

Effect of Augmented Capacity Development Intervention (ACDI) on the Performance of the Data Quality and Information Utilization in the Routine Health Information System (RHIS) Among Public Health Facilities of Gofa Zone, Southern Ethiopia: A Cluster Randomized Controlled Trial

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Declaration

As a chief investigator, I agree and put the signature below to confirm that this trial will be conducted adhering all requirements of principles outlined in the Good Clinical Practice (GCP) guidelines, Institutional Review Board (IRB) and other legal and regulatory requirements. The study will be carried out in adherence with the all protocol requirements and will not make any amendment without their permission.

I also assure that I will make the findings of the study publicly available through publication without any unnecessary delay and that an honest, accurate and transparent account of the study will be given.

Chief Investigator

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Trial Contact for Scientific and Public Queries

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	<p>Despite guiding the thematic areas of the project, this sponsors will have no role in the design of this study, the overall management of data, submission of manuscripts and report of findings.</p>

Trial Summary

Table 2: Trial Summary

Study Title	Effect of Augmented Capacity Development Intervention (ACDI) on the Performance of the Data Quality and Information Utilization in the Routine Health Information System (RHIS) Among Public Health Facilities of Gofa Zone, Southern Ethiopia: A Cluster Randomized Controlled Trial
Country of Recruitment	Ethiopia
Research Aims	<ol style="list-style-type: none"> 1) To evaluate the effect of Augmented Capacity Development Intervention (ACDI) on the quality of RHIS data in the public health facilities of Gofa Zone, Southern Ethiopia (Study I) 2) To evaluate the effect of Augmented Capacity Development Intervention (ACDI) on the performance of information utilization in the RHIS in public health facilities of Gofa Zone, Southern Ethiopia (Study II)
Study Type	<ol style="list-style-type: none"> 1. Type: Interventional 2. Design: cluster-randomized controlled trial 3. Allocation: randomized 4. Intervention model: two-arm, parallel group assignment 5. Blinding: single blind (outcome assessor) 6. The research team will be concealed for the allocation of groups
Study Participants	Randomly selected health facilities and health workers
Eligibility	<p>Inclusion Criteria</p> <ol style="list-style-type: none"> 1. Functional health facilities and administrative institutions that give consent to participate in the study. 2. The health workers serving in Health Management Information System (HMIS) units, Outpatient Department (OPD), Maternal and Child Health (MCH) departments, Performance Management Team (PMT) members, managers and health extension workers (HEW) of the facilities.

	Exclusion Criteria <ol style="list-style-type: none"> 1. Those workers and facilities who are not willing to participate in the study 2. Newly established health facilities (less than a year service) 3. The health workers who already had an intention to leave the health facilities in the coming eight months during the initiation of the study
Intervention	Intervention: Routine service plus Augmented Capacity Development Interventions (ACDI). The ACDI will comprise gap based training, supervision, mentorship, feedback, motivation, monitoring and evaluation.
	Control: Routine Practice (selective training and non-specific supervision) only
Outcome	Data Quality and Information Utilization
Planned Sample Size	<ol style="list-style-type: none"> 1. 248 health workers (124 interventions and 124 control) – (Study I) 2. 228 health workers (114 interventions and 114 control) – (Study II) 3. 6 Clusters of districts
Planned Trial Period	8 months <ul style="list-style-type: none"> • Baseline and follow-up data collection (every three month) • Initial and follow-up intervention (every two month)
Recruitment status	Recruiting

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Acronyms and Abbreviations

ACDI:	Augmented Capacity Development Intervention
ANC:	Antenatal Care
ANOVA:	Analysis of Variance
CHIS:	Community Health Information System
CI:	Confidence Interval
CRT:	Cluster Randomized Control Trial
DDCF:	Doris Duke Charitable Foundation
DHO	District Health Office
DQA:	Data Quality Assessment
DUP:	Data Use Partnership
EMR:	Electronic Medical Records
EPI:	Expanded Program on Immunization
GLMM:	General Linear Mixed Model
ICC:	Intraclass Correlation Coefficient
Inc:	Incorporation
IRB:	Institutional Review Board
ITT:	Intention to Treat (ITT)
HCS:	Health Centers
HEW:	Health Extension Workers
HF:	Health Facility
HI:	Health Information
HIS:	Health Information System
HITs:	Health Information Technicians
HMIS:	Health Management Information System
HP:	Health Post
HPs:	Health Posts
HW:	Health Workers
JSI:	John Snow, Inc.
MAT:	Management Assessment Tool

MCH:	Maternal and Child Health
NCoD:	National Classification of Diseases
OBAT:	Organizational and Behavioral Assessment Tool
OPD:	Outpatient Department
PhD:	Doctor of Philosophy
PI:	Principal Investigator
PMT:	Performance Management Team
PNC:	Postnatal Care
PRISM:	Performance of Routine Information System Management
RHIS:	Routine Health Information system
SOP:	Standard Operating Protocol
SPSS:	Statistical Package for the Social Sciences
ToT:	Training of Trainers
UHP:	Urban Health Post
VF:	Verification Factor
WHO:	World Health Organization

1. Introduction

1.1. Background of the Study

Consistent and timely availability of health and health related data are crucial source of public health actions both nationally and internationally (1,2). According to the World Health Organization (WHO), Health Information System (HIS) is defined as an integrated efforts to collect, process, report and use health information and knowledge to influence policymaking, program action, and research that are essential to the effective functioning of the health systems (2,3). The HIS is one of the six building blocks of a health system. Hence, HIS is a cross-cutting component of a health system that provides the road map for the overall policy and regulation of all other health system blocks such as service delivery, health workforce, access to essential medicines, financing, leadership, and governance (4).

The ultimate purpose of a HIS is to produce high-quality information for evidence-based decision-making (5). The health data guides policy development and implementation, planning health projects, allocating health resources, governance and regulation, health sector performance evaluation and monitoring which ultimately improves the health service delivery by influencing decision-makers and planners at all levels of a health system (2). Moreover, the information is also used for research and knowledge building (6,7).

The RHIS has two interlinked functions; the production of quality routine health data and the continuous utilization of the data for decision-making (8). Since the RHIS data are generated at a facility level, assuring high-quality data and continuous use of information at the lower-level HFs will have a higher impact on enhancing health systems and health service outcomes (9).

Augmented Capacity Development Intervention (ACDI)

Capacity is the ability of a health organization to achieve an intended target (10). Capacity Development is the process that enhances the capacities of health care providers and facilities to perform functions, meet objectives, and achieve intended results (11). Designing and implementation of modified capacity development mechanism is believed to be a crucial step towards reversing the gaps of RHIS in the current Ethiopian health system (12). The interventions will be implemented to improve the knowledge, practice, and skill of the experts and the system to

produce quality data and use the data efficiently and effectively (12). The intervention, named ACDI, to be implemented in these studies, include competency-based training, mentorship, supportive supervision, feedback, motivation, monitoring, and evaluation.

This studies are designed to implement the ACDI that are targeted to improve data quality and information utilization in RHIS among selected health facilities (HFs) including Health Posts (HPs), Health Centers (HCs), hospitals and administrative institutions (rural and urban districts health offices). Then, the effect of the intervention on the improvement of data quality and information utilization will be compared between intervention and control facilities to investigate whether the intervention will have any significant impact on data quality and information utilization (13).

1.2. Routine Health Information System Interventions in improving Data Quality and Information utilization

Implementing the RHIS interventions in the routine process has been believed to improve the data quality and information utilization (14). But the performance of existing health system interventions has been found poor in the developing world (15). A survey in Tanzania in 2017 showed that only 42% of the HFs had received supervisory visits from the district level on data management, where about 41% of the Health Workers (HWs) were not received any training on routine data management system (16). Another Community Helth Informtion System (CHIS) utility study in Kenya reveled that only 52% of the community health workers stated to have any form of incentive mechanisms in their working facilities (17).

Intervention studies have been carried out in different areas of the developing world (17,18). For instance, implementation of an Electronic Medical Record (EMR) intervention in HFs of Kenya declined the proportion of missing data from 31% to 13% and increased data accuracy from 40% to 81% at the district level (19). A study in Nigeria also reported an improvement in data quality after implementation of packges of interventions comprising Data Quality Assessment (DQA) and feedback, learning workshops, and supervision. Accordingly, report completeness rate has increased by 10%, timeliness by 12%, the report content completeness by 6% (15).

In all of the studies, improvement has been observed after the implementation of different interventions, but the WHO target of data quality was not attained and the scope of the

interventions has been limited. In addition to that, the survey reports of pieces of literature showed that upper-level management bodies and experts were not sufficiently addressed in the interventions as they might be responsible for decision making in the system and influence the performance of the RHIS (14).

On the other hand, information utilization has shown no increase (remained 38%) in Cote d'Ivoire after implementation of national HIS reforms to capacity building in the use of information in a four-year intervention period from 2008 to 2012 (13). Another finding from Tanzania reported a negative result of completeness of registers after implementation of interventions such as digitalization, training, and supervision (20). A contradictory finding was observed in Brazil where the performance of live birth data was reduced after the introduction of live birth information system as compared with the existing civil registry (21). The discrepancies were observed, perhaps, due to differences in the scope of interventions implemented, rigorousness, regularity of supervision and follow up (22).

In the current Ethiopian health sector, the RHIS interventions like training on Health Management Information System (HMIS), provision of HMIS implementation resources, non-specific supervision and monitoring and evaluation are implemented in the traditional ways, unable to attain the intended targets of HIS (23). For instance, the national survey in 2018 in Ethiopia indicated only 20% staff in public HFs reported that they have received training on data collection and compilation (24). According to another study in Awi Zone of Northwest Ethiopia, only 33% of health service providers have received training on HMIS (25), 36% as reported by a study in Eastern (9), and 31% in Western Oromia of Ethiopia (26). Often pieces of training are conducted in a traditional way as offered with little or no practical exercise without proper planning and follow-up or augmenting such training with other complementary strategies. Even the trainings provided are limited in scope mainly focusing on HMIS/DHIS2 orientation that do not address overall RHIS management process (27).

In the current health system of Ethiopia, there is the poor practice of supportive supervision from the supervisors either due to staff shortage, poor training, and experience on supportive supervision techniques and skills (limited capacity) of carrying out the supervision, or lack of resources to conduct the supervisions (28). The HFs that receive more support and feedback on data management and use, improve their knowledge and personal initiation to manage and use their data

at hand for various purposes (29). According to a study in hospitals of Oromia region of Ethiopia, only 18% of the health workers reported that they have received supervision from the Oromia Regional Health Bureau. As reported by the Amhara region of Ethiopia, health workers (HWs) who were supervised and received regular feedback were more than two times to utilize RHIS (30). In developing countries including Ethiopia, the management teams at the different levels of the health system often schedule regular visits, but the evidences show that these frequently do not happen as planned due to conflicting responsibilities and demands on supervisors' time, inadequate finances, transport, and accessibility problems (31,32). Many managers and expertise involved in the supervision programs do not have adequate training and competence in the supervision system (32).

In Ethiopia, the public health sector which uses a large amount of human resource is ineffective and inefficient, and the health service being delivered has been seriously affected by the poor human resource management as a result of poor practice of motivation schemas (33). Evidences indicate that health professionals are less motivated to use health information at their working units (9). Regarding individual and behavioral characteristics, out of all participants, only 53% were motivated to use routine Health Institution as reported by a study in the Amhara region of Ethiopia (34). Even though motivation is an important facilitator, most previous intervention studies did not consider motivation as a component of intervention in improving HIS performance (33).

This study, therefore, attempts to narrow down such limitations observed in the previous studies through comprehensive procedures implementing complex interventions based on a successive monitoring system.

1.3. Rationale

Improving the understanding of health professionals and managers on data management plays a vital role in assuring the quality of health data as well as continuous utilization of information for the improved health service management (14). This might possibly be attained through implementation of complex interventions on RHIS data management. Increasing the number of health workers that are skillful on RHIS data management is also found to be a major solution for assuring high-quality data and improving information utilization (2).

Increased attention has been gained on improving RHIS. However, there is inadequate previous evidence on the frequency, quality, and scope of interventions implemented to bring about the intended change on data quality and information utilization (35).

Currently, health data quality and its utilization are found poor in Ethiopia, particularly at the lower level of the health system which is primarily responsible for operational management. The basic reasons underlying poor quality of data in RHIS were not adequately addressed in Ethiopia. The previous studies revealed that data generated at health facilities were underutilized for decision making (16,38,41,42) and what determines information utilization is not clearly known. Only few experimental studies have addressed HPs and Health Extension Workers (HEWs) (17,41), which are the foundation for routine reports in current Ethiopian health system.

Most of the previous studies that assessed data quality and information utilization in RHIS have suffered from methodological limitations (13,14,43). For instance, some of the few available studies were used program-specific indicators from only one program area like malaria, tuberculosis, and HIV/AIDS (13,44–46). Besides, others were done only on a single or very few facilities or districts, therefore, their representativeness is questionable (1,43). Still other studies were cross-sectional in nature (16,30,41,42), as well as design-related limitations such as a lack of controls (1,43,47), failure to measure multiple time points (1,15,48,49). Randomized controlled trials, having a control arm, are the strongest research designs recommended as they are capable of clearly proving cause-and-effect relationships.

Limited previous intervention studies were available on data quality and information utilization. Most of these studies have reported improvement in data quality and information utilization, but some of the studies revealed no or negative effect, indicating contradictory findings of the interventions (13,20,21). They focused on technical aspects of improving the RHIS performance, and much less on the effect of the interventions on enhancing human-related and organizational factors (1,22,43). The studies that were carried out to evaluate the impact of interventions on RHIS performance had large differences in the scope of interventions (1,15). Very few (if not none) of these studies were implemented interventions in a comprehensive manner. Interventions used, in some of the previous studies, were narrow in scope only involving very few packages like training and guideline provision (1,15,43). Furthermore, these studies were carried out without repeated implementation of interventions where observing the real effect of the intervention might have

demanded sufficient time. The studies were also unable to account for individual and institutional level variations of variables that influence the improved quality and use of routine health data.

Therefore, clear evidence is required on the desired strategies which are effective for enhancing data quality and information utilization in decision making. The observed drawbacks can be thus resolved by designing newly adapted and comprehensive capacity development interventions like gap-based training, supervision, motivation, and feedback as well as monitoring and evaluation on data quality and information utilization. These can help to improve data quality and information utilization and consequently enable to achieve health service delivery at all levels of the health system (50).

Generally, this study is designed to assess the level of data quality and information utilization and examine the effect of ACDI in the RHIS among the public health facilities of Gofa zone, Southern Ethiopia. Furthermore, the study might come up with possible recommendations and innovative solutions for HIS related challenges that would help to encourage the production of high-quality data and continuous use of information in the RHIS in all levels of the health systems. It may also devise the effectiveness of interventions that might result in the improvement on data quality and information utilization practice in public health facilities.

Moreover, this study will be expected to inform health planners and decision-makers in designing the health policies and programs on HIS to improve the practice of health system and health service delivery outcomes. Since this study predominantly emphasizes on strategies of improving data quality and information utilization, the public as a whole as well as health facilities can also be benefited from the findings of the study. The study will benefit other stakeholders working in academic areas doing a research on RHIS that might also be used as being a reference for the future researches on the same or related topic.

1.4. Research Questions and Objectives

Research Questions

1. Do the Augmented Capacity Development interventions improve the quality of data in the RHIS in the public health facilities?
2. Do the Augmented Capacity Development Interventions improve the performance of information utilization in the RHIS in the public health facilities?

Objectives

General Objective

To evaluate the effect of Augmented Capacity Development interventions on the performance of data quality and information utilization in the RHIS among the public health facilities of Gofa zone, Southern Ethiopia

Specific Objectives

- 1) To evaluate the effect of Augmented Capacity Development Intervention on the quality of RHIS data in the in public health facilities of Gofa Zone, Southern Ethiopia (**Study I**)
- 2) To evaluate the effect of Augmented Capacity Development Intervention on the performance of information in the RHIS in public health facilities of Gofa Zone, Southern Ethiopia (**Study II**)

2. Methods and Materials

2.1. Study Setting

The study will be carried out in health facilities of Gofa Zone, Southern Ethiopia. Gofa Zone has a total area of 4551 square kilometers. The zone has 11 districts (7 rural and 4 urban) and 196 kebele (smallest administrative unit in Ethiopia) (51).

The projected population of the Zone for the year 2022 is about 713, 854 (357,359 are men and 356,495 are women) with a total of 145,684 households. A total of 92,801 (13.0%) of the population are urban inhabitants and the rest live in rural inhabitants (agriculturalists) (52).

Regarding human resources, the zone has 34 general practitioners, 6 medical specialists, 17 public health specialists (masters in all types), 133 public health officers, 885 nurses (all types), 28 Health Information Technician (HIT) experts, 335 HEWs, and a total of 1510 health professionals currently working in the public health facilities. The zone has 26 HCs, 179 HPs, two governmental hospitals (one General and one Primary), 103 private clinics (97 lower, five medium, one higher), and 22 drug establishments (two rural drug vender, 18 drug store, two pharmacy).

2.2. Study Design

A two-arm, parallel group, cluster-randomized, assessor blinded and superiority trial will be designed to evaluate the effect of the intervention on data quality and use, both of the studies. The districts (woredas) will be the unit of randomization with allocation ratio of 1:1. The districts to be selected from the zone will be considered as clusters, but there are different health facilities contained under each district. The intervention health facilities will receive the ACDI while the control arm will remain with the routine RHIS practice.

The rationale for adopting a Cluster Randomized Control Trial (CRT) design for these studies is that the implementation of the intervention is targeted at the institutional and the individual level. Therefore, there is a possibility of experimental contamination between subjects if the respondents are selected and allocated in two groups (intervention and control) from the same institution. The CRT is believed to minimize such design-related challenges through the inclusion of facilities, separated by geographical distances, in two different arms (53).

2.3. Timeline

The baseline data will be collected from January 1 to 30, 2023. The intervention will be implemented from February 1, 2022 to September 30, 2023 (8 months). Follow up data will be collected immediately after the end of every three-month implementation of the intended intervention. Therefore, a total of four cycles of data collection processes (including the baseline data collection) will be carried out (Table 3).

Schedule of the Trial Assessments

Table 3: Schedule of the Trial Assessments

Trial activity	Preparation stage	Baseline	Months								Endline
			1 st	2 nd	3 rd	4 th	5 th	6 th	7 th	8 th	
Written informed consent	x										
Inclusion/exclusion criteria (Enrolment)											
Data Collection		x			x			x			x
Initial training of intervention community		x									
Supportive supervision		x		x		x		x		x	
Feedback		x		x		x		x		x	
Mentorship				x		x		x		x	
Monitoring			x	x	x	x	x	x	x	x	
Evaluation (workshops)				x		x		x		x	
Certification of best achievers				x		x		x		x	

3.3. The Study Population

Randomly selected health facilities and HWs constitute the study population. The randomly selected HWs working in the health facilities of Gofa zone will be considered as the study population.

3.4. Eligibility

3.4.1. Inclusion Criteria

Functional public HFs and administrative facilities will be included for the studies. Those facilities and HWs who give consent to participate in the study will be recruited. The HWs serving in HMIS units, Outpatient Department (OPD), Maternal and Child Health (MCH) departments, Performance Management Team (PMT) members, managers and HEWs of the facilities will be included in the studies.

3.4.2. Exclusion Criteria

Those workers and facilities who are not willing to participate in the study will be excluded. Newly established health facilities will be not considered. The HWs who already had an intention to leave the current working institution in the coming eight months (intervention period) will be excluded from the studies.

3.5. Sample Size Determination

Both studies have the common assumptions of confidence level of 95%, drop out rate of 15% (54), and marginal error of 5%, and specific proportion of intervention and control groups with the outcome. Moreover, the two studies will share the assumption of intervention to control ratio of 1:1 and power of 80% to determine the sample size. Calculations are conducted by using OpenEpi version 3.01 software (55).

Study I

Sample size is estimated by the consideration of the proportion of the of the control group with data quality, 33% and the proportion of intervention group with data quality 63% (data quality measured by feedback status) (56).

Considering the dependencies within clusters with the assumed intraclass correlation coefficient (ICC) of 0.05 and an average cluster size of about 25 respondents produce a design effect (DE) of 1

$+ 0.05*(25-1) = 2.2$. Therefore, the required trial size will be $2.2*98 = 216$ participants. With the consideration of 15% a drop-out rate, the final sample size will be 248 (124 interventions and 124 control) participants in 6 clusters.

Therefore, a total of 248 HWs representing each program unit (antenatal care (ANC1), Pentavalent third dose (Penta3), Postnatal Care (PNC), Contraceptive Acceptance Rate (CAR), Malaria, HEWs, and managers) of the facilities will be included.

Study II

Sample size will be estimated by considering the percent of unexposed with an outcome of 23% (computers training status with information utilization) and the percent of exposed with an outcome of 57% (Routine health information system utilization and factors associated thereof among health workers at government health facilities in East Gojjam Zone, Northwest Ethiopia) (57).

Considering the ICC of 0.064, obtained from previous related study (30), and with an assumed average cluster size of 25 respondents, a design effect (DE) will be $1 + 0.064*(25-1) = 2.6$.

Therefore, the required trial size will be $2.6*76 = 198$ participants. With the consideration of 15% a drop-out rate, the final sample size will be 228 (114 interventions and 114 control) participants in 6 clusters.

3.6. Recruitment

3.6.1. Randomization Process

A multistage stratified cluster sampling technique will be employed to select study facilities. The zone has 11 districts (seven rural and four urban). The rural-urban stratification of the districts will be carried out. Four from seven rural districts (Demba Gofa, Zalla, Gezegofa and Melokoza) and two (Sawla and Laha) from four urban districts of the zone will be selected by simple random sampling. The clusters were districts which have other districts or villages between them as natural buffering zones.

Two randomly selected rural districts, Geze Gofa and Demba Gofa, as well as one urban district (Sawula) with all their respective health facilities will be included under intervention facilities. On the other hand, two randomly selected rural districts, Zalla and Mello Koza, and one urban district (Laha) with their respective health facilities will be the part of control facilities with the

intervention to control ratio of 1:1. The random allocation process was done by a researcher working in Arbaminch University, who is not a member of this research. The researcher used sealed envelopes to assign the groups in to arms.

Accordingly, 35 public health facilities (22 HPs, nine HCs, one hospital, two rural and one urban district) will be assigned to intervention arm as well as 36 public health facilities (23 HPs, nine HCs, one hospital, two rural and one urban district) will be assigned to the control arm.

Furthermore, proportionally allocated HWs from each HC, hospitals, districts and their respective departments as well as one randomly selected HEWs from each selected HP will be considered for the studies.

HWs will be selected from each intervention and control facilities based on the list that available in each department of the institution. Based on the eligibility criteria, a lists of participants were included from departments of each institution by simple random sampling method. If there is a shortage in the number of participants in the departments, all of the members might be recruited (Figure 1).

CONSORT 2010 Flow Diagram

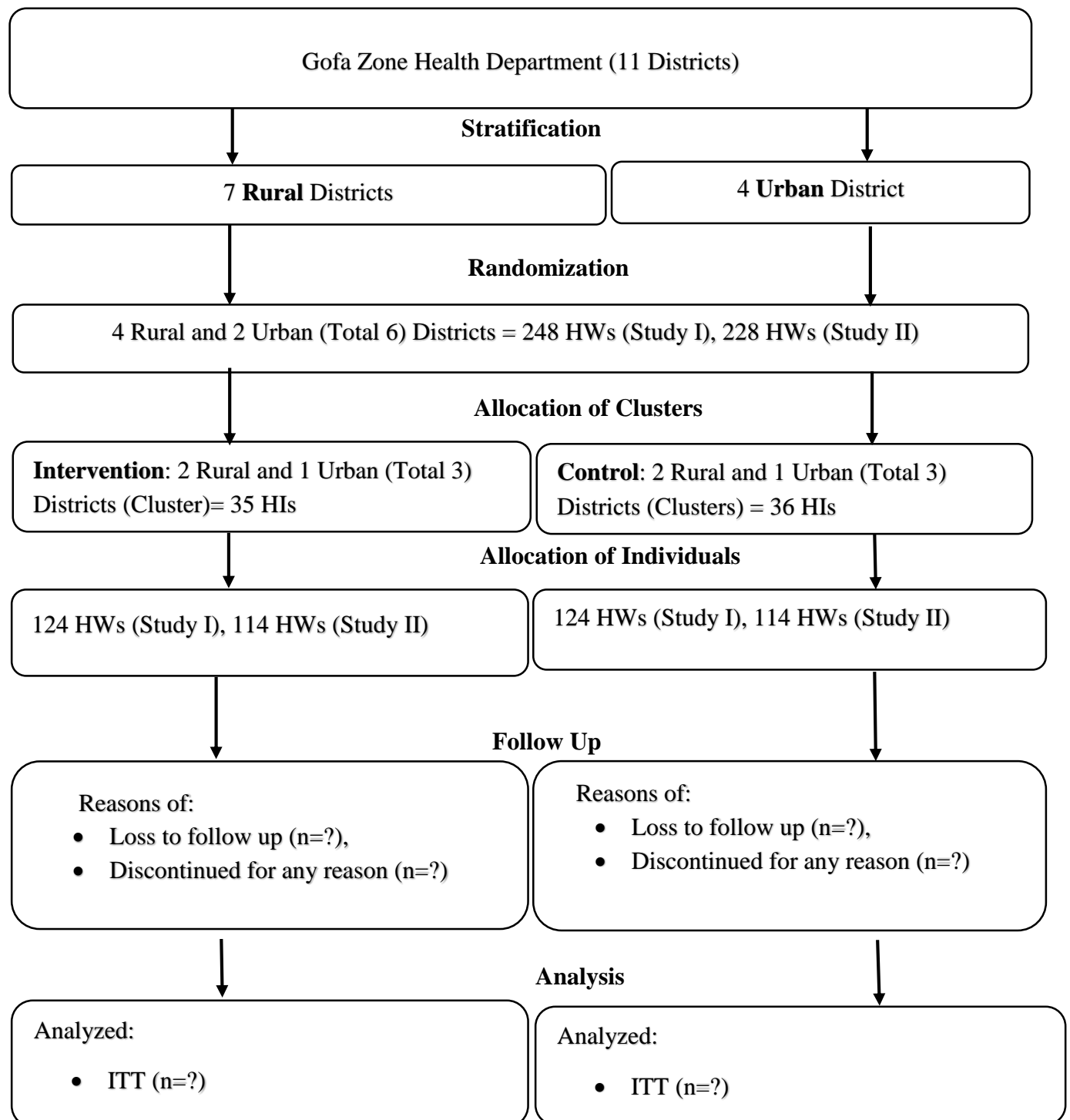


Figure 1. The CONSORT 2010 flow diagram of the trial

3.6.2. Blinding

All the baseline and follow up data will be collected by an assessor blinded to the treatment allocation, after having an intensive training on the techniques of data collection. Due to the nature of the intervention, the research participant receiving the intervention cannot be blinded to the allocation, but are strongly advised not to aware their allocation status to the assessor.

3.7. Outcome and Intervention

3.7.1. Outcome

The studies will have two outcome variables, data quality and information utilization. Data quality will be measured in terms of four outcome metrics (timeliness, accuracy, completeness and consistency). Information utilization will be measured in a composite variable structure.

I. Data Quality

Since data quality is a multidimensional construct, it is a function of each of its dimensions. The survey on data quality would involve an assessment of each of its dimensions. Several data quality dimensions are identified. The commonly recommended metrics of data quality by WHO are data accuracy, completeness, timeliness, and consistency (59,60). All of these common dimensions will be applied in these studies.

Dimension 1: Data Accuracy (Individual level)

Data accuracy rate will be determined by the verification factor (VF), comparing the data recorded in the summary forms (HMIS report) with the data in the registers from health facilities. For the districts, the results of aggregated reports will be compared with recounted reports of indicators from each reporting facilities (61). The VF will be calculated as recounted value divided by the reported value for each tracer indicator in the health facilities, expressed by percentages. An indicator will be considered accurate when the value reported in the summary forms lies within 10% (90%–110%) of the corresponding value from the recounted. A sample of four indicators including ANC1, penta3, PNC, CAR and malaria testing rate will be used for assessing data accuracy. If the value of the verified data exceeds 100%, which is considered as under-reporting whereas less than 100% will be over-reporting (62). A margin of error will be considered

acceptable at 5% (95% to 105%), fair at 10% (90% to 110%), unacceptable at greater than 10% (below 90% and above 110%) (63).

Dimension 2: Completeness Rate (Individual/Institutional level)

Completeness will be explained by report completeness and completeness of indicator data. Report completeness will be measured by the number of facilities reported against total facilities expected for a specified period (12 months report in these studies) (9). Completeness of indicator data, measures the extent to which facilities and districts that are supposed to report data on the selected core indicators are doing so. Completeness of indicator data will be examined by all the relevant data elements in a reports were filled and measured by calculating the proportion of data cells filled for all cases from the total expected in the reports (64). Completeness of specific data elements (ANC1, Penta3, PNC, CAR and number of suspects tested for malaria) will be computed (60).

Dimension 3: Report Timeliness (Institutional Level)

Timeliness of reporting will be determined by analyzing health institution summary forms that are remitted to the next level within a predetermined reporting period based on the Ethiopian national reporting schedule (59). According to the national reporting schedule, HPs are expected to reports by 21-22th of a month to HCs, the HCs to the district health office by 24-26th and district health office compile and report to the zonal health office by 27-2nd of the month (9).

Dimension 4: Consistency (Institutional level)

Consistency will be assessed through the consistency between related indicators, measured by examining if an agreement exists between those indicators (60). That will be computed by comparing the agreement between two related indicators (Penta1 and Penta3) (65,66). At least a 90% rate will be considered acceptable for both completeness and timeliness according to the Ethiopian national target (67).

II. Information Utilization

Information utilization will be computed by assessing sixteen dimensions comprising use of RHIS for treating patients, budget allocation, resource distribution, disease prioritization, prediction of outbreaks, drug/supply procurement, the day-to-day monitoring of health service activities, planning,

human resource development, displaying updated information, performance evaluation, evaluation of staff performance, selection of best experience within the health facilities, sharing of health data to other facilities and stakeholders, decision making and community mobilization and discussion. All these dimensions of the assessment tool have likert scale metrics, ranging from “never” to “always”, 1 for never, 2 seldom, 3 sometimes, 4 often and 5 always. Finally, the total number of responses of the respondents will be judged based on the average responses of each of sixteed questions. If the avegage value is 4.0_5.0, it will be categorized as Very Good, 3.0_3.9 as Good, 2.0_2.9 as Fair and less than 2.0 as Poor (8,34).

3.7.2. The Intervention

Health data management, at each level of the health system, can be improved through proper implementation of interventions that make the health workers competent on HMIS tasks and effective in RHIS management (1). Through implementation of different interventions, knowledge transfer and skill development in RHIS can be gained to enhance data quality and information utilization (68).

The major activities in this intervention studies (study I & II) include the development of checklists, conducting a preliminary and subsequent assessments on the level of data quality and information utilization. Then, the interventions such as training, supervision, mentorship, motivation, monitoring, and evaluation will be implemented and the improvement plan will be designed to map out specific actions to be identified in the initial and follow-up assessments. The identified gaps will be addressed, on a continuous basis, to improve the quality of data and information utilization.

Maternal health service indicators such as CAR and ANC will be used to measure the outcome. Other child health service indicators such as expanded program on immunization (EPI) indicators including penta1 and penta3 also be used (69). The number of malaria suspects tested, as an indicator of disease report, will also be included.

SOPs and training manuals will be organized and customized for each intervention initiatives. ACIDI, to be implemented in these studies, constitute the following capacity-building initiatives.

I. Training

Training is a crucial tool for healthcare workers to adequately understand how to operate the emerging initiatives related to RHIS programs and adapt to structural changes. Most staff working in the lower levels of the health systems, involved in the HMIS process (data collection, reporting, analyzing, and utilizing data), have limited capacity for routine data management (70). Training in the RHIS is limited in the current health system in Ethiopia. Even the few training opportunities are limited to staff in the HMIS department than in other program areas (9). Moreover, the existing training chances on RHIS were often run emphasizing on theoretical features without practical implementation system (12).

Most primary health care institution managers have poor capacity-building opportunities on the HMIS process despite their irreplaceable contribution on the assurance of institutional data quality and information utilization (14). Since managers are the users of the routine data, they need to have the necessary capacity to analyze, interpret and utilize RHIS data for decision-making (71). Apart from managers, staff working in health facilities, primarily involved in data production, have limited skills in data management. Such deficiencies will be addressed in this study.

The training will be organized in two tiers. The first tier is the training of the trainers (TOT) including HIS experts selected from the regional health bureau, zonal health department and district health offices. In this case, the trainers will be experts working in HMIS units in zonal and district health offices. The TOT will be organized at zonal level. The second tier is the training of the intervention team (selected staff from different departments, HMIS officers, managers, PMT members, and HEWs), that will be organized in their respective facilities. Training modules will be developed by these experts and delivered on data quality and information utilization activities. The training areas will encompass data recording and reporting procedures (72), health data quality training module (73), information utilization manual (74), information revolution roadmap (75), HMIS indicator reference guide (69), national classification of diseases (NCoD) instructions (76), and Ethiopian National Health Care Quality Strategy (77).

Six-day initial training of intervention team will be organized. Gap based subsequent training along with learning workshops will also be carried out for two days in every two months (for a total of four times). Preliminary assessment on the implementation status of RHIS data management will be carried out to identify implementation challenges. Based on the findings of the assessment, practical

solutions will be directed and on-job training will be delivered. Pre-intervention field visits and gap identification as well as presentation of the findings of the assessments will be emphasized in the initial training forum.

Generally, what makes this training different from the usual one is that, first, this training mainly focuses on managers along with other staff involved in data production than simply targeting HMIS officers. Second, the training will be more practical than theoretical. Third, every time, the training will be conducted after preliminary assessment (gap-based) and delivered on an on-job basis.

II. Supportive Supervision

Supportive supervision is a component of an intervention that is believed to optimize the health system, helps HWs to deliver quality services and improve RHIS performance (78). Supportive supervision is a method that mainly focus on joint problem solving, two-way communication and promotes quality in the health system (79).

The aim of supportive supervision in these studies is to improve the capacity and confidence of HWs and managers to develop specific skills on data quality and information utilization through focused observation, follow-up, and feedback on RHIS data management process.

Quarterly health system based integrated supportive supervision programs, currently practiced in the health sector in Ethiopia, have very limited scope to evaluate the overall image of RHIS data management process. Separate and program specific supervision system is recommended to overcome such constraints. However, this is poorly practiced for the RHIS in general and data quality and information utilization in particular.

In this study, checklist based supervisory assessment and action oriented written feedback system on data management process will be implemented for one day in every two month period (57). A total of five supportive supervision visits will be delivered for each intervention institution during the intervention period.

The assessment checklist will include DQA activities on data completeness, timeliness, consistency and accuracy. In each visit, DQA will be carried out in intervention facilities and summarized analyses and written feedback will be shared with intervention communities. In addition to the assessment of data quality metrics, the trend of information utilization culture such as data analysis,

data display, PMT implementation, data utilization for planning, and performance evaluation system will be addressed.

Moreover, organizational, technical and behavioral features of RHIS management addressing overall aspects of data quality and information utilization will be monitored. The progresses will be evaluated and further improvement areas will be emphasized. The findings of the supervision will be properly discussed and communicated back for further enhancement via learning workshops, mentorship sessions, and feedback system. The supervisory assessment will be executed by the experts trained on supervisory skills. In addition to supervisory assessment, monthly checklist guided self-assessment will be implemented by the intervention community.

III. Mentorship

Mentoring is the process where an experienced senior one is available to a junior; to make mutual relationship; to share information; to regard as a role model; to guide the performer; to provide feedback and appraisal; to teach all the facts that will enable the individual to perform effectively in an organization (80).

The mentorship program will be organized in every two months that will partly base on the findings of the assessment. Trained HIS experts, from the members of the intervention team, will be the mentors and the intervention communities will be the mentees. The selected mentors will receive mentorship skill training on mentorship manual before employing the process. Close observation, guidance and spot assistance based on initial and subsequent assessment findings will be assessed and forwarded for discussion. Provision of oral feedbacks, sharing of skills, knowledge, and experiences will be practiced. Innovation of best practices on data quality and information utilization system will be executed. Institution-level teamwork, cooperation, and integration system will be practiced. Continuous improvement, encouragement of self-reflection will be emphasized. The mentorship program will be conducted for three days in every two months (a total of four times) of the intervention period in each intervention institution.

IV. Monitoring & Evaluation

Monitoring is a process that generates information and allows the use of such information by management to review the progress of planned projects and their impact on a continuous basis.

Evaluation depends on the data and information produced by the monitoring system as a way of analyzing the trends in effects and impact of the planned project (81).

Facility based PMT meetings that aims to evaluate HMIS performance are unable to be conducted in regular process. Moreover, these sporadic meetings are mainly emphasizing only program indicators than reviewing data quality and information utilization activities in Ethiopia (82).

In this project, every two-month review meetings and learning workshops on supervision findings will be organized on data quality and information utilization in all intervention facilities.

Monitoring will be implemented for the correction and implementation of supervision feedbacks. Furthermore, DQA on timeliness, completeness, accuracy, and consistency of monthly reports, and monthly review meetings will be established and the implemented with data monitoring logbook. Strong monthly data reviewing process, before submission to the next reporting level, will be assured after reinvigoration or establishment of a specific PMT platform in each institution and department. Regarding evaluation, review meetings will be held every two months until the eight-month intervention period will be completed. Each workshop will last two days except the initial training program. Sessions will end after the development of improvement plan to be implemented in the coming months for the enhancement of the data quality and information utilization.

V. Motivation

With relations to the workplace, motivation is defined as, "the predisposition to behave intentionally to achieve specific, unmet needs and the will, and inner force that drives individuals to accomplish personal and organizational goals (83). Successful capacity development initiatives are partly dependent on having the right incentives in place because positive change can only be sustained where improved performance is recognized and awarded (84).

Motivation is categorized into two, financial and non-financial. The financial one is giving monetary value. On the other hand, the non-financial motivation mechanisms comprise the provision of additional responsibility, promotion, praise, appreciation, and recognition in public. It has a key role in initiating the workers for the intended job (85). Workers prefer to share the celebration of achievement with their peers and are delighted to be recognized in their working environment. Workers mostly demand to be acknowledged for their influence and achievement (86).

This project will involve non-financial motivation mechanisms, including individual and organizational certification of outstanding performance, appreciating the workers, departments and facilities by using verbal communication, encouraging the workers to share their successful experience for other facilities, promoting and scaling up their effective intervention approaches whereby inviting poor performing facilities to visit and share the experience of their good performance.

Being a component of behavioral determinants, motivation will be utilized and practiced along with learning workshops in this project.

In conclusion, these all capacity-building activities will be conducted sequentially every two months. First, initial and subsequent supervisory assessments will be executed. Then, feedback provision and learning workshops (in line with motivation) will be organized and followed by mentorship. The intervention facilities will receive all the stated interventions while the control facilities will be given the aforementioned training modules at the end of the study period. SOPs will be established for the implementation of each intervention packages and corresponding activities.

3.7.3. Other Exposures and Baseline Characteristics

Sociodemographic determinants such as age, sex, income, professional background, location of institutions, worker deployment, work experience, educational level, type of institution, and role of the health professionals will be addressed. Income will be assessed by observing a copy of monthly salary slip of each HWs. Professional background will be categorized based on their field of study. Place of institutions will be expressed in terms of urban and rural categorization. The HWs deployment will be assessed by identifying whether their deployment is contractual or permanent. The work experience will be explained in terms of the years of service they provided. Level of education will be identified by interviewing completed levels or status that the HWs attained like masters, degree, diploma, certificate, and below. The type of institution will be determined whether the institution is a district, hospital, HC, or HP. The role of the health professional category will include head of the institution, department head, HMIS institution officer and HW.

Behavioral determinants such as knowledge, skills, competence, motivation, and perception of the HWs who collect, analyze, and use health data will be assessed. Knowledge will be distinguished

by interviewing whether the interviewee will have any awareness of RHIS/HMIS process. It will be evaluated by rating the level of knowledge of respondents on the use of RHIS data stating very good to very poor on a scale of 1 to 5 based on eight relevant questions. The level of competence will be explained in terms of self-efficacy. At least seven questions will be presented to each interviewee and they are expected to rate their level of confidence from 0 to 100%. The motivation of the HWs will be expressed by the level of job satisfaction where the HWs will be asked to rate their agreement from 1 to 5 on eight questions. All results will be presented as a form of an aggregated report (99,176).

Organizational determinants include RHIS governance, planning, training, supervision, quality improvement standard, finance, RHIS capacity development, availability of staff to compile and analyze data, RHIS supplies for data collection and aggregation, and infrastructure for RHIS data management. Governance will address the presence of missions of management structure and updated charts. Planning will identify the availability of recent RHIS situation analysis, RHIS five-year strategic plan and RHIS targets. Training aspect will distinguish the availability of formal or on-the-job training opportunities on RHIS related. The RHIS supervision functions will be assessed in terms of the availability of RHIS supervisory checklists, regular visits and supervisory reports of the health system. The finance system will address the presence of specific financial records and reports on RHIS management (177).

Technical Determinants; include the availability of HMIS reporting format, computers in HMIS & other departments, forms, processes, method of data collection, and computer operating skills.

Indicators selection for assessing data quality and information utilization will be adapted from WHO global reference list of core health indicators (178).

Levels of Variables - Data Quality

Table 4: Exposure variables categorized in individual and institutional level with the outcome of data quality

Variable Type	Level	
	Individual	Institutional
Outcome	<ul style="list-style-type: none"> • Data Accuracy • Data Completeness 	<ul style="list-style-type: none"> • Report Completeness • Report Timelines • Consistency
Exposures	<ul style="list-style-type: none"> • Professional background • Training status • Receive supervision • Quality of Supervision • Level of job satisfaction • Ease of data management • Management support • DQA Experience • Type of intervention 	<ul style="list-style-type: none"> • Type of institution • Method of Reporting • PMT meeting • Budget allocation • Feedback • HMIS personnel • Motivation system • Availability of HMIS tools • Type of intervention

Information Utilization

Table 5: Exposure variables categorized in individual and institutional level with the outcome of information utilization

Variable Type	Level	
	Individual	Institutional
Dependent	<ul style="list-style-type: none">• Level of Information Utilization	
Independent	<ul style="list-style-type: none">• Professional background• Information utilization culture• Training status• Receive supervision• Quality of Supervision• Self-efficacy• Level of knowledge• Level of job satisfaction• Ease of data management• Type of intervention	<ul style="list-style-type: none">• Type of institution• DQA experience• Method of Reporting• PMT meeting• Budget allocation• Feedback• HMIS personnel• Motivation system• Availability of HMIS tools• Type of intervention

3.8. Data Collection Methods

A total of twelve diploma level HIT and six-degree holder (BSc) and masters (MPH) level supervisors (selected from zonal and district level) will be deployed for data collection after three-day intensive training. The questionnaire will be developed in English version and translated to the Amharic language for better understanding of respondents.

The data will be collected with a structured, pre-tested, and standardized questionnaire customized from PRISM assessment tools. The PRISM Tools offers the data collection instruments such as RHIS Overview Tool, Performance Diagnostic Tool, Electronic RHIS Performance Assessment Tool, Management Assessment Tool (MAT), Facility/Office Checklist, and Organizational and Behavioral Assessment Tool (OBAT). RHIS Overview Tool examines technical determinants of

data quality and information use. Performance Diagnostic Tool determines the overall the level of data quality and use of information. Electronic RHIS Performance Assessment Tool examines the functionality and user-friendliness of the technology in HMIS in the current routine health system. The MAT is designed to take rapid stock of RHIS management practices. Facility/Office Checklist, assesses the availability and status of resources needed for RHIS implementation. The OBAT identifies behavioral and organizational determinants of data quality and information utilization (87). This standard tool was developed by MEASURE Evaluation (in collaboration with WHO) and it is used in previous other studies (9).

The initial six-day training will be provided for HWs selected from intervention facilities on data quality and information utilization activities. Then, regular every two-month supervision, mentorship, review meeting and feedback system will be conducted by intervention team. Every three-month assessment will be carried out during the eight-month intervention period. The retention of the research participant in the follow-up window will be improved by including participants who had no recent plan to leave the facility and assuring clear assessment schedules.

The data will be collected using electronic formatted face to face interview questionnaires, document review templates, physical observation checklist that will be used for organizing surveys, reviewing documents and conducting observations. For document review, checklist adapted from MOH HMIS guideline will be used (34).

3.9. Statistical Analysis

Data will be checked for completeness, consistency and entered in to EpiData vision 4.6.0.2 and exported to SPSS Version 26 for analysis. Descriptive statistics including frequencies and proportions will be used for presenting categorical data where as mean, and standard deviation will be computed for continuous variables. The 95% confidence interval will be used.

Simple linear and logistic regression will be done for bivariate analysis to identify potential candidate variables for multivariable analysis in the regression models. Variables with a p-value of less than 0.25 in the bivariate analysis will be entered into the multivariable regression analysis. A p-value of less than 0.05 in the multivariable regression analysis will be reported to identify predictor variables significantly associated with the outcome variable (88). The results will be analyzed and presented in the form of texts, tables and graphs.

Pieces of available evidence indicate that the data to be collected from similar public health facilities or repeated time points possibly related to each other in the dataset. So, models that consider such dataset will be selected to account the dependency in the observation since it increases the precision of estimation (89).

Modifiers of the effect in the analyses will be assured by computing subgroup analyses. Moreover, the evaluation of potential factors influencing treatment effect (confounders) will also be assured and reported.

Separate and detailed descriptive analysis will be done for the each of the four data quality dimensions in the study I. Multivariable analysis will also be carried out for selected dimensions of data quality.

Study I

Mixed Analysis of Variance (ANOVA) Analysis will be done for timeliness, completeness, and consistency dimensions. Data accuracy will be analyzed using Repeated Measure General Linear Mixed Model (GLMM) to assess changes in data duality from the baseline to post-intervention phases. These methods, as a component of repeated measure designs, are designed because they are supposed to address the changes in outcome variable over time and the impact of predictors on the changes while accounting the effect of clustering (90).

Study II

The generalized estimating equations (GEE) will be designed to assess the impact of potential effect of clustering for the research participants of the same institution. The other goal of the design is to investigate whether there exists significant change in information utilization after implementation of intervention over repeated periods meanwhile comparing the intervention arm against the control (routine service) (91).

Handling Missing Data

The missing data and drop outs of the research participant due to loss to follow-up or other reasons will be handled in the analysis by replacing the missing follow-up value on item level with the Weighted Estimating Equations (WEE) method. This assumption is considered in line with designing intention to treat (ITT) analysis.

3.10. Validity and Reliability

A three-day initial training will be given to data collectors and supervisors on data collection techniques, categorization and coding of the questionnaire. The pretesting of the questionnaire will be conducted on 5% of the HWs (a total of 20) sampled from health facilities in Uba Debretsehay districts (is comparable to the study sites) to identify ambiguity, consistency, and acceptability of the questionnaire as well as the time needed to fill the questionnaires. The data of pretest will be analyzed to obtain Cronbach's alpha for measuring internal consistency of the questionnaire. A reliability coefficient of 0.70 or higher will be deemed reliable (92) although the questionnaire is standardized, adopted from PRISM series. During data collection, about 10% of collected samples will be rechecked daily for correctness and completeness by supervisors and PI and necessary feedback will be offered before the next actual process. In addition, about 10 HIS panel of experts will be individually consulted to rate and review the tool to obtain feedback on the appropriateness of the tool (93).

3.11. Ethical Considerations

3.11.1. Ethical Approval

Ethical approval of the protocol for this study will be received from the IRB of the College of Medicine and Health Sciences, Hawassa University. Ethical committee approval will also be received from SNNP Regional Health Bureau. Permission letter will be obtained from the Gofa Zone Health Department, District Health Offices and each of respective HFs.

3.11.2. Information and Informed consent

Informed written consent will also be obtained from each study participant. Information about the purpose of study will be provided to each participant and their anonymity and the confidentiality of responses and right to withdraw at any stage will be emphasized. All procedures will be conducted based on their voluntary participation.

3.12. Dissemination of Results

The result of this study will be presented to Hawassa University, to the College of Medicine and Health Sciences School of Public Health as partial fulfillment for Doctor of Philosophy in Public Health. The findings will be shared to SNNPR Health Bureau, Gofa Zone Health Department and

national DDCF project office. Furthermore, it will be disseminated to all health facilities included under the study. It will also be requested and presented (if accepted) in invited seminars and conferences to give tangible evidence to different stakeholders who are interested on the project. The study will be published in peer reviewed journals to give a piece of evidence for policymakers, researchers, concerned stakeholders. Dissemination of materials to all concerned stakeholders will be done after publication of both studies.

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