Point of Care Testing Guidelines

Revised guidelines issued by the Joint Working Group on Quality Assurance to assist Health Service managers and staff in their procurement, installation and use of devices suitable for performing tests on blood, urine and stools

The joint Working Group on Quality Assurance (JWG) believes that there may be considerable benefits to patients by using the latest methodology to carry out tests in close proximity to patients. Some of these tests may be performed by non-pathology staff or the patients themselves.

The appropriate use of these tests should be considered as a clinical governance issue and subject to examination of clinical effectiveness.

For the purposes of these guidelines, the word 'device' includes the whole range of items from simple urine dip-sticks to sophisticated analysers.

To achieve the best possible results from these devices it is essential that there is the closest possible liaison with the pathology services relating to all aspects of such tests.

To ensure reliable performance and manage the risks associated with point of care testing, the pathology laboratory must have a central role in management of these devices. The pathology staff are experts in:

- Mechanism and methodology of the analytical process
- Limitations of the method
- Patient preparation
- Interpretation
- Training
- Support
- Troubleshooting
- Quality control and quality assurance
- Risk management
- Health and safety and infection control

The key issues will be considered under the following headings:

- Cost benefit analysis
- Risk management
- Health and safety/infection control
- Training
- Operation
- Support
- Quality control and assessment
- Budgetary arrangements

1. Cost Benefit Analysis

- There must be a clear definition of the problem that the device would solve so that a full examination of all possible solutions can be made.
- The pathology department must be involved in the production and evaluation of the cost benefit analysis.

- In hospitals a full business case must be produced detailing all the financial onsequences of the purchase. These will include the direct costs of running, maintenance, consumables, quality control and service contract. The cost benefit analysis must include the full indirect costs for pathology involvement, including support, training and QC/QA monitoring, as well as the inevitable cost of replacement.
- The cost benefit analysis must recognise the need for any device to be compatible with existing equipment, both in the laboratory and in other areas of the hospital. The pathology department must be consulted about the compatibility of all devices.
- Any device being considered must have a CE mark to ensure it is fit for the purpose and of suitable quality.
- General Practitioners will need to consider all these points, but replacement costs may not be relevant to patients' devices used at home.

2. Risk Management

None of the devices is totally foolproof. It is essential that the risks associated with the use and interpretation of results obtained are properly managed by training and support from the pathology departments.

3. Health and Safety

- In hospitals and clinics, whether in the public or private sector, managers of the clinical service involved together with the pathology service must jointly develop and enforce policies consistent with current legislation and guidance. For example: the Health & Safety at Work Act 1974, Consumer Protection Act 1987, the Control of Substances Hazardous to Health Regulations 1988, Safe Working and the Prevention of Infection in Clinical Laboratories – Model Role for Staff and Visitors, HSC 1981, Protection against blood-borne infections in the work-place: HIV and hepatitis (ACDP) 1995.
- There should be close liaison between the safety officers of the testing site and pathology.
- A "permit-to-work" certificate, providing evidence of appropriate decontamination, must be issued before servicing or repair of equipment.
- The infection control physician/medical microbiologist must be involved in decisions on placement and maintenance of equipment.

4. Training

- Only staff whose training and competence has been established and documented should use any device, including simple dip-stick tests.
- Following procurement and installation, relevant staff must be trained in the safe and proper use of the device. The training course must be specified and supervised by the relevant pathology department and provided by the manufacturer or local staff trained to the satisfaction of the relevant pathology department.
- Training should include other issues such as patient preparation and interpretation of results. Once competence has been achieved and documented, the user can be added to the "named operator list".
- For some devices update training is necessary to maintain a high standard of performance. This is particularly important for staff who use a device infrequently, or have had a break in the use of the device. This should be included in the Standing Operating Procedure (SOP - see para 5.1).

5. Operation

Tests on the device in the designated area of use may only be carried out by those on the 'named operator list'.

5.1 Standard Operating Procedure

- An SOP must be produced, written to the standard required by inspectors from Clinical Pathology Accreditation (UK) Ltd, or equivalent accreditation agencies. This must be available to and followed by all users of the device.
- The document will include instructions on safe working practice, the interpretation of error messages, the recording of data and the relevant quality control procedures.
- If the hospital requires the testing area to be covered by accreditation, the SOP master copy must be held by pathology and available to accreditation agency inspectors.

5.2 Recording of Results

- All patient and quality control/quality assessment (QC/QA) results must be recorded. This record must include unequivocal patient identity, time of test, the result, relevant QC results and the identity of the user.
- The mechanism for the transfer of results from the device to the patient record must be unambiguous and stated in the SOP and monitored by the local manager for compliance.
- All patients' results must be treated as confidential and kept in a secure place. If patient results are stored in a computer system, local rules on access to the system, whether stand-alone or networked, should be maintained. Users should have access to the system by password which must be regularly updated. The storage of results should be in line with the storage maintained by the laboratory and compatible with RCP guidelines.
- Pathology staff must have free access to QC/QA results.

5.3 Log Book

Each device must have a "log-book" in either paper or electronic form in which details are recorded of maintenance, faults, corrective actions and repairs by named individuals. Pathology staff must have free access to the log books.

6. Support

- There must be a service level agreement between the users and the pathology service defining the responsibilities for maintenance, troubleshooting, repairs, continuing training and QA monitoring.
- Designated persons must be responsible for the day-to-day care of the system and control of environmental contamination, and for the maintenance of stocks of consumables and reagents within their shelf-life.
- If devices are not used or cared for appropriately the pathology department will have the responsibility of removing the device from service.
- A device that fails to perform to specification must be withdrawn immediately from service until full remedial action has been completed.
- The SOP must state who has the responsibility and the authority to withdraw the device from service.
- Pathology must be informed immediately of any failure.
- In the event of device failure alternative sites for the analyses should have been agreed, documented and made known to the users.

7. Internal Quality Control and Quality Assessment (QC and QA)

Clinical Pathology Accreditation (UK) Ltd require that pathology departments participate in recognised External Quality Assessment schemes (QA) relevant to their test repertoires.

- The local pathology department's staff must be responsible for ensuring that the performance of the device is checked by appropriate internal QC and external QA assessments such as would satisfy the CPA inspection criteria.
- The pathology department should be involved in clinical governance issues and should carry out regular audits of the reliability and effectiveness of the tests being carried out.
- Trust or hospital management must satisfy themselves that there is a demonstrable link between the users of the device and the pathology service to ensure the "quality" aspects and reliability of the results produced.
- Management must be made aware of the legal exposure involved if there is no supervision of devices through external QA schemes.

8. Budgetary Arrangements

In hospitals, prior to the procurement, there must be an agreement between the device's purchaser, its users and the pathology service for the budgetary consequences of the purchase. Definitions must be put in place for the responsibility for the ordering of reagents, consumables, servicing, training, support, quality control and quality assessment.

Advice to General Practitioners and Other Non-Hospital Sites

General Practitioners, pharmacists and other primary sector users are recommended to adopt the practices outlined for hospitals, including close liaison with pathology laboratories. This would help produce "quality" results and manage the associated risks. Oversight of EQA schemes would have resource implications.

Advice to Patients

When devices are issued to, or bought by patients for home monitoring, the consultant or general practitioner responsible for care must ensure that the patient receives adequate training. This has to cover all aspects of performance including the interpretation of results. The Health & Safety implications must also be explained to the patient. A specialist nurse who can work with the pathology department would be an appropriate person to undertake this task.

The manufacturers of devices designed specifically for patient use should supply suitable training materials which should have been developed in co-operation with experts in the relevant profession. Devices should not be purchased if such training materials are not available.

NPT: Summary of Actions and Responsibilities

This table is a summary of the main issues which need to be addressed in the provision of Near Patient Testing.

The table identifies who should perform the tasks and who should be responsible for ensuring that the issue has been properly addressed. ■

Summary of Actions and Responsibilities

Issue	*Action by*	*Responsible for action*	*Evaluated by*
Cost benefit analysis (business case)	Clinical Unit / Pathology	Trust Management	Trust Management / Pathology
Health & Safety	Pathology	Trust Management	Trust Management
Training (including record of trained staff)	Pathology	Trust Management	Trust Management
Standard Operating Procedures	Pathology	Trust Management	CPA (UK) Ltd
Routine Operation	Users	Line Manager (e.g. Ward Sister)	Pathology
Recording Results	Users	Line Manager	Pathology
Support	Pathology	Trust Management	Trust Management
Quality Control & EQA	Users	Pathology	Pathology
Budgetary Arrangements	Clinical Unit / Pathology	Trust Management	Pathology

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European Clinical Chemists Register

Launch of the Register

17.30-18.30 Tuesday 8th June 1999
Room of the Vault, Fortezza da bassa, Florence

This is an informal reception to find out more about European Registration of Clinical Chemists.

Food and drink will be available and officers of EC4 will be on hand to hear your views on the Register.

There is no need to reply to this invitation – just come along and contribute.