IFCC

Quality of Management & Quality of Analysis

A Handbook for developing Countries
Jointly Developed By C-CLM and C-AQ of the EMD

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Chapter 1

Impact of Management on Analysis

Need for Quality in Management

Dr. Elizabeth Frank

Introduction

A good management team is the key in making any enterprise a profitable and successful venture. It is no different for the clinical laboratory. For a long time the lab was perceived as a place where some analysis was done. The lab's positioning in healthcare has changed in the last decade as 70% of medical decisions are based on the lab result. It is, therefore, important for laboratory professionals to understand and give due importance to the management aspects. This will enable the lab to deliver accurate results by managing and maintaining the integrity of the entire work process of the laboratory.

How is management defined?

"Management" comes from the Old French *ménagement* which means "the art of conducting, directing". It also finds its origin in Latin from manu agere which means "to lead by the hand". It characterises the process of leading and directing all or part of an organisation, often a business, through the use of human, financial and intellectual resources

This definition is interesting because it traces the root meaning back to the Latin phrase meaning "to lead by the hand". Leading by the hand implies giving direction that is stronger than just a passing suggestion, yet still fairly gentle in approach. Leading by the hand is to lead by example. It also implies that the person doing the leading is first going where the follower is being led. The leader is not asking the follower to do something he is not willing to do himself. The management, therefore, needs to follow a set of universally agreed standards to lead well and to provide the required level of quality.

Does the Level of management effect quality?

Though it may seem that it is only the accuracy of testing and validity of methodology which will define the outcome of the result and the quality of the laboratory services, in reality every single aspect of management and organisation plays a pivotal role in providing a quality report and customer satisfaction. The management needs to be aware of the standards requirement and should strive to ensure adherence to this requirement at all levels of the process.

The sources of these standards are the International Standards Organization (ISO), National Standards bodies, guidelines from professional organisations, accreditation bodies and governmental regulations. The gold standard for the medical laboratory, in particular, is ISO 15189:2007

ISO 15189:2007 *defines the particular requirements for quality and competenc*e. It specifies the quality management system requirements specific to medical laboratories. The standard was developed by the ISO Technical Committee 212 (ISO/TC 212). ISO/TC 212 assigned ISO 15189 to a working group to prepare the standard based on the details of ISO/IEC 17025:1999' General requirements for the competence of testing and calibration laboratories. This working group included provision of advice to users of the laboratory service, the collection of patient samples, the interpretation of test results, acceptable turnaround times, how testing is to be provided in a medical emergency and the lab's role in the education and training of healthcare staff.

While the standard is based on ISO/IEC 17025 and ISO 9001, it is a unique document that takes into consideration the specific requirements of the medical environment and the importance of the medical laboratory to patient care.

The ISO 15189:2003 places great emphasis on management requirements as these undoubtedly affect the quality of the results delivered by the lab. It also makes the point that though section 5 mainly concentrates on technical issues, there is a constant overlap with basic management issues. Therefore, Section 4 is a set of support processes for management

activities that provides the foundation for pre-examination, examination and post- examination technical core processes. While ISO outlines the requirement for clinical labs, the Clinical Laboratory Standards Institute (CLSI) develops user-friendly documents which are easier to comprehend and interpret and simplifies the understanding of Quality Management Systems (QMS).

The QMS is defined as coordinated activities to direct and control the organisation with regard to quality. This covers the entire work process in the laboratory. The QMS is, therefore, made up of building blocks called quality system essentials. Each of these building blocks refers to the IS0 15189. Section 4 of the ISO, and parts of section 5, i.e. Personnel, (5.1), accommodation environment (5.2), post-examination procedures (5.7) and reporting of results (5.8), are the direct responsibility of the laboratory management.
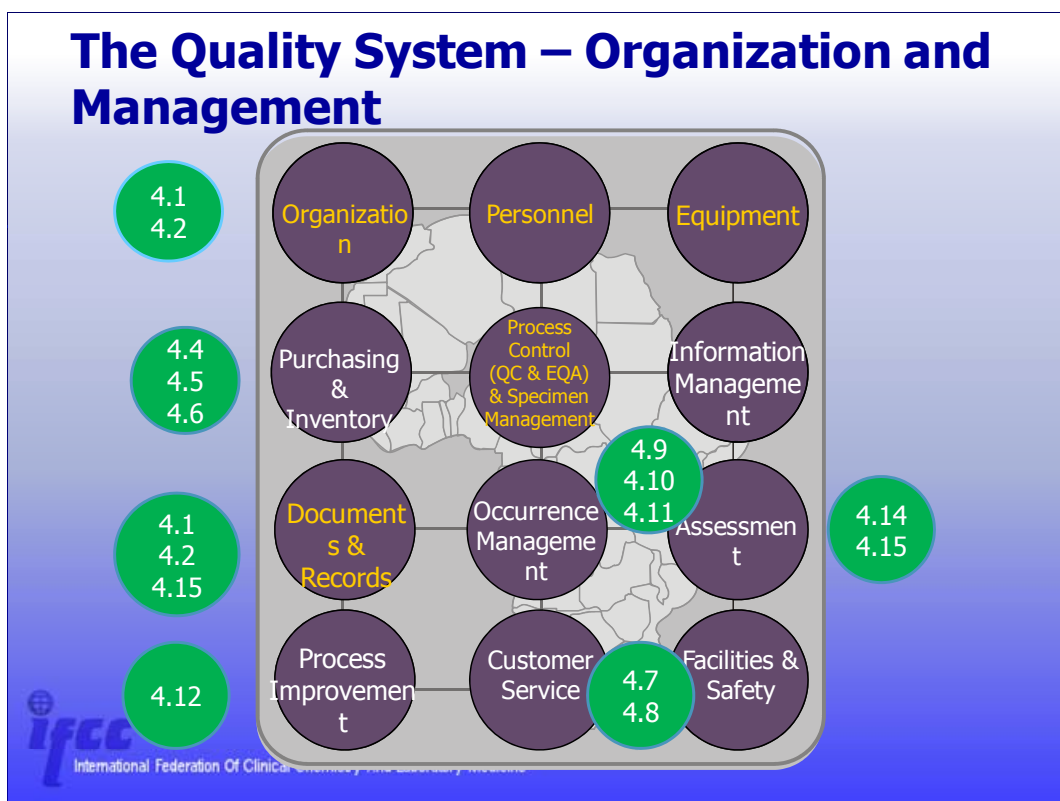

Fig Modified by the author from a CDC presentation "Quality system essential by Carolyn Collins MD. MPh.

Which people make up Laboratory Management?

Definitions 3.6 of ISO 15189 states that laboratory management - person(s) who manage the activities of a laboratory headed by a <u>laboratory director.</u>

<u>Who should direct the laboratory?</u>

5.1.3 The laboratory shall be directed by a person or persons having executive responsibility and the competence to assume responsibility for the services provided. Competence is here understood as the product of basic academic, postgraduate and continuing education, as well as training and experience of several years in a medical laboratory. The director, therefore, should be adequately qualified and trained in lab medicine. He/she should also have the relevant experience in the said field.

Responsibility of the Lab Director

5.1.4 The responsibilities of the laboratory director or designees shall include professional, scientific, consultative or advisory organisational, administrative and educational matters. These shall be relevant to the services offered by the laboratory. The laboratory director or designees for each task should have the appropriate training and background to be able to discharge the following responsibilities:

The lab director/medical advisor provides advice to patients and doctors requesting information about the choice of tests, the use of the laboratory service and the interpretation of laboratory data. He/she will also have administration and legal responsibilities. The director will be responsible for management of all the activity in the lab, to define, implement and monitor standards of performance and quality improvement. The director will be responsible for the accuracy of results and adherence to systems and protocols, financial planning and budgeting. The lab director also has the responsibility for continuing education, recruitment of staff and monitoring allied services of the laboratory. He/She will provide good customer service and maintain staff morale.

The director will also:

1) Serve as an active member(s) of the medical staff for those facilities served, if applicable;

2) Relate and function effectively (including contractual arrangements, if necessary), with,

 a) Applicable accrediting and regulatory agencies,

 b) Appropriate administrative officials,

 c) The healthcare community, and

 d) The patient population served;

3) Define, implement and monitor standards of performance and quality improvement of the medical laboratory service or services;

4) Implement the QMS (the laboratory director and professional laboratory personnel should participate as members of the various quality improvement committees of the institution, if applicable);

5) Monitor all work performed in the laboratory to determine that reliable data are being generated;

6) Ensure that there are sufficient qualified personnel with adequate documented training and experience to meet the needs of the laboratory;

7) Plan, set goals, develop and allocate resources appropriate to the medical environment;

8) Provide effective and efficient administration of the medical laboratory service, including budget planning and control with responsible financial management, in accordance with institutional assignment of such responsibilities;

9) Provide educational programs for the medical and laboratory staff and participate in educational programs of the institution;

10) Plan and direct research and development appropriate to the facility;

11) Select and monitor all referral laboratories for quality of service;

12) Implement a safe laboratory environment in compliance with good practice and applicable regulations;

13) Address any complaint, request or suggestion from users of laboratory services;

14) Ensure good staff morale.

The laboratory director need not perform all responsibilities personally. However, it is the laboratory director who remains responsible for the overall operation and administration of the laboratory, for ensuring that quality services are provided for patients.

The management responsibility covers the entire work process in the Laboratory. The management is committed to the customer and ensures quality in reporting. To achieve this, the management has to show commitment in a series of well planned actions which are synchronised with the lab's quality policy. It is also the management's responsibility to articulate the plan in simple understandable format to the people involved in the workflow process of the lab. The management will ensure that the plan is implemented in a timely and accurate manner and the process of implementation will be closely monitored and reviewed for further improvement.

Management is, therefore, as important as the technical process as it integrates and coordinates all the activities of the lab to achieve the goal of the lab, i.e. to provide accurate analysis on a timely basis

What are the laboratory management's responsibilities?

4.1 Organisation

The laboratory or the organisation of which the lab is a part of should be legally identified. The regulation in each country may vary. In some countries, the lab may need to be affiliated to a medical body. Where this is not the case, it is still mandatory that the lab has an identity based on local regulation (ISO 15189 :4.1). The laboratory should meet the needs of the patients and the clinical staff. In doing so, the lab should adhere to the standards. Roles and responsibilities should be clearly defined so that each knows his duties and responsibilities. There should be no conflict of interest so that the qualities of reports are not compromised and confidentiality of the reports is maintained**.**

4.2 Quality Management System

The key role of the management is to set a series of processes in motion that will ensure the quality of the laboratory. This is termed as the quality management system (QMS). This includes

making the quality policy, setting up detailed workflow plans from which stem procedures and instruction. The management will ensure that the same is communicated in detail to the personnel and that it is implemented in totality. The QMS shall include Internal Quality Control (IQC) and External Quality Assessment (EQA) as a mandatory part of laboratory practice. The management system will define the scope of activity, standards of service and commitment towards complying with international standards.

The management is responsible for developing a quality manual which describes the QMS and the structure of the documentation used, with reference to supporting documents and technical procedures. It is also the responsibility of the management to establish, implement and monitor the proper functioning of all equipment, reagents and analytical systems. The management needs to ensure that preventive maintenance is done on a regular basis and all the manufacturers' recommendations should be adopted and made available to laboratory staff.

4. 3 Document control

One of the most overlooked areas in a laboratory is documentation. The management must define the documentation procedure and maintain it regularly. All information pertaining to the quality system, or that is generated from the quality system must be controlled. The procedures laid down should ensure that the document is valid, current, accessible, easily identified and reviewed periodically. A process should be in place to handle obsolete documents. Procedures should also ensure the integrity of documents that are maintained on the computer. Access to and control of all documents, including those on computers, have to be defined and controlled.

4.4 Review of Contracts

The entire contract made with a supplier, a lab or with any agency must be reviewed periodically for compliance. The need for existing contracts must be regularly reviewed as the challenges and circumstances change. For example, changes in the type of workload or other new situations that may arise. The review of contract must be based on actual review of the facility providers as they have a direct impact on the quality of the services delivered by the laboratory.

4.5 Examination by referral laboratories

The management needs to have an effective system to evaluate and select referral labs as well as consultants. The management, together with the technical experts, will be responsible for selecting and monitoring the quality of referral labs or consultants. These arrangements made with referral labs need to be reviewed periodically

4.6 External services and supplies

The laboratory management will define policies and procedures for selection of any external service and supplies. This could range from reagents to equipment, consumables and the quality of the service provided. All purchased items should adhere to national and regional regulations and should meet the quality requirement. Evaluation of suppliers and maintainance of an inventory are all part of this process

4.13 Quality and technical records

The laboratory shall establish and implement procedures for identification and collection, indexing, accessing, storage, and safe disposal of the technical records. The kind of document and the period of retention of records may sometimes be defined by national, regional or local regulations.

Management reviews (4.15, 5.6)

The management needs to regularly review the quality system and all its medical service, including examination and advisory activities. The outcomes of the management review will be incorporated into a plan which includes goals and an action plan, thereby giving a definite road map for further progress.

There must be procedures in place to review IQC and EQA reports to ensure the quality of examination procedures of the lab. This ensures that there is continuing stability and effectiveness in support of patient care and that improvements and changes will be made in a timely manner.

5.1 Personnel

The management will be responsible for developing personnel policies and defining job descriptions, which should include qualifications required for and duties of the personnel. The management will maintain all relevant educational and professional qualification training to develop the experience and competence of the personnel. The management will decide the level of authority and function for each post.

5.2 Accommodation and environmental conditions

The management will be responsible for providing space ensuring client comfort and safety of clients and employees, without compromising on the quality of the service provided. The management will ensure that the operations in the lab are efficient and carry minimal risk of injury or occupational illness. Privacy of the patient during blood collection should be provided and the needs of patients with disability should be considered. Storage and disposal of dangerous materials shall be those specified by relevant regulations.

5.7 Post-examination procedures

The management will be responsible for the safe disposal of samples no longer required for examination (5.7.3). This shall be carried out in accordance with local regulations or recommendations for waste management.

In Conclusion

Any organisation must have strong leadership, which should breed a culture of quality and trust. The key requirements of leadership are:

- Commitment of laboratory leaders
- Vision
- Team building
- Resources - How to use what you have well

The Organisational Structure also needs to be clearly defined. To avoid assumptions, an organisational chart should be drawn up with the responsibilities at all levels clearly defined.

- Functional organisational chart
- Assignment of responsibility

The management team is responsible for strategic planning. The planning process should be based on the vision and goals set. The process of planning involves both short term and long term objectives.

Process of Planning

Short Term –

- Time management – Turnaround time of reports
- Who is going to do what - roles should be defined and responsibilities spelt out
- Use of human resources – the management needs to ensure adequate staffing
- Management of workflow – so that all processes are supervised and monitored for quality performance
- Financial resources
- Set benchmarks or standards – the team should have a goal set that would achieve the necessary standards. No compromises on quality will be allowed and bench marking should be against the internationally accepted standards

Long Term –Long term plans go beyond the immediate need and focus on the extended growth of the organisation. This will include planning for expansion, the resources needed and the expertise required to maintain the level of quality.

- Resource needs (human and financial)
- Quality program planning

Implementation

The success of planning is in its implementation. Much planning stays at the documentation stage and never sees the light of day. The implementation process needs to be defined and made simple and plain in achievable steps. This helps the team to make it happen. The management also has the responsibility to sustain the implementation process and, therefore, has the responsibility to direct sufficient resources to enable completion of the plan.

Monitoring

Any process needs to be monitored and measured to see if

- Plans have been accomplished as outlined
- Benchmarks and standards are met

The outcome of this is a system that is continuously evolving and improving, thereby remaining dynamic and sensitive to the clients' needs

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Chapter 2

Managing Laboratories - Basic Requirements

(Personnel, Equipment, Infrastructure)

Dr. Tony Badrick

The provision of an effective, efficient laboratory service requires the careful management of the staff, equipment and building utilities. These are complex tasks which require on-going attention. Often parts of this management may be undertaken by non-laboratory staff, but it is critical that the senior laboratory staff are aware of the capacity of a laboratory and its staff, of the problems that can occur should something go wrong and, most importantly, how to quickly react to a failure with staff, equipment or the building itself.

Where possible, the systems that are used, such as documents and processes, should be part of a quality system that is regularly audited and continuously improved. As an example, there should be regular fire drills to test out the fire evacuation processes. Based on the drill, changes should be made to improve the effectiveness of the evacuation and plans should be developed for other potential scenarios that may disrupt the laboratory service. Such situations as power loss, staff absenteeism due to illness and water loss should all have some plan. These plans help the senior laboratory staff understand the dependence of the laboratory on these critical inputs.

In this chapter, we will describe some tools and skills that can be used by managers to manage their staff and infrastructure. The tools are not complex, just a set of basic documents and processes and some tips for interviewing staff in different situations. These tools form part of the Staff Management System.

A.   MANAGING PEOPLE

The most important asset of a laboratory is its staff, so the selection, training and management of staff comprise a major part of the role of a manager. Managing staff is the prime responsibility of senior laboratory managers and an effective manager will usually have a productive and efficient laboratory. Management of people is a complex issue but there are a number of specific processes of management that can be documented.

The two major tools used by managers are conversation and various documents which make up the Staff Management System.

Key Documents of the Staff Management System

Personnel File
Position Description
Staff Leave Form
Application for New Staff

There are a number of documents which can assist the management of staff which are described below.

1.   The Position Description

A position description details the key responsibilities of a position and the requirements to perform a specific role. It must provide sufficient information to enable a person unfamiliar with the position to understand the position's purpose and functions, the requirements to competently perform the job, and where the position fits into the organisation. A position description forms the basis of many of the other elements of the Staff Management System.

A position description should provide:

Basic information:

Position Title

Position descriptions are based on the generic needs of the position, not the person in the position.

Position Purpose.

A concise statement describing why the position exists within the organisation.

Qualifications

Statement of the educational level and qualification required for the job.

Responsibilities of the position.

Responsibilities include the duties the person is expected to carry out and who he/she is responsible to.

Authorities

Lists the duties and tasks the staff member is authorised to perform.

Selection Criteria

Describes the skills and attributes required to fill the position.

Position Description Review

Position descriptions should be reviewed when:

- A position becomes vacant;

- A significant change in the position has been made

A staff member may request a review of the position description if they believe it is not an accurate description of his/her job.

If the review determines a substantial difference, the position will undergo a job evaluation process. This will include interviewing the appropriate people within the organisation. The staff member should be informed of any consequences of the position being re-evaluated. If the position is re-evaluated to a higher level the position may have to be opened for application.

2.   Recruiting New Staff

The most important function a manager may have is recruiting new staff. This difficult task requires training and experience and a process which should be followed to try and introduce standardisation and reduce subjectiveness. This way it does not matter who conducts the recruitment interview, the outcome should be the same. Once an employee enters the organisation, it is very difficult, time consuming and costly for all parties should the person not be appropriate.

An accurate position description can assist the recruitment and selection process. Should the position description, duties, classification, etc., be correct, the position description can be a time saver for managers developing accurate advertisements to fill posts. It should also assist the potential applicant in understanding the position for which they are applying.

The position description also becomes the source of selection criteria for the next step in recruitment and selection. The selection panel or committee receives or develops a list of selection criteria based on what is listed in the position description so that they can arrive at a recommendation for appointment of the most meritorious applicant.

Requirements expected from applicants entering the organisation might be different from those required in the past. In the future, for example, it may be necessary to ensure that all managers have a certain level of managerial skill, experience and education prior to entering

the position. It is imperative that the selection criteria be updated and accurate for every position description.

If the position description is inaccurate, there is a strong possibility of not attracting the best pool of applicants for the position. It could be detrimental and costly to the organisation as well as to the job applicant.

3. Training and Development of Staff

Any laboratory must be committed to providing for its employees the training necessary to enable them to perform their role, efficiently and effectively. This includes orientation and induction of new employees, training for current employer and retraining for employees whose responsibilities or duties change through advancement or organisational restructuring.

The position description also forms the basis for an effective training needs analysis and a professional development programme for staff. Gaps between knowledge, skills and abilities demonstrated by a staff member and the requirements contained in the position description can provide information on training needs. Conversely, the results of training efforts can be evaluated on the basis of progress made toward meeting job requirements.

All training should be accurately recorded and kept in the personnel file. Employees should also sign to state they have participated in the training. Review of training records should occur regularly to ensure currency.

B. STAFF INTERVIEWING TECHNIQUES

The ability of the manager to effectively communicate with staff is critical. Formal and informal interviews should be conducted in a professional manner.

In any professional conversation, the aim is to produce the greatest amount of relevant information in a short period of time. Interviewers need to be able to not only hear what is said,

but also be aware of what is not said. This requires a skill at questioning, which is not part of normal conversation skills. A uniform set of questions should be developed for each job, which is used for all interviews to ensure a standard process is used each time.

1.   The Recruitment Interview:

As an example of a critical interview, we describe the recruitment interview. In this interview the interviewers need to find out more about the candidate than their background. They need to find out how well the person will work in this laboratory and how well they will work with other people. The questions should be aimed at finding out about their opinions, ideas and values. To find out about these individual characteristics, the questions asked should be open-ended. Since these questions are open-ended, the candidate has the opportunity to give personal details or draw on previous experience/knowledge to answer.

The types of questions to be asked include:

Information sought: work experience

Among the jobs you have held previously, what were some of the aspects that motivated you?

Are there skills or work activities that you have an aptitude for?

How do previous positions you have held relate to this one?

Information sought: Communication skills:

Do you have preferences in how you are given instructions? Why?

Can you describe a communication problem you have experienced?

How would you describe your communication style?

If faced with conflict in the workplace, how do you personally deal with the situation?

At the end of the interview, a question to ask, to allow the candidate to put forward other relevant details about themselves, could be:

"Are there any qualities, experiences, or other factors about yourself you feel are pertinent to the position that we have not yet discussed?"

At all times during the interview, the interviewers should have clear in their minds the essential requirements for the position as well as the desirable requirements. Be careful not to delve into the candidate's private life.

2. Reference Checks

The manager should always perform a reference check; that is, talk to previous employers to see how well the candidate performed in other workplaces.

When getting information from the referee, the following points should be pursued:

Team fit

Punctuality

Initiative

Competence in current position

Responsibilities in current position

Communication skills

Other points which may demonstrate the potential employee's ability to perform the necessary requirements of the position.

Commitment to work place, e.g. sick leave, ownership of tasks.

Take care not to ask referee questions which may require a subjective or personal opinion rather than an objective opinion regarding the employee's abilities.

It may be helpful to rate the above points in order of importance for your position. This will help determine the suitability of the person for the position and assist the manager to have clear reasoning in their minds to justify their preferences in case they are challenged.

Here are some suggested questions, which will give you relevant information when performing reference checks.

What were the candidate's responsibilities?

This will help you verify the description given to you.

Before asking the question, offer a brief, but specific, description of the position for which the candidate is being considered.

Do you think the candidate is qualified to assume these responsibilities?

Emphasize that you are asking their opinion based on their observation of the candidate's work. You are not asking them to verify formal educational qualifications. Ask them to give reasons for their answer.

How would you describe your management style?

If the referee is uncomfortable about answering this, try outlining the management style the potential employee will be moving into in your organization. Explain that you want to detect

any radical differences in management style in order to determine whether the candidate is flexible enough to manage this? Why or why not?

How did the candidate perform with regard to..............................?

Insert whatever competencies or dimensions of job performance you think are important.

Is this candidate a team player or an independent worker?

This determines whether the candidate demonstrated respect for other employees' contributions and a willingness to consider others' opinions.

What was the candidate's attendance record?

Sensitivity to extenuating circumstances that may have contributed to poor attendance, such as illness or family problems, is required.

What areas of development were offered to the candidate and how did they respond?

This question is a good way to learn about potential performance weaknesses and their career potential.

What are the candidate's three strongest qualities?

This question provides the referee with an opportunity to highlight the characteristics that stand out.

Why did the candidate leave?

Not only will the question verify the candidate's reasons, it will also help you determine whether your position will give the candidate what they are looking for in a new position.

Did the candidate demonstrate commitment to the workplace?

Again, seek further advice if the reference check does not clarify the information you require.

3. Performance Management

As a manager you need to obtain the best performance from your staff. This involves building positive trustworthy relationships between both manager and individual staff member. Building relationships through conversations with staff is considered an effective way of engaging staff in meaningful work. Managers who build relationships in this way provide a less awkward, less stressful, more positive atmosphere for managing performance.

Managing Diminished Performance

A position description feeds into performance management and provides the basis for identifying instances where performance objectives of the position are not being met. Action planning in the performance appraisal process can be used to support the employee through diminished performance. The performance management process should identify reasons why there is poor performance and set goals and an action plan for ongoing improvement, whether that be additional training or monitoring.

Job Evaluation / Analysis

Job evaluation needs to take place on a regular basis to ensure an appropriate classification and level of remuneration for the position elements.

It involves the gathering of data about the job and the current position description. It is important that the position description accurately describes the duties to be undertaken and the knowledge, skills, and abilities required (that is, the selection criteria) so that an accurate assessment can be made of the position's work value.

4. Career Planning

Requirements outlined in position descriptions provide information to staff members of positions they may wish to apply for in the future. Staff can gain an understanding of the requirements and therefore calculate the gap between their current skills, knowledge, education, etc, and that required for advanced positions.

Training and professional development needs can be listed and set as targets.

5. Request for Staff

There should be process for requesting new staff which clearly outlines why staff are required (replacement of staff member who is leaving, resignation letter attached, or increase in staffing numbers).

Advertisements should state clearly the selection criteria you desire (e.g. experienced, tertiary qualifications, good team worker, etc.).

Remember that good recruitment advertising needs to do 2 things:

1) persuade good candidates to apply

2) present a distinctive corporate image to the marketplace.

6.   Other Staff Management Processes

There are a number of other staff management processes that should be carefully documented and managed. These include requests for leave and time off to attend conferences. A system of defined steps where the staff member completes an application for leave which is approved based on the capacity of the laboratory to have people away at a time, with a response to the staff member, either approving or denying the request, should be well defined so that all staff understand the process and can see that it is fair.

Every staff member should have a personnel file which details all their professional and relevant personal information.

C.   ACCOMMODATION AND ENVIRONMENTAL CONDITIONS

For a laboratory to provide patient results which are of suitable quality to diagnose and treat disease there must be sufficient space for the staff to effectively be able to perform the needed assays in a safe manner and for the equipment to function.

Laboratories are specialised places where there needs to be control over temperature, lighting, ventilation and water quality as well as access. They are dangerous places because of the potential risks from infectious material, chemicals, solvents, gases and electrical equipment. It is vital that these hazards are understood by staff and those patients and visitors are protected from these hazards. It will be necessary to limit access to the most dangerous areas.

Where possible it may be necessary to separate different sections of a laboratory to reduce cross contamination, odours, and excessive movement between testing areas.

If there are attached specimen collection rooms then these need to be large enough and safe enough so as not to endanger the patients, their relatives and staff during the collection procedures. If collection facilities are provided, the comfort of patients should be taken into consideration and there should a place where they can wait in comfort.

There should be a process for the safe removal and disposal of laboratory wastes including blood and solvents.

There should be sufficient appropriate storage space to ensure that all samples, slides, histology blocks, retained micro-organisms, documents, files, manuals, equipment reagents, laboratory supplies, records and results are protected.

All work areas should be kept clean and tidy to reduce clutter and potential hazards. The storage of dangerous materials should be carefully controlled.

1.   Laboratory Equipment

It is essential that the laboratory has equipment sufficient to provide the services required for the hospital and patient samples that it undertakes.

Operation and Calibration

The laboratory management should establish a programme that regularly monitors and demonstrates proper calibration and function of instruments, reagents and analytical systems. It shall also have a documented and recorded programme of preventive maintenance, which, at a minimum, follows the manufacturer's recommendations.

When manufacturer's instructions, operator's manuals or other documentation are available, they may be used to establish requirements for compliance with relevant standards or to specify requirements for periodic calibration, as appropriate, to fulfil part or all of this requirement.

Inventory of Equipment

Each item of equipment shall be uniquely labelled, marked or otherwise identified.

Records shall be maintained for each item of equipment contributing to the performance of examinations. These records shall include at least the following:

a) Identity of the equipment

b) Manufacturer's name, type identification and serial number or other unique identification

c) Manufacturer's contact person and telephone number, as appropriate.

d) Date of receiving and date of putting into service

e) Current location, where appropriate

f) Condition when received (e.g. new, used or reconditioned)

g) Manufacturer's instructions, if available, or reference to their retention

h) Equipment performance records that confirm the equipment's suitability for use

i) Maintenance carried out and that planned for the future

j) Damage to, or malfunction, modification or repair, of the equipment.

k) Predicted replacement date, if possible.

The performance records referred to in h) should include copies of reports/certificates of all calibrations and/or verifications including dates, time and results, adjustments, the acceptance criteria and due date of the next calibration and/or verification, together with the frequency of checks carried out between maintenance/calibration, as appropriate, to fulfil part or all of this requirement. Manufacturer's instructions may be used to establish acceptance criteria, procedures and frequency of verification for maintenance or calibration or both, as appropriate to fulfil part or all of this requirement.

These records shall be maintained and shall be readily available for the life span of the equipment or for any time period required by law or regulation.

Operating Instructions

Equipment shall be operated by authorised personnel only. Up-to-date instructions on the use and maintenance of equipment (including any relevant manuals and directions for use provided by the manufacturer of the equipment) shall be readily available to laboratory personnel.

Safety and Environment

Equipment shall be maintained in a safe working condition. This shall include examination of electrical safety, emergency stop devices and the safe handling and disposal of chemical, radioactive and biological materials by authorised persons. Manufacturer's specifications or instructions or both shall be used, as appropriate.

When selecting equipment, account should be taken of the use of energy, water and future disposal of the instrument or reagents and other disposables.

Management of Faulty Equipment

Whenever equipment is found to be defective, it shall be taken out of service, clearly labelled and appropriately stored until it has been repaired and shown by calibration, verification or testing to meet specified acceptance criteria. The laboratory shall take reasonable measures to decontaminate equipment prior to service, repair or decommissioning.

Computer Maintenance

When computers or automated examination equipment are used for the collection, processing, recording, reporting, storage or retrieval of examination data, the laboratory shall ensure that:

Computer software, including that built into equipment, is documented and suitably validated as adequate for use in the facility.

Procedures are established and implemented for protecting the integrity of data at all times.

Computers and automated equipment are maintained to ensure proper functioning and provided with environmental and operating conditions necessary for maintaining the integrity of data, and

Computer programmes and routines are adequately protected to prevent access, alteration or destruction by casual or unauthorised persons.

D.   SUMMARY

Managing laboratories is a science just as important as processing samples and this requires an understanding of what makes laboratories function. There are some basic processes that assist with this role and these have been described.

References

AS 4633-2004 (ISO 15189:2003) Medical Laboratories – particular requirements for quality and competence. Standards Australia, Sydney, Australia.

Chapter 3

Managing the Work process of Laboratory work flow

Dr. Herbert Stekel

Laboratory work flow – an introduction

In autumn 2008, I asked students about the workflow in a clinical laboratory. These students are going to become technicians and they had their first or second month of training. The question was, "imagine the work flow in a laboratory, where does the process start, where does it end?"

Most of them answered in the following way, "the process starts with the venepuncture, and it ends with the report given to the requester." If this is so, we fabricate printed paper and we are doing this by using blood as a raw material. This sounds to me like alchemy, doesn't it?

There is no doubt that the printed report or even the report on the screen of a personal computer in the ward is the primary product of a laboratory. However, the start of the process is simply a question. Clinicians have questions. "What level of blood glucose can we measure?" "Are there signs for any liver disease?" "How many white blood cells can we count in the blood of patient X?" "Is there any sign of inflammation?" To answer these questions we need some information about the patient and we need to analyse samples of the patient's blood, urine, cerebrospinal fluid, or whatever may be helpful to find the correct answers.
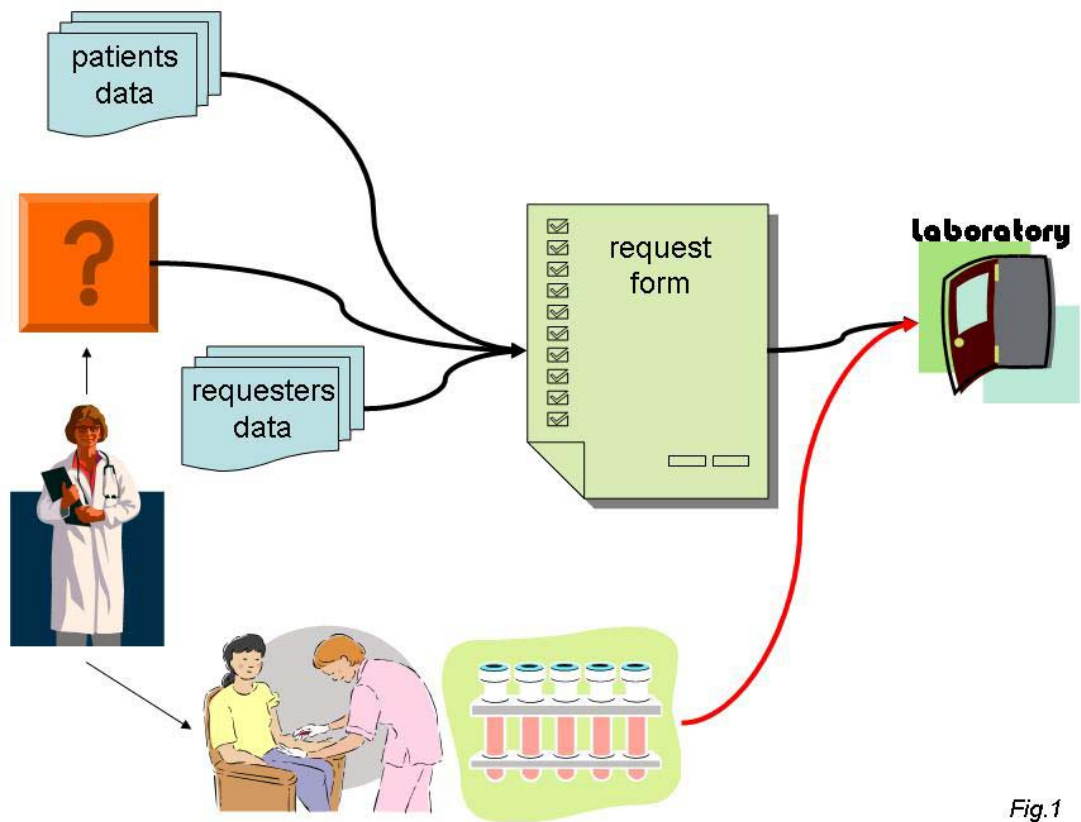
Fig. 1. The first steps in the laboratory process.

Figure 1 shows these first steps to start the laboratory process. The upper line, figured out with black arrows, is the data trail of the laboratory process. It starts with the collection of three kinds of data. The three parts are the question of the clinician, the patient's data, and the requester's data.
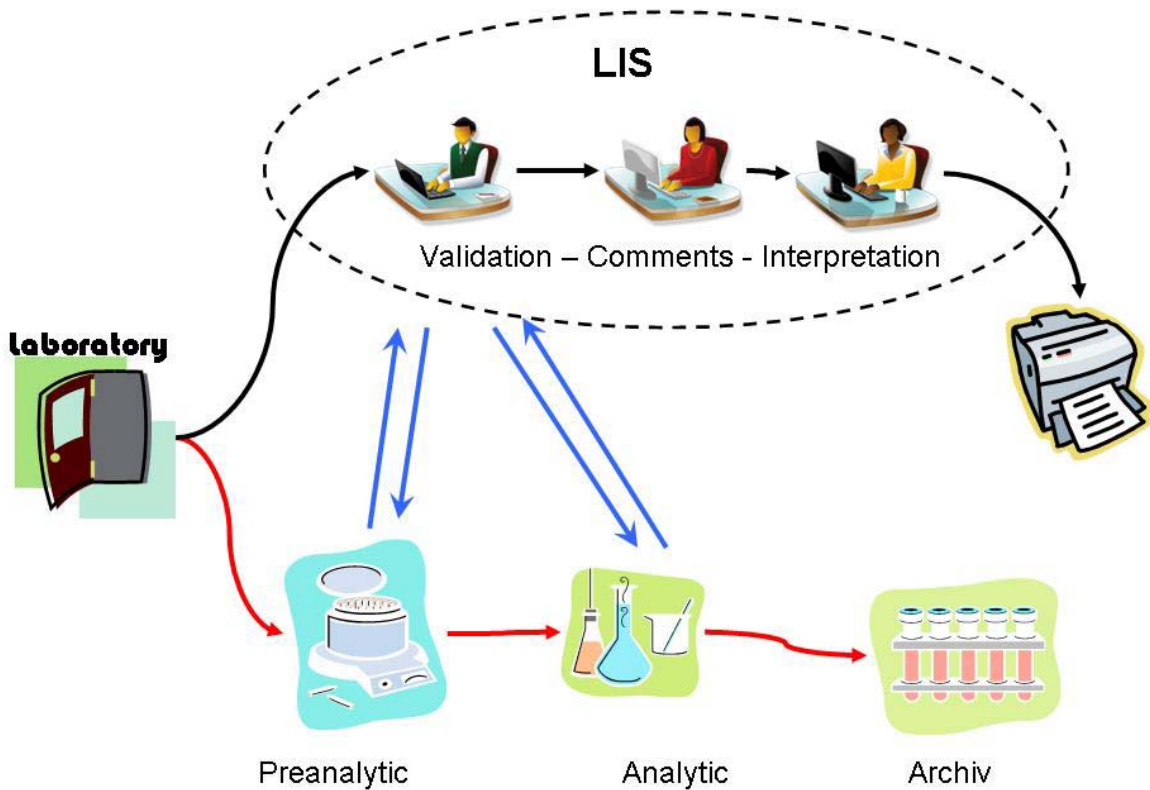
Fig. 2. The workflow behind the door of the laboratory.

Figure 2 shows the workflow behind the door of the laboratory. The two lines are clearly separated. The upper part with black arrows shows the data management of the lab. Requests are written into the laboratory information system, either by order entry or by readable forms, sometimes by keyboard. In the lower part workflow of the technical process is shown using red arrows. After the pre-analytic steps like centrifugation, de-capping and splitting, the analytic work is done. The workflow ends with the transport of specimen to the archive. Pre-analytic and mainly analytic steps are controlled by the LIS. The data communication between analysers and the LIS is symbolised by blue arrows. After the uploading of the results the post analytic routine covering technical validation, commenting and medical validation ends with the printing of the report.

What does the term workflow really mean?

It describes a sequence of connected steps, operations, declared as work of a single person or a group of persons, an organisation or parts of an organisation. A workflow may describe simple mechanisms as well as complex ones. It is a model to describe repeatable sequences of operations.

A process is a notion that can also be used in connection with biological or physical processes. A process description always needs a starting point, well defined inputs and outputs, purposes and an endpoint. It is also necessary to define a process owner. A workflow describes more generally any systematic pattern of activity.

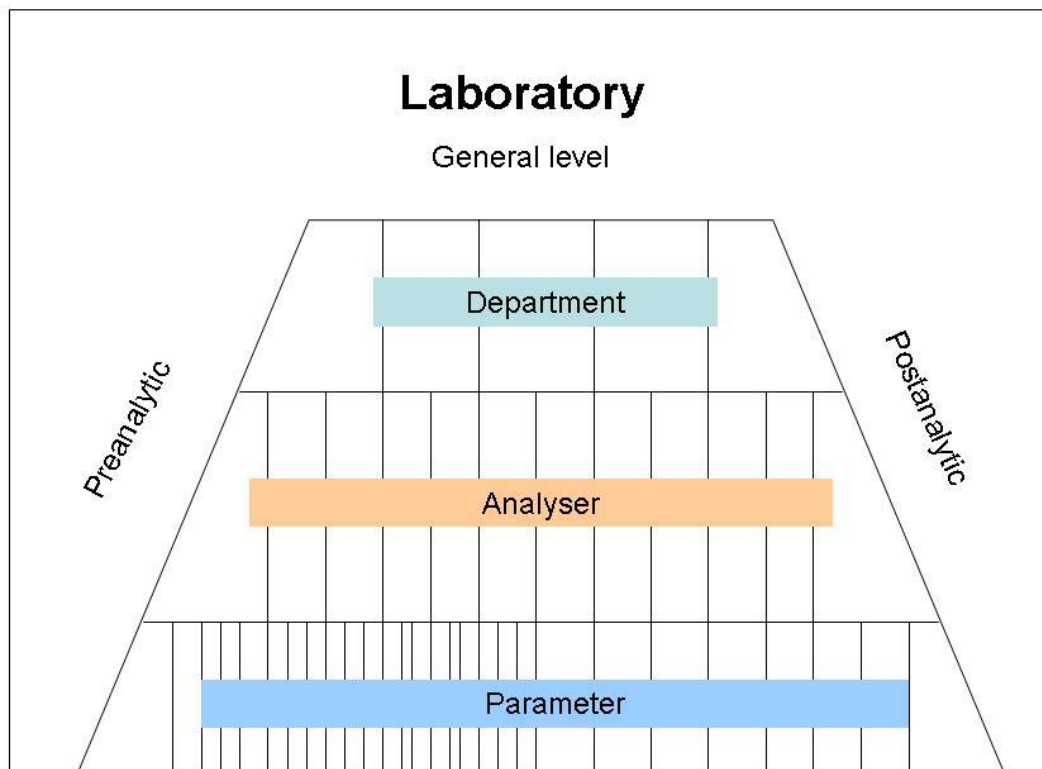We can describe workflow on different levels.

Fig.3

Fig. 3. The levels on which workflow description can be done. The lower the level, the more the description will get the characteristics of a process description, where a process owner has to be clearly defined. Level 1, the general level, depicts the overall view.
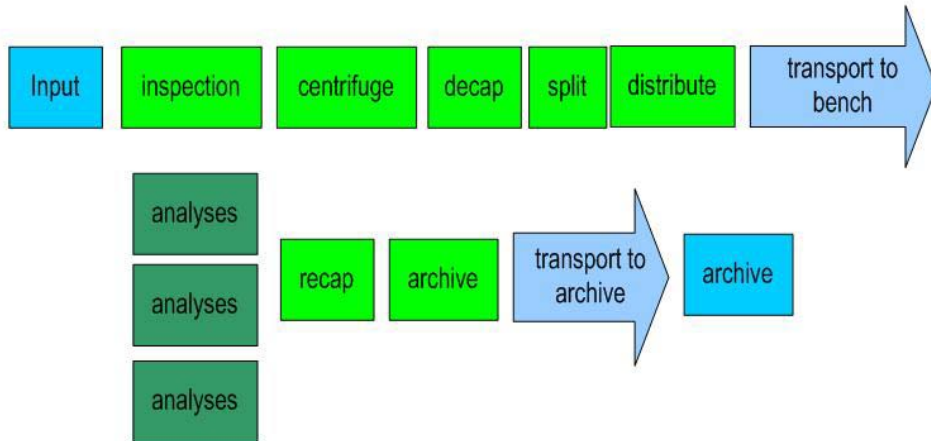
Fig.4

Fig 4. An overall view of the technical process, starting with the visual check of incoming material. The storage of specimen in the archive is the endpoint in this figure. Level 2 shows the workflow in the departments of the laboratory, e.g. clinical chemistry, microbiology, haematology... Details that are more specific can be shown on this level. Workflow concerning single analysers is based on level three. On this level details like quality control, ordering of reagents are reported. This is the level of manuals and standard operation procedures. Level four, the parameter level holds details concerning single parameters like HIV.
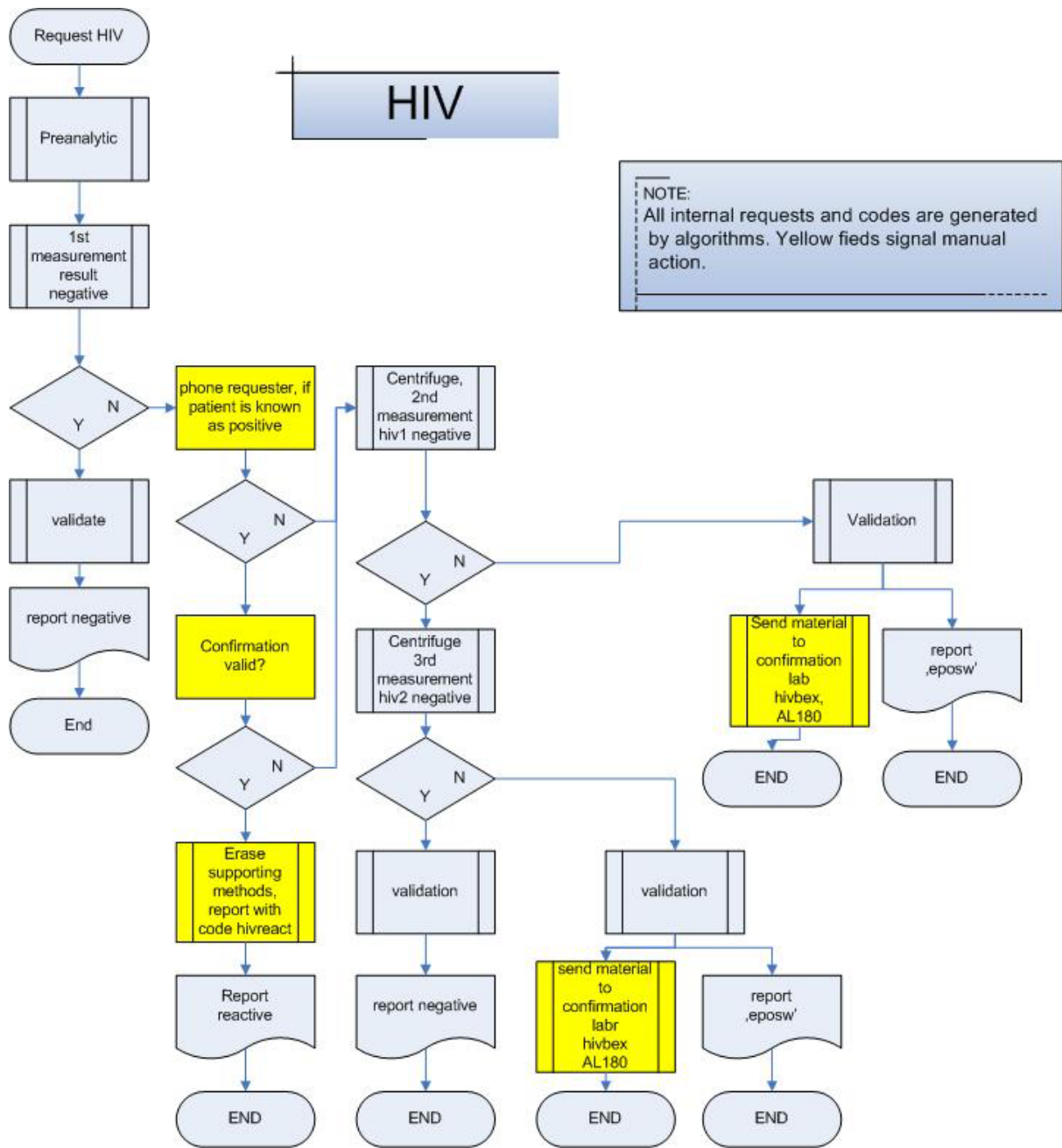
Fig. 5 Workflow graph for the use in the laboratory.

What fields of interest does workflow management cover?

Clinicians want a "nice" laboratory. This does not only mean that the lab is friendly, beautiful, and working in the background without any problems. NICE stands for a concept of four elements.

- "N" stands for "no costs." Clinicians as well as the owners are interested in reducing costs wherever possible.
- "I" stands for "in time." The worth of laboratory results decreases with increasing time between venepuncture and the printing of the report.
- "C" stands for "correct." Analysis and findings have to be correct to give the right answers to the clinician's questions.
- "E" finally stands for "everything." The higher the number of parameters offered by a laboratory the better for the requester.

The elements N and E are part of the strategic thoughts and policies of a laboratory. C and I are describers for the laboratory process.

From description to management

Laboratory management – like every kind of management - is simply the act of getting people together to accomplish desired goals and objectives. Management includes planning, organising, leading and controlling the laboratory. It also has to find the way to use human, financial, technical and, last but not least, environmental resources in the most efficient way.

If we take the Deming cycle as a basis for quality in laboratory work, the planning of the workflow will be described as the element "plan". Daily work would form "do". Process control and quality control as part of the process control will mark "check". And consecutive action will depict "act".

Define the goals!

Work flow management will address speed ("in time") and correctness of a laboratory.

The overall speed is often expressed as turnaround time (TAT). Checking the work flow under the aspect of speed needs the use of timestamps. Do not hesitate to use time stamps whenever and wherever they are set automatically by the laboratory information systems or by analysers.

Correctness of laboratory work, the accurate report, is crucial for fulfilling the duties of laboratory medicine. The use of internal and external quality control is, therefore, essential. There shall be no parameter without internal QC. External QC should be used as much as possible in any way.

Plan the workflow!

After the definition of the goals of the specific laboratory, some more detailed work must be done. Planning a new laboratory or making a further step in an existing one – in both cases documentation in a useful amount is essential. In this step it is also necessary to plan the measuring points in order to have enough information to judge the quality of the newly defined or redefined process.

There are several approaches to increase speed in laboratory work. One way to shorten the TAT is to increase the capacity of the laboratory's equipment. If we consider having one big analyser versus two or three small or midsize ones, we have to keep in mind that costs for quality control, calibration, universal material and also the service costs increase with the number of devices installed in the laboratory. On the other hand, the breakdown of a single machine will not stop the whole lab if there is a second one as a technical reserve. Considering personnel costs, two machines need more time to start up and shut down. Laboratory management has to deliberate about whether higher costs by using smaller and multiple equipment or lower costs by using bigger machines and eventually higher risk in case of drop out can be justified.

Efficient workflow also needs short time windows between each step. The planning should not only focus on the speed or throughput rate of the analysers. We have to take into account that there is a high impact of the time needed to transport specimen on the overall speed.

To say it in a more systematic way, the total TAT consists of multiple steps:

For example, time

- from arrival of material to first inspection
- for first inspection

- for transport to the centrifuge and loading of the centrifuge

- for unloading and transport to the distribution

- for de-capping, splitting and distributing

- for transport to the analyser or the manual workplace

- for analysis

Beyond this point, the speed of a laboratory is not defined by the work with the material but by the speed of data handling. This includes time

- for technical validation

- for medical validation

- for printing and delivering the report

The management of the laboratory needs facts and information to measure the intervals as given before. Time stamps are very helpful, especially when they are set by the laboratory information system without any work force.

However, it is not only the speed – remember I for "in time" – but also the C like "correctness" the management of the laboratory has to take into consideration. There must be a critical view on the quality of the results. This starts with the choice of parameters and methods offered by the laboratory. Therefore, many questions must be answered.

- What about specificity and sensitivity of a method?

- Is the method good enough to give helpful answer to the clinician's questions?

- Does the day-to-day accuracy allow consecutive reporting?

- What about comparison of methods?

- Moreover, what about the traceability?

- Is there any gap in the concept of quality control?

- Is external quality control available?

- Are all environmental conditions under control?

There exists a lot of literature that covers all items addressed above. Goals and best available practice are dependent on the specific circumstances.

The definition of laboratory workflow needs thought and it needs planning tools. Software is available with very different levels of complexity. Nevertheless, there currently exists no specific tool to optimise or even construct workflow in medical laboratories. Managing the workflow is the backbone of the daily work in the laboratory. Proper planning will lead to excellent results in the daily work

All figures by the author

Chapter 4

Measuring and Monitoring Quality in Analysis and reporting

(Non conformance event management Audits and assessments)

Prof Ken Sikaris

Introduction

When establishing a quality system, a large effort is put into documenting all the procedures used in the laboratory and training staff to carry out those procedures in a consistent and standard way. As laboratory scientists are both intelligent and curious, they have a natural tendency to wander from the strict procedure and either add extra steps or find short cuts in a procedure to attempt to improve on the way the procedure is done. Furthermore, reagent and instrument suppliers also keep changing the materials they provide to the laboratory (hopefully for the better). However if either staff members or suppliers are altering how they are working, there is a major risk that there will be inconsistency in process and also in patient results.

In order to check on potential changes that occur over time, quality systems need to periodically check that procedures are performed according to the way they are documented. This doesn't mean that nothing should ever change, as procedures should be changed for the better, however these changes should be incorporated into the standard documented procedure so that all staff can benefit from a change for the better.

Definitions

Audits are performed to ascertain the validity and reliability of information. They also provide a periodic systematic assessment of the success of a quality system in achieving its goals. Audits can be defined according to their target, for example; financial audit, staffing audit, procedures audit or product audit.

Because an audit can only sample these targets at a particular time or place, it is important that individual audits are part of a systematic plan to look at a variety of different areas (rather than just checking one area over and over again). The systematic nature of audits can be addressed by regular timing, as well as regularly looking across areas using different approaches such as 'vertical' and 'horizontal' sampling.

Horizontal audits investigate the same target (e.g., staff or procedures) that are in different departments. For example, a horizontal audit of staff training would look at the staff training records on departments A, B, C, D etc. This would usually not only check that staff training records are kept and are up to date, but also that staff are only working in areas that they have been trained and documented as having competence for. Other examples of horizontal audits may be safety audits across each department or audits of how reports are validated prior to release in each department.

Vertical audits investigate all the processes carried out in a department or section. This is usually achieved by following one (or more) randomly selected request, sample or report through the various areas of its processing through the laboratory such as phlebotomy, reception, sample preparation, analysis and reporting. In this audit, not all the staff or procedures in a department will be investigated, only the ones that touch on the 'vertical' path of the particular object through its relevant areas. This is an important opportunity to detect non-conformances across the pre-analytical, analytical and post-analytical phases of the laboratory.

The quality manager (or another appropriate manager) should establish a planned timetable of audits that should ideally focus on the areas of the laboratory that are known to be most critical for patient safety and use a mixture of horizontal and vertical approaches so that laboratory operations are crisscrossed with a wide net.

In addition to the scheduled plan of audits, unscheduled (random) audits can also be carried out particularly when there is evidence that there may be a problem. Evidence that an audit may be required may come from complaints, laboratory detected anomalies or the results of audits conducted in one area that could suggest that non-conformances could be occurring in other areas.

ISO 15189 requirements for Auditing

Section 4.14 of the ISO 15189 standard for Quality Systems in Medical Laboratories states that 'Internal Audits' should be carried out to ensure that operations comply with the requirements of the quality system – i.e., follow what is expected in documented procedures. Although the frequency of auditing should normally be every 12 months for the main elements of laboratory activity, emphasis should be placed in areas critically important to patient care.

Internal Auditing is conducted by the laboratories own 'internal' staff. Since staff generally think they are doing their work the right way, personnel shall not be allowed to audit their own activities. It is a requirement of all quality system standards including ISO 15189 that staff performing an audit should be independent of the work being audited.

An auditor that has no employment connection with the laboratory is even more objective about what is a written requirement and what is actually performed. External auditors will check whether what you have written in your own procedures is being followed by your own staff. External assessors can also assess whether your procedures fulfil external requirements such as accreditation requirements (ISO 15189) or local laws and regulations.

Documentation

In addition to audits being systematic and independent, the final aspect of objectivity is that audits should be documented. This applies not only to the recording of the results of an audit,

but before that with the planning of the audit and conduct of the audit. Just as internal staff must be trained and documented to be competent in carrying out procedures, internal (and external) auditors should also have training records that show that they are trained and competent auditors.

The person planning the laboratory's audits should ensure that an audit schedule is documented and an audit form is created that ensure that the following elements could be recorded.

A unique reference number for the audit

Date of the audit (scheduled or unscheduled)

The area(s) to be audited

e.g., Staff and/or Equipment and/or Records in a specified department

The specific target(s) of the audit

e.g., a particular procedure (horizontal audit)

or a particular sample (vertical audit)

The name of the trained auditor(s) who will be conducting the audit

Non-conformances found

Likelihood of recurrence, possible impact and risk of each finding

Who is responsible for corrective action

Immediate action for high risk issues

Deadline for action

Date correction action is completed

Sign off by relevant staff (quality manager)

Ideally, the process in conducting each audit could follow the following outline of steps that usually are the elements of every external assessment:

Inform supervisor of date and time of audit and the records that will need to be reviewed

Provide both assessors and laboratory area with a checklist of what will be covered and expected during the audit

Have an opening meeting so that auditors and staff can be introduced and know by whom, how and where the audit will be conducted and concluded

Auditors and staff participate in gathering evidence

Results are recorded, including specific details of any non-conformance found

Have a closing meeting where the supervisors can be made clearly aware of the corrective actions that are required.

Following up the results of an Audit

The results of audits (non-conformances) should be acted on by the supervisors of that area in an appropriately timely way, with major risks being addressed before minor risks. The results of the audits and their corrective actions should also be submitted and reviewed by laboratory management so that they can see if there is any pattern of non-conformance developing and then management can decide if extra resources are required to prevent these happening again in the future. For example, transcription errors are most common in manual procedures. While they may be corrected by having one staff member check what another staff member has recorded, it may be more efficient to interface instruments that have an electronic output directly to the laboratory's data system. Non-conformances increase when staffing, equipment or consumable resources are inadequate for the specified procedure therefore this must be an important consideration for the management of the laboratory.

Management can also be audited in regard to the quality system. Have they been made aware of significant audit and assessment findings? Are they aware of major complaints that have been recorded and whether those complaints have been addressed to their satisfaction? An annual management review is a requirement of quality systems such as those compliant to ISO 15189 and is expected to cover the issues raised through scheduled auditing.

It is important to appreciate that audits aren't designed to improve laboratory quality, simply to check whether the internal systems of the laboratory that maintain continuous quality improvement are operating in the way they were intended. While audits may uncover opportunities for improvement, because of their limited and sporadic nature, they will not be as reliable daily quality control procedures that form the routine quality system within each department.

Finally, it is important that all staff are made aware of the audit findings in their respective areas. This is to ensure that they are aware of corrective actions and changes in written procedures and they should formally acknowledge these as having been read. It is also important that staff are continuously reminded of the quality goals for their laboratory so that they can work with confidence.

Auditing Duties for various laboratory staff levels

Management	Quality Manager	Section Supervisor	All staff
Define audit policy	*Comply with audit policy*		
Assign responsibility for audit program	*Establish and maintain audit program using trained auditors*	*Provide auditors with records (eg training records)*	*Expect audits at least once a year*
	Coordinate schedule	*Coordinate schedule*	*Demonstrate usual procedure and answer any questions*
Be aware of major corrective actions	*Manage Corrective Actions*	*Undertake corrective actions*	*Be aware of corrective actions*
Consider audit outcomes at management review	*Inform management of audit outcomes*		
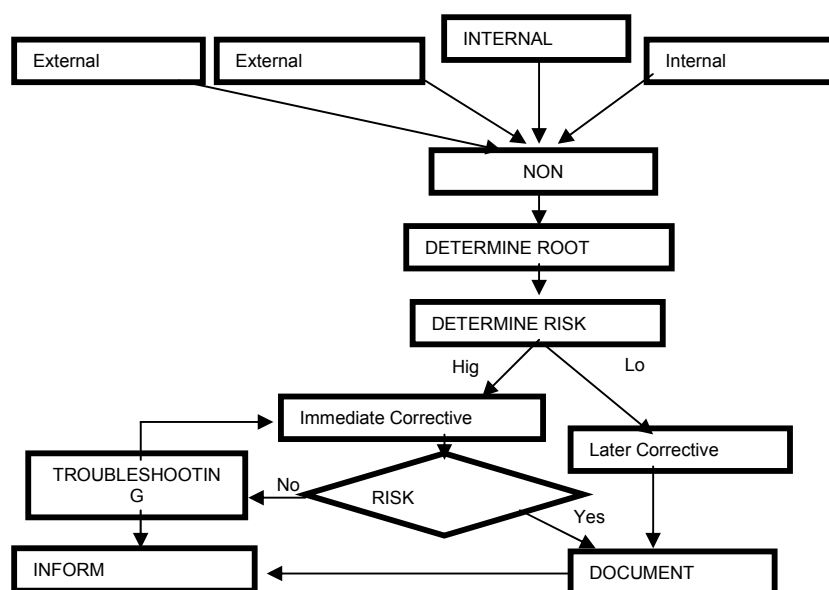
Risk Matrix

LIKELIHOOD	IMPACT				
	Level 1	Level 2	Level 3	Level 4	Level 5
Rare	Negligible	Low	Low	Medium	High
Unlikely	Low	Low	Medium	High	High
Possible	Low	Medium	High	High	Extreme
Probable	Medium	High	High	Extreme	Extreme
Certain	High	High	Extreme	Extreme	Extreme

Examples of Likelihood

Likelihood	Statistical frequency	Temporal frequency
Rare	<0.01%	> 5 years
Unlikely	0.01% - 0.05%	Yearly
Possible	0.05% - 49.9%	Monthly
Probable	50% - 95%	Weekly
Certain	>95%	Daily

Examples of Impact

Likelihood	Clinical Impact	Financial Impact
Level 1	Anxiety	$10
Level 2	First Aid	$100
Level 3	Doctor Visit	$1000
Level 4	Hospitalisation	$10,000
Level 5	Disability / Death	$100,000+

Examples of Risk Response

Impact	Urgency of Response	Sign off of Response
Negligible	***Consider*** *if corrective action is required at next quality meeting*	*Any staff*
Low	***Plan*** *for a corrective action*	*Supervisor*
Medium	***Should*** *reduce risk with immediate corrective action but must follow up with final corrective action*	*Area Manager*
High	***Must*** *reduce risk with immediate corrective action and follow up with final corrective action*	*Management Committee*
Extreme	***Stop*** *until final corrective action has been reliably implemented*	*CEO*

Chapter 5

Continuous Improvement

Dr. John Krahn

Introduction

Quality can be defined by describing parameters involving the pre-analytical, analytical, and post-analytical phases of laboratory practise. Continuous improvement should be directed to very specific parameters in these three phases. For example, if haemolysis is a problem during phlebotomy this would be pre-analytical, calibration error would be analytical and incorrect reference interval could represent post-analytical. An overall quality indicator would be turnaround time.

Continuous improvement should be embraced by all clinical laboratories and is mandated in many countries as part of the accreditation process of laboratories. This takes the form of continuous quality improvement (CQI), total quality management (TQM) and others. All these processes have in common the desire to improve the overall quality that the laboratory delivers.

Tools

There are a variety of tools available for CQI and it is important to use the proper tool for the specific improvement desired. The most useful tools are desired below.

DMAIC

The first tool name is the acronym DMAIC which stands for: Define, Measure, Analyse, Improve and Control.

Define: The problem or quality parameter should be defined so that it can be address. In the pre-analytical phase this be represented by things like haemolysis or mislabelling of samples.

Measure: This addresses the quantitative nature of the problem i.e., 10% of specimens are haemolysed or 3% of specimens are mislabelled. This is essential since this measurement must be repeated when improvements have been done to see if they have been effective.

Analyse: Analysis is very important to determine the causes or factors creating the quality problem. A formal way of doing this is the 5 WHYS or Root Cause Analysis (RCA) which will be described in more detail later.

Improve: The analysis phase should yield opportunities to improve the process. These should then be introduced into practice. This could involve introduction of new equipment, proper training of staff or whatever the analysis phase identified. After introduction of changes, the measurement process should be done again to ensure that the improvement has worked.

Control: Once the improvement has been achieved, the entire process must be frozen or embedded into daily work. In a clinical laboratory, this usually takes the place of putting in place authorised documents called "standard operating procedures" (SOPs) or policies that every laboratory worker understands and uses. There must also be a procedure in place that ensures that management knows that the SOPs are being followed and not modified without approval.

Root Cause Analysis (RCA)

A useful tool in RCA is the fishbone diagram. For this diagram, all the potential causes of the problem are identified and listed as in the figure below. An attempt should be made to identify all the causes and then to determine the ones that are the most important contributors. This can be done by using a Pareto graph which identifies the most and the least important areas to work on.
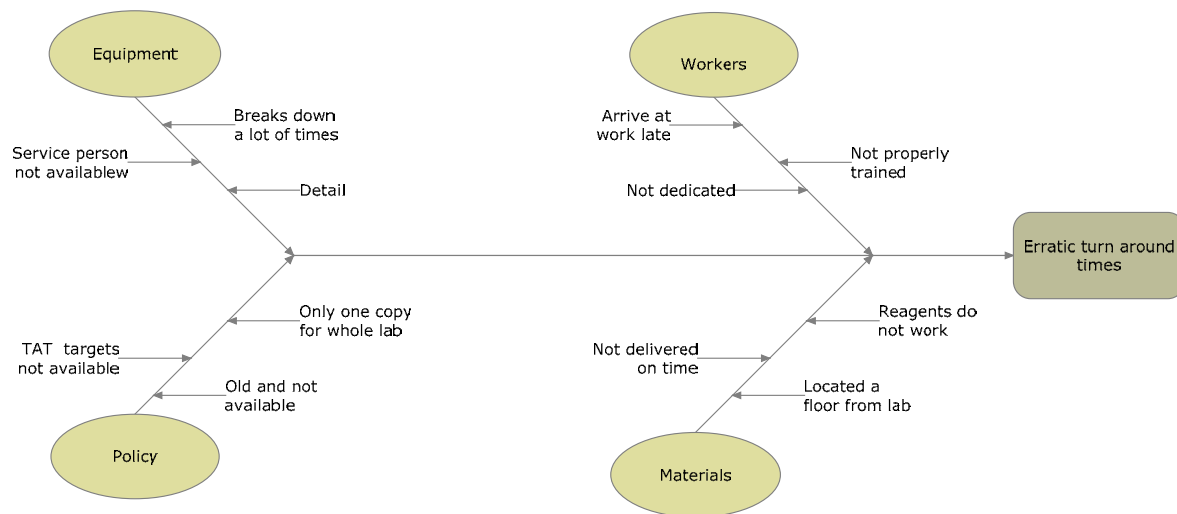
Figure 1: Root cause analysis with a fishbone graph

Another way of identifying the cause of the problem is termed as the % WHYs. This method indicates that to get as close as possible to the root cause, the investigator has to keep asking why until the real cause was found. The rule of thumb is that you must ask "why" at least 5 times. This may help determine the relationship between different root causes of a problem. It is one of the simplest tools and does not require sophisticated statistics, but can be done verbally as a brainstorming technique.

5S

Concept of the visual workplace – waste in looking for things

The 5S's are sort, set in order, shine, standardize and sustain. This appears at first glance to be common sense but it is surprising how much wasteful activity is created by things not being in their proper place. How does this affect quality? In a number of ways the biggest being mix-ups that lead to errors like wrong calibrator being used, wrong reagent, wrong patient sample being labelled etc.

- Sort – this step dictates that common items be aggregated so that mix-ups do not occur

- <u>Set In Order</u> – make everything visual by arranging and identify everything in the work area. Items should be located as close to the workstation as possible. The visual workplace should also concentrate on ensuring that vital events are visually obvious eg inventory below critical levels

- <u>Shine</u> – This refers to the fact that once the workplace has been cleaned and organized, it needs to be kept in that state. This should be a regular activity and is very important when leaving the workplace so the next worker can start without have to hunt for the the items required for their job.

- <u>Standardise</u> - make it easy to maintain - simplify and standardise

- <u>Sustain</u> – This is a management or supervisory function that ensures that the system introduced is maintained at the same level at all times.

Lean

Concept of Waste

The main thrust of Lean is to remove waste from any process. The Toyota company from Japan has used this process to become a world leader in the automotive industry. It has proven that this process not only improves quality but simultaneously reduces cost. Lean has now been adopted by many clinical laboratories.

The different kinds of waste are listed below:

Waiting

Any time when material, information, people or equipment is not available. A variety of scenarios are common in a laboratory but someone trained can readily identify "waiting" situations. Examples are samples waiting for centrifugation, results waiting to be released/called, equipment not available because of maintenance calibration and so on.

Transportation/Material Movement

Excessive movement by a worker to get materials required for the task at hand. This may mean that workstations and supplies are not placed in close proximity or that the specimen must be carried through a very large maze before all the tests are complete.

Over-processing

Efforts that create no value for the patient. This can range from excessively arduous approval process for tests, very complicated requisitions, excessive approvals required for quality control authorization. Running tests in duplicate or running an excessive number of standards or quality control specimens is another example.

Inventories

This implies that the lab has more material or data on hand than what is needed at present. It can be represented by batching specimens into large infrequent runs, storing specimens for much longer than required for analysis or by keeping excessive paper or electronic records so that record retrieval is difficult. In modern laboratories it can mean manual approval of patient tests where the computer has a large number of reports awaiting authorisation before they can be reported. Auto-verification can solve this problem.

Specimens waiting analysis

Paperwork in progress

Motions/Movement

Movement of people that does not add value. This implies that there is excessive movement by the laboratory worker to do the testing or to do the blood collection. The physical layout of the hospital could be a factor if the laboratory is located a long distance from where the wards are. In a similar way, if lab supplies are stored at a site distant from the lab. The analysis tool for this is often a spaghetti diagram which is a diagram which illustrates the movement required to complete the task at hand. The more complex the diagram, the greater the waste of manpower.

Defects

A defect in laboratory medicine would constitute anything that did not conform to the predetermined plan of how work should be done. Examples are test turnaround times that do not meet the lab's target time, wrong specimen collected, specimen collected and transported without proper attention to stability, wrong test performed, result sent to the wrong physician, specimen haemolysed during collection etc. Any work that contains any errors that forces the work to be redone is a defect. Omission of requested work also qualifies as a defect. The motto should be to do everything right the first time.

Overproduction

This means generating more product than the next step in the process can handle. In a medical laboratory setting, this can mean doing things in larges batches that the next procedure can process readily. Many laboratories have this problem with blood collections that occur during one hour in the AM and then create a large backlog of specimens all arriving at the lab at once. This can be solved by having specimens drawn over a longer period of time, by scheduling routine rounds or by drawing them in order of institutional priority so that the arrival of specimens is not all in a very short time in the morning. It can also apply to internal laboratory processes where inventories develop at different point ie prior to centrifugation, analysis or result authorisation

Re-prioritisation

Starting one task, being interrupted (phone, e-mail, page) and changing to another task before the first task is completed. This is a common laboratory problem and create waste of the workers time. Processes must be designed to prevent:

Poor utilisation of skills

This type of waste relates how workers are viewed and what they are allowed to do. In many cases, all the workers intellectual capital is not used ie wasted. All workers must be allowed to

participate in achieving the quality goals of the organisation. Workers must be involved in efforts to change the way the workplace functions.

There are many aspects about quality but a basic paradigm shift involves the fact that quality improvement cannot be achieved merely by setting up elaborate methods of detecting defects or errors before the end product (a laboratory result) is issued.

Six Sigma also targets waste, but the way Lean removes waste makes it perhaps the most aggressive quality improvement management technique.

Lean dictates that the process must promote individual processing: first in-first out FIFO), also known as single piece flow. When a sample comes in, it is immediately run. A fundamental concept in clinical laboratories was batching. This causes many different kinds of waste, among them waiting and transporting. It also creates many opportunities for errors. Fortunately, the diagnostic companies have to a large extent created instruments which eliminate batching and promote FIFO. They have also consolidated analytical platforms to eliminate multiple analysers and excessive aliquotting. Unfortunately, laboratories very often still do pre- and post-analytical batching. In many laboratories, this is where the greatest opportunity for quality improvement exists.

So how does Lean identify waste? The primary tool is process mapping where the entire process is broken into individual steps. In a process known as value stream mapping (VSM) each step is categorised as either having value or not. After this exercise, a new process map (with non-value steps eliminated) is created. These mapping tools help everyone to understand the "current state" and then create the "future state" where the non-value steps or waste are eliminated.

Six Sigma
The business literature often use the terms Lean and 6 Sigma synonymously but 6 Sigma in its purest form is different. It was introduced by Motorola as a way of reducing variability in their manufacturing processes. The method implies that statistics are available for all processes. 6

sigma, of course, is a statistical concept that says a process must be designed such that it meets specification to the mean ± 6 σ . This type of process then allows the process mean to change by 1.5 SD without causing a significant number of defects. The important concept here is to design processes where the variability has been absolutely minimised. An example of this would be if the laboratory desired to absolutely meet a turnaround time (TAT) of 1 hr, they may have to have a mean TAT of 45 min and a standard deviation (SD) of 2.5 min. Six SDs would then equal 60 min and 6 sigma would have been achieved.

Conclusion

The tools described above are all applicable in laboratory medicine and they should be used to create continuous quality improvement. It takes a while to learn which tool to apply to a particular quality project but as in many things in life, you must learn by doing. By gaining real life experience, the reader will quickly master the tools and start making huge quality improvements.

Chapter 6

Quality Control tools

Pre analytical quality control, Analytical quality control, Post-analytical quality control

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Abstract:

The impact of laboratory examination in patient care, diagnosis, drug monitoring, screening and prevention of diseases is increasing all over the world.

Quality of examinations performed in medical laboratories depends on the quality assurance system implemented.

This paper describes the different tools used to control the whole process of examination in the medical laboratory, pre-examination, analytical and post-analytical phases as well. These elements taking part in the quality of care provided by laboratories are described as compared to main standard in the field (EN ISO 15189 standard). This standard specifies particular requirements for the quality and competence of medical laboratories, and provides guidance for laboratory procedures.

Key words: medical laboratory, EN ISO 15189 standard, errors, pre-examination phase, analytical phase, post-analytical phase, pre-analytical variables, quality assurance, quality management, quality standards, quality control, good practices, traceability, Biological reference interval, patient care.

List of Abbreviations: EN, ISO, EQAS, QC, IQC, EEQ, NC.

Introduction

The impact of laboratory examinations in patient care is known as contributing to more than 60% of medical decisions. Each step of the history of the disease is concerned, from genetic predisposition to anticipate the symptoms, primary prevention to detect before signs (mass screening), secondary prevention as early diagnosis (screening focused), to diagnosis as detection or exclusion and evaluation of therapy, to improve care and recurrence control. Laboratory examinations contribute to improve quality of life and efficiency of patient care.

In this context, the quality of the results from the medical laboratory concerns not only professionals, but also everyone involved in patient safety. So, the health authority is responsible for providing regulations to minimise risk of errors in the laboratory which compromise patient safety.

The standard ISO 15189:2007 specifies particular requirements for the quality and competence of medical laboratories, and provides guidance for laboratory procedures to ensure quality and competence in medical laboratory examinations (1). Accreditation of laboratories can demonstrate continuous monitoring of quality and be entered into on a voluntary or a mandatory basis. Accreditation bodies can accredit any medical laboratory fulfilling the requirements given in this standard.

According to this standard, the mission of the medical laboratory is not limited to provide results but plays an important consulting role to clinicians (2, 3). As a member of the healthcare process, the laboratory is involved in the choice of pertinent test to perform and requesting examination according to the clinical goals, defining the frequency of request to avoid redundancy and the type of sample required for appropriate determination.

The role of the medical laboratory is to communicate findings in a meaningful way for patient care, thus requiring clinical information and clarification from the clinician, performing relevant

and useful tests, providing urgent findings, participating in the interpretation of results as part of the medical team.

So, medical laboratories have to provide guarantees about the reliability of the results fulfilling good practice requirements to ensure patient safety.

The management of quality in the medical laboratory includes quality control tools to implement the complete examination process. The process is usually divided into the pre-examination phase including the examination requisition, preparation of the patient, collection of the primary sample, transportation to and within laboratory, storage of the samples, as well as examination and post-examination phases (systematic review, formatting, interpretation, validation, reporting and transmission of the results).

Guidance to implement requirements defined at the international level in the EN ISO 15189 standard related to the control of laboratory good practices is described in this article.

The first part describes tools to ensure the pre-examination phase control, essentially achieved by auditing practices and conformity to the guide established by the laboratory. The second part includes quality control and external quality assessment to ensure high level of reliability of the results. The third part is dedicated to the control of post-analytical practices for delivering the reports, communicating, interpreting the results if necessary compared to biological reference intervals, archiving data and handling of the samples after examination.

I- Sample collection and pre-examination variables control

So great is the impact of pre-examination variables that the results could be affected enough to change the interpretation and lead to an erroneous treatment or care (4, 5). So, they have to be controlled, to be taken into account in written procedures, depending on the nature of each examination.

They include not only such factors as physiological or pathophysiological, those from

environmental conditions and drug or dietary effects, but also factors influenced by the collection protocol (time and site of sampling, container chosen, additives, etc.) and depend on the analyte (stability, necessity of a pre-treatment of the sample, or special condition for transportation, etc.).

Pre-examination (PA) phase is defined (1) as *"processes that start, in chronological order from the clinician's request including the examination request, preparation and identification of the patient, collection of the primary sample, transportation to and within the laboratory, ending when the analytical examination begins".*

According to this definition, collection of the primary sample is a part of the examination of the medical laboratory. If the collection of the primary samples is performed outside the laboratory, conditions necessary for a reliable result are defined by the laboratory. Interpretation of the results included in the laboratory tasks, needs to have clinical information available. Devices have to be settled to control the pre-analytical variables.

To control the PA phase, the laboratory management have to define the process, to write procedures to apply, to implement NC control, to set up indicators, corrective and preventive action according to the nature of the problem, to record data for assuring traceability, to evaluate practices using audit and reviews and to document (bibliography, data, experiences, etc.) all the instructions to provide proof.

I.1. To define processes

Pre-examination phase includes different steps depending on different personnel qualification (Figure 1)
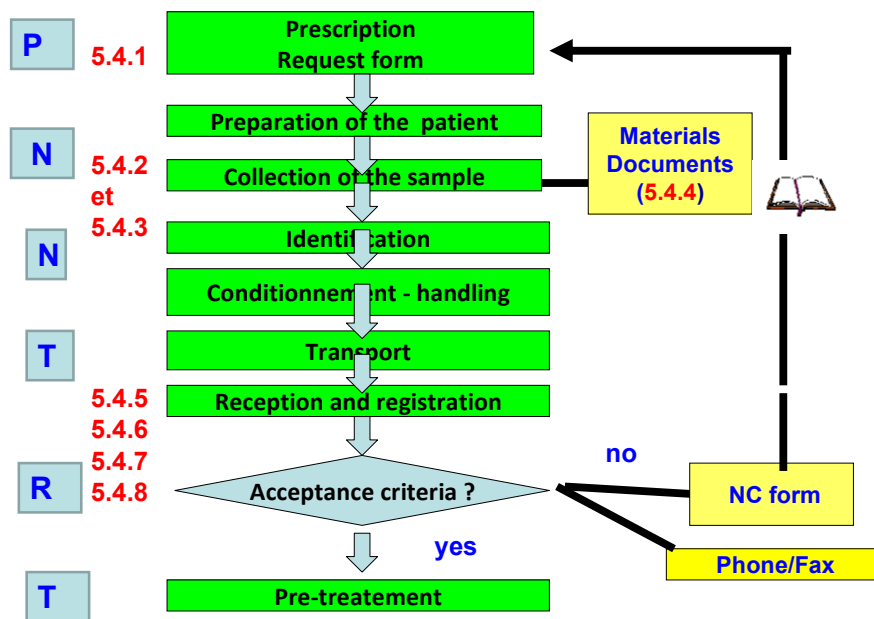
Figure 1: Pre-analytical (pre-examination) process.

(P: Practitioner, N: Nurse, T: Technician, R: Responsible)

In red, the chapter of the standard ISO 15189

1   Requisition:

Request form, as defined in a document, shall include (Table 1) name and signature of the requester, name of the phlebotomist, name of the patient (and birth name), surname, birth date, sex, nature of the primary sample, time of sampling, examinations to perform and clinical information.

Table 1: Content of the request form to order examinations.

1- Name of the patient surname, sex, date and name of birth
2- Name of physician or other requester, address, phone
3- Type of primary sample and the anatomic site of origin
4- Examinations requested
5- Clinical information, if necessary, for interpretation purposes
6- Date and time of primary sample collection
7- Date and time of receipt of samples by the laboratory

2   Preparation of the patient:

Conditions for patient preparation (fasting, special diet, drug intake, etc.) are defined in a written document according to the test required. Verification is necessary before sampling using a simple questionnaire.

3   Collection of primary sample:

Conditions for patient comfort, confidentiality and safety are required.

Written procedures describe all conditions to fulfil (6, 7) according to the examination (arterial, venous or capillary blood, volume to collect, container, etc.). Training of the phlebotomist has to be traceable.

4   Identification of primary samples:

A written procedure for means used to identify with a very low risk of error has to be implemented (8).

A procedure for primary samples coming from other places has to be settled (example: labelling includes the name of the patient, date of birth, time of sampling, identification system if available as barcode).

5   Transport:

Conditions for transportation of the primary samples vary with the examination. Procedures explain those conditions such as delay in transportation to the laboratory, sample preparation, packaging, and temperature control to insure integrity, safety and traceability (9).

6   Storage:

For each type of examination, conditions for sample storage are defined to ensure stability of analytes if conditions required are fulfilled (9, 10). Samples shall be stored for a specified time, under conditions ensuring stability of sample properties, to enable repetition of the examination after reporting of the result or for additional examinations.

7   Pre-treatment of primary samples:

Procedures describe, according to the test and method used, the operating procedures for centrifugation, decantation, deproteinisation, dilution, concentration, etc. Where a secondary sample is necessary, rules have to be defined for identification of aliquots.

8 Evaluation of conformity of the primary sample and request form:

Verification according to a check list is settled to detect non-conformity according to the data shown in Table 2. Some of them prohibit performing the test (11). Some others need to complementary information before performing. A report is sent to the requester to inform about action to display and re collection, if necessary.

Table2: List of pre-examination non conformities

Class	Type
REQUISITION	Redundant or inappropriate
PREPARATION OF THE PATIENT	Inappropriate fasting Inappropriate diet
COLLECTION	Inappropriate time Inappropriate site Inappropriate identification (wrong or missing) Inappropriate container Inappropriate additives
REQUEST FORM	No request No information Urgent non specified
CLINICAL INFORMATION	Lack of clinical information No pertinent information
SAMPLE	No sample insufficient volume (or inappropriate) Not identified Error of additive Haemolysis (visible after centrifugation) Contamination from infusion route clotting
TRANSPORT	Time out of range Temperature out of range Pneumatic tubes
ASSOCIATED DOCUMENT	Informed consent form
TRACEABILITY	Requester name and phone fax
EXAMINATION	Non pertinent Not defined Redundant test
CONFIDENTIALITY SAFETY	

9 Registration of request:

Details are registered on the informative system or a log book.

I.2. To write procedures (and control)

- A manual including instructions for the requester (content of the request form as given table 3) for preparation of the patient collection, identification of the sample, conditions for handling, transport, receipt of the samples is available.

Criteria for the definition of conformity of request and samples required are given as well. The checklist of document available is given Table 3.

- A procedure for guidance in case of non identified primary samples is provided to people in charge of the receipt of sample.

-The position to adopt in case of haemolysis of the sample (12, 13, and 14) has to be defined in a written instruction.

Table 3: Collection of primary sample: list of documents to provide (1).

- List of available examinations
- Request form or electronic request including indications for clinical information required
- Consent forms, when applicable,
- Information and instructions to provide to patients for preparation before primary sample collection according to the test
- Information for users of laboratory on medical indications and appropriate selection of method
- Instruction for the preparation of the patient to caregivers and phlebotomists,
- Instruction for identification and labelling of primary sample
- List of the containers and additives to use according to the test and body fluids
- Type and amount of the primary sample to be collected
- Special timing of collection, if required,
- Transport requirements, temperature and delay
- Recording the identity of the person collecting the primary sample
- S*afe disposal of materials used in the collection*
- *Instructions for storage of examined samples,*
- *Instructions for time limits for requesting additional examinations,*
- *Instructions for additional examinations,*
- *Instructions for repeat examination due to analytical failure or further examinations of same primary sample.*

I.3. To implement non conformity control, corrective action and preventive action

Criteria for acceptance, rejection of the samples and complementary information requesting **shall be defined** and applied to detect non conformities (table 2). Traceability of action is required.

Each non conformity is taken into account, documented and action recorded. Periodical review of those non conformities leads to corrective action after analysis of the root cause (figure 2). Indicators can be very helpful (figure 3 and figure 4)
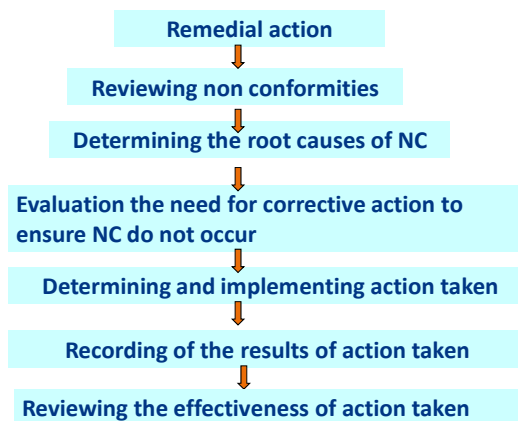

Figure 2: Corrective action: process for NC control

Remedial action

Reviewing non conformities

Determining the root causes of NC

Evaluation the need for corrective action to ensure NC do not occur

Determining and implementing action taken

Recording of the results of action taken

Reviewing the effectiveness of action taken

Figure 3: Non conformities to reduce

Non conformities 2009

No clinical data (40%)
Insufficient volume of the sample (30 %)
7 %
5 %
5 %

- No clinical data
- Insufficient volume of the sample
- No identification of the sample
- Blood without preparation
- Request without sample
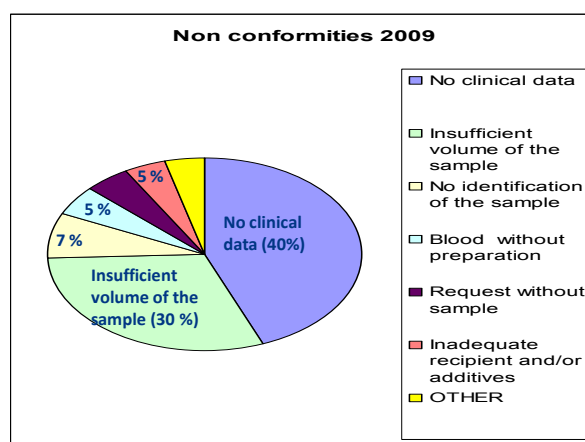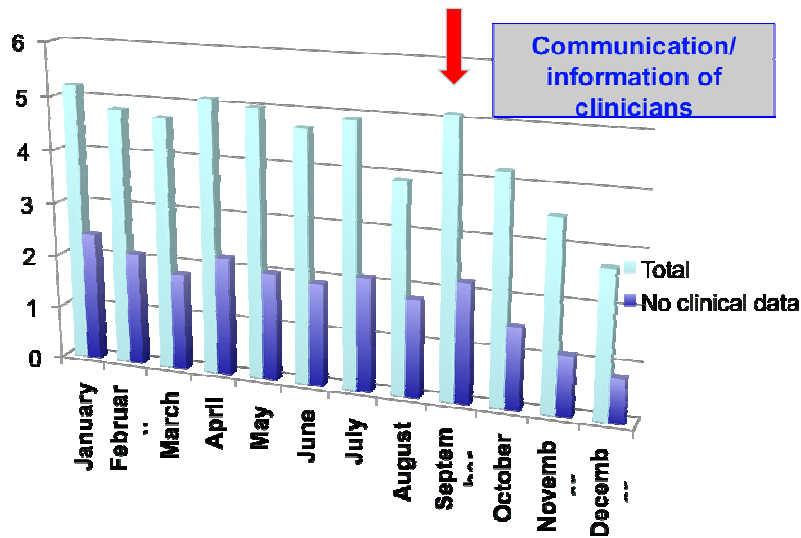- Inadequate recipient and/or additives
- OTHER

Figure 4: Receipt of samples: percentage of non conformities (2009)

Examples of actions to implement:

•Training of professionals: persons in charge of collection, transportation, nurses, technicians,

•Information of users: patients, physicians

•Evaluation of competences

•Audit of pre-analytical phase and transportation conditions

•Evaluation of satisfaction of users

•Insure resources for materials

•Quality control of biological samples

•Document control

I.4. To evaluate: audit, review

The laboratory **shall periodically review** its **sample volume** requirements for phlebotomy (and other samples such as cerebrospinal fluid) to ensure that neither insufficient nor excessive amounts of sample are collected.

Review of requests and samples

Authorised personnel shall systematically review requests and samples and decide which examinations are to be performed and the methods to be used in performing them

Traceability

Sample portions shall also be **traceable** to the original primary sample.

I.5. To document (bibliography, data, experiences...)

Components of pre-analytical phase uncertainty such as specification of the measurand, intra/inter individual (15) variability (diurnal, seasonal, fasting/non-fasting), sampling including preparation of the individual (tube additives, posture, venous stasis, time of collection, drugs, filling volume…), transport of sample and handling and storage of sample (time, temperature, centrifugation…) have to be documented according to the test through literature (10, 16).

The influence of haemolysis on the reliability of the results has to be taken into account according to well established rules (12, 13 and 14).

Consultation of databases (15, 16 and 17) is a very useful way to improve knowledge of the staff.

II- Analytical phase control

General

Each result, as the outcome of an experimental measurement, is always affected by inherent error. What to define is the level of allowable limit of error. This will depend on the level of impact of error and the means to avoid reporting of unacceptable results have to be applied. The knowledge of analytical variation provides information for interpretation of the results of examination.

The main efficient tools in controlling the analytical phase of the examination are operated by so called internal quality control and external quality control.

Quality control (QC) is defined as a process applied to measure, to examine, to try one or several characteristics and to compare with specified requirements to establish conformity and if not, to show defects and to implement curative and corrective actions.

Internal quality control

Internal quality control (IQC) refers to procedures which are designed to be carried out within a laboratory for the purpose of monitoring the performance of that laboratory.

Fundamental principle is that errors detected by means of control specimens exactly mirror errors occurring with patient specimens:

Internal QC consists in detection of errors, immediate correction and prevention to ensure day-to-day reproducibility of the results while external QC consists in a verification a posteriori, using comparison, of accuracy of results as compared to a reference system for guarantee inter-laboratory comparability (18, 19, 20, and 21).

1- OBJECTIVES of IQC:

1-1. To ensure the reliable and efficient functioning of the lab for reliable results

–To validate series of examinations
–To provide day to day within lab consistency of results
–To detect errors and alert staff
–To implement remedial action immediately

1-2. To provide an independent verification:

–Of calibration
–Of instrumental functioning
–Of stability of reagents
–Of robustness and reproducibility of procedures

1-3. To prevent deterioration of performance of analytical methods

1-4. To identify the nature of errors

1-5. To contribute to better patient care improvement of specificity and sensitivity

2- Main principles for IQC procedures:

1- The basic principle using QC samples is that QC samples should be treated in **exactly in the same way** as patient samples (18).

2- IQC is **intended to detect a change** of the performance from a state defined as usual and suitable.

3- **Use of QC sample with unknown value** is useful to evaluate the day to day coherency of the results, but is not useful to evaluate trueness of the method used. Participation in intra/inter-laboratory programs or QC sample with known values is necessary to estimate the reliability of the results and, if necessary to implement immediate correction (remedial action) or corrective action (to eliminate the root cause of the error).

4- **Frequency of QC sample determination** has to be decided as necessary, depending on the stability of the analytical process and at least once a series or once a working day. The frequency of QC determinations is a compromise between assurance, cost and overload and defined according to in the IQC procedure (Table 4). The minimum is to control at least once a day.

Table 4: *Procedure for IQC*

> 1. **Field:** validation of series of examination and detection of errors
> 2. **Scope: list of examinations and analysers concerned**
> 3. **Responsibilities**: choice, baying, following stocks, verification of conformity, handling of samples, verification des data, interpretation short time, long **time, remedial actions...**
> 4. **Materials:** levels of concentration
> 5. **Operating process:** frequency (each calibration, each run ...) number of level.
> 6. **Interpretation of results: immediate, short term and long term evaluation**
> 7. **Non conformities**
> 8. **Remedial actions**
> 9. **Documents:** forms for QC materials, assigned values, acceptable limits, corrective actions...
> 10. **Records:** time of retention defined

5- **Number and level of QC samples**: the number depends on the level of the decision limits and differs with each examination (for example, for HbA$_{1C}$, QC samples around 7 % is to choice to follow up a diabetic patient, but to check at the high level of the reference limit interval, another level is necessary around 5%)

6- **Immediate action**: delay between the determination and interpretation shall be short to be efficient (18).

7- **Clear instructions and assignments of responsibility** to provide to the operator when an alert occurs.

8- Internal quality control rules are partly based on **statistical evaluation.** Rules described by Westgard (22) are widely used

3- Statistical analysis of the data

The hypothesis being tested: using a stable system, only random errors occur. So distribution of repeated results follows a normal curve (Gaussian curve) of distribution. Each deviation from this "normal error" constitutes an alert.

Quality requirements have to be set and alerts given when results are outside the limits.

In the case of Gaussian distribution, the probability of a false alert is 1/20 for a probability of k=2 (95%) and 1/100 with k=3 (99%).

The purpose is to detect deviation higher than expected by chance. It is essential that the standard deviation used to calculate the control limits is calculated through a long period of time, if possible, to cover all events occurring usually for the analytical system. A result outside

the control limits means that accuracy (reproducibility, trueness or both) has probably changed from the initial state. This constitutes an alert and the analytical system is "out of control".

4- QC materials:

- Controlling analytical quality as a long term process, it is useful to use, if possible, the same lot of QC materials for a long period of time. Those materials have to be stable during this period. To ensure stability, different procedures are used, such as lyophilisation, freezing, addition of preservatives etc.
- Assigned values for QC samples are determined by the laboratory with its own methods during a period where stability of the materials is proved.
- The choice of QC materials is dependent on the test and on their availability and is based on criteria such as ability to mimic closely the behaviour of human physiological or pathological samples.
- Use of mixing samples to constitute serum pools has to be avoided, if possible, because of potential infectious hazards to lab workers. They have to be tested negative for hepatitis antigens and HIV.
- QC materials must be different from calibration specimens.
- Handling and preparation of QC materials is often one of the causes of observed nonconformity. Instructions for these processes must be defined precisely.
- The choice of the level and the number of levels are dependent for each test on the value of clinical decision limit. Usually, two levels are recommended.

5- Definition of goals for acceptance of results:

IQC system has to be implemented according to guidelines to verify the attainment of the intended quality of results.

- **Assigned values** are determined from the mean of repeated measurements of the same sample during a preliminary period using the method under control.
- **The dispersion of values observed** during this period of time is calculated as standard deviation (SD) and coefficient of variation (CV %).

- **The preliminary limits** to take into account are defined as mean $\pm$2SD and mean
- $\pm$3SD. However, determination, during a short period of time, of SD could give a poor picture of the usual variation which can occur when there are changes to reagent lots, standards, spectrophotometer characteristics… So, determination of SD using a long period of time, taking into account all usual events, is more representative of the usual functioning of the analytical system and thus contributes to an efficient system.

6- Procedure for IQC (Table 4)

Control charts as described by Levey Jennings (23) are very helpful to evaluate within day and day to day quality of results.

QC samples are assayed periodically and results are evaluated at different levels (18):

6-1- Immediate evaluation: results observed are compared to data derived from the preliminary period, mean $\pm$2SD and mean $\pm$3SD.

Case n°1: results are within the limits mean $\pm$2SD: the series can be validated as conforming to previous ones. It means that in less than 5% of cases, results would be expected to be outside this range.

Case n°2: results are outside mean $\pm$3SD for the 2 levels of QC samples: results are abnormally decreased or increased.

If the sign of the bias is the same and the bias (difference between observed value and assigned value) similar for the 2 samples: the error is systematic and constant, independent of the concentration level.

If the ratio of observed value/assigned value, expressed as a percentage, has the same sign and a similar value for the 2 samples, the error is systematic and proportional to the concentration level.

Systematic errors are usually linked to standards or calibration. Action has to be taken and non conformity recorded as shown Figure 5.

Figure 5: *Errors in analytical process*

Systematic error Trueness	Random error Fidelity
(Standards, calibration…)	*(Maintenance of analytical system…)*
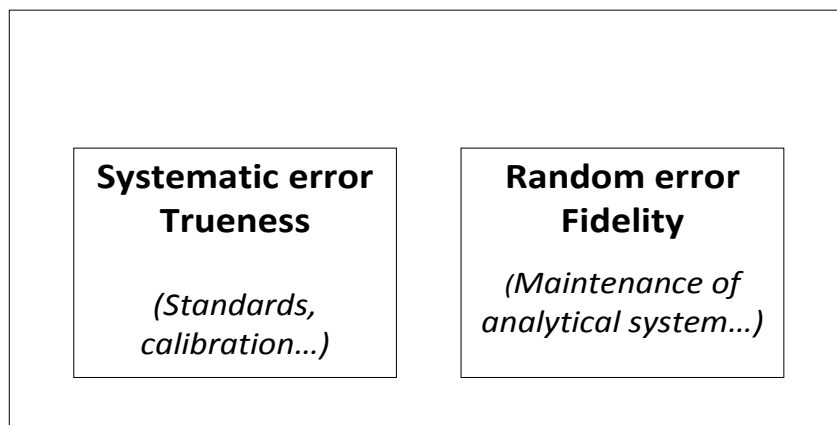
Case n°3: only one sample is outside mean $\pm$3SD, the other within outside mean $\pm$2SD or one is > mean $\pm$3SD, the other < mean $\pm$3SD: the error could be a random error. A verification of this defect assaying several times the same sample (repeatability) confirms a poor precision generally caused by a maintenance defect.

Case n°4: results are within mean $\pm$2SD mean $\pm$3SD: a simple verification using the QC samples can clarify this situation.

If the results obtained with QC samples are unsatisfactory according to the criteria defined, the results of patients should not be released and analysis repeated after the non conformity has been identified and corrected.

6-2 Short term evaluation

Results observed day to day can demonstrate a tendency (drift) to increase or decrease and constitute an alarm for preventive action before non conformity occurs (figure 6).

Figure 6: PSA- IQC Short time evaluation: drift detection
**Levey Jennings diagram**
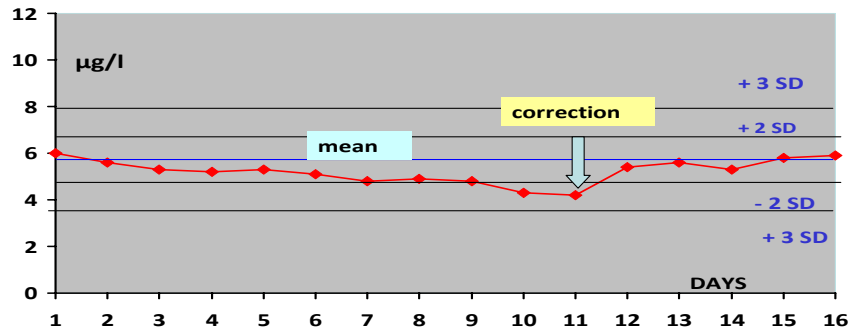
6-3 Long term evaluation (figure 7)

Mean and SD (CV) observed monthly during a long period of time have to be considered and evaluated as compared to specifications published in the literature based on the state of the art (24) or biological variation (25) or bench marking. The aim is to provide results as reliable as required for appropriate patient care. Criteria to fulfil this assertion are not yet well agreed (26, 27).

Analytical goals are given in term of total error, which can be calculated as the sum of bias and 2xstandard deviation.

Figure 7: PSA- Internal Quality Control - Long term evaluation (2009)
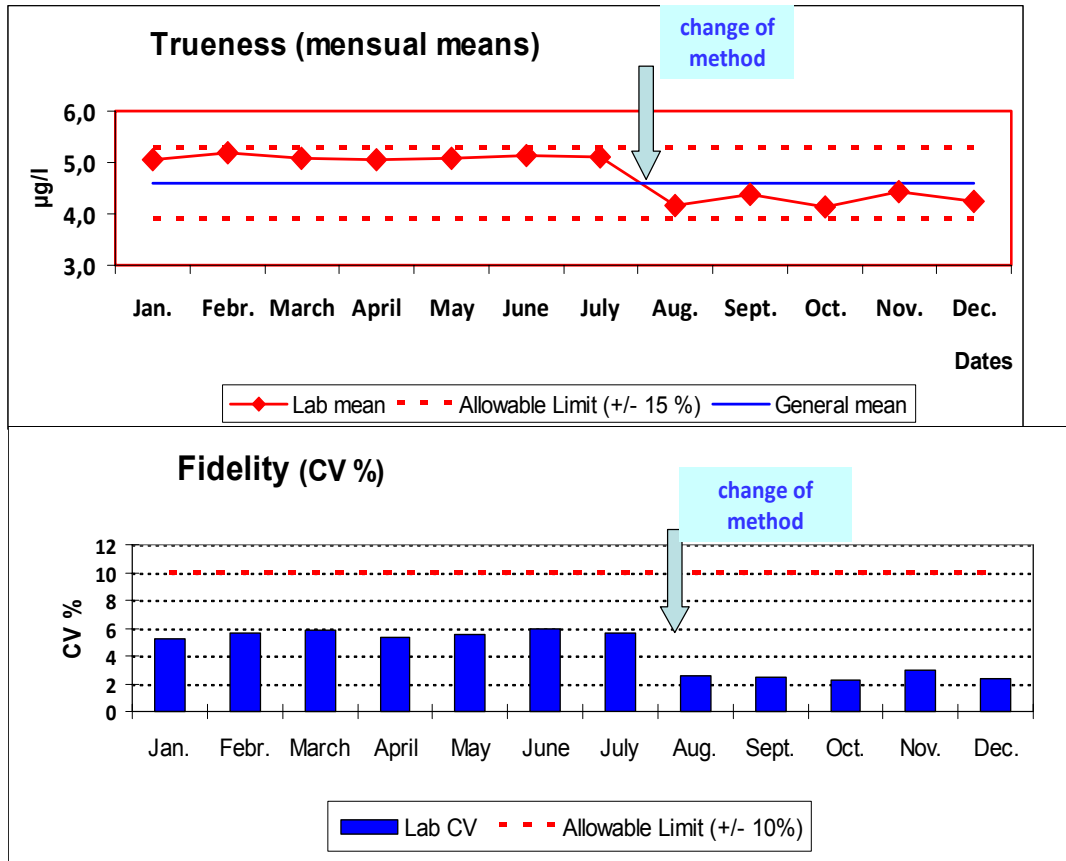
7-   Non conformities:

The quality system settled requires to record non conformities and, after correction (remedial action), to take into account the defect, to search the root cause and to improve the process using corrective actions (figure 8). The main non conformities occurring through internal quality control are given table 5.

Figure 8: Internal Quality Control

EVOLUTION OF THE TOTAL NUMBER OF NON-CONFORMITES (2009)
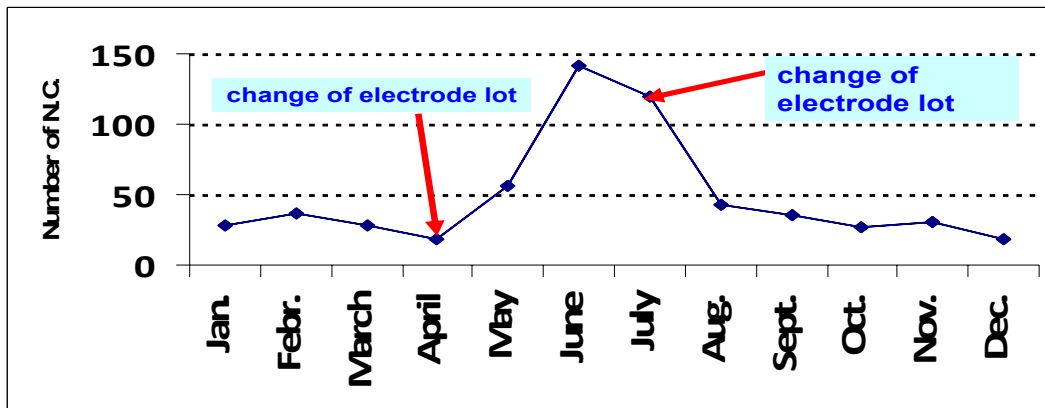**(electrode for natraemia) Analytical System xxx**

Table 5: Internal quality control- Main nonconformities

_____

•**QC samples abnormality:**
Preparation, evaporation, stability, interfering substance
•**Analytical System defect**:
      o   Calibration: blank, calculation
      o   Standard operating procedure defect
      o   Contamination
      o   Standard stability, assigned value
•**Reagents:** stability, incorrect solvent volume, inversion
      o   Standard: stability, incorrect assigned value
      o   Analysers: maintenance neglected, needle sampling, external temperature
• **Education and Training** of personnel**: missing or inappropriate**
•**Information missing**
•**Procedure for IQC:**
      o   Target values
      o   Acceptable limits

_____

8- QC software:

Different types of software can be used: software linked to the analyser used, dedicated to IQC, software dedicated to quality management or from the LIMS.

9- **Definitions**

Accuracy (28): Closeness of agreement between a measured quantity value and a true quantity value of a measurand".

Trueness of measurement (28):**"**Closeness of the agreement between the average of an infinite number of replicate measured quantity values and a reference quantity value" (true value). "Measurement trueness is inversely related to systematic measurement error".

Bias (28) is "the estimate of a systematic measurement error" and the numeric expression of trueness.

Bias is expressed as the difference between the expectation of the test results and accepted reference values

Total Error, TE: the sum of any set of defined errors that can affect the accuracy of an analytical result; e.g., the sum of the bias and imprecision

Precision (28)**:** closeness of agreement between quantity values obtained by replicate measurement of a quantity, under specified conditions

Uncertainty of measurement (28)**:** Parameter, associated with the result of a measurement that characterizes the dispersion of the values that could reasonably be attributed to the measurand.

External quality control

1- **Definitions**

EQC is a procedure utilizing the results of several laboratories which analyse the same specimens (21, 29)

Many different types of scheme are in use throughout the world, varying from simple arrangements involving the exchange of specimens:

–Between two labs for analysis of a single component

–To extensive national and international programmes involving hundreds of labs measuring many components

Proficiency testing (PT)

This is the general used term in North America. In a strict sense, PT focuses essentially on laboratory performance evaluations for regulatory purposes (29).

External Quality Assessment Schemes (EQAS): This is the general used term in Europe and South America. EQAS focus essentially also on laboratory performance evaluations but the purpose of the schemes is educational.

External Quality Assurance

Programmes (EQAP) are interlaboratory comparisons designed and operated to assure one or more of following aspects:

- Participant performance evaluation

Note: this evaluation is not limited to analytical performance, but can also include test interpretation, advice to the clinician on laboratory requests and on diagnosis

- Method performance evaluation

- Vigilance of IVD's

- Continuous education, training and help

The primary intention of the activities of an EQAP in laboratory medicine shall be to support quality improvements of the services provided by participating laboratories for the benefits of the patients.

Inter-laboratory comparison: Organisation, execution and evaluation of measurements or assays for the same entity or similar entities by two laboratories or more according to predefined conditions. (29)

2- Objectives

1. To provide a measurement of the quality of performance of an individual lab: this which can be compared with that of others, with that of selected labs or with defined standards of performance

2. To provide the proof of reliability of results

3. To stimulate implementation of IQC

4. To eliminate analytical systems of bad performance

5. To act as an educational stimulus to improvement of performance

3- Organisation:

1. These schemes has been organised by professional bodies, Government agencies or commercial companies.

2. In some countries, labs are required by law in external quality control schemes. Their results are inspected by a controlling and accrediting agency.

3. In others, participation is voluntary and the results of individual labs may only be known by the organisers

4. Other terms: proficiency testing, inter-laboratory QC, survey, external quality assessment, round robin

4- Limitations

1- EQA samples should be processed blindly, that is as any other sample, but special treatment is often carried out, especially if participation in a scheme is required by law.

2- EQC is not a substitute for IQC because testing is too infrequent and results known with delay

3- Correction of results using EQC results for calibration standards should not be tolerated.

4- Anonymity is necessary to prevent unjustified public pillory of poor performances

5- Information about reagents, standards, equipment may be available so that results could be considered accordingly, especially if methods are known to give different results

6- Quality of control specimens is the main limitation if stability and homogeneity requirements are not fulfilled. The behaviour of QC samples as compared to patient samples is essential to a reliable survey.

5- Requirements

Participation in inter-laboratory comparisons (EQAS), monitoring of results and implementation of corrective actions if necessary is required to ensure inter-laboratory comparability of results and use the same consensus criteria.

If no external quality control programme is available, the laboratory shall develop a mechanism for determining the acceptability of procedures.

The validation of measurement procedures prior to use represents a very efficient tool for controlling the analytical phase. It includes, if appropriate:

- The evaluation of the analytical range to determine the interval (lower and higher limits of linearity) within which measurement can be performed.

- The evaluation of the fidelity of measurement using QC samples

- The evaluation of detection limit, if useful

- The assessment of total error

- A comparison of methods using patients' samples

- A study, if useful of the influence of haemolysis, turbidity and bilirubin.

Most of the measurement procedures used in Europe are devices prepared according to the IVD directive (30). They have previously been validated by the manufacturers. Laboratories have only to verify the manufacturer's specifications.

Post examination phase

Definition: post-examination procedures (post-analytical phase)

Processes following the examination including systematic review, formatting and interpretation, authorisation for release, reporting and transmission of the results, and storage of samples of the examinations.

Main principles

1- A written report is provided for each examination.

2- Reports include: name of the patient, name of the requester, laboratory providing the report, date of receipt of the sample, date of collection, nature of examination performed, laboratory performing the test, method used if useful, results units (SI preferred), reference interval limits according to sex and age and identification of the person authorising the transmission of the report.

3- Results are validated by an authorised person and interpretation provided if necessary.

4- Comments on pre-analytical features, particularly sample quality, are given on the report, if appropriate.

Interpretation of the results

Reference Interval Limits

Efforts of standardisation to harmonise the results depending on the methods used through metrological traceability is in process with the aim, as a long term goal, to use the same reference intervals whatever the analytical system used in all medical laboratories.

Nevertheless, there is actually a very poor level of harmonisation, so that different biological intervals have to be used according to the analytical system used for most of examinations.

The ISO Standard EN ISO 15 189 states that biological reference interval shall be verified where a modification of the analytical or pre-analytical conditions occurs and periodically (1).

The determination of reference intervals used for interpretation in medical laboratories is documented according to data published in literature (31, 32 and 33). In this case, the

laboratory has to verify that the analytical method used and the population chosen (geographic area) for the determination of reference interval are similar to those of the laboratory.

An estimation of the biological reference interval can be demonstrated according to the IFCC recommendations (31, 34) which are difficult to implement in this context.

So, a simple verification of the data published and/or provided by the manufacturer, according to a protocol described by CLSI can be used (32, 35). The protocol consists in measuring 20 samples from 20 reference individuals:

- if 2 or fewer results are outside the proposed reference interval, this interval may be adopted;
- if 2 or more results are outside the proposed reference interval, measure another 20 samples from 20 reference individuals;
- if 2 or fewer results are outside the proposed reference interval, this interval may be adopted. If the contrary is the case, the proposed interval must be disregarded.
- Recently, simple software to verify reference limits also using 20 reference individuals has been published (36).

Evaluation of practices according to the data given in (Table 6) constitutes a tool for quality control of the post analytical phase. Indicators such as turnaround time, number of claims, results of surveys displayed by the laboratory to physicians are very useful to improve satisfaction of users (37, 38). Interpretative comments of results in the report give added value for pertinent care, but are dependent on the education, competency and specialty of the author and should be evaluated. This has been demonstrated by external quality assessment surveys (39).

Table 6: Post-analytical requirements (EN ISO 15 189) Action, Document, Traceability (record)

	GOOD PRACTICES	AIM	Reference (1)
REPORT			
General procedure	Provided for each examination	Indicator	
	Release of results are authorised by personnel with competency	Responsibility	5.7.1, 5.8.13
	Format for communication is defined with requesters	Record traceability	5.8.1
Procedure for urgency	Procedure in case of urgent results		5.4.11
	Procedure for critical values: Communication of critical results under conditions defined with clinicians and record of action	Safety, traceability	5.4.10, 5.8.7, 5.8.8, 5.8.10,
	Written report in case of NC with their nature and consequences	Traceability	5.4.8, 5.8.5
	Procedure for diffusion of results and Information of requesters and patients in case of delayed results, if useful		5.8.1, 5.8.9 5.8.13
	Procedure for alteration of results Name of responsible, person contacted. date, data modified	Responsibility Traceability	5.8.15, 5.8.16
	Policy: oral communication of results: following written report	Safety	5.8.14
	Conditions for Informatics transmission are defined	Confidentiality	5.8.14
	Instruction for the content of the report:		5.8.3c
	Delay for providing results are defined, verified and reviewed. Turnaround time	Indicator	5.8.2, 5.8.11
	Accurate transmission of data	Safety of data	
	Transmission assuring confidentiality of data from emission to receipt	Confidentiality	
	Verification of copy of data from other laboratory		5.8.12
Management of claims	Procedure for management of claims and corrective actions	Traceability: record and control, indicator	4.8 4.13.3
	Survey and corrective action	indicator	
STORAGE OF SAMPLE	Conditions for storage according to the test	Stability	5.4.14,5.7.2
Elimination of samples	Conditions for waste elimination	Safety	5.7.3
ARCHIVES Of DATA	**Procedure for management of archives:** time of retention	Traceability (record)	
	Requests form	Traceability (record)	4.13.3
	Results of examinations	Traceability (record)	4.13.3, 5.8.6
	Results of IQC and EQAS	Traceability (record)	4.13.3
	Data from calibration	Traceability (record)	4.13.3
	Analytical procedures	Traceability (record)	4.13.3
	Rough data	Traceability (record)	4.13.3
	Report of audit, review, AC, AP	Traceability (record)	4.13.3
LIMS	Open to consultation easily	Accessibility	Annex C.7.1
	Protection of data of LIMS from loss	Safety, traceability (record)	Annex C.7.1
	Protection of data non authorised access	Confidentiality	Annex C.7.1
	Protection against falsification	Safety	
	Local of storage	Safety and confidentiality	4.13.2

Conclusion

The variations observed in the results of examination are the consequences of biological (intra/inter-individual), pathological, pre-analytical and analytical variations (systematic errors random errors, rough error). Knowledge of each of them is the key for a pertinent interpretation of the results. The control of all the components is the best guarantee for patient safety.

The laboratory, as part of the overall healthcare process, is involved in the choice of appropriate test to perform, developing requesting protocols according to the clinical goals, defining the frequency of request to avoid redundancy and the type of sample required for the appropriate determination.

Medical laboratories play a major role in setting up quality assurance in healthcare. But improvement is only efficient when it involves all of the partners of the medical laboratory, physicians and manufacturers providing the analytical systems.

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