# Challenges of clinical chemistry analyzers utilization in public hospitals of selected zones of Oromia region, Ethiopia

Rebuma Benti Belete  ( ✉ rebuma@haramaya.edu.et )

   Haramaya University College of Health and Medical Sciences   https://orcid.org/0000-0003-4678-9847

Waqtola Gebisa Cheneke

   Jimma University

Aklilu Mamo Getachew

   Jimma University

Ahmedmemewer Seid Abdu

   Haramaya University

**Challenges of clinical chemistry analyzers utilization in public hospitals of selected zones of Oromia region, Ethiopia: a mixed method study**

Rebuma Belete[1*], Waqtola Cheneke[2], Aklilu Getachew[2], Ahmedmenewer Abdu[1]

[1]Department of Medical Laboratory Sciences, College of Health and Medical Sciences, Haramaya University, Harar, Ethiopia

[2]School of Medical Laboratory Sciences, Faculty of Health Sciences, Institute of Health, Jimma University, P.O.Box 378, Jimma, Ethiopia

Authors' email address

Rebuma Belete: rebuma@haramaya.edu.et

Waqtola Cheneke: waqtolachalt@gmail.com

Aklilu Getachew: akeachew.2@gmail.com

Ahmedmenewer Abdu: menewer59@gmail.com

*Corresponding author

Tel: +251922843016

# Abstract

**Background**: The modern practice of clinical chemistry relies ever more heavily on automation. Their utilization in clinical laboratories of developing countries is greatly affected by many factors. Thus, identifying the different challenges relating to clinical chemistry automation utilization faced by laboratories is important to work on and resolve.

**Method**: a mixed method study was conducted in 15 public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno-Bedele zones of Oromia region, Ethiopia from January 28 to March 15, 2019. Sixty eight key informants and ninety three laboratorians who were working in the clinical chemistry section were included in the study. Data were collected by self-administered questionnaires, indepth interviews and observation. The quantitative data were analyzed by simple descriptive statistics using SPSS 25.0 whereas qualitative data were analyzed thematically.

**Results**: There were 14 different models of clinical chemistry analyzers. More than two-thirds of analyzers were out-of-service. In another way, only 14 (15.1%) of the laboratorians had received user training of clinical chemistry analyzers. Majority of the laboratories were suffered from clinical chemistry reagents shortage. There were also inappropriate procurement processes of the clinical chemistry analyzers, misuse and underuse of clinical chemistry tests.

**Conclusion:** Due to many challenges, clinical chemistry analyzers in the studied hospitals were not utilized appropriately.

**Keywords**: Challenges; analyzers utilization; clinical chemistry analyzers; automation.

## Background

Clinical laboratory services have a great influence on clinical decisions and 60-70% of the most important decisions on admission, discharge, and medication are based on laboratory results. Due to this overwhelming dependence of clinical decisions on laboratory reporting, clinical laboratories have to improve their services [1]. The key to improvement of laboratory services is the implementation of correct automation technology [2].

The utilization of automation technology in clinical laboratories of developing countries is greatly affected by many factors such as their malfunction and absence of their maintenance, shortage of laboratory consumables, inadequate logistical support, absence of governmental standards, poor laboratory infrastructure and shortage of well-trained laboratory staff [3,4].

In low-income countries, as much as half of the equipment in medical institutions are inoperable and not in use; whereas some estimation is ranging up to 96% [5].Poor medical equipment handling and utilization, frequent power surges, the ages of the equipment, lack of operator training, lack of preventive maintenance, lack of spare parts, lack of maintenance capacity, and minimal knowledge regarding sophisticated equipment are factors that contribute to equipment breakdowns [6].

The modern practice of clinical chemistry relies ever more heavily on automation. No discipline in laboratory medicine uses more technologies than clinical chemistry [7,8]. Thus, identifying the different challenges relating to clinical chemistry automation utilization faced by laboratories is important to work on and resolve those obstacles.

Therefore this study aimed to assess challenges of clinical chemistry automation utilization in public hospital laboratories of selected zones of Oromia region, Ethiopia.

# Methods

### *Study design*

We used a mixed methods study where the qualitative study followed by the quantitative study to explain the quantitative findings in more depth.

### *Study period and setting*

A study was conducted in 15 public hospitals found in Southwest Shoa, Jimma, Ilubabor and Buno-Bedele zones of Oromia region, Ethiopia from January 28 to March 15, 2019. Oromia region is one of the 9 regions of Ethiopia having 20 administrative zones. Indepth interviews were conducted with 68 study participants (12 hospital clinical directors, 13 laboratory heads, 15 laboratory quality officers, 13 finance heads and 15 pharmaceutical storekeepers) whose were selected purposively for their expertise. In addition, a total of 93 laboratory personnel who were working in the clinical chemistry section were also included in the study.

### *Data collection tools*

The self-administered questionnaires were used to collect data from laboratory personnel working in clinical chemistry section, checklists were used to collect data concerning the facilities and clinical chemistry analyzers. Indepth interview guides and tape recorder were used to collect data from key informants.

### *Data processing and analysis*

The quantitative data were analyzed using SPSS version 25.0 (IBM, USA). Percentage and frequency were computed and results were presented using tables.

The qualitative portions of the study from open-ended questions and indepth interviews were analyzed thematically. Seven themes were generated from the findings of qualitative data. All indepth intervies were conducted in Afaan Oromoo and was translated into English language

during the process of transcription. The transcripts were then reviewed and analyzed. Finally, the data match each other were extracted and written by narrating the finding.

### *Data quality assurance*

Data collection tools were reviewed and appropriate modifications made accordingly before actual data collection. During data collection, filled questionnaires were checked for completeness and validity. After data collection, quantitative data was entered to EPI-Data3.1 and cleaned before analysis. The transcribed and translated data obtained from indepth interviews were read and checked against the recorded audio for accuracy of verbatim and transcripts.

## Results

### *Description of hospitals*

From 15 hospitals included in the study, 8 (53.3%) were primary hospitals, 5 (33.3%) were general hospitals and the left were specialized hospitals. In another way, 8 (53.3%) of hospitals had less than 5 years of service and the left had greater than 5 years of service.

### *Background characteristics of study participants*

As shown in **Table 1,** from laboratory personnel working in clinical chemistry section and participated in study 76 (81.7%) of them were males. Most of the respondents were within 25-29 age group (49.5%), BSc holders (75.2%) and had greater than 5 years of working experience (44.1%).

### *Description of clinical chemistry analyzers*

From 31 clinical chemistry analyzers assessed, 25 (80.8%), 25 (80.8%) and 23 (74.2%) were general chemistry analyzers, fully-automated analyzers and open reagent system analyzers respectively [**Table 2**].

## *Challenges of clinical chemistry analyzers utilization*

### **Diversity of platform**

There were 14 different brands and models of clinical chemistry analyzers in the assessed hospitals. Among 31, most of them (22.6%) were Dirui CS-T240 (Dirui Industrial Co., Ltd, China) followed by Biosystem A25 (BioSystems SA, Spain) [**Table 3**].

Concerning the problems encountered the laboratory due to diversity of clinical chemistry analyzers, laboratory head of one hospital gave his opinion as follows

"*Clinical chemistry analyzers you find in this hospital and other hospitals are different. Even though someone is an expert on one model of clinical chemistry analyzer, he/she may not on others.*"(Laboratory head 14, personal communication, 12 March 2019)

Laboratory quality officer of other hospital gave his opinion as follows

"*Different brands and models of clinical chemistry analyzers are found in different laboratories. This makes difficulty to get support such as reagents during stock out and other consumables from neighbor hospitals.*"(Laboratory quality officer 7, personal communication, 20 February 2019)

**Out of service of analyzers**

About 14 (45%) clinical chemistry analyzers were non-functional whereas 7 (23%) of them were functional but not in use; totally 21(68%) analyzers were out-of-service during the study period. The causes of non-functionality were installation problem (n=4), hardware malfunction (n=9), calibration and quality control failure (n=1) whereas the causes for functional but not in use of analyzers were reagent shortage (n=5) and lack of user training (n=2). In one hospital, 3 analyzers had been kept without being installed for 6 years because of vendor engineer unavailability.

The reasons why curative maintenances were not done for non-functional analyzers were due to delayed responses to repair requests (n=7) and unavailable spare parts (n=6) whereas the curative maintenance of one analyzer was on progress during the study period.

The interviewee indicated the problem as follows

*"The vendor engineers delay our request for maintenance of the analyzer. There is a time we wait for them for up to 4 months. The reason they give for delay is that there are few service engineers for many analyzers throughout the country. Many times we get technical support for minor troubleshoot from the vendor engineer by contacting them through telephone."*
(Laboratory head 13, personal communication, 7 March 2019)

Curative maintenances of clinical chemistry analyzers were also challenging in the assessed hospitals due to its expensiveness when compared to the financial capacity of hospitals.

*"Curative maintenance fee asked by vendor representative engineers is not affordable. They are also not interested to show the curative maintenance procedures to onsite biomedical*

*engineers and to laboratory personnel."* (Laboratory quality officer 10, personal communication, 28 February 2019)

**Reagents shortage**

During the study period, 7 (46.7%), 8 (53.3%), 9 (60.0%) and 5 (33.3%) hospitals had stock-out for clinical chemistry quality control (normal), clinical chemistry quality control (pathological), calibrator and all assay reagents respectively.

Interviewees indicated the problem of reagents shortage as follows

*"Stock-out of clinical chemistry reagents happens more frequently than other reagents in this hospital. Since we receive nearly expired reagents from Ethiopian Pharmaceuticals Supply Agency, stock-out occurs within a short period of time after procurement. The analyzer had given service for not more than four months in two years due to frequent reagent shortage occurrences."* (Laboratory head 9, personal communication, 22 February 2019*)*

*"Currently we are giving the service of four clinical chemistry tests: creatinine, urea, aspartate aminotransferase and alanine aminotransferase only. Both the vendor of the analyzer and Ethiopian Pharmaceuticals Supply Agency supply only the most frequently ordered reagents."* (Laboratory head 7, personal communication, 20 February 2019*)*

*"Even though clinical chemistry analyzer in this laboratory is an open system, there are difficulties to adapt to reagents from other manufacturers. It failed calibration for reagents from many other manufacturers."* (Laboratory head 10, personal communication, 28 February 2019)

There were 3 open system analyzers which did not adapt to other manufacturer's reagents. As clearly indicated by interviwee, this was done intentionally by vendors for the benefit they get from the sale of reagents.

**Lack of end users training**

Only 14 (15.1%) of the laboratory personnel had received user training. The trained individuals were also concentrated in a few hospitals. In addition, the interviwees showed that users training duration were from 1-2 days and mostly procedural orientation only. In other way, 49 (52.7%) and 74 (79.6%) of study subjects responded they could not perform quality control and calibration respectively [**Table 4**].

Interviwees also showed the gap as follows

"*The training given by the vendor representative engineer was not satisfactory. The engineer showed us only operation procedures of a limited number of tests for a day. Even though the analyzer can analyze the serum electrolytes, we could not perform by this analyzer because of skill gap.* " (laboratory quality officer 3, personal communication, 4 February 2019)

"*During the installation of the analyzer the vendor engineer had given training for two laboratory personnel. Both left this hospital; no re-training was given.*" (Laboratory quality officer 4, personal communication, 7 February 2019)

**Inappropriate selection and procurement process of analyzers**

Laboratory heads indicated the challenge as follows

"*There are also no criteria for procurement of analyzers at our hospital level. We ask laboratory personnel we know from other hospitals for best analyzer. There is no formal pre-*

*purchase consultation system with experts. In addition, we have no information whether consultants in this area available or not.*" (Laboratory head 7, personal communication, 20 February 2019*)*

*"Four years ago, I had purchased a semi-automated clinical chemistry analyzer. The salesperson tried to install it but now it is non-functional because of incomplete installation."(*Laboratory head 14, personal communication, 12 March 2019)

Laboratory quality officer of other hospital stated the problem as follows

*"The clinical chemistry analyzer we purchased is an open system. But it does not work with reagents from other manufacturers. The analyzer also not stable; frequent breakdown occurs. This is the result of inappropriate selection and procurement, which is not based on predefined criteria. Detail review and comparison with other brand and model was not done."* (Laboratory quality officer 10, personal communication, 28 February 2019)

**Underuse/misuse of clinical chemistry tests**

One hospital laboratory personnel indicated that there was misuse of clinical chemistry tests by physicians; they have been requesting all test lists on the request paper which leads to unnecessary expenditures in a hospital already plagued by consumables shortages. This also increases the load of the analyzer which in turn causes the frequent breakdown of the analyzer. In another way, the laboratory personnel of some hospitals especially of primary hospitals explained that physicians did not request clinical chemistry tests. In addition, one laboratory head gave his opinion as follows

*"Clinical chemistry tests requested rarely. We perform only 1 or 2 clinical chemistry tests per week by the analyzer.This causes expiration of analyzer consumables without service."* (Laboratory head 2, personal communication, 31 January 2019)

### Poor laboratory infrastructure

In the studied hospital laboratories, there were also challenges of infrastructures that had affected proper utilization of clinical chemistry automation. Power fluctuation, distilled water shortage and uncontrolled room temperature were among the identified.

All the assessed hospital laboratories had electric power supply and functional generator for power back up. But, there was complain of power fluctuation in most hospitals as explained by most key informants.

There was no control system of temperature in clinical chemistry section except one. Quality officer of one hospital stated it as follows

*"Clinical chemistry and hematology section has no temperature controlling system. The analyzer always shows error relating with high temperature. This is highly affecting our analysis."(*Laboratory quality officer 2, personal communication, 31 January 2019*)*

All laboratories used distilled water for clinical chemistry analyzers; but there was shortage. The hospitals vary by their source of distilled water. Only 2 (13.0%) of them had functional distiller to fulfill water consumption. About 3 (20.0%) hospital laboratories were using car battery water by purchasing from shops while 4 (27.0%) were used bottled water which was prepared for human consumption. The other 6 (40.0%) hospitals were used distilled water procured from Ethiopian Pharmaceuticals Supply Agency.

The laboratory head of one hospital said

*"The hospital has 2 fully automated clinical chemistry analyzers. One analyzer became out of service because it consumes high volume of distilled water i.e. up to 6 liters per hour. It is unaffordable to purchase distilled water for this analyzer since the water distiller we have produces not more than one liter per day.*" (Laboratory head 10, personal communication, 28 February 2019)

## Discussion

Clinical chemistry analyzer brands and models diversity was the major challenge which affected the utilization of automation in the studied hospitals. There were 14 different types of clinical chemistry analyzers each with different software and operating procedures. This challenge is occurred due to lack of proper analyzers standardization at national level. Even though there are standard lists of laboratory equipment at each level of hospitals in Ethiopia [9-11], they are not satisfactory to limit brand and model diversity of clinical chemistry analyzers. This creates difficulties in procuring reagents and spare parts and providing training for users and biomedical engineers. A survey conducted in the Dominican Republic in 26 clinical laboratories showed that there were 37 types of clinical chemistry and special clinical chemistry autoanalysis equipment [12]. Another study conducted in 15 African and Caribbean countries support this study where there were about 37 different manufacturers and more than 130 platforms of clinical chemistry [13].

Clinical chemistry analyzers functionality status (non-function and not in use) was also another major challenge for automation utilization in the study area. During the study period, 21 (68%) of clinical chemistry analyzers were out of service due to an installation problem,

hardware malfunction, calibration and quality control failure, reagent shortage and lack of user training. A study conducted in Jimma zone revealed 33.3% of clinical chemistry analyzers were out of service [14] and other study showed that about 39% of medical equipment found in Ethiopian public hospitals and other facilities was out of service at any one time [15]. World Health Organization estimated that up to 70% of laboratory and medical equipment in resource poor settings is out of service due to mismanagement of the technology acquisition process, lack of user-training and lack of effective technical support [16].

This study showed the majority of the laboratories were suffered from reagent shortages. This has been shown by 7 (46.7%), 8 (53.3%), 9 (60.0%) and 5 (33.3%) hospitals had stock outs for quality control (normal), quality control (pathological), calibrator and assay reagents respectively. Challenges related to laboratory supplies were also reported by the study done in Jimma zone [14] in Addis Ababa [17] and in Sub-saharan Africa [3].

According to Ethiopian hospital reform implementation guidelines, laboratory equipment should only be used by appropriately trained staff [6]. World Health Organization also recommends the vendor should be obliged to train laboratory personnel in the calibration and operation [18]. However in this study, 79 (84.9%) of the clinical chemistry analyzers operators had not received user training. Due to lack of training from study subjects only 19 (20.4%), 44 (47.3%) and 25 (26.9%) of them responded they could perform independently calibration, quality control running and monitoring and preventive maintenance respectively. Similar challenge also reported in studies done in Ethiopia [14,19].

The selection criteria used were only automation grade (semi-automated/fully-automated) and the cost of the analyzer. According to World Health Organization procurement guideline,

selection criteria should include detail review of equipment quality specifications and product specifications [18].

## Limitations

There were limitations in our study. Nonprobability sampling with likely sampling bias.This study does not have information from other stakeholders such as respective zonal health departments, Oromia regional health beareau and Ethiopian Public Health Institute.

## Conclusion

There were 14 different brands and models of clinical chemistry analyzers. More than two-thirds of analyzers found in the studied hospitals were out-of-service during the study period. In other way, only 14 (15.1%) of the laboratory personnel had received user training of clinical chemistry analyzers. Majority of the laboratories were suffered from clinical chemistry reagents shortage. There were also inappropriate procurement process of the analyzers, misuse and underuse of clinical chemistry tests in the studied hospitals, which affect the clinical chemistry automation utilization. Due to these barriers, clinical chemistry automation in the studied hospitals was not utilized appropriately.

## Abbreviations

Not applicable

## Ethics and consent to participate

Ethical clearance was obtained from the Institutional review board of Jimma University Institute of Health. Permission letter had been received from Oromia regional health beareau.

Written consent was taken from each study participant before data collection started. Confidentiality was kept by making interview in separate place and of any information provided during data collection procedure was anonymous.

## Consent for publication

Not applicable

## Competing interests

We declare that we have no competing interests.

## Authors' contributions

All authors have contributed in conception, design and acquisition, analysis and interpretation of the data. RB took the lead in drafting the manuscript. All authors revised the draft manuscript critically for important intellectual content.

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### Availability of data and materials

The data that support the findings of this study are available from the authors upon reasonable request.

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**Table 1** Background characteristics of laboratory personnel working in clinical chemistry section (n=93)

| Variable | | N (%) |
|---|---|---|
| Sex | Male | 76 (81.7) |
| | Female | 17 (18.3) |
| Age group (in years) | 20-24 | 10 (10.8) |
| | 25-29 | 46 (49.5) |
| | 30-34 | 24 (25.8) |
| | 35-39 | 7 (7.5) |
| | Missing | 6 (6.9) |
| Educational level | MSc | 2 (2.2) |
| | BSc | 70 (75.2) |
| | Diploma | 21 (22.6) |
| Professional work experience (in years) | <2 | 32 (34.4) |
| | 2-5 | 20 (21.5) |
| | >5 | 41 (44.1) |

**Table 2** Description of clinical chemistry analyzers by the level of hospitals (n=31)

| Variable | | Number of analyzers by level of hospital | | | Total N (%) |
|---|---|---|---|---|---|
| | | Primary | General | Specialized | |
| Analyzer type | General chemistry | 9 | 11 | 5 | 25 (80.8) |
| | Immunoassay | 0 | 0 | 2 | 2 (6.4) |
| | Integrated chemistry /immunoassay | 0 | 0 | 2 | 2 (6.4) |
| | Electrolyte analyzer | 0 | 0 | 2 | 2 (6.4) |
| Automation grade | Semi-automated | 3 | 3 | 0 | 6 (19.2) |
| | Fully automated | 6 | 8 | 11 | 25 (80.8) |
| Reagent form | Open system | 9 | 11 | 3 | 23 (74.2) |
| | Closed system | 0 | 0 | 8 | 8 (25.8) |
| Condition when received/purchased | New | 9 | 11 | 11 | 31 (100.0) |
| | Reconditioned | 0 | 0 | 0 | 0 (0.0) |

**Table 3** Types and number of clinical chemistry analyzers (n=31)

| Clinical chemistry analyzer | N (%) |
|---|---|
| Dirui CS-T240 (Dirui Industrial Co., Ltd, China) | 7 (22.6) |
| Biosystem A25 (BioSystems SA, Spain) | 4 (12.9) |
| Biosystem BTS 350 (BioSystems SA, Spain) | 3 (9.7) |
| Mindray BS 200E (Mindray Bio-Medical Electronics Co., Ltd, China) | 3 (9.7) |
| ABX Pentra 400 (Horiba ABX, France) | 2 (6.5) |
| HumaStar 200 (Human GmbH, Germany) | 2 (6.5) |
| COBAS Integra 400 Plus (Roche Diagnostics) | 2 (6.5) |
| VIDAS ® (BioMérieux SA, France) | 2 (6.5) |
| Humalyte plus 3 (Human GmbH, Germany) | 1 (3.2) |
| Opt Lion (OPTI Medical Systems, Inc., Georgia, USA) | 1 (3.2) |
| SBA 733 plus (Sunostik Medical Technology Co.,Ltd ,China) | 1 (3.2) |
| Photometer 5010 V5+ (Robert Riele GmbH & Co KG, Germany) | 1 (3.2) |
| Vegasys (AMS Diagnostics) | 1 (3.2) |
| 3000 Evolution (BSI) | 1 (3.2) |

**Table 4** Training and skills related to clinical chemistry automation utilization of study participants (n=93)

| Variable | | | N (%) |
|---|---|---|---|
| Taking training on clinical chemistry analyzer in the hospital | Yes | | 14 (15.1) |
| | No | | 79 (84.9) |
| Knowledge of clinical chemistry tests principle | Yes | | 29 (31.2) |
| | Partly | | 37 (39.8) |
| | No | | 27 (29.0) |
| Activities the laboratory personnel can perform without supervision from other collegues | Running test | Yes | 88 (94.6) |
| | | No | 5 (5.4) |
| | Calibration | Yes | 19 (20.4) |
| | | No | 74 (79.6) |
| | Quality control running and monitoring | Yes | 44 (47.3) |
| | | No | 49 (52.7) |
| | Preventive maintenance | Yes | 25 (26.9) |
| | | No | 68 (73.1) |
| | Troubleshooting minor problems | Yes | 18 (19.4) |
| | | No | 75 (80.6) |

# Supplementary Files

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