

An Evaluation of the Adverse Events Following Immunization Surveillance System: A Case of the Oral Cholera Vaccine Mass Campaign, Chimanimani and Chipinge Districts, Zimbabwe, 2019.

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Abstract

Background: Three cases of adverse events following immunization (AEFI), in Chimanimani and Chipinge districts, were notified during their oral cholera vaccine (OCV) mass campaigns post-Cyclone Idai. However, the coverage survey uncovered 93 AEFI cases. We determined the reasons for the AEFI surveillance system under-reporting and assessed performance of the system

Methods: We conducted a surveillance system evaluation using the updated CDC guidelines for surveillance system evaluation. Fifty-seven health workers and 50 community members were randomly selected from 39 health facilities. We reviewed completed AEFI reporting forms to check for data quality, simplicity, completeness, and timeliness of the system. We used questionnaires to determine HCWs and community's knowledge on the operations of the surveillance system. We used a health facility checklist to assess the system's stability. Data were analysed to generate means and frequencies. Three-point Likert scales were used to rate health worker knowledge on the AEFI system.

Results: Reasons for under-reporting were community's poor knowledge, perceiving adverse events as minor issues and fear of being blamed for causing adverse events by health workers. The community had poor knowledge with 27/50 (54%) answering at least one out of three questions correctly. The system had a low sensitivity of 3% and was unstable, 24/39 (62%) of the facilities relied on public transport.

Conclusion: Community's poor knowledge on AEFI, occurrence of mild adverse events and fear of being blamed led to under-reporting. The system was neither stable nor sensitive. Community sensitization on AEFI were thus improved.

Background

Vaccines are cost effective and are estimated to avert between two and three billion deaths each year [1–3]. Though vaccines are beneficial, they occasionally lead to undesirable effects including adverse reactions termed adverse events following immunization (AEFI) [4]. According to the World Health Organization (WHO), AEFI 'is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with usage of the vaccine'. Despite the strides made towards the reduction of vaccine preventable diseases, the increasing public's focus on AEFI is impacting negatively on the immunization coverage [4–6].

AEFI surveillance is one of the pillars that ensures the safety of immunization programmes [7]. In Zimbabwe, the AEFI surveillance is managed and coordinated by the Zimbabwean Expanded Programme of Immunization (ZEPI) team, a division of the Ministry of Health and Child Care (MoHCC) in collaboration with the national pharmacovigilance centre, Medicine Control Authority of Zimbabwe (MCAZ) [7, 8]. The objectives of the AEFI surveillance include early detection and reporting of suspected AEFI; analysis of reports and taking necessary action; minimising AEFIs during routine immunization and

mass campaigns and ensuring patient safety [8]. Figure 1 below shows an established information flow chart on AEFI reporting in Zimbabwe.

The Global Oral Cholera Vaccine (OCV) stockpile, used in epidemic and endemic settings and in humanitarian crises where the risk of cholera is high, was established in 2013 [9]. In March 2019, Cyclone Idai destroyed water and sanitation facilities in Chimanimani and Chipinge districts. Placing the two districts at higher risks of cholera outbreaks. Also, following reports of cholera cases in Cyclone Idai-affected areas in Mozambique, the districts had two rounds of mass drug administration of OCV between April and June 2019. *Euvichol*, which contains killed whole cells of *Vibrio cholerae* serogroups O1 and O139, was administered to anyone aged one year and above [10].

During the OCV campaigns, Chimanimani and Chipinge districts reported only three cases AEFI. However, 93 cases of AEFI were identified during an OCV coverage survey that was conducted in August 2019. We aimed to determine the reasons for under-reporting of the AEFI surveillance system during the OCV mass vaccination campaign in Chimanimani and Chipinge districts.

Methods

We conducted a mixed method study comprising descriptive cross sectional and surveillance system evaluation using updated CDC guidelines for surveillance system in Chimanimani and Chipinge districts. The two districts are separated from Mozambique to the east by porous borders. There are 75 health facilities, Chimanimani 23 and Chipinge 52, and some of these facilities serve people from Mozambique.

Sample Size

Using Dobson formula: $n = Z_a^2 (p) (1-p)/\delta^2$, where $Z_a=1.96$, $\delta = 0.05$ and assuming a 95% confidence interval, a non-response rate of 10% and $p = 0.034$ (3.4% prevalence of AEFI when using *Euvichol* vaccine) a sample size of 55 healthcare workers (HCWs) was calculated; and $p = 0.03$ (3% reporting rate of AEFI to health facilities) a sample size of 45 community members was calculated. Four hospitals with the largest OCV coverage were purposively selected. Five HCWs from each hospital available on the day of the interview and had participated in the OCV campaign were purposively selected. Thirty-five other health facilities, Chimanimani 11 and Chipinge 24 were randomly selected using the lottery method. From each facility, one nurse who participated in the campaign was selected by simple random sampling. At least two community members visiting the 39 health facilities on the day of the study were purposively recruited into the study using simple random sampling.

Data Collection

We reviewed completed AEFI reporting forms to check for data quality, simplicity, completeness, and timeliness of the system. We used pre-tested questionnaires that were specifically designed for this study

(Supplementary File 1) to determine HCWs and community's knowledge on the operations of the surveillance system. We used a health facility checklist to assess the system's stability. Qualitative data were obtained from open ended questions during the face-to-face interviews.

Data analysis

Questionnaires were checked for completeness and internal consistence before being created in Epi info version 7.2.2.6. This software was used to generate means, frequencies, and proportions. Sensitivity was calculated by dividing the AEFI cases notified during the campaign over the cases identified during the OCV survey multiplied by 100. HCWs' knowledge on the adverse events following immunization surveillance system (AEFISS) was assessed basing on six questions weighing one point each. These were assessed on a six-point Likert scale where a score of 1–2 was poor, 3–4 fair and 5–6 was good knowledge. Community member's knowledge levels on the AEFISS were assessed using a three-point Likert scale where a score of 0–1 was poor, 2 fair and 3 was good knowledge. Qualitative data from the interviews were sorted into themes and were analysed based on responses to specific questions (Fig. 2).

Results

Demographic characteristics of health workers

The two district nursing officers (DNOs) for the two districts were recruited as key informants. We interviewed 57 HCWs, the majority were female, 40/57 (70%) and 31/54 (54%) were registered general nurses (RGNs). The median age was 42 years ($Q_1 = 39$; $Q_3 = 51$) and the median years in service was 13 ($Q_1 = 10$; $Q_3 = 24$) (Table 1).

Table 1

Demographic characteristics of health workers in Chipinge and Chimanimani districts, 2019. n = number of healthcare workers.

Variable	Categories	Chimanimani n = 23(%)	Chipinge n = 34(%)	Total n = 57(%)
Gender	Female	16(70)	24(71)	40(70)
	Male	7(30)	10(29)	17(30)
Designation	PCN	10(43)	13(38)	23(40)
	RGN	11(48)	20(59)	31(54)
	SCN	0	1(3)	1(2)
	Tutor	2(9)	0	2(4)
Responsible authority	Government	3(25)	3(11)	6(15)
	Mission	2(17)	4(15)	6(15)
	Private	1(8)	5(19)	6(15)
	Rural district council	6(50)	13(48)	19(49)
	Town council	0	2(7)	2(6)
Years in service	Median years in service	12	13	13
	(Q ₁ ; Q ₃)	(10;26)	(8;24)	(10;24)
Age	Median age	42	43	42
	(Q ₁ ; Q ₃)	(39;50)	(38;51)	(39;51)

Community Members' Demographic Characteristics And Aefiss Knowledge

We interviewed 50 community members, the majority were female, 38/50 (76%) and the median age was 33 years (Q₁ = 25; Q₃ = 43). The majority of the community members, 31/50 (62%), had ever heard about adverse events following immunization and 23/50 (46%) knew at least two symptoms of AEFI. Sixteen out of 50 (32%) knew when to report an AEFI and 13/50 (26%) knew the benefits of getting information on AEFI prior to receiving vaccines. The overall knowledge level of the community members was rated as poor as 27/50 (54%) answered at least one question correctly. Community members that knew of

someone who had experienced an AEFI during the campaign were 6/50 (12%). All of them experienced mild symptoms and none of them reported to the health facility (Table 2).

Table 2

Community knowledge on AEFI surveillance system, Chipinge and Chimanimani districts, 2019. n = number of community members interviewed.

Variable	Frequency n = 50	Percentage %
Ever heard of AEFI	31	62
Nurse explained during immunization	23	46
When to return to the clinic if an AEFI occurred	16	32
Knew someone who had an AEFI during the OCV campaigns	6	12

Knowledge Levels Of Health Workers On Aefiss

Table 3 shows that 33/57 (58%) HCWs knew the target group for the OCV, 27/57 (47%) knew at least two presenting symptoms, 6/57 (11%) knew that symptoms experienced within 14 days of receiving OCV were considered an AEFI, 22/57 (39%) knew that five reporting forms were filled in at the facility, 26/57 (46%) knew that the AEFI were reported immediately and 55/57 (96%) knew the correct reporting channel. The overall rating of health workers' knowledge was fair with 31/57 (54%) answering three to four questions correctly.

Table 3

Knowledge levels of healthcare workers on AEFI surveillance system, Chimanimani and Chipinge, 2019. n = number of healthcare workers interviewed.

Variable	Frequency n = 57	Percentage %
Target group for the OCV AEFI	33	58
At least two presenting symptoms	27	47
Symptoms were considered as an AEFI within 14 days of receiving OCV	6	11
Five reporting forms were filled in	22	39
AEFI were supposed to be reported immediately	26	46
Reporting channel	55	96

Simplicity

The AEFISS was integrated with expanded programme on immunization (EPI) disease surveillance system. Nurses who had ever filled in a reporting form were 16/57 (28%). Of these 16, the majority 15/16 reported that the forms were easy to complete, half 8/16 took less than 10 minutes to complete the form. The majority 10/16 completed history taking between 10 and 20 minutes, 3/16 took more than 40 minutes to complete history taking and 7/16 required special training on how to complete the forms (Table 4).

Table 4
Simplicity of the AEFI surveillance system, Chimanimani and Chipinge, 2019. n = number of healthcare workers who once completed reporting forms.

Variable	Frequency n = 16	
Easy to complete	15	
Time taken to fill in the forms	< 10 minutes	8
	Between 10 to 20 minutes	4
	Between 20 to 40 minutes	3
	> 40 minutes	1
Required special training	3	

Stability

HCWs that were trained on AEFISS were 26/57 (46%). Table 5 shows that reporting forms were available at 31/39 (79%) facilities and 16/39 (41%) had the case definitions displayed on the walls. Functional phones were available at 27/39 (69%) facilities and 52/57 (91%) HCWs mainly used personal cell-phones to notify the next level due to unavailability of airtime and non-functionality of phones at facilities. Majority of the facilities, 24/39 (62%), did not have functional vehicles and they relied on public transport.

Table 5
Health facility AEFI system stability, Chimanimani and Chipinge, 2019. n = number of health facilities visited.

Variable	Chimanimani n = 12 (%)	Chipinge n = 27 (%)	Total n = 39 (%)
Reporting forms	11 (92)	20 (74)	31 (79)
Displayed standard case definitions	2 (17)	14 (52)	16 (41)
Working phone	10 (83)	17 (63)	27 (69)
Functional vehicles	3 (25)	12 (44)	15 (38)

Data Quality

From 01/01/2019 to 31/12/2019, six AEFI were recorded, three in each district. The information on all the forms was legible. Four out of the reported six cases had 100% completeness, one was 60% complete and the other one was 40% complete. The overall completeness was at 83%, was rated as good (Table 6).

Table 6
Data quality for reported AEFI cases, Chimanimani and Chipinge, 2019. n = number of reporting forms completed.

Section	Completeness n = 6	Percentage %
Demographics	6	100
Facility information	6	100
Type of AEFI	5	83
Treatment given	4	67
Outcome	4	67
Overall completeness		83

Timeliness

Five, of the six cases, were notified immediately to the DNO, the other case had not been reported to the district even by the time of the study. The province was notified of 4/6 cases in less than 24 hours. The overall timeliness was 75%, which was rated as fair. All the facilities that reported adverse events received feedback from the national level.

Sensitivity

The calculated system's sensitivity during the OCV campaign was 3%, hence the system had a low sensitivity.

Reasons For Under-reporting

Nine out of 57 (16%) HCWs reported that most of the adverse events were mild and the nurses would manage the symptoms and reassure clients without reporting. One HCW stated that, *'the adverse events were nothing compared to the devastating effects of Cyclone Idai, hence people worried more about getting a place to sleep than reporting nausea and abdominal pains that were self-resolving'*.

Respondents from the community also agreed that the effects were mild and did not warrant returning to the clinic for reporting.

Six community members out of 50 (12%) reported that HCWs only emphasized on the vaccine-benefits during the campaigns. These reports, including fear of being blamed for causing adverse events by HCWs, were also supported by the key informants as the reasons for under reporting.

Discussion

Our study noted that the reasons for under-reporting of AEFI during the OCV campaign in Chimanimani and Chipinge districts included community's poor of knowledge about AEFI, perceiving AEFI as mild and fear of being blamed for causing adverse events by HCWs. The majority of the community members did not know when to report to the health facility when they experienced an AEFI. Also, those that were reported to have had an adverse event did not report since they perceived their symptoms as mild. Similar findings were noted by Danova et al. 2017, where under-reporting was attributed to the higher occurrence of mild adverse events [11]. Also, Parrella et al. 2013, reported that serious AEFI were more likely to be reported compared to non-serious AEFI [12]. This emphasizes the need for health education of the public.

In our study, the majority of HCWs had fair knowledge on the AEFISS. However, they failed to list at least two symptoms and the duration considered to be an AEFI associated with OCV. These findings are consistent with findings by Muchekeza et al. 2014, where HCWs could not identify AEFI which subsequently resulted in under-reporting [13]. In addition, we noted that a third of the HCWs had ever filled the reporting forms. Hence, practice might have influenced the level of knowledge more than years in service. This correlation between practice and knowledge was also reported by Mehmeti et al. 2017 [14].

In our study, the AEFISS was simple as the forms were easy to fill in. This is contrary to findings by Agbokpe et al. 2018, where they noted that the AEFISS was not simple since the forms were too bulky and too technical [15]. The system was also found to be unstable. Two-thirds of the facilities relied on public transport and forms were not submitted on time. These findings are consistent with findings by Sithole et al. 2017, where the system's stability was compromised by the communication systems which led to delays in transmitting information [16].

Our study showed that the sensitivity of AEFISS in both districts was low. This was attributed to the passive nature of the system which relies on voluntary reporting [11, 16–18]. The low sensitivity might also be due to HCWs' lack of knowledge as well as inadequate community sensitization. Consistent with findings by Constantine et al. 2018, who showed that inadequate community sensitization and staff training led to a low sensitivity of the AEFISS [17]. Hence there is a need for staff training to promote a high sense of vigilance [6].

Our study had limitations. We might have introduced recall bias as we were asking questions about OCV which was given six months prior, hence it may underestimate the HCWs' knowledge levels.

Conclusions

The reasons for under-reporting were lack of knowledge for both HCWs and community members, occurrence of mild adverse events and fear of being blamed for causing adverse events. The AEFISS was simple, however, it was neither sensitive nor stable. We recommended intensified community sensitization on adverse events following immunization during EPI outreaches.

Abbreviations

AEFI

Adverse events following immunisation; AEFISS:Adverse events following immunisation surveillance system; CDC:Centres for Disease Control; EPI:Expanded Program on Immunisation; MCAZ:Medicines Control Authority of Zimbabwe; MoHCC:Ministry of Health and Child Care; OCV:Oral cholera vaccine; WHO:World Health Organisation; ZEPI:Zimbabwe expanded program on immunisation.

Declarations

Ethics approval and consent to participate

The protocol was approved by the Health Studies Office Institutional review review board on 18 November 2019 under (HSO/SE/11/2019). Permission to conduct the study was obtained from the Provincial Medical Director Manicaland province and District Medical Officers for Chimanimani and Chipinge districts. We obtained written informed, signed consents from all the respondents prior to interviews.

Consent for publication

Not applicable

Availability of data and materials

All data that was generated and analysed during the current study are included in this published article and its supplementary information files.

Competing interests

The authors declare that they have no competing interests.

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There was no funding for this study.

Authors' contributions

MRG, MM, AC, TJ, EG, SC, NTG and MT contributed considerably to the conceptualization and design of the study. MRG collected data. MRG, MM, AC, TJ, EG, SC, NTG and MT performed data analysis and

interpretation. MRG, MM and AC drafted the manuscript. All the authors read and approved the final manuscript.

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Figures

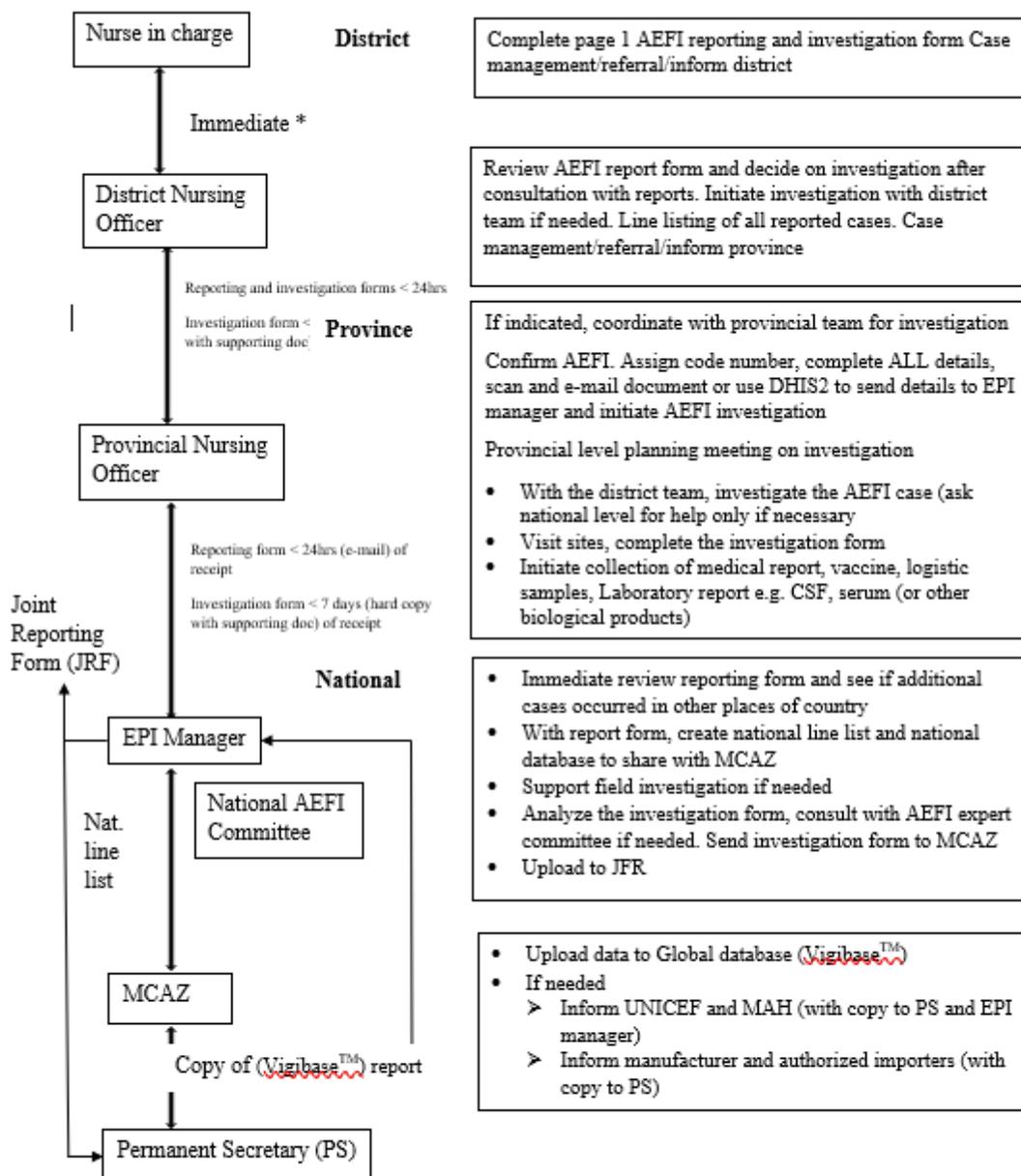


Figure 1 Zimbabwe flowchart on how AEFI information is communicated to various levels of health system.

*For deaths inform province and national level over telephone. AEFI: Adverse events following immunization; DHIS: District Health Information Software; EPI: Expanded Program on Immunization; MCAZ: Medicines Control Authority of Zimbabwe.

Figure 1

Zimbabwe flowchart on how AEFI information is communicated to various levels of health system. *For deaths inform province and national level over telephone. AEFI: Adverse events following immunization; DHIS: District Health Information Software; EPI: Expanded Program on Immunization; MCAZ: Medicines Control Authority of Zimbabwe.

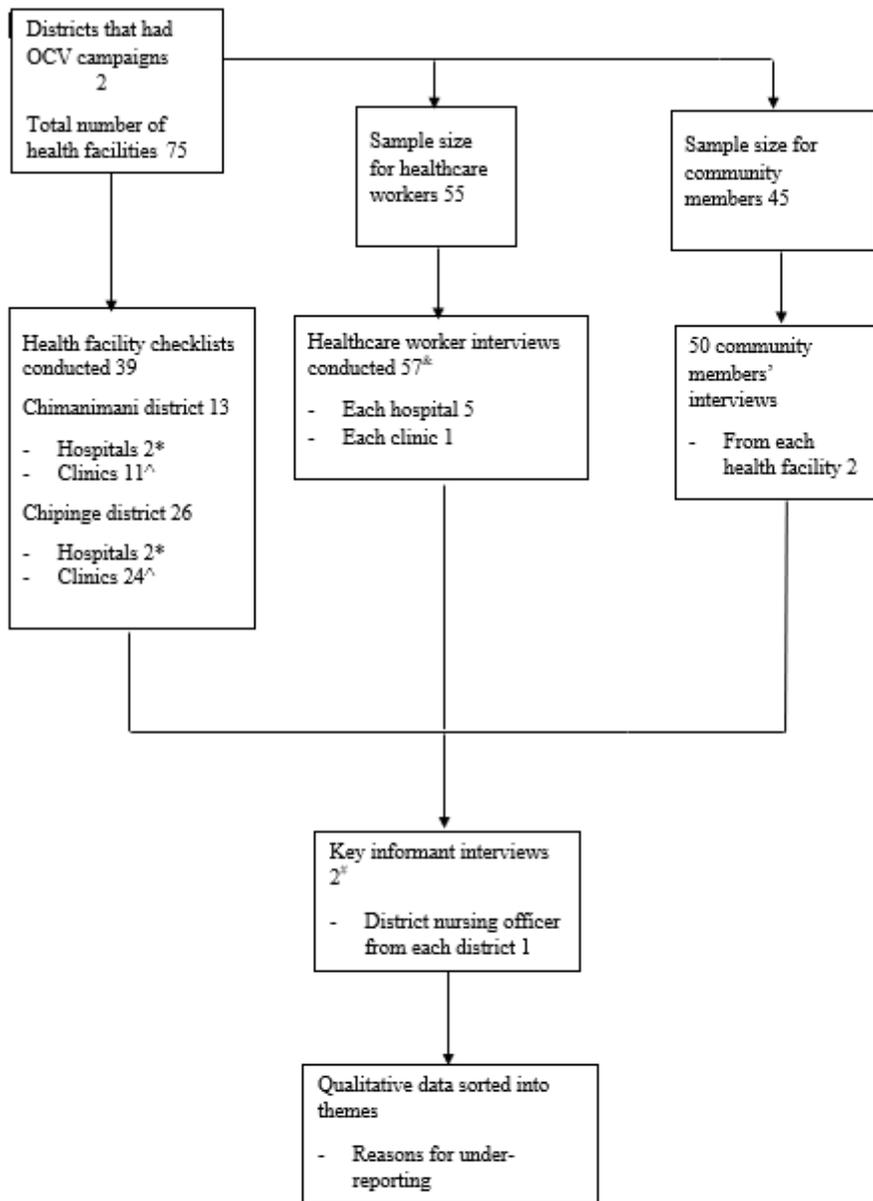


Figure 2 Development of qualitative data themes for the reasons for under-reporting of the adverse events following immunization surveillance system during the oral cholera vaccination campaigns, Chimanimani and Chipinge districts, 2019.

*Purposive sampling for high volume facilities; ^Simple random selection for clinics; & Purposive sampling for healthcare workers that were involved in OCV campaigns; #Purposive sampling for key informants, one from each district.

Figure 2

Development of qualitative data themes for the reasons for under-reporting of the adverse events following immunization surveillance system during the oral cholera vaccination campaigns, Chimanimani and Chipinge districts, 2019. *Purposive sampling for high volume facilities; ^Simple random selection for clinics; & Purposive sampling for healthcare workers that were involved in OCV campaigns; #Purposive sampling for key informants, one from each district

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