The management of in vitro diagnostic point-of-care testing

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In vitro diagnostic point-of-care testing (IVDPT) can improve patient care but improvements can only be properly realised by adequate management in order to ensure high-quality test results. Nurses perform IVDPT in all areas of clinical practice, from intensive care units to GP surgeries, using a wide variety of devices ranging from urinalysis strips to blood gas analysers.

Advantages
IVDPT can offer nurses and patients a number of benefits and advantages. A reduction in the time between taking a sample and providing a result can enable prompt interventions, speed up patient management and improve access to services.

When frequent testing is required or in remote areas, IVDPT can improve the quality of care by reducing clinic visits and hospital admissions.

Point-of-care testing is sometimes associated with improvements in patients’ involvement in their own care (Medicines and Healthcare products Regulatory Agency, 2004a; Medical Devices Agency, 2002).

Potential disadvantages
Without the economies of scale of centralised laboratory testing, combined with duplication of equipment and the need to train clinical staff, IVDPT can be an expensive option. The units and reference ranges of the test results may also differ from those previously provided by the laboratory, which can make comparison difficult and cause confusion. There is also the risk that the provision of IVDPT may prompt some inappropriate testing.

Important considerations
IVDPT requires careful consideration. Any perceived unmet needs should be discussed with the laboratory service as it may offer the service or be able to adapt its existing one. For example, a system to prioritise and fast-track urgent samples can often be implemented.

The choice of tests to be performed and the target patient group should be carefully considered in terms of the potential to improve the efficiency and effectiveness of patient management. There should be realistic potential for measurable clinical and economic benefits (MHRA, 2004a; MDA, 2002).

Nursing implications
IVDPT allows for the provision of a rapid result on a potential disease marker, often in the presence of the patient. As the range of available tests widens, this may have important repercussions for nursing. Ensuring informed consent before testing and

Learning objectives
Each week Nursing Times publishes a guided learning article with reflection points to help you with your CPD. After reading the article you should be able to:

- Define in vitro diagnostic point-of-care testing (IVDPT);
- Identify the potential advantages and disadvantages of IVDPT;
- Identify important sources of information and advice on IVDPT;
- Know how to report problems with IVDPT equipment to the MHRA.

BOX 1. EXAMPLES OF POINT-OF-CARE TESTING DEVICES

- Blood glucose strips and meters
- Urinalysis test strips
- Blood gas analysers
- Test kits for infectious disease markers
- Pregnancy test kits
providing explanations of the results of novel tests and their potential implications may provide new challenges. An awareness of the expected rate of false positive and false negative results will be required to inform this practice.

**Sources of support and information**

Hospital pathology laboratories have scientific and clinical staff with expertise in in vitro testing. Close liaison with a local hospital pathology laboratory can provide advice on the clinical need and effectiveness of proposed testing.

Laboratory staff may also provide advice on the choice of test equipment, its purchase, the interpretation of results, troubleshooting, quality control and staff training. A formal service level agreement with the laboratory can define this support in terms of range of services, roles and responsibilities.

**Equipment and staff competencies**

The procurement process is crucial. The required accuracy, the similarity between the actual and measured result and imprecision, and the similarity in results of two tests of the same sample are crucial factors in the choice of the equipment. The comparability of results with those from the laboratory should also be considered. Providing results in different units, for example, could cause confusion.

Equipment suitability will vary according as to who will be using it and the expected workload. Practical considerations such as adequate space for the equipment and storage of the required disposables should not be overlooked. Power, water, refrigeration and waste disposal requirements may all be important. Compatibility with existing IT should also be investigated.

As with the procurement of all medical devices and equipment, seeking the views of intended users, and those who will be required to support and maintain the equipment, is crucial.

The NHS Purchasing and Supplies Agency (PASA) undertakes evaluations of point-of-care testing kits and publishes reports on their performance. The reports are available at www.pasa.nhs.uk/evaluation.

The cost of providing IVDPCT requires careful investigation to ensure that ongoing expenditure is not overlooked. The initial purchase of equipment and consumables and any site alterations required for installation are just the starting point. Maintenance, consumables, waste disposal and cleaning are ongoing costs to consider.

Quality control materials and external assessment schemes require additional outlay. Staff time and training as well as insurance and laboratory support should also be taken into account.

Nurses undertaking IVDPCT should have an understanding of the analyte to be measured, its clinical significance and normal parameters. Training should include safe and adequate sample collection, how to use the device as intended by the manufacturer, and interpreting results. Knowledge of the performance characteristics of the tests, including their limitations, should be demonstrated by staff who must have access to the manufacturer’s instructions. For example, the units used for blood glucose measurement in the UK are mmol/L but other countries use mg/dl. Some meters have the facility to change units. Users therefore need to be aware of this and routinely check the units. Test results in mg/dl are 18 times higher than those expressed in mmol/L (MHRA, 2004b).

**Management and governance**

Appointing a point-of-care testing coordinator and multidisciplinary committee to oversee a point-of-care testing service can ensure robust management and governance of point-of-care testing provision throughout healthcare organisations. From the initial justification of point-of-care testing in terms of clinical effectiveness to systems of audit and assessment, their input is invaluable.

The coordinator and committee monitor staff training, introduce guidance and standard operating procedures and provide advice on adequate record-keeping. They can also provide advice on effective internal quality control schemes (checking results before they are issued) and arrange access to external quality assessment schemes.

The MHRA regulates manufacturers to ensure that their IVDPCT equipment is safe and performs as claimed. Problems or incidents that occur should be reported to the adverse incident centre at the MHRA. Incidents are investigated and action taken as appropriate to improve device safety. This may include issuing safety advice to the users of devices or even their removal from the market.

A single report from a nurse or other test-kit user can prevent further incidents and have a real impact on patient safety and public health.

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**Guided reflection**

Use the following points to write a reflection for your PREP portfolio:

- Describe your place of work and why this article is relevant to your practice;
- Detail the last time you were involved in the IVDPCT of a patient;
- Identify a new piece of information you have learnt from this article;
- Outline how this information could be of use the next time you have to perform an IVDPCT;
- Explain how you will disseminate what you have learnt to your colleagues.

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**REFERENCES**


This article has been double-blind peer-reviewed.

For related articles on this subject and links to relevant websites see www.nursingtimes.net