GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Name of Meeting** Quality, Safety and Improvement Committee **Date of Meeting** 15 February 2023 **Agenda item:** *4.5*

Update on Medical Devices Management

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Approval/Scrutiny route:	Professor Fu-Meng Khaw, National Director of Health Protection and Screening Services, Executive Medical Director

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 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 immediate priorities on this agenda.

Recommendation:

APPROVE	CONSIDER	RECOMMEND	ADOPT	ASSURANCE
☐	☐	☐	☐	☒

The Quality, Safety and Improvement Committee is asked to:

- Take **assuranc**e on the progress to clarify the arrangements for the management of Medical Devices
- **NOTE** the proposed immediate priorities and workplan

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	6 - Supporting the development of a sustainable health and care system focused on prevention and early intervention

Summary impact analysis	
Equality and Health Impact Assessment	Not undertaken
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.
Health and Care Standards	Theme 2 - Safe Care
Financial implications	None immediate, but consideration of resource requirements to support this and other clinical governance functions in future.
People implications	None immediate.

1. Purpose

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2. Background

Medical devices are any apparatus, applicance, software, material or other article, whether used along 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. 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 been transferred across to the Office of the Medical Director (OMD).

3. Progress

3.1 Governance

A key priority is to establish governance arrangements in line with the MHRA guidance, which requires management structures for medical devices to have clear lines of accountability up to board level.

The guidance recommends the appointment of Medical Device Safety Officers (MDSO) and the establishment of a Medical Devices Management Group (MDMG).

The organisation should also have a medical device management policy overseen by the MDMG. There are also recommendations including: monitoring and audit, reporting of adverse incidents, acquisition and selection of devices, modification and change of use.

3.2 Medical Devices Management Group

[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)

In March 2022, an inaugural meeting of the MDMG was convened, bringing together representatives from teams across the organisation where medical devices are deployed.

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.

Responsibility for the safe use of medical devices is also held at team/division level through designated Medical Device Safety Officers (MDSOs).

3.3 Medical Device Safety Officer

The Medical Device Safety Officer (MDSO) role 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.

3.4 Medical Devices Register

A PHW register of medical devices exists has been compiled. This is held at a corporate level and stored on SharePoint. It is currently managed by PHW's governance team and includes medical devices from across the organisation. When is sufficient support in the team, the management of the register will transfer across to the OMD. Some registers are managed at a team or divisional level.

3.5 Medical Device Policy and Procedure

PHW has a Policy for the use of medical devices, approved by QSIC in 2018. The Policy was due for renewal in November 2021 and as such is overdue. A revision of the policy needs to take into account the changes in MHRA regulation and guidance and as such, it is a priority.

3.6 External Groups

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.

3.7 Transfer of function from QNAHPs to OMD

It has been agreed that the support for medical devices management will transfer from QNAHPs to OMD.

A temporary resource will be established in OMD to facilitate the handover. This will require support from divisional/team leads to provide expertise and leadership to support the function.

A post will be created in the OMD to support the PHW-wide MDSO function and will include other policy elements relating to clinical governance, including medicines management and the Caldicott Guardian function. The role will: provide operational support in the management of the medical device registers, monitor the planned changes to Medical Device regulations and assess impact on Public Health Wales.

4. Priorities

Priorities

Key priorities for the OMD during the transition period are:

	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.	31 March 2023
2	Medical Devices Management Group meeting to be held to agree the amended policy and procedure before it is submitted to QSIC.	31 March 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.	31 March 2023

5. Recommendation

The Quality, Safety and Improvement Committee is asked to:

- Take **assurance** on the progress to clarify the arrangements for the management of Medical Devices
- **NOTE** the proposed immediate priorities and workplan