

Accreditation of POCT facilities

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Point-of-care testing (POCT) is one of the most rapidly growing areas within laboratory medicine. The need for POCT has developed because in many cases the central laboratory has been unable to meet the expectations of clinical users, particularly with respect to turnaround time.

It is widely recognized that inappropriate use of POCT presents a risk to patients, healthcare professionals and their employers through the possible production of erroneous results.

Within the modern healthcare environment there are currently a number of initiatives arising from professional bodies, regulatory authorities and government, aimed at improving quality.

This article discusses issues around improving quality in POCT and proposes a model system for the organization and management of POCT within the healthcare sector.

The development of a POCT policy together with procedures to detail the process of implementation and records to provide evidence of correct implementation

are discussed as the basis on which a quality management system may be used to attain the standards required by accrediting authorities.

Introduction

Over the past two decades the demand for point-of-care testing (POCT) facilities has increased. In part, this has been due to a perception that the central laboratory provides a poor service with respect to turnaround time (TAT). There is a requirement by clinicians to minimize TAT for certain tests [1] and this, together with improvements in POCT systems [2], has driven the demand for POCT.

Within intensive care units patients are frequently ventilated and it is accepted that blood gases, electrolytes and metabolites are performed by clinical staff using POCT systems [3].

In other critical care areas such as emergency departments there is an increasing need for rapidity of results driven by the clinical need for rapid diagnosis [4].

Additional factors can influence the introduction of POCT, such as reducing patient waiting times and admission rates [5]; for example, the UK target states that no patient should be waiting more than four hours in emergency departments from arrival to admission, transfer or discharge [6].

Along with increased usage of POCT in clinical areas, there has also been a rapid increase in the availability of home-testing POCT devices. It is now commonplace for diabetic patients to monitor their own blood glucose levels, and with an ever-ageing population it may be expected that there will be an increase in demand for these systems [7].

These factors have led to a rapid increase in the global market for POCT with worldwide costs increasing from USD 3 billion in 1997 to USD 5.4 billion by 2001 [8] and this is expected to double over the next decade [9].

Quality and accreditation in POCT

The concept of clinical governance within the healthcare sector as a framework by which quality improvement could be promoted, together with the introduction of accreditation standards for medical laboratories, has focused the debate towards the use of quality management systems as a mechanism by which quality may be continually improved.

There have been numerous sources of advice and guidance on quality improvement in the use of POCT, examples of some are provided below:

- 1995 Kost Guidelines for point-of-care testing. Improving patient outcomes [10]
- 1997 European Community Confederation of Clinical Chemistry (EC4)
- Essential Criteria for Quality Systems in Medical Laboratories [11]
- 1998 European Community Confederation of Clinical Chemistry (EC4)
- Additional Essential Criteria for Quality Systems of Medical Laboratories [12]
- 1999 The German Working Group on medical

laboratory testing (AML)

- Recommendations on the introduction and quality assurance of procedures for POCT in hospitals [13]
- 2000 The UK Joint Working Group on Quality Assurance (JWGQA) [14]
- Advice on the use of near-to-patient or point-of-care testing
- 2002 The UK Medicines and Healthcare products Regulatory Agency (MHRA)
- Recommendations regarding the selection of equipment and use of POCT [15]

Accreditation standards for medical laboratories and systems for assessing compliance vary from country to country. Some accrediting bodies make specific reference to POCT; for example, the College of American Pathologists (CAP) have produced a POCT checklist [16] based upon the Clinical Laboratory Improvement Act (CLIA '88).

Within the UK, Clinical Pathology Accreditation (CPA) has defined 'Standards for the Medical Laboratory' [17].

Although these standards make no specific reference to POCT, there is an expectation that any laboratory-controlled POCT will conform to the general laboratory standards. Facilities outside a hospital, such as primary care offices/general practitioner's surgeries, are required in some countries to seek advice from the local hospital laboratory before embarking on POCT.

Within the UK, Standard 13 of the Primary Health Care Standards and Criteria of the King's Fund Organisational Audit program states 'Near patient testing conforms to protocols developed with an accredited pathology department' [18].

Many medical laboratory accreditation standards now have a requirement for systems of quality management and continuous improvement; these include ISO 15189 and CPA UK. The focus on quality in the healthcare sector has increased the importance of accreditation of medical laboratories.

There can be little doubt that POCT will have to be

included within the laboratory accreditation process and that in many countries this process will become mandatory [19].

Management of POCT

If laboratory staff are to successfully manage POCT and attain the standards required by accrediting bodies, they will need to gain the consensus and support of other health professionals. This may best be achieved by the formation of a POCT group made up of individuals with both the desire and expertise to address POCT issues.

If the group is to have credibility with other professionals, members should be drawn from varying professional backgrounds and different clinical environments and provide frontline experience of POCT and/or expert advice.

Once convened, the POCT group should identify the objectives and set down terms of reference. Objectives of a POCT group could include but may not be limited to:

- To define an organization-wide policy for the evaluation, selection and utilization of POCT devices
- To produce procedures detailing how this policy is implemented together with systems that would provide ongoing evidence of appropriate and correct implementation
- To understand the needs and requirements of POCT users, thus ensuring that systems are operated in a clinically effective manner
- To ensure the production of high-quality results whilst minimizing risk to patient and user
- To ensure that users are trained in use of POCT devices and that competence is tested and recorded
- To ensure integrity of data and maintain confidentiality according to national legislation
- To gain a clear understanding of the costs of POCT compared with central laboratory testing, ensuring efficiency of use and financial prudence.

Documentation

The backbone of all accreditation systems is the documentation on which the system is built and assessed.

Figure 1 serves to demonstrate how policy, procedures and records are linked into a quality system [20]. The policy provides a statement of intent of how POCT is to be performed within an organization and the quality standards that are to be achieved.

Procedures and instructions provide practical detail and information on how the policy is implemented.

Finally, forms and records provide unequivocal evidence of the correct implementation of the policy according to the procedures.

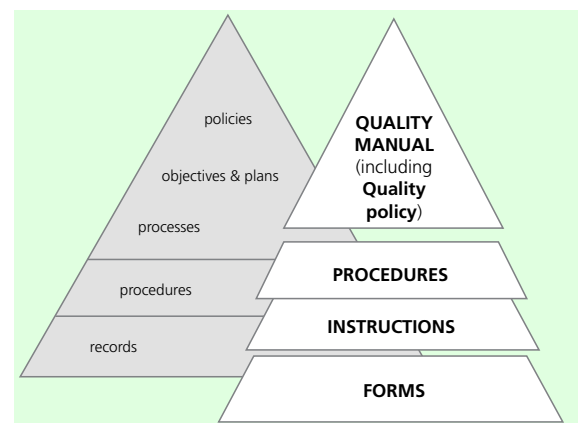


FIG. 1. Hierarchy of documentation From: Burnett D. A practical guide to accreditation. [20]

The POCT policy

The POCT policy serves as a high-level document that should consider areas impacting upon quality management in POCT.

Examples of possible areas to consider are provided in **Table I**.

The policy should be formally approved by top management within an organization and published in a medium that allows the widest possible access to potential users of POCT.

<ul style="list-style-type: none"> • Needs and requirements of users • Laboratory support • Selection of equipment • Siting of equipment • Technical validation • Concordance with laboratory results • Diagnostic validation • Health, safety and risk management • Training 	<ul style="list-style-type: none"> • Procedures • Preanalytical • Analytical • Quality Control • Postanalytical • Recording of patient data • Other records • Cost • Audit
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TABLE I. Main areas of POCT to consider

The policy should be reviewed and, where necessary, updated in accordance with a predefined schedule.

The POCT management procedure

The most significant procedure within any system is the management procedure that provides detail on how the system is operated.

The headings in **Table II** suggest possible content for a POCT management procedure. This provides detail on the process by which the policy would be implemented and the mechanisms that produce clear evidence of its implementation.

Many models have been proposed for management of POCT and each has to be tailored to the particular institution. Although models are proposed from both laboratory and nursing standpoints, there is agreement that the designation of a person or persons as POCT coordinator(s) with substantial time allocated to the task will greatly enhance the success of any POCT activity.

In a large- or medium-size hospital, POCT activity in wards, clinics or other designated areas might be represented on the working group by an area supervisor. The management structure of POCT serves as the basis on which all aspects of POCT are delivered.

1. Introduction

1.1 Purpose and scope

1.2 Responsibilities

1.3 References

1.4 Definitions

1.5 Documentation

2. Organization and management

2.1 Working Group on POCT

2.2 Membership

2.3 Agendas and minutes

2.4 Frequency of meetings

3. *In vitro* diagnostic devices (IVD)

3.1 IVD inventory

3.2 IVD maintenance

3.3 Stock control

4. Hazards and precautions

5. Training and certification

5.1 Trainers

5.2 Training courses

5.3 Register of certified users

6. Documentation

6.1 Procedures and working instructions

6.2 Manufacturer's information

6.3 Patient's records

6.4 Quality records

7. Assuring the quality of POCT

7.1 Internal quality control

7.2 External quality assessment

7.3 Internal quality audit

8. Interpretation and communication of results

TABLE II. Content of a management procedure for POCT

<ul style="list-style-type: none"> • Application for POCT device • Maintenance log form • Minutes of POCT group meetings • Patient and sample records pertaining to POCT • Internal quality control records • External quality assurance records 	<ul style="list-style-type: none"> • List of trained users • Multiple choice questionnaire • Training certificates • Internal audit forms • Non-conformance forms • Corrective action forms
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TABLE III. Examples of forms and records in POCT

Other procedures

There will be a need for detailed procedures relating to all aspects of POCT. These may vary from the organization of training and certification of non-laboratory staff to detailed procedures on how POCT equipment is used or maintained.

It is important that all procedures are reviewed and updated on a regular basis and that they are signed off by an authorized individual. Many accreditation systems demand that procedures are controlled documents [17] and that where individuals hold personal copies there should be a mechanism for updating them to prevent risks associated with use of out-of-date material.

Some would argue that ownership of personal copies of a procedure or even notes should be actively discouraged or even prohibited.

Records and forms

In order to provide evidence of the correct implementation of a policy it is necessary to document all aspects of POCT.

Documents should be devised to enable an accurate record to be kept and stored for future reference, examples of such documents are provided in Table III. Forms and records may be used by external assessors from accrediting authorities in the same way and will allow the identification of areas of non-compliance with accreditation standards.

Discussion

POCT is a rapidly developing area of diagnostic testing

within the healthcare environment. In modern hospitals, POCT may account for up to 20 % of in vitro diagnostic tests performed.

There are significant risks from inappropriate use of POCT devices both in terms of potential harm to patients and unnecessary expenditure, where changes to laboratory testing protocols could resolve possible problems in the delivery of a service.

The formation of a group to manage POCT within the organization formalizes the process of introducing and monitoring POCT. As members of the POCT group are drawn from multidisciplinary, multiprofessional backgrounds they represent the interests and concerns of users, laboratory staff and significantly add to the credibility of the group.

The formalization of a POCT policy is essential to defining the standards by which POCT will be implemented and performed within the organization. Procedures provide important detail on how the test is implemented and forms provide evidence of appropriate implementation.

The combination of all of the above ensures that the quality of POCT within an organization is maintained at the highest level and formally reviewed on a regular basis.

The process of organizing and managing POCT within a single organization, such as a hospital, is relatively straightforward.

However, within the primary care system there are an ever-growing number of POCT devices. It is important that the local laboratory becomes actively involved in the provision of POCT with the primary healthcare sector.

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