ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF MEDICAL LABORATORY

Critical laboratory test result management practice and associated factors at selected public health facilities of Addis Ababa, Ethiopia

By: Arsemawit Teferedegne (BSc)

Advisors:

1. Dr Fatuma Hassen (MPH, Ph.D.)
2. Dr Abay Sisay (MSc, Ph.D.)

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This is to certify that the thesis prepared by; ARSEMAWIT TEFEREDEGNE entitled:

Critical laboratory test result management practice and associated factors at selected public health facilities of Addis Ababa, Ethiopia and submitted in partial fulfillment of the requirements for a Master of Science degree in Clinical Laboratory Science (CLS) (Laboratory Management and Quality assurance specialty) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

Advisor; Dr Fatuma Hassen Signature _____Date _____

Advisor; Dr Abay Sisay Signature _____Date _____

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Contents

List of abbreviation/acronyms

CAP	College of American Pathologists
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments
CR	Critical Result
CRM	Critical result management
CV	Critical value
CVN	Critical value notification
EHR	Electronic Health Record
IT	Information Technology
ISO	International Organization for Standardization
LIS	Laboratory Information System
SOP	Standard Operating Procedure
SPHMMC	St. Paul's Hospital Millennium Medical College
TASH	Tikur Anbessa Specialized Hospital
TAT	Turnaround Time

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Abstract

Background: Critical result is a Result that requires immediate medical attention and action because it indicate a high risk of imminent death or major patient harm. In Ethiopian public hospitals where high patient volume, limited resources and varying infrastructure exists managing this result makes more difficult. Besides, there is very limited research information in this regard. Thus, this study aimed to assess the management practice of critical results and its associated factors at selected hospitals.

Methods: a descriptive cross-sectional study was conducted across four public hospitals found in Addis Ababa, using both quantitative and qualitative aspects, different data collection tools are used like staff questionnaire, document review and key informant interview then entered in to Microsoft excel for accuracy. Analysis was performed using SPSS version 23.

Result: we assessed critical laboratory result management practice across four public hospitals, among laboratory staff respondents 96.6% were laboratory technologists with varying years of experience. 95.7% reported no training in critical result management. among the 422 critical results 46.6% were hematological tests followed by carbohydrate (13.7%), liver function (11.8%), electrolytes (10.19%), renal function test (9.7%), cardiac marker 4.2% and coagulation tests (3.56%) from the 422 critical results only 34(8.1%) recognized and managed as critical results, 38.6% communicated in the given time interval. St. Paul's Hospital Millennium Medical College(SPHMMC) achieved a 93% rate of timely communication, while Yekatit 12 hospital managed only 4%. Communication of laboratory results was mainly with electronic health record (EHR) and most of the critical results were communicated with electronic health record like every other(non-critical) test (91.9%), which makes only 34(8.1%) of the results communicated as critical results, the communication methods used inconsistently, methods were in-person/verbal, phone call, and paper-based methods are used. and only 17.6% of the tests are confirmed in readback. There was 0% of documentation of critical results in all hospitals. Although Standard Operating Procedures (SOPs) existed, stakeholders were not involved in the preparation of Standard Operating Procedures. Most of the staffs reported high workload and resource limitation as a major factor for poor critical result management. Physicians expressed dissatisfaction with the current practice 90%, by stating the consequence of poor management in increasing hospital stay and delayed treatment, emphasizing the need for faster communication, standardized protocols and improved documentation for better patient treatment.

Conclusion: there is a significant gap in management of critical results, the findings indicate the urgent need for standardize protocol, enhancing training, and improved communication systems to ensure effective and prompt management of critical results in hospital settings. **Key words:** *Critical laboratory values, Patient safety, Communication in healthcare, Turnaround time, Accreditation, readback policy, stakeholder involvement.*

1. Introduction

1.1 Background

The critical value is a laboratory result representing a pathophysiological state that indicates a high risk of major patient harm or possible death(1). These results must be identified and reported as soon as possible for clinicians, so as to support effective, fast and correct medical decision based on the test outcomes(2). communicating critical results Timely can have a significant impact on medical decisions and improve patient outcomes(3). The idea of critical value has been started in 1970s when George Lundberg published a paper called “When to panic over abnormal values.” In the report, Lundberg referred to critical results as “panic” or “alert” results indicating pathophysiological state different from normal, posing a risk to a patient's life unless an immediate action is taken(4). now a days, the term “panic value” is no longer used because it represents emotional stress and confusion in communication between laboratory staff and clinicians(5).

Even though critical results are used in many countries currently, there are limited agreed rules and standards on how to manage critical results(6). Because of this reason, there is a big difference in how critical values are managed, even in countries with a better health system. For example some countries use electronic health record for communication some still uses phone call and paper based reporting, as studies shows in Australia there is no standard way of managing critical values(6). similarly, studies from USA, UK, Italy, China, and Croatia supports this, there no agreed policy or guideline on what to report, how fast to report or for whom to report critical results(7).

At the International level, ISO 15189, is one of the most commonly used standards for medical laboratories. It states that “the laboratory should ensure that critical results (CRs) where applicable are communicated effectively and meet the users' needs” this clause ensures the right people get the right information on time. However, like ISO 15189 other accreditation bodies and guidelines gives only general directions(8). So, each lab must handle critical results in their own way depending on the hospitals resources, staff, and the system they have some may use digital tools while others might not have enough staff or proper procedures. This difference makes it hard to have a consistent and standard way of managing critical results everywhere.

As a result of these differences between laboratories and countries everywhere, critical results reporting practices vary widely creating heterogenous and inconsistent practice. Solve the problem, some national organizations have done surveys in their own countries to better understand critical result management practice and find a way to improve it by creating harmonized critical result notification(9).

Some countries have taken a bigger step and made some progress in harmonization of laboratory critical result management practice. While, others continued battling with inconsistence practice and absence of national guidelines(10). For example, counties like China, USA, Singapore implements electronic alert systems and real-time communication protocols for critical laboratory results(10).

However, in low resource settings like African countries, the performance of laboratories when assessed with the ISO15189 quality requirement is reported as poor, with communication and management of critical results remains underdeveloped(11). Which leads to missed diagnosis and inappropriate or delayed treatment decisions. The survey conducted in Nigeria showed remarkable variability in the policy and procedures of critical value notification across clinical laboratories. Laboratories in Nigeria, didn't report critical values regularly, and most of the ones that dis had no official list of critical values or clear guidelines to follow(12). Similarly in Uganda an audit conducted in 2013 in a large outpatient HIV-center revealed that < 50% of critical results were responded upon within 24 hours. These findings are worrisome, considering the importance of management of critical values (CVs) in patient safety(13).

In Ethiopia as in many Sub-Saharan African countries public hospitals faces many challenges. These includes lack of adequate test menu, shortage of professionals, inadequate infrastructure, laboratory hand book, provision of urgent service, among these challenges critical result management is one of them but often overlooked(14).

Despite the availability of international standards like the ISO15189 there is no national policy for management of critical value test results, furthermore there is limited published literature assessing management practice of critical values in Ethiopia public hospitals(15). To address this gap, it is crucial to identify current critical points, possibilities for improvement and set basis for future standardization and guideline development. Therefore, the research aimed to assess current practice of critical laboratory result management and associated factors in selected public hospitals in Addis Ababa, Ethiopia.

1.2 Problem statement

Critical results are laboratory results that indicate a life-threatening condition that must be managed properly in order to prevent patient harm(16). these includes defining critical tests and critical limit in collaboration with clinicians, reliably identifying test results, and communicating timely for the responsible clinician with a complete communication cycle that involve read back to ensure successful interpretation of the communication at the receiving end.(11) Additionally, properly documenting in detail is necessary. These steps are essential also supported by the national standards such as ISO 15189 in ensuring proper critical result management(16).

In many public health hospitals, in Ethiopia specifically, in Addis Ababa the management of critical laboratory results lacks standardization and consistency**.** there is no established national standards or guidelines for

identifying, communicating and reporting of critical results(14). Therefore, each institution is expected to draw up its own list which creates variability and heterogenicity in practice. The study conducted in assessing Health Management Information System revealed data quality (accuracy, completeness, timeliness) was below the nationally expected level (85%) such deficiencies in data management can delay timely clinical decision-making, especially concerning critical laboratory results(17).

Furthermore, national survey on Physicians' satisfaction with clinical laboratory services at public hospitals in Ethiopia reported more than 50% of the physicians were not notified the critical result timely, and nearly one third of physicians were not provided the urgent services with a timely fashion(14). These gaps highlight serious challenge in the current system that could compromise patient safety.

The lack of standardized, timely, and well-documented communication of critical laboratory results poses a serious risk to patient safety. Delays in communication can lead to compromised patient care and increased morbidity and mortality(18). In addition, variability in management and handling of critical result challenges consistency in patient care(19).

Moreover, lack of proper documentation can lead to lack of traceability, hinders quality improvement and monitoring, ineffective for follow up which increase patient harm(18).

However, the situation of critical result management in Addis Ababa public hospitals is not yet documented. There is little knowledge about the presence of SOPs or internal guidelines, the frequency of appropriate reporting of critical results, or barriers that hinder staff to follow best practice(15). Further still, there are no published data that evaluate if these hospitals are compliant with ISO or their staff is aware, trained or ready for the management of critical results from the laboratory.

Understanding these discrepancies is crucial for enhancement of patient safety, quality of care and diagnostic accuracy. Analyzing strengths and weaknesses in critical result management, in the present study, we can offer government administrators and health policy makers with evidence-based suggestions. It can also be set as an indicator for the development of SOPs and national policy on laboratory services. Finally, study findings can be utilized for hospital level interventions, enhancement of accreditation program and harmonization of laboratory quality systems (LQSs) in Ethiopia.

1.3. Significance of the study

This study addresses the gap in critical laboratory management practice in public hospitals Addis Ababa, Ethiopia. Which is a serious issue that affects patient safety and treatment. There is a very little local researches on this topic, this study fills that gap by showing what is actually happening in practice. The findings will help hospital managers and lab professionals improve how they handle critical results through better communication, documentation, and training. It could also support the Health Bureau and policymakers in creating or improving guidelines. Overall, this research doesn't just aim to improve hospital practices it can also help save lives by making sure patients get timely and appropriate care.

2. Literature review

2.1 Introduction

A critical laboratory value, indicates that the patient is in imminent danger unless appropriate and timely action is taken(20). for example, if a routine blood test shows a person's serum potassium level is >6.0 mmol/L, it is a serious warning that the subject is at risk for hyperkalemia and will need hospitalization, otherwise, he or she might suffer from severe cardiac arrhythmias due to disrupts heart's electrical signals. However, if clinicians are able to get the information in time and provide the patients with effective interventions or treatments promptly, lives could be saved. Otherwise, there could be serious consequences and the best opportunities for rescuing the patients might be missed(21).

Critical results as mentioned above are Results that requires immediate medical attention and action because they indicate a high risk of imminent death or major patient harm(22). Critical result reporting originally was highlighted by Lundberg, who defined a critical value as a result suggesting that the patient was in imminent danger unless appropriate therapy was initiated promptly(4). therefore, efficient and timely communication of laboratory critical test results which needs urgent clinical decision making is an essential responsibility of medical laboratories in order to optimize clinical management and enhance patient safety(8).

However, effective management of critical results compromised by various challenges. such us communication breakdowns, lack of SOP/standard procedure, delays in result reporting, challenges in documentation, resource limitation, inadequate personnel for workload(22). It is important to be familiar with these systemic problems, and the care for the patients is often significantly jeopardized(20). As such, it is of interest to summarize what is known about management of critical results in this context, emphasize common drivers, and address the need for solid strategies to reduce risk and optimize outcomes for patients.

2.2. Key elements of critical laboratory result management

2.2.1. Accreditation standards

Nowadays, accreditation is increasingly applied globally in order to improve quality and ensure patient safety such as ISO 15189 which is a widely accepted accreditation body in medical laboratories. This standard requires clinical laboratories to design and establish a protocol for a critical risk result and a periodic evaluation of the system(15).

Within the ISO 15189 accreditation standard there are three subclauses that address the management of critical results. Subclause 5.8.7 states that a "laboratory shall have procedures for the immediate notification of clinical

personnel responsible for patient care when examination results for critical properties fall within established critical intervals"(23).

Subclause 5.8.8 requires a laboratory to "determine the critical properties and their critical intervals in agreement with the clinicians using the laboratory".

Subclause 5.8.10 demands that records be maintained of actions in response to critical results, with difficulties in meeting these requirements also recorded and reviewed during audits.

Accreditation standards in the USA The Joint Commission defines a critical test result as "a test that requires immediate communication of result irrespective of whether it is normal, significantly abnormal or critical" it also defines critical results as "a test result that is life threatening, or indicates significant morbidity or irreversible harm if immediate medical action is not taken"(7).

Similarly, College of American Pathologists (CAP) Guidelines also defines critical values as abnormal test results that are life threatening and require a rapid response from caregivers. CAP accreditation program requires critical values to be documented, with date, hour, laboratory analyst, professional notified and the reported result. It also requires a read-back policy for verbally communicated critical results(6).

Despite these clauses in ISO 15189 and the presence of this accreditation requirement standards give limited general guidance and no specific universally applicable procedure in managing critical results creating heterogeneous practices even among accredited laboratories with the same standard(7).

2.2.2. Communication methods

Effective communication of critical results is an important element in order to ensure timely treatment and patient safety. laboratories use different methods to communicate critical results to clinicians traditionally phone call or in person reporting has been widely used a study conducted in Croatia stated 90.9% of critical results are reported via phone similarly in one international survey 98.2% of results are communicated in a phone call(4). However these methods are time consuming, which delays the conduction of other laboratory activities, and increasing the probability of errors and delays in the process of critical value communication(24). For example, The BWH hospital setting, critical results for in patient are first reported to unit secretary, who then informs the nurse, and finally, the physician creating multiple steps that slow down communication and miscommunication(10). In contrast these days Information technology is increasingly becoming an essential component of medical laboratories which improves the management of critical laboratory results(8). Automated alert systems and EHR integration are key innovations aimed at addressing communication and reporting delays. These digital tools streamline the communication process, reduce human error, and improve the turnaround time for critical result

reporting. However, an electronic reporting system potentially could create dangerous delays in communication if not properly implemented(7).

Read back policy is a safety procedure which the receiver of critical result repeats the critical value back to the sender for accurate communication, a key component for critical result management. However, surveys show inconsistent implementation of read-back policies(19).

2.2.3. Turnaround time (TAT)

Turnaround time (TAT) refers to the total time taken starting from sample received to release result. Laboratories are responsible for the notification of critical results to clinicians so that clinical interventions can be made in an appropriate time frame(20).

Different laboratories have different variable set time limits that vary from 15 min to 3 h, which may be too long for life-threatening results(25). A systematic review, part of the Centers for Disease Control and Prevention (CDC)'s Laboratory Medicine Best Practices Initiative, have confirmed that the time to report a randomly selected CR, using an automated notification system, will be faster than a randomly selected manually reported critical value in approximately 61.8% of cases. factors that affect TAT to be delayed includes Excessive workload, lack of an SOP, inadequate training and miscommunication(8).

2.2.4. Documentation

The reporting of critical values became a mandatory quality practice in laboratory medicine procedure. Reports of critical results should be documented to identify the patient or patient's sample, the laboratory result, the reporter and recipient, the time of report, and verification of accurate communication(26). If intermediary personnel are involved in the report, each leg of communication should be documented. According to the ISO 15189 standard, the laboratory should keep records of "actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications. Subclause 5.8.10 further emphasis these by stating records be maintained of actions in response to critical results, with difficulties in meeting these requirements also recorded and reviewed during audits.(3) Studies from China and Croatia shows significant gaps in recording, especially in documenting who was notified and how the communication occurred. In Croatia reveals low mean scores, with practically no differences among hospital and general practice laboratories. Similarly, the study in India shows 100% of the CR recorded and 96.6% of the reports were properly recorded with full information and follow up documentation was often incomplete.(9) Another study reporting most of the medical records do not state the laboratory phone call challenging the of assessing the real clinical impact of the notifications(27).

2.3. Barriers to Effective Critical Laboratory Result Management in Sub-Saharan Africa

Despite the seriousness of critical results, the reviewed literatures revealed ununiform and heterogeneous management of critical results throughout the world(28). Studies in low and middle-income countries specially in Africa shows dangerously low rate of communication and management practice of CR management(13). A 2022 study conducted in tertiary hospitals in Kenya reported that Overall communication rates for the critical results was only 21%, with only 17.5% critical results were evidently communicated. which is significantly lower compared to other studies where rates of critical result communication range from 60% to over 90%(11). These indicates serious patient safety risks and may contribute to increased morbidity and mortality.

One of the several factors for poor CR management practice in Africa is lack of harmonized international and national guidelines. Many laboratories in Ethiopia(14), Nigeria(12), Kenya(11) and other similar contexts lacks national guide lines for the management of critical results. Similarly, accreditation of laboratories in Africa is very limited only 340 accredited laboratories exist in the whole Africa which only ISO 15189 Laboratory Support 28(8.2%) are in sub-Saharan Africa; the other 312 primarily private laboratories are located in South Africa(15). This implies a lack of adherence to international standards for critical result management.

Another critical factor for ineffective CRM includes, understaffing which leads to high workload, limitations in physical infrastructure, equipment shortages, moreover, financial constraints associated, lack of staff training and education can be mentioned for the lack of under developed quality system(11-13).

These systematic challenges indicate the effective management of critical laboratory results in Ethiopia and sub-Saharan Africa is unexplored(13). only few studies exist in low- and middle-income countries (LMIC) to document how critical results are handled. This gap in literature highlights the need for further research on the real-world implementation and barriers to effective critical result management practice, this study aims to fill a critical gap by assessing the current practice and identifying the factors affecting critical result management in Ethiopian public hospitals.

2.4. Conceptual framework

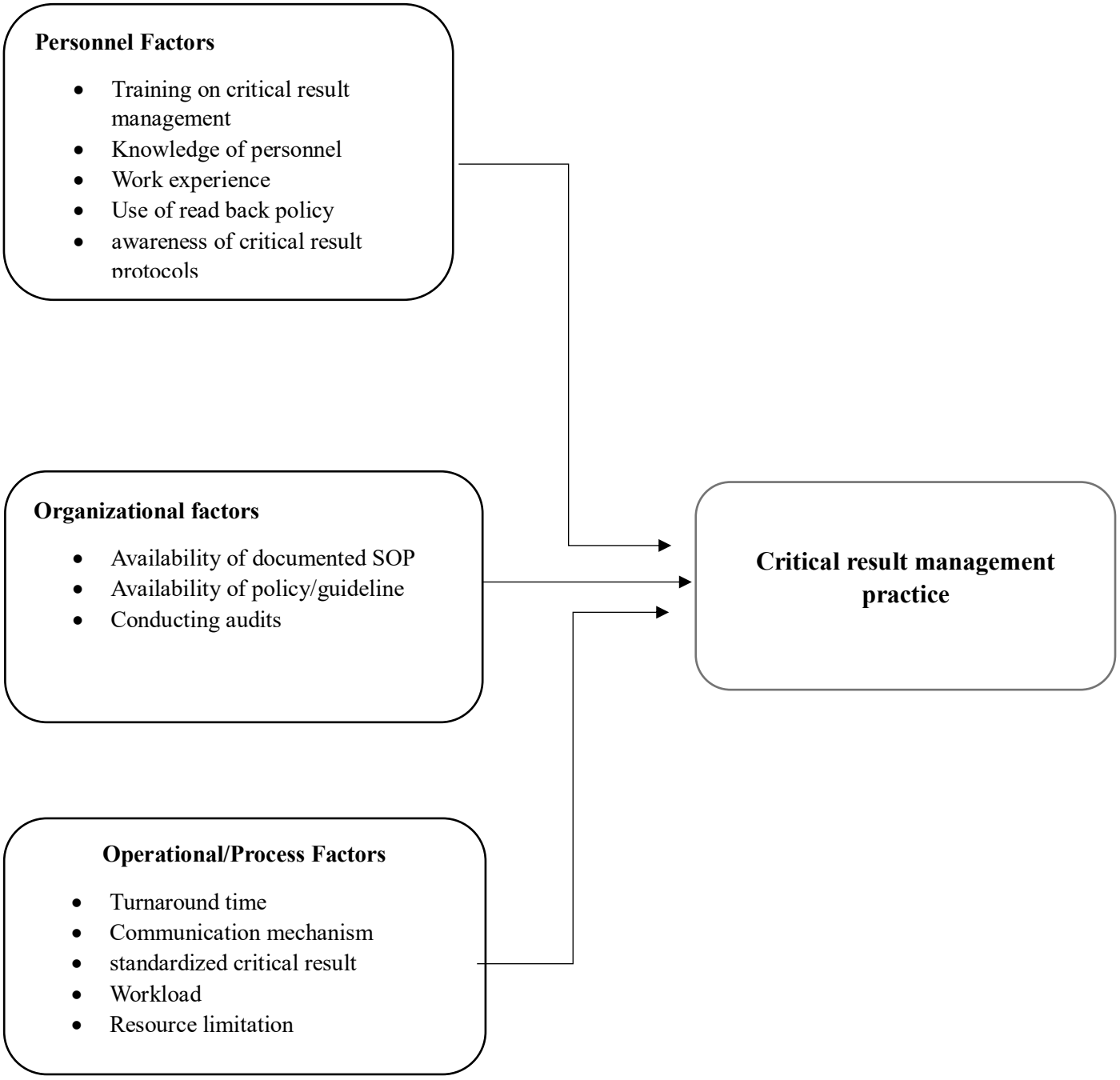

Figure 1 conceptual framework

This conceptual frame work is prepared to show the structure of factor affecting critical result management practice in selected public hospitals in Adiss Ababa, Ethiopia.it contains independent variable, and dependent variables.

3. Objective

3.1. General objective

- To assess the critical laboratory test result management practice and associated factors at selected hospitals Adiss Ababa, Ethiopia, 2024/2025

3.2. Specific objective

- To assess the management practice of critical laboratory results in the selected hospitals in Adiss Ababa, Ethiopia, 2024/2025
- To identify factors associated with critical result management in Adiss Ababa, Ethiopia, 2024/2025

4. Materials and Methods

4.1. Study area

This study was conducted in Addis Ababa which is the capital city of Ethiopia. Addis Ababa has a population size of 6.5 million residents.(29) In Addis Ababa there are around 14 public hospitals, six of the hospitals under the administration of the Addis Ababa Regional Health Bureau (AARHB) and eight of them under the federal ministry of health.(30)

The study was conducted in selected public hospitals that are located in Addis Ababa, namely Tikur anbessa specialized hospital, St. Paul Millennium Medical College's Hospital, Yekatit 12 medical collage hospital and Menelik II referral hospital. These hospitals are purposively selected for the following reasons, first all four of them are referral teaching hospitals that provide specialized, emergency and critical care services which makes them preferable for the study. There is also high workload, complex health cases that increases the chance of encountering critical results. The hospitals also ensure diversity and representativeness across different public healthcare settings in Adiss Ababa.

St. Paul Millennium Medical College's Hospital was built by Emperor Haile Selassie in 1969E.C. While the inpatient capacity is more than 700 beds, sees an average of 1200 emergency and outpatient clients daily.(31)

Tikur Anbessa Specialized Hospital (TASH) was found in 1972, TASH is the largest referral hospital in the country, with 700 beds also has 200 doctors, 379 nurses and 115 other health professionals dedicated to providing health care services.(32)

Yekatit 12 Hospital, officially known as Yekatit 12 Hospital Medical College, is a significant healthcare institution located in Addis Ababa, Ethiopia. Established in 1923, it has a long-standing history of providing medical services and training healthcare professionals. Currently the hospital has 130 specialist and sub specialists, 180 general physicians, residents and public health professionals, 520 nurses and 59 pharmacy professionals.(33)

Menelik II Referral Hospital was established in 1909 and named after Emperor Menelik II, becoming one of oldest modern hospitals in Ethiopia. It is one of the oldest hospitals in the country and serves as a tertiary care center with a capacity of over 800 beds. The hospital provides specialized services in various fields, including cardiology, neurology, and oncology, and serves approximately 15,000 patients daily with a staff of over 2,300.(34)

4.2. Study design

A descriptive, institutional-based cross-sectional study design was conducted that includes both quantitative and qualitative components.

4.3. study period

Prospective data were collected over two months, from April to May 2025, until a total of 422 critical laboratory results were recorded.

4.4. Population

4.4.1. Source population

- All laboratory test data in the laboratory
- All medical laboratory professionals and clinicians

4.4.2. Study population

- All critical laboratory values
- Medical laboratory professionals and clinicians

4.5 Inclusion and exclusion criteria

4.5.1. Inclusion criteria

- All critical laboratory results during the study period.
- All Medical laboratory professionals and clinicians that are directly involved in critical result management and willing to participate on the study

4.5.2 Exclusion criteria

- Laboratory results that are not classified as critical results
- Critical results that lack essential documentation (e.g., time of communication, recipient's name, read-back, or action taken).
- Interns/temporary staff <6month of experience

4.6. Study variable

4.6.1 Dependent variable

Critical result management practice

4.6.2. Independent variables

- Training on critical result management
- Knowledge of personnel
- Work experience
- Use of read back policy
- awareness of critical result protocol
- Availability of documented SOP
- Availability of policy/guideline
- Conducting audits
- Turnaround time
- Communication mechanism
- standardized critical result
- Workload
- Resource limitation

4.7. Sample size

The study used mixed method approach that includes prospective data collection, questionnaire and key informant interviews. for the prospective data the sample size was determined using a single population proportion and level of significance is 0.05, marginal error (d) is 5%, z-score at 95% CI is 1.96.

n= (Zα/2)2P (1-P) d 2

n= (1.96)2 *0.5*0.5/ (0.05)2 =384

Where: n =is initial sample size

Zα/2 = Z score in a normally distributed curve at 95% confidence interval

P = proportion of the cases

d = maximum allowable error by adding 10% non-response rate and missing cases the total sample size will be 422. The data will be collected disproportionally from 4 public hospitals. This approach ensured adequate representation from each hospital, focused on collecting a real time critical laboratory results using an observational checklist.

Name of hospital	FREQUENCY
TASH	122
SPHMMC	100
YEKATIT 12 HOSPITAL	100
MENELIKII HOSPITAL	100

Table 1Distribution of sample size by hospital

Questionnaire and interview

Also, a self-administered standardized questionnaire was used and this questionnaire was given to the laboratory workers and managers in the hospitals. A purposive sampling of 116 responses was analyzed; to have representation of participants who were closely linked to critical result management. This section sought to obtain details about knowledge, practices and institutional barriers to critical results management. Although the study primarily focused on medical laboratory professionals as the main study participants, a purposive sample of 40 physicians was included to gather more insight and have a glance of physician's perspective. The analysis and conclusion mainly focus on the key population of laboratory professionals.

key informant interview also collected with selected stake holders, like physicians and laboratory managers to get deeper insight in to the management practice.

4.7.1. Sampling method

The study employed a purposive sampling technique to select the study sites. Four public hospitals in Addis Ababa, Tikur Anbessa, St. Paul's, Yekatit 12, and Minilik hospitals were deliberately chosen because they are major referral centers with high patient flow and are representative of public hospital laboratory practices in the city. Within these hospitals, all eligible laboratory professionals who met the inclusion criteria during the study period were included in the study, effectively using a census approach at the participant level. This approach ensured that the data collected reflected the full range of experiences and practices related to critical result management in the selected hospitals.

For the prospective component, all critical laboratory results generated during a two-month observation period were collected and assessed, allowing real-time evaluation of critical result management practices.

4.7.2. Data collection tool

To assess critical laboratory test result management practice and associated factors at selected public hospital laboratories in Addis Ababa. Key informant interview, Document Review, and Questionnaire for Laboratory Staff and clinicians are used.

1. Self-administered questionnaire was developed in order to collect the study data from participants. The data collection questionnaire was prepared in consulting with advisor, program managers, literatures reviewed and referring different recent guidelines and other documents. The questionnaires covered the areas the awareness of SOP, training history, communication methods, documentation practice and perceived challenges.

2. document review: 422 test results were reviewed during a 2month period across the four hospitals. the form captured the date of the test done, the test type, communication method, turnaround time, and documentation practice.

Initially the study was designed to have both the retrospective and prospective document reviews. But, during data collection none of the four hospitals had a proper documentation of critical results. So retrospective data collection was not possible, therefore we stuck with only prospective data collection.

3. key informant interview: laboratory managers and clinicians were interviewed to get a deeper understanding about the management practice of critical results.

4.8. Data quality assurance

Before starting data collection, a preliminary assessment was done by visiting the four hospitals to observe the general practice and trends related to critical laboratory result management practice and assess the feasibility of the planned data collection tools. The visit helped the research team to understand better about the workflow and the approach.

The questioners before collecting the actual data was reviewed and refined to ensure its clarity and easily understandability for each respondent. After the required refinement taken place questionnaire was distributed to each study participants. Data collection was by trained and well experienced personnel with the necessary proper supervision or under control. The principal investigator rechecked the completeness of the questionnaire and its clarity. Each questionnaire was given different identification number and validated by double data entry.

4.9. Data management and analysis

Quantitative data after completed, screened and coded entered into Microsoft excel for data entry and cleaning. Then the data were exported and analyzed using SPSS software. The main outcome variable of the study was critical result management (CRM) practice measured using a single structured questionnaire answered by laboratory professionals “Is your hospital's critical result management practice good?” response was categorized as YES AND NO the outcome was used to dichotomize the outcome variable The analyzed quantitative data presented using descriptive statistic such as percentage, frequency distribution, and appropriate graph. Bivariate

logistic regression was performed to identify the association between each variable and dependent variable, variables with p value <0.25 entered in to multivariate logistic regression to control potential confounders.

The analysis of qualitative data will be done manually. The data will be summarized and analyzed thematically, with relevant quotations used to illustrate themes in the presentation of the study findings.

4.10. Ethical considerations

Before conducting the research, ethical clearance was obtained from the Department Research and Ethical Review Committee (DRERC) of Department of Medical Laboratory Sciences College of Health Sciences Addis Ababa University. Beside this, formal and official letter of cooperation was written from Department of Medical Laboratory Sciences to the study sites informed consent was obtained from each individual participant prior to conducting the study.

4.11. Dissemination of result

After the study was completed, the result was delivered to Addis Ababa University department Medical Laboratory Science and relevant bodies or stake holders. It will available in the library to serve as a reference material for students, researchers, experts or policy makers for intervention. This result will also be disseminated for publication in peer reviewed local and international journals and presenting in related conferences.

4.12. Operational definition

Critical laboratory result: are laboratory test results or findings that may be considered life-threatening and require urgent clinical attention.

Critical result management practice: an entire process of managing critical results starting from result identification, communication, policy implementation, reporting at a given time, documentation, and corrective action. Measured by document review, staff questionnaire, and key informant interview.

Documentation of critical results: a process of recording critical result management content like date, time, responsible laboratory individual, person notified and test results and for procedures and preventive actions for any problems encountered in transmitting critical result information. In this study documentation is considered present if recorded in real time and remain traceable in the laboratory information or quality records systems.

Read-back policy: In verbal communications, the notifier should confirm that the information has been received and understood correctly by repeating back the result of the test.

Availability of SOP for critical result management: existence of written, well documented procedure that guides how to handle critical results.

Communication method: the mode used to transmit critical results to the clinicians.

Stakeholder involvement: participation of the relevant body (clinician, hospital administration, laboratory professionals, patient care …) in the preparation of critical value limits and SOPs/policies and procedures.

Audit practice: routinely checking and evaluating critical result management practice.

Awareness on critical result management: knowledge of healthcare providers on critical result policies and procedures for timely communication and management of critical results.

Training on critical result management: a formal training given to professionals to identify and handle critical results. identified through self-administered questionnaire.

5. Result

5.1. Sociodemographic characteristics of study participants at selected public hospitals, AA, Ethiopia, 2025.

A total of 156 participants were included in the study, of these, 116 were laboratory professionals who completed a structured questionnaire. among them 112(96.6%) were lab technologists and 4(3.4) of them were laboratory managers with different years of experience. From the 116 participants 111(95.7%) never received any training on critical result management, only 5(4.3%) reported they had received such training. Additionally, there were also 40 physicians included in the study who responded a separate questionnaire designed to assess the perspective and awareness of critical result management practice

Variable	Category	Frequency (n)	Percent (%)
Professional Role	Lab Technologist	112	96.6%
	Lab Manager	4	3.4%
Years of work Experience	6 month -1 year	13	11.2%
	1–5 years	36	31.0%
	6–10 years	39	33.6%
	>10 years	28	24.1%
Training of critical Result management	Yes	5	4.3%
	No, never	111	95.7%

Table 2 Sociodemographic characteristics of study participants at selected public hospitals, AA, Ethiopia, 2025.

5.2. Distribution of critical results (by test type)

From the randomly collected 422 critical results when categorized in test type the majority tests 197(46.6%) were hematological followed by blood glucose test 58(13.7%). liver function tests 50(11.8%), electrolytes 43(10.19%) and renal function test 41(9.7%) cardiac marker took the smaller portion 18(4.2%) and coagulation test 15(3.56%).

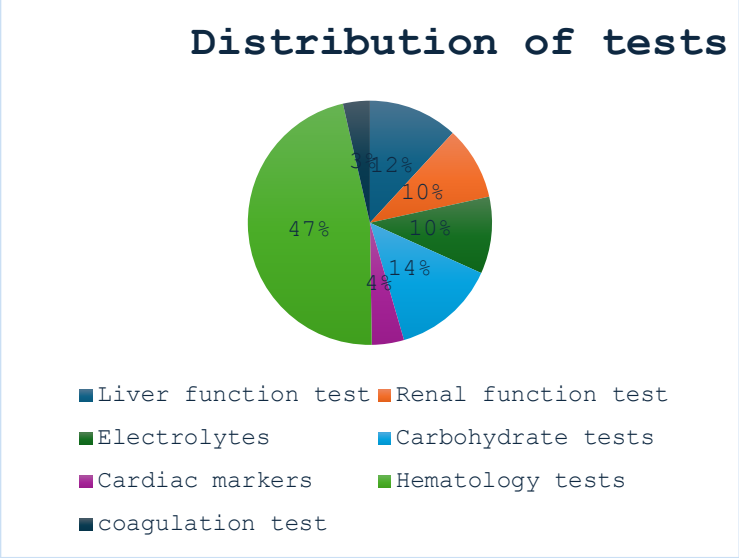

Figure 2 distribution of tests at selected public hospitals, AA, Ethiopia, 2025

5.3. Distribution of test by grouped department categories

From the 422 tests when categorized by grouped département categories most of the tests 204(48.3%) are ordered from emergency& ICU care units, 130(30.8%) of tests are from internal medicine/general ward followed by neonatal & pediatric department 46(10.9%), the other oncology& hematology unit and surgical & anesthesia department accounts 21(5%) each.

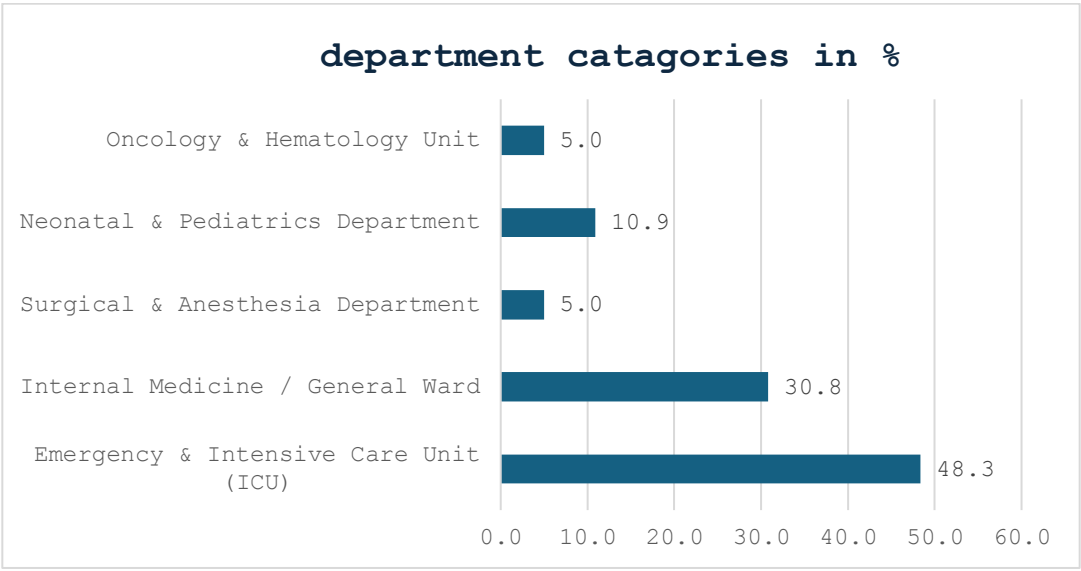

Figure 3 distribution of tests at selected public hospitals, AA, Ethiopia, 2025

5.4. Collected Critical Results

The collected 422 critical results are categorized by analyte type and abnormal thresholds. The table also represent the frequency and percentage of each test.

Analytes	Results	Number of tests
Hematological test		
Hemoglobin	<6.0g/dl, >21.0g/dL	64
Hematocrit	<21%, >65%	48
WBC	<4,000/µL,>100,000/µL	36
Platelet count	<20,000/µL, >1,000,000/µL	49
Carbohydrate test		
Glucose	<40 mg/dl, >500 mg/dL	58
Cardiac marker		
Troponin l	Any value above 99th percentile	18
Electrolytes		
Potassium	< 2.5 mmol/L, > 6.5 mmol/L	18
Sodium	< 120 mmol/L, > 160 mmol/L	12
Calcium	< 6.5 mg/dL, > 13.5 mg/dL	9
Phosphate	<1.0mg/dL, >6.5 mg/dL	4
Renal function tests		
Creatinine	>0.3mg/dL	31
BUN(blood urea nitrogen)	>100mg/dL	5
Uric acid	>13mg/dL	5
Liver function test		
Total Bilirubin	>20 mg/dL	39
INR (Prothrombin time)	>5.0	11
Coagulation test		
Activated Partial Thromboplastin Time (aPTT)	>100 seconds	15

Table 3 collected critical analytes and thresholds at selected public hospitals, AA, Ethiopia, 2025

5.5. Turnaround time (TAT) for critical result communication

The turnaround time was assessed whether the critical results were communicated within 30 minutes or delayed than 30 minutes. based on our prospective data out of 422 critical tests. Based on this study majority 259(61.4%) of test results were delayed, From the four hospitals SPHMMC showed the best performance, with 93% of critical results communicated with in the recommended time frame 30 minutes in contrast Yekatit 12 Hospital medical college had reported only 4% of the total critical results.

Hospital	**Within 30 minutes**	**delayed**
TASH	47(38.5%)	75(61.5%)
SPHMMC	93(93.0%)	7(7.0%)
YEKATIT 12	4(4.0%)	96(96.0%)
MENELIKII Hospital	19(19%)	81(81.0)
Total	163(38.6%)	259(61.4%)

Table 4 TAT for critical result communication at selected public hospitals, AA, Ethiopia, 2025

5.6. Communication methods used and Application of Readback policy for critical results The communication of critical results was assessed from the total of 422 critical test across the four public hospitals. The majority of the critical tests were sent by electronic health record system (388)91.9%, in person 18(4.3%), phone call 9(2.1%), and paper-based methods 7(1.7%). **However,** from the collected 422 critical results 388(91.9%) communicated by EHR **were reported in the same manner as routine tests (non-critical) with no sign of urgency** and without any proper flagging system referring them as a critical value. As a result, only 34(8.1%) recognized and managed as critical results.

Hospital	PHONE CALL	EHR	PAPER BASED	IN PERSON	Readback policy
TASH	0	106	0	16	0
SPHMMC	8	90	0	2	6
YEKATIT 12	1	92	7	0	0
MENELIKII Hospital	0	100	0	0	0
Total	9(2.1%)	388(91.9)	7(1.7%)	18(4.3%)	

Table 5 Communication methods used and Application of Readback policy for critical results at selected public hospitals, AA, Ethiopia, 2025

5.6.1. Application of Readback policy

Readback policy is a policy for a safety procedure which the receiver of critical result repeats the critical value back to the sender for accurate communication, a key component for critical result management. In this study, from the communicated critical results 34(8.1) only 6(17.6%) of them were communicated with application of readback policy.

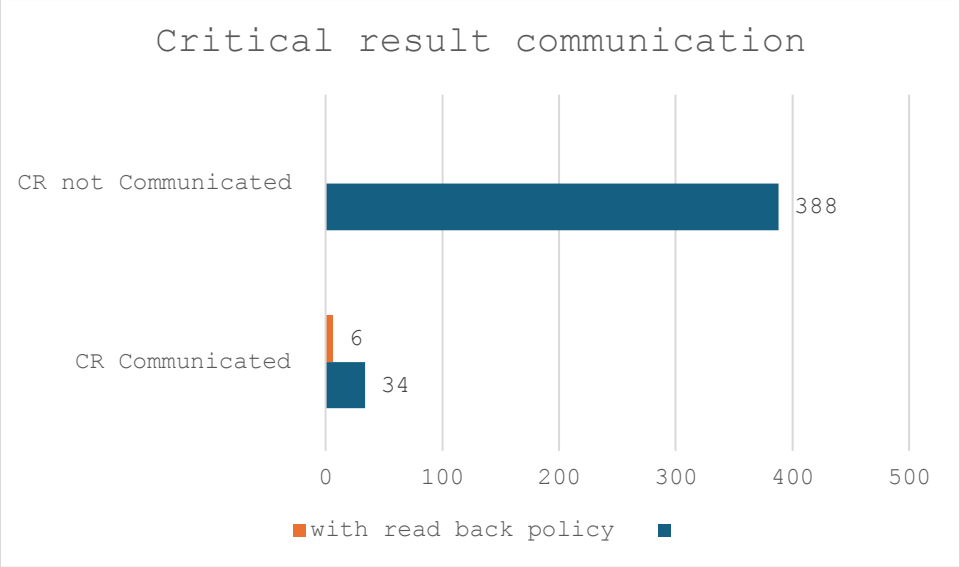

Figure 3 critical result communication and readback application at selected public hospitals, AA, Ethiopia, 2025

5.7. Institutional and Personnel Factors Affecting Critical Result Management

A defined list of critical laboratory test results was reported to be available by 94(81%) of respondents**.**

97(83.6%) of participants reported they are aware of the existence of hospitals policy for managing critical laboratory results. However, when participants are asked if they have read the hospitals policy only 68(58.6%) stated they have read it.

SOP specific to critical result management was assessed in each hospital because this is a key indicator of standardized handling of critical results. And all four hospitals in the study have SOP for critical result management.

In the development of SOPs laboratory staff, clinicians, hospital management participation is an essential criterion to ensure practical relevance of staff ownership, however from all four hospitals none of them involve stakeholders in sop preparation process.

The participants were asked if they have received trainings in critical result management practice from 116 participants only 5(4.3%) reported they took training the rest 111(95.7%) answered that no trainings provided.

Similarly, the participants were asked if their hospital conduct audits in critical result management practices where 51(44.0%) of the participants said their hospital conduct audits and the rest 65(56.0%) reported there are no audits on critical result management practice.

Participants were asked whether hospital management supports critical result management system, out of 116 respondents 77(62.1%) reported that their hospital doesn't have a functional management system where 44(37.9%) reported there is a system is actively in use.

When asked if their hospital communication mechanism is effective 74(63.8%) of the participants reported they don't think its effective while the rest 42(36.2%) agreed on its effectiveness.

One of the important factors read back policy where the receiver of the result repeats back the result of the test back to the sender to confirm accuracy was reported by only 48(41.4%) of the respondent while in the rest 68(58.6%) reported the policy is not in use.

Most of the participants, 82(70.7%) reported high workload affects critical result management.

Additionally,76(65.5%) percent of respondents also believed resource limitation has a significant effect in the management of critical results.

Variable	Category	Frequency(n)	Percent (%)
Availability of defined list of critical laboratory tests and results	Yes	94	81.0
	No	22	19.0
Hospital level awareness of critical result management policy	Yes	79	68.1
	No	37	31.9
Read the policy of CRM (if available)	Yes	68	58.6
	No	48	41.4
Availability of standard operating procedure (SOPs) for CRM	Yes	4/4 hospitals	100
Stakeholder involvement in SOP preparation	Not involved	4	100
Training received on CRM	Yes	5	4.3
	No	111	95.7
Regular audits conducted on CRM	Yes	51	44.0
	No	65	56.0
Availability of Functional hospital CRM system	Yes	44	37.9
	No	77	62.1
Effective communication exists	Yes	42	36.2
	No	74	63.8
Readback policy applied	Yes	30	25.9
	No	86	74.1
Workload affects CRM	Yes	82	70.7
	No	34	29.3
Resource limitation affects CRM	Yes	76	65.5
	No	40	34.5

Table 6 summary of Institutional and Personnel Factors Affecting Critical Result Management in public hospitals, Addis Ababa,2025

5.8 Factors Associated with Poor Critical Result Management Practice

The table shows the bivariable (COR) and multivariable (AOR) logistic regression analysis of factors associated with critical result management practice. Hospital management support and the presence of an effective communication mechanism were significantly associated with good practice, increasing the odds by 3.6 times (AOR = 3.58, 95% CI: 1.02–12.61) and 4 times (AOR = 4.05, 95% CI: 1.40–11.76), respectively. High workload negatively affected practice, with those reporting high workload being over 4 times more likely to have poor practice (AOR = 4.23, 95% CI: 1.25–14.36). Resource limitation was significant in the bivariable analysis but not in the multivariable model (AOR = 0.32, 95% CI: 0.09–1.10).

variables	category	Yes (good CRM)	No (poor CRM)	COR (95%CI)	p-value	AOR (95%CI)	p-value
hospital management support	yes	15(35.7%)	9(14.0%)	4.012(1.567,10.275)	0.004	3.579(1.016,12.608)	0.047
	no	27(64.3%)	65(86.0%)	1		1	
resources limitation	yes	8(33.3%)	63(68.5%)	4.345(1.670,11.301)	0.003	0.322(0.094,1.103)	0.071
	no	16(66.7%)	29(31.5%)	1		1	
Effective communication mechanism	yes	16(66.7%)	8(25.0%)	5.6(2.2,14.9)	0.001	4.05(1.4,11.76)	0.001
	no	68(33.3%)	24(75.0%)	1		1	
High workload	yes	9(37.5%)	66(71.7%)	4.231(1.648,10.861)	0.003	4.232(1.247,14.364)	0.021
	no	15(62.5%)	26(28.3%)	1		1	

Table 6 Factors Associated with Poor Critical Result Management Practice at selected public hospitals 2024, Addis Ababa

5.16. Physician Perspectives on Critical Laboratory Result (CR) Management

5.16.1. Communication mechanism

Phone	17(42.5%)
Paper based	11(27.5%)
SMS/text	0(0%)
EHR	25(62.5%)

Table 7 communication mechanism in public hospitals, Addis Ababa,2025

5.16.2. Satisfaction with Critical Result Management

Out of 40 physicians from the four public hospitals surveyed (36)90% reported being dissatisfied with the current critical result management while the rest 4(10%) remained neutral. none of the physicians expressed satisfaction with the system.

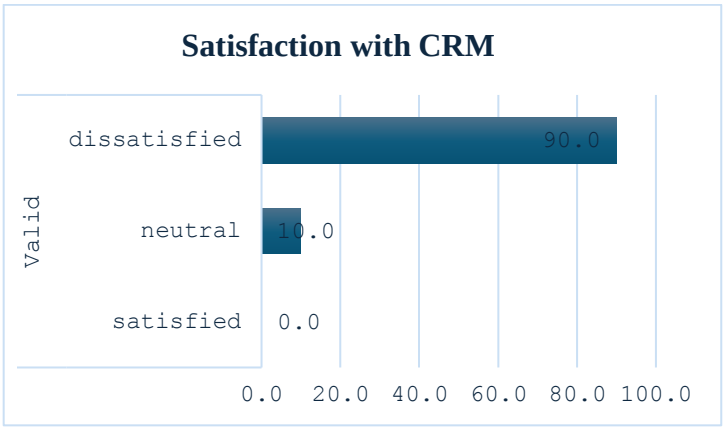

Figure 4 physicians' satisfaction with CRM at public hospitals, Addis Ababa,2025

5.16.3. Perceived consequences of poor critical result management

Among the physician's (40)100% of them reported poor critical result management can delay treatment that could have been given to the patients.in addition 26(65%) reported it causes increases hospital stay and 22(55%) indicated patient deterioration.

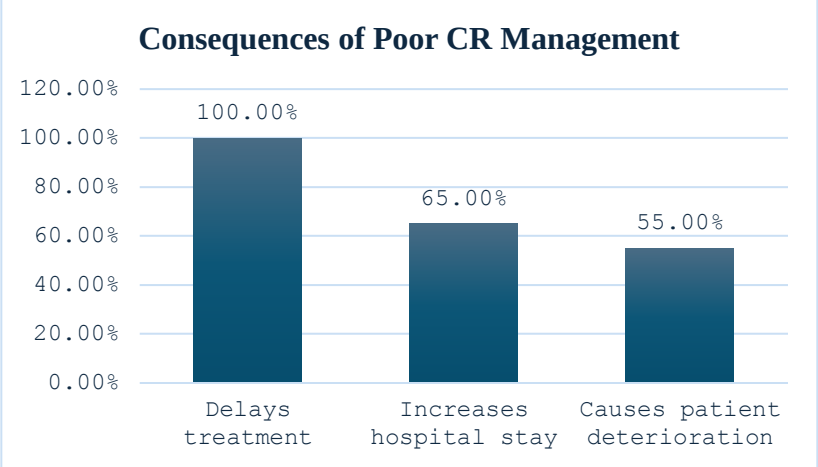

Figure 5 consequence of poor CR at public hospitals, Addis Ababa,2025

5.16.4. Suggested Improvements

The physicians were asked what improvements would they suggest for the communication of critical laboratory results for the better management of critical result nearly all 39(97.5%) of them stated faster communication methods will improve critical result management. Furthermore, 24(60%) of them reported Standardized protocols for communication will be effective while 20(50%) reported better training for laboratory staff is important, additionally 16(40%) highlighted the importance of improved documentation and tracking systems to ensure follow up and accountability.

5.16.5. Physicians Knowledge of Policies or SOPs for Critical Result Management

When the physicians asked about if they are aware of the hospital policy or procedure of critical result management 35(87.5%) of them reported they are not aware of such policy the remaining 5(12.5%) of them stated they are aware of the relevant SOP or guideline

5.16.6. Who Communicates the Critical Results?

Physicians were asked who communicates critical results more to them the response show of lack of consistency even from the same hospitals the majority selected EHR 24(60%) while 23(57.5%) reported laboratory personnel reported to them where 13(32.5%) of participants selected nurses communicated to them.

5.16.7. Reliability of the current system

All 40(100%) of the physicians asked reported current system of critical result communication is not reliable.

5.17. Qualitative result

Qualitative study was performed to analyze the management practice of critical results and to have a better understanding of laboratory managers and physicians' perspective.

Socio demographic characteristics

8 key informants were interviewed for this study. 4 laboratory managers, 1 from each hospital, and 4 physicians, again 1 from each hospital were included. 2 of the laboratory managers were females the rest of the key informants were male. The findings were categorized into theme manually and the information was summarized and presented using narrative approach.

Theme 1: Existence and Implementation of critical Result Management Procedures

All of the four hospitals reported to have SOPs to guide handling of critical results. But the details in SOPs and implementation vary.

In the SOPs hospitals must differentiate critical tests and set critical limits in collaboration with clinicians. Reporting procedures must include how critical results are identified; who can report and who can receive critical results; what is an acceptable timeframe within which results must be delivered or, if reporting fails, what escalation procedures should follow; what communication channels or systems should be used; what should be recorded and how; and how critical result procedures should be maintained and evaluated to assess impact on outcomes.

In the interview laboratory managers were asked how their laboratory handles critical results from detection to notification.

A laboratory manger from one hospital responded by saying *"We have such policies for Critical Result handling. The purpose of the SOP is to provide appropriate guidance to personnel. We check for critical results during result action, identify the ward and requesting physician, and notify the result as soon as possible."*

The participant said *"When a critical result is detected (from analyzer or LIS), lab personnel review and document it on the appropriate log sheet. The case team head communicates with clinicians or responsible persons within a given time. The communication is also documented with time, recipient, result, and the patient's department."*

However, during documented review, no evidence of documented critical result was seen and when asked to explain why the respondent answered "*Although There is a written procedure to document critical results, due to negligence and low motivation among employes there is failure in documentation practice"*

Another respondent said *"There is a written SOP for handling critical results. We have even posted critical tests and handling procedures on the wall. Based on that, lab professionals report critical results to clinicians. For outpatients, if it's urgent, we use the phone number on the LIS to call them."*

One participant reported *"Critical results are managed based on the SOP we have in every laboratory department, with the critical tests and values listed."*

Theme 2: Perceived Effectiveness and Challenges of Critical Result Management Systems

The participants were asked if they think current system in their hospital for managing critical results is effective all the four hospital managers expressed their concerns, identifying specific gaps and challenges that limit timely and reliable communication.

The respondent said *"The system for managing critical results in our laboratory is not well effective because there are gaps in identifying critical results within the recommended timeline. Lack of immediate reporting as results are detected and poor system integration reduce effectiveness."*

Similarly, the representative from one acknowledged some effectiveness but pointed the challenges their hospital faced in communication:

"At some points, it is effective, but there are issues to be addressed to manage patients timely. The system lacks a pop-up alert to notify physicians of critical results."

The interviewee mentioned the high workload in their hospital and the volume of critical results per day as major barriers: *"I think it is not that much effective because there is high workload and too many critical results in a day, which makes handling critical results it difficult."*

Similarly, one respondent said "*currently no its not our LIS system doesn't have a pop-up notification system, there is also high workload in our hospital so we are not handling it as we have to"*

Theme 3: Barriers to Effective Management and Communication of Critical Results

From the selected hospitals one reported, the lack of technological support was clearly stated:

"On the EMR, there is no 'pop-up' alarm to notify the critical result immediately as the lab reports the result."

The respondent highlighted: *"Several challenges arise during communication of critical results like incorrect contact information, high workload, misinterpretation of results, lack of communication mechanisms such as phone, and ignorance of results."*

Similarly, the interviewee stated *"As I mentioned earlier, high workload and too many critical results are some of them. Lack of communication mechanisms, a lack of a well-organized system, and many other factors can be barriers."*

The lab manager stated: *"there is a plenty of reasons and the major one is the communication mechanism between the lab professionals and the physicians which creates delays furthermore the high workload makes it more difficult"*

Theme 4: Absence of Follow-Up Systems for Clinician Action

All the four hospitals laboratory managers indicate the lack of such system and there is no way they could ensure if the physician responds promptly after the communication of the result

The participant stated they don't have the system to ensure the action taken but outlined an ideal set of measures, more as recommendations for what should be in place:

"We don't have such a system to ensure that critical results are acted upon in a timely manner, every laboratory should have a standardized procedure, record all communications with time, use an integrated LIS, review and use audit results, and have a clear communication mechanism."

The other three hospitals also admitted there is no system currently in place to verify that clinicians take timely action:

"We don't have any system to ensure that clinicians manage the critical result in a timely manner." Said one participant.

"We don't have any system to check that." stated the interviewee

One participant from the selected hospital stated *"We don't have any system to ensure that."*

Theme 5: Need for systematic improvements and standardization

The participants were asked what one thing they would change if they could to improve critical result management. participants from all four hospitals expressed their desire for structural improvements, their response vary based on their current system they have.

The respondent emphasized the need for interprofessional collaboration and list refinement:

"To standardize and limit the list of critical results in collaboration with other health professionals."

Another participant answered: *"The system should have a 'Pop-Up' alarm and there should be the phone number of the clinician to report the result as soon as possible… To create a system that can ensure the critical results can be managed timely—improve the way of communication with physicians."*

Respondent highlighted the absence of coordination and structure: *"To have a well-integrated and organized system."*

Similarly, another echoed the same general gap: *"To have a better system."*

Qualitative Results: Physicians' Perspectives on critical Laboratory Result Management

All the four physicians interviewed from the selected four hospitals provided almost similar response across the four interview questions. Due to the uniform response one or two representative quote is included for each theme.

Theme 1: Handling of critical results from detection to notification

Most of the answer from the physicians were similar which indicate a poor communication system.

Respondent said *"I am an ICU doctor, and I always go to the lab myself to check results sometimes, especially if it is urgent."*

These indicate a lack of systematic communication placing burden on physicians.

A clinician noted from emergency noted "most of the time we receive these results by LIS, so no one inform us directly. We usually find out when we check the system"

Theme 2: perception of the current system's effectiveness

The physicians from TASH and SPHMMC expressed the LIS system is accessible and generally accurate but if the lab professionals don't enter the data timely, we can't receive CR promptly which delay clinical decision making and patient care.

In the words of one interviewee *"The system is really good because it's electronic and you can access what you want whenever, so it's good, may be accurate, but not timely."*

Respondents from Menelik II and Yekatit 12 hospital said there is no well-established or standardized communication methods for CR management.

"I don't think the current system is effective at all, of course results show up on the system but if no one tell us its urgent we might not see it in time. The whole process needs a lot improvement." Participant answered.

Theme 3: Experiences of Delayed or Missed Critical Results

The physicians' answers are almost similar across the four hospitals confirming that delays and missed critical results happen frequently.

"Many tests are delayed or missed. I know laboratorians don't see the patient's condition, so they may not 'critical,' but it is seriously difficult, especially with electrolyte tests which are very important in our case, and delays can cause serious consequences." Participant from the selected hospital.

This response reveals that communication failures have a serious clinical risk and that improved awareness and urgency in the lab are needed.

Theme 4: Recommendations for Improvement

The physicians were asked what they recommend to improve the management of critical results they all emphasized the need for better communication, infrastructure and stronger coordination between laboratories and clinical staff in order to enhance effective critical result management."

One of the physicians stated *"If the hospitals prepare phones for communication, have sufficient staff, proper documentation, and a better communication system to link labs with clinicians easily, it will really help."*

6. Discussion

A descriptive, institutional-based cross-sectional study design was conducted to comprehensively assess critical result management practice across four public hospitals in Addis Ababa, Ethiopia. highlighting a gap in documentation, communication, stakeholder involvement in SOP preparation, and policy implementation. Although all the four hospitals have an SOP for critical result management stakeholders were not involved in the preparation of SOP which undermine the relevance of these protocols. International guidelines like ISO 15189 and CLSI GP47 emphasize that the development of SOPs for critical result management should involve multidisciplinary team like clinicians/practitioners, hospital managements, IT experts, patients and carers, laboratory staff to ensure clinical relevance.(3) Yet many studies have shown that laboratories worldwide do not consistently follow this practice. More over even if all the hospitals have SOPs most of the time, they don't implement them properly qualitative findings indicate that their implementation is inconsistent. For instance, one laboratory manager noted ""*Although There is a written procedure to document critical results, due to negligence and low motivation among employes there is failure in documentation practice"* this indicates a disconnect between policy and practice.

A major concern identified is there is no proper documentation in all the four hospitals, these compromises accountability, patient safety and accreditation standards. According to ISO 18915 laboratory should keep records of "actions taken that document date, time, responsible laboratory staff member, person notified and examination results conveyed, and any difficulties encountered in notifications".(12) Similar study in Nigeria shows from 371 critical results only 71(21%) are documented.(11) These results also show a low rate of documentation But our study shows no proper documentation across the four hospitals indicating an un urgent attention. since data recording enables laboratories to monitor and measure their performance in notifying critical results and identify possible improvements.

In the study, all the tests communicated by EHR 388(91.9%) are reported as a routine tests, without any proper flagging system referring them as a critical value. As a result, out of the 422 critical results only 34(8.1%) recognized and managed as critical results. These indicate a very serious gap in identification and communication of life-threatening laboratory results, similarly a study conducted in Nigeria found that out of 134 surveyed laboratories, only 69(51.5%) practiced critical result notification.(12) other surveys reported in many high-income countries show much higher rates.(35)

Furthermore, most of the hospitals does not apply readback policy, with only 17.6% of results confirmed through readback from the communicated results in SPHMMC showing a wide gap in the management, according to the Joint Commission, the receiving healthcare professional must read back the test result to confirm the received

result and inform the patient's identification.(1) The lack of this practice further highlights the critical gap in the management.

The study also highlights gaps in awareness regarding the SOP availability for critical result management. among the laboratory professionals only 58.6% of participants reported reading the policy in their hospital. Among clinicians most of the participants 87.5% were unaware of the existence of such policy. This huge gap in knowledge creates inconsistency in management, delays in patient care, increase hospital stays even adverse patient outcomes. Emphasizing the need for training for both healthcare providers. Notably, only 4.3% of laboratory technologists reported receiving trainings on critical results, as studies shown sustained training initiatives can enhance healthcare providers' competencies and performance in community health settings.(23)

Over 50% of participants reported high workload and resource limitations are a significant barrier in the management of critical results. These challenges are consistent with global reports that indicate that infrastructural and staffing constraints hinder effective critical result handling.(36) this finding is consistent with other studies for example, study done in university of Delaware found that 62.9% of participants reported Excessive workload as a major factor for poor critical result communication and management, Addressing these systemic issues is essential for improving patient safety and outcomes.

Binary logistics regression and multivariate analysis showing communication mechanism, resource limitation, high workload and lack of management having a significant effect in the management of critical results. These finding implies multifactorial nature of the problem

90% of physicians also express their dissatisfaction with the current system and recognizing the outcome of poor critical result management such as delayed treatment, increased hospital stays and even patient deterioration. This is supported by a systematic review which revealed that 20–60% of inpatient test results were overlooked or left unattended and the most significant adverse outcomes included missed diagnoses and inappropriate or delayed treatment decisions.(3) our study participants also emphasize the inconsistency in communication, lack of reliable documentation practice not implementing policies, not involving stakeholders in SOP development highlight the need of standardized protocol and a well-orchestrated system. Supporting this many studies implies the importance of critical result communication for patient safety, for instance, study in Brazil stated two-thirds of critical results lead to some change in therapeutic approach. And 95% of physicians consider it useful in decision-making and patient management.(1)

In this study, hospital management support and effective communication were positively associated with good critical result management, while high workload negatively affected practice. Resource limitation was not significant after adjustment, indicating that organizational support and communication are more important determinants of proper critical result management.

Future research should focus on longitudinal assessments to evaluate the impact of targeted interventions, such as implementing standardized communication protocols, enhancing staff training, and improving resource allocation. Moreover, exploring patient outcomes related to critical result management practices could provide further insights into the clinical significance of these systemic gaps.

6.1. Strength and limitation of the study

This study has several strengths. It was conducted in a major public hospital in Addis Ababa, which creates representativeness of the public healthcare settings. we also used multiple data collection tools to increase reliability and validity of the results.

However, the study also has some limitations. There is lack of similar studies to make adequate comparison. Moreover, critical value thresholds may vary slightly among laboratories, for the purposes of this study a standardized reference range was used to ensure consistency in data collection and analysis.

7. Conclusion

This study shows a significant gap in critical result management practice across the four selected public hospitals in Addis Ababa, Ethiopia. Various problems are revealed in critical result management practice starting from preparing SOP without the involvement of stake holders to low awareness among clinicians and laboratory professionals, poor documentation, minimal use of readback policies, inconsistent communication methods compromise patient safety and timely care. The study also identified factors that associate with poor CRM, these include effective communication system, high workload, limited hospital management system, and resource constraint. Furthermore, poor management of critical results lead to workload, wastage of healthcare resources, and general inefficiencies that put additional pressure on an already strained system. These findings highlight the need for harmonizing the critical result management practice, strengthening the system, policy enforcement.

8. Recommendation

As this study shows there is critical gap in the management practice of critical laboratory results in Ethiopian public hospitals, that directly affects patients' safety and timely clinical decisions. Therefore, its recommended all participating hospitals to have SOPs that align with international best practices and involve stakeholders including clinicians, laboratory professionals, hospital management, patient care in their development and review.

Furthermore, Laboratory professionals also must receive structured and regular trainings to improve their understanding of critical results and management of CRs. Additionally, as the study implies there is no documentation practice in all the laboratories studied which is a crucial practice for accountability, performance monitoring and compliance with accreditation standards. As a result, all the four hospitals must establish documentation systems and educate their employes on the importance of documentation. Moreover, in order to ensure ongoing improvements, regular audits and policy revision should be conducted also by having consistent engagement between laboratory staffs, clinicians, hospital administrators, quality assurance teams laboratories must improve patient care outcomes. Furthermore, hospitals should allocate sufficient human resource and invest reliable communication tool for better communication and management of critical results.

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Annexes

Annex I Information sheet

Title of the Research Project: Critical result management practice and associated factors in public hospitals Addis Ababa, Ethiopia.

Principal Investigator: Arsemawit Teferedegne (BSc, MSc candidate)

Name of the Organization:

Introduction You are invited to participate as a study subject in research conducted by MSc candidate, from Addis Ababa University. Your participation is voluntarily. The research teams will include one principal investigator, one advisor; from Addis Ababa University laboratory management department. Please take as much time as you need to read or listen in the information sheet. Purpose of the Research Project

Potential benefits to subjects and/or to the society

There will not be any payment for your participation in this research study as compensation. However, based on the result your hospital will have an opportunity to have much feedback on the essential gaps and also acknowledgment on the strong quality during project. In addition, participating in this study is adding reference information in the benefit of society beneficial

Participation and Withdrawal from the Study

The participation is voluntary and you have the right not to participate in this study. You may withdraw at any time and place without consequences of any kind.

Annex II

Informed consent

I had been informed that the objective of this study is to assess critical result management practice and associated factors in public hospitals Addis Ababa, Ethiopia. The results of this study have an importance to have a clear insight in government hospital, and to be used as an input for the future development of strategies or guidelines for evaluating critical result management in Ethiopia. Principal investigator requested me to participate in the study that would require my willingness to provide the required data. Therefore, with full understanding of the importance of the study, I agreed voluntarily to provide the requested information.

I_____ hereby give my consent for providing the requested information.

Signature: _____ Date_____

Annex III

Data Collection Tool: Laboratory professional perspective management Practices of Critical Laboratory Results

A self-administered questionnaire to assess about critical laboratory test result management practice and associated factors at selected health facilities of Adiss Ababa, Ethiopia.

1. participant code
2. hospital name or code
3. what is your professional role?
○ Laboratory technologist
○ Laboratory technician
○ Laboratory manager
○ Other (please specify)
4. years of work experience
○ Less than 1 year
○ 1-5 years
○ 6-10 years
○ More than 10 years
5. Is your hospital's critical result management practice good?
○ Yes
○ No
6. does your hospital have a written critical result management protocol?
○ Yes
○ No
7. (if yes for Q6) have you read them?
○ Yes
○ No
8. Does stakeholder (e.g. laboratory managers, clinicians, hospital administrations) involved in SOP preparation?
○ Yes
○ No
9. is your hospital critical result communication mechanism effective?

○ Yes
○ No
10. is the readback policy used when communicating critical results?
○ Yes
○ No
11. does your hospital have a proper documentation system for critical result?
○ yes
○ no
12. what communication mechanism does your hospital uses for communicating critical results?
○ Phone call
○ Electronic health record
○ In person/verbal
○ Paper based
○ Other (please specify)
13. does your hospital conduct audits regarding critical result management practice?
○ Yes
○ No
14. Does your hospital revise its policy regularly?
○ Yes
○ No
15. have you received training related to critical result management?
○ Yes
○ No
16. What challenges do you face in managing critical laboratory results? (Check all that apply)
○ Lack of standardized protocols
○ Insufficient staff training
○ High workload
○ Poor communication systems
○ Limited resources (e.g., phones, computers)
○ Other (specify): _____

Annex IV

Physicians' Perspectives on Critical Results Management

A self-administered questionnaire to assess about critical laboratory test result management practice and associated factors at selected health facilities of Adiss Ababa, Ethiopia.

1. Participants code
2. Hospital name or code
3. How do you usually receive critical laboratory results? (check all that apply)
○ Phone call
○ Electronic health record
○ Paper based reporting
○ In person/verbal
○ Other (please specify)
4. Have you experience delays in receiving critical laboratory results?
○ Yes
○ No
5. If yes, what were the consequences? (check all that apply)
○ Delayed treatment
○ Increase hospital stays
○ Patient deterioration
○ Other (please specify)
6. Who usually communicates critical results to you?
○ Laboratory personnel
○ Nurse
○ Medical records staff
○ Other (specify):
7. How satisfied are you with the communication and timeliness of critical results notifications?
○ Satisfied
○ Neutral
○ Dissatisfied
8. Do you believe the current method of critical result communication is reliable?
○ Yes

○ No
9. What improvements do you suggest for better critical result communication? (check all that apply)
○ Faster communication methods
○ Standardized protocols for communication
○ Better training for laboratory staff
○ Improved documentation and tracking systems
○ Other (please specify)
10. Are you aware of hospital's policy or SOP for critical result management?
○ Yes
○ No

Annex VI

Interview Guide for Laboratory Managers

Date: _____

Facility: _____

Questions:

1. Can you describe how your lab handles critical results from detection to notification?

2. Do you think the current system for managing critical results is effective? Why or why not?

3. What are the main barriers your team faces in managing and communicating critical results?

4. How do you ensure that critical results are acted upon by clinicians in a timely manner?

5. If you could change one thing to improve critical result management, what would it be?

Interview guide for physician

Participant code:

Date: _____

Facility: _____

Questions:

1. How are you typically informed about critical laboratory results in this hospital?

2. Do you feel the current system ensures timely and accurate communication of critical results? Why or why not?

3. Have you ever experienced a situation where a critical result was delayed or missed? What happened?

4. What would you recommend to improve the handling of critical lab results in your hospital?

10. DECLARATION

I declare that this thesis Paper entitled "Critical result management practice and associated factors in selected public hospitals Addis Ababa, Ethiopia" is my original work in partial fulfillment for a Master of Science degree in Clinical Laboratory Management and Quality Assurance.

Name	**Signature**	**Date**
Arsemawit Teferedegn	_____	_____

"This paperwork has been submitted for examination with our approval as advisors."

Advisors	**Signature**	**Date**
Dr. Fatuma Hassen	_____	_____
Dr. Abay Sisay	_____	_____

Place of submission

Department of Medical Laboratory Sciences, college of Health Sciences, Addis Ababa University

Date of Submission ……