SYSTEM AND SITE READINESS FOR CONDUCTING ACTIVE SURVEILLANCE

Of ADVERSE EVENT FOLLOWING IMMUNIZATION IN ADDIS ABABA, ETHIOPIA.

MSc Research thesis

Eden Dagnachew Zeleke

June 2021

Addis Ababa, Ethiopia

System and site readiness for conducting active surveillance of adverse Events following Immunization in Addis Ababa, Ethiopia.

A research thesis submitted to Addis Ababa University, College of health sciences, CDT Africa.

In partial fulfillment of the Requirement for the Degree of MASTERS IN CLINICAL TRIAL.

Investigator:

Eden Dagnachew (ID.No:9847/12)

Email: Eden.dagnachew@aau.edu.et

Phone number: +251934774373

Advisors:

Professor Eyasu Makonnen

Email: eyasumakonnen@yahoo.com, eyasu.makonnen@aau.edu.et

Dr. Getnet Yimer

Email: ali.578@osu.edu

June 2021

Addis Ababa, Ethiopia

STATEMENT OF DECLARATION

By my signature below, I declare and affirm that this thesis is my own work. I have followed all ethical principles of scholarship in the preparation, data collection, data analysis and completion of this thesis. All scholarly matter that is included in the thesis has been given recognition through citation. I affirm that I have cited and referenced all sources used in this document. Every effort has been made to avoid plagiarism in the preparation of this thesis. This thesis is submitted in partial fulfillment of the requirement for a postgraduate degree from the Addis Ababa University at College of Health Sciences, Center for Innovative Drug Development and Therapeutic Trials for Africa (CDT Africa). The thesis is deposited in the Addis Ababa University Digital Library and is made available to local, national and international scientific community. I solemnly declare that this thesis has not been submitted to any other institution anywhere for the award of any academic degree, diploma or certificate. Brief quotations from this thesis may be used without special permission provided that accurate and complete acknowledgement of the source is made. Requests for permission for extended quotations from, or reproduction of, this thesis in whole or in part may be granted by the Head of the Department or all advisers of the theses when in his or her judgment the proposed use of the material is in the interest of scholarship and publication. In all other instances, however, permission must be obtained from the author of the thesis.

STUDENT NAME

Eden Dagnachew Zeleke RANK (BSc) SIGNITURE _____Date: _____

RESEARCH ADVISORS

Prof. Eyasu Makonnen RANK (PhD, Professor (Full))

SIGNITURE_____DATE_____

Dr. Getnet Yimer RANK (MD, PhD) SIGNITURE_____DATE_____

APPROVAL BY THE BOARD OF EXAMINATION

This thesis by Eden Dagnachew Zeleke is accepted in its presence from the board of examiners as satisfying the thesis requirement for the "Master of Science Degree in Clinical Trial."

This is to verify that this thesis has been accepted in partial fulfillment of the requirement for a "Master of Science Degree in Clinical Trial."

SUBMITTED BY:

EDEN DAGNACHEW ZELEKE (BSC) _____ _____.

NAME OF STUDENT SIGNATURE DATE

EXAMINERS:

Dr. Yimtubezinash Woldeamanuel MD, M.Sc., PhD _____ _____

NAME RANK SIGNATURE DATE

Dr. Gizachew Yismaw PhD, Post Doc. fellow _____ _____

NAME RANK SIGNATURE DATE

RESEARCH ADVISORS:

1. PROF. EYASU MAKONNEN PhD, Professor _____ ____

NAME OF PRINCIPAL ADVISOR RANK SIGNATURE DATE

2. DR. GETNET YIMER ALI MD, PhD _____ _____

NAME OF CO-ADVISOR RANK SIGNATURE DATE

DEPARTMENT HEAD:

DR. ABEBAW FIKADU PHD. Associate professor _____ ____

NAME OF DEPARTMENT HEAD RANK SIGNATURE DATE

ACKNOWLEDGEMENT

Thanks to Almighty God, the Lord of wisdom, knowledge, and understanding.

I would like also to express my gratefulness to Addis Ababa University, CDT Africa for allowing me to study masters in a clinical trial.

My special gratefulness goes to my Advisor Dr.Getnet Yimer, as he offered me to conduct this research together with the GOHi investigator and for the invaluable comments, suggestions, advice, time, and commitment to the success of this thesis together with my Advisor Professor Eyasu Makonnen. Additionally, I would like to thank all team members in the Active Adverse Event Following Immunization Surveillance [Professor Wondwossen Gebreyes (Executive Director of Global One Health initiative (GOHi) at The Ohio State University), Shu-Hua Wang (Professor, Internal Medicine Medical Director, Ben Franklin TB Program, Columbus Public Health), Sarah D Bennett (CDC/DDPHSIS/CGH/GID), Laura Conklin (CDC/DDPHSIS/CGH/GID), Dr.Leul Lisanwork (Monitoring and Evaluation Expert of GOHi)].

My sincere thanks go to my family members for their continuous enormous encouragement throughout my entire life journey.

Table of Contents

LIST OF TABLES

LIST OF FIGURES

ABBREVIATION AND ACRONYMS

AEFI - Adverse Event Following Immunization

AESIs - Adverse Events of Special Interest

AFP – Acute flaccid Paralysis

CDC - Centers for Disease Control and Prevention

CDT Africa - Center for Innovative Drug Development and Therapeutic Trials for Africa

CIOMS - Council for International Organizations of Medical Sciences

DPT - Diptheria, Tetanus toxoids and Pertussis Vaccine

DDPHSIS - Deputy Director for Public Health Service and Implementation Science

DHIS2 - District Health Information Software 2

EPHI - Ethiopia Public Health Institute

EFDA - Ethiopian Food and Drug Authority

EPI - Expanded Program on Immunization

GID - Global Immunization Division

GVAP - Global vaccine action plan

GVSB - Global vaccine safety Blueprint

GVSI - Global vaccine safety initiative

Hib – Haemophilus influenza type B

HMIS – Health Management Information System

ICD – International classification of disease

LMIC – Low and Middle-Income Countries

MNT – Maternal Neonatal Tetanus

NIP - National Immunization Program

NMRAs - National Medicines Regulatory Authorities

NRA - National Regulatory Authority

PVC - Pharmacovigilance Center

PHEM – Public Health Emergency Management

PMS – Post Market Surveillance

SPHMMC – Saint Paul Hospital Millennium Medical College

TASH – Tikur Anbessa Specialized Hospital

UNICEF - United Nation Children's Fund

VVM - Vaccine vial monitor

WHO - World Health Organization

ABSTRACT

Background: Vaccine pharmacovigilance (PV) aims to detect, assess, comprehend, communicate and manage adverse events following immunization (AEFI). To help distinguish vaccine related AEFIs from coincidental occurrences, an active PV prospective surveillance programs (e.g. hospital-based sentinel sites) are needed. We describe our experience in assessing system and facility readiness for implementing a pilot active AEFI PV in Addis Ababa, Ethiopia.

Method: Three hospitals were selected for this study after objectively evaluating all the government hospitals in Addis Ababa using parameters ;ongoing collaborations with the Ethiopian Food and Drug Authority (EFDA), previous experience in research, being referral government hospital and proximity to key AEFI stakeholders in Addis Ababa. We developed a readiness assessment together with scoring tool and system readiness assessment tool by adapting published framework. The site assessment was conducted via in person interview of specific departments in each hospital while a desk review of AEFI guideline, Expanded Program for Immunization (EPI) guideline, EFDA and Ethiopian Public Health Institute (EPHI) website was done for system readiness.

Results: Three out of thirteen (23.1%) hospitals in Addis Ababa met the criteria for our site assessment. During the system readiness assessment, we found that essential components were in place, Specific regulation and proclamation on AEFI surveillance except mentioning responsibility of every stakeholder on the guideline was, however absent. Based on the scoring tool, Tikur Anbessa Specialized Hospital (TASH) scored 94 out of 155 (60.6%), Saint Paul Hospital Millennium Medical College scored 75 out of 155 (48.38%) and Gandi Memorial Hospital scored 62 out of 155 (40%). Paper-based records were used by all departments except those of laboratory and radiology in TASH and SPHMMC. International Classification of Disease (ICD) 9/10 coding was only used in TASH. Copies of national AEFI guidelines were not present in all departments and reporting forms were found only in 4 departments surveyed across the three hospitals. Staff at both Gandi Memorial Hospital and SPHMMC reported absence of training on AEFI surveillance.

Conclusion: TASH has the highest score after assessing readiness for piloting active AEFI surveillance. We also identified the following areas for improvement in all hospitals to ensure successful implementation: training, making guideline and reporting forms available, and ensuring a system that accommodates paper-based and electronic record systems.

CHAPTER ONE: INTRODUCTION

1.1 Background

World Health Organization (WHO) defines a vaccine as "a biological preparation that improves immunity to a particular vaccine-preventable disease"**(1)**. A vaccine mainly contains a disease-causing microorganism of a specific vaccine-preventable disease and is usually made of either live-attenuated or inactivated (killed) forms of microbes, its toxin, or one of the surface proteins. Immunization is one of the most effective public health interventions for vaccine-preventable diseases if used correctly**(1, 2).** Currently, vaccines avert 2-3 million deaths each year caused by vaccine-preventable diseases**(3).**

The Expanded Program on Immunization (EPI) was started in Ethiopia in 1980**(4)**. The vaccines that have been administered are Bacillus Calmette–Guérin, Measles, DPT-HepB-Hib or pentavalent, Rotavirus, Pneumococcus vaccine (PCV), Oral Polio Vaccine, Human Papillomavirus (HPV) vaccine, Measles-containing-vaccine second-dose and, Tetanus Toxoid **(4, 5).**

Based on evidence that came from randomized control trials, it is believed that a safe and effective vaccine has been delivered by the National Immunization Program (NIP). Nevertheless, no vaccine is entirely safe because of Adverse events following immunization (AEFI) is inevitably occur after vaccination **(1)**. Contrasting to drugs, the expectation from vaccinations is much higher, and adverse events associated with vaccines are less acceptable by the general public as they are given to healthy people. AEFI may provide a reason for opponents of vaccination against national vaccination recommendation, although the events are rare and might not be related to the vaccine**(1, 6).**

An AEFI is "any untoward medical occurrence which follows immunization and does not necessarily have a causal relationship with the usage of the vaccines"**(7).** AEFI may be unexpected signs, symptoms, diseases, or abnormal laboratory findings. In 2012, the Council for International Organizations of Medical Sciences (CIOMS) and WHO amended cause-specific categorizations of AEFI: vaccine product-related reaction, vaccine quality defect related-reaction, immunization error, immunization anxiety related-reaction, and coincidental event. Cause-specific categorization of

AEFI is important for decision-making about a vaccine product since it clearly distinguishes the types of possible reactions associated with the components of vaccines**(1, 2).**

1.1.1. Adverse Events Following Immunization Surveillance

Vaccine Pharmacovigilance is the science which works on detection , assessment, understanding , taking an action , and communicating AEFIs or immunization-related issues **(1, 8)**. AEFI surveillance can deliver reliable data and communicate updated information on the benefit-risk profile of vaccine safety, potentially preserving public trust in vaccinations **(9)**.

Types of AEFI Surveillance

Surveillance of immunization safety can be active or passive **(10)**.These are systems that monitor events reported by different stakeholders in which active surveillance uses actively collected data (sentinel site) or measure outcomes while passive surveillance uses not actively collected data**(11)**. Active vaccine safety surveillance can also be achieved through formally designed epidemiological studies**(12)**. Active surveillance has the capability of identifying more AEFI, especially those presenting to sentinel sites, like hospitals, and able to compare the rate of AEFI based on vaccination status and temporal period, unlike Passive surveillance systems which encounter drawbacks like unverified diagnoses, scarce reporting of severe adverse events data, limited elaboration of a temporal link between AEFI and vaccination and implausible reporting of delayed adverse events (10). Sentinel surveillance can be achieved by recruiting healthcare providers or through hospitals to regularly report specified health events (13).

WHO recommends that all countries maintain passive surveillance for AEFI **(14).** However, active surveillance might also be needed in some circumstances like during the introduction of a novel vaccine with limited safety data from other countries, if a well-established new vaccine is introduced to a country , if a new signal detected through a passive system and , to evaluate a vaccine in a specific population**(12)**.

To achieve AEFI monitoring, an institutional arrangement that involves a functional National Regulatory Authority (NRA), National Immunization Program (NIP), disease surveillance unit of Ministry of Health, and center for Pharmacovigilance should be established. They should work in

collaboration with WHO and United Nation Children's Fund(UNICEF) with clearly defined roles and responsibilities which can ensure the vaccines safety and Pharmacovigilance system functions very well **(2, 15).** Vaccines manufacturers and national control laboratories should also be involved in the system if they are in the position of vaccine production in that country **(16).**

A clear and credible data and information flow pathway should also be established and maintained to ensure that data are consistently gathered, analyzed, and reported to NRAs, manufacturers, and the Pharmacovigilance centers **(2, 15).**

Even though active surveillance is believed that it can supplement passive surveillance, it is well known that it requires huge capacity, time, and resources. Although WHO's COVID-19 Vaccines Safety Surveillance Manual mention the need for countries "to ascertain if they have the capacity to implement active surveillance of adverse events of special interest (AESIs)" which help them to ensure the time to implement active surveillance systems (17). As a result, countries use the result of the assessment to strengthen their capacity, fulfill the identified gaps and get ready for the surveillances.

1.2 Statement of the problem

Based on the finding of one-on-one interviews with more than 70 surveillance officers from the Ministries of Health, WHO regional office for Africa staff and partners conducted July–August 2018, serious challenges in African regions were recognized on their Vaccine Preventable Disease surveillance systems (18). These changes include fragmented system, scarcity of public resources, difficulties in controlling the power of community-based surveillance, use of vertical (disease-specific) approaches, difficulties with staff retention and training, and transportation issues. WHO identified six components as a widespread and constant area for assessment and future improvement of Vaccine Preventable Disease surveillance in the African region (i.e. governance and management, the standard setting for surveillance, surveillance process and reporting, laboratory network, specimen management, and detection and response). The level of maturity of each of the components was defined and rated from 1 to 4, with level 1 referring to low maturity (a weak surveillance system with major gaps), level 2 (significant deficiencies in several dimensions), level 3 (some deficiencies in several dimensions) and level 4 (targeted areas for improvement) the highest level of maturity. As a result based on WHO internal expertise, eight African countries were identified under category 1, 20 countries under category 2, 10 countries under category 3, and 9 countries under category 4. Ethiopia was categorized under category 3 **(18).**

Another study **(19)** compared the current Pharmacovigilance system at the national medicine regulatory authority (NMRAs) in four East African countries including Ethiopia, Kenya, Rwanda, and Tanzania. The finding was that there were gaps like inadequate reporting of suspected medicine-related harm from stakeholders, only Kenya and Tanzania allocated budget for Pharmacovigilance activities and an electronic individual case safety report (ICSR) system, and all countries lacked data on drug utilization.

AEFI monitoring and surveillance can also be influenced by the knowledge, perception, and practice of health care workers. Poor level of knowledge were identified in china **(20)** and again in Nairobi on identifying the cause of AEFI, reporting method and investigation and management of post-immunization anaphylaxis's; poor perception like fear of personal consequence and lack of

awareness of nurse's role in reporting an AEFI and poor practice were identified problems**(21)**. In another study **(22)**,issues identified as a problem was that parents (caregivers) did not count adverse events as serious enough to report**.** Low competency of health care system in identifying AEFI in sub-Saharan Africa like Ghana was also reported in a study conducted in 2018 **(23)**

Active AEFI surveillance is employed through active reporting. Active reporting needs more time and resource which make it expensive than passive surveillance (24). In Ethiopia, there is no recent published evidence that evaluated the readiness of the system and the sites responsible for immunization safety surveillance. Hence, assessing readiness for implementation of active surveillance for AEFI of the overall system and selected hospitals that practically provide immunization services in Addis Ababa will have significant programmatic implications for the country.

1.3 Significance of the study

Implementation of active surveillance for AEFI at key sites may provide Ethiopia an opportunity to better understand the roles of Expanded Program for Immunization (EPI), Ethiopian Public Health Institute (EPHI), and Ethiopian Food and Drug Authority (EFDA), and prepare the country for future introductions of active surveillance for novel Corona virus vaccine AEFI. Ethiopia may have the opportunity to contribute evidence to a better understanding of the role of active AEFI surveillance in low and middle-income countries. Before recommending the implementation of active surveillance, we propose to conduct a readiness assessment (system and site readiness) to properly identify the current status in terms of the pre-requisites to its implementation.

Therefore, the results of this readiness assessment will be helpful for different organizations:, (a) the study hospitals will be able to identify areas of improvement to improve their performance in the collecting, analyzing, and reporting AEFI, (b) the hospitals which will be included in the assessment and concerned stakeholders will use the findings to properly prepare themselves for active AEFI surveillance, (c) at the national level the findings will help evaluate national Pharmacovigilance systems and identify areas requiring attention to improve the reporting and response capacity.

CHAPTER TWO: LITERATURE REVIEW

Since active vaccine safety surveillance is time taking and expensive, it needs adequate preparation and readiness in terms of resource and expertise before program establishment **(12)**. There is an imbalance between vaccine safety activity and the introduction of new and complex vaccines in low and middle-income countries (LMIC). LMIC has been introducing vaccines at the same time with high-income countries for which the safety surveillance system is inadequate and limited **(14)**. In 2012, WHO developed a Global vaccine safety blueprint (GVSB) to help LMIC establish a vaccine safety monitoring system . This blueprint provides a framework to plan, implement and strengthen vaccine safety activities like monitoring and communication of AEFI. Countries which undertake vaccine safety system should have minimal capacity, i.e., staff, funding, a clear mandate, well-defined structure, and role, collaboration with WHO PIDM, health care worker for reporting, reporting form, national database/ system, national AEFI expert review committee (ARC), a clear strategy for risk communication and implemented and harmonized method and tools **(14, 25).**

Situational analysis of global vaccine safety blueprint found a weakness in SWOT analysis including unsustainable funding at the international level, Lack of human resources, Slow implementation of funds, Lack of national immunization program involvement in PMS, Lack of collaboration between NRA and MOH (NIP), Lack of training and advocacy, Training demand exceeds WHO capacity, Limited collaboration with organizations that have training capacity, Lack of international data-exchange agreements**(26)**. Lack of tracking, as well as a collection of AEFI data from vaccine exporting countries, fear of reporting, the perception of a lack of 'political will' across NRAs, were additional barriers identified in the survey **(26)**.

In 2012, 11 countries (i.e. Albania, Brazil, India (Maharashtra State), Iran (the Islamic Republic of), Kazakhstan, Mexico, Senegal, Sri Lanka, Tunisia, Uganda, and Viet Nam) participated in baseline assessment of AEFI surveillance systems as post-market surveillance (PMS) Network **(26)**. The result was that the national EPI was responsible for AEFI reporting in all countries, the existence of at least two designated national focal persons responsible for AEFI surveillance, the AEFI surveillance system is covered by law or other regulations, and usually supported by national AEFI surveillance guidelines in all PMS network country and among staff except 1 country while nine of

the PMS network country have documented the roles and responsibilities of key players. National AEFI reporting forms were utilized by all countries. Only six of the countries have guidelines on specific reportable AE which are consistent with WHO generic guidelines, only 5 countries use AEFI case definitions recommended by WHO, and in only one country the NRA reported use of the Brighton Collaboration case definitions for reporting. Except for one country which did not specify the time for reporting, all countries followed recommended reporting of serious AEFI within 24-48 hours. All except two countries took mandatory action to report serious AEFI **(26)**. Nine of the eleven countries had a focal person from the EPI/AEFI system for monitoring, reporting, and investigation of AEFI. All PMS network countries except one country had a national review committee and five of them had well-documented criteria to select those members **(26).**

In an article published in 2018, the status of implementation of national plans for Pharmacovigilance of African countries and its association with low reporting was assessed**(15)**. The identified problems included absence of a robust AEFI monitoring system, Lack of guidelines and AEFI review committee, unavailability of trained personnel, and weak collaboration among stakeholders. African countries developed a plan by prioritizing them and only 25 implemented Meetings between NRA, EPI, and other stakeholders, 13 countries implemented Constitution of National AEFI expert committees, 7 countries implemented Training of expert committees in causality assessment and only 2 countries implemented Simulations of investigations (15).

A recent study **(19)** also mentioned that the national medicine regulatory authority (NMRA) of Ethiopia, Rwanda, Tanzania, and Kenya were supported by act, rule, and regulation which also clearly defined the role and responsibility of NMRA, the mandate of market authorization holders(MAH) to conduct post-market surveillance (PMS) and report individual case safety report.

According to the Global Vaccine Action Plan(GVAP) Monitoring, Evaluation & Accountability Secretariat 2019 yearly Report **(27)**, 25 countries in the Americas Region, 35 in the European Region, 12 in the Eastern Mediterranean Region, 9 in the South East Asian Region, 12 in the Western Pacific Region, and 27 in the African Region reported at least 10 AEFI per 100,000 surviving infants. Gillian Lim analyzed AEFI data from Ontario integrated Public Health Information System database **(28)** found that the AEFI reporting rate in 2018 was 5.1 per 100,000

populations. The highest AEFI reporting rate in 2018 was an infant under one year age category (30.1 per 100.000 populations). AEFI reporting rates in Zimbabwe between 1997-2017**(29)** also showed that the range from 0 - 30.2 per 100,000 surviving infants and 0.2 per 100,000 surviving infants in 2017**.** Ethiopia reported only 2% of AEFI in 2017/2018, while Kenya reported 8% of AEFI **(19).**Studies confirmed that active surveillance surpasses passive systems in identifying more AEFI cases. The study in the Czech Republic report 6 times higher AEFI cases identified by active surveillance (209/100,000 doses) compared to passive surveillance (34/100,000 doses) **(10).**

WHO-UNICEF joint reporting form and GVSI recommend countries with passive vaccine safety surveillance systems record at least 10 reported AEFI per 100,000 surviving infants per year **(25, 30).**

A narrative review by P. Cashman*et al.***(31)** Reported that only the US and one province in Vietnam established active surveillance by data linkage while Canada establishes active AEFI surveillance by a direct survey of participants now formalized as the Canadian National Vaccine Safety Network (CANVAS). Ethiopia has established surveillance on diseases and disease conditions which are now included in PHEM guideline and this surveillance includes Acute Flaccid Paralysis (AFP) , measles surveillance in which Neonatal tetanus surveillance has been integrated with both surveillance, Pediatric Bacterial Meningitis/Hib Surveillance, and rotavirus surveillance **(32, 33).**

An effective surveillance system is indispensable for keep up public trust in the safety of vaccines, if able to identify, respond to and report AEFI. However ensuring immunization safety and monitoring of AEFI remain the major challenges of national immunization programs in the world **(2, 34)**

CHAPTER THREE: OBJECTIVE

3.1 General objective

- Assessment of system and site readiness for implementing pilot active AEFI surveillance in Addis Ababa, Ethiopia.

3.2 Specific objective

- To assess system-level readiness to implement pilot active AEFI surveillance in selected hospitals in Addis Ababa, Ethiopia.
- To assess hospital-level readiness to implement pilot active AEFI surveillance in selected hospitals in Addis Ababa, Ethiopia.

CHAPTER FOUR: METHODS

4.1 Study area and period

This study was conducted in Addis Ababa, the capital city of Ethiopia. The estimated population of Addis Ababa in 2020 was 4,793,699 with an annual growth rate of 4.37% (https://worldpopulationreview.com/world-cities/addis-ababa-population). The city has ten sub-cities, each of them having an average of 10-12 Woreda /districts. There are 13 governmental Hospitals, 32 health centers, 30 private hospitals, and 7 NGO clinics. The readiness assessment was conducted in 3 government hospitals from February 9 – March 4, 2021, G.C.

4.2 Study design

The study design was mixed-methods.

4.3Population

4.3.1 Source population

The study hospitals were Tikur Anbessa Specialized Hospital, Saint Paul millennium medical college Hospital and Mahteme Gandi Memorial Hospital. These hospitals were chosen because of ongoing collaborations with EFDA, many of their staff had previous experience in research and proximity to key AEFI stakeholders in Addis Ababa. The hospitals were chosen in collaboration with staff from US CDC (Sarah D Bennett).

4.3.2study population

The study populations were heath professionals who were working in the facility- in - charge, vaccination clinic, Emergency Department (both Pediatrics and Adult), Pediatrics ward, Adult ward, laboratory, radiology department, Medical records, Surveillance office, and pharmacy in the selected hospitals.

4.4 Inclusion and Exclusion criteria

4.4.1 Inclusion criteria

Department head, team leader and clinical management who were working in vaccination clinic, Emergency Department (both Pediatrics and Adult), Pediatrics ward, Adult ward, laboratory, radiology department, Medical records, Surveillance office, pharmacy , and facility in charge in the selected hospitals. We took those participants because of they were most relevant and could give us accurate information.

4.4.2 Exclusion criteria

Selected Participant who was absent during the study period.

4.5 Sample Size

The estimated sample size was thirty three i.e. one representative from each selected department.

4.6 Study variable

4.6.1. Dependent variable

- System level readiness
- Site readiness

4.6.2. Independent variable

- Existence of policy , rule , regulation and proclamation
- Availability of AEFI guideline and AEFI reporting form
- Data readiness
- Record system readiness
- Study specific readiness
- Governance readiness
- Organizational readiness

- Business process readiness

4.7 Data collection Method

4.8.1 Data collection instrument

For the hospital readiness assessment, two primary tools were used. The “readiness assessment tool” included questions (both closed and open-ended) and had a "scoring tool” which assisted investigators in grading the hospital after the visit.

The development of the readiness assessment tool was guided by a framework developed by Carr (2014)**(35)** which described seven primary dimensions of “research readiness”. These dimensions included data readiness, record system readiness, organizational readiness, study-specific readiness, governance readiness, and business process readiness. This framework was adapted to the Ethiopian context to describe the readiness for conducting active AEFI surveillance. The following questions were taken from the WHO PV tool and the systems assessment which was done in Ethiopia in 2019.

- **Data readiness** – “Does the hospital have quality data recording and reporting practices?”
- **Record system readiness** –””Are the records available at the hospital able to capture key information needed for active AEFI surveillance?
- **Organizational readiness** – “Is the organizational environment supportive of “taking on” active surveillance?” What is the reporting flow for notifiable diseases at the hospital?
- **Study-specific readiness** – **“**Are the clinical staff knowledgeable and/or interested in AEFI surveillance?”
- **Governance readiness** – “Does the study meet legal and local health system regulatory compliance?”
- **Business process readiness** – “Does the hospital have the capacity and capability to take on active AEFI surveillance?”

If Ethiopia decides to roll out AEFI surveillance more broadly, the tools and scoring system used in this readiness assessment could also be utilized to identify additional sites to implement AEFI surveillance. Hence, the tools will be available on request from the CDT-Africa office and the GOHi Eastern Africa office.

4.8.2 Procedure of data collection

In the system readiness assessment, a staff from Ohio State University's Global One Health Eastern Africa Office (GOHi) and a Master's student from CDT Africa/AAU conducted a desk review of Public Health Emergency Management (PHEM) guideline, Pharmacovigilance (AEFI) guidelines, EPI guideline and the EFDA, EPHI websites to understand any existing initiatives [(Policy, rule, and regulation) or reporting tools for Adverse Event Following Immunization (AEFI)].

The system readiness assessment was followed by the hospital readiness assessment. At each hospital, a GOHi staff (Data collector) and master's student from CDT Africa administered survey instruments, speak with key clinical and management staff in the hospital to understand reporting protocols, hospital organization, cadres of staff, and describe the current status of collaboration and coordination among EFDA, EPI, and EPHI and observe non-identifiable clinical records. If an appropriate interviewee was not available during the study period, we selected the most senior staff after attempting to reach the main interviewee while we took an appointment and also went there some other time to interview the medical directors. When it was necessary one Staff member was assisted in introducing us to other staff and assisting with reviewing clinical records to collect data and record system readiness. Following the site visit, the investigators had tallied the overall visit score to identify the facility which is most ready to conduct active surveillance. Other factors for consideration, in addition to the overall score, were facility leadership and stakeholder interest in participation.

4.8.3 Data quality control

To assure the quality of data, properly designed data collection tools were used and training was provided by United States Center for Disease Control and Prevention (US CDC). The overall study process was supervised by supervisor of MSc student of CDT Africa, Addis Ababa University. Scoring was checked twice and cross-check with the photo captured.

4.8.4 Method of data processing and analysis

The investigator (the MSc student) summarized the results of the "readiness assessment tool" and scored the hospital using the "scoring tool". The readiness assessment tool included specific criteria for scoring to minimize subjectivity in grading. The results were presented in a table. The hospital

with the highest readiness score was approached to know if they were willing to implement active AEFI surveillance.

4.9Ethical Considerations

Ethical clearance was obtained from CDT Africa Scientific and Ethics committee, College of Health Sciences, Addis Ababa University. A formal letter asking permission and support was written from CDT Africa to the Addis Ababa Health Bureau (to get ethical clearance for Gandi memorial hospital), TASH and SPHMMC. After having approval from the heads of the hospital, there were communications with the head of each participating department. Verbal consent was obtained before all interviews. Interviewees were informed on the purpose of the readiness assessment, that they could stop the interview at any time, and that the assessment was not a review of their job performance. All data were collected without any personal identifiers, and only information regarding their institution was collected.

CHAPTER FIVE: RESULTS

Site readiness Assessments

A total of 32 participants involved in the site readiness assessment with 96.96% of response rate . Among the interviewee 19 were male (59.38%) and 13 were female (40.62%).

Three hospitals, i.e. Tikur Anbessa specialized hospital (TASH), Saint Paul hospital Millennium medical college (SPHMMC), and Gandi Memorial Hospital were assessed using a standard assessment tool for collecting information about essential capacity components for identification, management, and reporting of AEFI. In two of the three hospitals (TASH and SPHMMC), eleven departments were included in the assessment. However, Gandi memorial hospital did not have pediatrics ward, pediatrics emergency ward, adults ward, AFP and measles surveillance unit, and Radiology (only Ultrasound) department as the hospital was providing solely maternal and neonatal care. As a result, we used the neonatal intensive care unit (NICU) instead of pediatrics ward, obstetrics and gynecology ward instead of the adult ward, Health Management Information System (HMIS) unit instead of AFP and measles surveillance unit, and ultrasound unit instead of the radiology department. Besides, while TASH and Gandi memorial hospital's vaccination clinic were providing all vaccines according to the National Expanded Program on Immunization (EPI) for eligible children and women of reproductive age, Saint Paul hospital Millennium medical college (SPHMMC) administered vaccine for neonates only BCG and OPV 0. All responses were entered into the tool with an assigned score for quantitative data and place for qualitative data.

Overall findings

Figure 1shows the overall performance of the surveillance sites.

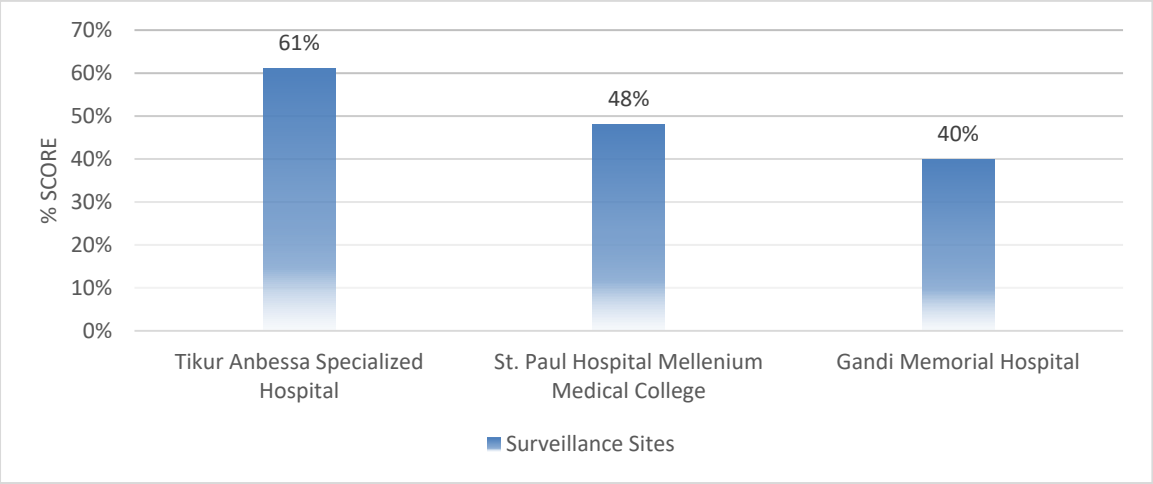

Figure 1: Overall AEFI surveillance preparedness score for sites, February 9-march 4, 2021

Table 1 shows the performance of the three hospitals in the AEFI surveillance domain. Based on the proposed standard scoring tool, TASH scored 94 out of 155, Saint Paul scored 75 out of 155 and Gandi Memorial hospital scored 62 out of 155.

Table 1: Total scores for the three hospitals across the assessed departments

Department		**TASH score**	**SPHMMC score**	**Gandi Memorial hospital score**
1	Office of Facility-in-Charge	7 / 7 (100%)	6 / 7 (85.71%)	4 / 7 (57.14%)
2	Vaccination clinic (if applicable)	17 / 27 (62.96%)	14 / 27 (51.85%)	14/ 27 (51.85%)
3	Pediatrics Emergency department	15 / 27 (55.5%)	14 / 27 (51.85%)	0 / 27 (0%)
4	Pediatric ward	15 / 27 (55.5%)	16 / 27 (59.26%)	15 / 27 (55.5%)
5	Laboratory	9 / 14 (64.29%)	8 / 14 (57.14%)	13 / 14 (92.85%)
6	Radiology department (informational only)	X	X	X
7	Medical records department	10 / 13 (76.92%)	3/ 13 (23.1%)	5 / 13 (38.46%)

8	AFP and measles surveillance	8 / 12 (66.6%)	6 / 12 (50%)	2 / 12 (16.6%)
9	Pharmacy department	4 / 10 (40%)	1 / 10 (10%)	6 / 10 (60%)
10	Adult Ward	2 / 9 (22.2%)	1/ 9 (11.1%)	2 / 9 (22.2%)
11	Adult emergency department	7 / 9 (77.7%)	6 / 9 (66.6%)	1 / 9 (11.1%)
TOTAL	*Sum of score column*	*94 / 155(60.64%)*	*75 / 155(48.38%)*	62 / 155(40%)

Site-level findings

I. Data and record system readiness

This section mainly discusses the hospital's data recording and reporting practice and whether records available at the hospital able to capture key information needed for active AEFI surveillance. **Table 2** summarizes the data and record system readiness in all participating hospitals.

Data recording practice

Five departments from each hospital were interviewed about their record-keeping method. The result showed that five departments each (vaccination clinic, pediatrics ward, pediatrics emergency ward, adult ward, and adult emergency ward) from Tikur Anbessa Specialized Hospital (TASH) and Saint Paul hospital Millennium Medical College (SPHMMC) had been using a paper-based recording system while the laboratory department of TASH had been using only the digital (electronic) record-keeping system and didn't maintain a back-up paper record. Both paper and electronic record-keeping system had been using by SPHMMC laboratory department and by both TASH and SPHMMC radiology department. According to the finding, the main drawback of the electronic software's employed by laboratory department of SPHMMC and TASH did have the feature to allow generating specific data such like list of children with low platelet count. From Gandi memorial hospital, all interviewed department (vaccination clinic, ultrasound unit, neonatal intensive care unit, laboratory department, adult ward, and adult emergency ward) had been using the paper-based record-keeping system.

The medical department of all participating hospitals was assigned a unique ID for children in which SPHMMC and Gandi memorial hospital generated using random numbers, while TASH generated using date of birth or date of the card. For every child in all participating hospitals, results from the laboratory and radiology departments were matched using medical record number to their medical chart. Regarding the duration of the record retention period, radiology departments of both TASH and SPHMMC transferred the records to the hospital archival for long-term storage after keeping the records for 2 months and 2 years in their department, respectively. Although the laboratory department of all participating hospitals did not transfer their records for long term storage, while TASH and Gandi memorial hospital discarded after keeping it for 2 years and 10 years in their departments, respectively, and SPHMMC laboratory department kept in the department locker in which the oldest record was 10 years old.

Except for Gandi memorial hospital, both TASH and SPHMMC had been employing DHIS2 to manage health information. According to the result, TASH had also been using International classification of disease (ICD) 9 / 10 coding system partially, while the other two hospitals did not use it. Instead, TASH had been using the WHO coding system which was being customized to Tikur Anbessa specialized hospital. The reason for not continuing to using ICD 9/10 coding system was because of its long, exhaustive, and time-consuming list and was also generalized, i.e. lacked specific coding for a different type of single disease. For example, there was one coding for brain tumor despite the existence of various sub-types of brain tumor that the hospital believed should be specified in a coding system that must be in place.

Regarding the recording of AEFI that occurred after vaccination in the expanded immunization program (EPI), only TASH records AEFIs occurred after vaccination. According to the finding, the AEFI recording system included variables like vaccine given, Death, Anaphylaxis, sepsis, Abscess, severe local reaction, BCG lymphadenitis and complied target disease report.

Pediatrics ward, pediatric emergency ward, adult ward, adult emergency ward, and vaccination clinic of all three hospitals maintained a register for the patients, and the register was called Health Management Information System (HMIS) book. However, the HMIS book for the vaccine clinic doesn't include variables as AEFI occurred in all three hospitals. Despite that only TASH had a

separate AEFI recording book. This HMIS registration book had been kept in the locker for both pediatrics and pediatrics emergency departments of SPHMMC, and according to the finding, the oldest record was 6 years old. Although TASH kept the HMIS book for 4 years in the pediatric ward and 5 years in the pediatric emergency ward.

The vaccination clinic of all participating hospitals had officially documented data for the total number of vaccines provided for children each month.

All wards found in the three hospitals had provided an individual medical chart for every patient which included children. In the pediatric ward and pediatric emergency ward of all Participating hospitals, no children come with their child's health record book or vaccination records. In all hospitals pediatrics ward and pediatrics emergency ward, there was no provided space and a system that requested for recent vaccination status (like vaccination in the last 30 days).They only mentioned about the child who received the vaccine for his/her age in the history sheet.

AEFI reporting practice

From Tikur Anbessa specialized hospital except for pediatric emergency department, five departments, i.e., adult ward, adult emergency ward, pediatrics ward, vaccination clinic, and pharmacy department mentioned that AEFI had to be reported to anyone or any organization. None from Saint Paul hospital millennium medical college and pharmacy department from Gandi memorial hospital did mention on the reporting of AEFI.

The vaccination clinic of TASH reports cases of AEFI to Pediatrics ward and Lideta Health center pharmacy from where they collected the vaccine. The reporting flow is shown in Figure 2.

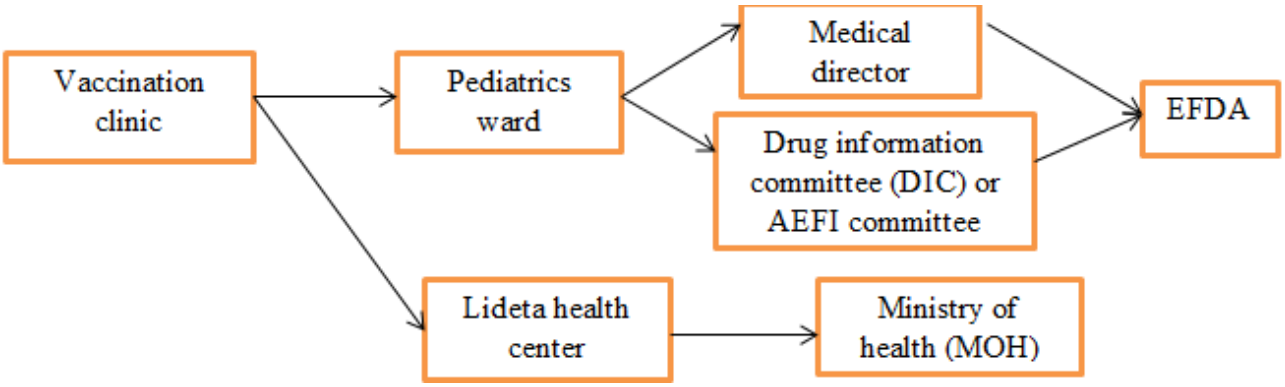

Figure 2: AEFI reporting flow in Tikur Anbessa specialized hospital

The AEFI was reported within 24 hours using the reporting form. They also receive feedback from the Lideta health center and health bureau, but not for all reported AEFIs. The variables included in the report were administered vaccine, date, type of AEFI, vaccine-related information (Vaccine vial monitor (VVM) stage and expiration date). The Pharmacovigilance focal or Drug information committee (DIC) received reports from pediatrics ward and reported to EFDA within 72 hours. They had been using Hard copy, med safety application, and ADR online system for reporting. The Focal person also had a phone number for reporting ADR which including AEFI. All the rest of the departments had been reporting AEFIs to the Drug information committee (DIC).

In Gandi memorial hospital the flow of information about AEFI started from ADR focal person report to the pharmacy department and pharmacy department to the medical director. After the facility summarized the case, it was reported to EFDA. **Figure 3**shows AEFI reporting flow in Gandi memorial hospital.

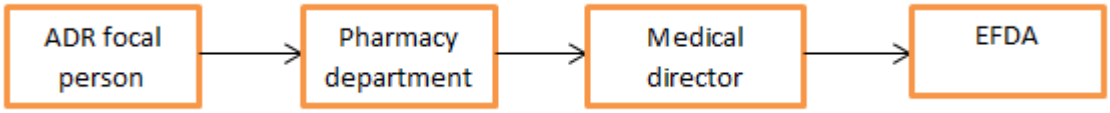

Figure 3: Gandi memorial hospital AEFI reporting flow

According to the finding, only TASH and Gandi memorial hospital facility leaders reviewed AEFI reports, while Saint Paul hospital Millennium medical college (SPHMMC) did not have the experience of reviewing AEFI reports by facility leaders. Although TASH had been reviewing

AEFIs of serious adverse events, it was not reported to the medical director unless it was treated by the health professionals in charge.

Surveillance of measles and acute flaccid paralysis

The disease prevention and health promotion team from SPHMMC and public health emergency management (PHEM) team from TASH and Gandi memorial hospital was responsible for identifying and reporting cases of measles and acute flaccid paralysis. The disease prevention and health promotion team of SPHMMC gathered cases from service area and reported to HMIS office and MOH every month. The sample was sent to EPHI. However, they didn't receive feedback for every sample they sent to EPHI.

The surveillance office (public health emergency management) team of TASH identified cases of measles and AFP that were reported and confirmed by physicians using case definition. The identified cases were reported to EPHI after reviewed by the facility in charge and received feedback. Different departments were included in the surveillance of AFP or measles cases, i.e., outpatient pediatrics clinic, vaccination clinic, emergency department, inpatient pediatrics ward, inpatient adult ward, laboratory, gynecology/obstetrics ward, neonatal ward, ICU, and orthopedic ward.

The surveillance office (public health emergency management) team of Gandi memorial hospital also reported cases of AFP and measles to EPHI after reviewed and approved by the medical director.

Who reviews measles and acute flaccid paralysis cases and what to review?

The facility in charge (medical director) of TASH and SPHMMC reviewed and approved for the report of measles and AFP reported cases whenever there was a case. According to SPHMMC, the variables that had been reviewed were the number of the patients, whether the sample was collected from the patients, whether the parents were informed, results of any testing, and other related information. They had a format to review measles and AFP reports. Although Tikur Anbessa specialized hospital reviewed for diagnosis, whether it fulfilled the case definition, number of cases, vaccination history which was the same as Gandi Memorial hospital.

However, there was no dedicated responsible body for identifying cases of AEFI in the surveillance office of all participating hospitals.

AEFI guideline and reporting form

All departments participated from each hospital had no copy of national adverse events following immunization (AEFI) surveillance/reporting guidelines, while the pharmacy department and vaccination clinic from TASH and Gandi Memorial Hospital had reporting forms.

Table 2: Data and record system readiness

		TASH (n=11)	SPHMMC (n=11)	Gandi memorial hospital (n=10)
Data and record system readiness				
Record system	Paper based	5/7 (71.4%)	5/7 (71.4%)	6/6 (100%)
	Electronic	1/7 (14.3%)	0 (0%)	0
	Both	1/7 (14.3%)	2/7 (28.57%)	-
Backup paper based record system used.		1/2 (50%)	-	-
Have copies of national guideline for surveillance of AEFI		0/5 (0%)	0/5 (0%)	0/4 (0%)
Have copies of AEFI reporting form		2/5 (40%)	0/5 (0%)	2/4 (50%)
Record AEFI occurring after vaccination (vaccination clinic)		Yes	No	No
Have the system to Report AEFIs to anyone or any organization		5/6 (83.3%)	1/6 (16.7%)	0/5 (0%)
maintain a patient register		5/5 (100%)	5/5 (100%)	5/5 (100%)
DHIS2 used		Yes	Yes	No
ICD 9/10 coding system used		Partially	No	No

Department responsible for reporting cases of measles and AFP	Public health emergency management (PHEM)	Disease prevention and health promotion team	Public health emergency management (PHEM)
Facility leader review measles and AFP reports	Yes	Yes	Yes
Facility leader review AEFI reports	Yes (only serious AEFI)	No	yes

II - Study-specific readiness

This section mainly assesses whether the clinical staff were knowledgeable and had interest in AEFI surveillance. According to the result, all departments had interest to participate in AEFI surveillance. **Table 3** summarizes the study specific readiness in all participating hospitals.

Only four departments were familiar with the national Guidelines for Surveillance of AEFI; the facility in charge and adult emergency from TASH, again facility in charge of the remaining two hospitals. From participants interviewed about the definition of AEFI; five of them from Gandi, four from Saint Paul, and three from TASH mentioned that it was an untoward/unexpected medical occurrence; five participants from Gandi, four from saint Paul and five from TASH mentioned that it followed immunization while two participants from saint Paul and one from TASH mention that it did not necessarily have a causal relationship with the vaccine.

Table 3: **Study-specific readiness**

		TASH (n=11)	SPHMMC (n=11)	Gandi memorial hospital (n=10)
Familiar with the National Guidelines for Surveillance of AEFI		2/8 (25%)	1/8 (12.5%)	1/7 (14.29%)
How would you	untoward/unexpected medical	3/8 (37.5%)	4/8 (50%)	5/8 (62.5%)

define an AEFI?	occurrence			
	follows immunization	5/8 (62.5%)	4/8 (50%)	5/8 (62.5%)
	does not necessarily have causal relationship with vaccine	1/8 (12.5%)	2/8 (25%)	0/8 (0%)
Have interest to participate in AEFI active surveillance.		10/10 (100%)	10/10 (100%)	9/9 (100%)

II. Organizational readiness and Business process readiness

This section discusses whether the organizational environment supportive of taking on surveillance which includes the hospital management willingness and the hospital has the capacity to taking on the surveillance**. Table 4** summarizes the organizational and business process readiness of all participating hospitals.

According to the result, all three hospital management agreed on the goodness of their facility for more intensive AEFIs surveillance. Except TASH, the two hospitals didn't undertake any activity like training, an awareness campaign to promote AEFI reporting, or improve awareness of AEFIs. Although TASH had undertaken training only during the establishment of a Pharmacovigilance center in the facility.

Table 4: **organizational readiness and Business process readiness**

	TASH	SPHMMC	Gandi memorial hospital
Agreed to take on more intense surveillance for AEFIs	√	√	√
Undertook any activity like training, awareness campaign to promote AEFI reporting or improve awareness of AEFIs.	√	×	×

IV- Governance readiness

This section discusses whether the surveillance is meeting legal and local health system regulatory compliance.

All hospital applied rules, regulations, and guidelines, i.e., Attendance of staff, dress code, performance evaluation, professional conduct in clinical areas, and disciplinary action (including probation, suspension, termination, expulsion) for staff. Although all staff members were aware of policies and took their job description. However there were no specific rules, regulations, and operational guidelines regarding AEFI surveillance that were prepared for each hospital and that should be applied by staff.

System-level readiness

The system assessment was done from the Ethiopian Food and Drug Authority (EFDA) and Ethiopian Public Health Institute (EPHI) websites until May 23, 2021. The assessment included whether they had any initiatives, policy, regulation, proclamation, guideline, manuals, directives, established structure, communication ways (Card, fax, toll-free number, online format, etc.) on AEFI surveillance and Expanded program on immunization (EPI) to support the reporting of AEFI .

Findings from Ethiopian Food and Drug Authority (EFDA) Website

Policy, regulation, and proclamation

It was noted that the Ethiopian health policy has been mandated on the development of quality control capability to assure efficacy and safety of products**(36)**. The Ethiopian Food and Drug Administration (EFDA) was responsible according to proclamation 1112/2019, to ensure the safety, quality, and efficacy of medicines and with the regulation no 299/2013 to report any complaints including the safety of medicine**(37)**. As per Proclamation No.1112/2019, the Medicine manufacturer, the importer shall perform periodic monitoring of the quality, safety, and efficacy or effectiveness of its manufactured or imported medicine, perform post-marketing surveillance to establish a vigilance system and continuously provide adverse event information**(38)**. Proclamation

No. 661/2009 has been provoked because of matters provided by Proclamation No.1112/2019 **(38, 39)**.

Structure for Pharmacovigilance system

It was seen that there was a designated responsible body for Collection, detection, assessment, monitoring, and prevention of adverse events following immunization (AEFI) in the Ethiopian Food and drug authority (EFDA) which was named as Product safety directorate [Regulatory Standards Setting and Information Delivery (RSSID)] **(40)**. The Ethiopian Pharmacovigilance Center was under this directorate which worked towards monitoring of drug safety through advocacy and collecting reports from health providers, analyzing data, consulting experts, and taking appropriate regulatory measures together with its partners in the various sectors of drug supply and management. There was also a database for Pharmacovigilance data management system (PVDMS 1.0) which also captured data on Adverse Events following Immunization (AEFI)**(41).**

The guideline for Pharmacovigilance is found on the website. The latest edition (third) was published in 2014 **(42, 43)**. The institution also developed directives for Pharmacovigilance activities including for vaccine**(44).** The EFDA website has a section for reporting ADR including AEFI which called e-service **(45)**. Other possible ways to report AEFI included AEFI reporting form, mobile app (med safety) that can be downloaded from Google Store for Android mobiles and App Store for iPhones, and toll-free: 8482. Pharmacovigilance newsletters were published on the website which discusses and includes issues on AEFI **(41, 46)** . There was also a Pharmacovigilance newsletter published on the website which included information on several reported AEFI, i.e. one AEFI in 2011**(47)**, two AEFI in 2013**(48)** , twelve AEFI in 2014**(49),** and Four AEFI in 2015**(50)**.

The Pharmacovigilance guideline

The Guidelines for Surveillance and Response to Adverse Events Following Immunization (unpublished) detail the reportable AEFI's, roles and responsibilities of stakeholders involved in AEFI surveillance, how and where to report, AEFI investigation, analysis of AEFI data, laboratory testing of specimens, AEFI causality assessment including action and response to AEFI and communications and media management (51). Recently published National PV roadmap also discuss on plan to perform active surveillance in collaboration with public health programs which includes EPI and also to conduct refresher/ gap filling training for health professionals that includes on AEFI(52).

AEFI reporting form

The content of the AEFI reporting form included form number, full address of vaccinated person, medical record number (MRN), vaccination registration number, vaccinated person phone number, sex, date of birth/age/age range, full name of the health professional who reported the AEFI, facility name, department, address, phone number / Email, occurred AEFI reported date, the date the form filled(Today date), health facility name the vaccine administered, vaccination time/date, vaccine name, vaccine dose, vaccine batch number, vaccine expire date, vaccine diluent batch number, vaccine diluent expire date and time of reconstitution. It was presented with only the official national language (Amharic)**(44)**.

Findings from the Ethiopian Public health institute (EPHI) website

Ethiopian public health institute (EPHI) has a unit called Public Health Emergency Management (PHEM) which has been working as two teams at the national level, i.e., Public Health Emergency Preparedness and Capacity Building Team and Early Warning & Communication Team. They have been working on different responsibilities which included developing guidelines, detecting disease outbreaks, collecting; analyzing; interpreting data reported, supporting surveillance, and so on. On the EPHI website, there were weekly and immediately reportable diseases which included vaccine-preventable diseases like AFP and measles. The website mentioned contact line to report any of the conditions mentioned under weekly and immediately reportable diseases (Tel: +251 11 275 8631 OR +251 11 276 5340 ; Fax: +251 11 275 8634 ; Email: PHEMcenter@ephi.gov.et)**(53, 54).** There is published a guideline about public health emergency management, measles surveillance and outbreak management, meningococcal meningitis surveillance, and outbreak management guideline **(40, 55, 56).**

It was also noted that there were vaccines and diagnostic production directorate involved in research on the vaccine and Diagnostic production including independent evaluation of the safety and efficacy of imported human vaccines. The directorate had two case teams namely production and research teams and quality control case teams **(57)**.

PHEM Guideline

The guideline included information on integrated disease surveillance, immediate and weekly reportable disease in Ethiopia including their Standard case definition and Simplified Case Definitions for Community Level, reporting tools, reporting procedure, Reporting Periodicity, Reporting Procedures, Surveillance Data Analysis, and Interpretation. It also mentioned the formal and informal flow of data surveillance and information throughout a health system**(55)**. However, it did not include AEFI surveillance in its system.

Ethiopian Expanded program on immunization (EPI) guideline

Ethiopia recently updated the implementation guidelines for EPI. The guidelines define AEFI, discuss AEFI classification, that AEFI should be documented, reported, investigated, monitored, and communicated with the parents, health workers and the community (58).

CHAPTER SIX: DISCUSSION

This study assessed and compared the readiness of three selected hospitals in Addis Ababa to provide an overview of their operational structure, record keeping, reporting and reviewing practice; interdepartmental linkage, and data management to establish an active AEFI surveillance site. The existence of PHEM unit, health structures at each level that conduct reporting of priority diseases and events of public health concern, in all the three facilities shows there is an existing system, which can be leveraged to serve as a source of vaccine safety data to report notifiable events following immunization. In addition, the presence of a recording system for each vaccine given and register such as HMIS for every patient visiting each department is an opportunity, which can be modified to incorporate AEFI occurrence and strengthen the reporting system. As the finding indicated, each client has a unique medical record number, which will enable link medical records to vaccine registries. This is vital to track laboratory results and medical information to assess causal association to immunization. All these are key for early detection and analysis of adverse events and appropriate and quick response to guarantee the safety of vaccines and help establish public confidence.

According to the overall AEFI surveillance preparedness score, TASH has the highest score based on the domains we have used for assessment, and also it would be the first choice to conduct AEFI Active surveillance.

Tikur Anbessa specialized hospital has employed electronic medical record software called "icare Ethiopia". This software manages different departments under it. This includes reception, laboratory information system (LIS) for laboratory department, pharmacy management information system (PMIS) for pharmacy department and likewise. Having already established an electronic data record system could be an initiative to add a platform for reporting AEFI.

Long-term archival of patient data in the departments could help for conducting research retrospectively and compare with actively collected data. However, the laboratory departments of TASH and SPHMMC discarded after finishing their retention period.

More than 30 countries in Africa and Asia have installed the WHO-recommended DHIS2 dashboard packages into their national HMIS and Ethiopia is one of them. According to our findings, except Gandi memorial hospital, all participating hospitals had been using DHIS2. Globally and nationally DHIS2 has been employed for running nationwide programs or build capacity to respond to deadly disease outbreaks and so on. Some of the evidence can be mention as follow. Mass measles-rubella and polio campaign in Uganda using DHIS2 for national real-time performance monitoring **(59)**, Nigeria has been using DHIS2 to manage immunization data since 2014 **(60)** and Ghana since 2016 **(45),** Improving EPI reporting rates and timeliness with DHIS2 in Togo **(61)**and Bangladesh uses DHIS2 to manage immunization children in their MR mass campaign **(62).**

The World Health Organization (WHO), UNICEF, and GAVI, the Vaccine Alliance have partnered with DHIS2 to improve national immunization program coverage through better data collection, analysis, and use. WHO standard DHIS2 toolkit for immunization includes AEFI tracker metadata package which facilitates the reporting of AEFI events and data collection during the investigation of an adverse event**(63)**.The package includes data collection forms for a facility, district, and national levels and standard dashboards for analysis**(64)**. Ethiopia better adopts this package on the already established DHIS2 dashboard.

The existence of a patient register book in all hospitals could indicate good record-keeping experience. And AEFI recording platform in the TASH vaccination clinic can mention as additional quality for this hospital. However, the absence of AEFI recording system in Gandi and SPHMMC might need work to improve their vaccine safety monitoring. Being paper-based registration could also be a reason for incompleteness, low-quality data, high chance of patient data duplication, susceptibility to damage, and taking space.

The absence of habit by caregivers/parents to bring vaccination card of their children and physicians/health professional not asking about recent vaccination status in all participating hospitals might decrease the chance of detecting AEFIs.

Ideally, there is a clear pathway to report AEFI seen in each department to the next level in TASH and Gandi. However only 83.3% of participants from TASH, none from SPHMMC, and 20% from Gandi memorial hospital mention that they report AEFI. The existence of an assigned ADR focal

person in the pharmacy department of TASH and Gandi could be considered as their strength, while absence of this system at SPHMMC is considered its limitation. In addition, the AEFI reports reviewed by facility leaders in TASH and Gandi memorial hospital could help in ensuring data quality.

Despite the existence of reporting form, there is a gap in the distribution of the copies at the department level. Only Two departments (40%) of the participant from TASH, Two (50%) from Gandi memorial hospital, and none from SPHMMC had copies of the reporting form. Even if Ethiopia has no different independent guideline for AEFI, there is a Pharmacovigilance guideline that includes AEFI. However, none of the participants from all hospitals had copies of the guidelines which show the gap in the distribution. This might be one of the reasons for low awareness among staff about the AEFI reporting and reporting pathway.

There was a surveillance unit for acute flaccid paralysis and measles cases in all participating hospitals with a clear pathway for reporting. The collected cases of AFP and measles being reviewed by the facility in charge of all participating hospitals can be mentioned as a guarantee to ensure the completeness, quality of data. Absence of feedback for every report from SPHMMC and Gandi memorial hospital is considered one problem. This could discourage the staff and contribute to a low reporting rate. Unavailability of an assigned responsible body for AEFI surveillance in this unit can also be considered a problem in all participating hospitals. But the existence of an already established surveillance unit can serve as a good start to include AEFI surveillance in their service.

Regarding their level of familiarity with the national guideline for Pharmacovigilance, below-median, i.e., 25% of participants from TASH, 12.5% from SPHMMC, and 14.3% from Gandi memorial hospital were familiar with the guideline. 37.5%, 50%, and 62.5% of participants from TASH, SPHMMC, and Gandi memorial hospital respectively were defined AEFI as untoward medical occurrence; 62.5%, 50%, and 62.5% from TASH, SPHMMC and Gandi memorial hospital respectively were defined AEFI as it follows immunization and 12.5%, 25% and none from TASH, SPHMMC and Gandi memorial hospital respectively were defined AEFI as it doesn't have a causal relationship with the vaccine.

As per the finding, all participating hospitals' medical directors agreed on the goodness of their facility to take over extensive active surveillance on AEFI in the future. Having the first prominent Pharmacovigilance center in the country and trained manpower and utilizing DHIS2 currently were strengths of TASH. SPHMMC indicated to take the presence of adequate resources and information exchange platforms among staffs (email group and telegram group), well-organized quality directorate, and community hotline as an advantage to be an active surveillance site for AEFI. Gandi memorial hospital also claims to have the infrastructure and human resource which can be advanced to be utilized for AEFI surveillance. However; a robust active surveillance system needs a trained and motivated workforce, financing, functional electronic health information system, community engagement, good monitoring, and evaluation system, and a strong regulatory base.

Absence of specific rules and regulations for AEFI surveillance in all participating hospitals might be a bottleneck for the establishment of active AEFI surveillance and might delay the process even in the winner hospital.

The existence of the Pharmacovigilance center under the already established directorate responsible for AEFI surveillance could show the system level strength. There is existing regulation and proclamation for different stakeholders on reporting ADR. However, there is no independently specified statement on rule, regulation, or proclamation for stakeholders like for professionals on vaccine Pharmacovigilance. WHO recommends for countries national medicine policy to include essential statement on Pharmacovigilance(65). In the united states of America, manufacturers are required by regulation (21CFR 600.80) to report to the vaccine adverse event reporting system(VAERS) program all adverse events made known to them for any vaccine, and also healthcare providers are required by law to report AEFI to VAERS **(66)**.

The existence of an already established policy could be an initiative and inception for bettering the system. Alberta has policy provided under the authority of the Public Health Act (Act) and Part 2 of the Immunization Regulation which outlines the following immunization**(67)**.

There was no different independent pathway for reporting AEFIs though the existence of the two pathways both online and offline could be advantageous. Unlike Ethiopia, united states of America employs different pathway for reporting AEFIs which gives options like submitting Vaccine Adverse

Event reporting system(VAERS) online**(60)**and download a writable PDF form**(68)** and upload when ready**(38)**. Another option also includes phone(1-800-822-7967) and via email(info@vaers.org).The platform also discusses reportable events following immunization**(66).** Canada supports reporting AEFI using AEFI form for consumers, health care providers, hospital and industry. Except industries, others are expected to submit to the local public health unit. Industries can use fax or mail**(69)**. Online reporting is also possible **(70)**. United kingdom has an online platform to report ADRs which includes vaccines on the yellow card website**(42)**and mobile application (yellow card mobile App)**(67)**. Australia employs an online platform to report adverse events for drugs including vaccine**s** which is called Therapeutic Goods Administration(TGA) online**(71),** and they can also be reported using fax and email to the TGA safety monitoring program**(72)**. Belgium also uses an online adverse event reporting system that includes side effects for the vaccine**(73)**and it also uses a paper notification sheet. Two possible ways are available for Italy to report ADRs which include vaccine, i.e., filling in the alert card of suspected adverse reaction and sending it to the Pharmacovigilance Manager of the facility by e-mail or fax or directly online on the VigiFarmaco website **(53).** Singapore has a separate website for online reporting of AEFI**(54)**and manual submission form**s (54).** Israel also has an online portal for reporting ADR**(40).** Malaysia has an online web form **(74)** , manual submission by mail/fax/email **(75)**.Victoria has an online reporting website**(76)** and through immunization hotline and email. Western Australia has reporting website [Western Australia Vaccine Safety Surveillance (WAVSS) System] **(59)**which is now part of the national reporting hub called SAFEVAC. Coming to Africa, Ghana also employs online reporting system which includes adverse event following immunization**(77)** . Kenya ADR reporting system is called Pharmacovigilance electronic reporting system (PV-ERS). This system also allows reporting of AEFI online or by uploading downloadable AEFI reporting form. Reportable AEFI also discussed on the website (78).Since the investigation and assessment of causality of drug and vaccine need a different method, expertise, there is a need to build different pathways for monitoring vaccine safety.

The existing Pharmacovigilance newsletter in Ethiopia publishes AEFI related issues. This is the same with Bangladesh **(79)**.

The AEFI reporting form of Ethiopia is comparable in its content with the WHO standard AEFI reporting form**(76)**. Many countries have developed different independent reporting forms for

reporting AEFI i.e. USA**(68)** , Australia**(79) ,** Malaysia**(80) ,** Dubai **(81),** Manitoba**(82),** Singapore**(54) ,** Ghana**(83)**and Kenya**(84).**This might help in increasing the attention of different stakeholders on AEFI surveillance and create an easy environment to report cases of AEFI.

According to the finding, an already established surveillance system from the EPHI side and publication from the expanded program of immunization indicates that the program supported the AEFI surveillance can be taken as an initiative for active AEFI surveillance.

Limitations

One limitation of this study is the small number of facilities surveyed; the AEFI reporting practices of the three hospitals may not represent the AEFI reporting practices throughout Ethiopia. However, this evaluation was intended to assess readiness for pilot implementation of hospital-based sentinel site surveillance and variability in practices across these three facilities; similar evaluations may need to be undertaken in any other facilities being considered for implementation to ensure that activities can be adapted to each facility. In addition, the study did not assess EFDA or any intermediary levels in the reporting flow (e.g., Lideta Health Center) where AEFIs are reported to. AEFI surveillance involves activities, like reporting, investigation, analysis, causality assessment, and communication and feedback to stakeholders and reporters, that occur at multiple levels from facility to national level. Ensuring adequate awareness, training and resources at these levels will also be important for successful implementation.

CHAPTER SEVEN: CONCLUSION AND RECOMMENDATION

7.1 conclusion

TASH has the highest score on the facility readiness assessment for pilot implementation of hospital-based active AEFI sentinel site surveillance. The already established PV structure, guideline, reporting form, involvement of EPHI in AEFI follow-up could be possible facilitator of successful implementation of active surveillance. However, the readiness assessment identified areas for

improvement to ensure successful implementation of active AEFI surveillance including training and increased awareness of AEFI and AEFI surveillance, making AEFI guidelines and reporting forms available, and ensuring a system that accommodates paper-based and electronic record systems.

7.2 Recommendation

Capacity area	Recommendation
data recording and analysis	The system to be supported by functional information technology and electronic reporting system, which demands enhancing digital infrastructure and HIS
	EPHI and EFDA to support improvements for ensuring consistent documentation and review of AEFI reports and hospitals shall include AEFI recording space on their HMIS.
AEFI Reporting Practice	EPHI and EFDA to support the provision of initial and refresher needs-based training, mentorships, and supportive supervision to cover reporting, data analysis, and investigation and report preparation
	To develop training materials, training modules, and directives suitable for the Ethiopia immunization and safety surveillance program
	EPHI, EFDA, and management at hospitals to develop a surveillance and data management infrastructure improvement plan and advocate for resources for its gradual advancement
	EPHI and EFDA to provide technical assistance to AEFI surveillance sites for improved clinician- PHEM interface to improve reporting
	EPHI to strengthen the feedback mechanism and result in communication to referring sites
	Hospitals to advocates for an awareness campaign to health workers and caregivers about the need to report, to whom, and how to report AEFI

	EPHI and EFDA to introduce/strengthen the use of technologies to report and improve AEFI surveillance
AEFI Guideline and reporting form	EFDA and AEFI surveillance sites to improve Guidelines availability, and enhance their operationalization
Organizational and business level readiness	Hospital management to identify roles and responsibilities of staff involved in immunization safety surveillance
	Hospital management to introduce/strengthened electronic medical record-keeping to improve data quality and the efficiency of data acquisition.
Governance readiness	The active AEFI surveillance sites shall support the system with specific rule, regulation and operational guideline to be applied by stakeholders for improving the implementation.

REFFERENCE

1. WHO. Immunization safety surveillance : guidelines for immunization programme managers on surveillance of adverse events following immunization. 3rd ed. 2016.

2. WHO. Global Manual on Surveillance of Adverse Events Following Immunization. September 2014(Revised March 2016).

3. WHO. https://www.who.int/news-room/fact-sheets/detail/immunization-coverage. 2020.

4. Health FMo. Ethiopia national expanded programme on immunization Available at: https://extranet.who.int/countryplanningcycles/sites/default/files/country_docs/Ethiopia/ethiop_cmyp_latest_revised_may_12_2015.pdf. 2015.

5. Choi K, Records K, Low LK, Alhusen JL, Kenner C, Bloch JR, et al. Promotion of Maternal-Infant Mental Health and Trauma-Informed Care During the Coronavirus Disease 2019 Pandemic. Journal of obstetric, gynecologic, and neonatal nursing : JOGNN. 2020.

6. World Health Organization ROfS-EA. Causality assessment of an adverse event following immunization (AEFI) Available at: https://www.who.int/vaccine_safety/publications/gvs_aefi/en/. 2018.

7. https://www.who.int/vaccine_safety/initiative/detection/AEFI/en/ WAa.

8. Pharmacovigilance CWWGoV. Defi nition and Application of Terms for Vaccine Pharmacovigilance Available at: https://www.who.int/vaccine_safety/initiative/tools/CIOMS_report_WG_vaccine.pdf?ua=1. 2011.

9. Vannice KS, Keita M, Sow SO, Durbin AP, Omer SB, Moulton LH, et al. Active Surveillance for Adverse Events After a Mass Vaccination Campaign With a Group A Meningococcal Conjugate Vaccine (PsA-TT) in Mali. Clinical infectious diseases : an official publication of the Infectious Diseases Society of America. 2015;61 Suppl 5:S493-500.

10. Danova J, Kocourkova A, Celko AM. Active surveillance study of adverse events following immunisation of children in the Czech Republic. BMC Public Health. 2017;17.

11. FOOD AND DRUGS AUTHORITY : GUIDELINES FOR SURVEILLANCE OF ADVERSE EVENTS FOLLOWING IMMUNIZATION IN GHANA ;https://www.rrfa.co.za/wp-content/uploads/2014/01/GUIDELINES-FOR-SURVEILLANCE-OF-ADVERSE-EVENTS-FOLLOWING-IMMUNIZATION-IN-GHANA.pdf.

12. Organization WH. CIOMS Guide to Active Vaccine Safety Surveillance. 2017.

13. Roush S. Chapter 19: Enhancing Surveillance.

14. Ezzet F, Dorazio R, Herzberg R. Horseshoe and pelvic kidneys associated with abdominal aortic aneurysms. American journal of surgery. 1977;134(2):196-8.

15. Akanmori BD TTea. Vaccine Safety and Pharmacovigilance in the African Region: Recent Updates. Journal of Immunological Sciences. 2018.

16. WHO. MODULE 5: Vaccine safety institutions and mechanisms.

17. African Union Development Agency – NEPAD: AU-3S. 2021. An African Perspective on Implementing and Conducting Safety Surveillance of COVID-19 Vaccines. AUDA-NEPAD, Midrand, South Africa.

18. Africa WROf. Investment case for vaccine-preventable diseases surveillance in the African Region, 2020–2030. 2019.

19. Barry A, Olsson S, Minzi O, Bienvenu E, Makonnen E, Kamuhabwa A, et al. Comparative Assessment of the National Pharmacovigilance Systems in East Africa: Ethiopia, Kenya, Rwanda and Tanzania. Drug safety. 2020;43(4):339-50.

20. Z. Li AX, and L. Song, . Investigation on Knowledge, Attitude and Practice (KAP) about Adverse Events Following Immunization (AEFI) among staff on immunization programme in Shandong Province, China,. Chinese Journal of Vaccines and Immunization. 2012.

21. Calistus Wanjala Masika HA, and Tom Were. Knowledge, Perceptions, and Practice of Nurses on Surveillance of Adverse Events following Childhood Immunization in Nairobi, Kenya. BioMed Research International. 2016.

22. *et.al* MC. Evaluation of the adverse events following immunization surveillance system in Guruve District, Mashonaland Central 2017. The Pan African Medical Journal.

23. Daniel N. A. Ankrah DMD*ea*. Reporting of adverse events following immunizations in Ghana – Using disproportionality analysis reporting ratios. HUMAN VACCINES & IMMUNOTHERAPEUTICS. 2018;14(1):172–8.

24. Stajduhar KI BD, Norgrove L, Allen D, Waskiewich S. Using quality improvement to enhance research readiness in palliative care. J Healthc Qual 2006, 28(4):22–28.

25. Dorazio RA, Ezzet F, Nesbitt NJ. Long-term follow-up of asymptomatic carotid bruits. American journal of surgery. 1980;140(2):212-3.

26. Organization WH. Global vaccine safety blueprint :The landscape analysis. 2012.

27. Senn S, Bakshi R, Ezzet N. n of 1 trials in osteoarthritis. Caution in interpretation needed. Bmj. 1995;310(6980):667.

28. Gillian Lim WMea. Annual Report on Vaccine Safety in Ontario. 2018.

29. Masuka JT, Khoza S. Adverse events following immunisation (AEFI) reports from the Zimbabwe expanded programme on immunisation (ZEPI): an analysis of spontaneous reports in Vigibase(R) from 1997 to 2017. BMC Public Health. 2019;19(1):1166.

30. WHO. The Global Vaccine Action Plan 2013.

31. Cashman P, Macartney K, Khandaker G, King C, Gold M, Durrheim DN. Participant-centred active surveillance of adverse events following immunisation: a narrative review. International Health. 2017;9(3):164-76.

32. Health FMo. ETHIOPIA NATIONAL EXPANDED PROGRAMME ON IMMUNIZATION : COMPREHENSIVE MULTI-YEAR PLAN 2016 - 2020. 2015.

33. World Health O. Causality assessment of an adverse event following immunization (AEFI): user manual for the revised WHO classification. 2nd ed ed. Geneva: World Health Organization; 2018 2018.

34. WHO. Adverse events following immunization in South-East Asia Region 2008-2010 : report on WHO support to the training programme. 2011.

35. Carr H dLS, Liyanage H, Liaw ST, Terry A, Rafi I. . Defining dimensions of research readiness: a conceptual model for primary care research networks. BMC family practice. 2014 Dec 1;15(1):169. 2014.

36. https://docs.dhis2.org/en/topics/metadata/immunization/adverse-events-following-immunization-aefi-tracker-design.html.

37. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/food-medicine-and-healthcare-administration-and-control-councils-of-ministers-regulation-no-299-2013/. 2014.

38. Talip BA, Sleator RD, Lowery CJ, Dooley JSG, Snelling WJ. An Update on Global Tuberculosis (TB). Infectious Diseases: Research and Treatment. 2013;6:IDRT.S11263.

39. https://extranet.who.int/nutrition/gina/en/node/26273. 2010.

40. Sahile Z, Tezera R, Haile Mariam D, Collins J, Ali JH. Nutritional status and TB treatment outcomes in Addis Ababa, Ethiopia: An ambi-directional cohort study. PLoS One. 2021;16(3):e0247945.

41. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/pv-newsletter-v2-issue-2/. 2012.

42. Ethiopia FMoHo. National guidelines for TB, Drug Resistant TB And Leprosy In Ethiopia, Sixth Edition 2018. Available from: Available from: https://www.afro.who.int/publications/national-guidelines-tb-drug-resistant-tb-and-leprosy-ethiopia-sixth-edition.

43. WHO. Companion Handbook to the WHO Guidelines for the Programmatic Management of Drug-Resistant Tuberculosis. Geneva: World Health Organization; 2014. 5, Treatment strategies for MDR-TB and XDR-TB. 2014. Available from: Available from: https://www.ncbi.nlm.nih.gov/books/NBK247431/.

44. Ethiopian Food and Drug Authority : Pharmacovigilance Directive. 2020.

45. Effective Design, Implementation, Integration, and Evaluation of Digital Health Systems to Enhance the Strategic Use of Data for Immunisation Programming ;District Health Information Software 2 (DHIS2) & Immunisation : Country Case Study: Ghana https://s3-eu-west-

1.amazonaws.com/content.dhis2.org/general/Ghana+DHIS2++Immunisation+Case+Study_Final_September2020.pdf.

46. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/pharmacovigilance-newsletter-no-15/. 2019.

47. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/pv-newsletter-v1-issue-3-nov-2011/. 2011.

48. Ethiopian Food and Drug Authority : file:///F:/Desk%20review/support%20material/PV_newsletter_V3_Issue_1.pdf. 2013.

49. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/pharmacovigilance-newsletter-no-10/. 2014.

50. Ethiopian Food and Drug Authority : http://www.fmhaca.gov.et/publication/pharmacovigilance-newsletter-no-11/. 2015.

51. Ethiopian Food, Medicine and Healthcare Administration and Control Authority ; Guideline for Surveillance and Response to Adverse Events Following Immunization ; Second edition ;February 2016.

52. EthiopianFoodandDrug Authority ,Roadmaptoward a strengthened nationalPharmacovigilancesysteminEthiopia,fora Period ofFiveYears ; http://www.fmhaca.gov.et/publication/national-pharmacovigilance-roadmap-2020/.

53. Woldeyohannes D, Assefa T, Aman R, Tekalegn Y, Hailemariam Z. Predictors of time to unfavorable treatment outcomes among patients with multidrug resistant tuberculosis in Oromia region, Ethiopia. PLOS ONE. 2019;14(10):e0224025.

54. Alemu A, Bitew ZW, Worku T. Poor treatment outcome and its predictors among drug-resistant tuberculosis patients in Ethiopia: A systematic review and meta-analysis. International Journal of Infectious Diseases. 2020;98:420-39.

55. Ethiopian Public Heath Institute ; Public health emergency managment guideline : https://ephi.gov.et/images/guidelines/phem-guideline-final.pdf. 2012.

56. Ethiopian Public Health Institute : Guideline on measles survellance and outbreak managment ;https://ephi.gov.et/images/guidelines/guideline-on-measles-surveillance-and-outbreak-management2012.pdf. 2012.

57. Diriba G, Kebede A, Tola HH, Alemu A, Tadesse M, Tesfaye E, et al. Surveillance of drug resistance tuberculosis based on reference laboratory data in Ethiopia. Infectious Diseases of Poverty. 2019;8(1):54.

58. National Implementation Guideline for Expanded Program on Immunization (Revised edition): June 2021 Addis Ababa, Ethiopia.

59. https://community.dhis2.org/t/information-for-action-dashboards/37340.

60. Shuaib F, Garba AB, Meribole E, Obasi S, Sule A, Nnadi C, et al. Implementing the routine immunisation data module and dashboard of DHIS2 in Nigeria, 2014-2019. BMJ global health. 2020;5(7).

61. Chen RT, Shimabukuro TT, Martin DB, Zuber PL, Weibel DM, Sturkenboom M. Enhancing vaccine safety capacity globally: A lifecycle perspective. Vaccine. 2015;33 Suppl 4:D46-54.

62. https://dhis2.org/bangladesh-immunization-campaign/.

63. https://dhis2.org/immunization/.

64. https://dhis2.org/who-package-downloads/#aefi.

65. Strengthening pharmaceutical systems. Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries [Internet]. World Health Organization; 2009. Available from: http://apps.who.int/medicinedocs/documents/s21303en/s21303en.pdf

66. WHO. Global tuberculosis report 2020. Geneva: World Health Organization 2020. Available from: Available from: http://apps.who.int/iris.

67. Alene KA, Yi H, Viney K, McBryde ES, Yang K, Bai L, et al. Treatment outcomes of patients with multidrug-resistant and extensively drug resistant tuberculosis in Hunan Province, China. BMC Infectious Diseases. 2017;17(1):573.

68. Asgedom SW, Teweldemedhin M, Gebreyesus H. Prevalence of Multidrug-Resistant Tuberculosis and Associated Factors in Ethiopia: A Systematic Review. Journal of Pathogens. 2018;2018:7104921.

69. WHO. Update of the WHO guidance on the treatment of drug susceptible tuberculosis. Geneva: World Health Organization 2021. Available from: Avialble from: https://www.who.int/news/item/16-04-2021-update-of-the-who-guidance-on-the-treatment-of-drug-susceptible-tuberculosis.

70. https://sideeffects.health.gov.il/.

71. . Infection and drug resistance.

72. https://www.safevac.org.au/Home/Info/VIC.

73. Bogale L, Tsegaye T. Unfavorable Treatment Outcome and Its Predictors Among Patients with Multidrug-Resistance Tuberculosis in Southern Ethiopia in 2014 to 2019: A Multi-Center Retrospective Follow-Up Study. 2021;14:1343-55.

74. Vigilance and Crisis Management Executive Directorate ; Guideline on good pharmacovigilance practices (GVP). 2015.

75. iPHIS User Guide: Adverse Events Following Immunization (AEFIs). 2020.

76. https://www.who.int/vaccine_safety/initiative/tools/AEFI_reporting_form_EN_Jan2016.pdf.

77. http://www.fdaghana.gov.gh/report-abuse.php [Accessed May 3 2021].

78. https://pv.pharmacyboardkenya.org/ [Accessed may 3 2021].

79. http://www.dgda.gov.bd/index.php/newsletter.

80. National Guideline on immunization safety surveillance : http://www.epid.gov.lk/web/images/pdf/Publication/AEFI_Guidelines_Sri_lanka_2016.pdf. 2016.

81. https://www.npra.gov.my/easyarticles/images/users/1108/ADR%20form/ADR_Form_Healthcare_Prof_web-01.202_20210204-03Febth_1.pdf.

82. https://www.gov.mb.ca/health/publichealth/cdc/docs/mhsu_2334.pdf.

83. http://www.fdaghana.gov.gh/img/applicationform/Revised%20AEFI%20Reporting%20Form_CLEAN.pdf.

84. https://pharmacyboardkenya.org/files/?file=AEFI_Reporting_Form_White.pdf [Accessed may 3 2021].

ANNEX

Participant Information sheet

English version

Title: System and site readiness for conducting active surveillance of adverse Events following Immunization in Addis Ababa, Ethiopia.

Investigator: Eden Dagnachew Zeleke, MSc in a clinical trial candidate, Department of CDT Africa, Addis Ababa University

Phone number: +251934774373

Email: eden.dagnachew@aau.edu.et

Dear participant

Please take some time to read the following information. If at any point you have any questions, please don't hesitate to ask the researcher.

Overview

You have been invited to take part in a study which explores the system and site readiness for conducting active surveillance on adverse events following immunization (AEFI) in Addis Ababa, Ethiopia.

You are kindly asked to participate in the face-to-face interviews which will last about five minutes.

Purpose of the study

The purpose of the present study is to assess system and site readiness for implementing pilot active AEFI surveillance in Addis Ababa, Ethiopia on 2021 G.C in an attempt to improve hospitals' performance on collecting, analyzing, and reporting AEFI. The findings will help study hospitals prepare themselves for active AEFI surveillance. The findings will also help strengthen the national

Pharmacovigilance system and identify areas requiring attention in order to improve the reporting and response capacity (e.g., data flow, investigation and causality assessment capacity).

Risk during participating in this study

There is no anticipated risk while participating in this study.

Confidentiality and privacy

The information you provide will remain confidential. No one except the researcher will have access to the information. If you don't want to share any of the information with us you don't have to do it so.

የ ተሳ ታፊዎችየ ሚ ጃ ገ ፅ

ር ዕ ስ፡ ክ ትባ ትን ተከ ትለ ውየ ሚከ ሰ ቱትን ሞኮ ፎክ ስ ተ ቶች በ ን ቃትለ ሚካ ታተ ልየ ስ ር ዓ ትእ ና የ ቦ ታዝ ግጁ ነ ትአ ዲስ አ በ ባ በ ኢትዮ ጵ ያ ፡ ፡

ሚ ሚ ሪ ፡ ኤደ ን ዳ ኛ ቸው፣ ሁለ ተ ኛ ድግ ሪ በ ክ ልኒ ካ ል ትሪ ያ ል ፣ በ ሲዲ ቲአ ፍሪ ካ ዲፓ ር ትሜ ን ት ፣ በ አ ዲስ አ በ ባ ዩ ኒ ቨ ር ሲቲ

ስ ል ክ ቁ ጥ ር ፣ +251934774373

ውድ ተሳ ታፊ
የ ሚከ ተሉት ን ሚ ጃ ዎች ለ ሜን በ ብእ ባ ክ ዎየ ተወሰ ነ ጊ ዜይ ውሰ ዱ፡ ፡ በ ሜን ኛ ውም ጊ ዜ ጥያ ቄ ዎች ካ ሉዎት እ ባ ክ ዎን

ተ ሞ ራ ሚ ውን ከ ሜከ የ ቅ ወደ ኋ ላ አ ይበ ሉ፡ ፡

<u>አ ጠቃ ላ ይእ ይታ</u>

እ ር ሶ ክ ትባ ትን ተከ ትሎ በ አ ዲስ አ በ ባ ፣ ኢ ትዮ ጵ ያ ውስ ጥ ክ ትትል ን በ ሚከ ተ ሉ ሞኮ ፎክ ስ ተ ቶች ላ ይን ቁ ቁ ጥ ጥር ለ ሜድ ረ ግ የ ሜያ ስ ች ል ስ ር ዓ ትና የ ቦ ታዝ ግጁ ነ ትበ ሜጀ ስ ስ ጥና ት ላ ይእ ን ዲሳ ተ ፉ ተ ፃ ብዘ ዋል፡ ፡
ለ አ ምክ ት ደ ቂ ቃ ያ ህ ል የ ሜቆ ይየ ፊ ት ለ ፊ ት ቃ ለ ሜኪ ይቆ ች እ ን ዲሳ ተ ፉ በ ት ህ ት ና ይጠ የ ቃ ሉ፡ ፡

የ ጥና ቱ ዓ ላ ማ

የዚህ ጥናት ዓላማየ ሆስፒታሎችን ማነብሰብ፣ ሞትንተን እናሪፖርት ሚድረጉን ለማሻሻል
አዲስአበባ ላይ በማራ ላይየ ዋለውን የማራ AEFI
ቁጥጥርንለሞተግበርየ ስርዓትእናየቦታዝግጁነ ትማ ምግ ምግ ው ፡ ግኝቶቹየ ክትባትክትትልንተከት
ለውን ቁለሆኑ አሉታዊክስተቶችሆስፒታሎችንራሳቸውን ለማጥና ትይረዳሉ፡ ፡ ግኝቶቹየ ሪፖርትና ምላሽ
አቅምን ለማሻሻል (ለምሳሌየ ሚጃፍሰት፣ ምር ሚራእናምክንያታዊነ ትምዘናአቅም)
ብሄራዊየ ሚድታኒ ትቁጥጥርስርዓትን ለማጠና ከርእናትኩረትየ ሚሹቦ ታዎችን ለማሳየ ትይረዳሉ፡ ፡

በዚህ ጥና ትውስ ጥሲሳ ተፉአደጋ

በዚህ ጥና ትውስ ጥበ ሚነ ተፉበ ትጊዜየ ሚከበ ቅአደጋየ ለም ፡

ሚነ ጥራዊነ ትእናግላዊነ ት

ያቀረቡትሚጃበ ሚነ ጥር ይቀጫል፡ ፡ ከተሚራሚሪ ውብቀር ማን ምዋ ሚጃተደራሽነ ትአያገኝም ፡ ማን
ኛውን ምሚጃከእኛጋርለማጋራትየ ሚይፈልጉከሆነ እንደዚህ ሚድረግየ ለብዎትም።

Hospital Readiness Assessment Tool

COVER SHEET

Q1. Hospital name: _____

Q2. Date of hospital assessment: __ __ / __ __ / __ __ __ __ (DD / MM / YYYY)

Q3. Information about informed consent from each department Interviewee :

No.	Department Representative	Consent obtained (Circle)
a.	office of the facility- in – charge	Yes /No
b.	vaccination clinic	Yes /No
c.	Adult Emergency Department	Yes /No
d.	Pediatrics Emergency Department	Yes /No
e.	Adult ward	Yes /No
f.	Pediatrics ward	Yes /No
g.	laboratory	Yes /No
h.	Radiology department	Yes /No
i.	Medical records	Yes /No
j.	Surveillance office	Yes /No
k.	Pharmacy	Yes /No

Informed consent

Greetings,

My name is ____ and I am working for the ----------. The aim of our visit today is to determine whether this facility would be a good place to pilot a new surveillance system for adverse events following immunization. The World Health Organization recommends that all countries providing vaccinations conduct surveillance for adverse events following immunization. However, many countries, because of many other priorities, struggle to meet these recommendations and there is a need to develop new ways to identify and report adverse events following immunization.

You have been selected to participate in this survey because of your responsibility in the hospital. Now I am going to ask you some questions about the readiness of your facility now. Do you have time?

- Yes, I have
- No, I don't have time
- Not now, please come later

All the Information you provide us will be kept confidential. Anonymized information obtained from you will only be shared with experts working on this problem and could also be used in a scientific publication without identifying you. The interview is completely voluntary and you have the right to participate in this study or decline and also to withdraw at any time. Your participation is voluntarily. There are no rights or wrong answers; we just want to find out your views. The interview will take up to ---------- minutes to complete.

May I proceed?

- Yes, I agree to participate in this survey

- No, I do not agree to participate in this survey (terminate)

ፍቃደኝነት ትንሣኤየ ቂያቅጽ

ስሜ---------ይባላል። የ ምህራበትቦታ ----------
ይባላል። የ ዛሬዉጉብኚታችንአላማይህማህሪያቤትበቅርቡለሚከሄደዉክትባትንተከትሎለሚሞከዩጎን ዮሽጉዳኖችየ ዳሰሳጥና ትብቁሚሆኑንለሚጋገጥነው። የ አለምከፍድርጂትየ ክትባትፕሮግራምያላችዉሃገሮቸበማኡክትባቱንተከትሎለሚሞከዩጎንዮሽጉዳኖችየ ዳሰሳጥና ትእንዲያደረጉይሜክራል። ምነምእንኩዋንብዙሃገራቶችበሌሎችቅድሚያበሚሰጡዋቸውዛገሮችየ ተነሳይሄንንለሞተግበርፈተናውስጥበመግባታቸውክትባትንተከትሎለሚሞከዩጎንዮሽጉዳኖችልየ ታናለሚሞላከተውአካልለማሳወቅየ ሚያንሌላዘዴሚፈለግአስፈላጊሆኖተገኝቶዋል።

እርሶዎለዚህየ ዳሰሳጥና ትየ ተሚጠቅበዚህሆስፒታልባሎዎትሃላፊነ ትየ ተነሳነው። አሁንማህሪያቤትዎለዳሰሳጥና ትያለዉንዝግጁነ ትላይጥያቄዎችንአቀርብሎታለሁ። ጊዜአሎዎት?

- አዎ
- አይሰአትየ ለኚም
- እባክዎንሌላይምጡ

ሁሉምየ ሰጡን ሚጃበማኡሚስጥራዊነ ቱየ ተጠበቀነው። የ ርስዎማንነ ትሊያጋልጡይችላሉተብለዉየ ሜታ ሰቡማንኛውምሚጃዎችለጉዳዩ (ችግሩ)
ከሚሞላከታቸዉግለሰቦችውጪኣናጋራምጣተጨሜሪምየ ጥናታዊዉጽሁፈህትሞትላይለሰጡትሚጃስምዎአይጠቀስም። ይህቃለማጠይቅፍጹምጣፈቃደኚነ ትላይየ ተማሳረተሲሆንንበተጨሜሪምደግጣጠዚህጥናትላይየ ማሳተፈያለማሳተፈእንዲሁምጣፈለጉትሰአትየ ማቋዋረጥጦብትዎየ ተጠበቀነው። ተሳትፎዎፈጹምጣፈቃደኚነ ትላይየ ተማሳረተነው። በሚሰጡትምላሽላይምነምአይነ ትፍረጃአይኖርምሆኖምእኛምነፈልገዉየ እርሶዎንእይታብቻነው። ቃለምልልሱ ---------ያህልደቂቃይፈጃል።

ቃለምልልሱይቀጥል?

- አዎበዚህጥናትላይለማሳተፍፍቃደኛነኝ
- አይበዚህጥናትላይለማሳተፍፍቃደኛአይደለሁም

*******Office of Facility In-Charge*******

	Question	Response / Notes	Score elements	Score
Q4a	Are you familiar with National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1

Q4b	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q4c	Who (or which department) is responsible for reporting AEFI to local public health authorities?		X	X

Q4d	Do you or other facility leaders review AEFI reports? *If yes, describe who is responsible, what do they review, how do they review, how frequently is this done.*	Yes / No	1 – Yes	__ / 1
Q4e	Who (or which department) is responsible for reporting cases of measles, acute flaccid paralysis?		X	X

Q4f	Do you or other facility leaders review measles or AFP reports? *If yes, describe who is responsible, what do they review, how do they review, how frequently is this done.*		X	X

Q4g	*After explaining objectives of readiness assessment (above):* Would this facility be a good site for more intense surveillance for AEFIs (similar to surveillance for measles or AFP)? Why or why not?	Yes (good site) / No (not a good site)	1 – Yes	__ / 1
Q4h	In your opinion, what would be needed to implement improved surveillance for AEFIs at this facility?		X	X

Q4h 1	Does your facility do any activities (e.g., training, awareness campaigns) to promote AEFI reporting or improve awareness of AEFIs? *If yes, describe what is done, how frequently, when last done.*		X	X

Q4i	Are vaccinations provided to children at birth or up to 5 years of age at this facility? *If yes, ensure at least one of staff members interviewed is a nurse, vaccinator, or in-charge of vaccination clinic, see Q3 above and section "Vaccination clinic (if applicable)" below.*	Yes / No	1 – Yes	__ / 1

Q4j	FACILITY AEFI policies (rules, regulations and guidelines) exist and are applied.	1. Attendance of staff 2. Dress code 3. Performance evaluation 4. Professional conduct in clinical areas 5. Disciplinary action procedures (including probation, suspension, termination, expulsion) for staff	X	X
Q4j1	Staff are aware of the policies *(Randomly interview two staff to verify whether)*		X	X

Q4k	Disciplinary measures are taken for misconduct as per the policy *(Verify through interview with department head and review of records whether)*		X	X
Q4l	Written job descriptions exist for all staff at the department	1. Nurses 2. Doctors 3. Specialists	X	X
Q4L 1	Verify by randomly asking two staff: If they have received their job descriptions		X	X

4	**Total score** ***Sum of score for interview / table.***			**__ / 7**

Additional notes:

*******Questions for Vaccination clinic (if applicable) *******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**

Q5a	How many vaccinations were provided in 2019/2020/2021? In November 2019? December 2019? In November 2020? In December 2020? January 2021? *Note to interviewer: we are looking for data officially documented, not just from memory of interviewee (especially true for 0 reporting).*	November 2019: _____ December 2019: _____ November 2020: _____ December 2020: -------- January 2021:----------	Total 5 points, 1 point for each data element, even if 0	__ / 5
Q5b	Does the clinic maintain records of vaccinations given for each child at the clinic (e.g., register)?	Yes / No	1 – Yes	__ / 1
Q5c	Are these records (e.g., register) paper or electronic based?	Paper / Electronic / Both	X	X

Q5d	If paper based, are they legible? *Note to interviewer: can you read, without assistance of interviewee, the 1st record on at least 5 different pages of register?*	Yes / No	Total 2 points: 2 – did not need assistance 1 – assistance required for some records 0 – totally illegible	__ / 2
Q5e	If electronic based, what software is being used? Is a back-up paper record maintained?	Back-up paper: Yes / No	X	X

Q5f	What are the variables recorded in register? *Take photo(s) demonstrating layout and legibility, avoid names and dates of birth.*	List of variables: Photo number(s):	Total 3 points, 1 point each for: 1 – name of child 1 – date of birth child 1 – AEFI occurred	__ / 3
Q5g	Does the hospital have a copy of national adverse events following immunization (AEFI) surveillance / reporting guidelines? AEFI reporting form? *Ask to see copy(ies) of each.*	Guideline: Yes / No AEFI reporting form: Yes / No	Total 2 points, 1 point each for: 1 – Guideline, Yes 1 – Reporting form, Yes	__ / 2

Q5h	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q5i	Does facility record adverse events following immunization (e.g., fever, anaphylaxis, rash) occurring after vaccination?	Yes / No	1 – Yes	__ / 1

Q5j	Describe the AEFI recording system. *Take photo(s) demonstrating record keeping (e.g., register, logbook, card, or form). Avoid capturing name or date of birth of child.* *Look for following elements: name and date of birth of child, date of AEFI, vaccine administered, type of AEFI (diagnosis, sign or symptom, etc.), whether AEFI was severe.*	Description of record system: Photo number(s):	Total 6 points, 1 point each for: 1 – name of child 1 – date of birth of child 1 – date of AEFI 1 – vaccine administered 1 – type of AEFI 1 – severity	__ / 6

Q5k	Does the facility report AEFIs to anyone or any organization outside the vaccination clinic? To whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? If yes from whom do they receive feedback. *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2

Q5l	If the child/adult receiving vaccination needs immediate medical attention for an adverse event, what are the next steps? *Describe process to provide medical attention, treat, or refer child.*		Total 2 points, 1 point each for: 1 – describes logical response to child needing medical attention for AEFI 1 – mentions reporting AEFI	__ / 2
Q5m	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
5	**Total score** ***Sum of score for interview / table.***			**__ / 27**

Additional notes:

*******Questions for Emergency Department *******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**
Q6a	Do children come with their child health record book or vaccination records? *If some or no children, describe how they verify vaccination history.*	Most children (≥50% of children) Some children (<50% of children) No children	2 – most children 1 – some children 0 – no children	__ / 2

Q6b	For a child 5 years or younger, do you record recent vaccinations (vaccinations in last 30 days)? *If yes, describe what is recorded and where / how it is recorded.* *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Yes / No Photo number(s):	1 – Yes	__ / 1
Q6c	Does each child have a medical chart in this department?	Yes / No	X	X

Q6d 20	What data are included in the medical chart? *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Record number of child: Yes / No Name of child: Yes / No Age of child: Yes / No Date of birth: Yes / No Date of illness onset: Yes / No Date of admission: Yes / No Outcome (discharge, death, transfer, other): Yes / No Date of outcome: Yes / No Final diagnosis: Yes / No Vitals: Yes / No Physical exam findings: Yes / No Laboratory findings: Yes / No Radiology findings: Yes / No Other variables (list): Photo number(s):	Total 6 points, 1 point each for: 1 – Record ID 1 – Name 1 – Age OR Date of birth 1 – Date illness onset 1 – Date admission 1 – Final diagnosis	__ / 6

Q6e	When the charts are transferred, to which department do they go? When are they transferred? How often are they transferred? *Go to department storing charts, describe organization of chart storage.*		X	X
Q6f	Does this department maintain a patient register (e.g., logbook, computer file, other)?	Yes / No	1 – Yes	__ / 1
Q6g	Who maintains or updates the register?		X	X

Q6h	What variables are recorded in the register? *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Record number of child: Yes / No Name of child: Yes / No Age of child: Yes / No Date of birth: Yes / No Date of illness onset: Yes / No Date of admission: Yes / No Outcome (discharge, death, transfer, other): Yes / No Date of outcome: Yes / No Final diagnosis: Yes / No Other variables (list): Photo number(s):	Total 6 points, 1 point each for: 1 – Record ID 1 – Name 1 – Age OR Date of birth 1 – Date illness onset 1 – Date admission 1 – Final diagnosis	__ / 6

Q6i	Are the registers paper or electronic based?	Paper / Electronic / Both	X	X
Q6j	If paper based, are registers legible? *Note to interviewer: can you read, without assistance of interviewee, the 1st record on at least 5 different pages of register?*	Yes / No	Total 2 points: 2 – did not need assistance 1 – assistance required for some records 0 – totally illegible	__ / 2
Q6k	If electronic based, what software is being used? Is a back-up paper record maintained?	Back-up paper: Yes / No	X	X

Q6l	What is the oldest record in the register maintained in this department?	Paper, date of record: __ / __ / ____ (DD / MM / YYYY) Electronic, date of record: __ / __ / ____ (DD / MM / YYYY)	X	X
Q6m	When the registers are transferred, to which department do they go? When are they transferred? How often are they transferred? *See interview Medical Records with instructions/scoring for locating register previous to one maintained on ward.*		X	X
Q6n	Are you familiar with the National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1

Q6o	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q6p	If it is found that a child had an adverse event following immunization, is this reported?	Yes / No	1 – Yes	__ / 1

Q6q	Does the facility report AEFIs to anyone or any organization outside the vaccination clinic? If yes, to whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? From whom do they receive feedback. *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2
Q6r	Do you have copies of the National AEFI guidelines? AEFI reporting forms. *Ask to see guidelines and reporting form.*	Guidelines: Yes / No Reporting form: Yes / No	Total 2 points, 1 point each for: 1 – Guidelines, Yes 1 – Reporting form, Yes	__ / 2

Q6s	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
6	**Total score** ***Sum of score for interview / table.***			**__ / 27**

Additional notes:

*******Questions for Pediatric Ward*******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate.

	Question	**Response / Notes**	**Score elements**	**Score**
Q7a	Do children come with their child health record book or vaccination records? *If some or no children, describe how they verify vaccination history.*	Most children Some children No children	2 – most children 1 – some children 0 – no children	__ / 2

Q7b	For a child 5 years or younger, do you record recent vaccinations (vaccinations in last 30 days)? *If yes, describe what is recorded and where / how it is recorded.* *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Yes / No Photo number(s):	1 – Yes	__ / 1
Q7c	Does each child have a medical chart in this department?	Yes / No	X	X

Q7d	What data are included in medical chart? *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Record number of child: Yes / No Name of child: Yes / No Age of child: Yes / No Date of birth: Yes / No Date of illness onset: Yes / No Date of admission: Yes / No Outcome (discharge, death, transfer, other): Yes / No Date of outcome: Yes / No Final diagnosis: Yes / No Vitals: Yes / No Physical exam findings: Yes / No Laboratory findings: Yes / No Radiology findings: Yes / No Other variables (list): Photo number(s):	Total 6 points, 1 point each for: 1 – Record ID 1 – Name 1 – Age OR Date of birth 1 – Date illness onset 1 – Date admission 1 – Final diagnosis	__ / 6

Q7e	When charts are transferred, to which department do they go? When are they transferred? How often are they transferred? *Go to department storing charts, describe organization of chart storage.*		X	X
Q7f	Does this department maintain a patient register (e.g., logbook, computer file, other)?	Yes / No	1 – Yes	__ / 1
Q7g	Who maintains or updates the register?		X	X

Q7h	What variables are recorded in the register? *Take photo(s) demonstrating recording. Avoid photos of name or date of birth of children.*	Record number of child: Yes / No Name of child: Yes / No Age of child: Yes / No Date of birth: Yes / No Date of illness onset: Yes / No Date of admission: Yes / No Outcome (discharge, death, transfer, other): Yes / No Date of outcome: Yes / No Final diagnosis: Yes / No Other variables (list): Photo number(s):	Total 6 points, 1 point each for: 1 – Record ID 1 – Name 1 – Age OR Date of birth 1 – Date illness onset 1 – Date admission 1 – Final diagnosis	__ / 6

Q7i	Are the registers paper or electronic based?	Paper / Electronic / Both	X	X
Q7j	If paper based, are registers legible? *Note to interviewer: can you read, without assistance of interviewee, the 1st record on at least 5 different pages of register?*	Yes / No	Total 2 points: 2 – did not need assistance 1 – assistance required for some records 0 – totally illegible	__ / 2
Q7k	If electronic based, what software is being used? Is a back-up paper record maintained?	Back-up paper: Yes / No	X	X

Q7l	What is the oldest record in register maintained in this department?	Paper, date of record: __ / __ / ____ (DD / MM / YYYY) Electronic, date of record: __ / __ / ____ (DD / MM / YYYY)	X	X
Q7m	When registers are transferred, to which department do they go? When are they transferred? How often are they transferred? *See interview Medical Records with instructions/scoring for locating register previous to one maintained on ward.*		X	X
Q7n	Are you familiar with National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1

Q7o	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q7p	If it is found that a child had an adverse event following immunization, is this reported?	Yes / No	1 – Yes	__ / 1

Q7q	Does the facility report AEFIs to anyone or any organization outside the vaccination clinic? If yes, to whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? From whom do they receive feedback? *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2
Q7r	Do you have copies of the National AEFI guidelines? AEFI reporting forms. *Ask to see guidelines and reporting form.*	Guidelines: Yes / No Reporting form: Yes / No	Total 2 points, 1 point each for: 1 – Guidelines, Yes 1 – Reporting form, Yes	__ / 2

Q7s	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
7	**Total score** ***Sum of score for interview / table.***			**__ / 27**

Additional notes:

*******Questions for Laboratory*******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate.

	Question	**Response / Notes**	**Score elements**	**Score**
Q8a	Are records of laboratory findings kept in the laboratory?	Platelets: Yes / No Serum creatinine: Yes / No Blood culture: Yes / No CSF glucose: Yes / No CSF gram stain: Yes / No	Total 5 points, 1 point each for: 1 – Platelets 1 – Creatinine 1 – Blood culture 1 – CSF glucose 1 – CSF gram stain	__ / 5
Q8b	Are the laboratory records paper or electronic based?	Paper / Electronic / Both	X	X

Q8c	If paper based, are the registers legible? *Note to interviewer: can you read, without assistance of interviewee, the 1st record on at least 5 different pages of register?*	Yes / No	Total 2 points: 2 – did not need assistance 1 – assistance required for some records 0 – totally illegible	__ / 2
Q8d	If electronic based, what software is being used? Is a back-up paper record maintained?	Back-up paper: Yes / No	X	X
Q8e	What is the oldest laboratory record maintained in the department?	Paper, date of record: __ / __ / ____ (DD / MM / YYYY) Electronic, date of record: __ / __ / ____ (DD / MM / YYYY)	X	X

Q8f	Are the laboratory records transferred elsewhere for long-term storage? *If yes, describe to where, how often. Visit if possible and describe file system and whether laboratory records were retrievable.*		X	X
Q8g	How is the laboratory results matched to children in on wards? *Describe system.*		1 – uses unique Record ID that matches to ward / medical records ID	__ / 1

Q8h	Is it possible to generate a list of children ≤ 5 years of age with low platelets (platelet count ≤ 150,000) in last 3 (completed) months? 6 months? 12 months? List includes Record ID, platelet count, date of test? *If no, why not?*	3 months: Yes / No 6 months: Yes / No 12 months: Yes / No Record ID: Yes / No Platelet count: Yes / No Date of test: Yes / No	Total 6 points, 1 point each for: 1 – 3 months 1 – 6 months 1 – 12 months 1 – Record ID 1 – Platelet count 1 – Date of test	__ / 6
Q8i	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X

8	**Total score** ***Sum of score for interview / table.***			**__ / 14**

Additional notes:

*******Questions for Radiology Department*******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**
Q9a	Are the records of radiological findings kept in this department?	Chest x-ray: Yes / No Head CT: Yes / No	Total 2 points, 1 point each for: 1 – Chest x-ray 1 – Head CT	__ / 2

Q9b	Are the radiological results paper or electronic?	Paper / Electronic / Both	X	X
Q9c	Are the films (e.g., chest x-ray, head CT) digital?	Yes / No	X	X
Q9d	What is the oldest radiological record maintained in the department?	Paper, date of record: __ / __ / ____ (DD / MM / YYYY) Electronic, date of record: __ / __ / ____ (DD / MM / YYYY)	X	X

Q9e	Are the radiological records transferred elsewhere for long-term storage? *If yes, describe to where, how often. Visit if possible and describe file system and whether radiological records were retrievable.*		X	X
Q9f	How are the radiological results matched to children in on wards? *Describe system.*		1 – uses unique Record ID that matches to ward / medical records ID	__ / 1
Q9g	Are you familiar with National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	X

Q9h	Do you have copies of the National AEFI guidelines? AEFI reporting forms. *Ask to see guidelines and reporting form.*	Guidelines: Yes / No Reporting form: Yes / No	Total 2 points, 1 point each for: 1 – Guidelines, Yes 1 – Reporting form, Yes	X
Q9i	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
9	**Total score** ***Sum of score for interview / table.***			**X Section not scored**

Additional notes:

*******Questions forMedical Records Department*******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	Response / Notes	Score elements	Score
Q10a	Are children assigned a unique record ID? *Describe how record IDs are assigned (e.g., random number, based upon date of birth or other factors, etc.).*	Yes / No	1 – Yes	__ / 1
Q10b	Are medical charts stored on site for all hospitalized patients? *Describe process for locating specific medical chart. Are records retrievable?*	Yes / No	1 – Yes, assessed that records are organized, retrievable	__ / 1

Q10c	Are ward registers stored on site? *Describe process for locating specific ward registers. Locate last emergency and pediatric ward registers.*	 Last emergency register located: Yes / No Last peds register located: Yes / No	Total 2 points, 1 point each for: 1 – Last emergency register located 1 – Last Peds ward register located	__ / 2
Q10d	Does the department report any data to Ministry of Health or Public Health Authorities on a routine (e.g., daily, weekly, monthly) basis? *Describe what is reported, to whom, how reported (electronic, paper), frequency of reporting.*	Yes / No	1 – Yes	__ / 1

Q10e	Does the department / facility use DHIS2?	Yes / No	1 – Yes	__ / 1
Q10f	Does the department use ICD 9 or 10 coding system? *Describe use of ICD 10 codes in facility and reporting.*	Yes / No	1 – Yes	__ / 1

Q10g	Can department produce list of children ≤ 5 years of age with seizures (ICD 10: R56.0) in last 3 (completed) months? 6 months? 12 months? List includes Record ID, discharge diagnosis, date of admission? *If no, why not?*	3 months: Yes / No 6 months: Yes / No 12 months: Yes / No Record ID: Yes / No Discharge diagnosis: Yes / No Date of admission: Yes / No	Total 6 points, 1 point each for: 1 – 3 months, Yes 1 – 6 months, Yes 1 – 12 months, Yes 1 – Record ID, Yes 1 – Discharge diagnosis, Yes 1 – Date of admission, Yes	__ / 6
Q10h	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
10	**Total score**			**__ /**

	Sum of score for interview / table.			**13**

Additional notes:

*******Questions forAFP and Measles Surveillance*******

See Greeting and Consent . Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**
Q11a	Can you describe how you identify cases of AFP or measles that are treated at this facility? *Describe process for identifying cases.*		X	X

Q11b	Which departments are included in your surveillance for AFP or measles cases?	Outpatient pediatrics clinic: Yes / No Vaccination clinic: Yes / No Emergency Department: Yes / No Inpatient pediatrics ward: Yes / No Inpatient adult ward: Yes / No Laboratory: Yes / No Other department/ward, list:	Total 5 points, 1 point each for: 1 – Outpatient peds 1 – Vaccination 1 – Emergency 1 – Inpatient peds ward 1 – Inpatient adult ward 1 – Laboratory	__ / 6

Q11c	What are the three main challenges you face in identifying AFP or measles cases at this facility?	1) 2) 3)	X	X
Q11d	Are you familiar with the National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1

Q11e	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q11f	Is anyone in your department or on your team responsible for identifying cases of AEFI that are treated at your facility?	Yes / No	1 – Yes	__ / 1

Q11g	If yes, can you describe how you identify cases of AEFI that are treated at this facility?		1 – describes a system for AEFI case identification at facility	__ / 1

Qllh	If no, if you or a colleague in your department or on your team were responsible for identifying cases of AEFI, beyond training and tools (e.g., guidelines and forms), what challenges would you face incorporating surveillance for AEFI into your workflow? *Note to interviewer: note challenges associated with training and tools, but ask for three challenges beyond these items.*	1) 2) 3)	X	X
Q11i	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
11	**Total score**			__ /

	Sum of score for interview / table.			**12**

Additional notes:

*******Pharmacy Department*******

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**
Q12a	Are you familiar with the National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1

Q12b	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine*.		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	__ / 3
Q12c	Is anyone in your department or on your team responsible for identifying cases of AEFI that are treated at your facility?	Yes / No	1 – Yes	__ / 1

Q12d	If yes, can you describe how you identify cases of AEFI that are treated at this facility?		1 – describes a system for AEFI case identification at facility	__ / 1
Q12e	Does the department report AEFIs to anyone or any organization outside the vaccination clinic? To whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? From whom do they receive feedback? *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2

Q12f	Do you have copies of the National AEFI guidelines? AEFI reporting forms. *Ask to see guidelines and reporting form.*	Guidelines: Yes / No Reporting form: Yes / No	Total 2 points, 1 point each for: 1 – Guidelines, Yes 1 – Reporting form, Yes	__ / 2
Q12g	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X
12	**Total score** ***Sum of score for interview / table.***			**__ / 10**

Additional notes:

*****Question for Adult Ward*****

See Greeting and Consent. Complete cover sheet with respondent information, consent to participate

	Question	**Response / Notes**	**Score elements**	**Score**
Q13a	Are you familiar with the National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1
Q13b	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal*		Total 3 points, 1 point each for: 1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship	__ / 3

	relationship with the usage of the vaccine.		with vaccine	
Q13c	If it is found that a patient had an adverse event following immunization, is this reported?	Yes / No	1 – Yes	__ / 1
Q13d	Is anyone in your department or on your team responsible for identifying cases of AEFI that are treated at your facility?	Yes / No	1 – Yes	__ / 1
Q13e	If yes, can you describe how you identify cases of AEFI that are treated at this facility?		1 – describes a system for AEFI case identification at facility	__ / 1

Q13f	Does the department report AEFIs to anyone or any organization outside the vaccination clinic? To whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? From whom do they receive feedback? *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2
Q13g	How would you verify vaccination statuses if you said AEFIs are reported?		X	X
Q13h	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X

13	**Total score** **Sum of score for interview/table**			**-----/9**

Additional notes:

***** Question for Adult Emergency Ward*****

See Greeting and Consent . Complete cover sheet with respondent information, consent to participate.

	Question	**Response / Notes**	**Score elements**	**Score**
Q14a	Are you familiar with the National Guidelines for Surveillance of Adverse Events Following Immunization (AEFI)?	Yes / No	1 – Yes	__ / 1
Q14b	How would you define an AEFI? *(Do not read) An AEFI is an untoward (or*		Total 3 points, 1 point each for:	__ / 3

	unexpected) medical occurrence (e.g., unfavorable or unintended sign, abnormal laboratory finding, symptom, or disease) which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine.		1 – untoward/unexpected medical occurrence 1 – follows immunization 1 – does not necessarily have causal relationship with vaccine	
Q14c	If it is found that a patient had an adverse event following immunization, is this reported?	Yes / No	1 – Yes	__ / 1
Q14d	Is anyone in your department or on your team responsible for identifying cases of AEFI that are treated at your facility?	Yes / No	1 – Yes	__ / 1
Q14e	If yes, can you describe how you identify cases of AEFI that are treated at this facility?		1 – describes a system for AEFI case identification at facility	__ / 1

Q14f	Does the department report AEFIs to anyone or any organization outside the vaccination clinic? To whom? How do they report? What do they report? When do they report? How often do they report? Do they receive feedback? From whom do they receive feedback? *Describe system in place for reporting.*		Total 2 points, 1 point each for: 1 – Provides name of person, email, or phone number to whom they report 1 – Reports any AEFI	__ / 2
Q14g	How would you verify vaccination statuses if you said AEFIs are reported?		X	X
Q14h	Would you be willing to participate in a study safety reporting following immunization?	1-Yes 2- No	X	X

14	**Total score** **Sum of score for interview/table**			**------/9**

Additional notes:

FINAL FACILITY SCORING TOOL

Health Facility Name: _____

Date of Assessment: __ __ /__ __ / __ __ __ __ (DD / MM / YYYY)

FINAL FACILITY SCORING TOOL

Health Facility Name: _____

Date of Assessment: __ __ /__ __ / __ __ __ __ (DD / MM / YYYY)

Table Number	**Department**	**Score**
4	Office of Facility-in-Charge	__ / 7
5	Vaccination clinic (if applicable)	__ / 27

6	Emergency department	__ / 27
7	Pediatric ward	__ / 27
8	Laboratory	__ / 14
9	Radiology department (informational only)	X
10	Medical records department	__ / 13
11	AFP and measles surveillance	__ / 12
12	Pharmacy department	__ / 10
13	Adult Ward	__ / 9
14	Adult emergency department	__ / 9
15	Optional department (informational only)	X
TOTAL	*Sum of score column*	__ / 155