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For Action by:
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LHB/Trust Directors of Therpies and Health Science,
LHB/Trust Medical Directors
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Action required by: Immediately

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Prif Ymgynghorydd Gwyddonol (Iechyd)
Y Grŵp Iechyd a Gwasanaethau Cymdeithasol

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Llywodraeth Cymru
Welsh Government

Date: 12 July 2017

Dear Colleague

WHC/2017/034 Policy on the Management of Point of Care Testing (POCT). What, When and How?

1. The Welsh Scientific Advisory Committee periodically reviews and updates existing guidance to ensure it reflects current best practice and scientific developments.

2. The above policy on Point of Care Testing, updates earlier guidance for Health Care professionals on how to implement and manage a safe Point of Care Testing Service (WSAC 2008) incorporating updated information from the Medicines and Healthcare Products Regulatory Agency (2013), Health and Care Standards (2015) and reflects technology advances and policy priorities.

3. A copy of the updated guidance entitled 'Policy on the Management of Point of Care Testing (POCT), What, When and How?' can be found here: http://gov.wales/topics/health/nhswales/circulars/health-professional/?lang=en

4. The main changes are :

- scope increased to include use: in the home, a clinic, in general practice, care homes, high street pharmacy and screening venue or during transit
- guidance is mapped to NHS Wales Health Care Standards in the context of providing a Point of Care Testing service
- the guidance is informative rather than prescriptive
- laboratory services replaced by Point of Care Departments. Service Level Agreement section removed
- incorporates principles of Prudent Healthcare

- additional sections on audit, risk management and information management
- website for information and guidance for health boards to support the role out of Point of Care Testing services in Primary Care. http://nww.poctmatters.wales.nhs.uk

5. I would be grateful if you could raised awareness of this guidance and ensure your organisation is compliant with the requirements therein.

Yours sincerely

Rob Orford

Llywodraeth Cymru
Welsh Government

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Policy on the Management of Point of Care Testing (POCT). What, When and How?

Welsh Scientific Advisory Committee

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Contents

1. Introduction

1.1. What is Point of Care Testing (POCT)?

This document updates earlier guidance for Health Care professionals on how to implement and manage a safe Point of Care Testing (POCT) service (WSAC 2008) incorporating updated information from the Medicines and Healthcare Products Regulatory Agency (2013) and Health and Care Standards (2015).

For the purpose of this document, POCT is defined as any diagnostic test undertaken by staff other than a laboratory healthcare scientist, which can include health care support workers, nurses, paramedics, pharmacists, podiatrists, dieticians, dentists and medical staff. This is usually carried out near the patient, and can be in the home, a clinic, in general practice, care homes, high street pharmacy, screening venue, at the hospital, or during transit.

Examples of POCT devices include:
Blood glucose and ketone devices, Urinalysis test strips and devices , Pregnancy test kits and devices, Coagulation devices, CRP devices, Creatinine devices, Lactate devices, $HbA_{1C,}$ analysers, Haematology analysers, Rapid test kits for infectious disease markers, Bilirubin analysers, blood gas analysers, electrolyte analysers, lipid analysers and cardiac marker test kits and analysers.

1.2. When can Point of Care Testing be used?

Healthcare organisations have an obligation to ensure that care is delivered by healthcare professionals that is **Safe and Clinically Effective and that Prudent Healthcare practices underpin their care.** *Care, treatment and decision making should reflect best practice based on evidence to ensure that people receive the right care and support to meet their individual needs. (Health and Care Standards for Wales, 2015 Standard 3.1),*

Clinical Effectiveness Patients should receive the most appropriate care in the right setting at the right time. Do only what is needed, no more, no less and do no harm.
Patient care should be evidence based. Reduce inappropriate variation using evidence based practices consistently and transparently.
Patients should receive the right care that is cost effective Care for those with the greatest health need first, making the most effective use of all skills and resources.
Supporting shared decision making Achieve health and wellbeing with the public, patients and professionals as equal partners through co-production.

2. Evidence based patient care

In deciding whether to implement POCT it is essential for potential users to establish a clinical need. The clinical need should be evidence based clearly identifying the risks and benefits of introducing a POCT service. The following should be undertaken:

2.1 Undertake a needs assessment

Map the patient's pathway, analyse and challenge what is done. Can things be improved?
What evidence is there that POCT may be clinically effective in this pathway?
How will this pathway redesign affect cost?
Will POCT be able to meet demand and capacity?

There is good evidence that optimisation of pathways using well designed use of POCT can be both clinically effective and cost efficient. However, POCT can offer little or no benefit in a poorly designed pathway and can be more costly than traditional laboratory tests. (Appendix 1)

2.2 Undertake risk and benefits mapping

POCT that is favourably assessed can improve patient outcome by providing a faster result and a shorter time-frame to therapeutic interventions, improve patient compliance with treatment, improve treatment optimisation, decrease the need for hospital visits, increase patient satisfaction, convenience and acceptability, reduce length of stay, reduce complications and reduce the overall cost to NHS Wales. *All aspects of care are provided in a timely way ensuring that people are treated and cared for in the right way, at the right time, in the right place and with the right staff (Standard 5.1).*

Examples of the benefit of POCT in different applications are provided below. Risks associated with POCT can be mitigated by ensuring that the best practice guidance in the section on "how to implement POCT" is followed.

Setting	Application	Benefit	Risk
Home	Management of long term conditions - diabetes/ Heart Failure. Early detection of complications e.g. infection in patients on chemotherapy Home ventilation unit for measurement of patients on Oxygen therapy.	• Better awareness / self motivation to manage condition – less complications • Avoid need to attend hospital • Avoid cost of transport • Avoid time off work/ patient • Patient convenience / acceptability	No evidence that POCT improves outcome Over testing / inappropriate testing. Lack of knowledge and skills of user of device. Device not sensitive or
General Practice	Management of long term conditions. Antibiotic stewardship.	• Patient convenience / acceptability • Improved access to	

	Enhanced Service for Anticoagulation monitoring. Out-Of-Hours Service.	relevant population • Reduction in acute admissions. • Avoid cost of transport. • Avoid time off work/ patient convenience. • Improve relationship with • GP – supporting shared decision making.	specific for clinical pathway. No Quality assurance. No audit trail. Loss / incomplete patient information. Variation in service Inequitable service Benefits not realised Not cost effective. Potential for Patient harm
Community / Pharmacy	Management of long term conditions Anticoagulation monitoring Health Checks	• Patient convenience / acceptability • Improved access to relevant population • Reduce need to visit GP	
Ambulance	Pre-hospital testing Monitor patients during inter hospital transport. Treatment of sick neonates in transit	• Faster triage through Emergency Department • Earlier intervention • Reduce risk of complications during transport	
Urgent care centres	Urgent care for non-life threatening conditions Rule out testing	• Avoid need to attend Emergency Department	
Emergency Department	Rapid triage testing and treatment	• Reduced length of stay in Emergency Department • Treatment of patients with time-dependent conditions	
Theatre	Monitoring operative procedures	• Reduce post OP care requirement • Convert to day case – reduce need for hospital bed	
Intensive Treatment Unit / Critical Care Unit	Monitoring vital parameters	• Improved mortality and morbidity • Reduce length of stay	

3. How to implement the right test that is cost effective?

3.1 Seek Advice - contact your local POCT Department

Health services must ensure the safe and effective procurement, use and disposal of devices and diagnostic systems. (Standard 2.9).

Each Health Board will have a dedicated team of POCT professionals who will be able to provide advice on how to implement and manage your POCT service.* They can advise you on the right device; a device that "fits " your clinical need, and a device that provides results that are compatible with your local laboratory (if indicated). The latter is essential to minimise variation in the event that the service is shared with your local Pathology laboratory to ensure that the right sensitivity, specificity, calibration and units are used and the correct interpretation is made.

There are existing "All Wales" procurement frameworks and preferred supplier lists in place for a number of devices underpinned by agreed quality specifications.

Support from your local POCT Department can also include the training, competence assessment, maintenance of devices and monitoring the quality of the service. For organisations that do not have a POCT Department, support may also be available from one of the other Health Boards. A resource should be identified for this support and incorporated into a Service Level Agreement (SLA). The SLA should define the scope of the service provided and the responsibilities of both parties.

- Information on who to contact for advice in your Region is available on http://nww.poctmatters.wales.nhs.uk

4 Minimise avoidable harm

4.1 Ensure appropriate training and competence

Health services should ensure there are enough staff with the right knowledge and skills available at the right time to meet need (Standard 7.1). Only Staff that have been adequately trained should carry out POCT procedures. Competency must be assessed and training and competency records maintained**.** *An ongoing programme of training and competency covers all staff and users. (Standard 2.9).*

Training must include the following:

- Intended purpose of the device
- Consequences of improper use
- Limitations of use
- Patient preparation, sample collection and application
- Health and Safety awareness
- Reporting & recording of results
- A Practical demonstration
- How to deal with abnormal or unexpected results?
- What routine maintenance and (calibration) of the equipment is required?
- When and how to do IQC?
- What to do if the IQC fails?
- When and how to do EQA?
- What to do if the EQA fails?
- Competence assessment procedure
- How and When to undertake Refresher training or e-learning?

Your local POCT Department will be able to provide assistance in developing these procedures. A number of "All Wales" training guides have already been developed for Blood gases, international normalized ratio (INR), blood glucose, ketones, HbA1c, Lipids, pregnancy testing and urinalysis. These are available to download from http://nww.poctmatters.wales.nhs.uk.

The POCT supplier may also have educators who will provide assistance in training. However, third party training may not cover all aspects to comply with this Policy. Check with your local POCT Department whether their training is approved by the All Wales POCT Co-ordinators Committee.

Users should be aware that liability under the Consumer Protection Act (1987) will only remain with the manufacturer or supplier of a device if the user can demonstrate that POCT equipment has been used in strict accordance with the manufacturer's instructions.

4.2 Competence assessment

It is important that users can demonstrate their competence to perform POCT irrespective of grade of staff. Managers should ensure that all POCT users have up to date records of practical demonstration of competency. They should work within their competence; record their learning in a portfolio and ensure that evidence of continued competence is available. The "All Wales" POCT

co-ordinators have designed a series of POCT core competencies and specific device competencies which are available as Agored Cymru Units and available at: **http://www.agored.org.uk**

These competencies are mapped to NHS Knowledge Skills Framework (KSF) and based on the National Occupational Standards (NOS) *CHS 217 Perform point of care testing.* The following describes the minimum standard to which an individual is expected to work to undertake POCT. **https://tools.skillsforhealth.org.uk/competence/show/html/id/2842/**

4.3 Understand Quality Assurance principles

Users of POCT should have a sound understanding of the principles of quality assurance (QA). This is a systematic process of verifying that a product, or service being developed, is meeting specific requirements and includes:

- Internal quality control (IQC)
- External quality assessment (EQA)
- Clinical audit
- Risk Management

For POCT this includes the measures taken to ensure investigations are reliable and safe and includes the following:

- Having the right governance structure in place
- Correct identification of the patient
- Choosing the right test
- Obtaining the right sample (at the right time)
- Undertaking the right test procedure
- Undertaking IQC and EQA checks
- Recording results promptly and correctly
- Interpreting results accurately
- Taking appropriate action
- Documenting all procedures and actions
- Identifying and preventing errors
- Implementing quality improvements

A training module which covers the core essential requirements for POCT is available from Agored Cymru, Unit Code PB62CY002 - POCT Principles and Practice.

As a minimum Quality Assurance should include undertaking Internal Quality Control and External Quality Assessment.

4.4 Internal Quality Control

This is a means of checking that the results are safe before they are issued. The user knows what value to expect and knows what range of values is acceptable for that control material.

If the value is within this range it provides reassurance that the system is working correctly. If the values are outside the range this alerts the user that there is a potential problem with the test process. It is essential that the results of QC are recorded appropriately. Often the manufacturer IQC limits are very wide and the user should establish their own limits to fit the clinical purpose.

What you need to consider?

- What material is available?
- What is the storage and stability?
- What frequency should I be testing IQC?
- What acceptance limit should I use?
- What procedure do I need to follow if the results are outside acceptable limits?
- I have an electronic QC; do I still need to perform IQC?
- Is there an easier way to make sure that the devices are safe to use?

Your local POCT Department will be able to advise you on suitable IQC material and how to manage performance.

4.5 External quality assessment

This is when samples with unknown values are tested and reviewed by an external agency. They may compare your results against those obtained from a number of different practices using the same method to determine the degree of variation and whether your results are within this acceptable variation. Alternatively, your results may be compared against a reference laboratory method, the "true" result. These agencies provide useful information on the degree of variation in diagnostic accuracy and reliability of POCT devices across Wales. In the absence of an EQA programme being available, you can also undertake paired analysis of samples with your local laboratory. The local POCT Department will help organise this or recommend the most appropriate accredited EQA provider for you to register with.

4.6 What to do if you get a poor result?

Performance surveillance can either be undertaken directly by the EQA provider or through your local POCT coordinator. Non compliance (e.g. if you didn't return) and poor performance reports (e.g. if the results were outside the acceptable limits) are often generated by the EQA scheme providers immediately after each distribution. Some EQA providers also follow with a repeat sample.

When the individual or POCT site performance is outside the performance criteria on two out of three consecutive occasions, the individual will be offered help by the EQA providers. Failure to respond to this contact or to improve performance will lead to a further contact by the providers. In the UK Persistent poor performance (i.e. no improvement after two contacts) will result in referral to the National Quality Assessment Advisory Panels (NQAAP). If no further improvement is made within a reasonable time period after NQAAP intervention, Health Inspectorate Wales is informed.

4.7 Measuring Outcomes – Audit

Quality metrics, clinical effectiveness, and cost efficiency should be monitored where possible. Prudent healthcare places a greater value on patient outcomes; rather than the volume of activity or procedures delivered, it aims to rebalance the NHS and create a patient-centered system. The following are examples of outcome measurements.

Outcome	Metric
Has this intervention resulted in improved patient experience?	• e.g. patient satisfaction surveys to identify whether more convenient, greater awareness or greater self motivation to manage condition.
Has this intervention resulted in improved disease outcome?	• e.g. rate of secondary complications. improvement in symptoms, re-admission, urgent acute admissions, survival rate percentage of patients with improved diagnostic test .
Has this intervention resulted in improved treatment optimisation?	• e.g. side effects, quality of life
Has this intervention resulted in a cost reduction?	• e.g. reduction in staff resource, avoidance of transport cost, reduction of admission to secondary care, reduce length of stay.

4.8 Risk Management

POCT is usually carried out in a busy environment with little or no 'thinking-time' before a change in patient management is instigated. The major risks arise from poor operator competency, lack of supervision, governance, failure to implement quality assurance processes, inappropriate testing by inexperienced personnel, lack of understanding on the limitations of use and uncertainty on how to act on the results. Adequate checks and balances must therefore be in place to prevent medical errors and reduce risks. *Risks are identified, monitored and where possible, reduced or prevented. (Standard 2.1).*

The following is an example of Failure Mode Effect Analysis (FMEA) risk model for undertaking POCT glucose. An FMEA uses three criteria to assess a risk which includes: 1) the impact of the effect, 2) the likelihood of occurrence and 3) detection and preventative process. Understanding the risks and implementing good quality assurance procedures will mitigate the risk.

The process	**What could go wrong ? (failure type)**	**Impact**	**Likelihood**	**What procedures have I implemented to mitigate risk ?(detection)**
identifying the patient	• wrong patient			positive patient identifiers. name, date of birth electronic ID via CRN/ NHS no.
taking the correct	• sample contaminated: by food / drink			user understands pre-analytical effects

sample	• by alcohol wipe • by interstitial fluid • patient dehydrated or in peripheral shutdown			competence assessed
undertaking the testing	• incorrect sample volume • incorrect filling reagents / strips contaminated or stored at incorrect temperature or humidity. • Device faulty			user trained and assessed as competent electronic operator lock out IQC check of reagent strips and device – QC lock out if outside limits Temperature indicators on reagent boxes Electronic recording of strip information / errors
Recording the result	• transcription error – poor light/ busy			electronic transfer of data to clinical portal/ patient notes audit trail of date / time / operator
Interpretation of the result	• drug interferences galactose/ maltose / haematocrit effects dehydrated/ shut down			user trained in limitations of procedure user aware of pre-analytical effects
Acting on the result	• Not acting on a hypo and hyperglycaemic result			user trained on critical ranges and alerts appropriate personnel.

5 Information management

Health services have systems in place, including information and communications technology, to ensure the effective collection, sharing and reporting of high quality data and information within a sound information governance framework. (Standard 3.4)

5.1 Ensure good record keeping

Good record keeping is essential to ensure that people receive effective and safe care. Health services must ensure that all records are maintained in accordance with legislation and clinical standards guidance. (Standard 3.5).

It is important to keep documented records of all procedures so that a full audit trail can be undertaken in the event of a poor EQA result or wrong patient result. Information that should be recorded includes:

- The internal QC for each device, along with the name of the operator, date and time
- Corrective action taken for out-of-control results
- Any review of QC results
- The consumables and reagent lot numbers
- Maintenance and service procedures undertaken including who and when

The patient's result should be permanently recorded in the patient's medical record along with the date, the time and the identity of the person performing the test. This is best achieved using POCT devices with automated full bi-directional connectivity to an external data system.

5.2 Supporting shared decision making

Where possible, POCT devices that allow seamless connectivity to external data systems such as the All Wales POCT Information System, Laboratory Information System, Wales Clinical Portal or the electronic patient record, must be used. This minimises subjectivity, transcription errors and loss of information. Your local POCT Department will be able to advise on the right equipment and devices that can be interfaced. Connectable POCT devices ensure that:

- Patients are clearly identified
- Information is collected to support outcome measurement
- Provides safer and quicker information transfer
- Eliminate duplication
- Facilitates sharing of information

6 Maintenance

It is essential that the routine maintenance and calibration of equipment is carried out according to the manufacturer's instructions. Your local POCT Department can advise on setting up maintenance schedules and establish operating procedures; however, resources for equipment maintenance are borne by the user. *Processes ensure that equipment, and devices are maintained, cleaned and calibrated in accordance with manufacturer's guidelines, ensuring they are appropriate for their intended use and for the environment in which they are used.*
Suitable and sustainable systems, policies and procedures are in place for medical device decontamination by competent staff in an appropriate environment. (Standard 2.9)

7 Safety

Staff shall be trained in safety procedures as detailed in the individual device training documents. . POCT co-ordinator can provide an advisory role on health and safety matters. The requirements of *Health and Safety at Work Act 1974, the COSHH regulations 1988 and the Safe Working and Prevention of Infection in Clinical Laboratories Code 1991,* will apply to POCT sites as detailed in the training documents.

8 References

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8. Internal Quality Control in Point of Care Testing: Where's the Evidence?; J. Holt, D. Freedman ; Annals of Clinical Biochem 2015, Vol. 52(5)

Appendix (1) CHECK LIST

Question	Yes/No	Action/Date
Have you identified a clinical need which is evidence based?		
Have you contacted your local POCT Department for advice and consultation?		
Have you undertaken a cost assessment? Examples of what to consider are in App 2		
Have you undertaken a Risk assessment?		
Is the device approved by your local POCT Department?		
Do you have written operating and training procedures in place?		
Have you arranged for all users to receive appropriate training and competency assessment?		
Have you addressed all Health and Safety requirements?		
Are you able to interface with existing IT?		
Have you arranged to monitor performance – IQC/ EQA/ Audit?		
Is there a Service Level Agreement between you and the POCT Department if appropriate)?		

Appendix (2) Example Cost Considerations

Capital Costs		**Revenue costs**		**Professional costs**	
Purchase/lease of POCT equipment		Consumables: reagents / calibrators etc		Staff training	
Ancillary equipment: centrifuges, incubators, pipettes etc.		routine maintenance (including service contract)		Management of the POCT programme	
Working environment		Internal Quality Control material		Staff operator time	
Depreciation		EQA Subscription		Conforming to legal requirements	
Interfacing with information management systems		data-handling licences		POCT Department support / IM&T support.	
		Waste disposal		Laboratory support	
Total running costs					
Cost per patient					

Appendix (3) SERVICE LEVEL AGREEMENT SPECIFICATION (If appropriate)

This SLA requires a Quality Management system for the planned systematic approach to POCT. Details to be agreed between the user and the POCT Department.

1. Specify each application, e.g. glucose testing in GP surgery: well person screening in Occupational Health Department, Diabetic clinic etc
2. Specify the site, e.g. wards, accident and Emergency, Outpatient clinics
3. Specify personnel involved
4. Specify the type of procedure
5. Specify the lead contact person for:
    a. POCT Department and the User.
6. Clearly specify the responsibilities of the POCT Department.
7. Clearly specify the responsibilities of the users
8. Define the training procedure and competence assessment as indicated in the approved training documents.
9. Recording patient results
    a. There must be an agreed protocol to record all patient results, include date, time and operator so that a clear audit trail is established back to the patient.
10. Specify performance monitoring requirement
11. Specify cost for provision of POCT department support

The agreement must be signed by both parties to form a binding contract.

Appendix (4) Stakeholder input

Representation on this Committee included:

- Standing Specialist Advisory groups (SSAG).
- General Practice
- Pharmacy
- Representation from each Health Board
- All Wales POCT Co-ordinators Group.