demand-side) contribute to reduced immunization system performance and have been well characterized in low- and middle-income countries (LMICs).[5–9] Interventions that overcome supply-side and demand-side barriers to vaccination are critical to improving vaccination coverage in LMICs so as to avert deaths, illnesses and their associated costs and sequelae. Results from meta-analyses suggest that vaccination reminders and incentives increase vaccination uptake in high income settings[10–13] while in LMICs there is some evidence for the effectiveness of reminders but mixed evidence for incentives.[14,15] Increasingly high levels of mobile phone ownership[16] and access[17,18]

in LMICs present an opportunity for evaluating the impact of reminders and incentives delivered via mobile phones as they may reach more health service users, including those from traditionally disadvantaged populations.

This chapter provides an overview of the burden of disease due to measles and global measles control efforts. Barriers to measles vaccination are also reviewed as well as the historical use of reminders and incentives to improve vaccination uptake. In addition, a short discussion on metrics used to measure vaccination uptake and the potential role of mobile phone delivered reminders and incentives to improve vaccination uptake are briefly presented, followed by an exploration of the theoretical mechanisms through which reminders and incentives may influence vaccine-seeking behavior. Finally, a review of the parent study for Aims 2 and 3 of the thesis, i.e., the M-SIMU study is described in detail and a description of the study area is provided.

2.2. Measles disease and global control efforts

2.1.1 Measles virus and clinical features

Measles is caused by a negative-strand RNA virus of the genus *Morbillivirus*, Family *Paramyxoviridae*. It primarily affects children and is transmitted when aerosolized measles virus (MV) is inhaled or introduced into the conjunctiva. After a 10-14 day incubation period, the initial symptoms of measles illness – fever, cough, runny nose and conjunctivitis – appear in the infected person and usually last up to three days. These unspecific symptoms are followed by the development of lesions on the inside lining of the cheeks, known as Koplik's spots, which are

specific to measles. A maculopapular rash beginning in the facial area and eventually spreading to the rest of the body begins one to two days after the appearance of Koplik's spots. Symptoms may be different in immunocompromised people.[19–21] Measles is extremely infectious and can be transmitted to as many as 9 out 10 susceptible, exposed people.[22]

Although measles virus infection is self-limiting in most people, infection with the virus can lead to secondary infections due to measles-induced immune suppression and to sequelae such as pneumonia, diarrhea, blindness, acute post-infection measles encephalitis, measles inclusion body encephalitis and subacute sclerosing panencephalitis (SSPE).[19,23,24] Complications occur most frequently among children age <5 years, adults age >20 years, pregnant women and immunocompromised individuals such as persons infected with human immunodeficiency virus (HIV) and malnourished persons.[23] The frequency of complications among measles cases can range from as high as 25% (diarrhea) to as low as 0.01% (SSPE)[25]. There is no measles-specific antiviral treatment though management of sequelae may include rehydration, vitamin A administration and antibiotic treatment of secondary bacterial infections.[21] The case fatality ratio (CFR) for measles is typically 5% in endemic low-income settings[21] but can be as high as 10%[23] or even higher during outbreaks or in emergency situations.[26,27] Measles CFR is influenced by factors such as access to quality care, nutritional status and MCV coverage.[21] Infection with measles leads to life-long protective immunity[28] among people who recover.

2.2.2. Burden of disease

Measles is a substantial cause of mortality and morbidity. In 2015, there were an estimated 7 million (95% confidence interval [CI] 4.2 million – 28.7 million) measles cases and 89,780 (95% CI 45,700 – 269,600) measles deaths globally. The WHO regions contributing the largest proportion of measles deaths were South East Asia (43%) and Africa (42%) meaning that 85% of global measles deaths occurred in these two regions. Despite the substantial burden of measles disease, 2016 morbidity and mortality estimates represent a 76% and 84% decline, respectively, since 2000.[1] Measles outbreaks occurred in at least six countries globally in 2016 i.e., Romania, Italy, Cambodia, Kenya, Nigeria and Sierra Leone.[29,30] The quality of measles morbidity and mortality data is hampered by low rates of diagnosis and reporting,[31] leading to reliance on modelled estimates. For example, in 2016, 132,137 measles cases were reported to the World Health Organization (WHO), compared to the model-estimated 7 million cases.

No current data on age-specific measles morbidity could be found, but measles is known to be a major cause of childhood mortality. In 2015, measles was estimated to cause 74,000 of 3.4 million global non-neonatal deaths among children age <5 years. Of note, childhood measles morbidity has declined by 85% since 2000 when it accounted for 485,000 of non-neonatal deaths among children age <5 years. A little over 50% of global measles deaths in 2015 occurred in sub-Saharan Africa (SSA) and together with South Asia, these two regions accounted for 91% of global measles deaths among children age <5 years.[2]

In addition to the individual burden of morbidity and mortality, measles can also impose a substantial economic burden on families and the health sector. The cost of measles treatment in six LMICs (Bangladesh, Brazil, Colombia, Ethiopia, Tajikistan and Uganda), for example, was estimated to range from $2.83 (Ethiopia) to $77.90 (Brazil) per case in 2015 US dollars (USD).[32] Though the estimated measles treatment costs in these LMICs pales in comparison to costs in high-income countries - $511 per case in 2015 USD – these costs represent a substantial proportion of total health expenditure (THE) per capita in LMICs. For example, 2014 THE per capita was $27 and $947 in Ethiopia and Brazil, respectively.[33] Furthermore, the health sector and societal costs in the event of an outbreak are considerable. For example, the combined health sector and societal cost of a 2011-12 outbreak in Ethiopia resulting in 5,257 cases was $555,866 (cost indexed to 2015 USD).[34] In 2016, the Measles and Rubella (MR) Initiative spent $5.4 million to support measles outbreak activities in four LMICs.[29]

2.2.3. Measles vaccines

Measles vaccines have been in use since 1963 when the first live attenuated vaccine and first inactivated vaccine were licensed in the US. In 1967 the formalin-inactivated measles vaccine was withdrawn because it increased the risk of atypical measles in recipients when they were infected with wild-type MV and was also poorly immunogenic. Live attenuated vaccines, which are developed by serial passage at varying temperatures in chick embryo, dog kidney and sheep kidney cells, among others, also have a history of safety concerns. In 1975 the first licensed live attenuated vaccine was withdrawn due to frequent reactogenicity events (fever and rash) among recipients. In 1992 a high-titer live attenuated measles vaccine was withdrawn following increased mortality in female child recipients. Despite this storied history, other live attenuated

measles vaccine strains developed since the late 1960s are safe, effective and continue to be used worldwide. Measles vaccine strains in use today are those derived from the first licensed live attenuated vaccine strain, e.g., AIK-C, Schwarz and Edmonston-Zagreb or non-Edmonston strains such as Leningrad-4, Shanghai-191 and CAM-70. There are no known significant differences in effectiveness or safety profile of these strains. Current measles vaccine can be found as stand-alone products or in combination with other vaccines such as rubella, mumps and varicella commonly designated as MR, MMR or MMR-V vaccines.[21,22,35–38]

Measles vaccine induces protective antibody levels in approximately 85% of children vaccinated at age 9 months and in 90-95% of children vaccinated at age 12 months. Thus, age is an important predictor of antibody response; vaccine-induced antibodies increase with increasing age at time of vaccination up to approximately 15 months of age.[39] MCV administration at age <9 months reduces the likelihood of developing vaccine-induced immunity because of interference from circulating maternal anti-measles antibodies and immune system immaturity. Nevertheless, vaccination recommendations typically take into account the age-specific risk of measles infection and expected immunogenicity to designate the recommended measles vaccination age. For example, a supplemental dose of MCV at age 6 months is recommended for HIV-infected or exposed infants, for refugee infants and during outbreaks.[38] Of the 68 countries providing measles vaccination schedule information to the WHO, most recommend the first dose of measles vaccine at age 9 months; the range is 6 months (Malaysia) to 18 months (Ghana).[40] Vaccine-induced immunity against measles is long-lived, lasting "decades".[39] MCV is typically administered during routine immunization activities and may also be administered through supplemental immunization activities (SIAs) such as mass vaccination campaigns in LMICs.

SIAs are recommended to increase MCV coverage levels in settings with low coverage and to provide an opportunity for administration of a second measles dose.[41] Measles vaccine is highly cost-effective. It costs roughly $1 per dose and every $1 invested in measles vaccination within LMICs is estimated to avert $58 in direct medical, direct non-medical and indirect costs.[41,42] Further, there is evidence that an ancillary benefit of measles vaccine is that it reduces all-cause mortality, beyond the effect expected against measles disease alone.[43]

2.2.4. Global measles control

Since 2001, global measles control efforts have been led by the Measles & Rubella Initiative (MR Initiative; formerly the Measles Initiative), a collaboration between WHO, the US Centers for Disease Control and Prevention (CDC), UNICEF, the American Red Cross and the United Nations Foundation. The MR Initiative is also supported by numerous other organziations.[41] Based on targets set by WHO regions and adopted by member states, the MR Initiative seeks to attain elimination of measles – defined as the interruption of endemic measles transmission for ≥12 months in a setting with strong surveillance[19,44] – in all six WHO regions by 2020, with elimination of the disease in at least four WHO regions (Americas, Western Pacific [WPRO], European [EUR] and Eastern Mediterranean [EMRO]) having been expected by 2015.[41] Additionally, the following interim targets towards measles elimination were endorsed by the World Health Assembly (WHA) in 2010 and were set to be achieved by 2015: attainment of ≥90% national and ≥80% district-level coverage for one dose of MCV (MCV1), reduction of measles incidence to <5 cases per million population globally, and reduction of 2000 global measles mortality by 95%.[41] Although measles is eradicable, [19,39] no global target for measles eradication has been set.

In its 2010-2020 plan, the MR Initiative lays out a five-component strategy for nations to attain measles elimination goals: 1) achieve high vaccination coverage for two doses of MCV, 2) implement strong disease surveillance coupled with program evaluation, 3) implement rapid outbreak response, 4) increase vaccination confidence and vaccine demand through public engagement and communication and 5) implement research to identify cost-effective processes, improved vaccination strategies and improved diagnostic tools.[41] Importantly, successful measles control is integral for the realization of Sustainable Development Goal (SDG) 3 i.e., "Ensure healthy lives and promote well-being for all at all ages". Specifically, measles control will facilitate achievement of two SDG targets, namely, riddance of "preventable" deaths in children age <5 years by 2030 and universal access to vaccines.[45]

In the absence of other effective interventions, measles vaccine is a cornerstone for measles elimination efforts. Measles vaccine is expected to avert 14.1 million deaths between 2011 and 2020.[4] Of note, progress towards measles elimination targets is an indicator of success in the 2011-2020 Global Vaccine Action Plan (GVAP), a strategic framework endorsed by the WHA in 2012 to ensure achievement of global vaccination targets and the ensuing health and socioeconomic benefits.[4]

Despite the availability of a highly effective vaccine and a global disease control program, measles elimination is not on track. All MR Initiative and WHA 2015 measles control targets were missed. By 2015, only 61% of 194 countries reporting immunization data to WHO attained

≥90% national MCV1 coverage and global measles incidence was 36 per million population. In fact, global MCV1 coverage, estimated at 85% in 2015, had been stagnant since 2009 and in the same year MCV2 coverage was 61% across the 160 countries that had introduced a routine second dose.[46] The substantial decline in measles mortality mentioned previously (85%) fell short of the ≥95% measles mortality reduction target. Finally, while at least four WHO regions were expected to attain measles elimination by 2015, only the Americas region, which eliminated measles in 2002,[41] met the target and was certified free of endemic measles in 2016.[46] Of note, whereas five of 37 WPRO countries/areas and 21 of 53 EUR countries had eliminated measles as of 2015, no country in the other WHO regions (AFRO, EMRO, SEARO) had eliminated measles.[46]

Increasing MCV1 and MCV2 coverage levels is crucial for putting measles control back on track and for achieving the overall goal of measles elimination in WHO regions. High coverage with two doses of MCV is a prerequisite for measles elimination, a lesson learned from settings with successful measles control programs such as the US.[47] Specifically, attainment of ≥95% coverage for both MCV1 and second dose MCV (MCV2) at the national and district levels is required.[41] In turn, these high levels of MCV1 and MCV2 coverage are necessary to establish the ≥89-94% population immunity (herd protection) needed to interrupt measles virus transmission.[19]

There are pronounced differences in measles vaccine coverage at the regional, national and sub-national levels. In 2016, there was a ≥24% difference in MCV1 and MCV2 coverage between

WPRO, the WHO region with the highest coverage (MCV1, 96%; MCV2, 93%), and AFRO which had the lowest coverage (MCV1, 72%; MCV2, 24%). Similar to global coverage, MCV1 coverage in AFRO was stagnant between 2011 and 2016, having increased by only one percentage point in those years.[48] Within AFRO, 2016 MCV1 coverage ranged from 99% (Comoros) to 20% (South Sudan).[49] More than half of the 21 million children not receiving measles vaccine worldwide in 2016 were in six countries in AFRO, SEARO and EMRO, i.e., Democratic Republic of Congo, Ethiopia, Nigeria, India, Indonesia and Pakistan.[46]

At the sub-national level, measles vaccination uptake may vary by wealth and educational status. In one evaluation restricted to LMICs, 2010-2014 MCV coverage was higher by ≥20% in the richest vs. poorest quintile and among the most vs. least educated in, respectively, 21 of 68 and 24 of 54 LMICs assessed. In the same evaluation, MCV coverage was higher in urban areas compared to rural areas in most (54%) of the 68 LMICs evaluated.[50] Furthermore, MCV coverage at the sub-national level may also vary by geographic region or community. For example, in Nigeria MCV coverage is lower in the northern vs. the southern regions[51] and other examples of regional variation can be found in other settings.[52,53] MCV coverage also tends to be lower in refugee populations living in non-conflict settings as indicated by measles outbreaks among refugee communities in countries such as Ivory Coast[54], Kenya,[55] and Tanzania.[56] Encouragingly, MCV coverage across sexes seems equitable in LMICs.[50] Nevertheless, interventions to improve MCV coverage should reach sub-groups who may have relatively low coverage such as poorer families, lower education caregivers and rural dwellers.

2.3. Barriers to measles vaccination in LMICs

Barriers to childhood vaccination are generally grouped into supply-side factors – issues associated with availability of vaccine, access to and quality of health services – or demand-side factors i.e., factors related to parental knowledge, attitudes and beliefs about vaccination and vaccination services (**Figure 2.1**). Common barriers to vaccination in LMICs are well summarized in several reviews.[5,6,8,9,57–59] Low MCV coverage and inequalities in MCV coverage could be attributed to both supply-side and demand-side factors; specific examples are provided in the following sections.

2.3.1. Supply-side barriers

Supply-side barriers may include inaccessible vaccination services due to cost, distance or difficult travel environments, unfriendly health facility staff, poor or incomplete communication by health staff, health facility staff's poor vaccine knowledge, long wait times and vaccine stock-outs.[5,6,9,57–59]

Studies conducted in a number of settings have validated these common supply-side factors as barriers to MCV receipt. Long distance to health facilities and long wait times at health facilities has been identified as a barrier to measles vaccination in the Lao People's Democratic Republic (PDR), Malawi, Pakistan and Papua New Guinea (PNG).[60–63] Furthermore, longer distance to a health facility was associated with lower likelihood of *timely* measles vaccination in Kenya.[64] Additionally, difficulty accessing vaccination services in conflict settings is a generally recognized threat to measles control programs[41,51] and even temporary insecurity can discourage

caregivers from seeking measles vaccinaton.[62] Shortage of vaccine supplies has been identified as a reason for low measles vaccination uptake in Lao PDR and Nigeria.[60,65] MCV stock-outs likely influence vaccination coverage in other settings as well. Between 2010 and 2015, MCV stock-outs occurred in 5-14% of countries globally and just between January and August 2017, MCV stock-outs had been reported in at least three countries, i.e., Ghana, Greece and Romania.[66–69] Ironically, fear of wastage and stock-out may result in the refusal by health facility staff to open multi-dose MCV vials, which are used in Gavi-supported[70] and other countries, unless a substantial number of children needing MCV are present. This refusal to open multi-dose vials leads to missed opportunities for administering MCV when children are turned away[62,71]and is thought to drive the high proportion of missed opportunities for multi-dose vial vaccines relative to other single-dose vaccines.[72] In addition, health facility staff's poor vaccine knowledge has been shown to result in the false contraindication for administration of MCV to children aged older than 12 months.[5] Finally, caregivers' apprehension of unfriendly treatment by health care workers have been reported as reasons for not vaccinating children against measles in Nigeria and PNG (**Table 2.1**).[62,65]

2.3.2. Demand-side barriers

Demand-side barriers may include caregivers' negative beliefs about vaccination, concern about adverse events following immunization (AEFI), under-prioritization of vaccination relative to other competing activities, and lack of knowledge about the frequency of vaccination or location of vaccination services. Costs due to travel or other indirect costs associated with vaccination are another barrier to MCV-seeking.[5,6,8,9,58–60] Outside demand-side barriers identified in reviews, forgetfulness has been cited as a reason for unintentional missed vaccinations in a variety of

LMICs[73–77] by 5.5%[76] to 26%[75,77] of surveyed caregivers. Further, caregivers have cited failure to receive reminders as a reason for missed vaccinations.[75] In most LMICs there is a substantial gap between the DTP primary series, typically given within the first four months of life, and MCVs which are typically administered at 9 months of age or later. This gap may contribute to higher likelihood of caregivers forgetting to seek MCV.

Misapprehensions about the need for measles vaccine and concerns about vaccine side effects are generally recognized barriers to measles vaccine-seeking.[41] Studies in Brazil, China, Lao PDR, PNG and Nigeria found that caregivers failed to vaccinate their children against measles at all or in a timely manner due to concerns about the number of vaccinations given to children,[60,62] fear of or miscomprehension about adverse events following vaccination,[60,62,78–80] and beliefs that MCV was ineffective or unnecessary.[60,65,78,79] Conversely, knowing that vaccines can prevent illness was associated with higher MCV uptake in Pakistan.[61] Furthermore, potentially incorrect assessment of contraindications by caregivers[79] and not knowing MCV due dates[60,65,79,81] were identified as reasons for delaying or missing MCV in China, India, Lao PDR and Nigeria. Even when caregivers may initially know the MCV due date, the long interval between the time when early infancy vaccines are administered and the recommended age for MCV may result in caregivers forgetting, as hypothesized variously.[82–84] Competing priorities, such as community/social events and domestic chores have also been documented to result in missed measles vaccinations in Lao PDR and PNG.[60,62] Finally, at least one study documented travel cost as a barrier to measles vaccination in PNG (**Table 2.2**).[62]

2.3.3. Interplay of demand-side barriers with socio-demographic characteristics and with supply-side barriers

Caregiver attributes such as educational attainment, socioeconomic status, family size, age, residence (rural vs. urban), social networks and cultural practices determine vaccine-seeking for their children.[5,9,58,59,85] These factors have been shown to specifically influence MCV-seeking in various settings. Older[86,87] or younger[64] maternal age (alternately), higher maternal or paternal education level,[60,79,87–91] higher socioeconomic status,[60,79,87,88,91] and urban residence[92] have been associated with higher MCV1 uptake in diverse settings such as Brazil, China, Gambia, Kenya, Lao PDR, Pakistan and Uganda. At the same time, high educational attainment,[63,64] urban[93] or rural[94] residence (alternately), higher socioeconomic status,[90] small household size[63,90,95] and younger maternal age[64,95] have been associated with *timely* measles vaccination in Burkina Faso, Kenya, Guatemala, Malawi, Peru and Tanzania. Also, as noted previously, a WHO assessment found substantial inequalities in MCV coverage in LMICs by socioeconomic status and educational attainment.[50] Caregiver attributes may determine MCV status because they likely influence caregivers' beliefs about, knowledge of, and attitudes towards vaccination and vaccination services (**Figure 2.1**).

Aside from caregiver attributes, supply-side factors such as access to, quality of and availability of vaccination services influence demand-side factors (**Figure 2.1**). For example, poor communication by health facility staff could result in caregivers not knowing when upcoming vaccinations are due, caregivers' low perception of vaccination benefits and caregivers' miscomprehension about contraindications and vaccine-side-effects.[5]

2.4. Metrics used to measure vaccination uptake

By far, the most commonly used metric to measure infant vaccination uptake is the proportion of children age 12-23 months who received a certain vaccine by age 12 months. Commonly referred to as vaccination coverage, this metric has been used since 1980 by leading public health organizations such as the WHO and the United Nations Children's Fund (UNICEF). Global and national vaccination coverage estimates are pervasively used as indicators of the quality of preventive health services, to set global disease control targets for vaccine-preventable diseases (VPDs), to identify vaccination system improvement priorities and to assess suitability of vaccination systems for the introduction of new vaccines.[96]

A less-often considered, but important metric is vaccination timeliness. Vaccination timeliness speaks to the assessment of the appropriateness of the timing of vaccination. As a metric, vaccination timeliness measures the proportion of children receiving a vaccine within a certain window of the recommended age of vaccination. The recommended age for a vaccine is designed to maximize its disease control potential in view of the local epidemiology and burden of the VPD while at the same time taking into account the vaccine's safety and convenience of the recommended vaccination age given other regularly scheduled child health facility visits.[97] Thus, the timing of vaccination has implications for the safety and effectiveness of vaccines as well as disease control program costs. Early vaccination could reduce vaccine effectiveness as in the case of measles vaccine when administered before age 6-9 months (due to interference with the immune response from circulating maternal antibody). Additionally, children who are inappropriately vaccinated early would need an additional vaccine dose at the appropriate age to improve vaccine effectiveness, at additional cost. Delayed vaccination can increase the risk of

disease among those with delayed vaccination and importantly among children who are too young to be vaccinated or those with contraindications for a vaccine(s). For communicable VPD, a certain level of vaccination coverage within a community or population reduces the risk for disease transmission within that community/population i.e., "herd immunity" or "community immunity". Given that communities typically have a certain proportion of susceptible people that cannot be vaccinated due to age or contraindications and the possibility of primary vaccination failure, delaying vaccination among eligible children increases the pool of susceptible persons and so increases the risk of disease transmission in the community as has been shown for pertussis, measles and *Hemophilus influenzae* type b (Hib) in high-income settings such as the US, New Zealand and Canada.[98,99] Further, delaying vaccination can increase the risk of vaccine adverse events; for example, there is a theoretical increased risk of intussusception with administration of Rotateq or Rotarix at ages >32 weeks or ≥25 weeks, respectively.[100] Finally, delayed vaccination can reduce the likelihood of receiving other vaccines and of achieving full immunization. A study in Kenya showed that delayed receipt of the first dose of pentavalent vaccine was a significant predictor for not receiving the third dose of pentavalent and measles vaccines as well as for not being fully vaccinated by age 12-23 months.[64] Similarly, a US study showed that vaccination with delay significantly reduced the probability of full vaccination by 24.7%.[101]

Despite their pervasive use, vaccination coverage estimates are imperfect indicators of vaccination timeliness as demonstrated in several settings. For example, Nepal 2012 national estimates of vaccination coverage by age 12 months were: 96%, 90% and 90% for bacillus Calmette-Guerin (BCG), DTP3 and third dose polio (Polio3) vaccines, respectively. However, a

recent study found that 49%, 42% and 45% of a birth cohort had received no doses of BCG, DTP3 or Polio3, respectively, by age six months whereas BCG is recommended at birth and DTP3 and Polio3 are recommended for administration at age 14 weeks in Nepal. Thus, the proportions not vaccinated by age six months reflect a six month delay in BCG administration and a 10 week delay in DTP3 and Polio3 administration.[102] In a different analysis of DHS vaccination data from 45 LMICs, the median proportion of children receiving not BCG by age four weeks (four week delay) was 51% and was 90% for DTP3 at age 4 months (two week delay). In contrast, median vaccination coverage by age 12 months was 89% and 65% for BCG and DTP3, respectively.[103] In Kenya, vaccination timeliness estimates have been shown to be lower than vaccination coverage estimates by as much as 54 percentage points.[64,104] Other additional LMIC studies found substantial delays in vaccination, leading to considerable discrepancies in vaccination coverage estimates compared to vaccination timeliness estimates.[85,90,91,94,105–109]

2.5. Potential of mHealth interventions to improve MCV coverage and timeliness

In the face of stagnated MCV coverage, innovative interventions have the potential to substantially increase vaccination coverage and timeliness to levels needed to meet existing targets and to eliminate measles. The MR Initiative's strategic plan and the GVAP recommend implementation of demand-side interventions as one way to increase vaccine coverage.[4,41] The GVAP further notes that novel interventions exploiting mobile phones may also have a positive impact on vaccine coverage and that mobile phone-based interventions may be used to increase public demand for vaccines.[4] In the context of a supportive supply-side environment, mobile-phone delivered demand-side interventions that reach caregivers across the different strata of

socioeconomic characteristics influencing vaccination uptake have the potential to significantly improve MCV coverage and timeliness.

In LMICs, access to mobile phones has rapidly accelerated. In 2017, 96% of people living in United Nations-classified developing countries[110] owned a mobile phone, compared to 23% in 2005. In Africa, 75% of inhabitants owned a mobile phone in 2017 compared to only 12% in 2005.[16] In Kenya, 86% of inhabitants own a mobile phone. Mobile phone access levels surpass mobile phone ownership estimates as mobile phone sharing is prevalent in these settings.[17,18] Beyond the traditional use of mobile phones to place phone calls and to send text messages, in some LMICs such as Kenya, mobile phones are also used to conduct financial transactions whereby money is transacted through mobile phones, i.e., mobile money (mMoney). In Kenya, the leading mobile network provider, Safaricom has operated the most widely used mMoney service, "M-PESA", since 2007. In 2013, M-PESA deposits and withdrawals totaled $7.2 billion and $6.3 billion, respectively,[111] and its widespread use has been documented in the academic literature.[112–114]

Due to the reach of mobile phones, mHealth interventions are perceived to have great potential for improving the health of people in LMICs, including the potential to improve vaccination metrics. In particular, high mobile phone access can be leveraged to deliver short message service (SMS or text message) vaccination reminders and mMoney vaccination incentives to improve vaccination coverage and timeliness. SMS reminders have been shown to improve non-vaccine related health outcomes in LMICs such as HIV testing uptake,[115] HIV treatment,[116–118]

antenatal care-seeking[119] and delivery by skilled attendants,[120] among others. There is some suggestion that SMS reminders may improve vaccination coverage and timeliness in LMICs, though this evidence has not been quantitatively synthesized.[104,121–126] At the same time, there is some evidence that incentives can improve non-vaccination health outcomes and health utilization in LMICs.[15,127–130] Current evidence of the impact of incentives on vaccination uptake is mixed,[15,127,131] and could benefit from generation of additional evidence. Mobile phone-based delivery of incentives may be more advantageous than manual delivery as it may save on costs associated with manual disbursement of the incentive and manual retrieval by the client. For example, a study in Niger showed that mMoney transfers in a social poverty alleviation program was associated with improved childhood nutrition compared to manual cash transfers.[132] An added advantage of mMoney incentives over manually-delivered monetary incentives is that they may be more safely delivered in areas where robbery is a security concern. Despite several projects evaluating the direct impact of mMoney incentives on health promotion,[133] only one study demonstrating a positive impact of mMoney incentives on vaccination coverage and timeliness could be found.[104] Additional studies assessing SMS vaccination reminders and mMoney vaccination incentives would contribute to our understanding of their impact.

2.6. Evidence for the use of vaccination reminders in LMICs

Since as early as 1998, the use of reminders to improve childhood vaccination coverage has been recommended in high income settings such as the US.[134–136] In high income settings, reminders with or without additional interventions have been shown to significantly improve the odds of childhood vaccination coverage, including MCV coverage.[10,135] At least five and eight studies have explored the impact of non-text message and text message reminders, respectively, on

pediatric vaccination coverage in LMICs, with mixed results. Although systematic reviews of the impact of various interventions on childhood vaccination coverage in LMICs have been conducted,[14,131] no stand-alone review of the effect of reminders is readily available in the published literature.

2.6.1. Non-SMS reminders

The impact of non-SMS reminders on DTP and full immunization uptake has been assessed previously. These studies assessed the impact of reminders such as modified vaccination cards and stickers and most found that non-text message reminders increased childhood vaccination coverage by 5% to 42%.[137–141] Of interest, none of these studies evaluated the impact of non-text message reminders on MCV coverage either as a primary or secondary outcome. These studies are summarized in the following sections.

2.6.1.1. DTP coverage

In Pakistan, researchers evaluated the impact of a novel immunization card, designed to emphasize upcoming immunization appointments and intended to function as a reminder for urban caregivers, coupled with or without immunization education on coverage for the third dose DTP vaccine (DTP3). In relative terms, the likelihood of DTP3 vaccination was significantly higher by 25% (control coverage= 55%) among children whose caregivers were randomized to receive the redesigned immunization card and significantly higher by 31% (control coverage= 55%) among children whose caregivers received the card coupled with education, both compared to caregivers who received neither.[137] Another randomized controlled trial (RCT) evaluating the

same intervention but among rural caregivers in Pakistan demonstrated similar results with 70% higher risk of DTP3 vaccination (control coverage= 39%) among caregivers randomized the redesigned card group coupled with or without education, compared to caregivers receiving neither intervention (**Table 2.3**).[138]

However, one study conducted in Kenya found a null effect of non-text message reminders on vaccination coverage. The study evaluated the impact of sticker reminders – one placed on the mother-child health (MCH) booklet and another placed in a visible area of the house – on coverage with the second and third infant doses of pentavalent vaccine (DTP, hepatitis B and Hib vaccines; [Penta]). In contrast to the other non-text message studies described, there was no significant difference in coverage for Penta3 among infants whose caregivers received the sticker reminders compared to infants whose caregivers received standard care (**Table 2.3**).[125]

2.6.1.2. Full or age-appropriate vaccination

In rural Guatemala, a randomized-controlled trial assessed the impact of targeted vaccination reminders delivered by community health workers (CHWs) on receipt of all age-appropriate recommended vaccinations; CHWs in the control group did not change their usual practices. Among children aged 10-23 and 48-53 months, CHW-delivered reminders resulted in 4.6% significantly higher age-appropriate childhood vaccination coverage compared to control children on the absolute scale.[139] A study in urban/sub-urban Nigeria found that randomly-assigned reminder and recall (for missed appointments) mobile phone calls to caregivers either with or without theoretical training for immunization providers significantly increased the

likelihood of receipt of all recommended vaccinations by age 12 months (RR 1.70; control coverage= 39%) in both groups relative to children whose caregivers did not receive reminder/recall phone calls (**Table 2.3**).[140]

2.6.2. Text message reminders

Text message (SMS) reminders have been shown to significantly improve healthcare appointment attendance[142] and vaccination uptake[10] in mostly high income settings. Various reviews have qualitatively described assessments of the impact of SMS vaccination reminders on vaccination uptake in LMICs though none have provided pooled quantitative estimates of their impact.[143–145] Here, we provide a short description of these studies. In Chapter 3, we present results from a systematic review and meta-analysis of the impact of SMS vaccination reminders on vaccination coverage and timeliness in LMICs as presented in published research studies through April 2018.

In the following sections, vaccination timeliness is defined as the proportion of children vaccinated within ≤4 weeks of the national vaccination program recommended age. Vaccination coverage as vaccination timeliness plus the proportion of children vaccinated >4 weeks after the recommended age up to a specified age, provided that there is no conflict between the definition of timeliness and coverage. For example, WHO defines MCV1 coverage as the proportion of children receiving MCV1 by age 12 months in countries where MCV1 is recommended before age 12 months[96] but defines MCV2 coverage as the proportion of children vaccinated according to the national MCV2 vaccination guidelines.[146] Therefore, for a country such as Kenya that

recommends MCV1 at age 9 months and MCV2 at age 18 months, MCV1 timely coverage would include children vaccinated at age ≤10 months, MCV1 overall coverage would include children receiving measles vaccine at age ≤12 months, and MCV2 coverage would include children receiving MCV2 at age 18 months.

2.6.2.1. DTP3 overall coverage

Five studies – three RCTs and two quasi-experimental studies - evaluating the impact of text message reminders on DTP3 overall coverage yielded mixed results. Compared to control children, the likelihood of receiving DTP3 in older infancy was significantly higher among SMS reminder recipients in one RCT conducted in Burkina Faso[123] and one quasi-experimental study conducted in Bangladesh.[126] But, SMS reminders had no impact of DTP3 overall coverage in the other studies conducted in China, Guatemala and Kenya.[104,124,147] It should, however, be noted that in one of these studies, DTP3 overall coverage in the control arm was so high (98%)[104] as to preclude meaningful improved uptake.

2.6.2.2. DTP3 timely coverage

Findings from evaluations of the impact of SMS reminders on DTP3 timely coverage were heterogeneous across six RCTs[104,121–123,147,148] and two quasi-experimental studies.[125,149] SMS reminders significantly improved DTP3 timely coverage in two RCTs conducted in Nigeria and Zimbabwe[121,122] and in both quasi-experimental studies, one of which was conducted in Kenya and the other in Vietnam.[125,149] However, four RCTs conducted in Burkina Faso, Guatemala,

Kenya and Pakistan did not find significant increases in DTP3 timely coverage after the use of SMS reminders .[104,123,147,148]

2.6.2.3. MCV coverage

One RCT[104] and two quasi-experimental studies[124,150] evaluated the effect of text message reminders on MCV coverage with variable results. One RCT conducted in Kenya and one quasi-experimental study conducted in China assessed the effect of SMS reminders on MCV1. The RCT did not find a significant increase in MCV1 overall coverage with the use of SMS reminders whereas the quasi-experimental study found a significant increase.[104,151] The other quasi-experimental study assessed the impact of SMS reminders on MCV2 uptake in the Philippines and found that SMS reminders did not significantly improve MCV2 coverage.[150]

2.6.2.4. MCV timeliness

SMS reminders may improve MCV1 timeliness. Two studies evaluating the impact of SMS reminders on MCV1 timeliness were found. In both studies, one a RCT conducted in Kenya and the other a quasi-experimental study conducted in Vietnam, SMS reminders significantly improved MCV1 timeliness.[104,149]

2.6.2.5. Full immunization coverage (FIC)

Based on current studies, there is limited evidence that SMS reminders significantly improve FIC. The four studies assessing the impact of SMS reminders on FIC defined full immunization as receipt of BCG, 3 doses each of DTP, polio and hepatitis B vaccines, one dose of MCV

with[104,126,149] or without[124] 3 doses of Hib vaccine. SMS reminders did not significantly improve FIC in one RCT conducted in Kenya[104] nor in a quasi-experimental study conducted in China.[124] In contrast, SMS reminders significantly improved FIC in two quasi-experimental studies conducted in Bangladesh and Vietnam.[126,149]

2.6.2.6. Full immunization timeliness

Similar to MCV timeliness, only one study – the RCT conducted in Kenya – assessed full immunization timeliness. In this study, full immunization timeliness was defined as receipt of BCG, three doses of DTP, polio, Hib and hepatitis B vaccines and MCV1 within two weeks of the MCV1 due date as MCV1 is recommended at the oldest date among the vaccines included in the definition. That study found that SMS reminders significantly improved full immunization timeliness.[104]

2.6.2.7. Other vaccines

Third dose polio vaccine (Polio3) coverage: The impact of SMS reminders on Polio3 coverage was assessed in two RCTs and one quasi-experimental studies with all finding no significant impact. SMS reminders did not significantly improve Polio3 coverage in two RCTs conducted in Guatemala and Kenya, respectively. Though it should be noted that in the Kenya RCT, control arm Polio3 coverage by age 12 months was 97%, leaving little room for meaningful improvement.[104,147] Similarly, reminders did not significantly improve Polio3 coverage in one quasi-experimental study conducted in China.[149]

Polio3 timeliness: Polio3 timeliness was assessed in two RCTs and one quasi-experimental study with mixed results. One RCT conducted in Zimbabwe and a quasi-experimental study in Vietnam found that SMS reminders significantly improved Polio3 timeliness.[121,149] In contrast, there was no significant increase in Polio3 timeliness among children whose caregivers received SMS reminders compared to control children in a Kenya RCT.[104]

Primary series pneumococcal conjugate vaccine (PCV) coverage: Two RCTs assessing PCV coverage were conducted in Guatemala and Kenya. The primary PCV series consists of two doses in Guatemala and three doses in Kenya. These two RCTs did not find any significant increases in PCV primary series coverage among SMS reminder recipients compared to those who did not receive SMS reminders.[104,147]

PCV timeliness: PCV primary series timeliness was assessed in one study conducted in Zimbabwe where the PCV primary series consists of three doses. This RCT found that SMS reminders significantly improved PCV primary series timeliness.[121]

2.6.2.8. Summary of existing evidence

Few studies in LMICs have assessed the impact of SMS reminders on vaccination coverage and timeliness. Heterogeneity in findings from these few studies makes it challenging to draw conclusions as to whether SMS reminders can be effectively used to improve vaccination coverage and timeliness. Importantly, at least one study demonstrated that mobile-phone based interventions, including reminders, have the potential to improve vaccination coverage even

among caregivers who do not own a mobile telephone and traditionally hard-to-reach groups such as rural-dwellers, low-income families, children of the least educated and families with poor access to health facilities due to distance.[104] Additional studies evaluating the impact of text message reminders on vaccination coverage and timeliness could contribute to the current understanding of their impact, particularly effects on vaccination timeliness versus effects on vaccination coverage in later infancy. More studies would also provide more data points to allow stratified meta-analysis to identify factors that may influence the efficacy of text message reminders such as baseline vaccination coverage, the number of reminder messages sent, the frequency of reminders and the content of messages sent, among others. Further, additional studies would inform the reproducibility of findings from previous studies. Finally, more robustly designed studies with low risk of bias are needed.

2.7. Use of incentives to improve childhood vaccination coverage in LMICs

The impact of monetary and non-monetary incentives provided to health service clients on pediatric and adult health outcomes as well as health service utilization has been evaluated in several LMICs. These evaluations have included small research studies, small health programs as well as large social welfare programs. Whereas some large social welfare programs have specifically targeted health, any impacts on health have been ancillary for others. Outside vaccination, incentive programs in LMICs have demonstrated significant improvements in childhood nutritional status, reductions in childhood anemia prevalence, reductions in childhood illness episodes, increases in breastfeeding practices as well reductions in child mortality, among other health outcomes. Improvements in health outcomes have been shown even during humanitarian crises. In addition, incentives have been associated with increases in utilization of

health services such as HIV counseling, reproductive health and childhood preventive care, among others. These incentives have been either conditional, meaning that they are disbursed subject to health service clients' compliance with the targeted health behavior, or unconditional, meaning that incentives are provided regardless of the compliance. In the literature reviewed, these programs provided incentives up to $336 per year per household. [15,127–129]

The association between the value of the incentive and the magnitude of impact observed is not clear. For example, a study in Malawi found that any incentive amount, from $0.10 to $3.00, significantly increased the proportion of adults retrieving HIV testing results, compared to no incentive. This finding suggests that the presence of an incentive, regardless of the value, had a positive effect.[152] In contrast, a study in Kenya found that lower value incentives did not significantly increase voluntary circumcision whereas higher value incentives did.[130] At the same time, behavioral economists caution that incentives can have no effect or a negative effect if the incentive amount is not high enough or even if it is too high.[153,154] Social protection programs, which were observed to provide the largest amounts of incentives, may offer relatively large incentive amounts as they are intended to have broader economic effects outside of health. Focusing on pediatric vaccination, the following sections describe experience with conditional and unconditional monetary and non-monetary incentives on vaccination coverage in LMICs.

2.7.1. Impact of large-value cash transfers on pediatric vaccination

The impact of social welfare program conditional cash transfers (CCTs) and unconditional cash transfers (UCT) targeting health and non-health outcomes in Nicaragua, Honduras, Mexico,

Colombia and Zimbabwe have been assessed in various studies.[127,155,156] Notably, these programs largely focused on general health and educational outcomes, involved relatively large amounts of cash transfers ranging from a maximum of $52 to $284 annually, and with the exception of one study,[155] did not condition cash transfers on discrete vaccination outcomes.

2.7.1.1. DTP

CCTs significantly improved DTP coverage in Honduras, Colombia and Nicaragua though the impact in Nicaragua was not sustained. The proportion of children age 42-92 days receiving DTP1 whose families participated in a cluster-randomized CCT program in Honduras (*Programa de Asignacion Familiar [PRAF]*) significantly increased absolutely by 6.9% compared to control; the program provided £2.53 to £16.10 monthly ($4.74 to $30.17 in 2015 USD) conditioned on school attendance, and attendance at monthly child and antenatal care (ANC) visits (**Table 2.4**).[157]

In Colombia, families participating in *Familias en Accion (FA)* received approximately $15.38 monthly ($20.28 in 2015 USD) conditioned on preventive healthcare visits for children age 0-6 months, among other incentives. The proportion of children age <24 months with up-to-date DTP vaccination was 8.9% higher among *FA* program participants, after adjustment for changes in vaccination uptake in the pre- vs post-program period. This difference was statistically significant at the 10%, but not 5%, level. Up-to-date DTP vaccination among children age >24 months was not statistically different among *FA* vs. control children (**Table 2.4**).[158]

In Nicaragua the *Red de Protection Social* (*RPS*) provided cash transfers of up to $37.33 bimonthly ($51.38 in 2015 USD) conditioned on parental health education, childhood preventive

healthcare visits and satisfactory weight gain. *RPS* significantly improved DTP3 coverage overall, among children age 12-23 months living >5km from a health facility and among children whose mothers had fewer than 4 years of education by 9%, 12% and 10% on the absolute scale, respectively. However, the significant increase in DTP3 occurred only in the first year of the program and was not sustained into the second year (**Table 2.4**).[156]

2.7.1.2. MCV

Measles vaccine coverage among children in families receiving CCTs significantly increased in Nicaragua but not in Mexico or Honduras. In contrast to the impact of CCTs on DTP coverage in Honduras, there was no significant difference in measles vaccine coverage among children participating vs. not participating in the *PRAF* program (program described previously; **Table 2.4**).[157]

The social welfare program *Progresa* in Mexico provided up to $25 bi-monthly ($37.43 in 2015 USD) to families, conditioned on child health care appointment attendance, among others. There was a 3.0% absolute increase in the proportion of *Progresa* children receiving measles vaccine by age 12-23 months compared to control. Though this increase was significant 6 months after the start of *Progresa*, by 12 months after the program start date, the increase was no longer significant at the 5% level (**Table 2.4**).[159]

Under the *RPS* program in Nicaragua described previously, MCV coverage among *RPS* children age 12-23 months was significantly higher compared to control children in the first year, but not in the second program year. In the first year of *RPS*, MCV absolute coverage was higher among

intervention children by 15% overall, 17% among those living >5km from a health facility and 15% among children with mothers who had <4 years of education (**Table 2.4**).[156]

2.7.1.3. FIC

Overall FIC among children participating in Nicaragua's *RPS* and aged 12-23 months was significantly higher by 23% and 15% in absolute terms during the first and second year of the program, respectively. *RPS* CCTs also improved FIC in the same age group among 'hard-to-reach' children i.e., among children living >5km from a health facility by 27% in the first year of the program and by 23% and 14% on the absolute scale in the first and second year of the program, respectively, among children with mothers who had <4 years of education (**Table 2.4**).[156]

2.7.1.4. Other vaccination outcomes

CCTs resulted in significant increases in BCG coverage in Mexico – though that effect was short-lived – and in Nicaragua, though the effect was short-lived in one sub-group. Under *Progresa* in Mexico there was a 5% significant absolute increase in the proportion of children receiving BCG by age 12 months compared to control, six months after initiation of the program. However, BCG coverage by 12 months of age after program initiation was not significantly different in *Progresa* vs. control children (**Table 2.4**).[159] In Nicaragua, CCTs significantly increased BCG coverage by 9% and 6% on the absolute scale in the first and second years, respectively of *RPS*. Additionally, CCTs significantly increased absolute BCG coverage among children living >5km from a health facility in both *RPS* years by 13% and 7%. Among *RPS*

children born to mothers with <4 years of education, BCG coverage was significantly higher than control children's BCG coverage in the first year by 9% on the absolute scale but not in the second year of *RPS* (**Table 2.4**).[156]

A cluster-randomized controlled research study in Zimbabwe evaluated the impact of an up to $30 ($35.27 in 2015 USD) bi-monthly cash payment on infant birth registration, up-to-date vaccination (BCG, DTP, polio and MCV), growth monitoring, school attendance and parental skills training. In one study group payment was conditioned on the fulfillment of the outcomes of interest but in another, cash transfers were unconditional. No significant differences in appropriate vaccination for age were observed in either the CCT or UCT group compared to control (**Table 2.4**).[155]

2.7.2. Impact of small-value incentives on pediatric vaccination

At least four studies have evaluated the impact of monetary and non-monetary incentives, such as coupons and food, on vaccination in LMICs. Studies in India,[160] Kenya,[104,161] and Pakistan[162] suggest that monetary and non-monetary incentives have the potential to improve vaccination coverage and also suggest that incentive-based interventions have the potential to impact hard-to-reach populations. Moreover, all of the identified studies provided a conditional incentive; where the caregiver was only given the incentive if the child was vaccinated. No studies providing small incentives for vaccination without a condition (i.e. unconditional) were found.

2.7.2.1. DTP

Conditional monetary and non-monetary incentives significantly improved the proportion of children receiving DTP3 within two weeks of the recommended age in Pakistan and in Kenya. In a quasi-experimental study conducted in Pakistan, coupons redeemable for food or medicine purchases and valued at $2.00 ($2.35 in 2015 USD) were offered at every vaccination visit through the DTP3 visit. The likelihood of DTP3 receipt by age 18 weeks among children in the coupon group was double (RR 2.20, 95% CI: 1.95–2.48, p<0.001) the likelihood among children in the control group (no coupons; **Table 2.5**).[162]

In a cluster RCT conducted in Kenya, the likelihood of Penta3 coverage at age ≤18 weeks was significantly higher among children whose caregivers received text message reminders coupled with a monetary $2.35 in 2015 incentive for each vaccine received within two weeks of the recommended due date, compared to children whose caregivers received no intervention (RR 1.12; 95% CI 1.03, 1.22). Notably, the likelihood of Penta3 receipt by age 18 weeks in the same study was not significantly different among children whose caregivers received text message reminders coupled with a smaller $0.88 (2015 USD) incentive compared to control (RR 1.07; 95% 0.98, 1.17) and perhaps points to the effects of the value of the incentive as has been posited prior.[130,154] Further, Penta3 coverage by age 12 months was not statistically significantly different among text message and incentive groups compared to control ($0.88 incentive RR 1.00; 95% CI 0.98, 1.02 and $2.35 incentive RR 1.01; 95% CI 0.99, 1.02), but this may be explained by high Penta3 coverage by age 12 months (98%) in the control arm (**Table 2.5**).[104]

2.7.2.2. MCV

Small incentives coupled with SMS reminders have been shown to improve measles vaccination timeliness and vaccination by age 12 months in one study. The same cluster RCT conducted in Kenya[104] evaluated the impact of incentives, coupled with text message reminders on timely measles vaccination i.e., proportion vaccinated by age 9 months + 2 weeks as well as coverage by 12 months of age. The probability of timely measles vaccination was significantly higher in the group receiving text message reminders coupled with a conditional $0.88 incentive (RR 1.37; 95%CI: 1.19–1.59) as well as in the group receiving reminders coupled with a conditional $2.35 incentive (RR: 1.42; 95%CI: 1.23–1.63) compared to control. When coverage was assessed at age 12 months, measles vaccine coverage was significantly higher only in the group receiving text message reminders coupled with the $2.35 incentive (RR: 1·07; 95%CI 1.01–1.14), though the absolute difference in the proportion of intervention children vaccinated compared to the proportion of control children vaccinated (6% absolute difference) was lower than observed for timely measles vaccination (21% absolute difference; **Table 2.5**).[104]

2.7.2.3. Age-appropriate and full vaccination

There is mixed evidence on the impact of small incentives on age-appropriate and full vaccination. A different quasi-experimental study in Kenya evaluated the impact of distribution of a hygiene kit valued at $0.40 in 2009-2010 ($0.43 in 2015 USD) coupled with water treatment and hand hygiene education on vaccination coverage. Compared to baseline, age-appropriate vaccination among children age 2-13 months increased significantly by approximately 9% ($p = 0.04$) in the intervention area. However, age-appropriate vaccination in the same age group increased significantly from baseline in the control area by 15.6% ($p < 0.001$).[161] Although, for

reasons unclear to the author of this dissertation, the study's authors did not compare coverage in the intervention vs. control area, the difference-in-difference crude RR estimate calculated by the dissertation author suggests that children in the intervention area were significantly less-likely to have up-to-date vaccination compared to control area children (RR 0.93; 95% CI 0.87, 0.99; **Table 2.5**).

In the cluster RCT evaluating the impact of a $0.88 or $2.35 incentive coupled with text message reminders on vaccination uptake in Kenya, intervention children were, respectively, 1.37 (95% CI 1.18, 1.59) or 1.42 (95% CI 1.23, 1.65) times more likely to be fully immunized (BCG, Penta3, Polio3 and MCV) by age 9 months and 2 weeks than control children. However, by age 12 months, full immunization among children receiving the $0.88 incentive coupled with SMS reminders was not significantly different than control children (RR 1.04; 95% CI 0.96, 1.11). But FIC by age 12 months among children receiving the $2.35 incentive coupled with SMS reminders was significantly higher than FIC among control children (RR 1.09; 95 CI 1.02, 1.16; **Table 2.5**).[104]

A cluster RCT in India showed a 6.66 fold (95% CI 4.53, 8.80) higher likelihood of full vaccination (BCG, DTP3, Polio3 and MCV) among children age 1-3 years who received lentils and a set of plates valued at $1.75 ($2.20 in 2015 USD), coupled with provision of a monthly vaccination camp, compared to control children (**Table 2.5**).[160]

2.7.3. Summary impact of incentives on vaccination coverage and timeliness

In summary, monetary and non-monetary incentives ranging in value from small to large have been shown to improve BCG, DTP, measles, age-appropriate and full vaccination coverage in a

variety of LMICs but have been ineffective in others. In some cases, incentives were coupled with additional interventions such as education[161] and text message reminders.[104] Incentives may overcome barriers to vaccination that are associated with travel costs, competing priorities and caregiver motivation. When coupled with other interventions that address other barriers to vaccination, incentives have the potential to substantially increase vaccination coverage, including improving vaccination uptake in hard-to-reach populations.

2.8. Theoretical role of reminders and incentives in improving pediatric vaccination uptake

The intended effect of reminders and incentives is to increase caregivers' demand for vaccines. Reminders and incentives may enable, reinforce or predispose caregivers to seek vaccination for their children. Together, the Health Behavior Model (HBM) and the PRECEDE/PROCEDE planning model, discussed in detail in the following sections, can be used to conceptualize how reminders and incentives for pediatric vaccinations may theoretically influence caregivers' vaccine-seeking behavior.

2.8.1. The Health Behavior Model

The Health Behavior Model (HBM), developed to address low vaccination coverage,[163,164] is particularly pertinent to an assessment of the role that reminders and incentives may play in improving vaccination coverage in LMICs. The HBM theoretical constructs posit that an individual's likelihood of engaging in positive health behavior is influenced by: perceived susceptibility of the disease/condition, perceived severity of the disease/condition, perceived benefits of engaging in the positive health behavior, perceived barriers to engaging in the positive health behavior and cues to action (**Figure 2.2**).[164,165] In the context of pediatric vaccination, perceived susceptibility, severity and benefits speak to a caregiver's perceptions about the likelihood of the infant being infected with the VPD in question, the severity of the VPD if infected, and the extent to which vaccination can either prevent illness or reduce its severity. Perceived barriers speak to factors, believed or actual, that inhibit the caregiver's ability to seek vaccination for the child, such as travel expenses. In the context of SMS reminders for vaccination, messages could include wording designed to heighten the caregiver's perception of their child's susceptibility to VPD, the severity of the VPD and the benefits of vaccination. SMS

vaccination reminders coupled with incentives could overcome barriers of forgetfulness and transport or other costs. Also if coordinated with the health system to ensure availability of vaccination services, SMS vaccination reminders could overcome caregivers' concerns related to availability of those services. Finally, SMS reminders and incentives could function as cues to action by triggering motivated caregivers to undertake the actual act of vaccinated their children.[164]

2.8.2. The PRECEDE/PROCEED planning model

The PRECEDE/PROCEED planning framework can provide a structure for understanding how interventions may impact individual-level factors that influence behavior. Within PRECEDE/PROCEED, individual-level factors influencing behavior are organized into three categories: predisposing, reinforcing and enabling factors (**Figure 2.3**). Predisposing factors influence an individual's motivation to engage in the behavior. Reinforcing factors encourage continued practice of the behavior and enabling factors facilitate motivated individuals' engagement in the target behavior.[166] The HBM theoretical constructs can be translated into predisposing, reinforcing or enabling factors and we can then map out how text message reminders and incentives may impact these constructs/factors to bring about vaccine-seeking behavior.

Predisposing factors: The perception that an infant is susceptible to VPD, that VPD are severe and/or that vaccines are beneficial may predispose a caregiver to seek vaccination. Additionally, the perception of reduced barriers to vaccination such as the availability of transport funds, may

predispose a caregiver to seek vaccination. Reminders could predispose caregivers to seeking vaccination for their infants by influencing caregivers' perception of the severity of VPDs and the benefits of vaccination (**Figure 2.4**). Studies in both high- and low-income settings have shown that in addition to information about vaccine due dates, reminder messages can include language conveying the risk and severity of VPDs as well as the benefits of vaccination. For example, in a RCT conducted in Australia, reminder postcards included language such as "The children who are most likely to catch measles are those who have not been 51mmunized".[167] In another RCT conducted in Kenya (M-SIMU study), the phrase "Vaccines save Kenyan babies' lives", was appended to text message reminders".[168] Monetary incentives may predispose caregivers – who were previously indisposed to seeking vaccines for their infants due to the perceived barrier of transportation costs – to seek vaccination (**Figure 2.4**).

Reinforcing factors: For caregivers who are already motivated to vaccinate their infants and if applicable, have previously vaccinated their children, the continued perception that infants are susceptible to severe VPD may reinforce (continued) vaccine-seeking. Additionally, HBM 'cues to action' may encourage continued engagement in vaccine-seeking (**Figure 2.4**). Thus, reminders conveying the susceptibility and severity of VPD as described above may reinforce vaccine-seeking through perpetuating the perception of susceptibility and severity. Reminders and incentives may also continue to encourage (reinforce) caregiver vaccine-seeking through HBM 'cues to action' such as affirming vaccine due dates, incentivizing vaccination (in the case of conditional incentives) and perhaps through the Hawthorne effect whereby caregivers may modify vaccine-seeking behavior because they perceive that they are being monitored.[169] As an

example, the Hawthorne effect was hypothesized to induce improved malaria case-management among healthcare workers in Kenya receiving SMS reminders.[170]

Enabling factors: For caregivers already predisposed to vaccinating their children, vaccination reminders and incentives may facilitate vaccine-seeking by either prompting caregivers to seek vaccines (HBM 'cues to action') or by minimizing caregivers' perceived barriers (**Figure 2.4**). Reminders may cue already motivated caregivers by providing them with actionable information such as the vaccine due date and venue. Incentives conditioned on timely vaccination could further spur caregivers into action by creating urgency for seeking vaccination. Finally, for caregivers who perceive expenses related to vaccine-seeking as a barrier but are otherwise motivated, incentives may facilitate vaccine-seeking.

2.8.3. Motivation crowding theory: Social science perspectives on monetary incentives

Economists and psychologists have considered the mechanisms through which monetary incentives modify behavior and the implications of their use. Social science theory about the mechanisms through which monetary incentives influence behavior change are relevant for public health interventions such as this dissertation's aims looking at the short- and long-term impact of monetary incentives on caregivers' vaccine-seeking behavior. Monetary incentives are thought to influence an individual's extrinsic motivation i.e., the motivation induced by a desire to receive the incentive, as well as an individual's intrinsic and social motivation to engage in the incentivized behavior i.e., motivation to engage in the behavior that is not driven by a desire to receive the incentive. By changing preferences (for intrinsic/social vs. extrinsic rewards) and

changing how an individual perceives the behavior in question, incentives can improve ("crowd-in"), diminish ("crowd-out") or have no effect on intrinsic and social motivation to engage in the incentivized behavior.[171] Theoretical mechanisms about how incentives crowd-in or crowd-out intrinsic/social motivation can be explored using the example of incentives to improve caregiver vaccine-seeking.

Incentives can crowd-in (improve) intrinsic/social motivation through a number of theoretical mechanisms. For a caregiver who would otherwise be only motivated to vaccinate their children by external rewards, the mere presence and/or value of incentives can signal to the caregiver that vaccination is important, thereby changing their preference from external rewards to intrinsic/social rewards. Furthermore, if incentives are unconditional rather than conditional, psychologists theorize that a caregiver may perceive incentives as supportive (rather than controlling), as promoting self-esteem and promoting autonomy over vaccine-seeking.[171] Thus, unconditional incentives may provide an opportunity for a caregiver to engage in vaccination for self-determined intrinsic/social reasons (rather than for an extrinsic conditional reward), thereby 53ignaling that intrinsic motivation is important. Additionally, in the process of vaccinating the child, the caregiver may derive information about the importance of vaccination – for example, that vaccination protects the health of the child and of the community – which may function as intrinsic/social motivations to vaccinate the child or the child's siblings in the future.

On the other hand, theoretical mechanisms propose how the design and perceptions of monetary incentives can crowd-out intrinsic/social vaccine-seeking behavior. The presence and value of

the incentive could signal that vaccination is difficult, risky or, if the value of the incentive is perceived to be low, that vaccination is not important. In addition, the presence of the incentive could signal to the caregiver that their intrinsic/social motivation is unreliable or insufficient, thus the need for an external stimulus.[154] If conditional, a caregiver may further perceive the incentive to be controlling, dismissive of their intrinsic/social motivation and reducing their autonomy over vaccine-seeking.[171] Finally, vaccine-seeking in particular may have a substantial level of social motivation. A caregiver may seek vaccination to not only protect the health of their child but also that of the community. They may also vaccinate their child to promote their image as a good parent and a good community member. Incentivizing vaccine-seeking may diminish a caregiver's social motivation by modifying their "decision frame from social to monetary" or by "diluting the signal"[154] of their social motivation within themselves or to other community members.

If priced correctly, monetary incentives can lead to a short-term improvement in the practice of the target behavior as a result of the impact of the incentives on extrinsic motivation. This impact on extrinsic motivation is usually larger relative to any motivation crowding-out effect that the incentives may have.[154] However, once incentives are discontinued, practice of the target behavior may return to baseline levels, if incentives had no effect on intrinsic/social motivation, or diminish, if incentives crowded out intrinsic/social motivation.[154,171] Several economic and psychology studies have demonstrated the crowding out effect. For example, one study evaluated the proportion of parents picking up children late from daycare before and after the imposition of a $3 dollar fine for late pick-up. Late pick-up increased after the $3 fine was imposed and continued even after the fine was discontinued. It is theorized that the fine enabled parents to

place a value (low penalty) on late pick-up and to replace what was previously a social decision frame with a monetary one, resulting in persistently lowered intrinsic/social motivation to pick up children on time.[154,171]

In contrast, there is no evidence of crowding out in the health behavior literature. However, few studies, none of which were conducted in LMICs and none of which assessed vaccination impact, have assessed the long-term effects of monetary incentive interventions. From the few studies that have performed long-term impact assessments of incentive interventions, there is a suggestion that incentives may either not substantially impact or may crowd-in intrinsic/social motivation to engage in health behavior.[172] Four US studies – two evaluating the impact of monetary incentives on smoking cessation, one on increased gym attendance and one on weight loss – found short-term increases in the target behavior for persons who received incentives compared to those that did not, but no significant long-term differences.[173–176] These findings suggests that while monetary incentives increased extrinsic motivation to engage in the behaviors, they had no impact on intrinsic/social motivation. Three different studies, one each assessing the impact of monetary incentives on smoking cessation, gym attendance and weight loss, found both short-term and long-term increases in the target behaviors among incentivized individuals compared to controls.[177–179] Findings from those studies suggest that incentives improved both extrinsic and intrinsic/social motivation to practice the target behaviors. Additional assessments of the long-term effects of incentive interventions on health behaviors, particularly from LMICs, would help build empirical evidence to inform our understanding of whether incentives crowd-in or crowd-out intrinsic/social motivation to engage in positive health behaviors.

2.9. The M-SIMU study

2.9.1. Relevance and overview

The M-SIMU study is a precursor of two studies included in this dissertation and that contribute to Aims 2 and 3 of this thesis. Aim 2, the evaluation of the impact of SMS reminders with or without *unconditional* incentives, follows up on seminal findings from the M-SIMU study by exploring scalable approaches to implementing vaccination reminders and incentives i.e., the M-SIMI study. Aim 3 will enroll M-SIMU caregivers with children born after completion of the M-SIMU study and will provide an assessment of differences in caregivers' vaccine seeking after the M-SIMU study, i.e., the MSBC study.

A seminal study, M-SIMU is the first known RCT to evaluate the impact of text message reminders, with or without small conditional mobile phone-delivered monetary incentives, on vaccination coverage in rural SSA. The M-SIMU study, as mentioned previously, was conducted in 2013-15 in Gem and Rarieda (Asembo) sub-counties, Siaya County, Kenya. The study was conducted within the Kenya Medical Research Institute (KEMRI) and CDC Health and Demographic Surveillance System (HDSS). The M-SIMU study is described in detail in two published papers,[104,168] but is summarized here for ease of reference.

2.9.2. M-SIMU study design, procedures and outcomes

The M-SIMU study was a cluster RCT in which 152 villages were randomly assigned to one of four study arms: control (no intervention); text message reminders only (SMS); text message reminders coupled with a KES 75 incentive (SMS+75KES; 1USD = 85KES at the time); text message reminders coupled with a KES 200 incentive (SMS+200KES). Like reminder messages, monetary incentives were delivered to mobile phones using mMoney transfer services.

Children aged <5 weeks were identified by KEMRI-employed Village Reporters (VRs), who notified the study team of potentially eligible children. These children were screened for study eligibility criteria and eligible children enrolled by study-employed Community Interviewers (CIs) after caregivers provided informed consent. Caregiver-infant pairs were enrolled regardless of whether the caregiver owned a mobile phone or not. Caregivers not owning a mobile phone were asked to identify a mobile phone that they had access to, and one to which the study could send mMoney incentives and/or SMS reminders. Caregivers not owning a mobile phone commonly identified a shared phone in the household or compound. As a last resort, the enrolling CI's phone could be used if the caregiver was unable to identify a shared phone. At enrollment, Cis collected sociodemographic information. Study-employed Health Facility Recorders (HFRs) stationed at designated health facilities recorded infants' vaccinations and submitted vaccination notifications via text message to a study database. When infants reached age 12 months Cis performed household visits to record infants' vaccination status and dates of vaccination from the MCH booklet, or verbal report in the absence of the MCH booklet.

Caregivers of infants in control villages only received a general health SMS message at the beginning of the study. Caregivers in intervention study villages received text message reminders for each of the three doses in the Penta series and for the first dose of MCV. One text message was sent three days and one day before the vaccine due date. Per the Kenya Expanded Programme on Immunisation (KEPI) the first, second and third doses of Penta are recommended at ages 6, 10 and 14 weeks, respectively, while first dose MCV is recommended at age 9 months.[180] Caregivers in the incentive villages received the applicable incentive if the infant was vaccinated within two weeks of the vaccine due date.

The primary outcome assessed was full immunization coverage (FIC) i.e., receipt of BCG, DTP3, Polio3 and MCV1 at age 12 months in the intervention arms vs. the control arm. Other key outcomes assessed were DTP3 and MCV1 coverage by age 12 months. In addition, key vaccination timeliness outcomes assessed were DTP3 and MCV1 coverage within 2 weeks of the recommended vaccination age and FIC at age ≤9 months and 2 weeks.

2.9.3. M-SIMU findings

The primary M-SIMU analysis was restricted to 1600 children whose vaccination status was confirmed using MCH booklet, out of 2018 children enrolled total. Of the children included in the analysis, 360, 388, 446 and 406 were enrolled in the control, SMS, SMS+75KES and SMS+200KES arms, respectively. With the exception of MCV, vaccination coverage in the control arm for most vaccines at age 12 months was high, ranging from 97% (Polio3) to 98% (Penta3). MCV1 coverage at age 12 months was 84%. [104]

Table 2 summarizes M-SIMU findings on vaccination coverage and vaccination timeliness for the vaccines assessed by study arm. In summary, compared to the control arm, the M-SIMU study found that the likelihood of:

- FIC by age 12 months was 9% significantly higher in the SMS+200KES arm
- MCV1 receipt by age 12 months was 7% significantly higher in the SMS+200 KES arm
- FIC by age 9 months and 2 weeks was 18%, 37% and 42% significantly higher in the SMS, SMS+75KES and SMS+200KES arms, respectively
- MCV1 receipt at age 9 months and 2 weeks was 18%, 37% and 42% significantly higher in the SMS, SMS+75KES and SMS+200KES arms, respectively
- Penta3 receipt at age 16 weeks was 12% significantly higher in the SMS+200KES arm (**Table 2.6**).[104]

Importantly, the M-SIMU study showed that text message reminders and incentives could increase vaccination coverage and timeliness in a rural setting with relatively high vaccination coverage. Further, the study found no significant differences in impact by mobile phone ownership status, maternal education and residential distance from a health facility.[104]

2.10. Research setting

This dissertation analyzed prospectively collected as well as existing data from studies conducted in Gem and Rarieda (Asembo area) sub-counties located in Siaya County, Nyanza Region, Kenya. Kenya, a country in East Africa, falls under AFRO and has a population of approximately 46 million. Most of Kenya's 46 million people are rural-dwellers; only 26% of Kenya's population lives in urban areas. Though Kenya is a lower middle income country with a Gross National Income (GNI) per capita of $1290, roughly one-third of the population lives below the international poverty line i.e., access to <$1.90 per person, per day.[181] Per capita health expenditure was $77.70 in 2014,[182] translating to approximately $3 billion of health spending in total. In the same year, government entities contributed to 61% of the country's health expenditure while 26% of spending on health was by households.[183,184]

2.10.1. National-, County- and Sub-county-level basic indicators

At 49 deaths per 1,000 live births, Kenya has the 46th highest under-5 mortality rate (U5MR) globally. The country's infant mortality rate (IMR) is 36 deaths per 1,000 live births, which is slightly above the global IMR (32 deaths per 1,000 live births) and six-fold to nine-fold higher than the IMR in high income countries such as the United States, Canada and the United Kingdom.[181] In 2015, there were an estimated 74,429 deaths in Kenyan children aged <5 years. Most (45.3%) of those deaths occurred in the first 28 days of life. Leading causes of neonatal mortality were intrapartum-related events (31.0%), preterm birth (26.0%), sepsis and meningitis (15.5%), congenital anomalies (13.2%) and pneumonia (6.2%). Among children age 1-59 months, leading causes of death were pneumonia (20.3%), diarrhea (13.1%), injuries (11.6%), HIV/AIDS (10.2%) and malaria (9.3%). Other notable, vaccine-preventable causes of post-

neonatal death were pertussis and measles, which caused 3.4% and 0.6% of deaths in children age 1-59 months, respectively.[2]

One of 47 counties in Kenya, Siaya County is located in Nyanza Region in western Kenya. Lake Victoria forms the southern and partial western border of Siaya County. In 2011, Siaya County U5MR and IMR were 167 and 111 per 1,000 live births, respectively.[185] Although these data are somewhat dated, they still underscore that child mortality in Nyanza County is higher than nationally; in 2010 national U5MR and IMR were 85 and 55 per 1,000 live births.[186] Siaya County is classified as a "moderately marginalized" county based on its County Development Index (CDI) ranking. Developed by Kenya's Commission on Revenue Allocation, the CDI is a composite measure of county-level development derived using county-level poverty, infrastructure, health and education indicators. Siaya County has the 27th largest CDI (0.5455) which is slightly higher than the average index across all counties (0.52044) but well below the CDI for the most developed County (Nairobi; CDI = 0.7663). Marginalization in Siaya County is primarily driven by poor infrastructure and education.[187]

The study area, Gem sub-county and Asembo (within Rarieda sub-county), is part of the well-established KEMRI and CDC HDSS (**Figure 2.8**). Households within the HDSS are enumerated and the HDSS collects sociodemographic, economic, vital status and health information on residents at least once every two years, but typically more frequently for vital status and health indicators. Various research studies are conducted in the HDSS including clinical trials, malaria prevention and treatment studies and tuberculosis (TB) treatment studies.[188] The study area is

rural with approximately 135,000 residents and covering roughly 500 square kilometers.[189] The 2008 combined U5MR and IMR for Gem and Asembo were 212 and 113 per 1,000 live births, respectively.[188] These data suggest that IMR in the study area is comparable to County-level IMR but the study area U5MR is higher than Siaya County's. Additionally, both the study area's U5MR and IMR are markedly higher than the national U5MR and IMR described previously. High childhood mortality rates in the study area are in part attributed to malaria endemicity. The study area is also characterized by high HIV prevalence (15.4%) and high TB prevalence (6 cases per 1,000 population).[188]

2.10.2. Measles control in Kenya

As a member of AFRO, Kenya is a party to the Region's measles control targets. By 2020, the Region aims to achieve: 95% national- and district-level MCV1 coverage; ≥95% national- and district-level MCV coverage during SIAs; <1 confirmed case per 1,000,000 population measles incidence; annual identification of ≥1 measles case per 100,000 population in ≥80% districts; collection of adequate serum samples from ≥80% of suspected measles cases; and isolation of virus for confirmed chains of transmission. As noted previously, the region has set a target to eliminate measles by 2020. These targets are to be achieved through: establishment of a routine two-dose measles schedule; provision of SIAs every 2-4 years; case-based measles surveillance and management of measles cases per Integrated Management of Childhood Illnesses (IMCI) guidelines.[190]

In 2016 Kenya national MCV1 coverage was 75%, appreciably lower than the 89% national-level DTP3 coverage in the same year. Since 1984, the earliest year for which Kenya MCV1 coverage data are available from WHO, MCV1 coverage has fluctuated with the lowest coverage being 55% in 1984 and the highest at 93% in 2012. Since 2013, MCV1 coverage has been at or below 79% (**Figure 2.10**).[191] There is considerable variation in MCV1 coverage at the sub-national level, with coverage in eight regions in 2014 ranging from 69.8% (North Eastern) to 97.2% (Central).[52] With specific regard to the research area, MCV1 coverage among children age 12-23 months in Nyanza Region was estimated at 85.3% in 2014 and this regional coverage was similar to the 84.8% MCV1 coverage estimate for Siaya County in the same year.[52] A 2013 vaccination coverage survey of 1,681 children age 12-23 months in the study area estimated MCV1 coverage at 83.0%,[64] not markedly different from County- and Regional-level estimates (**Table 2.7**). MCV2 was introduced into the KEPI in 2013 and is recommended for administration at age 15-18 months.[192] MCV2 coverage in 2016 was estimated at 32%.[191] Thus, although Kenya has introduced a second routine dose of MCV, national- and administrative-level coverage for both doses is below the ≥95% coverage target required to interrupt measles transmission and lags behind coverage for vaccines given in early infancy such as DTP3.

Since 2002, Kenya has instituted SIAs, though not always in a timely manner. For example, a one year delay in a SIA originally intended for 2005 is thought to have led to a 2006 measles outbreak in Kenya.[193] The most recent SIA, for measles and rubella jointly, was conducted in May 2016 and was estimated to have a remarkable 95% coverage nationally, though only 77% of districts achieved ≥95% coverage through the SIA.[194]

Though the number of confirmed measles cases in Kenya has declined steadily, from 215 cases in 2013 to 61 cases in 2016, measles incidence in 2016 remained at 1.3 per 1,000,000 population, which is above the WHO AFRO elimination target of <1 non-imported case per 1,000,000 population by 2020. These data should be interpreted with caution as there is some suggestion of weaknesses in measles surveillance in Kenya. For example, Kenya did not meet one indicator of measles surveillance quality i.e., investigation of ≥2 cases of non-measles febrile rash per 100,000 population.[190,194] Measles control in Kenya is also challenged by the constant arrival of refugees from neighboring countries in conflict such as Somalia and South Sudan. These refugee populations often have low MCV coverage, leading to measles outbreaks among refugee populations in Kenya, which may spread to the general population as happened in 2011.[195] More recently, a measles outbreak in a refugee camp in north-eastern Kenya was reported in April 2017.[196]

In summary, Kenya has made strides in measles control through introduction of a routine second dose of MCV, high MCV coverage through SIAs and reducing measles incidence. However, measles surveillance needs strengthening and MCV coverage levels are not on track to achieve 2020 Regional targets.

2.10.3. Measles vaccination in Kenya: Barriers and sociodemographic determinants

Four studies were identified that specifically addressed barriers to measles vaccination in Kenya. With the exception of one which performed secondary data analysis of Demographic and Health Survey (DHS) data, all were cross-sectional surveys of caregivers, members of community-based

organizations, members of district health management teams or health facility staff. Barriers identified in these studies were similar to supply- and demand-side barriers identified in other settings. Supply-side factors included high cost or long distance to health facilities,[64,197–199] infrequent provision of measles vaccine at public health facilities,[199] inconvenient schedule of vaccination services, hostile treatment by healthcare workers and health staff shortages.[197] Demand-side barriers identified by ≥5% of 400 community members and health staff in one study included competing priorities (29%), cultural beliefs (17%), fear of vaccination side effects (%), vaccine myths (6%) and incorrect assumption of contraindications by caregivers (5%).[197]

Three studies, including two of the cross-sectional surveys above assessing barriers to vaccination and an additional secondary data analysis, assessed sociodemographic determinants of measles vaccination. Not receiving ANC, being a later born child, belonging to a lower wealth quintile and ethnic identity were identified as determinants of not receiving MCV or receiving MCV with delay.[198,200] In addition, maternal age was identified as a determinant of not receiving MCV or receiving MCV with delay, though lower likelihood of receiving MCV was associated with younger maternal age in one study[130] but with older maternal age in the other.[64] Lower educational attainment and delayed receipt of the first dose of pentavalent vaccine were also identified as a determinants for not receiving MCV.[64]

Two of the studies identifying barriers to, and sociodemographic determinants of, measles vaccination were conducted in Nyanza Region i.e., the same region encompassing the study area. The barriers to measles vaccination described previously were identified in these two studies as were all sociodemographic determinants with the exception of ANC, birth order, wealth quintile

and ethnicity.[64,197] Therefore, in general, the barriers and sociodemographic determinants described are thought to be representative of those expected in the study area.

2.10.4. Experience with SMS reminders and incentives for vaccination

Kenya has considerable experience with mHealth interventions. An assessment of eHealth projects in Kenya identified at least 47 mHealth projects implemented in more than half of Kenya's counties by 2016. mHealth projects leveraging SMS in Siaya County have included studies assessing HIV, malaria and maternal child health outcomes including vaccination.[201] Relatively few studies of monetary incentives to improve health outcomes in Kenya were found. Target outcomes in the studies identified included male circumcision for HIV prevention,[130,202] vaccination[104,203] and pregnancy in adolescents and young adults,[204] with four of these studies conducted within Nyanza region.

Experience with text message reminders and small incentives for vaccination in the study area began with a 2011 pilot study which demonstrated that it was logistically possible and acceptable to deliver text message reminders and small incentives - in the form of mMoney and airtime – for the Penta vaccine series to caregivers in the study area. Although the study was not powered to evaluate the impact of the interventions on vaccination coverage, there was some suggestion that the interventions improved Penta2 coverage.[203] As mentioned previously, the 2013-2015 M-SIMU study showed that text message reminders with or without small, conditional monetary incentives could improve MCV1 overall and timely coverage, as well as timeliness and overall coverage for other vaccination outcomes.[104]

In summary, the research area was uniquely well-suited for the dissertation research. As briefly described previously, the dissertation research included two new data collection activities: 1) a RCT to evaluate the impact of text message reminders, with or without a small *unconditional* monetary incentive, on MCV coverage (M-SIMI study) and 2) a vaccination survey among children subsequently born to caregivers who participated in the M-SIMU study (MSBC study). The RCT and vaccination survey were conducted within a HDSS with the necessary infrastructure (community networks, human resources, supplies and equipment) and with an established research track record. Additionally, the target study population had previous experience with research studies in general and, specifically, with mobile phone delivered interventions to improve vaccination coverage. Finally, the research was conducted in an area with sub-optimal MCV uptake, allowing for assessment of the interventions, which if shown to be efficacious, could have the potential to improve the populations' health.

Chapter 2 References

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Chapter 2 Tables

Table 2.1. Supply-side barriers to measles vaccination. Summary from studies conducted in LMICs

Citation	Country	Study design	Study population	Inadequate vaccine supplies	Limited access to health facility (cost, distance, etc.)	Long wait time at health facility	Hostile treatment by healthcare workers	Insecurity	Healthcare workers fear of wastage (multi-dose vials)	Healthcare workers' poor vaccine knowledge
Ambe 2001[65]	Nigeria	Cross-sectional survey	Caregivers	X			X			
Favin 2012[5]	Not specified	Review	Not applicable							X
Gibson 2015[64]	Kenya	Cross-sectional survey	Caregivers		X					
Hutchins 1993[72]	Multiple	Review	Not applicable						X	

Citation	Country	Study design	Study population	Inadequate vaccine supplies	Limited access to health facility (cost, distance, etc.)	Long wait time at health facility	Hostile treatment by healthcare workers	Insecurity	Healthcare workers fear of wastage (multi-dose vials)	Healthcare workers' poor vaccine knowledge
Mitchell 2009[61]	Pakistan	Cross-sectional survey	Caregivers		X					
Mvula 2016[63]	Malawi	Prospective cohort study	Caregivers		X					
Namuigi 2005[62]	Papua New Guinea	Cross-sectional survey	Caregivers		X	X	X	X	X	
Phimmasane 2010[60]	Lao PDR	Qualitative survey and case-control study	Public health physicians, nurses and caregivers	X	X					

Table 2.2. Demand-side barriers to measles vaccination. Summary from studies conducted in LMICs

Citation	Country	Study design	Study population	Lack of knowledge about measles and/or measles vaccination	Competing priorities	Concern about number of vaccinations/ fear of injections	Concern about vaccination adverse events
Ambe 2001[65]	Nigeria	Cross-sectional survey	Caregivers				
Deshpande 2001[81]	India	Cross-sectional survey	Caregivers				
Hu 2013[79]	China	Cross-sectional survey	Caregivers				X
King 2016[78]	Nigeria	Not applicable (correspondence)	Not applicable				X

Citation	Country	Study design	Study population	Lack of knowledge about measles and/or measles vaccination	Competing priorities	Concern about number of vaccinations/ fear of injections	Concern about vaccination adverse events
Mitchell 2009[61]	Pakistan	Cross-sectional survey	Caregivers	X			
Namuigi 2005[62]	Papua New Guinea	Cross-sectional survey	Caregivers		X	X	X
Phimmasane 2010[60]	Lao PDR	Qualitative survey and case-control study	Public health physicians, nurses and caregivers	X	X	X	X

Citation	Country	Study design	Study population	Belief that MCV is ineffective or unnecessary	Transportation cost	Incorrect assessment of contraindications by caregivers	Not knowing MCV due date
Ambe 2001[65]	Nigeria	Cross-sectional survey	Caregivers	X			X
Deshpande 2001[81]	India	Cross-sectional survey	Caregivers				X
Hu 2013[79]	China	Cross-sectional survey	Caregivers	X		X	X
King 2016[78]	Nigeria	Not applicable (correspondence)	Not applicable	X			
Mitchell 2009[61]	Pakistan	Cross-sectional survey	Caregivers				
Namuigi 2005[62]	Papua New Guinea	Cross-sectional survey	Caregivers		X		

Citation	Country	Study design	Study population	Belief that MCV is ineffective or unnecessary	Transportation cost	Incorrect assessment of contraindications by caregivers	Not knowing MCV due date
Phimmasane 2010[60]	Lao PDR	Qualitative survey and case-control study	Public health physicians, nurses and caregivers	X			X

Table 2.3. Studies evaluating the impact of non-text message reminders on vaccination coverage

Citation	Study design*	Vaccine and dose†	Country	Reminder intervention	Reminder coverage (%)	Comparison coverage (%)	Effect size (95% CI) or (p-value) ‡
Usman, 2009[137]	RCT	DTP3	Pakistan (urban)	Redesigned immunization card	69	55	RR 1.25 (1.11, 1.40)
				Redesigned immunization card + immunization education	74	55	RR 1.31 (1.18, 1.46)
Usman, 2011[138]	RCT	DTP3	Pakistan (rural)	Redesigned immunization card	67	39	RR 1.70 (1.50, 2.00)
				Redesigned immunization card + immunization education	66	39	RR 1.70 (1.40, 2.00)
Haji, 2016[125]	Quasi-experimental	Penta3	Kenya	Stickers	84	83	OR§ 0.94 (0.53, 1.67)
Busso 2015[139]	RCT	Up-to-date Polio3, Penta3, MCV, 1st & 2nd DTP and Polio boosters	Guatemala	Targeted reminders by CHW	53.5	49.4	RD 4.6 ($p < 0.05$)
Brown, 2016[140]	RCT	BCG, Polio0-3,	Nigeria	Mobile phone reminder/recall	99	57	RR 1.72 (1.50, 1.98)

Citation	Study design*	Vaccine and dose†	Country	Reminder intervention	Reminder coverage (%)	Comparison coverage (%)	Effect size (95% CI) or (p-value) ‡
		DTP3, HepB3, MCV1 and YF		Mobile phone reminder/recall + provider training	97	57	RR 1.70 (1.47, 1.95)

*RCT = randomized controlled trial

† BCG = bacillus Calmette–Guérin vaccine; CCT = conditional cash transfer; DTP = diphtheria, pertussis and tetanus vaccine (suffix denotes the dose number); FIC = full immunization coverage; HepB = hepatitis B vaccine; MCV = measles containing vaccine (suffix denotes the dose number); Penta = DTP, *Haemophilus influenzae* type b (Hib) and hepatitis B combination vaccine (suffix denotes the dose number); Polio = Polio vaccine (suffix denotes the dose number); UCT = unconditional cash transfer; YF = yellow fever vaccine

‡RR = Relative risk; RD = Risk difference; OR = Odds ratio; Effect sizes may be adjusted or unadjusted as represented in the cited research

§OR for not receiving Penta3

Table 2.4. Findings from studies evaluating the impact of large cash incentives on vaccination in LMICs, by vaccine type

Citation	Study or analytic design*	Outcome assessed†	Country (*program*)	Incentive (value in 2015 USD)	Effect (95% CI) or (p-value) ‡
DTP					
Morris 2004[157]	RCT (cluster)	DTP1 by age 92 days	Honduras (*PRAF*)	$4.74 – 30.17 monthly	RD 6.9% (1.0, 12.8)
Attanasio 2005[158]	Observational	Appropriate DTP vaccination for age among children <24 months old	Colombia (*FA*)	$20.28 conditioned on preventive care visits	RD 8.9% (0.05< p ≤0.10)
Barham 2009[156]	Randomized, controlled	DTP3 among children age 12-23 months	Nicaragua (*RPS*)	$51.38 bimonthly conditioned on health education, preventive health care visits, and satisfactory weight gain	Year 1: RD 9% (p ≤0.05) Year 2: RD 3% (p >0.10)
	See above	DTP3 among children age 12-23 months living >5 km from a health facility	Nicaragua (*RPS*)	See above	Year 1: RD 12% (p ≤0.05) Year 2: RD 5% (p >0.10)
	See above	DTP3 among children age 12-23 months born to mothers with <4 years of education	Nicaragua (*RPS*)	See above	Year 1: RD 10% (p ≤0.05) Year 2: RD 2% (p >0.10)
MCV					

Citation	Study or analytic design*	Outcome assessed†	Country (*program*)	Incentive (value in 2015 USD)	Effect (95% CI) or (p-value) ‡
Morris 2004[157]	See above	MCV1 by age 12 months	Honduras (*PRAF*)	See above	RD -0.2% (-9.4, 9.0)
Barham 2005[159]	Randomized, controlled	MCV1 by age 12 months	Mexico (*Progresa*)	$37.43 bi-monthly conditioned on attending healthcare visits	Month 6: RD 3% (p ≤0.05) Month 12: RD 3% (0.05< p ≤0.10)
Barham 2009[156]	See above	MCV1 among children age 12-23 months	Nicaragua (*RPS*)	See above	Year 1: RD 15% (p ≤0.01) Year 2: RD 6% (p >0.10)
	See above	MCV1 among children age 12-23 months living >5km from a health facility	Nicaragua (*RPS*)	See above	Year 1: RD 17% (p ≤0.01) Year 2: RD 2% (p >0.10)
	See above	MCV1 among children age 12-23 months born to mothers with <4 years education	Nicaragua (*RPS*)	See above	Year 1 RD: 15% (p ≤0.01) Year 2: RD 5% (p >0.10)
FIC					
Barham 2009[156]	See above	FIC among children age 12-23 months	Nicaragua (*RPS*)	See above	Year 1: RD 23% (p ≤0.01) Year 2: RD 15% (p ≤0.01)
	See above	FIC among children age 12-23 months living >5km away from a health facility	Nicaragua (*RPS*)	See above	Year 1: RD 27% (p ≤0.01) Year 2: RD 13% (p ≤0.10)

Citation	Study or analytic design*	Outcome assessed†	Country (*program*)	Incentive (value in 2015 USD)	Effect (95% CI) or (p-value) ‡
	See above	FIC among children age 12-23 born to mothers with <4 years of education	Nicaragua (*RPS*)	See above	Year 1: RD 23% (p ≤0.01) Year 2: RD 14% (p ≤0.05)
OTHER OUTCOMES					
Barham 2005[159]	See above	BCG by age 12 months	Mexico (*Progresa*)	See above	Month 6: RD 5% (p ≤0.05) Month 12: RD 1% (p >0.10)
Barham 2009[156]	See above	BCG among children age 12-23 months	Nicaragua (*RPS*)	See above	Year 1: RD 9% (p ≤0.01) Year 2: RD 6% (p ≤0.01)
	See above	BCG among children age 12-23 months living >5km away from a health facility	Nicaragua (*RPS*)	See above	Year 1: RD 13% (p ≤0.01) Year 2: RD 7% (p ≤0.05)
	See above	BCG among children age 12-23 months born to mothers with <4 years of education	Nicaragua (*RPS*)	See above	Year 1: RD 9% (p ≤0.01) Year 2: RD 4% (p ≤0.10)

Citation	Study or analytic design*	Outcome assessed†	Country (*program*)	Incentive (value in 2015 USD)	Effect (95% CI) or (p-value) ‡
Robertson 2013	RCT	Up-to-date vaccination by age 4 years (CCT children)	Zimbabwe (*Research study*)	Up to $35.27 bi-monthly conditioned on birth registration, appropriate vaccination for age, growth monitoring, school attendance and parental education	RD 1.8% (-5.0, 8.7)
	See above	Up-to-date vaccination by age 4 years (UCT children)	Zimbabwe (*Research study*)	See above	RD 3.1% (-3.8, 9.9)

*RCT = randomized controlled trial

† BCG = bacillus Calmette–Guérin vaccine; DTP = diphtheria, pertussis and tetanus vaccine (suffix denotes the dose number); FIC = full immunization coverage; HepB = hepatitis B vaccine; MCV = measles containing vaccine (suffix denotes the dose number); UCT = unconditional cash transfer; YF = yellow fever vaccine; CCT = conditional cash transfer

‡ RD = Risk difference; Effect sizes may be adjusted or unadjusted as represented in the cited research

Table 2.5. Findings from studies evaluating the impact of small-value incentives on vaccination in LMICs, by vaccine type

Citation	Study or analytic design*	Outcome assessed†	Country	Incentive (value in 2015 USD)	RR‡ (95% CI)
DTP					
Chandir 2010[162]	Observational	DTP3 by age 18 weeks	Pakistan	Coupons valued at $2.35	2.20 (1.95, 2.48)
Gibson 2017[104]	RCT	Penta3 by age 18 weeks	Kenya	$0.88 monetary incentive	1.07 (0.98, 1.17)
				$2.35 monetary incentive	1.12 (1.03, 1.22)
	See above	Penta3 by age 12 months	Kenya	$0.88 monetary incentive	1.00 (0.98, 1.02)
				$2.35 monetary incentive	1.01 (0.99, 1.02)
MCV					
Gibson 2017[104]	See above	MCV1 by age 9 months and 2 weeks	Kenya	$0.88 monetary incentive	1.73 (1.19, 1.59)
				$2.35 monetary incentive	1.42 (1.23, 1.63)
	See above	MCV1 by age 12 months	Kenya	$0.88 monetary incentive	1.03 (0.97, 1.10)
				$2.35 monetary incentive	1.07 (1.01, 1.14)
AGE-APPROPRIATE AND FULL VACCINATION					
Briere 2012[161]	Observational	Age-appropriate vaccination among children age 2-13 months	Kenya	Hygiene kit valued at $0.43	0.93 (0.87, 0.99)
Gibson 2017[104]	See above		Kenya	$0.88 monetary incentive	1.37 (1.18, 1.59

Citation	Study or analytic design*	Outcome assessed†	Country	Incentive (value in 2015 USD)	RR‡ (95% CI)
		Full immunization by age 9 months and 2 years		$2.35 monetary incentive	1.42 (1.23, 1.65)
		Full immunization by age 12 months	Kenya	$0.88 monetary incentive	1.04 (0.96, 1.11)
				$2.35 monetary incentive	1.09 (1.02, 1.16)
Banerjee 2010[160]	RCT	Full immunization among children age 1-3 years	India	Lentils and plate valued at $2.20	6.66 (4.53, 8.80)

*RCT = randomized controlled trial

†DTP = diphtheria, pertussis and tetanus vaccine (suffix denotes the dose number); Penta = DTP, *Haemophilus influenzae* type b (Hib) and hepatitis B combination vaccine (suffix denotes the dose number); MCV = measles containing vaccine (suffix denotes the dose number)

‡RR= Risk ratio

Table 2.6. M-SIMU proportion vaccinated and RR of vaccination by age and vaccine type

M-SIMU Study Arm					
Age at which coverage assessed	**Vaccine**	**Control N = 360**	**SMS N = 388**	**SMS+75KES N = 446**	**SMS+200KES N = 406**
12 months	FIC %	82.2	85.6	85.9	89.7
	RR	*Ref*	1.04	1.04	1.09
	(95%CI)	*Ref*	(0.97, 1.12)	(0.96, 1.11)	(1.02, 1.16)
	p-value		0.29	0.33	0.014
	MCV1%	83.9	87.1	87.0	89.9
	RR	*Ref*	1.04	1.03	1.07
	(95%CI)	*Ref*	(0.97, 1.11)	(0.97, 1.10)	(1.01, 1.14)
	p-value		0.28	0.36	0.034
9 months + 2 weeks (timeliness)	FIC %	50.3	58.8	70.0	71.7
	RR	*Ref*	1.18	1.37	1.42
	(95%CI)	*Ref*	(1.00, 1.39)	(1.18, 1.59)	(1.23, 1.65)
	p-value		0.045	<0.0001	<0.0001
	MCV1%	50.8	59.5	70.9	71.9
	RR	*Ref*	1.18	1.37	1.42
	(95%CI)	*Ref*	(1.01, 1.38)	(1.19, 1.59)	(1.23, 1.63)
	p-value		0.038	<0.0001	<0.0001
16 weeks (timeliness)	Penta3%	74.2	74.2	79.4	83.0
	RR	*Ref*	1.01	1.07	1.12
	(95%CI)	*Ref*	(0.91, 1.11)	(0.98, 1.17)	(1.03, 1.22)
	p-value		0.90	0.16	0.0092

Adapted from Gibson and colleagues.[104]

Table 2.7. MCV coverage at the national, regional, county and study area level. Regions in Kenya and Counties in Nyanza Region with the highest and lowest coverage are included for context.

Level of coverage	MCV1	MCV2
Kenya national	75%	32%
Regions in Kenya		
Central (Max.)	97%	--*
North Eastern (Min.)	70%	--*
Nyanza (Study Region)	85%	--*
Counties in Nyanza Region		
Nyamira (Max.)	98%	--*
Homa Bay (Min.)	80%	--*
Siaya (Study County)	85%	--*
Study area in Siaya County		
Gem and Asembo	83%	--*

MCV coverage estimates are from WHO/UNICEF,[40] Kenya DHS 2014[52] and Gibson and colleagues.[64]

*Vaccination coverage estimates not available

Chapter 2 Figures

Figure 2.1. Conceptual framework depicting supply- and demand-side factors that influence caregivers' demand for vaccination

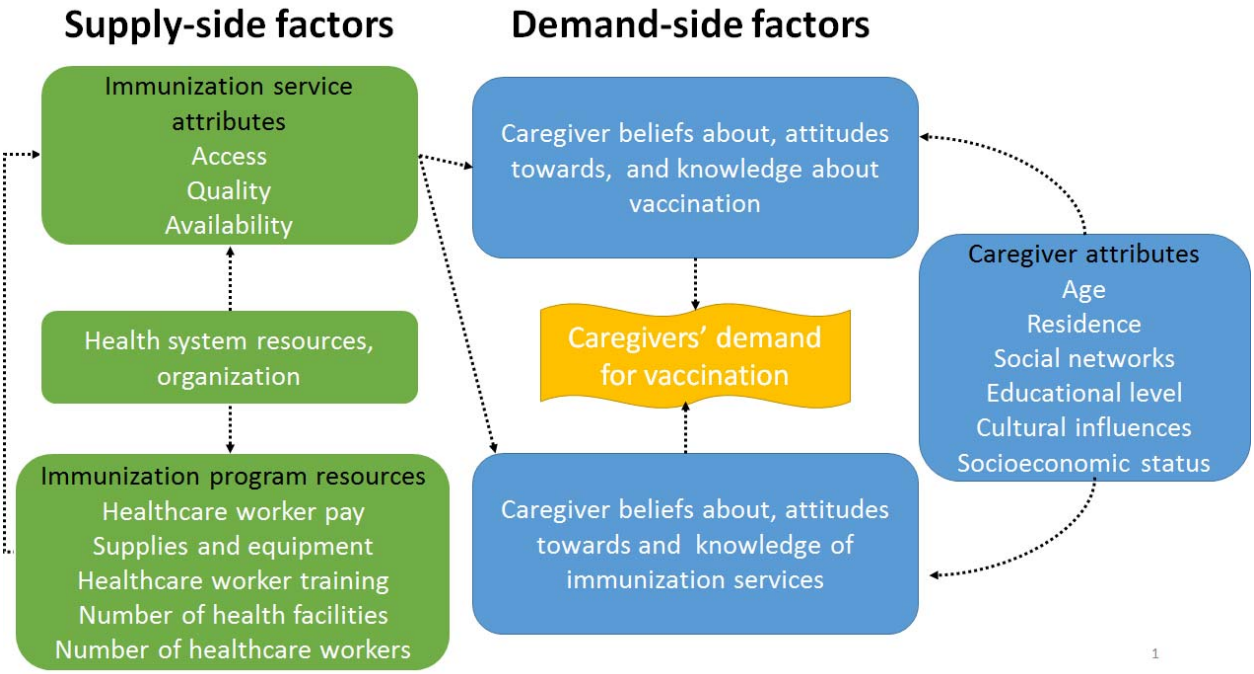
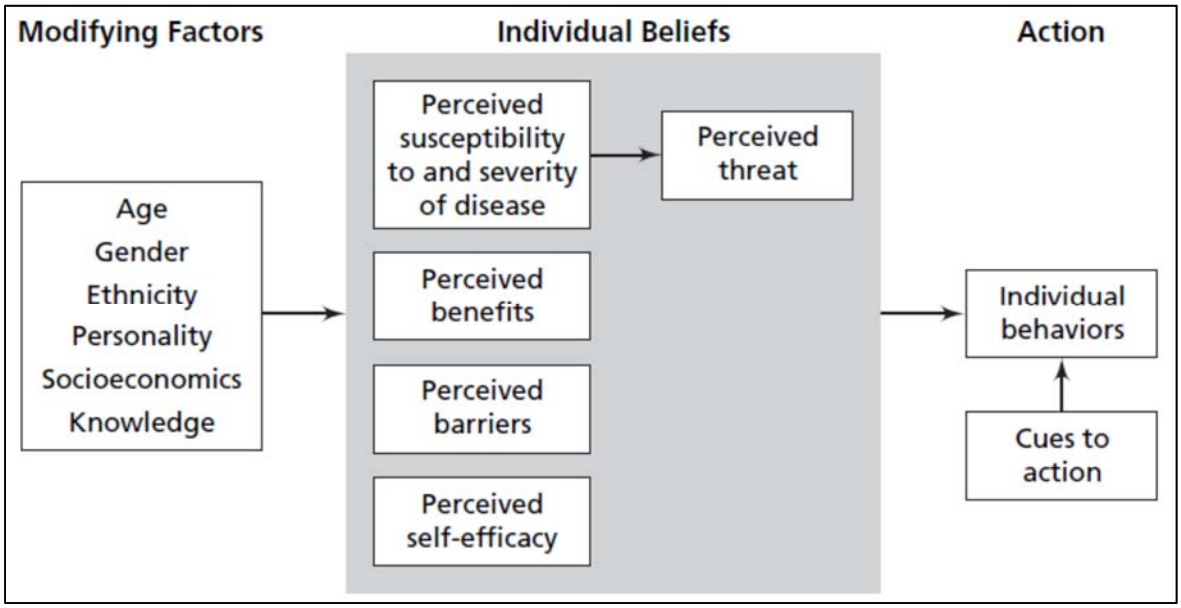
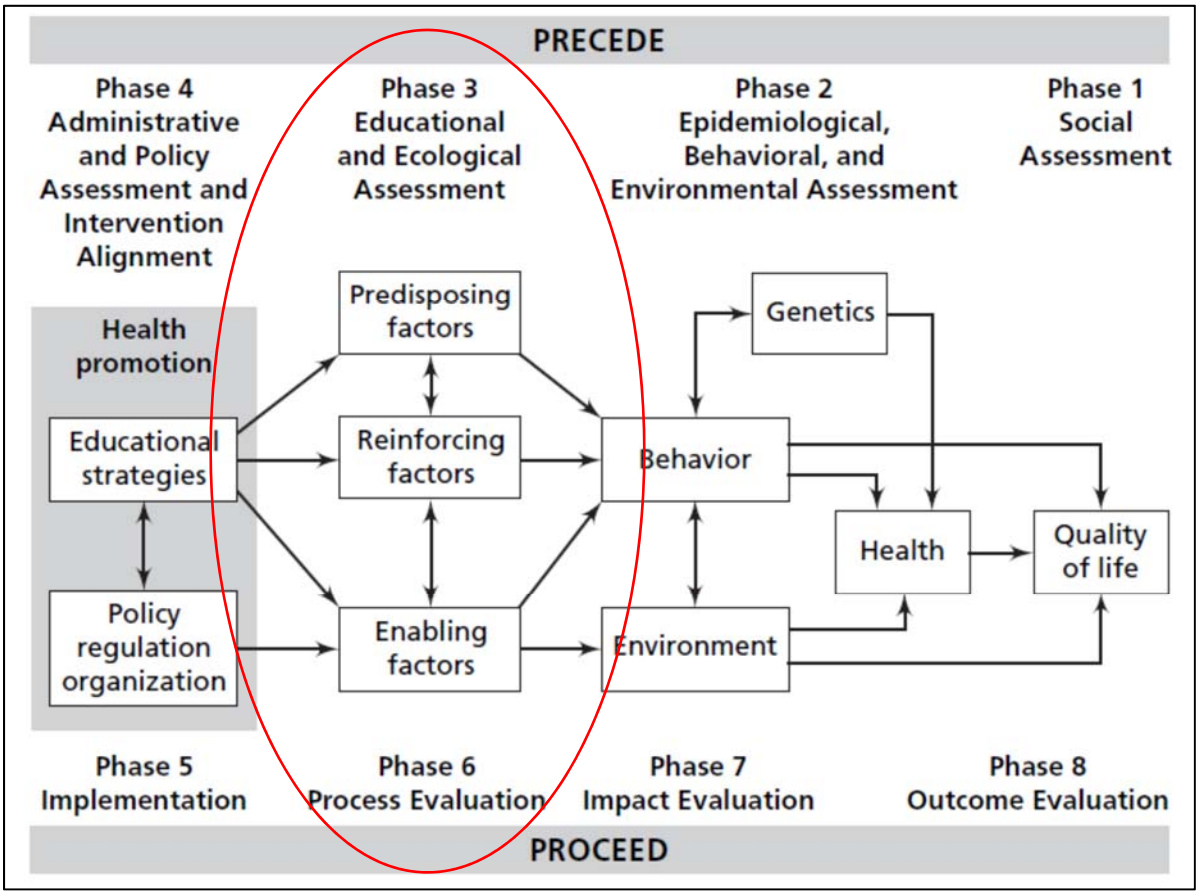


Figure 2.2. The Health Belief Model



HBM graphic adapted from Champion and colleagues.[165]

Figure 2.3. The PRECEDE/PROCEED model. Red oval highlights the constructs of focus.



PRECEDE/PROCEED model graphic adapted from Gielen and colleagues.[166]

Figure 2.4. Conceptual framework: Theoretical mechanisms by which reminders and incentives influence vaccine-seeking as mapped on Health Belief Model constructs and PRECEDE/PROCEED phases

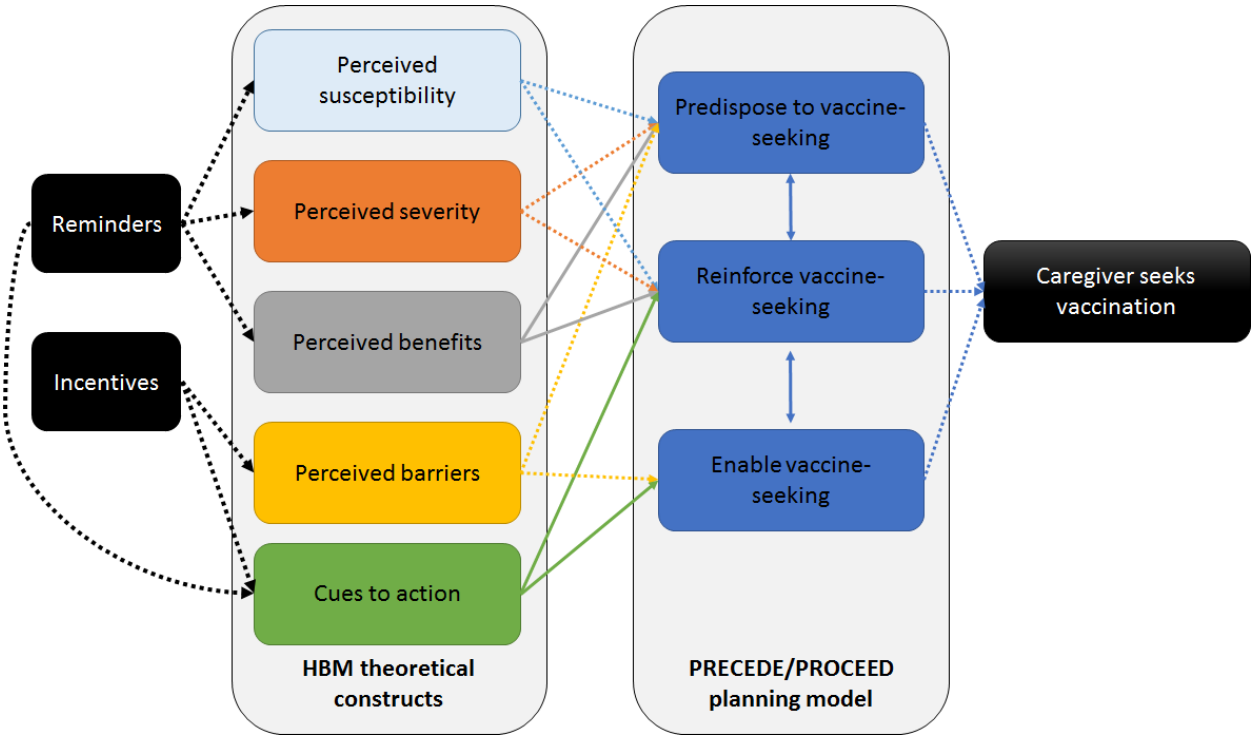


Figure 2.5. Geographical context of the study area, Gem and Asembo, Siaya County, Nyanza Region, Kenya. Figure adapted from Odhiambo and colleagues.[188] Red rectangles designate Gem sub-county and Asembo area of Rarieda sub-county.

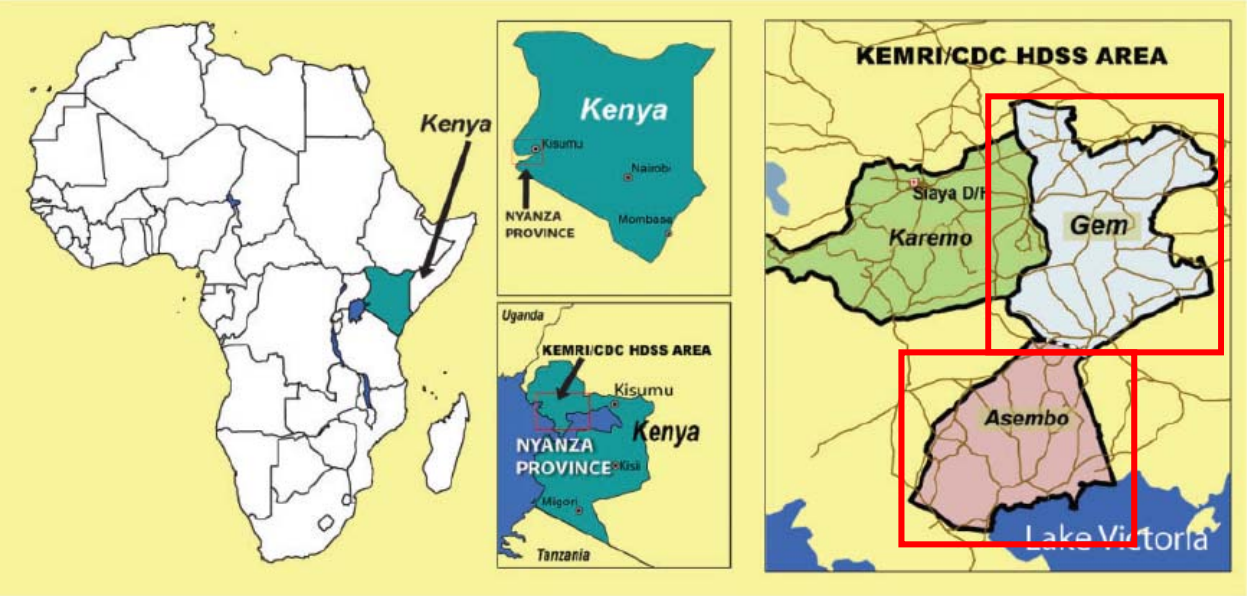
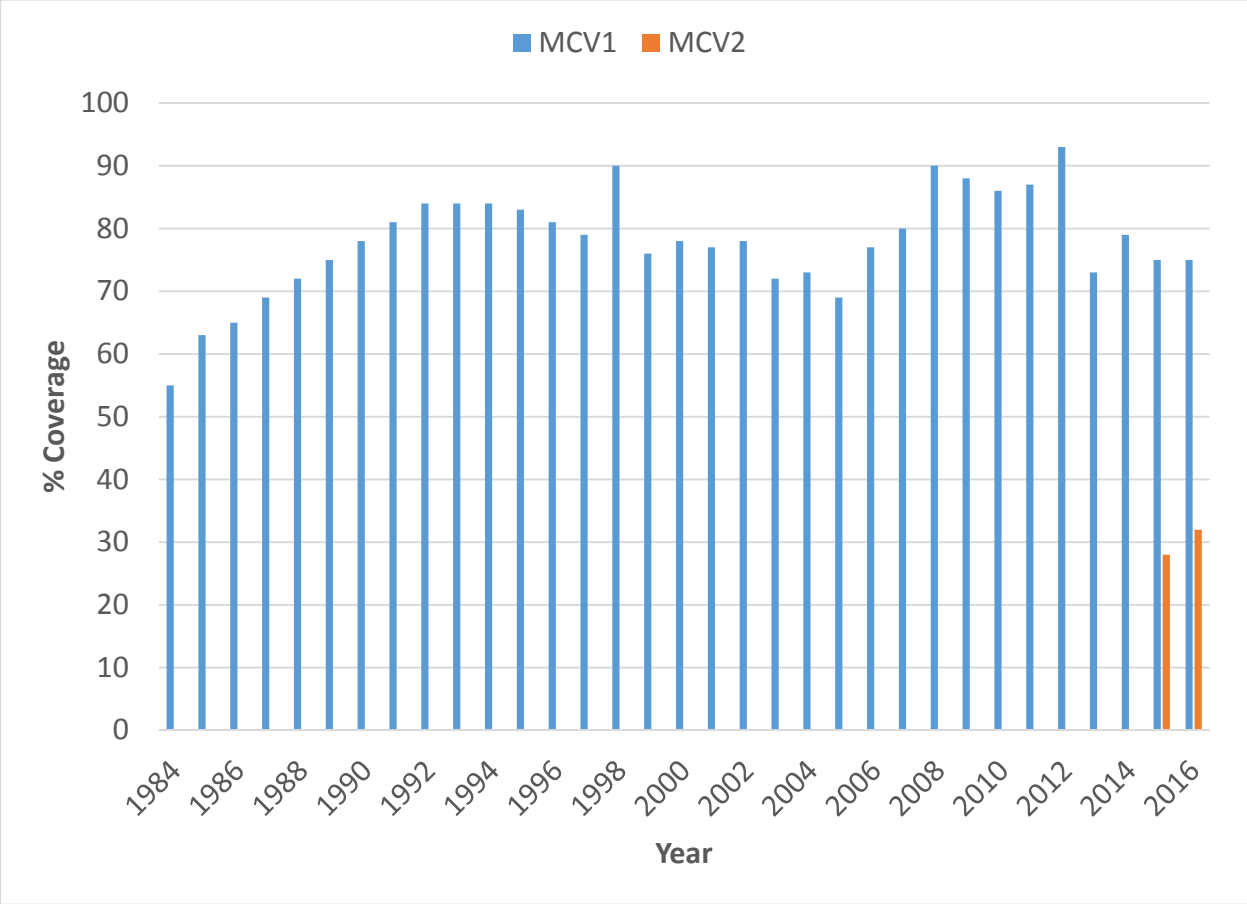


Figure 2.6. Kenya national MCV1 coverage by age 12 months and MCV2 coverage at age 18 months, 1984 – 2016



CHAPTER 3: TEXT MESSAGE REMINDERS TO IMPROVE VACCINATION UPTAKE IN LOW- AND MIDDLE-INCOME COUNTRIES: AN UPDATED SYSTEMATIC REVIEW AND META-ANALYSIS

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3.1. Abstract

Objective: To assess the effect of short message service (SMS) reminders on vaccination coverage and timeliness in low- and middle-income countries.

Methods: We searched PubMed, Scopus, Embase, Web of Science, Cochrane Library, and Global Health databases for studies assessing the impact of SMS reminders on vaccination uptake. We performed random-effects meta-analyses to estimate pooled relative risks (pRR) and risk differences (pRD) for vaccination timely coverage (generally the proportion vaccinated within ≤4 weeks of the recommended age) and vaccination overall coverage (generally proportion vaccinated >4 weeks after the recommended age). We performed random-effects meta-analyses to estimate pooled relative risks (pRR) and risk differences (pRD) for vaccination timeliness and coverage of third dose diphtheria, tetanus toxoid, pertussis vaccine (DTP3) and full immunization. The number of studies assessing first dose measles-containing vaccine (MCV1) overall coverage, MCV1 timely coverage, second dose MCV coverage and full immunization timely coverage was insufficient to perform meta-analyses.

Findings: Seven randomized controlled trials (RCTs) and four quasi-experimental studies were included. Compared to no SMS reminders, SMS reminders did not significantly improve DTP3 overall coverage across three RCTs (N= 1,641; pRR 1.11 [95% CI: 0.95, 1.31]; pRD 6.3% [95% CI: -5.2%, 17.8%]) but they significantly improved DTP3 overall coverage across two quasi-experimental studies (N= 2,415; pRR 1.12 [95% CI: 1.04, 1.20]; pRD 9.0% [95% CI: 3.4%, 14.6%]). SMS reminders significantly improved full immunization coverage (FIC) in a meta-analysis of three quasi-experimental studies (N= 8,266; pRR 1.27 [95% CI: 1.16, 1.39]; pRD 18.1% [95% CI: 8.5%, 27.6%]). SMS reminders significantly improved DTP3 timely coverage modestly across six RCTs (N= 2,846; pRR 1.12 [95% CI: 1.01, 1.25); pRD 7.0% [95% CI: 0.1%,

14.0%]) and more robustly across two quasi-experimental studies (N= 8,115; pRR 1.29 [95% CI: 1.05, 1.60]; pRD 18.7% [95% CI: 8.8%, 28.6%]). The quality of evidence from meta-analyses was graded low or very low. Findings across studies included in meta-analyses were moderately or highly heterogeneous for DTP3 overall coverage across RCTs and DTP3 timely coverage.

Conclusion: Current evidence suggests that SMS reminders improve DTP3 timely coverage though the effect may be modest. SMS reminders may improve DTP3 overall coverage and FIC though there is mixed evidence. Drivers of heterogeneity in findings across different studies need to be determined. If vaccination SMS reminders are implemented, concurrent assessment of effectiveness is recommended.

3.2. Introduction

In 2016, approximately 5.6 million children below the age of 5 years died globally, with 80% of deaths occurring in sub-Saharan Africa and southern Asia.[1] Annually, vaccines against diseases such as tetanus, pertussis and measles prevent approximately 2-3 million deaths, yet 1.5 million children die from vaccine-preventable diseases.[2] In 2016, 62 of 136 World Bank-classified low- and middle-income countries (LMICs) did not achieve the national coverage target of 90% for third dose diphtheria-tetanus-pertussis (DTP3) by age 12 months set in the 2011-2020 Global Vaccine Action Plan (GVAP). Many LMICs are also not on track to achieve the GVAP 2020 target of 90% coverage nationally for all other recommended vaccines.[3–5] Increasing the proportion of children receiving recommended vaccines, nationally and within all sub-national populations, will reduce the number of childhood deaths.

High levels of mobile phone access and ownership in LMICs – estimated at 98.7 mobile phone subscriptions per 100 people in 2017[6] – afford an opportunity to stimulate demand for vaccination through the use of short message service (SMS; or text message) reminders to caregivers of infants or to adults who are due for vaccination. Findings from predominantly high income settings suggest that SMS reminders significantly improve vaccination uptake.[7] However, the cumulative evidence of the impact of SMS reminders on vaccination uptake in LMICs and the quality of that evidence have not been well characterized. Some previously published reviews of the impact of interventions on vaccine uptake within LMICs did not disaggregate the impact of mobile phone based (mHealth) interventions such as SMS reminders from the impact of non-mHealth interventions.[8,9] In addition, other reviews focusing on mHealth interventions did not perform meta-analysis.[10–14] To date, only one scoping review has focused

on the impact of SMS reminders in LMICs; however, it did not include any quantitative synthesis.[15] Furthermore, several planned reviews have not yet progressed to publication.[16–18] In addition, reviews that excluded evidence from studies that are not randomized controlled trials (RCTs) could discard valuable information.[17,18]

As some governments, donors, and other stakeholders begin to implement SMS vaccination reminders at scale[19,20] and others consider introducing SMS vaccination reminders, it is important to understand their impact to date as well as the quality of evidence. This systematic review and meta-analysis aimed to assess whether SMS reminders significantly improve vaccination coverage and timeliness in LMICs, as compared to no SMS reminders, and whether their impact differs by vaccine antigen, the coverage outcome versus the timeliness outcome and by study design. The scope of this systematic review and meta-analysis covers both children and adults. However, in this paper, we present findings from the review and meta-analysis of the impact among only children.

3.3. Methods

3.3.1. Protocol and registration

This systematic review and meta-analyses followed Preferred Reporting Items for Systematic Review and Meta-Analyses (PRISMA) guidelines (Checklist, Appendix pp 19-21).[21] The review was registered on PROSPERO (registration number CRD42018096436).[22]

3.3.2. Information sources and search

Initial searches of PubMed, Scopus, Embase, Web of Science, Cochrane Library, and Global Health databases were performed on March 30, 2016 and June 2, 2017. An additional search to find articles published through April 30, 2018 was conducted. Key search concepts were SMS reminders and vaccination; specific search terms are provided in **Table 3.1**. Search results were imported into RefWorks, which is a citation manager application, and automatically de-duplicated using RefWorks. Search results were imported into Microsoft® Excel® (Microsoft Corporation, Redmond, Washington) after de-duplication.

3.3.3. Study selection and eligibility criteria

Search results were independently screened by two authors (EK, DG). An independent arbitrator provided a final decision in case of discordant conclusions. In primary screening, titles and abstracts were reviewed to identify search results potentially including data on the impact of SMS reminders on vaccination uptake. We retrieved the full-text of screened-in publications and reviewed these according to secondary screening inclusion criteria: (i) research article published in a peer-reviewed journal; (ii) randomized controlled or quasi-experimental study design; (iii) study evaluated the impact of SMS reminders on vaccination uptake; (iv) study conducted in a LMIC as defined by the World Bank;[23] (v) study reported (or provided data needed to estimate) risk ratios or risk differences, and, (vi) written in English language or non-English language using the Roman alphabet that could be feasibly translated in Google Translate™.

3.3.4. Data collection

For all eligible studies, one author (EK) extracted information about participants, interventions, comparators, outcomes and study design (PICOS).[21] Except in one instance, specified in **Table 3.4**, the intervention and comparator data were as defined by the study. We contacted investigators for additional data on vaccination timeliness and to address any questions. Data were abstracted using pre-defined table shells; abstracted data were reviewed for accuracy by a different author (DG) than the one performing abstraction.

3.3.5. Risk of bias and quality of evidence assessment

Within-study risk of bias was assessed for all studies passing through secondary screening using the Cochrane Collaboration's domain-based evaluation tool.[24] We, however, excluded the performance bias domain from the Cochrane Collaboration's tool as it is not possible to blind participants to the receipt of SMS vaccination reminders. Risk of bias figures were generated using RevMan Version 5.3. (Copenhagen: The Nordic Cochrane Centre, The Cochrane Collaboration).

Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group criteria were used to assess the quality of evidence for the pooled estimate of the impact of SMS vaccination reminders for each outcome and vaccine type. Using the GRADE scoring system, RCTs were assigned a score of 4 and non-RCTs were assigned a score of 2 at the beginning of the assessment. For each set of evidence from an outcome-vaccine type analysis, one point was deducted if: any of the included studies had high risk of bias in any of the

Cochrane Collaboration domains assessed; there was moderate to high statistical heterogeneity in meta-analysis; and if study populations were judged by the scorer as being not representative based on study selection criteria. Studies could receive an additional point if the summary estimate was greater than 2 and statistically significant.[25,26]

3.3.6. Statistical analysis

We used abstracted data to estimate the risk ratios (RR), differences in risk (RD) and associated 95% confidence intervals (95% CI) for vaccination in SMS reminder (intervention) groups compared to non-intervention groups. We focused on review of DTP3, first dose measles containing vaccine (MCV1), second dose measles containing vaccine (MCV2) and full immunization because some are targets of the 2011-2020 GVAP, are used for monitoring routine immunization system performance and/or are used for monitoring Sustainable Development Goals (SDG 3.8).[4,27] Full immunization included vaccines specified in the respective study.

We performed DerSimonian and Laird random-effects meta-analysis to calculate pooled RR (pRR), pooled RD (pRD) and estimated the heterogeneity statistic using the Mantel-Hanszel model.[28] Separate meta-analyses were performed for DTP3 timely and overall coverage as well as full immunization coverage. We defined overall coverage as the proportion of children vaccinated >4 weeks after the recommended due date and timely coverage as the proportion of children vaccinated within four weeks of the recommended due date. Within each meta-analysis, we estimated separate pRR and pRD for RCTs and quasi-experimental studies. Statistical analyses were performed using Stata version 14 (College Station, TX: StataCorp).

3.4. Results

3.4.1. Study selection and participants

The search terms identified 1,604 studies. After removal of duplicates, 731 abstracts underwent primary screening. From the primary screening, 138 full-text records were reviewed using secondary screening criteria. After application of secondary screening criteria, 11 articles were included in meta-analyses. Reasons for screening out are provided in **Figure 3.1**. Reasons for exclusion from secondary analysis by study are provided in **Table 3.2.** Of note, two studies that evaluated SMS reminders for adult vaccination were excluded because we focused on childhood vaccination in this analysis.[29,30] We undertook a quantitative synthesis of 11 studies[20,31–40] which examined the effect of SMS reminders to improve pediatric vaccination timeliness and coverage (**Table 3.3**).

The 11 included studies were comprised of seven RCTs [31,33–38] and four quasi-experimental studies.[20,32,39,40] Five studies were conducted in sub-Saharan Africa (Burkina Faso, Kenya [n=2], Nigeria, and Zimbabwe),[31,34,35,37,40] five in Asia (Bangladesh, China, Pakistan, Philippines and Vietnam),[20,32,36,38,39] and one study in Central America (Guatemala).[33] All included studies were published between 2015 and 2018. During analysis, one RCT[38] was grouped with quasi-experimental studies because only the study's control arm was included in RR estimation; in that study, control households received SMS reminders and the study collected pre- and post-RCT vaccination coverage data (**Table 3.4**). Additionally, one of the studies was a cluster RCT with

no change in statistical significance when analyzing it as an individually randomized controlled trial.[35]

3.4.2. Interventions and comparisons

All included studies used SMS to either remind caregivers about infants' scheduled vaccination dates[31,33–40] or to notify caregivers about community vaccination sessions.[20,32] The number of reminders ranged from one to four per scheduled vaccination visit. The timing of messages ranged from ten days prior[39] to the scheduled day of vaccination.[32,40] Three studies did not specify the reminder message schedule.[20,37,38] One study sent additional recall messages to unvaccinated children.[34] All comparator groups received no SMS reminders but some received health education,[31] vaccination counseling[36] or non-SMS reminders[20,33,35,37,39,40] per immunization program standard procedures or as part of the research study procedures (**Table 3.3**).

3.4.3. Outcomes

The effect of SMS reminders on overall or timely coverage was the primary or secondary objective for all but one study.[33] Studies evaluated the impact of SMS reminders on coverage for: first,[20,31,32,35–38] second[20,31,32,35–38,40] and third[20,31–38,40] doses of diphtheria, tetanus and pertussis combination vaccine (DTP1 – DTP3) or pentavalent/ Quinvaxem (DTP, *Haemophilus influenzae* type B and hepatitis B combination) vaccine; first,[20,31,35,37,38] second[20,31,35,37,38] and third[20,31,33,35,37,38] doses of polio vaccine (Polio1 – Polio3); pneumococcal conjugate vaccine (PCV) primary series;[31,33,35,37] MCV1;[20,35,38] second dose measles containing vaccine (MCV2);[39]

and full immunization.[20,32,35,38] Studies assessing full immunization defined it as receipt of bacille Calmette-Guerin (BCG) vaccine, three doses of pentavalent/Quinvaxem vaccine and MCV1[20,32,35] or BCG, DTP3, three doses of hepatitis B vaccine and MCV1.[38]

Vaccination status was ascertained using caregivers' verbal report[31,32,38], health facility vaccination records,[31,33–35,37,39] child health cards,[32,35,36,38] or a digital immunization registry.[20] For two studies that collected both verbal and written vaccination data, written records were included in the meta-analysis either because we abstracted only that data[32] or because that study's authors only analyzed written vaccination records.[35] One study author provided additional vaccination timeliness data through correspondence.[33]

3.4.3.1. DTP3 overall coverage

Five studies[32,33,35,37,38] – three RCTs (N= 1,641 participants) and two quasi-experimental studies (N= 2,415) – evaluated the impact of SMS reminders on DTP3 overall coverage. Comparison group DTP3 overall coverage ranged from 42%[37] to 98%[35] and was measured 3.5 months[33] to 38 weeks[35] after the recommended due date (**Table 3.4**). Of the three RCTs,[33,35,37] only one study found a significant effect of SMS reminders on DTP3 overall coverage.[37] When pooled, data from the RCTs showed an 11% increase (pRR 1.11; 95% CI: 0.95, 1.31; p= 0.198) in the likelihood of DTP3 overall vaccination at older ages among SMS reminder infants compared to non-SMS reminder infants which equated to 6.3% higher (pRD 95% CI: -5.2%, 17.8%; p= 0.285) DTP3 overall coverage, though these findings were not statistically significant. The findings across the studies were highly heterogeneous (I-squared 90.0%; **Figures 3.4 & 3.5**). A

sensitivity meta-analysis whereby we excluded one RCT that was unlikely to realize an increase in DTP3 overall coverage due to high baseline DTP3 overall coverage (98.1%)[35] neither changed the interpretation of the meta-analysis nor the heterogeneity (**Figures 3.6 & 3.7**).

Of the two quasi-experimental studies[32,38], DTP3 overall coverage was significantly higher among SMS reminder recipients in one.[32] Pooled estimates from the quasi-experimental studies showed a 12% (pRR 1.12, 95% CI: 1.04, 1.20; p= 0.002) statistically significant increase in the likelihood of DTP3 overall vaccination at older ages among infants receiving SMS reminders compared to control infants, translating to 9.0% (pRD 95% CI: 3.4%, 14.6%; p= 0.002) significantly higher DTP3 overall coverage among SMS reminder infants. Findings were homogeneous across quasi-experimental studies (I-squared 0%; **Figures 3.4 & 3.5**).

3.4.3.2. MCV1 overall coverage

Two studies, one RCT[35] (N= 748 participants) and one quasi-experimental study[38] (N= 213), assessed the impact of SMS reminders on MCV1 overall coverage. Meta-analysis was not performed as there was only one RCT and one quasi-experimental study. Comparison group MCV1 overall overage was 81% in the quasi-experimental study[38] and 84% in the RCT.[35] In both studies, MCV1 coverage by age 12 months was assessed.

In the RCT, SMS reminder infants had a 4% (RR 1.04; 95% CI: 0.98, 1.10; p= 0.210) statistically insignificant increase in the likelihood of receiving MCV1 by age 12 months compared to control infants, a 3.2% (RD 95% CI: -1.8%, 8.3%; p= 0.210) statistically

insignificant absolute increase. In the quasi-experimental study, SMS reminder infants had a 12% (RR 1.12; 95% CI: 1.00, 1.25; p= 0.046) statistically significant increase in the likelihood of measles vaccination by age 12 months compared to control infants, which translated to a 9.7% (RD 95% CI: 0.3%, 19.0%; p= 0.046) absolute increase in MCV1 overall coverage among SMS reminder infants (**Table 3.4,** RRs and RDs not shown).

3.4.3.3. MCV2 coverage

One quasi-experimental study (N= 50) assessed the impact of SMS reminders on MCV2 coverage.[39] In this study, SMS reminders did not significantly increase the likelihood of second dose measles vaccination (RR 1.12; 95% CI: 0.79, 1.58; p= 0.529) or absolute coverage with MCV2 by age 17 months (RD 8.0%; 95% CI: -16.8%, 32.8%; p= 0.529) as compared to no SMS reminders (**Table 3.4**, RRs and RDs not shown).

3.4.3.4. Full immunization coverage (FIC)

Four studies, one RCT (N= 748 participants)[35] and three quasi-experimental studies (N= 8,266)[20,32,38] evaluated the effect of SMS reminders on FIC. Comparison group FIC ranged from 53%[32] to 82%[35] (**Table 3.4**). No meta-analysis was performed for RCTs as there was only one RCT with a FIC outcome.[35] In this RCT, the likelihood of full immunization as well as absolute FIC were slightly higher but not significantly so, among SMS reminder infants compared to control infants (RR 1.04; 95% CI: 0.98. 1.11; RD 3.3%; 95% CI: -1.9%, 8.6%; p= 0.213; **Figures 3.8 & 3.9**).

Among the three quasi-experimental studies, two found that SMS reminders significantly increased FIC as compared to no reminders.[20,32] The pooling of quasi-experimental studies found a 27% (pRR 1.27; 95% CI: 1.16, 1.39; p< 0.001) statistically significant increase in the likelihood of full immunization among SMS reminder infants compared to control infants, which translated to an 18.1% (pRD 18.1%; 95% CI: 8.5%, 27.6%; p< 0.001) absolute increase in FIC among SMS reminder infants. There was low to moderate heterogeneity in the findings across the three quasi-experimental studies (pRR I-squared= 41.2%; pRD I-squared= 69.4%; **Figures 3.8 & 3.9**).

3.4.3.5. DTP3 timely coverage

The impact of SMS reminders on DTP3 timely coverage was assessed in six RCTs[31,33–37] (N= 2,847) and two quasi-experimental studies[20,40] (N= 8,115). The proportion of comparison group achieving DTP3 timeliness ranged from 25%[37] to 83%[40] (**Table 3.5**).

The likelihood of achieving DTP3 timeliness was significantly higher among SMS reminder infants compared to control infants in two[31,34] of the six RCTs and insignificantly higher in three[33,37,41] of the remaining four RCTs. When pooled, SMS reminder infants had a 12% (pRR 1.12; 95% CI: 1.01, 1.25; p= 0.036) statistically significant increase in the likelihood of achieving DTP3 vaccination timeliness and 7.0% (pRD 95% CI: 0.1%, 14.0%; p= 0.047) higher DTP3 timely coverage compared to infants who did not receive SMS reminders. RCT findings were moderately heterogeneous (pRR I-squared= 69.7%; pRD I-squared= 76.8%; **Figures 3.10 & 3.11**).

Both quasi-experimental studies assessing DTP3 timely coverage found significant increases in DTP3 timely coverage among SMS reminder infants compared to control infants. When pooled, SMS reminder infants had a 29% (pRR 1.29; 95% CI: 1.05, 1.60; p= 0.016) statistically significant increase in the likelihood of achieving DTP3 timely coverage compared to control infants, translating to 18.7% (pRD 95% CI: 8.8%, 18.6%; p< 0.001) significantly higher DTP3 timely coverage among SMS reminder infants. Findings across quasi-experimental studies were highly heterogeneous (I-squared 94.3%; **Figures 3.10 & 3.11**).

3.4.3.6. MCV1 timely coverage

MCV1 timely coverage was assessed in one RCT and one quasi-experimental study.[20,35] In both studies, SMS reminder infants were significantly more likely to achieve MCV1 timeliness and had higher MCV1 timely coverage compared to control infants. MCV1 timely coverage was 8.7% (RD 95% CI: 1.6%, 15.8%) higher among the RCT SMS reminder infants and 21.9% (RD 95% CI: 20.2%, 23.6%) higher among the quasi-experimental SMS reminder infants, compared to the respective control infants (**Table 3.5**; RDs not shown).

3.4.3.7. Full immunization timely coverage

Only one study[35] evaluated the impact of SMS reminders on full immunization timely coverage. This RCT found significantly full immunization timely coverage among children in the intervention group (58.8%) compared to comparison group (50.3%; **Table 5.3**). A pooled analysis was not conducted due to lack of additional studies.

3.4.4. Risk of bias

None of the included studies had low risk of bias across all of the five domains assessed. Four,[31,35–37] three,[31,33,34] two[33,37] and one[34] of the RCTs had high or unclear risk of detection bias, selection bias due to lack of allocation concealment, attrition bias and selection bias due to lack of random sequence generation, respectively. None of the RCTs had reporting bias (**Figure 3.2**). All five of the quasi-experimental studies had high or unclear risk of selection bias and detection bias. One quasi-experimental study each had unclear risk of attrition bias[32] and reporting bias[20] (**Figure 3.3**).

3.4.5. Quality of evidence

Among RCTs, the evidence for the impact of SMS reminders on DTP3 overall and timely coverage was rated low. Evidence from RCTs received a low GRADE score due to issues with methodological quality i.e., high or unclear risk of bias, moderate to high heterogeneity in findings across studies and modest impact i.e., RR <2. Among quasi-experimental studies, the evidence for the impact of SMS reminders on DTP3 overall coverage, FIC and DTP3 timely coverage was deemed to be of very low quality, low quality and very low quality, respectively. Quasi-experimental study scores were downgraded because of high or unclear risk of bias in several Cochrane domains as well as high heterogeneity in DTP3 timely coverage findings (**Table 3.6**).

3.5. Discussion

Based on current evidence, SMS reminders can significantly increase DTP3 timely coverage and may increase DTP3 and full immunization overall coverage. Previous reviews of the impact of SMS reminders have either used evidence predominantly from high-income settings[7] or have not performed quantitative analyses to synthesize available data.[10,11,15] This is the first analysis to pool evidence on the effect of SMS reminders on vaccination in LMICs.

Pooled estimates from both RCTs (n= 6) and quasi-experimental studies (n= 2) showed significant increases in DTP3 timely coverage of 7% to 18% among infants whose caregivers received SMS reminders. The pooled estimate of the effect of SMS reminders on DTP3 overall coverage was 6.3% RCTs (n= 3) but was not statistically significant, while the summary increase from quasi-experimental studies (n= 2) was 9.0% and was statistically significant. Only one RCT assessed FIC and found a 3% statistically insignificant increase, whereas quasi-experimental studies (n= 3) found 18% significantly higher FIC among infants whose caregivers received SMS reminders. Taken together, the evidence from RCTs and quasi-experimental studies suggests that SMS reminders may improve DTP3 and full immunization overall coverage. Lack of studies prevented synthesis of evidence for the impact of SMS reminders on MCV1 overall coverage as well as MCV1 and full immunization timely coverage though 1 of 2, 2 of 2 and 1 of 1 studies found significant increases in MCV1 overall coverage, MCV1 timely coverage and FIC among SMS reminder infants.

The pooled estimates for the effect of SMS reminders on DTP3 uptake and FIC should be interpreted with caution. The number of studies included in each meta-analysis was few, with moderate to high heterogeneity in findings across studies, particularly for the RCTs. Furthermore, the evidence for the impact of SMS reminders on coverage and timeliness was assessed to be of low to very low quality per GRADE criteria.[25,26] The quality determination was driven by high or unclear risk of bias within each study and the heterogeneity in findings for DTP3 overall and timely coverage outcomes. Moreover, the magnitude and direction of bias are unknown. Lastly, two studies[20,32] included supply-side interventions in addition to SMS reminders and so the observed impact on DTP3 vaccination and full immunization may not be wholly attributable to the demand-side effect of SMS reminders.

Still, decision-makers may be keen to implement SMS reminders for vaccination at scale given the relatively low delivery costs compared to those of other efficacious interventions like education, outreach campaigns, and incentives.[8,9] In Zimbabwe, the marginal cost of significantly improving DTP3 timely coverage using SMS reminders was estimated at $0.99 per child.[31] Additionally, with high levels of mobile phone access, and a shrinking digital divide where mobile phone access is increasingly available among traditionally 'hard-to-reach' sub-groups,[42] there is potential to inexpensively achieve equitable vaccine uptake compared to traditional health facility or community based interventions.

Yet, current evidence, which has limited generalizability, may be insufficient to support scaled implementation of SMS reminders in all settings. Most studies recruited participants from health

facilities, rather than the community, an important selection bias. Thus, the findings may not accurately reflect the impact of SMS reminders for children who have had no contact with the immunization program (left-outs) and who, in some settings, make up a considerable proportion of under-vaccinated children.[43] Furthermore, we found substantial unexplained heterogeneity in effect size across RCTs and quasi-experimental studies. The extent to which non-individual-level confounding or effect modifying factors such as SMS reminder delivery characteristics (e.g. frequency, timing, length, etc.), baseline vaccination uptake, or mobile phone ownership may have contributed to the heterogeneous impact in these LMIC studies is not well understood. The frequency and content of text messages have been shown to influence the uptake of HIV counseling and testing[44] and one US-based study found higher influenza vaccination coverage among people receiving supplementary educational content along with SMS reminders.[45]

Moreover, rather than utilize a single intervention, like SMS reminders, comprehensive mobile phone-based interventions may be more successful given that they can target different reasons for delayed or under-immunization. In one study, SMS reminders coupled with a mobile-money incentive significantly improved DTP3 timely coverage, MCV1 overall coverage and FIC whereas SMS reminders alone did not improve those outcomes.[35]

Finally, it is unclear whether SMS reminders generate demand for vaccination among those who would otherwise not receive vaccination. One study, which conducted community-based recruitment, found that SMS reminders significantly improved MCV1 and full immunization uptake by age 9 months and 2 weeks (i.e., timeliness endpoint) but not by age 12 months, the

age-cutoff used in WHO vaccination coverage estimates.[35,46] A plausible explanation for this observation could be that SMS reminders elicited more timely vaccination among caregivers already predisposed to vaccinate their children, but did not stimulate demand among vaccine-hesitant caregivers. Thus, outside a strict definition of vaccination timeliness, similar proportions of children were vaccinated in the intervention and comparison groups.

This systematic review has several limitations. We could not estimate the magnitude or direction of bias and its influence on the estimated RRs. One implication of the small number of included studies is that we could not perform stratified analyses, aside from those by vaccine and study design, to explain heterogeneity. Furthermore, there was inconsistency in the definition of timely uptake used across the studies. There is no consensus on a single definition for vaccination timeliness and our timeliness analysis included studies assessing DTP3 vaccination on,[31,40] or within nine days,[37] two weeks[33,35] and four weeks[34] of, the recommended vaccination age. We also did not search the grey literature and so will have missed findings from those sources if they exist. However, the risk of publication bias in this analysis may be low; two of 11 studies included in the systematic review did not find a significant impact of SMS reminders on any outcome.[33,36] Finally, in estimating RR we were unable to adjust for any confounders as we did not have access to participant-level data for all except one study.[35] Although evidence from meta-analysis was assessed to be of poor quality, the GRADE scoring rubric may not adequately assess interventions to improve vaccination coverage and timeliness. In the GRADE assessment, we were unable to assign an additional point to meta-analyses that found statistically significant increases in vaccination uptake of as much as 18% as GRADE guidelines stipulate a RR cut-off value of >2. This cut-off is likely inappropriate cut-off for several reasons: in settings with

vaccination coverage or timeliness of >50% it is impossible to obtain a RR >2; RR <2 can still represent substantial gains in vaccination coverage or timeliness; and, it is rare to observe RR effect sizes of >2 for demand-side vaccination interventions in LMICs.[8,9] Still, the evidence may have been of moderate quality at best.

To better understand the potential of SMS reminders to improve vaccination coverage and timeliness, additional well-designed studies with sufficient sample size in more diverse LMIC settings are needed. In addition, programs introducing SMS reminders at scale should consider conducting concurrent implementation research. Specific areas of interest for study and program research activities include assessment of the impact of SMS reminders on vaccination timeliness and coverage by age 12 months, evaluation of the influence of population characteristics, message attributes and other programmatic factors on observed effect sizes as well as optimization of reminder attributes.

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Chapter 3 Tables

Table 3.1. Database search terms

Database	Search terms
PubMed	(("text message" OR "text messaging" OR "short message service" OR "SMS" OR "information communication technology" OR "ICT" OR "text reminder")) AND (((((((immunization program[MeSH Terms]) OR vaccination[MeSH Terms]) OR immunization[MeSH Terms])) OR vaccination) OR vaccine) OR immunization) OR immunisation)
Scopus and EmBase	("text message" OR "text messaging" OR "short message service" OR "SMS" OR "information communication technology" OR "ICT" OR "text reminder") AND (immunization OR vaccination OR immunisation OR vaccine)
Web of Science and Global Health	**TOPIC (Web of Science) / KEYWORD (Global Health):** (("text message" OR "text messaging" OR "short message service" OR "SMS" OR "information communication technology" OR "ICT" OR "text reminder") AND (immunization OR vaccination OR immunisation OR vaccine)) *OR* **TITLE:** (("text message" OR "text messaging" OR "short message service" OR "SMS" OR "information communication technology" OR "ICT" OR "text reminder") AND (immunization OR vaccination OR immunisation OR vaccine))

Table 3.2. Studies excluded after full-text review and reasons for exclusion

	Citation	Reason for exclusion
1	Abahussin AA, Albarrak AI. Vaccination adherence: Review and proposed model. *J Infect Public Health*. 2016;9(6):781-789. doi:10.1016/j.jiph.2016.09.006.	Review
2	Abaza H, Marschollek M. mHealth Application Areas and Technology Combinations. *METHODS Inf Med*. 56}:E105-E122. doi:10.3414/ME17-05-0003.	Review
3	Abbas AH, Yusof Y. Children vaccination reminder via SMS alert. 2011 Int Conf Res Innov Inf Syst. 2011:1-5. doi:10.1109/ICRIIS.2011.6125750.	Description of a text message platform/system
4	Adams WG. Text messaging increases receipt of influenza vaccine among low-income, urban children. *J Pediatr*. 2012;161(3):568-569. doi:10.1016/j.jpeds.2012.07.009.	Commentary; not a research article
5	Ahlers-Schmidt CR, Chesser AK, Nguyen T, et al. Feasibility of a randomized controlled trial to evaluate Text Reminders for Immunization Compliance in Kids (TRICKs). *Vaccine*. 2012;30(36):5305-5309. doi:10.1016/j.vaccine.2012.06.058.	Non-LMIC setting (US)
6	Ahlers-Schmidt CR, Chesser A, Hart T, Paschal A, Nguyen T, Wittler RR. Text messaging immunization reminders: feasibility of implementation with low-income parents. *Prev Med (Baltim)*. 2010;50(5-6):306-307. doi:10.1016/j.ypmed.2010.02.008.	Letter to the editor
7	Ashish K. Scope of leveraging mhealth for routine immunization strengthening in India. *Trop Med Int Heal*. 2017;22:269. doi:10.1111/(ISSN)1365-3156.	Conference abstract
8	Atnafu A, Otto K, Herbst CH. The role of mHealth intervention on maternal and child health service delivery: findings from a randomized controlled field trial in rural Ethiopia. *mHealth*. 2017;3:39. doi:10.21037/mhealth.2017.08.04 [doi].	SMS reminders to healthcare workers, not caregivers.
9	Aragones A, Bruno DM, Ehrenberg M, Tonda-Salcedo J, Gany FM. Parental education and text messaging reminders as effective community based tools to increase HPV vaccination rates among Mexican American children. *Prev Med Reports*. 2015;2:554-558. doi:10.1016/j.pmedr.2015.06.015.	Non-LMIC setting (US)
1	Atnafu A, Bisrat A, Kifle M, Taye B, Debebe T. Mobile health (mHealth) intervention in maternal and child health care: Evidence from resource-constrained settings: A review. *Ethiop J Heal Dev*. 2015;29(3):140-153. http://ejhd.org/index.php/ejhd/article/view/357.	Review
1	Badawy SM, Kuhns LM. Texting and Mobile Phone App Interventions for Improving Adherence to Preventive Behavior in Adolescents: A Systematic Review. *JMIR mHealth uHealth*. 2017;5(4):e50. doi:10.2196/mhealth.6837.	Systematic review

	Citation	Reason for exclusion
1	Barnabas R V. Texting Can Be Healthy. *Sci Transl Med*. 2012;4(132):132ec76-132ec76. doi:10.1126/scitranslmed.3004204.	Op-ed
1	Bar-Shain DS, Stager MM, Runkle AP, Leon JB, Kaelber DC. Direct messaging to parents/guardians to improve adolescent immunizations. *J Adolesc Health*. 2015;56(5 Suppl):S21-6. doi:10.1016/j.jadohealth.2014.11.023.	Non-LMIC setting (US)
1	Baskin E. Increasing influenza vaccination rates via low cost messaging interventions. *PLoS One*. 2018;13(2):e0192594. doi:10.1371/journal.pone.0192594 [doi].	Non-LMIC setting (US)
1	Bay SL, Crawford DJ. Using Technology to Affect Influenza Vaccine Coverage Among Children With Chronic Respiratory Conditions. *J Pediatr Health Care*. 2017;31(2):155-160. doi:10.1016/j.pedhc.2016.06.007.	Non-LMIC setting (US)
1	Bedada SY, Gallagher K, Aregay AK, et al. Assessment of source of information for polio supplementary immunization activities in 2014 and 2015, Somali, Ethiopia. *Pan Afr Med J*. 2017;27(Suppl 2):7. doi:10.11604/pamj.supp.2017.27.2.10728 [doi].	Non-vaccination outcome
1	Berenson AB, Rahman M, Hirth JM, Rupp RE, Sarpong KO. A human papillomavirus vaccination program for low-income postpartum women. *Am J Obstet Gynecol*. 2016;215(3):318.e1-9. doi:10.1016/j.ajog.2016.02.032.	Non-LMIC setting (US)
1	Bernstein HH, Bocchini JA. Practical Approaches to Optimize Adolescent Immunization. *Pediatrics*. February 2017. http://pediatrics.aappublications.org/content/early/2017/02/02/peds.2016-4187.abstract.	Report; not a research article
1	Bondurant KL, Wheeler JG, Bursac Z, Holmes T, Tilford JM. Comparison of Office-Based Versus Outsourced Immunization Recall Services. *Clin Pediatr (Phila)*. 2017;56(6):555-563. doi:10.1177/0009922816673307.	Non-LMIC setting (US)
2	Bright T, Felix L, Kuper H, Polack S. Systematic review of strategies to increase access to health services among children over five in low- and middle-income countries. *Trop Med Int Health*. 2018;23(5):476-507. doi:10.1111/tmi.13044 [doi].	Systematic review
2	Bright T, Felix L, Kuper H, Polack S. A systematic review of strategies to increase access to health services among children in low and middle income countries. *BMC Health Serv Res*. 2017;17(1):252. doi:10.1186/s12913-017-2180-9.	Systematic review
2	Brown VB, Oluwatosin OA, Akinyemi JO, Adeyemo AA. Effects of community health nurse-led intervention on childhood routine immunization completion in primary health care centers in Ibadan, Nigeria. *J Community Health*. 2016;41(2):265-273. doi:10.1007/s10900-015-0092-3.	Mobile phone call reminders (not SMS-based reminders)

	Citation	Reason for exclusion
2	Castano PM, Stockwell MS, Malbon KM. Using digital technologies to improve treatment adherence. *Clin Obstet Gynecol*. 2013;56(3):434-445. doi:10.1097/GRF.0b013e3182988a3b.	Review
2	Chai SJ, Tan F, Ji Y, Wei X, Li R, Frost M. Community-level text messaging for 2009 H1N1 prevention in China. *Am J Prev Med*. 2013;45(2):190-196. doi:10.1016/j.amepre.2013.03.014.	RR could not be estimated; study is a pre-post design without enough data provided to adjust for correlation
2	Crawford J, Larsen-Cooper E, Jezman Z, Cunningham SC, Bancroft E. SMS versus voice messaging to deliver MNCH communication in rural Malawi: assessment of delivery success and user experience. *Glob Heal Sci Pract*. 2014;2(1):35-46. doi:10.9745/GHSP-D-13-00155.	Did not assess impact on vaccination uptake
2	Creel L, Pandit-Rajani T, Devlin K, Khana L, Brady N. Community health workers as frontline health responders in complex environments: Insights and lessons from Nepal and Pakistan. *BMC Proc*. 2017;11(6). doi:10.1186/s12919-017-0074-9.	Conference abstract
2	Crocker-Buque T, Mindra G, Duncan R, Mounier-Jack S. Immunization, urbanization and slums - a systematic review of factors and interventions. *BMC PUBLIC Heal*. 17. doi:10.1186/s12889-017-4473-7.	Systematic review
2	Crocker-Buque T, Edelstein M, Mounier-Jack S. Interventions to reduce inequalities in vaccine uptake in children and adolescents aged <19 years: a systematic review. *J Epidemiol Community Health*. 2016;71(1):87 LP-97. http://jech.bmj.com/content/71/1/87.abstract.	Systematic review
2	Datta SS, Ranganathan P, Sivakumar KS. A study to assess the feasibility of Text Messaging Service in delivering maternal and child healthcare messages in a rural area of Tamil Nadu, India. *Australas Med J*. 2014;7(4):175-180. doi:10.4066/AMJ.2014.1916.	Non-vaccination outcomes assessed
3	Dempsey AF, Zimet GD. Interventions to Improve Adolescent Vaccination: What May Work and What Still Needs to Be Tested. *Am J Prev Med*. 2015;49(6 Suppl 4):S445-54. doi:10.1016/j.amepre.2015.04.013.	Review
3	Dombkowski KJ, Cowan AE, Reeves SL, Foley MR, Dempsey AF. The impacts of email reminder/recall on adolescent influenza vaccination. *Vaccine*. 2017;35(23):3089-3095. doi:10.1016/j.vaccine.2017.04.033.	Non-LMIC setting (US)
3	Dombkowski KJ, Harrington LB, Dong S, Clark SJ. Seasonal influenza vaccination reminders for children with high-risk conditions: a registry-based randomized trial. *Am J Prev Med*. 2012;42(1):71-75. doi:10.1016/j.amepre.2011.09.028.	No text message intervention

	Citation	Reason for exclusion
3	Dombkowski KJ, Harrington L, Hanauer D, Kennedy A, Clark S. Current and Potential Use of New Technologies for Reminder Notifications. *Clin Pediatr (Phila)*. 2012;51(4):394-397. doi:10.1177/0009922811420715.	Review
3	Fadda M, Galimberti E, Fiordelli M, Romanò L, Zanetti A, Schulz PJ. Effectiveness of a smartphone app to increase parents' knowledge and empowerment in the MMR vaccination decision: A randomized controlled trial. *Hum Vaccines Immunother*. 2017;13(11):2512-2521. doi:10.1080/21645515.2017.1360456.	Non-LMIC setting (Italy)
3	Fava JP, Colleran J, Bignasci F, Cha R, Kilgore PE. Adolescent human papillomavirus vaccination in the United States: Opportunities for integrating pharmacies into the immunization neighborhood. *Hum VACCINES \& Immunother*. 13}(8}):1844-1855}. doi:{10.1080/21645515.2017.1325980.	Non-LMIC setting (US)
3	Fedele DA, Cushing CC, Fritz A, Amaro CM, Ortega A. Mobile Health Interventions for Improving Health Outcomes in Youth: A Meta-analysis. *JAMA Pediatr*. 2017;171(5):461-469. doi:10.1001/jamapediatrics.2017.0042.	Meta-analysis
3	Francis DB, Cates JR, Wagner KPG, Zola T, Fitter JE, Coyne-Beasley T. Communication technologies to improve HPV vaccination initiation and completion: A systematic review. *Patient Educ Couns*. 2017;100(7):1280-1286. doi:10.1016/j.pec.2017.02.004.	Systematic review
3	Frew PM, Lutz CS. Interventions to increase pediatric vaccine uptake: An overview of recent findings. *Hum Vaccines Immunother*. 2017;13(11):2503-2511. doi:10.1080/21645515.2017.1367069.	Review
3	Gatuha G, Jiang T. KenVACS: Improving vaccination of children through cellular network technology in developing countries. *Interdiscip J Information, Knowledge, Manag*. 2015;10:37-46.	Description of platform development
4	Ghadieh AS, Hamadeh GN, Mahmassani DM, Lakkis NA. The effect of various types of patients' reminders on the uptake of pneumococcal vaccine in adults: A randomized controlled trial. *Vaccine*. 2015;33(43):5868-5872. doi:10.1016/j.vaccine.2015.07.050.	Adult study
4	Ghazisaeedi M, Sheikhtaheri A, Allahverdi B, Azizi B. Design and implementation of a children vaccination reminder system based on short message service. *Tehran-Univ-Med-J*. 2016;74(6):448-456. http://tumj.tums.ac.ir/article-1-7663-en.html.	Full-text Persian with English language abstract; unable to translate
4	Goodman A, Bushar J, Kendrick S, Pierretti A, Grider T. Text4baby as a valuable tool for providers and patients. *J Women's Heal*. 2013;22(3):1-48. doi:10.1089/jwh.2013.Ab01.	Conference abstract
4	Henrikson N, Zhu W, Nguyen M, Baba L, Berthoud H, Hofstetter A. Health system-based HPV vaccine reminders: Randomized trial results. *Cancer Epidemiol Biomarkers Prev*. 2017;26(3):435. doi:10.1158/1055-9965.EPI-17-0031.	Conference abstract

	Citation	Reason for exclusion
4	Herrett E, van Staa T, Free C, Smeeth L. Text messaging reminders for influenza vaccine in primary care: protocol for a cluster randomised controlled trial (TXT4FLUJAB). *BMJ Open*. 2014;4(5):e004633	Protocol
4	Herrett E, Williamson E, van Staa T, et al. Text messaging reminders for influenza vaccine in primary care: a cluster randomised controlled trial (TXT4FLUJAB). *BMJ Open*. 2016;6(2):e010069.	Non-LMIC setting (US)
4	Hofstetter AM, Barrett A, Camargo S, Rosenthal SL, Stockwell MS. Text message reminders for vaccination of adolescents with chronic medical conditions: A randomized clinical trial. *Vaccine*. 2017;35(35 Pt B):4554-4560. doi:S0264-410X(17)30920-9 [pii].	Non-LMIC setting (US)
4	Hofstetter AM, Vargas CY, Camargo S, et al. Impacting delayed pediatric influenza vaccination: A randomized controlled trial of text message reminders. *Am J Prev Med*. 2015;48(4):392-401. doi:10.1016/j.amepre.2014.10.023.	Non-LMIC setting (US)
4	Hofstetter AM, DuRivage N, Vargas CY, et al. Text message reminders for timely routine MMR vaccination: A randomized controlled trial. *Vaccine*. 2015;33(43):5741-5746. doi:10.1016/j.vaccine.2015.09.042.	Non-LMIC setting (US)
4	Hoisnard L, Seringe E, Lebascle K, Astagneau P. Influenza preventive measures: Campaigns to promote vaccination and surgical mask among health-care workers. *Antimicrob Resist Infect Control*. 2017;6. doi:10.1186/s13756-017-0201-4.	Conference abstract
5	Jacobson Vann J, Jacobson R, Coyne-Beasley T, Asafu-adjei J, Szilagyi P. Patient reminder and recall interventions to improve immunization rates. *Cochrane Database Syst Rev*. 2018;(1):CD003941. doi:10.1002/14651858.CD003941.pub3.www.cochranelibrary.com.	Systematic review
5	Jaser E, Ahmad I. ICT intervention to enhance health services to mothers and children in remote communities in Jordan. *Lect Notes Inst Comput Sci Soc Telecommun Eng*. 2012;95 LNICST:303-310. doi:10.1007/978-3-642-32320-1_19.	Description of platform development and implementation
5	Jordan ET, Bushar JA, Kendrick JS, Johnson P, Wang J. Encouraging influenza vaccination among text4baby pregnant women and mothers. *Am J Prev Med*. 2015;49(4):563-572. doi:10.1016/j.amepre.2015.04.029.	Non-LMIC setting (US)
5	Jung Y, Kwon M, Song J. Stepwise intervention including 1-on-1 counseling is highly effective in increasing influenza vaccination among health care workers. *Am J Infect Control*. 2017;45(6):635-641. doi:10.1016/j.ajic.2016.11.012.	Non-LMIC setting (Republic of Korea)
5	Kaewkungwal J, Singhasivanon P, Khamsiriwatchara A, Sawang S, Meankaew P, Wechsart A. Application of smart phone in "Better Border Healthcare Program": a module for mother and child care. *BMC Med Inform Decis Mak*. 2010;10:69. doi:10.1186/1472-6947-10-69.	Risk ratios and risk differences could not be estimated using available data

	Citation	Reason for exclusion
5	Kalan R, Wiysonge CS, Ramafuthole T, Allie K, Ebrahim F, Engel ME. Mobile phone text messaging for improving the uptake of vaccinations: a systematic review protocol. *BMJ Open*. 2014;4(8):e005130. doi:10.1136/bmjopen-2014-005130.	Protocol
5	Kang HS, De Gagne JC, Son YD, Chae SM. Completeness of Human Papilloma Virus Vaccination: A Systematic Review. *J Pediatr Nurs*. 2018;39:7-14. doi:S0882-5963(17)30422-0 [pii].	Systematic review
5	Kazi AM, Jafri LA. The use of mobile phones in polio eradication. *Bull World Health Organ*. 2016;94(2):153-154. doi:10.2471/BLT.15.163683.	Commentary
5	Kazi AM, Murtaza A, Khoja S, Zaidi AK, Ali SA. Monitoring polio supplementary immunization activities using an automated short text messaging system in Karachi, Pakistan. *Bull World Health Organ*. 2014;92(3):220-225. doi:10.2471/BLT.13.122564.	Text messaging used to collect data
5	Keeshin SW, Feinberg J. Text Message Reminder-Recall to Increase HPV Immunization in Young HIV-1-Infected Patients. *J Int Assoc Provid AIDS Care*. 2017;16(2):110-113. doi:10.1177/2325957416682302.	Non-LMIC setting (US)
6	Kempe A, O'Leary ST, Shoup JA, et al. Parental Choice of Recall Method for HPV Vaccination: A Pragmatic Trial. *Pediatrics*. 2016;137(3):e20152857. doi:10.1542/peds.2015-2857.	Non-LMIC setting (US)
6	Kharbanda E. Helping mothers to get the message about influenza: Are texts the future for increased immunization? *Expert Rev Vaccines*. 2015;14(April):333-335. doi:10.1586/14760584.2015.993384.	Review
6	Kharbanda EO, Stockwell M, Fox H, Andres R, Lara M, Rickert V. Text messaging to promote HPV vaccination. *J Adolesc Heal*. 2011;1)(2):S4-S5. doi:http://dx.doi.org/10.1016/j.jadohealth.2010.11.016.	Conference abstract
6	Kharbanda EO, Stockwell MS, Fox HW, Andres R, Lara M, Rickert VI. Text message reminders to promote human papillomavirus vaccination. *Vaccine*. 2011;29(14):2537-2541. doi:10.1016/j.vaccine.2011.01.065.	Non-LMIC setting (US)
6	Kim SS, Patel M, Hinman A. Use of m-Health in polio eradication and other immunization activities in developing countries. *Vaccine*. 2017;35(10):1373-1379. doi:10.1016/j.vaccine.2017.01.058.	Review
6	Kimmel MC, Platt RE, Steinberg DN, et al. Integrating Maternal Mental Health Care in the Pediatric Medical Home: Treatment Engagement and Child Outcomes. *Clin Pediatr*. 56(12):1148-1156. doi:10.1177/0009922816679510.	Non-LMIC setting (US)
6	Lassi ZS, Bhutta ZA. Community-based intervention packages for reducing maternal and neonatal morbidity and mortality and improving neonatal outcomes. *Cochrane Libr*. 2015. doi:10.1002/14651858.CD007754.pub3.	Systematic review

	Citation	Reason for exclusion
6	L'Engle KL, Mangone ER, Parcesepe AM, Agarwal S, Ippoliti NB. Mobile Phone Interventions for Adolescent Sexual and Reproductive Health: A Systematic Review. *Pediatrics*. August 2016. http://pediatrics.aappublications.org/content/early/2016/08/22/peds.2016-0884.abstract.	Systematic review
6	Lee HY, Koopmeiners JS, McHugh J, Raveis VH, Ahluwalia JS. mHealth Pilot Study: Text Messaging Intervention to Promote HPV Vaccination. *Am J Health Behav*. 2016;40(1):67-76. doi:10.5993/AJHB.40.1.8.	Non-immunization outcomes
6	Lehnert JD, Shevach A, Walker S, Wang R, Fitzgerald TJ, Graitcer SB. Development and pilot testing of a text message vaccine reminder system for use during an influenza pandemic. *Hum Vaccin Immunother*. February 2018:1-7. doi:10.1080/21645515.2018.1440162 [doi].	Non-LMIC setting (US)
7	Lewkowitz AK, O'Donnell BE, Nakagawa S, Vargas JE, Zlatnik MG. Social media messaging in pregnancy: comparing content of Text4baby to content of free smart phone applications of pregnancy. *J Matern Fetal Neonatal Med*. 2015;7058(April):1-7. doi:10.3109/14767058.2015.1017460.	Non-immunization outcomes
7	Lund S, Nielsen BB, Hemed M, et al. Mobile phones improve antenatal care attendance in Zanzibar: a cluster randomized controlled trial. *BMC Pregnancy Childbirth*. 2014;14(1):29. doi:10.1186/1471-2393-14-29.	Adult study
7	MacDougall DM, Halperin SA. Improving Rates of Maternal Immunization: Challenges and Opportunities. *Hum Vaccin Immunother*. 2015;5515(April). doi:10.1080/21645515.2015.1101524.	Review
7	Manakongtreecheep K. SMS-reminder for vaccination in Africa: research from published, unpublished and grey literature. *Pan Afr Med J*. 2017;27(Suppl 3):23. doi:10.11604/pamj.supp.2017.27.3.12115.	Scoping review
7	Matheson EC, Derouin A, Gagliano M, Thompson JA, Blood-Siegfried J. Increasing HPV vaccination series completion rates via text message reminders. *J Pediatr Heal Care*. 2014;28(4):e35-e39. doi:10.1016/j.pedhc.2013.09.001.	Non-LMIC setting (US)
7	McClure CC, Cataldi JR, O'Leary ST. Vaccine Hesitancy: Where We Are and Where We Are Going. *Clin Ther*. 39(8):1550-1562. doi:10.1016/j.clinthera.2017.07.003.	Review
7	McGlone MS, Stephens KK, Rodriguez SA, Fernandez ME. Persuasive texts for prompting action: Agency assignment in HPV vaccination reminders. *Vaccine*. 2017;35(34):4295-4297. doi:S0264-410X(17)30877-0 [pii].	Non-LMIC setting (US)

	Citation	Reason for exclusion
7	McIver R, Dyda A, McNulty AM, Knight V, Wand HC, Guy RJ. Text message reminders do not improve hepatitis B vaccination rates in an Australian sexual health setting. *J Am Med Inform Assoc*. 2015:1-5. doi:10.1093/jamia/ocv145.	Non-LMIC setting (US)
7	Mokaya E, Mugoya I, Raburu J, Shimp L. Use of cellular phone contacts to increase return rates for immunization services in Kenya. *Pan Afr Med J*. 2017;28:24. doi:10.11604/pamj.2017.28.24.12631.	Non-SMS intervention (mobile phone calls)
7	Moniz MH, Hasley S, Meyn LA, Beigi RH. Improving Influenza Vaccination Rates in Pregnancy Through Text Messaging. *Obstet Gynecol*. 2013;121(4):734-740.	Non-LMIC setting (US)
8	Morris J, Wang W, Wang L, Peddecord KM, Sawyer MH. Comparison of reminder methods in selected adolescents with records in an immunization registry. *J Adolesc Heal*. 2015;56(5):S27-S32. doi:10.1016/j.jadohealth.2015.01.010.	Non-LMIC setting (US)
8	Niederhauser V, Johnson M, Tavakoli AS. Vaccines4Kids: Assessing the impact of text message reminders on immunization rates in infants. *Vaccine*. 2015;33(26):2984-2989. doi:10.1016/j.vaccine.2015.04.069.	Non-LMIC setting (US)
8	Noble K, Holden M, Warner G. A solution to improving uptake of hepatitis B immunisation in at risk groups, through collaboration and adopting an integrated approach with pharmacists as service providers. *Int J Pharm Pract*. 2010;18(s2):43. doi:http://dx.doi.org/10.1111/j.2042-7174.2010.tb00511.x.	No text messaging intervention
8	Nyaku M, Wardle M, Eng J V, et al. Immunization delivery in the second year of life in Ghana: the need for a multi-faceted approach. *Pan Afr Med J*. 2017;27:4. doi:10.11604/pamj.supp.2017.27.3.12182.	Other – no intervention and assessment of knowledge, attitudes and practices
8	Odone A, Ferrari A, Spagnoli F, et al. Effectiveness of interventions that apply new media to improve vaccine uptake and vaccination coverage : a systematic review. *Hum Vaccines Immunother*. 2014;11(1):72-82. doi:10.4161/hv.34313.	Systematic review
8	O'Leary ST, Lee M, Lockhart S, et al. Effectiveness and Cost of Bidirectional Text Messaging for Adolescent Vaccines and Well Care. *Pediatrics*. 2015;47(2):peds.2015-1089. doi:10.1542/peds.2015-1089.	Non-LMIC setting (US)
8	Oliver K, Frawley A, Garland E. HPV vaccination: Population approaches for improving rates. *Hum Vaccin Immunother*. 2016;12(6):1589-1593. doi:10.1080/21645515.2016.1139253.	Review

	Citation	Reason for exclusion
8	Oliver-Williams C, Brown E, Devereux S, Fairhead C, Holeman I. Using Mobile Phones to Improve Vaccination Uptake in 21 Low- and Middle-Income Countries: Systematic Review. *JMIR mHealth uHealth*. 2017;5(10):e148. doi:10.2196/mhealth.7792.	Systematic review
8	Ooi KS, Cheah Y-N. Virtual Health Connect: a Community-Based Immunisation Scheduler and Manager. *Comput Informatics, 4th Int Conf 2013*. 2013;(27):441-446.	Description of a platform
8	Oyo-Ita A, Wiysonge CS, Oringanje C, Nwachukwu CE, Oduwole O, Meremikwu MM. Interventions for improving coverage of childhood immunisation in low- and middle-income countries. *Cochrane database Syst Rev*. 2016;7:CD008145. doi:10.1002/14651858.CD008145.pub3.	Systematic review
9	Patel A, Stern L, Unger Z, et al. Staying on track: A cluster randomized controlled trial of automated reminders aimed at increasing human papillomavirus vaccine completion. *Vaccine*. 2014;32(21):2428-2433. doi:10.1016/j.vaccine.2014.02.095.	Non-LMIC setting (US)
9	Pantoja T, Opiyo N, Lewin S, et al. Implementation strategies for health systems in low-income countries: An overview of systematic reviews. *Cochrane Database Syst Rev*. 2017;2017(9). doi:10.1002/14651858.CD011086.pub2.	Review
9	Phillips AL, Kumar D, Patel S, Arya M. Using text messages to improve patient-doctor communication among racial and ethnic minority adults: An innovative solution to increase influenza vaccinations. *Prev Med (Baltim)*. 2014;69:117-119. doi:10.1016/j.ypmed.2014.09.009.	Commentary
9	Poorman E, Gazmararian J, Parker RM, Yang B, Elon L. Use of Text Messaging for Maternal and Infant Health: A Systematic Review of the Literature. *Matern Child Health J*. 2014:969-989. doi:10.1007/s10995-014-1595-8.	Systematic review
9	Posadzki P, Mastellos N, Ryan R, et al. Automated telephone communication systems for preventive healthcare and management of long-term conditions. *Cochrane database Syst Rev*. 2016;12:CD009921. doi:10.1002/14651858.CD009921.pub2.	Review
9	Pubudu De Silva A, Lionel Harischandr PA, Beane A, et al. A data platform to improve rabies prevention, Sri Lanka. *Bull World Health Organ*. 2017;95(9):646-651. doi:10.2471/BLT.16.188060.	Lessons from the field
9	Rand CM, Tyrrell H, Wallace-Brodeur R, et al. A Learning Collaborative Model to Improve Human Papillomavirus Vaccination Rates in Primary Care. *Acad Pediatr*. 18(2, S):S46-S52.	Non-LMIC setting (US)
9	Rand CM, Brill H, Albertin C, et al. Effectiveness of centralized text message reminders on human papillomavirus immunization coverage for publicly insured adolescents. *J Adolesc Heal*. 2015;56(5):S17-S20. doi:10.1016/j.jadohealth.2014.10.273.	Non-LMIC setting (US)

	Citation	Reason for exclusion
9	Rand CM, Vincelli P, Goldstein NPN, Blumkin A, Szilagyi PG. Effects of Phone and Text Message Reminders on Completion of the Human Papillomavirus Vaccine Series. *J Adolesc Heal*. 2017;60(1):113-119. doi:https://doi.org/10.1016/j.jadohealth.2016.09.011.	Non-LMIC setting (US)
9	Regan AK, Bloomfield L, Peters I, Effler P V. Randomized Controlled Trial of Text Message Reminders for Increasing Influenza Vaccination. *Ann Fam Med*. 15(6):507-514. doi:10.1370/afm.2120.	Non-LMIC setting (US)
1	Reddy, R., Karthick, S., Sterlin, S. & Vigneshwari, S. Developing an application for rural development to provide medical services. *Int. J. Appl. Eng. Res.* 2015; 10, 7743–7749.	Full text not found
1	Roberts JR, Morella K, Dawley EH, et al. Direct-to-adolescent text messaging for vaccine reminders: What will parents permit? *Vaccine*. 2018;36(20):2788-2793. doi:S0264-410X(18)30466-3 [pii].	Non-LMIC setting (US)
1	Rock, C. *et al.* Abstracts of the 19th ECCMID (European Congress of Clinical Microbiology and Infectious Diseases). Helsinki, Finland. May 16-19, 2009. *Clin. Microbiol. Infect.* 2009; 15 Suppl 4, S38	Conference abstract
1	Russell, S. L. PIN62 Effectiveness of Text Message Reminders for Improving Vaccination Appointment Attendance and Series Completion Among Adolescents and Adults. *Value Heal.* 2017; 15, A248	Conference abstract
1	Schneyer, R. J., Yang, C. & Bocchini, J. A. Immunizing adolescents. *Curr. Opin. Pediatr.* 2015; 27, 405–417.	Review
1	Senarath U, Godakandage S, Jayawickrama H, et al. Development of an m-health intervention for the infant and young child feeding counselling in the plantation sector of Sri Lanka. *Ann Nutr Metab*. 2017;71:553. doi:10.1159/000480486.	Conference abstract
1	Seth R, Akinboyo I, Chhabra A, et al. Mobile Phone Incentives for Childhood Immunizations in Rural India. *Pediatrics*. March 2018. http://pediatrics.aappublications.org/content/early/2018/03/12/peds.2017-3455.abstract.	Cannot estimate vaccine type-specific risk ratios and risk differences
1	Sharma, A. *et al.* Automatic Text Message Based Vaccination Reminders to Improve Compliance. *J. Investig. Med. Febr.* 2015; 63, 459.	Conference abstract
1	Singh S, Sahu D, Agrawal A, Vashi MD. Ensuring childhood vaccination among slums dwellers under the National Immunization Program in India - Challenges and opportunities. *Prev Med (Baltim)*. 2018;112:54-60. doi:S0091-7435(18)30113-0 [pii].	Review
1	Smulian EA, Mitchell KR, Stokley S. Interventions to increase HPV vaccination coverage: A systematic review. *Hum Vaccin Immunother*. 2016;12(6):1566-1588. doi:10.1080/21645515.2015.1125055.	Systematic review

	Citation	Reason for exclusion
1	Sondaal SFV, Browne JL, Amoakoh-Coleman M, et al. Assessing the Effect of mHealth Interventions in Improving Maternal and Neonatal Care in Low- and Middle-Income Countries: A Systematic Review. *PLoS One*. 2016;11(5):e0154664. doi:10.1371/journal.pone.0154664.	Systematic review
1	Stockwell, M. S. & Fiks, A. G. Utilizing health information technology to improve vaccine communication and coverage. *Hum. Vaccines Immunother.* 2013; 9, 1802–1811.	Review
1	Stockwell, M. S., Hofstetter, A. M., Durivage, N. & Barrett, A. Text Message Reminders for Second Dose of Influenza Vaccine : A Randomized Controlled Trial. *Pediatrics*. 2015; 135.	Non-LMIC setting (US)
1	Stockwell, M. S. *et al.* Text4Health: impact of text message reminder-recalls for pediatric and adolescent immunizations. *Am. J. Public Health*. 2012; 102, e15-21.	Non-LMIC setting (US)
1	Stockwell, M. S. *et al.* Effect of a Text Messaging Intervention on Influenza Vaccination in an Urban, Low-Income Pediatric and Adolescent Population: A Randomized Control Trial. *J. Am. Med. Assoc.* 2012; 307, 1702–1708.	Non-LMIC setting (US)
1	Stockwell, M. S. *et al.* Influenza vaccine text message reminders for urban, low-income pregnant women: a randomized controlled trial. *Am. J. Public Health*. 2014; 104 Suppl, e7–e12.	Non-LMIC setting (US)
1	Stowers, C., Healey, L. & O'Connor, C. Short message service reminder intervention doubles sexually transmitted infection/HIV re-testing rates among men who have sex with men. *Sex. Health*. 2014; 11, 590–591.	Non-LMIC setting (US)
1	Sweisi, N. A., Eldresi, F. & Adams, C. e-government services to support vaccination programmes: Libya, a successful implementation. 3rd International Conference on e-Government. 2007.	Abstract
1	Szilagyi, P. & Adams, W. Text Messaging: A new tool for improving preventive services. *JAMA*. 2012; 307, 1–27.	Editorial
1	Thomson, A., Robinson, K. & Vallée-Tourangeau, G. The 5As: A practical taxonomy for the determinants of vaccine uptake. *Vaccine*. 2015; 34, 1018–1024.	Review
1	Uddin J, Biswas T, Adhikary G, et al. Impact of mobile phone-based technology to improve health, population and nutrition services in Rural Bangladesh: a study protocol. *BMC Med INFORMATICS Decis MAKING*. 17. doi:10.1186/s12911-017-0502-9.	Protocol
1	Vilella, A. *et al.* The role of mobile phones in improving vaccination rates in travelers. *Prev. Med. (Baltim).* 2004; 38, 503–9.	Non-LMIC setting (US)
1	Voos, J. *et al.* Medical event notification system using SMS technology. *J. Phys. Conf. Ser.* 2013; 477, 12015.	Description of platform development and implementation

	Citation	Reason for exclusion
1	Wakadha H, Chandir S, Were EV, et al. The feasibility of using mobile-phone based SMS reminders and conditional cash transfers to improve timely immunization in rural Kenya. *Vaccine*. 2013;31(6):987-993. doi:10.1016/j.vaccine.2012.11.093	No control/comparison group
1	Warwick, Z., Dean, G. & Carter, P. B safe, B sorted: results of a hepatitis B vaccination outreach programme. *Int. J. STD AIDS.* 2007; 18, 335–337.	No control/comparison group
1	Watterson, J. L., Walsh, J. & Madeka, I. Using mHealth to Improve Usage of Antenatal Care, Postnatal Care, and Immunization: A Systematic Review of the Literature. *Biomed Res. Int.* 2015.	Systematic review
1	Yudin MH, Mistry N, De Souza LR, et al. Text messages for influenza vaccination among pregnant women: A randomized controlled trial. *Vaccine*. 2017;35(5):842-848. doi:10.1016/j.vaccine.2016.12.002.	Non-LMIC setting (Canada)
1	Yudin MH, Mistry N, de Souza L, et al. Text message reminders do not increase the likelihood of influenza vaccination among pregnant women. *Am J Obstet Gynecol*. 2015;213(6):904. doi:10.1016/j.ajog.2015.09.053.	Conference abstract

Table 3.3. Key characteristics of included studies

RANDOMIZED CONTROLLED TRIALS					
Reference	**Study & participant recruitment sites**	**Country income classification***	**Mobile phone ownership/access required**	**Targeted vaccines and SMS reminder intervention†**	**Comparison**
1. Bangure 2015[31]	Zimbabwe; Kadoma City Health facility (N=3)	Low	Ownership required	*Vaccine/dose (scheduled age):* Penta1, OPV1, PCV1 (6w) Penta2, OPV2, PCV2 (10w) Penta3, OPV3, PCV3 (14w) *Frequency:* 7 days, 3 days and 1 day before scheduled vaccination	Usual care (health education)
2. Domek 2016[33]	Guatemala; Guatemala City Health facility (N=2)	Lower middle	Ownership required	*Vaccine/dose (scheduled age)*: Penta2, Polio2, PCV2, Rota2 (4m) Penta3, Polio3 (6m) *Frequency:* 6, 4 and 2 days before scheduled vaccinations	Usual care (written reminder in child immunization card)
3. Eze 2015[34]	Nigeria; Egor area in Edo State Health facility (N=8)	Lower middle	No‡	*Vaccine/dose (scheduled age)*: DTP2 (10w) DTP3 (14w)	No reminder/recall messages

					*Frequency:*1 day before scheduled vaccination	
4.	Gibson 2017[35]	Kenya; Rarieda and Gem sub-counties Village (N=152)	Lower middle	Ownership or access required	*Vaccine/dose (scheduled age)*: Penta1 (6w) Penta2 (10w) Penta3 (14w) Measles (9m) *Frequency:* 3 days and 1 day before scheduled vaccination	Usual care (next due date written in immunization card)
5.	Kazi 2018[36]	Pakistan; Ibrahim Haidry union council, Karachi Household recruitment	Lower middle	Ownership at the household level	*Vaccine/dose (scheduled age):* Penta1 (6w) Penta2 (10w) Penta3 (14w) *Frequency*: 4 reminders on the week when vaccination is recommended	Pentavalent series counseling at enrollment
6.	Schlumberger 2015[37]	Burkina Faso; Do medical district Health facility (N=1)	Low	Ownership or access required	*Vaccine/dose (scheduled age)*: Penta1, PCV1, Rota1, OPV1 (2m) Penta2, PCV2, Rota2, OPV2 (3m) Penta3, PCV3, Rota3, OPV3 (4m) MCV1, YF (9m)	Usual care (vaccine schedules in child health cards, EPI posters, information from neighborhood EPI committees and health facility staff)

				Frequency: Not specified	
QUASI-EXPERIMENTAL STUDIES					
Reference	**Study & participant recruitment sites**	**Country income classification***	**Mobile phone ownership/access required**	**SMS reminder intervention**	**Comparison**
7. Chen 2016[38]	China; Sichuan province Village (N=32)	Upper middle	No	*Vaccine/dose (scheduled age)*: BCG, HBV1 (birth) HBV2 (1m) Polio1 (2m) DTP1, Polio2 (3m) DTP2, Polio3 (4m) DTP3 (5m) HBV3 (6m) MCV1 (8m)§ *Frequency:* Not specified	No text message reminders (baseline)
8. Garcia-Dia 2017[39]	Philippines; Bago City Health facility (N=1)	Lower middle	No; study provided mobile phones	*Vaccine/dose (scheduled age)*: MCV2/MMR (12-15m) § *Frequency:* One reminder 7-10 days before scheduled appointment	Usual care (household reminder visits)
9. Haji 2016[40]	Kenya; Langata, Machakos and Njoro districts Health facilities (N=9)	Lower middle	Ownership or access required	*Vaccine/dose (scheduled age)*: Penta2 (10w) Penta3 (14w)	Usual care (written reminder in child immunization card). Plus health education,

				Frequency: 2 days before, and on, the scheduled vaccination day	vaccination counseling
10. Nguyen 2017[20]	Vietnam; Ben Tre province Sub-sample of all births in Ben Tre province	Lower middle	Ownership required	*Vaccine/dose (scheduled age)* Hepatitis b (birth) BCG (0-30 d) Quinvaxem1, Polio1 (2m) Quinvaxem2, Polio2 (3m) Quinvaxem3, Polio3 (4m) MCV1 (9-11m) *Frequency:* Not specified	Paper-based reminders[47]
11. Uddin 2016[32]	Bangladesh; Sunamgonj district and Dhaka city Community clusters (N=40)	Lower middle	No	*Vaccine/dose (scheduled age)*: BCG (birth) Penta1 (6w) Penta2 (10w) Penta3 (14w) MCV1 (9m) *Frequency:*1 day before scheduled EPI vaccination session, opening time and closing time on the scheduled day	No reminders (control areas) and baseline in intervention area for difference-in-differences analysis

*As classified by The World Bank.[23] †Abbreviations: BCG = Bacille Calmette-Guerin; DTP2, DTP3 = Second and third dose diphtheria, tetanus & pertussis antigen-containing vaccine; m = months; MCV1 = First dose measles-containing vaccine; PCV1, PCV2, PCV3 = First, second and third dose pneumococcal conjugate vaccine; Penta1, Penta2, Penta3 = First, second and third dose pentavalent vaccine (DTP, *Haemophilus influenzae* type B and hepatitis B combination vaccine); Polio1, Polio2, Polio3 = First,

second and third dose polio vaccine; Quivaxem1, Quinvaxem2, Quivaxem3 = first, second and third dose of Quivaxem vaccine (DTP, *Haemophilus influenzae* type B and hepatitis B combination vaccine); Rota1, Rota2, Rota3 = First, second and third dose rotavirus vaccine; w = weeks; YF = Yellow fever vaccine. ‡ Participants who did not own a phone were not allocated to the intervention arm. §Vaccination schedule not specified in paper, obtained from external source[46]

Table 3.4. Vaccination coverage in intervention children compared to comparison children for key outcomes assessed

RANDOMIZED CONTROL TRIALS					
Reference	**Key outcomes assessed**	**Intervention**		**Comparison**	
		n	**%**	**n**	**%**
Domek 2016[33]	DTP3 by age ~8-9.5 months[†]	160	84.4	161	80.7
Gibson 2017[35]	DTP3 by age 12 months	388	96.7	360	98.1
	MCV1 by age 12 months	388	87.1	360	83.9
	FIC by age 12 months	388	85.6	360	82.2
Schlumberger 2015[37]	DTP3 by unspecified age[‖]	274	60.3	298	42.3
QUASI-EXPERIMENTAL STUDIES					
Reference	**Key outcomes assessed**	**Intervention**		**Comparison**	
		n	**%**	**n**	**%**
Chen 2016[38]	DTP3 by age 12 months	104[‡]	89.4	109[‡]	83.3
	MCV1 by age 12 months	104	90.4	109	81.0
	FIC by age 12 months	104	81.7	109	71.4
Garcia-Dia 2017[39]	MCV2/MMR by age 15-17 months	25	76.0	25	68.0
Nguyen 2017[20]	FIC by age 12 months	3,374	99.2	3,997	75.4
Uddin 2016[32,§]	BCG + DTP3 at age >18 weeks to 11 months	524/ 677	73.5/ 80.2	517/ 484	79.7/ 75.6
	FIC at age > 9months and 28 days to 11 months	208/ 156	60.1/ 66.0	196/ 122	63.3/ 53.3

[*]Abbreviations: BCG = bacille Calmette-Guerin; DTP3 = third dose diphtheria, tetanus & pertussis antigen-containing vaccine; FIC = Full immunization coverage (as defined by authors); MCV1 = First dose measles-containing vaccine; Penta3 = third dose pentavalent vaccine (DTP, *Haemophilus influenzae* type B and hepatitis B combination vaccine). [†]The range in age was due to enrollment at age 8-14 weeks. All enrolled children were followed for six months. [‡]Only data from the study's control group were used because an additional intervention (smartphone app) was used in the study's intervention group. To estimate the RR and RD, we used the study's control group's endline data as the "intervention" data and the study's control group's baseline data as the "comparison" data.

[§]Intervention and comparison numbers and percentages depict pre- and post-intervention data, respectively. RRs and RDs estimated using a difference-in-differences approach e.g., the RR represents the degree to which the relative change in vaccination uptake among SMS reminder recipients exceeds the relative change in vaccination uptake in the comparison group over the same period. [‖]Specific age could not be determined but included assessment of vaccination status among catch-up age children (M Schlumberger, personal communication); the same study assessed timeliness within 9 days of the recommended age therefore this measure indicates coverage at older ages.

Table 3.5. Vaccination timely coverage in intervention children compared to comparison children for key outcomes assessed

RANDOMIZED CONTROL TRIALS					
Reference	**Key outcomes assessed***	**Intervention**		**Comparison**	
		n	**%**	**n**	**%**
Bangure 2015[31]	DTP3 at age 14 weeks	152	95.0	152	75.0
Domek 2016[33]	DTP3 at age ≤6.5 months	160	60.6	161	59.6
Eze 2015[34]	DTP3 at age ≤18 weeks	452	69.0	453	60.3
Gibson 2017[35]	DTP3 at age ≤16 weeks	388	74.2	360	74.2
	MCV1 at age ≤9 months + 2 weeks	388	59.5	360	50.8
	Full immunization at age ≤9 months + 2 weeks	388	58.8	360	50.3
Kazi 2018[36]	DTP3 at age 14 weeks	150	31.3	150	26.0
Schlumberger 2015[37]	DTP3 by age 4 months + 10 days	154	29.2	114	25.4
QUASI-EXPERIMENTAL STUDIES					
Reference	**Key outcomes assessed***	**Intervention**		**Comparison**	
		N	**%**	**N**	**%**
Haji 2016[40]	Penta3 at age 14 weeks	372	96.5	372	83.1
Nguyen 2017[20]	Quinvaxem3 by age 5 months	3,997	53.6	3,374	77.2
	MCV1 by age ~10.8 months	3,997	70.4	3,374	92.3

*Abbreviations: BCG = bacille Calmette-Guerin; DTP3 = third dose diphtheria, tetanus & pertussis antigen-containing vaccine; FIC = Full immunization coverage (as defined by authors); MCV1 = First dose measles-containing vaccine; Penta3 or Quinvaxem3 = third dose pentavalent vaccine or Quinvaxem vaccine (DTP, *Haemophilus influenzae* type B and hepatitis B combination vaccine). †Only data from the study's control group were used because an additional intervention (smartphone app) was used in the study's intervention group. To estimate the RR and RD, we used the study's control group's endline data as the "intervention" data and the study's control group's baseline data as the "comparison" data.

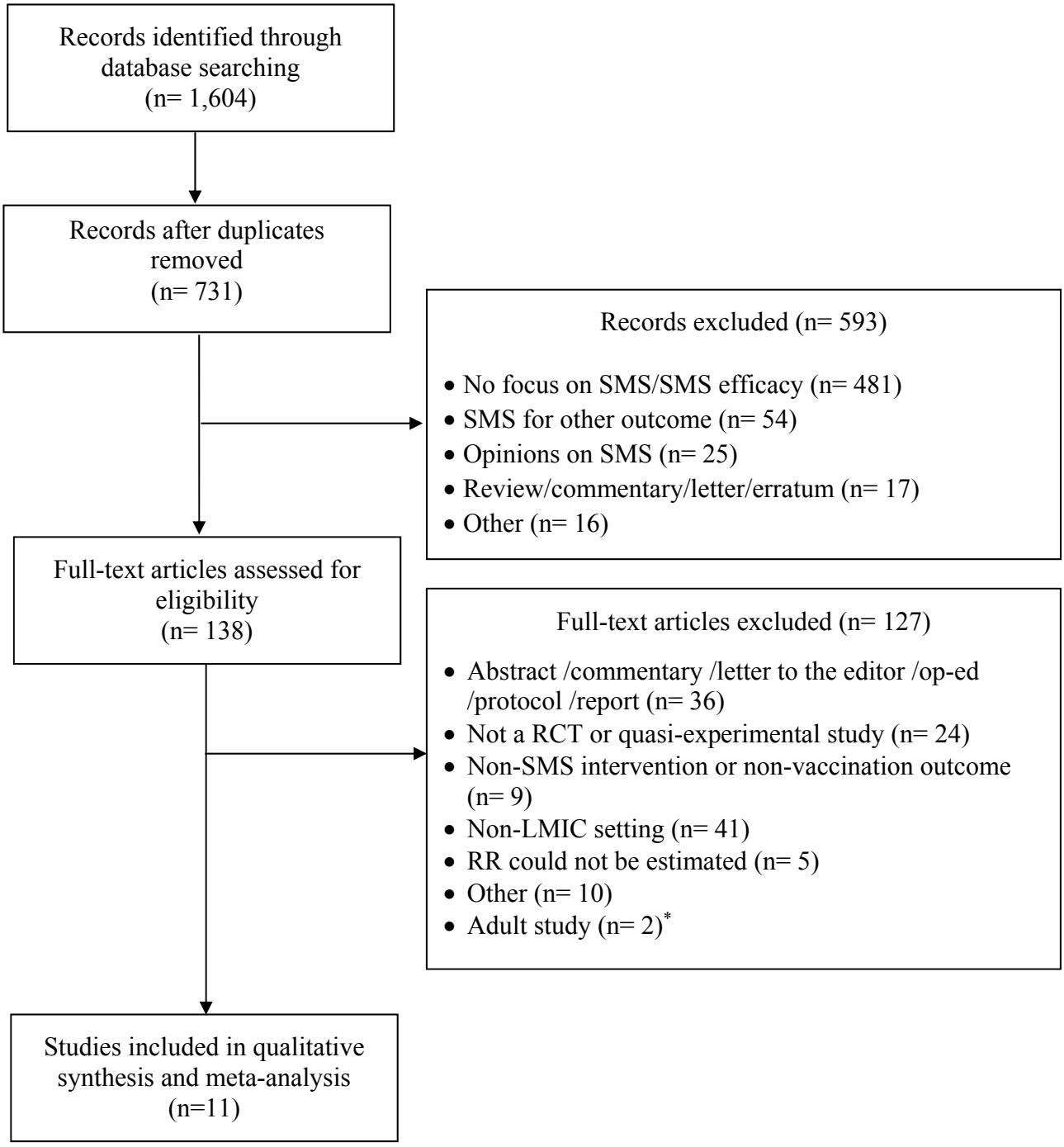
Table 3.6. Quality of evidence assessment using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group's criteria

DTP3 OVERALL COVERAGE, RCTs							
	No. participants (No. studies)	**Methodological quality**	**Consistency**	**Directness**	**Effect size**	**Pooled estimate (95% CI)**	**Quality**
Score	1,641 (3 studies)	-1	-1	0	0	RR: 1.11 (0.95,1.31) RD: 6.3% (-5.2%, 17.8%	Low; Score= 2
Explanation - Methodological quality	High risk of selection bias and attrition bias,[33] unclear risk of detection bias and attrition bias[37] (**Figure 3.2**)						
Explanation - Consistency	Considerable heterogeneity (subgroup I-squared = 90.0%; **Figure 3.4**)						
DTP3 OVERALL COVERAGE, QUASI-EXPERIMENTAL STUDIES							
	No. participants (No. studies)	**Methodological quality**	**Consistency**	**Directness**	**Effect size**	**Pooled estimate (95% CI)**	**Quality**
Score	2,415 (2 studies)	-1	0	0	0	RR: 1.12 (1.04,1.20) RD: 9.0% (3.4%, 14.6%)	Very low; Score= 1
Explanation - Methodological quality	High risk of selection bias,[32,38] unclear risk of detection bias[32,38] and attrition bias[32] (**Figure 3.3**)						
FIC, QUASI-EXPERIMENTAL STUDIES							
	No. participants (No. studies)	**Methodological quality**	**Consistency**	**Directness**	**Effect size**	**Pooled estimate (95% CI)**	**Quality**

Score	8,266 (3 studies)	-1	0	0	0	RR: 1.27 (1.16,1.39) RD: 18.1% (8.5%, 27.6%)	Low; Score= 2
Explanation - Methodological quality	High risk of selection bias,[20,32,38] high[20] and unclear[32,38] risk of detection bias, unclear risk of attrition bias[32] and reporting bias[20] (**Figure 3.3**)						
DTP3 TIMELY COVERAGE, RCTs							
	No. participants (No. studies)	**Methodological quality**	**Consistency**	**Directness**	**Effect size**	**Pooled estimate (95% CI)**	**Quality**
Score	2,846 (6 studies)	-1	-1	0	0	RR: 1.12 (1.01, 1.25) RD: 7.0% (0.1%, 14.0%)	Low; Score= 2
Explanation - Methodological quality	High[33,34] or unclear[31] risk of selection bias, high[35] or unclear[31,36,37] risk of detection bias and high[33] or unlear[37] risk of attrition bias (**Figure 3.2**)						
Explanation - Consistency	Moderate heterogeneity (I-squared= 69.7% - 76.8%; **Figure 3.11**)						
DTP3 TIMELY COVERAGE, QUASI-EXPERIMENTAL STUDIES							
	No. participants (No. studies)	**Methodological quality**	**Consistency**	**Directness**	**Effect size**	**Pooled estimate (95% CI)**	**Quality**
Score	8,115 (2 studies)	-1	-1	0	0	RR: 1.29 (1.05, 1.60) RD: 18.7% (8.8%, 28.6%)	Very low; Score= 0
Explanation - Methodological quality	High[20] or unclear[40] risk of selection bias, high risk of detection bias,[20,40] and unclear risk of reporting bias[20] (**Figure 3.3**)						
Explanation - Consistency	High heterogeneity (I-squared= 94.3% - 97.9%; **Figure 3.11**)						

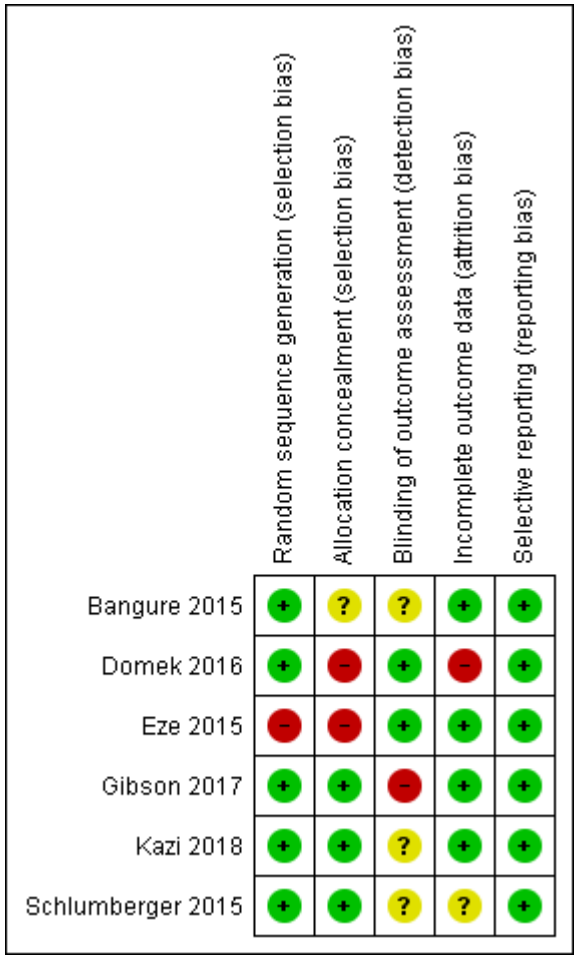
Chapter 3 Figures

Figure 3.1. PRISMA study selection flow diagram



*Adult studies are excluded from this analysis focusing on vaccination coverage and timeliness among children, but they are not an exclusion criterion in the protocol

Figure 3.2. Risk of bias summary and risk of bias graph for included randomized controlled trials. The within-study risk of bias for each domain assessed is shown in the risk of bias summary. The risk of bias graph shows the proportion of studies with low, unclear or high risk of bias for each domain assessed.



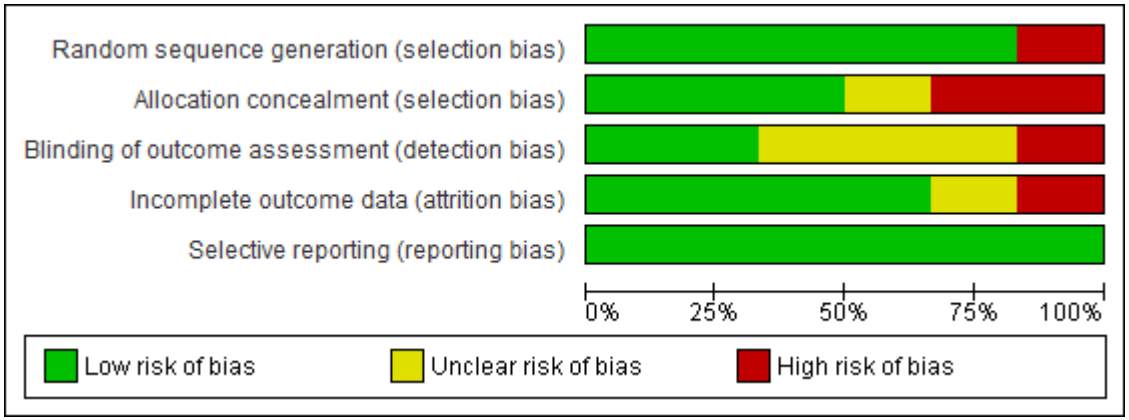
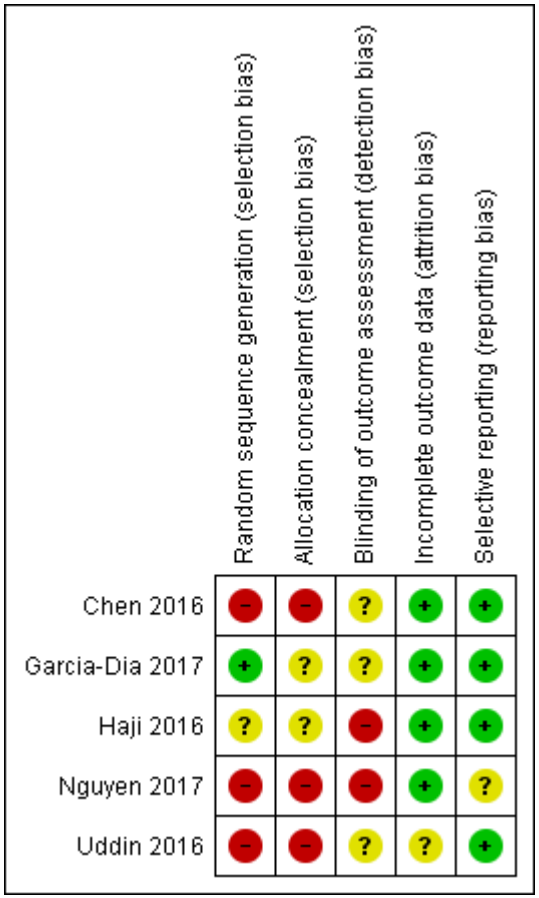


Figure 3.3. Risk of bias summary and risk of bias graph for included quasi-experimental studies. The within-study risk of bias for each domain assessed is shown in the risk of bias summary. The risk of bias graph shows the proportion of studies with low, unclear or high risk of bias for each domain assessed.



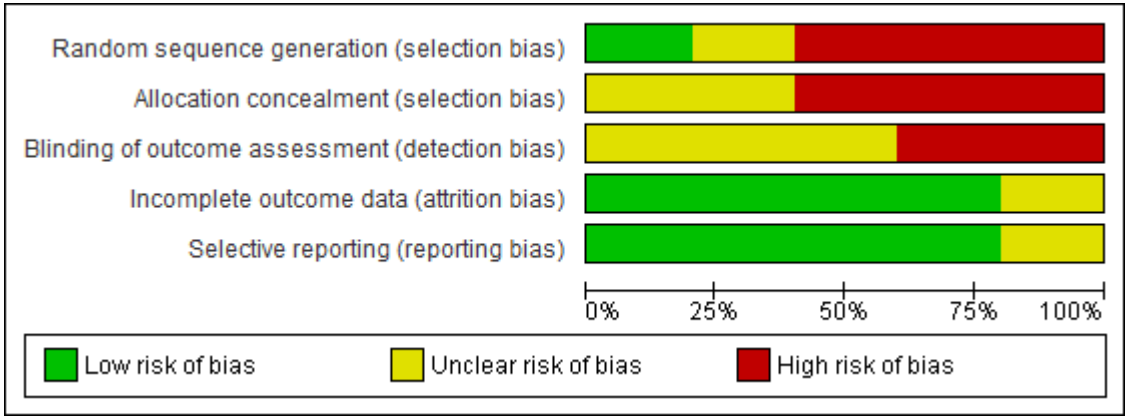


Figure 3.4. Summary relative risk of DTP3 overall coverage among SMS reminder infants compared to non-SMS reminder infants, by study design

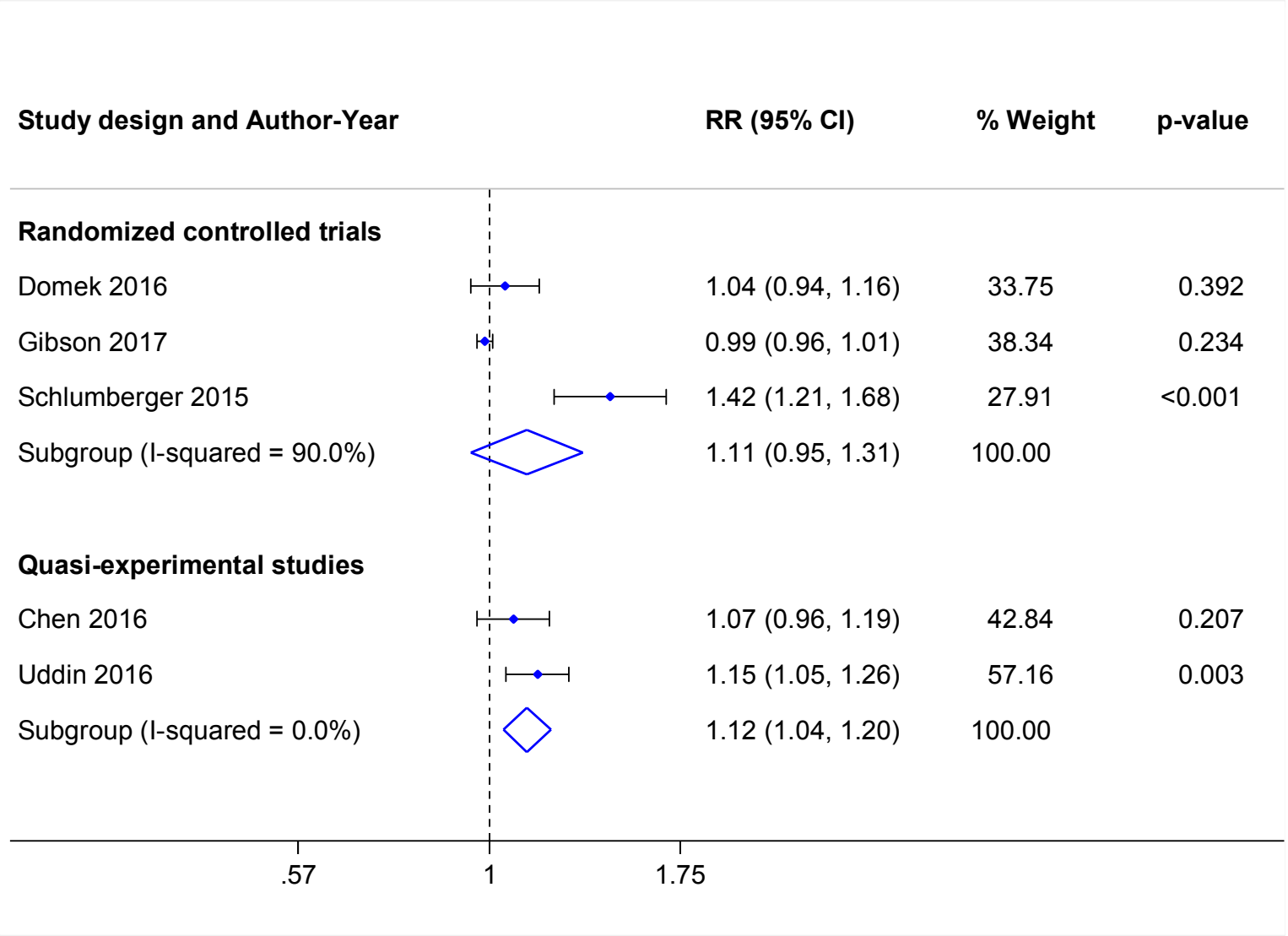


Figure 3.5. Summary difference in DTP3 overall coverage at older ages among SMS reminder infants compared to non-SMS reminder infants, by study design

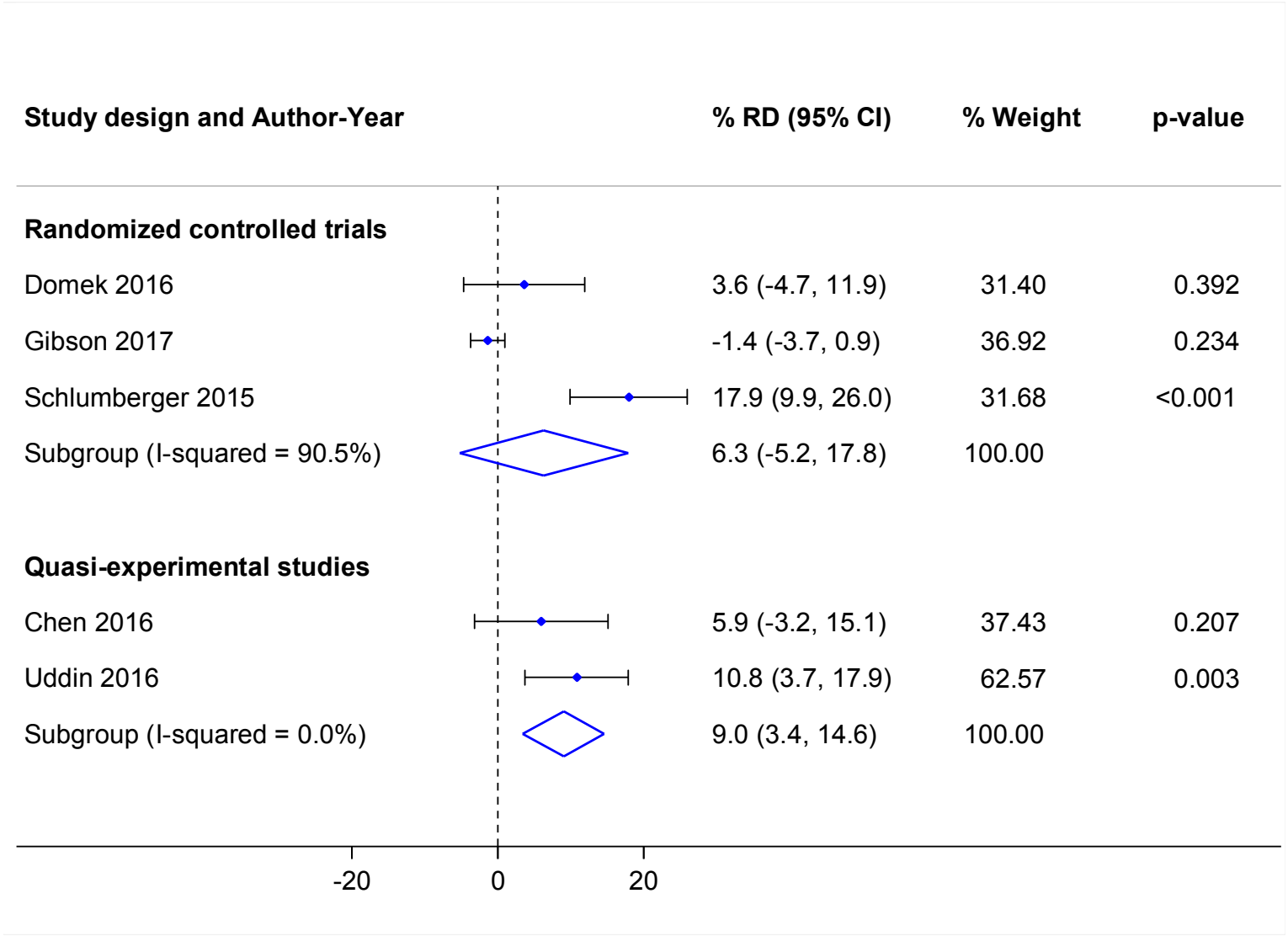


Figure 3.6. Sensitivity analysis: Summary relative risk of DTP3 vaccination coverage among SMS reminder infants compared to non-SMS reminder infants, by study design

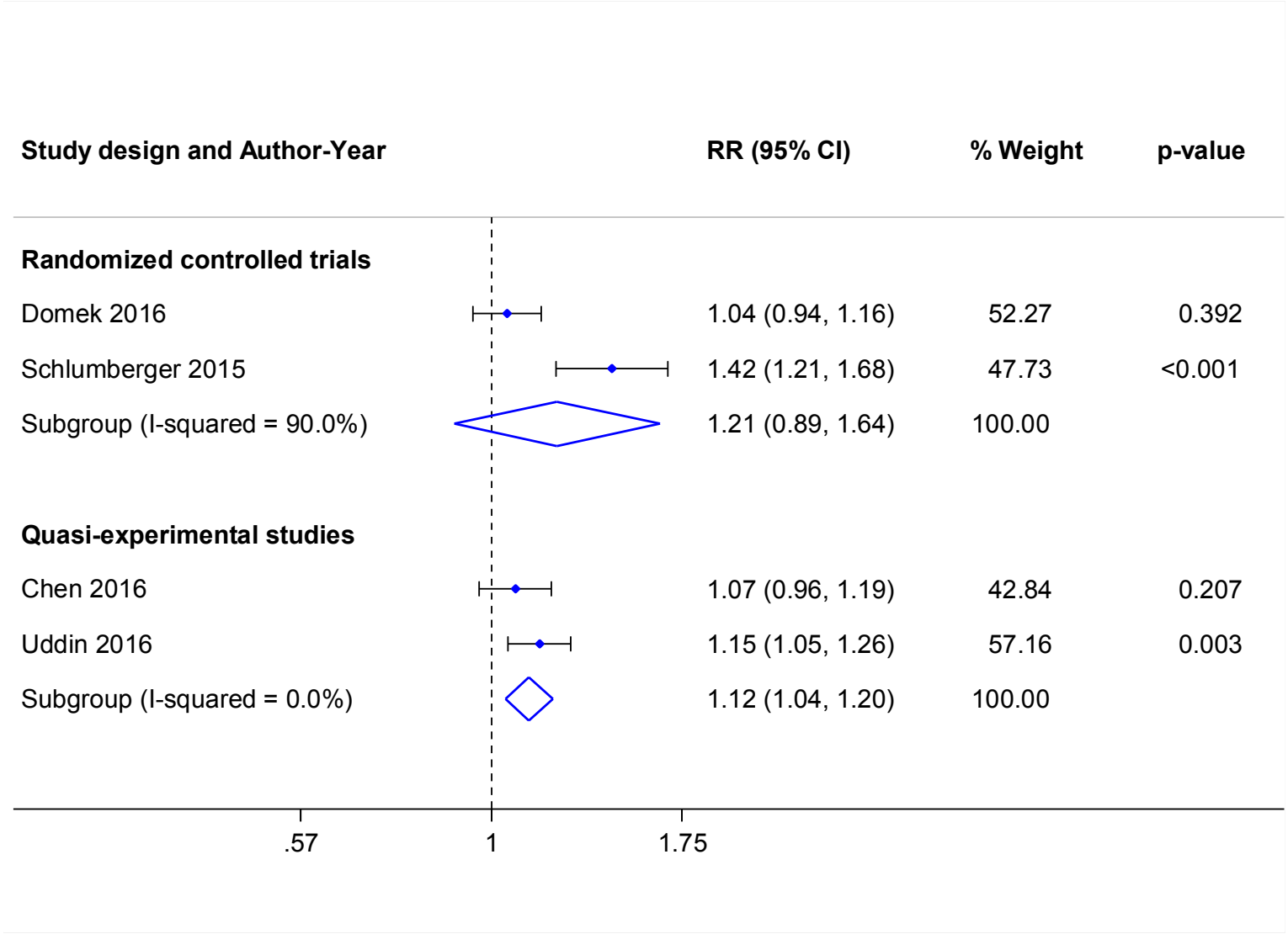


Figure 3.7. Sensitivity analysis: Summary difference in DTP3 overall coverage among SMS reminder infants compared to non-SMS reminder infants, by study design

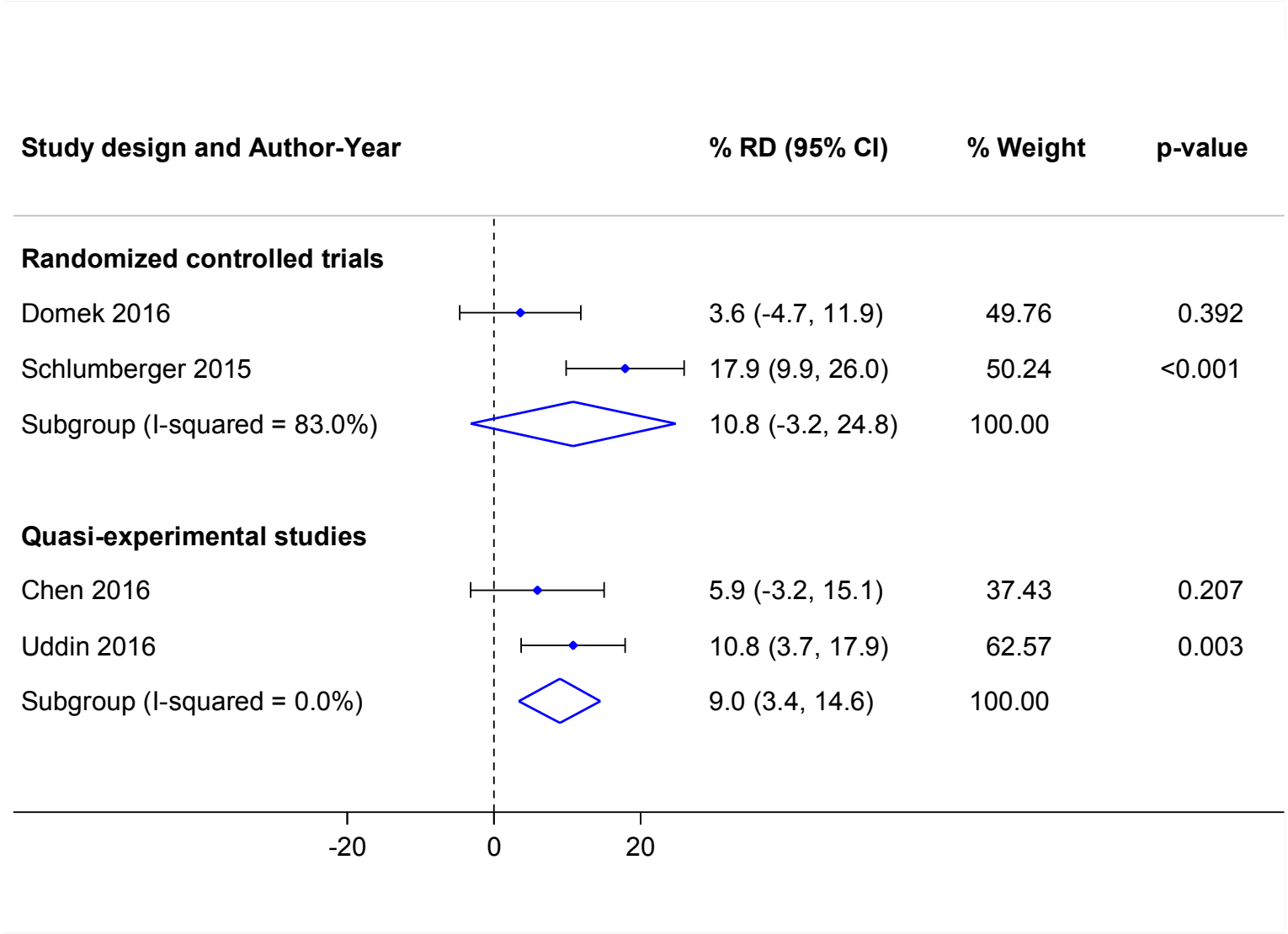


Figure 3.8. Summary relative risk of achieving full immunization coverage among SMS reminder infants compared to non-SMS reminder infants, by study design

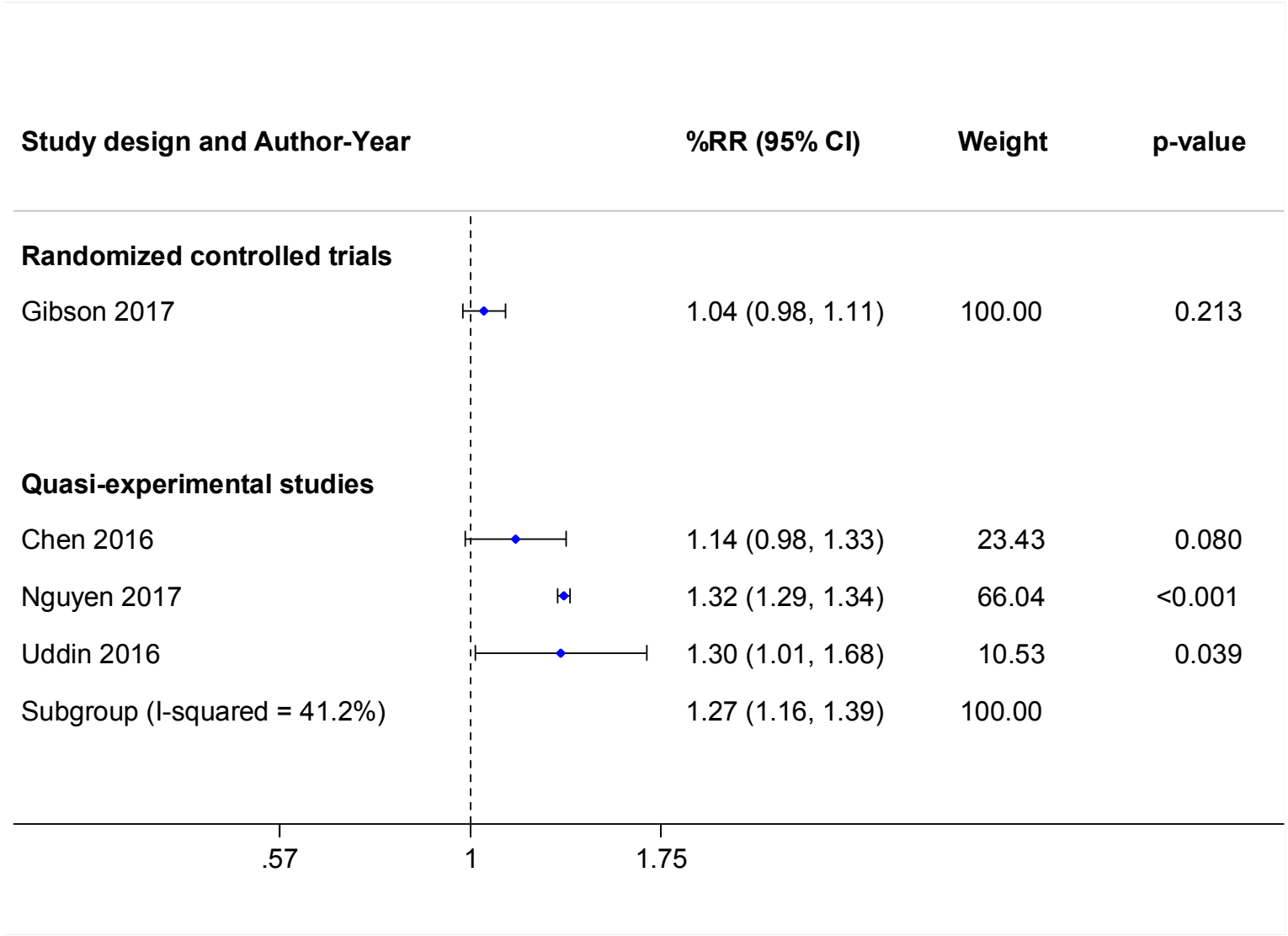


Figure 3.9. Summary difference in full immunization coverage among SMS reminder infants compared to non-SMS reminder infants, by study design

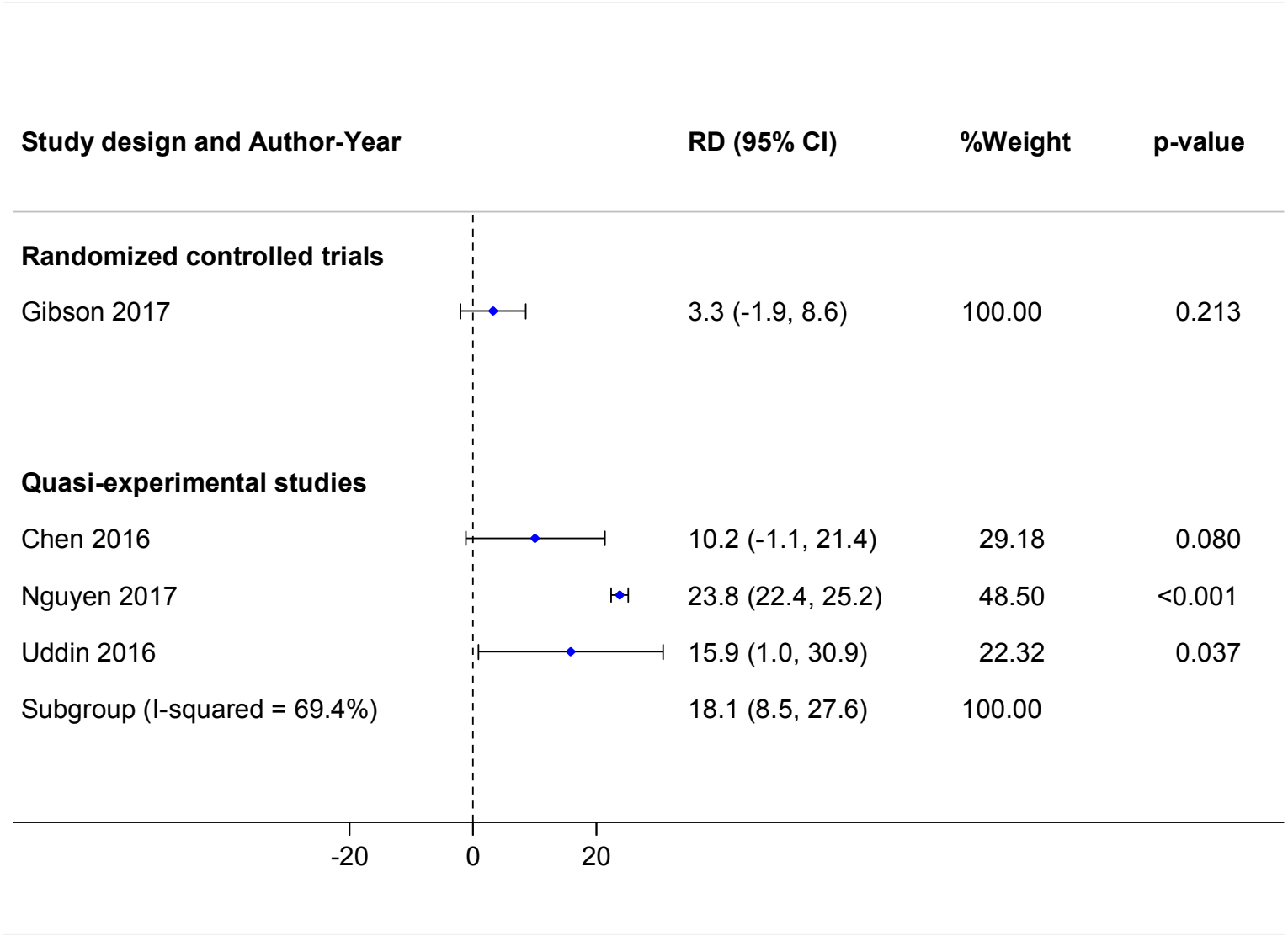


Figure 3.10. Summary relative risk of achieving DTP3 timeliness among SMS reminder infants compared to non-SMS reminder infants, by study design

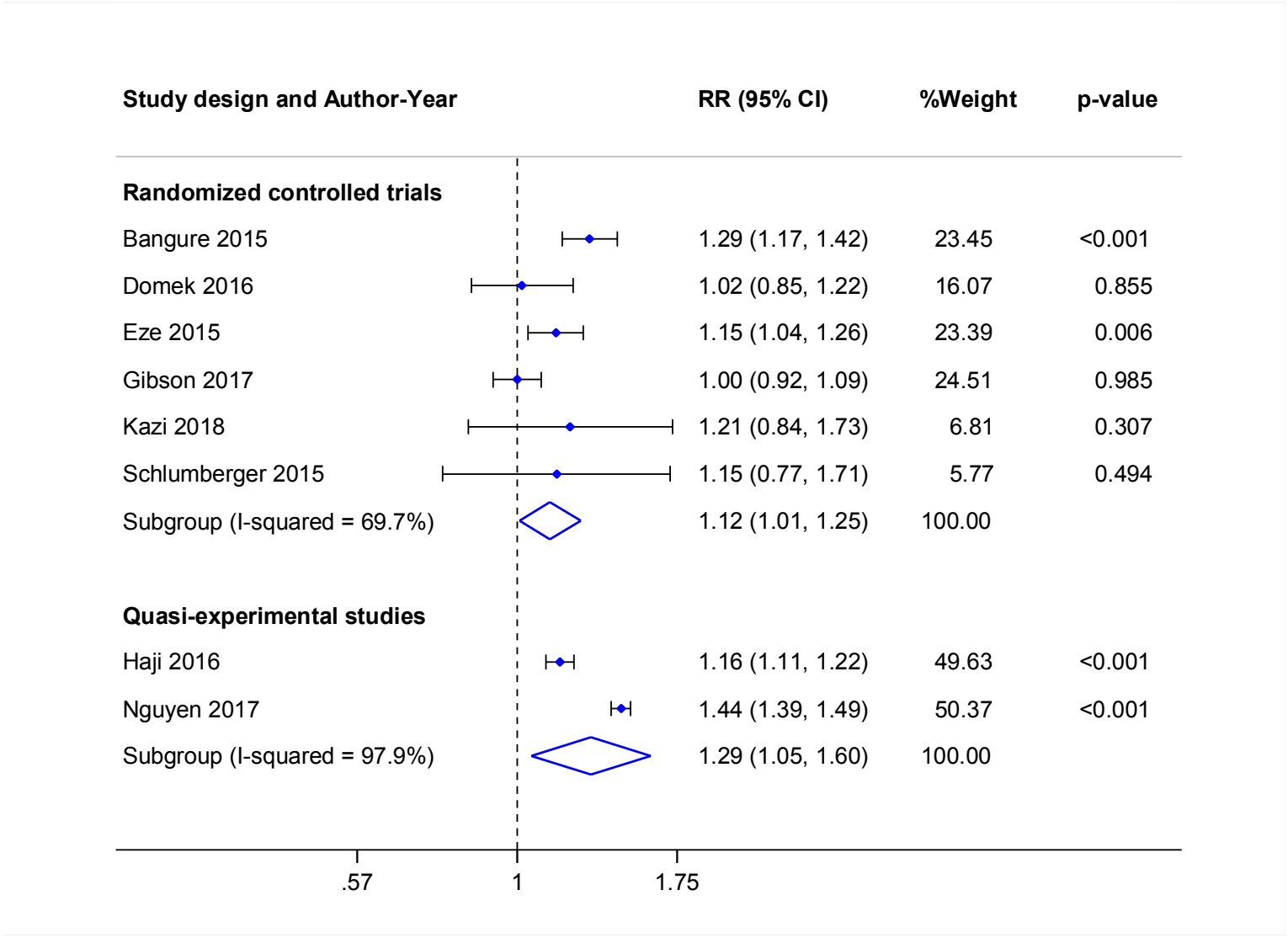
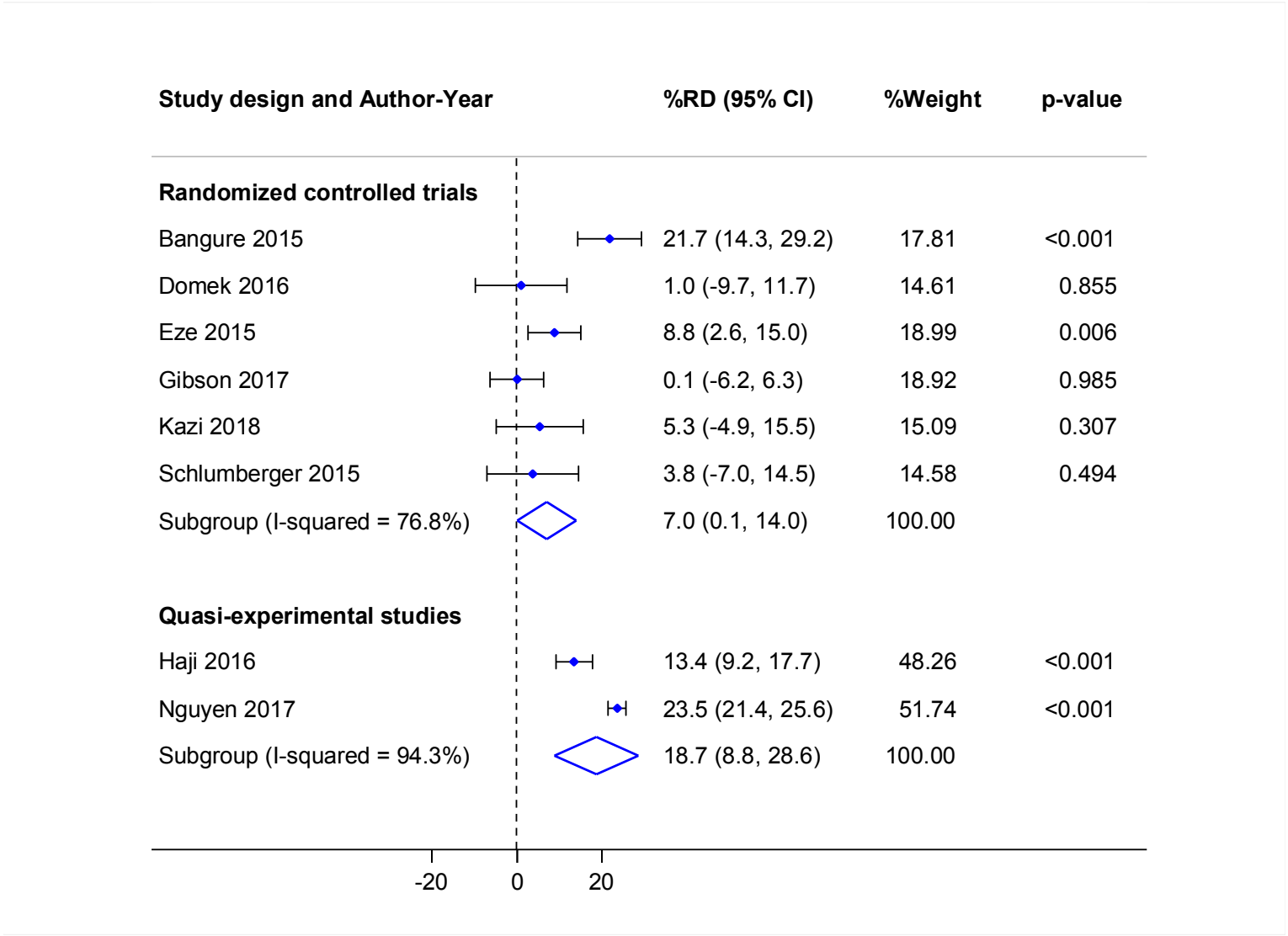


Figure 3.11. Summary difference in DTP3 timely coverage among SMS reminder infants compared to non-SMS reminder infants, by study design



CHAPTER 4: A RANDOMIZED CONTROLLED TRIAL ASSESSING THE EFFICACY OF TEXT MESSAGE REMINDERS WITH OR WITHOUT UNCONDITIONAL MONETARY INCENTIVES TO IMPROVE MEASLES VACCINATION COVERAGE AND TIMELINESS IN RURAL WESTERN KENYA (THE M-SIMI STUDY)

4.1. Abstract

Background

High levels of mobile phone ownership and access in low and middle income countries provide an opportunity to improve vaccination coverage through the use of mobile phone based interventions. A previous cluster randomized controlled trial that we conducted (the M-SIMU study) found that short message service (SMS, or text message) reminders coupled with or without conditional monetary incentives improved vaccination uptake in rural Kenya. Because conditional incentives require real-time monitoring of vaccination status, they are challenging to scale up. We conducted a different trial, the 'Mobile and Scalable Innovations for Measles Immunization' (M-SIMI) study, to evaluate the impact of SMS reminders with or without an *unconditional* monetary incentive - which may represent a more scalable approach - on first dose measles vaccination (MCV1) timeliness and coverage in rural western Kenya.

Methods

Infants age 6 to 8 months old were identified from the community by Community Health Volunteers. Infants meeting study eligibility criteria were enrolled into an individually-randomized controlled trial and assigned to one of three study arms: Control; SMS reminders only (SMS only); and SMS plus 150 Kenya Shillings (KES) incentive (SMS+150KES). Infants randomized to the Control arm received no intervention. Those randomized to the SMS only arm were sent two SMS reminders for measles vaccination, three days and one day before the scheduled vaccination date. Infants randomized to the SMS +150 KES arm were sent two SMS reminders on the same schedule as SMS only arm infants as well as a KES 150 (~US $1.50 as of December 2016) incentive, sent three days before the scheduled measles vaccination date. At

enrollment, Community Interviewers (CIs) collected data on baseline characteristics. When infants reached age 12 months, CIs conducted a follow-up visit to ascertain vaccination status.

The primary outcome was measles vaccination by age 10 months (timeliness endpoint). MCV1 receipt by age 12 months, time to measles vaccination, and the mean number of days undervaccinated for measles were secondary outcomes. Using log-binomial regression, the relative risk (RR) and 95% confidence interval (95% CI) of vaccination in each intervention arm compared to the control arm was computed for measles vaccination by age 10 months and by age 12 months, separately. The risk difference (RD) and 95% CI for measles vaccination in each intervention arm compared to the control arm by age 10 months and age 12 months, separately, was also computed using binomial regression. Both the RR and RD were analyzed using intention-to-treat (ITT) and per-protocol (PP) principles. Regression models adjusted for any unequally distributed baseline characteristics that were also likely to influence vaccine-seeking. Stratified analysis for key demographic variables was performed to assess effect modification of the intervention on measles vaccination by age 10 months. Time to measles vaccination by age 12 months for each arm was plotted using the Kaplan-Meier method and the median, first quartile (Q1) and third quartile (Q3) obtained. Differences in the mean number of days undervaccinated were compared using the two-sample t-test with unequal variances.

Results

Of 639 infants assessed for eligibility, 537 met inclusion criteria and were randomized to each of the study arms (N= 179 in each arm). The analytic sample included 160 Control arm, 146 SMS only arm and 149 SMS+150KES arm infants. The proportion of infants receiving MCV1 by age 10, i.e., **MCV1 timely coverage**, was 68.1% (N= 109), 78.1% (N= 114) and 77.9% (N= 116) in the Control arm, SMS only arm and SMS+150KES arm, respectively. The proportion of infants

receiving MCV1 by age 12 months, i.e., **MCV1 overall coverage**, was 78.1% (N= 125), 84.2% (N= 123) and 84.6% (N= 126) in the Control arm, SMS only arm and SMS+150KES arm, respectively.

The likelihood of measles vaccination by age 10 months was not significantly higher in the SMS only arm compared to the Control arm (adjusted RR [aRR] 1.13; 95% CI: 0.99, 1.30; p= 0.070) but was significantly higher in the SMS+150KES arm compared the Control arm (aRR 1.16; 95% CI: 1.01, 1.32; p= 0.035). Regression models were adjusted for maternal age which was unevenly distributed across study arms. The adjusted difference in timely vaccination coverage in the SMS only arm compared to the Control arm was 9.2%, though not significantly different (95% CI: -0.6, 19.0; p= 0.066) while timely coverage was significantly higher in the SMS+150KES arm compared to the Control arm (aRD 10.0; 95% CI: 0.8, 20.3; p= 0.034). Results from the ITT analysis were similar to those from the PP analysis with the exception that MCV1 timely coverage in the SMS only arm was significantly higher than that in the Control arm (per-protocol aRD 10.2; 95% CI: 0.1, 20.3; p= 0.048). Neither mobile phone ownership status, age at enrollment, birth order, travel time to a health facility or maternal educational level significantly modified the effect of the interventions (stratum-specific p-values >0.05 and overall interaction term p-values >0.05).

The likelihood of measles vaccination by age 12 months was not significantly higher among intervention arm infants compared to Control arm infants (SMS only: aRR 1.07 95% CI: 0.96, 1.19; p= 0.199; SMS+150KES: aRR 1.09; 95% CI: 0.97, 1.20; p= 0.156). Similarly, compared to the Control arm, MCV1 overall coverage was not significantly higher in the SMS only arm (aRD 5.7; 95% CI: -3.0, 14.3; p= 0.199) or in the SMS+150KES arm (aRD 6.8; 95% CI: -1.8, 15.3; p= 0.119). Inferences from the ITT analysis were the same as from the PP analysis.

There was no significant difference in time to measles vaccination across study arms (log-rank test p= 0.182) nor in the mean number of days undervaccinated.

Conclusions

SMS reminders coupled with an unconditional incentive may be used to improve measles vaccination timeliness in settings without substantial supply-side barriers to vaccination. There is some suggestion that, when implemented with fidelity, SMS reminders alone may also improve vaccination timeliness. Common determinants of vaccine-seeking behavior did not modify the effect of the interventions on measles vaccination timeliness. The analysis was underpowered to observe an effect of the interventions on vaccination coverage by age 12 months.

Funding

Bill & Melinda Gates Foundation

4.2. Introduction

Vaccination is estimated to prevent up to 3 million deaths annually[1] and is projected to avert as many as 426 million of cases of disease between 2011 and 2020.[2] However, the full potential of vaccines to prevent morbidity and mortality, remains unrealized due to sub-optimal vaccine coverage and inequitable access to vaccines. Higher vaccination coverage and more equitable access to vaccines would increase by 1.5 million the number of deaths averted every year.[3]

In 2016, there were an estimated 89,780 measles deaths and 186,811 reported measles cases globally. This reported number of measles cases likely underestimates the true burden of disease as 52% of reporting countries in 2016 were deemed to have weak measles surveillance, [4] caregivers may not seek measles treatment and surveillance systems may under-report measles cases.[5–7] According to the 2011-2020 Global Vaccine Action Plan (GVAP), measles was expected to be eliminated in four of six World Health Organization (WHO) regions by 2015,[8] but had been eliminated in only the Americas region by 2016. Failure to achieve the elimination target is largely attributable to suboptimal measles vaccination coverage.[4] In 2016, global coverage with the first and second dose measles-containing vaccines (MCV) was 86% and 64%, respectively,[9] both levels falling below the 95% coverage with two vaccine doses needed for measles elimination.[10] Beyond protecting against measles virus infection, MCVs are also thought to reduce all-cause mortality in children.[11]

Inequalities in vaccination coverage are evident at the global level whereby, for example, coverage with the first dose of measles-containing vaccine (MCV1) is greater than 90% in the

Americas, Europe and Western Pacific WHO regions and 87%, 77% and 72% in the South-East Asia, Eastern Mediterranean and Africa WHO regions, respectively. Furthermore, and possibly correlated to disparities in vaccination coverage by WHO region, MCV1 overall coverage in low-income and lower-middle-income countries was 76% and 81% in 2016, respectively, compared to 94% in upper-middle-income and high-income countries.[9] Moreover, inequalities in vaccine coverage by socioeconomic status and geographic residence are widely acknowledged.[12]

At the national level in 2016, MCV1 overall coverage in Kenya was 75% with 61 reported measles cases, though this burden is likely an underestimate for similar reasons described previously for global estimates. For example, Kenya did not meet measles surveillance targets in 2016, suggesting weak measles surveillance.[13] In addition, there were an estimated 248 measles deaths among Kenyan children younger than 5 years old in 2015 suggesting a higher number of measles cases as measles case fatality ratio is typically 5% in non-outbreak and non-emergency situations.[9,14] MCV1 overall coverage in Siaya County has been estimated at 83 to 84%,[15,16] well below the 95% coverage target.

Caregivers of children in low and middle-income countries (LMICs) attribute failure to vaccinate or delayed vaccination to supply-side factors – including inadequate vaccine supplies, difficult access to health facilities and unfriendly treatment by healthcare workers – and to demand-side factors including lack of knowledge about vaccination, competing priorities and concerns about vaccine safety.[16–27] Demand-side interventions, such as reminders, education and incentives have been shown to increase demand for childhood vaccination in a variety of LMICs.[28–39] and

may be used to improve vaccination coverage in settings with limited supply-side barriers to vaccination. Given high levels of mobile phone ownership and access in LMICs – in 2017 there were 98.7 and 77.8 mobile phone subscribers per 100 inhabitants in developing and African countries, respectively[40] – mobile phone based interventions (mHealth) to improve vaccination coverage may be particularly well-placed to reach a substantial number of caregivers. Studies evaluating the use of mobile phone call reminders in Nigeria and Kenya,[19,33] text message reminders in Bangladesh, Burkina Faso, Kenya, Nigeria and Zimbabwe[30–32,38,39] as well as text message reminders coupled with mobile money (mMoney; electronic funds transferred via mobile phone) and conditional incentives in Kenya,[35] found that the interventions significantly improved vaccination timeliness and/or coverage. mMoney refers to funds transferred using mobile banking, which is ubiquitous in Kenya and can be described as conduct of financial transactions using mobile phones.[41]

We sought to evaluate the impact of short message service (SMS or text message) reminders with or without an unconditional mMoney incentive on childhood measles vaccination timeliness and coverage in Gem sub-county, Siaya County, Kenya. Previously, we conducted the Mobile Solutions for Immunization (M-SIMU) cluster-randomized controlled trial in Gem and Rarieda sub-counties, Kenya. The M-SIMU study showed that SMS reminders alone and SMS reminders coupled with a Kenya Shilling 75 (KES; ~US $0.75 as of December 2016) or KES 200 (~US $2.00) mMoney incentive conditioned on receipt of vaccination within two weeks of the recommended date significantly improved the likelihood of timely MCV1 coverage i.e., vaccination within two weeks of the vaccine due date. Further, the M-SIMU study found that SMS reminders coupled with the conditional KES 200 mMoney incentive significantly improved

the likelihood of measles vaccination by age 12 months, raising coverage in the study sample from 84% to 90%.[35]

In this low-resource setting, scaling up conditional incentives may not be feasible as they require real-time monitoring of vaccination receipt in order to determine if caregivers meet the conditions for receiving the incentive. In a setting without routinely collected electronic vaccination records, real-time monitoring of vaccination receipt would need to be performed by either already stretched health facility staff likely to under-prioritize monitoring, or by newly employed staff, creating new expenses. Thus, unconditional incentives which do not require monitoring of vaccination receipt, may be more feasibly delivered at scale. Unconditional incentives may also have the added benefit of being less likely to reduce caregivers' intrinsic motivation to seek vaccination for their children compared to conditional incentives, which run the risk of reducing intrinsic vaccine-seeking behavior by appearing controlling.[42]

The Mobile and Scalable Innovations for Measles Immunization (M-SIMI) individually randomized controlled trial aimed to evaluate the effect of SMS reminders, with or without an unconditional mMoney incentive, on first dose measles vaccination coverage by 10 months of age. Secondary outcomes were first dose measles vaccination by age 12 months, time to measles immunization and the number of days undervaccinated.

4.3. Methods

4.3.1. Trial design and participants

The M-SIMI study was a three-arm parallel individually randomized controlled trial, conducted in Gem sub-county, Siaya County, Kenya villages falling within the Kenya Medical Research Institute/ Centers for Disease Control and Prevention collaboration (KEMRI/CDC) Health and Demographic Surveillance System (HDSS). The Gem sub-county KEMRI/CDC HDSS is a predominantly rural setting with relatively high malaria, HIV and tuberculosis prevalence, high infant mortality and over 90% DTP3 coverage among infants.[16,43] The study setting is described in more detail within **Chapter 2**.

Community health workers – referred to as community health volunteers (CHVs) in the study setting – identified households with children age 6-8 months. Community Interviewers (CIs), hired by the study, visited CHV-identified households to provide general information about the study and to perform screening if the caregiver was willing. Eligible infants and their caregivers (infant-caregiver pair) were required to: be aged 6-8 months; be self-reported residents of the village, not have received a dose of routine measles vaccine; and not have plans to move within six months of enrollment (**Appendix 7.1**). Shortly after enrollment, the study team made a decision to confirm age eligibility using the date of birth as recorded in the maternal child health (MCH) booklet, thus MCH availability was a de facto eligibility criterion applied after study commencement. For infants meeting eligibility criteria, CIs provided detailed study information using an informed consent document written in the caregiver's preferred language i.e., Dholuo, Kiswahili or English (**Appendices 7.2 – 7.4**). An impartial witness was involved in the informed

consent process in cases where the caregiver could not read. Eligible infants whose caregivers provided consent were enrolled into the study.

CIs received training on research ethics and study procedures prior to study commencement. The study was approved by the KEMRI Scientific and Ethics Review Unit (SERU; KEMRI/SERU/CGHR/003/3311). The Johns Hopkins Bloomberg School of Public Health Institutional Review Board (JHSPH IRB) deferred ethical oversight to KEMRI SERU. The study was registered on ClinicalTrials.gov (ClinicalTrials.gov Identifier: NCT02904642).

4.3.2. Interventions

Enrolled infants were randomized to one of three study arms: Control, SMS reminders only (SMS only), or SMS reminders coupled with a KES 150 incentive (SMS+150 KES; where KES 150 ≈ $1.50 USD as of December 2016). KES 150 was selected based on formative research previously conducted in the study area. At enrollment all participants received the following text message, which included some health-related motivational content:

"*Thank you for enrolling baby <<infant's name>> in MSIMI Study. The greatest wealth is health. This study is sponsored by KEMRI*."

Control arm participants received no interventions. SMS only arm participants received two SMS reminders; one sent three days before the scheduled measles vaccination date and the other

sent one day before the scheduled measles vaccination date. SMS+150KES arm participants received reminders on the same schedule as the SMS only arm participants and also received the KES 150 incentive three days before the scheduled measles vaccination date i.e., on the same day as the first, 3-day reminder.

SMS reminders were sent in the caregiver's preferred language i.e., Dholuo, Kiswahili or English; caregivers were queried as to their preferred language at enrollment. The 3-day reminder comprised of a standard reminder portion, a phrase intended to motivate caregivers and, for SMS+150KES arm participants, a portion explaining that the study was sending the incentive to assist with travel expenses. The same motivational phrase was included in the 3-day reminder for all participants. The 1-day reminder was the same across participants and consisted of a reminder portion as well as a motivational phrase that was different from the 3-day reminder motivational phrase (**Table 4.1**). Caregivers in the Control arm were expected to receive one text message (a message welcoming them to the study that was not a reminder) total and those in the intervention arms were expected to receive three text messages total.

SMS reminders were programmed to be sent out automatically using RapidSMS, an open-source platform.[44] At enrollment, CIs submitted an SMS to the RapidSMS server containing the infant's name, infant's date of birth, and caregiver's preferred phone number. Based on the information submitted, SMS reminders were sent from the RapidSMS server to the phone number provided by the caregiver on the schedule previously described i.e., three days and one day before the scheduled measles vaccination date. The Kenya Expanded Programme on Immunization (KEPI)

recommends MCV1 administration at age nine months.[45] The study defined the recommended measles vaccination age as 274 days since birth i.e., assuming 30.42 days per month on average. Thus, the scheduled measles vaccination date was 274 days from the infant's date of birth, if falling on a weekday. If falling on a Saturday or Sunday, the scheduled measles vaccination date was defined as the following Monday.

RapidSMS was also programmed to automatically create a cumulative incentive payment list for infants enrolled in the SMS+150KES arm. The payment list included infants' Study IDs, caregivers' preferred phone numbers and payment dates i.e., three days before the scheduled vaccination date. Using the RapidSMS-generated payment list, study staff manually transmitted the KES 150 incentive from a smart phone using the M-PESA mobile money platform operated by Safaricom, one of Kenya's mobile network providers.[46]

4.3.3. Outcomes

The primary outcome was the proportion of infants receiving MCV1 by age 10 months, i.e., **MCV1 timely coverage**. Age 10 months was defined as 304 days since the date of birth. The proportion receiving MCV1 by age 10 months was obtained using the formula below:

$$\frac{number\ of\ infants\ receiving\ MCV1\ when\ aged < 304\ days}{Number\ of\ infants\ in\ the\ analytic\ sample}$$

Secondary outcomes were the proportion of infants receiving MCV1 by age 12 months, i.e., **MCV1 overall coverage**, time to measles vaccination by age 12 months and the number of days undervaccinated. Age 12 months was defined as 365 days from birth. The proportion receiving MCV1 by age 12 months was calculated using the following formula:

$$\frac{number\ of\ infants\ receiving\ MCV1\ when\ aged < 365\ days}{Number\ of\ infants\ in\ the\ analytic\ sample}$$

Analytic approaches, including details on the time to measles vaccination and days undervaccinated analyses, are described in the statistical methods section. All outcomes were specified a priori.

4.3.4. Procedures, data collection and cleaning

At the screening/enrollment visit, CIs collected vaccination status, sociodemographic, economic, mobile phone access, mobile phone usage, healthcare utilization and other general health information from caregivers (**Appendix 7.5**). CIs conducted a follow-up visit when infants were aged ≥12 months to collect vaccination status as well as information on caregivers' opinion of the interventions, reasons for delayed measles vaccination (i.e., not vaccinated by age 10 months), incentive use and other general health information (**Appendix 7.6**). Vaccination status, used for the study's primary and secondary outcomes, was collected at the enrollment and follow-up visits from either MCH booklet records or the caregiver's verbal report if the MCH

booklet was not available. If the child's vaccinations were not up-to-date at the 12 month follow-up visit, the CI referred the caregiver to the nearest health facility for vaccinations.

Electronic versions of the enrollment and follow-up questionnaires (**Appendices 7.5 & 7.6**) were created using Open Data Kit (ODK), an open-source platform for creating, collecting and storing aggregating data.[47] CIs used smart mobile phones loaded with the ODK Collect app to access and complete the electronic versions of the questionnaires and to submit completed forms to the data server.

On a regular basis, data were queried for inconsistencies e.g., vaccination date occurring after the respective visit date, vaccination date occurring before date of birth, inconsistent data between the enrollment and follow-up visit. Data queries were provided to the data manager and resolved by the Field Supervisor (FS) or CI by either re-visiting the household or reviewing health facility records to confirm data. To assure data quality, the Kenya site Principal Investigator (PI) conducted accompanied interviews in a fraction of households whereby the PI was present during study visits to assess whether the questionnaires and study procedures were administered as intended. In addition, following CI visits, the FS conducted repeat interviews in a random sample representing 5% of study households to enable comparison of data collected by the CI to that collected by the FS.

4.3.5. Sample size

The study aimed to measure a ≥15% increase in MCV1 timely coverage, in the intervention arms compared to the control arm. Data from the M-SIMU study estimated MCV1 timely coverage in the study area at approximately 70%.[35] We presumed that a ≥15% increase in the proportion of children receiving MCV1 by age 10 months would represent a meaningful public health increase in MCV1 timeliness i.e., an increase to 85% of infants receiving MCV1 by age 10 months. Assuming 70% outcome in the M-SIMI control group, a 15% absolute difference in the primary outcome between control and intervention arms, a type 1 error (alpha) of 0.05, a power (1-beta) of 0.80 and applying a continuity correction, 134 infants would be required in each study arm. The sample size calculation used is shown in **Figure 4.1**. The sample size was adjusted to account for up to 25% loss-to-follow up i.e., assuming that up to 25% of infants would not be included in the analytic sample due to death, outmigration, verbal report of measles vaccination at 10 months of age, and other reasons. After accounting for potential losses to follow-up, the estimated sample size to assess the primary outcome was 537 infants total, translating to 179 infants enrolled in each of the three study arms.

4.3.6. Randomization and blinding

Simple randomization with an allocation ratio of 1:1:1 to the Control, SMS only or SMS+150 arm was performed using a list of computer-generated random numbers. A list of 537 "Allocation IDs", i.e., one unique ID for each study arm allocation, were generated. Allocation IDs were structured into five groups because five CIs were involved in screening and enrollment. Thus, the Allocation IDs were labelled #1A – #108A; #1B - #108B; #1C - #107C; #1D - #107D and #1E - #107E. The study group associated with each Allocation ID followed the random

sequence generated, thus, within each sequential Allocation ID group, the sequence of study group allocation was random. The Allocation ID and respective study arm i.e., Control arm, SMS only arm or SMS+150KES arm were printed on a card and placed into an opaque envelope which was labelled with the Allocation ID and sealed. Randomization and preparation of the allocation envelopes was performed by the Data Manager who had no contact with participants.

During the enrollment period, the site PI provided CIs, who did not have access to the allocation sequence, with a pre-defined number of allocation envelopes on a weekly basis. After determining that an infant was eligible for the study, the CI opened the allocation envelope to identify the study arm allocation so as to provide the relevant information for the study arm assigned during the informed consent process. CIs opened each allocation envelope sequentially e.g., the allocation envelope labelled with Allocation ID #2A was opened after the allocation envelope labelled with Allocation ID #1A. If a caregiver refused participation after the allocation envelope had been unsealed, the CI returned the unsealed allocation envelope to the PI. The Allocation ID of the unsealed envelope was then switched with that of a yet unused, sealed, randomly picked allocation envelope such that the study arm associated with the Allocation ID of the previously unsealed envelope had a chance of being different from the original study arm. Switching was performed to try ensure that CIs continued to be blinded to the allocation sequence. The modified Allocation IDs/allocation envelopes were then returned into circulation (**Appendix 7.7**).

Given the nature of the interventions, participants were not blinded to the study arm allocated. CIs, who assigned participants to the study interventions during the screening/enrollment visit and also assessed vaccination status at the follow-up visit, were also not blinded to the intervention assigned. However, given the 4-6 month lag time between enrollment and follow-up and the high number of enrollees (537) compared to the five CIs, it is unlikely that CIs would remember most participants' allocation. In addition, follow-up interview questions that required the CI to identify the participants' assigned study arm appeared after vaccination status data were collected (**Appendix 7.6**). The data analyst had access to participants' study arm allocation during analysis as some of the analysis, e.g., vaccination risk factors among Control arm children, required knowledge of study arm allocation.

4.3.7. Statistical methods

4.3.7.1. Assessment of baseline characteristics

The distribution of participant characteristics by study arm at baseline was assessed to evaluate whether any characteristics that are predictive of vaccination status were unequally distributed across groups; **Table 4.2** summarizes variables that were included in the assessment and describes creation of derived variables. Derived variables were calculated using the entire study sample as opposed to only the analytic sample so as to be more representative. Only infants with an MCH booklet at the follow-up visit were included in endpoint analyses as MCH booklet vaccination data were considered to have better reliability and validity than caregiver verbal reports which can over- or under-estimate vaccination coverage.[48–51] In order to evaluate possible selection bias of the analytical sample as compared to those who were lost to follow-up and/or were excluded because they did not have an MCH booklet at the follow-up visit, we compared

baseline participant characteristics of participants in the analytic sample to those excluded from the analytic sample.

4.3.7.2. Analysis of MCV1 timely coverage and MCV1 overall coverage

The primary endpoint – differences in the proportion of infants receiving MCV1 by age 10 months in the intervention arms as compared to the control arm – was assessed using log-binomial regression. To estimate the primary endpoint for each arm, children were censored at age 10 months, i.e., the numerator included all children who were alive by age 10 months and had received MCV1 when aged ≤304 days while the denominator included all children who were alive by age 10 months. Any predictive baseline characteristics determined to be unequally distributed at the 5% significance level were included in the log-binomial model to allow adjustment for potential confounders. The log-binomial model was used to estimate the risk ratio (RR) and 95% confidence interval (95% CI) of measles vaccination by age 10 months in each of the intervention arms compared to control. The model was specified as follows:

$$Log\ Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS150 + \ldots + \beta_p X_p$$

where:

Pr(Y = 1) is the probability of receiving MCV1 by age 10 months;

β_0 is the constant i.e., the log risk of measles vaccination by age 10 months in the Control arm given a zero value for all other predictors;

β_1 is the log risk ratio of measles vaccination by age 10 months in the SMS only arm compared to the control arm for otherwise similar infants;

SMS is an indicator variable with a value of 1 if the infant was randomized to the SMS only arm and a value of 0 otherwise;

β_2 is the log risk ratio of measles vaccination by age 10 months in the SMS+150KES arm compared to the control arm for otherwise similar infants;

SMS150 is an indicator variable with a value of 1 if the infant was randomized to the SMS+150KES arm and a value of 0 otherwise;

β_p is the log risk ratio of measles vaccination by age 10 months for a one unit increase in variable X_p among otherwise similar infants;

and

X_p is a potentially confounding variable(s).

Additionally, to assess the absolute difference in timely vaccination coverage, risk differences (RD) along with 95% CIs were computed with the model specified as follows:

$$Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS150 + ... + \beta_p X_p$$

where:

Pr(Y = 1) is the probability of receiving MCV1 by age 10 months;

β_0 is the constant i.e., the probability of measles vaccination by age 10 months in the Control arm given a zero value for all other predictors;

β_1 is the difference in the probability of measles vaccination by age 10 months in the SMS only arm compared to the Control arm for otherwise similar infants;

SMS is an indicator variable with a value of 1 if the infant was randomized to the SMS only arm and a value of 0 otherwise;

β_2 is the difference in the probability of measles vaccination by age 10 months in the SMS+150KES arm compared to the control arm for otherwise similar infants;

SMS150 is an indicator variable with a value of 1 if the infant was randomized to the SMS+150KES arm and a value of 0 otherwise;

β_p is the difference in probability of measles vaccination by age 10 months for a one unit increase in variable X_p among otherwise similar infants;

and

X_p is a potentially confounding variable(s).

The primary endpoint was analyzed according to intention-to-treat (ITT) principles, meaning that all participants in the analytic sample were included in their respective study arm regardless of whether interventions were delivered per protocol. A primary endpoint modified per-protocol sensitivity analysis was conducted to evaluate how the primary endpoint was influenced by including only participants who received the interventions as intended. The modified per-protocol was defined as having received two SMS reminders at the defined schedule i.e., 3 days and 1 day before the scheduled vaccination date. This modified per-protocol definition was selected for consistency with the definition used in the precursor M-SIMU study[35] and also to

ensure sufficient sample size as barriers to sending incentives per-protocol were anticipated. Without modification, the per-protocol sample size was anticipated to be too small to assess the primary endpoint. The same analytic approach as for MCV1 timely coverage was used to assess whether the interventions significantly increases measles vaccination coverage by age 12 months, a secondary outcome.

4.3.7.3. Risk factor and sub-group analyses

In order to evaluate whether the impact of interventions on measles vaccination by age 10 months varied significantly for different levels of baseline participant characteristics, we performed stratified (sub-group) analysis. To identify independent variables to include in the sub-group analysis, a risk factor analysis of baseline participant characteristic variables associated with differential MCV1 timely coverage among only Control arm participants was conducted. A univariate log-binomial regression of MCV1 timely coverage on each baseline participant characteristic assessed was performed to obtain RR and 95% CI for measles vaccination by age 10 months in one or more levels of the categorical independent variable compared the reference level. The univariate log-binomial regression models were specified as follows:

Risk factor analysis regression model

$$Log\ Pr(Y=1|Control) = \beta_0 + \beta_1.VAR_{L1} + \beta_p.VAR_{LP}$$

where:

Pr(Y = 1) is the probability of receiving MCV1 by age 10 months, given enrollment in the Control arm;

β_0 is the constant i.e., the log risk of measles vaccination by age 10 months among Control arm participants having the reference value (level 0; L_0) of the variable in question;

β_1 is the log risk ratio of measles vaccination by age 10 months among Control arm participants falling into a different category of the variable in question, i.e. level 1 (L_1), compared to those in the reference category L_0;

VAR_{L1} is an indicator variable with a value of 1 for L_1 of the categorical variable and has a value of 0 otherwise;

β_p is the log risk ratio of measles vaccination by age 10 months among Control arm participants falling into level P (L_P) the categorical variable in question, compared to those in the reference category L_0;

VAR_p is an indicator variable with a value of 1 for L_P of the categorical variable and has a value of 0 otherwise;

Variables significant at the 10% level were included in sub-group analysis. Stratification by mobile phone ownership status and travel time to the health facility were pre-specified in the study protocol. Maternal education was included because there is some suggestion that it may modify the impact of SMS reminders with or without incentives on vaccination coverage. In the M-SIMU study, the stratum-specific relative risk of vaccination among less educated caregivers receiving SMS reminders with or without incentives compared to less educated caregivers receiving no interventions was found to be significantly higher than the stratum-specific relative risk of vaccination among more educated caregivers receiving interventions compared to more

educated Control arm caregivers, although the overall interaction term was not statistically significant.[35] The analysis showing potential effect modification by maternal education status was published after completion of the M-SIMI study protocol, therefore maternal education was included post-hoc.

In the sub-group analysis, regression models unadjusted for and adjusted for maternal age were run. Unadjusted regression was performed to detect any significant sub-group differences that might be missed in adjusted regression models due to small numbers of infants included in the respective strata. The significance level for sub-group analysis was 5%. Regression models for the sub-group analysis were defined as below:

Sub-group analysis regression model

$$Log\ Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS150 + \beta_3.VAR + \beta_4.SMS*VAR + \beta_5.SMS150*VAR\ [+ \beta_p.X_p]$$

where:

Pr(Y = 1) is the probability of receiving MCV1 by age 10 months;

β_0 is the constant i.e., the log risk of measles vaccination by age 10 months in the Control arm given a zero value for all other predictors;

β_1 is the log risk ratio of measles vaccination by age 10 months in the SMS only arm compared to the control arm for otherwise similar infants;

SMS is an indicator variable with a value of 1 if the infant was randomized to the SMS only arm and a value of 0 otherwise;

β_2 is the log risk ratio of measles vaccination by age 10 months in the SMS+150KES arm compared to the control arm for otherwise similar infants;

SMS150 is an indicator variable with a value of 1 if the infant was randomized to the SMS+150KES arm and a value of 0 otherwise;

β_3 is the log risk ratio of measles vaccination by age 10 months for a one unit increase in VAR among otherwise similar infants;

VAR is the variable under assessment in the sub-group analysis;

β_4 is the log relative change in the risk of measles vaccination in the SMS only arm compared to the Control arm, for one level of VAR vs. a different level of VAR;

SMS*VAR is an interaction term created by multiplying the values of SMS and VAR;

B_5 is the log relative change in the risk of measles vaccination in the SMS+150KES arm compared to the Control arm, for one level of VAR vs. a different level of VAR;

SMS150*VAR is an interaction term created by multiplying the values of SMS150 and VAR;

β_p is the log risk ratio of measles vaccination by age 10 months for a one unit increase in variable X_p among otherwise similar infants;

and

X_p is a potentially confounding variable(s).

4.3.7.4. Analysis of time to measles vaccination

Survival analysis was performed to assess whether time to measles vaccination differed significantly across the study arms. Time origin was defined as the point of enrollment and thus participants were considered at risk beginning from the time they enrolled in the RCT. The outcome assessed was time (in days) to measles vaccination by age 12 months, a two-state non-recurrent event. Events were right-censored at age 365 days. The cumulative probability of measles vaccination was plotted using the failure functions estimated using the Kaplan-Meier method. The 25th, 50th and 75th percentile times to measles vaccination for each study outcome and study arm were obtained. Equality of the cumulative incidence functions were tested using the log-rank test. A sensitivity analysis of time to measles vaccination was performed whereby the time origin was defined as age 271 days, i.e., the intended start of intervention deployment, and infants who received MCV1 before age 271 days were left-censored.

4.3.7.5. Estimation of number of days undervaccinated

In the analysis of the number of days undervaccinated, observations were censored at age 12 months. Infants were considered undervaccinated if they were vaccinated on or after age 10 months (304 days) or if they were unvaccinated by age 12 months. For infants who were vaccinated after age 303 days, the number of days undervaccinated was calculated as the age of vaccination in days minus 303. For infants who were not vaccinated by age 12 months, the number of days undervaccinated was calculated as 364 minus 303. The mean, median, 25th percentile and 75th percentile of days undervaccinated were calculated for all infants and also for infants who were vaccinated on or after age 10 months. Mean days undervaccinated were compared across study arms using two-sample t-tests with unequal variance.

4.3.7.6. Analysis of caregivers' experiences, attitudes and opinions

The frequency and percent of caregivers' reasons for delayed vaccination, recollection of intervention receipt, use of the monetary incentive and opinions of the intervention were tabulated.

With the exception of the risk difference and days undervaccinated analyses, the statistical analyses performed were pre-specified in the IRB-approved study protocol.

4.4. Results

CHVs identified 639 potentially eligible infants between December 6, 2016 and March 31, 2017. Of those, 102 infants were excluded for the following reasons: received routine measles vaccine (44 infants), not residents of the study area (20 infants), not aged between 6 and 8 months (13 infants), did not have an MCH booklet (11 infants), caregivers refused participation (10 infants), planning to move (2 infants), MCH booklet date incongruences (1 infant) and inability to communicate with a deaf and mute caregiver (1 infant). A total of 537 infants – the target sample size - were randomized to the Control, SMS only and SMS+150KES arms (179 infants each; **Figure 4.3**).

Follow-up visits when the infants achieved 12 months of age were conducted between April 19, 2017 and October 8, 2017. Follow-up visits were completed for 170, 157 and 158 infants in the Control arm, SMS only arm and SMS+150KES arm, respectively. Nine infants enrolled in the Control arm could not be followed up as they had migrated out of the study area. Of 24 and 21 infants not followed up in the SMS only and SMS+150KES arms, respectively, 19 in each arm out-migrated, caregivers of two infants in the SMS only arm refused to complete the follow-up visits, and three infants in the SMS only arm as well as two infants in the SMS+150KES died before the 12 month follow-up visit without collection of vaccination data post-enrollment. In addition, 10 Control arm infants as well as nine infants each in the SMS only arm and the SMS+150KES arm were excluded from analysis. Eight infants in each arm were excluded because they did not have an MCH booklet available at the follow-up visit although verbal vaccination reports were obtained from caregivers. Two pairs of twins (Control n= 2; SMS only n= 1; SMS+150KES n= 1) were also excluded from analysis because individual twins within

each pair were enrolled in different study arms; it was determined that the effects of the respective intervention could not be reliably isolated within these twin pairs. Thus, the analytic sample included 160 (89.4%), 146 (81.6%) and 149 (83.2%) out of all infants enrolled in the Control, SMS only and SMS+150KES arms, respectively (**Figure 4.3**).

4.4.1. Baseline characteristics

At enrollment, more than half of caregivers included in the analytic sample owned a mobile phone (68.6%; n= 312), a higher proportion compared to previous mobile phone ownership levels.[35] The vast majority of caregivers (97.8%; n= 445) used the Safaricom network. Slightly more male infants (52.5%; n= 239) were enrolled than female infants and most infants (64.2%; n= 292) were enrolled when they were aged 6 months. Prior to enrollment, 95.8% (n= 436) of enrolled infants had received the third dose of pentavalent vaccine (Penta3; diphtheria, pertussis, tetanus, hepatitis B, *Haemophilus influenzae* type b). Approximately two-thirds (64.2%; n= 232) of participants lived within 30 minutes of a health facility and a similar proportion of mothers attained primary education or higher (65.7%; n= 299). Close to one-fifth (18.9%; n= 86) of infants were firstborn children and a little over 80% (n= 371) of infants were delivered at a health facility. Half (50.1%; n= 228) of mothers were aged 25 years or younger and almost one-third (31.8%; n= 144) of mothers reported having attended more than four antenatal care (ANC) visits (**Table 4.3**).

With the exception of maternal age, baseline characteristics were evenly distributed across study arms. In the Control arm, 50.0% (n= 80) of mothers were aged ≤25 years while the percentages

in the SMS only and SMS+150KES arm were 58.9% (n= 86) and 41.6% (n= 62), respectively (**Table 4.1**). The difference in the distribution of maternal age across study arms was statistically significant (p= 0.012). **Because maternal age was unevenly distributed across study arms and because it has been shown to be a determinant of childhood vaccination status within the M-SIMI study area,**[16] **maternal age was included as an independent variable in regression models**.

The 82 (Control arm n= 19; SMS only arm n= 33; SMS+150KES n= 30) participants who were excluded from the analytic sample were similar to participants in the analytic sample except for birth order and maternal age. The percentage of firstborn children was significantly higher among excluded participants than those the analytic sample (41.5% vs. 18.9%; p< 0.001) as was the percentage of mothers aged 25 years or younger (68.3% vs. 50.1%; p= 0.002; **Table 4.4**). Restricted to infants who were excluded, the proportion of firstborn infants was 31.6% in the Control arm compared to 48.5% and 40.0% in the SMS only arm and SMS+150KES arm, respectively. The proportion of mothers aged 25 years or less among excluded participants was 57.9% in the Control arm, 60.6% in the SMS only arm and 83.3% in the SMS only arm (data not shown).

4.4.2. Deployment of interventions

All intervention arm participants were sent at least one SMS reminder. Overall, per-protocol SMS reminders were sent to 252 (85.4%) intervention participants. Specifically, per-protocol reminders were sent to 126 participants each in the SMS only and SMS+150KES arms,

representing 86.3% and 84.6% of participants in each arm, respectively. Reminders for 20 participants in the SMS only arm were not sent out per-protocol for the following reasons: two reminders sent but second reminder sent on scheduled vaccination date (8 participants); only one reminder sent (11 participants); and reminder sent after scheduled vaccination date (1 participant). In the SMS+150KES arm, reasons for not sending out reminders per-protocol for 23 participants were: three reminders sent (2 participants); two reminders sent but second reminder sent on vaccination date (6 participants); only one reminder sent (14 participants); and reminders sent after scheduled vaccination date (1 participant; **Table 4.5**).

mMoney incentives were sent to all participants in the SMS+150KES arm. Ninety-one (61.1%) incentives were sent out three days before the scheduled vaccination date, as intended in the study protocol. All but four participants were sent incentives on or before the scheduled vaccination date. Incentives were sent out between one and 28 days after the scheduled vaccination date for the four participants (**Table 4.9**). By day of week, 14 (9.4%) incentives were intended to be paid on a Sunday, 30 (20.1%) on a Monday, 23 (15.4%) on a Tuesday, 64 (43.0%) on a Friday and 18 (12.1%) on a Saturday. None of the approximately 20% of payments intended to be sent on a Sunday or Saturday were sent on the intended date. Of payments intended to be sent on a Monday, Tuesday or Friday, 70% or more were sent on the intended date (**Table 4.10**).

4.4.3. MCV1 timely coverage

4.4.3.1. Intent-to-treat analysis (ITT)

The ITT analysis of MCV1 timely coverage included all Control (N= 160), SMS only (N= 146) and SMS+150KES (N= 149) participants in the analytic sample. Respectively, 109 (68.1%), 114 (78.1%) and 116 (77.9%), of infants in the Control, SMS only and SMS+150KES arms received MCV1 by age 10 months. Compared to Control arm infants, those in the SMS only arm were not statistically significantly more likely to receive measles vaccine by age 10 months in the crude analysis (crude RR [cRR] 1.15; 95% CI: 1.00, 1.31; p= 0.050) or in the regression model adjusted for maternal age (adjusted RR [aRR] 1.13; 95% CI: 0.99, 1.30; p= 0.070). The likelihood of timely MCV1 was not significantly higher in the SMS+150KES arm compared to the Control arm in the unadjusted analysis (cRR 1.14; 95% CI: 1.00, 1.31; p= 0.055) but was after adjustment for maternal age (aRR 1.16; 95% CI: 1.01, 1.32; p= 0.036; **Table 4.6**). In multivariable risk difference analyses, approximately 10 additional infants per 100 received MCV1 by age 10 months in the SMS only arm; however, there was no statistically significant difference in MCV1 timely coverage compared to the Control arm (adjusted risk difference [aRD] 9.2; 95% CI: -0.6, 19.0; p= 0.066). MCV1 timely coverage was significantly higher in the SMS+150KES arm by 10.6% compared to the Control arm (aRD 10.6; 95% CI: 0.8, 20.3; p= 0.034) compared to the Control arm (**Table 4.7**).

4.4.3.2. Sub-group analysis

The univariate risk factor analysis conducted among only Control arm infants included all baseline characteristics; age at enrollment was dichotomized i.e., age 6 months vs. age 7-8 months owing to the small number of infants enrolled at age 8 months (**Table 4.3**). Phone

ownership and being aged 7-8 months at enrollment were associated with higher likelihood of measles vaccination by age 10 months at the 10% significance level cRR 1.28 (95% CI: 0.98, 1.67; p= 0.073) and cRR 1.21 (95% CI: 0.99, 1.49; p= 0.068), respectively. Being a later-born child was associated with lower likelihood of timely measles vaccination (cRR 0.83; 95% CI: 0.67, 1.03; p= 0.092). Time to health facility, which was pre-specified for inclusion in the sub-group analysis was not significantly associated with timely measles vaccination (cRR 1.04; 95% CI: 0.83, 1.30; p= 0.727). Similarly, maternal educational level, specified post-hoc, was not significantly associated with measles vaccination status (cRR 1.19; 95% CI: 0.93, 1.53; p= 0.166; **Table 4.8**). Thus, phone ownership status, age at enrollment, birth order and time to health facility were included in sub-group analyses. Of note, there were no significant differences in MCV1 timely coverage among higher wealth households compared to less wealthy households (**Table 4.8**).

The probability of timely measles vaccination arm in the SMS only arm and in the SMS+150KES did not differ significantly at the 5% level for different levels of phone ownership, age at enrollment, birth order and time to health facility in either the unadjusted (all stratum-specific p>0.05; **Figures 4.4[A]** & **[B]**) or adjusted (all stratum-specific and overall interaction term p>0.05 **Figures 4.5[A]** & **[B]**) regression models.

4.4.3.3. Per-protocol analysis

The per-protocol analysis included all Control arm participants (N= 160) and only those participants in the SMS only and SMS+150KES arms who were sent the 3-day and 1-day

reminder (N= 126 for each arm). Per-protocol MCV1 timely coverage in the intervention arms was similar to ITT timely coverage; 109 (68.1%), 100 (79.4%) and 99 (78.6%) infants in the Control, SMS only and SMS+150KES arms were vaccinated by age 10 months, respectively. In the unadjusted per-protocol regression model, infants in the SMS only arm were significantly more likely to receive timely measles vaccination compared to infants in the Control arm (cRR 1.16; 95% CI: 1.01, 1.34; p= 0.031) but the likelihood of timely measles vaccination was not significantly different after adjustment for maternal age (aRR 1.15; 95% CI: 1.00, 1.32; p= 0.052). The likelihood of timely measles vaccination in the SMS+150KES arm was significantly higher compared to the Control arm in both unadjusted (cRR 1.15; 95% CI: 1.00, 1.33; p= 0.046) and adjusted (aRR 1.17; 95% CI: 1.02, 1.35; p= 0.024) regression models (**Table 4.11**). The adjusted difference in MCV1 timely coverage between SMS only infants compared to Control infants with similarly aged mothers was 10.2% (95% CI: 0.1, 20.3; p= 0.048) and 11.6% (95% CI: 1.4, 21.7; p= 0.025) for SMS+150KES infants compared to Control infants (**Table 4.12**).

4.4.4. MCV1 overall coverage

4.4.4.1. ITT analysis

All participants in the analytic sample were included in the ITT analysis of MCV1 overall coverage. Respectively, 125 (78.1%), 123 (84.2%) and 126 (84.6%) of Control, SMS only and SMS+150KES infants received MCV1 by age 12 months. The likelihood of measles vaccination by age 12 months among SMS only arm infants was 1.08 and 1.07 times that of infants in the Control arm in the crude and adjusted analysis, respectively, but this higher risk did not achieve statistical significance in the crude analysis (95% CI: 0.97, 1.20; p= 0.171) or in the analysis adjusted for maternal age (95% CI: 0.96, 1.19; p= 0.199). Infants in the SMS+150KES arm were

more likely to receive measles vaccine by age 12 months in the crude analysis (cRR 1.08; 95% CI: 0.97, 1.20; p= 0.147) and in the adjusted analysis (aRR 1.09, 95% CI: 0.98, 1.21; p= 0.124) though in neither case did the association achieve statistical significance (**Table 4.13**). Approximately, 6 additional infants per 100 and 7 additional infants per 100 in the SMS only arm and SMS+150 KES arm, respectively, received measles vaccination compared to the Control arm; this difference in risk was not statistically significant (aRD 5.7%; 95% CI: -3.0, 14.3%; p= 0.199 [SMS only arm]; aRD 6.8%; 95% CI: -1.8, 15.3%; p= 0.119 [SMS+150KES arm]; **Table 4.14**).

4.4.4.2. Per-protocol analysis

The per-protocol analysis of MCV1 overall coverage included 160 infants in the Control arm and 126 infants each in the SMS only arm and SMS+150KES arm. By age 12 months, 125 (78.1%) infants in the Control arm had received MCV1 compared to 126 (84.9%) in the SMS only arm and 146 (84.1%) in the SMS+150KES arm. Coverage estimates in the intervention arms were similar to estimates in the ITT analysis. The likelihood of measles vaccination in the SMS only arm in the crude analysis was 1.09 times (95% CI: 0.97, 1.21; p= 0.138) that in the Control arm and 1.08 times (95% CI: 0.97, 1.20; p= 0.163) that in the Control arm in the adjusted analysis. Neither of these relative risks were statistically significant. Similarly, the likelihood of measles vaccination in the SMS+150KES arm was 1.08 times that in the Control arm but this higher likelihood was not statistically significant in both the crude analysis (95% CI: 0.96, 1.20; p= 0.194) and the adjusted analysis (95% CI: 0.97, 1.21; p= 0.166; **Table 4.15**). Absolute MCV1 overall coverage was not statistically significantly different in the SMS only arm compared to the Control arm in the crude analysis (cRD 6.8%; 95% CI: -2.2, 15.7%; p= 0.137) or in the adjusted

analysis (aRD 6.3%; 95% CI: -2.6, 15.2%; p= 0.165). Similar to the SMS only arm, approximately 6 additional infants per 100 were vaccinated in the SMS+150KES arm than in the Control arm, but this difference was not statistically significant in the crude analysis (cRD 6.0%; 95% CI: -3.0, 15.0%; p= 0.193) or in the adjusted analysis (aRD 6.4%; 95% CI: -2.5, 15.3; p= 0.161; **Table 4.16**).

4.4.5. Time to measles vaccination

In the time to measles vaccination including all participants in the analytic sample, three vaccination events occurring after age 365 days, one in the SMS only arm and two in the SMS+150KES arm, were excluded due to right-censoring. However, those infants contributed to analysis through age 365 days. Forty-two infants including 16 (11.4%) Control, 12 (8.2%) SMS only and 14 (9.4%) SMS+150KES infants who received measles vaccination prior to age 271 days, the targeted intervention start date were included in the primary survival analysis. The median age of entry into the survival analysis was 204 days (Age 6 months and 20 days; Q1= 195, Q3= 218 days) in the Control arm, 203 days (Q1= 193, Q2= 222 days) in the SMS only arm and 204 days (Q1= 193, Q2= 221) in the SMS+150KES arm. The cumulative probability of failure, i.e., measles vaccination by age 12 months was 78.3% in the Control arm, 84.3% in the SMS only arm and 84.6% in the SMS=150KES arm (**Table 4.17**). The median time to measles vaccination was age 286 days (Age 9 months and 12 days; Q1= 276, Q3= 324 days) in the Control arm, age 284 days (Q1= 276, Q3= 298 days) in the SMS only arm and 282 days (Q1= 275, Q3= 302 days) in the SMS+150KES arm (**Figure 4.6**). There was no significant difference in time to measles vaccination across study arms (log-rank test p= 0.182) even after performing

testing stratified by maternal age (maternal age ≤25 years log-rank test p= 0.195, maternal age >25 years log-rank test p= 0.576, stratified log-rank test p= 0.158; **Table 4.18**).

The sensitivity analysis of time to measles vaccination excluded the 42 previously described infants who received MCV1 before the targeted intervention start date i.e., infants who received MCV1 before 271 days of age. Thus, the sensitivity analysis included 146, 135 and 137 Control, SMS only and SMS+150 participants, respectively. The cumulative probability of measles vaccination by age 12 months was 75.7% in the Control arm, 82.8% in the SMS only arm and 83.0% in the SMS+150KES arm (**Table 4.19**). The median time to measles vaccination in the Control arm was 288 days (age 9 months and 17 days; Q1= 279, Q3= 337 days), 286 days in the SMS only arm (Q1= 278, Q3= 302 days) and 284 days in the SMS+150KES arm (Q1= 277, Q3= 303 days; **Figure 4.7**). There was no statistically significant difference in the time to measles vaccination across study arms in unstratified testing (log-rank test p= 0.118) or in testing adjusted for maternal age (stratified log-rank test p= 0.101; **Table 4.20**).

4.4.6. Days undervaccinated

Within the analytic sample, infants in the Control arm, SMS only arm and SMS+150KES arm were undervaccinated against measles for 14.9 days (standard error: 2.0), 10.5 days (1.8) and 10.1 days (1.8) on average, respectively, by age 12 months. The mean number of days undervaccinated was not statistically significantly different in the SMS only arm compared to the Control arm (two-sample t-test p= 0.108) or in the SMS+150KES arm (p= 0.071). The median number of days undervaccinated was zero in all study arms, but this median value was driven by

the >50% MCV1 timely coverage in the study arms. The number of infants undervaccinated for one or more days was 51 (31.9%), 32 (21.9%) and 33 (22.1%) in the Control arm, SMS only arm and SMS+150KES arm, respectively (**Table 4.21**).

In the analysis restricted to undervaccinated infants, the average number of days undervaccinated was 46.9, 48.2 and 45.5 in the Control arm, SMS only and SMS+150KES arm, respectively. There was no statistically significant difference in the mean number of days undervaccinated among Control infants who were not vaccinated by age 10 months compared to similar SMS only arm infants (p= 0.788) and to similar SMS only arm infants (p= 0.788). The median and 75th percentile of days delayed was 61, the highest possible number of days undervaccinated due to right censoring at age 12 months. The 25th percentile of median days undervaccinated was 29 in the Control and SMS only arm compared to 15 in the SMS+150KES arm.

Infants not vaccinated by age 12 months (61 days undervaccinated) made up the highest number of undervaccinated infants in all study arms, 35 (68.6%) in the Control arm, 23 (71.9%) in the SMS only arm and 23 (69.7%) in the SMS+150 KES arm. Among infants vaccinated with delay, i.e., vaccination when aged 10 or 11 months, the number of days undervaccinated ranged from 2-34 in the Control arm, 1-37 in the SMS only arms, and 2-19 in the SMS+150KES arm. Five (9.8%), two (6.3%) and five (15.2%) Control arm, SMS only arm and SMS+150KES arm infants were undervaccinated for 1-7 days. Three (5.8%) Control arm infants and two infants each in the SMS only arm (6.3%) and the SMS+150KES arm (6.1%) were undervaccinated for 8-14 days. Three (5.8%) Control arm, four (12.5%) SMS only arm and three (9.1%) SMS+150KES arm

infants were undervaccinated for 15-21 days. No SMS+150KES arm infants were undervaccinated for more than 19 days. Five (9.8%) Control arm infants and no SMS only arm infants were undervaccinated for 22-35 days. One (3.1%) SMS only arm infant was undervaccinated for 37 days (**Table 4.21**).

4.4.7. Reasons for delayed vaccination

The reason for delayed vaccination was obtained for 95 (81.9%) of the 116 infants that did not receive MCV1 by age 10 months. Caregivers of 10 Control arm, three SMS only arm and eight SMS+150KES arm infants were not queried about the reason for delayed measles vaccination as the interviewer did not identify them as having delayed vaccination. Of the 95 infants (41 Control, 29 SMS only and 25 SMS+150KES) whose caregivers were queried, reasons for not receiving MCV1 by age 10 months included: an ongoing nurses strike (n= 34; 35.8%), vaccine stock-out (15; 15.8%), infant's illness (8; 8.4%), being away on travel (7; 7.4%), vaccination not recorded in the MCH booklet per caregiver (6; 6.3%), not knowing the vaccination due date (5; 5.3%), nurse's refusal to open multi-dose vaccine vial given few infants presenting for measles vaccination (3; 3.2%), caregiver forgot (2; 2.1%) and competing priorities (2; 2.1%). In addition, one caregiver each reported that MCV1 was not given by age 10 months because of: far distance to the clinic, delay in the infant's pentavalent vaccine series, the caregiver's perception that measles vaccine is not important, the caregiver's omission to carry the MCH booklet to the clinic, a recommendation by the caregiver's friend to not vaccinate and the caregiver being ill. Seven caregivers (one Control arm, 4 SMS only arm, 2 SMS+150KES arm) were queried but did not provide a reason for not being vaccinated (**Table 4.22**). There was no significant difference in cause of delayed vaccination across study arms (chi-squared p= 0.529).

4.4.8. Intervention receipt, use of incentive, opinions of interventions

4.4.8.1. Reported receipt of SMS reminders

Whereas at least one SMS reminder was sent out by the study team to participants, 98 (67.1%) and 120 (80.5%) of SMS only arm and SMS+150KES arm caregivers, respectively, reported that they received at least one SMS reminder. In addition, 47 (32.2%) and 27 (18%) of SMS only and SMS+150KES caregivers, respectively, reported that they did not receive reminders. One SMS only and SMS+150KES caregiver each did not remember whether they received a reminder and one SMS+150KES caregiver interviewed was different from the enrolled caregiver and so did not know. Due to the arrangement of the questionnaire, caregivers who reported not receiving any reminders were not queried as to whose phone the reminders were sent. But based on caregivers' mobile phone ownership at the end of the study, 19 (40%) and 10 (37%) of SMS and SMS+150KES caregivers, respectively, who reported not receiving any SMS reminders also did not own a mobile phone at the end of the M-SIMI study.

Of the 98 SMS only arm caregivers who reported receipt of at least one SMS reminder, 66 (67.4%) owned the phone receiving reminders and 32 (32.7%) received reminders on a shared phone. Thirty (30.6%) of SMS only arm caregivers reported receiving one reminder, 62 (63.3%) reported two reminders, one (1.0%) reported three reminders and 5 (5.1%) reported receiving at least one reminder but did not know the exact number. The proportion of caregivers who reported receiving two reminders among caregivers who owned the phone to which reminders were sent was significantly larger than the proportion among caregivers who shared the phone to which reminders were sent (71.2% vs. 46.9%; p= 0.019). The proportion of caregivers who did

not know the number of reminders received was significantly higher among those sharing a phone compared to those who owned the phone receiving messages (15.6% vs. 0%; p= 0.001; **Table 4.23**).

In the SMS+150KES arm, 82 (68.3%) of caregivers reporting receipt of at least one SMS reminder owned the phone receiving reminders while 38 (31.7%) shared the phone receiving reminders (**Table 4.23**). Twenty-one (17.5) of SMS+150KES arm caregivers reported receiving one reminder, 94 (78.3%) reported two reminders, two (1.7%) reported receiving three reminders and 3 (2.5%) did not know how many reminders were received. The proportion of caregivers who did not know the number of reminders received was significantly higher among SMS+150KES caregivers who shared a phone compared to those who owned the phone receiving reminders (7.9% vs. 0%; p= 0.010; **Table 4.23**).

4.4.8.2. Caregiver opinions about SMS reminders

Of the 98 SMS only arm caregivers who reported receiving at least one SMS reminder, 88 (89.8%) opined that the reminders influenced the decision to vaccinate the infant; 80 (90.9%) of their infants were vaccinated by age 12 months. Most caregivers (n= 80; 81.6%) felt that two SMS reminders were adequate while eight (8.2%) of caregivers would have preferred more; other caregivers either shared a mobile phone or had no opinion. Close to 90% of caregivers were happy with the length of the SMS reminders, the rest either shared a mobile phone or had no opinion.

Among the 110 SMS+150KES arm caregivers reporting receipt of at least one SMS reminder, 110 (91.7%) felt that the reminders influenced their decision to vaccinate their infant; 96 (87.3%) were vaccinated by age 12 months. Similar to caregivers in the SMS only arm, most caregivers (n= 94; 78.3%) felt two reminders were sufficient; 15 (12.5%) felt that the reminders were too few while the rest either shared a phone or had no opinion. With regard to the length of the SMS reminders, 106 (88.3%) of caregivers were satisfied with the length of the reminder used, one (0.8%) caregiver felt that the message was too short while 13 (10.8%) did not opine as they shared a phone (**Table 4.24**).

4.4.8.3. Caregivers' reported receipt of incentive, use of incentive and opinions

Of 149 SMS+150KES arm caregivers, 105 (70.5%) reported that they received the mMoney incentive, of whom 76 (72.4%) owned the phone to which the mMoney incentive was sent. Receipt of the incentive influenced the decision of 88 of the 105 caregivers to vaccinate their infant; 78 infants of these 88 caregivers received MCV1 by age 12 months. Respectively, 16 (15.2%), 67 (63.8%) and 20 (19.0%) of caregivers cashed out the incentive on the same day, within 1-3 days of receiving the incentive and more than three days after receiving the incentive. Two (1.9%) of the caregivers did not cash out the incentive. Approximately 95% reported a positive experience related to receiving the incentive while four (3.8%) had no opinion about the experience. One (1.0%) caregiver reported a very negative experience but further details were not recorded. Only one caregiver reported that they would be less likely to vaccinate their infant in the future in the absence of an incentive. Incentives were commonly used to cover transport costs (n= 59; 56.2%), for housing expenses (n= 21; 20.0%) and to purchase food (n= 16; 15.2%).

Other uses of the incentive included purchase of medicine, infants' clothing and purchase of mobile phone airtime (via mMoney) by one of the two caregivers that did not cash out the incentive. The other caregiver that did not cash out the incentive had not used it as of the time of the 12 month follow-up visit (**Table 4.25**).

4.5. Discussion

SMS reminders coupled with an unconditional KES 150 incentive significantly increased, as compared to control infants, the proportion of infants receiving measles vaccine by age 10 months whereas SMS reminders alone did not. In the per-protocol analysis, timely measles coverage by age 10 months was significantly higher in the SMS only arm compared to the Control arm, suggesting that when delivered as intended, SMS reminders may significantly improve timely measles vaccination coverage. In addition, MCV1 timely coverage estimates for SMS only and SMS+150KES infants were comparable, suggesting no added benefit of unconditional incentives over SMS reminders only. The interventions did not differentially impact MCV1 timeliness significantly by strata of mobile phone ownership status, travel time to a health facility, age at enrollment, birth order or maternal educational level. The interventions did not significantly improve secondary outcomes of measles vaccination coverage by age 12 months nor the time to vaccination. This study was novel in that it evaluated the impact of SMS reminders coupled with *unconditional* monetary incentives on vaccination timeliness and coverage. To our knowledge, it is only the second study, after the M-SIMU study,[35] to evaluate the impact of SMS reminders coupled with monetary incentives on vaccination uptake and the first to evaluate the combined impact of SMS vaccination reminders coupled with *unconditional* incentives.

The finding from this study that SMS reminders coupled with an incentive significantly increase measles vaccination timeliness is consistent with the M-SIMU study[35] and reproduces a positive finding within the same study population; both studies included participants sampled from Gem sub-county. In the M-SIMU study, SMS reminders alone significantly increased MCV1 timely

coverage by 10% while SMS reminders coupled with conditional monetary incentives significantly improved MCV1 timely coverage by approximately 20%. Of note, the impact of SMS reminders coupled with *unconditional* monetary incentives on MCV1 timely coverage in the M-SIMI study was less than that observed for SMS reminders coupled with conditional incentives in the M-SIMU study, suggesting differential impact of *unconditional* versus conditional incentives. Of note also is that the impact of SMS reminders alone in the M-SIMI study was comparable to that observed in the M-SIMU study.[35]

Despite their modest impact, the observation that SMS reminders with or without unconditional monetary increased timely measles coverage by approximately 10 percentage points in the M-SIMI study is of public health significance. Delay in vaccination reduces herd immunity and can lead to accumulation of a susceptible pool of susceptible persons particularly in this setting with high HIV prevalence. Furthermore, measles vaccine fails to induce protection in about 15% of infants receiving a first dose at age 9 months,[52] making it more important to improve population immunity by vaccinating as many infants as possible given that the number of secondary measles infections increases with decreasing vaccination coverage.[53]

It is encouraging that there were no differential effects of the interventions on timely measles vaccination among caregivers who owned a mobile phone (a potential indicator of socioeconomic status) vs. those that did not, households with shorter vs. longer travel time to a clinic, firstborn vs. later-born infants or less educated vs. more educated caregivers. In part, the Sustainable Development Goals aspire for equitable access to vaccines (Target 3.8)[54] yet

characteristics such as socioeconomic status, health facility access, birth order and education level can influence access to vaccination.[55–58] The findings from this study suggest that the observed increases in timely vaccination coverage did not occur at the expense of already disadvantaged sub-groups. Previously, the M-SIMU study found that increases in full vaccination coverage among infants of less educated caregivers who received SMS reminders with or without a conditional monetary incentives, compared to similar control infants, were significantly higher than increases in vaccination coverage among infants of more educated caregivers who received the interventions, compared to similar control arm caregivers.[35] This finding suggested that the interventions were more impactful for disadvantaged infants. Although this pattern was not observed in the M-SIMI study, the interventions did not appear to amplify inequitable access to vaccination.

The interventions in the M-SIMI study did not significantly improve measles vaccination coverage by age 12 months or the time to measles vaccination, in contrast to the M-SIMU study in which SMS reminders coupled with a conditional 200 KES incentive significantly improved measles vaccination coverage by age 12 months and the time to vaccination.[35] This discrepancy in findings could be due to several reasons.

First, the M-SIMI study was underpowered to detect the level of difference observed in the study. For a study to detect a 6.1% or 6.5% absolute increase in vaccination coverage by age 12 months, as observed in this study (**Table 4.13**), the analytic sample would need to include at least 677 or 593 participants, respectively, in each group which is greater than this study's total

analytic sample of 455. One approach to increasing the power of an underpowered study is to combine similar study arms. When we combined data from the SMS only and SMS+150KES arms of the M-SIMI study and compared MCV1 overall coverage in the intervention arms to the Control arm, we found no statistically significant differences in the likelihood of measles vaccination by age 12 months (aRR 1.08; 95% CI: 0.98, 1.19; p= 0.114) or in the absolute difference in vaccination coverage (aRD 6.2%; 95% CI: -1.3, 13.8%; p= 0.106; **Table 4.26**). However, the combined sample size of the intervention arms (N= 295) was still underpowered to detect a 6.2% absolute difference in vaccination coverage.

Second, the incentive amount and nature of the incentive differed in the M-SIMI study compared to the M-SIMU study. In the M-SIMI study, caregivers received a maximum monetary incentive of KES 150 (~US $1.87 in August 2015 after indexing to 2015 KES and applying exchange rate). In contrast, caregivers in the M-SIMI study received as much as KES 800 as this study incentivized the pentavalent vaccine primary dose in addition to MCV1 (KES 800 = ~US $9.41 in August 2015.[35] Formative research for the M-SIMU study whereby caregivers in the study area were asked what amount of money might motivate a caregiver to prioritize attending the vaccination visit rather over other activities found a larger proportion of caregivers (93%) felt that KES 200 would be motivational compared to 83% who felt that KES 150 would be motivational (D. G. Gibson, unpublished data, September 2014). Therefore, one could theorize that the KES 200 M-SIMU incentive offered for each of four vaccine doses elicited more extrinsic motivation for caregivers to seek vaccination compared to the KES 150 M-SIMI incentive as higher incentive amounts are thought to elicit higher impact.[59] In addition, the incentive was delivered unconditionally in the M-SIMI study whereas in M-SIMU the incentive

was sent only if the infant was vaccinated within two weeks of the vaccine due date. There is mixed evidence on whether the impact of conditional incentives varies from that of unconditional incentives. Systematic reviews have found positive health effects of both conditional and unconditional incentives for outcomes such as HIV prevention and treatment and health care seeking.[60–62] Only one systematic review and meta-analysis found that unconditional incentives improved return rates for mailed surveys whereas conditional incentives did not.[63] Furthermore, the role of monetary versus non-monetary nature of incentives on the impact of conditional versus unconditional incentives is not well understood. Even in the absence of conditions, it is theorized high levels of community interest in achieving the outcome could mimic the effects of conditions.[64] In terms of vaccination outcomes, evaluations of large conditional and unconditional cash transfer programs in Central and South America found that the transfers significantly increased uptake for some vaccines but not for others, with neither type of cash transfer program having consistently significant findings across different vaccines.[65–68] In the one cluster randomized controlled trial that simultaneously assessed the impact of both conditional and unconditional cash transfers on childhood health in Zimbabwe, neither intervention significantly improved the proportion of children who were up-to-date on their vaccinations even though families could receive as much as $212 (incentive value indexed to 2015 USD).[69] In the behavioral economics literature, conditional incentives are theorized to have a negative impact whereby they may inhibit intrinsic motivation through reducing one's perception of choice and agency.[42] Thus, there is no clear evidence of differential impact of conditional versus unconditional incentives and it remains unclear if the different modality of the incentive in the M-SIMI study compared to the M-SIMU study may have influenced the different findings on the impact of reminders plus incentives on MCV1 overall coverage.

Finally, we may have observed differences in the impact of SMS reminders coupled with an incentive in the M-SIMI study compared to the impact observed in the M-SIMU study because, as mentioned previously, M-SIMU caregivers received reminders and incentives for four vaccine doses as opposed to only MCV1 in the M-SIMI study. The repeated vaccination prompts during the M-SIMU study may have induced greater vaccine seeking among caregivers as more frequent reminders may be associated with greater impact.[70]

Nevertheless, we observed that the 78.1% MCV1 overall coverage estimate in the M-SIMI Control arm differed markedly from the expected 83-84% coverage based on previous estimates of coverage in the study area[16,35] and in Siaya County.[15] In particular, we expected similar MCV1 overall coverage in M-SIMU[35] and M-SIMI studies as they were conducted in the same geographical area. The lower MCV1 overall coverage observed in the M-SIMI study suggested that there may have been procedural differences between the studies or secular changes affecting baseline measles vaccination coverage. One procedural difference between the studies is that while the M-SIMU study included infants who received measles at any age (infants were enrolled within one month of age), the M-SIMI study excluded 44 infants who had received measles vaccination before enrollment (**Figure 4.3**). To assess whether excluding these infants may have impacted the estimate of MCV1 overall coverage in the Control arm, we equitably distributed the 44 infants across study arms and designated them to have received measles vaccination by age 12 months. After including these infants who were excluded for having received measles vaccination before enrollment, Control arm MCV1 overall coverage was 79.9% but the likelihood of vaccination in the Control arm was not significantly lower than that in the

SMS only arm (aRR 1.07; 95% CI: 0.97, 1.18; p= 0.184) or the SMS+150KES arm (aRR 1.08; 95% CI: 0.98, 1.19; p= 0.116; **Table 4.27**). Baseline MCV1 overall coverage in the M-SIMI study remained below that in the M-SIMU after including infants who had received measles vaccine before enrollment, so it seems unlikely that M-SIMI eligibility criteria influenced the lower Control arm MCV1 overall coverage in M-SIMI.

Another possible explanation for lower MCV1 overall coverage in the M-SIMI Control arm compared to M-SIMU was a nurses' strike that began on June 5, 2017[71] and was ongoing at the time of the M-SIMI study's completion. Of the 455 infants in the analytic sample, 32.1% reached age 12 months after the strike began. MCV1 overall coverage was 88.4% among infants reaching age 12 months before the strike began and 79.3% among those reaching their first birthday after the strike launched. We found that the risk of receiving MCV1 by age 12 months was about 10% lower among infants who reached age 12 months after the strike began (RR 0.90; 95% CI: 0.83, 0.97; p= 0.010, data not shown). However, MCV1 overall coverage was not significantly higher in the intervention infants who reached age 12 months before the strike compared to Control infants who also reached age 12 months before the strike nor among intervention compared to Control infants who reached age 12 months after the strike begun (data not shown). It is still plausible though that the nurses' strike reduced the potential impact of interventions as caregivers seeking MCV1 in public health facilities would have been unable to get their infants vaccinated. Another supply-side factor that might have minimized MCV1 uptake is that few clinics in the study offer MCV daily (D. G. Gibson, unpublished data, July 2013).

To leverage the information from the M-SIMI and M-SIMU studies, which were conducted in the same study area and assessed similar interventions with the exception of the value of the monetary incentive and conditional nature, we performed a post-hoc random-effects meta-analysis to pool the data from the two studies. In this pooled analysis, SMS reminders alone improved measles vaccination timeliness (RR 1.15; 95% CI: 1.04, 1.28; p= 0.007; **Figure 4.8**) as did SMS reminders coupled with an unconditional KES 150 incentive or a conditional KES 200 incentive (RR 1.28; 95% CI: 1.05, 1.56; p= 0.014; **Figure 4.9**). However, SMS reminders alone did not significantly improve MCV1 overall coverage (pooled RR 1.05; 95% CI: 0.99, 1.11; p= 0.105; **Figure 4.8**) whereas SMS reminders coupled with an incentive significantly improved the likelihood of measles vaccination by age 12 months (pooled RR 1.07; 95% CI: 1.02, 1.13; p= 0.007; **Figure 4.9**). This accumulated evidence suggests that SMS reminders alone can improve measles vaccination timeliness. But, reminders' impact on the proportion of infants receiving MCV1 in this setting is less clear. In this setting where MCV1 overall coverage is typically >80%,[15,16,35] reaching the additional 10-15% coverage needed for measles control is challenging as these remaining children represent those with the greatest barriers to vaccination. SMS reminders alone may not be sufficient to surmount the barriers faced by these children, whereas the addition of other interventions such as incentives, could overcome those barriers. Beyond the M-SIMI study area, a study conducted in the Philippines found no impact of SMS reminders on MCV2 coverage while another study conducted in China found a significant increase in MCV1 overall coverage compared to baseline following the use of SMS reminders.[72,73] Pooled evidence from the M-SIMI and M-SIMU studies strongly suggest that in a setting with limited supply-side barriers to vaccination, SMS reminders coupled with an incentive can significantly improve

MCV1 timeliness as well as the proportion of infants receiving MCV1 by age 12 months but the impact of SMS reminders alone is unclear.

Caregivers' opinions of the interventions and their experiences with them were generally positive (**Tables 4.23 – 4.25**). It appears that a smaller proportion of caregivers agreed with the number of SMS reminders compared to other modalities such as the length of the reminder. However, some caregivers were unable to respond since the phone was shared. In addition, not all reminders may have been relayed to caregivers who were sharing phones. This study sent the same number of reminders as the M-SIMU study, yet satisfaction with the number of reminders during the M-SIMU study was higher than we found in this study.[35] More formative research into the optimal number of vaccination reminders in this setting may help finesse the intervention and perhaps influence outcomes. In the HIV literature, too frequent reminders have been linked to desensitization to reminders.[74] Encouragingly, virtually all caregivers who reported receiving the incentive also reported increased or the same likelihood of vaccinating their children in the future. One criticism of incentives is that they may dampen intrinsic motivation to engage in positive behaviors, leading to reduced practice of the incentivized behavior once incentives are withdrawn.[42,75,76] The most commonly reported use of the incentive was to cover transportation costs, which we theorized was a barrier to vaccination that the incentive could help overcome. Although incentives were also used to cover other costs such as housing expenses and food it still might have encouraged caregivers to vaccinate their infants by reframing their perceived self-efficacy, perceived barriers or acting as a cue to action.[77,78]

Supply-side factors were more commonly cited as reasons for delayed vaccination than demand-side factors. Of 88 caregivers who gave a reason for delayed measles vaccination, 60 cited supply-side factors including the nursing strike, vaccine stock-out, vaccination not recorded in MCH booklet or forgetting to carry the MCH booklet, nurse's refusal to open the vial and far distance to the clinic. The high contribution of supply-side factors was likely driven by the nurses' strike. Still, this setting with high DTP3 coverage highlights the use of multi-dose measles vaccine vials and measles vaccine stock-outs as barriers to vaccination. Multi-dose vials as a barrier to measles vaccine is widely discussed anecdotally and has been documented in some studies.[21,24] Caregiver forgetfulness and not knowing the vaccine due date was cited by a few caregivers and more frequently by Control arm caregivers. Vaccine hesitancy does not appear to be common in this setting – only one caregiver expressed the feeling that vaccination was not important and one other caregiver was discouraged from vaccination by a friend – but caregivers may have been reluctant to express hesitancy to study staff, particularly among those caregivers who did not provide a reason for delayed vaccination. These findings underscore the need for supply-side as well as demand-side interventions to improve vaccination uptake.

This study has several limitations. First, the analytic sample comprised 84.7% of enrolled participants. Excluded infants were more likely to be firstborn children and to have mothers aged 25 years or less. Similar patterns were observed in the M-SIMU study and are attributed to cultural practices around pregnancy and birth whereby mothers return to their rural home to receive support caring for newly-born infants.[35] The proportion of firstborn children and younger mothers among excluded participants was higher in the intervention arms compared to the Control arm. Firstborn infants and children of younger mothers are thought to be less at risk of

being unvaccinated or receiving vaccination with delay than later-born infants and children of older mothers, respectively.[16,56–58,79] Thus, the effect estimates for the intervention arms may have been biased towards the null. Due to limited resources we were unable to mitigate the impact of losses to follow-up or missing MCH records. We had limited resources to track infants who were lost to follow-up or to attempt to ascertain vaccination status from clinic records. We were reluctant to include verbal report of vaccination status because evidence from other settings implies that they may under- or over-estimate actual vaccination coverage.[48–51] We know little about the validity of verbal vaccination report in this setting, but preliminary analysis from a different study indicates that it has high sensitivity with less than perfect specificity (K. Hayford, unpublished data, February 2018), suggesting that verbal report could over-estimate vaccination coverage in this setting.

Another limitation of this study is that only 85.4% of SMS reminders and 61.1% of mMoney incentives were sent out as intended i.e., three days and one day before the scheduled vaccination date for reminders and three days before the scheduled vaccination date for the incentive. Delivery of SMS reminders was hampered mainly by power outages during which the RapidSMS server would not send out reminders until power was restored and the server computer turned on. To a minimal extent, reminders were not sent out per-protocol because of inaccurate dates of birth submitted to the server by CIs via SMS, which in turn impacted the timing of the reminders. mMoney incentives were delayed because they were sent out manually by study staff during weekdays but on weekends when staff were not working. In the per-protocol analysis, measles vaccination timeliness was borderline significant for the SMS only arm and the absolute increase in vaccination coverage was significantly higher in the SMS only

arm compared to the Control arm (**Tables 4.11 and 4.12**). These findings were not borne out in the intent-to-treat analysis, suggesting that efficacy in the SMS only arm might have been impacted by imperfect delivery of reminders. At the same time the difference in findings in the per-protocol versus intent-to-treat analyses may provide some insight into the real-world effectiveness of SMS reminders when delivered within a program setting which may experience similar or other challenges to sending out reminders strictly as intended. The per-protocol analysis did not take into account per-protocol delivery of the incentive for the SMS+150KES arm. Only 81 infants in the SMS+150KES arm received both reminders and the incentive per-protocol. Measles vaccination coverage by age 10 months and age 12 months in this sub-sample, 77.8% and 83.6%, respectively, was similar to coverage in the analytic per-protocol sample (data not shown). Given the small sub-sample size (81 infants) and the similarity of its vaccination coverage estimates to the per-protocol sample, regression to obtain RR and RD was not performed because the sample size may have been too small to detect any significant differences. Additional research is needed to determine whether the timing of the incentive may impact its effect.

A related limitation is that only 67.1% and 80.5% of SMS only arm and SMS+150KES arm caregivers reported receiving at least one reminder. Further, only 70.5% of SMS+150KES arm caregivers reported receiving the incentive. If truly 20% or more participants did not receive the interventions, the observed effects would have been biased towards the null. A higher proportion of SMS+150KES arm participants receiving the interventions compared to SMS only arm participants could explain the differential impact of the interventions on MCV1 timeliness (**Table 4.13**). However, measurement of intervention receipt was susceptible to recall bias as we

asked caregivers whether they had received the interventions about three months after they had been sent. Beside recall bias, reported receipt of interventions may have been influenced by phone ownership, whereby caregivers who owned a phone may have been more likely to receive the interventions and to remember having received the intervention compared to who shared the phone to which interventions were sent. Because of how the questionnaire was structured, we do not know the proportion of caregivers who reported receiving one or more reminder, stratified by phone ownership type among all caregivers. But among only caregivers who reported receiving one or more reminders, a higher proportion of caregivers who owned a phone reported receiving two reminders compared to the proportion of caregivers sharing a phone who reported receiving two reminders (**Table 4.23**). We did not observe differential impact of interventions among caregivers who owned a phone versus those who shared a phone (**Figures 4.4 and 4.5**), suggesting that phone ownership impact did not impact receipt of the interventions, but the study was not powered to detect sub-group differences. Curiously, the proportion of SMS+150KES caregivers who reported receiving SMS reminders was higher than the proportion who reported receiving the incentive. This could perhaps be explained if SMS messages were more likely to be passed along than the incentive for SMS+150KES caregivers who shared a phone. Indeed, 10 (27.0%) of 37 SMS+150KES caregivers who reported receiving SMS reminders via a shared phone also reported not receiving the incentive (data not shown). We did, however, verify that SMS reminders and incentives were sent as one study staff's phone number was included with in all batches of SMS reminders and incentives sent out as a quality control measure; as such we are confident that the interventions were dispatched.

An additional limitation of this study is that CIs, who collected measles vaccination status at the follow-up visit, were responsible for assigning the study arm at enrollment and were therefore not blinded to study arm allocation. To minimize the risk of outcome ascertainment bias, the follow-up questionnaire was structured to collect vaccination data prior to any questions that identified the study arm allocation. For CIs to be biased when ascertaining vaccination status, they would have had to rely on their memory of the participant's study arm allocation during the enrollment visit, which was conducted four to six months prior to the follow-up visit. Each CI enrolled approximately 107 participants and so we think it is unlikely. Nevertheless, the study's Field Supervisor performed repeat interview for approximately 5% of enrolled infants and only one discrepancy was identified and resolved by a review of the child's vaccination status. Therefore, we have no evidence of outcome ascertainment bias.

Based on findings from the M-SIMU study, we do not recommend the use of small monetary unconditional vaccination incentives in settings with relatively high yet suboptimal MCV1 vaccination timeliness and coverage. Although large unconditional monetary incentives in some social programs within LMICs have been observed to have positive a positive impact on vaccination uptake, in this study we found that they had no added benefit on MCV1 timeliness over SMS reminders alone and that their non-significant impact on MCV1 overall coverage was comparable to the impact of SMS reminders alone, yet the cost of their implementation was higher than the cost of SMS reminders alone. Given that SMS reminders are relatively inexpensive to implement, we recommend continued evaluation of the impact of SMS reminders, particularly in large studies that may be able to detect modest increases in vaccination uptake by 12 months of age or later.

Chapter 4 References

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Chapter 4 Tables

Table 4.1. Content for SMS reminder messages

	3-day reminder		1-day reminder	
Study arm	**Content**	**Characters**	**Content**	**Characters**
SMS only	Tell Mama <<*infant's name*>> that Measles vaccine is due this week. Most Gem babies get vaccinated, be one of them!	114 including spaces; count includes up to 17 characters for the child's name	Tell Mama <<*infant's name*>> that Measles vaccine is due this week. Go to the clinic if you haven't already. Vaccines save Kenyan babies lives.	142 including spaces; count includes up to 17 characters for the child's name
SMS+150KES	Tell Mama <<*infant's name*>> that Measles vaccine is due this week. We are sending 150ksh to assist with travel. Most Gem babies get vaccinated, be one of them!	159 including spaces; count includes up to 17 characters for the child's name		

Table 4.2. Variables included in analysis of distribution of baseline characteristics across study arms

Characteristic	Existing or derived variable	Description
Mobile phone access	Existing	Binary: 0= Shares; 1= Owns
Mobile phone network	Derived	Binary: 0= Other ; 1= Safaricom Participants were asked to select a mobile phone network operator from four options (Safaricom, Airtel, Orange, YU or DK). Other vs. Safaricom was used because Safaricom commands most of the mobile phone operator market share. For example, in the first quarter of 2017 and out of 6 mobile network operators, Safaricom operated 71.9% of mobile phone subscriptions and 77.3% of m-Money transfers[80]
Infant's sex	Existing	Binary: 0= Female; 1= Male
Infant's age at enrollment	Derived	Categorical: 0= 6 months; 1= 7 months; 2= 8 months Infant's age at enrollment was calculated by subtracting the infant's date of birth from the date of enrollment. The number of days was divided by 30.42 (in the analysis one month = 30.42 days) so as to obtain the number of months. Infants whose calculated age was <7 months were categorized as being aged 6 months at enrollment; those whose calculated age was ≥7 months but <8 months categorized as being aged 7 months and those with calculated age ≥8 months as being aged 8 months.
Penta3 received before enrollment	Existing	Binary: 0= Not vaccinated; 1= Vaccinated
Travel time to health facility	Derived	Binary: 0= ≤30 minutes; 1= >30 minutes Travel time to health facility was collected as a categorical variable i.e., 0-15 minutes, 16-30 minutes, 31-45 minutes, 46-60 minutes and >60 minutes. The 30 minute cutoff was selected because the median category was 16-30 minutes (**Figure 4.2A)**. In addition, studies conducted in Uganda and South Africa have shown that patients within 30 minutes travel time to a health facility have higher levels of HIV care-seeking[81] and higher levels of access to healthcare.[82]
Maternal education	Derived	Binary: 0= ≤7 years; 1= >7 years

Characteristic	Existing or derived variable	Description
		Maternal education level was collected in a series of two variables, one categorical (Primary, Secondary, Post-secondary or none) and the other continuous (Class or form completed). Caregivers selecting no education or primary education with class <8 were classified as having ≤7 years of education. The cutoff at 7 years was used because primary school education in Kenya is 8 years; this cutoff allows distinguishing caregivers with less than primary education vs. those with primary education or more. In addition, 7 years was the median years of maternal education in this sample (**Figure 4.2B**)
Birth order	Derived	Binary: 0= Firstborn; 1= Later-born Birth order was collected as a categorical variable i.e., 1= 1st; 2= 2nd; 3= 3rd; 4= 4th; 5= 5th; 6= 6th; 7= 7th; and 8= >7th born. Firstborn vs. later-born was used as studies in various settings have shown that, compared to later-born children, firstborn children are more likely to receive MCV,[58] to receive MCV in a timely manner,[79] as well as to be up-to-date for other vaccines.[56,57,79]
Location of last delivery	Derived	Binary: 0= At home; 1= Health facility Location of last delivery was collected as a categorical variable 1= At home with no Skilled Birth Attendant (SBA)/ Midwife; 2= At home with SBA/Midwife; 3= Health Facility; 4= Don't know. At home vs. health facility was selected because it might reflect caregivers' health-seeking behavior.
Maternal age	Derived	Binary: 0= ≤25 years; 1= >25 years Maternal age was collected as a continuous variable. Age 25 years was selected as the cutoff because the median maternal age was 25 years (**Figure 4.2C**).
Number of ANC visits for enrolled infant	Derived	Binary: 0= ≤4 visits; 1= >4 visits Number of ANC visits was collected as a continuous variable. Four visits was selected as the cutoff based on the 2002 recommendation from WHO for a minimum of four ANC visits.[83] The new eight-visit minimum recommended by WHO in November 2016 was not used because M-SIMI mothers experienced pregnancy prior to issuance of the new guidelines.[84]
Socioeconomic quintile	Derived	Binary: 0= Bottom 40%; 1= Upper 60% A series of variables to record asset ownership was collected i.e. the number of the following items owned by the household was collected: goats, cattle, sheep,

Characteristic	Existing or derived variable	Description
		poultry, donkey, pigs, plough, foam mattress, spring mattress, straw mattress, cell phone, radio, bicycle, sofa, lantern, TV. Using the same method used by the KEMRI HDSS to quantify SES, multiple correspondence analysis (MCA) was used to generate a SES index. The index was grouped into quintiles. The socioeconomic quintile variable was generated by coding the bottom two quintiles as being in the bottom 40% and the top three quintiles as being the upper 60% of the wealth distribution. The 40% cutoff was selected because socioeconomic status was calculated as a five-component index and a 40% cutoff was thought to be more likely capture inequitable health care access compared to a 20% cutoff.

Table 4.3. Baseline characteristics of infants in the analytic sample

	Control (N = 160) No. (%)	SMS only (N = 146) No. (%)	SMS+150KES (N = 149) No. (%)	Total (N=455) No. (%)
Mobile phone access				
Shares	49 (30.6)	48 (32.9)	46 (30.9)	143 (31.4)
Owns	111 (69.4)	98 (67.1)	103 (69.1)	312 (68.6)
Mobile phone network				
Other	5 (3.1)	4 (2.7)	1 (0.7)	10 (2.2)
Safaricom	155 (96.9)	142 (97.3)	148 (99.3)	445 (97.8)
Infant's sex				
Female	77 (48.1)	70 (47.9)	69 (46.3)	216 (47.5)
Male	83 (51.9)	76 (52.1)	80 (53.7)	239 (52.5)
Infant's age at enrollment				
6m	104 (65.0)	92 (63.0)	96 (64.4)	292 (64.2)
7m	53 (33.1)	52 (35.6)	51 (34.2)	156 (34.3)
8m	3 (1.9)	2 (1.4)	2 (1.3)	7 (1.5)
Penta3 before enrollment				
Not vaccinated	6 (3.8)	7 (4.8)	6 (4.0)	19 (4.2)
Vaccinated	154 (96.3)	139 (95.2)	143 (96.0)	436 (95.8)
Time to health facility				
≤30 minutes	110 (68.8)	85 (58.2)	97 (65.1)	292 (64.2)
>30 minutes	50 (31.3)	61 (41.8)	52 (34.9)	163 (35.8)
Maternal education				
≤7 years	53 (33.1)	54 (37.0)	49 (32.9)	156 (34.3)
>7 years	107 (66.9)	92 (63.0)	100 (67.1)	299 (65.7)
Birth order				
Firstborn	33 (20.6)	31 (21.2)	22 (14.8)	86 (18.9)
Later-born	127 (79.4)	115 (78.8)	127 (85.2)	369 (81.1)
Location of last delivery				
At home	30 (18.9)	28 (19.2)	25 (16.8)	83 (18.3)
Health facility	129 (81.1)	118 (80.8)	124 (83.2)	371 (81.7)
Maternal age				
≤25 years	80 (50.0)	86 (58.9)	62 (41.6)	228 (50.1)
>25 years	80 (50.0)	60 (41.1)	87 (58.4)	227 (49.9)
Number of ANC visits for enrolled infant				
≤4 visits	114 (71.3)	99 (67.8)	96 (65.3)	309 (68.2)
>4 visits	46 (28.7)	47 (32.2)	51 (34.7)	144 (31.8)
Socioeconomic quintile				
Bottom 40%	72 (45.0)	55 (37.7)	52 (34.9)	179 (39.3)
Upper 60%	88 (55.0)	91 (62.3)	97 (65.1)	276 (60.7)

Table 4.4. Comparison of the distribution of baseline characteristics among infants in the analytic sample compared to excluded infants

	Analytic sample (N= 455)	**Verbal report (N= 24)**	**Lost to follow-up (N= 54)**	**Twins (N= 4)**	**All excluded (N= 82)**	**p-value***
	No. (%)	**No. (%)**	**No. (%)**		**No. (%)**	
Mobile phone access						
Shares	143 (31.4)	7 (29.2)	19 (35.2)	0	26 (31.7)	0.960
Owns	312 (68.6)	17 (70.8)	35 (64.8)	4 (100)	56 (68.3)	
Mobile phone network						
Other	10 (2.2)	2 (8.3)	0	0	2 (2.4)	0.892
Safaricom	445 (97.8)	22 (91.7)	54 (100)	4 (100)	80 (97.6)	
Infant's sex						
Female	216 (47.5)	9 (37.5)	31 (57.4)	3 (75.0)	43 (52.4)	0.407
Male	239 (52.5)	15 (62.5)	23 (42.6)	1 (25.0)	39 (47.6)	
Infant's age at enrollment						
6m	292 (64.2)	15 (62.5)	32 (59.3)	0	47 (57.3)	0.206
7m	156 (34.3)	9 (37.5)	22 (40.7)	4 (100)	35 (42.7)	
8m	7 (1.5)	0	0	0	0	
Penta3 before enrollment (MCH card record only)						
Not vaccinated	18 (4.0)	3 (13.0)	3 (5.8)	0	6 (7.6)	0.150
Vaccinated	437 (96.0)	20 (87.0)	49 (94.2)	4 (100)	73 (92.4)	
Penta3 before enrollment (MCH card and verbal record)						
Not vaccinated	18 (4.0)	3 (12.5)	3 (5.6)	0	6 (7.3)	0.175
Vaccinated	437 (96.0)	21 (87.5)	51 (94.4)	4 (100)	76 (92.7)	
Time to health facility						
≤30 minutes	292 (64.2)	12 (50.0)	36 (66.7)	2 (50.0)	50 (61.0)	0.579
>30 minutes	163 (35.8)	12 (50.0)	18 (33.3)	2 (50.0)	32 (39.0)	
Maternal education						
≤7 years	156 (34.3)	10 (41.7)	15 (27.8)	2 (50.0)	27 (32.9)	0.811

	Analytic sample (N= 455)	Verbal report (N= 24)	Lost to follow-up (N= 54)	Twins (N= 4)	All excluded (N= 82)	p-value*
	No. (%)	No. (%)	No. (%)		No. (%)	
>7 years	299 (65.7)	14 (58.3)	39 (72.2)	2 (50.0)	55 (67.1)	
Birth order						
Firstborn	86 (18.9)	7 (29.2)	27 (50.0)	0	34 (41.5)	**<0.001**
Later-born	369 (81.1)	17 (70.8)	27 (50.0)	4 (100)	48 (58.5)	
Location of last delivery						
At home	83 (18.3)	3 (12.5)	10 (18.5)	0	13 (15.9)	0.598
Health facility	371 (81.7)	21 (87.5)	44 (81.5)	4 (100)	69 (84.1)	
Maternal age						
≤25 years	228 (50.1)	12 (50.0)	42 (77.8)	2 (50.0)	56 (68.3)	**0.002**
>25 years	227 (49.9)	12 (50.0)	12 (22.2)	2 (50.0)	26 (31.7)	
Number of ANC visits for enrolled infant						
≤4 visits	309 (68.2)	17 (73.9)	43 (79.6)	4 (100)	64 (79.0)	0.051
>4 visits	144 (31.8)	6 (26.1)	11 (20.4)	0	17 (21.0)	
Socioeconomic quintile						
Bottom 40%	179 (39.3)	9 (37.5)	27 (50.0)	0	36 (43.9)	0.438
Upper 60%	276 (60.7)	15 (62.5)	27 (50.0)	4 (100)	46 (56.1)	

*p-value for comparison of analytic sample to all excluded

Table 4.5. Number and timing of SMS reminders by intervention study arm and overall

SMS delivery	SMS N=146 n (%)	SMS+150KES N=149 n (%)	Total N=295 n (%)
Per-protocol*	126 (86.3)	126 (84.6)	252 (85.4)
Not per-protocol	20 (13.7)	23 (15.4)	43 (14.6)
3 reminders sent	0 (0)	2 (8.7)	2 (4.6)
Reminder before day of appointment not sent	7 (35.0)	7 (30.4)	14 (32.5)
Reminder three days before appointment not sent	4 (20.0)	7 (30.4)	11 (25.6)
Second reminder sent on day of appointment	7 (35.0)	6 (26.1)	13 (30.2)
Reminders sent 2 days before and on day of appointment	1 (5.0)	0 (0)	1 (2.3)
Reminders sent after appointment date	1 (5.0)	1 (4.3)	2 (4.8)

*Per-protocol SMS delivery = 2 reminders sent, one three days before and the other one day before scheduled vaccination date

Table 4.6. Intent-to-treat analysis: Crude and adjusted risk ratios for measles vaccination by age 10 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	cRR* (95% CI)	p-value	aRR* (95% CI)	p-value
Control (N= 160)	109 (68.1)	Ref	--	Ref	--
SMS only (N= 146)	114 (78.1)	1.15 (1.01, 1.32)	0.050	1.13 (0.99, 1.30)	0.070
SMS+150KES (N= 149)	116 (77.9)	1.14 (1.00, 1.31)	0.055	1.16 (1.01, 1.32)	**0.035**

*cRR = Crude risk ratio; 95% CI = 95% confidence interval; aRR = Adjusted risk ratio

Table 4.7. Intent-to-treat analysis: Crude and adjusted risk differences for measles vaccination by age 10 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	% cRD* (95% CI)	p-value	% aRD* (95% CI)	p-value
Control (N= 160)	109 (68.1)	Ref	--	Ref	--
SMS only (N= 146)	115 (78.1)	10.0 (0.1, 19.8)	**0.048**	9.2 (-0.6, 19.0)	0.066
SMS+150KES (N= 149)	116 (77.9)	9.7 (-0.1, 19.5)	0.052	10.6 (0.8, 20.3)	**0.034**

*cRD = Crude risk difference; 95% CI = 95% confidence interval; aRD = Adjusted risk difference

Table 4.8. Univariate risk factor analysis for not receiving MCV1 by age 10 months among Control children

	MCV1 status			
	Not vaccinated (N= 51) n (%)	**Vaccinated (N= 109) n (%)**	**cRR (95% CI)**	**p-value**
Owns phone				
No	21 (42.9)	28 (57.1)	Ref	
Yes	30 (27.0)	81 (73.0)	1.28 (0.98, 1.67)	**0.073**
Infant's sex				
Female	25 (32.5)	52 (67.5)	Ref	
Male	26 (31.3)	57 (68.7)	1.02 (0.82, 1.26)	0.877
Infant's age at enrollment				
6m	38 (36.5)	66 (63.5)	Ref	
7-8m	13 (23.2)	43 (76.8)	1.21 (0.99, 1.49)	**0.068**
Penta3 before enrollment (MCH card record only)				
No	4 (80.0)	1 (20.0)	Ref	
Yes	47 (30.3)	108 (69.7)	3.48 (0.60, 20.17)	0.164
Time to health facility				
≤30 minutes	36 (32.7)	74 (67.3)	Ref	
>30 minutes	15 (30.0)	35 (70.0)	1.04 (0.83, 1.30)	0.727
Maternal education				
≤7 years	21 (39.6)	32 (60.4)	Ref	
>7 years	30 (28.0)	77 (72.0)	1.19 (0.93, 1.53)	0.166
Birth order				
Firstborn	7 (21.2)	26 (78.8)	Ref	
Later-born	44 (34.6)	83 (65.4)	0.83 (0.67, 1.03)	**0.092**
Location of last delivery				
At home	11 (36.7)	19 (63.3)	Ref	
Health facility	40 (31.0)	89 (69.0)	1.09 (0.81, 1.46)	0.571
Maternal age				
≤25 years	23 (28.7)	57 (71.3)	Ref	
>25 years	28 (35.0)	52 (65.0)	0.91 (0.74, 1.13)	0.398

	MCV1 status			
	Not vaccinated (N= 51) n (%)	**Vaccinated (N= 109) n (%)**	**cRR (95% CI)**	**p-value**
Number of ANC visits for enrolled infant				
≤4 visits	40 (35.1)	74 (64.9)	Ref	
>4 visits	11 (23.9)	35 (76.1)	1.17 (0.95, 1.45)	0.140
Socioeconomic quintile				
Bottom 40%	22 (30.6)	50 (69.4)	Ref	
Upper 60%	29 (33.0)	59 (67.0)	0.96 (0.78, 1.19)	0.745

Table 4.9. Distribution of timing of incentive payments relative to the scheduled vaccination date for SMS+150KES arm participants

When M-PESA sent*	Number of participants (%)
Day -3	91 (61.1)
Day -2	15 (10.1)
Day -1	21 (14.1)
Day 0	18 (12.1)
Day +1	1 (0.7)
Day +8	1 (0.7)
Day +10	1 (0.7)
Day +28	1 (0.7)
Total	149 (100)

*Reference point is scheduled vaccination date. For example, Day -3 is three days before scheduled vaccination date

Table 4.10. Distribution of timing of incentive payments by day of the week

	Actual day when M-PESA sent, relative to the intended date								
Day of week when M-PESA intended to be sent	**On intended date**	**1 day later**	**2 days later**	**3 days later**	**4 days later**	**11 days later**	**13 days later**	**31 days later**	**Total**
Sunday	0 (0)	11 (78.6)	3 (21.4)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	14 (9.4)
Monday	29 (96.7)	1 (3.3)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	30 (20.1)
Tuesday	17 (73.9)	3 (13.0)	1 (4.4)	0 (0)	0 (0)	0 (0)	1 (4.4)	1 (4.4)	23 (15.4)
Friday	45 (70.3)	0 (0)	0 (0)	17 (26.6)	1 (1.6)	1 (1.6)	0 (0)	0 (0)	64 (43.0)
Saturday	0 (0)	0 (0)	17 (94.4)	1 (5.6)	0 (0)	0 (0)	0 (0)	0 (0)	18 (12.1)
Total	91 (61.1)	15 (10.1)	21 (14.1)	18 (12.1)	1 (0.7)	1 (0.7)	1 (0.7)	1 (0.7)	149 (100)

Table 4.11. Per-protocol analysis: Crude and adjusted risk ratios for measles vaccination by age 10 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	cRR* (95% CI)	p-value	aRR* (95% CI)	p-value
Control (N= 160)	109 (68.1)	Ref	--	Ref	--
SMS only (N= 126)	100 (79.4)	1.16 (1.01, 1.34)	**0.031**	1.15 (1.00, 1.32)	0.052
SMS+150KES (N= 126)	99 (78.6)	1.15 (1.00, 1.33)	**0.046**	1.17 (1.02, 1.35)	**0.024**

*cRR = Crude risk ratio; 95% CI = 95% confidence interval; aRR = Adjusted risk ratio

Table 4.12. Per-protocol analysis: Crude and adjusted risk differences for measles vaccination by age 10 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	% cRD* (95% CI)	p-value	% aRD* (95% CI)	p-value
Control (N= 160)	109 (68.1)	Ref	--	Ref	--
SMS only (N= 126)	100 (79.4)	11.2 (1.1, 21.3)	**0.029**	10.2 (0.1, 20.3)	**0.048**
SMS+150KES (N= 126)	99 (78.6)	10.4 (0.3, 20.6)	**0.044**	11.6 (1.4, 21.7)	**0.025**

*cRD = Crude risk difference; 95% CI = 95% confidence interval; aRD = Adjusted risk difference

Table 4.13. Intent-to-treat analysis: Crude and adjusted risk ratios for measles vaccination by age 12 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	cRR* (95% CI)	p-value	aRR* (95% CI)	p-value
Control (N= 160)	125 (78.1)	Ref	--	Ref	--
SMS only (N= 146)	123 (84.2)	1.08 (0.97, 1.20)	0.171	1.07 (0.96, 1.19)	0.199
SMS+150KES (N= 149)	126 (84.6)	1.08 (0.97, 1.20)	0.147	1.09 (0.97, 1.20)	0.156

*cRR = Crude risk ratio; 95% CI = 95% confidence interval; aRR = Adjusted risk ratio

Table 4.14. Intent-to-treat analysis: Crude and adjusted risk differences for measles vaccination by age 12 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	% cRD* (95% CI)	p-value	% aRD* (95% CI)	p-value
Control (N= 160)	125 (78.1)	Ref	--	Ref	--
SMS only (N= 146)	123 (84.2)	6.1 (-2.6, 14.8)	0.169	5.7 (-3.0, 14.3)	0.199
SMS+150KES (N= 149)	126 (84.6)	6.4 (-2.2, 15.1)	0.144	6.8 (-1.8, 15.3)	0.119

*cRD = Crude risk difference; 95% CI = 95% confidence interval; aRD = Adjusted risk difference

Table 4.15. Per-protocol analysis: Crude and adjusted risk ratios for measles vaccination by age 12 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	cRR* (95% CI)	p-value	aRR* (95% CI)	p-value
Control (N= 160)	125 (78.1)	Ref	--	Ref	--
SMS only (N= 126)	107 (84.9)	1.09 (0.97,1.21)	0.138	1.08 (0.97,1.20)	0.163
SMS+150KES (N= 126)	106 (84.1)	1.08 (0.96,1.20)	0.194	1.08 (0.97,1.21)	0.166

*cRR = Crude risk ratio; 95% CI = 95% confidence interval; aRR = Adjusted risk ratio

Table 4.16. Per-protocol analysis: Crude and adjusted risk differences for measles vaccination by age 12 months in intervention arms compared to the Control arm

Study arm	Vaccinated n (%)	% cRD* (95% CI)	p-value	% aRD* (95% CI)	p-value
Control (N= 160)	125 (78.1)	Ref	--	Ref	--
SMS only (N= 126)	107 (84.9)	6.8 (-2.2, 15.7)	0.137	6.3 (-2.6, 15.2)	0.165
SMS+150KES (N= 126)	106 (84.1)	6.0 (-0.3, 15.0)	0.193	6.4 (-2.5, 15.3)	0.161

*cRD = Crude risk difference; 95% CI = 95% confidence interval; aRD = Adjusted risk difference

Table 4.17. Cumulative failure functions by study arm and analysis time for measles vaccination by age 12 months. Time origin is age at enrollment

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
182	0	0							
183	1	0					1	0	
184				0	0		2	0	
185	3	0		2	0				
186				4	0				
187	5	0		6	0		4	0	
188	7	0		11	0		8	0	
189	9	0		12	0		11	0	
190	12	0		15	0		22	0	
191	20	0		20	0		29	0	
192	22	0		28	0		32	0	
193	27	0		34	0		35	0	
194	30	0		41	0		38	0	
195	37	0		42	0		43	0	
196	43	0		44	0		48	0	
197	50	0		49	0		50	0	
198	53	0		52	0		52	0	
199	60	0		56	0		56	0	
200	64	0		60	0		61	0	
201	69	0		64	0		62	0	
202	73	0		69	0		63	0	
203	76	0		72	0		68	0	
204	80	0					70	0	

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
205	82	1	0.012 (0.002, 0.083)	74	0		77	0	
206	86	0	0.012 (0.002, 0.083)	78	0		81	0	
207	87	0	0.012 (0.002, 0.083)	81	0		85	0	
208	89	0	0.012 (0.002, 0.083)	84	0		89	0	
209	91	0	0.012 (0.002, 0.083)	89	0		91	0	
210	93	0	0.012 (0.002, 0.083)				92	0	
211	95	0	0.012 (0.002, 0.083)						
212	99	0	0.012 (0.002, 0.083)	90	0		94	0	
213	103	0	0.012 (0.002, 0.083)	92	0		96	0	
214	104	0	0.012 (0.002, 0.083)	94	0		97	0	
215	106	0	0.012 (0.002, 0.083)				98	0	
216	111	0	0.012 (0.002, 0.083)	98	0		103	0	
217	114	0	0.012 (0.002, 0.083)	100	0		105	0	
218	116	0	0.012 (0.002, 0.083)				107	0	

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
219	122	0	0.012 (0.002, 0.083)	102	0		109	0	
220	123	0	0.012 (0.002, 0.083)	103	1	0.010 (0.001, 0.067)	110	0	
221	124	0	0.012 (0.002, 0.083)	106	1	0.019 (0.005, 0.074)	111	0	
222				107	0	0.019 (0.005, 0.074)	115	0	
223	125	0	0.012 (0.002, 0.083)	110	0	0.019 (0.005, 0.074)	117	0	
224	127	0	0.012 (0.002, 0.083)	111	0	0.019 (0.005, 0.074)	119	0	
225	129	0	0.012 (0.002, 0.083)	114	0	0.019 (0.005, 0.074)	120	0	
226				115	0	0.019 (0.005, 0.074)	122	0	
227				116	0	0.019 (0.005, 0.074)	126	0	
228	132	0	0.012 (0.002, 0.083)	118	0	0.019 (0.005, 0.074)	127	0	
229	134	0	0.012 (0.002, 0.083)	121	0	0.019 (0.005, 0.074)	131	0	

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
230	137	0	0.012 (0.002, 0.083)	122	0	0.019 (0.005, 0.074)	135	0	
231	138	0	0.012 (0.002, 0.083)	123	0	0.019 (0.005, 0.074)			
232				127	0	0.019 (0.005, 0.074)	136	0	
233	140	0	0.012 (0.002, 0.083)	130	0	0.019 (0.005, 0.074)	137	0	
234	142	0	0.012 (0.002, 0.083)	132	0	0.019 (0.005, 0.074)	138	0	
235	143	0	0.012 (0.002, 0.083)						
236	146	0	0.012 (0.002, 0.083)	137	0	0.019 (0.005, 0.074)			
237	147	0	0.012 (0.002, 0.083)	139	0	0.019 (0.005, 0.074)	139	0	
238	150	0	0.012 (0.002, 0.083)						
239	152	0	0.012 (0.002, 0.083)				141	0	
240							143	0	
241	153	0	0.012 (0.002, 0.083)						

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
242							144	0	
243	154	0	0.012 (0.002, 0.083)				146	0	
244	156	0	0.012 (0.002, 0.083)	142	0	0.019 (0.005, 0.074)	147	0	
245	157	0	0.012 (0.002, 0.083)						
247							149	1	0.007 (0.001, 0.047)
248							148	1	0.013 (0.003, 0.053)
251	159	1	0.018 (0.004, 0.077)						
253				144	1	0.026 (0.008, 0.079)			
255				143	1	0.033 (0.012, 0.086)			
257				142	1	0.039 (0.016, 0.093)	147	2	0.027 (0.010, 0.070)
258							145	1	0.034 (0.014, 0.079)
259				141	1	0.046 (0.021, 0.101)			
260				140	1	0.053 (0.025, 0.109)	144	1	0.040 (0.018, 0.087)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
261	158	1	0.025 (0.008, 0.079)						
262	157	1	0.031 (0.011, 0.084)	139	1	0.060 (0.030, 0.117)			
263	156	2	0.043 (0.019, 0.097)				143	1	0.047 (0.023, 0.096)
264				138	2	0.074 (0.040, 0.133)			
265	154	1	0.049 (0.023, 0.104)	136	1	0.080 (0.045, 0.141)	142	1	0.054 (0.027, 0.104)
266	153	1	0.056 (0.028, 0.111)						
267							141	1	0.060 (0.032, 0.113)
268	152	1	0.062 (0.032, 0.118)				140	1	0.067 (0.037, 0.121)
269	151	5	0.093 (0.056, 0.154)				139	2	0.081 (0.047, 0.137)
270	146	2	0.105 (0.065, 0.168)	135	1	0.087 (0.050, 0.149)	137	2	0.094 (0.057, 0.153)
271	144	3	0.124 (0.080, 0.189)				135	3	0.114 (0.073, 0.177)
272	141	2	0.136 (0.091, 0.203)	134	3	0.108 (0.066, 0.173)	132	3	0.134 (0.089, 0.200)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
273	139	5	0.168 (0.117, 0.237)	131	3	0.128 (0.083, 0.196)	129	3	0.154 (0.105, 0.223)
274	134	8	0.217 (0.160, 0.291)	128	10	0.196 (0.140, 0.271)	126	9	0.215 (0.157, 0.290)
275	126	2	0.230 (0.171, 0.304)	118	5	0.230 (0.170, 0.308)	117	7	0.262 (0.199, 0.340)
276	124	4	0.254 (0.193, 0.331)	113	6	0.271 (0.206, 0.352)	110	6	0.302 (0.235, 0.383)
277	120	8	0.304 (0.239, 0.383)	107	3	0.292 (0.225, 0.373)	104	7	0.349 (0.278, 0.431)
278	112	3	0.323 (0.256, 0.402)	104	7	0.339 (0.268, 0.423)	97	7	0.396 (0.323, 0.479)
279	109	6	0.360 (0.291, 0.440)	97	3	0.360 (0.287, 0.444)	90	2	0.409 (0.335, 0.493)
280	103	3	0.379 (0.308, 0.459)	94	8	0.414 (0.339, 0.499)	88	7	0.456 (0.380, 0.540)
281	100	3	0.397 (0.326, 0.478)	86	4	0.441 (0.365, 0.526)	81	6	0.497 (0.420, 0.579)
282	97	5	0.428 (0.356, 0.509)	82	4	0.469 (0.392, 0.553)	75	3	0.517 (0.439, 0.599)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
283	92	1	0.435 (0.362, 0.515)	78	4	0.496 (0.418, 0.580)	72	3	0.537 (0.459, 0.619)
284	91	6	0.472 (0.398, 0.552)	74	3	0.516 (0.438, 0.600)	69	2	0.550 (0.473, 0.631)
285	85	3	0.491 (0.416, 0.571)	71	3	0.537 (0.458, 0.619)	67	3	0.570 (0.493, 0.651)
286	82	7	0.534 (0.459, 0.613)	68	2	0.550 (0.472, 0.632)	64	2	0.584 (0.506, 0.664)
287	75	2	0.546 (0.471, 0.625)	66	1	0.557 (0.479, 0.639)	62	2	0.597 (0.520, 0.676)
288	73	1	0.553 (0.478, 0.631)	65	2	0.571 (0.492, 0.652)	60	2	0.611 (0.533, 0.689)
289	72	2	0.565 (0.490, 0.643)	63	9	0.632 (0.555, 0.710)	58	1	0.617 (0.540, 0.695)
290	70	2	0.578 (0.502, 0.655)	54	4	0.659 (0.583, 0.735)	57	3	0.638 (0.561, 0.714)
291	68	1	0.584 (0.509, 0.661)	50	2	0.673 (0.597, 0.747)	54	2	0.651 (0.575, 0.727)
292	67	1	0.590 (0.515, 0.667)	48	3	0.693 (0.618, 0.766)	52	4	0.678 (0.602, 0.751)
293							48	1	0.685 (0.609, 0.757)
294	66	1	0.596 (0.521, 0.672)	45	1	0.700 (0.625, 0.772)			

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
295	65	1	0.602 (0.528, 0.678)	44	2	0.714 (0.639, 0.785)	47	1	0.691 (0.616, 0.764)
296	64	4	0.627 (0.553, 0.702)				46	2	0.705 (0.630, 0.776)
297				42	4	0.741 (0.668, 0.809)	44	2	0.718 (0.645, 0.788)
298	60	2	0.640 (0.566, 0.713)	38	2	0.755 (0.683, 0.821)	42	2	0.732 (0.659, 0.800)
299	58	1	0.646 (0.572, 0.719)	36	1	0.762 (0.690, 0.827)	40	2	0.745 (0.673, 0.812)
300	57	2	0.658 (0.585, 0.731)	35	1	0.768 (0.697, 0.833)			
301	55	2	0.671 (0.598, 0.742)						
302	53	2	0.683 (0.611, 0.754)	34	2	0.782 (0.712, 0.845)	38	4	0.772 (0.702, 0.835)
303							34	1	0.779 (0.709, 0.841)
304				32	1	0.789 (0.720, 0.851)			
305	51	1	0.689 (0.617, 0.759)				33	1	0.785 (0.716, 0.847)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
306	50	3	0.708 (0.637, 0.776)						
307				31	1	0.796 (0.727, 0.857)	32	2	0.799 (0.731, 0.859)
308							30	1	0.805 (0.738, 0.864)
309	47	1	0.714 (0.643, 0.782)				29	1	0.812 (0.746, 0.870)
312	46	1	0.720 (0.650, 0.788)						
313				30	1	0.802 (0.735, 0.862)			
315	45	2	0.733 (0.663, 0.799)						
316							28	1	0.819 (0.753, 0.876)
317				29	1	0.809 (0.742, 0.868)	27	1	0.826 (0.761, 0.881)
318							26	2	0.839 (0.776, 0.893)
319	43	2	0.745 (0.676, 0.810)	28	2	0.823 (0.757, 0.880)			
322							24	1	0.846 (0.783, 0.898)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
323				26	1	0.830 (0.765, 0.885)			
324	41	1	0.751 (0.683, 0.815)	25	1	0.837 (0.772, 0.891)			
325	40	1	0.758 (0.689, 0.821)						
332	39	1	0.764 (0.696, 0.826)						
336	38	1	0.770 (0.703, 0.832)						
337	37	2	0.783 (0.716, 0.843)						
340				24	1	0.843 (0.780, 0.897)			
364	35	0	0.783 (0.716, 0.843)	23	0	0.843 (0.780, 0.897)	23	0	0.846 (0.783, 0.898)

Table 4.18. Results from unstratified and stratified log-rank tests assessing the equality of failure functions across study arms

Arm	Unstratified test, all participants		Maternal age ≤25y stratum test		Maternal age >25y stratum test		Stratified test, all participants	
	Observed events	Expected events	Observed events	Expected events	Observed events	Expected events	Observed events	Expected events
Control	124	141.69	65	75.06	60	66.68	125	141.74
SMS only	123	117.14	75	73.86	48	45.03	123	118.89
SMS+150KES	126	115.17	54	45.08	72	68.29	126	113.37
p-value		*0.182*		*0.195*		*0.576*		*0.158*

Table 4.19. Sensitivity analysis: Cumulative failure functions for measles vaccination by age 12 months. Time origin is intervention start (271 days of age).

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
271	144	3	0.021 (0.007, 0.063)				135	3	0.022 (0.007, 0.067)
272	141	2	0.035 (0.015, 0.081)	134	3	0.022 (0.007, 0.068)	132	3	0.044 (0.020, 0.096)
273	139	5	0.069 (0.038, 0.125)	131	3	0.045 (0.020, 0.097)	129	3	0.067 (0.035, 0.124)
274	134	8	0.125 (0.081, 0.191)	128	10	0.119 (0.075, 0.187)	126	9	0.133 (0.086, 0.203)
275	126	2	0.139 (0.092, 0.207)	118	5	0.157 (0.105, 0.230)	117	7	0.185 (0.129, 0.262)
276	124	4	0.167 (0.115, 0.238)	113	6	0.201 (0.143, 0.280)	110	6	0.230 (0.167, 0.310)
277	120	8	0.222 (0.163, 0.299)	107	3	0.224 (0.162, 0.304)	104	7	0.281 (0.214, 0.366)
278	112	3	0.243 (0.181, 0.322)	104	7	0.276 (0.208, 0.360)	97	7	0.333 (0.261, 0.420)
279	109	6	0.285 (0.218, 0.366)	97	3	0.299 (0.229, 0.384)	90	2	0.348 (0.274, 0.435)
280	103	3	0.306 (0.237, 0.388)	94	8	0.358 (0.284, 0.446)	88	7	0.400 (0.323, 0.488)
281	100	3	0.326 (0.256, 0.410)	86	4	0.388 (0.311, 0.476)	81	6	0.444 (0.365, 0.532)
282	97	5	0.361 (0.289, 0.445)	82	4	0.418 (0.340, 0.506)	75	3	0.467 (0.387, 0.554)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
283	92	1	0.368 (0.295, 0.452)	78	4	0.448 (0.368, 0.536)	72	3	0.489 (0.408, 0.576)
284	91	6	0.410 (0.335, 0.495)	74	3	0.470 (0.390, 0.558)	69	2	0.504 (0.423, 0.591)
285	85	3	0.431 (0.354, 0.515)	71	3	0.493 (0.412, 0.580)	67	3	0.526 (0.445, 0.612)
286	82	7	0.479 (0.401, 0.564)	68	2	0.507 (0.426, 0.595)	64	2	0.541 (0.459, 0.626)
287	75	2	0.493 (0.415, 0.577)	66	1	0.515 (0.434, 0.602)	62	2	0.556 (0.474, 0.641)
288	73	1	0.500 (0.422, 0.584)	65	2	0.530 (0.448, 0.616)	60	2	0.570 (0.489, 0.655)
289	72	2	0.514 (0.435, 0.598)	63	9	0.597 (0.515, 0.680)	58	1	0.578 (0.496, 0.662)
290	70	2	0.528 (0.449, 0.611)	54	4	0.627 (0.546, 0.708)	57	3	0.600 (0.519, 0.683)
291	68	1	0.535 (0.456, 0.618)	50	2	0.642 (0.561, 0.722)	54	2	0.615 (0.534, 0.697)
292	67	1	0.542 (0.463, 0.625)	48	3	0.664 (0.584, 0.743)	52	4	0.644 (0.564, 0.724)
293							48	1	0.652 (0.572, 0.731)
294	66	1	0.549 (0.470, 0.631)	45	1	0.672 (0.592, 0.749)			
295	65	1	0.556 (0.477, 0.638)	44	2	0.687 (0.607, 0.763)	47	1	0.659 (0.579, 0.738)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
296	64	4	0.583 (0.504, 0.664)				46	2	0.674 (0.595, 0.751)
297				42	4	0.716 (0.639, 0.790)	44	2	0.689 (0.610, 0.765)
298	60	2	0.597 (0.518, 0.678)	38	2	0.731 (0.654, 0.803)	42	2	0.704 (0.626, 0.778)
299	58	1	0.604 (0.525, 0.684)	36	1	0.739 (0.662, 0.810)	40	2	0.719 (0.641, 0.792)
300	57	2	0.618 (0.540, 0.697)	35	1	0.746 (0.670, 0.816)			
301	55	2	0.632 (0.554, 0.710)						
302	53	2	0.646 (0.568, 0.723)	34	2	0.761 (0.686, 0.829)	38	4	0.748 (0.673, 0.818)
303							34	1	0.756 (0.681, 0.824)
304				32	1	0.769 (0.694, 0.836)			
305	51	1	0.653 (0.575, 0.729)				33	1	0.763 (0.689, 0.831)
306	50	3	0.674 (0.597, 0.749)						
307				31	1	0.776 (0.703, 0.842)	32	2	0.778 (0.705, 0.844)
308							30	1	0.785 (0.713, 0.850)
309	47	1	0.681 (0.604, 0.755)				29	1	0.793 (0.721, 0.856)

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
312	46	1	0.688 (0.611, 0.761)						
313				30	1	0.784 (0.711, 0.849)			
315	45	2	0.701 (0.626, 0.774)						
316							28	1	0.800 (0.729, 0.863)
317				29	1	0.791 (0.719, 0.855)	27	1	0.807 (0.737, 0.869)
318							26	2	0.822 (0.753, 0.881)
319	43	2	0.715 (0.640, 0.786)	28	2	0.806 (0.735, 0.868)			
322							24	1	0.830 (0.762, 0.887)
323				26	1	0.813 (0.743, 0.874)			
324	41	1	0.722 (0.648, 0.793)	25	1	0.821 (0.752, 0.880)			
325	40	1	0.729 (0.655, 0.799)						
332	39	1	0.736 (0.662, 0.805)						
336	38	1	0.743 (0.670, 0.811)						
337	37	2	0.757 (0.685, 0.823)						

Failure time in days of age	CONTROL			SMS only			SMS+150KES		
	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)	Beginning total (N)	Failed (n)	Cumulative failure function (95% CI)
340				24	1	0.828 (0.760, 0.887)			
364	35	0	0.757 (0.685, 0.824)	23	0	0.828 (0.760, 0.887)	23	0	0.830 (0.762, 0.887)

Table 4.20. Sensitivity analysis: Results from unstratified and stratified log-rank tests assessing the equality of failure functions across study arms

Arm	Unstratified test, all participants		Maternal age ≤25y stratum test		Maternal age >25y stratum test		Stratified test, all participants	
	Observed events	Expected events	Observed events	Expected events	Observed events	Expected events	Observed events	Expected events
Control	109	126.78	58	68.71	51	58.10	109	126.81
SMS only	111	103.80	70	67.15	41	38.78	111	105.94
SMS+150KES	112	101.42	48	40.13	64	59.12	112	99.25
p-value		*0.118*		*0.174*		*0.483*		*0.101*

Table 4.21. Number of days undervaccinated by study arm for all infants and only undervaccinated infants

All infants					
Days undervaccinated	**Control (N= 160)**	**SMS only (N= 146)**	**p-value***	**SMS+150KES (N= 149)**	**p-value***
Mean (SE)	14.9 (2.0)	10.5 (1.8)	0.108	10.1 (1.8)	0.071
Median (Q1, Q3)	0 (0, 21.5)	0 (0, 0)	N/A	0 (0, 0)	N/A
Undervaccinated infants only					
Days undervaccinated	**Control (N= 51)**	**SMS only (N= 32)**	**p-value***	**SMS+150KES (N= 33)**	**p-value***
Mean (SE)	46.9 (3.1)	48.2 (3.8)	0.788	45.5 (4.2)	0.788
Median (Q1, Q3)	61 (29, 61)	61 (29, 61)	N/A	61 (15, 61)	N/A
1-7 days, n infants (%)	5 (9.8)	2 (6.3)	N/A	5 (15.2)	N/A
8-14 days, n infants (%)	3 (5.8)	2 (6.3)	N/A	2 (6.1)	N/A
15-21 days, n infants (%)	3 (5.8)	4 (12.5)	N/A	3 (9.1)	N/A
22-35 days, n infants (%)	5 (9.8)	0	N/A	0	N/A
37 days, n infants (%)	0	1 (3.1)	N/A	0	N/A
61 days, n infants (%)	35 (68.6)	23 (71.9)	N/A	23 (69.7)	N/A

Abbreviations: SE = standard error; Q1 = first quartile; Q3= third quartile; N/A = not applicable

*p-value from two-sided t-test

Table 4.22. Reasons for delayed measles vaccination

	Control (N= 160) n (%)	**SMS only (N= 146) n (%)**	**SMS+150KES (N= 149) n (%)**	**Total (N= 455) n (%)**
Not vaccinated by age 10 months	51 (31.9%)	32 (21.9%)	33 (22.2%)	116 (25.5%)
Reason for delay queried	41 (80.4%)	29 (90.6%)	25 (75.8%)	95 (81.9%)
Reason for delay	**Control (N = 41) n (%)**	**SMS only (N= 29) n (%)**	**SMS+150KES (N= 25) n (%)**	**Total (N= 95) n (%)**
Nurses' strike	12 (29.3)	13 (44.8)	9 (36.0)	34 (35.8)
Vaccine not in stock	6 (14.6)	4 (13.8)	5 (20.0)	15 (15.8)
Child was ill	4 (9.8)	2 (6.9)	2 (8.0)	8 (8.4)
Reason not given	1 (2.4)	4 (13.8)	2 (8.0)	7 (7.4)
Travelling	4 (9.8)	2 (6.9)	1 (4.0)	7 (7.4)
Not recorded in MCH booklet	5 (12.2)	0 (0)	1 (4.0)	6 (6.3)
Didn't know date	3 (7.3)	0 (0)	2 (8.0)	5 (5.3)
Nurse refused to open vial	2 (4.9)	0 (0)	1 (4.0)	3 (3.2)
Forgot	1 (2.4)	1 (3.4)	0 (0)	2 (2.1)
Competing priorities	1 (2.4)	1 (3.4)	0 (0)	2 (2.1)
Clinic too far	0 (0)	0 (0)	1 (4.0)	1 (1.1)
Previous vaccine delayed	1 (2.4)	0 (0)	0 (0)	1 (1.1)
Vaccine not important	0 (0)	0 (0)	1 (4.0)	1 (1.1)
Forgot MCH booklet	0 (0)	1 (3.4)	0 (0)	1 (1.1)
Discouraged by friend	1 (2.4)	0 (0)	0 (0)	1 (1.1)
Caretaker was ill	0 (0)	1 (3.4)	0 (0)	1 (1.1)

Table 4.23. Caregivers' reported receipt of SMS reminders

	SMS only (N= 146)				SMS+150KES (N= 149)			
	All n (%)	**Own n (%)**	**Share n (%)**	**p-value**	**All n (%)**	**Own n (%)**	**Share n (%)**	**p-value**
Received ≥1 SMS reminder	98 (67.1)	66 (67.4)	32 (32.7)	-*	120 (80.5)	82 (68.3)	38 (31.7)	-*
Received one reminder	30 (30.6)	18 (27.3)	12 (37.5)	0.303	21 (17.5)	12 (14.6)	9 (23.7)	0.225
Received two reminders	62 (63.3)	47 (71.2)	15 (46.9)	**0.019**	94 (78.3)	68 (82.9)	26 (68.4)	0.073
Received three reminders	1 (l.0)	1 (1.5)	0 (0)	0.484	2 (1.7)	2 (2.4)	0 (0)	0.332
Don't know	5 (5.1)	0 (0)	5 (15.6)	**0.001**	3 (2.5)	0 (0)	3 (7.9)	**0.010**

*p-value not calculated as ownership of phone number to which reminder was sent was only collected for participants who reported that they received a reminder; there is no corresponding data on phone ownership for participants who reported that they did not receive any reminders

Table 4.24. Caregivers' opinions about SMS reminders

	SMS only (N= 98)	**SMS+150KES (N= 120)**
	n (%)	**n (%)**
SMS influenced decision to vaccinate	88 (89.8)	110 (91.7)
Received MCV1 by age 12 months	80 (90.9)	96 (87.3)
Number of SMS reminders		
Too few	8 (8.2)	15 (12.5)
Just right	80 (81.6)	94 (78.3)
Shared mobile phone	7 (7.1)	9 (7.5)
Don't know	3 (3.1)	2 (1.7)
Length of SMS reminders		
Too short	0 (0)	1 (0.8)
Right length	88 (89.8)	106 (88.3)
Shared mobile phone	8 (8.2)	13 (10.8)
Don't know	2 (2)	0 (0)

Table 4.25. SMS+150KES arm caregivers' experience with, and opinions about, incentives

	SMS+150KES (N= 149)
	n (%)
Received MCV1 incentive	105 (70.5)
Owned phone	76 (72.4)
Incentive influenced decision to vaccinate	88 (83.8)
Received MCV1 by age 12 months	78 (88.6)
Mobile money cashed out	
Day when received	16 (15.2)
Within 1-3 days of receipt	67 (63.8)
More than 3 days after receipt	20 (19.0)
Not cashed out	2 (1.9)
Experience receiving incentive	
Very positive	98 (93.3)
Somewhat positive	2 (1.9)
Neutral	4 (3.8)
Very negative	1 (1.0)
Likelihood of future vaccination in the absence of incentive	
More likely	95 (90.5)
Less likely	1 (1.0)
The same	8 (7.6)
Don't know	1 (1.0)
M-PESA use	
Transport cost	59 (56.2)
Housing expenses	21 (20.0)
Food	16 (15.2)
Airtime	1 (1.0)
Medicine	5 (4.8)
Infant's clothing	2 (1.9)
Not used yet	1 (1.0)

Table 4.26. Adjusted risk ratio and risk difference for measles vaccination by age 12 months in the interventions (combined) compared to the Control arm

Study arm	Vaccinated n (%)	aRR* (95% CI)	p-value	aRD* (95% CI)	p-value
Control (N= 160)	125 (78.1)	Ref	--	Ref	--
SMS only & SMS+150KES (N= 295)	249 (84.4)	1.08 (0.98, 1.19)	0.114	6.2 (-1.3, 13.8)	0.106

*aRR = Adjusted risk ratio; 95% CI = 95% confidence interval; aRD = Adjusted risk difference

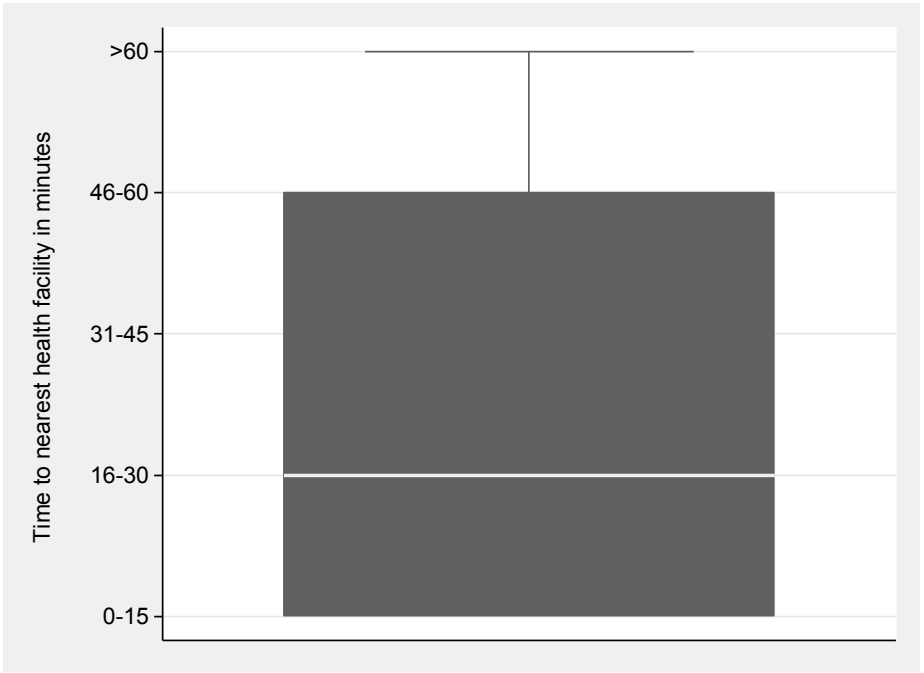
Chapter 4 Figures

Figure 4.1. Sample size formula from Levin and colleague,[85] including descriptions of the formula components

$$n^* = n_{\text{unc}} \left[\frac{1 + \sqrt{1 + 8c|P_1 - P_2|/A}}{2} \right]^2$$

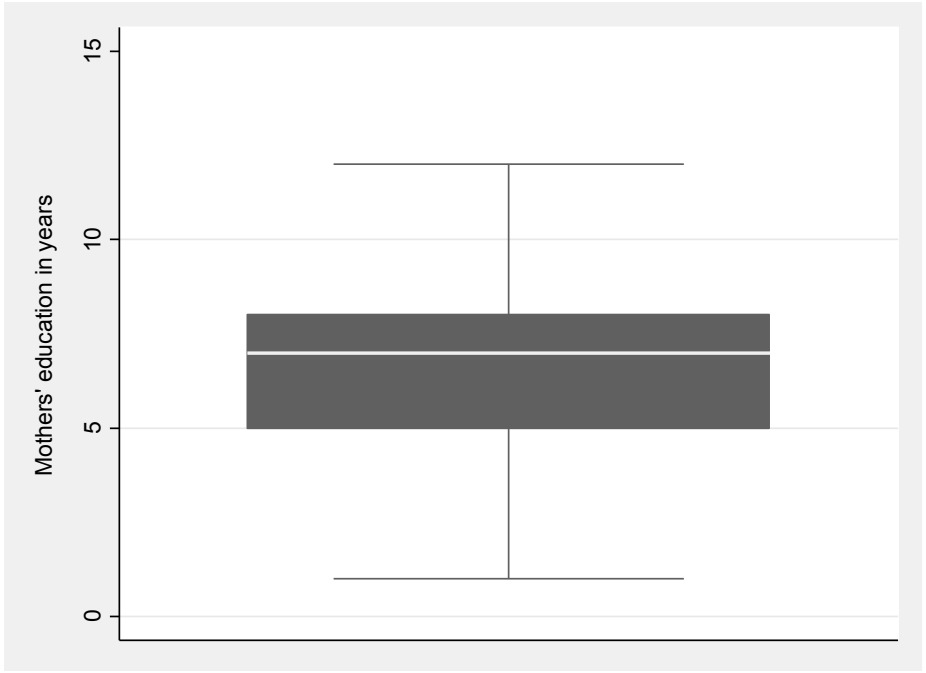
Formula component	Calculation or value
n^*	Continuity-corrected sample size. Formula as above
n_{unc} (uncorrected sample size)	$\frac{A}{(P_1 - P_2)^2}$
A	$[z_{\alpha/2}\sqrt{2PQ} + z_{\beta/2}\sqrt{(P_1Q_1 + P_2Q_2)}]^2$
P	$\frac{0.85 + 0.70}{2} = 0.775$
Q	$1 - P$
P_1	Proportion in control group = 0.70
P_2	Proportion in intervention group ≥0.85
c	0.5

Figure 4.2A. Distribution of travel time to the nearest clinic in M-SIMI households



Minimum	0-15 minutes
Maximum	>60 minutes
25th percentile	0-15 minutes
Median	16-30 minutes
75th percentile	46-60 minutes

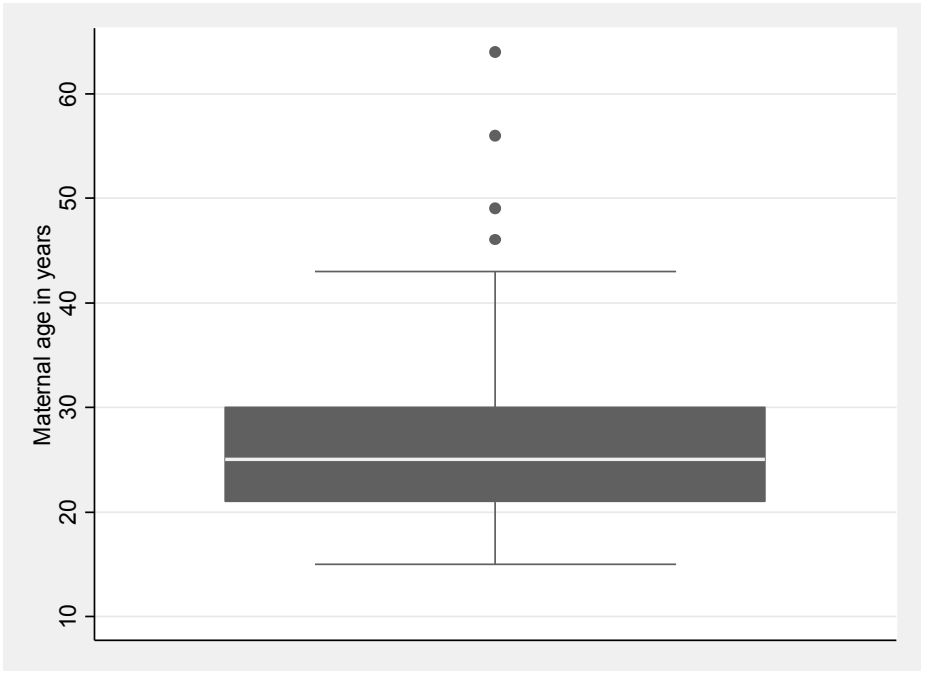
Figure 4.2B. Distribution of maternal education in years*



Minimum	1 year
Maximum	12 years
25th percentile	5 years
Median	7 years
75th percentile	8 years

*Missing data for eight mothers

Figure 4.2C. Age distribution of M-SIMI infants' mothers



Minimum	15y
Maximum	64y
25th percentile	21y
Median	25y
75th percentile	30y

Figure 4.3. Screening, enrollment and follow-up flow diagram for the M-SIMI study

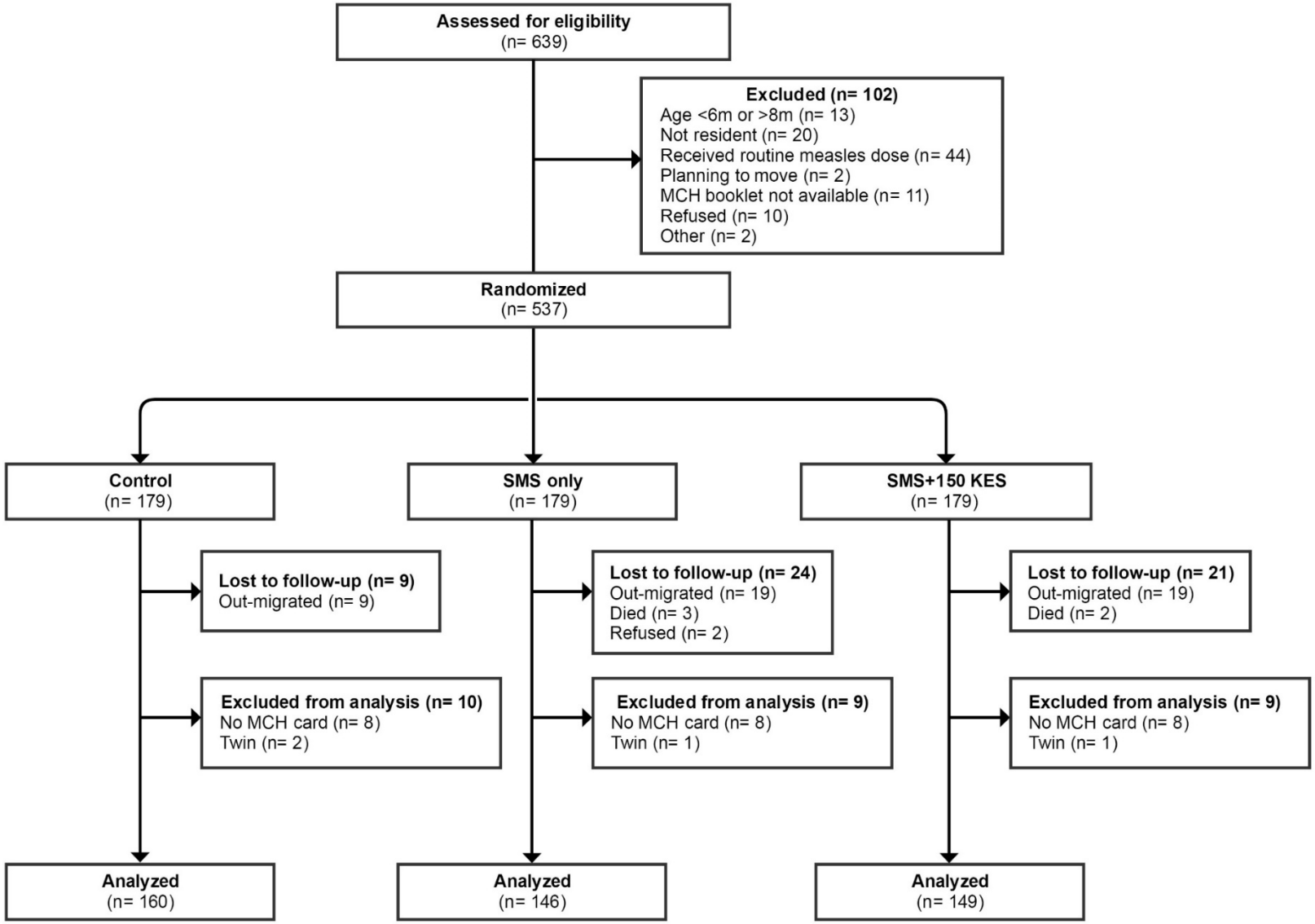
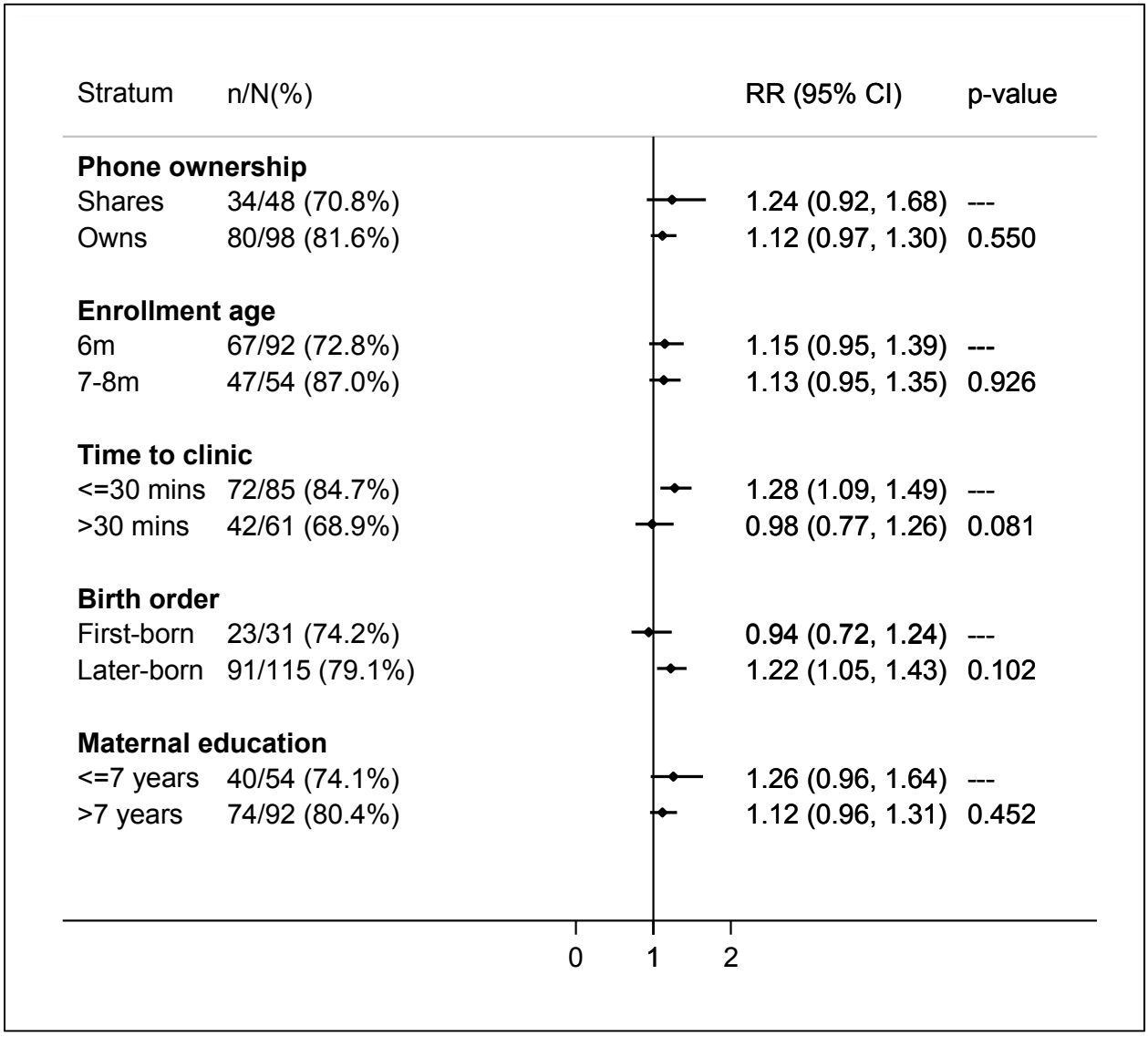
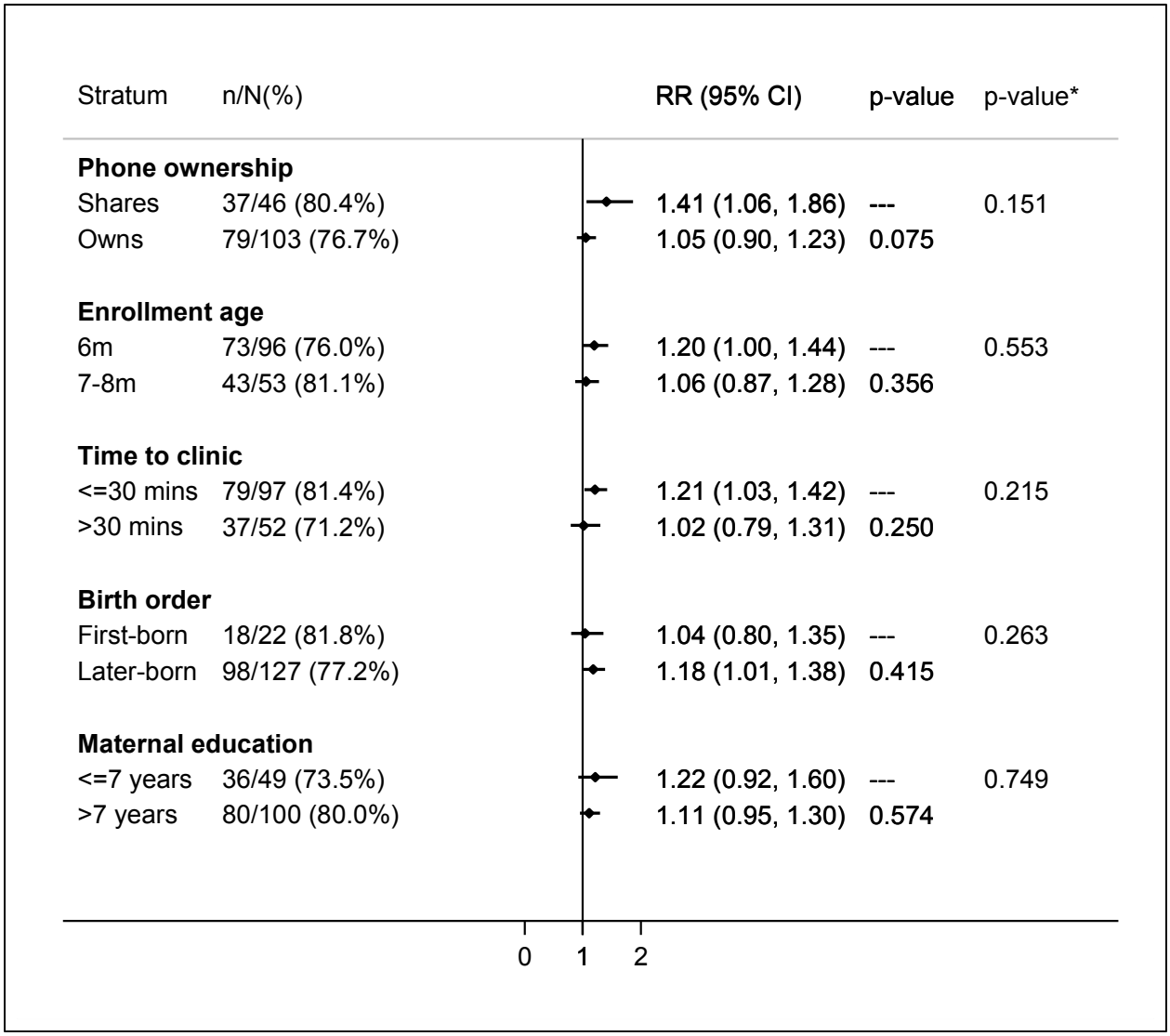


Figure 4.4 Sub-group analysis of the impact of SMS reminders with or without KES 150incentive on MCV1 timely coverage, by study arm, *without adjustment for maternal age*

4.4[A]. SMS only vs. Control



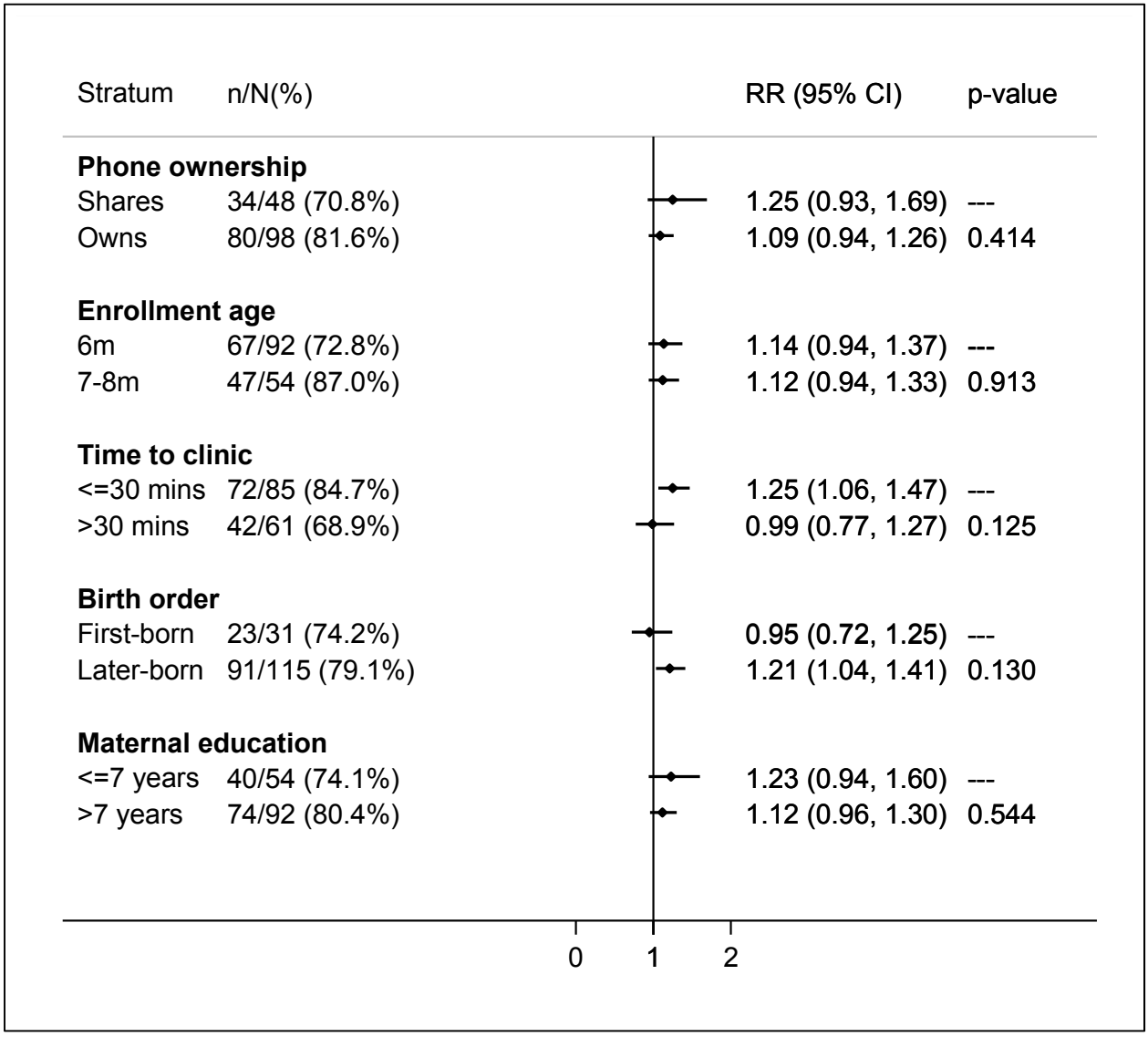
4.4[B]. SMS+150KES vs. Control



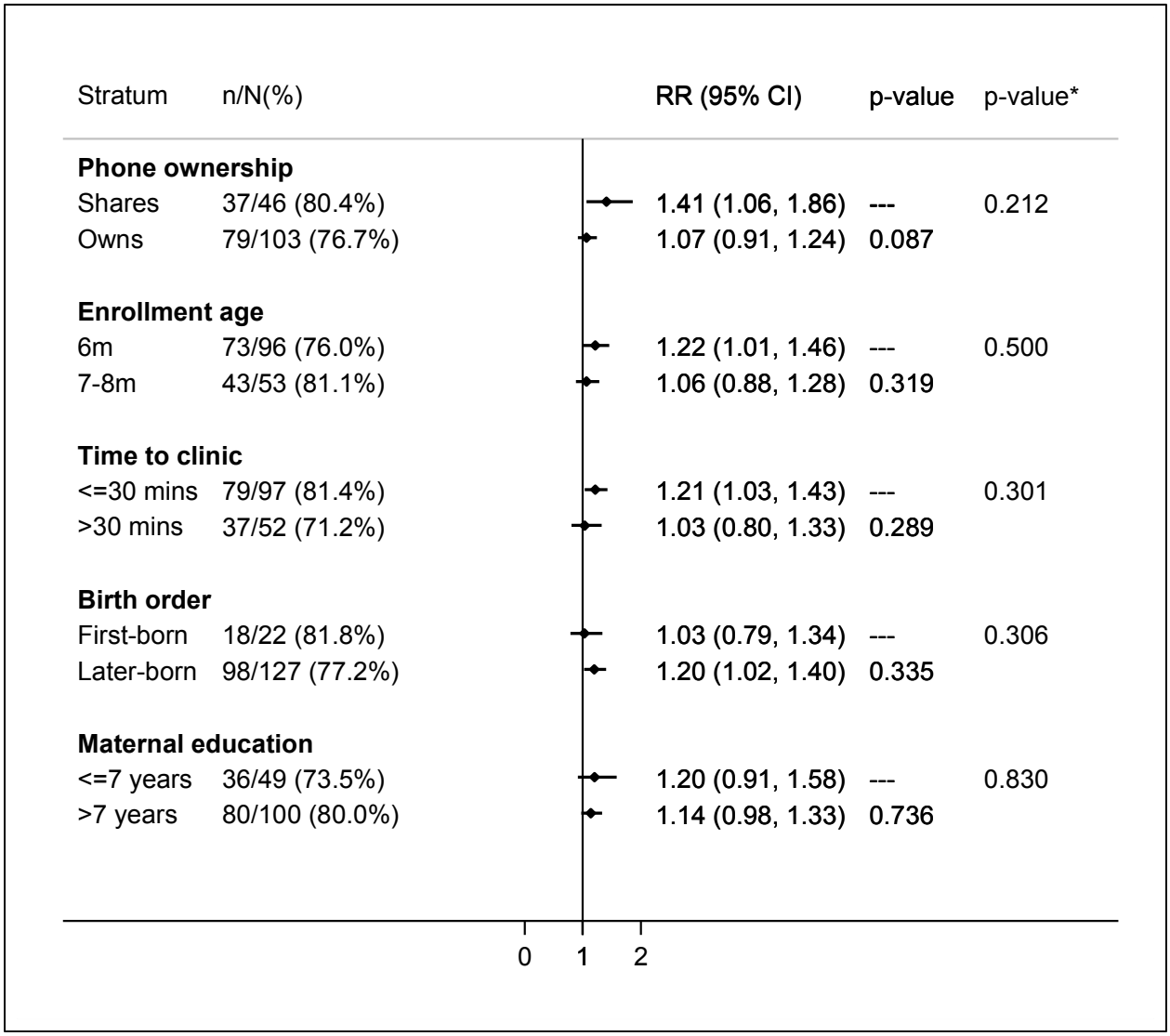
*Overall interaction term p-value

Figure 4.5. Sub-group analysis of the impact of SMS reminders with or without KES 150 incentive on MCV1 timely coverage, by study arm, *adjusted for maternal age*

4.5[A]. SMS only vs. Control



4.5[B]. SMS+150KES vs. Control



*Overall interaction term p-value

Figure 4.6. Cumulative incidence of measles vaccination by age 12m since enrollment. Time origin is age at enrollment

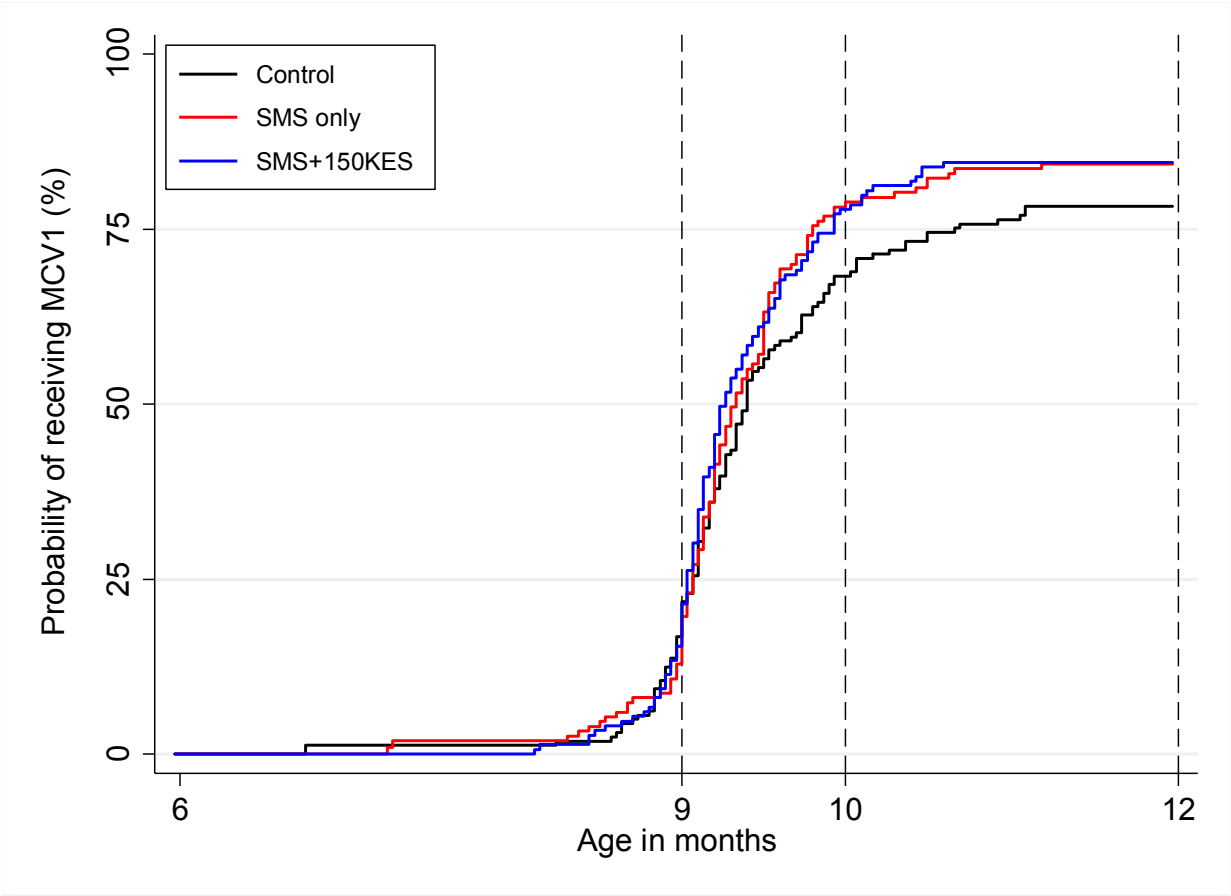


Figure 4.7. Sensitivity analysis: Cumulative incidence of measles vaccination by age 12m since enrollment. Time origin is intervention start (271 days of age).

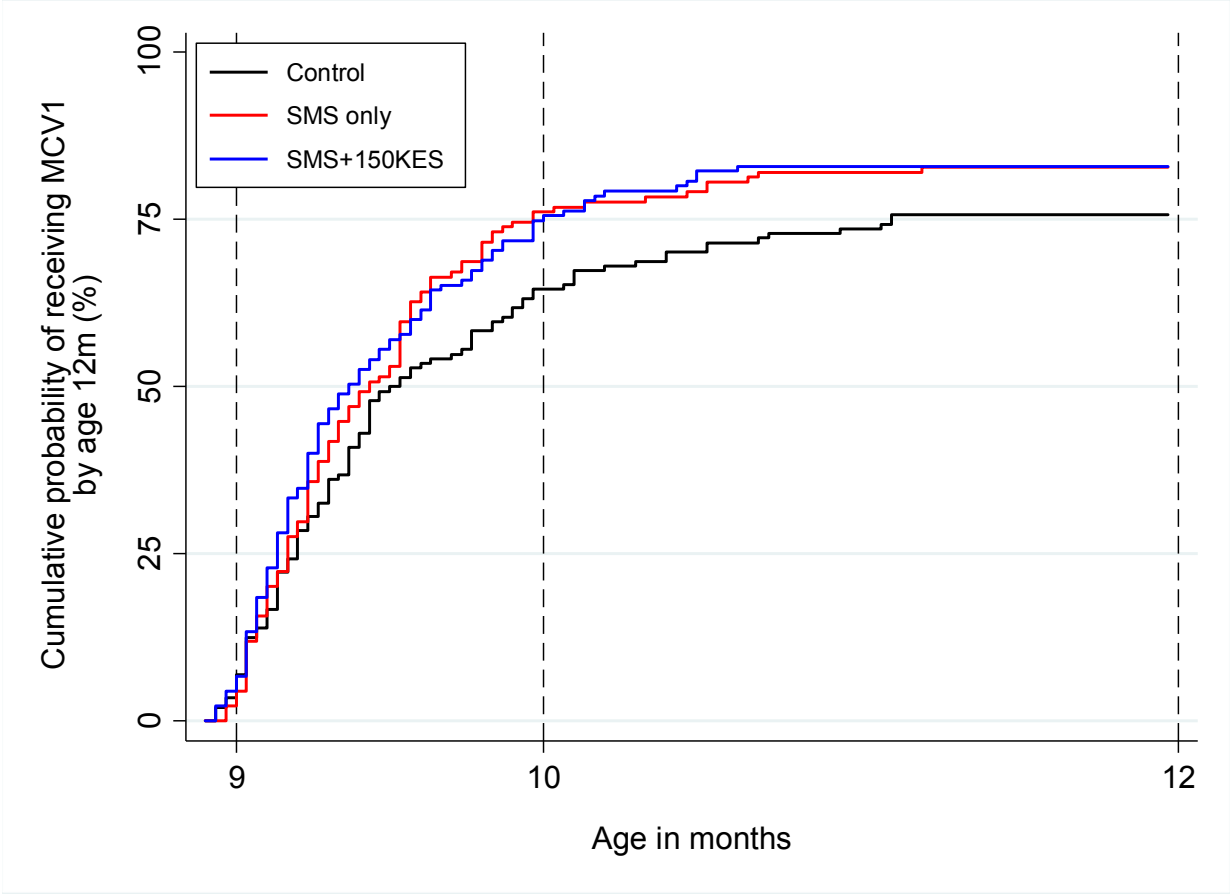


Figure 4.8. Pooled relative risk of measles vaccination comparing the effect of SMS reminders compared to no SMS reminders in the M-SIMI and M-SIMU studies

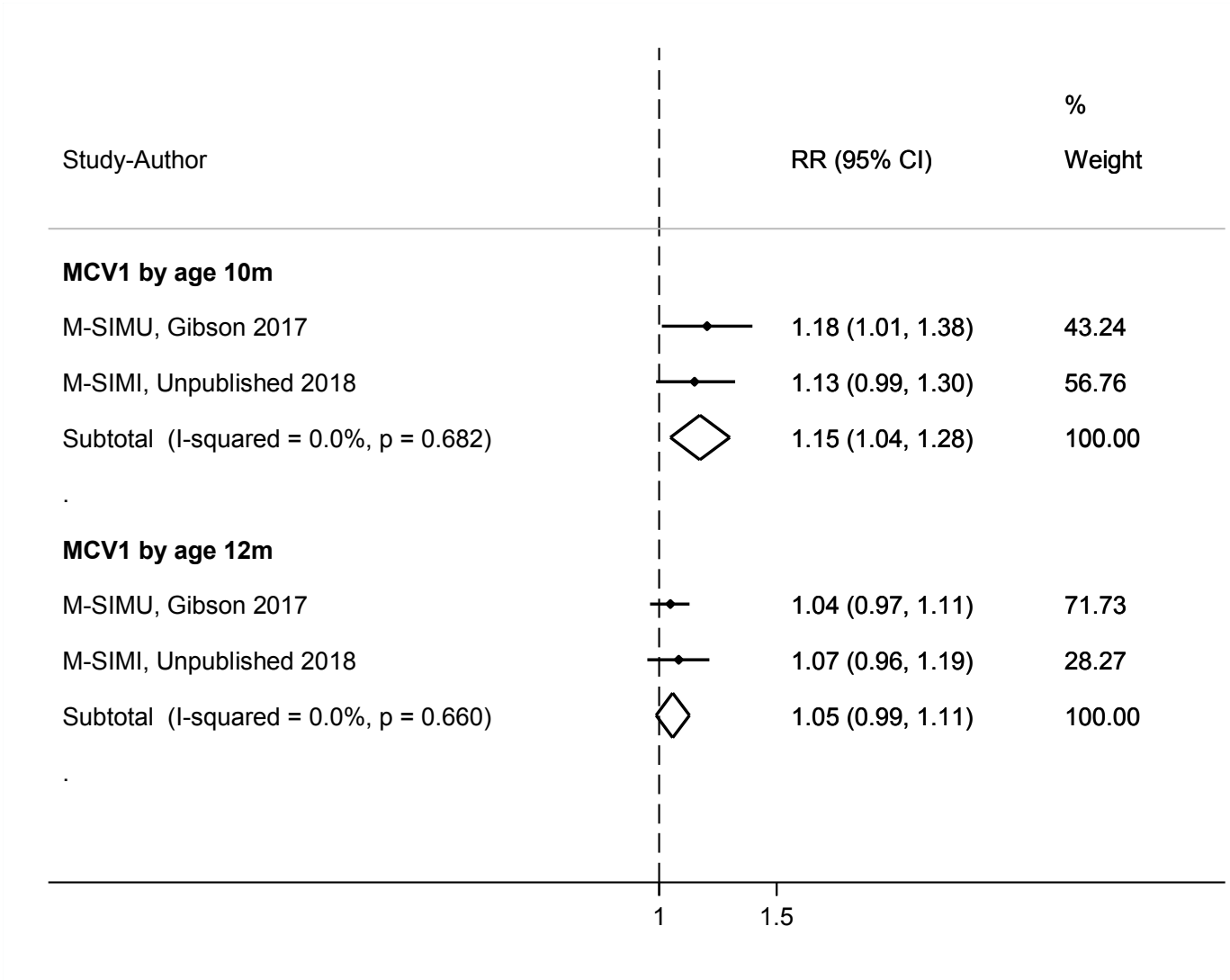
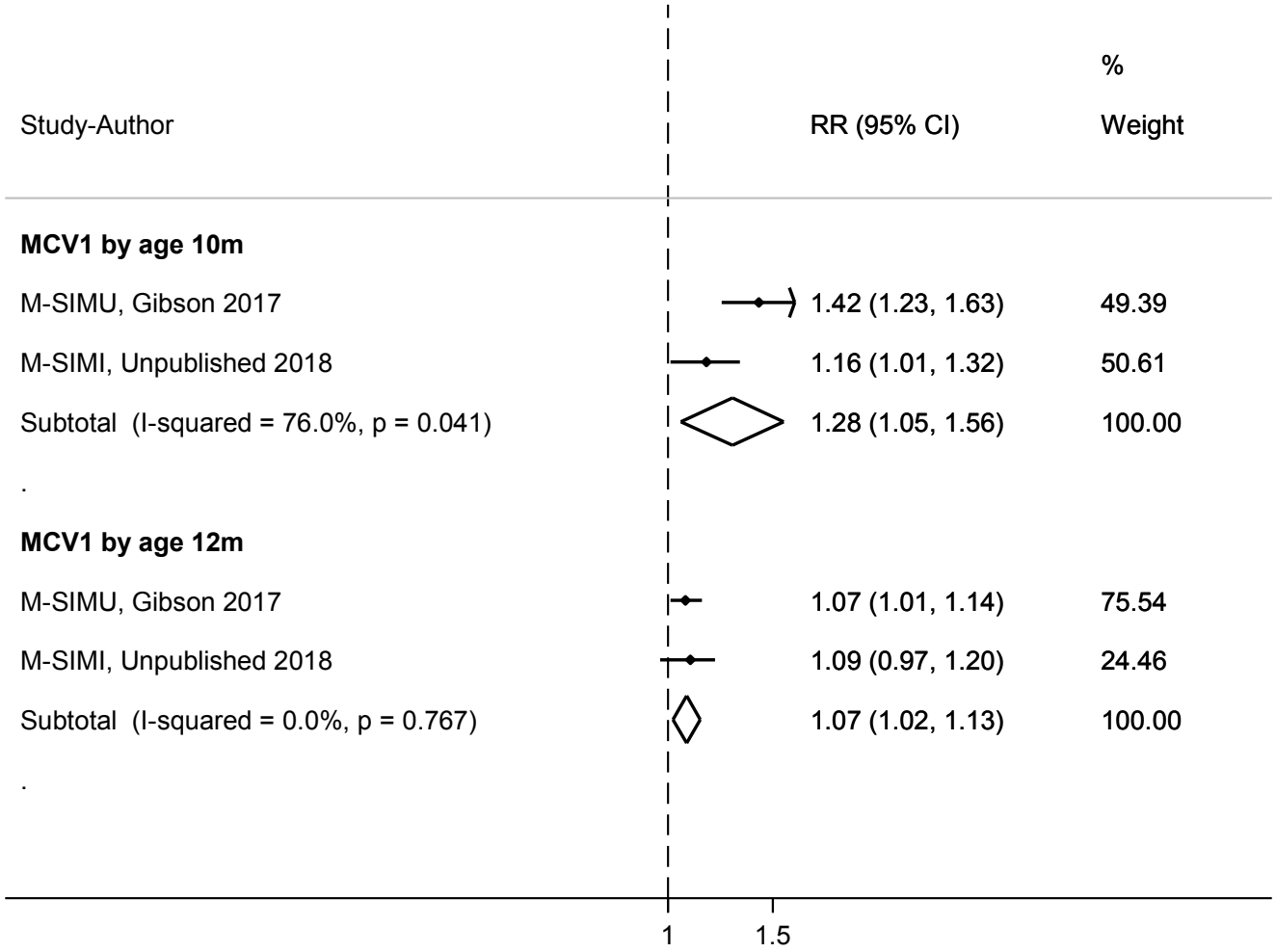


Figure 4.9. Pooled relative risk of measles vaccination comparing the effect of SMS reminders coupled with an unconditional KES 150 incentive or a conditional KES 200 incentive, to no interventions in the M-SIMI and M-SIMU studies



CHAPTER 5: A POST-TRIAL FOLLOW-UP STUDY TO EVALUATE THE IMPACT OF SHORT-TERM TEXT MESSAGE REMINDERS WITH OR WITHOUT CONDITIONAL MONETARY INCENTIVES ON LONG-TERM PARENTAL VACCINE-SEEKING BEHAVIOR (THE MSBC STUDY)

5.1. Abstract

Background

In the context of stagnant measles vaccination coverage in low- and middle-income settings, short message service (SMS or text message) reminders and monetary incentives have the potential to generate more demand for vaccination. The M-SIMU study, a cluster randomized controlled study conducted in Kenya showed that SMS vaccination reminders alone or when coupled with small monetary incentives significantly improved first dose measles vaccination timeliness. In addition, SMS vaccination reminders coupled with the higher of two incentive amounts significantly improved measles vaccination coverage. SMS vaccination reminders and incentives were withdrawn were withdrawn subsequent to study completion. The long-term impact of short-term SMS vaccination reminders and incentives has not been previously studied. We conducted an evaluation to assess caregivers' vaccine-seeking practices after withdrawal of M-SIMU interventions.

Methods

We conducted an observational post-trial follow-up study – The **M**-SIMU **S**ubsequent **B**orn **C**hild study (MSBC) – to collect data on vaccination among children born to M-SIMU caregivers after the M-SIMU study (i.e., subsequent children; SC) and also second-dose measles-containing vaccine (MCV2) status among M-SIMU children. Because we followed-up M-SIMU families, the study setting for the MSBC study was the same as that of the M-SIMU study i.e., the Kenya Medical Research Institute Health and Demographic Surveillance System in Gem and Rarieda (Asembo area) sub-counties, Siaya County. Study Community Interviewers (CIs) visited M-SIMU households and performed screening to ascertain eligibility criteria. We collected

sociodemographic status, vaccination status of the SC, and MCV2 status of the M-SIMU child from enrolled infant-caregiver pairs. During the M-SIMU study caregivers were randomized to receive either SMS vaccination reminders plus 200 Kenya Shillings (KES) incentives (SMS+200 KES), SMS reminders plus 75 KES incentives (SMS+75KES), SMS reminders only (SMS only) or no interventions (Control). The primary objective was to assess whether first dose measles-containing vaccine (MCV1) timely coverage, i.e., the proportion of children vaccinated at or before age 9 months and 2 weeks (9m+2w) was significantly different among SC of SMS+200KES caregivers compared to SC of Control caregivers. As a secondary objective, the difference in MCV1 timely coverage among SMS+75KES SC and SMS only SC compared to Control SC was assessed. Additional secondary objectives were to assess differences in MCV1 uptake by age 12 months (MCV1 overall coverage) and third dose pentavalent vaccine (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b; pentavalent 3) coverage at age 16 weeks or earlier (pentavalent 3 timely coverage) among SMS+200KES SC, SMS+75KES SC, and SMS only SC compared to Control SC. A final secondary objective was to compare MCV2 coverage by age 24 months among intervention M-SIMU children compared to Control M-SIMU children. Binomial regression with generalized estimating equations and robust error variance were performed to estimate risk differences (RD) and associated 95% confidence intervals (95% CI) with accounting for clustering. Poisson regression was used where binomial models failed to converge. Regression models adjusted for unequally distributed characteristics at MSBC enrollment or at M-SIMU baseline. Regression models included an interaction term between time (during M-SIMU vs. after M-SIMU) and the caregiver's M-SIMU study arm to allow for estimation of risk difference-in-differences (DIDs). DIDs represented the absolute

effect of the removal of M-SIMU interventions on vaccination uptake after accounting for secular trends.

Results

Of 1,599 M-SIMU households, 1,467 were contacted of which 218 were eligible for enrollment in the MSBC study, i.e., 44, 60, 56 and 58 Control, SMS only, SMS+75KES and SMS+200KES households, respectively. MCV1 timely coverage was, 58.1% (25/43), 49.2% (29/59), 38.2% (21/55) and 40.7% (24/59) among Control SC, SMS only SC, SMS+75KES SC and SMS+200KES SC, respectively. During the M-SIMU study, MCV1 timely coverage was 60.5% (26/43), 61.0% (36/59), 60.0% (33/55) and 67.2% (39/58) among Control, SMS only, SMS+75KES and SMS+200KES M-SIMU children, respectively.

MCV1 timely coverage among children of SMS+200KES caregivers was non-significantly lower by 25.2% after withdrawal of M-SIMU interventions compared to during the M-SIMU study, i.e., MCV1 timely coverage in SMS+200KES SC compared to SMS+200KES M-SIMU children (DID 95% CI: -55.3%, 4.8%; p= 0.099) resulting in 18.1% lower MCV1 timely coverage among SMS+200KES SC compared to Control SC though this difference was not statistically significant (adjusted RD [aRD] 95% CI: -39.3%, 3.1%; p= 0.095). After withdrawal of M-SIMU interventions, MCV1 timely coverage was non-significantly lower by 21.3% among children of SMS+75KES caregivers (DID 95% CI: -47.4%, 4.8%; p= 0.110) and by 11.2% among children of SMS only caregivers (DID 95% CI: -36.1%, 13.7%; p= 0.376) compared to during the M-SIMU study. These decreases translated to significantly lower MCV1 timely coverage among SMS+75KES SC (aRD -21.7%; 95% CI: -41.9%, -1.6%; p= 0.035) and non-significantly lower MCV1 timely coverage among SMS SC (aRD -11.5%; 95% CI: -32.8%, 9.8%; p= 0.290) as compared to Control SC.

MCV1 overall coverage among Control SC, SMS only SC, SMS+75KES SC and SMS+200KES SC was 84.4% (27/32), 76.9% (40/52), 63.6% (28/44) and 60.9% (28/46), respectively, compared to 84.4% (27/32), 90.4% (47/52), 75.0% (33/44) and 87.0% (40/46) among Control, SMS only, SMS+75KES and SMS+200KES M-SIMU children. MCV1 overall coverage was not significantly lower among children of SMS+200KES caregivers (DID -24.5%; 95% CI: -50.9%, 2.0%; p= 0.070), SMS+75KES (DID -8.6%; 95% CI: -32.0%, 14.9%; p= 0.473) caregivers or SMS only caregivers (DID -10.4%; 95% CI: -29.8%, 9.0%: p= 0.295) after the M-SIMU study compared to during the M-SIMU study. Compared to Control SC, MCV1 overall coverage was 20.8% lower and 6.2% lower among SMS+200KES SC and SMS only SC, respectively, however these differences were not significant (SMS+200KES aRD 95% CI: -42.1%, 0.6%; p= 0.057 and SMS only aRD 95% CI: -22.2%, 9.8%: p= 0.451). MCV1 overall coverage was significantly lower by 18.4% among SMS+75KES SC compared to Control SC (aRD 95% CI: -36.2%, -0.5%; p= 0.044).

Pentavalent 3 timely coverage among Control SC, SMS only SC, SMS+75KES SC and SMS+200KES SC was 70.5% (31/44), 70.0% (42/60), 62.5% (35/56) and 56.9% (33/58), respectively; this was not statistically significantly lower among intervention SC compared to Control SC nor after the M-SIMU study compared to during the M-SIMU study (all p> 0.05).

MCV2 coverage by age 24 months was 52.8% (19/36), 31.1% (14/45), 20.5% (8/39) and 25.6% (11/43) among Control, SMS only, SMS+75KES and SMS+200KES M-SIMU children respectively. The likelihood of receiving MCV2 by age 24 months was significantly lower among SMS+200KES M-SIMU children compared to Control M-SIMU children (adjusted RR 0.53; 95% CI: 0.30, 0.96; p= 0.035) as was the likelihood among SMS+75KES M-SIMU

children compared to M-SIMU Control children (adjusted RR 0.42; 95% CI: 0.20, 0.86; p= 0.019).

Conclusions

These findings suggest lower MCV-seeking after withdrawal of SMS reminders alone or coupled with incentives among caregivers who previously received these interventions. Despite differences in MCV1 timely and overall coverage being significant only among subsequent children of SMS+75KES caregivers compared to those of Control caregivers, these results point to decreased MCV-seeking after withdrawal of SMS reminders alone or coupled with small monetary incentives. There were substantial reductions in MCV1 timely and overall coverage after the M-SIMU study, substantial differences in MCV1 timely and overall coverage in SMS+200KES SC and SMS only SC compared to Control SC as well as significant reductions in MCV2 coverage among SMS plus incentive children. However, these findings should not be generalized to the entire M-SIMU sample as MSBC households may not be representative. Follow-up of more M-SIMU households is recommended to clarify M-SIMU caregivers' vaccine-seeking practices after withdrawal of M-SIMU interventions. Long-term follow-up for other health-related interventions, particularly those including monetary incentives, is recommended.

Funding

Bill & Melinda Gates Foundation

5.2. Introduction

Measles is a leading global cause of child morbidity and mortality, yet first and second dose measles-containing vaccine (MCV1; MCV2) coverage levels at the global level and in most low- and middle-income countries (LMICs), including Kenya, remain stagnant and are below 90-95%, the coverage required to interrupt measles transmission.[1,2] Innovative demand-side solutions to improve measles vaccination uptake in LMICs can jump-start stagnant vaccination uptake and assist in achievement of Sustainable Development Goal (SDG) 3, among other SDGs.[3–5]

The M-SIMU study, a cluster randomized controlled study conducted in Kenya, evaluated the impact of two innovative demand-side interventions, short message service (SMS) vaccination reminders and small monetary incentives on vaccination timeliness and coverage.[6] Although not the first study to assess the impact of SMS reminders or incentives on vaccination uptake in a LMIC,[7–19] the M-SIMU trial was the first to examine the combined effect of SMS reminders and monetary incentives. The M-SIMU study found that: SMS reminders coupled with the higher of two incentive amounts significantly improved the proportion of infants receiving third dose pentavalent vaccine (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus influenzae* type b; pentavalent 3) at age ≤16 weeks (i.e., pentavalent 3 timely coverage); SMS reminders with or without incentives significantly improved the proportion of infants receiving MCV1 at age ≤9 months and 2 weeks (MCV1 timely coverage); and that SMS reminders coupled with the higher of two incentive amounts significantly improved MCV1 coverage by age 12 months (MCV1 overall coverage).[6]

M-SIMU interventions were intended to act as nudges to encourage caregivers to seek vaccination for their children. We expected that vaccine-seeking among caregivers who participated in the M-SIMU study would be sustained at M-SIMU levels in the period after the M-SIMU study, or that if vaccine-seeking declined in the absence of M-SIMU interventions it would not fall below pre-M-SIMU levels. However, some stakeholders expressed concern that exposing caregivers to M-SIMU interventions would result in decreased coverage once the incentives were withdrawn.

The use of monetary incentives to promote behavior change, as was explored for vaccine-seeking in the M-SIMU study, is contentious. At the community level, some feel that incentives reward negative health behaviors.[20–22] At the same time, behavioral economists have theorized that incentives, which are extrinsic motivators, may "crowd-out" intrinsic motivation to practice the behavior that is being incentivized. As such, in the absence of incentives, practice of the target behavior falls below pre-incentive levels. Crowding-out has been demonstrated for some non-health behaviors whereby the incentivized behavior is not practiced at pre-incentive levels after the incentive is withdrawn.[23–25] With regard to incentives for health-related behaviors no studies have demonstrated that incentives crowd-out intrinsic motivation.[26] Despite the absence of evidence that incentives crowd-out intrinsic motivation to engage in positive health behaviors, and the relatively high vaccination coverage levels in the study area and in the control arm, we took seriously stakeholders' concern that exposing caregivers to the M-SIMU interventions would result in decreased coverage once the incentives were withdrawn.

To evaluate vaccine seeking after withdrawal of M-SIMU interventions, we conducted a post-trial follow-up study (The **M**-SIMU **S**ubsequent **B**orn **C**hild study; MSBC) of vaccination uptake in the period after the M-SIMU study among subsequent children born to caregivers previously enrolled in the M-SIMU study as well among M-SIMU children. To our knowledge, there is no literature on the effect of withdrawing SMS or any other types of reminders.

5.3. Methods

5.3.1. Study design and setting

The MBSC study was an observational post-trial follow-up study of parental vaccine-seeking behavior after participation in the M-SIMU study. The M-SIMU study was a cluster-randomized controlled trial conducted in Gem and Rarieda sub-counties, Siaya County, Kenya in 2013-2015. The M-SIMU study evaluated the impact SMS reminders alone or coupled with KES 75 (~US $0.88 in August 2015) or KES 200 (~US $2.35 in August 2015) mobile phone-delivered incentives on vaccination coverage and timeliness. The M-SIMU study enrolled caregivers and infants aged 0-4 weeks from 152 within the Kenya Medical Research Institute (KEMRI) Health and Demographic Surveillance System (HDSS).[27] Participants were randomized at the village level to either the Control arm, SMS only arm, SMS plus 75KES arm (SMS+75KES) or SMS plus 200KES (SMS+200KES) arm. Caregivers received two SMS reminders and one incentive for each of the following vaccine doses: first to third dose pentavalent (diphtheria, tetanus, pertussis, hepatitis B and *Haemophilus* type b) vaccines and first dose measles-containing vaccine (MCV1). The M-SIMU study and results have been described in detail elsewhere.[6,28]

Because we followed-up M-SIMU families, the study setting for the MSBC study was the same as that of the M-SIMU study i.e., the KEMRI HDSS in Gem and Rarieda (Asembo area) sub-counties, Siaya County.[6] The study setting has been described in detail in **Chapter 2**. In short, Gem and Rarieda sub-counties are mainly rural areas characterized by high infant mortality, high prevalence of HIV, tuberculosis and malaria and contrastingly, high coverage with the Pentavalent vaccine series.[6,27,29] The MSBC study leveraged the M-SIMU randomized controlled trial design to compare measles vaccination timeliness and coverage among children born to M-

SIMU intervention arm caregivers after the M-SIMU study to vaccination coverage and timeliness among children subsequently born to M-SIMU Control arm caregivers.

The study is reported following 'Strengthening the Reporting of Observational Studies in Epidemiology' (STROBE) guidelines.[30]

5.3.2. Participants and procedures

The 1,599 M-SIMU caregivers included in the M-SIMU primary analysis[6] were identified from M-SIMU study records. Using the caregiver's last known contact information, study-employed Community Interviewers (CIs) located M-SIMU caregivers and conducted a household visit. At the household visit, CIs explained the MSBC study and evaluated eligibility for caregivers willing to undergo screening. M-SIMU caregivers were eligible to enroll in the MSBC study if: the vaccination status of the child enrolled in the M-SIMU (M-SIMU child) study was verified using the maternal and child health (MCH) booklet at age 12 months; the M-SIMU child had an immediate younger sibling (i.e., subsequent born child) aged at least 10 months old; and the vaccination status of the subsequent child (SC) could be verified via MCH booklet. Enrollment was restricted to caregivers whose SC had MCH booklets because as in the M-SIMU study, vaccination status as recorded in the MCH booklet was considered more reliable than caregivers' verbal report only.[6] In addition, caregivers were excluded from the MSBC study if they were currently or previously enrolled in the M-SIMI study. The M-SIMI study was a randomized controlled trial investigating the impact of SMS reminders with or without unconditional incentives on first dose measles vaccine uptake. This study is described in detail in **Chapter 3**

and it coincided with the MSBC study. Caregivers enrolled in the M-SIMI study were excluded from the MSBC study as the MSBC study sought to evaluate vaccine-seeking behavior of caregivers who had not been exposed to SMS reminders or incentives for vaccination since the M-SIMU study. Caregivers meeting eligibility criteria were enrolled into the MSBC study after providing informed consent. In the event that a SC had not reached age 10 months, CIs requested to revisit the household when the SC achieved 10 months of age.

CIs administered a questionnaire to enrolled caregivers to collect demographic data on the SC including, sex, date of birth and birth order, as well as the caregiver's demographic information such as date of birth and educational attainment. CIs also collected the vaccination history of the SC, second-dose measles vaccination status of the M-SIMU child and health-seeking behavior of the caregiver including the number of antenatal care (ANC) visits undertaken for the SC and whether the SC was delivered in a health facility. Finally, caregivers were asked about other potential influences of vaccine-seeking behavior such as whether they received vaccination reminders or participated in studies evaluating interventions to improve vaccination uptake after their participation in the M-SIMU study. SC's vaccination status and dates of birth were recorded from the MCH booklet, otherwise all other data were self-reported. CIs collected these data using smartphones which had the electronic study questionnaire loaded through the Open Data Kit open-source platform.[31] The MSBC screening form, questionnaire and consent forms are provided in **Appendix 7.8**, **Appendix 7.9** and **Appendices 7.10-7.12**, respectively.

The MSBC received ethical approval from the Kenya Medical Research Institute (KEMRI) Scientific and Ethics Review Unit (KEMRI/SERU/CGHR/092/3456). The study was not reviewed by the Johns Hopkins Bloomberg School of Public Health Institutional Review Board as it was determined to be under the jurisdiction of KEMRI SERU.

5.3.3. Variables and data sources

5.3.3.1. Outcomes

The primary objective of the study was to determine if timely measles vaccination coverage differed significantly among SC of M-SIMU SMS+200KES arm caregivers compared to SC of M-SIMU Control arm caregivers. Thus, the primary outcome was the proportion of SC who had received first dose measles-containing vaccine (MCV1) at age 9 months and 2 weeks (9m+2w) or younger. Secondary outcomes included the proportion of SC receiving MCV1 by age 12 months, the proportion of SC receiving the third dose of pentavalent vaccine (pentavalent 3) at age 16 weeks or younger, and the proportion of M-SIMU children receiving the second dose of measles-containing vaccine (MCV2) at or before age 24 months.

Children were determined to be vaccinated if a vaccination date was entered in the MCH booklet. The age of vaccination was calculated as the documented vaccination date minus the child's date of birth as documented in the MCH booklet. In calculations, one month was equivalent to 30.42 days and to assess if children met the time cutoff, the age in days was rounded off to the nearest integer. For all proportions, the denominator was the number of infants at least one day older than the respective age cutoff.

SC met the primary outcome definition if they received measles vaccination at or before age 288 days and so the proportion of SC receiving MCV1 by age 9m+2w was calculated as follows:

$$\frac{number\ of\ IYS\ aged > 288\ days\ who\ received\ measles\ vaccine\ at\ age\ \leq 288\ days}{Number\ of\ IYS\ aged > 288\ days}$$

SC were considered to have received measles vaccination by age 12 months if measles vaccine was received at ≤364 days of age, thus the secondary outcome, proportion of SC receiving measles vaccine by age 12 months was calculated as below:

$$\frac{number\ of\ IYS\ aged > 364\ days\ who\ received\ measles\ vaccine\ at\ age\ \leq 364\ days}{Number\ of\ IYS\ aged > 364\ days}$$

For the secondary outcome, proportion of SC receiving Penta3 at age ≤16 weeks, SC were considered to have achieved the outcome if they were age ≤112 days at the time of Penta3 vaccination. Therefore, this secondary outcome was calculated as:

$$\frac{number\ of\ IYS\ aged > 112\ days\ who\ received\ Penta3\ at\ age\ \leq 112\ days}{Number\ of\ IYS\ aged > 112\ days}$$

Finally, M-SIMU infants who received MCV2 before age 730 days were considered to have received MCV2 by age 24 months. As such the secondary outcome, proportion of M-SIMU infants receiving MCV2 by age 24 months was calculated using the formula below:

$$\frac{number\ of\ M-SIMU\ children\ aged \geq 730\ days\ who\ received\ MCV2\ at\ age < 730\ days}{Number\ of\ IYS\ aged \geq 730\ days}$$

5.3.3.2. Exposures

The exposure assessed was experience receiving SMS vaccination reminders with or without monetary incentives. Caregivers who were randomized to the SMS only arm in the M-SIMU study were considered to have been exposed to SMS vaccination reminders while those in the SMS+75KES or SMS+200KES arms were considered to have been exposed to SMS reminders and monetary incentives. Caregivers allocated to the M-SIMU Control arm were considered unexposed to the M-SIMU interventions. M-SIMU study allocation was obtained from M-SIMU records. Exposure in the M-SIMU study was defined according to intention-to-treat principles meaning that the analysis assumed exposure to the interventions for caregivers randomized to the M-SIMU study arms without consideration of whether the SMS only arm caregivers actually received the SMS reminders or whether SMS+incentive arm caregivers received SMS reminders and the monetary incentives.

5.3.3.3. Potential confounders

We considered that uneven distribution of caregiver characteristics that may determine access to healthcare or health- or vaccine-seeking behavior could potentially confound the analysis. We assessed in the sub-sample of M-SIMU households included in the MSBC study, the distribution of sociodemographic characteristics across M-SIMU caregiver study arms comparing separately, the distribution of characteristics at the time of enrollment in to the MSBC study and at the time of enrollment in the M-SIMU study. For the MSBC study, distribution of the following characteristics was assessed: SC's sex, history of receipt of any vaccination, sibship, location where the SC was delivered, mobile phone access type (owned vs. shared), maternal age, number of ANC visits attended during pregnancy with the SC, age of the SC and M-SIMU child at the time of the MSBC study and the birth interval between the M-SIMU child and the SC. Distribution of the following characteristics at the time of enrollment into the M-SIMU study was also assessed: M-SIMU child's sex, location of deliver of the M-SIMU child, mobile phone access type (owned vs. shared), maternal educational attainment, travel time to the preferred health facility, region of residence (Asembo or Gem) and socioeconomic wealth quintile. To mitigate the risk of obtaining confounded results, any unequally distributed variables were included in regression models so as to adjust for potential confounders.

Data for these variables were obtained from caregiver self-report during the MSBC or M-SIMU enrollment visit. Some characteristics were collected at the M-SIMU enrollment visit but not at the MSBC enrollment visit (maternal educational attainment, travel tie to health facility, region of residence and household assets) because we hypothesized that these characteristics would not have changed substantially between the time of the M-SIMU study and the MSBC study. Except

for mean age at enrollment in to the MSBC study and the mean birth interval, characteristics were coded into categorical variables as described in **Table 5.1**. Significance of differences in the distribution of characteristics at the 5% significance level was assessed using the Chi-squared test for binary variables and one way analysis of variance (ANOVA) with Bonferroni adjustment for multiple testing.

5.3.3.4. Effect modifiers

Because this study sought to evaluate whether there were significant differences in the proportion of children vaccinated in the presence of SMS vaccination reminders with or without monetary incentives, i.e., the proportion of M-SIMU children vaccinated, compared to the proportion of children vaccinated in the absence of these interventions, i.e., the proportion of SC vaccinated, we included an interaction term between the caregiver's study arm and the child's birth order to assess statistical interaction. Details of the model and the variables included in the difference in differences analysis are included below.

In addition, we also performed sub-group analyses to evaluate whether differences in vaccine coverage among SC and M-SIMU children of caregivers enrolled in the M-SIMU intervention arms compared to children of M-SIMU control arm caregivers varied across strata of sociodemographic characteristics at the time when caregivers received the interventions, i.e., at the time of enrollment into the M-SIMU study. Characteristics included in the sub-group analyses were: M-SIMU child's sex, location of M-SIMU child's delivery, mobile phone access

type, maternal educational attainment, maternal age, travel time to a health facility, region of residence and socioeconomic wealth quintile.

5.3.4. Bias

The M-SIMU study was a randomized controlled trial and it found no difference in baseline characteristics among participants included in the analytic sample.[6] Differential selection of M-SIMU caregivers to participate in the MSBC study by study arm would bias the effect estimate towards or away from the null, depending on whether the selection bias differentially impacted vaccination coverage estimates of SC born to M-SIMU intervention arm caregivers or SC born to M-SIMU Control arm caregivers. To minimize the risk of selection bias, we planned to screen all caregivers included in the M-SIMU analytic sample for eligibility to enroll in the MSBC. Moreover, we compared M-SIMU baseline characteristics (M-SIMU child's sex, location of M-SIMU child's delivery, mobile phone access type, maternal education attainment, maternal age, SES quintile and residence in Gem vs. Rarieda sub-counties) of caregivers who were followed up in MSBC to those who did not participate in the MSBC study to evaluate any statistically significant differences in their characteristics.

In addition, M-SIMU intervention arm caregivers may have been more likely than Control arm caregivers, who received no intervention, to incorrectly recall their study arm either because of trouble remembering whether they were randomized to receive the KES 75 or KES 200 incentive, or because they were among 3-7% of M-SIMU intervention arm caregivers who reported not receiving interventions during the M-SIMU study.[6] To minimize information bias

related to misclassification of the exposure, we used M-SIMU records to identify caregivers'' M-SIMU study arm, rather than using caregivers' self-report of M-SIMU study arm allocation.

Furthermore, differential misclassification of vaccination status could have occurred if vaccination history was collected verbally. M-SIMU intervention arm caregivers may have been more likely to report vaccination of their children out of a desire to be regarded favorably by study staff as they were aware that the M-SIMU study interventions sought to encourage vaccination of their children. Thus, we collected vaccination history as recorded in the MCH booklet to minimize the risk of differential outcome misclassification.

5.3.5. Study size

Study sample size calculations were centered on the expected fertility of M-SIMU mothers. On average, M-SIMU mothers reported having 1.9 children under age 5 years living in their respective households (D.G. Gibson, unpublished data, May 2017). Total fertility rate in the study area was estimated at 5.3 children per woman in 2008.[27] Thus, we assumed that all mothers enrolled in M-SIMU were at risk of having at least one child born after the child that was enrolled in the M-SIMU study. A previous analysis that included mothers from the study area estimated the mean birth interval (i.e., time between two subsequent births) in the study area at 27.1 ± 10.1 months.[32] The M-SIMU study enrolled mothers of children born between October 2013 and October 2014. We assumed that the MSBC study would be conducted through December 2017 i.e., that the MSBC study would enroll SC born on or before February 2017. For M-SIMU mothers to have borne children on or before February 2017, the birth interval between

the M-SIMU child and the SC would range from 9 months (the minimum birth interval in the study area[32]) to 40 months (the number of months between October 2013 and February 2017). Assuming a similar distribution of birth intervals as observed prior (mean 27.1 ± 10.1 months),[32] we estimated that up to 89.9% of 1,599 M-SIMU mothers included in the primary analysis[6] would have a subsequent born child by February 2017. We further assumed that we would fail to enroll 10% of potentially eligible caregivers due to outmigration, ineligibility, refusals, death of the SC and other reasons. Thus, we anticipated enrolling up to 1,278 SC into the MSBC study. Specifically, by M-SIMU caregiver study arm, we anticipated enrolling up to: 288 Control arm SC, 310 SMS only SC, 356 SMS+75KES SC; and 324 SMS+200KES SC.

We also estimated the effect size able to be detected with a sample size of 1,278. In the effect size estimation we assumed: a type 1 error (alpha) of 5%; power (1-beta) of 80%; 50.8% measles coverage among SC of M-SIMU Control arm caregivers at age 9m+2w (data from M-SIMU); at least 157 SC enrolled per M-SIMU caregiver study arm; 38 clusters (villages) per M-SIMU caregiver study arm; an average cluster size of four SC; and a coefficient of variation (CV) equal to 0.089 which was the CV observed in the M-SIMU study.[6] Based on these assumptions and accounting for clustering, the study was powered to detect an absolute difference of ≥18% in the proportion of SC born to M-SIMU SMS+200KES arm caregivers receiving MCV1 by age 9m+2w (the primary objective's time cutoff) compared to those of M-SIMU Control arm caregivers. We felt that a difference of ≥18% in MCV1 timely coverage would represent a meaningful enhancement effect or inhibitory effect (depending on the direction of the difference) of SMS reminders coupled with incentives on long-term parental vaccine-seeking behavior.

5.3.6. Statistical analysis and bias

5.3.6.1. MCV1 timely coverage

Log-binomial regression, or log-Poisson regression with robust error variance (modified Poisson) where log-binomial models failed to converge, was used to estimate the difference in risk (RD) of the primary outcome, receipt of MCV1 at age ≤9m+2w, among children of caregivers who were enrolled in the M-SIMU study intervention arms (separately) compared to children of M-SIMU Control arm caregivers. Associated 95% confidence intervals (95% CI) for RDs were also estimated. Generalized estimating equations (GEE) were used to account for spatial clustering; although there was two-way nested clustering (household and village), the models defined village as the clustering variable, as recommended previously.[33] The working correlation structure specified in regression models was exchangeable and variance was estimated using the Huber/White/sandwich estimator. In addition, regression models included a variable indicating time i.e., after M-SIMU (SC) versus during M-SIMU (M-SIMU child) so as to adjust for secular trends. Furthermore, to allow for difference in differences estimation, an interaction term between the caregiver's M-SIMU study arm and the time variable was also included in the model.

In the RD model, the difference in differences estimate was calculated on the normal scale and represented the *difference in risk differences* i.e., the difference in risk of vaccination among SC of M-SIMU intervention arm caregivers compared to SC of M-SIMU Control arm caregivers minus the difference in risk of vaccination among M-SIMU intervention arm children compared to M-SIMU Control arm children. The RD model was specified as follows:

$$Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS75 + \beta_3.SMS200 + \beta_4.time + \beta_5.SMS*time + \beta_6.SMS75*time + \beta_7.SMS200*time$$

where:

Pr(Y = 1) is the probability of receiving MCV1 at age 9m+2w or earlier 2w;

β_0 is the constant i.e., the risk of receiving MCV1 at age 9m+2w or earlier in M-SIMU Control arm children given a zero value for all other predictors;

β_1 is the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm;

SMS is an indicator variable with a value of 1 if the caregiver was randomized to the M-SIMU SMS only arm and a value of 0 otherwise;

β_2 is the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS+75KES arm compared to those whose caregivers were randomized to the Control arm;

SMS75 is an indicator variable with a value of 1 if the caregiver was randomized to the M-SIMU SMS+75KES arm and a value of 0 otherwise;

β_3 is the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS+200KES arm compared to those whose caregivers were randomized to the Control arm;

SMS200 is an indicator variable with a value of 1 if the caregiver was randomized to the M-SIMU SMS+200KES arm and a value of 0 otherwise;

β_4 is the difference in the risk of receiving MCV1 at age 9m+2w or earlier among SC of **M-SIMU Control arm caregivers** compared to their older M-SIMU siblings;

time is an indicator variable with a value of 1 if the child is the younger sibling (SC) of the M-SIMU child and a value of 0 if the child was enrolled in M-SIMU;

β_5 is the difference in: the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm, minus the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among SC** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm;

*SMS*time* is an interaction term with a value of 1 if the caregiver was randomized to the M-SIMU SMS only arm and if the infant is the younger sibling of an M-SIMU child and a value of zero otherwise;

B_6 is the difference in: the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS+75KES arm compared to those whose caregivers were randomized to the Control arm, minus the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among SC** whose caregivers were randomized to the SMS+75KES arm compared to those whose caregivers were randomized to the Control arm;

*SMS75*time* is an interaction term with a value of 1 if the caregiver was randomized to the M-SIMU SMS+75KES arm and if the infant is the younger sibling of an M-SIMU child and a value of zero otherwise;

B_7 is the difference in: the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS+200KES arm compared to those whose caregivers were randomized to the Control arm, minus the difference in the risk of receiving MCV1 at age 9m+2w or earlier **among SC** whose caregivers were randomized to the SMS+200KES arm compared to those whose caregivers were randomized to the Control arm;

and,

*SMS200*time* is an interaction term with a value of 1 if the caregiver was randomized to the M-SIMU SMS+200KES arm and if the infant is the younger sibling of an M-SIMU child and a value of zero otherwise.

5.3.6.2. MCV1 overall coverage and pentavalent 3 timely coverage

Similar to the primary outcome analysis, log-binomial regression, or log-Poisson regression with robust error variance (modified Poisson) where log-binomial models failed to converge, was used to estimate the difference in risk (RD) of receiving MCV1 by age 12 months and pentavalent 3 at age ≤16 weeks, separately. Vaccination risk among children of caregivers enrolled in the individual M-SIMU study intervention arms was compared to the risk among children of M-SIMU Control arm caregivers. Associated 95% CI for RDs were also estimated. As previously, GEE were used to account for clustering at the village level, the exchangeable working correlation structure was specified and variance was estimated using the Huber/White/sandwich estimator. Regression models were the same as those used for assessment of the primary outcome, with the difference being in that the outcome was, first, MCV1 by age

12 months and second, pentavalent 3 at age ≤16 weeks. As previously, regression models included a variable indicating time i.e., after M-SIMU (SC) versus during M-SIMU (M-SIMU child) so as to adjust for secular trends. Furthermore, to allow for difference in differences estimation, an interaction term between the caregiver's M-SIMU study arm and the time variable was also included in the model. Significance was assessed at the 5% level.

5.3.6.3. MCV2 by age 24 months among M-SIMU children

Log-binomial regression was used to estimate the RR, RD and associated 95% CIs of receiving MCV2 among M-SIMU children. GEE were used to account for clustering. Similar to the previously described regression models, these models defined village as the clustering variable, specified exchangeable correlation and estimated variance using the Huber/White/sandwich estimator. Significance was assessed at the 5% level. The RR model was specified as follows and included any variables assessed to be unequally distributed at M-SIMU baseline or at MSBC enrollment:

$$Log\ Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS75 + \beta_3.SMS200 + \beta_p.X_p$$

where:

Pr(Y = 1) is the probability of receiving MCV2 by age 24 months;

β_0 is the constant i.e., the log risk of MCV2 receipt by age 24 months among children previously enrolled in the M-SIMU Control arm given a zero value for all other predictors;

β_1 is the log risk ratio of MCV2 receipt by age 24 months among children previously enrolled in the M-SIMU SMS only arm compared to those previously enrolled in the M-SIMU Control arm for otherwise similar children;

SMS is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS only arm and a value of 0 otherwise;

β_2 is the log risk ratio of MCV2 receipt by age 24 months among children previously enrolled in the M-SIMU SMS+75KES arm compared to those previously enrolled in the M-SIMU Control arm for otherwise similar children;

SMS75 is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS+75KES arm and a value of 0 otherwise;

β_3 is the log risk ratio of MCV2 receipt by age 24 months among children previously enrolled in the M-SIMU SMS+200KES arm compared to those previously enrolled in the M-SIMU Control arm for otherwise similar children;

SMS200 is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS+200KES arm and a value of 0 otherwise.

β_p is the log risk ratio of MCV2 receipt by age 24 months for a one unit increase in variable X_p among otherwise similar infants;

and,

X_p is a potentially confounding variable(s).

In addition, the following model was used to estimate RDs:

$$Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS75 + \beta_3.SMS200 + \beta_p.X_p$$

where:

Pr(Y = 1) is the probability of receiving MCV2 by age 24 months;

β_0 is the constant i.e., the probability of receiving MCV2 by age 24 months in the Control arm given a zero value for all other predictors;

β_1 is the difference in the probability of receiving MCV2 by age 24 months among children previously enrolled in M-SIMU SMS only arm compared those previously enrolled in the Control arm for otherwise similar infants for otherwise similar children;

SMS is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS only arm and a value of 0 otherwise;

B_2 is the difference in the probability of receiving MCV2 by age 24 months among children previously enrolled in M-SIMU SMS+75KES arm compared those previously enrolled in the Control arm for otherwise similar infants for otherwise similar children;

SMS+75KES is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS+75KES arm and a value of 0 otherwise;

B_3 is the difference in the probability of receiving MCV2 by age 24 months among children previously enrolled in M-SIMU SMS+200KES arm compared those previously enrolled in the Control arm for otherwise similar infants for otherwise similar children;

SMS+200KES is an indicator variable with a value of 1 if the child was previously enrolled in the M-SIMU SMS+200KES arm and a value of 0 otherwise;

β_p is the difference in the risk of MCV2 receipt by age 24 months for a one unit increase in variable X_p among otherwise similar infants;

and,

X_p is a potentially confounding variable(s).

5.3.6.4. Sub-group analysis

No sub-group analysis was performed.

5.3.6.5. Sensitivity analysis

To test the robustness of the primary outcome results and also to increase the sample size, we combined data from the SMS+75KES and the SMS+200KES arms so as to compare measles vaccination coverage at age 9m+2w or earlier among children of M-SIMU SMS only arm caregivers and children of SMS plus incentive arm caregivers to coverage among children of M-SIMU Control arm caregivers.

As with previous analysis, log-binomial regression, or log-Poisson regression when the log-binomial model failed to converge, was used to estimate the RR, RD and associated 95% CIs of receiving MCV1 at age 9m+2w or earlier in children of caregivers who were allocated to receive M-SIMU interventions compared to Control arm caregivers. GEE was used to account for clustering and clustering and variance modeled similarly to the previously described models. The models were also adjusted for birth order and, to allow for estimation of the ratio of risk ratios

and the difference in risk differences, an interaction term between the caregiver's M-SIMU study arm and child's birth order was also included in the model. Aside from caregiver's study arm, no other variables were included in the regression models. The RR model was specified as follows:

$$Log\ Pr(Y=1) = \beta_0 + \beta_1.SMS + \beta_2.SMS{+}incentive + \beta_3.SC + \beta_4.SMS{*}SC + \beta_5.SMS{+}incentive{*}SC$$

where:

Pr(Y = 1) is the probability of receiving MCV1 at age 9m+2w or earlier

β_0 is the constant i.e., the log risk of receiving MCV1 at age 9m+2w or earlier among **M-SIMU Control arm children**;

β_1 is the log risk ratio of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm;

SMS is an indicator variable with a value of 1 if the caregiver was randomized to the M-SIMU SMS only arm and a value of 0 otherwise;

β_2 is the log risk ratio of receiving MCV1 at age 9m+2w or earlier **among M-SIMU children** whose caregivers were randomized to the SMS+75KES or SMS+200KES arm compared to those whose caregivers were randomized to the Control arm;

SMS+incentive is an indicator variable with a value of 1 if the caregiver was randomized to the M-SIMU SMS+75KES or SMS+200KES arm and a value of 0 otherwise;

β_3 is the log risk ratio of the vaccination outcome among SC of **M-SIMU Control arm caregivers** compared to their older M-SIMU siblings;

SC is an indicator variable with a value of 1 if the child is the younger sibling (SC) of the M-SIMU child and a value of 0 if the child was enrolled in M-SIMU;

β_4 is the log ratio of: the risk ratio of the vaccination outcome **among M-SIMU children** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm, divided by the risk ratio of the vaccination outcome **among SC** whose caregivers were randomized to the SMS only arm compared to those whose caregivers were randomized to the Control arm;

*SMS*SC* is an interaction term with a value of 1 if the caregiver was randomized to the M-SIMU SMS only arm and the infant is the younger sibling of an M-SIMU child and a value of zero otherwise;

B_5 is the log ratio of: the risk ratio of the vaccination outcome **among M-SIMU children** whose caregivers were randomized to the SMS+75KES or SMS+200KES arm compared to those whose caregivers were randomized to the Control arm, divided by the risk ratio of the vaccination outcome **among SC** whose caregivers were randomized to the SMS+75KES or SMS+200KES arm compared to those whose caregivers were randomized to the Control arm;

and,

*SMS+incentive*SC* is an interaction term with a value of 1 if the caregiver was randomized to the M-SIMU SMS+75KES or SMS+200KES arm and the infant is the younger sibling of an M-SIMU child and a value of zero otherwise.

In addition, to assess if trends in MCV2 coverage were similar to trends in MCV2 timely coverage (i.e., receipt of MCV2 by age 19 months), a sensitivity analysis of the relative risk and differences in risk of MCV2 coverage by age 19 months across previous M-SIMU randomization arm was performed. The regression model for this sensitivity analysis was the same as that used for the MCV2 coverage by age 24 months outcome. Significance was assessed at the 5% level.

Analyses were performed using Stata version 14.2.

5.4. Results

5.4.1. Participants

Post-trial follow-up visits were conducted between August 4, 2018 and November 30, 2018. CIs visited 1,467 of 1,599 M-SIMU households (91.7%); 132 M-SIMU households were not visited as funding for the study ended before the households could be visited. Of the households visited, 218 (14.9%) follow-up visits were completed. Follow-up visits were not conducted for the remaining households either because they did not meet MSBC eligibility criteria (n= 1,000; 68.2%) or were lost to follow-up (n= 249; 17.0%). Of 1,000 caregivers not meeting MSBC eligibility criteria, 711 (71.1%) did not have a child born after M-SIMU, 203 (20.3%) had a SC younger than age 10 months, 62 (6.2%) had a SC but were enrolled in the M-SIMI study and 24 (2.4%) did not have an MCH booklet for the SC. Among the 249 households lost to follow-up, 223 (89.6%) moved away from the study area after the M-SIMU study, 22 (8.8%) were not at home at the time of the visit and four (1.6%) SC died prior to the screening visit. The 218 participants followed up in the MSBC study included: 44, 60, 56 and 58 households previously randomized to the M-SIMU Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm, respectively. The total M-SIMU sub-sample included in the MSBC study represented 13.6% (218/1599) of the entire M-SIMU sample and 12.2% (44/360), 15.5% (60/388) 12.6% (56/445) and 14.3% (58/406) of households enrolled in the M-SIMU Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm, respectively (**Figure 5.1**).

5.4.2. Descriptive data

At enrollment into the MSBC study, SC were approximately 18 months old on average (mean 17.9 months, SD 6.0) and were born approximately 25 months after their older M-SIMU siblings

(mean 25.2 months, SD 6.1). A little over half of the SC were female (n= 119; 54.3%). All SC had received at least one vaccination at enrollment into the MSBC study. Most SC had 1-3 siblings (n= 130; 59.4%) and close to three-quarters of SC were born at a health facility (n= 162; 74.0%). In terms of caregiver characteristics, about 70% of caregivers owned a phone (n= 151; 68.9%) and nearly half of mothers were aged ≤28 years (n= 107; 48.9%). Roughly 25% of mothers attended more than four ANC visits during pregnancy with the SC (n= 51; 23.3%). There were no statistically significant differences in characteristics of SC and their caregivers at the time of the MSBC interview. At the time follow-up in the MSBC study, M-SIMU children were approximately 3.5 years old on average (mean 43.2, SD 3.5). M-SIMU children of SMS+200KES arm caregivers (mean age 41.8 months, SD 3.2) were significantly younger than those of SMS only arm caregivers (mean age 43.8 months, SD 3.7; p= 0.010) and significantly younger than M-SIMU children of SMS+75KES arm caregivers (mean age 43.5 months, SD 3.5; p= 0.046; **Table 5.2**). Because children were left-censored at the respective age cut-off for analysis of the various outcomes, the age of M-SIMU children at the time of the MSBC interview was not controlled for in regression models.

Characteristics of M-SIMU participants (n=1,599) at the time of enrollment into the M-SIMU study were similar across the four study arms and have been described previously. In short, half of the M-SIMU children were female, 72% of M-SIMU children were delivered at a health facility, slightly less than half of the caregivers owned a mobile phone and approximately 74% of mothers had more than seven years of education. A little over half of caregivers were 25 years old or younger, about 60% of households were within 30 minutes of travel time to a clinic and close to 80% lived in Gem sub-county.[6]

At the time of participation in the M-SIMU study, the sub-sample of M-SIMU participants later followed up in the MSBC study had statistically significant differences in sociodemographic characteristics compared to those who were not followed up. The M-SIMU sub-sample included in the MSBC study had lower levels of phone ownership at entry into the M-SIMU study compared to M-SIMU participants not followed-up in MSBC (38.8% [n= 85] vs. 51.0% [n= 704]; p= 0.001). In addition, compared to M-SIMU participants not followed up in MBSC, a larger proportion of those followed had longer travel times to a health facility (46.1% [n= 101] vs. 38.0% [n= 524]; p= 0.022) and lived in Rarieda sub-county, i.e., in Asembo (28.3% [n= 62] vs. 19.8% [n= 273]; p= 0.004; **Table 5.3**). Specifically by study arm, compared to M-SIMU SMS+75KES arm households excluded from the MSBC study, a lower proportion of M-SIMU SMS+75KES households included in the MSBC study owned a mobile phone (26.8% [n= 15] vs. 49.9% (n= 194); p= 0.001) and a higher proportion lived more than 30 minutes away from a health facility (48.2% [n= 27] vs. 32.4% [n= 126]; p= 0.020). In addition, compared to M-SIMU SMS+200KES arm households excluded from the MSBC study, a lower proportion of SMS+200KES included in MSBC owned a mobile phone at the start of the M-SIMU study (33.9% [n= 20] vs. 49.9% [n= 173]; p= 0.023; **Table 5.4**).

In comparing M-SIMU baseline characteristics across M-SIMU study arm of the sub-sample included in the MSBC study, there were no statistically significant differences in the distribution of M-SIMU child's sex, location of delivery for the M-SIMU child, maternal education, maternal age, travel time to a health facility, region of residence or socioeconomic quintile. However, phone ownership at the start of the M-SIMU study was not equally distributed in this sub-

sample; 52.3% (n= 23) of Control arm caregivers owned a phone at the beginning of the M-SIMU study compared to 45.0% (n= 27) of SMS only arm caregivers, 26.8% (n= 15) of SMS+75KES arm caregivers and 33.9% (n= 20) of SMS+200KES arm caregivers (p= 0.040; **Table 5.5**). **Because of this imbalance, regression analyses were adjusted for mobile phone ownership status at the start of M-SIMU**.

In addition, because the previously described imbalances suggested that Control MSBC households were not comparable to intervention MSBC households, a post-hoc sensitivity analysis was performed whereby forward selection was used to create a model including additional characteristics that may have confounded the analysis. Additional characteristics assessed were: travel time to the nearest health facility, region of residence, maternal educational attainment as measured at the beginning of the M-SIMU study and the number of ANC visits attended for the subsequent child.

5.4.3. Outcome data and main results

5.4.3.1. MCV1 timely coverage

MCV1 timely coverage was, 58.1% (25/43), 49.2% (29/59), 38.2% (21/55) and 40.7% (24/59) among Control SC, SMS only SC, SMS+75KES SC and SMS+200KES SC, respectively. Three SC who were enrolled before reaching age 9 months and 2 weeks, as well as their M-SIMU siblings, were excluded from the MCV1 timely coverage analysis. Among the sub-sample of Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm M-SIMU children followed-up in the MSBC study, MCV1 timely coverage during the M-SIMU study was respectively, 60.5% (26/43), 61.0% (36/59), 60.0% (33/55) and 67.2% (39/58; **Table 5.6**). Table

5.6 also includes MCV1 timely coverage for the entire M-SIMU sample[6] for ease of reference by the reader.

Children of SMS+200KES caregivers (primary outcome)

In the primary objective analysis, there was a 25.2% absolute decrease in MCV1 timely coverage after the M-SIMU study compared to during the M-SIMU study among children of SMS+200KES caregivers, though this reduction in timely coverage was not statistically significant (adjusted risk difference-in-differences [DID] 95% CI: -55.3%, 4.8%; p= 0.099). This translated to 18.1% lower MCV1 timely coverage among SMS+200KES SC compared to Control SC that was not statistically significant (95% CI: -39.3%, 3.1%; p= 0.095). There were no substantial differences in crude estimates compared to estimates adjusted for M-SIMU baseline phone ownership status (**Figure 5.2**). Results for secondary analyses are described in the following sections

Children of SMS+75KES arm caregivers

MCV1 timely coverage was lower after the M-SIMU compared to during the M-SIMU study among children of SMS+75KES caregivers by 21.3% but this decrease was not statistically significant (adjusted DID 95% CI: -47.4%, 4.8%; p= 0.110). However, in the period after the M-SIMU study, MCV1 timely coverage was significantly lower by 21.7% among children whose caregivers were previously enrolled in the M-SIMU SMS+75KES arm compared to those whose caregivers were in the M-SIMU Control arm (95% CI: -41.9%, -1.6%; p= 0.035). Crude and adjusted RRs were similar (**Figure 5.3**).

Children of SMS only arm caregivers

MCV1 timely coverage was 11.2% lower among children of SMS only caregivers after the M-SIMU study compared to during the M-SIMU study, although this difference did not achieve statistical significance (adjusted DID -11.2%; 95% CI: -36.1%, 13.7%; p= 0.376). This decrease translated to a statistically insignificant difference of 11.5% in MCV1 timely coverage among SMS only SC compared to Control SC (95% CI: -32.8%, 9.8%; p= 0.290). Crude and adjusted RR and RD estimates did not differ markedly (**Figure 5.4**).

Sensitivity analyses of primary outcome

In the sensitivity analysis that combined data from the SMS+200KES and SMS+75KES arms, SMS+incentive SC had 23.3% lower MCV1 timely coverage than their older M-SIMU siblings but this difference in timely coverage was not statistically significant (adjusted DID 95% CI: -48.1%, 1.5%, p= 0.065). In the period after the M-SIMU study, MCV1 timely coverage was significantly lower by 19.8% among SMS+incentive SC compared to Control SC (aRD 95% CI: -38.1%, -1.5%; p= 0.034). Crude and adjusted estimates were comparable (**Figure 5.5**).

In the post-hoc sensitivity analysis, mobile phone ownership at the start of the M-SIMU study, region of residence (Gem vs. Asembo), travel time to the nearest health facility, maternal educational attainment at the start of the M-SIMU study as well as the number of ANC visits attended for the SC were included as covariates. There were small changes towards the null for most RRs for all intervention households. Of note, the difference in MCV1 timely coverage

comparing SMS+75KES SC to Control SC borderline statistically significant (RD p= 0.050) compared to a p-value of 0.035 in the main secondary outcome analysis (**Table 5.7**).

5.4.3.2. MCV1 overall coverage

Among SC of Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm caregivers, MCV1 overall coverage was 84.4% (27/32), 76.9% (40/52), 63.6% (28/44) and 60.9% (28/46), respectively. In the sub-sample of M-SIMU children surveyed in the MSBC study, MCV1 overall coverage was 84.4% (27/32), 90.4% (47/52), 75.0% (33/44) and 87.0% (40/46) for Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm participants (**Table 5.6**). Estimation of MCV1 overall coverage excluded 44 SC (12 Control, 8 SMS only, 12 SMS+75KES and 12 SMS+200KES) who had not reached age 12 months, as well as their M-SIMU siblings. MCV1 overall coverage estimates for the entire M-SIMU sample are also presented in Table 5.6. In the following results, RRs and associated 95% CIs for the MCV1 overall coverage outcome were estimated using Poisson regression as binomial models failed to converge.

<u>Children of SMS+200KES caregivers</u>

Compared to during the M-SIMU study, MCV1 overall coverage among children of SMS+200KES caregivers after the M-SIMU study was lower by 24.5% though this decrease was not statistically significant (adjusted DID 95% CI: -50.9%, 2.0%; p= 0.070). The absolute decrease in MCV1 overall coverage among SMS+200KES arm SC compared to Control SC was 20.8% and was not statistically significant (aRD 95% CI: -42.1%, 0.6%; p= 0.057). Crude point

estimates diverged somewhat from adjusted estimates and the p-value for the comparison of MCV1 overall coverage among SMS+200KES SC and Control SC indicated significantly lower coverage among SMS+200KES SC (**Figure 5.6**)

Children of SMS+75KES caregivers

After the M-SIMU study, MCV1 overall coverage was lower by 8.6% among SMS+75KES children compared to during the M-SIMU study but this difference was statistically insignificant (adjusted DID 95% CI: -32.0%, 14.9%; p= 0.473). But SMS+75KES SC had significantly lower MCV1 overall coverage than Control SC in the period after the M-SIMU study (aRD 18.4%, 95% CI: -36.2%, -0.5%, p= 0.044). There were some small differences in the point estimates derived from the crude model compared to the adjusted model, but these differences did not impact the interpretation of the results (**Figure 5.7**).

Children of SMS only caregivers

Children of caregivers previously enrolled in the M-SIMU SMS only arm had 10.4% non-significant lower MCV1 overall coverage after the M-SIMU study compared to during the M-SIMU study (adjusted DID 95% CI: -29.8%, 9.0%; p= 0.295). This reduction resulted in 6.2% statistically insignificant lower coverage among SMS only SC compared to Control SC (95% CI: -22.2%, 9.8%; p= 0.451). Crude estimates of RDs were slightly larger than adjusted estimates, but did not impact interpretation of the results (**Figure 5.8**).

5.4.3.3. Pentavalent 3 timely coverage

Pentavalent 3 timely coverage among SC born to M-SIMU Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm caregivers was 70.5% (31/44), 70.0% (42/60), 62.5% (35/56) and 56.9% (33/58), respectively. Among M-SIMU children followed up in the MSBC study, 72.7% (32/44), 71.7% (43/60), 76.8% (43/56) and 69.0% (40/58) Control arm, SMS only arm, SMS+75KES arm and SMS+200KES arm children received pentavalent 3 by age 16 weeks or younger (**Table 5.8**). Entire M-SIMU sample pentavalent 3 timely coverage is also presented in Table 5.8.

SMS+200KES arm children

Pentavalent 3 timely coverage was lower among SMS+200KES children after withdrawal of M-SIMU interventions compared to during the M-SIMU study, but not significantly so (adjusted DID -9.9%; 95% CI: -30.7, 10.8; p= 0.348). SMS+200KES SC had statistically insignificant lower pentavalent 3 timely coverage compared to Control SC (aRD -13.1%; 95% CI: -31.8, 5.5; p= 0.167). Results from the crude and adjusted analyses were comparable (**Figure 5.9**).

SMS+75KES arm children

After the M-SIMU study, pentavalent 3 timely coverage was 12.9% lower in SMS+75KES SC compared to coverage during the M-SIMU study in SMS+75KES M-SIMU children but this difference did not achieve statistical significance (95% CI: -35.2, 9.5; p= 0.259). Pentavalent 3 timely coverage was lower by 10.3% among SMS+75KES SC compared to Control SC in the period after the M-SIMU study though this difference was statistically insignificant (95% CI: -

31.4%, 10.7%; p= 0.336). Estimates from the crude and adjusted analyses were comparable (**Figure 5.10**).

SMS only arm children

There were no notable differences in pentavalent 3 timely coverage among children of SMS only caregivers after the M-SIMU study as compared to timely coverage during the M-SIMU study (adjusted DID 0.4%; 95% CI: -17.1%, 17.9%; p= 0.964) or timely coverage among Control SC (aRD -1.2%; 95% CI: -19.4%, 17.0%; p= 0.897). Crude and adjusted estimates were comparable (**Figure 5.11**).

5.4.3.4. MCV2 coverage by age 24 months among M-SIMU children

MCV2 coverage by age 24 months was estimated among only M-SIMU children. Of 218 M-SIMU children assessed, 163 (74.8%) had an MCH booklet that could be used to verify second dose measles vaccination status. Thus, MCV2 coverage by age 24 months was assessed in 163 M-SIMU children. The proportion of M-SIMU Control arm, SMS only arm, SMS+75KES and SMS+200KES arm M-SIMU children receiving MCV2 by age 24 months was 52.8% (19/36), 31.1% (14/45), 20.5% (8/39) and 25.6% (11/43), respectively (**Table 5.9**).

MCV2 coverage among SMS+200KES M-SIMU children was significantly lower than coverage among Control M-SIMU children by 27.0% (95% CI: -49.0%, -5.0%; p= 0.016). Similarly, MCV2 coverage among SMS+75KES M-SIMU children significantly lower by 29.2 percentage

points compared to coverage among Control M-SIMU children (95% CI: -52.1%, -6.2%; p= 0.013). MCV2 coverage by age 24 months among SMS only M-SIMU children was 22.0% lower than coverage among Control M-SIMU children, but this difference was not statistically significant (95% CI: -45.2; 1.1; p= 0.062). For all comparisons, results from crude models differed slightly from the results from the adjusted model but the differences were not substantial and did not affect interpretation of the results (**Table 5.9**).

Sensitivity analysis: MCV2 by age 19 months among M-SIMU children

In this sensitivity analysis, the likelihood of receiving MCV2 by age 19 months among M-SIMU intervention children was lower compared to the likelihood among M-SIMU Control children. However, none of these reduced likelihoods achieved statistical significance. Similarly MCV2 timely coverage was statistically insignificantly lower among M-SIMU intervention arm children compared to Control intervention children (**Table 5.10**).

5.5. Discussion

This study is novel in being the first to assess the impact of withdrawal of SMS vaccination reminders and incentives on vaccine-seeking behavior among caregivers who previously received these interventions. Our findings indicate that withdrawal of SMS vaccination reminders alone, or SMS vaccination reminders coupled with incentives, may result in decreased vaccine-seeking for MCV.

In the period after withdrawal of these interventions, MCV1 timely coverage, our primary outcome, and coverage by age 12 months were lower among subsequent children whose caregivers previously received the interventions, compared to subsequent children whose caregivers did not previously receive these interventions. These reductions could not be attributed to secular changes as difference-in-difference estimates accounted for secular trends, nor could the reductions be attributed to baseline differences in vaccine- or health-seeking among households that previously received M-SIMU interventions compared to Control households; inclusion of potentially confounding characteristics associated with vaccine- or health-seeking in sensitivity regression models had minimal impact on the findings. Although the decreases in MCV1 timely coverage and coverage by age 12 months were statistically significant only in the case of SMS+75KES SC compared to Control SC, the point estimates for other comparisons were in the same direction. Taken together this suggests that reductions in coverage may follow withdrawal of SMS reminders and/or incentives.

When compared to MCV1 timely and overall coverage among Control SC in the period after withdrawal of M-SIMU interventions, the largest reduction was observed among SMS+200KES SC, followed by SMS+75KES SC and lastly by SMS only SC, suggesting a dose-response relationship whereby the magnitude of reductions lessened with decreasing intensity of the interventions. Second, the primary outcome sensitivity analysis whereby SMS+200KES and SMS+75KES households were combined showed that: MCV1 vaccine-seeking among SMS+incentive caregivers declined significantly after withdrawal of M-SIMU interventions, i.e., SMS+incentive SC timely coverage was significantly lower than SMS+incentive timely coverage among M-SIMU children, and that MCV1 timely coverage among SMS+incentive SC declined to below baseline levels, i.e., MCV1 timely coverage among SMS+incentive SC was significantly lower compared to Control SC. Moreover, and perhaps most concerning, we found that MCV2 coverage by age 24 months among children who were previously enrolled in the M-SIMU study was lower among children who were randomized to M-SIMU intervention arms compared to Control M-SIMU children, and significantly lower among SMS+75KES and SMS+200KES children. This finding on MCV2 coverage by age 24 months among M-SIMU children is noteworthy because these were the very children previously enrolled in the M-SIMU study. Therefore, differences in MCV2-seeking among M-SIMU children can be more confidently associated with withdrawal of interventions compared to changes among SC who are temporally distal to the M-SIMU study and withdrawal of M-SIMU interventions. Finally, we observed small though statistically insignificant decreases in pentavalent 3-seeking among SMS+200KES and SMS+75KES caregivers.

Reduced vaccine-seeking after withdrawal of M-SIMU interventions among caregivers who previously received them may be linked to a decrease in intrinsic vaccine-seeking motivation either because the presence and/or value of monetary incentives crowded-out caregivers' intrinsic vaccine-seeking motivation or because withdrawal of M-SIMU interventions relayed a negative signal to caregivers. The theory that incentives crowd-out intrinsic motivation to perform the incentivized behavior in the absence of incentives is well established.[24,34,35] As mentioned previously, to date, no studies have demonstrated that incentives to promote health-related behaviors crowd-out intrinsic motivation. Previous studies have shown that after withdrawal of incentives practice of incentivized behaviors, such as exercising, weight loss and smoking cessation, is maintained or that it decreases but not to below pre-incentive levels.[26,36–42] Thus, this study is novel not only in being the first to assess the impact of withdrawal of SMS reminders and incentives on vaccine-seeking, but also in being the first to suggest that incentives may have crowded-out intrinsic motivation for a health-related behavior. This study's findings are in contrast to caregivers' attitudes at the end of the M-SIMU study whereby all but one of 747 caregivers interviewed said that they were as or more likely to vaccinate their child in the absence of incentives.[6]

A variety of mechanisms through which incentives may inhibit intrinsic motivation have been proposed and these seem plausible in the context of incentives for vaccination. Namely, the presence of incentives may have changed prosocially-motivated caregivers' decision frame from social to monetary, may have signaled to caregivers that their vaccine-seeking was inadequate or that vaccination is risky (hence its incentivization). Additionally, if the incentives were priced too low, caregivers may have perceived that vaccination was not important. The incentive

amount in the M-SIMU study was selected based on feedback from mothers living close to the study area, but a ceiling amount of 200 KES was set by the study due to financial considerations. Perhaps a larger incentive value would have been identified had options above 200 KES been offered. Finally, the conditionality of incentives – M-SIMU caregivers received incentives only if their children were vaccinated with the recommended vaccination age – may have inhibited caregivers' intrinsic motivation if they felt the conditions encroached on their free choice to vaccinate their child after the two week deadline. [6,34,35] We posit that caregivers on the vaccine-hesitancy spectrum would have been most susceptible to inhibition of intrinsic motivation by incentives and that the mechanism through which incentives may have inhibited intrinsic motivation may have been different by caregiver. The mechanism by which withdrawal of SMS reminders may have reduced caregiver's intrinsic vaccine-seeking motivation is not clear. However, one could speculate that the act of withdrawing M-SIMU interventions and, not the presence of the interventions themselves, may have inhibited caregivers' intrinsic motivation by signaling that increasing vaccination uptake is not important i.e., if important the study would have continued providing incentives.

In a post-hoc analysis, we investigated characteristics associated with not seeking MCV1 for SC among caregivers whose M-SIMU children previously received MCV1. Respectively, 22.7% (n= 10), 23.3% (n= 14), 35.7% (n= 20) and 41.4% (n= 24) Control, SMS only, SMS+75KES and SMS+200KES caregivers who vaccinated their M-SIMU children at age ≤9m+2w did not do so for their SC. In addition, 9.1% (n= 4), 13.3% (n= 8), 21.4% (n= 12) and 27.6% (n= 16) of Control, SMS only, SMS+75KES and SMS+200KES caregivers who previously vaccinated their M-SIMU children against measles by age 12 months did not do the same for their SC.

Altogether, the data suggested that compared to Control caregivers, caregivers who previously received SMS reminders and incentives were more likely to lapse in MCV1-seeking for SC if they resided in Gem sub-county, were in the bottom two socioeconomic quintiles or were younger mothers (i.e., age ≤25 years). These characteristics may inform the mechanism responsible for reduced vaccine-seeking or perhaps inform future efforts to mitigate the patterns of long-term vaccine-seeking we observed.

However, the results from this analysis do not present conclusive evidence on the impact of short-term SMS vaccination reminders with or without incentives on long-term vaccine-seeking as there are several important limitations. First, we included only 13.3% (213 of 1,599) of M-SIMU caregivers in the MCV1 and pentavalent 3 coverage analyses and only 10.2% (163 of 1,599) of M-SIMU children in the MCV2 coverage analysis. With these participants distributed across four M-SIMU study arms, small differences in individual children's vaccination status had the potential to substantially influence interpretation of the results. Due to these small sample sizes, the magnitude of the effect of the withdrawal of M-SIMU interventions and associated significance levels may not reflect true patterns in MCV1-seeking after withdrawal of M-SIMU interventions.

Second, there was some suggestion that MSBC Control households were different from MSBC intervention households at the start of the M-SIMU study. In comparing M-SIMU baseline characteristics, MSBC intervention households had significantly lower levels of mobile phone ownership compared to MSBC Control households. There was also some suggestion that SMS

plus incentive households enrolled in the MSBC study were less likely to reside in Asembo and more likely to have long travel times to a health facility at the start of the M-SIMU study, though there were no significant differences in these characteristics within the MSBC sample (**Tables 5.2 – 5.5**). Taken together, these differences could suggest that MSBC SMS plus incentive households were more likely to have characteristics that predict lower vaccine-seeking. Lower mobile phone ownership among MSBC caregivers previously enrolled in M-SIMU intervention arms suggests that they may have had lower vaccine-seeking at baseline as compared to MSBC Control caregivers as mobile phone ownership may be indirectly associated with vaccine-seeking through other direct determinants of vaccine-seeking such as wealth, literacy and educational attainment.[43] Residence in Asembo has been associated lower child mortality, better knowledge of malaria treatment and higher obstetric health-seeking compared to residence in Gem.[27,44,45] In addition, longer travel time to a health facility can be associated with decreased vaccine- or health-seeking.[46–53] Further, the previously described differences suggest bias of effect estimates away from the null when they are not accounted for. Indeed, we observed small changes in RD and DID estimates after including region as a covariate in one of the sensitivity regression models whereby estimates shifted slightly towards the null and no reductions were statistically significant. Still, there may be other unknown confounders that we did not account for and that may challenge the internal validity of the MSBC results.

In addition, we observed that MCV1 timely coverage in the sub-sample of M-SIMU Control children included in the MSBC study was substantially greater than coverage among all Control M-SIMU children and that MCV1 timely and overall coverage in the sub-sample of SMS+75KES M-SIMU children included in the MSBC study were substantially lower than

among all SMS+75KES M-SIMU children. Relatedly, in the sub-sample of M-SIMU children followed-up in the MSBC study, vaccination timeliness and coverage were not higher in any of the intervention arm children compared to Control M-SIMU children.[6] Moreover there were significant differences in the distribution of baseline characteristics among MSBC households compared to M-SIMU households not included in MSBC. Thus, the sub-sample of M-SIMU households included in the MSBC study does not seem to be representative of the entire M-SIMU sample and so the results of the MSBC study cannot be generalized to the entire M-SIMU sample.

Furthermore, we cannot definitively establish a causal relationship between withdrawal of M-SIMU interventions and reduced MCV-seeking for several reasons. First, 3% - 13% of M-SIMU caregivers interviewed at the end of the M-SIMU study reported that they either did not receive SMS reminders or incentives. The M-SIMU study had no way of establishing whether caregivers actually received the interventions and so with incomplete information about the level of exposure in MSBC intervention households we cannot fully infer causality. Second, the analysis assumed that Control SC were representative of intervention SC in the counterfactual where intervention households were never enrolled in the M-SIMU study, but this may not have been accurate. Third, reduction in intrinsic motivation after withdrawal of incentives has not previously replicated for health outcomes. Fourth, we did not directly measure intrinsic motivation prior to, during or after the M-SIMU study and therefore we cannot make direct linkages between changes in vaccine-seeking and intrinsic motivation. Finally, we are not confident in the mechanisms by withdrawal of M-SIMU interventions could have reduced intrinsic vaccine-seeking motivation.

We do not think that supply-side constraints influence the study findings. Although there was an ongoing nurses' strike in Kenya that began two months before the start of the MSBC study and ended shortly before completion of the MSBC study,[54,55] we do not think that this strike would have differentially affected vaccine-seeking among caregivers previously enrolled in the M-SIMU study by M-SIMU study arm. One way that the strike could have differentially affected children was if there were substantial differences in the age of the children at the time of the MSBC follow-up survey; younger children reaching vaccination age at the time of the strike would have had less likelihood of being vaccinated. But we found no significant differences in age at the MSBC survey among SC and among M-SIMU children SMS only and SMS+75KES M-SIMU children were older than SMS+200KES, biasing them towards higher likelihood of vaccination (**Table 5.2**). However, the results from this analysis suggest that there was no effect of age on MCV2 coverage among SMS only and SMS+75KES M-SIMU children.

Despite the limitations outlined above, our study had several strengths. First, we attempted to follow each M-SIMU caregiver, minimizing the risk of selection bias. Second, the MSBC study was built on the backbone of a cluster randomized controlled trial, which by design minimizes selection bias. Although we found some differences in characteristics across M-SIMU study arms, we adjusted for possible confounders in regression models. Another strength of this study is the difference-in-differences analytic approach used. This approach allowed us to adjust for secular trends in comparisons of coverage among intervention SC and their M-SIMU siblings as it included an adjustment for the trend seen among Control children across birth cohorts. In

addition, we had data on SC from all study arms, i.e., we did not use M-SIMU Control children as historical controls, allowing us to observe secular trends among Control children.

The findings from this analysis are concerning in that they suggest that withdrawal of SMS reminders with or without incentives resulted in reduced vaccine-seeking. However, given the previously described limitations of the MSBC sample, it is essential for more M-SIMU households to be followed up so as to increase the post-trial follow-up sample size and to increase the likelihood that post-trial follow-up households are representative of the entire M-SIMU sample. A larger, more representative MSBC sample would produce more robust results and allow more confident interpretation of the results.

To conclude, we recommend evaluations of the impact of withdrawing short-term health interventions, particularly for studies assessing the impact of monetary incentives and other demand-generation interventions in LMICs. In addition, we recommend studies that assess the impact of behavioral interventions to generate demand for health service on intrinsic motivation among health service clients in LMICs. If confirmed through other studies, the findings from this analysis should signal to stakeholders the importance of sustaining behavioral health interventions, particularly those involving incentives, and the possible negative effects of withdrawing them. They should also encourage the evaluation of group incentives over individual incentives for health-related demand-generation incentives.

Chapter 5 References

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Chapter 5 Tables

Table 5.1. Categorization of potential confounders assessed

Characteristic	Existing or derived variable	Description
Mobile phone access	Existing	Binary: 0= Shares; 1= Owns Caregivers reported whether they owned or shared a mobile phone
Infant's sex	Existing	Binary: 0= Female; 1= Male Caregivers reported the sex of the SC
Any vaccination received	Existing	Binary: 0= Not vaccinated; 1= Vaccinated Caregivers reported whether the SC had ever received any vaccine
Maternal education	Derived in the M-SIMU study	Binary: 0= ≤7 years; 1= >7 years Maternal education level was collected in a series of two variables, one categorical (Primary, Secondary, Post-secondary or none) and the other continuous (Class or form completed). Caregivers selecting no education or primary education with class <8 were classified as having ≤7 years of education. The cutoff at 7 years was used because primary school education in Kenya is 8 years; this cutoff allows distinguishing caregivers with less than primary education vs. those with primary education or more.
Sibship	Derived	Binary: 0= 1-3 siblings; 1= >3 siblings Birth order was collected as a categorical variable i.e., 2nd, 3rd, 4th, 5th, 6th, 7th or >7th. Birth order has previously been shown to predict vaccination status.[56–59] Because none of the SC could be firstborn children we created a binary variable with a cut-off at 3 siblings as a previous study in Israel showed higher varicella vaccination coverage for children with ≤3 siblings compared to those with more siblings.[60]
Location of last delivery	Derived	Binary: 0= At home; 1= Health facility Location of last delivery was collected as a categorical variable 1= At home with no Skilled Birth Attendant (SBA)/ Midwife; 2= At home with SBA/Midwife; 3= Health Facility; 4= Don't know. At home vs. health facility was selected because it might reflect caregivers' health-seeking behavior.
Maternal age	Derived	Binary: 0= ≤28 years; 1= >28 years

Characteristic	Existing or derived variable	Description
		Maternal age was collected as a continuous variable. Age 28 years was selected because it was the median maternal age of SC.
Number of ANC visits for SC	Derived	Binary: 0= ≤4 visits; 1= >4 visits Number of ANC visits was collected as a continuous variable. Four visits was selected as the cutoff based on the 2002 recommendation from WHO for a minimum of four ANC visits.[61] The new eight-visit minimum recommended by WHO in November 2016 was not used because M-SIMI mothers experienced pregnancy prior to issuance of the new guidelines.[62]
Socioeconomic quintile	Derived in the M-SIMU study	Binary: 0= Bottom 40%; 1= Upper 60% A series of variables to record asset ownership was collected i.e. the number of the following items owned by the household was collected: goats, cattle, sheep, poultry, donkey, pigs, plough, foam mattress, spring mattress, straw mattress, cell phone, radio, bicycle, sofa, lantern, TV. Using the same method used by the KEMRI HDSS to quantify SES, multiple correspondence analysis (MCA) was used to generate a SES index. The index was grouped into quintiles. The socioeconomic quintile variable was generated by coding the bottom two quintiles as being in the bottom 40% and the top three quintiles as being the upper 60% of the wealth distribution. The 40% cutoff was selected because socioeconomic status was calculated as a five-component index and a 40% cutoff was thought to be more likely capture inequitable health care access compared to a 20% cutoff.

Table 5.2. Distribution of MSBC household characteristics, by study arm and overall

	Control (N= 44)	SMS only (N= 60)	SMS+75KES (N = 56)	SMS+200KES (N = 58)	Total (N= 218)
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
Sex					
Female	27 (61.4)	30 (50.0)	29 (51.8)	32 (55.2)	118 (54.1)
Male	17 (38.6)	30 (50.0)	27 (48.2)	26 (44.8)	100 (45.9)
Received any vaccination at enrollment					
Not vaccinated	0	0	0	0	0
Vaccinated	44 (100)	60 (100)	56 (100)	58 (100)	218 (100)
Sibship					
1-3 siblings	28 (63.6)	37 (61.7)	27 (48.2)	37 (63.8)	129 (59.2)
>3 siblings	16 (36.4)	23 (38.3)	29 (51.8)	21 (36.2)	89 (40.8)
Location of last delivery					
At home	12 (27.3)	16 (26.7)	16 (28.6)	13 (22.4)	57 (26.1)
Health facility	32 (72.7)	44 (73.3)	40 (71.4)	45 (77.6)	161 (73.9)
Mobile phone access					
Shares	14 (31.8)	17 (28.3)	19 (33.9)	18 (31)	68 (31.2)
Owns	30 (68.2)	43 (71.7)	37 (66.1)	40 (69)	150 (68.8)
Maternal age					
≤28 years	18 (40.9)	30 (50.0)	24 (42.9)	35 (60.3)	107 (49.1)
>28 years	26 (59.1)	30 (50.0)	32 (57.1)	23 (39.7)	111 (50.9)
Number of ANC visits in MSBC pregnancy					
≤4 visits	31 (70.5)	44 (73.3)	45 (80.4)	44 (75.9)	164 (75.2)
>4 visits	11 (25.0)	16 (26.7)	11 (19.6)	12 (20.7)	50 (22.9)
Doesn't know	2 (4.5)	0 (0)	0 (0)	2 (3.4)	4 (1.8)
	Control (N= 44)	**SMS only (N= 60)**	**SMS+75KES (N = 56)**	**SMS+200KES (N = 58)**	**Total (N= 218)**
	Mean (SD)	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**	**Mean (SD)**
SC age in months at MSBC follow-up					
	18.1 (6.7)	18.9 (6.3)	17.1 (5.2)	17.3 (5.6)	17.8 (5.9)
Birth interval					
	25.5 (7.1)	24.7 (6.4)	26.4 (5.1)	24.6 (5.7)	25.3 (6.1)

	Control (N= 44)	SMS only (N= 60)	SMS+75KES (N = 56)	SMS+200KES (N = 58)	Total (N= 218)
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)
M-SIMU children's age in months at MSBC follow-up					
	43.6 (3.2)	43.8 (3.7)	43.5 (3.5)	41.8 (3.3)	43.2 (3.5)

Table 5.3. Comparison of baseline M-SIMU characteristics among participants enrolled in the MSBC study compared to M-SIMU participants not included in the MSBC study

	Included in MSBC (N= 218)	**Excluded from MSBC (N= 1381)**	**Total (N= 1599)**	**p**
	No. (%)	**No. (%)**	**No. (%)**	
M-SIMU child's sex				
Female	109 (50.0)	691 (50.0)	800 (50.0)	0.992
Male	109 (50.0)	690 (50.0)	799 (50.0)	
Last delivery				
At home	71 (32.6)	374 (27.1)	445 (27.8)	0.093
At a health facility	147 (67.4)	1007 (72.9)	1154 (72.2)	
Mobile phone access				
Shares	133 (61.0)	677 (49.0)	810 (50.7)	**0.001**
Owns	85 (39.0)	704 (51.0)	789 (49.3)	
Maternal education				
≤7 years	64 (29.4)	347 (25.1)	411 (25.7)	0.184
>7 years	154 (70.6)	1034 (74.9)	1188 (74.3)	
Maternal age				
≤25 years	123 (57.2)	701 (50.9)	824 (51.7)	0.084
>25 years	92 (42.8)	677 (49.1)	769 (48.3)	
Time to clinic				
≤30 minutes	118 (54.1)	856 (62.0)	974 (60.9)	**0.027**
>30 minutes	100 (45.9)	525 (38.0)	625 (39.1)	
Region				
Asembo	62 (28.4)	273 (19.8)	335 (21.0)	**0.003**
Gem	156 (71.6)	1108 (80.2)	1264 (79.0)	
SES quintile				
Lower 40%	88 (40.4)	541 (39.2)	629 (39.3)	0.738
Upper 60%)	130 (59.6)	840 (60.8)	970 (60.7)	

Table 5.4. Comparison of baseline M-SIMU characteristics of participants enrolled in the MSBC study compared to M-SIMU participants not included in the MSBC study, *by study arm*

CONTROL ARM				
	Included in MSBC (N= 44)	**Not included in MSBC (N= 316)**	**Total (N= 360)**	**p**
	No. (%)	**No. (%)**	**No. (%)**	
M-SIMU child's sex				
Female	24 (54.5)	162 (51.3)	186 (51.7)	0.683
Male	20 (45.5)	154 (48.7)	174 (48.3)	
Last delivery				
At home	13 (29.5)	70 (22.2)	83 (23.1)	0.275
At a health facility	31 (70.5)	246 (77.8)	277 (76.9)	
Mobile phone access				
Shares	21 (47.7)	157 (49.7)	178 (49.4)	0.808
Owns	23 (52.3)	159 (50.3)	182 (50.6)	
Maternal education				
≤7 years	33 (75.0)	244 (77.2)	277 (76.9)	0.744
>7 years	11 (25.0)	72 (22.8)	83 (23.1)	
Maternal age				
≤25 years	25 (59.5)	149 (47.2)	174 (48.6)	0.132
>25 years	17 (40.5)	167 (52.8)	184 (51.4)	
Time to clinic				
≤30 minutes	23 (52.3)	179 (56.6)	202 (56.1)	0.584
>30 minutes	21 (47.7)	137 (43.4)	158 (43.9)	
Region				
Asembo	13 (29.5)	62 (19.6)	75 (20.8)	0.129
Gem	31 (70.5)	254 (80.4)	285 (79.2)	
SES quintile				
Lower 40%	15 (34.1)	117 (37.0)	132 (36.7)	0.705
Upper 60%	29 (65.9)	199 (63.0)	228 (63.3)	
SMS ONLY ARM				
	Included in MSBC (N= 60)	**Not included in MSBC (N= 328)**	**Total (N= 388)**	**p**
	No. (%)	**No. (%)**	**No. (%)**	
M-SIMU child's sex				
Female	31 (51.7)	148 (45.1)	179 (46.1)	0.350
Male	29 (48.3)	180 (54.9)	209 (53.9)	
Last delivery				
At home	19 (31.7)	91 (27.7)	110 (28.4)	0.535
At a health facility	41 (68.3)	237 (72.3)	278 (71.6)	
Mobile phone access				
Shares	33 (55.0)	150 (45.7)	183 (47.2)	0.186

Owns	27 (45.0)	178 (54.3)	205 (52.8)	
Maternal education				
≤7 years	42 (70.0)	249 (75.9)	291 (75.0)	0.331
>7 years	18 (30.0)	79 (24.1)	97 (25.0)	
Maternal age				
≤25 years	34 (56.7)	169 (51.8)	203 (52.6)	0.491
>25 years	26 (43.3)	157 (48.2)	183 (47.4)	
Time to clinic				
≤30 minutes	30 (50.0)	195 (59.5)	225 (58.0)	0.173
>30 minutes	30 (50.0)	133 (40.5)	163 (42.0)	
Region				
Asembo	17 (28.3)	70 (21.3)	87 (22.4)	0.233
Gem	43 (71.7)	258 (78.7)	301 (77.6)	
SES quintile				
Lower 40%	22 (36.7)	122 (37.2)	144 (37.1)	0.938
Upper 60%	38 (63.3)	206 (62.8)	244 (62.9)	
SMS+75KES ARM				
	Included in MSBC (N= 56)	**Not included in MSBC (N= 389)**	**Total (N= 445)**	**p**
	No. (%)	**No. (%)**	**No. (%)**	
M-SIMU child's sex				
Female	27 (48.2)	201 (51.7)	228 (51.2)	0.628
Male	29 (51.8)	188 (48.3)	217 (48.8)	
Last delivery				
At home	18 (32.1)	121 (31.1)	139 (31.2)	0.876
At a health facility	38 (67.9)	268 (68.9)	306 (68.8)	
Mobile phone access				
Shares	41 (73.2)	195 (50.1)	236 (53)	**0.001**
Owns	15 (26.8)	194 (49.9)	209 (47)	
Maternal education				
≤7 years	35 (62.5)	286 (73.5)	321 (72.1)	0.085
>7 years	21 (37.5)	103 (26.5)	124 (27.9)	
Maternal age				
≤25 years	26 (47.3)	194 (50)	220 (49.7)	0.705
>25 years	29 (52.7)	194 (50)	223 (50.3)	
Time to clinic				
≤30 minutes	29 (51.8)	263 (67.6)	292 (65.6)	**0.020**
>30 minutes	27 (48.2)	126 (32.4)	153 (34.4)	
Region				
Asembo	17 (30.4)	75 (19.3)	92 (20.7)	0.056
Gem	39 (69.6)	314 (80.7)	353 (79.3)	
SES quintile				
Lower 40%	25 (44.6)	156 (40.1)	181 (40.7)	0.518

Upper 60%	31 (55.4)	233 (59.9)	264 (59.3)	
SMS+200KES ARM				
	Included in MSBC (N= 58)	**Not included in MSBC (N= 348)**	**Total (N= 406)**	**p**
	No. (%)	**No. (%)**	**No. (%)**	
M-SIMU child's sex				
Female	27 (46.6)	180 (51.7)	207 (51.0)	0.466
Male	31 (53.4)	168 (48.3)	199 (49.0)	
Last delivery				
At home	21 (36.2)	92 (26.4)	113 (27.8)	0.124
At a health facility	37 (63.8)	256 (73.6)	293 (72.2)	
Mobile phone access				
Shares	38 (65.5)	175 (50.3)	213 (52.5)	**0.032**
Owns	20 (34.5)	173 (49.7)	193 (47.5)	
Maternal education				
≤7 years	14 (24.1)	93 (26.7)	107 (26.4)	0.679
>7 years	44 (75.9)	255 (73.3)	299 (73.6)	
Maternal age				
≤25 years	38 (65.5)	189 (54.3)	227 (55.9)	0.111
>25 years	20 (34.5)	159 (45.7)	179 (44.1)	
Time to clinic				
≤30 minutes	36 (62.1)	219 (62.9)	255 (62.8)	0.900
>30 minutes	22 (37.9)	129 (37.1)	151 (37.2)	
Region				
Asembo	15 (25.9)	66 (19.0)	81 (20.0)	0.224
Gem	43 (74.1)	282 (81.0)	325 (80.0)	
SES quintile				
Lower 40%	26 (44.8)	146 (42.0)	172 (42.4)	0.682
Upper 60%	32 (55.2)	202 (58.0)	234 (57.6)	

Table 5.5. Distribution of M-SIMU baseline characteristics by study arm among MSBC participants, by study arm and overall

	Control (N= 44)	SMS only (N= 60)	SMS+75KES (N = 56)	SMS+200KES (N = 58)	Total (N= 218)	p-value
	No. (%)	No. (%)	No. (%)	No. (%)	No. (%)	
M-SIMU child's sex						
Female	24 (54.5)	31 (51.7)	27 (48.2)	27 (46.6)	109 (50.0)	0.855
Male	20 (45.5)	29 (48.3)	29 (51.8)	31 (53.4)	109 (50.0)	
Last delivery						
At home	13 (29.5)	19 (31.7)	18 (32.1)	21 (36.2)	71 (32.6)	0.906
At a health facility	31 (70.5)	41 (68.3)	38 (67.9)	37 (63.8)	147 (67.4)	
Mobile phone access						
Shares	21 (47.7)	33 (55.0)	41 (73.2)	38 (65.5)	133 (61.0)	**0.043**
Owns	23 (52.3)	27 (45.0)	15 (26.8)	20 (34.5)	85 (39.0)	
Maternal education						
≤7 years	11 (25.0)	18 (30.0)	21 (37.5)	14 (24.1)	64 (29.4)	0.397
>7 years	33 (75.0)	42 (70.0)	35 (62.5)	44 (75.9)	154 (70.6)	
Maternal age						
≤25 years	25 (59.5)	34 (56.7)	26 (47.3)	38 (65.5)	123 (57.2)	0.267
>25 years	17 (40.5)	26 (43.3)	29 (52.7)	20 (34.5)	92 (42.8)	
Time to clinic						
≤30 minutes	23 (52.3)	30 (50.0)	29 (51.8)	36 (62.1)	118 (54.1)	0.558
>30 minutes	21 (47.7)	30 (50.0)	27 (48.2)	22 (37.9)	100 (45.9)	
Region						
Asembo	13 (29.5)	17 (28.3)	17 (30.4)	15 (25.9)	62 (28.4)	0.957
Gem	31 (70.5)	43 (71.7)	39 (69.6)	43 (74.1)	156 (71.6)	
SES quintile						
Lower 40%	15 (34.1)	22 (36.7)	25 (44.6)	26 (44.8)	88 (40.4)	0.579
Upper 60%	29 (65.9)	38 (63.3)	31 (55.4)	32 (55.2)	130 (59.6)	

Table 5.6. MCV1 timely coverage and MCV1 overall coverage among subsequent children (SC) and M-SIMU children, by study arm and overall

Outcome assessed in	Control n/N (%)	SMS only n/N (%)	SMS+75KES n/N (%)	SMS+200KES n/N (%)	Total n/N (%)
MCV1 by at age 9m+2w or younger					
SC, 2017 (N= 215)	25/43 (58.1)	28/59 (47.5)	20/55 (36.4)	23/58 (39.7)	96/215 (44.7)*
M-SIMU children in MSBC, 2014-2015 (N=215)	26/43 (60.5)	36/59 (61.0)	33/55 (60.0)	39/58 (67.2)	134/215 (62.3)
All M-SIMU children, 2014-2015 (N= 1,599)	183/360 (50.8)	231/388 (59.5)	315/445 (70.8)	292/406 (71.9)	1021/1599 (63.9)
MCV1 by age 12 months					
SC, 2017 (N= 174)	27/32 (84.4)	40/52 (76.9)	28/44 (63.6)	28/46 (60.9)	123/174 (70.7) †
M-SIMU children in MSBC, 2014-2015 (N= 174)	27/32 (84.4)	47/52 (90.4)	33/44 (75.0)	40/46 (87.0)	147/174 (84.5)
All M-SIMU children, 2014-2015 (N= 1,598)	302/360 (83.9)	338/388 (87.1)	387/444 (87.2)	365/406 (89.9)	1392/1598 (87.1)

*MCV1 timely coverage estimates among SC exclude three infants, one each born to a Control arm, SMS only arm and SMS+75KES arm caregiver, who were enrolled into MSBC before reaching age 9 months and 2 weeks

†Estimation of MCV1 coverage by age 12 months in SC excluded 46 SC – eight, nine, 13 and 12 born to M-SIMU Control arm, SMS only arm, SMS+75KES and SMS+200KES arm caregivers, respectively - who had not reached age 12 months at the MSBC visit.

Table 5.7. Sensitivity analysis of MCV1 timely coverage: Risk differences during and after the M-SIMU study among children of intervention arm caregivers compared to those of Control caregivers. RDs are adjusted for the following M-SIMU baseline characteristics: mobile phone ownership status, travel time to nearest health facility, region of residence and maternal educational attainment.

	Control	SMS+200KES		SMS+75KES		SMS only	
		aRD* (95%CI)	p	aRD* (95%CI)	p	aRD* (95%CI)	p
After M-SIMU	Ref	-17.8 (-39.0, 3.5)	0.101	-21.1 (-42.2, -0.0)	0.050	-11.1 (-32.8, 10.6)	0.315
During M-SIMU	Ref	6.7 (-11.7, 25.1)	0.476	-0.6 (-18.3, 17.1)	0.950	-0.5 (-20.0, 19.0)	0.958
Risk difference in differences (DID)	Ref	-24.4 (-54.4, 5.5)	0.110	-20.5 (-46.4, 5.4)	0.121	-10.6 (-35.3, 14.2)	0.401

*aRD = Adjusted risk difference

Table 5.8. Pentavalent 3 timely coverage among subsequent children (SC) and M-SIMU children, by study arm and overall

Outcome assessed in	Control n/N (%)	SMS only n/N (%)	SMS+75KES n/N (%)	SMS+200KES n/N (%)	Total n/N (%)
SC, 2017 (N= 218)	31/44 (70.5)	42/60 (70.0)	35/56 (62.5)	33/58 (56.9)	141/218 (64.7)
M-SIMU children in MSBC, 2014-2015 (N=218)	32/44 (72.7)	43/60 (71.7)	43/56 (76.8)	40/58 (69.0)	158/218 (72.5)
All M-SIMU children, 2014-2015 (N= 1,599)	267/360 (74.2)	288/388 (74.2)	354/445 (79.5)	337/406 (83.0)	1246/1599 (77.9)

Table 5.9. MCV2 coverage by age 24 months, by M-SIMU study arm, risk ratios and differences in MCV2 vaccination among children previously enrolled in M-SIMU intervention arms compared to M-SIMU Control children. Adjusted RR and RD control for M-SIMU baseline mobile phone ownership.

Study arm	MCV2 coverage n/N (%)	cRR* (95% CI)	aRR* (95% CI)	p	%cRD* (95% CI)	%aRD* (95% CI)	p
Control (N= 36)	19/36 (52.8)	ref	ref	--	ref	ref	--
SMS only (N= 45)	14/45 (31.1)	0.60 (0.34, 1.06)	0.61 (0.35, 1.08)	0.088	-21.3 (-44.8, 2.2)	-22.0 (-45.2, 1.1)	0.062
SMS+75KES (N= 39)	8/39 (20.5)	0.39 (0.19, 0.80)	0.42 (0.20, 0.86)	**0.019**	-32.3 (-55.1, -9.4)	-29.2 (-52.1, -6.2)	**0.013**
SMS+200KES (N= 43)	11/43 (25.6)	0.49 (0.27, 0.87)	0.53 (0.30, 0.96)	**0.035**	-27.0 (-49.2, -4.7)	-27.0 (-49.0, -5.0)	**0.016**
Total (N= 163)	52/163 (31.9)	--	--	--	--	--	--

*cRR = crude risk ratio; aRR = adjusted risk ratio; cRD = crude risk difference; aRD= adjusted risk difference

Table 5.10. Sensitivity analysis: Relative risks and differences in the risk of receiving MCV2 by *age 19 months* among intervention arm M-SIMU children compared to Control M-SIMU children. Adjusted RRs and RDs control for M-SIMU baseline mobile phone ownership.

Study arm	MCV2 coverage n/N (%)	cRR*	aRR*	p	%cRD*	%aRD*	p
Control (N= 36)	14/36 (38.9)	ref	ref	--	ref	ref	--
SMS only (N= 45)	12/45 (26.7)	0.69 (0.35, 1.36)	0.72 (0.37, 1.40)	0.286	-12.0 (-34.9, 10.9)	-14.4 (-36.5, 7.7)	0.203
SMS+75KES (N= 39)	6/39 (15.4)	0.40 (0.17, 0.90)	0.44 (0.19, 1.02)	0.055	-23.5 (-45.2, -1.8)	-19.7 (-41.5, 2.2)	0.078
SMS+200KES (N= 43)	9/43 (20.9)	0.54 (0.25, 1.16)	0.61 (0.29, 1.30)	0.203	-17.8 (-40.5, 5.0)	-18.5 (-40.6, 3.6)	0.101
Total (N= 163)	41/163 (25.2)	--	--	--	--	--	--

*cRR = crude risk ratio; aRR = adjusted risk ratio; cRD = crude risk difference; aRD= adjusted risk difference

Chapter 5 Figures

Figure 5.1. Participant flow for the MSBC study

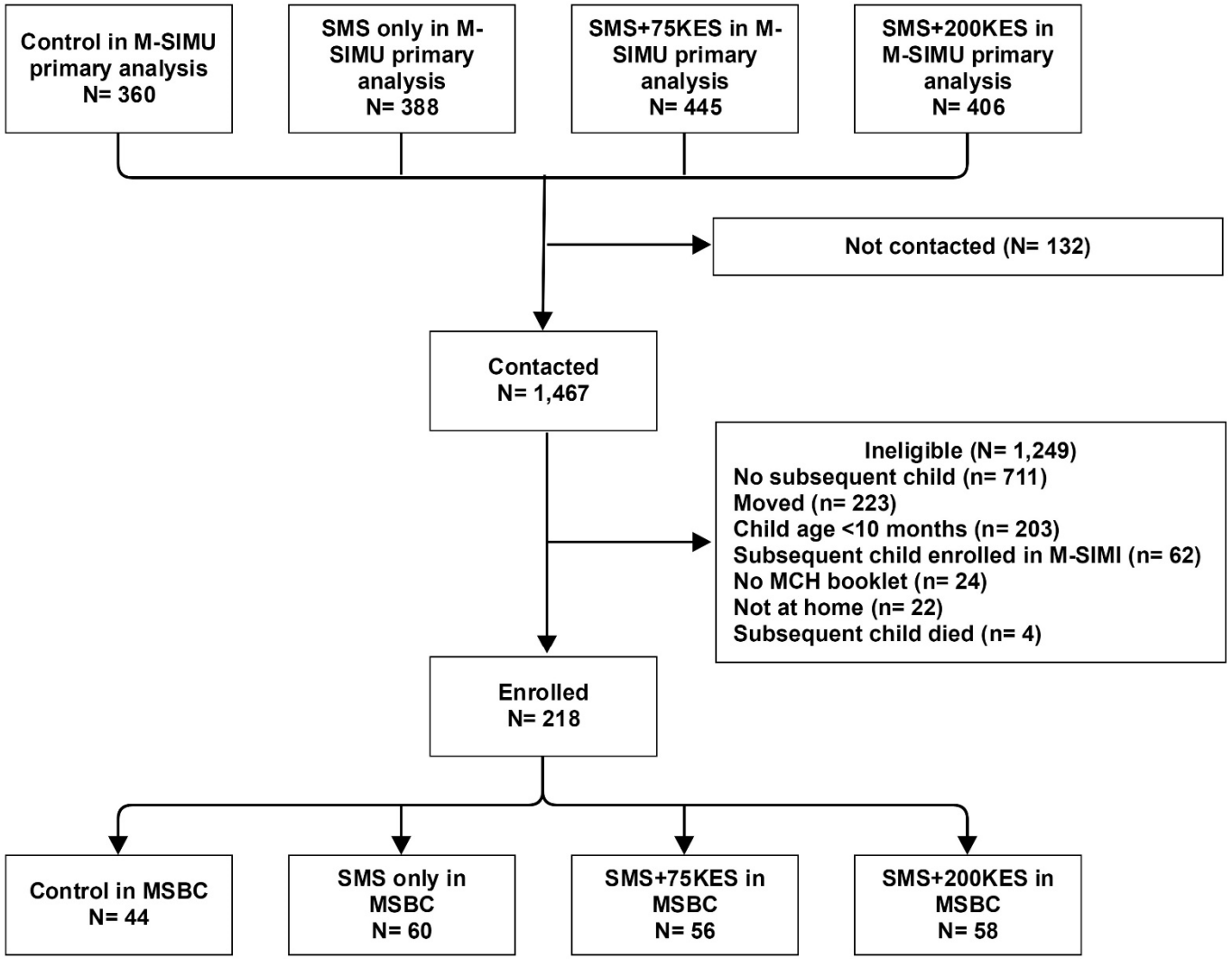


Figure 5.2. MCV1 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS+200KES* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

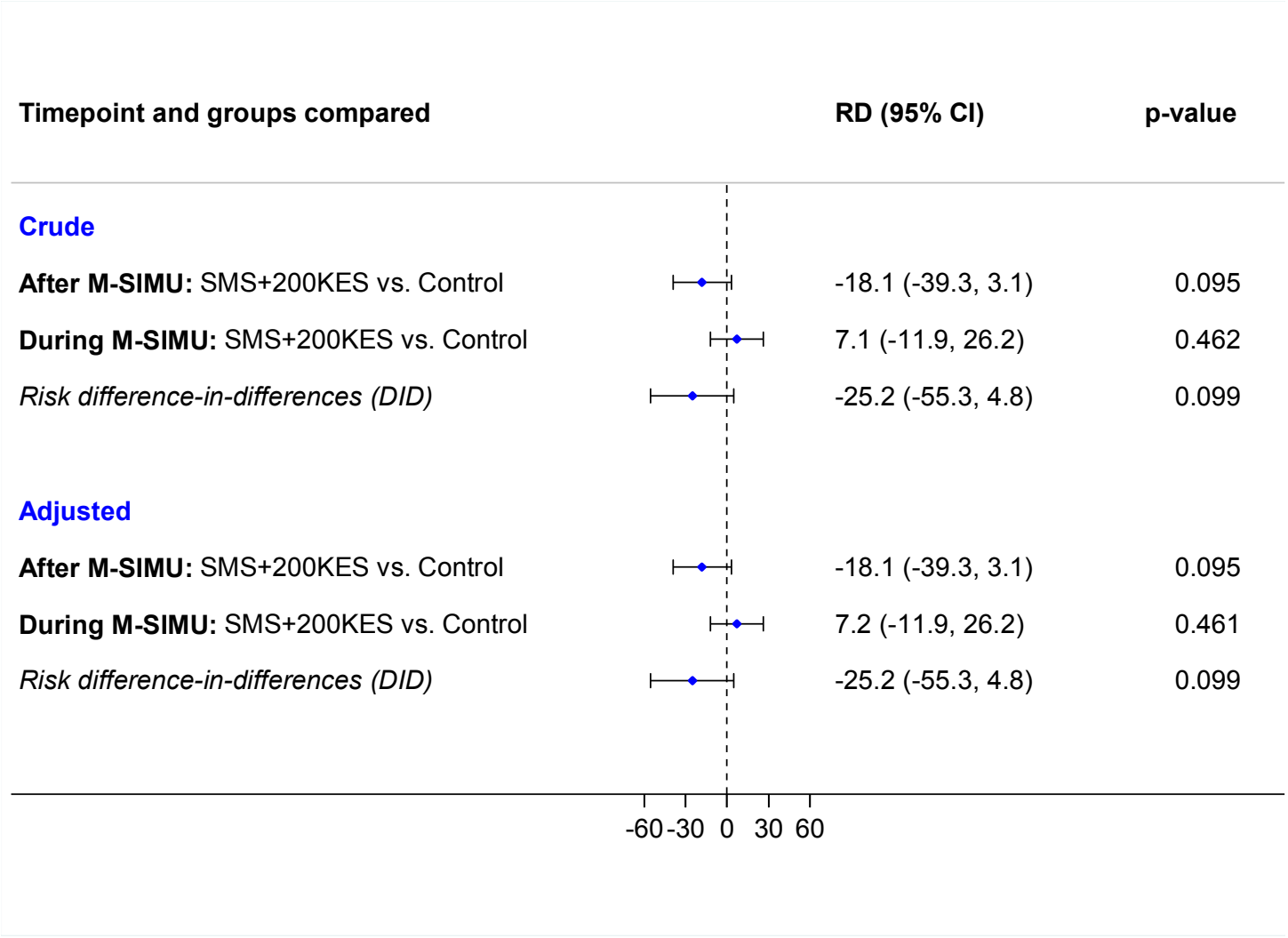


Figure 5.3. MCV1 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study comparing children of *SMS+75KES* and Control arm caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

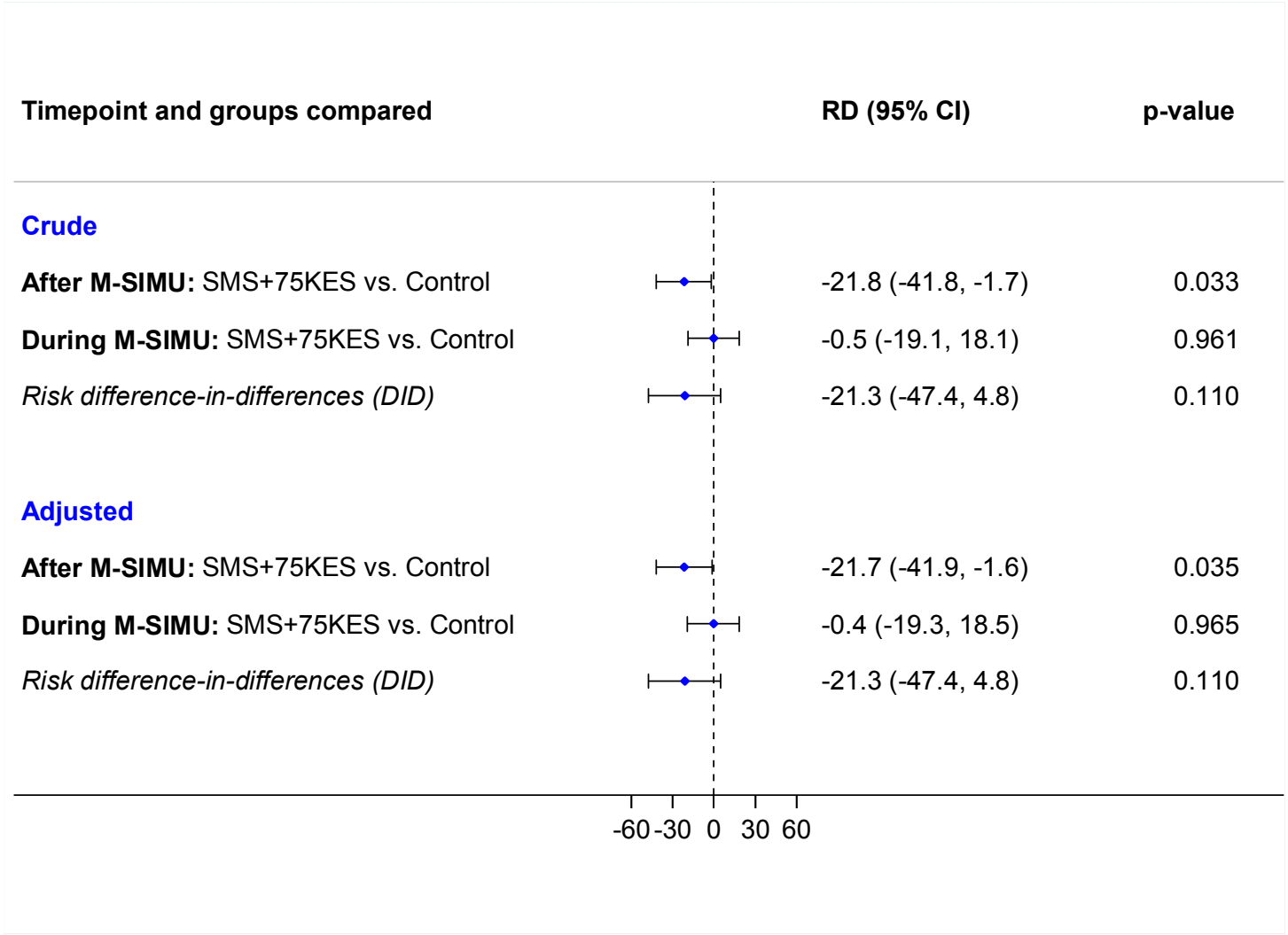


Figure 5.4. MCV1 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study comparing children of *SMS only* and Control arm caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

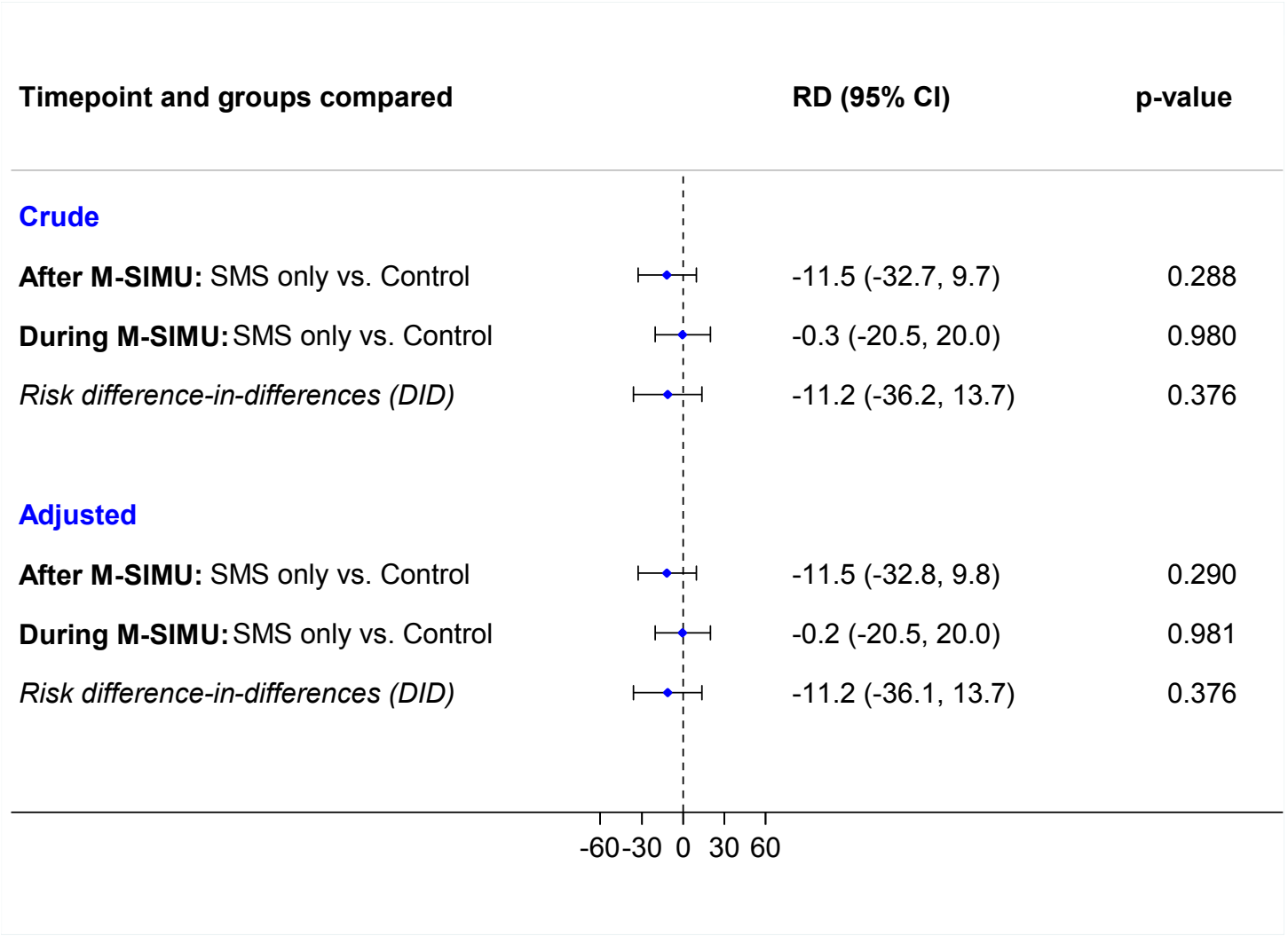


Figure 5.5. Sensitivity analysis of MCV1 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS+incentive* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

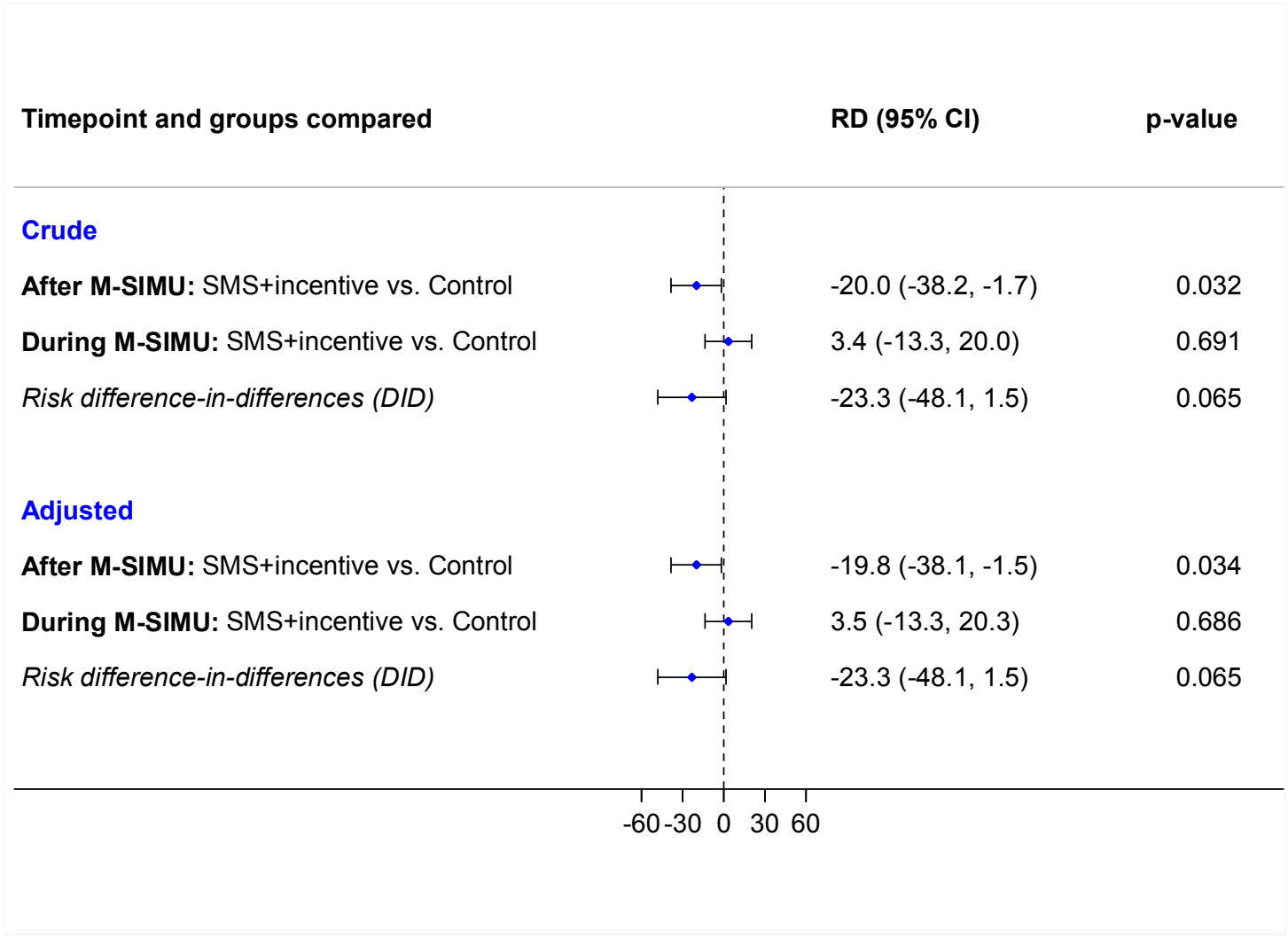


Figure 5.6. MCV1 overall coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS+200KES* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

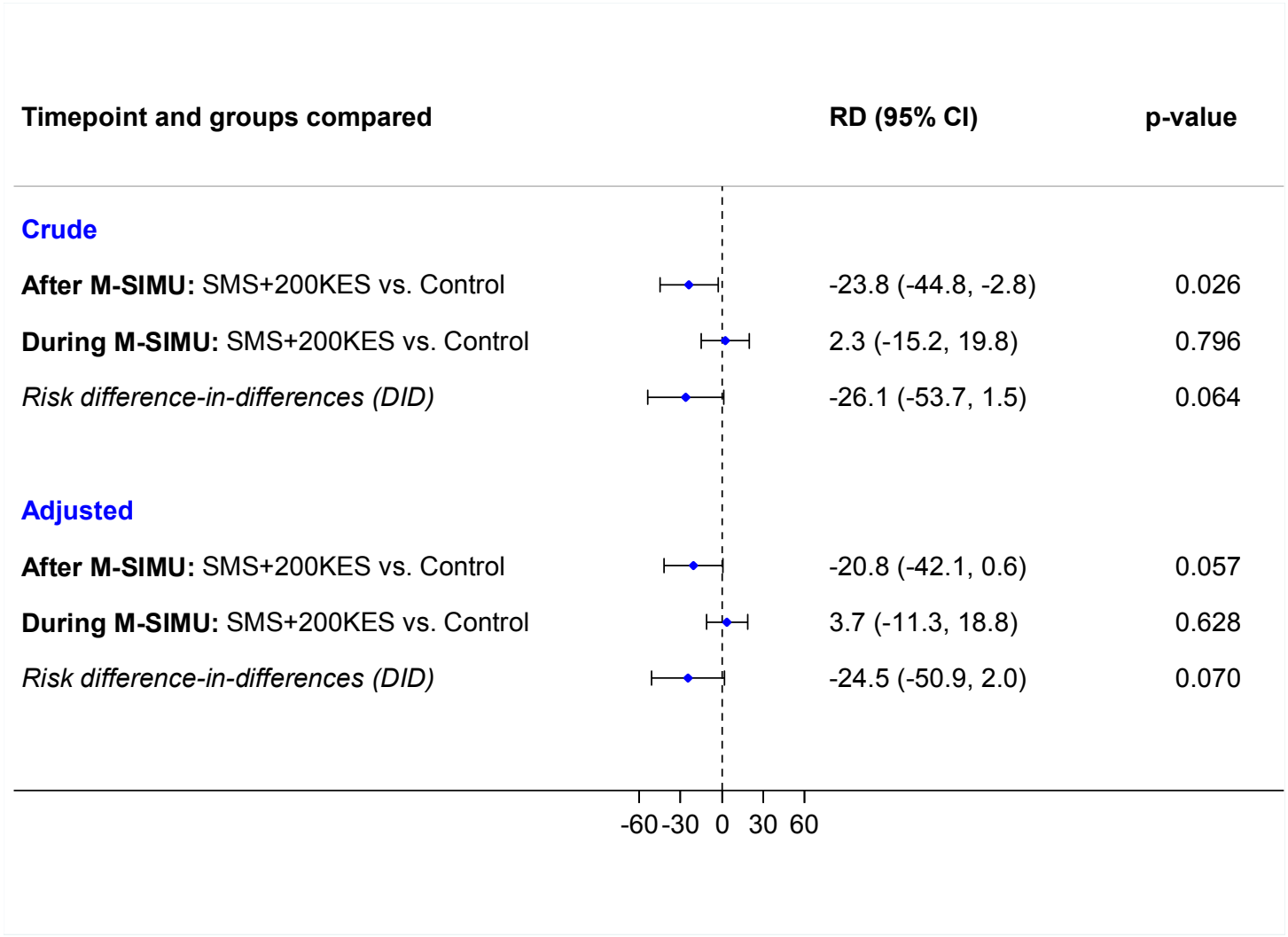


Figure 5.7. MCV1 overall coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS+75KES* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

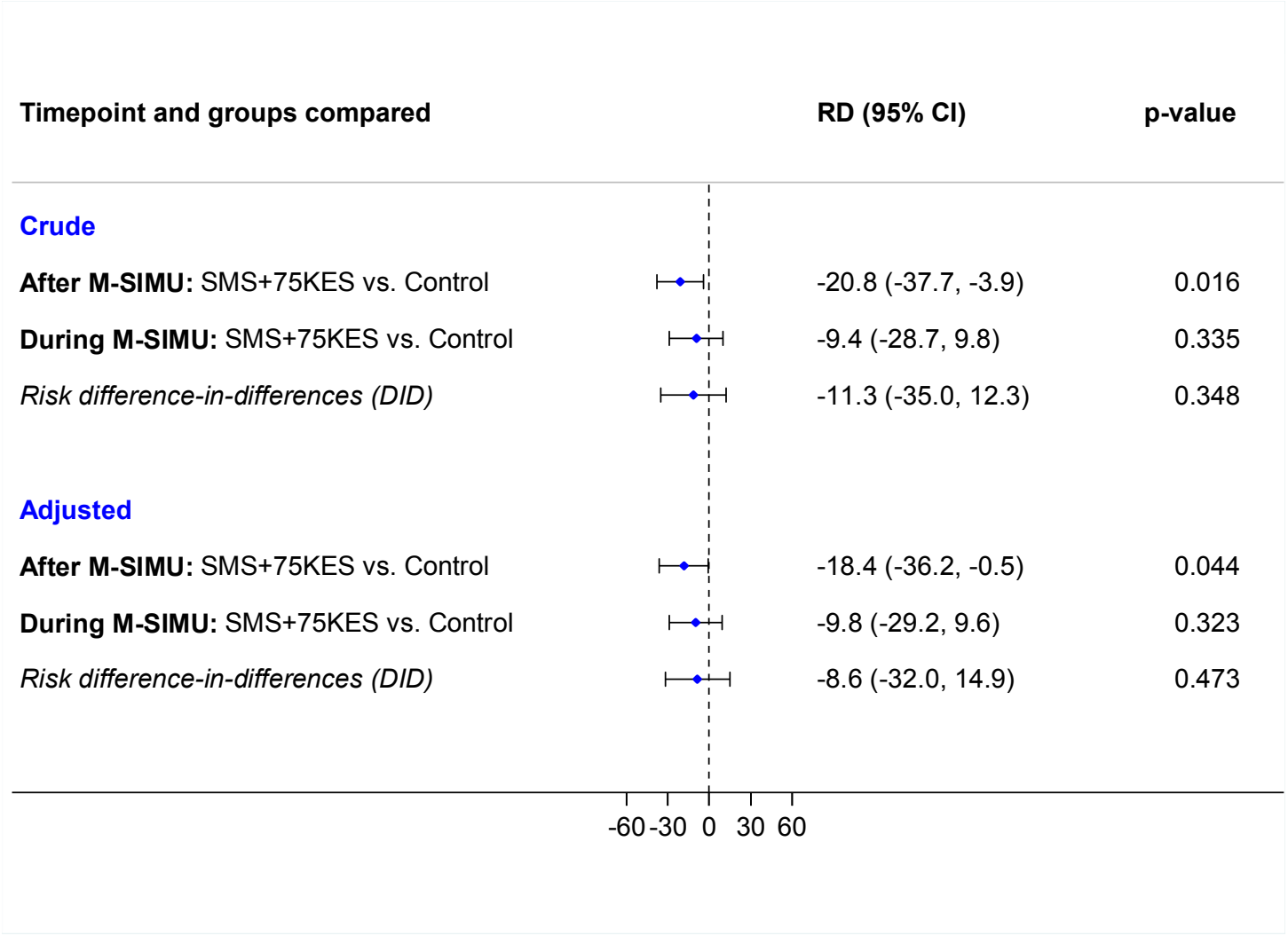


Figure 5.8. MCV1 overall coverage: Crude and adjusted differences risk differences during and after the M-SIMU study among children of *SMS only* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

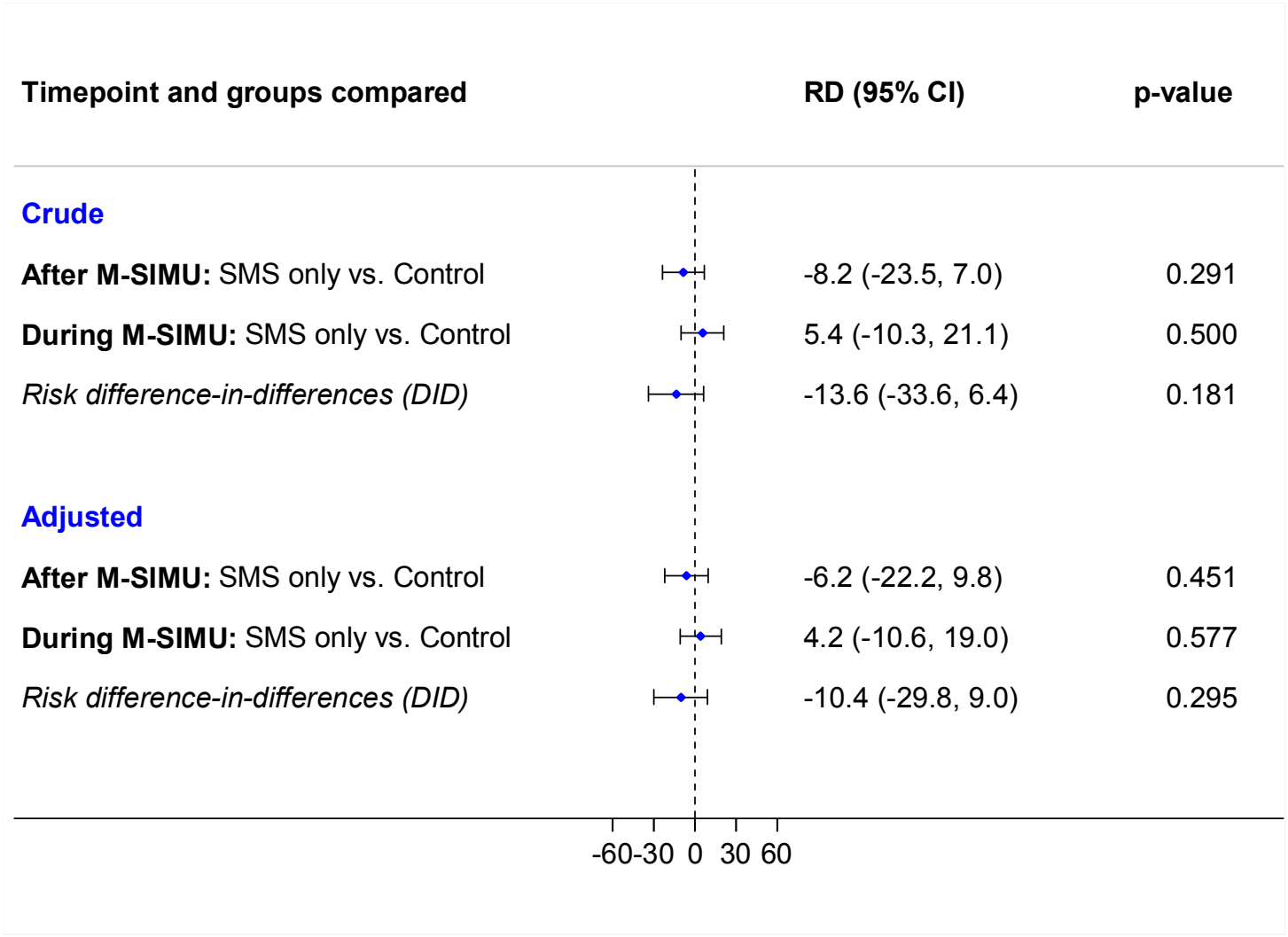


Figure 5.9. Pentavalent 3 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS+200KES* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

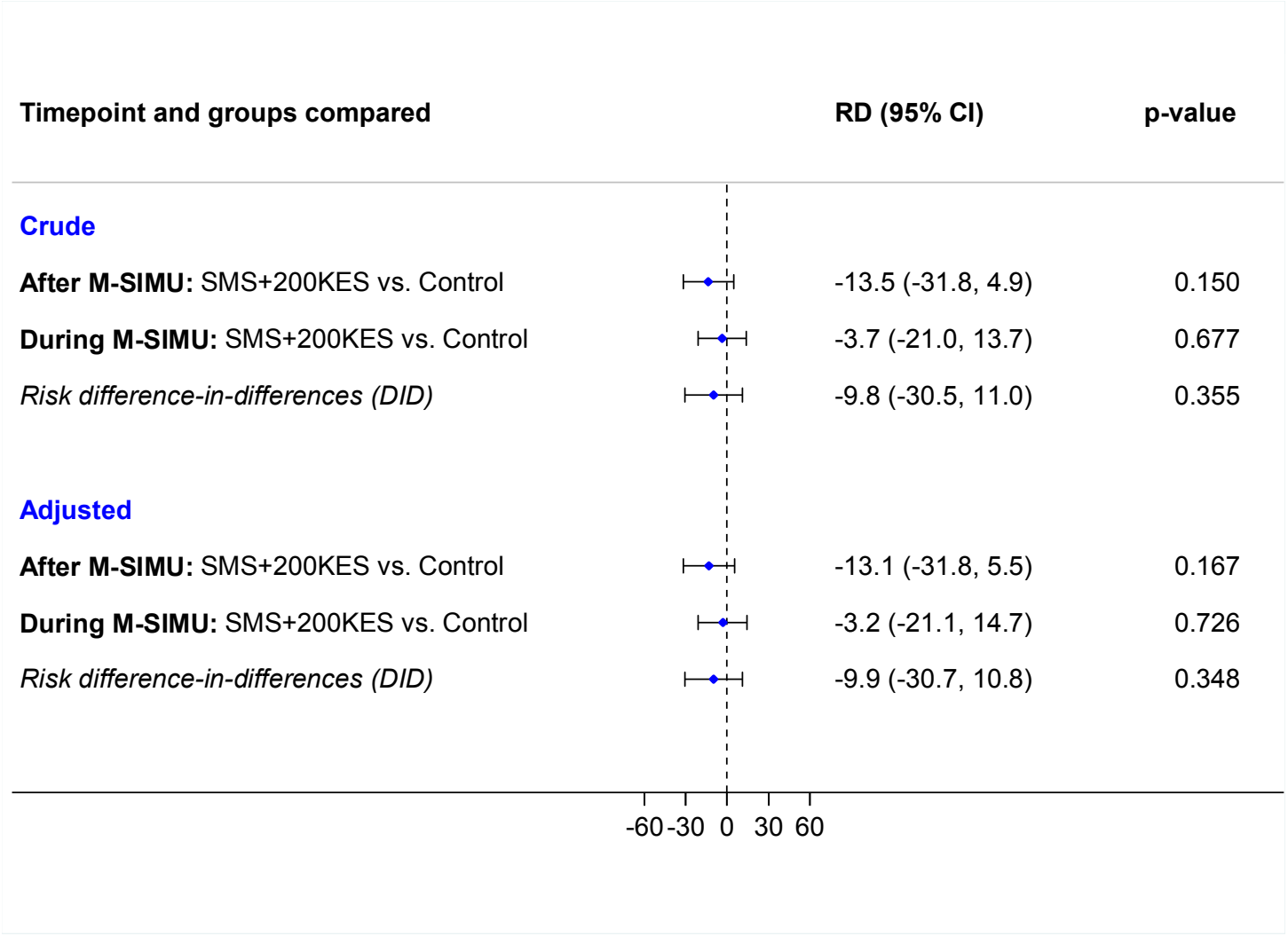


Figure 5.10. Pentavalent 3 timely coverage: Crude and adjusted differences in the risk of receiving pentavalent 3 at age ≤16 weeks during and after the M-SIMU study among children of *SMS+75KES* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.

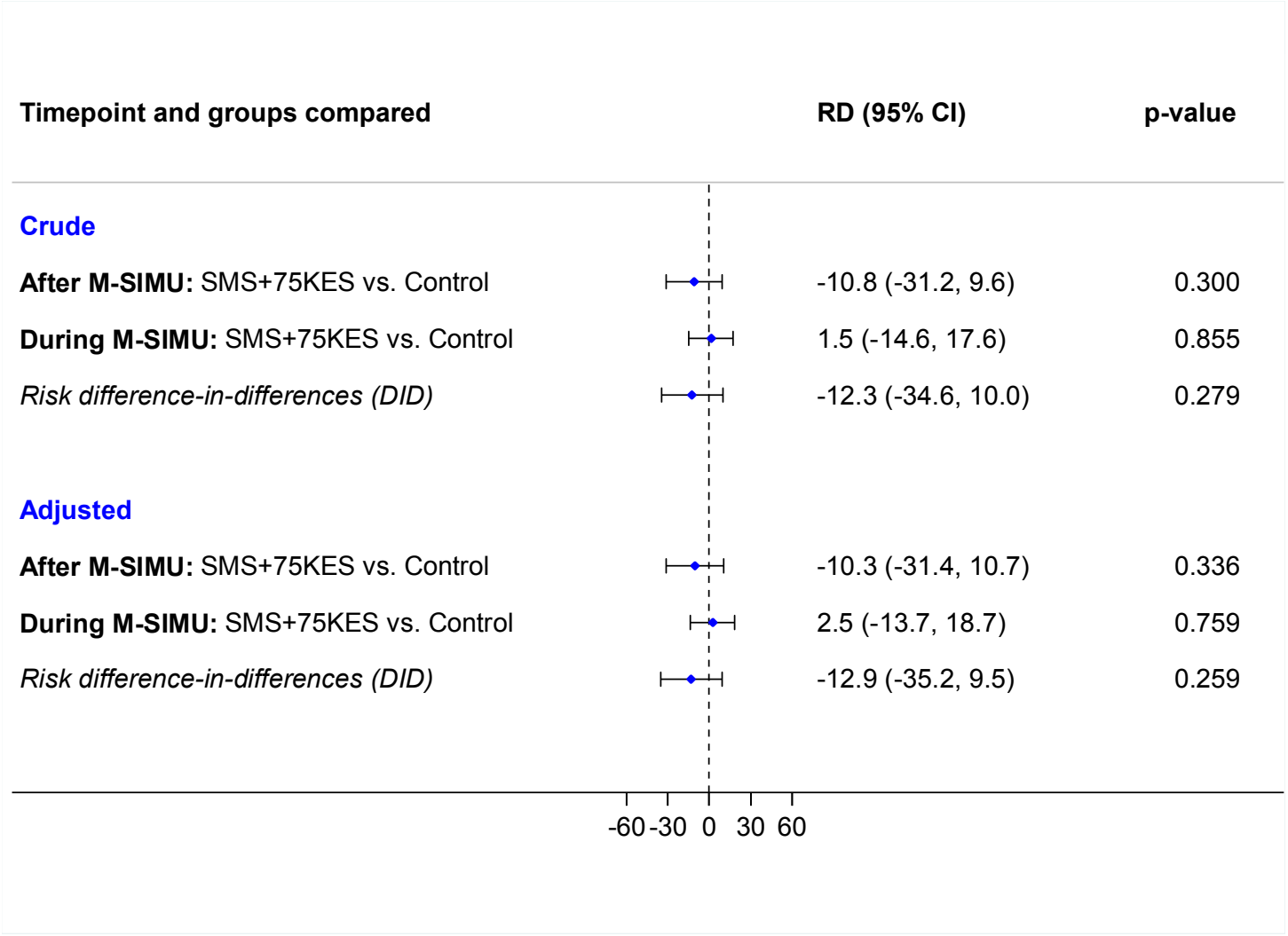
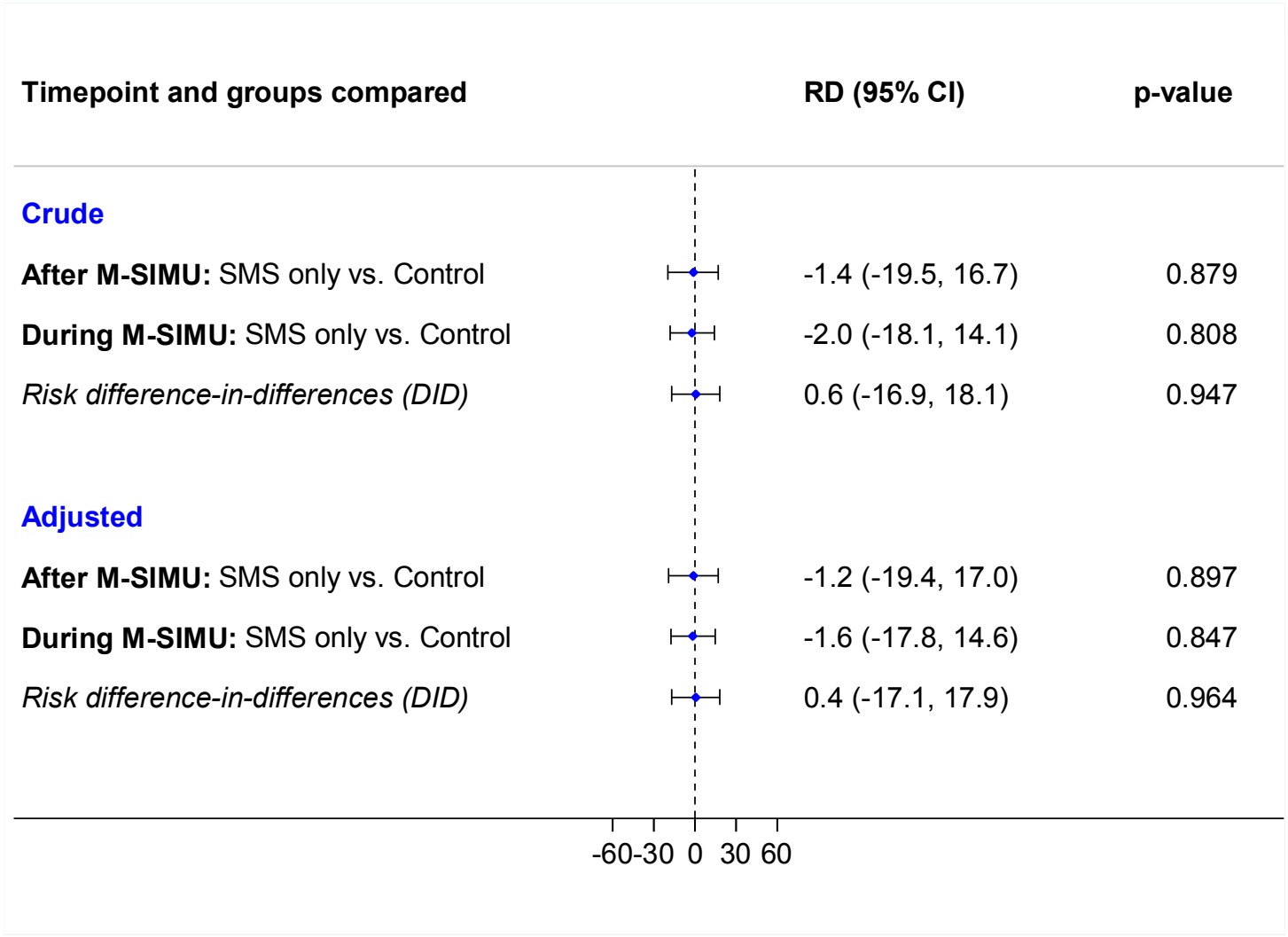


Figure 5.11. Pentavalent 3 timely coverage: Crude and adjusted risk differences during and after the M-SIMU study among children of *SMS only* caregivers compared to those of Control caregivers. Adjusted risk differences control for M-SIMU baseline phone ownership status.



CHAPTER 6: CONCLUSION

6.1. Overview of thesis

Health interventions delivered via mobile phone (mHealth) have the potential to increase demand for vaccination in low- and middle-income countries (LMICs) where predominantly low vaccination coverage intersects with high mobile phone access. Targeted client communications such as short message service (SMS or text message) vaccination reminders and incentives transmitted via mobile phone may generate demand for vaccination, thereby helping to achieve global measles elimination and equitable access to vaccines as envisioned in the 2011-2020 Global Vaccine Action Plan (GVAP) and Sustainable Development Goals (SDGs).[1,2] In most LMICs, first dose measles-containing vaccine (MCV1) coverage continues to fall below 90%. Some countries had not introduced second dose measles-containing vaccine (MCV2) as of 2016 and those that recently introduced it struggle reach a large population of children. Yet 90%-95% coverage with two doses of MCV are required to eliminate measles. At the same time, vaccination timeliness is a metric that is not often used to assess vaccination program performance. The findings from this thesis may be informative for measles control programs and vaccination systems in LMICs.

6.2. Aim I: Impact of SMS reminders on pediatric vaccination coverage and timeliness in LMICs

In this aim we conducted a systematic review and meta-analysis to evaluate the impact of SMS reminders on pediatric vaccination uptake in LMICs. We identified 11 research articles that met inclusion criteria. Using data from those studies, we performed meta-analyses to estimate the pooled effect of SMS reminders on third dose diphtheria, tetanus and pertussis (DTP3) overall

vaccination coverage, full immunization coverage (FIC) and DTP3 timely coverage. Meta-analyses to assess the impact of SMS reminders on MCV1 uptake could not be performed due to an inadequate number of studies. Based on pooled estimates, SMS reminders significantly increased the likelihood of achieving DTP3 timely vaccination in data from RCTs (pooled risk ratio [pRR] 1.12; 95% CI: 1.01, 1.25; p= 0.036) and from quasi-experimental studies (pRR 1.29; 95% CI: 1.05, 1.60; p= 0.016). The magnitude absolute effect of SMS reminders on DTP3 timely coverage was moderate based on evidence in RCTs (pooled risk difference [pRD] 7.0%; 95% CI: 0.1%, 14.0%; p= 0.047) and more substantial based on evidence from quasi-experimental studies (pRD 18.7%; 95% CI: 8.8%, 28.6%; p= 0.001). SMS reminders may also improve DTP3 overall coverage and FIC, but the evidence for impact on these vaccination outcomes came from only quasi-experimental studies (DTP3 overall coverage pRD 9.0%; 95% CI: 3.4%, 14.6%; p= 0.002 and FIC pRD 18.1%; 95% CI: 8.5%, 27.6%; p< 0.001). This is the first meta-analysis of the impact of SMS reminders on vaccination uptake in LMICs.

6.2. Aim 2: Impact of SMS reminders with or without *unconditional* monetary incentives on MCV1 coverage and timeliness

To assess this aim, we conducted a parallel randomized controlled trial in rural Siaya County, Kenya, whereby infants were allocated to receive no interventions, SMS reminders only or SMS reminders coupled with a small, unconditional ~US $1.50 mobile-money (mMoney) incentive. We found that SMS reminders coupled with the unconditional monetary incentive significantly improved MCV1 timely coverage, i.e., the proportion of children vaccinated within two weeks of the recommended date, by 10.6% as compared to control (adjusted RD [aRD] 95% CI: 0.8%, 20.3%; p= 0.034). Although the effect of SMS reminders on MCV1 timely coverage was not

statistically significant (aRD 9.2%; 95% CI: -0.6%, 19.0%; p= 0.066), we observed that the magnitude of its impact on timely coverage was similar to the impact of SMS reminders coupled with an incentive, and that the impact of SMS reminders alone likely did not achieve significance due to inadequate sample size. Neither one of the two interventions significantly improved MCV1 overall coverage, i.e., the proportion of children vaccinated by age 12 months, (SMS plus incentive aRD 6.8%; 95% CI: -1.8%, 15.3%; p= 0.119 and SMS only aRD 5.7%; 95% CI: -3.0%, 14.3%; p= 0.199). However, the M-SIMI study was not powered to detect the magnitude of effect that we measured. In addition, the added effect of the unconditional incentive over SMS reminders alone was negligible. The Mobile and Scalable Innovations for Measles Immunization (M-SIMI) study is the first study to assess the combined impact of SMS reminders and *unconditional* incentives.

6.3. Aim 3: Vaccine-seeking after withdrawal of temporary SMS reminders and incentives

In this aim we sought to assess vaccine-seeking after withdrawal of SMS reminders and small conditional monetary incentives that were previously provided to caregivers in rural Western Kenya as part of a cluster randomized controlled trial (the Mobile Solutions for Immunization; M-SIMU study). The M-SIMU study sought to evaluate the impact of SMS reminders and small, conditional monetary incentives on vaccination coverage and timeliness. We conducted a post-trial follow-up survey that found an indication of reduced vaccine-seeking among caregivers who previously received SMS reminders and incentives, after these interventions were withdrawn.

Specifically, children who were born after the M-SIMU study to caregivers who previously received SMS reminders alone (SMS only), or combined with either a ~US $0.88 (SMS+75KES) or ~US $2.35 (SMS+200KES) incentive, had lower MCV1 timely coverage than their older siblings who were enrolled in the M-SIMU study. Decreases in MCV1 timely coverage ranged from 11.2% among subsequent children (SC) of SMS only caregivers (risk difference-in-differences [DID] 95% CI: -36.1%, 13.7%; p= 0.376) to 25.2% among children of SMS+200KES caregivers (DID 95% CI: -55.3%, 4.8%; p= 0.099). Despite these decreases, MCV1 timely coverage was not significantly lower among SC of SMS only and SMS+200KES caregivers, compared to SC of caregivers who did not receive M-SIMU interventions (Control). However, the decrease in MCV1 timely coverage among children of SMS+75KES caregivers after withdrawal of M-SIMU interventions translated to 21.7% lower coverage than would be expected among children whose caregivers never received SMS vaccination reminders or incentives (RD 95% CI: -41.9, -1.6%; p= 0.035).

Similarly, MCV1 overall coverage was also substantially lower among children born after the M-SIMU study to caregivers who previously received M-SIMU interventions compared to MCV1 overall coverage in their older siblings that were enrolled in the M-SIMU study. These decreases in MCV1 overall coverage ranged from 10.4% in SC of SMS only caregivers (DID 95% CI: -29.8%, 9.0%; p= 0.295) to 24.5% among SC of SMS+200KES caregivers (DID 95% CI: -50.9, 2.0%; p= 0.070). In the period after the M-SIMU study, MCV1 overall coverage was lower, though not significantly, among SC of SMS only and SMS+200KES compared to Control SC but significantly lower by 18.4% among SMS+75KES SC compared to Control SC (RD 95% CI: -36.2, -0.5%; p= 0.044).

Also of note, MCV2 coverage by age 24 months among SMS+75KES and SMS+200KES children who were previously enrolled in the M-SIMU study was significantly lower compared to coverage among Control M-SIMU children by 29.2% (95% CI: -52.1%, -6.2%; p= 0.013) and by 27.0% (95% CI: -49.0%, -5.0%; p= 0.016), respectively. This is remarkable because MCV2 is recommended at age 15-18 months, which is after these children were discontinued from the M-SIMU study and MCV2 coverage was assessed in the very same children previously enrolled in the M-SIMU study, i.e., not in SC.

Taken together, we determined that these findings indicated decreased measles vaccine-seeking after withdrawal of SMS vaccination reminders and small, conditional monetary incentives. The M-SIMU Subsequent Born Child (MSBC) study is the first study to assess the impact of withdrawal of SMS reminders and incentives on vaccine-seeking.

6.4. Strengths and limitations

This dissertation work has some strengths and limitations. By pooling together studies in the meta-analysis of the impact of SMS reminders on vaccination uptake, we were able to obtain large sample sizes that were used to assess reminders' impact on DTP3 overall and timely coverage as well as full immunization coverage. However, the studies included were at risk of bias as assessed using Cochrane risk of bias domains.[3] In addition there was substantial heterogeneity in meta-analyses that we were unable to mediate by stratification due to the small number of studies. Furthermore, the quality of evidence from meta-analyses was poor owing to

the risk of bias and heterogeneity in findings. However, we are not in complete agreement that the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) Working Group rubric used to score the quality of evidence from the meta-analysis was wholly appropriate but were confined to using that tool as we did not find a more appropriate scoring system.

The assessment of the impact of SMS reminders with or without unconditional incentives on MCV1 timely and complete coverage in the M-SIMI study was strengthened by the randomized controlled design which reduced the risk of bias and confounding. An additional strength of this study is that we enrolled from the community. Studies that enroll from health facilities are limited because they do not capture children who have no contact with the health system, i.e., left-outs. A limitation of this study is that a substantial number of participants (82 of 537; 15.3%) were lost to follow-up. However, in sample size calculations we inflated the target sample size by 25% in anticipation of losses to follow-up. Consequently, the analytic sample size was within the sample size needed to assess a ≥15% increase in MCV1 timely coverage. In addition, we were not able to verify if the interventions reached caregivers. Although we asked participants at the final visit if they received the interventions, those data are subject to recall bias. We did, however, verify that SMS reminders and incentives were sent as one study staff's phone number was included with in all batches of SMS reminders and incentives sent out as a quality control measure. Furthermore, study staff who conducted follow-up visits were not blinded to study arm allocation. But we believe that the risk of bias from unblinded allocation to be low as: each study Community Interviewer enrolled more than 100 participants; there was a 4-6 month lag between conducting the enrollment visit and the follow-up visit; and we found only one discrepancy in

outcome ascertainment (which was later clarified) comparing outcome data collected independently by Community Interviewers and the Field Supervisor within a 5% random sample of participants. Future studies with similar procedures to the M-SIMI study could mitigate the risk of outcome ascertainment bias by assigning staff to collect vaccination status at homes different from those where they performed enrollment.

The MSBC study had several strengths. First, we attempted to contact all M-SIMU households thus minimizing the risk of selection bias. Second, we followed up households that were previously enrolled in a randomized controlled trial and so had access to a Control group. In addition, we had information about baseline characteristics of the MSBC participants which allowed to assess if Control households were exchangeable with intervention households. This is particularly important because we conducted difference-in-differences (DID) analysis in the absence of information about baseline characteristics of participants in the period before the M-SIMU study. Related to this, an additional strength is that we adjusted for temporal trends in using the DID approach to assess the magnitude of the difference in vaccine seeking after the M-SIMU study compared to during the M-SIMU study in intervention households. However, the MSBC study had several limitations. We followed up only 14% of the entire M-SIMU sample size and this sample may not have been representative of the entire M-SIMU sample. In addition, while crowding theory could account for why vaccine-seeking decreased among intervention arm caregivers after withdrawal of SMS reminders and incentives, we did not specifically measure intrinsic behavior. Finally, the decreased vaccine-seeking we measured might be explained by some other mechanism outside crowding theory.

Despite the limitations described above, we believe that the strengths of this dissertation work engender confidence in the findings and that these findings have some implications for public health policy and future research.

6.5. Implications for policy and future research

The findings from this thesis work may be informative for governments, donors, public health researchers and other stakeholders. The findings from the systematic review and meta-analysis show that although the evidence for the impact of SMS reminders on vaccination coverage and timeliness is mixed, there is neither overwhelming evidence that SMS vaccination reminders significantly improve vaccination impact nor that they have a deleterious impact. Therefore, stakeholders considering implementation of SMS vaccination reminders at scale or to evaluate their impact in research studies should feel encouraged but should also consider two important findings from this thesis work. First, we found that the quality of evidence from meta-analyses was poor as judged using GRADE criteria[4,5] as all included studies had high risk of bias in at least one of the Cochrane domains[3] assessed. Thus, future RCTs or quasi-experimental studies assessing SMS impact on vaccination uptake should be well designed so as to avoid bias and should communicate methods thoroughly and clearly so as to avoid erroneous grading by quality assessors. In addition, we found only 11 assessments that met review inclusion criteria. More high quality assessments of the impact of SMS reminders on vaccination uptake in LMICs are needed and those that assess impact of MCV1 coverage and timeliness, MCV2 coverage and full immunization would be particularly informative. Additional studies would allow for stratified analyses and meta-regression that may inform modalities of SMS reminders and population characteristics that influence impact. Furthermore, future assessments need to include large

sample sizes as there is some suggestion from the meta-analysis that SMS reminders may have a modest but meaningful public health impact, which may not achieve statistical significance in small studies. Moreover, any programs implementing SMS vaccination reminders at scale, as in Ivory Coast,[6] should perform impact assessments. Finally, future assessments of the impact of SMS reminders on vaccination uptake should assess the impact of SMS modalities such as content, wording and frequency of reminders. The impact of these modalities on the magnitude of effect has not been assessed for vaccination but they have been shown to influence the effect of SMS reminders for other outcomes.[7,8]

Findings from the M-SIMI study contribute to the understanding of the impact of SMS reminders on MCV1 timeliness. Although M-SIMI findings were not included in the systematic review and meta-analysis (Aim 1) because they are not yet published, they support previous findings that SMS reminders improve MCV1 timely coverage.[9] The M-SIMI study was underpowered to detect a 6% increase in MCV1 overall coverage, but if statistically significant in a larger study, this magnitude represents a meaningful impact in an area with typically 84% MCV1 overall coverage. Increasing vaccination coverage in a setting with high yet suboptimal coverage, in the 'last mile' can be challenging as the remaining unvaccinated proportion may be children of caregivers who refuse vaccination or are on the extreme end of the vaccine hesitancy spectrum.[10] Vaccine refusal in 'last mile' households could be influenced by low levels of disease as well as mistrust of government as these 'last mile' households in LMICs are usually also the most marginalized.[11,12] An additional important finding from the M-SIMI study is that unconditional incentives are unlikely to improve vaccination coverage. In the M-SIMI study we found that MCV1 timely and overall coverage estimates were similar among children whose caregivers

received SMS reminders only and those whose caregivers received SMS reminders coupled with an unconditional monetary incentive. Previously, the M-SIMU study which was conducted in the same study setting at the M-SIMI study, found that SMS reminders coupled with conditional monetary incentives significantly improved MCV1 coverage and timeliness and the magnitude of their effect was superior to the effect of SMS reminders alone.[9] The M-SIMI study, in conjunction with M-SIMU, adds additional evidence in the ongoing debate about whether conditionality is needed for incentive and cash transfer.

Results from the analysis of vaccine-seeking behavior after withdrawal of SMS vaccination reminders and incentives in the MSBC study point to the importance of sustaining interventions with demonstrated impact. However, the MSBC sample size was small and participants may not have been representative of the M-SIMU sample; follow-up of additional M-SIMU households is recommended. Taken together with findings from the M-SIMI and M-SIMU[9] studies, findings from the MSBC have several implications. First, we recommend that incentives should only be introduced if they are intended to be sustained as we observed reductions in vaccine-seeking after withdrawal of SMS vaccination reminders and incentives among caregivers who previously received these interventions. As part of planning for research studies evaluating the impact of incentives, researchers should establish with donors, governments and other stakeholders, plans for sustaining incentives should they be shown to be impactful. However, findings from this dissertation research do not provide clarity on the merits of conditional versus unconditional incentives. On the one hand, the results from the M-SIMU study compared to those from the M-SIMI study suggest that conditional incentives have superior impact. On the other hand, reductions in vaccine-seeking after withdrawal of M-SIMU interventions may be linked to the

conditionality of M-SIMU interventions as conditional incentives in particular are thought to reduce agency.[13] In addition, outside the M-SIMU and M-SIMI studies, other studies in LMICs have shown a positive impact of both conditional[14,15] and unconditional[16] incentives while one study found no impact for either one.[17] Even when shown to have impact, the duration of effect and consistency in impact of incentives across vaccine types within studies has varied.[9,14,16] This points to the need for more studies assessing the impact of monetary incentives on vaccination uptake and also assessing the impact of the number and value of incentives. For example, a possible explanation for the increase in MCV1 overall coverage in the M-SIMU study but not in the M-SIMI study may not lie in the conditionality of the incentive but may have been linked to the frequency of incentives; the M-SIMU study delivered incentives for four vaccine doses while the M-SIMI study delivered one incentive total. In addition, studies evaluating behavioral interventions should assess the impact of their withdrawal on the behavior under study as findings from the MSBC study suggest that unintended consequences of removing M-SIMU interventions did not apply only to caregivers who previously received incentives, as posited in crowding theory,[13,18] but also in caregivers who received SMS reminders alone. In that vein, follow-up of M-SIMI caregivers so as to assess the impact of withdrawal of SMS reminders and unconditional incentives is recommended. Finally, during research study development, donors, researchers and governments should articulate plans for sustaining behavioral interventions that are shown to significantly improve outcomes.

Chapter 6 References

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CHAPTER 7: APPENDICES

Appendix 7.1. M-SIMI screening form

Interviewer:_____ Date of Interview: DD/MM/YYYY

Compound name:_____ Village #_____ Compound#_____

INCLUSION CRITERIA

For mother/caregiver:**IF NO FOR Q1 or Q2…CHILD IS NOT ELIGIBLE**

1. Are you the caregiver of an infant between 6 and 8 months old?……YES……NO

If NO, child is ineligible to enroll. Please stop the interview here.SKIP TO LAST Q AND SUBMIT

2. Do you currently live in this village?.....YES……NO

If NO, child is ineligible to enroll. Please stop the interview here.SKIP TO LAST Q AND SUBMIT

EXCLUSION CRITERION: **IF YES FOR Q3, CHILD IS NOT ELIGIBLE**

3. Has your child already received measles vaccine at a health facility?.....YES……NO

If YES, child is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT OTHERWISE, CI SHOULD CONGRAGULATE MOTHER ON BEING ELIGIBLE FOR MSIMU STUDY AND TAKE INFORMED CONSENT

IF MOTHER IS ELIGIBLE, TAKE INFORMED CONSENT IN APPROPRIATE LANGUAGE

4. Did the CI describe the study, answer any questions by the mother and indicate that her participation is voluntary?.....YES……NO

4.1 Did mother provide informed consent?.....YES……NO

4.2 Did CI provide mother with a signed copy of the consent and retain a signed copy of the consent?.....YES……NO IF NO, CI STOPS ENROLLMENT

Appendix 7.2. M-SIMI consent form in Dholuo

KEMRI/CDC AND JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Nying Nonro: Randomized Controlled Trial of the Impact of Mobile Phone Delivered Reminders and Travel Subsidies to Improve Childhood Immunization Coverage Rates and Timeliness in western Kenya

Jotim Nonro: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigaor, KEMRI/CGHR; Joyce Were, KEMRI/CGHR; David Obor, KEMRI/CGHR; Daniel Feikin, CDC/Division of Viral Diseases; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Gwenge mag nonro: Gem kod Asembo

PI Version Date: 22May 2016

Flesch-Kincaid readability level: 7.2
Luo version

CHAKRUOK

Nyinga en …….. to atiyo gi jotim nonro ma owuok KEMRI/CGHR kod Johns Hopkins kar tiegruok mar weche mag ngima manitie America. Wan kae mondo wang'e kabende diher donjo e nonro matemo chanjo nyithindo mang'eny. Adhi wachoni mang'eny kuom gima watimo to kanitie gima ok odonjoni to inyisa mondo alerni matut. Wabiro bedo gi saa mar penjo bang'e kawasetieko. Ka aseduoko penjoni to abiro penji ka bende diher donjo e nonroni.

Gima omiyo itimo nonroni

Watimo nonroni nikech ei Kenya nyithindo mang'eny yudo chanjo molewo to moko ok yudi chanjo moro amora. Watimo nonroni mondo wang'e kawanyalo tiyo gi ong'we yamo (simu) mondo wajiw mine mondo oter nyithindgi e chanjo mar anyiew e kinde ma chanjono onego ochiwe. Nonroni ber nikech chanjo nyalo geng'o touche kod tho ne nyithindo. Wadwaro mondo wafweny yore manyithindo mang'eny nyalo yudogo chanjo.

Ang'o ma omiyo ikwayi mondo idonji e nonroni?

Wakwayi ni mondo idonji e nonroni nikech in gi nyathi manitie e kind dweche auchiel kod aboro to kendo idak e gweng' mawatime nonroni. Wageno ni mine gi nyithindo 600 ma owuok e gwengegi biro donjo e nonroni.

Chenro mar nonro

- Ka iyie donjo e nonroni to ibiro keti e achiel kuom kidienje adek manene oyier ka itiyo gi yo ma ng'ato ang'ata ok nyal ng'eyo kidieny ma miyo man gi nyathi nyalo lware. Kuom ranyisi, inyalo dir siling to ka onyiso wich to iketo miyo e kidieny mar wich. Bende ka siling onyiso simba to ikete e kidieny mar simba. Ibiro ti kod ong'we yamo e yore ma opogore opogore kuom jiwo mine mondo oter nyithindo e chanjo e kidieny ka kidieny. Wadwaro mondo wafweny ni kuom yore ma watiyogo e kidienje adek, ere manyalo miyo mine ter nyithindo e chanjo e saa ma owinjore?

Magi e gik mabiro timore ka idonjo e nonroni:

- Kawuono, ibiro nyisowa nying nyathini gi tarik mane onyuole.
- Kawuono, wabiro kwayi nambani mar simu kata mar ng'at machiegni kodi ma inyalo tiyogo.
- Kawuono, ibiro yudo ote machuok mapwoyi kuom donjo e nonroni.
- Wabobiro e odi ka nyathini oseromo dweche 12. Ekindeno, wabiro penjo kuom chanjo mar nyathini, ngimane, jo odi, ewi ote machuok to gi kaka nineno nonroni. Magi duto biro kawo seche madirom dakika 30.
- Ka gweng'u en achiel kuom gwenge ma jotich KEMRI/CGHR time limbe bang' dweche ang'wen ka dweche ang'wen, to weche ma wakawo kuomi ibiro ket kanyakla gi weche ma jotich KEMRI/CGHR kawoga.

(Som weche mabirogi isomo ne kidieny ka kidieny kaka owinjore)

- Gweng'i nitie e kidieny mokwongo (1), e chakruok mar nonro ibiro yudo ote machuok achiel ewi weche mag ngima. Inyalo tero nyathini e klinik mora mora ma ihero.
- Gweng'i nitie e kidieny mar ariyo (2), wabiro oro ni ote machuok ariyo mondo oparni kapok ibiro e chanjo mar anyiew. Wabiro oro ote machuok mokwongo ndalo adek kapok chieng' chanjo ochopo to mar ariyo chieng' ma onindo ni chieng' chanjo. Inyalo kelo nyathini e klinik moro amora ma ihero.
- Gweng'i nitie e kidieny mar adek (3), wabiro oroni ote machuok ariyo mondo oparni kapok ibiro e chanjo adek mokwongo. Wabiro oro ote ma okuongo ndalo adek kapok chieng' chanjo ochopo to mar ariyo chieng' ma onindo ni chieng' chanjo. Bende wabiro oroni shillings 150 ka chieng' chanjo pok ochopo.

Rach kata hinyruok ma dibedie

Maricho manyalo timore ne ng'at ma nitiere e nonroni tin. Jomoko nyalo neno ni penjo mipenjogi kawo sechegi mang'eny. Kaka pile, nyathi nyalo winjo malit e seche ma ichanje. Kata kamano, onge chanjo ma itemo manyien ma ibiro mi nyithindo e nonroni ka oweyo ma imiyoga nyithindo gi migao mar sirikal ma otelo ni weche mag ngima. Nyalore ni weche ma imiyowa nyalo chopo ni joma moko maok gin jotich nonroni. Wabiro temo matek mondo kik mano timre.

Ber madibedie

Moko kuom mabeyo manyalo timore ni nyathini en yudo chanjo e saa ma owinjore. Chanjo nyalo geng'o tuo kod tho. Wabiro ori e klinik machiegni kodi ka nyathini pok oyudo chanjo te ma onego omiye e kinde ma orwako dweche auchiel chakre nyuolne. Ok wabi chiwo pes wuoth kata chudo moro amora ma idwaro e klinik. Wabiro miyo migao mar ngima dwoko mar nonroni

mondo okony e chanjo mar nyithindo ei Kenya. Dwokogi bende nyalo konyo nyithindo moko mag Africa mondo oyud chanjo e saa ma owinjore.

Keto wechegi ma kiling'ling'

Wabiro temo mondo waket wechegi ma kiling'ling' kaka nyalore. Ka iyiero donjo e nonroni to ibiro miyi namba mar nonro. Nambani ibiro keti e gik nonro duto makar nyingi. Gik mitiyogo e nonro ibiro kan ei kabat molor kod kiful kata e kompyuta man gi passwad manitie e senta KEMRI/CGHR, Kisian. Ok wabi tiyo gi nyingi e gano kata e oboke moro amora ewi nonroni. Wabiro keto nyingi gi nambani mar simu ma'opondo ma ng'ato ang'ata ma ok en jatich mar nonroni ok nyal nwang'o.

Chiwruok e nonroni

Ok ochuno ni nyaka idonji e nonroni. Bende inyalo yiero mondo iwuogi e nonroni e saa moro amora bang' ka isedonjo. Ok ochuno ni nyaka idwok penjo moro amora ma ok idwar dwoko. Yiero ni mondo idonji kata kik idonji e nonroni ok bimoni yudo thieth kata mono nyathini yudo chanjo e klinik machiegni kodi. Kapok iyiero mar donjo e nonroni, bed thuolo mar penjo ewi gimoro amora.

Ng'ano ma anyalo tudora godo ka an gi penjo kata ywagruok?
Ka in gi penjo kata ywagruok kaluore gi yiero mari mar donjo e nonroni to tudri kod Benard Omondi Ochieng' , jachung' mar nonroni KEMRI/CGHR Kisian , Kisumu-Busia Highway, P.O. Box 1578, 40100 katago ne simu e namba 0722245636/ 057-2022929 EXT 413.Ka iparo ni iyudo hinyruok e nonroni e yo moro amora, kata ka in gi penjo ewi ratiro mari kaka jachiwre e nonroni to idwaro tudori gi nga't ma ok en achiel kuom jotich nonroni, tudri kod: Jagoro, KEMRI Ethics Review Committee, P.O. Box 54840 00200, Nairobi; Namba simu: 020-2722541,0722205901, 0733400003; Email: erc@kemri.org.

Bende in gi penjo moro amora ma inyalo penja?

Bende diher mar donjo e nonroni?

Seyi mari (kata alama) mantiere piny mar oboke ni nyiso ni:

- Osenyisa gima omiyo itimo nonroni, chenro, mabeyo madibedie kod maricho.
- Osemiya thuolo mar penjo ka pok aketo seyi.
- En yierona donjo e nonroni.

Nying nyathi: _____ Tarik mar nyuol: _____

Nying mar Janyuol/Jarit: _____

Seyi mar Janyuol/Jarit: _____ Tarik:_____

(Ket "X" ka okinyal keto seyi)

Nying mar jakaw ayie: _____

Seyi mar jakaw ayie: _____ Tarik: _____

(Kuom joma oknyal somo, janeno maok en achiel kuom anyuola kata jatich nonroni, nyaka ket seyi)

Asesomo ma alero oboke mar ayie ne ng'at ma nyinge ondik malo kanyo ma aneno ka oyie gi keto alama.

Nying janeno: _____

Seyi mar janeno: _____ Tarik: _____

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

Appendix 7.3. M-SIMI consent form in Kiswahili

KEMRI/CDC NA SHULE YA AFYA YA UMMA YA JOHN HOPKINS
WARAKA WA IDHINI

Kichwa cha Utafiti: Majaribio ya kuthibitisha athari ya vikubusho vya runununu na ruzuku ya usafiri kwa kuboresha viwango vya uenezaji wa kinga na kalenda ya matukio magharibi mwa Kenya.

Wapelelezi: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigaor, KEMRI/CGHR; Joyce Were, KEMRI/CGHR; David Obor, KEMRI/CGHR; Daniel Feikin, CDC/Division of Viral Diseases; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Eneo ya utafiti: Kaunti ya Siaya

Tarehe ya makala ya Mpelelezi mkuu: 22 May 2016

Flesch-Kincaid readability level 7.6

Toleo la Kiswahili

Utangulizi

Jina langu ni _____ ninafanya kazi na watafiti kutoka KEMRI/CGHR na shule ya umma ya Johns Hopkins iliyo kule Marekani. Tuko hapa kujua ikiwa ungependa kujumuishwa katika utafiti unaolenga kuwezesha watoto wengi kupata chanjo. Nitakuelezea kwa kina kuhusu utafiti huu. Ikiwa kuna jambo lolote hauelewi, tafadhali niulize ili nikueleze zaidi. Mwishowe, utakuwa na nafasi ya kuuliza maswali. Baada ya kujibu maswali yako, nitakuuliza ikiwa unataka kujumuishwa katika utafiti huu.

Kusudi la utafiti

Tunafanya utafiti huu kwa sababu watoto wengi nchini Kenya huchelewa kupata chanjo au hukosa kupata kabisa. Tunafanya utafiti kubaini ikiwa tunaweza kutumia simu ya runununu kuhimiza akina mama kuleta watoto wao ili wapate chanjo ya ukambi wakati unaofaa. Utafiti huu ni muhimu kwa sababu chanjo zinaweza kukinga watoto dhidi ya ugonjwa na hatimaye kifo. Tunataka kutafuta mbinu ya kuwezesha watoto wengi kupata chanjo.

Kwa nini unaulizwa kushiriki?

Tunakuuliza kushiriki katika utafiti huu kwa sababu una mtoto wa kati ya miezi sita na nane na pia unaishi katika moja ya vijiji vinavyo husika katika utafiti huu. Tunatarajia akina mama na watoto 600 kushiriki katika utafiti huu kutoka eneo hii.

Utaratibu wa utafiti

- Utachaguliwa kwa moja ya vikundi tatu kwa mbinu ya kubahitisha. Utakuwa na nafasi sawa ya kuwa katika moja ya vikundi hivyo tatu. Kila kikundi kitakuwa na mbinu tofauti ya kutumia simu ya rununu kuhimiza chanjo. Tunataka kulinganisha vikundi hivi tatu ili tubainishe njia bora zaidi ya kuhakikisha watoto wengi wanapata chanjo wakati unaofaa.

Ukijijumuisha katika utafiti huu, yafuatayo yatafanyika:

- Leo, utapeana jina na tarehe ya kuzaliwa ya mtoto wako.
- Leo, tutakuulizia nambari yako ya simu au ya mtu unayoweza kufikia kwa urahisi.
- Leo, utapata ujumbe fupi ya kukupongeza kwa kujiunga na utafiti huu.
- Mtoto wako akifikisha umri wa miezi 12, tutakuja nyumbani kwako kuulizia kuhusu chanjo. Pia tutaangalia kitabu cha kliniki cha mama na mtoto. Hii inatarajiwa kuchukua takriban dakika 30.

(*Sehemu inayofuata ina aya ambayo yafaa kusomwa kulingana na kikundi ambacho mhusika alichaguliwa. Aya inayohusika pekee ndiyo itakayosomwa kwa kila mama)*

- Kijiji chako kiko katika kikundi cha kwanza. Hapo mwanzo wa utafiti, utapokea ujumbe fupi moja inayoangaza mambo ya afya. Unaweza kupeleka mtoto wako kwa kliniki yoyote unayopenda.
- Kijiji chako kiko katika kikundi cha pili. Tutakutumia ujumbe fupi mbili za kukukumbusha juu ya chanjo ya ukambi. Tutatuma ujumbe fupi ya kwanza siku 3 kabla siku ya chanjo na ya pili siku moja kabla siku ya chanjo. Unaweza kupeleka mtoto wako kwa kliniki yoyote unayopenda.
- Kijiji chako kiko katika kikundi cha tatu. Tutakutumia ujumbe fupi mbili za kukukumbusha kabla ya kuendea chanjo ya ukambi. Tutatuma ujumbe fupi ya kwanza siku 3 kabla siku ya chanjo na ya pili siku moja kabla ya siku ya chanjo. Tutakutumia shilingi 150 siku mbili kabla siku ya chanjo kufika.

Mabaya au madhara yanayoweza kutokea

Madhara yanayoweza kutokea kwa sababu ya utafiti huu ni haba. Wengine wanaweza kuhisi maswali yanayouulizwa yanachukua muda wao mwingi. Kama kawaida, chanjo ya sindano inaweza kusababisha maumivu madogo kwa mtoto wako. Lakini hakuna chanjo yoyote ya majaribio itakayotumiwa katika utafiti huu isipokuwa chanjo ya kawaida inayotolewa na Wizara ya Afya. Inawezekana kwamba habari zako zitaweza kufikiwa na mtu ambaye sio mmoja ya watafiti. Hata hivyo tutajaribu tuwezavyo ili tuzuie habari zako kufikiwa na watu ambao hawahusiki.

Mazuri yanayoweza kutokea

Jambo nzuri ambalo linaweza kutendeka kwa mtoto wako ni kupata chanjo kwa wakati mwafaka. Chanjo zinaweza kuzuia magonjwa na hatimaye kifo. Ikiwa mtoto wako hatakuwa amepata chanjo zinazofaa katika umri wa miezi kumi, tutakukuelekeza kwa kliniki kilicho karibu nawe lakini hatuta gharamia malipo yoyote. Tutapea matokeo ya utafiti huu Wizara ya Afya ili isaidie kuboresha kupatikana kwa chanjo nchini Kenya. Pia, matokeo hayo yataweza kusaidia watoto wengi barani Afrika kupata chanjo wakati mwafaka.

Usiri

Tutajaribu kuweka yale utakayotueleza kwa siri ipasavyo. Baada ya uamuzi wako wa kushiriki katika utafiti huu, utapewa nambari ya utafiti ambayo itatumika kwa vifaa vyote vya utafiti badala ya kutumia jina lako. Vifaa vyote vitawekwa ndani ya kabati inayofungwa na kifuli au kwenye tarakilishi iliyo na nambari ya siri ya KEMRI/ CGHR. Jina lako au chochote kile kinachoweza kukutambulisha hakitatumiwa katika ripoti za utafiti huu. Hatutafichua jina lako au nambari yako ya simu kwa mtu yeyote asiye mfanyikazi wa KEMRI/ CGHR anayehusika na utafiti huu.

Kushiriki katika utafiti huu

Sio lazima ushiriki katika utafiti huu. Unaweza kujiondoa katika utafiti huu wakati wowote licha ya kuanza. Pia, sio lazima ujibu swali lolote usilotaka kujibu. Huduma yoyote ya afya unayopata katika kliniki ikiwemo chanjo kwa mtoto wako haitaathiriwa kwa sababu ya uamuzi wako wa kushiriki au kutoshiriki katika utafiti huu. Kabla ya kufanya uamuzi wa kushiriki au kutoshiriki katika utafiti huu, kuwa huru kuuliza swali lolote.

Ni nani ambaye nitawasiliana naye ikiwa nina maswali au malalamishi?

Ikiwa una maswali au malalamishi juu ya kushiriki katika utafiti huu, wasiliana na Benard Omondi Ochieng', msimamizi wa utafiti huu wa KEMRI/ CGHR, Kisumu-Busia Higway sanduku la posta 1578 40100 au nambari ya simu 0722245636/057-2022929 EXT 413. Ukiumia kwa njia yoyote ile au ukiwa na maswali kuhusu haki yako kama mshiriki katika utafiti na unataka kuzungumza na mtu asiyehusika moja kwa moja na utafiti huu, tafadhali wasiliana na katibu, KEMRI National Ethical Review Committee, sanduku la posta 54840 00200, Nairobi, nambari ya simu: 020 2722541, 0722 205901, 0733 400003; barua pepe: erc@kemri.org

Je, una swali lolote?Je, ungependa kushiriki katika utafiti huu?

Kutia sahihi (au alama) kwenye fomu hii inamaanisha:

- Nimefahamishwa juu ya kusudi, taratibu, faida na madhara ya utafiti huu.
- Nimepewa nafasi ya kuuliza maswali kabla ya kutia sahihi.
- Nimekubali kushiriki katika utafiti huu kwa uamuzi wangu.

Jina la mtoto: _____Siku ya kuzaliwa: _____

Jina la Mzazi/Msimamizi: _____

Sahihi ya Mzazi/Msimamizi:_____ Tarehe: _____

(Weka "X" kama huwezi kuandika)

Jina la anayechukua makubaliano: _____

Sahihi ya anaye chukua makubaliano: _____ Tarehe: _____

(Kwa wale wasioweza kusoma, msimamizi lazima akague na kuweka sahihi hapo chini)

Nimesoma na kuelezea kuhusu fomu ya makubaliano kwa aliyetajwa hapo juu na kutazama anapoweka alama ya kukubaliana.

Jina la Msimamizi:_____

Sahihi ya Msimamizi: _____Tarehe: _____

Peana kopi moja kwa mshiriki na uweke kopi moja kwenye rekodi za utafiti

Appendix 7.4. M-SIMI consent form in English

KEMRI/CDC AND JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title: Randomized Controlled Trial of the Impact of Mobile Phone Delivered Reminders and Unconditional Travel Subsidies on Measles Vaccination in Western Kenya

Investigators: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigator, KEMRI/CGHR; Joyce Were, KEMRI/CGHR;David Obor, KEMRI/CGHR;Daniel Feikin, CDC/Division of Viral Diseases; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Study Location: Siaya County and neighboring villages

PI Version Date: 22May 2016

Flesch-Kincaid readability level: 7.2
English version (Local language version will be made available)

Introduction

My name is <insert name> and I am working with researchers from KEMRI/CGHR andJohns Hopkins School of Public Health; USA.We are here to find out if you would like to be in a research study that tries to get more infants vaccinated. I am going to give you some information about what we are doing. If there is anything you don't understand please ask me to stop and I will take time to explain. There will be time at the end for you to ask questions. After answering your questions, I will ask you if you want to join the study.

Purpose of study

We are doing this study because many Kenyan infants get their vaccines late or not at all. We are studying if we can use mobile phones to encourage mothers to bring children on time for measles vaccine. This study is important because vaccines can protect infants from getting sick and dying.We want to explore ways to get more children vaccinated.

Why you are being asked to take part

We are asking you to join this study because you have a child who is six to eight months old and hasn't received measles vaccine. We anticipate about 600 mothers and infants to join this study from this area.

Study Procedures

- You will be randomized to one of three groups. Randomization means it will be selected by chance, like using a coin flip. You will have an equal chance of being in each of the three groups. Each group will have a different way of using mobile phones to encourage immunization. We want to compare the three groups to see which is the best way to get children vaccinated.

If you join this study, this is what will happen during the next two to four months:

- Today, you will provide your child's name and date of birth. We will ask you some questions about your child's previous vaccines. We will also ask you questions about you and your family. This will take up to one hour.
- Today, we will ask for your mobile phone number or that of someone who has a phone that you have easy access to.
- When you bring your child to the clinic for measles vaccine at nine months, you should bring your MCH booklet with you.
- When your child is 12 months old, we will come to your house. We will ask questions about your child's vaccinations, health, your household, SMS messages, and how you liked this study. **We will look at your maternal and child health card**. This should take about 1 hour.
- When your child is 24 months old, we might come to your house. If we come, we will ask questions about your child's vaccinations and how you liked the study. We will look at your maternal and child health card. This should take about 1 hour.
- If your household is part of the HDSS, we will link these data to the HDSS data.

(The following section has different paragraphs to be read depending on which group the village has been assigned to. Only the relevant paragraph will be read to each mother.)

- You are in **Group 1**. Today, you will get a SMS message congratulating you for joining our study. You will not receive any other SMS from us.
- Youare in **Group 2**. Today, you will get a SMS message congratulating you for joining our study.We will send you two SMS reminders before measles vaccine visit. This visit is due when your baby is nine months old. We will send the first SMS three days before the vaccine is due. We will send the second SMS on the day before the vaccine is due. We will not send you any other SMS other than those I just described to you.
- You are in **Group 3**.Today, you will get a SMS message congratulating you for joining our study.We will send you two SMS reminders before measles vaccine visit. This visit is due when your baby is nine months old. We will send the first SMS three days before the vaccine is due. We will send the second SMS on the day before the vaccine is due. We will not send you any other SMS other than those I just described to you. Three days before your child turns nine months old, we will send you 150 KES. This money will be sent to the phone number you provided us today.

Potential Harms, Injuries, Discomforts, Inconveniences or Risks
The risks from being in this study are small. Some people might find the questions asked of them take too much time out of their day. Vaccine jabs might cause brief pain to your child, as usual. But no new or experimental vaccines will be given in this study – only the regular, safe vaccines usually given by the Ministry of Health. With any research study, there is a small chance your personal information may be revealed to people not in the study. We will do our best to prevent this.

Potential Benefits
Possible benefits to your child include getting him/her vaccinated on time. Vaccines can prevent disease and death. We will refer you to nearest clinic if your child does not have all vaccines by

12 months of age, but will not provide transportation or pay for any healthcare costs. We will give the results of the study to Ministry of Health to help improve child vaccinations in Kenya. The results might also help other African children to get their vaccines on time.

Confidentiality
We will try to keep your personal information as private as possible. After you decide to take part, you will receive a study number. This number will be used to label all study materials, rather than using your name. All study materials will be kept in a locked cabinet or password protected computer at the KEMRI/CDC center in Kisian. Your name and identity will not be shown in any reports about this study. We will not share your name or mobile phone number to anyone else besides the KEMRI/CGHR staff involved in this study.

Participation
You do not have to take part in this study. You can decide to stop being part of this study at any time after you start. You don't have to answer any questions you don't want to. The health care you receive at area clinics, including the vaccines your child gets, will not be affected by your decision to take part, or not take part, in this study today. Before deciding whether you want to take part, please feel free to ask any questions.

Who do I call if I have questions or complaints?
If you have questions or complaints as a result of being in this study please contact Mr. Benard Ochieng, Co-Principal Investigator at KEMRI/CGHR Kisian, off of Kisumu-Busia Highway, P.O. Box 1578 40100 or call 0722245636/057-2022929 EXT 413057-2022929 EXT 413.If you feel you have been harmed in any way, or if you have questions about your rights as a research subject, and want to talk about the study with someone who is not directly involved in this research project, please contact The Secretary, KEMRI Ethics Review Committee, P.O. Box 54840-00200, Nairobi; Tel: 020-2722541, 0722205901, 0733400003; Email address: erc@kemri.org

Do you have any questions for me?Do you want to take part in this research study?

Your signature (or mark) on this form means:
- I have been informed about the study's purpose, procedures, possible benefits, and risks.
- I have been given the chance to ask questions before I sign.
- I have agreed to be in this study of my own free choice.

Name of child:_____ Date of birth: _____

Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____ Date:_____

(Put "X" if cannot sign name)

Name of Person administering the consent: _____

Signature of person administering consent: _____ Date: _____

(For those who are not able to read, a witness, who is not a family member or study staff, must verify and sign below.)

I have read and explained the consent form to the person named above and watched them indicate consent with a mark.

Name of Interpreter/Witness: _____

Signature of Interpreter/Witness: _____Date _____

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

Appendix 7.5. M-SIMI enrollment visit questionnaire

○ Asembo ○ Gem

CI [ ][ ] Visit date [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Compound name:

[ ]

GPS Coordinates:_____

Child's First Name: [__][__][__][__][__][__][__][__][__][__][__][__]

Child's Juok Name: [__][__][__][__][__][__][__][__][__][__][__][__]

Child's Last Name: [__][__][__][__][__][__][__][__][__][__][__][__]

Child's sex

○ Male ○ Female

Childs DOB according to Mother/caretaker [__][__] / [__][__] / [__][__][__][__]

Is DOB in MCH book the same as the mother reports….YES…NO…..MCH BOOKLET NOT PRESENT

If NO…what is the child DOB according to the MCH?[__][__] / [__][__] / [__][__][__][__]

Child's Location ID: [__][__][__]---[__][__][__][__]---[__][__]---[__][__][__]

Does child live here? (Circle ONE).....YES……MOVED AWAY……DIED

Mom First Name: [__][__][__][__][__][__][__][__][__][__][__][__]

Mom Last Name: [__][__][__][__][__][__][__][__][__][__][__][__]

Mom DOB: [__][__] / [__][__] / [__][__][__][__]

Were you previously enrolled in m-SIMU study? …..Yes …..No

Relationship of primary caregiver to newbornchild (Circle One)….
MOTHER….FATHER….GRANDMOTHER…….STEPMOTHER…….AUNT……OTHER (SPECIFY)_____

What arm is the mother enrolled? …..ARM 1 …..ARM 2 …..ARM 3

What was the allocation ID# assigned for infant/caregiver? (Please type)

Indicate to mothers that an SMS message will be sent to mothers participating in this study and that we will need to ask questions about mobile phone ownership, usage, and the telephone number for which SMSs can be sent

Section A will be for people in control and SMS only arms. Section B will be for those in MPESA arms

SECTION A- CONTROL and SMS ONLY arms

8. Will you be using your own phone to receive SMS for this study? ….YES……..NO…***If YES, SKIP to Q10a***

8a. If not yours, then whose mobile phone will you use to receive SMS for this study? (CIRCLE ONE)..... HUSBAND……..OTHER PERSON IN HOUSEHOLD……..OTHER PERSON IN COMPOUND……..NEIGHBOR……..CI

Indicate to mother that if she cannot identify a phone that she has access to, the CI will receive SMS messages.

9 What is the phone number that can be used to send you SMS? [__][__][__][__][__][__][__][__][_][_]

If CI will receive SMS, write in CI Mobile Phone number

If mother unsure about the phone number, have mother check with the person that owns the phone. LEAVE Q9 BLANK and return to mother in 1 day to confirm the availability of a phone

10. Which mobile network is this number for? (CIRCLE ONE)…SAFARICOM….AIRTEL...ORANGE..YU…..DK

SECTION B: 150 KES arm

8. Will you be using your own phone to receive SMS and **money** for this study? YES…NO..***If YES, GO Q10***

8a. Whose mobile phone will you use to receive SMS and money for this study?(CIRCLE ONE) HUSBAND……..OTHER PERSON IN HOUSEHOLD……..OTHER PERSON IN COMPOUND……..NEIGHBOR……..CI

Indicate to mother that if she cannot identify a phone that she has access to, the CI will receive SMS messages. THIS IS A LAST, LAST, LAST RESORT

9. What is the phone number that can be used to receive SMS & money[_][_][_][_][_][_][_][_][_][_][_]

CI should confirm that this phone number is registered with a mobile money account

If CI will receive SMS, write in CI Mobile Phone number

If mother unsure about the phone number and whether the account is registered for MPESA, have mother check with the person that owns the phone. LEAVE Q9 BLANK and return to mother in 1 day to confirm availability

10. Which mobile network is this number for? (CIRCLE ONE)…SAFARICOM…AIRTEL...ORANGE...YU…DK

FOR ALL PARTICIPANTS, COMPLETE THE REST OF THE QUESTIONNAIRE

11. Which language do you want to receive SMS messages in? (CIRCLE ONE)…ENGLISH…LUO…KISWAHILI

Send enrollment SMS…. RCT village# compound# phone# BabyDOB Language ChFname ChLname StudyARM

12 Has the CI sent the enrollment SMS? You should receive a thank you SMS…..YES…NO

12.1 Did mother receive the SMS? YES……NO, PHONE NOT WITH HER……NO, NO COVERAGE…. NO, PHONE OFF/NO POWER……OTHER_____

13. Does mother/caretaker **receive** SMS messages? (Circle One)……..YES……NO…….. ***If NO, Skip to Q14***

13.1 On average, how many SMS do you receive in **1 week?**....0….1-3…4-7….8-10….11-20…..>20

13.2 How soon do you receive the SMS messages? (CIRCLE ONE)…….

…….INSTANTLY…….. LESS THAN 1 HR…… 1-6 HOURS……7-24 HOURS…….>1 DAY…….DK

13. 3 Do you read SMS messages on your own? (Circle One)……YES……NO ***If YES, skip to Q14***

13.3.1 Who helps you read SMS messages? (Circle One)…..Spouse….Child….

… Other person in household….Other person in compound…Neighbor…Friend….Other

14. Does mother/caretaker **send** SMS messages? (Circle One)……..YES……NO…….. ***If NO, SKIP to Q15***

14.1 On average, how many SMS do you send in **1 week?**....0….1-3……4-7….8-10….11-20…..>20

14.2 Do you compose SMS messages on your own? (Circle One)……YES……NO ***If YES, skip to Q15***

14.2.1 Who helps you compose SMS messages? (Circle One) …..Spouse….Child….

…..Other person in household….Other person in compound…Neighbor…Friend…Other

Immunization history - *ask care-taker*

15. **Bende nyathini ne oyudo chanjo mar geng'o tuoche, e klinik kata kane sirikal okelo chanjo mar nyithindo e gweng?**
Did (name) ever receive any vaccination to prevent him/her getting diseases, including vaccination received in a national immunisation day campaign?) ----○ Ee (Yes) ○ Ooyo (No) ○ *Akia (Don't know)

*If**"YES" or"Don't Know"**, then Skip to Question #17 If "**NO**" go to Q16

16 **Ka ooyo to ere gimomiya pod ok oter nyathi chanjo? (**If No, what's the reason?)

○ nengo ne malo (cost was high) ○ kar chanjo bor (vaccination site far) ○ Din ok oyie (against faith/religion)
○ aluoro (fear of vaccination) ○ chanjo ok tii (don't work for me) ○ NA
○ ler machielo (other, specify)

17. **Be in gi kadi mar Klinik ma ondikie chanjo mosechiw?**
(Do you have a card where (name's) vaccinations are recorded down? **Ka iyei, nyisa go?** (if YES, may I see it please?) ○ Ee (Yes, seen) ○ Eee, ok aneno(Yes, not seen) ○ Ooyo, onge kad (No card) ○ mother not found, no card

If card is NOT AVAILABLE, proceed to verbal report questions;

If AVAILABLE, observe and read from the card the following immunization questions

Where card is available, fill the "FROM CARD" column only using the information from the card, in the tablebelow. If a card is not available or does not have a specific vaccination, obtain from the verbal report and mark"verbal report" column. Fill HF using codesbelow

	FROM CARD		VERBAL		
Vaccine	Given: Yes/No	Date Received	Given: Yes/No/DK	Age at vaccination	Health Facility where vacc. given
BCG				weeks	
Polio-Birth				weeks	
Polio1				weeks	
Polio2				weeks	
Polio3				weeks	
Penta1				weeks	
Penta2				weeks	
Penta3				weeks	
PCV1				weeks	
PCV2				weeks	
PCV3				weeks	

Measles				weeks	

6. in which clinic was vaccines given?

Use the key below for numbers against the health facilities, where the child got the vaccinations mentioned above, to fill in the table above, where applicable.

● 01. Abhidha ● 02. Lwak Mission ● 03. Mahaya ● 04. Ongielo ● 05. Saradiddi ● 06. Nyagoko

● 07. Ndori ● 08. Akala ● 09. Aluor ● 10. Njejra ● 11. Rera ● 12. Nyawara

● 13. Uriri ● 14. Bondo District Hospital ● 15. Madiany Sub District Hospital ● 16. Matangwe Hospial

● 17. Siaya District Hospital ● 18. Yala Sub District Hospital ● 19. Nyanza Provincial Hospital (Russia)

● 20. Kisumu District Hospital ● 21. Bar-Olengo ● 22. Ting'-Wang'i ● 23. K'otieno ● 24. Ng'iya Mission

● 26. Mamoko/Other (Ier/specify) 1. vaxwhother ● 25. Nyathengo ● 27. UNK

● 28. Mamoko/Other (Ier/specify) 2. vaxwhother2 ● 29. Obaga

● 30. Masala ● 31. Asayi ● 32. Gongo ● 33. Masogo ● 34. Ogero ● 35. Sirembe

● 36. Wagai ● 37. Kogelo ● 38. Bar Agulu ● 39. Mulaha

Did your child receive supplemental measles vaccine? …..Yes …..No

19.Do you intend to bring your infant for measles vaccinations? (Circle One)..YES……NO……..DK

19.1 *If YES to Q19*, where are you likely to take your child for next vaccination?*Use codes above* [_][_]

19.2 *If NO or DK to Q19*, what is the reason you would not bring your child for vaccine? (Circle One)

COST WAS HIGH……VACCINATION SITE FAR…….AGAINST FAITH OR RELIGION…..FEAR OF VACCINATION ……DON'T WORK FOR ME…….OTHER (Specify)_____

20. How long does it take you to travel to the clinic you picked above (minutes)?.....0-15…16-30…

….31-45……46-60….>60

21. How do you primarily get to that clinic? (Circle One) WALKING….BICYCLE…MOTORCYCLE… TAXI ….MATATU ….OTHER(Specify)_____

21.1.If **NOT walking** for Q21, how much does it cost for one way transportation to that clinic listed? (Circle One) ….0-50Ksh…..51-100Ksh……101-150Ksh…..151-200Ksh…..>200Ksh…..MY OWN TRANSPORT

22. Do you think vaccines are free or will you have to pay to have your child vaccinated?(Circle One)...FREE…….PAY……DK

23. How many CHILDREN UNDER 5 YRS of AGE, slept in this house last night? [___] [___]

23A. What is the birth order of the M-SIMI child (1=first born)? …1st….2nd….3rd….4th….5th….6th…..7th….>7

24. Did the M-SIMI child sleep under a bed-net last night

25. How many persons are sleeping in the household regularly? This includes children under 5 [__] [___]

26.How many ANC visits did you make in your last pregnancy? [___] [___] or NA

26.1 If >=1 visit, how many of ANC visits were in 1st trimester of last pregnancy. [_] [_] or DK

27. Number of tetanus toxoid immunizations mother received in last pregnancy? [___] [___] or DK

28. Where was your last child born?....AT HOME WITH NO SBA……AT HOME WITH SBA/MIDWIFE..... ……..HEALTH FACILITY (Name:_____)……DK

31 a What is the **most** important income-generating activity of the household administrator?

- ○ Subsistence farming
- ○ Commercial farming
- ○ Salaried worker (eg. teacher, nurse, office)
- ○ Small business (eg. sell maize)
- ○ Business owner (eg. duka, kiosk)
- ○ Skilled labor (eg. carpenter, tailor, jua kali)
- ○ Unskilled labor (eg. shamba, construction)
- ○ Other, Specify:
- ○ Fishing
- ○ Housewife
- ○ Not working

29 b What is the **most** important income-generating activity of the spouse?

- ○ Subsistence farming
- ○ Commercial farming
- ○ Salaried worker (eg. teacher, nurse, office)
- ○ Small business (eg. sell maize)
- ○ Business owner (eg. duka, kiosk)
- ○ Skilled labor (eg. carpenter, tailor, jua kali)
- ○ Unskilled labor (eg. shamba, construction)
- ○ Other, Specify:
- ○ Fishing
- ○ Housewife
- ○ Not working
- ○ NA

30 What is the **main source of drinking** water for your household?

○ Lake ○ Unprotected spring ○ Stream /River ○ Borehole/well ○ Pipe in compound
○ Pond ○ Protected spring ○ Rainfall ○ Pipe in dwelling ○ Public tap ○ Other

2.3 What do you do to this water before you drink it? ○ Untreated ○ Boiled ○ Chlorine ○ Alum ○ Alum&Chlorine ○ Filtered ○ Filtered&Boiled ○ Filtered&Alum ○ Boiled&Alum ○ Other

2.4 What is the **primary** source of fuel for cooking in your household in the **past month**? ○ Paraffin stove ○ Charcoal ○ Gas cooker ○ Firewood ○ Other

3.1 **Livestock ownership *(includes ownership inside and outside study area)***

How many of each type of livestock does your household own at the moment? *If none, write and shade "000".*

Goats	Cattle	Sheep	Poultry	Donkey	Pigs
0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9	0 1 2 3 4 5 6 7 8 9

33 **Other items of ownership *(includes ownership inside and outside study area)***

How many of each of the following items does your household own at the moment? *If none, write and shade "000".*

Plough	[mattress Foam	mattress Spring	mattress Straw]	Cell phone	Radio	Bicycle	Sofa	Lantern	TV
0	0	0	0	0	0	0	0	0	0
1	1	1	1	1	1	1	1	1	1
2	2	2	2	2	2	2	2	2	2
3	3	3	3	3	3	3	3	3	3
4	4	4	4	4	4	4	4	4	4
5	5	5	5	5	5	5	5	5	5
6	6	6	6	6	6	6	6	6	6
7	7	7	7	7	7	7	7	7	7
8	8	8	8	8	8	8	8	8	8
9	9	9	9	9	9	9	9	9	9

35. What is the average monthly household income before taxes where the child lives (if applicable)? (Circle One).....<2500……2500-5000…..5001-7500……7501-10,000……10,001-15,000…..15,000-20,000……>20000…DK…REFUSED

FOR MOTHER/CAREGIVER OF ENROLLED INFANT, If mother not alive/away fill education for caregiver

36. Mother/Caregiver Age (Years)_____

37 Level of Education
- ○ None
- ○ Primary
- ○ Sec
- ○ Post-Sec

Class/Form/YR: 0 1 2 3 4 5 6 7 8

YRS of Education: 0 1 2 3 4 5 6 7 8 9

37

	English Read	English Write	English Speak	Kiswahili Read	Kiswahili Write	Kiswahili Speak
Easily:	○	○	○	○	○	○
With difficulty:	○	○	○	○	○	○
Not at all:	○	○	○	○	○	○

N/A=not applicable; Y=yes; N=no; **Sec**=Secondary sch.; **Post-sec**=post-secondary

Level of edu= highest level attempted
Class/form/year= highest attempted

SECTION 4. **Marital status Of Mother: Where individual is less than 15 years old, Fill N/A for**

38 What is your/name current marital status? ○ Single ○ Married/cohabiting ○ Divorce/separated ○ Widowed ○ Don't know ○ N/A

39 *(Ask either sexes)* If currently married/cohabiting, what type of marriage are you/name in? ---------- ○ Monogamous ○ Polygamous ○ Don't know ○ N/A

COMMENTS_____

Appendix 7.6. M-SIMI follow-up visit questionnaire

○ Asembo ○ Gem

CI [ ][ ] : Visit date [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

1.1Village #(from study ID)_____ 1.2 Compound#(from study ID)____

1.3 Compound Name: [__][__] [__][__] [__][__][__][__][__][__][__][__][__][__] [__][__] [__][__][__][__]

1.4 Study ID: [__][__][__]---[__][__][__][__]---[__][__]

1.5 Child First Name: [__][__] [__][__] [__][__][__][__][__][__][__][__][__][__]

1.6 Child Juok Name: [__][__] [__][__] [__][__][__][__][__][__][__][__][__][__]

1.7 Child Last Name: [__][__] [__][__] [__][__][__][__][__][__][__][__][__][__]

1.8 Is Child's HH currently living in within DSS borders? YES….NO…

1.8.1 IF YES, Child's Location ID (FOR HH CURRENTLY LIVING IN): [_[_[_]---[_[_[_[_]--[_[__]---[__]

1.8.2 IF NO, provide village name and describe where located_____

1.9 GPS Coordinates:_____

1.10 Child's DOB according to Mother/caretaker [__][__] / [__][__] / [__][__][__][__]

1.11 Is enrolled mother/caregiver still alive? ALIVE AND PRESENT……MOVED AWAY…….DEAD…..DK

1.11.1 If ALIVE to 1.11, Mother First Name: [__][__] [__][__] [__][__][__][__][__][__][__][__]

1.11.1.a Mother Last Name: [__][__] [__][__] [__][__][__][__][__][__][__][__]

1.11.1.b Phone number used in M-SIMI [__][__] [__][__] [__][__][__][__][__][__]

1.11.2 If MOVED AWAY OR DEAD to 1.11, what is relationship of new primary caregiver to infant (Circle one)…. MOM….DAD….GRANDMOTHER….STEPMOM….AUNT...NA…OTHER (SPECIFY)_____

1.11.3 If DK to 1.11, elaborate on why DK was picked (open-ended)_____

1.12 Is enrolled child (Circle One): ALIVE…..DEAD…..UNKNOWN

1.12.1 If DIED, date of death? [__][__] / [__][__] / [__][__][__][__]

1.12.2 If ALIVE OR UNK, Did infant move from cmpd in study ID? YES…NO…CAN'T FIND CHILD

1.12.2.b If YES to 1.12.2, what village?(open-ended)_____

Immunization history - *ask care-taker*

2.1. **Bende nyathini ne oyudo chanjo mar geng'o tuoche, e klinik kata kane sirikal okelo chanjo mar nyithindo e gweng?**
Did (name) ever receive any vaccination to prevent him/her getting diseases, including vaccination received in a national immunisation day campaign?) ----○ Ee (Yes) ○ Ooyo (No) ○ *Akia (Don't know)

*If **"YES" or "Don't Know"**, then Skip to Question #2.3. If "**NO**" go to Q2.2

2.2 **Ka ooyo to ere gimomiya pod ok oter nyathi chanjo? (If No, what's the reason?)**

○ nengo ne malo (cost was high) ○ kar chanjo bor (vaccination site far) ○ Din ok oyie (against faith/religion)
○ aluoro (fear of vaccination) ○ chanjo ok tii (don't work for me) ○ NA
○ ler machielo (other, specify) | | | | | | | | | | | | | | | | | | | | | | | |

3. **Be in gi kadi mar Klinik ma ondikie chanjo mosechiw?**
(Do you have a card where (name's) vaccinations are recorded down? **Ka iyei, nyisa go?** (if YES, may I see it please?)
○ Ee (Yes, seen) ○ Eee, ok aneno(Yes, not seen)
○ Ooyo, onge kad (No card) ○

2.3. If card is NOT AVAILABLE, proceed to verbal report questions;

If AVAILABLE, observe and read from the card the following immunization questions

2.4 Where card is available, fill the "FROM CARD" column Only using the information from the card, in the table below. If a card is not available or does not have a specific vaccination, obtain from the verbal report and mark "verbal report" column. Fill HF using codes

	FROM CARD		VERBAL		
Vaccine	Given: Yes/No	Date Received	Given:Yes/No/DK	Age at vaccination	Health Facility where vacc. given
BCG				weeks	
Polio-Birth				weeks	
Polio1				weeks	
Polio2				weeks	
Polio3				weeks	
Penta1				weeks	
Penta2				weeks	
Penta3				weeks	
PCV1				weeks	
PCV2				weeks	
PCV3				weeks	
Measles				weeks	

2.5 If measles vaccine given late (age received >10 months)), what are reasons for delay?.....COST WAS HIGH.....CLINIC TOO FAR.....DIDN'T KNOW VAC DATE....FORGOT ABOUT VACCINATION.... TRAVELLING.....VACCINES NOT IMPORTANT.... VACCINE NOT IN STOCK .....OTHER (SPECIFY)_____

. . in which clinic was vaccines given?

Use the key below for numbers against the health facilities, where the child got the vaccinations mentioned above, to fill in the table above, where applicable.

● 01. Abhidha ● 02. Lwak Mission ● 03. Mahaya ● 04. Ongielo ● 05. Saradiddi ● 06. Nyagoko

● 07. Ndori ● 08. Akala ● 09. Aluor ● 10. Njejra ● 11. Rera ● 12. Nyawara

● 13. Uriri ● 14. Bondo District Hospital ● 15. Madiany Sub District Hospital ● 16. Matangwe Hospial

● 17. Siaya District Hospital ● 18. Yala Sub District Hospital ● 19. Nyanza Provincial Hospital (Russia)

● 20. Kisumu District Hospital ● 21. Bar-Olengo ● 22. Ting'-Wang'i ● 23. K'otieno ● 24. Ng'iya Mission

● 26. Mamoko/Other (ler/specify) 1. vaxwhother ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ● 25. Nyathengo ● 27. UNK

● 28. Mamoko/Other (ler/specify) 2. vaxwhothe2 ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐ ● 29. Obaga

● 30. Masala ● 31. Asayi ● 32. Gongo ● 33. Masogo ● 34. Ogero ● 35. Sirembe

● 36. Wagai ● 37. Kogelo ● 38. Bar Agulu ● 39. Mulaha

2.6. **Nyathi ne oyudo dos mar Vitamin A?** *(Did <name> receive a Vitamin A dose, like this one (show example) during the last 6 months?* VitA ○ Kamano/Ee (Yes) ○ Ooyo (No) ○ NA ○ DK

2.7. **Bende nyathini ne oyudo chanjo mar alura/ang'iew kane sirikal okelo chanjo mar nyithindo e gweng'?** *(Did your child receive the measles vaccine during a measles vaccination campaign?)*

○ Ee, tarik? (Yes, date?) campdate ☐☐ / ☐☐ / ☐☐☐☐ ○ Ooyo (No) ○ Akia (Don't know) Meascamp

IF MEASLES VACCINE WAS GIVEN:

C1. How long did it take you to travel to the clinic where measles vaccine was given (minutes)? .....0-15…16-30...31-45……46-60….>60

C2. How did you primarily get to that clinic? (Circle One) WALKING….BICYCLE…MOTORCYCLE… TAXI ….MATATU ….OTHER(Specify)_____

C2.1.If **NOT walking** for Q21, how much does it cost for one way transportation to that clinic listed? (Circle One) ....0-50Ksh…..51-100Ksh……101-150Ksh.....151-200Ksh…..>200Ksh…..MY OWN TRANSPORT

C3. Who took care of other children while you were at the health facility for measles vaccination?.....SPOUSE..SOMEONE ELSE IN HH…… SOMEONE IN COMPOUND……SOMEONE OUTSIDE COMPOUND……..NO OTHER CHILDREN

C4. If you have a salaried job, did your visit to the health facility cause you to miss work?.....YES……NO……NA

C5. If you work inside the home, did your visit to the health facility cause you to miss work?.....YES……NO……NA

ALL CAREGIVERS:

C6. Who primarily cares for your child/children when they are sick? .....ME .....SPOUSE ….SOMEONE ELSE IN HH …… SOMEONE IN COMPOUND ……SOMEONE OUTSIDE COMPOUND

2.8 What factor was most important in determining which clinic you brought your infant to for immunizations?...

….COST….DISTANCE….STAFF TREAT ME WELL… VACCINES ALWAYS IN STOCK…..NEW CAREGIVER, DID NOT BRING……OTHER (SPECIFY)_____

4.4 How far is the nearest Mpesa/mobile money agent from your compound in walking time?.....<10 minutes……10-21 minutes…..20-40 minutes….41-60 minutes….> 1 hour….DK

4.5 Are you registered with MPESA/ORANGE/YU/or other mobile money network?....YES…NO….DK

If YES to 4.5, when did you register for the mobile money network? <1 MONTH AGO…..1-3 MONTHS AGO….3-6 MONTHS AGO….6-12 MONTHS AGO…> 1 YEAR AGO

4.6 (Aside from SMS and small money…*Only say this for those in intervention arms*), what motivated you to bring your child in for immunization?.....FAMILY TOLD ME….VACCINE GOOD FOR KID….OTHER MOTHERS DO IT….CHW TOLD ME…..CLINIC STAFF TOLD ME….NA….OTHER(SPECIFY)_____

For those in arm 1 (control), skip to question 7.1

FOR THOSE IN ARMS 2 and 3 (SMS and SMS+150KES arms)

5.1 Did you receive SMS reminders for ANY OF your child's immunization appointments? ...YES…NO….NEW PRIMARY CAREGIVER…DON'T REMEMBER

5.1.1 If NO to 5.1, why do you think you did not receive REMINDERS? NEW PRIMARY CAREGIVER…..PERSON WHO OWNED PHONE DID NOT GIVE…..KEMRI DID NOT SEND…I MOVED AWAY….PERSON WHO OWNED PHONE MOVED AWAY …OTHER (SPECIFY)___**THEN *SKIP TO Q6.1***

5.1.2 IF DON'T REMEMBER OR NEW PRIMARY CAREGIVER for 5.1, **SKIP TO Q6.1**

5.2 For MEASLES vaccine, whose mobile phone were reminders sent to? MINE….SOMEBODY ELSE

5.2.1 If MINE for 5.2, how many SMS did you receive for Measles vaccine …0…1……2…..3…. DK

5.2.1.a If <2 SMS for Measles, Why do you think you did not receive some of the SMS messages?.... I WAS AWAY….PHONE NOT CHARGED….LOST/BROKE PHONE…KEMRI DID NOT SEND…VACCINATED AFTER RECEIVING FIRST REMINDER…VACCINATED INFANT BEFORE ANY REMINDER received…OTHER (SPECIFY)____

5.2.2 If SOMEBODY ELSE for 5.2, how many SMS did you receive for Measles? ...0..1..2..3..DK

5.2.2.a If <2 SMS for Measles, Why do you think you did not receive some of the SMS messages?.... OWNER OF PHONE AWAY….OWNER OF PHONE FORGOT TO TELL ME…..I WAS AWAY….PHONE NOT CHARGED….LOST PHONE…KEMRI DID NOT SEND……OTHER (SPECIFY)____

5.3 Overall, did the SMS influence your decision to bring your child for immunization? YES….NO….DK

5.4 Overall, what did you think of the number of SMS sent to you? TOO MANY…..TOO LITTLE….JUST RIGHT….MOBILE PHONE SHARED…..DK

5.5 How did you find the length of the SMS reminders….TOO SHORT, RIGHT LENGTH, TOO LONG…MOBILE PHONE SHARED….DK

5.6 What was your opinion of the small phrase at the end of the reminder? ENJOYED IT….DIDNT LIKE IT…DON'T REMEMBER IT…MOBILE PHONE SHARED….NO OPINION

FOR THOSE IN ARM 3 (SMS+150KES)

6.1 Did you receive mobile money as part of this study....YES….NO…DON'T REMEMBER

6.2.1 If NO, why do you think you did not receive payment? NEW PRIMARY CAREGIVER…..PERSON WHO OWNED PHONE DID NOT GIVE…..KEMRI DID NOT SEND…I MOVED AWAY….PERSON WHO OWNED PHONE MOVED AWAY…MY PHONE BROKE…CHANGED SIM CARD…PROBLEM WITH MPESA ACCOUNT …OTHER (SPECIFY)_____ ***then SKIP to Q7.1***

6.2.2 IF DON'T REMEMBER for 6.2, **SKIP TO Q7.1**

6.2 For Measles vaccine, whose mobile phone was money sent to? MINE….SOMEBODY ELSE

6.2.1 If MINE for Q6.3, Did you receive the payment for measles vaccine?: YES…NO…DON'T REMEMBER….

6.2.1.a If YES for 6.3.1, when did you cash out the incentive? SAME DAY…..1-3 DAYS….>3 DAYS…..NOT CASHED OUT

6.2.1.b If NO for 6.3.1, why do you think you didn't receive a payment…. ….PHONE WAS LOST/BROKE….KEMRI DID NOT SEND…PROBLEM WITH MPESA ACCOUNT…CHANGED SIM CARD…. … ….DK….OTHER(SPECIFY)_____

6.2.2 If SOMEBODY ELSE for Q6.3, Did you receive the payment for measles vaccine?: YES…NO…..DON'T REMEMBER

6.2.1.a If YES for 6.3.2, when did you cash out the incentive? SAME DAY…..1-3 DAYS….>3 DAYS…..NOT CASHED OUT

6.2.1.a If NO for 6.3.1, why do you think you didn't receive a payment….OWNER OF PHONE AWAY…OWNER OF PHONE WITHHELD MONEY ….PHONE WAS LOST….KEMRI DID NOT SEND….PROBLEM WITH MPESA ACCOUNT….DK….OTHER (SPECIFY)

6.3 Did our telling you that you would receive small money influence your decision to bring your child for immunizations?....YES…NO…DK……NOT PRIMARY CAREGIVER ….DK WOULD RECEIVE PAYMENT

6.4 What did you use the MPESA for? TRANSPORT COST…FOOD…AIRTIME…HOUSING EXPENSES …SCHOOL EXPENSES….MEDICINE…NOT USED BY MOTHER…..OTHER….DK (**Select all that apply)**

6.5 How was your experience in receiving cash through Mpesa/ZAP/Orange/Yu-Cash and KEMRI/CDC?... .....VERY POSITIVE….SOMEWHAT POSITIVE…..NEUTRAL….SOMEWHAT NEGATIVE….VERY NEGATIVE….DK…Not Primary Caregiver

6.6 For future vaccines for this child or other children, would you be more/less/same likely to bring them in for vaccination if you do not get any small money?.....MORE LIKELY…LESS LIKELY……THE SAME……DK

6.7 Would you have preferred to receive airtime over mobile-money cash (Same KSH for both)?....YES….NO…DK….

6.8 Between SMS reminders and incentives, what influenced you most in bringing your child for vaccination" ….SMS REMINDER….INCENTIVE….INCENTIVE AND REMINDER EQUALLY….NEITHER…DK

******FOR ALL STUDY PARTICIPANTS**

7.1 Does your child usually sleep under an INSECTICIDE treated bednet?.....YES…..NO……DK

7.1.1 *If YES for 7.1,* Did child sleep under an INSECTICIDE treated bed net last night?..YES..NO..DK

7.1.2 *If NO to 7.1*, Does your child usually sleep under a bed net? ..... YES…..NO…..DK

7.1.2.b *If YES for 7.1.2,* Did your child sleep under a bed net last night?...YES….NO…..DK

7.2 How many times has your infant been to the health facility for an illness (e.g. fever, respiratory problem, diarrhea) in the last 2 weeks (excluding immunization visits)? [__][__]

7.3 How many times has your infant been hospitalized in the last 1 month (e.g. fever, respiratory problem, diarrhea) (excluding immunization visits)?...[__] [__]

8.1 Comments_____

Appendix 7.7. M-SIMI randomization Standard Operating Procedure (SOP)

Purpose: Describe procedures for random allocation to M-SIMI study arms

Step	Equipment/materials	Responsible
1. Generate 1:1:1 random allocations to the M-SIMI study arms (control, SMS only, SMS+incentive) for 537 IDs	Computer	Data analyst
2. Divide the 537 random allocations into 5 blocks; 2 blocks will have 108 allocations and 3 blocks will have 107 allocations. Create allocation IDs by numbering each allocation within a block as follows: • Block 1: 1A – 108A • Block 2: 1B – 108B • Block 3: 1C – 107C • Block 4: 1D – 107D • Block 5: 1E – 107E **The sequence of allocations should be random**	- Allocations - Spreadsheet or other program to document groups	Data Analyst
3. For each allocation, prepare allocation envelopes as follows: • Print the allocation ID and study arm on a card • Place the card in an opaque envelope • Seal the envelope and stamp the seal (to document when the seal is broken) • Write the allocation ID corresponding to the allocation (e.g. 1A) on the outside of the envelope	- Envelope - Stamp - Card - Study arm allocations - Allocation IDs	Data Analyst and Study Coordinator
4. Preliminarily assign each CI to randomize participants using allocation envelopes from a particular Block e.g., CI#1 = Block A i.e., Allocation IDs 1A – 108A and so on	None	Study Coordinator/Field Supervisor

Step	Equipment/materials	Responsible
5. Provide each CI with 10 allocation envelopes per week (assuming 2 enrollments/day)	Sealed, stamped allocation envelopes	Field Supervisor
6. After determining eligibility, obtaining verbal consent and before obtaining written consent: • Open the sealed, stamped allocation • Allocations should be opened in sequence i.e., allocation 1A should be opened before allocation 2A • Take note of which arm the participant is allocated • Write "ENROLLED" at the participant's study ID on the allocation card • During consent, describe the procedures for the applicable study arm	- Sealed, stamped allocation envelopes - Informed consent form - Pen	CI
7. Record the allocation ID in ODK	Smartphone loaded with ODK enrollment survey	CI
8. Return the allocation cards for participants who have been enrolled to the FS or PI weekly or at other agreed-upon frequency	Enrolled participants' allocation cards	CI
9. Safely store allocation cards for enrolled participants. These may be destroyed once enrollment is complete	Enrolled participants' allocation cards	Data Analyst
10. If the allocation envelope is opened but the participant is not enrolled, return the allocation card to the FS or PI	Allocation card	CI

Step	Equipment/materials	Responsible
11. Allocations for envelopes that have been opened but no participant was enrolled should be returned into the pool as follows: • Randomly select a sealed allocation envelope from the remaining pool of sealed allocation envelopes • Unseal this envelope • Switch the allocation IDs of the two cards. Ensure that the allocation IDs are changed on the card • Place the revised allocations into sealed envelopes and stamp the envelopes. Ensure that the correct allocation ID is recorded on the outside of the allocation envelope • Return the revised allocation envelope into circulation or to the pool of unsealed allocations, as applicable	Allocation cards	Study Coordinator/Data analyst
12. If a CI exhausts the allocation envelopes from the assigned Block provide the CI with allocation envelopes from another Block	Allocation envelopes	Field Supervisor

Appendix 7.8. MSBC screening form

Interviewer: _____ Date of Interview: DD/MM/YYYY

Compound name: _____ Village #_____ Compound#_____

EXCLUSION CRITERIA

For mother/caregiver: **IF YES FOR Q1…CHILD IS NOT ELIGIBLE**

1. Is the mother/infant enrolled in the M-SIMI study (KEMRI/SERU/CGHR/003/3311)? .....YES…….NO

   If YES, child is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT

INCLUSION CRITERIA

For mother/caregiver: **IF NO FOR Q2, Q3 or Q4…CHILD IS NOT ELIGIBLE**

2. Were you enrolled in the MSIMU study? ……YES…….NO

   If NO, caregiver is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT

3. Are you the caregiver of an infant aged 10 months or older and who was born after you joined the MSIMU study (MSB child)? ……YES…….NO

   If NO, caregiver is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT

4. Can the vaccination status of that child be verified using the MCH booklet? .....YES…….NO

   If NO, child is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT

For CI: **IF NO FOR Q5 or Q6…CHILD IS NOT ELIGIBLE**

5. Was the vaccination status of MSIMU child verified using MCH booklet? ……YES…….NO

   If NO, caregiver is ineligible to enroll. Please stop the interview here. SKIP TO LAST Q AND SUBMIT

IF MOTHER IS ELIGIBLE, TAKE INFORMED CONSENT IN APPROPRIATE LANGUAGE

6. Did the mother provide informed consent? ……YES…….NO

If NO, caregiver is ineligible to enroll. Please stop the interview here.SKIP TO LAST Q AND SUBMIT

OTHERWISE, CI SHOULD CONGRATULATE MOTHER ON BEING ELIGIBLE FOR MSBC STUDY AND TAKE INFORMED CONSENT

Appendix 7.9. MSBC questionnaire

○ Asembo ○ Gem

CI [ ][ ]   Visit date [ ][ ] / [ ][ ] / [ ][ ][ ][ ]

Compound name:

[ ]

1 GPS Coordinates: ______________________________

2 Child's First Name: ______________________________

3 Child's middle Name: ______________________________

4 Child's surname: ______________________________

5

Child's sex

○ Male ○ Female

6. Child's DOB according to Mother/caretaker [__][__] / [__][__] / [__][__][__][__]

7. Is DOB in MCH book the same as the mother reports….YES…NO…..MCH BOOKLET NOT PRESENT

7.1. If NO…what is the child DOB according to the MCH?[__][__] / [__][__] / [__][__][__][__]

8. Child's Location ID: [__][__][__]---[__][__][__][__]---[__][__]---[__][__][__]

9. Caregiver First Name: [__][__][__][__][__][__][__][__][__][__][__][__]

10. Caregiver Last Name: [__][__][__][__][__][__][__][__][__][__][__][__]

11. Caregiver DOB: [__][__] / [__][__] / [__][__][__][__]

12. Is the caregiver of the MSIMU subsequent born child the same as the caregiver of the MSIMU child…YES…NO…. If NO, go to 12.1

12.1Relationship of primary caregiver to MSBC child (Circle One)….

MOTHER….FATHER….GRANDMOTHER…….STEPMOTHER…….AUNT…...O

THER (SPECIFY)_____

FOR ALL PARTICIPANTS, COMPLETE THE REST OF THE QUESTIONNAIRE

13. Do you own a mobile phone? ….YES……..NO…***If YES, SKIP to Q14***

13.1. If no, whose mobile phone do you use to receive SMS and MPESA? (CAN CIRCLE MORE THAN ONE)..... HUSBAND…....OTHER PERSON IN HOUSEHOLD……..OTHER PERSON IN COMPOUND……..NEIGHBOR……..….CI

Immunization history - *ask care-taker*

16. **Bende nyathini ne oyudo chanjo mar geng'o tuoche, e klinik kata kane sirikal okelo chanjo mar nyithindo e gweng?**
Did (name) ever receive any vaccination to prevent him/her getting diseases, including vaccination received in a national immunisation day campaign?) ----○ Ee (Yes) ○ Ooyo (No) ○ *Akia (Don't know)

*If**"YES" or"Don't Know"**, then Skip to Question #18 If "**NO**" go to Q17

17. **Ka ooyo to ere gimomiya pod ok oter nyathi chanjo? (**If No, what's the reason?)

○ nengo ne malo (cost was high) ○ kar chanjo bor (vaccination site far) ○ Din ok oyie (against faith/religion)
○ aluoro (fear of vaccination) ○ chanjo ok tii (don't work for me) ○ NA
○ Ier machielo (other, specify)

18. **Be in gi kadi mar Klinik ma ondikie chanjo mosechiw?**
(Do you have a card where (name's) vaccinations are recorded down? **Ka iyei, nyisa go?** (if YES, may I see it please?) ○ Ee (Yes, seen) ○ Eee, ok aneno(Yes, not seen) ○ Ooyo, onge kad (No card) ○ mother not found, no card

If card is NOT AVAILABLE, CHILD IS INELIGBLE. SKIP TO THE LAST Q AND SUBMIT;

If AVAILABLE, observe and read from the card the following immunization questions

Fill the "FROM CARD" column using the information from the card, in the table below. Fill HF using codes below

	FROM CARD	
Vaccine	Given: Yes/No	Date Received
BCG		
Polio-Birth		
Polio1		
Polio2		
Polio3		
Penta1		
Penta2		
Penta3		
PCV1		

PCV2			
PCV3			
Measles			Measles vaccine health facility

19. in which clinic was vaccines given?

the key below for numbers against the health facilities, where the child got the vaccinations mentioned above, to fill in the table above, where licable.

● 01. Abhidha ● 02. Lwak Mission ● 03. Mahaya ● 04. Ongielo ● 05. Saradiddi ● 06. Nyagoko

● 07. Ndori ● 08. Akala ● 09. Aluor ● 10. Njejra ● 11. Rera ● 12. Nyawara

● 13. Uriri ● 14. Bondo District Hospital ● 15. Madiany Sub District Hospital ● 16. Matangwe Hospial

● 17. Siaya District Hospital ● 18. Yala Sub District Hospital ● 19. Nyanza Provincial Hospital (Russia)

● 20. Kisumu District Hospital ● 21. Bar-Olengo ● 22. Ting'-Wang'i ● 23. K'otieno ● 24. Ng'iya Mission

vaxwhother

● 26. Mamoko/Other (ler/specify) 1. [ ] ● 25. Nyathengo ● 27. UNK

vaxwhothe2

● 28. Mamoko/Other (ler/specify) 2. [ ] ● 29. Obaga

● 30. Masala ● 31. Asayi ● 32. Gongo ● 33. Masogo ● 34. Ogero ● 35. Sirembe

● 36. Wagai ● 37. Kogelo ● 38. Bar Agulu ● 39. Mulaha

22. Did anybody, such as a CHW, remind you about any of [NAME'S] immunization or do anything to encourage you to take [NAME] for vaccination? …..YES ……NO

22.1. If **YES**, who reminded or encouraged you? _____

23. Apart from the MSIMU study, did you participate in any other studies that try to improve the number of children receiving vaccines? …..YES ……NO

23.1. If **YES**, name of study? _____

24. How many CHILDREN UNDER 5 YRS of AGE, slept in this house last night? [___] [___]

24.1. What is the birth order of the **MSB** child (2=second born)?

….2nd….3rd….4th….5th….6th…..7th….>7

26. How many persons are sleeping in the household regularly? This includes children under 5 [__] [___]

27. How many ANC visits did you make in your last pregnancy? [___] [___] or NA

27.1. If>=1 visit, how many of ANC visits were in 1st trimester of last pregnancy. [_] [_] or DK

28. Number of tetanus toxoid immunizations mother received in last pregnancy? [___] [___] or DK

29. Where was the MSB child born?....AT HOME WITH NO SBA……AT HOME WITH SBA/MIDWIFE..... ……..HEALTH FACILITY (Name:_____)……DK

SECTION 4. **Marital status Of Mother: Where individual is less than 15 years old, Fill N/A for**

30 What is your/name current marital status? - - ○ Single ○ Married/cohabiting ○ Divorce/separated ○ Widowed ○ Don't know ○ N/A

31 *(Ask either sexes)* If currently married/cohabiting, what type of marriage are you/name in? ---------- ○ Monogamous ○ Polygamous ○ Don't know ○ N/A

QUESTIONS ABOUT THE CHILD WHO WAS ENROLLED IN MSIMU

THE FOLLOWING FOUR QUESTIONS ARE TO BE COMPLETED BY THE CI:

32. In which MSIMU arm was the mother enrolled? …..ARM 1 (Control) …..ARM 2 (SMS) …..ARM 3 (SMS+75KES) …..ARM 4 (SMS+200KES)

33. What was the study ID for the infant enrolled in MSIMU? (Please type)

34. What was the DOB for the infant enrolled in MSIMU? …..MM/DD/YYYY

35. What is the first name of the child who was enrolled in MSIMU? (Please type)

QUESTIONS TO BE ANSWERED BY THE MOTHER

36. Do you have a card where [NAME'S] vaccinations are recorded? …..YES…..NO

36.1. **IF YES,** CI please answer: did the child receive a second dose of measles vaccine (MCV2)? …..YES….NO

36.1.1. **IF YES,** CI please record the date of vaccine. (Please type)

36.2. **IF NO,** did the child receive a second dose of measles vaccine?.....YES…..NO

36.2.1. **IF YES,** what was the age of the child (in months) when they received the second dose of measles vaccine? (Please type)

COMMENTS_____

Appendix 7.10. MSBC consent form in Dholuo

KEMRI/CDC AND JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Nying Nonro: Evaluation of the impact of short-term incentives and text message reminders on long-term parental vaccine-seeking practices: A vaccination coverage survey among MSIMU subsequent born children (The MSBC study)

Jotim Nonro: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigaor, KEMRI/CGHR; Joyce Were, KEMRI/CGHR; David Obor, KEMRI/CGHR; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Gwenge mag nonro: Gem kod Rarieda, sub-counties ei Kaunti ma Siaya

PI Version Date: 12th May 2017

Flesch-Kincaid readability level: 7.5
Luo version

CHAKRUOK

Nyinga en ……...…….. to atiyo gi jotim nonro ma owuok KEMRI/CGHR kod Johns Hopkins kar tiegruok mar weche mag ngima manitie America. Wan kae mondo wang'e kabende diher donjo e nonro mang'iyo kaka jonyuol manene jokanyo e nonro mar MSIMU tero nyithindgi e chanjo. Wabiro iri nikech na in achiel kuom jogo mana gin jokanyo mar MSIMU.

Bende iyiena mondo awach kodi ewi nonro maluo MSIMU ni? Ka iyie, ahi wachoni mang'eny kuom gima watimo . Inyalo yiero donjo kata tamori.

Bende iyiena mondo awach kodi ewi nonroni?
Ka iyie:

Gima omiyo itimo nonroni

Watimo nonroni mondo wang'e kaka jonyuol tero nyithindgi e chanjo tok bedo e nonro mar MSIMU. Wadwaro ng'eyo ka timbe motenore gi tero nyithindo e chanjo lokore bang' bedo jakanyo e nonro machalo gi MSIMU, matiyo gi simu, ote machuok kod pesa matin mondo ojiw jonyuol oter nyithindo e chanjo e seche ma owinjore. Nonroni ber nikech chanjo nyalo geng'o tuoche kod tho ne nyithindo, to inyalo ti kod simu mondo nyithindo mang'eny oyudi chanjo. Nonroni biro konyowa duoko penjo manene openji bang' kanewachiwo duoko mar MSIMU ni jotim nonro mamoko kaachiel gi jotelo mag thieth.

Ang'o ma omiyo ikwayi mondo idonji e nonroni?

Wakwayi ni mondo idonji e nonroni nikech nene in achiel kuom jogo manene odonjo e nonro mar MSIMU to in gi nyathi madirom ja dweche 12. Wageno ni mine 1440 manene odonjo e nonro mar MSIMU biro donjo e nonroni.

Chenro mar nonro

- Ka iyie donjo e nonroni, wabiro kwayi mondo ikonwa nying nyathi kod tarik mar nyuolne. Wabiro penji penjo ma otenore kodi, ewi chanjo mar nyathini, ngimane, joodu kod pachi e weche mag chanjo. Wabiro kwayo mondo wane bug nyathi mar klinik. Magi duto biro kao saa achiel.
- Wabiro ng'iyo bug klinik mar nyathi manene en jakanyo mar MSIMU kendo wapenji ewi chanjo mane nyathino oyudo bang' MSIMU.
- Wabiro keto kanyakla weche ma imiyowa gi weche moko manene imiyowa e kinde manene watimo nonro mar MSIMU.

Rach kata hinyruok ma dibedie

Maricho manyalo timore ne ng'at ma nitiere e nonroni tin. Jomoko nyalo neno ni penjo mipenjogi kawo sechegi mang'eny. E nonro mathoth, seche moko weche ma jachiwre ochiwo nyalo chopo ni joma ok gin jotich nonro. Wabiro temo matek mondo kik mano timre e nonroni.

Ber madibedie

Wabiro ori e klinik machiegni kodi ka nyathini pok oyudo chanjo te ma onego omiye e kinde ma orwako dweche apar gi ariyo. Ok wabi chiwo pes wuoth kata chudo moro amora ma idwaro e klinik. Chanjo nyalo geng'o tuoche kod tho. Wabiro miyo migao mar ngima dwoko mar nonroni

mondo okony e chanjo mar nyithindo ei Kenya. Dwokogi bende nyalo konyo nyithindo moko mag Africa mondo oyud chanjo e saa ma owinjore.

Keto wechegi ma kiling'ling'

Wabiro temo mondo waket wechegi ma kiling'ling' kaka nyalore. Ka iyiero donjo e nonroni to ibiro miyi namba mar nonro. Nambani ibiro keti e gik nonro duto makar nyingi. Gik mitiyogo e nonro ibiro kan ei kabat molor kod kiful kata e kompyuta man gi passwad manitie e senta KEMRI/CGHR, Kisian. Ok wabi tiyo gi nyingi kata nambani mar nonro e gano kata e oboke moro amora ewi nonroni. Wabiro keto nyingima opondo ma ng'ato ang'ata ma ok en jatich mar nonroni ok nyal nwang'o.

Chiwruok e nonroni

Donjo e nonroni en yiero mari, omiyo ok ochuno ni nyaka idonji e nonroni. Bende inyalo yiero mondo iwuogi e nonroni e saa moro amora bang' ka isedonjo. Ok ochuno ni nyaka idwok penjo moro amora ma ok idwar dwoko. Yiero ni mondo idonji kata kik idonji e nonroni ok bimoni yudo thieth kata mono nyathini yudo chanjo e klinik machiegni kodi. Kapok iyiero mar donjo e nonroni, bed thuolo mar penjo ewi gimoro amora.

Ng'ano ma anyalo tudora godo ka an gi penjo kata ywagruok?
Ka in gi penjo kata ywagruok kaluore gi yiero mari mar donjo e nonroni to tudri kod Benard Omondi Ochieng' , jachung' mar nonroni KEMRI/CGHR Kisian , Kisumu-Busia Highway, P.O. Box 1578, 40100. Kata go ne simu e namba 0722245636/ 057-2022929 EXT 413. Ka iparo ni iyudo hinyruok e nonroni e yo moro amora, kata ka in gi penjo ewi ratiro mari kaka jachiwre e nonroni to idwaro tudori gi nga't ma ok en achiel kuom jotich nonroni, tudri kod: Jagoro, KEMRI Ethics Review Committee, P.O. Box 54840 00200, Nairobi; Namba simu: 020-2722541,0722205901, 0733400003; Email: seru@kemri.org.

Bende in gi penjo moro amora ma inyalo penja? Bende diher mar donjo e nonroni?

Seyi mari (kata alama) mantiere piny mar oboke ni nyiso ni:
- Osenyisa gima omiyo itimo nonroni, chenro, mabeyo madibedie kod maricho.
- Osemiya thuolo mar penjo ka pok aketo seyi.
- En yierona donjo e nonroni.

Nying nyathi: _____ Tarik mar nyuol: _____

Nying mar Janyuol/Jarit: _____

Seyi mar Janyuol/Jarit: _____ Tarik:_____

(Ket "X" ka okinyal keto seyi)

(Ket alama mar lith lwedo maduong'ka ok inyal ndiko "X")

Nying mar jakaw ayie: _____

Seyi mar jakaw ayie: _____ Tarik: _____

(Kuom joma oknyal somo, janeno maok en achiel kuom anyuola kata jatich nonroni, nyaka ket seyi)

Osesom kendo olerne ng'at ma nyinge ondik malo kanyo oboke mar ayie, aneno ka oyie gi keto alama.

Nying janeno: _____

Seyi mar janeno: _____ Tarik: _____

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

Appendix 7.11. MSBC consent form in Kiswahili

KEMRI/CDC NA SHULE YA AFYA YA UMMA YA JOHNS HOPKINS

WARAKA WA IDHINI

Kichwa cha Utafiti: Majaribio ya kuthibitisha athari ya vikumbusho vya runununu na ruzuku kwa taratibu za wazazi kuwapeleka watoto kupata chanjo: Dodoso la viwango vya uenezaji wa kinga baadhi ya watoto waliozaliwa kufuata utafiti wa MSIMU (The MSBC Study)

Wapelelezi: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigaor, KEMRI/CGHR; Joyce Were, KEMRI/CGHR; David Obor, KEMRI/CGHR; Daniel Feikin, CDC/Division of Viral Diseases; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Eneo ya utafiti: Kaunti ndogo za Gem na Rarieda, Kaunti ya Siaya

Tarehe ya makala ya Mpelelezi mkuu: 12 Mei 2017

Flesch-Kincaid readability level 7.5

Toleo la Kiswahili

Utangulizi

Jina langu ni _____ ninafanya kazi na watafiti kutoka KEMRI/CGHR na shule ya afya ya umma ya Johns Hopkins iliyo kule Marekani**. Tuko hapa kwa sababu ulijijumuisha na utafiti wa "mobile solutions for immunization" yaani MSIMU. Je, tuna ruhusa yako ili kukueleza kuhusu utafiti unaofuatilia utafiti wa MSIMU? Ukikubali, tutakueleza kuhusu utafiti huo kisha utaamua kama ungependa kujijumuisha.**

Je, umenipa ruhusu ili kukueleza kuhusu utafiti unaofuatilia utafiti wa MSIMU?

Kama ndio:

Tuko hapa kujua ikiwa ungependa kujumuishwa katika utafiti unaolenga taratibu za wazazi kuwapeleka watoto kupata chanjo. Nitakuelezea kwa kina kuhusu utafiti huu. Ikiwa kuna jambo lolote hauelewi, tafadhali niulize ili nikuelezee zaidi. Mwishowe, utakuwa na nafasi ya kuuliza maswali. Baada ya kujibu maswali yako, nitakuuliza ikiwa unataka kujumuishwa katika utafiti huu.

Kusudi la utafiti

Tunafanya utafiti huu ili kuelewa taratibu za wazazi kupeleka watoto kupata chanjo baada ya kujiunga na utafiti wa MSIMU. Tungependa kuchunguza kama taratibu za wazazi kupeleka watoto kupata chanjo hubadilika baada ya kujiunga na tafiti, kama vile utafiti wa MSIMU,

ambazo hutumia rununu, vikumbusho vya rununu, na ruzuku kuhimiza wazazi kuwapatia watoto wao chanjo wakati unaofaa. Utafiti huu ni muhimu kwa sababu chanjo zinaweza kukinga watoto dhidi ya ugonjwa na hatimaye kifo, na rununu zinaweza kusaidia watoto wengi kupata chanjo. **Utafiti huu utatusaidia katika kujibu maswali ambayo yamejitokeza kutoka wanasayansi na maafisa wa afya baada ya kuwasilisha matokeo ya utafiti wa MSIMU.**

Kwa nini unaulizwa kushiriki?

Tunakuuliza kushiriki katika utafiti huu kwa sababu ulijijumuisha na utafiti wa MSIMU na pia ulipata mtoto baada ya kushiriki katika utafiti wa MSIMU na mtoto huyo ana umri wa miezi 12 au zaidi kwa wakati huu. Tunatarajia wazazi na watoto 1440 waliojishirikisha na MSIMU kushiriki katika utafiti huu.

Utaratibu wa utafiti

- Ukijijumuisha katika utafiti huu, tutakuuliza jina la mtoto na tarehe ya kuzaliwa. Tutauliza maswali kukuhusu. Pia tutauliza maswali kuhusu chanjo ambazo mtoto amepewa, afya ya mtoto, jamii yako na maoni yako kuhusu chanjo. **Tutaangalia kitabu cha kliniki cha mama na mtoto**. Shughuli hizi zitachukua takriban lisaa limoja.

- **Tutaangalia kitabu cha kliniki cha mama na mtoto kilichotumiwa kwenye mtoto uliyejumuisha katika utafiti wa MSIMU** na pia tutauliza maswali kuhusu chanjo zozote alizopata baada ya utafiti wa MSIMU kuisha.

- Tutajumuisha taarifa zako, taarifa za mtoto aliyehusishwa katika utafiti waMSIMU na taarifa za jamii yako kutoka rekodi za utafiti wa MSIMU.

Mabaya au madhara yanayoweza kutokea

Madhara yanayoweza kutokea kwa sababu ya utafiti huu ni haba. Wengine wanaweza kuhisi maswali yanayouulizwa yanachukua muda wao mwingi. Inawezekana kwamba habari zako zitaweza kufikiwa na mtu ambaye sio mmoja ya watafiti. Hata hivyo tutajaribu tuwezavyo ili tuzuie habari zako kufikiwa na watu ambao hawahusiki.

Mazuri yanayoweza kutokea

Ikiwa mtoto wako hatakuwa amepata chanjo zinazofaa katika umri wa miezi 12, tutakukuelekeza kwa kliniki kilicho karibu nawe lakini hatutagharamia malipo yoyote. Tutapea matokeo ya utafiti huu Wizara ya Afya ili isaidie kuboresha kupatikana kwa chanjo nchini Kenya. Pia, matokeo hayo yataweza kusaidia watoto wengi barani Afrika kupata chanjo wakati mwafaka.

Usiri

Tutajaribu kuweka yale utakayotueleza kwa siri ipasavyo. Baada ya uamuzi wako wa kushiriki katika utafiti huu, utapewa nambari ya utafiti ambayo itatumika kwa vifaa vyote vya utafiti

badala ya kutumia jina lako. Vifaa vyote vitawekwa ndani ya kabati inayofungwa na kifuli au kwenye tarakilishi iliyo na nambari ya siri ya KEMRI/ CGHR. Jina lako au chochote kile kinachoweza kukutambulisha hakitatumiwa katika ripoti za utafiti huu. Hatutafichua jina lako kwa mtu yeyote asiye mfanyikazi wa KEMRI/ CGHR anayehusika na utafiti huu.

Kushiriki katika utafiti huu

Kushiriki katika utafitu huu ni kwa hiari yako, kwa hivyo sio lazima ushiriki katika utafiti huu. Unaweza kujiondoa katika utafiti huu wakati wowote licha ya kuanza. Pia, sio lazima ujibu swali lolote usilotaka kujibu. Huduma yoyote ya afya unayopata katika kliniki ikiwemo chanjo kwa mtoto wako haitaathiriwa kwa sababu ya uamuzi wako wa kushiriki au kutoshiriki katika utafiti huu. Kabla ya kufanya uamuzi wa kushiriki au kutoshiriki katika utafiti huu, kuwa huru kuuliza swali lolote.

Ni nani ambaye nitawasiliana naye ikiwa nina maswali au malalamishi?

Ikiwa una maswali au malalamishi juu ya kushiriki katika utafiti huu, wasiliana na Benard Omondi Ochieng', msimamizi wa utafiti huu wa KEMRI/ CGHR, Kisumu-Busia Higway sanduku la posta 1578 40100 au nambari ya simu 0722245636/057-2022929 EXT 413. Ukiumia kwa njia yoyote ile au ukiwa na maswali kuhusu haki yako kama mshiriki katika utafiti na unataka kuzungumza na mtu asiyehusika moja kwa moja na utafiti huu, tafadhali wasiliana na katibu, KEMRI Ethics Review Committee, sanduku la posta 54840 00200, Nairobi, nambari ya simu: 020 2722541, 0722 205901, 0733 400003; barua pepe: seru@kemri.org

Je, una swali lolote?Je, ungependa kushiriki katika utafiti huu?

Kutia sahihi (au alama) kwenye fomu hii inamaanisha:

- Nimefahamishwa juu ya kusudi, taratibu, faida na madhara ya utafiti huu.
- Nimepewa nafasi ya kuuliza maswali kabla ya kutia sahihi.
- Nimekubali kushiriki katika utafiti huu kwa uamuzi wangu.

Jina la mtoto: _____Siku ya kuzaliwa: _____

Jina la Mzazi/Msimamizi: _____

Sahihi ya Mzazi/Msimamizi:_____ Tarehe: _____

(Weka "X" kama huwezi kuandika)

(Tia alama ya kidole gumba kama huwezi kuweka "X")

Jina la anayechukua makubaliano: _____

Sahihi ya anaye chukua makubaliano: _____ Tarehe: _____

(Kwa wale wasioweza kusoma, msimamizi lazima akague na kuweka sahihi hapo chini)

Fomu ya makubaliano imesomwa na kuelezwa kwa aliyetajwa hapo juu na nimetazama anapoweka alama ya kukubaliana.

Jina la Shahidi:_____

Sahihi ya Shahidi: _____Tarehe: _____

Peana kopi moja kwa mshiriki na uweke kopi moja kwenye rekodi za utafiti

Appendix 7.12. MSBC consent form in English

KEMRI/CDC AND JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH

INFORMED CONSENT DOCUMENT

Study Title: Evaluation of the impact of short-term incentives and text message reminders on long-term parental vaccine-seeking practices: A vaccination coverage survey among MSIMU subsequent born children (The MSBC study)

Investigators: Dustin Gibson, Principal Investigator, Johns Hopkins School of Public Health (JHSPH); Benard Ochieng, Co-Principal Investigator, KEMRI/CGHR; Joyce Were, KEMRI/CGHR;David Obor, KEMRI/CGHR; Eunice W. Kagucia, JHSPH; Katherine O'Brien, JHSPH; Kyla Hayford, JHSPH

Study Location: Gem and Rarieda sub-counties, Siaya County
PI Version Date: 12th May 2017

Flesch-Kincaid readability level: 7.5
English version

Introduction
My name is .....and I am working with researchers from KEMRI/CGHR and Johns Hopkins School of Public Health; USA. **We are approaching you because you took part in the mobile solutions for immunization(MSIMU) study. Do we have permission to talk to you about a follow-up survey to the MSIMU study? If you say yes, we will describe the follow-up survey and you can choose to take part or not to take part in the survey.**

Do I have permission to talk to you about the follow-up survey?

If yes:

We are here to find out if you would like to be in a research study looking at vaccination practices of caregivers after participation in the mobile solutions for immunization (MSIMU study). I am going to give you some information about what we are doing. If there is anything you don't understand please ask me to stop and I will take time to explain. There will be time at the end for you to ask questions. After answering your questions, I will ask you if you want to join the study.

Purpose of study

The purpose of this study is to understand caregivers' vaccination practices after participating in the MSIMU study. We want to see if vaccination practices change after participation in studies like MSIMU which use mobile phones, reminders and small incentives to encourage mothers to vaccinate their children on time. This study is important because vaccines can protect infants from getting sick and dying and mobile phones can help to get more children vaccinated. **This**

study will help us address questions that have come up after we shared results of the MSIMU study with scientists and health officials.

Why you are being asked to take part

We are asking you to join this study because you participated in the MSIMU study and you gave birth to a child after the MSIMU study who is now aged 12 months or older. We think about 1440 mothers from the MSIMU study will take part in this study.

Study Procedures

- If you join this study, we will request you to provide your child's name and date of birth. We will ask questions about you. We will also ask questions about your child's vaccinations, health, your household, and your thoughts about vaccination. **We will look at your maternal and child health card**. This should take about 1 hour.

- **We will look at the maternal and child health card of the child that participated in the MSIMU study** and ask you questions about vaccinations that the child received after the MSIMU study.

- We will link information about you, the child that participated in the MSIMU study and your household from the MSIMU study.

Potential Harms, Injuries, Discomforts, Inconveniences or Risks
The risks from being in this study are small. Some people might find the questions asked of them take too much time out of their day. With any research study, there is a small chance your personal information may be revealed to people not in the study. We will do our best to prevent this.

Potential Benefits
We will refer you to nearest clinic if your child does not have all vaccines by 12 months of age, but will not provide transportation or pay for any healthcare costs. Vaccines can prevent disease and death. We will give the results of the study to Ministry of Health to help improve child vaccinations in Kenya. The results might also help other African children to get their vaccines on time.

Confidentiality
We will try to keep your personal information as private as possible. After you decide to take part, you will receive a study number. This number will be used to label all study materials, rather than using your name. All study materials will be kept in a locked cabinet or password protected computer at the KEMRI/CGHR center in Kisian. Your name and identity will not be shown in any reports about this study. We will not share your name with anyone else besides the KEMRI/CGHR staff involved in this study.

Participation
Your choice to participate in this study is voluntary, therefore, you do not have to take part in this study. You can decide to stop being part of this study at any time after you start. You don't have to answer any questions you don't want to. The health care you receive at area clinics,

including the vaccines your child gets, will not be affected by your decision to take part, or not take part, in this study today. Before deciding whether you want to take part, please feel free to ask any questions.

Who do I call if I have questions or complaints?
If you have questions or complaints as a result of being in this study please contact Mr. Benard Ochieng, Co-Principal Investigator at KEMRI/CGHR Kisian, off Kisumu-Busia Highway, P.O. Box 1578 40100 or call 0722245636/057-2022929 EXT 413057-2022929 EXT 413. If you feel you have been harmed in any way, or if you have questions about your rights as a research subject, and want to talk about the study with someone who is not directly involved in this research project, please contact The Secretary, KEMRI Ethics Review Committee, P.O. Box 54840-00200, Nairobi; Tel: 020-2722541, 0722205901, 0733400003; Email address: seru@kemri.org

Do you have any questions for me? Do you want to take part in this research study?

Your signature (or mark) on this form means:

- I have been informed about the study's purpose, procedures, possible benefits, and risks.
- I have been given the chance to ask questions before I sign.
- I have agreed to be in this study of my own free choice.

Name of child:_____ Date of birth: _____

Name of Parent/Guardian: _____

Signature of Parent/Guardian: _____ Date:_____

(Put "X" if cannot sign name)

(Put a thumb print if cannot put "X")

Name of Person administering the consent: _____

Signature of person administering consent: _____

Date: _____

(For those who are not able to read, a witness, who is not a family member or study staff, must verify and sign below.)

The consent form has been read and explained to the person named above and I watched him/her indicate consent with a mark.

Name of Witness: _____

Signature of Witness: _____Date _____

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

Appendix 7.13. Curriculum vitae

CURRICULUM VITAE

E. Wangeci Kagucia

PERSONAL DATA

Business Address:
International Vaccine Access Center
415 N Washington St.
Baltimore, MD 21231
Phone: 617-281-4853
Email: ekagucia@jhu.edu

EDUCATION AND TRAINING

PhD/ Expected 2018	**Johns Hopkins Bloomberg School of Public Health (JHSPH). Baltimore, MD** Department of International Health. Division of Global Disease Control & Epidemiology Thesis title: *mHealth interventions to improve measles vaccination coverage and timeliness: an assessment of the immediate and long-term impact on vaccine-seeking in rural Kenya* Thesis co-advisors: Laura Hammitt, MD and Dustin Gibson, PhD
MHS/ 2007	**Johns Hopkins Bloomberg School of Public Health (JHSPH). Baltimore, MD** Department of International Health. Division of Disease Prevention & Control
Certificate/ 2006	**Johns Hopkins Bloomberg School of Public Health (JHSPH). Baltimore, MD** Vaccine Sciences and Policy Certificate
BA/ 2005	**Wellesley College. Wellesley, MA** Double major in Biological Sciences and Africana Studies
Study abroad/ 2004	**University of Cape Town, Cape Town, South Africa** Coursework in statistics, history and African studies

PROFESSIONAL EXPERIENCE

Sep 2014 – Present **Graduate Research Assistant**
May 2011 – Aug 2014 **Research Associate**
Feb 2011 – May 2011 **Senior Research Program Coordinator II**
International Vaccine Access Center (IVAC), Johns Hopkins Bloomberg School of Public Health. Baltimore, MD

- Assist Principal Investigators in conduct of the following projects:
    - Randomized controlled trial of the impact of mobile phone-delivered unconditional incentives and reminders to improve measles vaccination coverage and timeliness in Western Kenya and post-trial follow-up of the Mobile Solutions for Immunization (M-SIMU) study. Responsibilities: coordinate study, assist in protocol development, liaise with study partners

in Kenya, communicate with the IRB, conduct data analysis using Stata, interpret data and communicate results (2016 - present)
- Evaluation of the accuracy and feasibility of oral fluid and dried blood spots for monitoring effective vaccination coverage. Responsibilities: coordinate study, liaise with study partners in Kenya, assist in preparation of progress reports to donor, and conduct data analysis using Stata (2014 – present)
- Randomized controlled trial of the impact of mobile phone-delivered travel subsidies and reminders to improve childhood immunization rates and timeliness in Western Kenya (the M-SIMU study). Responsibilities: liaise with Kenya study partners, communicate with the IRB, assist in preparation of progress reports to donor, and assist with interpretation and communication of findings (2013-2016)
- The Pneumonia Etiology Research for Child Health (PERCH) – a multi-site study of pneumonia etiology. Responsibilities: coordinate IRB communication at central coordination center and with seven sites, provide operational support to sites, coordinate meetings of the study Executive Committee including development of meeting materials, conduct analysis of pertussis epidemiology in PERCH sites and contribute to manuscript write-up (2013-2016)
- Assessing pneumococcal serotype epidemiology following introduction of pneumococcal conjugate vaccine (PCV7). Responsibilities: develop data abstraction instruments, organize data in a standardized format, contact and follow-up investigators at more than 30 sites, assess data quality, analyze data using Stata, assist in manuscript write-up (2011-2013)

Jun 2015 – Oct 2015 **Patient Safety Intern, MedImmune/Astrazeneca, Gaithersburg, MD**
Kelly Services, INC.
- Conducted analysis comparing the safety of quadrivalent influenza vaccines versus trivalent influenza vaccines using the Vaccine Adverse Events Reporting System (VAERS) data

Feb 2009 – Feb 2011 **Senior Research Program Coordinator II**
May 2007 - Feb 2009 **Senior Research Program Coordinator**
Center for Immunization Research, Johns Hopkins Bloomberg School of Public Health. Baltimore, MD

Principal responsibilities
- Coordinated Phase I Dengue vaccine trials within FDA and ICH GCP guidelines including: recruitment and screening of volunteers, coordination of study visits, data entry, quality assurance/quality control, maintenance of study essential documents, communication with the Sponsor and Sponsor representatives, assisting in the preparation of semi-annual and annual study reports.
- Managed regulatory processes for study protocols including Phase I and Phase II Dengue, Malaria and West Nile vaccine trial protocols as well as a center-wide general screening protocol.

- Conducted Good Clinical Practice (GCP) training workshops for vaccine trials, including instruction and development and of didactic lectures, interactive exercises and pre-training and post-training evaluations.

PROFESSIONAL ACTIVITIES

Society Membership

2010	Certified Clinical Research Professional (CCRP), Society for Clinical Research Associates (SoCRA)
2007	Member, Delta Omega Honorary Society in Public Health, Alpha Chapter

EDITORIAL ACTIVITIES

Peer review activities

2015	*Tropical Medicine and Health*
2012	*Microbial Drug Resistance*

HONORS AND AWARDS

2017	Third place poster, Vaccine Day, Johns Hopkins Bloomberg School of Public Health (JHSPH)
2016	JHU Global mHealth Initiative Scholarship to attend the 2016 Global Digital Health Forum, JHSPH
2016	Clements-Mann Fellowship, Department of International Health, JHSPH
2014	Academic Scholarship, Department of International Health, JHSPH
2005	Academic Scholarship, Department of International Health, JHSPH
2005	Durant Scholar *magna cum laude*, Wellesley College
2001-2005	Davis United World College Scholar, Wellesley College
2001	First Year Distinction, Wellesley College

PUBLICATIONS

2017	DeLuca AN, Hammitt LL, Kim J, Higdon MM, Baggett HC, Brooks WA, Howie SRC, Deloria Knoll M, Kotloff KL, Levine OS, Madhi SA, Murdoch DR, Scott JAG, Thea DM, Amornintapichet T, Awori JO, Chuananon S, Driscoll AJ, Ebruke BE, Hossain L, Jahan Y, **Kagucia EW**, Kazungu S, Moore DP, Mudau A, Mwananyanda L, Park DE, Prosperi C, Seidenberg P, Sylla M, Tapia MD, Zaman SMA, O'Brien KL, The PERCH Study Group. Safety of the induced sputum procedure in children hospitalized with severe or very severe pneumonia. *Clin Infect Dis* **2017**; 64(suppl 3):S301–8
2017	Gibson DG, Ochieng B, **Kagucia EW**, et al. Mobile phone-delivered reminders and incentives to improve childhood immunisation coverage and timeliness in Kenya (M-SIMU): a cluster randomised controlled trial. *Lancet Glob Heal*. 2017;5(4):e428-e438.
2016	Barger-Kamate B, Deloria Knoll M, **Kagucia EW**, et al. Pertussis-Associated Pneumonia in Infants and Children From Low- and Middle-Income Countries Participating in the PERCH Study. *Clin Infect Dis* 2016;63(suppl 4):S187-S196. doi:10.1093/cid/ciw546

2016 Gibson DG, **Kagucia EW**, Ochieng B, Hariharan N, Obor D, Moulton LH, Winch PJ, Levine OS, Odhiambo F, O'Brien KL, Feikin DR. The Mobile Solutions for Immunization (M-SIMU) Trial: A Protocol for a cluster randomized controlled trial that assesses the impact of mobile phone delivered reminders and travel subsidies to improve childhood immunization coverage rates and timeliness in western Kenya. *JMIR Research Protocols*. 2016; 5(2):e72

2015 Gibson DG, Ochieng B, **Kagucia EW**, Obor D, Odhiambo F, O'Brien KL, Feikin DR. Individual level determinants for not receiving immunization, receiving immunization with delay, and being severely underimmunized among rural western Kenyan children. *Vaccine*. 2015 Nov 27;33(48):6778-85

2013 Feikin DR, **Kagucia EW**, Loo JD, Link-Gelles R, Puhan MA, et al. (2013) Serotype-Specific Changes in Invasive Pneumococcal Disease after Pneumococcal Conjugate Vaccine Introduction: A Pooled Analysis of Multiple Surveillance Sites. *PLoS Med* 10(9): e1001517.

2013 Durbin AP, Wright PF, Cox A, **Kagucia W**, Elwood D, Henderson S, Wanionek K, Speicher J, Whitehead SS, Pletnev AG. The live attenuated chimeric vaccine rWN/DEN4Δ30 is well-tolerated and immunogenic in healthy flavivirus-naïve adult volunteers. *Vaccine*. 2013 Nov 19;31(48):5772-7. Epub 2013 Aug 19.

CURRICULUM VITAE PART II

E. Wangeci Kagucia

TEACHING

1. Introduction to International Health. Primary Instructors: William Brieger, Karen Charron, Anna Kalbarczyk (Online Course, JHSPH)
   Term 2 AY 2016-2017: **Teaching Assistant**
2. Introduction to International Health. Primary Instructors: William Brieger, Karen Charron, Anna Kalbarczyk (Online Course, JHSPH)
   Term 3 AY 2015-2016: **Teaching Assistant**
3. Clinical Vaccine Trials and Good Clinical Practice. Primary Instructor: Karen R. Charron (Online Course, JHSPH).
   Term 4 AY 2014-2015: **Teaching Assistant**
4. Vaccine Trials: Methods and Best Practices. Primary Instructors: Karen R. Charron and Amber B. Cox (Online course, Coursera [https://www.coursera.org/course/vacctrials])
   Fall 2012. **Guest lecture on managing essential documents for clinical trials**.
5. Clinical Vaccine Trials and Good Clinical Practice. Primary Instructor: Karen R. Charron (Online Course, JHSPH).

Spring 2010 & Fall 2010: Course coordination including development of course materials, moderation of LiveTalks, and grading of student assignments. **Recorded guest lecture, "Maintaining Clinical Trial Essential Documents"**.

RESEARCH GRANT PARTICIPATION

2014 – Present	Estimating Effective Vaccination Coverage with Immune Markers: Validation of anti-tetanus toxoid IgG and anti-measles IgG assays for use with dried blood spots and oral fluid samples Sponsor: Bill and Melinda Gates Foundation Principal Investigators: Katherine O'Brien and Kyla Hayford Role: Graduate research assistant
2012-Present	Randomized Controlled Trial of the Impact of Mobile Phone Delivered Reminders and Conditional Cash Transfers to Improve Childhood Immunization Coverage Rates and Timeliness in Kenya Sponsor: Bill and Melinda Gates Foundation Principal Investigators: Katherine O'Brien, MD and Daniel Feikin, MD Role: Project coordinator (2012-2014); Graduate research assistant (2014-present)
2011-2012	Review of Changes in Incidence of Serotype-specific Pneumococcal Disease in Infants and Young Children Following Routine Pneumococcal Conjugate Vaccine Introduction Sponsor: Bill and Melinda Gates Foundation Principal Investigators: Katherine O'Brien, MD and Daniel Feikin, MD Role: Project coordinator

Study coordinator for the following studies:

2009	Phase I Study of the Safety and Immunogenicity of rDEN4Δ30-200,201 a Live Attenuated Virus Vaccine Candidate for the Prevention of Dengue Serotype 4 Sponsor: NIH/NIAID/RCHSPB Principal Investigator: Anna P Durbin, MD
2009	Safety and Immunogenicity of a 2-Dose Regimen of rDEN2/4Δ30 Dengue Vaccine with Boosting at 4 Versus 6 Months Sponsor: NIH/NIAID/RCHSPB PI: Anna P Durbin, MD
2008	Safety and Immunogenicity of a 2-Dose Regimen of rDEN1Δ30 Dengue Serotype 1 Vaccine with Boosting at 4 versus 6 Months Sponsor: NIH/NIAID/RCHSPB Principal Investigator: Anna P Durbin, MD
2008	Phase I Study of the Safety and Immunogenicity of rDEN3/4Δ30(ME), a Live Phase I Study of the Safety and Immunogenicity of rDEN3/4Δ30(ME), a Live Attenuated

Virus Vaccine Candidate for the Prevention of Dengue Serotype 3
Sponsor: NIH/NIAID/RCHSPB
Principal Investigator: Anna P Durbin, MD

PRESENTATIONS

Scientific Meetings

Apr 2018

Poster
E. Wangeci Kagucia, Benard O. Ochieng, Joyce A Were, Kyla Hayford, Katherine L. O'Brien, Dustin G. Gibson
"Evaluation of the impact of text message reminders with or without unconditional monetary incentives on infant measles vaccination timeliness and coverage in rural western Kenya"
2018 Annual Conference on Vaccinology Research (ACVR), Bethesda, MD

Apr 2018

Oral abstract
K. Hayford, B. Ochieng Omondi, J.A.Were, **E. Kagucia**, D. Gibson, M. Pasetti, K. O'Brien, M.R. Odiere
"Can IgG antibodies to tetanus toxoid distinguish fully vaccinated children form under- and unvaccinated children? An opportunity to use serology to monitor vaccination programs"
2018 Annual Conference on Vaccinology Research (ACVR), Bethesda, MD

Apr 2018

Poster
Lindsay R. Grant, **Wangeci Kagucia,** Carolynn DeByle, Karen Rudolph, Kate Gould, Robert C. Weatherholtz, Raymond Reid, Katherine L. O'Brien, Jason Hinds, Laura L. Hammitt
"Serotype-specific pneumococcal colonization prevalence and density among American Indians in the PCV13 era using PCR and microarray"
11th International Symposium on Pneumococci and Pneumococcal Diseases (ISPPD), Melbourne, Australia

Apr 2017

Poster
E. Wangeci Kagucia, Dustin Gibson
"Use of text message reminders to improve pediatric vaccination in low- and middle-income countries: A systematic review and meta-analysis"
Vaccine Day 2017, Johns Hopkins Vaccine Initiative, Baltimore, MD

Apr 2015

Platform Session (oral presentation)
Breanna Barger-Kamate, **Eunice Kagucia**, Maria Knoll, Katherine O'Brien, Karen Kotloff
"Burden of Pertussis Pneumonia from 1-6 Months of Age in Seven African and Asian Countries"
Pediatric Academic Societies Annual Meeting, San Diego, CA

Mar 2015	Oral Abstract Presentation Gibson D, **Kagucia E**, Omondi B, O'Brien K, Feikin D. "Association between delayed pentavalent vaccination and immunization drop-out in rural western Kenya: Findings from a cross-sectional survey" *Consortium of Universities for Global Health (CUGH) 6th Annual Global Health Conference, Boston, MA*
Apr 2010	Poster Presentation Lok JK, **Kagucia EW**, Allen MA, Andrada A, Chavis S, Cox AB, Drayton-Weaver SL, DiLorenzo S, Elwood DT, Hentrich A, Lewis RT, Lovchik J, Sabundayo BP, Shaffer D, Perry H, Thumar B, Wanionek K, Yoder N, Durbin AP. "Clinical Development of the NIH Live Attenuated Tetravalent Dengue Vaccine Candidate, TetraVax-DV" *The Thirteenth Annual Conference on Vaccine Research, Bethesda, MD*
Nov 2009	Scientific Session Anna P. Durbin, Stephen S. Whitehead, Daniel Elwood, **Wangeci Kagucia**, Bhavin Thumar, Kimberli A. Wanionek, Dennis Pierro, Brian R. Murphy, Alexander C. Schmidt "Safety and Immunogenicity of a 2-Dose Regimen of rDEN1Δ30 Dengue Serotype 1 Vaccine with Boosting at four versus six Months" *American Society of Tropical Medicine and Hygiene 58th Annual Meeting, Washington DC*