

Quality of Laboratory Service for Focused Antenatal Care Services on the Era of COVID 19 at Public Health Facilities of Jimma Town South West Ethiopia

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Abstract

Background: Identifying pathological and normal physiological changes in pregnant women is among the responsibility of focused antenatal care which laboratory services share it. Focused antenatal care laboratory service is a unit of laboratory in which pregnant women's samples analyzed to detect pathogen or pregnancy-related metabolic change (anemia, gestational diabetes).

Method: Case study Evaluation design using both qualitative and quantitative methods was employed at public health facilities of Jimma town from May 03 to 2021. Donabedian's Structure-Process-Outcome model was used. A total of 414 admitted clients were included by consecutive sampling technique. Moreover, 81 client-provider interactions, 81 clients' charts, one year selected documents and 14 key informants were included. Simple and multivariable linear regression analysis techniques were used. Qualitative data were analyzed manually and presented as triangulation with the quantitative results. The overall quality of the service was determined based on judgmental criteria.

In-depth interviews, client surveys, document reviews, observation, and resource inventory were methods of data collection. Availability, compliance, and satisfactions were the dimension of this study. All health facilities in Jimma town were included. Consecutively sampled 414 pregnant women were included in the survey. SPSS version 26 was used for quantitative data analysis while qualitative data was analyzed, transcribed, and translated manually. A triangulation of qualitative and quantitative findings was done.

Result: All facilities had tap water and a tanker for water storage as a backup, five of them had a generator as a backup for the electric interruption, all had a microscope and only referral and the general hospital had a CBC analyzer. 5 health facilities professionals disinfect the working area and all professionals put on personal protective equipment before starting routine activities, no professionals conducted internal quality control for focused antenatal care laboratory reagents and kit on observation session, from 414 pregnant women 223(53.6%) were satisfied with overall laboratory service.

Conclusion and recommendation: The overall quality of laboratory service for focused antenatal care follow-up pregnant women was judged as good. Improving the quality of laboratory service needs integrated effort from all lab personnel, the town health department, the Oromia health Bureau, the Oromia regional lab, and the federal ministry of health.

Keywords: Jimma town • Embedded single case study • FANC laboratory • Public health facilities

Abbreviations: EA: Evaluability Assessment, EQA: External Quality Assessment FANC: Focused Antenatal care, HBV: Hepatitis B virus, Hepatitis B surface antigen; HIV: Human immune Deficiency virus, IQC: Internal quality control, PU: Protein Urea, RDT: Rapid Diagnostic Test, VDRL: Venereal disease research laboratory, WHO: World health organization

Introduction

Pregnancy is a factor for both physiological and anatomical change significantly; in order to keep the normal development of the fetus, it can affect most organ systems of the mother. These changes will terminate with minimal residual effect after the mother give birth. Differentiating normal physiological change and pathological condition is mandatory for health professionals to give appropriate services for pregnant women. Hematological, cardiac, respiratory, hormonal, glucose metabolism, protein metabolism, lipid metabolism, and minerals metabolism are among the change that encounters pregnant women [1].

World Health Organization (WHO) recommends four comprehensive antenatal care visits for pregnant women before giving birth to guarantee adequate screening, treatment, and care. Focused Antenatal Care (FANC) is an intervention given to pregnant mothers by skilled health professionals to pregnant mother and their baby to keep the best health condition for both. This intervention helps professionals to identify pathological or normal physiological changes of pregnant women with different screening methods. Besides this risk identification, health promotion, health education, and prevention of pregnancy-related problems are components of this intervention [2]. It is a way of reaching pregnant women with helpful intervention to control preventable mortality and morbidity and to have safe and healthy birth delivery [3].

Medical Laboratory service is a component of health interventions that are fortified with various biomedical instruments, equipment, materials, and reagents (chemicals) for performing different medical laboratory diagnostic or investigative activities by using biological specimens (whole blood, serum, plasma, urine, stool, sputum, exudates etc.) for the purpose of disease detection, management, and healthy living assessments [4]. A focused antenatal care laboratory is unit of laboratory in which a sample of pregnant women is analyzed in order to detect pathogen or pregnancy-related metabolic change. Urine and blood tests are among the component of antenatal care programs that help to assess the health condition of pregnant women for early determination and management of pregnancy-related metabolic change and infectious pathogens. Urine analysis, hematocrit determination, rapid Hepatitis B Virus (HBV) test, Venereal Disease Research Laboratory (VDRL) test, and blood grouping with Rh factor are basic laboratory assays that should be done for pregnant women. In addition, these tests have a role in the prevention of mother-to-child transmission of infectious pathogen like HIV, HBV, and Syphilis. For the mother's first FANC visit Complete blood count, Blood group and antibody screen, syphilis serology, Hepatitis B serology, and HIV abs testing are recommended. The most important test in the second antenatal testing screen is gestational diabetes screening and protein detection in urine to rule out preeclampsia [5].

Credible and reliable laboratory service helps in evidence-based decision-making in the health care system [6]. It increases the accuracy of disease detection and early management of service user. In developed countries, the majority of medical decisions are based on medical laboratory tests; for example in the United States, 70% of all medical decisions are based on accurate and reliable laboratory tests. Whereas in developing countries like Sub-Saharan, the majority of treatment decisions are based on clinical judgment [7].

To assure quality laboratory service, all aspect of laboratory operation including organizational, structural, and process needs to be addressed. Continuous monitoring of the total testing process of the clinical laboratory is essential to provide quality laboratory service. The total testing process of laboratory service is a process and procedure in pre-analytical analytical and post-analytical laboratory activity [8]. In Ethiopia, the Ethiopian health nutrition and research institute with a regional laboratory have the mandate to establish and support a laboratory quality assurance system.

Assessing the quality of laboratory service for FANC in the Era of COVID-19 is crucial for early identification and taking corrective action

to reduce maternal and perinatal mortality. However, up to the knowledge of the principal investigator, while searching different literature, there was no study done to assess the quality of laboratory service for FANC on the Era of COVID-19 in Ethiopia in General. Therefore, this study helps to assess the quality of laboratory service for FANC on the Era of COVID-19 among women's received FANC at public Hospitals in Jimma Zone using both qualitative and quantitative studies. The finding will help improve all concerned bodies' understanding of the level of service quality and serves as an important tool for planning and resource allocation that aimed to improve the service.

Materials and Methods

Evaluation design and setting

This study was conducted in Jimma town, which is the capital town of the Jimma zone, in the Oromia region located 354 km away from Addis Ababa, the capital city of Ethiopia in the southwest direction. There are 13 urban and 4 rural kebeles in the town. According to the housing and population census conducted in 1998, the total population size of the town was projected to be 190,598, in 2017 of which 95,841 are males and 94,757 were females. Regarding health service facilities, under the Jimma town health office there are 4 health centers, one general and one referral government hospital.

Case study evaluation design with the mixed method of data collection was used to evaluate the process of quality laboratory service for FANC follow-up pregnant women in public health facilities of Jimma town southwest Ethiopia from May 03 to 30, 2020 Qualitative and quantitative data was collected concurrently, analyzed separately, and integrated during interpretation of findings.

Variables and measurement

A formative evaluation approach was used to evaluate the quality of FANC tests for pregnant women. The availability of resources was assessed using 15 indicators, compliance dimension was measured using, 10 indicators. In addition, maternal satisfaction was assessed using 9. A pregnant woman who scored more than 19.5 was considered satisfied and a pregnant woman who scored below 19.5 was considered as dissatisfied. The mean score was used as cut -of value and it was 19.42.

The indicators were developed from other related evaluation and some laboratory guidelines. The judgment parameter was determined based on the calculated indicators score. Investigators judged 91%-100% excellent, >81%-90% very good, 71%-80% good, 61%-70% fair, <=60% poor respectively.

Sample size and sampling procedure

Single population formula ($n = (z\alpha/2)^2 p(1-p)/d^2$) was used to determine the sample size for women for exit interviewee. $P=43.3\%$ which was taken from study conducted in Addis abeba, the margin of error was 0.5, the added none respondent rate was 10% and the final sample size was 414 for client exit interviews [9]. Six-month FANC register and 414 client cars was assessed from six public health facilities that provide laboratory service, 14 key informants was interviewed and 30 observation session was conducted. The consecutive sampling technique was used to select women for an exit interview and the purposive sampling technique was used for selecting Key informants, and program documents.

Data collection tools and procedures

All questionnaires, checklists, and document reviews have been prepared by considering WHO guidelines. Data collection instrument for quantitative method: structured questionnaire for availability, maternal satisfaction, and observation session was translated to afaan Oromo and Amharic language back to English for a checkup and was used for data collection whereas for the qualitative method interview guide had been adopted and was translated to afaan Oromo language and in-depth interview was made with the concerned body. For this purpose tape recorder was used.

A structured questionnaire, which contains specific components on the background characteristics of the client, socioeconomics, and satisfaction for laboratory service of FANC and received information at FANC, was prepared for the interview. For an in-depth interview, the semi-structured guide was prepared for a different level of key informants of FANC service in Jimma town public health facilities in relation to the availability, compliance, and satisfaction. An observation checklist was

prepared to conduct a direct observation of facilities infrastructure, and laboratory service provision starting from client reception to result in dispatch for pregnant women who will be sent to a laboratory for a comprehensive investigation. In addition, document review checklists was prepared to collect data from program documents of FANC care users that would check activity plans, manuals, and reports to assess compliance to MCH national guidelines. All the data collection tools were developed from WHO guidelines [10].

Data management and quality control

For quantitative data analysis statistical package for social science version, 26 was used and this result was compared based on evaluation matrix judgment to determine the level of quality of the service. The satisfaction of each respondent was measured by a 5-Likert scale which was ranked into five quintiles (lowest, second, middle, fourth, and highest) to access maternal satisfaction with laboratory service. Score 5 was given for very satisfied, 4 for satisfied, 3 for neither satisfied nor dissatisfied, 2 for dissatisfied, and 1 for very dissatisfied. The mean satisfaction level was used as cut-off value and it was found to be 19.42.

The qualitative data was gathered, transcribed into the text format of the local language, and translated into the English language. Then it was analyzed manually using thematic analysis with respective dimensions and results were presented in a narrative format. The final interpretations of the results were based on evaluation weights and statistical analysis results of the evaluation.

Descriptive statistics were calculated for all variables. In bi-variate analysis crude odds ratio and confidence interval were determined to select candidate variables for multivariate analysis at the level of significance ($p < 0.05$). Binary and multivariate logistic regressions were used to determine the adjusted odds ratio and corresponding 95% confidence interval. The maximum likelihood estimate of the independent effect of the predictor variables was used to see the level of significance. The strength of association will be interpreted using the adjusted odds ratio and 95% CI. The criterion for statistical significance was set at $p < 0.05$.

Ethical consideration

Ethical clearance was obtained from the institutional review board of Jimma University and informed written consent. A written letter of cooperation from the Jimma town health department office was written to the health centers. Before data collection, explaining the purpose of the study, and the confidentiality and privacy of the participants in the study were maintained throughout the process of data collection. Telling the participants as voluntary participation and their right to refuse or withdraw at any time was taken into consideration. The evaluation teams were trained on how to handle sensitive and emotional issues and on the importance of keeping confidentiality. Conflict of interest was identified and dealt with by participants openly and honestly so that it would not compromise the evaluation processes and results.

Result

Availability dimension

Human resource availability: A total of 103 laboratory personnel were working in the study period in all (six) public health facilities of Jimma town. Of these personnel 83(80.58%) were working in Jimma university medical center hospital while 14(13.59%) and 6(5.82%) were working in Shenen gibe general hospital and health centers, respectively. Regarding education level, 76.70% were BSC holder, 14(13.59) were diplomas and 11(9.71%) were MSc holder (Table 1).

This finding was supported by an in-depth interview, as "this facility needs more personnel. Because, it have a side lab for different department like an emergency, MCH and the newly opened COVID center beside this the turnover rate of personnel is high in this facility because of annual education opportunity and some personnel leave the facility when they full fill their duty therefor the facility hire personnel annually". Another key informant from health center said "our responsibility is only reporting as there is a shortage of personnel the mandate of hiring human resource is up to town health department". It is also explained by another 35 years male key informant from town health department reported as; "most of the time we don't hire new personnel but we hire personnel that had worked in Jimma zone, nevertheless currently there is a shortage of personnel in Jimma zone also even some health centers laboratory were closed due to shortage".

Table 1. Human resource availability at public health facilities of Jimma Town, 2021.

| Human resource | Jimma health center | Higher two health center | Mendera kochi health center | Becho bore health center | Shenen gibe general hospital | Jimma university medical center | Total |
|-----------------------------------|---------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------------|-------|
| Number of Laboratory technician | 0 | 0 | 0 | 1 | 4 | 9 | 14 |
| Number of Laboratory technologist | 2 | 1 | 1 | 1 | 10 | 64 | 79 |
| Number Msc lab professionals | 0 | 0 | 0 | 0 | 1 | 10 | 11 |

Table 2. Availability of infrastructure at public health facilities of Jimma Town, 2021.

| Available resource and infrastructure | Name of facilities | | | | | |
|--|---------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------------|
| | Jimma health center | Higher two health center | Mendera kochi health center | Becho bore health center | Shenen gibe general hospital | Jimma university medical center |
| Separate sample collection area | No | No | No | No | Yes | Yes |
| Tape water with backup | Yes | Yes | Yes | Yes | Yes | Yes |
| Availability Generator | Yes | Yes | Yes | Yes | Yes | Yes |
| Availability and functionality of hand washing station near the toilet | No | Yes | No | Yes | Yes | No |

Table 3. Availability of laboratory equipment, reagent and documents at public health facilities of Jimma Town, 2021.

| Are the following FANC reagent and kits available? | Jimma health center | Higher two health center | Mendera kochi health center | Becho bore health center | Shenen gibe general hospital | Jimma university medical center |
|--|---------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------------|
| HBSag test kit | Yes | No | No | Yes | No | Yes |
| VDRL/RPR test kit | Yes | No | Yes | Yes | Yes | No |
| HIV test kit | Yes | Yes | Yes | Yes | Yes | Yes |
| Urine dipstick | Yes | Yes | Yes | Yes | Yes | Yes |
| CBC reagents | No | No | No | No | Yes | Yes |
| Isotonic normal saline | Yes | Yes | Yes | Yes | Yes | Yes |
| Giemsa stain | Yes | Yes | Yes | Yes | Yes | Yes |

Availability of infrastructure: The hand washing station near the toilet was not functional for Jimma medical center, Jimma health center, and mendera kochi health center during the study period, even if there is difference in space and comfort. All facilities had result waiting area, only referral hospitals and the general hospital had separate sample collection areas, all facilities had tap water and tanker for backup, and only one facility has no generator (Table 2).

"Water and electric interruption is common here. This makes it difficult to give services like a laboratory. Therefore, facilities should have back up for these infrastructures, and most facilities have had bought generator and water tanker either from their health care finance, or have had got as a donation" (36-year-old key informant). "The town health department does not give concern to shortage of room for facilities that is why we work with in a single room year to year in spite the patient follow is increasing yearly" (29-year laboratory technologist).

"The tap water on hand washing station frequently break due to miss use and it was not repaired for a long time" (32 service provider).

"We have put a bench near the laboratory for client waiting area but this is not enough compared with patient follow" (47-year laboratory technologist).

Availability of laboratory equipment, reagent and documents: All facilities have functional microscopes and centrifuges, there were only in referral and general hospital functional CBC analyzers and all health centers have no functional hemoglobin measuring machine.

All facilities have job aid and SOP for FANC tests but all have no IQC materials for FANC tests except VDRL, there was in only a referral hospital and higher two health center laboratory log books for FANC result registration, two of health centers have no documented TAT for FANC tests. In all health centers there was no thermometer for room temperature monitoring, 2 facilities have a lab log book for FANC tests separately.

Regarding kit and reagent, Becho bore and mendera, Kochi health centers have HBSag kit, VDRL, urine dipstick, HIV test kit, and ABO blood grouping for at least three months. ABO blood grouping, urine dipstick, and HIV test kit for at least three months and in Jimma health center. However, there was a service interruption for HBSag and VDR. In general hospitals, there was a shortage of HBSag but there were VDRL, HIV, ABO

blood grouping, urine dipsticks, and CBC reagents (Table 3).

A 28 years old lab professional key informant explores, the presence of a shortage of lab regents and kits in the facilities "Laboratory wares like slide, cover slide, and urine cup are accessible on market and even it is reusable for ." Another key informant also responded as "...methods used to measure hematocrit was manual which is not advisable for a facility having high patient load and now we have planned to have CBC machine at least in Jimm a health center"

From the key informant responses, the major resource for a shortage of regents for ANC lab tests was shortage of budget. A 32-year-old facility head responded as "I think the main problem of shortage of lab reagent and kit emerges from currency problem as country and shortage of budget for health facility due to inappropriate plan that might be as a result of information gap"

Another major reason for the shortage of regents was the drug/regent procurement process; we are recommended to purchase all regents and drugs from EPSA, but we couldn't find the required quantity and type. 34 years old male pharmacist explored as "We do not participate in the purchasing process of laboratory reagents and kit and therefore purchaser sometimes may bring unwanted reagent and kit, inadequate quantity of input even reagents that have near expiry date and improperly stored reagent."

Compliance Dimension

Compliance with biosafety standard: For biosafety, all personnel were vaccinated for HBSag, out of 30 observation sessions conducted all personnel dispose of sharp infectious wastes separately, all professionals were put on personnel protective equipment and six personnel participated in observation session 5 (83.33%) were cleaned and disinfect the working area before starting routine activities (Table 4). This has been supported by an in-depth interview as "Nowadays most personnel have got safety training and no shortage of PPE currently additionally the outbreak of covid-19 have contributed to put on PPE strictly" (28 years key informant).

Compliance with customer handling, quality control and sample processing standard: No professionals conducted internal quality control for FANC reagents and kits on the observation session. out of 10 personnel participated on observation session, 6(60%) have greeted pregnant women who came laboratory, 9(90%) professionals have identified for

Table 4. Compliance lab personnel with biosafety standards at public health facilities of Jimma Town, 2021.

| Indicators | Jimma health center | Higher two health center | Mendera kochi health center | Becho bore health center | Shenen gibe general hospital | Jimma university medical center | Total |
|--|---------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------------|-------|
| Number of personnel vaccinated for Hbsag during observant session | 2 | 1 | 1 | 2 | 2 | 2 | 10 |
| Number of laboratory personnel put on PPE before starting routine activity | 2 | 1 | 1 | 2 | 2 | 2 | 10 |
| Proportion of observation session in which personnel disposed of sharp infectious waste separately | 5 | 5 | 5 | 5 | 5 | 5 | 30 |
| Number of personnel clean and disinfect working area before starting routine activity | 1 | 1 | 0 | 1 | 1 | 1 | 5 |

Table 5. Compliance with customer handling, quality control and sample processing standard at public health facilities of Jimma Town, 2021.

| Activities | Name of facilities | | | | | |
|--|---------------------|--------------------------|-----------------------------|--------------------------|------------------------------|---------------------------------|
| | Jimma health center | Higher two health center | Mendera kochi health center | Becho bore health center | Shenen gibe general hospital | Jimma university medical center |
| Are the laboratory professionals do the following activities | | | | | | |
| Number of laboratory personnel greeting pregnant women who came to laboratory during observation session | 2 | 1 | 0 | 1 | 1 | 1 |
| Number of laboratory personnel checking for completeness of request paper | 2 | 1 | 1 | 2 | 2 | 2 |
| Proportion of client who get information to bring appropriate sample outside laboratory | 3 | 4 | 5 | 5 | 3 | 2 |
| Number of laboratory personnel orient pregnant women to bring appropriate sample outside laboratory | 1 | 1 | 1 | 1 | 1 | 1 |
| proportion of laboratory result given to pregnant women as per TAT during observation session | 3 | 3 | 4 | 5 | 4 | 2 |
| Number of laboratory personnel follow job aid for HBsa, HIV, VDRL, tests | 5 | 5 | 5 | 5 | 5 | 5 |
| Number of laboratory personnel centrifuge urine for sediment dx | 0 | 0 | 0 | 0 | 0 | 0 |
| Number of laboratory personnel who do IQC for FANC tests during observation session | 0 | 0 | 0 | 0 | 0 | 0 |

Table 6. FANC tests performed at public health facilities of Jimma Town, 2021 (n=414).

| Are the following FANC tests performed? | Referral hospital | General hospital | Jimma HC | Higher two HC | Becho bore HC | Mendera kochi HC | Private laboratory | Total | Percent |
|--|-------------------|------------------|----------|---------------|---------------|------------------|--------------------|-------|---------|
| Proportion of pregnant mother who tested for Hbsag | 92 | 53 | 50 | 40 | 37 | 26 | 40 | 338 | 78.84 |
| Proportion of pregnant mother who tested for VDRL | 103 | 94 | 55 | 30 | 40 | 20 | 23 | 365 | 91.28 |
| Urine | 98 | 102 | 60 | 35 | 40 | 33 | 0 | 368 | 97.61% |
| Proportion of pregnant mother who tested for Hematocrit | 107 | 70 | 0 | 0 | 0 | 0 | 0 | 177 | 46.95% |
| Proportion of pregnant mother who tested for Blood group & rh | 105 | 97 | 60 | 38 | 40 | 30 | 0 | 370 | 98.14 |
| Proportion of pregnant mother who tested for Blood glucose level | 27 | 0 | 0 | 0 | 0 | 0 | 0 | 27 | 7.16 |
| Proportion of pregnant mother who tested for Stool examination | 26 | 18 | 15 | 10 | 12 | 12 | 0 | 93 | 24.67 |

completeness of request paper, 9(90%) professional have ordered to bring appropriate urine sample, 6(60%) professionals have tolled waiting time of laboratory result. In addition, no professionals centrifuged urine for sediment in all observation sessions, 7(70%) professionals were not clean the microscope after the procedure and all recorded results on a log book before dispatching the result among 30 clients who came to the laboratory during observation session 22(73%) have informed to bring appropriate sample outside the laboratory. Regarding external quality assessment participation, all facilities participate EQA for the HIV test and only 1 facility participates EQA for the hepatitis B test (Table 5).

A 28-year BSC midwifery key informant responded as "I'm the MCH coordinator of this facility and I have four years of experience regarding FANC laboratory tests we order all tests, especially for first ANC the problem in this facility is laboratory personnel does not test HBSag routinely. They tell us as there is a shortage of kit for routine test, On the other hand, the prevalence of the Hepatitis b virus is increasing now a day and it is mandatory to screen mothers".

One of the major resound was explained by a 28 KI as "We may not greet all pregnant women who came here because of patient load I focus on

provision of service timely for all client". Another key informant responded as "Conducting EQA for lab test is the concern of regional lab but they give emphasis for only few test like HIV"

Compliance dimension

Regarding document review all facilities have ANC register. From this register 3455 pregnant women have visited ANC six months back from the study period and all have screened for HIV, 3012(87.17%) have screened for syphilis in the facilities and 2955(85.53) pregnant women for HBSag screening. Out of 3455 pregnant women screened for HIV 26(0.75%) are positive and out of positive pregnant women, 7(26.92%) are ART follow. Among 2955 HBSag-screened pregnant women 34(1.15%) were positive. Concerning the syphilis test among 3425 screened pregnant women 12 were positive.

Similarly, from 414 client card from the client survey conducted in all facilities, information for urine analysis, hemoglobin measurement, random glucose assay, and stool exam were gathered. Among 414 client card 298(71.98%) have screened for HBSag out of which 9(2.17) were positive. 342 were screened for Syphilis from these 5(1.2%) were positive.

The majority of the respondents (89%) were screened for urine analysis out of which 31(8.42%) were positive for protein urea. But Only, 27(6.52%) were screened for blood glucose in referral hospitals, and 93(22.46%) were screened for intestinal parasites among these 5 clients had infected with *G.lablia* and 2 were infected with hookworm. Out of 414 clients, 40(9.66%) have screened for Hbsag in a private laboratory and 23(5.55%) have screened for syphilis in a private laboratory (Table 6).

Client satisfaction

Socio-demographic character: A total of 414 pregnant women were involved in this study and the response rate was 100%. Among these 183 (44.2%) were from health centers 111 (26.8%) were from the general hospital and 120 (29.0%) were from a referral hospitals. Of 414 pregnant mothers 222 (53.6%) were in the age group of 17-23, 405 (97.8%) were married, 296(71.5%) were Muslim, 143 (34.5%) had family monthly income between 1500-2000 Ethiopian birr, 150 (36.2%) had attended primary school education and 206 (49.8%) were housewife (Table 7).

Obstetrics history: Of 414 pregnant women 159(38.2%) were with their first pregnancy, 9(2.2%) have encountered still birth, 7(1.7%) have chilled with birth defect 30(7.2%) have encountered spontaneous abortion and 409(98.3%) have number of chilled between 0-4 (Table 8).

Level of women's satisfaction towards FANC

Of 414 pregnant women, 40.9% were strongly satisfied with the welcoming of laboratory personnel, and 37.5% were satisfied with the

cleanness of the sample reception area. Half (46.2%) were moderately satisfied about the information they gain to bring samples outside the laboratory, 32.7% were satisfied with the accessibility and availability of toilets, 42.5% were satisfied about keeping their result confidential. Moreover, 40.4% were moderately satisfied about the turnaround time of laboratory results and 39.2% were moderately satisfied with result waiting area (Table 9)

Form the overall likert scale satisfaction level used, the mode was 20, the maximum score was 33, the minimum was 8, mean score was 19.42 and the standard deviation was 5.38. Based on these the mean was used as cut point. Therefore any score below 19.42 was considered as unsatisfied and score 19.42 and above was considered as satisfied. Similarly for all satisfaction variable score below the mean value were considered as unsatisfied and having a score equal to mean and above was considered as satisfied. Based on the cut-of-value determined 191(46.1%) pregnant women was unsatisfied and 223(53.9%) was satisfied.

Discussion

In this study process evaluation of quality of laboratory service for focused antenatal care follow-up pregnant women in public health facilities of Jimma town southwest Ethiopia was assessed based on Donabedian structure-process-outcome model. The finding of this study shows that the overall quality of the laboratory for FANC follow-up pregnant women was 71.01. The result for availability, compliance, and satisfaction separately were 21.56/30, 21.58/30, and 27.88/40 respectively.

Enough space (sample collection area, client waiting area reagent, and kit store), electric supply and water supply are basic infrastructure that health facilities should fulfill in order to give clinical laboratory services. In case power interruption happen, the facility should have a backup generator and similarly reliable supply of running water with 5000 L tanker for backup should be avail [11,12]. But the finding of this study shows that among six facilities 3 health centers have only one room which compromises the standard Jimma health center had three rooms, general hospital had 5 and referral hospital had 10 rooms. Only referral hospitals and general hospital had separate sample collection area and all have client waiting area. This was consistent with study conducted in Addis Abeba [13]. This implies that shortage of space for different laboratory activities is common for most of the facilities. The finding was supported by an in-depth interview as the town health department do not

Table 7. Socio-demographic character at public health facilities of Jimma Town, 2021(n=414).

| Variables | Frequency (414) | Percent | |
|--------------------|---------------------|---------|------|
| Age | 17-23 | 157 | 37.9 |
| | 24-30 | 222 | 53.6 |
| | 31-37 | 31 | 7.5 |
| | 38-45 | 4 | 1 |
| Marital status | Single | 6 | 1.4 |
| | Divorced | 2 | 0.5 |
| | Married | 405 | 97.8 |
| | Widowed | 1 | 0.2 |
| Level of education | No education | 81 | 19.6 |
| | Read and write only | 57 | 13.8 |
| | Primary education | 150 | 36.2 |
| | Secondary education | 87 | 21 |
| | Higher education | 39 | 9.4 |
| Occupation | Government worker | 53 | 12.8 |
| | Farmer | 6 | 1.4 |
| | Merchant | 91 | 22 |
| | House wife | 206 | 49.8 |
| | Daily labor | 30 | 7.2 |
| | Student | 25 | 6 |
| | NGO worker | 3 | 0.7 |
| | Religion | Muslim | 296 |
| Orthodox | 58 | 14 | |
| Protestant | 53 | 12.8 | |
| Catholic | 6 | 1.4 | |
| Waaqeffanaa | 1 | 0.2 | |
| Monthly income | 1000-1500 | 132 | 31.9 |
| | 1500-2000 | 143 | 34.5 |
| | Above 2000 | 139 | 33.6 |

Table 8. Obstetrics history at public health facilities of Jimma Town, 2021(n=414).

| Variable | Category | Frequency | Percent |
|---|----------|-----------|---------|
| Number of pregnancy | 01-Mar | 354 | 85.5 |
| | 04-Jul | 60 | 14.5 |
| Number of delivery in health facilities | 0 | 165 | 39.9 |
| | 1 | 119 | 28.7 |
| | 2 | 81 | 19.6 |
| | 3 | 30 | 7.2 |
| | 4 | 16 | 3.9 |
| | 5 | 3 | 0.7 |
| History of still birth | Yes | 8 | 1.9 |
| | No | 406 | 98.1 |
| History of spontaneous abortion | Yes | 30 | 7.2 |
| | No | 384 | 92.8 |
| Number of FANC visit | 01-Mar | 318 | 76.8 |
| | 04-Aug | 96 | 23.2 |
| Number of children | 0-4 | | |
| | >4 | | |

Table 9. Level of women's satisfaction on FANC at public health facilities of Jimma Town, 2021(n=414).

| Variable | Strongly Dissatisfied | Dissatisfied | Neutral | Satisfied | Strongly satisfied |
|--|-----------------------|--------------|------------|------------|--------------------|
| Greeting and welcoming | 0(0%) | 30(7.2%) | 89(21.5%) | 125(30.2%) | 170(41.1%) |
| Cleanness of sample reception area | 9(2.2%) | 33(8.0%) | 99(23.9%) | 155(37.4%) | 118(28.5%) |
| Information about test order | 0(0%) | 55(13.3%) | 168(40.6%) | 138(33.3%) | 53(12.8%) |
| Information to bring sample outside the laboratory | 0(0%) | 51(12.3%) | 190(45.9%) | 133(32.1%) | 40(9.7%) |
| Accessibility of toilet | 3(.7%) | 82(19.8%) | 125(30.2%) | 135(32.6%) | 69(16.7%) |
| Result waiting area | 16(3.8%) | 111(26.7%) | 163(39.2%) | 79(19.0%) | 47(11.3%) |
| Turnaround time | 3(.7%) | 93(22.5%) | 166(40.1%) | 98(23.7%) | 54(13.0%) |
| Confidentiality | 0(0%) | 22(5.3%) | 69(16.7%) | 176(42.5%) | 147(35.5%) |

give concern to the shortage of room for facilities that is why we work with in a single room year to year inspire the patient follow is increasing yearly. Inappropriate use of space, absence of plan to repair facilities and lack of follow up about this issue by concerned body could be possible reason for shortage of room. This may hamper safe laboratory service because of the crowdedness of working area by different activities which facilitate injuries in the laboratory. All facilities(100%) have water tanker and 5(83.33) have generator as backup for water and electric interruption and this have been supported with an in-depth interview as "since water and electric interruption is common here facilities have bought generator and water tanker as back up". This finding was higher when compared to other study conducted in Addis Abeba which had reported as 61.5% for generator. Gaps in number of public health facilities in the town and frequency of electric interruption could be factors that contribute for the difference.

Adequate lab professionals is another factor that can affect the quality of the service. As this study shows referral hospitals, general hospital, and health centers have 83, 14, 6 laboratory professionals. There was 103 laboratory personnel in all health facilities. Among these, health centers have fulfilled 75% of its minimum national guideline requirement for human resource and both hospital fulfill 100% [14]. This is consistent with study conducted in Addis Abeba that have result of 77.5% for health center and 92.4% for hospital [13]. This indicate that there is shortage of laboratory personnel in health center than hospital commonly for most facilities which might be as result of personnel preference, shortage of budget to hire personnel on health center and poor human resource management. This had been supported by interview from jimma medical center as this facility needs more personnel because it have side lab for different department like emergency, MCH and newly opened covid center'

Furthermore, facilities have to fulfill basic reagent and kit for laboratory in general and FANC tests in particular like HBSag kit, HIV test kit, VDRL reagent, urine dipstick and kit for hematocrit test. The finding of this study shows that out of 6 facilities all had HIV test kit while there was service interruption for Hbsa and VDRL in higre two health center and Hbsa in shenen gibe hospital. Even if there was no service interruption in referral hospital and Jimma health center, there was no sufficient Hbsag test kit that serve for at least three month during study period. Similarly 4(66.66) facilities have no hematocrit tests totally. This implies that Service interruption is common for FANC test which may be the result of frequent stock out of lab reagent and kit that could attribute to shortage of supplier, poor inventory management system, lack of consumption data and poor adherence to standards in some facilities. This has been supported with in-depth interview as ".stock out of laboratory inputs encounter frequently for example if you take syphilis test it was interrupted for around two months due to stakeout. When compared with other study, availability of HIV test kit in all, HBSag test kit in 4(66.66) facilities, and VDRL test kit in 5(83.33) are higher when compared with study conducted in Addis Abeba, that had 84.6%, 53.8% and 76.9% for HIV, HBSag and VDRL test kit respectively. Difference in client follow might be the reason for observed difference. On the other hand availability of hemoglobin measurement only 2(33.33) facilities was lower than similar study which state 92.3% and availability of urine dipstick test in all facilities is similar with this study.

For safety matter, all laboratory personnel who was giving service during observation session was vaccinated for HBSg which indicate that and all personnel were have put personal protective equipment like gown, glove and face mask while conducting routine activities in the study period this reduces the risk of exposure of skin and mucous membrane to infectious pathogen. This result was comparable to other study conducted in Addis Abeba and higher compared to study conducted in Nigeria. The outbreak of covid-19 might alarm for using PPE by all personnel. Similarly all facilities have incinerator for bio safety and all have sharp container. This fulfills the clinical laboratory safety manual guide. Additionally personnel have to clean and disinfect working area to prevent transmission of contagious agent to personnel, to client and the public. This study shows among observation sessions conducted 66% were cleaned and disinfected the working area with bleach and 70% alcohol. This is less compared to study conducted in Nigeria which had reported 85.4%. There may be several reason for the gap observed among personnel. It could be due to lack of supportive supervision by authorized body, negligence of personnel, lack of awareness and lack of involvement of personnel in infection prevention training.

Regarding internal quality control laboratory should follow standard operating procedure and should conduct routine quality assessment

to ensure reliable test of client specimen. For FANC reagent and kit all facilities didn't conduct internal quality control during observation session and this had been supported with in-depth interview as it is also our negligence not doing internal quality control for FANC tests it was not as such difficult to have IQC sample for this test'. This is similar with study conducted in Addis abeba. This gap may attribute to shortage of IQCE material on market, less willingness to do by personnel and absence of quality assessment scheme in town could also be another bottle neck. Additionally participating on external quality assessment(EQA) is mandatory in order to assess the competency of laboratory and to have quality and credible laboratory result. In spite, the finding of this study shows that all lab participate EQA for HIV test only, 1 facility participate EQA for HBsg test, 1 facility participate on hematology and no facility participate EQA for other FANC tests. This might be an indication of absence of quality monitoring system for all laboratory assays

During sample collection client should get appropriate information and there should be clear communication between them this is part of pre-analytic requirement [8]. The finding of this study shows that, among 30 client came to laboratory during observation session 19(63.33%) have informed about test ordered. This is higher when compared to similar study conducted in Addis abeba which might be as result of difference in patient load and comparable with study conducted in Ethiopia to assess the patient satisfaction in clinical laboratory. This implies that all personnel have not similar understanding about client handling. Additionally to determine waiting time of client, each laboratory should to have turnaround time for each tests and should be tolled to client and dispatched accordingly. Among 6 facility 4 of them have TATA for each tests and among 30 client who have got service during observation session 22(73.33%) have told the waiting time even if most of it were not release accordingly. This is higher when compared with similar study. The reason for not dispatching result as per TAT might be electric interruption, patient load and lack of lab assistant in facilities. Furthermore before dispatching results of laboratory it have to be registered on log book which is part of post analytical laboratory procedure requirement. In this study from 30 observation sessions conducted all laboratory personnel was registered the finding of the result which implies there could be common understanding about the importance of recording laboratory result.

ANC register have been reviewed in document review session this register 3455 pregnant women have visited ANC six month back from study period and all have screened for HIV , 3003(86.91%) have screened for syphilis in the facilities and 2955(85.53%) pregnant women have screened for HBSag. This is higher when compared with study conducted in Tanzania which has result of 82.96% women screened for HIV and only 6.51% women screened for syphilis. The possible justification for high screening of pregnant women in this study might be as result of payment free laboratory screening for pregnant women and difference in awareness about importance of lab screening among client and ANC service provider.

Regarding pregnant women satisfaction in these study 223 (53.9%) pregnant women was satisfied this is less when compared to study conducted in Ethiopia public hospital 76%, Nekemt referral hospital which reported 60.4% and similar with study conducted in Addis abeba which stated 55%. The possible justification for less satisfaction in this study could be less attention might give to this service because of covid-19 pandemic during the study period.

Conclusion and Recommendation

In this study, the overall quality of laboratory service for of focused antenatal care follow-up pregnant women judged as good. On the availability dimension, facilities lack fulfillment of basic infrastructure like separate laboratory room for FANC clients, the hand-washing facility near the toilet was not functional for some facilities. In addition, there were a shortage of reagent and kit like HBSag test kit, VDRL reagent, and kit for hematocrit measurement for FANC tests. Shortage of lab personnel in mendera Koch and higher two health centers was also another gap observed in this study. Regarding compliance with standard laboratory procedures, the result of the judgment given was good. But facilities under this study needs improvement on complacence with standards like disinfecting the working area, performing internal quality control, disposing of infectious and non-infectious wastes separately, and communicating about the taste order with the client. In addition, procedures like urine analysis was performed without centrifuging. Similarly, all pregnant women visiting health centers were missed hemoglobin screening.

The overall judgment for the satisfaction dimension was fair. Some pregnant women were satisfied on the welcoming of lab personnel and most are moderately satisfied with the information they got from professionals about test orders. Concerning the availability and accessibility of the toilet, most clients were moderately satisfied while others are unsatisfied with the laboratory result waiting area. Additionally, pregnant women who had served in referral hospitals had longer TAT of laboratory results and most of them were unsatisfied with it.

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Availability of data and materials

The data supporting our findings are found at, kept in confidential, and stored at the correspondent author both in hard and soft copies. If someone wants our data, we are voluntary to share it and the corresponding author should be contacted through the email address under the author's information.

Authors' Contributions

NM, developed the proposal, carried out data collection, conducted the analysis, was involved in reviewing the manuscript and had full access to all the data in the study and had final responsibility for the decision to submit for publication. AA and TK provided general guidance in overall study progress and participated in reviewing the proposal, reviewing the analysis and participating in final study document development. All authors read and approved the final manuscript and are accountable for all aspects of the work.

Ethics approval and consent to participate

Ethical clearance was obtained from the Institutional Review Board (IRB) of Jimma University, Faculty of Public Health. Following the endorsement by the IRB, written permission was presented to Jimma Medical Centre. Furthermore, confidentiality was assured throughout the process.

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