Poor Immunization Data Quality Led to Wrong Decision Making in Pertussis Outbreak Management in Southern Ethiopia: a Cross Sectional Study

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Abstract

**Background:** The aim of this study was to investigate the quality of immunization data and monitoring systems in the Dara Malo district (woreda) of the Gamo Administrative Zone, Southern Nations, Nationalities and Peoples Region (SNNPR) of Ethiopia.

**Method:** A cross-sectional study was conducted from August 4 to September 27, 2019 in Dara Malo District. The district was purposively selected during the management of a pertussis outbreak based on the hypothesis ‘there is no difference in reported and recounted immunization status of children 7 to 23 months in Dara Malo District of Ethiopia’. The study used the World Health Organization (WHO)-recommended Data Quality Self-Assessment (DQS) tools. The accuracy ratio was determined using data from the routine Expanded Program of Immunization (EPI) and household survey. Facility data spanning the course of 362 months were abstracted from EPI registers, tally sheets, and monthly routine reports. In addition, household surveys collected data from caretakers or immunization cards or oral reports. Trained DQS assessors collected the data to explore the quality of the monitoring system at health posts, health centers and district health offices. A quality index (QI) and proportions of completeness, timeliness and accuracy ratio of the first and third doses of pentavalent vaccines and the first dose of measles-containing vaccines (MCV) were made.

**Results:** In this study, 336-month facility data were extracted. In addition, 595 children aged 7 - 23 months, with a response rate of 94.3%, were assessed and compared for immunization status using register and immunization cards or caretakers’ oral reports through the household survey. At the district level, the proportion of the re-counted vaccination data on EPI registers for first dose pentavalent was 95.20%, three doses of pentavalent was 104.2% and first dose of measles was 98.6%. However, the ratio of vaccination data compared using tallies against the reports showed evidence of overreporting with 50.8%, 45.1% and 46.5% for first pentavalent, third pentavalent and first dose of measles vaccinations, respectively. The completeness of the third dose of pentavalent vaccinations was 95.3%, 95.6% and 100.0% at health posts, health centers and at the district health office, respectively. The timeliness of the immunization reports was 56.5% and 64.6% at health posts and health centers, respectively, while the district health office does not have timely submitted on time to the next higher level for twelve months. The QI scores ranged between 61.0% and 80.5% for all five categories, namely, 73.0% for recording, 71.4% for archiving and reporting, 70.4% for demographic information, 69.7% for core outputs and 70.4% for data uses and were assessed as suboptimal at all levels.

**Conclusion:** Immunization data completeness was found to be optimal. However, in the study area, the accuracy, consistency, timeliness and quality of the monitoring system were found to be suboptimal. Therefore, poor data quality has led to incorrect decision making during the reported pertussis outbreak management. Availing essential supplies, including tally sheets, monitoring charts and stock management tools, should be prioritized in Daro Malo District. Enhancing the capacity of healthcare providers on planning, recording, archiving and reporting, analyzing, and using immunization data for evidence-based decision making is recommended.
Background

Immunization is recognized as one of the most successful and cost-effective public health interventions to ensure the healthy lives of children. Every year, vaccines save 2–3 million lives, while millions more are protected from disease and disability. Immunization is one of the best buys in global health strategies and has contributed to achieving Millennium Development Goal 4 (MDG 4) three years ahead of target, reducing the child mortality rate by 23% in Ethiopia [1]. Immunization improvements also contribute to achieving sustainable development goals (SDGs)[2]. Ethiopia recognizes the crucial role immunization plays in child health and affirms its responsibility to ensure that every child is protected from vaccine-preventable diseases.

In 2017, approximately 85% of infants worldwide received 3 doses of pentavalent vaccine (Diphtheria, Pertussis, Tetanus, Hepatitis B, and Hemophilus Influenzae type b). However, notwithstanding the progress that has been made, lower-middle-income countries continue to encounter a substantial burden of vaccine-preventable diseases, and their vaccination coverage is lagging behind that of upper-middle-income countries [3], leaving 19.9 million children vulnerable to vaccine preventable diseases [4]. Among those, approximately 60% are in 10 developing countries, including Ethiopia [5].

Studies have found a high burden of vaccine preventable diseases among vaccinated children due to the low vaccination coverage rate, inappropriate timing of the vaccination, and inadequate potency of the vaccine [6]. The average three doses of pentavalent vaccine coverage in low-income countries was 15 percentage points lower than that of high-income countries in 2011 [7]. Based on 2017 WHO and UNICEF estimates of national immunization coverage, the three doses of pentavalent vaccination in Africa were 72% [5]

The Expanded Program of Immunization (EPI) in Ethiopia, which was launched in 1980, has shown steady progress in increasing coverage for all antigens [8]. Additional vaccines beyond the traditional vaccines, Hib and Hep-B in 2007, PCV in 2011 and MCV2 in 2019, were included in the routine immunization program (Additional file 1) [8]. The study area, Dara Malo district, in 2017 and 2018 reported 103.0% and 94.8% for three doses of pentavalent vaccination, respectively [9]. Despite the reported high immunization coverage, from August 2018 through January 2019, there was an outbreak of whooping cough, with 1840 cases and six subsequent deaths. The outbreak investigation team hypothesized that poor data accuracy and poor quality of monitoring systems were the most likely reasons for the occurrence of the outbreak. The team observed discrepancies between the reported and household survey coverages [10]. Therefore, conducting DQS would have helped to strengthen the community-based surveillance system and identify activities that can improve the routine EPI services in the district [11]. This study aims to investigate the quality of immunization data and monitoring systems in the Dara Malo district of the Gamo Administrative Zone, SNNP region of Ethiopia.

Methods
Study area and population

Dara Malo is one of 160 districts administered under the SNNP region in Ethiopia. The district has 24 of the lowest administrative structures, which consist of one urban village and 23 rural villages [9]. Based on the 2007 Ethiopian national census, the projected population of the Dara Malo district in 2018 was 107,715. Form the total population, 16,814 (15.6%) were under five-year-old children, and an estimated 3,436 (3.19%) were under one year of age [9]. However, 23 health posts and four health centers offer only outreach immunization services once a month. From July 2018 to June 2019, the reported third dose pentavalent and measles vaccination coverages were 94.8% and 94.0%, respectively. Fourteen (60.8%) villages (kebeles) where 69,587 people live in Dara Malo district were affected by pertussis and measles outbreaks (Fig. 1) [10].

Study design and sampling methods

A cross-sectional study was conducted from August 4 to September 27, 2019 in the Dara Malo district, Gamo Administrative Zone, southern Ethiopia. The facility-based survey collected data from 23 health posts, four health centers and a district health office. The household data were collected from sampled households. The sample size was determined using a single population proportion formula with the assumptions of 53% proportion of third dose pentavalent vaccination coverage, 5% marriage of error with 95% confidence interval and 10% non-response rate [12]. The calculated sample size was 631.

Data collection and analysis

The WHO (2005) recommended self-assessment tools that were customized for this study [11]. The tools were adapted to capture the accuracy, completeness, and timeliness of routine immunization data from different sources, namely, registers, tally sheets, household surveys, and reports. In addition, the data quality monitoring tools help to capture the availability of essential supplies such as vaccines, diluents, syringes, vaccination cards, tally sheets and registers.

The data were collected by twelve trained health professionals with Bachelor of Sciences (BSc.) level of educational achievements whom had experiences of document reviews. In addition, two trained health workers with master's degrees in public health oversaw the quality of the collected data.

Two-day training was facilitated for data collectors and supervisors on the objective of the study, data collection methods and ethical issues. Collected data were checked for completeness and consistency on a daily basis, and data were double entered for consistency.

Facility-based survey data on first and third doses of pentavalent and first dose of measles containing vaccines were reviewed from July 2018 through June 2019. In addition, trained assessors evaluated the data quality monitoring system using WHO’s (2005) DQS tools [11]. Finally, household surveys were conducted to collect primary data on immunization status for children aged between 7 and 23 months.
The data were entered into a spreadsheet, cleaned, summarized and analyzed using Microsoft Excel® and Statistical Packaged for Social Sciences Research (SPSS IBM V 20) [14]. The accuracy ratio, proportions of completeness and timeliness were calculated. The definitions and assumptions are presented below.

**Accuracy ratio:** Based on WHO’s definition, data accuracy is the ratio between the number of vaccinations verified or re-counted from a source at one level (numerator) compared to the number of vaccinations reported by that level to more central levels (denominator) [11]. In this study, first and third doses of pentavalent and the first dose of measles vaccination recounted from the register, tally sheet, and caretakers’ report during household survey were taken as a numerator and report of health posts, health centers and woreda health office then submitted to the next higher level were considered denominators. To characterize the report consistency, national recommended categories were used, i.e. consistent if the ratio reported was $\geq 90.0$ and $<110.0\%$; overreported if it was $<90.0\%$; and underreported if the ratio was $\geq 110.0\%$ [15]. In addition, the overreporting health entities were further classified with reasons for inconsistencies, namely, missing tally sheets, discrepant recounted tally sheets against reports and both missed and/or discrepant reports.

**Completeness:** According to WHO’s definition data completeness is a percentage with the number of reports received in the numerator and the number of reports expected during a period of time as a denominator [11]. In this study, the number of the health posts, health centers and woreda health office reports received at the next higher-level health system tier for 12 months (July 2018 – June 2019) were computed against the number of expected reports [15].

**Timeliness:** Defined by the WHO as a percentage with the number of reports that were received on time (using a deadline set by the EPI office) as the numerator and the number of reports expected during a period of time as denominator [11]. In this study timeliness was considered for health post, health centre and woreda health posts if there was an evidence of written a date at least in once in each report in line with the national health information management system recommendation received before 22nd – 23rd and 26th day of each month at the next reporting level for 12 months (July 2018 – June 2019) were considered to evaluate timeliness at each level [15].

**Quality Index:** WHO’s (2005) DQS tools, has 45 elements of variables for health facilities and 51 elements of variables for district health office. These tools are adapted for this study and assessed by trained data collectors on the quality of the immunization monitoring system [11]. The variables were categorized into five; namely, recording; archiving and reporting; demographics; core outputs or analysis and evidence of use of data for action. Trained data collectors provided scores for each question. A “no” response scored “0”; and “yes” response was scored from “1 to 3” based on its importance; and a “NA” response was not considered in the denominator. The QI was calculated after summing up all scores of evaluators and divided by sum of possible maximum scores in five categories [11].

**Results**
**Accuracy ratio**

Data from three hundred and thirty-six facility months were extracted. In addition, 595 children aged 7–23 months, with a response rate of 94.3%, were assessed and compared for immunization status between register and immunization card or through caretakers’ oral reports on household surveys. At the district level, the proportion of the re-counted vaccination data on EPI registers for the first dose of pentavalent was 95.2%, 104.2% for the third dose and 98.6% for measles (Fig. 2). The ratio of vaccination data compared using tallies against the reports had evidence of overreporting, which were 50.8%, 45.1% and 46.5% for first pentavalent, third pentavalent and first dose of measles vaccination, respectively. Eighteen (64.3%) facilities were classified as discrepantly recounted, and the remaining 10 (37.3%) were both missing and discrepantly recounted facilities (Fig. 2).

**Completeness and timeliness of the reporting**

Table 1 illustrates the completeness and timeliness of reports on the third dose of pentavalent and first dose of measles at primary health care entities. The completeness of both the third dose of pentavalent and measles ranged from 95.3–100.0%. The lowest completeness report was for health posts at 95.3%, and the highest completeness percentage was 100.0% for district health offices. The timeliness of immunization reports ranges from lowest 0.0% for the district health office, followed by 55.8% for the health posts and highest 66.4% for health centers.

| Reporting facility       | Completeness of reports (%) | Timeliness of reports (%) |
|--------------------------|-------------------------------|----------------------------|
|                          | Pentavalent (3rd dose) | Measles | Pentavalent (3rd dose) | Measles |
| Heath Posts               | 95.3%                        | 95.7%    | 56.5%                   | 55.8%   |
| Health Centers            | 95.6%                        | 95.8%    | 64.6%                   | 64.6%   |
| District Health Office    | 100.0%                       | 100.0%   | 0.0%                    | 0.0%    |

**Quality of the monitoring system**

Table 2 and Fig. 3 illustrate the quality index (QI) scores using five major broad categories: recording, archiving and reporting, demographics, core output and data use. The lowest QI score was 61.0% for recording at the health post, and the highest QI was 79.2% for demographic information at health centers. The quality of the monitoring system for the district health office ranges from 69.7% on core outputs or analysis to 73.3% for the recording category.
Table 2
Quality Index (QI) for the five components of a monitoring system at the health posts, health centers and district health office, 2019.

| Name of Cluster | Recording | Archiving & reporting | Demographics | Core output | Data use |
|-----------------|-----------|------------------------|--------------|-------------|----------|
| Wacha           | Maximum score | 270 | 234 | 72 | 126 | 108 |
|                 | Acquired score | 154 | 171 | 47 | 79 | 69 |
|                 | QI         | 57.0% | 73.1% | 65.3% | 62.7% | 63.9% |
| Dara Dime       | Maximum score | 225 | 195 | 60 | 105 | 90 |
|                 | Acquired score | 153 | 157 | 40 | 57 | 56 |
|                 | QI         | 68.0% | 80.5% | 66.7% | 54.3% | 62.2% |
| Shela Deda      | Maximum score | 225 | 195 | 60 | 105 | 90 |
|                 | Acquired score | 129 | 112 | 40 | 63 | 60 |
|                 | QI         | 57.3% | 57.40% | 66.7% | 60.0% | 66.7% |
| Bobe Noyere     | Maximum score | 315 | 273 | 84 | 147 | 126 |
|                 | Acquired score | 199 | 180 | 57 | 100 | 92 |
|                 | QI         | 63.2% | 65.9% | 67.9% | 68.0% | 73.0% |
| Health Posts    | Maximum score | 1035 | 897 | 276 | 483 | 414 |
|                 | Acquired score | 635 | 620 | 184 | 299 | 277 |
| Health Centers  | Maximum score | 180 | 156 | 48 | 84 | 72 |
|                 | Acquired score | 122 | 104 | 38 | 56 | 49 |
| District Health Office | Maximum score | 15 | 42 | 27 | 33 | 27 |
|                 | Acquired score | 11 | 30 | 19 | 23 | 19 |
Discussion

This study evaluated the immunization data accuracy and quality of the monitoring system using one-year data extracted from 23 health posts, four health centers and a district health office. The results have provided objective evidence showing the existence of wide differences between reported and recounted immunization status of children in the Daro Malo district. EPI data used to assess the performance of the Dara Malo district were found to have poor accuracy, consistency, completeness and timeliness. This might have led the health system to misunderstand the quality of services, as the district health system lacks the capacity to effectively use the quality of the immunization monitoring system for evidence-based timely decision making and response to vaccine preventable disease outbreaks [16–18]. Hence, the most likely reason for delayed identification, verification and control measures against the reported pertussis outbreak might be related to the poor immunization data quality and its use for health improvement in Daro Malo districts [19].

The accuracy ratio calculated between routine immunization reports and evidence of hand-written information on the EPI register was consistent with the Ethiopian national recommended good quality category [15]. However, there were wide discrepancies between these routine immunization reports, tallies and household survey data. The lowest overreporting was revealed as 60.8% for the first dose of pentavalent vaccination, and the highest overreporting was 44.9% for the third dose of pentavalent, which was documented in health centers. Similarly, overreporting was observed at health posts and at the district health office level. The high level of overreporting might have occurred due to lack of supplies. This was consistent with the observed availability of tally sheets in two-thirds of primary healthcare entities (64.3%; 18/28). This finding was much higher than the reported poor data concordance between child registers and facility tally sheets [20–23].

The timeliness of immunization reports ranged from zero percent at district health offices to 64.6% for health centers. This finding was in line with the observed schedule for arranged outreach immunization services, which overlaps with the reporting deadline schedule in all 12 months. Since there were no static immunization services in the district, the health office prolongs the reporting period to include most recent activities until the health posts and health centers complete outreach services and submit the latest reports.

The completeness of immunization reports ranged from 95.0–100.0%. The results showed that almost all reports during the study period were available in the next highest reporting level of primary health care entities. This finding was consistent with the high rate of completeness reported in Iran [24].

The study shows that in the health posts, health centers and in the district health office, there are problems with data recording, analyzing and use of data for evidence-based decision making at the point of data production. The results of QI in all five major categories, namely, demographic information, recording, achieving and reporting, core outputs (analysis) and use for data for evidence-based decisions, were suboptimal at all primary health care entities. This could be explained by a number of influencing factors, to mention some: lack of capacity and skill to improve performance of essential health services,
poor technical support, lack of verification, motivation and rewarding mechanisms at the system level. This finding was consistent with the quality index of 55.0% reported by Tunisa by Chahed et al. (2013) [25]. Similarly, Yawson et al. (2017) confers that in Ghana, more than two-thirds of districts were challenged to achieve effective coverage [26]; Machingaidze et al. (2013) [21] and Bosch-Capblanch et al. (2009) identified a shortage of skilled manpower, which affects the strength of the immunization system in Africa and 41 low-income countries, respectively [27]. However, the results of the facility and community-based survey revealed that there are areas that need improvement at the primary health care entity level in terms of accuracy, timeliness and immunization monitoring system.

Conclusions

Immunization data completeness was found to be optimal. However, in the study area, the accuracy, consistency, timeliness and quality of the monitoring system were found to be suboptimal. Therefore, poor data quality has led to incorrect decision making during the reported pertussis outbreak management. Enhancing the capacity of healthcare providers on planning, recoding, archiving and reporting, analyzing, and using immunization data for evidence-based decision making is recommended.

Abbreviations

DQS: Data Quality Self-Assessment; EPI: Expanded Program of Immunization; FMOH: Federal Ministry of Health; HEW: Health Extension Workers; HMIS: Health Management Information System; HP: Health Post; IRB: Institutional Review Board; MCV: Measles Containing Vaccine; MDG: Millennium Development Goal; PHCU: Primary Health Care Unit; QI: Quality Index; SDGs: Sustainable Development Goals; SNNPR: Southern Nations, Nationalities, and Peoples' Region; UNICEF: United Nations Children's Fund; USAID: United States Agency for International Development; VPD: Vaccine Preventable Disease; WHO: World Health Organization

Declarations

Ethics approval and consent to participate

This study protocol was carried out in accordance with the Declaration of Helsinki and ethics approval was obtained from John Snow Inc. Institutional Review Board - certificate reference number: IRB # 19-18 and from the Southern Nations, Nationalities and Peoples Regional Health Bureau ethics review board-reference number: ZS/1-6/36/22. Permission to conduct the research was obtained from the local health office, primary health care units and health posts. Written informed consent was obtained from all mothers and/or care takers before participation in the research process. The study participants were informed that they have the full right to participate or not to participate in the study and even they can quit responding in the middle of the interview if they desire to do so. To maintain the confidentiality of the collected data, anonymity was maintained throughout the research process.
Consent for publication

Not applicable.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors’ contributions

The authors of this manuscript are MDA, BFD, ZTT, ADM, AAA, BBT, ET, DR, WSA, IA, ZAK, SS, AAA, TS and RM. MDA, ADM, BFD, DR and BBT made substantial contributions to conceiving and designing the study, and MDA, ZAK, and AAA were responsible for overseeing the field work, cleaning the data, analysing the data, interpreting the analysis and drafting the manuscript. All authors read the final document and approved it. MDA, the corresponding author, submitted the manuscript for publication.

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Annexure

Map of Ethiopia by regional states locating the study area Daro Malo Woreda with Pertussis Attack Rate (2018)
The GIS ARCview map presents the location of Ethiopia, SNNPR and Dara Malo district. In addition, the pertussis case attack rates were presented with spatial analysis by village (Kebele).

Consistency of immunization data that were reported and recounted at health posts, health centers and district health offices over one year, July 2018 – June 2019.

The bar chart clearly depicts that the report and register data were consistent as per the national recommended \(<110.0\%\) and \(\geq 90.0\%\) and the high level of overreporting between reports compared with household survey and recounted tallies.

Quality indices for five categories of quality monitoring systems at health posts, health centers and district health offices, September 2019.

The radar chart clearly shows that the quality of the monitoring system in all five categories was sub-optimal at the health post, health centre and district health office levels.

**Table 1: Completeness and timeliness of immunization reports by reporting primary health care entities, 2019**

The table presents the proportion of completeness and timeliness of routine immunization reports by three levels, i.e., 0.5 health posts, health centers and district health offices.

**Quality indices (QIs) for the five components of a monitoring system at health posts, health centers and district health offices, 2019**

The table depicts maximum scores, acquired scores, quality indices by cluster and primary health care entities.

**Additional file 1: The Ethiopian vaccination schedule of routine EPI, September 2019**

The table presents the Ethiopian vaccination schedule by age.