## B5

### 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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## B7

### 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

phase (46–68.2% of the total errors). This phase begins with the test request, ends with the commencement of the analysis and includes several steps outside the laboratory especially for the inpatients. Among all samples, samples for hematology tests are more prone to errors in the pre-analytical phase, since they are plasma samples that should be non-hemolyzed, non-coagulated and must be at appropriate volume.

**Design & methods:** During the course of preparation for accreditation the rejection criteria have been developed, documented and the rejected samples have been recorded in DEU Hospital Central Laboratory since November 2007. The aim of the present study was to evaluate the rejected samples for some hematological tests which are due to errors that originate mainly from wrong blood collection during this 4 month period. Following hematological tests were considered for this study: Erythrocyte Sedimentation Rate (ESR), activated Partial Thromboplastin Time (aPTT), D-Dimer, Fibrinogen (Fib), Fibrin Degradation Products (FDP), Complete Blood Count (CBC) and Prothrombin Time (PT).

**Results:** Total number of all tests was 171,344 and the number of rejected tests was 3,384. Only 4.4% of the tests were from outpatients. During this time frame, total number of each test, number of rejected tests and the reason for rejection and percentage of the rejected tests were given in the Table below.

The distribution of the rejections

| | CBC | ESR | Fib | aPTT | PT | D-Dimer | FDP |
|---|---|---|---|---|---|---|---|
| Total test number | 94422 | 20873 | 2322 | 22749 | 26015 | 3977 | 986 |
| Rejected number of tests | 605 | 436 | 113 | 996 | 1026 | 155 | 53 |
| Reasons of rejection | | | | | | | |
| Unproportional | 31 | 157 | 62 | 659 | 668 | 83 | 29 |
| Hemolyzed | – | – | 5 | 71 | 75 | 13 | 1 |
| Coagulated | 570 | 279 | 45 | 262 | 278 | 58 | 23 |
| Other | 4 | – | 1 | 4 | 5 | 1 | – |
| Percent rejected (%) | 0.64 | 2.09 | 4.87 | 4.38 | 3.94 | 3.90 | 5.38 |

**Conclusion:** In conclusion, 1.97% of all hematological tests and 4.2% of the coagulation tests were rejected due to errors of blood collection in 4 months period. Only 4.4% of the tests were from outpatients. This shows us that there is a great need for laboratory and clinical collaboration for the safety of the patients.

*Keywords:* Accreditation; Hematology; Sample rejection; Sample rejection criteria

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## B8

## Evaluation of early morning inpatient test turnaround time

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**Objective:** Joint Commission International Accreditation Standards for Clinical Laboratories requires that the laboratory has to have a means of measuring turnaround time and a way of ensuring that turnaround time is acceptable. The objective of this study is to evaluate timeliness of service by measuring the early morning-run inpatient test turnaround times (TAT).

**Design & methods:** The present study evaluated TATs for early morning-run inpatient complete cell blood count (CBC) and electrolyte tests. Data were collected up to a total number of 1000 for each analysis. The time period between specimen collection and reporting or releasing of the test results was measured as TAT. Daily morning blood collection times were classified in four different time intervals (Group I: 04:00–04:59 AM, Group II: 05:00–05:59 AM, Group III: 06:00–06:59 AM, Group IV: 07:00–07:59 AM). Corresponding TATs were tracked and recorded in four different clusters (TAT.I: 04:15–07:59 AM, TAT.II: 08:00–08:59 AM, TAT.III: 09:00–09:59 AM, TAT.IV: 10:00–10:59 AM). Reporting compliance rates for each pair of collection and TAT for CBC and electrolyte tests were determined. Median TATs were measured. We compared the frequency of these variables present in the shortest — and in

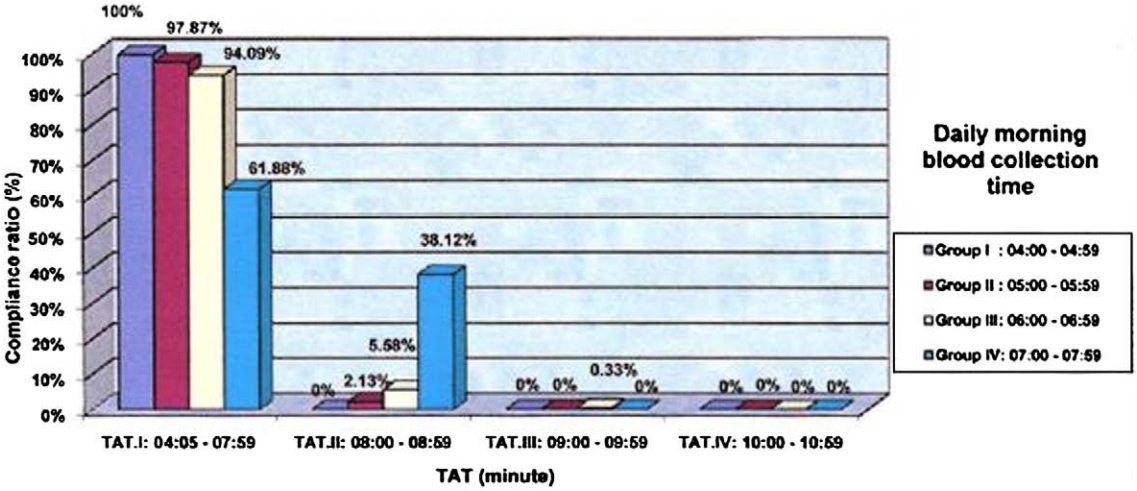



Fig. 1. Distribution of compliance rates for CBC in four different specimen collection times and corresponding TAT clusters.