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Detection and monitorization of nonconformities: Contribution to the operation of the central laboratory in Dokuz Eylul University Hospital

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Objectives: The clinical laboratory encounters problems and nonconformities quite frequently during routine operation. Generally, momentary solutions are found for these problems and then forgotten since they are not documented. It is well known that documentation of every type of action is necessary for good laboratory practice. All problems and unconformities should be written in a predetermined format and these documents should be monitored and analyzed periodically.

Design & methods: During the course of preparation for accreditation, a problem report form has been designed and used in Dokuz Eylul University Hospital Medical Laboratory. These reports have been analyzed monthly and the problems as well as the solutions have been shared with the laboratory personnel.

Results: The use of these forms in practice has begun in September 2007 and 275 forms have been written out by March 2008. One hundred sixty nine of the problems have been solved by the laboratory manager. Among the unsolved problems, 32 were directly related to the hospital administration. No significant difference was observed considering the monthly distribution of different types of problems. The most frequently encountered problems were related to LIS (22.2%), followed by erroneous sample receipt (21.8%).

The implementation of the documentation and evaluation of problems enabled us to review the processes and to find permanent solutions. Furthermore, it led to widespread use of these solutions in routine practice.

It was noticed that insufficient information was the most frequent cause of errors made in the laboratory.

Conclusion: Educational programs were undertaken for all laboratory staff in addition to personal feedback to related personnel.

Keywords: Nonconformity; Problem report form; Accreditation; Documentation

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B6

Point-of-care testing management protocol using ISO 22870 guidelines and French requirements

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Objectives: Point-of-care testing (POCT) refers to analyses assayed near the patient outside the central biochemistry laboratory (BL) by non-laboratory staff.

Design & methods: Five projects have been successfully conducted in our hospital since 2000.

Results: When medical staff inquires if its department could be equipped with a POCT analyzer, we use a POCT project management organized in four phases:

Phase 1: Justification of the request. The usefulness of the analyzer must be justified by patient care improvement (reduced turn-around time of emergency analysis results, better management of patients for non-emergency analysis). The surcharge and the extra charge of work generated must be evaluated.

Phase 2: Establishment of the project. A schedule is set for the next phases and the roles of the different parts (medical department, central laboratory, hospital administration, and manufacturer) are formalized.

Phase 3: Choice of apparatus. The main criteria are analytical performance and analyzer's ergonomics.

Phase 4: Protocol agreement. A protocol of agreement is finally signed between both departments and validated by our hospital administration. It defines the specific requirements and the sharing of the responsibilities. The BL is in charge of the material, quality controls, training, biological advice, maintenance, overall quality management (procedures, non-conformities, quality indicators) using ISO 22870 guidelines and specific French requirements, incident management, data management in the laboratory information system and biological validation of results. The medical department is in charge of blood sampling, assays and data collection. A biologist POCT coordinator is in charge of the management of the analyzer as well as the relationships between both departments. The manufacturer has to install the analyzer, train both parts, and ensure repairs.

Conclusion: This protocol ensures that the POCT assays are performed with the same level of quality as assays performed in the central laboratory, and that the staff of the medical department is properly trained to perform testing.

Keywords: Point-of-care; Management

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The evaluation of the rejected hematology samples within the scope of accreditation in Dokuz Eylul University Hospital Central Laboratory

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Objectives: The testing process in a clinical laboratory is quite complicated and recent research has revealed that the errors in the testing process are mostly in the pre-analytical