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BARNSELY HOSPITAL NHS FOUNDATION TRUST

POINT OF CARE TESTING

GUIDELINES

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1. INTRODUCTION

Technological advances have provided the facility for an ever-increasing range of analyses to be performed outside diagnostic laboratories. While it remains desirable for the vast majority of investigations to be done in centralised laboratories there are circumstances where it is appropriate for certain tests to be undertaken outside this environment. Point of Care Testing (POCT) or near patient testing (NPT) is the term applied to tests done by non-laboratory personnel outside a recognised diagnostic laboratory. When well planned and correctly implemented, POCT can offer significant benefits to patient care but lack of attention to detail can result in it being an unmitigated disaster.

The local laboratory has valuable expertise in all aspects of analytical work and, from the very earliest stage, the establishment of a POCT service should be a joint venture between the head of the clinical team/department and senior members of the relevant diagnostic laboratory.

This document outlines the issues which must be addressed when establishing a POCT service.

The basic questions which have to be answered are:

- What is going to be measured?
- How is it going to be measured?
- Who is going to perform the measurement?
- On whom is the test going to be done?
- What number of tests is to be expected?
- What costs will be incurred?

Different considerations apply if the proposed test is entirely new or if it is already available through the local diagnostic laboratory. Only when the above information has been amassed can it be determined whether or not POCT is the best means of providing the service. It cannot be assumed that laboratory testing or POCT is automatically superior. For this reason early discussion between the clinical service and the laboratory is essential.

To avoid difficulties, it is Trust policy that analytical equipment can be ordered by non-laboratory areas only after consent from the relevant clinical laboratory has been obtained.

Once it has been determined that NPT is desirable specific points have to be considered and procedures followed.

2. RESPONSIBILITY

The roles and responsibilities of the clinical service and the laboratory in all aspects of the POCT service have to be clearly defined, agreed and fully documented. It has to be agreed who will be responsible for:

- purchasing the equipment
- ensuring that there is an adequate maintenance contract
- maintaining a sufficient supply of and ordering the necessary consumables
- the initial training of users
- keeping an up-to-date record of authorised users
- on-going user training
- the regular maintenance of the equipment
- Health and Safety issues associated with the use of the equipment
- the necessary quality control
- requesting an investigation
- the results produced
- acting on the result(s) obtained
- repairing the analyser when it breaks down.

There also has to be agreement as to how results will be obtained when the analyser is not functioning.

3. CHOICE OF EQUIPMENT

The choice of analytical equipment has to be agreed between the clinical service and the laboratory. Attention has to be paid to its ease of use, reliability, accuracy and precision. If POCT is to be used alongside laboratory testing the comparability of results must be established. The cost of the equipment and the cost of the reagents and consumables required to perform the tests have to be considered and agreement reached about the financing of the service. Responsibility for ordering and ensuring adequate quantities of supplies has to be defined.

All bids for analytical equipment must go through the Medical and Surgical Equipment Committee and POCT equipment must not be ordered without the knowledge of and consent of the head of the relevant diagnostic laboratory.

4. SITING AND MAINTENANCE OF THE EQUIPMENT

A suitable location has to be found for the equipment. It has to be easily accessible to the designated user staff but not in the public domain. It must be adequate to allow safe performance of the tests and to provide sufficient secure storage space for any associated reagents and consumables.

Although modern equipment is robust it still requires regular preventative maintenance to ensure the quality of the results. Agreement has to be reached as to

who will undertake this and what will happen if the analyser fails. The required maintenance is usually simple and, after appropriate training, is best undertaken by the regular users of the equipment with supervision from the laboratory. A maintenance log book or on-board log has to be legibly and fully completed and kept with the analyser at all times so that it is available for scrutiny in the event of analytical problems.

5. TRAINING AND USE OF THE EQUIPMENT

Thorough training and good documentation are two of the major determinants of the success of POCT and require a very large investment of time and energy. It is essential that the local laboratory is intimately involved with this but help will usually also be forthcoming from the manufacturer.

First, it has to be decided who is to be allowed to use the POCT equipment and how they are to be trained. It is usual to identify, depending on the size and scope of the POCT scheme, at least one member of the laboratory staff who will take responsibility (with the manufacturer) for the initial training of the POCT users. All users have to be trained and certified as proficient in the use of the equipment. If the POCT equipment is widespread, it is common and good practice to have nominated key users in each clinical area, who have had somewhat more in-depth training and who can be responsible for overseeing the POCT equipment in their area and for training new members of staff. Once trained and independently assessed as competent each user should be issued with a Trust **competency** certificate to that effect and should be entered onto an up-to-date register of authorised users. Only authorised users should use the POCT equipment and they should attend regular update training sessions.

Training must not only address all aspects of the use of the equipment but it must ensure that patient samples are correctly obtained and that all Health and Safety and COSHH standards are met and maintained throughout the procedure from obtaining the sample to disposal.

6. RESULTS

It has to be decided who is to be permitted to request POCT investigations and how the requests are to be made eg. is an in-house request form required?

All results from POCT must be recorded in a log book kept with the equipment or held electronically. This must include legible information about:

1. the name of the patient (preferably with a unique identifier such as the hospital number and/or the date of birth)
2. the date and time of the analysis
3. the result obtained

4. the batch number of reagents used for the test and their expiry dates
5. the name of the operator

Quality control sample results must also be recorded and the log book/electronic record must be stored safely for at least the lifetime of the equipment.

The POCT documentation has to contain clear instructions as to what should be done with the results, who should interpret and act upon them and what procedures should be followed if abnormal results are obtained. Where feasible, results from POCT should be entered into the Pathology computer system.

It has to be appreciated that the prime responsibility for the result(s) obtained lies with the individual who produces them.

7. QUALITY CONTROL / ASSURANCE

The results from POCT may be used to implement treatment changes even more rapidly than laboratory generated data so everyone has to have confidence in their validity. All users of POCT must understand the concepts of and importance of quality control and assurance.

There must be detailed, documented procedures which cover the running of internal quality control samples, the recording of the results and the actions to be taken if acceptable results are not obtained. The POCT service should also be enrolled in an external quality assurance system, either one of the nationally administered schemes in which the hospital laboratory participates or, if more appropriate, a scheme organised by the local laboratory.

8. OPERATIONAL POLICY AND SERVICE LEVEL AGREEMENT

Provision of a POCT service within the hospital has the advantage that the laboratory is to hand whereas in the primary care setting the laboratory will not be able to offer assistance so readily.

Both environments require comprehensive documentation for the POCT service that covers all the points discussed above. An operational policy detailing the day to day use of the POCT equipment and a service level agreement setting out the responsibilities of the parties involved and naming the key individuals can provide a useful way of achieving this.