CPQ Medicine (2018) 1:6
Mini-Review

Errors in the Total Testing Process (TTP) of Microbiological Samples

Dr. Michael Naafs, A. B.

Department of Medicine, Naafs International Health Consultancy, Netherlands

***Correspondence to:** Dr. Michael Naafs, A. B., Department of Medicine, Naafs International Health Consultancy, Netherlands.

Copyright

Received: 12 June 2018

Published: 28 June 2018

Keywords: *Phlebotomist; Urinary Tract; Q-Probe Study*

Abstract

Errors in the total testing process(TTP) of the microbiology laboratorium can occur in the preanalytical, analytical and postanalytical phase. The prevalence of errors in the reanalytical phase is high (30%-70%) and therapy resistant for decades. Automation reduced errors in the analytical phase and improved quality and time to results (TTRs) significantly. Postanalytical errors can be reduced further by improved communication and interdepartmental cooperation. Efforts to improve the TTP must be enhanced further in favour of patient safety.

Introduction

It is a fundamental principle for any laboratory test procedure that the value of the test is compromised or even negated by using specimens that have not been properly collected, labeled, handled or stored prior to and during the testing process.

Microbiological tests are not as standardized as some other lab tests. The way in which a sample is processed and the results are interpreted depends heavily on the information provided with the specimen. Erroneous results as a result of specimen mis-management can affect patient care and outcomes, as well as hospital

infection control, patient's length of stay in the hospital, costs and laboratory efficiency [1]. Errors can occur in the preanalytical, analytical and postanalytical process [2]. In this mini-review factors contributing to these errors are discussed.

Preanalytical errors

Mislabeling is a common cause of laboratory error. A 2001 study looked at the introduction of a hand-held computer to halt this type of error. Patient identification (BD Diagnostics) was initiated to scan bar-code identification on both patient ID wristbands and phlebotomist or sample-taker badges. Physician test orders could also be scanned. Other deterrents included rejecting blood culture specimens for inadequate sample volume or because incomplete identification forms accompanying clinical specimens were submitted [3,4].

In another attempt to halt errors in the preanalytical phase researchers at the University of Washington and San Francisco started a laboratory incident-report classification study. A database was created for the period from June 2000 to September 2001 to document the laboratories incident-reports of 129 reports 92 or 71% occured during the preanalytical phase of testing. This phase includes collection of patient information and physician-ordered lab tests, specimen collection, specimen identification, labelling, transportation, handling and storage and it ends in the laboratory with specimen processing [5].

Between 2003 and 2005 "lab quality" research at the University of California at Los Angeles (UCLA) calculated an error rate at 16.000 of 4,29 million blood specimens or approximately 0,4%. Of this number UCLA reported that 12% were considered "critical errors", defined as those with incorrect labelling-one patient's name on another patient's tube o blood. UCLA freed up personnel of other tasks and parts of the specimen-processing were automated and an electronic error -reporting system was installed. Once more, errors were drastically reduced [4]. Chawla *et al.* performed in 2010 a retrospective analysis of preanalytical errors in a large clinical chemistry laboratory of the 96.328 tubes received during the one-year collection period 1469 samples were fond unsuitable for further processing. This accounted for 1,52% of all samples collected. Rejections arose as a result of the following reasons; 0,74% were rejected due to hemolysis, 0,47% were specimens without proper requisition strips and 0,23% had insufficient sample quality [6].

Urinary tract infection (UTI) in the United States is the most common bacterial infection and urine cultures often make up the largest portion of workload for a hospital-based microbiology laboratory. Appropriately managing the factors affecting the preanalytic phase of urine culture contributes significantly to the generation of meaningful culture results that ultimately affect patient diagnosis and management. Urine culture contamination can be reduced with proper techniques for urine collection, preservation, storage and transport, the major function affecting the preanalytical phase of urine culture [7].

La Rocco *et al.* performed in 2016 a large systematic review and meta-analysis of articles publised between 1965 and 2014, regarding preanalytical practices on contamination and diagnostic accuracy of urine cultures. The authors concluded that no recommendations can be made for or against delayed processing of urine stored at room temperature, refrigerated, or preserved in boric acid. This does not preclude the use of refrigeration or chemical preservatives in clinical practice. It does indicate, however, that more systematic studies evaluating the utility of these measures are needed. If noninvasive collection is being considered for

women, midstream collection with cleansing is recommended, but no recommendations for or against midstream urine collection without cleansing is made. If noninvasive collection is being considered for men, midstream collection with cleansing is recommended and first-void urine is not recommended. No recommendation for or against is made for collection of midstream urine without cleansing. If noninvasive collection is being considered for children, midstream collection with cleansing is recommended and collection in sterile urine bags, from diapers, or midstream without cleansing is not recommended [7].

There are large quality gaps associated with the preanalytic phase of urine culture, however. The major goal of proper specimen management is to ensure that specimen quality is mantained during collecting and transport [2]. Urine specimens can easily become contaminated with periurethral, epidermal, perianal and vaginal flora. This contamination can be reduced with proper attention to techniques for urine collection, transport, preservation and storage, the major components of the preanalytic phase of urine culture.

A Q-probe study conducted by the College of American Pathologists in 1998 and again in 2008 examined the frequency of urine culture contamination (defined as more than two isolates in quantities greater than 10.000 CFU (colony forming units)/ml and associated facility practices of urine collection and specimen management. Contamination rates of 41,7% (low performance facilities), 15% (median performers) and 0,8% (high performers) corresponded to the 10th,50th and 90th percentile of facilities, respectvely [8,9]. Contamination rates had no correlation to collection site, use of collection kits, preservatives, or thermally insulated transport. However, contamination rates were substantially affected by postcollection processing, especially refrigeration of the specimen. Also, collection instructions given in the outpatient setting had a statistically significant impact on contamnation rates in some cases. The authors concluded that no significant progress in reducing urine culture contamination during the intervening years has been made [9]. Specimen refrigeration is associated with lower overall urine culture contamnation rate. Providing patient instruction is also associated with lower contmination rates [9].

A report by Bonini *et al.* found that preanalytical errors predominated in the laboratory ranging from 31,6% to 75% [10]. In addition to mislabeling and patient misidentification, frequent types of error are inappropriate test requests, order entry errors, inappropriate containers, inadequate sample collection and transport, inadequate sample/anticoagulant volume ratio, and sorting and routing errors [11].

Prevention of preanalytical errors:
A comprehensive plan to prevent preanalytical errors has 5 interrelated steps:
1 Developing clear written procedures.
2 Enhancing health care professional training.
3 Automating functions, both for support operations and for executive operations.
4 Monitoring quality indicators.
5 Improving communication amng health care professionals and fostering interdepartmental cooperation [12-14].

Written procedures must clearly explain how to identify a patient, collect and label a specimen, and subsequently transport the specimen and prepare it for analysis. Those individuals performng the preanalytical procedures must understand not only what the procedures are but also why they are important to follow.

They need to know not only what happens if the correct steps are not followed, but also what errors can occur and what effect they can have on the sample and ultimately the patient. There must be ongoing training for these employees and competencies must be assessed annually [15].

Modern robotic technologies and information systems can also help reduce preanalytical errors. Computerized order entry simplifies test ordering and eliminates a second person from transcribing the orders. Automated phlebotomy tray preparation provides a complete set of labeled blood tubes and labels for hand labeling in a single tray for each patient. Preanalytical robotic workstations automate some of the steps and reduce the number of manual steps involving more people. Barcodes also simplify specimen routing and tracking [15].

In 2008 a working group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) developed a model of quality indicators (QIs),16 of which concern the preanalyical phase [16]. The preanalytical phase is largely out of control of the laboratory personnel, especially in the out of hospital setting, until the specimen arrives at the laboratory reception. The development of these QIs in accreditation programs for laboratory medicine is a fundamental step in providing sound evidence of quality and procedures of the TTP (total testing process). Effective improvements in the initial steps of the TTP can be achieved only if further efforts are made in this way to achieve consensus in the preparation, adoption and montoring of effective standard operating procedures [16].

Monitoring errors

The success of any efforts made to reduce errors must be monitored to assess the efficacy of the measures taken. Quality indicators (QIs) must be used for assessment. In the testing process areas involving non-laboratory personnel, interdepartmental commuication and cooperation are crucial to avoid errors. Therefore, the entire health care system must be involved in improving the total testing process (TTP). There must be adequate and effective training of personnel throughout the institution to be competent in following processes and procedures [15].

Incident reporting in laboratory diagnostics

While major efforts have been made to monitor the preanalytic phase and provide reliable solutions, it is surprising that concrete formal programs of incident reporting have not been so pervasive in laboratory diagnostics [17]. The major focus in health care is placed on incident reporting for several medical conditions with lesser effort devoted to translating this noteworthy practice into laboratory diagnostics. If in fact, laboratory errors are being underreported, then current statistics reveal only a small portion of the medical errors taking place. There is an urgent need to establish a reliable policy of error recording, possibly through information aids [18] and settle universally agreed "laboratory sentinel events" throughout the total testing process (TTP). This would be gaining important information about serious incidents and holding both providers and stakeholders accountable for patient safety. The Drafting Group of WHO's International Classification for Patient Safety (ICPS) has also developed a conceptual framework that might be suitable for diagnostic errorw [19].

Analytical errors

These errors happen during the test and include equipment malfunction, sample mix-ups, interference, undetected failure in quality control, use of expired or inappropriate reagents and procedures not followed [20]. Abdollahi *et al.* performed a large clinical laboratory study in a large teaching hospital and estimated that 23,2% of errors occur in the analytical phase, 65% in the preanalytical hase and 11,8% in the postanalytical phase [20]. While analytical errors represent a smaller percentage of errors than those in the preanalytical phase, vendors can design platforms with features that reduce this type of error.

A common analytical phase risk is the use of expired reagents or testing patient samples on reagents that have not passed quality (QC) inspection. Advanced diagnostic platforms are ensuring compliance by providing automated software features to prevent the use of expired reagents and to track external QC. These systems also provide lab -configured notifications to remind staff that an external QC time point is approaching, thus preventing patient sample testing if QC is past due and ensuring patent testing is never delayed to accomodate QC [21].

Reductions in financial and human resources have led to the merger of clinical microbiology laboratories. As a result of the consequential increases in sample volumes, automation was introduced to facilitate high-volume analytical processes. This automation indeed reduced the time to results (TTRs), improved quality, increased reproducibility, and provided more discrete colonies than manual methods [22]. Moreover, automatic instruments have facilitated the traceabilty of different steps in analytical procedures, as recommended by international quality rules. However, microbiological process automation remains incomplete, numerous steps remain manual, both in the preanalytical phase and in the analytical phases. Therefore, the use of different or redundant systems may cause difficulties in sample management. This major drawback will be improved in the next generation of instruments and artificial intelligence algorithms [22].

Postanalytical errors

These include erroneous validation of analytical data, failure in reporting or addressing the report, excessive turn-around time, inproper data entry and manual transcription error, and failure or delay in reporting critical values (13%-20%).As post-post analytical errors (25%-46%) are considered delayed or missed reaction to laboratory reporting, incorrect interpretation, inappropriate or inadequate follow-up plan and failure to order appropriate consultation [23].

Susceptibility and culture results should be reported to clinicians as soon as possible to allow them to streamlne or stop antimicrobial therapy, as appropriate. Microbiology results may be qualitative or quantitative and often include a combination of results elements. These factors can contribute to the risk of incorrect interpretation of the information. Microscopy or cell count results may be overlooked, even when they are important as indicators of colonization, contamination or an inflammatory response to infection. Single or multiple organisms can grow in cultures, each with different susceptibility and potentially different clinical relevance. Report design is paramount in supporting the safe interpretation of results [24]. Avoiding unfamiliar terminology in the comprehension of results is another challenge. The addition of laboratory comments in result reports has been proven to assist clinicians with the interpretation of information.

Antimicrobial susceptibility results should be withheld for isolates that reflect colonization rather than infection. Direct verbal communication between microbiologist and the clinician is of crucial importance and should be structurally organized in weekly clinical meetings [24].

Conclusion

Clinical chemistry laboratories are reported to have an error rate between 0,5% and 1,5%. These figures are not known for microbiology labs, but if it is of the same magnitude and underrepoting is considered, it concerns huge numbers in these high-volume facilities. Only urine cultures are performed 4,7 million times/year in e.g. Australia [24]. The prevalence of errors in the preanalytical phase is high and ranging from 30% to 70%. Despite numerous efforts as the development of quality indicators, accreditation programs, training of personnel, incident reporting and monitoring, significant drops in the prevalence of preanalytical errors have not occured. So, the preanalytical phase is rather therapy resistant. One of the reasons is that the preanalyical phase is largely out of control of the laboratory personnel. In addition, out of hospital facilities are also clients which make correction more difficult. There are still large quality gaps in the preanalytical phase. In contrast, automation has improved the quality of the analytical phase as well as the time to results (TTRs) significantly. Post-analytical errors can be reduced by improving interdepartmental communication and cooperation. Efforts to improve the total testing process (TTP) must be enhanced further as patient safety in health care is crucial.

Bibliography

1. Nucifora, K. (2015). The Importance of Proper Specimen Collection and Handling. Lab Reating Matters.

2. Schofield, C. B. (2006). Preventing errors in the microbiology lab. *MLO. Med. Lab. Obs, 38*(12), 10.

3. Woeste, S. (2004). Technology to reduce specimen collection errors. *Lab. Med., 35*(8), 471-75.

4. Landro, L. (2006). Hospitals move to cut dangerous lab errors. *The Wall Street Journal.*

5. Astion, M. L., Shojania, K. G., Hamill, T. R., *et al.* (2003). Classifying laboratory incident reports to identify problems that jeorpadize patient safety. *Am. J. Clin. Pathol., 120*(1), 18-26.

6. Chawla, R., Goswami, B., Tayel, D., *et al.* (2010). Identification of the Types of Preanalytical Errors in the Clinical Chemistry Laboratory: 1-Year Study of G.B. Pant Hospital. *Lab. Med., 41*(2), 89-91.

7. La Rocco, M. T., Franek, J., Leibach, E. K., *et al.* (2016). Effectiveness of Preanalytical Practices on Contamination and Diagnostic Accuracy of Urine Cultures: A Laboratory Medicine Best Practices: Systematic Review and Meta-analysis. *Clin. Microb. Rev., 29*(1), 105-47.

8. Valenstein, P. & Meir, F. (1998). Urine culture contamination: a College of American Pathologists Q-Probes study of contaminated urine cultures in 906 institutions. *Arch. Pathol. Lab. Med., 122*(2), 123-29.

9. Bekeris, L. G., Bruce, A. I., Walsh, M. K., *et al.* (2008). Urine culture contamination: a College of American Pathologists Q_Probes study of contaminated urine cultures in 127 laboratories. *Arch. Pathol. Lab. Med., 132*(6), 913-17.

10. Bonini, P., Plebani, M., Ceriotti, F., *et al.* (2002). Errors in laboratory medicine. *Clin. Chem.*, *48*(5), 691-98.

11. Hammerling, J. A. (2012). A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today. *Lab. Med., 43*(2), 41-44.

12. Bates, D. W., Gawanda, A. A. (2003). Improving safety with information technology. *N. Engl. J. Med., 348*(25), 2526-34.

13. Plebani, M. & Bonni, P. (2002). Wrong biochemistry results. Interdepartmental cooperation may help avoid errors in medical laboratories. *BMJ, 324*(7334), 423-24.

14. Lippi, G. & Guidi, G. C. (2007). Risk management in the preanalytcal phase of laboratory testing. *Clin Chem. Lab. Med., 45*(6), 720-27.

15. Da Rin, G. (2009). Pre-analytical workstations: A tool for reducing lab errors. *Clin. Chem. Acta., 404*(1), 68-74.

16. Plebani, M. (2012). Quality indicators to Detect Pre-Analytical Errors in Laboratory Testing. *Clin. Biochem. Rev., 33*(3), 85-88.

17. Lippi, G., Dimundic, A. M., Matiuzzi, C. (2010). Overview on patient safety in healthcare and laboratory diagnostics. *Biochem. Med., 20*, 131-43.

18. Lippi, G., Bonelli, P., Rossi, R., *et al.* (2010). Development of a preanalytical errors recording software. *Biochem. Med., 20*, 90-95.

19. World Health Organization. (2011). The Conceptual Framework fort he International Classification for Patient Safety.

20. Abdollahi, A., Saffar, H., Saffar, H. (2014). Types and Frequence of Errors during Different Phases of Testing at a Clinical Medial laboratory of a Teaching Hospital in Tehran, Iran. *N. Am. J. Med. Sci., 6*(5), 224-28.

21. Tieman, B. F. (2017). The role of lab automation in reducing diagnostic errors. MLO.

22. Dauwalder, O., Landrieve, L., Laurent, F., *et al.* (2016). Does bacteriology laboratory atomation reduce time to rsults and increase quality management? *Clin. Microbiol. Inf., 22*(3), 236-43.

23. Hawkins, R. (2012). Managing the Pre-and Post-analytical Phases of the Total Testing Process. *Ann. Lab. Med., 32*(1), 5-16.

24. Antimicrobial Stewardship in Australan Health Care. (2018). Australian Commission on Safety and Quality of Health Care.