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Patient Safety and Rational Laboratory Diagnostic

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ABSTRACT

Many nonanalytic factors can change the concentration of one or more substances in the sample, so the results obtained are not an indicator of the physiological state of the patient. Cyclic variations, physical activity, stress, and other factors significantly affect the obtained result analysis. In the interpretation of results, these specificities have to be considered, otherwise they will be interpreted as pathologic, which leads to wrong conclusion. Error reduction and improving quality make an integral part of laboratory diagnostics. While it has been reported that the pre-analytical phase is error-prone, only recently it has been demonstrated that most of these errors occur in the pre-pre-analytical phase. Developments in automation have played a major role in decreasing some pre-analytical errors.

KEYWORDS health security, pre-analytical phase, pre-pre-analytical phase

Laboratory diagnostic is a highly dynamic sector of health care and in race to improve health, it takes central place. A lot of research projects are aimed at improving the diagnostic system. Improvement of laboratory diagnostics refers to standardization and simplification of laboratory procedure, to the constant development of more complex tests, great advances in instrument technology and ambitions for fully integrated laboratory information system (Casson, 2003 a, 2003 b).

By using automation, a group of 40 or more analyses can be done in a short period of time. In daily work routine, such big demands can be justified only in certain special cases. It frequently occurs, however, that excessive and unjustified demands, not for specific parameters but for "all and everything", are sent to laboratory where conclusions are made based on results obtained. This can be helpful in some less clear situations, but it cannot become a diagnostics model. Many beginners, in addition to necessary parameters, often ask for a large number of unnecessary ones, probably led by the idea "not to miss something". However, experienced physicians require less parameters but only the specific ones - in other words, those parameters which may provide useful information. The question is: Can a patient's health be safe with just a small number of parameters analyzed? Health security may be obtained with relativelly small number of parameters which are selected well.

When you come to a conclusion, it is necessary to use the method of induction or deduction, and to make more analyses which will help you to confirm or to exclude certain findings. That is why we should use protocols whenever it is possible. It is the right and rational diagnostic way (D. Popopvic & M. Popovic, 2008; Vukotic, 2000).

In regular medical practise, laboratory tests results are integral part of clinical decision making, helpful in guiding medical diagnoses or monitoring response to therapy and predicting health outcome. Concentration of many analytes in a blood sample is considered to be a good indicator of physiological state of patient. Usually, analytical results obtained represent the real concentration of tested substances of a patient, i.e. they represent his/her physiological state. The influence of some factors indicates that this assumption is not always true. Analytical error factors are reduced to the lowest possible level by using quality control (Sonntag, 2009). Similarly, many non-analytical factors can change concentration of one or more substances of the sample, and in such case the results obtained do not represent indicators of the physiological state of patient. Cyclic varations, physical activity, stress and other factors significantly affect results obtained in analyses (Dufour, 2003).

Laboratory testing is a highly complex process, commonly called the total testing process (TTP). It is usually subdivided into three traditional phases: pre-analytical phase, intra- analytical phase and post- analitical phase. The pre-analytical phase can be further subdivided into the "conventional " pre-analytical phase, which occurs under the control of laboratory, and the pre-pre-analytical phase which occurs outside the laboratory and consists of the selection of appropriate tests on the basis of clinical question, ordering, collecting and handling, transportation and reception of samples prior to testing. The "conventional" pre-analytical step involves the processes required to make sample suitable for analysis: centrifugation, aliquoting, diluting and sorting specimens into bathes for their introduction into automated analyzers (Bonnini, Plebani, Ceriotti & Rubboli, 2002; Da Rin, 2010; Lippi et al., 2013; Plebani, 2006; Plebani, 2010).

Summarizing the error frequencies found in publications, the pre-preanalytical phase was affected by 46-68.2%, the pre-analytical phase by 3.0-5.3%, the analytical phase by 7-13%, the post-analytical phase by 12.5-20%, and the post-post-analytical phase by 25-45.5% of all of the errors (Bonnini, Plebani, Ceriotti & Rubboli, 2002; Da Rin 2010; Plebani, 2006; Plebani, 2007).

The pre-pre-analytical phases

The pre-pre-analytical phases performed outside the laboratory are: formulating a clinical question and selecting appropriate examinations, ordering, collecting, handling, and transporting samples. Newer model for the preanalytical phase also includes patient satisfaction with the collection process, professional staff satisfaction with this phase and general customer service satisfaction with the many of testing offered (Plebani, 2007; Plebani, 2012).

Errors can occur in each of these steps, the most common

being inappropriate test requests, incorrect or incomplete information on the test request, patient or speciment identification errors, use of inappropriate container and excessive waiting time in transporting sample in the laboratory (Laposata & Dighe, 2007; Lippi & Guidi, 2007).

Proper patient identification is a crucial aspect of patient safety in any healtcare organization, being a neccessary component for providing safe clinical and diagnostics services. Patient identification errors are associated with harm, or the potential for harm, when incorrect information is used to link a particular individual to an action or activity. Therefore, the patient safety risk associated with patient identification can be considered as a mismatching between a given patient and their care (Valenstein & Sirota, 2004; Wagar, Tamashiro, Yasin, Hilborne & Bruckner, 2006).

Patient misidentification in clinical laboratories occurs: in requesting the sample, in taking the sample, in carryng out the invegestion, and in reporting the results. Errors in the process of taking the sample include placing the wrong label or tag on the specimen. Errors in the process of carrying out the investigation include mixing up the request and the type of investigation required.

To prevent this type of error, it is necessary to positively confirm the identity of the patient before venipuncture (Da Rin, 2010; Plebani, 2006).

The pre-analytical phases

The pre-analytical phases is one of the most labor-intensive aspects of clinical work. It occupies up to two-thirds of the total time spend by personnel on clinical laboratory procedures, consumes a large percentage of laboratory labor budget, approximately 19% of the overall cost of analising a single specimen, and exposes laboratory staff to biohazards whenever the samples are splashed or test tubes broken (Da Rin, 2010).

In addition, due to the largely manual nature of pre-analytical processing, there are many opportunities for laboratory errors, e.g. mislabeling aliquot tubes, centrifugation (time and/or speed),visible hemolysis after centrifugation, lipemic samples, pour-off, failure to place stat specimens in stat queues, excessive waiting time in processing the specimen that invalidates its analysis. The risk of human error in this phase is exacerbated by the fact that currently laboratories are handling ever-increasing workloads while experiencing a reduction in personnel: the consequent physical and mental fatigue also leads to errors (Chawla, Goswami, Tayal & Mallika, 2010); Da Rin, 2010; Plebani, 2006).

The automation of pre-analytical processing and the accompanyng pressure to avoid making errors often lead to low satisfaction rating in this area of laboratory and to high rates of employee turnover. The system must be able to identify the patient to whom a specimen belongs and which tests have been requested on the sample.

A mechanism is necessary to determine the specimen tube type to avoid improper container, the volume of the sample and the conditions. The pre-analytical workstation must have been an area with robotic systems for removing caps, placing samples into centrifuges, making aliquots and sorting samples according to laboratory destination. (Chawla, Goswami, Tayal & Mallika, 2010; Salinas et al., 2009).

Our intention was to show that the use of automated pre-analytical robotic workstations effectively reduces the labor associated with specimen processing and the number of laboratory errors that occur in sorting, labeling and aliquoting specimens (Bonelli, 2011; Da Rin, 2010; De Capitani, Marocchio & Tolio, 2002).

Conclusion

Health security may be obtained with relativelly small number of parameters which are well selected. When you ask for parameters, the parameters should give you the answer if there is a clearly defined question.

In interpretation of results, many non-analytical factors need to be considered, otherwise they will be interpreted as pathologic, which leads to wrong conclusion. Inadequate preparation of patient for certain analysis and disrespect of rules referring preparation and sample analyzing, can lead to drastic deviation of results from the real values.

The reasons for automation of the pre-analytical phase have become so compelling that it is no longer simply a competitive advantage for laboratories, but rather a competitive necessity.

REFERENCES

Bonelli, P., Aloe, R., Dazzi, P., Fontana, R., Graiani, R., Sandei, F. & Lippi, G. (2011). Automation of the preanalytical phase in a clinical laboratory: personal experience. Biochemia Medica, 21(2), 1-20. | | Bonini, P., Plebani, M., Ceriotti, F. & Rubboli, F. (2002). Errors in laboratory medicine. Clin Chem., 48(5), 691-8. | | Casson, J. (2003 a). A system for routine biochip array analysis Part I: The technology. European Clinical Laboratory, 22(3), 14-15. | | Casson, J. (2003 b). A system for routine biochip array analysis Part II: Application. European Clinical Laboratory, 22(4), 16-19. | | Chawla, R., Goswami, B., Tayal, D. & Mallika, V. (2010). Identification of the Types of Preanalytical Errors in the Clinical Chemistry Laboratory: 1-Year Study at G.B. Pant Hospital. Lab Med, 41, 89-92. | | Da Rin, G. (2010). Pre-analytical workstations as a tool for reducing laboratory errors. Journal of Medical Biochemistry, 29, 315-24. | | De Capitani, C., Marocchio, A. & Tolio, T. (2002). Automation of the Pre-Analytical Phase: A Performance Evaluation of Alternative Scenarios. Journal of Laboratory Automation, 7(2), 89-93. | | Dufour, D. R. (2003). Sources and control of preanalytical variation. In Kaplan, L. A., Pesca, A. J. & Kazmiercazak, S.C. Clinical Chemistry: Theo, Analysis, Correlation.(4th ed.) (pp 64-82). Mosby. | | Laposata, M. & Dighe, A. (2007). "Pre-pre" and "post-post" analytical error: high-incidence patient safety hazards involving the clinical laboratory. Clin Chem Lab Med., 45(6), 712-9. | | Lippi, G., Becan-McBride, K., Behůlová, D., Bowen, R.A., Church, S., Delanghe, J., Grankvist, K., Kitchen, S., Nybo, M., Nauck, M., Nikolac, N., Palicka, V., Plebani, M., Sanberg, S. & Simundic, A.M. (2013). Preanalytical quality improvement: in quality we trust. Clin Chem Lab Med, 51(1), 229-41. | | Lippi, G. & Guidi, D. C. (2007). Risk management in the preanalytical phase of laboratory testing. Clin Chem Lab Med, 45, 720-7. | | Plebani, M. (2006). Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med., 44(6), 750-9. | | Plebani, M. (2007). Laboratory errors: How to improve pre- and post-analytical phases? Biochemia Medica,17(1), 5-9. | | Plebani, M. (2010). The detection and prevention of errors in laboratory medicine. Annals of Clinical Biochemistry, 47, 101-10. | | Plebani, M. (2012). Pre-analytical errors and patient safety. Journal of Medical Biochemistry, 31, 265-70. | | Popović, D. & Popovic, M. (2008). Dilemmas and controversies in the interpretation of laboratory results. Journal of Medical Biochemistry, 2, 139-43. | | Salinas, M., Lopez-Garrigos, M., Flores, E., Guitiérrez, M., Lugo, J. & Uris, J. (2009). Three years of preanalytacal errors: Quality specifications and improvement through implementation of statistical process control. Scandinavian Journal of Clinical and Laboratory Investigation, 69(8), 822-6. | | Sonntag, O. (2009). Analytical errors and interferences. Clin Chem Lab Med, 47, 64 | | Valenstein, P. N. & Sirota, R. L. (2004). Identification errors in pathology and laboratory medicine. Clin Lab Med, 24(4), 979-96. | | Vukotić, D.P. (2000). Etičke kontroverze u medicini. Crnogorska akademija nauka i umjetnosti, 41, 84-106. | | Wagar, E. A., Tamashiro, L., Yasin, B., Hilborne, L. & Bruckner, D. A. (2006). Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. Arch Pathol Lab Med, 130(11), 1662-8. |