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Extra-analytical clinical laboratory errors in Africa: a systematic review and meta-analysis

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ABSTRACT

Background

Clinical laboratory testing is a highly complex process involving a different procedure. Laboratory errors may occur at any stage of the test process, but most errors occur during extra-analytical phases. The magnitude of clinical laboratory errors, in particular extra-analytical errors, was inconsistent in different studies.

Methods

A systematic review and meta-analysis were conducted based on the Preferred Reporting Items for Systematic Review and Meta-Analysis guidelines. The extracted data were entered into a Microsoft Excel spreadsheet and transferred to STATA version 11 for the analysis. Random effect model was used to estimate pooled prevalence of extra-clinical laboratory errors and l² statistic was used to assess heterogeneity between the studies. Funnel plot analysis and Egger weighted regression test were performed to detect the publication bias. Egger weighted regression test with P-value <0.05 was considered to be a statistically significant publication bias.

Results

A total of 1,381 studies were searched, 19 were included in this systematic review and metaanalysis. A total of 621,507 pre-analytical and 51,859 post-analytical outcomes of quality indicators were reported. A total of 145,515 samples were assessed for rejection and 62,513 laboratory requests were evaluated for incompleteness. The pooled prevalence of pre-analytical and post-analytical errors in Africa was 17.5% (95% CI: 11.55, 23.45) and 10.99% (95% CI: 5.30, 16.67) respectively. The pooled prevalence of specimen rejection and laboratory request forms incompleteness in Africa was 2.0% (95% CI: 0.86, 3.14) and 7.55% (95% CI: 2.30, 12.80) respectively.

Conclusion

The study found high prevalence of pre- and of post-analytical clinical laboratory errors in Africa. In addition, the study showed that the standard completion of the laboratory request forms was poor and there were significant numbers of specimen rejections. Therefore, clinical laboratories should ensure compliance with standard operating procedures, the laboratory information system, the cooperation of the entire staff and the targeted training of sample collectors.

INTRODUCTION

Clinical Laboratory services play an important role in the diagnosis and monitoring of diseases in the health-care system (1) and approximately 80% of all diagnostics are performed on the basis of laboratory tests (2). Clinical laboratory testing is a process that generally consists of preanalytical, analytical and post-analytical phases. The pre-analytical phase covers all the processes from the time of request by the physician until specimen processing before analysis, while the analytical phases includes the analysis of the patient sample and the post-analytical phases refers to the activities performed after actual analysis of the sample (3).

Laboratory errors may occur at any phase of the testing process, but majority of the errors occur in the pre- and post-analytical phases, which account for 93% of the total errors. The pre-analytical phase is a major source of laboratory errors that have a significant impact on the outcome of other phases. It is estimated that about 70% of the errors observed in the laboratory are due to the pre-analytical errors (4). Common pre-analytical errors are: ordering inappropriate tests, incomplete requisition forms, invalid handwriting on forms, failure to identify the patient, incorrect sampling time, hemolysis of samples, lipemic samples, inappropriate sample transport and storage (3).

Following pre-analytical errors, a high error rate (18.5–47% of total errors) occurred in the postanalytical phase (5). Common post-analytical errors include failure to report critical values, prolonged turnaround time (TAT), transcription error and incorrect interpretation of laboratory results (6). Its nature of complexity makes laboratory errors heterogeneous and difficult to measure. The majority of clinical laboratory error studies used different study designs; study periods, sample sizes, quality indicators (QIs) and reporting techniques (5). Therefore, it is important to ensure that care has to be taken in each and every step of the laboratory service (7, 8).

Quality indicators are objective measures of quality laboratory service that can evaluate all phases of the total testing process (TTP) and can be applied over time across all sections of the laboratory. Therefore, it is important to ensure systematic and consistent data collection/analysis by using comprehensive set of indicators addressing all phases of the TTP (9).

In most African countries, clinical laboratory services are still below standard and the participation of laboratories in accreditation is below the expected level. The aim of this study was to estimate the pooled magnitude of extra-analytical clinical laboratory errors. The implementation of objective measures and quality policies will ensure that clinical laboratories provide efficient and customer-based services that provide staff and customer satisfaction.

EXTRA ANALYTICAL ERRORS IN AFRICAN CLINICAL LABORATORIES

Most of the studies conducted on clinical laboratory errors used different data collection approaches, different time periods for data collection, and included different laboratory sections and different reporting methods (10). In the current study, the articles included showed variations in quality indicators and the magnitude of errors was inconsistent.

According to the current review in Africa, the prevalence of pre-analytical errors ranged from 2.7 % (11) to 43.7% (12) based on the total outcomes of the QIs. The significant variation between the findings of the studies may be due to the difference in the study design and sample size.

In addition, clinical laboratory specimens which are sent to the laboratory often lead to rejection due to different reasons, such as: hemolysis, clotted, insufficient volume and lipemic specimens. It is estimated that the majority of laboratory specimens are rejected due to hemolysis (13). In the current study, the magnitude of specimen rejection ranged from 0.28 % (14) to 4.6% (15). The variation between the findings may be due to the difference in the study design and sample size used, in particular the retrospective studies may be affected by the quality of records, and the occurrence of rejection may not be properly documented.

In the pre-analytical phase, the first step is to fill in the laboratory request form. The information required to be provided in the request forms includes: clinician and patient details, diagnosis, medications and the requested tests. Failure to fill all the required information may confuse the laboratory and incorrectly interpret the test results, and even the life-threatening emergency tests may be omitted from the analysis until such errors resolved (13). The current study showed a high degree of incompleteness in laboratory test request form (LRF) and the study findings varied from 4.8% (15) to 40.1% (16). The variation may be due to the difference in sample size and the number of pre-analytical QIs in the LRF. The findings of studies conducted in Ethiopia by Ali M and Addis Z, et al showed a consistent level of LRF incompleteness that may be due to the similar QIs, duration of data collection, study design and study area (16, 17).

Post-analytical phase is the final phase of the total testing process, which includes the evaluation of laboratory test results; the timely reporting of test results, the storage and disposal of samples, the archiving of laboratory documents and records (18). In the current study, post-analytical errors showed a high variation of results ranging from 1.3% (19) to 33.3% (20). This variation may be due to the difference in study design, sample size and study area. The implementation of laboratory information system in clinical laboratories could improve post analytical errors and QIs have also been used to quantify the performance of laboratories (9, 10).

METHODS

Data source, protocol and registration

The systematic review protocol was registered with the International Prospective Register of Systematic Reviews (with the PROSPERO CRD- 42020170040). This systematic review and meta-analysis on extra-analytical clinical laboratory errors was performed based on the Preferred Reporting Items for Systematic review and Metaanalysis (PRISMA) guideline (21). The findings of different articles were included in this review to determine the pooled prevalence of extra-analytical clinical laboratory errors in Africa.

The studies were found using the PubMed, Scopus, Web of science, Google Scholar and Cochrane Library databases via internet searches. All published literature was searched until December 2019 and searches in the PubMed were conducted under the following keywords and Medical Subject Headings (MeSH) (22): Clinical OR Medical [All Fields] AND Laboratory [All Fields] AND "Pre-analytical errors" OR "Postanalytical errors" [All Fields] "Pre-examination errors" OR "Post-examination errors" [All Fields] OR "Clinical Chemistry" OR "Clinical Biochemistry" [All Fields] AND Africa [All Fields]. In addition, we used the MeSH terms for specimen rejection and incompleteness of laboratory request form as: Clinical OR Medical [All Fields] AND Laboratory [All Fields] AND "specimen rejection" OR "sample rejection" OR "incompleteness of laboratory request form" [All Fields] OR "Clinical Chemistry" OR "Clinical Biochemistry" [All Fields] AND Africa [All Fields].

Study selection and outcomes

Studies conducted on extra analytical clinical laboratory errors in African countries were included in this systematic review and meta-analysis. Duplicate articles were removed, and the remaining articles were screened based on their title and abstract. Finally, full-text articles were evaluated using inclusion and exclusion criteria, and eligible studies were included into the systematic review and meta-analysis.

The prevalence of pre-analytical and post-analytical errors in each study was calculated using the number of defects/failures as the numerator; and total outcomes QIs (sum of "defects" and "successes") reported as the denominator. Prevalence of pre-analytical and post-analytical errors were our primary outcome measures. In addition, specimen rejection and incompleteness of LRF were also our study outcome, which are the component variables of the pre-analytical errors.

Eligibility criteria

All articles conducted on clinical laboratory errors in African countries with clear abstracts, objectives, methodologies (cross-sectional or cohort study designs), and published in English language were included in this study. Any published articles conducted on pre-analytical errors, postanalytical errors, laboratory specimen rejection and LRF incompleteness with clear results and two or more QIs were included into this systematic review and meta-analysis.

Review articles and other non-original documents, e.g. reports, commentary, case-report and case-series studies and duplicated articles were excluded from the study. In addition, articles with unknown study designs, published in languages other than English, and studies with biased and inappropriate results were also excluded.

Data extraction and quality assessment

Studies which fulfilled the eligibility criteria were subjected to data extraction by three reviewers through prepared data extraction sheet. The three reviewers worked independently, and the findings were carefully cross-checked. Any difference between the data extractors was resolved by discussion and consensus through verification. Absolute and relative frequencies of extraanalytical clinical laboratory errors were extracted for further analysis.

In all of the selected studies: author, study area, study period, year of publication, study design,

sample size and prevalence of extra-analytical clinical laboratory errors were extracted. That data was entered into Microsoft Excel. The quality of the articles was assessed by the reviewers based on the Joana Brigg's institute critical appraisal checklist for prevalence studies (23).

Statistical analysis

The data entered into the Microsoft excel sheet was exported to the STATA version 11 statistical software for further analysis. The prevalence of pre-analytical and post-analytical error was analyzed using random effect model. Subgroup analysis was performed on the prevalence of pre-analytical errors between middle income and low-income African countries.

In addition, the pooled prevalence of specimen rejection and of the incompleteness of LRF were analyzed.

Variability between studies (heterogeneity) was evaluated using I² Statistic with values of 25%, 50% and 75% interpreted as low, moderate and high heterogeneity respectively (24). Publication

Figure 1A flow chart showing the phases of selecting the literatures
for the systematic review and meta-analysis



bias between the studies was tested by funnel plots analysis and Egger weighted regression test. The P value <0.05 in the Egger's test was considered as evidence of statistically significant publication bias (25).

RESULTS

Literature search results

The search results were found in 43 African countries and a total of 1,381 articles were retrieved from the databases. Of the total, 164 duplicated searches were removed, and the remaining 1,217 searches were screened by the title of the study. In addition, 77 articles were removed on the basis of abstract review and a full assessment of the paper was carried out in the 72 articles. Furthermore, 53 articles were excluded from the study based on the exclusion criteria. Finally, 19 articles were found to be eligible and included in the analysis (Figure 1).

Study characteristics

Of the 19 studies, 8 were conducted in Ethiopia (12, 16, 17, 19, 26-29), 3 in South Africa (30-32), 3 Nigeria (14, 33, 34), 2 Egypt (15, 20), 2 Kenya (11, 35) and 1 Uganda (36). Of the total studies, 5 studies were conducted on both pre-analytical and post-analytical phases of clinical laboratory errors; however, 3 studies were conducted only on the pre-analytical phase clinical laboratory errors.

In the beginning, 8 studies with 621,507 pre-analytical and 51,859 post-analytical QIs outcomes were included. The overall outcomes of QIs with two possibilities: "success" and "defect/ failure" or "yes" and "no" in the both phases were 673,366. The study periods varied from 1 month to 13 months and the lowest and highest prevalence of pre-analytical errors were 2.7% and 43.7%, respectively. In addition, the lowest and highest post-analytical error rates were 1.3% and 33.3% respectively (Table 1). In addition, six studies were included and a total of 145,515 samples were assessed for the pooled prevalence of specimen rejection. The lowest prevalence of sample rejection was 0.28%, but the highest reported prevalence of specimen rejection was 4.6% with a study period ranged from 2 weeks to 3 years (Table 2).

Furthermore, 14 studies were included and a total of 62,513 LRFs were evaluated for LRF incompleteness. The overall outcomes of QIs in evaluating the LRF were 547,777. The lowest prevalence of incompleteness in LRF was 4.8% (15), but the highest prevalence of incompleteness in LRF was 40.1% (16). The finding highlights the need to review and update the LRF, improve training and communication between the laboratory and clinical staff, and review the practice for specimen rejection (Table 3).

Prevalence of pre-analytical errors in African clinical laboratories

In random-effect model analysis, the pooled prevalence of pre-analytical clinical laboratory errors in Africa was 17.5% (95% CI: 11.55, 23.45) (Figure 2).

Slightly higher preanalytical error was found in low income 17.65% (95% CI: 6.09, 29.21) than in middle income 17.35% (95% CI: 8.22, 26.49) African countries.

The pooled prevalence of incompleteness in LRF in African clinical laboratories

In random-effect model analysis, the pooled prevalence of LRF incompleteness in Africa was 19.6% (95% CI: 14.17, 25.05) (Figure 3).

The pooled prevalence of specimen rejection in African clinical laboratories

In random-effect model analysis, the pooled prevalence of specimen rejection in Africa was 2.0% (95% CI: 0.86, 3.14) (Figure 4).

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| Table 1The descriptions of the included studies conducted on pre-analytical and post-analytical errors in African clinical laboratories | | | | | | | |
|--------------------------------------------------------------------------------------------------------------------------------------------|--------------------------|-----------------------------|------------------------------------------------------------------------------------|------|-------------------|------------------|--------------------------------------------|
| S.N. | Author | Study area | Sample size | Year | Pre-A N (%) | Post-A N (%) | Laboratory section |
| 1 | Rizk MM, et al | Alexandria, Egypt | 31, 944 requests and 50,440 samples (252,200 Pre-A and 27,612 Post-A Qis) | 2014 | 13,067 (5.2%) | 4,540 (16.4%) | Clinical Chemistry |
| 2 | Sharaki O, et al | Alexandria, Egypt | 514 RWS (8,426 Pre-A and 1,461 Post-A QIs outcomes) | 2014 | 3,684 (43.7%) | 487 (33.3%) | Clinical Chemistry |
| 3 | Addis Z, et al | Gondar, Ethiopia | 1,533 RWS (21,462 Pre-A QIs) | 2015 | 6,227 (29%) | N/A | Clinical Chemistry and Hematology |
| 4 | Wondimagegn MW, et al | Oromia, Ethiopia | 754 RWS (7,540 Pre-A QIs) | 2016 | 751 (10%) | N/A | Hematology and CD4 |
| 5 | Kimengech KK, et al | Nairobi, Kenya | 346 RWS (5,536 Pre-A and 4,844 Post-A Qis) | 2017 | 148 (2.7%) | 84 (1.7%) | Clinical Chemistry |
| 6 | Ambcahew S, et al | Gondar, Ethiopia | 3,259 RWS (948,885 Pre-A and 9,777 Post-A Qis) | 2018 | 3,379 (6.9%) | 291 (3%) | Clinical Chemistry |
| 7 | Tadesse H, et al | Addis Ababa, Ethiopia | 1,633 RWS (17,570 Pre-A and 8,165 Post-A QIs outcomes) | 2018 | 4,337 (24.7%) | 104 (1.3%) | Clinical Chemistry |
| 8 | lsa HA, et al | Jos, Nigeria | 15,287 RWS (259,888 Pre-A QIs) | 2018 | 46,413 (17.9%) | N/A | More than 2 Lab sections |

RWS=request with sample, Qis=quality indicators, Pre-A=pre-analytical, Post-A=post-analytical, N/A=not available, S.N.=Serial number.

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| Tab | Table 2The descriptions of the included studies conducted on sample rejection in African clinical laboratories | | | | | | | |
|-------|-------------------------------------------------------------------------------------------------------------------|----------------------------------|------|---------------------------------|-----------------|----------------|------------------------------|--------------------------------------------|
| S. N. | Author | Study area | Year | Study design | Study period | Sample size | Sample rejection N (%) | Laboratory section |
| 1 | Jacobsz LA, et al | Cape Town, South Africa | 2011 | Retrospective | 2 wks. | 32,910 | 481 (1.46%) | Clinical Chemistry and Hematology |
| 2 | Rizk MM, et al | Alexandria, Egypt | 2014 | Comparative cross- sectional | 7 mos. | 50,440 | 2,314 (4.6%) | Clinical. Chemistry |
| 3 | Tesfaw HM, et al | Addis Ababa, Ethiopia | 2015 | Cross-sectional | 16 mos. | 8,063 | 116 (1.44%) | More than 2 Lab sections |
| 4 | Jegede F, <i>et al</i> | Kano, Nigeria | 2015 | Retrospective | 3 yrs. | 7,920 | 22 (0.28%) | More than 2 Lab sections |
| 5 | Shiferaw MB <i>, et al</i> | Bahirdar, Ethiopia | 2018 | Retrospective | 22 days | 42,923 | 221 (0.5%) | More than 2 Lab sections |
| 6 | Ambcahew S, <i>et al</i> | Gondar, Ethiopia | 2018 | Cross-sectional | 2 mos. | 3,259 | 123 (3.8%) | Clinical Chemistry |

Qis=quality indicators, LTR=Laboratory test request, mos.=months, wks.=Weeks, Yrs.=years, S.N.=serial number.

| Tab | le 3 The c LRF i | The descriptions of the included studies conducted on _RF incompleteness in African clinical laboratories | | | | | | | |
|------|---------------------|--------------------------------------------------------------------------------------------------------------|------|---------------------------------|-------------------|-----------------------------|--|--|--|
| S.N. | Author | Study area | Year | Sample size | Incomplete LRF | Laboratory section | | | |
| 1 | Nutt L, et al | Tygerberg, South Africa | 2008 | 2,550 LTR (38,250 total Qis) | 5,818 (15.2%) | Pathology | | | |
| 2 | Zemlin AE, et al | Cape Town, South Africa | 2009 | 482 LTR (3,856 total Qis) | 873 (22.6%) | Pathology | | | |
| 3 | Atewu A, et al | Addis Ababa, Ethiopia | 2014 | 960 LTR (7680 total Qis) | 1,434 (18.7%) | More than 2 Lab sections | | | |

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| | | | | 21 044 170 | | |
|----|------------------------------|-----------------------------|------|-----------------------------------|------------------|------------------------------|
| 4 | Rizk MM, et al | Alexandria, Egypt | 2014 | (223,608 total Qis) | 10,753 (4.8%) | Clinical Chemistry |
| 5 | Sharaki O, et al | Alexandria, Egypt | 2014 | 514 LTR (3,598 total Qis) | 366 (10.2%) | Clinical Chemistry |
| 6 | Addis Z, <i>et al</i> | Gondar, Ethiopia | 2015 | 1,533LTR (15,330 total Qis) | 6,153 (40.1%) | Chemistry and Hematology |
| 7 | Ali M | Hawassa, Ethiopia | 2015 | 1,900 LTR, (22,800 total Qis) | 8,984 (39.4%) | More than 2 Lab sections |
| 8 | Wondimagegn MW, et al | Oromiya, Ethiopia | 2016 | 754 LTR (3,770 total Qis) | 579 (15.4%) | Hematology and Immunology |
| 9 | Jegede F, et al | Kano, Nigeria | 2016 | 1,085 LTR (19,530 total Qis) | 2,797 (14.3%) | Blood transfusion |
| 10 | Ambcahew S, <i>et al</i> | Gondar, Ethiopia | 2018 | 3,259 LTR (32,590 total Qis) | 3,256 (10%) | Clinical Chemistry |
| 11 | Isa HA, et al | Jos, Nigeria | 2018 | 15,287 LTR (152,870 total Qis) | 28,826 (19%) | More than 2 sections |
| 12 | Tadesse H, et al | Addis Ababa, Ethiopia | 2018 | 1,633 LTR (16,330 total Qis) | 3,944 (24.2%) | Clinical Chemistry |
| 13 | Namwase B | Makerere, Uganda | 2018 | 323 LTR (3230 total Qis) | 579 (17.9%) | Pathology |
| 14 | Kipkulei JC, <i>et al</i> | Eldoret, Kenya | 2019 | 289 LTR (4335 total Qis) | 984 (22.7%) | Hematology |

Qis=quality indicators, LTR=laboratory test request, LRF=laboratory test request form, Clinical.C= Clinical Chemistry.

The pooled prevalence of post-analytical errors in African clinical vaboratories

In random-effect model analysis, the pooled prevalence of post-analytical errors in Africa was 10.99% (95% CI: 5.30, 16.67) (Figure 5).

Heterogeneity, publication bias and sensitivity analysis

The I² statistics showed a high level of heterogeneity (99.7%, 99.9%, 100% and 100%) between the included studies for all outcome variables. In order to minimize heterogeneity, the pooled prevalence of pre-analytical, post-analytical errors, specimen rejection and LRF incompleteness was estimated using the random-effects model and sub-group analysis conducted based on economic status of the study country.

In addition, the overall result of the Egger's test indicated that no publication bias was found on the pooled estimate of pre-analytical errors (P=0.377), post-analytical errors (P=0.352) and specimen rejection (P=0.229). However, the publication bias was found in the pooled estimate of LRF incompleteness (P=0.007).

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Figure 3Forest plot on the prevalence of incompleteness in LRF
from random effect model analysis

| Author | Voor | | | | % |
|-------------------------|---------------------------|-----------|------------------------|----------------------|---------|
| Autio | теан | | | E3 (95% CI) | vveigni |
| Ali M | 2015 | | | 39.40 (38.77, 40.03) | 7.15 |
| Jegede F et al | 2016 | ٠ | | 14.30 (13.81, 14.79) | 7.15 |
| Kipkulei JC et al | 2019 | | * | 22.70 (21.45, 23.95) | 7.13 |
| Namwase B | 2018 | • | | 17.90 (16.58, 19.22) | 7.13 |
| Nutt L et al | 2008 | ٠ | | 15.20 (14.84, 15.56) | 7.15 |
| Zemlin AE et al | 2009 | | ● | 22.60 (21.28, 23.92) | 7.13 |
| Ambcahew S et al. | 2018 | ٠ | | 10.00 (9.67, 10.33) | 7.15 |
| lsa HA et al | 2018 | R | 1 | 19.00 (18.80, 19.20) | 7.15 |
| Wondimagegn MW et a | al 2016 | * | | 15.40 (14.25, 16.55) | 7.13 |
| Addis Z et al | 2015 | | • | 40.10 (39.32, 40.88) | 7.14 |
| Atewu A et al | 2014 | | | 18.70 (17.83, 19.57) | 7.14 |
| Rizk MM et al | 2014 | ٠ | | 4.80 (4.71, 4.89) | 7.16 |
| Sharaki O, et al | 2014 | * | | 10.20 (9.21, 11.19) | 7.14 |
| Tadesse H, et al | 2018 | | • | 24.20 (23.54, 24.86) | 7.15 |
| Overall (I-squared = 10 | 0.0%, p< 0.01) | | | 19.61 (14.17, 25.05) | 100.00 |
| NOTE: Weights are from | m random effects analysis | | | | |
| | | 0 5 10 15 | | | |

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As a result, trim and fill analysis was used to overcome the impact of small-study effect, 8 additional studies were filled to the model, and a pooled estimate of LRF incompleteness in the random-effect model was found to be 7.55% (95%CI: 2.30, 12.80).

Sensitivity analysis was conducted on the prevalence of pre-analytical errors, post-analytical errors, LRF incompleteness and specimen rejection in Africa. A random effect model was also used to analyze the sensitivity tests to evaluate the effect of each study on the pooled estimates by omitting each study stepwise. And the analysis showed that the omitted studies have no significant effect on the pooled prevalence of pre-analytical errors.

DISCUSSION

Laboratory errors may occur at any phase of the TTP and can directly lead to increased healthcare costs, reduced patient satisfaction, delayed diagnosis, misdiagnosis and serious risk to the health of the patient (37). Therefore, this study was conducted to determine the pooled prevalence of pre- and post-analytical errors, specimen rejection and LRF incompleteness in African countries.

| Figure 5 | | Fore from | st plot on the prevalence random effect model and | of pos alysis | t-analytica | lerr | ors | |
|----------|----------------|--------------|------------------------------------------------------|------------------|-------------|------|----------------------|--------|
| | | | | | | | | % |
| | Author | | Year | | | | ES (95% CI) | Weight |
| | Kimengech k | K et al | 2017 | ٠ | | | 1.70 (1.34, 2.06) | 20.14 |
| | Ambachew S | S et al | 2018 | • | | | 3.00 (2.66, 3.34) | 20.14 |
| | Rizk MM et a | al | 2014 | | | | 16.40 (15.96, 16.84) | 20.13 |
| | Sharaki O et | al | 2014 | | | -•- | 33.30 (30.88, 35.72) | 19.45 |
| | Tadesse H e | t al | 2018 | • | | | 1.30 (1.05, 1.55) | 20.15 |
| | Overall (I-squ | uared = 9 | 99.9%, p<0.01) | | | | 10.99 (5.30, 16.67) | 100.00 |
| | NOTE: Weig | hts are f | rom random effects analysis | | 1 | | | |
| | | | | 01 5 10 |) | | | |

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In the current study, the prevalence of pre-analytical errors ranged from 2.7% to 43.7%. The significant difference between these findings may be attributed to the variation in the number of Qis, study design, sample size and the performance of laboratories. Studies conducted by Sharaki O, et al (20) and Addis Z, et al (16) revealed high prevalence of pre-analytical errors which may be due to the similarities in the study design, QIs data collection procedure and operational definitions. The lowest prevalence of preanalytical errors may be due to different methods of data collection, the presence of dedicated staffs and the participation of the laboratory in the accreditation process.

In addition, the prevalence of specimen rejection (0.28% to 4.6%), incompleteness of LRF (4.8% to 40.1%) and post-analytical errors (1.3% to 33.3%) also revealed a wide inconsistency between the studies in Africa. This variation may be due to the difference in the sample size, the awareness of clinicians, the operational definition of laboratory errors, the quality requirements of the laboratory and the dedication of health professionals.

In random effect models, the pooled estimate of pre-analytical errors and post-analytical errors in Africa was 17.5% (95% CI: 11.55, 23.45) and 10.99% (95% CI: 5.30, 16.67) respectively. The findings of this study were much higher than a study conducted in Iran (pre-analytical 4.1% and post-analytical 0.74%) (38) and Pakistan (pre-analytical error 0.02% and post-analytical error 0.01%) (39). This may be due to variations in the study area, sample size, laboratory information system, the status of laboratory accreditation and socio-economic differences between countries. The studies included in this systematic review and meta-analysis were conducted in Africa where limited resources and substandard facilities available.

In random effect models, the pooled prevalence of sample rejection and LRF incompleteness in Africa was found to be 2.0% (95% CI: 0.86, 3.14) and 19.6% (95% CI: 14.17, 25.05), respectively. The pooled prevalence of sample rejection was comparable to that of a study conducted in Saudi Arabia (2.07%) (40). In addition, the current pooled estimate of sample rejection was higher than studies conducted in India (0.15%) (41) and Turkey (0.65%) (42). However, it was lower than studies in Greece (4.1%) (43) and India (3.45%) (3).

In addition, the pooled prevalence of LRF incompleteness was lower than the study conducted in India (27.82%) (44). This difference may be due to variations in sample size, duration of the study period and performance of participating laboratories.

CONCLUSION

The present study showed a high pooled estimate of pre-analytical and post-analytical errors. In addition, the study found that the standard completion of LRF was poor and there were significant numbers of specimen rejections, which concerned the importance of quality indicators to determine errors in the overall TTP. LRF Incompleteness could lead to misdiagnosis and mismanagement of patients and in appropriate specimen rejections had a significant effect on patient care and could thus affect customer satisfaction.

Therefore, adherence to standard operating procedures, establishment of laboratory information system and targeted training for sample collectors is needed. Moreover, staff co-operation and computerized test requesting procedure for specimen collection are of vital importance to make progress in the pre-analytical and postanalytical testing process.

Strength and limitations

The current study was the first study to use a quantitative approach to pool the prevalence of extra analytical clinical laboratory errors in African countries. The limitation of this study was that only articles published in English language were included in this study, and the number of QIs in each study was not uniform, which could be a cause for high variability in the study findings.

Abbreviations

(ISO) International Organization for Standardization
(LRF) Laboratory Test Request Forms
(MA) Meta-Analysis
(MeSH) Medical Subject Headings
(PRISMA) Preferred Reporting Items for Systematic review and Meta- analysis
(Qis) Quality Indicators
(SR) Systematic Review
(TAT) Turnaround Time
(TTP) Total Testing Process.

Authors' contributions

DA and MT conceptualized this study and designed the study protocol; DA, AW and MT conducted data search, quality assesment, data extraction, statistical analyses and statistical interpretation. All authors write and approved the manuscript.

Availability of data and materials

Most of the main data generated or analyzed during this study are included in this article. However, additional files that support the findings of this study are also available from the corresponding author upon request.

Consent to publication

All participants provided written informed consent to publish this study.

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