Evaluating Effectiveness and Impact of Chanjoplus Platform in Supporting Immunization Coverage and Data Management System in Busia County

by Collince Osewe

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Research Protocol

EVALUATING EFFECTIVENESS AND IMPACT OF CHANJOPLUS PLATFORM IN SUPPORTING IMMUNIZATION COVERAGE AND DATA MANAGEMENT SYSTEM IN BUSIA COUNTY

PROJECT LOCATION:	BUSIA COUNTY
PROJECT OWNER:	CHANJOPLUS - KENYA
SPONSOR:	CANADIAN GOVERNMENT
PROJECT START DATE:	1ST OCTOBER 2019
PROJECT END DATE:	30th NOVEMBER 2021
PRINCIPAL INVESTIGATOR:	DR. STEPHEN MBURU, PhD

MINISTRY OF HEALTH

Grand Challenges Canada
Grands Défis Canada

EXECUTIVE SUMMARY

High quality and timely immunization data are vital to inform data-driven immunization program management including efficiency in service delivery, monitoring and improving performance as well as prioritizing resources and activities. In order to maximize on data driven immunization program management, all efforts must therefore be concentrated on proper effective and reliable child registration systems that enables identification and subsequent registration of these children .Unless we get registration right, chances are that we can end up with a distorted unreliable data-enabled immunization value chain which would significantly affect the validation and issuance of life saving vaccines, data access and follow-up as well as unreliable data analytics, thereby leaving many children vulnerable to vaccine-preventable health burdens.

In this regard Chanjoplus intends to conduct a longitudinal study in Busia County in seven different sub-counties of Matayos, Samia, Bunyala, Nambale, Butula, Teso North and Teso South. This research proposal will specifically focus on evaluating the impact of Chanjoplus data management system on child immunization coverage in the County. The study will employ cross sectional survey with three stage stratified cluster sampling design.

This research proposal comprises of three chapters, the first chapter of introduction highlights the background, immunization challenges and the current intervention, study problem, objective and study questions among other areas. Chapter two covers literature review with specific focus on healthcare fundamentals, public and clinical health, Kenya expanded program on immunization and technology intervention for immunization. Chapter three covers research methodology specific to the design, population, sampling method and data collection instruments among other areas.

A total of 77 Caregivers from the community health units, 273 caregivers and 325 Community health volunteers selected using simple random sampling method will participate in the study.

Community health volunteers and caregivers will use questionnaires to collect quantitative data and the interview guides and Focused group discussions will be used to collect qualitative data, while Key informant interviews for healthcare providers.

Data analysis and reporting will be done at the Baseline, Midline and end line levels with a specific procedure to process, analyze and present collected responses.

INVESTIGATORS AFFILIATION

I, Dr. Stephen Mburu, PhD do hereby declare that the content of this Research Protocol is entirely owned by Chanjoplus. Where there's work or contributions of other individuals, it has been duly acknowledged.

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TABLE OF CONTENTS

ACKNOWLEDGEMENTS

This Protocol for evaluating effective and impact of Chanjoplus platform has been conceptualized and developed through a systematic and collaborative effort of key stakeholders from Chanjoplus Project Implementation Team, County Health Management, Officials from Ministry of Health, and Development Partners. In particular, Chanjoplus appreciates the financial, strategic, scientific and technical leadership provided by Mr. Collince Osewe (CEO); and Dr. Stephen Mburu (Principal Investigator).

We acknowledge the guidance and support provided by health officials at the national and county levels. Special thanks to Dr. Collins Tabu (Head, National Vaccines and Immunization Programme-NVIP); Teclar Kogo (M&E, NVIP); and Onesmus Kamau (Head, MOH Division of Health Informatics); Dr. Isaac Omeri (Chief Officer, Health and Sanitation Busia County); Mr. Tito Kwena (County Immunization Focal Person); and Mr. Lazarus Luvayi (County Community Health Strategist).

Internally, Chanjoplus management wish to recognize and appreciate the role played by the Project Implementation Team comprising of Mr. Joseph Barasa (Project Manager), Ms. Monica Namnaba (Project Manager), Mr. Peter Khaemba (Project Officer), and Ms. Marilyn Chege (Project Officer). Further, the management acknowledges support provided by various departments and individuals who participated in developing this protocol. In particular; we acknowledge Ms. Irene Gathoni (Chief Finance Officer), and Mr. Cyrus Mushira (ICT Director) for their logistical and planning support.

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ABBREVIATIONS AND ACRONYMS:

CHU – Community Health Unit

CHV – Community Health Volunteer

COVID-19 – Corona Virus Disease

DHIS – District Health Information Software

DTP- Diphtheria Pertussis Tetanus

GAVI – Global Alliance for Vaccines and Immunizations

GCC – Grand Challenges Canada

GVAP – Global Vaccine Action Plan

HIS- Health Information Software

ICT – Information and Communications Technology

IPV – Inactivated Polio Vaccine

KDHS- Kenya Demographic and Health Services

KEPI – Kenya Expanded Programme on Immunization

KII – Key Informant Interview

KNBS- Kenya National Bureau of Statistics

MOH – Ministry of Health

NVIP- National Vaccines and Immunization Program

OPV- Oral Polio Vaccine

RMNCAH – Reproductive, Maternal, Newborn, Child and Adolescent Health

SARA – Service Availability and Readiness Assessment

SDG – Sustainable Development Goals

SME – Subject Matter Expert

USSD – Unstructured Supplementary Service Data

VPN – Virtual Private Network

WHO – World Health Organizations

GLOSSARY OF TERMS

Chanjoplus: This is an acronym derived from 'chanjo' - a Swahili word that means immunization; and 'plus' which in our context stands for factors such as data management that support the delivery of immunization services.

Clinical health: A form of healthcare that deals with diagnosis, treatment and prevention of a disease, illness, injury and other impairments of an individual.

Cluster sample: This is a probability sample in which each sampling unit is a collection, or cluster of elements.

Database: Collection of data, or information, that is specially organized for ease of storage, access and retrieval and update.

Design effect: This is a coefficient which reflects how sampling design affects the computation of significance levels compared to simple random sampling. A design effect coefficient of 1.0 means the sampling design is equivalent to simple random sampling.

Epidemiology: The study of the distribution and determinants of health-related states or events, and the application of this study to the control of diseases and other health problems. Descriptive studies can be used to study distribution while analytical studies are used to study determinants.

Health outcome: Changes in health that result from measures or specific health care investments or interventions.

Immunization: Process of inducing immunity to an infectious organism or agent in an individual or animal through vaccination. Recommended schedule of immunizations for infants and young children includes vaccines against diphtheria, polio, tetanus, measles, mumps, and rubella.

Information and Communications Technologies (ICTs): Refers to a full range of devices that facilitate electronic means of processing and transmission of information. These include but not limited to computers, mobile phones, TVs, radios and fax.

Informed consent: The process by which a researcher discloses appropriate information to a patient so that the patient may make a voluntary choice to

accept or refuse to participate in research or experiment.

Intervention: Combination of programme elements or strategies designed to produce behaviour changes or improve health status among individuals or an entire population.

Key informant interviews: Qualitative in-depth interviews with experts, community leaders or professionals to collect information firsthand knowledge about the community or subject of interest.

Low-Resource settings: Underserved rural and urban areas characterized by poor infrastructure, inferior technologies, limited access to basic needs and poor lifestyle.

mHealth: Short form of mobile health – a new form of electronic health that makes use of mobile devices to provide healthcare services and information.

Mortality: Relative incidence of death within a particular group categorized according to age or some other factors such as gender.

Protocol: In computing, the term protocol refers to the set of rules that computers use to communicate with each other. Examples include Types of Protocol Hypertext Transfer Protocol (HTTP), Transmission Control Protocol (TCP), Internet Protocol (IP), File Transfer Protocol (FTP), Internet Message Access Protocol (IMAP), Simple Mail Transfer Protocol (SMTP), and Post Office Protocol version 3 (PoP3.

Stratified sampling: Subdividing the target population into nonoverlapping groups called strata from which subsamples are drawn and combined to estimate parameters for the entire population.

Unstructured Supplementary Service Data (**USSD**)**:** Global System for Mobile Communications (GSM) protocol that uses short codes to send text messages.

Vaccination: The administration of vaccines to helps the body's immune system recognize and fight pathogens like viruses or bacteria, which then keeps us safe from the diseases they cause.

CHAPTER ONE

INTRODUCTION

3. Background

During the year 2018, 116.3 million infants, i.e. (86%) of infants globally received 3 doses of diphtheria-tetanus-pertussis (DTP3) vaccine that protects children against infectious diseases (WHO, 2019). This translates to 30% increase from 90 million infants vaccinated by close of the year 2000. The most notable increase is the fast trajectory of Inactivated Polio Vaccine (IPV) in countries that previously only used Oral Polio Vaccine (OPV). Noteworthy also are trajectories for the Pneumococcal Conjugate and Rotavirus Vaccines as lower income countries have been able to achieve higher coverage than the global average. Nonetheless, the WHO report indicates that 19.4 million children did not receive basic vaccines due to poor access to immunization services. Further, 13.5 million out of 19.4 million children did not receive any form of vaccine hence exposing them to infectious diseases that can cause serious illness and fatal disabilities.

According to WHO, (2019), monitoring data at sub-national levels is critical in helping countries prioritize and tailor vaccination strategies and operational plans to address immunization gaps and reach every person with lifesaving vaccines. The Global Vaccine Action Plan (GVAP) is a roadmap to prevent millions of deaths through more equitable access to vaccines by year 2020. The resolution urges countries to strengthen governance and leadership of national immunization programmes, and improve monitoring and surveillance systems to ensure up-to-date information, policy guidelines, and programmatic decisions to optimize performance and impact.

The third goal of United Nations' Sustainable Development Goals (SDG3) focuses on healthy lives and promote well-being for all at all ages (McInnes, 2018; United Nations, 2017). Noteworthy *is* ***target 3.2*** *that states: "By 2030, end preventable deaths of newborns and children under 5 years of age, with all countries aiming*

to reduce neonatal mortality to at least as low as 12 per 1000 live births and under-5 mortalities to at least as low as 25 per 1000 live births".

Over the past decade, immunization coverage in sub-Saharan Africa has stagnated at 72% exposing populations to preventable diseases and outbreaks (Madhi & Rees, 2018). According to the Madhi, nearly 31 million children under the age of 5 years suffer from vaccine-preventable diseases every year. Unfortunately, more than half a million of them die due to lack of access to the vaccines they need. In contrast, other diseases such as polio, are on the edge of complete eradication.

To augment GVAP efforts, each WHO region developed its own detailed plan to achieve the agreed goals. In Africa, the member states developed Regional Strategic Plan for Immunization 2014-2020 (WHO-Regional Office for Africa, 2015). The objectives of this strategic plan include improvement of immunization coverage beyond current levels; attain and maintain elimination of other vaccine-preventable diseases; and complete interruption of poliovirus transmission.

Kenya has reported an increase in immunization coverage in the country from 70% in 2017 to 82% in 2018 (MOH-Kenya, 2019). However, there still challenges affecting immunization coverage at national and sub-national levels. In Kenya and Busia County in particular, some of the challenges include constant relocation of the residents around Kenya-Uganda border, poor management of immunization data, ineffective vaccination tracking, and fragmented health facilities.

Globally and locally, e-Health solutions are being sought in order to bridge the gaps in the health care systems and to enable efficient delivery of services. The World Health Organization defines e-Health as the combined use of electronic communication and information technology in the health sector (WHO & ITU, 2012). In practical terms, e-Health is the means of ensuring that the right health information is provided to the right person at the right place and time to support delivery of quality and efficient healthcare. Thus, e-Health should be viewed as

essential infrastructure supporting information exchange between all participants in the health care system and key enabler and driver to improved health outcomes for all Kenyans (Njoroge, Zurovac, Ogara, Chuma, & Kirigia, 2017).

Besides the global and regional targets for immunization coverage, Kenya has set a target of 90% which is yet to be achieved (Donfouet, Agesa, & Mutua, 2019; Shikuku et al., 2019). The National Vaccines and Immunization Program (NVIP) is now focusing on reducing dropout rates and missed opportunities amongst other strategies in order to achieve the target of at least 90% national vaccination coverage.

At the sub-county level, latest statistics indicates that Busia County has immunization coverage that staggers between 41% and 69%. In the Year 2010 of children under 5 years was over 69% in the county with all the seven sub-counties reporting good response to all immunization campaigns (Busia-County, 2018). In the 2019, the national health information system indicated an average of 53% coverage while the Reproductive, Maternal, Newborn, Child and Adolescent Health (RMNCAH) scorecard depicted a downward trend from 88% in the second quarter to 41% in the fourth (MOH-Kenya, n.d.). These insistencies coupled with observed downward trend need to be investigated to get the actual immunization coverage. Nonetheless, we note that these inconsistences may be due challenges experienced by the County's proximity to Kenya-Uganda border. There are cases of cross-border movement whereby a significant population of Ugandan citizens opt to seek health services in Busia County hence presenting a challenge in tracking of vaccine uptake, coverage and lost to follow-up cases.

4. Immunization Challenges

Globally, immunization programmes aim to control preventable diseases and deaths during in mothers and children under the age of two years. To achieve the SDG3's target of less than 12 per 1000 live births, most countries in Africa have developed innovative strategies (Gibson et al., 2016; Shikuku et al., 2019; Verguet et al., 2013; Vouking, Tadenfok, & Ekani, 2017). Despite these efforts,

most low-income countries are still facing challenges related to acceptability, affordability and accessibility of vaccination programmes (Deogaonkar, Hutubessy, Van Der Putten, Evers, & Jit, 2012). Some of the key barriers to full immunization coverage include low education, low income, gender discrimination, cultural practices, religion and negative perception on immunization (Lakew, Bekele, & Biadgilign, 2015). To overcome these challenges, there is need for the adoption of innovative social mobilization and mobile-based solutions (Maiga & Namagembe, 2014; Mburu, 2017; Schomakers, Lidynia, & Ziefle, 2019).

Since 1980, the Kenyan Government established the Kenya Expanded Programme on Immunization (KEPI). KEPI's main goal was prevention of killer diseases like measles, polio, pertussis, tuberculosis, diphtheria, and tetanus through vaccination. Over time KEPI incorporated new vaccines including hepatitis B, haemophilus influenza type B, rotavirus vaccine, and pneumococcal vaccine. Later, the government consolidated all vaccination services with and outside KEPI by establishing Unit of Vaccines and Immunization Services (UVIS). The Unit's mandate to standardize and manage all vaccination services and practices at national and county levels.

Some of the obligations of UVIS include coordination of vaccination services; advice on immunization schedules; ensuring equitable access to appropriate vaccination services; and ensuring universal immunization of children (GOK, 2013). According to the Kenya Demographic and Health Survey (KDHS) report of 2014, 79% of children aged 12- 23 months received all basic vaccines while 75% were fully immunized (KNBS, 2015). However, the latest report by the national government indicate that the immunization rate increased from 70% in 2017 to 82% in 2018 (MOH-Kenya, 2019).

To accelerate the country's attainment of 90%, there are various communal and mobile-based interventions that have been implemented to reach out underserved communities. A study conducted by Gibson et al. (2016) to assess impact of mobile delivered reminders and travel subsidies to improve childhood

immunization coverage and timeliness in western Kenya in 2016 showered that sending SMS reminders together with providing the mother an incentive to cover transport significantly improved immunization coverage. It is evident from the study that timely immunization protects children against specific diseases and preventable deaths.

To monitor immunization progress, GAVI and WHO tasked member countries to improve quality and use of immunization data with the proposed approach being the uptake of electronic systems. This will enhance programmatic decision making at all levels. Furthermore, electronic data is capable of providing demographic and health data that improves access to immunization services. Nevertheless, technology has its own challenges relating to usability and cost of maintenance. Moreover, transitioning from paper-based to electronic system presents a challenges to communities with low-level literacy and computer skills. According to the County Government of Busia - Health Strategic and Investment Plan (2018-2022), there are certain challenges faced in immunization service delivery including; Poor documentation, insufficient defaulter tracking, high dropout rates and cross border movement. Being a border county, movement across borders for health and other services is a common practice. However, this poses a challenge in tracking vaccine uptake and leads to seemingly higher defaulting rates.

Defaulter tracking also becomes a challenge with all the movement across the border and within the county because there is no link between the various health facilities. Without proper documentation, infants who receive their subsequent vaccinations from a different health facility from the one they began their vaccine schedule are all classified as dropouts.

From the pilot conducted in Kibera, Nairobi County, it was concluded that Proper identification and registration of infants enhances validation and issuance of lifesaving vaccines to the registered infants as each registered infant is uniquely identified and therefore can be accounted for

throughout the immunization value chain. Flagging off vaccine defaulters and making follow-ups within the immunization value chain can only be streamlined if the process of identification and registration of the infants is adequately taken care of.

Proper registration reduces the workload for service providers who are otherwise overwhelmed with several reporting tools from mother to child booklet to permanent registers as well as reporting forms to ministry of health, reconciliation of immunization records from these multiple sources of documentation jeopardizes the grade of confidence of any data emanating from such an exercise.

5. Chanjoplus immunization platform

Chanjoplus is mobile and web-based application that was developed in 2015 and initially piloted in Kibera located in Nairobi. There are several reasons why mobile platform was chosen as the primary solution. These include but not limited to ubiquitous wireless connectivity across Kenya; device portability, and relatively low cost of owning a smartphone compared to laptop or desktop computers. To make Chanjoplus fit for the purpose, we employed collaborative design by involving different stakeholders in the early design stage. The first version of the Chanjoplus app was deployed in June 2016 and pilot testing conducted between September 2016 and March 2019. The current mobile and web-based version of Chanjoplus platform does the following immunization functions:

1. Scheduling appointments: Chanjoplus has a module that automatically generates and sends information to immunization to healthcare providers for timely interventions. Once the caregiver (parent or guardian) presents the child's immunization card, the health provider enters these details into the system. The system then pushes this information to corresponding community health volunteers for access via the mobile app.
2. Management of health records: when a child is brought a health facility for scheduled vaccination, the healthcare provider uses the mobile or web portal to record that

child's immunization details such as the vaccine, date, batch number, manufacturer, site and cost. The updated record is the uploaded to Chanjoplus database system through secure virtual private network (VPN).

3. Immunization tracking: The system has a module that tracks immunization appointments and automatically send alerts on pending or missed appointments. The tracker also provides the healthcare provider with contact information such as family phone number for ease of follow-up or visit by community health volunteers.
4. Health education and awareness: Chanjoplus has a public interface that provides caregivers health tips and information related to immunization benefits; vaccine side-effects; hormonal reactions in childhood; and how to monitor child's growth during the first two years.

Through Chanjoplus platform, the researchers will work with community health workers to identify and register every child at the household level as well as vaccination officers to register these children at the facility level using feature phones that do not require internet connectivity. This is because USSD integration does NOT necessarily require a smartphone as well. After registration (capturing of every child's demographic information) the captured data is automatically sent to Chanjoplus data center where it is anonymized by generating digital identities used to uniquely identify each registered infant whose vaccination schedule is to be tracked.

When an infant is brought to the clinic for routine immunization with or without the clinic booklet, their immunization history is accessible to the vaccination officer through a USSD-enabled feature phone with details such as the last vaccine given and the vaccine due. The immunization officer has the capacity to identify the vaccine given and then updates the given vaccine through Chanjoplus platform.

To access Chanjoplus on the client side, a registered caregiver must first dial *304# USSD code on their phone as shown in Figure 1.1. The next step is to

enter personal identification number (PIN) and then search for identity of the infant brought to the facility for routine immunization.

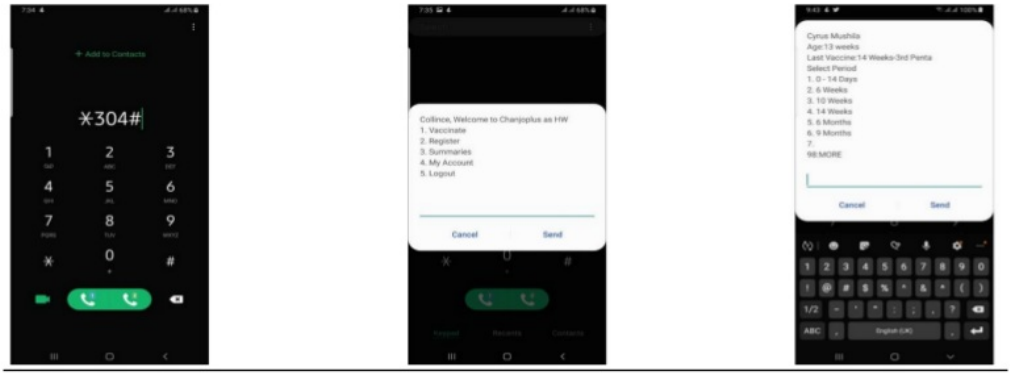

Figure 1.1: Chanjoplus USSD Interface

On the supply (clinician) side, Chanjoplus has a web dashboard shown in Figure 1.2 used to access records even without internet connection. This makes Chanjoplus a unique solution accessible even in areas with unreliable internet connectivity

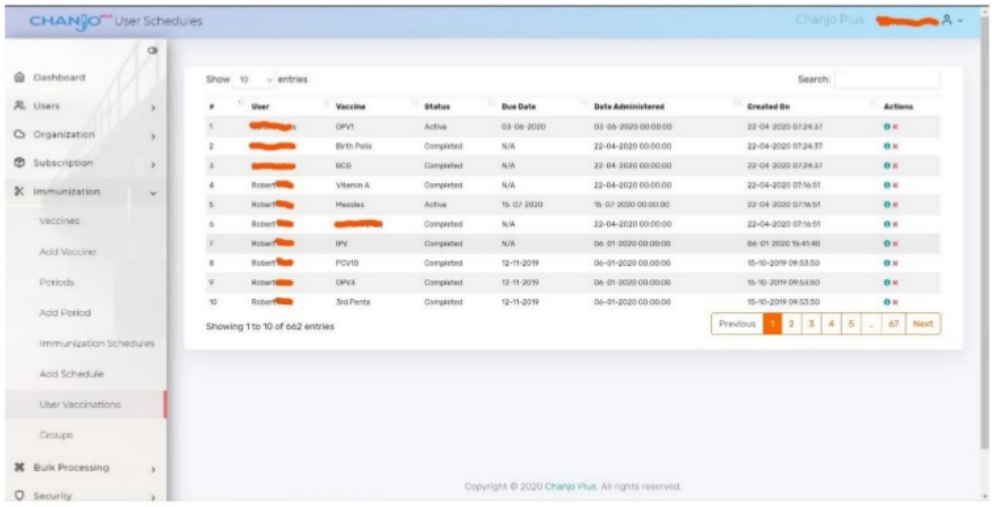

Figure 1.2: Chanjoplus health provider's web portal

For timely decision making, Chanjoplus has analytics dashboard that gives real time trends of vaccine uptake as shown in Figure 1.3. This interface provides

health workers with real-time information based on actual usage and cold-chain management of vaccines.

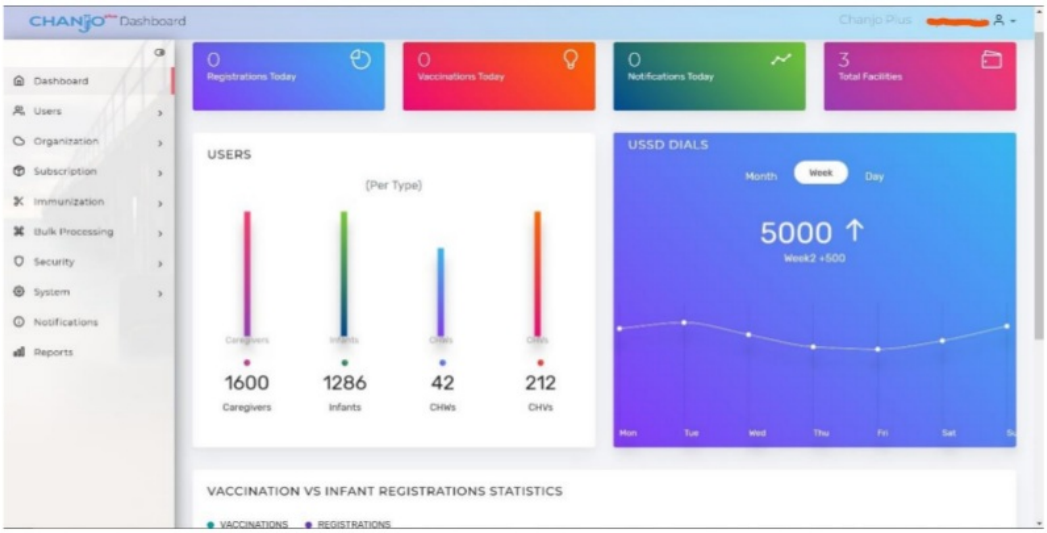

Figure 1.3: Chanjoplus analytics dashboard for decision making

6. Problem Statement

Despite global efforts to strengthen equitable access to immunization, coverage in Sub-Sahara Africa has stagnated at 72% (Madhi & Rees, 2018). This means that approximately 28% of children under five years are exposed to preventable diseases and deaths. In Kenya, the Ministry of Health (MOH) has reported an increase in immunization coverage in the country from 70% in 2017 to 82% in 2018 (MOH-Kenya, 2019). However, the Kenyan government is still experiencing political, socio-economic and technical challenges in immunization coverage due to issues such as relocations of the population, shortage of health workers, poor data management, and insufficient health facilities.

To achieve the national target of 90% immunization coverage, the Ministry of Health and County Governments are exploring innovative solutions. One of the strategies is to create demand for immunization through mobile communication and social mobilization in underserved communities (Verguet et al., 2013). This is because poor immunization coverage in low-resource settings may be attributed to poor lifestyle, low education; and lack of information (KNBS, 2015).

To bridge this gap, there is need for the national and county governments to adopt information technology (ICT) to improve immunization coverage and decision making processes. Nonetheless, technology has its own challenges such as high maintenance costs, incomplete data, and requires expertise in deployment and management (Mburu & Oboko, 2018). This study seeks to systematically evaluate how mobile and web-based technologies can be used to improve on immunization coverage and decision making; while reducing cost and inconsistencies associated with paper-based immunization management systems.

7. Purpose of the Study

The purpose of this study is to establish how Chanjoplus SMS and Web platforms can be used in Busia County to improve on immunization coverage and decision making while reducing cost and inconsistencies associated with paper-based tracking system.

8. Specific Objectives

1. To determine the status of immunization coverage and immunization data management in Busia county.
2. To evaluate the uptake of Chanjoplus as an intervention for improving immunization coverage and data management by community health units from sub-county to county level in Busia County.
3. To evaluate the impact of Chanjoplus data management platform on immunization coverage and data management in Busia County.
4. To establish cost implications and sustainability of using the Chanjoplus data management platform in comparison to the paper-based alternative for data storage and management.

9. Study Questions

1. What is the status of immunization coverage and immunization data management in Busia County?

2. What is the uptake of Chanjoplus data management system as an intervention for improving immunization coverage and data management by community health units from sub-county to county level in Busia County?
3. How has Chanjoplus data management system impacted immunization coverage and data management in Busia County?
4. What are the cost implications of the Chanjoplus platform compared to the paper-based immunization data management system in Busia County?

10. Justification of the Study

Immunization is an important component of global health in preventing disease outbreak and reducing child and neonatal mortality. Immunization programmes plays a crucial role in achieving 14 out of the 17 Sustainable Development Goals (SDGs). The Chanjoplus platform closely reflects the rallying call of SDGs of leaving no one behind. Busia county among the 47 Counties in Kenya is one of the counties that is yet to achieve 90% immunization coverage target set by the national government. The main setbacks for achieving the immunization targets include poor management of immunization data, high cost of offering immunization services, and lack of accountability across immunization programs.

To accelerate the achievement of national and global immunization targets, joint action should be directed towards interventions that make use of mobile technologies to enhance access to immunization services in an affordable, accessible and in an environment that promotes accountability and documentation of the achievements and failures. This study seeks to provide Chanjoplus implementers, healthcare providers, national government, county governments, policymakers, and development partners with recommendations on practical approaches to achieving 90% immunization coverage alongside other SDG targets relating to maternal and child health.

11. Scope and Limitations

The geographical scope of the study is within Busia County for a period of 25 months. It will be conducted in the seven sub-counties namely; Butula, Budalangi, Bunyala, Nambale, Teso North, Teso South and Matayos. The study will focus on the effectiveness and impact of the Chanjoplus platform in supporting immunization and data management in the County. The key action lines include tracking of fully immunized children; evaluating cost-effectiveness of mobile-based interventions as well as impact of data analytics in decision making.

CHAPTER TWO

2.1. Health and Wellness

Health refers to a relative state in which one is able to function well physically, mentally, socially, and spiritually to express the full range of one's unique potentialities within the environment in which one live (Svalastog, Donev, Kristoffersen, & Gajović, 2017). In keeping with the concept of health as a fundamental human right, the Ottawa Charter emphasizes certain prerequisites for health which include peace, adequate economic resources, food, shelter, stable ecosystem and sustainable resource use (Nutbeam, 2008). The Ottawa Charter identifies three basic strategies for health promotion:

- Advocacy for health to create the essential conditions for health;
- Enabling all people to achieve their full health potential;
- Mediating between the different interests in society in the pursuit of health.

These strategies require comprehensive understanding of health systems and structures in order to design interventions that aligns to social and economic conditions of the local community. The global community should aim at changing social, environmental and economic conditions that have a negative impact on the well-being of all at all ages. This can be achieved through creating supportive environments for health, enforcing health policies, strengthening community actions for health, and developing professional skills.

2.2. Public and Clinical Health

Public goes beyond the treatment of individuals to encompass health promotion, prevention of disease recovery and rehabilitation through organized efforts of a society (Binns & Low, 2015). It is aimed at improving health, prolonging life and enhancing quality of life in a society through health promotion, disease prevention and other forms of health interventions. On the other hand, clinical health refers to a form of healthcare that deals with diagnosis, treatment and prevention of a disease, illness, injury and other impairments of an individual. Unlike public health in which practitioners are concerned with collective community well-being, clinicians are concerned with a particular patient's disease, symptoms, medication, laboratory tests & reports on how to treat the

patient. In this study, we are concerned with public health in which Chanjoplus seeks to contribute to the health outcome of mothers and immunization of their children.

In every society, provision of health care is essential. It should be made accessible at costs a community or an individual can afford. Public health promotion should include actions like education and awareness on disease prevention and control, nutrition, sanitation, family planning, immunization and lifestyle. To address public health challenges, epidemiology provides information required for directing appropriate actions and interventions. In the following sections we explore how ICT can be used to support public health promotion and interventions in underserved regions.

2.3. Kenya Expanded Programme On Immunization

The term immunization refers to administration of a vaccine into a healthy person to prevent that person from getting a certain disease (Reid & Fleck, 2014). Although breast milk offers the child protection against many diseases as it contains antibodies passed from the mother, it is still important to protect the child from infectious diseases. Numerous vaccines are recommended during childhood as they protect newborns against Vaccine Preventable Diseases (VPDs) that used to be devastating and life threatening like measles and polio.

In Kenya, the Ministry of Health established Kenya Expanded Programme on Immunization (KEPI) in 1980 as part of the global Expanded Programmes on Immunization (Okwo-Bele & Cherian, 2011; Tiande, 1990). The goal was to provide vaccination against tuberculosis, polio, diphtheria, whooping cough, tetanus and measles (Ndiritu et al., 2006). Overtime, KEPI introduced vaccines like yellow fever, influenza type B, hepatitis B, haemophilus, and pneumococcal. Later, the government consolidated the gains made by KEPI by establishing the National Vaccine and Immunization Unit (NVIP) under the Division of Family Health. Since then, vaccination has been one of the most successful and cost-effective public health interventions that has eliminated or significantly eradicated most of the killer diseases in Kenya. Apart from routine

vaccination, the NVIP provides vaccines for typhoid, tetanus, hepatitis B, anti-rabies, snake venoms and any other emergence vaccines as may be prescribed during disease outbreaks. To further streamline vaccination and immunization programmes, the Ministry of Health published the *National Policy Guidelines on Immunization 2013* that provides comprehensive procedures and directions on acceptable vaccination practices and priorities. Apart from routine vaccination, the unit also provides vaccines for Tetanus, Hepatitis B, typhoid, anti-rabies, snake venoms and any other emergence vaccines as may be prescribed during outbreaks. The establishment of UVIS has improved the national immunization coverage significantly. Statistics from the Kenya Demographic and Health Survey (KDHS) shows that about 75% of children aged between 12 and 23 months were fully immunized by 2014 (KNBS, 2015). Latest statistics published on government website indicates that country's immunization coverage increased from 70% in 2017 to 82% in 2018 (MOH-Kenya, 2019).

2.4. Health Sector Immunization Challenges

In Sub-Sahara Africa, there are several challenges that hinder timely vaccination of children (Vouking et al., 2017). These include but not limited to the following:

- Lack of community participation, and civic actors needed to provide advocacy for immunization services within communities;
- Inadequate skills at national and sub-national levels for managing and coordinating immunization services due to new staff members with limited exposure to the management of the health systems in general;
- Lack of prerequisite skills in data management at national and sub-national levels including data analysis and use of data for decision making;
- Poor data quality and recurrent stock-out of tools leading to delayed and incomplete data reporting;
- Poor collection and management of vaccine utilization data;
- Poor vaccine management practices at national and sub-national levels;
- Poor supply chain management leading to stock out and vaccine wastage
- New vaccines introduced into the routine programme exert pressure on existing structure.

So far there are very few mobile-based interventions focusing on immunization coverage and decision making being evaluated scientifically. We argue that community mobilization interventions to change or impact beliefs and attitudes of the caregivers and health providers are absolutely needed. Furthermore, the national and sub-nationals need timely access to data for purpose of improving accessibility, affordability, availability and management of immunization services. The purpose of this study is to evaluate effectiveness of mobile-based innovations in supporting immunization coverage and timely access to data for informed decision making in Busia County.

2.5. Technology Interventions for Immunization

An important aspect in the Global Vaccine Action Plan (GVAP) is the realization that demand and supply insufficiencies need to be addressed to achieve universal immunization coverage. Safeguarding more newborns using appropriate vaccination is a vital element in struggles to reduce child impermanence by two-thirds and realize SDG 3. Mobile based immunization has shown to motivate positive behaviour change in resource constrained settings. Moreover, they have modestly improved immunization coverage in other countries like the United States but its effectiveness to improve immunization coverage in sub-Saharan Africa has not been appraised but the approach is technically feasible (Gibson et al., 2016). However, there are barriers that hinder deployment of mHealth interventions in developing countries (Mechael & Searle, 2010; WHO GOe, 2013). These include poor infrastructure, inadequate technical skills, economic constraints, conflicting priorities and legal policies.

In this study, the researchers are concerned with public health in which Chanjoplus seeks to contribute to health outcomes of mothers and their children. The researchers' intention is to explore how ICT can be used to improve immunization coverage and decision making in Busia County.

CHAPTER THREE

METHODOLOGY

The purpose of this chapter is to describe the approach used in this study to evaluate effectiveness and impact of Chanjoplus in supporting data management that has the potential to improve immunization coverage in Busia County.

Study Design

The methodology to be employed in this study is longitudinal with repeated measures cross-sectional designs (Menard, 2008). In the repeated cross-sectional design, the researchers will draw random samples to be measured at different points in time. The samples drawn will contain different sets of respondents but with comparable set of attributes that makes it possible to generalize the findings (Mburu & Oboko, 2018). Figure xxx the longitudinal design with repeated measures obtained from baseline, midline and endline cross-sectional studies at T_1, T_2 and T_3 points in time.

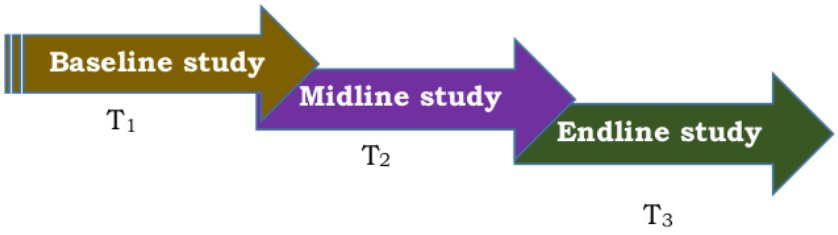

Figure xx: Longitudinal repeated cross-sectional design

Although repeated cross-sectional designs produce weaker causal inference compared to experimental designs, good sampling procedure is critical to measuring change in attitude or behaviour within groups rather than individuals (Hillygus & Snell, 2015). Thus, to permit comparisons across households across time and space dimensions, this study will employ multistage random sampling method. In the first stage, sub-county administrative boundaries will be used to partition the target population in Busia County into seven non-overlapping strata. In the second stage, the Service Availability and Readiness Assessment (SARA) sampling approaches proposed by WHO (2015) will be used to select

health facilities and community health units (CHUs) from each stratum. The final stage of the sampling method will involve selection of community health volunteers (CHVs), and households from each of the selected Community Health Units (CHUs) using a simple random sampling.

Target population

The target population is a group of elements that provide the overall context and represents the collection of people, households or facilities about which inferences and estimates are desired. In the context of this study, the target population comprises children aged under two years, caregivers (parents or guardians), community health volunteers (CHVs), and healthcare providers The latest Busia County Strategic Investment Plan (2018-2023) shows that the County had estimated population of 869,978 in 2018. With annual growth rate of 2.54%, the estimated population of 946,476 for the year 2020 is show in Table xxx. (citation).

	Sub-County Units	Population trends				
		2018	2019	2020	2021	2022
1	Bunyala	78,117	80,776	84,986	86,998	89,200
2	Butula	142,682	147,540	155,228	158,903	162,926
3	Matayos	130,359	134,797	141,822	145,179	148,855
4	Nambale	110,798	114,570	120,541	123,395	126,518
5	Samia	109,467	113,194	119,093	121,912	124,998
6	Teso North	138,089	142,790	150,231	153,788	157,681
7	Teso South	160466	165929	174576	178709	183233
	TOTAL	869,978	899,596	**946,476**	968,885	993,412

Inclusion Criteria

In this context, inclusion criteria refer a set of characteristics that will be used to identify the study subjects from the target population(s). Delimiting characteristic of the participants in a scientific study is critical to controlling internal and external validity while improving feasibility and likelihood of

obtaining reliable inferences from an intervention study. In this regard, the following inclusion criteria will be used to determine eligible participants from the populations;

1. The caregivers who are either a family member or paid helper who routinely looks after infants under 18 months and should be able to use a mobile phone with a registered SIM card and a valid national identity card and able to read and write Kiswahili or English;
2. Registered healthcare providers who are trained to use Chanjoplus platform in selected health facilities;
3. Community Health Volunteers (CHVs) recognized by the county government and the local administration. They should be able to read and write with a grasp of the community's local language and be a resident of the target Sub-county. The selected CHVs will also be trained to use Chanjoplus to process data collected from selected CHUs.

Study Settings

The study will be conducted in Busia County located about 460 kilometers from Nairobi. The total population of Busia County is 899,596 according to the KNBS Census of 2019. Of the total number of people living in Busia County 48% are men and 52% are female. Children between zero and 14 years make up 47.1% of the general population with under one year 3.6%, and under five years 17.5%. Women of Reproductive Age (WRA) 15 to 49 years consist of 26.4% of the general population in Busia County. The number of House Holds in Busia County is 173,996 with an average of 5 members per house hold. According to the study design, independent surveys will be conducted to cover the target population from seven sub-counties: Matayos, Bunyala, Samia, Nambale, Butula, Teso North, and Teso South.

Sampling Method

Sampling method depends on the population size, degree of precision, statistical power, cost, and ability of the researchers to gain access to the study subjects (L. Fleiss, Levin, & Paik, 2004; Scheaffer, III, & R. Lyman Ott, 2012; WHO, 2015).

In this section, we describe the sampling methods and procedures used to select representative samples from health facilities, community health units (CHUs), community health volunteers (CHVs), and households having children aged below 2 years.

3.5.1. Selection of Facilities and CHUs

3.5.2. Selection of Community Health Units

In Kenya, the health system is classified into four tiers and six levels with tier 1 being the community, tier 2 the dispensaries and health centers, tier 3 being the sub-county and county hospitals and tier 4 the provision and national hospitals (Kenya Health Sector Strategic Plan III, 2012–2017). Determining appropriate sample size for community health units depends on target population, desired precision and number of households. To obtain appropriate sample for each stratum from tier 1, the researcher used the following expression (WHO, 2015):

$$\mathbf{n} = \mathbf{deff\ x}\ \frac{\mathbf{z^2\ x\ p\ x\ q} + \mathbf{e^2}}{\mathbf{e^2} + \frac{\mathbf{z^2\ x\ p\ x\ q}}{\mathbf{N}}}$$

where n = sample size; deff = design effect of 1.0; N = population of CHUs per stratum; e is margin of error at ±5%; z = critical value of 1.96 for a 95% two-tailed normal distribution; p = conservative proportion of 50% for parameters of interest and q = 1-p.

However, given that CHUs per stratum are few (less than 30), the principal investigator modified the calculation in the above formula by replacing ***z*** values by ***t*** distribution values with ***(N-1) degrees of freedom***, and 5% level of precision. Justification for replacing of the z with t-values is based on Tchebysheff's Theorem, and principles of the Central Limit Theorem that requires use of t-values for small populations (L. Fleiss et al., 2004; Mburu & Oboko, 2018; Scheaffer et al., 2012; WHO, 2015)

$$n = \text{deff}\, x \frac{t^2 \, x \, p \, x \, q + e^2}{e^2 + \frac{t^2 \, x \, p \, x \, q}{N}}$$

For example, to determine the sample size for Bunyala, the following expression was used with t value of 2.11 and 17 degrees that gave a raw value of 9.45:

$$n = 1.0 \, x \frac{2.11^2 \, x \, 0.5 \, x \, 0.5 + 0.05^2}{0.05^2 + (2.11^2 \, x \, 0.5 \, x \, 0.5)/18}$$

The same approach was used to compute the raw values for all the seven strata that proportionately adjusted to desires sample sizes provided in Table 3.1:

Table 3.1: Samples of community health units per stratum

Sub-county	CHUs	Calculated Size	Adjusted Samples
Bunyala	18	09.45	9
Butula	21	10.18	10
Matayos	19	09.71	10
Nambale	24	10.80	11
Budalangi	29	11.65	12
Teso North	35	12.47	12
Teso South	38	12.81	13
Total			**77**

3.5.3. Selection of Households

Busia County Strategic Plan provides detailed projections of the target population comprising of households, children below 2 years, women of reproductive age, and caregiver adults as shown in Table xxx.

	Cohorts Description	Population Estimates				
		2018	2019	2020	2021	2022
1	Projected annual population	869,978	899,596	946,476	968,885	993,412
2	Households (approx. 5 members per household)	173,996	179,919	189,295	193,777	198,682
3	Children below 1 year/12 months	31,733	32,814	34,524	35,341	36,236
4	Children below 5 years	153,285	158,504	166,764	170,712	175,033
5	Population below 15 years	415,773	429,928	452,332	463,042	474,763
6	Women of reproductive age 15 to 49 years	198,274	205,025	215,709	220,816	226,406

7	Projected number of pregnant women	33,056	34,181	35,962	36,814	37,746
9	Project annual deliveries	33,056	34,181	35,962	36,814	37,746
10	Estimated live births	33,056	34,181	35,962	36,814	37,746
13	Adults (25-59)	238,250	246,361	259,199	265,336	272,053

The projected populations provided in Table xxx and Table xxx above provides crucial values used to determine the number of households to be sampled from each strata. The following expression was used to determine the sample size at ±5% precision, *design effect of 1.0* and 95% confidence (Scheaffer et al., 2012):

$$\mathbf{n = deff\ x\ \frac{N\ x\ p\ x\ q}{\frac{e^2}{z^2}\ x\ (N-1)+p\ x\ q}}$$

where n = sample size; D = design effect; N = population of households per stratum; e is margin of error at ±5%; z = critical value for two-tailed normal distribution; and p = proportion of estimated parameters.

To determine the sample size from projected population of **189,295** households for the year 2020, we use the z-value of 1.96, conservative p values of 0.50, q of 0.50 and 0.05 precision as follows:

$$n = 1.0\ x\ \frac{189{,}295\ x\ 0.5\ x\ 0.5}{\frac{0.05^2}{1.96^2}\ x\ (189{,}295 - 1) + 0.5\ x\ 0.5}$$

This calculation returns minimum sample size of **384** households. This sample size was distributed according to population proportion provided in Table 3.2 to obtain proportionate sample for each of the seven sub-counties (strata). Further, to take care of possible non-response and attrition during the longitudinal study, we adjusted the proportionate samples by a factor of 10% to obtain the desired samples shown in the table.

Table 3.2: Samples of households sampled from each Strata

Stratum	Population	Proportion	Proportionate Samples	Adjusted Samples
Bunyala	84,986	0.090	35	39

Butula	155,228	0.164	63	69
Matayos	141,822	0.150	58	64
Nambale	120,541	0.127	49	54
Budalangi	119,093	0.126	48	53
Teso North	150,231	0.159	61	67
Teso South	174576	0.184	71	58
Total	946,476		**385**	**424**

3.5.4. Selection of Community Health Volunteers

To get the sample size of community health volunteers (CHVs), the principal investigator used the simple random sampling from a target population of 2074 CHVs using the following expression:

$$\mathbf{n = deff\ x\ \frac{N\ x\ p\ x\ q}{\frac{e^2}{z^2}\ x\ (N-1) + p\ x\ q}}$$

where n = sample size; deff = design effect of 1.0; N = population per stratum; e is margin of error at ±5%; z = critical value for two-tailed normal distribution; and p = proportion of estimated parameters.

$$\mathbf{n = 1.0\ x\ \frac{2074\ x\ 0.5\ x\ 0.5}{\frac{0.05^2}{1.96^2}\ x\ (2074-1) + 0.5\ x\ 0.5}}$$

This calculation returns a sample of approximately **325 of** CHVs to be selected from the seven strata. This sample size of was distributed according to population proportions to obtain proportionate samples provided in Table 3.3. Further, to take care of possible non-response and attrition, we adjusted the samples by a factor of 10% to obtain the desired sample sizes shown in the table. The selected CHVs will be presented to the project management team and the County Health Management Committee for confirmation and approval to participate in the longitudinal study.

Table 3.3: Samples of community health volunteers per stratum

Sub-county	Proportions	Proportionate samples	Adjusted Samples
Bunyala	0.090	29	32
Butula	0.164	53	58
Matayos	0.150	49	54
Nambale	0.127	41	45
Budalangi	0.126	41	45
Teso North	0.159	52	57
Teso South	0.184	60	66
Total		**325**	**357**

Research Team

The survey team comprises of the Principal Investigator (s), stratum coordinators, County Health Management Advisory committee and short-term data enumerators. The team provided in Annex A7 will also be supported physically or remotely by officers and stakeholders from the Ministry of Health and implementing partners.

12. Data collection

Data collection will combine quantitative and qualitative methods, and will use standardized data collection tools and techniques.

3.7.1. Operationalization of Variables

In survey research, independent and dependent variables are used to define the scope of study. Before conducting the survey, the researcher must predicate a model that identifies the expected relationships among these variables. The indicators (variables) in Annex 2 have been operationalized into data capture tools provided in Annex A6 that will be used to collect quantitative and qualitative data during the baseline, midline and endline surveys.

3.7.2. Data Collection Instruments

In this study, data collection tools have been developed according to the objectives and variables of the study to obtain information on broad areas. The key dimensions of this study include level of immunization coverage, current status of data management, uptake of Chanjoplus platform, impact and sustainable utilization of the platform. The primary data collection tools provided in Annex 6 include questionnaires, focus group discussion (FDG) and key

informant interview guides. Primarily, questionnaires and FDG guide will be used to collect quantitative data from the caregivers and CHVs eligible to participate in the study. The health care providers will be engaged using a Key Informant Interviews (KII) guide that seek to obtain information from professionals on the use of Chanjoplus data management system and its impact on immunization coverage, decision making and sustainability beyond the lifetime of the Project. Before the actual survey is executed, pilot tests will be conducted to test both the instrument and survey procedures.

3.7.3. Training of Survey Team

A two-days training of enumerators will be conducted before the commencement of each survey. The training will mainly focus on the objectives of the survey, survey design, data collection instruments and analysis techniques. It is expected that training approaches such as role-play and practical demonstrations will be used to deliver the content. After the face-to-face training, the enumerators will be required to conduct a two-day pilot test to determine the reliability of the data collection tools and methods.

3.7.4. Communication to Respondents

The survey requires visits to households, community health units and health facilities to collect data based using different tools provided in Annex 6. During data collection phase, the field coordinators will contact the participants to confirm their availability for the survey. The enumerators will then be required to follow-up with the respondent in order to agree on convenient time and place for a face-to-face or online interview.

13. Data Quality Assurance

The term data quality assurance is used to describe features of data that can be measured or assessed against universally defined quality standards (Soti et al., 2015; Yamanaka et al., 2016). In Kenya, the Ministry of Health has defined Data Quality Assurance (DQA) protocol used to ensure health data adheres to dimensions of quality (GOK, 2014). These are accuracy, completeness, reliability, confidentiality, precision, and integrity. However, in this study, we adopt

universally defined dimensions of data quality summarized in Table 3.4 (Askham et al., 2013; Yamanaka et al., 2016).

Table 3.4: Primary dimensions for data quality assessment

Dimension	Definition	Measurement	Adherence Strategy
Accuracy	Degree to which information accurately reflects real world object or event being described	Percentage to which data reflects real world object or event	Repeated measurement or verification of primary data against trusted source or accuracy rules
Timeliness	Degree to which data represents reality from the required point in time	Date/time	Provide the time the real event or object being recorded occurred
Completeness	The proportion of stored data against critical data to be measured in any item, record, dataset or database	Absence of null or blank values	If measure of data item or indicator is mandatory, 100% completeness will be achieved
Integrity	Degree to which data conforms to business rule or specific format of its definition	Percentage of data items deemed valid	Definition of database, metadata and syntax rules as to the types, format and range of allowable data values
Consistency	The absence of difference when comparing two or more representations of the same thing against values, formats and definitions	Analysis of pattern and value frequency	Consent and protocol approval procedure to be followed
Uniqueness	Data item in a dataset or database is not recorded more than once	Count against stored records or dataset	No duplicate recording or storage of the same data item within the same dataset

Once data is collected, the County Health Management Advisory committee will perform manual verification and validation of data collected from paper registers, community health volunteers, and households. Before analysis and reporting, the Principal Investigator will examine 10% of survey datasets and database records to identify any quality issues that need to be resolved before analysis.

Data management and Analysis

Data Management

Data management and analysis is an important element of a credible and successful study. To enforce good management of data collected during the lifetime of this study, data governance framework and procedures will be established. The purpose of the framework is to provide standard procedures for data quality, storage, ownership, exchange, and use for analysis and decision making. The following are standard procedures that will be used to manage data quality before storage, analysis or presentation to target audience:

1. *Questionnaire checking*: Questionnaires will be checked for incompleteness or incorrect filling.
2. *Coding responses*: Codebooks will be used to code responses to numerical values for analysis using Microsoft Excel and statistical software.
3. *Cleaning*: After coding the responses, datasets extracted from data collection tools will be coded and pre-processed using electronic spreadsheets and code-sheets.
4. *Cross-validation:* Sensitive or controversial datasets will be shared privileged County or Ministry of Health officials for validation in terms of completeness, and integrity as per the requirements of the Data Quality Assurance (DQA) Protocol.

Data Analysis

In this study, data analysis and reporting will be done at various levels to compare planned targets with actual results. During baseline survey phase, data analysis will be used to better understand current vaccination coverage and related data management at different levels of care. Analysis at midline and endline studies will be used to measure the outcome and impact of Chanjoplus interventions, as well as utilization and sustainability of the platform beyond the project lifetime

Before analysis, the available datasets will be subjected to preliminary test for quality, integrity and reliability using manual and statistical tools such as Statistical Package for the Social Sciences (SPSS. Once the datasets satisfy these preliminary requirements, the next step is to conduct descriptive and inferential statistics at 95% level of confidence. Descriptive statistics such as frequencies

and cross tabulations will be used to reveal important social, demographic and health attributes obtained from the study. To get measure the effect of predictor variables on the outcome variable, Structural Equation Modelling (SEM) and multivariate analyses tools like will be used.

Depending on the number of subjects in each study cohort, Figure xx shows operationalized model that will be subjected into path analysis using covariance-based tools such as IBM's Amos or variance-based tools such as SmartPLS (citation). Bootstrapped p and z or t values obtained from the regression models will be used to estimate the strength of association between independent variables and the dependent variable. To augment the finding obtained from path analysis models, other multivariate analysis techniques such Analysis of Variance (ANOVA) and Principal component analysis (PCA) will be used. The triangulated findings will be used to measure effectiveness of taken Chanjoplus data management platform as a predictor to improved immunization coverage.

14. Ethical Considerations

In a study that involves human subjects, deployment of clinical tests or health interventions requires careful considerations of human rights, privacy, and protection against any form of risks (Khanlou & Peter, 2005; Moodley et al., 2013). To uphold these ethical requirements, we have developed a framework attached in Annex A3 meant to safeguard human subject's rights, confidentiality, and protection against possible physical or psychological harm. The following are the components of the framework that will guide this study in adherence to ethical practice when handling or interacting with human subjects:

3.10.1. Risks and Benefits

Potential risks involved in participating in this research as well as benefits expected by the participants have been identified for management during the experiment. The goal is to minimize potential physical or psychological harm while maximizing potential healthcare benefits.

Psychological Harm Participation in research may result in undesired, feelings of guilt, and loss of self-esteem. Most psychological risks are minimal and these effects are usually transient. The subjects will benefit from health education on

immunization personal data collected will be coded as early as possible in the activity and securely stored so that only the investigator and authorized staff may access it. Data stored on computers, mobile devices, and/or data-storage devices will be encrypted and password protected; Data in paper format will be kept in a locked area with access limited only to authorized research staff.

3.10.2. Human rights

The researcher will ensure protection of human rights regarding ethical principles of autonomy, beneficence and justice. In case subjects' identities are to be undisclosed, anonymous questionnaires will be used. Moreover, participants will have the right to withdraw at any time without penalty.

3.10.3. Informed consent

It is essential that subjects who serve as respondents in a scientific research provide informed consent either explicitly or implicitly. In this study, documents such as participants' informed consent form provided in Annex A4.

In summary, this chapter describes the methodology to be employed during the cross-section surveys. To adhere to health policies, guidelines, standard operating procedures (SoPs) and ethical practice, this proposal will be submitted to the Kenyatta National Hospital/University of Nairobi Ethics Research Committee (KNH/UON-ERC) for consideration and approval.

3.10.2. Safety in view of COVID - 19

According to MOH (2020) there is need for partners to have sustained provision of community health services during the COVID - 19 pandemic. In Kenya, the pandemic is at Community transmission with confirmed cases with no history of travel or contact with an infected person. In order to continue with community services as part of essential services, Health education and preventive and promotive health messaging will be provided while maintaining hygiene, hand washing and physical distancing. Training of research assistants and enumerators will be done will observing the COVID-19 guidelines of physical

distancing and, hand washing and use of masks. Every training will have a maximum of fifteen people.

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ANNEXES

A1. Estimated Budget

Budget line Description	Cost (Ksh.)
Research protocol preparation and submission for approval	25,000
Development of data instruments, interview guides and focus group discussion guidelines	50,000
Project management (Internet connectivity, airtime, stationery, printing, photocopies, coordination)	435,000
Training of coordinators, survey supervisors and data enumerators	100,000
Pilot test of Chanjoplus and data collection instruments	700,000
Hiring of training site (conference hall)	78,000
Supplies and equipment (Data collection media such as cameras, mobile phones, and training equipment (projectors, flipcharts)	167,000
Remuneration and wages (Allowances for principal investigator, trainers, supervisors, research assistants, drivers and local guides)	840,000
Travel and accommodation (Commuter fare, fuel or rental of vehicles)	200,000
Participants service costs (meals, calls and conference materials, and facilitation charges)	250,000
Hiring of data science and health experts (payment of service charge, transport and per diem)	186,000
Dissemination (Reports preparations, presentation in conferences and publishing in refereed journals	200,000
Contingency (%)	250,000
Miscellaneous	350,000
Total	**3,831,000**

A2. Indicators Logical Framework

	OBJECTIVES	INDICATORS	VERIFICATION	RISKS
Impact	Increased percentage of Fully immunized children in Busia County	FIC percentage increasing from 78% to 90%	Chanjoplus data management platform and DHIS	(A) Increased immunization coverage to 90%
Outcomes	Reduced number of infants missing immunization appointments	Increase number of FIC from 78% to 90%	Chanjoplus system	(R): Resistance to change by health providers and CHVs
	Immunization Data management	Increase completeness, timeliness, accuracy and consistency of immunization data across all levels of services delivery	Chanjoplus system and DHIS2 (HIS-kenya)	(A): Increased accuracy of immunization data. (R): Resistance to change by the key stakeholders and technophobia
	Policy and decision making	Aid in immunization services decision making and policy development	Baseline, Midline and End line surveys	(A): The study conducted will lead to recommendations on policy development and immunization activities decision making.
Outputs	Number of CHVs Trained	720 CHVs trained on the platform	Chanjoplus system and	(A): The training is well delivered

	and on boarded	and project objectives	training registers	for all to understand (A): All CHV invited for the training are present and at the end of the training have an understanding of the project and data system
	Number of health providers Trained and on boarded	153 health workers trained to use Chanjoplus platform	Chanjoplus system and training registers/Reports	(A): The training is well delivered for all to understand (A): All HPs invited for the training are present and at the end of the training have an understanding of the project and data system
	Number of care givers registered	72000 caregivers and infants registered	Chanjoplus system	(A): All caregivers agree to be registered. (R): Resistance from the caregivers. (R): Caregivers missing phones or ID Cards (R): Foreigners seeking care in Kenya
	Number of infants tracked	Infants missing immunization tracked within 7 days	Chanjoplus system	(A) All caregivers and infants tracked will honour their appointments

		of their appointment date		
Activities	Develop a training manual for CHVs and Health Providers	Training manual ready and tested	Training manuals	(A): Training manual captures all the aspects of the project
	Training of CHVs and HPs and onboarding	1OO% attendance of training meetings	Training registers	(A): All CHVs and HPs invited for training will be in attendance
	Registration of infants on the platform	72,000 infants and caregivers registered	Chanjoplus system	(A): All caregivers will accept to be registered and give correct information during registration.
	Tracking of infants missing immunization appointments	SMS send to caregivers whose infants missed immunization schedule within 7 days	Chanjoplus system	(A): Phone numbers used by caregivers during registration can be accessed during project implementation for ease access to SMS reminders
Input	• Human Capital: content developer, medical professional, programmer, Principal researcher, research assistants • Funding: equity loan, sponsorship and grants, Chanjoplus revenues • Infrastructure: office, computers, mobile phones, and tablets			

A3. Participants' Protection Framework

The reason we are giving you this document is for you to understand about our study particularly your rights, risks and benefits. Once you have understood the content, you can decide if you wish to participate. After all, you can also decide to voluntarily withdraw from the study any time you fill deemed fit.

Who is doing this study?

Our names are *Stephen Mburu, Collince Osewe* and *Joseph Baraza*. We are conducting a survey to investigate the impact of a mobile-based intervention known as Chanjo-Plus on maternal and child care.

What is the purpose of this study?

Given that Chanjoplus is relatively new, the complexity of implementing solutions suitable for realistic maternal and child health needs is evident in failed attempts to integrate it into healthcare systems in low resource settings. The purpose of this study is to demonstrate the impact and sustainability of mHealth intervention in accessing health care prior to actual deployment. The findings from the study will be used as a blueprint for system developers and policy makers in healthcare sector to manage deployment of mHealth interventions.

What happens in this study?

Currently, we have deployed Chanjoplus as a pilot project but with intention to scale-up in Busia County. It is after deployment in Busia that we intend to carry out the cross-sectional surveys upon approval by Kenyatta National Hospital/University of Nairobi Ethics Research Committee (KNH/UON-ERC). Once approved, we plan to:

- Obtain baseline information regarding current difficulties of accessing maternal and immunization services and how much Chanjoplus can be of help.
- Register antenatal and postnatal clients to Chanjoplus intervention for at least five months after training to use Chanjoplus.

- Compare the baseline survey on immunization coverage and data-driven decision making against findings obtained during midline and endline surveys.

Risks and discomforts

Though there are no known risks and discomfort before the commencement of the study, necessary measures will be undertaken if encountered. In case any issue crops up during the study, we will assist you as a participant to seek for further clarifications from the principal investigator and the County administration.

What are the benefits to being in this study?

Because participation is voluntary, the participant will not receive any participation payment, gifts or rewards. However, if necessary, we will offer technological support such as free SMS alerts and resources that may be needed during the study.

What are the possible costs to participating?

Participants will not incur any financial cost other than the time required to participate in the planned study.

Confidentiality:

The information provided in this study will be treated as confidential hence it will not be used for any other purpose other than for this study. In case as a participant you wouldn't want your identity disclosed, we shall not disclose it in whichever form or media.

Compensation for Injury:

This research is a voluntary non-intrusive survey hence no research related risks are anticipated. As a participant you have the right to participate, not participate, or withdraw from the study at any time. In case any physical or physiological risks occur during the study, necessary steps will be undertaken to mitigate the risk or injury.

A4. Consent Form

I (full name of participant……have read the above information / the above information has been explained to me by (full name of person taking consent) ……, and I have fully understood the information. I have had opportunity to ask questions, and all my questions have been answered to my satisfaction. I understand that I may at any time during the study revoke my consent without any loss or penalty. I consent to be enrolled in the study.

Signature…… Date……
(Participant)

Signature…… Date……
(Person taking consent)

Signature……Name (Print)……
(Witness)

Date……

If you require any further information or clarifications, please contact the principal investigator using the contact details below:

Mr. Joseph Baraza
Chanjoplus
P.O. Box 10311-00100
NAIROBI

A5. Cover Letter

Dr. Stephen Mburu, PhD
University of Nairobi
P.O. Box 30197-00100
Nairobi, Kenya.

Date.....

Dear Respondent,

RE: VOLUNTARY PARTICIPATION IN FIELD STUDY

My name is Dr. Stephen Mburu, a health informatics researcher based at the School of Computing and Informatics, University of Nairobi. My research interest is use of Information technologies to enhance access to healthcare particularly in underserved areas in Kenya. As the Principal Investigator for Chanjoplus, my role is to establish effectiveness of Chanjoplus mobile and web-based in enhancing on immunization coverage and decision making while reducing cost and inconsistencies associated with paper-based tracking system.

To achieve this objective, we invite your voluntary participation in the field study. As a participant you have the rights to participate, or withdraw from the study at any time. In case any physical or physiological harm that may affect your participation occurs during the study, necessary steps will be taken to mitigate such risks or injuries. To safeguard your privacy, the information you provide during the study will be treated as confidential and will only be used for the purpose of this study. We appreciate your sacrifice to making this study a success.

Your Sincerely,

Dr. Stephen Mburu.
Specialist, Health Informatics

A6. Data collection instruments

Questionnaire for Measuring Impact of Chanjo-Plus on immunization coverage in Busia County- Community Health Volunteers

In this study, we are interested in getting your views on whether Chanjoplus service has improved immunization coverage in the county.

Personal Details (for analysis purposes only)

Sub-County	CHU	Education	Age

Current status of immunization coverage in Busia County [Baseline]

1. Number of households within your community?
2. Average number of infants in each household? ☐
3. Number of fully immunized children under 18 months? ☐
4. Rate the level of immunization defaulters in your community?

   ☐High ☐ Medium ☐ Low

5. What are some of the immunization challenges you face in your community?

   ……
   ……
   ……
   ……
   ……

6. Do you have a mobile phone?

   ☐ Yes ☐ No

7. Does immunization data management affect immunization coverage in your community?

   ☐ **Yes** ☐ **No**

8. Would you embrace use of mobile phone for registration of infants and care givers?

   ☐ Yes ☐ No

9. Would you accept immunization notifications to be sent to your mobile phone?

☐ Yes ☐ No

10. Will the reminders for immunization schedules be useful to you?

☐ Yes ☐ No

11. Will the use of Chanjo-Plus platform increase immunization coverage in the community?

☐ Yes ☐ No

Uptake of Chanjo-Plus as an intervention for improving immunization coverage data management for informed decision making [Midline]

1. Have you used Chanjo-Plus platform to register infants and caregivers in your community?

☐ Yes ☐ No

2. How many infants have you registered on Chanjo-Plus platform in your community? ☐

3. Have you received immunization notifications on your mobile phone?

☐ Yes ☐ No

4. Are those notifications useful to you?

☐ Yes ☐ No

5. Has Chanjo plus platform increased immunization coverage in your community?

☐ Yes ☐ No

6. What are some of challenges that Chanjo-Plus platform is solving in your community?

……
……
……
……

7. How is immunization data management affecting immunization coverage in your community?

……
……
……
……

8. What is your current experience in using Chanjo-Plus registration platform?

☐ Excellent
☐ Very good
☐ Good
☐ Poor
☐ Very poor

9. what are some of the parts that you would like to be included in the Chanjoplus mobile platform for ease of use?

……
……
……

Impact of Chanjoplus on immunization coverage and utilization by community health units from sub-county to the county level [Endline]

1. Has Chanjo-Plus platform bridged the gap of immunization defaulters in your community?

☐ Yes ☐ No

2. Were the immunization notifications on your mobile phone useful to you?

☐ Yes ☐ No

3. Does Chanjo-Plus platform help in monitoring immunization coverage?

☐ Yes ☐ No

4. has the use of the Chanjo-Plus platform in increased immunization coverage?

☐ Yes ☐ No

5. Has Chanjo-Plus solved some of the immunization challenges in your community?

☐ Yes ☐ No

6. Do you think your experience in mobile based immunization registration process increased after use Chanjo-Plus platform?

☐ Yes ☐ No

7. *Please indicate extent to which Chanjo-Plus has helped to monitor immunization coverage and uptake in your community?*

7.1. Chanjo-Plus provides very useful approach in managing immunization data

☐ Strongly ☐ Agre ☐ Not ☐ Disagree ☐ Strongly

7.2. Chanjo-Plus service is very useful in reminding caregivers to take their children for immunization.

☐ Strongly ☐ Agre ☐ Not ☐ Disagree ☐

7.3. Chanjo-Plus helps me in tracking immunization history of infants in my community

☐ Strongly ☐ Agre ☐ Not ☐ Disagree ☐ Strongly

General Comments

1 Please tell us how satisfied you are with Chanjo-Plus platform?

- ☐ Strongly satisfied
- ☐ Satisfied
- ☐ Not sure
- ☐ Dissatisfied
- ☐ Strongly dissatisfied

2 Please use the space below to suggest how we can improve Chanjo-Plus SMS and registration services

_____

_____

_____

Questionnaire for Measuring Effectiveness of Chanjo-Plus on immunization coverage in Busia County [Caregivers]

In this study, we are interested in getting your views on whether Chanjo-Plus service has improved immunization coverage in the county.

Personal Details (For analysis purposes only)

Sub-County	CHU	Education	Age

Current status of immunization coverage in Busia County(Baseline)

1. How many children under 18 months are in your house?
2. How many have received the measles vaccine at 9months? ☐
3. How many have not received the measles vaccine at 9 months? ☐
4. Where do you take your children for immunization? ☐
5. How do you get reminders for immunization?

☐ TV ☐ Radio ☐ CHVs ☐ None

6. Do you have a mobile phone?

☐ Yes ☐ No

7. Would you embrace mobile phone registration of your Children for immunization tracking purposes?

☐ Yes ☐ No

8. Would you accept Chanjp-Plus immunization notifications to be sent to your mobile phone?

☐ Yes ☐ No

9. Will the reminders for immunization schedules be useful to you?

☐ Yes ☐ No

10. Do you think use of Chanjo-Plus platform will reduce missed immunizations in your house?

☐ Yes ☐ No

Uptake of Chanjo-Plus as an intervention for improving immunization coverage data management for informed decision making (Midline)

1. Have you been registered as a caregiver on Chanjo-Plus platform?

☐ Yes ☐ No

2. Have your children been registered on Chanjo-Plus platform?

☐ Yes ☐ No

3. Have you received Chanjo-Plus immunization notifications on your mobile phone?

☐ Yes ☐ No

4. Has immunization notifications helped you take your child for vaccinations?

☐ Yes ☐ No

5. Have the notifications reduced missing of vaccinations in your house?

☐ Yes ☐ No

6. What is your current experience with Chanjo-Plus platform?

☐ Excellent
☐ Very good
☐ Good
☐ Poor
☐ Very poor

Impact of Chanjoplus on immunization coverage and utilization by community health units from sub-county to the county level (Endline)

1. Have all your children received measles vaccine at 9months?

☐ Yes ☐ No

2. Has Chanjo-Plus platform contributed to full immunization of your children?

☐ Yes ☐ No

3. Rate the extent to which Chanjo-plus has contributed to full immunization of your children?

☐ High ☐ Medium ☐ Low

4. Did you receive immunization notification on your phone?

☐ Yes ☐ No

5. How useful were those immunization notifications to you?

☐ Extremely useful ☐ Very useful ☐ Useful ☐ Not useful

6. Do you think the level of immunization coverage has increased after use of chanjo-plus platform?

☐ Yes ☐ No

7. Do you recommend continuous use of Chanjo-Plus platform in delivery of immunization in your community?

☐ Yes ☐ No

8. General Comments

9. Please tell us how satisfied you are with Chanjo-Plus platform?

☐ Strongly satisfied
☐ Satisfied
☐ Not sure
☐ Dissatisfied
☐ Strongly dissatisfied

10. Please use the space below to suggest how we can improve Chanjo-Plus SMS and registration services

_____
_____

KEY INFORMANT INTERVIEW GUIDE

1. What is the latest immunization coverage of this facility/sub county/County?
2. What do you consider as factors that influence uptake of immunization in your facility/Sub county/County?
3. *Contextual e.g. distance to the facility, cost to the facility time taken to reach the facility religion, gender, timings of the facility*
4. Do you think enough information is given to clients regarding vaccines and their safety?
5. What is your perception regarding electronic medical records?
6. What are the barriers to getting quality data? How can these barriers be overcome?
7. How has Chanjoplus system impacted uptake of immunization
8. How has Chanjoplus system improved immunization data management?
9. In your opinion how is Chanjoplus immunization system sustainable to meet needs?
10. How can Chanjo plus improve the immunization data management system?

A7. Roles and Responsibilities

Various Project members from Chanjoplus Limited, University of Nairobi, County Government of Busia, Ministry of Health, and Grand Challenge Canada will have designated roles and responsibilities. The table below shows individual and corporate roles and responsibilities.

Role	Responsibilities	Facilitator(s)
Project Sponsor	• Resolving major issues escalated by project manager	• Solina Teav, Grand Challenge Canada
Principal Investigator	• Design of the Study Methodology • Managing all activities relating to data collection and analysis • Disseminate Study Status reports to stakeholders • Guide Chanjoplus in implementation of mobile-based interventions	• Stephen Mburu, UON
Project Lead	• Overall Project Quality Control • Internal Resource Mobilization • Chair Project Steering Committee Meetings • Identify and manage project risks	• Collins Osewe, CEO Chanjoplus Limited
Project Manager	• Manage day to day running of the project • Issuing project status reports Coordination of project activities in the various business areas	• Joseph Barasa, Chanjoplus Limited
Project Steering Committee	• Communications to external stakeholders on project progress • Approval of project plans • Approve the major project milestones • Advisory Role	• County Health Management Team • MOH-Kenya • Chanjoplus Limited • UON
Project Implementation Team	• Business Area process owners • Subject Matter Expert (SME) • Business Area project deliverables and milestones • Manage project scope within respective business area • Sign off on business area user requirements and processes • Authorizing Change Requests • Change Agent in respective functional area	• Chanjoplus Limited • Busia County Government • Grand Challenge Canada • MOH-Kenya • Director, SCI-University of Nairobi

CHANJO plus
...Life Saving Vaccines 4EVERYCHILD

Evaluating Effectiveness and Impact of Chanjoplus Platform in Supporting Immunization Coverage and Data Management System in Busia County

GRADEMARK REPORT

FINAL GRADE

/0

GENERAL COMMENTS

Instructor

PAGE 1

PAGE 2

PAGE 3

PAGE 4

PAGE 5

PAGE 6

PAGE 7

PAGE 8

PAGE 9

PAGE 10

PAGE 11

PAGE 12

PAGE 13

PAGE 14

PAGE 15

PAGE 16

PAGE 17

PAGE 18

PAGE 19

PAGE 20

PAGE 21

PAGE 22

PAGE 23

PAGE 24

PAGE 25

PAGE 26

PAGE 27

PAGE 28

PAGE 29

PAGE 30

PAGE 31

PAGE 32

PAGE 33

PAGE 34

PAGE 35

PAGE 36

PAGE 37

PAGE 38

PAGE 39

PAGE 40

PAGE 41

PAGE 42

PAGE 43

PAGE 44

PAGE 45

PAGE 46

PAGE 47

PAGE 48

PAGE 49

PAGE 50

PAGE 51

PAGE 52

PAGE 53

PAGE 54

PAGE 55

PAGE 56

PAGE 57

PAGE 58

PAGE 59

PAGE 60

PAGE 61

PAGE 62

PAGE 63

PAGE 64

PAGE 65

PAGE 66