

(JWG) on Quality Assurance¹, most recently in 1999. Professional organisations such as the Association of Clinical Biochemists, the Institute of Biomedical Science and the Royal College of Pathologists are represented on JWG, and the Department of Health and Clinical Pathology Accreditation Ltd. are observers. The Medical Devices Agency issued a Device Bulletin² on the Management and Use of POCT Devices. (MDA DB2002(03))

Clinical Pathology Accreditation (UK) Ltd (CPA) is the accreditation body for Pathology services in the UK. It does not currently have a specific standard for POCT, but uses the JWG Guidelines in its accreditation inspections, in which it includes any facilities of a hospital Trust where POCT is under Pathology supervision (and hence is likely to be conducted with appropriate attention to analytical quality procedures, user training, equipment maintenance and safe practices). The hospital Pathology Directorate is the best source of advice on how this should be organised appropriately for POCT equipment.

The purpose of this document is to draw together the main points from these existing guidelines for the benefit of Critical Care Directors and staff who are already working with POCT devices or intending to purchase and manage them.

The need for POCT in Critical Care

A recent survey³ revealed that there is a perceived need amongst critical care directors for some pathology analysis on site, in many cases extending beyond just blood glucose and blood gas analysis. One of the major advantages of POCT is the reduced turnaround time. If this reduced turnaround time results in improved clinical decision making and management outcomes (for instance waiting for results before discharging a patient) then a cost benefit analysis would justify the implementation of point of care testing. However if the POCT results are available in minutes but they are not acted upon for hours until the next consultant ward round then there is little justification for the capital outlay.

The benefits of POCT should be based on standards comparable to those in conventional Pathology laboratories, in terms of risk management, quality and staff training. Working closely with the hospital's Pathology Directorate will ensure that POCT is implemented and managed safely and effectively, in accordance with the recommendations and guidance above.

For various reasons, historical, geographic, and financial, POCT in critical care has usually been introduced in a piecemeal fashion. Different professional groups have been charged with “looking after the Blood Gas machine” which, in turn, has developed into a more comprehensive range of pathology tests including metabolic and coagulation screens.

Some common examples include:

- Small laboratory areas in the critical care unit managed by healthcare scientists on the clinical staff of the unit, these individuals may be charged with other responsibilities such as clinical measurement and respiratory technology within the unit. In larger units this technical cover may be available through all hours.
- The clinical measurement department (often run by medical physics or the clinical perfusionists) has responsibility for POCT in critical care, operating theatres and other areas such as A&E.
- A senior nurse, or more unusually, a doctor will have responsibility for POCT on the unit.
- The Pathology Department assumes direct control and supervision of POCT with dedicated biomedical scientists visiting the unit to carry out preventative maintenance, quality control and most importantly training.

In the survey approximately 50% of POCT in critical care was supervised and managed directly by the Pathology Department.

The survey showed that a large majority of users of POCT laboratory equipment had little or no formal training in laboratory science, safety or management.

A substantial number of people making choices about the purchase of analysers and the assays had little or no formal training in laboratory science, safety or management and often acted without consulting the Pathology Department.

The survey showed that 30% of Critical Care Units carried out no quality control procedures and that nearly 70% claimed not to subscribe to an external Quality Assurance scheme.

Clinical Governance

Under Clinical Governance and Controls Assurance directives and standards it is pointed out that all NHS organisations are subject to legal and statutory requirements relating to the “duty of care”. This requires employers to provide competent fellow employees, safe equipment and place of work, and safe working practices.

POCT devices (and every other piece of critical care equipment) are covered by the 42 page “medical device management” standard for controls assurance. (NHS Executive 2002 Governance in the New NHS)

This states that a suitable device management procedure should be implemented with the aim that whenever a medical device is used, it should be:

- Suitable for its intended purpose
- Properly understood by the professional user
- Maintained in a safe and reliable condition

A key element of this standard is training, “User knowledge and skills have major implications for safety.” The standard requires that:

- Instructions must be clear concise and readily available.
- Training needs to be timely and effective and include procedures for the routine maintenance of devices by users.
- Planned preventative maintenance, carried out following manufacturers guidance by properly trained technicians is the other key element in ensuring devices are safe and reliable.
- Users and technicians need to understand the basic principles on which devices work (generic training) as well as how to use a particular model (specific training)
- Training programmes should where possible include input from the manufacturer

Staff education and development

Modern POCT equipment is designed for ease of use, but this can encourage clinical staff to assume that user training is unnecessary. It is essential that users of even the simplest equipment understand that they must be trained in its use and training must be provided by a scientifically or technically qualified person, and that a record is kept of trained staff, with dates of training and any updates. The laboratory should be consulted about a training programme in the first instance and are likely to advise that they should manage or supervise it. A "key trainer" system is effective in units where there are large numbers or a high turnover of staff, but key trainers should themselves first be trained and accredited by the Pathology department.

Training should be based on pre-analytical, analytical and post-analytical procedures, in a competency-based programme. These include:

- basic principles of the measurement
- correct sample preparation and identification
- correct analytical procedure in accordance with the manufacturer's specification and/or Standard Operating Procedure, including any calibration procedures
- the importance of analytical Quality Control and External Quality Assurance
- the agreed quality control procedures and record keeping for the POCT equipment
- the possible medico-legal consequences of improper use
- appropriate documentation of results and/or IT interfacing with the Laboratory Information System and results server
- safe disposal of samples and sharps
- effective clinical use of results; there should be discussion with the laboratory about appropriate reference ranges on POCT equipment
- audit

All users should then

- perform at least 3 complete analyses under supervision to ensure competence
- sign a training register
- understand that they will be subject to regular competence checks.

A simple POCT handbook should be given to each member of staff on completion of training on the use of the POCT equipment in the unit. Until the completion of this training and award of the handbook, staff should not be allowed to use the instruments. This should be reinforced by the use of PIN numbers or passwords, and exchange of these with untrained users should ideally be a disciplinary offence.

Staffing and Management

The CPA guidelines specify that an individual must take professional responsibility for the critical care POCT and that this person should be either a suitably qualified medical consultant or a clinical scientist of equivalent status. The survey showed that in approximately 70% of the units this is already the case (assuming that the 21% of ICU consultants claiming professional responsibility are aware of Health and Safety, Committee on Substances Hazardous to Health (COSHH) and Quality Assurance procedures etc).

Facilities and equipment

Appropriate, preferably dedicated, POCT space should be provided which is consistent with safe working practices for the tests carried out, including acceptable temperature, adequate ventilation, disposal facilities for contaminated waste, gloves and face visors and protection from other caustic materials. Sluices are not suitable sites for POCT equipment. POCT rooms should not be used as general storage areas.

In order to fulfil the minimum requirements:

- Preventative maintenance, according to the manufacturer's recommendations, should be documented.
- Quality control procedures should be carried out daily by qualified staff.
- Storage space and POCT surfaces should comply with COSHH and Health and Safety regulations.
- Spillages or splashes of biological fluids must be cleaned up immediately. Instructions specifying the correct procedures for this should be prominently displayed and the correct decontaminants should be readily available.

- Activities such as smoking, eating and drinking must not occur in the POCT area. Refrigerators should be dedicated to the storage of reagents and samples only.

Decisions on equipment procurement should only be made after careful evaluation of the options, preferably in conjunction with the hospital Pathology and Supplies Departments. Clinicians and managers should be aware of the clinical and financial risks of purchasing equipment without full evaluation of the clinical needs. The NHS Purchasing and Supplies Agency has produced guidance on procurement of blood gas analysers.

Policies and procedures

The policies and procedures should be laid out in the ICU POCT handbook given to trained users as mentioned above. This should include:

- The Trust POCT Policy
- Training competencies to be maintained
- The requirements of the “universal precautions” policy of the unit.
- A written protocol (Standard Operating Procedure, SOP, for the correct use of the POCT equipment)

This should be displayed near the analysers and should outline the action to be taken in the event of equipment breakdown. This will vary according to site, but there should be clear provision for either 24-hour technical support of the equipment, or alternative arrangements for sending samples to the main laboratory when POCT equipment is non-functional.

Records of all reagents and consumables, including any spare parts routinely stored, should be kept with a logbook of equipment maintenance and troubleshooting.

There should be a clear policy, with the involvement of the laboratory, on recording and storing patient results. POCT equipment may be networked to the laboratory, or results may be stored locally in the unit.

Quality and Audit

POCT administrators, and preferably users, should undertake daily internal quality control procedures. This checks that equipment is functioning correctly and producing reliable results and also that the user is following the correct analytical procedure.

The critical care POCT service should also participate in an External Quality Assessment Scheme, which is accredited by the CPA. This should be operated in conjunction with the laboratory who will provide advice. Results from such schemes should be reviewed regularly at quality assurance meetings, which should include medical and nursing staff.

There is a need for one person to take overall responsibility for the validation of results generated by POCT. This person should be aware of all possible problems that could contribute to erroneous POCT results including drug interference's with assays, other interfering substances and sample preparation. This should be in accordance with standards and reference ranges agreed with the hospital laboratory.

There should also be formal clinical audits of the POCT service with procedures in place to use the results of audits to improve the service. Conducting joint audits with the Pathology department is likely to be beneficial for both parties and contribute to improvement of the whole diagnostic service.

Awareness of and implementation of all MDA bulletins, hazard notices and safety advice regarding in vitro POCT devices is of overriding importance.

For example the MDA safety notice SN 9616 “Extra-Laboratory Use of Blood Glucose Meters and Test strips: Contra-Indications, Training and Advice to the Users” (1996) contra-indicates their use in most seriously ill patients, high levels of oxygen, hydrogen ion or bilirubin interfere with the chemistry of the strip, but these devices are still widely used in critical care.

Conclusion

Critical care staff and hospital management should be aware that significant clinical risks are inherent in POCT and that if inappropriate equipment is purchased, there may be significant wasted resources. Appropriate implementation and safe and effective operation of POCT is a Clinical Governance issue. There should be close liaison with the hospital laboratory as soon as POCT is planned so that the service need can be evaluated⁴. If POCT equipment is to be purchased, then the clinical and economic benefits should first be considered, then incorporated into the business case. Some outcomes studies on POCT have been published.⁵

Partnership with the pathology laboratory should continue throughout the implementation and management of the service. Employment of dedicated scientists within critical care in close liaison with the hospital pathology department, or actually based there but included in the Critical Care team, is not universal, but is an effective way to improve overall standards.

References (dominic please check for accuracy)

- 1) Near to Patient or Point of Care Testing Guidelines: Joint working Group on Quality Assurance, January 1999 (Diagnostic Services Ltd, Mast House, Derby Road, Liverpool L20 1EA)
- 2) Management and Use of Point of Care Test Devices MDA Bulletin DB2002(03) March 2002
- 3) D Cox & R Naidoo “ The intensive care laboratory – a report of current UK practice and recommendations for the implementation of required minimum standards: *Care of the Critically Ill*, 1995,11,3; 98-103
- 4) CP Price (2001): Point of Care Testing: BMJ vol. 322 1285-1288
- 5) J Kendall, B Reeves, M Clancy (1998): Point of care testing: randomised controlled trial of clinical outcome: BMJ vol. 316:1052-1057]

Other resources

- 1) ***www.pointofcare.net***
- 2) PM Rainey: Outcomes assessment for point of care testing Clin Chem 1998 vol 44 1595-6
- 3) CP Price: Point of Care Testing in Haematology, Haematol 1998 vol 3 93-106
- 4) Kost GJ et al: The laboratory-clinical interface: point of care testing, Chest 1999 vol 115 1140-54
- 5) D Cox & R Naidoo: “The Intensive Care Laboratory” in “*Critical Care, Standards, Audit and Ethics*” ed. Tinker, Browne and Sibbald: Arnold, London 1996