

Pre-analytical phase: Risk Management and Risk Assessment in a Hospital Laboratory

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The importance of the pre-analytical phase in the context of laboratory medicine activities is well known. However, little has been done with proactive functions in managing this phase: one must pass from error gathering to an activity linked to problem solving, in a risk management perspective. The very analysis of errors and their frequency is the basis of the solution proposed and implemented at the Tradate hospital facilities (Busto Arsizio Hospital Corporation) medical analysis laboratory. Starting from risk analysis and assessment centered on three aspects of the pre-analytical phase (inadequate patient preparation, wrong tube / non-compliant container, off-schedule sample delivery / reception errors) managed as non-compliances, graded on a scale (probability, detectability and seriousness) in order to generate a risk priority index. This risk assessment model has given the starting point to analyze the territorial wards and structure stakeholder needs. The model made it possible to develop a software (SW) in which proactivity is a prerequisite. The SW was developed keeping within the laboratory (work group) often outsourced competences (analysis and programming). This choice is reinforced by the reasons of the fulfillments provided for by Financial Law 2007 (Art. 1, comma 796, letter O of Law 296/2006 - Guidelines on the Contents of the Plan on the Laboratory Network: Updating of the Organizing and personnel standards consistent with the efficiency increase processes made possible by the availability of automated methods). The solution is a document with hypertext links (non-modifiable HTLM) made of tables, each containing: a) container image and relevant identification, b) list of exams related to said container, c) Analysis Facilities / Area, d) information for sample gathering and preservation by Facilities / Laboratory, and, e) possible preservation material safety specifications. Facilities / Area identification is linked to the division in wards of the Hospital Corpora-

tion, thus making laboratory analysis addressing easier both in the area and in the facilities which actually perform the test. The SW is also a preventive control system which supports the efficiency of the pre-analytical phase in all the organizational units pertaining to the laboratory. Area facilities identification also makes it possible to further expand to other hospital offices / facilities, thus making effective division in wards easier. It is integrated to the corporation ethical code, thus becoming part of one of the behavioral organizing models, an incentive to further improve the activities performed by the corporations through their collaborators. Decision Making, developed in 2006, led to a decrease of pre-analytical errors (on the three variables) from 7.8% in 2005 to 2.2% in 2007 and 1.3% in 2009. More specifically, on the first year, 2007, inadequate patient preparation was 0.2%, wrong tube/non-compliant container 1.1%, off-schedule sample delivery 0.9%, for a total of 2.2%. In 2008, total data further decreased: 1.03 (0.2%; 0.03%, 0.8%). Besides stakeholder collaboration, this success is also linked to the innovative implementation of risk assessment activities as per ISO 27001. This is the ethical model: the laboratory, well aware of container characteristics, realizing (data from 2005) that the latter's choice makes up one of the sources of error, solves the problem by choosing to implement a decision making activity in letting the stakeholders choose laboratory tests and containers. The new integrated procedures, which follows step by step the choices of the physician, also develops the model's principle of efficiency: the improvement the SW is made possible by the product's simplicity of use and upgrading.

Key-words: risk assessment, pre-analytical phase, tubes/containers, decision making, laboratory medicine software, risk management, safety and prevention, Laboratory Department.