



Update on the management of Medical Devices

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Approval/Scrutiny route:	Professor Fu-Meng Khaw, Executive Medical Director
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Purpose

The purpose of this paper is to inform QSIC of the progress on the establishment of a managed and governed system for the deployment of medical devices in Public Health Wales.

The paper provides an update on the transfer of the co-ordination and oversight of Medical Devices as a function of the Office of the Medical Director.

It sets out the policy and guidance context and the workplan for 2023-24.

Recommendation:

APPROVE <input type="checkbox"/>	CONSIDER <input type="checkbox"/>	RECOMMEND <input type="checkbox"/>	ADOPT <input type="checkbox"/>	ASSURANCE <input checked="" type="checkbox"/>
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The Committee is asked to:

- **Take assurance on** the progress on the arrangements for the management of Medical Devices
- **Note** the completion of immediate priorities and the workplan for 2023-24

Link to Public Health Wales [Strategic Plan](#)

Public Health Wales has an agreed strategic plan, which has identified seven strategic priorities.

This report contributes to the following:

Strategic Priority	Choose an item.
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Summary impact analysis

Equality and Health Impact Assessment	Not undertaken
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Risk and Assurance	PHW's Executive Medical Director is the lead Executive for medical devices. The support for the function will transfer to the Office of the Medical Director.
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Health and Care Standards	Theme 2 - Safe Care
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Financial implications	None immediate, but consideration of resource requirements to support this and other clinical governance functions in future.
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People implications	None immediate.
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1. Purpose

The purpose of this paper is to inform QSIC of the progress on the establishment of a managed and governed system for the deployment of medical devices in Public Health Wales.

The paper provides an update on the co-ordination and oversight of Medical Devices as a function of the Office of the Medical Director (OMD). The update follows a previous report to QSIC on 15 February 2023.

It sets out the policy and guidance context and the immediate priorities on this agenda.

2. Background

Medical devices are any apparatus, appliance, software, material or other article, whether used alone or in combination, intended by the manufacturer to be used by human beings for a medical purpose. It includes in-vitro diagnostics medical devices, which are devices used to test samples (e.g. blood or tissue), and include active implantable medical

devices which are implanted into the patient, such as cardiac pacemakers.¹

The Medicines and Healthcare Products Regulatory Agency (MHRA) updated guidance on the management of medical devices in [February 2021](#)², which outlines a systematic approach to the acquisition, deployment, maintenance, repair and disposal of medical devices. The guidance is primarily aimed for those in hospital and community-based organisations responsible for the medical devices to ensure that systems are in place for the safe and effective deployment of medical devices. As such, it is a best practice guidance document with the primary aim of reducing the potential for harm arising from the use of medical devices. There are also separate [guidance documents](#) for the use of *in vitro* diagnostics (IVD).

In June 2021, Business Executive Team agreed that the Executive Medical Director would take on the executive oversight for the deployment of medical devices by Public Health Wales.

Initially supported by the Quality, Nursing and Allied Health Professionals (QNAHPs) Directorate, the function has transferred across to the Office of the Medical Director (OMD).

3. Progress

3.1 Governance

A Medical Devices Management Group (MDMG) continues to meet quarterly to oversee the deployment of medical devices in Public Health Wales (PHW).

The MDMG is established as recommended by the MHRA guidance to ensure that medical devices management in PHW complies with relevant regulation, legislation and guidance. The MDMG also sets out to provide assurance to the Business Executive Team and the Quality, Safety and Improvement Committee (QSIC) that there are systems in place to meet its responsibilities to minimise risks associated with the use of medical devices by PHW.

The MDMG is also responsible for ensuring that there is a policy and procedure in place that is compliant with existing regulation and guidance.

¹ DHSC 2021: Factsheet: Medical Devices Overview. [Factsheet: medical devices overview - GOV.UK \(www.gov.uk\)](#)

² DHSC 2021: Managing Medical Devices. [Safeguarding public health \(publishing.service.gov.uk\)](#)

The Medical Devices Regulations Group is the key all-Wales forum co-ordinating responses and activity with the MHRA, particularly around helping to develop guidance on the Government's future regulations. This Group has senior clinical scientist representation from all NHS Wales organisations, Welsh Government representation and is chaired and administered by HEIW. In developing the guidance, the MHRA has established a number of focus groups, one of which is looking at IVDs with a member of the HPSS Infection division representing PHW.

3.2 Policy and Procedure

At its meeting on 7 June 2023, the MDMG approved the revised Medical Devices Management Policy and Procedure, which are currently out for wider consultation. The final draft will be submitted to QSIC later in 2023.

The Policy and Procedure have been assessed for compliance against the MHRA guidance.

3.3 Medical Devices Register

A PHW register of medical devices is held at a corporate level and stored on SharePoint. The register is now hosted by the OMD. Some registers are managed at a team or divisional level.

The register is maintained through the use of an agreed Protocol.

3.4 Transfer of function from QNAHPs to OMD

The support for medical devices management has transferred over to the OMD.

A clinical governance manager role has been established in the Office of the Medical Director, which will include the Medical Device Safety Officer (MDSO) role. The MDSO is responsible for ensuring effective reporting and response to medical device adverse incidents and sharing lessons learnt. MDSOs are also an organisation's main contact for national Medical Devices Safety Networks. As such, they are the experts and have up-to-date knowledge of the regulation and guidance on medical devices. The clinical governance manager will liaise with nominated leads from teams/divisions/directorates for medical devices to oversee this function.

The clinical governance manager will also support medicines management and the Caldicott Guardian function.

Key priorities were previously identified for the OMD during the transition period as follows and these have been completed:

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	Description of Key Priorities	Completion date
1	A review of the Medical Devices Policy and Procedure to ensure they align to the new regulations and guidance.	June 2023
2	Medical Devices Management Group meeting to be held to agree the amended policy and procedure before it is submitted to QSIC.	June 2023
3	Identify a medical device leads in each division/team who will have oversight of the deployment of medical devices in their team. And to formally nominate MDSOs from across the organisation.	June 2023

The MDMG has agreed a workplan for 2023-24 which is enclosed as Appendix 1.

4. Recommendation

Members of QSIC are asked to:

- **Take assurance on** the progress on the arrangements for the management of Medical Devices
- **NOTE** the completion of immediate priorities and the workplan for 2023-24