THE REPUBLIC OF UGANDA
MINISTRY OF HEALTH

EVALUATION REPORT FOR HOSPITAL BASED SENTINEL SURVEILLANCE SYSTEM FOR ADVERSE EVENTS OF SPECIAL INTEREST AFTER VACCINATION WITH COVID-19:

AUGUST-SEPTEMBER 2024

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Abbreviations and acronyms

AEFI	Adverse Event Following Immunisation
AESI	Adverse Events of Special Interest
AFENET	African Field Epidemiology Network
COVID-19	Corona virus disease of 2019
CDC	Centers for Disease Control and Prevention
CRFs	Case Report Forms
CTUs	COVID 19 Treatment Units
DHIS2	District Health Information Software 2
GIST	Global Immunisation Safety Team
HBSSS	Hospital Based Sentinel Surveillance System
JRF	Joint Reporting Form
KII	key informant interviews
MOH	Ministry of Health
NDA	National Drug Authority
NRHs	National Referral Hospitals
ODK	Open Data Kit
RRHS	Regional Referral Hospitals
UNEPI	Uganda National Expanded Program on Immunisation
UNICEF	United Nations Children's Fund
WHO	World Health Organisation

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Executive Summary

Introduction

On March 11, 2020, the World Health Organization declared the outbreak of Coronavirus Disease (COVID-19) a public health emergency of international concern.

Uganda launched its COVID-19 vaccination program on March 10, 2021, prioritizing high-risk groups such as individuals with comorbidities, people over 50 years of age, and essential workers (healthcare personnel, security forces, and teachers). The goal was to reduce morbidity and mortality while ensuring the continuity of essential services. Given that the vaccines were authorized under emergency use listing, the country implemented a hospital-based sentinel site surveillance system (HBSSS) to detect safety signals of ten rare adverse events of special interest (AESI) and assess potential safety concerns following COVID-19 vaccination.

Methods

The HBSSS was implemented in eight referral hospitals: Soroti, Arua, Kabale, Mbale, Naguru, Mulago, Lacor, and Lubaga.

The evaluation aimed to assess the impact and feasibility of HBSSS as a vaccine safety surveillance model for low- and middle-income countries. Data was collected through desk reviews and key informant interviews at both the national level and all eight sentinel sites. The evaluation focused on several key themes, including the implementation process, facilitators of HBSSS, benefits, feasibility, lessons learned, and recommendations.

Results

Findings indicated that AEFI (Adverse Events Following Immunization) reporting improved significantly during the HBSSS implementation period, increasing from 30 per 100,000 to 85 per 100,000 by 2023.

Respondents attributed the success of HBSSS to several key factors, including training support, the availability of data collection tools, funding, experience sharing, motivated staff, and the commitment of dedicated stakeholders.

Conclusion

Overall, the HBSSS was successfully implemented, and improved the effectiveness of the AEFI/AESI surveillance system in Uganda. To sustain these gains and enhance vaccine safety monitoring, we recommend expanding AESI surveillance to lower-level hospitals to ensure sustainability.

1.0 Introduction

On 11th March 2020, the World Health Organization (WHO) declared the outbreak of the Corona virus disease (COVID-19) a public health emergency of international concern(Jebril, 2020). Uganda registered its first Covid-19 case on 21st March 2020 (Kawuki, Sserwanja, Obore, & Tak Fai Lau, 2021)and by December 2020, there were over 34,000 Ugandans that had contracted the disease and 251 had died.

On March 10, 2021, COVID-19 vaccination started in Uganda Under Emergency Use Listing (EUL) with populations of high-risk groups that included; people with comorbidity, elderly above 50 years of age, essential workers (health workers, security personnel and teachers) to ensure reduced morbidity, mortality, and continuity of essential services. The available Covid-19 vaccines included: AstraZeneca, Johnson and Johnson, Pfizer and Moderna.

By 11th December 2022, most of the persons targeted in Phase 1 had at least received first and second doses of COVID-19 vaccines. The elderly persons numbering 2,999,128 (89%), had received their first dose and 44.6% received a second dose; a higher number of Health workers 277,483 (184.9%) turned up for first dose instead of an estimated 150,000, and 159,845 (106.1%) for the second dose; 577,758 (105%) teachers turned up compared to the estimated number of 500,000 up for the first dose and 335,291(61%) for second dose.

Systematic vaccine safety surveillance is indispensable in ensuring public trust of the Expanded Program on Immunisation (EPI) and quality of vaccines. . In addition, acknowledging that routine passive reporting systems might not be sufficient to allow the rapid assessment and appropriate public health response during COVID-19 vaccine introduction; active safety surveillance is recommended, Guillard-Maure C et al., 2017.

The hospital-based sentinel surveillance system (HBSSS) was designed to detect safety signals of rare adverse events of special interest (AESI) or to evaluate safety signals arising from other sources, following vaccination with COVID-19 vaccines in Uganda. This was a 2-year project from 2021-2024 with funding from Centers for Disease Control and Prevention (CDC) Global Immunisation Safety Team (GIST) supported by AFENET.

1.1 Overview of the Hospital Based Sentinel Surveillance System (HBSSS)

The COVID-19 vaccine introduction in Uganda provided an opportunity to conduct active, sentinel surveillance for AESI to generate robust, standardized vaccine safety data to inform national decision-making and contribute to global understanding of the safety profiles of COVID-19 vaccines.

1.1.2 Primary Objectives

The overall aim of the HBSSS was to monitor the safety of COVID-19 vaccines in Uganda in near real-time for pre-specified AESI conditions and to inform decision making in order to maintain public confidence in the vaccination program

1.1.3 Specific Objective

The specific objective of the HBSSS was to assess the risk of pre-defined AESI following vaccination with a COVID-19 vaccine by brand.

1.1.4 Secondary objectives

1. To strengthen Uganda's active AEFI Surveillance system
2. To describe lessons learned from implementing active surveillance for various COVID 19 vaccine products.

1.1.5 Site assessment and selection

To select sentinel sites for participation in the Covid-19 AESI surveillance in Uganda, an assessment of all potential Regional Referral Hospitals (RRHs) and National Referral Hospitals (NRHs) was conducted using a prepared CARESAFE site assessment tool.

1.1.6 Selection criteria

Target hospitals included public or private hospitals at tertiary level of service delivery. The selection criteria considered national/ regional representation, availability of functional surveillance governance structures at the potential sites, active search capacity for signal detection and AEFI reporting system. Additionally, selected Hospitals had to demonstrate sound institutional capacity for proper data management, access, storage and retrieval of archived data including laboratory and imaging findings. Availability of trained / trainable personnel (physician or clinicians or nurses) to carry out active search and transmitting completed case report forms (CRFs) into electronic database uploaded on a defined server. Participating RRHs were those with good vaccine management and accountability systems

Additionally, hospitals had to demonstrate sufficient institutional capacity in terms of catchment area size greater than 2 million people. Selected hospitals had established and functional COVID 19 Treatment Units (CTUs), with demonstrable good data management and archiving. Selected hospitals were situated in settings with high population density, movement and high trade. Other basis for selection included: Hospitals situated in settings with special humanitarian situations like refugees, availability of database system (electronic/ manual), human resources, secure space, access, immunization data retrieval and security.

1.1.7 Definition of Adverse Events of Special Interest

Adverse Events of Special Interest (AESI), are pre-defined medically significant events with cause-effect potential with vaccine product(s) warranting ongoing, careful, pro-active post market evaluation that need to be carefully monitored and any potential association to vaccination confirmed by further investigation(Voss et al., 2023). To monitor and evaluate the safety of COVID-19 vaccines in near real-time and maintain public confidence in the vaccination program, a subset of ten AESI drawn from a total of 27AESI was prioritized based on our capacity as a country and resources needs. All patients that presented with the pre-determined AESI were included in the evaluations regardless of vaccination status with a COVID-19 vaccine, so that the unvaccinated, age-matched cohort could provide background frequencies of the specified AESI.

1.1.8 Retrospective surveillance and baseline assessment

Retrospective surveillance for background frequencies of the AESI (before vaccine roll-out) was conducted for 12 months (specifically April, 2020 to March 2021). Trained surveillance staff at each health facility conducted systematic search for the pre-defined AESI in the target population before COVID 19 vaccine introduction. The surveillance staff were supported to carry out examination of relevant medical records including DHIS2 for all participating facilities for background and baseline AESI assessment.
The surveillance team obtained clinical information on cases and completed the chart abstraction forms

which were used by clinicians to classify the cases per the Brighton Collaboration criteria(Law, 2022). Total number of pre-specified AESI conditions per health facility were recorded in the AESI Line List.

1.1.9 Prospective surveillance

Surveillance data after the introduction of COVID vaccines in Uganda was recorded on different forms. For facilities with paper-based medical records, designated surveillance staff (e.g., surveillance officers or nurses/ physicians at the participating sites) were trained to abstract AESI through daily review of medical charts (e.g., admission records, Out Patient Department and inpatient records, imaging and laboratory reports, etc.) to identify the pre-defined AESI. Additionally, medical charts for all eligible patients for COVID-19 vaccines were reviewed by surveillance staff; (children 12-17 years, adults above 18, those with co morbidities regardless of the age). The time frame for the prospective surveillance was 6 months, but with provision of extension

Between 2022 and 2024, US CDC/GIST supported Adverse Event of Special Interest (AESI) Hospital Based Sentinel Surveillance System (HBSSS) in 8 national and regional referral hospitals namely: Soroti , Arua, Kabale, Mbale, Naguru, Mulago , Lacor Hospital and Lubaga Hospitals.
This evaluation report therefore examines the work that was implemented, success stories, challenges and provides recommendations for future vaccine safety implementation strategies.

2.0 Evaluation Purpose

To evaluate the impact of and feasibility for use of HBSSS as a future vaccine safety surveillance approach in Uganda.

2.1 Primary Objective

1. Identify and describe successes and challenges experienced by Uganda during vaccine safety HBSSS planning, development, and implementation phases.

2.2 Secondary Objectives

1. Assess benefits and consequences of HBSSS implementation on existing vaccine safety surveillance practices in country (i.e., reporting, investigations, causality assessments).
2. Assess feasibility of using HBSSS to generate improved data on adverse events of special interest (AESI) conditions (including background rates).
3. Document implementation process and lessons learned to inform global vaccine safety partners on the use of HBSSS in low- and middle-income settings.

2.3 Rationale

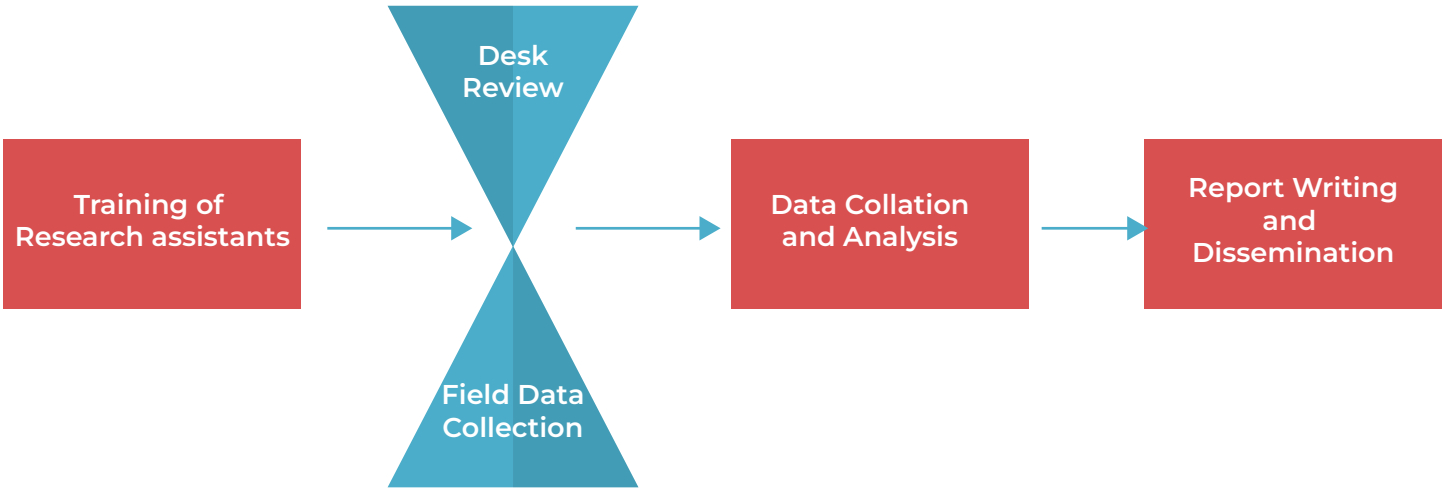
Data from clinical trials have shown that Covid-19 vaccines are safe and efficacious. Early use has identified some safety concerns associated with some vaccine platforms. However, even with this data, the sample size for clinical trials are not powered to detect rare and serious Adverse Events Following Immunisation (AEFI) or those with late onset. Thus, for EUL vaccines it is very important to set up rigorous vaccine safety surveillance systems to detect known and new vaccine safety signals, investigate and respond to ensure safety of the population and maintain public confidence.

Therefore, the CDC/GIST together with the WHO developed protocols to support active surveillance. The GIST has worked with in-country partners to adapt and tailor materials to support in-country surveillance

activities, including hospital-based sentinel site surveillance (HBSSS), to detect and evaluate AESI. In 2021, using the standardized template protocols developed, the GIST began providing support for HBSSS during COVID-19 vaccine introduction in Ethiopia, Malawi, and Uganda, with data collection activities occurring from April 2022 to September 2024. The three countries represent three unique approaches to vaccine safety HBSSS implementation, with significant differences in data collection methods (paper-based vs. electronic medical records), electronic data collection platforms (DHIS2 vs. ODK), ability to generate background rates for AESI, sentinel site locations (urban vs. rural), available diagnostic capacities (tertiary vs. secondary facilities) staffing (use of existing facility staff vs hiring of a dedicated team), number and types of AESI conditions under surveillance, baseline safety surveillance functionality prior to implementation, and funding needed to support HBSSS implementation.

Given the rapid nature of vaccine introduction and urgent need to generate AESI data for in-country decision making, CDC-funded vaccine safety HBSSS projects which needed to be evaluated to understand their impact and feasibility for use as future vaccine safety surveillance approaches during new vaccine introduction or emergency use.

Figure 1: Framework for assessment



3.0 Methods

The evaluation adopted a cross sectional study design using qualitative methods and included a desk review to capture key safety indicators from the joint reporting forms. Three phases were followed:

Phase one included using an already-drafted surveillance program logic model and evaluation questions, to develop an evaluation protocol and interview guides. This phase also included a desk review to capture baseline data on vaccine safety surveillance in Uganda, using the WHO/UNICEF Joint Reporting Form, CDC

GIST support prior to and during HBSSS implementation, and review of documented donor-supported contributions.

Phase two included key informant interviews (KIIs) with stakeholders involved in the HBSSS project to identify successes and challenges experienced during project planning and development phases, as well as during the ongoing implementation phase. Interview guides (n=3) were tailored to the facility-level, district/regional-level, and national-level stakeholders that participate in vaccine safety. Health facility (including regional and national referral hospitals) KIIs focused on daily tasks for HBSSS, documenting case detection and reporting practices, as well as average weekly time spent on HBSSS activities. District-level KIIs documented reporting and investigation practices. National-level KIIs documented reporting and investigation practices, as well as potential benefits or consequences of HBSSS implementation on existing vaccine safety surveillance practices in the country (i.e., reporting, investigations, causality assessments). The interview guides also included questions to assess ongoing, discontinued, and planned immunization safety activities in-country, aimed at documenting vaccine safety expertise, surveillance system functionality, stakeholder relationships, active surveillance sustainability, and vaccine safety data integration following HBSSS.
Phase three included analysis and reporting of evaluation findings.

3.1 Description of the AEFI surveillance system in Uganda

The AEFI surveillance system at the national level is comprised of both Uganda National Expanded Program on Immunisation (UNEPI) and the National Drug Authority (NDA).

3.2 Evaluation site and population

This evaluation took place in Uganda, where CDC/GIST is supporting on-going HBSSS for AESI following COVID-19 vaccination. The participating study sites included public or private tertiary hospitals that participated in Covid-19 HBSS. These include: Soroti Regional Referral Hospital (RRH), Mulago National Referral Hospital (NRH), Naguru NRH, Lubaga Hospital, Arua RRH, Lacor Hospital, Mbale RRH and Kabale RRH.

3.3 Evaluation population

The participants that participated in this evaluation included: HBSSS project staff at national and sub-national level, hospital teams trained on AESI case detection and chart review, HBSSS coordinators, implementing partners, district surveillance officers, national surveillance officers, district and/or national AEFI investigation teams, national AEFI committee members, National Drug Authority (NDA) team involved in vaccine safety surveillance, and Uganda National Expanded Program on Immunisation (UNEPI) team involved in surveillance. The study participants were health workers at the different levels of health system from the national to the sub-national level who had been supporting the AEFI/AESI surveillance system and therefore, these were adults above 18 years of age. In addition, since all our respondents were health workers at the different levels of health system, all our data tools were designed in English and there was no need to interpret the tools in any local language since health workers use English as a mode of communication.

3.4 Categories of hospital staff interviewed and justification

1. **Physician/medical officer**
   - These conduct assessment and management of AESI patients
   - Have wide knowledge on the policies, how the system operates, and what can be done to improve

2. **Nurses and midwives**
   - Triage clients
   - Support review of medical records to identify cases
   - Support in AESI case identification

3. **Laboratory staff**
   - Responsible for conducting investigations as requested by the physician

4. **Surveillance officers**
   - Responsible for ensuring line lists for all AESI cases are in place
   - Ensure all surveillance activities are conducted as per protocol

5. **Data management officers**
   - Responsible for ensuring availability of data reporting tools
   - Lead data harmonization meetings
   - Archiving and data management

Categories of district or regional staff interviewed and justification

1. **Head Community Health Department**
   - Responsible for overall supervision of the community health department
   - Ensures all surveillance systems and early warning disease systems are working well
   - Responsible for ensuring early detection, reporting and prevention of disease occurrence

2. **District Surveillance Officer**
   - Ensures all surveillance systems are working well
   - Responsible for ensuring early detection, reporting and prevention of disease occurrence

Categories of national level stakeholders interviewed and justification

1. **HBSSS coordinators**
   - Responsible for overall coordination of the active AESI surveillance for Covid-19 in the selected sites
   - Site selection
   - Responsible for training of the staffs involved in HBSSS
   - Conduct regular supervision to ensure all implementing sites follow protocol

2. **Ministry of Health-UNEPI Surveillance Officer**
   - Guide overall AEFI/AESI implementation in the country
   - Conduct supportive supervision of surveillance activities
   - Coordination of all surveillance activities to ensure sustainability
   - Formulation of policies and guidelines
   - Work as secretariat for national AEFI committee

3. National Drug Authority

- Support overall AEFI/AESI implementation in the country
- Conduct supportive supervision of surveillance activities to ensure compliance
- Work as secretariat for national AEFI committee
- Management of national database for AEFI/AESI and global reporting
- Work with MOH-UNEPI in the formulation of policies and guidelines for AEFI/AESI

4. National AEFI committee

- Independently review AEFI/AESI data and advise MOH
- Conduct review and classification of all serious AEFI

3.5 Sampling technique and procedures

A purposive sampling method was used to recruit 60 total participants for interviews, representing each stakeholder level: national, regional/district, and facility. An estimated 4-6 participants from each of the 8 facilities participated to ensure representation from all facilities that participated in the surveillance study. An estimated 1-3 participants from each of the national-level stakeholder agencies participated in interviews. Stakeholders that were identified at each level included: National – representatives from the National AEFI Committee, WHO, UNEPI, NDA, CDC/AFENET, national surveillance study coordinators and Director Public Health-MOH. Facility – Medical Superintendents/medical directors of healthcare facilities, clinicians acting as surveillance study team leads, surveillance study team members. Regional/district – Head community Health department, and Regional/District surveillance officer.

Table 1:Qualitative interview

S.no	Type of interview	Number of individual interviewed
1	National level	12
2	Regional or district	8
3	Facility staff	40
	Total	60

3.6 Data collection

Desk review was used to capture baseline data on vaccine safety surveillance, CDC GIST financial support prior to and during HBSSS implementation, and other donor-financial support. The desk review activities involved identifying and scanning the WHO/UNICEF electronic Joint Reporting Forms (eJRF) before HBSSS (2020 &2021) and during HBSSS (2022 & 2023). We focused on the section named “safety indicators” and reviewed all the indicators under this section namely: availability of a vaccine adverse events review committee, availability of a national system to monitor adverse events following immunization, number of total adverse events, including suspected or confirmed reported to the national level, of the total adverse events reported, how many were “serious”.

Key informant interview (KII) guides were used to capture qualitative data to gain detailed understanding of the project.

3.7 Data management

All data collected was kept by the data manager on a hard drive using a password protected computer.

3.8 Analytic plan and outputs

We computed baseline AEFI reporting indicators, by WHO/UNICEF Joint Reporting Forms on Immunization and funding costs for donor-supported activities in Uganda.
Key Informant Interview (KII) data was recorded and transcribed. Data from interviews was coded iteratively using an inductive approach. ATLAS Ti software was used to facilitate coding and analysis of data.

Stakeholder engagement meetings will be held for dissemination of findings and discussion on how these findings can inform immunization safety monitoring in-country. This evaluation activity is expected to generate vital information on the benefits of conducting and future considerations for AESI surveillance. A scientific manuscript with the findings will be submitted to a peer-reviewed journal. Another output of the project will be the generation of lessons learned. All relevant findings will inform the revision and implementation of the HBSSS in other countries.

3.9 Reporting and dissemination of results

Reports were compiled by the evaluators and will be shared with key stakeholders, including the local and national authorities, global stakeholders, and expert committees. Preliminary and final reports with key results for each of the evaluation aspects will be prepared and shared with key stakeholders, including the immunization program and study participants. Results will be presented at professional and scientific meetings and will be published in a peer reviewed journal. Manuscript authorship will be based on contributions made regardless of investigator status.

3.10 Ethical considerations

Informed Consent: Interviewers obtained informed consent from different categories of respondents at the national and sub-national levels for the qualitative part. Permission was sought from the directors of the selected regional referral hospitals. Written informed consent was obtained after comprehensive explanation of the study and its objectives. Participants were informed of their rights to refuse or withdraw at any time during the interview. The respondents were free to respond to questions they wanted to respond and were not coerced to answer any question. Anonymity was guaranteed by not writing participants' names.

Confidentiality: Data was kept confidential with no identifying personal information available to staff. Personal information was not used in data analysis or any publications/presentations of this assessment. Original questionnaires (paper-based) was kept in a locked cabinet in a secure room. Computerized data was kept on password-protected computers.

3.11 Evaluation approval

This study was approval by the AIDS Support Organisation Research Ethics Committee (TASO REC) as the local IRB in Uganda under no: TASO-2024-400.

This protocol has also been approved by the Uganda National Council of Science and Technology (UNCST) under number: HS4771ES.

4.0 Results

These have been structured in line with the evaluation objectives.

4.01 Baseline findings

The desk review showed that the country was unable to capture safety indicators for the year 2020, probably due to none reporting likely to have been contributed by the Covid-19 pandemic and lock down; the following years (2021, 2022 and 2023) show that the country had a vaccine adverse events review committee that was well constituted and operational, and a national system to monitor adverse events following immunization. The other AEFI indicators are as tabulated in the table below.

Table 2:Vaccine safety policy issues:2021-2023

S.no	Type of interview	Number of individual interviewed
1	National level	12
2	Regional or district	8

Table 3: AEFI indicator by year before and during HBSSS: 2021-2023

Year	Denominator	Number of AEFI	Number serious	AEFI/100,000
2021	13,640,929	4 030	373	30
2022	12,551,896	4 566	45	36
2023	320,863	274	104	85

Table 4: CDC GIST support for vaccine safety before and during HBSSS: 2021-2024

S.no	Recipient Organisation	2021	2022	2023	2024
1	National Drug Authority	31,680,000	46,800,000	170,976,000	120,695,000
2	MOH-UNEPI				
3	AFENET	3,650,000,000	182,500,000	365,000,000	

Table 5: Other contributions to vaccine safety before and during HBSSS: 2021-2024

S.no	Donor Organisation	2021(UGX)	2022	2023	2024
1	AKROS Research	0	0	38,065,600	0
2	WHO	614,908,387	1,311,973,182	340,453,492	198,890,069

Table 6: Key stakeholders involved in the project.

	National / community / local stakeholders
1	Central (MOH) and local government
2	National drug authority (NDA)
3	Residential District Council (RDC)
4	Hospital/site leadership and staff
5	Site hospitals staff including health workers and biostatisticians
6	Local communities/population/patients and community/local leadership
7	Causality Assessment Committee
8	East Africa Centre for Vaccines and Immunization
9	VHTs
10	DHOs
	Implementing partners / funding agencies
1	UNEPI
2	WHO
3	CDC
14	The African Field Epidemiology Network (AFENET)

4.02 Findings from the qualitative interviews

The results are presented under the following themes: implementation process (including facilitators of the project, challenges and solution during project implementation); impact- benefits of project implementation; feasibility consideration; recommendations for scaling up; sustainability mechanisms for active safety surveillance; and lessons learned and recommendations

4.03 Implementation process

The key steps/processes of implementation

The implementation process covers the HBSSS site selection; Training of Sentinel site teams/staff; Protocol Implementation; AESI case detection; vaccination status determination; reporting; causality assessments (including key information needed for causality assessment; and the most often missing data/information) and a typical day working for the HBSSS program.

Perception on HBSSS site selection

The sites include: Soroti Regional Referral Hospital (RRH), Mulago National Referral Hospital (NRH), Naguru NRH, Lubaga Hospital, Arua RRH, Lacor Hospital, Mbale RRH and Kabale RRH which were selected based on key factors. These included the catchment area (in terms of size/volumes of the population served), the existing AEFI surveillance systems at different hospitals, and what hospitals were reporting. It was also ensured that the selected health facilities were geographically distributed (north, west, east and central as well as urban versus rural) across the country to ensure representation, but also that they had the diagnostic capacity/ infrastructure (staffing and facilities) that can support the conduct of the needed medical investigations.

> *we looked at the number of reports the regional facilities are reporting. We had to pick a facility from the different regions like in West Nile, we had to pick a facility to represent West Nile region, we went to western region and we picked Kabale, we went to the East and we picked Soroti, also from the engagement that we requested to include private facilities that is to say PNFPs like Rubaga and Lacor because initially the protocol was only looking at public facilities [National].*

In addition to these factors, informed by the engagement with various stakeholders, a few private facilities were also included in order to ensure the private sector representativeness and perspective.

> *even beyond the known regional referrals, I think there are other bigger private hospitals that were considered to cater for that representativeness not necessarily that this is a statistical sample per se. At least to take in the demographics that are likely to attend private facilities compared to that go to government facilities so that it brings in that number being private facilities [National].*

Training of Sentinel site teams/staff

There was training on case definitions, detection and management offered to all those that were selected to be involved in the project. The training was primarily before the start of the project and was supplemented by an on-job training especially for the members that joined the site team later. This training mainly resulted into knowledge acquisition especially on: importance of vaccines and vaccine safety surveillance; elaborated COVID-19 signs and symptoms; case presentation using the Brighton level criterion level of certainty; different adverse events of special interest; follow up of patients with adverse events following vaccination; how the causality assessment is conducted (the whole process).

> *we used to see these conditions; people used to come in with the conditions...we used to just see them like any other patient who has come. But when I was taken through the training, when these people used to come [name], I was so keen with now these people, like whoever would come and complain, who had a complaint related to what is in the project, I would go deeper [Nurse].*

Reflecting on the training process, participants also reported on what could have been improved saying that it should have been started earlier; should have lasted longer to allow comprehensive understanding; and incorporating in refresher courses to keep them updated would have been helpful in keeping them updated.

4.03 Protocol Implementation

The actual protocol implementation basically included the AESI case detection, vaccination status determination, reporting, causality assessments. To achieve these, other processes such as the site team meetings, medical chart reviews, follow up investigation and medical support for the patient were conducted. Only the AESI case detection, vaccination status determination, reporting, causality assessments processes are described below.

AESI Case Detection

This was the first step. Eligible prospective patients were screened for or identified for an AESI condition during triaging when they presented themselves at the hospital by looking at them for the cases of special interest. What worked well was starting with taking history, to see whether immunization was involved, followed by confirmation of the vaccination status and other medical investigations for a diagnosis. Building rapport with the patient was key.

> *it's quite hard to look at somebody and just mention that this could be an AEFI not until you've taken history or had a talk with the patient. Otherwise, not until they've told you I've had my immunization that was when I started getting this, probably it could be one reason that brought them to hospital, so as you interact with them or do the assessment, that's when you are able to get it [Nurse]*

For the retrospective surveillance, following patients records on the adverse events, patient files would be retrieved, studied and data extracted. This part of the process was described as difficult due to missing information (as detailed in the challenges section).

> *the file that you've just maybe landed on like this one, you have to get the details, you have to call, you have to search, it used to be a little harder [Nurse].*

Vaccination Status Determination

This included confirmation with the vaccination card and the national vaccination database. Specifically, to determine/confirm the COVID-19 vaccination status of eligible patients, it involved confirmation with the vaccination card first; followed by checking in the vaccination database/records including a full documentation with a batch number for follow up.

Findings indicated that the kind of challenges that were commonly encountered were that most patients did not have their vaccination cards with them when they came to the health facilities and would only always tell/notify with word of mouth which was quite hard to prove. Therefore, such challenges required one to go through all the available records for vaccination. Contact numbers were also used to follow up patients where this information was not available at the health facilities or national vaccination system. Following up patients was described as difficult highlighting scenarios of the teams going to the communities and bouncing back, making it a back and forth sometimes.

Reporting

After identifying a possible AESI at the health facility, it was fully documented as much as possible and reported using the provided tools including using ODK for consideration by the causality assessment committee.

Causality Assessment process

Overall, several process including case detections, case notification/reporting, investigation and analysis, record keeping, feedback were involved in the causality assessment. At the facility level, the site team assessed the patient's biodata including their full details such as their contact/addresses, next of kin contacts, and whether the necessary tests have been/were conducted or requested. In the process, the counseling of the patients in case of fear and anxiety and any other support in treatments may be offered.

Key information needed for causality assessment

Firstly, one of the key pieces of information in the investigation was the vaccination status that if available made the casualty assessment go smooth. While a number of sources of information to confirm the vaccination status could be used such as the national immunization database, the findings indicated that the vaccination card was the first, best and easiest reference in this study/Ugandan setting.

> *It is smooth when all the information required in the file about the client is available. You need to have the COVID-19 vaccination card. Because when you are inputting this information, in ODK, one of the compulsory pieces of information required is the vaccination information [Site leader].*

In addition to the vaccination card, the other information that was needed to make the assessment go smooth was availability of other personal data such as national identification card, address/ contact (phone and village) as well as major medical/laboratory investigations (both the basic and complicated procedure) attached. Absence of such investigations meant that the case could be lost, or review and decisions delayed since some of the investigation maybe done late or never be possible in the instance that the patient died already.

> *It is smooth when all the investigations required from the client is also done and updated within the file. You discuss and reach somewhere, you find that, there is some information required from the patient especially investigation but is not there, it becomes a challenge, especially when you are updating the Brighton's' level of certainty...sometimes you may not be able to follow up the client. You call, the client's phone is off. The client is already discharged or has died. So, it becomes a challenge [Records Assistant].*

> *For assessments, if we don't have full data of the patient, we kind of get stuck. If investigations are not fully recorded or not done or no results attached, it's quite hard to conclude. It is easy when you have all the full details of what is needed, the vaccination card is available, the investigation or supportive investigation is done with results attached [Clinician].*

Most often missing data/information:

It is important to note that full patient details were often missing making the process a 'prolonged go back and forth' with most of the cases during causality. It was common, especially in the retrospective process/ surveillance, that most of them were lacking or were conducted, but poorly recorded or not attached to the patient's data. They described a scenario where the laboratory results are requested using a different form, conducted in the laboratory where they are reclaimed by a patient, and then re-written in the patient notes which overall, create huge risks for data gaps in the process.

It was mostly investigations sometimes times they might be done but not attached to the files, so it's quite hard to see. A test is done, but the results are not attached, or the major tests not done. Or the vaccination status…remember lab requests, the tests come in another booklet. So, if it's re-written in the notes and the patient claims the results, it's hard [Clinician].

The other data that was commonly missing was the vaccination cards and patient addresses/location. Participants indicated that for most patients, besides their names, age and sex, the address contacts were sometimes wrong information that did not belong to a patient, or not available for instance the phone numbers. In some instances, the available contacts were for others close to the patient which was difficult especially when disclosing the information would be harmful to the patient.

4.04 Facilitators of HBSSS

Factors that were found to be important facilitators for the successful implementation of this surveillance project at the hospitals were related to availability of data collection tools, experience sharing, training, funding, dedicated stakeholders including staff that were motivated, , learning sessions through the causality reviews, , coordination and reporting (feedback and coordination meetings).

Motivated by the need to fill the gap

Buy – in was also another facilitator for the project. There were high expectations from the national (MOH) and health facilities involved about the project impact. There was full interest and participation of the health facilities and staff that was engaged in the study which was very key in the implementation of the project. It was reported that the buy-in by stakeholders was because they appreciated it as an area of concern and were therefore driven by the need to contribute to evidence that could fill the gap created by the vaccine misinformation, fear and rumours.

the whole interest was to first of all be part of the study and to start off the study activities and also the other thing that I think I witnessed from the other sites, was the interest about COVID-19 vaccine itself, they were so much interested, because the study was giving them information and they were interested in seeing what will be the study outcomes visa vie the media publications and various social media information they were hearing about the vaccine [National level].

There was already a need and there was interest about the problem that was being heard in the public, so meaning they were interested in getting to know and see really how they identify these cases which have been talked about by other people, and they are part of the process of reviewing, documenting, confirming and presenting about them, yes those are the key things that worked out during the trainings [National level].

Some of the participants were motivated by their reported great expertise based on their experience from other research engagements, thus become very resourceful to the HBSSS project.

Funding and Financial motivation

The HBSSS project had a specific budget dedicated to its implementation even if the activities were conducted alongside the routine health services. All participants indicated that financial motivation was very key for the

success of the project. Timely financial motivation for the hospital teams in terms of personal allowances and facilitation towards the site meetings logistics was critical in the success of the project. This motivation of the site teams was associated with their improved attitudes towards conducting project tasks alongside other routine hospital work.

> *when you motivate data collectors or the study team participants in real time and routinely and they know the timelines, it makes things very easy. And these are some of the things we have done because we have been able to disperse their allowances on time, and moderate support just for their refreshments for their meetings [National level].*
> *people were up to it and whenever they found a case, they would require everyone [to engage], and we had regular meetings for that matter, so their attitude was the right attitude, and they seem to be happy with what they are doing most likely because they were motivated with money [Medical Records Officer].*

Financial facilitation of the causality review committee in terms of sitting allowances in addition to the hosting of meetings at places of convenience made the implementation process smooth. It was also noted that having an opportunity for the virtual attendance at the review meetings facilitated the members who could not attend physically to make contribution to the review process. This was noted as critical component since the must attend at the physical attendance at meetings and related travel in the beginnings of the project were constraining some members given that they also needed to attend to other hospital duties.

> *it goes well when you convene the causality [review assessment]to a place of their convenience, and when they are facilitated to be there...these are people with big businesses and activities that they are doing on a day to day to earn, so they must be assured that the facilitation is available for catering for their allowances and their honoraria's for the days for the sessions that they are attending [National level].*

> *they also have platform of the virtual part of the committee members who are not able to present themselves physically, they join virtually, and that also constitutes the entire committee forum, so those are some of the things that I would say facilitated us [Surveillance Officer].*

Simplified tools eased the process

There was a general perception among the key informants that the case definition and the tools and all the relevant materials that were used at the sites were simplified which made the data collection and reporting process easier since they were new to most of the site teams. In particular, the teams noted that the Brighton's criteria were not only new and exciting but was also simple to use compared to other clinical case definitions they had experienced before.

> *another thing is the case definitions that were simplified and use of the tool that most of our site staff had never interacted with, the Brighton Collaboration criteria...it worked well because it was so much interesting and it was with much simplicity, compared to using the lengthy various clinical case definitions that we have seen, so having the Brighton which was a bit simplified with guidance ,and key summary points that would lead them in identifying an AESI were very key things that worked out very well for us [National level].*

In relation to the tools, participants indicated that although some processes such as data abstraction was

manual, the inclusion of digital App in the system/ODK which was portable greatly facilitated the data collection and reporting process of the adverse events.

> *because of the system of collecting adverse events, we went digital so the mobile apps and other means that we were able to use, also we were able to use a platform, I forget the name of the platform, where you send an SMS so because of that, we got more in touch with the people, so it's a good thing [National].*

Evidence in the national databases

Another factor that was reported to have facilitated the process was the availability of databases at the national level (national database for COVID-19 vaccination) which were critical in the confirmation/validation of the individuals' vaccination status. These databases especially the EPIVAC system (the national COVID-19 Vaccination portal) were especially useful in situations when the vaccination cards were not available or accessible to confirm the vaccination status.

> *the presence of the national database for COVID-19 vaccinations, because the EPIVAC system where you validate and verifying the vaccination status of the cases, this has also been one of the facilitators or factors that has helped us in the success of this study [Surveillance officer].*

Training of good quality/ well conducted

It was reported that the training (of the data collectors or the study team) was of good quality and was well perceived which contributed to positive expectations regarding the project outcome and process. In particular, participants indicated that the training was of high interest to the team, engaging and introduced new aspects such as the Bridgton's criteria of assessing vaccine related adverse events, the reporting of adverse events, comprehensive COVID-19 information, case presentation and follow up among others.

The other component that participants felt made the training of good quality was mode, in particular the face-to-face training. Participants felt that convening the different team in central points including Kampala, Jinja among others for the face-to-face sessions enabled better learning than if the virtual training was used.

> *what worked well in that meeting is that we trained people about this Brighton criteria's, I think the representations was quite engaging and there was a lot of participation from the participants [Team Leader].*

> *what worked well is the face to face, because during that time there were more of virtual training but you know virtual trainings have limitations but what worked well was to invite participants for the face-to-face trainings...and we felt it was really effective [National].*

Good coordination system

A good coordination system was one of factors described as a success of the project. The project team leads at the health facility and the whole coordination including the reporting structures/systems right from the hospital to the national level was described as regular contact, clear and commendable. In addition, real time technical support and follow up of sites to address specific gaps and challenges that would be unique to individual sites/hospitals made the process easier.

the HBSSS was well organized in terms of hierarchy, so, you know the reporting systems and how the coordination happens, people knew who to report to and where, and that was so useful. And then the very responsible persons in the hospital were in constant contact with them. Also, the other thing is the hospitals had the contact persons or leads, and those leads would then become a useful linkage, so that has what worked well, the coordination was very good [National level].

Several stakeholders involved in the HBSSS project

From the findings, several partners were involved and supported different activities of the project. These stakeholders included the local government (the District Health Teams and other staff), central government (especially MOH, UNEPI), government agencies such as NDA and donors including CDC, WHO, and AFENET. Generally, it was reported that most partners were providing key support in creating an enabling environment for the project to succeed including overall coordination and oversight, legal and pharmacovigilance expertise by the NDA, availing facilitation/allowances for the study teams, as well as support in terms of vehicles and finances for fuel and other logistical support.

We have made presentations and data, evidence-based information to the stakeholders and these stakeholders range from the funders, CDC team, we also have teams from WHO, we have teams from AFENET, then the teams from MOH, UNEPI, then also stakeholders like the AEFI National Causality committee, then the hospital site leaderships [National level].

WHO provides technical support especially when developing policies; also provide financial support for investigations and also technical expertise with need of any safety follow up of vaccines [National].

Stakeholder engagement was good overall

The different stakeholder engagement activities which many participants highly appreciated that they were timely intensive and comprehensive included presentations at various stages of the project from initial consultations (starting from inception phase) to updates and feedback sessions to share evidence and progress. Importantly, the directors of the different hospitals were responsible in identification of the hospital/site teams that were trained which was a very strong point not only for the initial processes but also the whole project implementation. Furthermore, hospital directors were directly invited and attended some of the review meetings in which they demonstrated that such engagement encouraged progress tracking and informed decision making.

on one of our causality review meetings, the director [hospital name] chaired a session at a time that [hospital name] had not made good progress. So, the director himself took them on and said, "I can't be embarrassed here, Therefore, as we go back, I am going to be monitoring your activities". That gave us a very good leverage...to routinely share gaps early enough so that remedial actions are put in place before they escalate to higher level [National level].

you know stakeholder engagement starts from the inception of the study activities; we have tried because right from the time we were starting the study. Yes, the directors of the hospitals were responsible in identification of the teams that were to be trained because they are the ones who identified for us the people we trained [National level].

Progress and feedback meetings with site leadership, the causality assessment committees, and preliminary presentations to other external stakeholders including conferences such as the 8TH AFENET international conference in Kenya, and the International Pharmacovigilance Conference in Uganda were also conducted. Progress meetings and coordination activities (between the causality committee, national level, and the sites) were key in keeping stakeholders abreast with the site-specific progress and needs which deepened their interest and involvement with the project.

> *we have invited them and presented to them....so, we had entirely good stakeholder engagement. We went ahead and made preliminary [conference]presentations to other external stakeholders..., so that is equally engaging the stakeholders and keeping them a breast with information about the study [National level].*

> *it's always definitely good to continuously keep giving them information and sharing with them feedback on the progress of their sites [National level].*

The key informants also felt that the stakeholder engagement was good since all the concerns that arose and needed responses were considered and addressed in time while keeping all the stakeholders up to date. This was in addition to the monthly and annual progressive reports that were given to certain key stakeholders depending on the type of the information. Stakeholders' engagements were conducted at many levels including the regional level, and DHOs, MOH, NDA, AEFI committee, CDC attended.

Gaps in stakeholder engagement

Findings from a few participants indicated some gaps in the stakeholder engagement process. Participants empathized that the project should have included and prioritized all of stakeholders according to their roles stating the regulatory component of the vaccine safety surveillance which they felt was somehow limited.

> *there was no component on the regulator side...and you also realize that the study was being done in the hospitals where you need more support from the regulator side to go there and see how things are being implemented, also when you look at the side of the regulators, vaccine safety is given little priority [national].*

> *for stakeholders' engagement, I think the group was very big and we were almost swallowed up, and yet we should have been a central part of this...because much as they consulted us, it was in the beginning. Then suddenly [a more personal experience], I mean, it is interesting but so, I would say 50,50, I think it could have been better [National].*

In addition, community engagement activities were reportedly not conducted well which presented some challenges during the tracking/follow up. A mismatch between community and project expectations were reported which participants believed would have been avoided by comprehensive community engagement.

> *from the aspect of the community level, their expectation was a bit different. When you go, they expect you to maybe offer them their transport, and yet when you reach there, after finishing engagement, all you to do is appreciate them. So, it was challenging. That's the challenging bit. But for the one at district level, it's much easier. They understand those protocols and it's okay. But community involves that aspect. It was challenging [Data manager].*

4.05 Challenges faced and solutions during the project implementation

The key challenges that were faced include:

1. Site team changes and drops

There were reports of some team members leaving/dropping off due to delayed financial allowances for the project sites teams, an issue that affected the team composition in some sites. Discrepancies between the perceived or promised versus the actual financial motivation was reported. In one hospital, there were concerns that the financial allowances delayed especially in the beginning which forced some team members to be demotivated and leave the project (almost a 50% reduction in number). In relation to motivation-based challenges, some participants raised concerns of inadequate finances towards follow up activities including limited, or lack of airtime needed to make the follow up phone calls.

> *the constitution of the team was first effective, but of course, you know, later-on, people lost the zeal to continue working. The few people persisted and continued...., people initially thought that they would get a lot of money. When we left there [training], they sent their per-diem, but some didn't get it so, people lost morale and dropped off. People could not be able to continue, we persisted for 4 months, then people gave up...we went there when we were 13, but time came when we remained only 5 [Clinician].*

> *others the motivation, the money delayed coming in, those who lost interest. So, the attrition rate was high and am saying this from the experience of the support supervision, you go there at regional referrals, trained like 10 people, but you only find 3 of the original people [national].*

Such drastic team changes had potentially great effect on the workload and related consequences among those that stayed committed to the project. Besides the financial challenges, there were reports that some health workers dropped off due to failure to balance their regular workload with additional surveillance project activities. For some health facilities, the team changes were due to changes such as a member leaving a health facility.

> *we had a high attrition rate whereby participants who were trained fell off during the implementation phase...loss of interest, others being changed within facilities because you know when we were selecting, we wanted those who were representative and others would change, others were claiming the workload was too much [National].*

2. Poor data quality and missing information

One of the biggest challenges encountered during the study was an issue of poor-quality data systems especially the issue of missing or scanty information which affected the project negatively by delaying the retrospective case tracking and review process. Some basic demographic information such as sex and contact numbers missing in the patients' records were reported. Also missing key information such as the medical/ laboratory investigations and vaccination card (were either lost or poorly recorded or not yet in the national vaccine database) was a key challenge that made it difficult to ascertain whether a patient had received a vaccine or not [cross ref for details in the Causality Assessment process subheading]

the greatest challenge was poor quality of the data captured at the sites because you notice that at some sites, the tools lack certain demographics like the telephone contacts, sometimes the village of the case. So, if you can't get the contact, it becomes very challenging for you to look for this case or for the next of kin. The data capture in the primary data collection tools in our sites is still a very big gap [National level].

you would find that some of the cases that could be submitted by the sites lack some evidence like COVID-19 vaccination card needed to confirm that it was a vaccinated case. So, this was a bit of a challenge. You know most of the cases were retrospective and charts would lack some information…this affected the process of looking at the real cases. So, these are some of the challenges that we have encountered in the process [National level].

Such poor-quality data was linked to many missed opportunities in case detection. Below is a long extract that shows a scenario where difficulties in a vaccination status confirmation related to information gaps leaving out a potential case.

But for the ones where they don't have a card, in the system they are missing, we would now definitely leave them out. Though there is one case, up to today we still feel convinced that actually it would be true that he's eligible and should be in the study, we have tried all means…because we feel surely, he might be one of the cases, though it is just the COVID-19 status, which is a block to that. Though also among the challenges, we still had things to do with the follow-up. yeah. It came in a bit later, but in the initial stages, follow-up was a challenge, the support, it was not forthcoming. So, we relied basically on what we have. If the patient's file is adequate enough, with the information, we go with that. Or phone call, that is the most we would go. But later on, the follow-up support came in, there was fuel provided, and some facilitation support started moving to villages and other districts to check these people [data manager].

3. Limited investigation capacity at site hospitals

In line with poor record keeping system, key medical investigations which would have been useful in review and decision-making processes were largely missing, either because they were not conducted, or they were conducted and not properly recorded. Such limitations in the capacity at hospitals to conduct the necessary investigations to confirm/validate the conditions were noted as one of the key challenges.

we were not able to validate all the information in time on the causality and attribution to vaccines and the side effects of the vaccines we were seeing….so, there was a big gap between what is being said and what you can track backwards in terms of evidence….you may need investigations like the CT scan, chest Xray, and you're wondering what happened before and there is no evidence [National level].

Oversight in information gathering was reported even when the study was structured. Overall, the participants were concerned that the country has a very poor record keeping culture that there was no system to tract the person's health challenges/history before the vaccination versus what happened after vaccination.

you find that the first time when this person presented with the symptoms, no one paid attention, so we pick them on the second visit. So, the time when we should have really done the required investigation, they were not done, so you want to do them now. I call it going backwards and therefore you may not pick the exact parameters that you want. Imagine somebody was vaccinated 6 months ago presented with a rush a day after the vaccination, then they keep quiet, or it is treated as any other popular rash, but it persists, then we

meet them today with the same issue. So, the evidence has gaps because the investigation that could have been done were not actually done [Medical Office].

the challenge might have been oversight in gathering certain details, even though it was a structured study. The history still posed a problem, and missing investigations remained an issue... that is a very major issue of data in this country, from what I've experienced, it is really a challenge [National level].

Therefore, the hospitals lack of such data on these investigations in existing/previous medical records and limited capacity to conduct some of these investigations on the current cases, made them rely on the private facilities to do that for patients. The reliance on private health facilities was however very inefficient and presented difficult situations in cases where the investigations including C-T scans, D-dima were too expensive beyond what most patients could afford.

But now challenges come when maybe they cannot afford like a C-T scan, like D-dima, those ones are expensive, yeah. So that's where we could get hurdles in...you could get the case, you accept the case, you get everything, but now, how to confirm it. Investigations. So, investigations, finances [Clinician].

some investigation like d-dimer, that test is not done in the hospital. So, there was some challenges in doing the test, because you tell the patient to go and do the test from outside that it is expensive 50,000ugx and above. So, the patient could tell you that I don't have the money, it was a challenge [Laboratory Staff].

The lack of key medical information sometimes resulted into major delays, the missing out (leaving out) some potential cases and or documentation of only personal accounts which were generally biased or confusing. An instance where two care takers of a baby patient gave 2 different accounts of the situation was reported. Besides, the patient verbal reports, there were challenges of lack of coordination between the patient, the public and private hospitals which contributed to missing data/investigations and frustration (for both the patient and the health workers) in the whole patient follow process.

we need to have documented evidence of what happened and the nature of causality. One time I remember I had to go to the hospital to interact with the parents of a child that reported and had been admitted in [health facility name], but the father was giving different information from the mother, that made our work a little challenging. [National level].

I followed up a client they had referred to [private facility name]. I think, the doctor who was supposed to sign on the letter was not there - had left it to the interns. Interns also abandoned. They feared to refer the patient. So, when I called back the patient, the patient said they didn't give us the referral form...So when we tried again to follow up, the patient could not be reached. So those are some of the challenges, the missing investigations required to ascertain the Brighton's level is what is mostly a challenge [Records Assistant].

4. Transport facilitation needs/inadequacies

It was reported that transport costs were sometimes needed during processes for confirming the vaccination status, or other investigations to confirm a condition. The transport was especially needed during medical investigations for the patients who were living far/long distances from the site hospitals. In some instances, where the capacity of the hospital/sites were limited to carry out investigations, there was need to transport

either the patients or the medical experts such as pathologists where verbal autopsies were needed. Such transportation costs in terms of the time, vehicle, and the money for fuel, although they were later in the project provided for, significantly delayed the process of investigations and reviews.

> *they don't have the investigation capacity, sometimes there are no funding, tests are not there, so you move the participant very far, some of them we had to bring them to Kampala [National level].*

> *ministry was very reactive and would actually send the teams to the ground almost immediately, but the challenge that would happen, is that the investigation capacity of many of the facilities or where people are was limited, and sometimes some of these cases are so far, so that means somebody had to carry those people who are affected to a regional hospital or another hospital to a distance, so the investigation became quite challenging and that limited us [National level].*

> *there is a death for instance, the child is buried immediately, there is no postmortem, you end up doing verbal autopsies, sometimes the information recorded is very biased [……] and that was the problem. The other one is also it's not easy, we had to mobilize the pathologists from Kampala to go and travel everywhere and sometimes it causes delay, so those are the major challenges that were mainly logistical and reporting issues [Nurse].*

5. Workload challenges for site teams

A description of the daily tasks of the HBSSS team at the hospital indicated that the project activity was an increased load on their work/tasks which most times many felt that it made them remain pending. Even when the teams kept learning lessons on how to do better their work alongside the HBSSS project activities including changes in the meeting schedules to less frequent compared to when they started, a report of 'so busy days with extended working into late nights for some of them' was reported. For some of them, a focus on their routine work meant it was especially difficult for them to achieve/progress well on the HBSSS project. For example, some members described how they could have missed potential cases if they are in one ward due to being in different ward for a routine task for example.

> *it becomes very busy because by the time we, the time we take, doing this other activity. This means the other work is pending, because we usually meet, we had scheduled every Thursday. We first meet, before we can go to our units respective [Team Leader].*

> *It was okay the only challenge could have been the fact that sometimes you are in a different ward, you can't be everywhere all the time. So, if someone not trained or oriented to it receives that case in your absence, they may treat it as any other case and let it go. So, it needed presence on every aspect of point of care in order to pick them. So, we could not be everywhere [Medical Officer].*

In relation to workload challenges, there were reported delays in reporting and causality review processes/ meetings. There was a feeling of difficulty in convening causality assessment meetings/committee because of the various engagement of the members of the committee members (conflicting time demands/priorities outside the HBSSS project). It was also reported that there was delayed reporting and presentation of cases which affected the surveillance process including investigations.

one of the major challenges about HBSSS, the issue about investigations, two things; one is reporting. The reporting comes but it comes late to us and the committee, so by the time you go to investigate or send in investigators, many times, the event has already dissolved...and so you can't make a good objective assessment [National level].

getting the national causality committee is a bit hard because of the various engagement that they have, so convening them when we need is not something that has come out so easy, but however we have tried our best to have them and they have done their best to validate the cases [National level].

I think causality assessment goes smoothly when you have all the information, one, when they come early, when the case is presented early enough...I think they were reported late, when they are reported late the events have long gone and the investigators go when the patience has recovered long time ago. So, when they report such cases you can't make sense of it, of what the case was, so that issue of delayed investigations [National level].

6. Protocol discrepancy

Discrepancies in the protocol were also reported to have been a challenge at some point. Some people felt that the data collection tool at the facility level was not in harmony with the criteria that the national review committee was using during the review meeting. They noted that while the Brighton's criteria were used at the health facility level, the assessment committees and other partners especially the national drug authority used a different approach/criteria.

we had discrepancy on the protocol that we were using for HBSSS and causality assessment. So, the information used by the project to qualify the events as AESI or AFI was different when we went for causality assessment meetings. Yes, because you find that you qualified a case here as AESI, yet they use different criteria when you go for causality...That's where I always felt that they needed to harmonize the tool, protocol so that when we enter things in, we know that we are at per [Medical Officer].

we used the Brightman's criteria to provide the AFI, but the causality assessment team - that was the national assessment teams from NDA and the other people were not using the Brightman's criteria. So, their criteria were different, yes. It created a discrepancy between what we were qualifying here and what they were qualifying the other side. So, there is need to harmonize those two [Medical Officer].

Discrepancies were also indicated in the lack of harmonisation in the reporting system for the adverse events, especially in the early phase of the project, which was reported by some participants. Challenges related to more than two possible reporting systems raised confusion in the case identification and tracking. Participants described scenarios where some patients may report directly to the health facilities while others may call/report to the regulatory authority (NDA), highlighting the need for mechanisms that ensure that no events go missing or unattended to.

the area of reporting has always been an issue, the reporting through HRS and what goes through NDA has been an ongoing thing on how they can harmonize those...because as you know the patient can easily call NDA and say, I was vaccinated and this is what happened, not necessarily going through a hospital or even when they go to the hospital. They may not know that its patient X that reported, so marrying the two

systems is a challenge [national].

we had to harmonize between the NDA and Ministry of Health because when we just started, there was some bit of confusion, do you report to the Ministry of Health Hotline or NDA, but with time that was harmonized, as they generated the USSD codes and how to report, because initially [National].

7. Misinformation and rumours created community resistance

Misinformation was one of the key challenges that were faced during the HBBSS implementation process. Various rumours were reported including those that spread on social media which created a lot of hesitancy and mistrust from the community towards effective engagement with anything related with COVID-19. Generally, many people had concerns about COVID-19 as a disease as well as the COVID-19 vaccine with some community members believing that every health issues they experienced were linked to the vaccine.

I think the challenges were that there was a lot of miss information and disinformation. Even things which were known as other diseases or infection were being attributed to vaccines. Somebody would get an illness and say because you vaccinated me, that is why I am feeling this illness... they have concern and look out for vaccine safety issues because they live in the community. There is usually some fear about what will the vaccine cause, what will happen or hearing rumour? [National level].

It was noted that people's experiences with several rumours on the vaccine negatively affected how they perceived any investigation (had doubt about many tests) that was being conducted by the health facilities including the HBSSS project. For example, key informants described several scenarios of hesitancy to provide individual COVID-19 vaccine related information among the community members including failure to say whether they had been vaccinated or not or disappearing on the day of the appointment for a certain needed investigation follow up. Such fears delayed the investigation process.

you get these patients after line listing during follow up, or you can even make appointments when it's a prospective case. You make appointment with a client or the next of kin, the attendants, [but you] will find they have escaped. Like there's one GBS which I got on the ward after interacting with them, they say that the card is at home...but when I interacted with them afterwards, going [community] the following day, I found that they had run away. Calling on the contact they gave me, they could not pick the call. Afterwards, they had to switch off the phone. So those are the scenarios [Records Assistant].

8. Delayed surveillance process and reduced risk perception

There were concerns that the surveillance activities of the HBSSS project although relevant started later than was necessary. Having started in 2022, compared to when the vaccination started (during 2021, 2020), this surveillance project delay made it difficult to track all the cases, most of which were poorly documented. Besides having to track all the cases retrospectively since the vaccination had scaled down, risk perception had reduced and there was already misinformation regarding the vaccines which altogether affected the HBSSS processes including the case tracking.

timelines of conducting the studies versus the time for the vaccination; you realized that the vaccination started way back around 2020, then it was massively rolled out around September -November 2021, but our study started in 2022 around August, September when we started training. But you realize that vaccination

was already scaling down and the risk was already being seen as low amongst the population [National level].

Inadequate feedback mechanisms for clinicians and communities/patients

There were challenges related to limited community advocacy, and engagement including lack of feedback. Key informants felt that the community was not well informed on the need for the surveillance aspect of the COVID-19 vaccine – a vaccine that was administered in the past compared to the HBSSS project. In addition, there were due to limited finances, some gaps in the dissemination aspect whereby participants felt that the community did not get an opportunity to receive feedback from the decisions on some of the investigated cases. This lack of feedback to communities regarding a case sometimes made communities doubt or fear the whole surveillance process.

people never seemed to understand that one, people wonder why you are asking them questions on things of long ago. I think the community aspects in terms of advocacy [lacked], I think we didn't have strong sufficient advocacy at the community level to make people understand the importance of why we ask them questions for things that happened already and sometimes they don't even report [National level].

Then feedback to the community when an investigation happens is also an issue, we never get to hear what happened. If they report that the child was vaccinated and got a problem and the causality assessment is done, the report is not disseminated back to the community. That this is actually what caused the event so, that kind of promotes the hesitancy here and the rumours because they are never verified, or if they are, the information is never given to the community [Clinician].

9. Funding challenges

Overall, there were reports on challenges related to inadequacies in the finances/funding aspect of the project which of course was a foundation to a significant part of the challenges described in this section. Participants narrated about a confusion at some point of implementation process showing that funding issues emerged including misalignments on who would fund what aspect of the project and who would fund the other. Such challenges affected the causality assessment meetings in a way that it was associated with a backlog for the committee.

the challenges were quite a number…the committee at one point had a lot of backlogs for assessing and so on, and [names partner], there was some kind of misalignment between the stakeholders on how to get these people funded and be able to do their work to clear that back log. Up to now, I think it is still there so that's one of the challenges [Surveillance officer].

Lack of enough funds, especially when it comes to investigating rare conditions. For example, we had a case of fibrosis of the lung, which we haven't even completed investigating up to now. Additionally, sometimes people think they need to be compensated for damages or other related issues, but we don't have the funding to cover that [National].

4.06 Key solutions implemented to address the challenges

Flexibility in schedules and meetings

Fitting causality assessments reviews within the schedule of the review committee with WHO focal point assistance was one of the solutions to ensure that the committees members attended. The scheduling with the hospital sites was also transitioned to virtual from entirely physical (used in the beginning) meetings which was key in time saving and attendance.

> *we also conduct review meetings, virtual review meetings with the sites, where we call the sites for a virtual call, other than the causality meetings where we have them physically, we also hold virtual calls with the sites [National].*

> *the ability to work both physically and virtually has been crucial. Our secretariat members are willing to work in both modes, which means we don't always have to be physically present to address issues. That flexibility has been the most important factor for me [National].*

Support supervision and coordination process

Most participants reported that routine support supervision was enhanced which was key in identifying gaps and addressing them accordingly in process. In addition, the national UNEPI vaccine system was leveraged to fill hospital/patient information/data gaps and coordination process improved for example through the creation of the coordination platform.

> *we had to create a coordination platform with all the sites, with the national team where we keep sharing the feedback. After data analysis, we share the feedback instantly on the progress and give information where there's a gap and we can address that [National level].*

> *with the sites, we have done a routine support supervision, that one we have enhanced, we identify a site which has a gap, a challenge, we go on ground to help that site.... we leveraged on the national Epi-vaccine system to check out for these cases that are lacking information, and we verify UNEPI with the COVID-19 vaccination [National level].*

Training new team members

The challenge of changes in team composition/attrition due to several reasons was solved by training of new health workers to join the team. It was reported that especially during the causality assessment meetings, site team leads were encouraged to train and fill up the teams. However, although the training for replacements was on job and hands on, there were reports from some of those that were trained that the training was short leaving them not feeling equipped well enough in time.

> *what we tried to do, every time we invite them for causality assessment, we remind them on what we have to do, in terms of the materials we prepared them very well, on loss of participants we recommended team leads during follow up to train new people [National].*

the training was not equipped enough at the very first time when they trained us because when we had the training, it took us not much time as the original people...they just taking us through, it was hands-on, okay, if I may use the word. You train as you work [Nurse].

Facilitating patient follow up

Findings indicate that fuel for the hospital sites to follow on cases (field activities) for the necessary information was later provided to the hospitals by the HBSSS project. The need for follow up of patients into their communities was noted when most cases that were presented at the review meetings were sometimes disqualified or delayed due to lack of evidence especially the expensive medical investigations. In some instances, the medical experts were transported to the communities, and for the patients, the medical investigations were supported. Financing all the necessary investigations where the patient was unable to or cost sharing with the patients where they could afford some part of the cots was reported as one of the key solutions that enabled the project to deal with the missing information/investigations and the related expenses.

we had to give support, fuel to the sites to do follow up of the cases within their regional coverage, so this one has helped us a lot because the sites could follow up the cases physically, drive there, see the cases, and probably get the information from the cases at their homes [National level].

And the other thing was also the support to the cases to do some laboratory and radiological investigations, because when they were making presentations, we identified that cases were being dropped because they lacked evidence of laboratory and radiology results...we could support the investigation either 100% for those who completely can't afford, or we cost share with the case. if the person can afford the certain percentage, we would give the top up, and this one helped us to get the time and evidence-based information from the sites [National level].

Encouraging detailed patient registry

Regarding challenges with missing information/patient records, one of the key mitigation measures included efforts to re-orient health workers to ensure that detailed key information about the patient including village, sub county and right phone numbers are included in the patient registers to make it easy to track. Phone numbers and addresses were used to track patients in their communities to confirm their vaccination status.

4.07 Impact- benefits of HBSSS project implementation

Findings indicate some impact on the health facilities and community as described in the different key benefits the participants felt that can be attributed to the project. These are related to timely reporting and investigation of suspected AEFI, increase in number of AEFI reports, staff knowledge about vaccine safety surveillance and improved patient care.

Increased capacity in vaccine safety surveillance

Capacity building/development in terms of improved vaccine safety surveillance at hospital was one of the impacts of the project in line with its aims and anticipated outcomes. Health workers/ staff on the study team participated in different trainings including vaccinology benefited from the project in terms of increased knowledge on vaccine impact and surveillance, in particular, COVID-19 vaccine and the related adverse events.

it has widened people's thinking beyond the routine vaccination of the children and people have been trained about vaccines and vaccine safety, so we now have a bigger pool of health care workers and people in the country who know about this [National].

In addition to knowledge in vaccinology and the Brighton criteria, these health workers' experience through engagement with the review committee and their mentorship (by the same committee) increased their capacity to understand the role of the committees and the process of review, thus making them aware of how they can significantly contribute through their daily medical practice to such processes for the benefit of patients. A great improvement in the skills/abilities for the presentation of cases to the review committee compared to when they began was reported which was a key indicator for increased technical capacity in surveillance of vaccine safety. For some of them, it was their first time engaging with the causality committees.

> *it was the first time most of our sites were participating in making case presentations before a causality committee, they had never heard of this, and it was the first time when we were bringing them before a causality committee. And it was really a challenge at the start, but in the process, the committee did mentorship and built their capacity, and this has improved over time [National level].*

> *we were able to train them on issues to do with vaccinology, and in the vaccinology, it was entirely looking at issues to do with the vaccine products and their safety, so we believe that at the sites now, their capacity has been enhanced and they will be able to carry out a similar related studies on any other vaccine at the site and really be able to file these cases [National level].*

These health workers involved in this activity were believed by participants to be critical in future as trainers of trainees needed for the continuation of the HBSSS, a similar project or a surveillance system.
It is important to note that the project was reportedly an opportunity for the capacity building for not only the health workers at the hospitals/site teams, but also the national teams including the national coordinators and causality review/assessment committees. It was reported that the HBSSS project experience and lessons added a lot of momentum to other surveillance and causality assessment work, improved information transmission, and enhanced preparation for other pandemics.

> *We've gained a lot, particularly in terms of meeting virtually, better information transmission, and training on criteria like Brighton's. The lessons from COVID-19 have been invaluable for strengthening routine immunization, which is the best way to prepare for pandemics. We're now focusing on improving routine immunization, energized by the solid structure built during the COVID-19 surveillance [National].*

Increased awareness and reports on adverse events

It was noted that the awareness on adverse events and the need to report them had increased. This awareness, they said, led to an improvement in the health facilities' reporting of these adverse events noting that it had created an extent of pending workload for the causality assessment committee. Participants indicated a notable level of awareness across the different units at the health facilities and an increased suspicion index in the involved hospitals. They particularly noted that a suspicion index of the hospital staffs as well as across the districts was likely to increases if someone is actively looking.

> *there is a perceived strengthening. Even though it was with a selected team, there has been collaboration*

with other departments and units. For example, when I was in [hospital name], there was a case where someone got a vaccine and exhibited unusual behaviour. That person wasn't part of the team, but they detected and reported it [National level].

The project also improved communities' awareness of the need to make notification and reporting of potential events. Some of the site team members had engaged their community members in informal advice setting encouraging them to report any complaint they thought was related to COVID-19 vaccine.

I would just advise them whoever would complain, even in my village, I would just advise them, 'you go to the hospital, you first find out what could be the problem, because we vaccinated, but other people got issues, and so you never know, maybe you might be one of them and we can easily cure it [Nurse].

the aspect of sensitization. Many people didn't know, and kept quiet until this project came on board and that's when they realized that I think it could be because of the vaccine. So, I think that aspect of community sensitization to make sure that in case they realize something maybe happening, they can know where to go and where to report it [Data manager]

Improved patient care

Some improved patient care was also reported by participants who expected that it would have been greater if the project had started earlier along the initial COVID-19 vaccination activities. The reported improvement in the care for patients was partly linked to the hospital's experience and understanding of the critical role/need of improved data management and investigations during the review/surveillance process. For instance, in some hospitals, it was reported that investigations that would have been previously ignored were being conducted, thus offering patients the possible comprehensive examination. The same diligence was said to be happening in terms of other different patient data, and beyond the site teams that were directly involved with the project.

this research also improved on the health care delivery. There are some of the investigations they were sometimes neglecting. So, when a case is found, thorough investigation is done on a patient before the case is part of the study [Records Officer].

I feel it has greatly impacted the accuracy of the information. The back-and-forth movement in the process makes people realize the importance of certain data that should have been collected. It's retrospective, kind of like a post-mortem, but if it was prospective, even the patient being monitored would benefit because the necessary data would be collected in real-time.... going forward, I think it has truly made an impact, but it would be more effective if it was done deliberately from the start [National level].

On the other hand, a few participants felt that the observed improvement in data collection and patient care was driven by the need to have data for the causality assessment committee and not an improvement in the actual health care. Similarly, although knowledge was said to have increased to some extent, some gaps were reported sending mixed reactions. Although some facilities indicated plans to utilize the lessons, participants had concerns over how best the gained knowledge and improvements would be put to best use.

because I know that I am going to be asked about this information, about this case, I would actually ask for more. so, you would find that some of these investigation teams in the hospitals, when they wanted more information from the hospital, they would go by themselves, while the existing chart doesn't have enough information. So, I do not think it has made a very, very big difference [National].
There have been gains, but the challenge remains in utilizing the data effectively. We're generating a lot of data, but the capacity to use it is still lacking. That's why I mentioned the importance of training health workers on how to better use the data [Clinician].

I think the training has helped, the knowledge they have gained is supposed to be there, because I know logistics have now gone down but the knowledge at least and the awareness of the health workers has improved so we are now trying to put in place our own systems to keep the process on going [Director].

Proof of vaccine safety surveillance feasibility

One of the successes that participants felt was key was that the protocol was fully implemented well in reference to time and deliverables and emphasized that what remained was the need to go beyond the project phase. They therefore excitedly emphasized that its implementation to the end was a proof of concept and indicator that HBSSS is feasible to implement in Uganda. The lessons from the implementation itself offered an opportunity to understand the information that can inform not only continuity, but also scale up of the HBSSS or a similar project to other health facilities (details are described in the section on Feasibility And Sustainability Of Using HBSSS below.

I don't think there is anything left [undone], we have thoroughly tried to exhaust it in line with our protocol, and in line with our protocol, we have exhausted what we were supposed to do [National level].
if I look at the targeted sites, the participating sites, and specifically at the surveillance of COVID-19 vaccines, I will say that yes it has helped us gather all the necessary information. What remains now is to see how we can scale up, because for me, it's like a proof of concept – we have shown that it is possible. The next step is figuring out how to expand this to other hospitals, which goes hand in hand with training and fostering a mindset change in other people [National level].

In terms of signal detection, we've enhanced it. Now, we need to see that active searches take place in other hospitals not included in the study [National level].

4.08 Feasibility of using HBSSS

During the evaluation process, participants also provided their perceptions on the sustainability of using the HBSSS to generate improved data on adverse events of special interest (AESI) conditions and other negative effects following vaccinations. Many participants recommended that the active surveillance for vaccine safety should be routinely done at hospitals going forward. The active surveillance, they said, should not only focus on adverse events of special interest, but also track patients' complaints and forward them to the concerned persons/offices to proactively address them.

Scale up the active vaccine safety surveillance justified

As earlier noted, findings indicate that participants strongly felt that active vaccine safety surveillance should not only be continued beyond this project into a routine health service, but also scaled up to other

facilities. They strongly noted that such a safety surveillance activity is very relevant as it enables the needed understanding of vaccine efficacy, and people's illegibility and safety given the increase in vaccine technology and products. They emphasized that as long as there are new vaccines, there is need to keep a track of what is happening to be able to support both learning and early preparations of the health workers, but also feedback to the community as their feelings about one vaccine can impact any vaccine, overall. Such consequences can have a backsliding effect on all the efforts of promoting vaccines, thus leaving communities unprotected.

> *We need it because through surveillance, we can see the efficacy of the vaccine, and what may happen, and people who could be eligible. Yeah. It is very necessary to scale it up. It is key [Clinician].*

Timely adverse events tracking is easier than retrospective approaches:

In their justification for scale up, participants stressed the importance of focusing on ensuring that the vaccine safety surveillance is started on time/earlier stages of vaccination in order not to miss any cases. They noted that scaling up the HBSSS activities, offers an opportunity to avoid most challenges of delayed protocol development and approval, delayed surveillance and reliance on the retrospective approach which, based on their experience and lessons from this HBSSS project, they reported was a bit difficult to implement.

> *the timeliness of the implementation of the study versus the vaccination activity and the biggest recommendation is that studies [surveillance] should be starting alongside the on-going exercise, activity or immediately after, so that you are able to get the information in time [Surveillance Officer].*

> *I would think if there is plan of introduction of any new vaccine it starts early enough because retrospective data collection is very challenging and also approval of protocol usually takes time because we had a challenge when the HBSSS was approved vaccination had already gone down [National].*

Controlling vaccine hesitancy

An opportunity to control for vaccine hesitancy was reported as one of the important benefits that scaling up active and timely surveillance brings to the health system. Participants noted that although it requires extensive resources, the active surveillance is relevant in advancing benefits, access and coverage of vaccines by reducing the negative influences of vaccine hesitancy. The study lessons showed that rampant hesitancy was partly attributed to lack of such vaccine safety surveillance activities that when conducted not only create a sense of patient care (when they are followed up), but also promotes knowledge, and trust in the vaccines. Some of the participants strongly advised that there should not be any vaccination (because it would be not useful), if there can't be active safety surveillance for it to generate evidence that not only improve vaccines safety, but also the related population confidence.

> *it's the only way we could go and minimize on vaccine hesitancy. As NDA, MOH or as government, we always call people lets vaccinate, but after vaccinating we don't follow them up, people continue to see that no one is following them up and that increases vaccine hesitancy especially for the new vaccines [National].*

> *For the first time that you have almost 8 Regional Referral Hospitals looking out for the safety aspect of the vaccine. Well, the vaccines are safe, but the safety component has not been included so much 2) patients appreciate when you follow them up a parent on active surveillance, feel cared for when you call them*

[National].

What's the gain of making the vaccine available if you won't be able to survey for adverse events? Because all you know is that the adverse event may end up making more people not take up the vaccine....a big part of them because of fears and worries. So, if you can't make people confident to take the vaccine, then there's no business getting it [National].

4.09 Recommendations for scaling up

Based on the lessons of the observed project impact, the challenges, facilitators and feasibility, participants provided key recommendations for scale of the active vaccine safety surveillance activities. The recommendations were related to ensuring sustainability of the gains, from the HBSSS project which were related to the need for improvements in human resources, capacity building, health data infrastructure, coordination and monitoring, budgeting/funding. Overall, scaling up the HBSS project activities into routine services was expected to ensure surveillance of all vaccines' safety in a timely manner (and not long after the vaccination program begins). The scaling up requires several factors to be developed or addressed as described in the following subheadings:

Orient other health facilities

In relation to scaling up, other health facilities that were not involved in the study would require adequate orientation on what is involved and the implications (in time of benefits and resources involved). Particularly, orientation processes could address health facilities on the required resources, the issues of vaccine and related side effects as well as the increasing community hesitancy and how best to handle them.

It is important to scale up because not all cases that we receive were vaccinated from here, we work from Eastern Region, Elgon zone, where we serve about 14 districts and one city. We could spot some health facilities with a bit much population and go and orient them on what is happening on vaccine efficacy and hesitancy, and how to health educate the clients when they come [Records. Assistant].

It will also eliminate vaccine hesitancy because the members or the staff's health workers will continue health educating the clients about the importance of vaccines in order to eliminate hesitancy [National].

Develop and strengthen human resource for active vaccine safety surveillance.

Empower frontline workers: Participants indicated a strong need to develop/strengthen human resource in charge of the active vaccine safety surveillance. Among these, they recommended the need to empower the frontline workers including the clinicians and people who are actually involved in the routine vaccination programs with the aim of building their capacity to be able to investigate adverse events.

They should be able to take samples, fill the forms, building the capacity of the health care workers at the grassroots. Also, the clinicians need to be brought on board since these are regional referrals, so the clinicians who are managing these people, those are the ones whose capacity need to be built [National].

Other participants recommended hiring of an extra specific staff at health facilities with clear primary roles to support the surveillance activities, going beyond the regular/current general surveillance officer. They said that such developments would be key in addressing the workload issues given that the existing staff already

have their duties and roles with significant staffing gaps in most health facilities. In particular, participants recommended that it would be better that such human resource capacity consideration be focused on strengthening the community health department which most of them were concerned that it was weak.

> *a hospital, through the health community department, can have that area where they can have people actively moving around for such presentations to make sure it's not just a routine surveillance, but active. It will call for more human resource and training [Medical Officer].*

> *the community health department, which is being transformed into a public health department, is weak across the country in terms of human resources. While there may be some capacity, it's not strong enough for us to be fully confident in our vaccine safety efforts...because people will say; this is extra work. So, I think there is a need for the MOH to consider this since it is a new component. Someone should be hired for this particular work, not as an additional...and that recommendation should really come out clearly [National].*

> *enough funds, especially when it comes to investigating rare conditions. For example, we had a case of fibrosis of the lung, which we haven't even completed investigating up to now. Additionally, sometimes people think they need to be compensated for damages or other related issues, but we don't have the funding to cover that.*

Refresher and other courses are needed

Refresher courses were another key issue that study participants raised concerning efforts to ensure scale up of surveillance. They said that such refresher courses would be central to keeping the those involved in the surveillance activities updated about the recommended guidelines such as the Brighton's criteria and the diseases/events of interest amidst the busy hospital tasks. Such continuous training opportunities also address challenges that may arise due to inevitable team compositions in instances where some of them leave the hospital or drop off the team for any reason. This need for refresher courses/continuous training was strongly expressed in the reflections indicating that the HBSSS projects should have also had a refresher course in between the 2 years of implementation.

> *I would say more trainings should be conducted... because it was conducted at the beginning, and this was a 2- year project. You are engaged in other activities so you find you might have used other criteria, so at least there should have been another training in between [Laboratory].*

> *I don't think they missed out anything except the fact that the project has taken about 2 years. They would have only added like a refresher course along the way to bring people's minds back because some of the cases were really rare like you don't even see them at times so when they get like one, if you not up to date, you might miss out [Medical Doctor].*

> *I would recommend a continuous training, if you have done initial training then maybe as the evaluation is going on, like after four months, and six months [National].*

Training duration that provides extended/adequate training days were recommended. Specifically, it was recommended that refresher courses and other training such as the one that was conducted at the start of

the HBSSS project should be designed to provide adequate time for proper learning that is not rushed. They described the training in the HBSSS project as rushed and felt that it would have been good if the training days were extended to ensure more room for the comprehensive material and diseases that were discussed.

> *the training schedule felt a bit packed. With 13 ESIs, going through extensive content in just four days, it might have been beneficial to extend the duration slightly. The content covered was substantial, and there was a lot to learn in a limited time [National].*

Enhance team composition

Findings indicated a need for a multidisciplinary approach to vaccine safety surveillance to ensure that all the required perspectives are considered across a whole surveillance chain in future. For instance, there were suggestions for consideration of the legal, media and the social science expertise on the surveillance team. The social sciences and media expert, they said, would support the weak behavioural and external media/ communication component in relation to the vaccines including hesitancy. A legal expert would offer the necessary support for dealing with the evolving legal issues that may arise along the adverse events in relation to vaccines. It was suggested that such expertise could be incorporated in an ad-hoc manner working closely with the lead stakeholders.

> *I know we have had support from the MOH - UNEPI and the AG's office to address those issues, but I think in future, we may have a stand-by legal team that can always help us.... on that committee, we're just full of doctors, but I think we need social scientists to help us deal with behavioural aspects of hesitancy that affect disease and vaccine uptake [National].*

> *We may need in the future to also have maybe a communications team because those have been our biggest weaknesses. We need to communicate better, have better funding, and then maybe the legal issues around vaccines. Because these issues keep evolving [Clinician].*

Improve data infrastructure / capacity at health facilities

Participants felt that scaling up requires building a resilient surveillance system that has highly improved data management tools and processes including considerations for digital data systems. Besides, going digital, participants recommended that the data collection and management system should be built with adequate capacity to not only enable automated processes, but also both retrospective and prospective case surveillance.

> *I think we need to train people better and then to put in place resilient systems to collect data on adverse events and may be going digital. I think that would be a good thing... and having resilient mechanisms to collect data on any events that may occur [Hospital Director].*

> *the proper filling of the primary data collection tools needs to be highly improved and the improvement should be capturing all the data about these cases, any patient, regardless of being a case or not, because anybody may have interest about a given condition at a certain time...so the primary data collection tool should have all the details of this patient...the telephone numbers, next of kin contacts, so that it helps us in follow up and contact tracing [National].*

All participants strongly felt that improved data management system in which both quantitative and qualitative data expertise is adequate would be key in making data/evidence informed decisions and effectively communicating the risks and benefits of vaccines to the public. Further emphasizing the need for better data systems, they indicated that such efforts should include those focused on building a system that is not only of high quality to deliver credible data, but also user friendly to enable its effective use. For instance, they described how use of the SPT forms could potentially not improve the quality of the current project data.

> *they were using SPT (smart paper technology), but you know the challenge; it was new, and the training of the users was done briefly... you find people must scan all the SPT forms and the quality of the SPT forms affects the upload and it definitely could have affected most of the peoples' data from being uploaded in the system. So those are the areas we need to improve on [Team Leader].*

> *we should emphasis scaling up electronic medical history so that they can have a permanent record, or medical records linked to people's identity or trackable methods that we will know who we are vaccinating [National].*

Furthermore, ensuring that data/investigation protocols are available is key. Based on the lessons from the HBSSS project implementation in line with ensuring that the necessary data is available and credible, some participants emphasized the need for data/investigation protocols. They recommended that such protocols and guidelines should be comprehensive including aspects of herbal medicines (which is used by a significant fraction of the population in the country) in relation to vaccines. Findings indicated that the generation and utilization of credible data is key in building community trust and improved vaccination program through increased vaccination coverage as well as costs.

> *I think more thorough guidance on gathering complete history and investigations from the start would help. Having clear protocols that cover all possible factors—like the use of herbal medicines—could avoid some of the gaps we've seen in the data [National].*

> *then you get quality data, I think we would rather have this well done because you're sure that once the public has gained your trust then in the long run you will have a lower cost of the immunization program because you will not have wastage [National].*

Ensure early stakeholder engagement

Participants highlighted the need to actively engage stakeholders right from the project inception through implementation to completion. It is important to keep the stakeholders well informed and share routine gaps that can be identified early enough so that remedial actions are put in place before escalating to a higher amount or higher level. Early stakeholder engagement is key in ensure that priorities among stakeholder are harmonised and efforts and resources consolidated to adequately offer support to the process.

> *Early engagement, at the initial beginning of the project, the stakeholders need to be involved, and they give them impute but bringing them at the tail end to update them in the protocol doesn't work [Medical doctor]. I think for any program really the planning has to be adequate, even time and ensuring mobilizing stakeholders, if there are any delays it could have been from the competing priorities from the stakeholders*

involved so you need to bring them on board early enough and even reaching their timelines and sharing this as a priority [National].

It was recommended that future engagements should include not only the technical arm, but also the media which reports indicated were largely missing.
I think that maybe we need to have the stakeholders at the national level in the scientific technical part and then the general part which includes a wider spectrum of stakeholders including lay people and the media, so that they can have an idea about this surveillance, and I think also hospitals needs to know about this very well [National].

And the other one that was missing which I remember very well was media. Maybe we deliberately didn't include them there because we thought they were going to do something, but they were not there [National].

Provide for and implement community engagement

Community is one of the key stakeholders in vaccine safety surveillance. Some participants indicated that to ensure scalability of the benefits/impact of vaccine safety surveillance requires adequate continuous community engagement. Engaging the local structures and the public for instance through continuous education of communities about the vaccines including side effects is key in addressing the challenges related to misinformation, rumours and fears among the public. Community representation and engagements ensure that the public receives appropriate information for use at their level, including addressing emerging issues such as fear, and hesitancy.

and then of course continuous engagements with the public to address their fears and educate them on all aspects of vaccines including side effects and all that they can, addressing their fears basically [Hospital Director].

Improve regulation systems

Some participants felt that partnership engagement efforts should adequately prioritize vaccine regulatory systems. This was based on a key example in the participants' perception that vaccine regulation component was not given the priority and funds it required; a challenged that they felt stem beyond this HBSSS project to routine vaccine programs. There is a need to have a mechanism of how to continuously support the surveillance activities at all levels including prioritizing regulatory perspectives in all processes including systems and tools for monitoring, supervision and funding/resource mobilisation.

so, the regulators are not usually involved so much in vaccine safety surveillance and that's why you see the resources allocated to other drugs compared to the vaccine's safety are very minimal [National].

conduct of causality assessment meetings in ensuring data is entered in the system they are meant to use, and ensuring that the regulators are still able to follow up and look out these things

Concerning the regulatory system improvement, they stressed that there is need to ensure that the reporting mechanisms are harmonised with considerations to ensure that reporting is streamlined to allow timely data access and use by key authorities, i.e., the MOH, and NDA.

Conduct continuous supervision and monitoring

Besides the recommendation for improvements in the safety surveillance team, participants indicated a strong need for continuous support supervision, monitoring and evaluation in order to effectively implement, continuously monitor and improve the quality of the process and outcomes. It is important to however note that while this projects supervision was rated high but majority, a few participants had concerns on some inadequacies in the supervision process. One of the participants at national level noted; *the support supervision, I felt it was not enough, we did like only two support supervision, but I think people need to be followed up to see what they are doing'*. They said that supervision should cover not only the staff performance, but also the cold chain and related logistics for vaccine programs to ensure that they are up to date and standard.

> *then the third thing I also recommend maybe; especially in the immunization department, we can always cross-check on their vaccine storage to see if they meet the required conditions for the safety of vaccines [Records. Assistant].*

> *and also, the other thing with continuity definitely should be keeping in touch with the sites on routine basis and giving them the support that require to be able to conclude whatever cases they have identified and the platform for presentation is very key [Surveillance Officer].*

They also noted that the supervision system/process should also particularly focus on ensuring that there is adequate support to ensure that the simple and user-friendly surveillance tools and data bases are not only available, but accessible and properly used by relevant stakeholders. Such tools should be digital and designed to have all the needed information that is.

> *this one is a bit about the databases that are used for some of these roll-out of vaccinations or campaigns, they need to be a bit user friendly, teams need to be really followed up to ensure that data of these people are captured in the system [Surveillance Officer].*

> *The coordinators of the project should try to liaise with the MOH team in charge of the EPIVAC…such that it would be easy for us to access the vaccination status, if at all it's there in the system, such that we would have more cases brought on board. Yes, that was a major challenge. So, if that coordination could work and they grant us that access, I think it would be one of the great achievements in the study [data manager].*

Integrate HBSSS into existing health structures

Overall, integration of the vaccine safety surveillance into the routine/existing hospital services was one of the key recommendations for scaling up in a sustainable way especially given that the HBSSS used existing structures such as surveillance officers, tools and data bases. They described integration to mean fitting vaccine safety surveillance into the standard practice as a continuous part of the health system, and not just doing it in a study setting/mode. They however further noted that integration required a significant mindset change to ensure that stakeholders and all health workers (not just a surveillance team) consider active vaccine safety surveillance as feasible within the routine system. An example of integration by some countries in a similar setting of the low- and middle-income countries was highlighted.

> *I am aware that some low- and middle-income countries have tried to integrate such programs into their*

systems. Integration requires some level of investment and a change in mindset to ensure that these programs are seen as feasible and necessary [National].

another thing is to come out clearly—there needs to be a mindset change. Every clinician, every person involved in healthcare, must have a component of surveillance integrated into their work…. all people working should have the surveillance bit in them. Everyone should have it as their responsibility, from the nurse or the person doing triage to the clinician [National].

Although integration could come with extra workload for health workers, and need for modification in the tools, it was perceived by many participants to be a best approach to scaling up active surveillance across the country. They believed that integration into routine services would ensure that active surveillance is conducted across all vaccines and not only a few of them that have either funding or specific support. They also emphasized that integration should cut across all the process including actual implementation, supervision and monitoring as well as tools noting that the tools needed are developed by the HBSSS project already.

Integration of course our human resources is limited, I think anyone who has looked at our system and has looked at the staffing knows there is a huge gap, there is an issue when it comes to human resources, but I think integration is critical because if the focus becomes on one disease, then that becomes an issue [National].

we maintain the elements, we integrate it in our plans, our workload systems whether it's supervision, whether it's reviewing the data, supporting the tools because we are now actually going towards digital for a lot of our surveillance work, it's just integrating in our current workload [National].

A further in put by stakeholders in put in form of dissemination meetings was suggested by one participant as one of the key beginning steps to further get their input into the best possibilities of continuity in an integrative way for active surveillance.

Decentralise the vaccine safety surveillance

In addition to the proper planning alongside a financial investment needed for vaccine safety surveillance, some participants emphasized the need for a decentralised surveillance system which they described as regionalisation. They believed that such approach to vaccine safety surveillance would be critical in ensuring specific regional perspectives/considerations in the process.

we should decentralize our efforts. Instead of centralizing everything in one location, like Lagos, we should have regional perspectives and learnings…from the learnings of this study, we should be able to inform specific regions on how to handle these issues, including communication strategies. We've learned a lot through this process, and regionalization will help us apply those lessons more effectively [National].

Establish regional causality assessment committees

Decentralisation would mean that the causality assessment is conducted at the regional level instead of only national level which would however require that the regional committees are trained and equipped with technical knowledge for the task. Besides ensuring that the regional perspectives are considered, regionalisation could result in timely causality assessment and risk communication (that is reduced delays

at national level due to limited inadequate human resources at the committees). Appropriate regionalisation must be accompanied by the required capacity building. This would ensure that the regional team are as competent as the national team, with the only difference being the level at which they operate.

> *I think that's an excellent suggestion because it would reduce the backlog and lead to more timely decision-making. You would know the outcome earlier, which would allow for timely responses, such as implementing risk communication...currently, if causality assessment takes three months due to data challenges and back-and-forth communication, it can delay the entire process, affecting the program and other related activities. So, regionalizing the AEFI committee would be important [National].*

> *The capacity should be the same to ensure that decisions made at the regional level, like in Karamoja, are not challenged elsewhere. It should meet international standards, but it would be beneficial to have this structure in place [National].*

Scaling to lower health facilities

Community based active surveillance was recommended in order to enable early identification of potential cases outside the hospitals (in communities) instead of only waiting for the advanced cases at the facilities. This was considered important based on the health seeking context in Uganda where generally people go to the referral hospital only when the disease is advanced.

> *not in only hospitals because a lot of our activities go on in the community, at the districts. I think surveillance should continue, but we should also involve the districts, we should involve the communities, because here we are just at the top of the pyramid, but it is better when the activities go down to district levels, health centres, communities. So, it should be extended to all throughout the health system [Hospital Director].*

> *recommend that we expand the number of sites and go to lower-level sites, not only Regional Referrals... none of us prefer to go the Regional Referral, you only go there when things are bad so I would think in future protocols, they should think of representatives in the health centre 3 and 4 and general hospitals because we didn't have general hospitals in our protocol [National].*

Invest in risk communication

Participants believed that the financial investment for active safety surveillance activities should be accompanied by an investment in risk communication and feedback which is central in proving the community with the right information. They noted that this requires a strategic plan informed by the understanding that presence (or lack of) vaccine safety surveillance information sharing can affect immunization programs at the national level. They emphasized the proactive measures including risk communication should therefore be put in place in a way that covers comprehensively both current issues and those that are likely to happen, considering upcoming vaccines like the malaria vaccine, which will also present adverse vaccine safety issues including the rampant misinformation.

> *We need to put in place measures to mitigate and contain these challenges so that our vaccination programs are not overrun. There's also a lot of anti-vaccination propaganda, so we need a budget for risk communication to counter this. Risk communication should follow once we have identified and understood*

the problem, so we can communicate accordingly [National].

we need feedback to the community, we are in an error of a lot of hesitance and misinformation and these events happen and there is nothing that is given to the public, then they are right to conclude and continue even spreading the rumours further, so AESI safety surveillance I think needs to be given priority in terms of misinformation going around.

Another recommendation was related to sustainability measures as detailed in the section on *[Sustainability Mechanisms for Active Safety Surveillance Benefits Need Improvement]*.

4.10 Sustainability mechanisms for active safety surveillance benefits need improvement

Enhance existing sustainability efforts

The national level participants reported that capacity building and sustainability considerations were embedded in the project activities and design. It was also stated that sustainability issues were also discussed during various review and initial meetings with stakeholders. Relatedly, most national level participants felt that sustainability was assured given that the key foundations were set including the fact that the project team was not entirely newly hired, but rather part of the hospital staff.

why we are saying that sustainability can be carried on, we have not employed any external person in the sites...we have been relying on the staff within the hospitals, the data person, the clinician. So, with that capacity now well built and them having formed a team being led by the community and public health departments within the hospitals, I believe that sustainability can be carried on and they are able to look up to continuity of such related studies [Director].

in that meeting we had to agree that this is going to happen in the HBSSS system, we ensure that if HBSSS is being implemented, it has got to strengthen the existing systems, it was not created as a parallel system, I think in that meeting we talked so much about the sustainability and the scale up [National].

Adequate financial investment in vaccine surveillance is needed

The findings indicate that the scaling and integration process should ensure that a financial structure/ budget is in place to plan and detect vaccine related issues going forward, including prospectively identifying cases, conducting causal assessments, and public feedback or engagement. However, despite the reported considerations for capacity building and sustainability in the protocol in addition to the integration proposal by almost all participants, most of them were significantly worried and not confident about sustaining such programs especially in the low- and middle-income settings. Most participants were largely sceptical about the sustainability of active safety surveillance in their indicated worry that the country lacks a laboratory infrastructure system that can offer the required diagnostic capacity/investigative capability for confirming the adverse events following vaccination.

I don't know if we have the infrastructure that is adequate to do the diagnostic investigative part of the investigation. I think it's an area that still needs a lot of support, you have to send samples to other labs outside Uganda so I wouldn't say we are yet there [National].

In general, maintaining such programs without ongoing donor support is challenging, especially in countries with high disease burdens and limited resources [National].

Most of the worry was associated to the perception that the surveillance process cannot largely be sustained for long if the HBSSS and related activities are totally dependent on external funding/donors. Their worries were based on the fact that the HBSSS project was specifically funded and not entirely streamlined within the routine/usual health facility service. Emphasizing their negative feelings on a sustainability plan, they mentioned that although the site/hospital team members were part of the hospital staff, they were facilitated differently outside the routine financial motivation and rewards (especially the salary) without which they strongly felt that scaling up process would be limited and unsustainable.

we are grateful that we built capacity for people there, but how are we going to sustain it? I cannot give you an answer on how we shall do it because these people have been getting facilitation, some small enumerations which usually comes after every three months and now who is going to do it? [National]

It's a significant challenge. The support from CDC and WHO has been substantial. One major objective was to develop a sustainability plan to continue the work once these organizations pull out. However, given the level of investment needed, I doubt we could sustain the project without substantial external support. Even with integration into existing systems, the necessary investment might not be adequately covered by the government alone. For critical programs like this, specific and deliberate investment is essential [National].

To address the potential challenges and threats towards sustainability, major recommendations that were made include the need for domestic investment and commitment for safety surveillance even with the meager financial health resources in the country. Such investments would address concerns that while funding was central to safety surveillance, it was largely inadequate.

the challenge I think we have is that vaccine safety an orphan, no one follows it, we are able to buy fridges, we are able to buy big cars, but safety is little, yes vaccines are safe but people want you to follow them up. So for me I think budget allocation for vaccine safety is the biggest driver that will allow how the vaccine and other things are continuing [National].

Participants noted that beyond the physical infrastructure, financial commitment should aim to ensure adequate district and hospital personnels with clear roles are available for the surveillance activities. Such workers could, if possible, work entirely on vaccine surveillance or provide more than 50% of their time dedicated to the same. Many felt that such investments towards prioritizing vaccine safety interventions including key support to the national immunization programs including UNEPI, generate evidence to inform policy and programs, inform community safety and risk communication interventions. could have adequate gains that can be sustained.

At the district level, where we have primary healthcare focused on prevention, there must be an officer aligned with this role. Even if they handle clinical work, 70% of their time should be dedicated to surveillance or prevention, with the remaining 20-30% on clinical tasks. There should be a clear allocation of time [National].

I vote to really support prioritization of vaccine safety and allocate resources for that simply because the technology of vaccines has been very successful.... Vaccine safety surveillance is crucial...so it becomes very important to identify even the small, unwanted effects to put in place mitigation measures, risk communication, and to strengthen the immunization program [National].

4.11 Limitations

There was a delay in the approval of the HBSSS project (submitted Oct 2021, approved 03 June 2023) leading to late implementation. At the time, the pandemic was waning and there was a low risk perception to Covid-19 in Uganda. This led to a decline in vaccine consumption that made it nearly impossible for the HBSSS teams to register prospective Covid-19 vaccine AESI. The teams identified more of the AESI retrospectively with their associated challenges.

4.12 Lessons learned and recommendations

1. Several factors including good quality training, enhanced coordination system, stakeholder engagement and financial motivation for the team facilitated the process. Others included:
    - Flexibility in meetings schedules
    - Financial support for follow-up investigations

2. Limited investigative capacity at the hospitals, transport costs for patient follow up, delayed protocol implementation, workload challenges, community resistance due to rumours and misinformation, poor quality data characterised by missing information affected the process

3. The HBSSS was perceived to have significant benefits, including increased awareness of vaccine safety surveillance even at the community level, enhanced capacity for monitoring vaccine safety, improved signal detection, more efficient reporting, and better patient care.

4. Expanding surveillance to additional health facilities is essential to maintain preparedness for both existing and emerging vaccine products and technologies.

5. Scaling up monitoring beyond adverse events of special interest to include all vaccine-related adverse effects is both relevant and timely.

6. Sustainability of active vaccine safety surveillance was perceived possible only if at least the same project funding is dedicated to the program a long side a better stakeholder mapping with clear roles.
    - It is very key to plan and allocate the necessary resources, especially finance for diagnostic facilities and human resources to ensure that people whose primary deliverables include vaccine safety surveillance are available.

7. Integration of active vaccine safety surveillance was recommended including:
    - Decentralization of causality assessment committee
    - Community based vaccine safety surveillance (including lower health facilities since most people first contact these before they go to referral facilities).

8. Overall, establishing a strategic and resilient national system for active vaccine safety surveillance is crucial for sustaining its benefits.
    - These includes aspects of ensuring that proactive measures are in place to respond to the old and new/emerging vaccine related diseases

9. Causality assessment is more efficient when cases are reported promptly and thoroughly investigated, including a complete history, detailed event chronology, and potential diagnoses

10.
    - Critical Investigations always delayed
- Laboratory investigations were difficult to conduct; thus some cases were missed.
    - Lack of evidence in literature delayed decision making on rare cases

11. Although stakeholder engagement at the national and institutional level (ministry of health, health facilities, districts) was good, we recommend strengthening community engagement to include:
    - Risk Communication
    - Community and media

12. Training including refresher course should be given adequate time to allow for comprehensive understanding

13. Adequate financial investment in vaccine surveillance is needed i.e. external and domestic funding for safety surveillance even with the meager financial health resources in the country should be availed

5.0 Conclusion

Overall, the HBSSS was successfully rolled out and improved the effectiveness of the AEFI/AESI surveillance system in the country. We recommended involvement of district hospitals to ensure sustainability.

6.0 References

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