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Guidelines for Safe and Effective Management and Use of Point of Care testing in Primary & Community Care

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Presentation Overview

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- Introduction to Point of Care Testing (POCT)
- POC tests used in Primary & Community Care
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Background

- Guidelines for Safe and Effective Management and Use of Point of Care Testing in hospital settings were published in 2007 (www.imb.ie)
- The aim of the latest guidelines is to extend these principles to Primary & Community Care settings
- The latest guidelines have been approved by:-
 - the Pharmaceutical Society of Ireland (PSI)
 - the Health Service Executive (HSE)
 - the Faculty of Pathology (RCPI)
 - the Association of Clinical Biochemists in Ireland (ACBI)
 - the Academy of Medical Laboratory Science (AMLS) and
 - the regulatory agency for medical devices in Ireland, the Irish Medicines Board (IMB).
- The guidelines are also supported by the Health Information and Quality Authority (HIQA).
- Expected Publication Date: **November 2009**



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Point of Care Testing (POCT)

- Point of care testing (POCT) involves the performance of a test in the immediate vicinity of a patient to provide a rapid result outside the conventional laboratory environment
- Primary and Community Care settings include GP surgeries, community pharmacies, community clinics, health centres, industrial medical centres and anticoagulation clinics
- Not a new concept but the variety and complexity of the tests and instruments available has evolved dramatically
- The capacity to provide a rapid test result which can be acted upon directly permits increased clinical effectiveness and improved outcome for patients. *However this is only true if the result delivered is accurate and reliable*



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Point of Care Testing (POCT)

- The majority of problems that arise with POCT are due to incorrect sampling technique, poor operator experience and training, inappropriate interpretation of results and absence of appropriate quality control
- Can lead to inaccurate results which in turn may have serious implications for patients
- Currently the level of POCT in Primary and Community Care can range from simple tests such as urinalysis or pregnancy tests to more complex analysis such as cardiovascular risk monitoring and prothrombin time / INR monitoring.
- Includes test kits operated alone or with an instrument which can provide either a qualitative or quantitative result.



POC tests in Primary & Community Care

<i>Medical Device</i>	<i>Medical Device category</i>
Blood glucose (+ self-testing devices)	IVD
Urinalysis (with or without a reader)	IVD
Cholesterol, Triglyceride and HDL	IVD
Anticoagulant therapy monitoring (+self-testing devices)	IVD
Pregnancy and ovulation tests (+ self-testing devices)	IVD
Prostate Specific Antigen test	IVD
Haemoglobin	IVD
Chlamydia trichomonas kits	IVD
Faecal occult blood tests	IVD
Helicobacter pylori tests	IVD
Blood Pressure Monitor	GMD
Pulse Oximeter	GMD
Thermometer	GMD

What is an IVD?

Any medical device which is a:

reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment, or system

whether used alone or in combination intended by the manufacturer to be used *in-vitro* for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information



What is an IVD? (cont'd)

- concerning a physiological or pathological state, *or*
- concerning a congenital abnormality, *or*
- to determine the safety and compatibility with potential recipients, *or*
- to monitor therapeutic measures



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General Medical Devices

As defined in the **Medical Devices Directive 93/42/EEC**, a medical device is any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by its manufacturer to be used for human beings for the purpose of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap
- investigation, replacement or modification of the anatomy or of a physiological process
- control of contraception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.



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Regulatory Requirements for POC tests

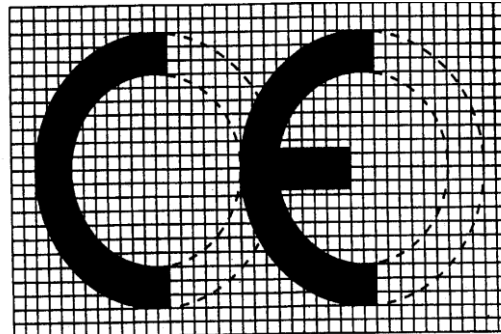
- ***In-vitro* Diagnostic Medical Devices (IVDs)** are regulated by the *In-vitro* Diagnostic Medical Devices Directive **98/79/EC** and related Irish Regulations. The IVD Directive has been mandatory since December 2003 and has been implemented in Ireland via the Statutory Instrument S.I. No. 304 of 2001, European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001.
- **General Medical devices** are regulated by the Medical Devices Directive **93/42/EEC** and related Irish Regulations. The Medical Devices Directive (93/42/EEC) has been mandatory since June 1998 and has been implemented in Ireland via the Statutory Instrument S.I. No. 252 of 1994, European Communities (Medical Devices) Regulations, 1994.



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Compliance with the legislation

- All manufacturers must ensure that any medical device placed and used on the Irish Market complies with the relevant legislation. Compliance with this legislation is demonstrated by displaying a CE mark on the device.



The Irish Medicines Board (IMB)

- The IMB is designated as the Competent Authority for medical devices in Ireland.
- Its role is to ensure that all medical devices sold into the Irish market comply with the relevant legislation
 - This means that a medical device must achieve the performance criteria specified by the manufacturer and in doing so must not compromise the health and safety of patients, service providers and any other persons.
- The IMB also ensure that all adverse incidents which occur in Ireland are investigated by manufacturers and that appropriate corrective action is implemented to prevent recurrence.



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Adverse Incident Reporting

- An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects.
- For example, an incorrect result could lead to a delay or inappropriate treatment, a life-threatening illness or injury or a serious deterioration in the state of health, or even death.
- Any adverse incident involving a POC medical device should be reported to the manufacturer.
- The manufacturer in turn has a legal requirement to report all adverse incidents that occur with medical devices on the Irish Market to the IMB.
- Direct user reporting of adverse incidents to the IMB is not mandatory but is strongly encouraged by the IMB www.imb.ie



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Overview of POCT Guidelines

- Aim to provide guidance to Primary and Community Care settings on the implementation and management of a POCT service with a specific focus on the safe use of Point of Care (POC) tests.
- Intended to provide recommendations for best practice for POCT in Primary and Community Care environments to ensure accurate and reliable patient results.
- Practitioners carrying out any POC service should be cognisant of the regulatory and professional requirements and standards specified by regulatory and professional bodies governing such testing and their profession e.g. statutory code of conduct.

Implications of the legislation for POCT service providers

- Check with the manufacturer / supplier that the device is CE marked and complies with the relevant legislation prior to purchase and use
- Ensure that the manufacturer's instructions for use (IFU) are followed and that the device is only used for the purpose intended by the manufacturer
- Ensure that all staff are appropriately trained and are familiar with the IFU and the interferences and limitations of the device
- Ensure that staff understand the meaning of an 'adverse incident' and know what to do on discovery of an 'adverse incident'
- Establish service and maintenance programmes for medical devices in accordance with manufacturer's instructions
- Cooperate with corrective actions conducted by the manufacturer, e.g. recall of an affected batch of test strips

Implementation of POCT in Primary & Community Care

- There are three different aspects to POCT;
1)Diagnosis 2)Monitoring 3)Screening
- It is important that Primary and Community Care settings have a clearly defined and well-structured approach to POCT to ensure that it is performed in a safe and appropriate manner and that the results generated are accurate and reliable.
- Prior to implementation of a test, in particular in a GP surgery, careful consideration should be given to the ability of the local hospital laboratory to provide the service in a timely manner



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Implementation of POCT in Primary & Community Care

- Where POCT is being used primarily for screening purposes as is usually the case in a pharmacy setting, then a robust system of patient consent, follow-up and referral should be put in place
- POCT results which are used for diagnosis or critical patient management decisions, or which give unexpected results should be confirmed by hospital laboratories to ensure accurate diagnosis and to facilitate correct patient management decisions



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Key Recommendations

- Where POCT services are provided, a system for clinical and managerial governance of the service should be established including a person designated as responsible and accountable for the service
- It is advisable that providers of POCT are aware of other laboratory services in their locality which can provide specialist advice and expertise if required and be cognisant of utilising them as appropriate.
- It is recommended to consult the Guidelines for Safe and Effective Management and Use of Point of Care Testing which recommends communication between the hospital and Primary and Community Care sectors
- Only trained and fully competent staff should perform POCT
- Standard operating procedures should be developed and implemented for all aspects of the POCT service, including the performance of the POC test, record keeping, interpretation of results, patient referral criteria, quality assurance, patient and staff safety and health



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Key Recommendations contd...

- **Quality assurance** is key to assuring the accuracy and reliability of a POCT service and quality control testing should be performed for POC tests in accordance with manufacturer's instructions. It is further recommended that POCT providers should participate in External Quality Assurance (EQA) schemes, where available
- Patient results should only be interpreted and reviewed by appropriately trained personnel
- All patient and quality control results should be recorded appropriately either via paper or electronic format in accordance with defined procedures and the Data Protection Act
- Appropriate referral criteria should be in place to ensure that confirmatory testing is performed and patients are referred for further medical attention as necessary



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Key Recommendations contd...

- All adverse incidents that occur with POCT devices must be reported to the manufacturer and/or the Irish Medicines Board (IMB) using the appropriate form located on the IMB website (www.imb.ie) and/or the appropriate professional regulatory body, if necessary
- POCT should be reviewed and monitored on an ongoing basis and a test should be withdrawn or suspended in the event of a safety related issue e.g. a recall
- POCT devices should be CE marked as this is an indication that the device meets the requirements of the relevant legislation
- It is the responsibility of the service provider to ensure that appropriate occupational health advice is provided to staff performing POCT
- Records should be kept of staff who have been trained in carrying out and/or interpreting test results



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Conclusion

- Point of care testing has an important role to play in the delivery of an efficient healthcare service because of its ability to provide a rapid test result near a patient which can be acted upon directly
- This can lead to increased clinical effectiveness and improved outcome for patients. *However this is only true if the result delivered is accurate and reliable.*
- POCT is not a replacement for conventional laboratory testing but rather a supplement to it.
- The implementation of these guidelines should provide the framework to facilitate the safe use of POCT in Primary and Community Care settings which in turn will deliver healthcare benefits for patients.



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Useful References

- Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
- S.I. No. 252 of 1994 European Communities (Medical Devices) Regulations, 1994
- Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in-vitro* diagnostic medical devices
- S.I. No. 304 of 2001 European Communities (*In-vitro* Diagnostic Medical Devices) Regulations, 2001
- ISO 22870: 2006 Point-of-care testing (POCT) – Requirements for quality and competence
- IMB publications: www.imb.ie
 - Guidelines for Safe and Effective Management and Use of Point of Care Testing
 - User Adverse Incident Report Form (available for download)
 - IMB Guide to the Vigilance System for Medical Devices
 - IMB Guide to Field Safety Corrective Actions for Medical Devices and *In-vitro* Diagnostic Medical Devices
 - IMB Guide to the *In-vitro* Diagnostic Medical Devices Legislation
 - IMB Guide to Incident Reporting for *In-vitro* Diagnostic Medical Devices



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Acknowledgements

- The IMB is grateful for the time and contributions of the Working Group on Point of Care Testing in Primary and Community Care settings.
- Special thanks to the POCT Consultative group, ACBI, AMLS, Faculty of Pathology, PSI, HSE, HIQA and the ACMD.



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Medical devices brochures – Summer 2009



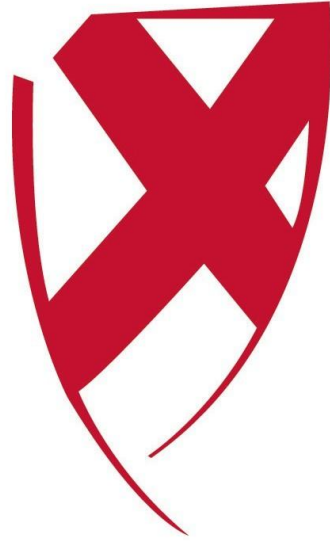
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Thank You!

Any Questions?



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