GIG CYMRU NHS WALES | Iechyd Cyhoeddus Cymru Public Health Wales	**Name of Meeting** Quality, Safety and Improvement Committee **Date of Meeting** 19 August 2021 **Agenda item:** 3.9

Update on Medical Devices

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Approval/Scrutiny route:	Business Executive Team Quality, Safety and Improvement Committee

Purpose

The purpose of this paper is to provide the Quality, Safety and Improvement Committee with an update on the work that is being undertaken to strengthen the governance of medical devices. The Quality, Safety and Improvement Committee is also asked to consider implementing the recommendations set out in the new guidance from the Medicines and Healthcare products Regulatory Agency.

Recommendation:

APPROVE	CONSIDER	RECOMMEND	ADOPT	ASSURANCE
☒	☒	☐	☐	☒

The Quality, Safety and Improvement Committee is asked to:

- Take **assurance** on the work that has been undertaken to strengthen the governance of medical devices.
- **Consider** the recommendations set out in the new MHRA guidance.
- **Confirm the** Executive Lead for future management of medical devices.

Link to Public Health Wales Strategic Plan Public Health Wales has an agreed strategic plan, which has identified seven strategic priorities and well-being objectives. This report contributes to the following:	
Strategic Priority/Well-being Objective	All Strategic Priorities/Well-being Objectives

Summary impact analysis	
Equality and Health Impact Assessment	Full assessment not undertaken as no equality impact issues identified.
Risk and Assurance	BAF Risk 2
Health and Care Standards	This report supports and/or takes into account the Health and Care Standards for NHS Wales Quality Themes. Governance, Leadership and Accountability
Financial implications	N/A
People implications	N/A

1. Situation

This paper is intended to provide the Quality, Safety and Improvement Committee with a progress report on work that has been undertaken to strengthen the governance of medical devices.

The paper also provides an update on new guidance which has been issued by the Medicines and Healthcare products Regulatory Agency (MHRA) on 'Managing Medical Devices.'

2. Background

Work continues to progress to address the gaps and risks that have been identified in relation to the management of medical devices.

A review of medical devices identified that there were a number of medical device registers in place throughout the organisation, but there was no corporate oversight. The review also identified a risk that there may be medical devices, such as defibrillators and software and apps which may be unaccounted for but in use across the organisation. A further risk was identified in relation to CE marking and whether medical devices which are being used are CE marked.

3. Summary of work undertaken and findings

A gap analysis has been undertaken which summarises the ongoing work to improve and strengthen the organisational arrangements for the governance of medical devices. It also details further actions which will need to be undertaken to fulfil the new recommendations of the MHRA. Please refer to Appendix 1.

3.1. Work undertaken/improvements made:

- A corporate medical devices register has been developed and is currently being populated. The register contains information on devices used throughout the organisation, with the exception of the microbiology laboratories and CSW/BSW lab medical devices.

- All Directorates and sites across Public Health Wales have been asked to provide information on any medical devices (including software or apps) (with the exception of microbiology services – please see below) that they use, provide, hold or have developed and this information has been added to the new register.

- Work has been undertaken to rationalise the number of registers which were in existence across Public Health Wales. The information in these registers has been added to the new corporate medical devices register (with the exception of the microbiology laboratories, where it has been agreed that they will continue to implement the iPASSPORT quality management system and the QPulse quality management database will be maintained for the bowel/cervical screening laboratory).

- Microbiology Services are currently updating their registers for medical devices and will transfer this data into the new iPASSPORT database in the future.

- Devices which are being used in non-clinical areas, such as defibrillators, have also been added to the corporate register, making it easier to monitor and manage these devices.

- The review identified some software and apps which have been developed and have the potential to be classified as a medical device.

3.2. Issues identified and further work to be undertaken

Work has been undertaken to populate the new corporate register as fully as possible but some gaps remain. One of the main issues in trying to collect data on the various devices is that work to support the Covid response is being prioritised. In addition to this, a significant number of staff are working from home (particularly staff working in the non-clinical areas) and so have been unable to check relevant documentation such as manufacturer instructions or CE markings. Work will continue to be progressed to address the gaps and follow up any areas where responses remain outstanding as soon as possible.

3.3 Scope of registers

The definition of medical devices is very wide and includes items such as needles, syringes and dressings. It is not pragmatic to list every single individual item and a corporate approach needs to be agreed.

It is anticipated that this will be discussed once the new Medical Devices Management Group (see section 4.5 below) has been established.

3.4 iPassport, Qpulse and corporate medical devices register

Work will be undertaken to establish a corporate oversight between the corporate medical devices register and the iPASSPORT and QPulse systems.

Options for cross referencing/linking the registers will be explored to see if this is technically possible.

3.5 Software

The following software/apps has been identified and further work is being undertaken to assess whether they are medical devices and need to be registered with the MHRA:

- News app - The Improvement Cymru team commissioned a company to develop an app to detect the likelihood of sepsis in an individual. The user inputs various details such as person's heart rate, temperature and blood glucose readings into an app and the app provides a score which indicates the likelihood of sepsis. Professional advice has been sought on the matter and Legal and Risk Services have advised that the app is likely to be a medical device and should be registered with the MHRA. The Integrated Governance team are assisting the Improvement Cymru team on the appropriate registration route with the MHRA.

- CSIMS – This is being developed by the Informatics team and will be a single IT system for Cervical Screening Wales. It will be extended to other screening programmes in the future. The CSIMS Project Board concluded that it is not a medical device. As the software is developed further and has greater functionality this may bring it within the realm of a medical device and this will need to be monitored.

- Tarian - Further advice will be sought on the status of the Tarian system.

4. MHRA Guidance

As referred to above the MHRA has developed new guidance on the management of medical devices. The guidance is very detailed and aims to help organisations establish systems that promote the use of medical devices for safe and effective health care.

An overview of the main recommendations are set out below and have been incorporated into the gap analysis at Appendix 1.

4.1. Executive responsibility for medical devices

The MHRA guidance recommends that a director or board member with overall responsibility for medical device management should be appointed. The management structure for medical devices should have clear lines of accountability up to board level.

The current Medical Devices and Equipment Management Procedure states that the Executive Director of Public Health Services/Medical Director is the Board's nominated Director responsible for medical devices.

At the June meeting of the Business Executive Team meeting it was agreed that the Executive Director of Public Health Services/Medical Director would retain responsibility for the management and governance of medical devices and the Executive Director of Quality, Nursing and Allied Health Professionals would be responsible for the governance of the corporate medical devices register.

The Executive Director of Quality, Nursing and Allied Health Professionals will be responsible for assessing compliance with policies and procedures.

This strengthens current arrangements for the management of medical devices as it allows a separation of responsibilities to enable independent review.

4.2. Medical Device Safety Officers (MDSO)

The guidance recommends that healthcare organisations should appoint Medical Device Safety Officers (MDSO). Part of the MDSO role is to report adverse incidents to the MHRA and other official agencies.

The current Medical Devices and Equipment Management Procedure states that the Head of Estates and Facilities is the nominated medical devices liaison officer and responsible for ensuring the reporting of adverse incidents relating to medical devices.

It has been agreed that this arrangement will be reviewed.

4.3. Policies

The MHRA recommends that organisations should have in place a medical devices management policy/procedure and a policy or other mechanism in place for the acquisition, selection and purchasing of medical devices.

The guidance sets out detailed specifications in relation to the management of medical devices. It is also recommends that organisations should set out a medium to long-term approach for the management of medical devices, including strategic replacement taking into account cost, performance and risk across the entire equipment lifecycle. The current policy and procedure will be reviewed in due course to ensure compliance with the MHRA guidance.

4.4. Records

The MHRA recommends that records should be maintained within one system wherever possible, but where this is not possible or practical there should be suitable cross references between the various record systems.

Options for linking systems or using one system will be explored.

4.5. Medical devices Management Group

The MHRA recommends that a medical devices management group should be established to develop and implement policies across the organisation.

The Executive Director of Public Health Services/Medical Director and Director of Integrated Governance met to discuss arrangements. The Executive Director of Public Health Services/Medical Director will chair the group in the first instance.

A significant amount of corporate support from within Public Health Services is currently being directed towards the Covid response and so corporate support from elsewhere in the organisation will be secured to support the operation of the group.

5. Recommendations:

The Quality, Safety and Improvement Committee is asked to:

- Take assurance on the work is being progressed to strengthen the governance of medical devices.

    - Consider and approve whether Public Health Wales should adopt the recommendations set out in the new MHRA guidance:
        - Management responsibility
        - Medical Device Safety Officers
        - Policies
        - Records
        - Medical devices management group.
    - Approve the Executive Lead

GAP ANALYSIS			**APPENDIX 1**
Requirement	**Gaps identified**	**Actions taken**	**Progress/issues**
All medical devices held, used, purchased, provided or under development are accounted for across the organisation.	There may be medical devices which are not accounted for in non-clinical areas i.e. defibrillators	All directorates and sites across Public Health Wales have been contacted and asked to provide information on any medical devices they have purchased/use/hold or have developed. A corporate medical devices register has been developed and the information received to date has been collated and added to the new register.	The majority of divisions have submitted a return, but waiting for a response in some areas. There are some gaps in the information received, such as whether CE marking has been applied and this needs to be addressed. The register will be discussed at the Health & Safety group to raise the profile of medical devices and the importance of ensuring that all devices are accounted for.
Software and apps which may be medical devices and are used or have been developed by Public Health Wales are accounted for and checked to ensure that	There may be software/apps in use or which have been developed that are medical devices which are not CE marked or registered with the	All directorates have been contacted and asked to provide information on any software or apps they have purchased or	The majority of divisions have submitted a return and most divisions do not use software/apps which may be medical devices. Some software/apps have however been identified which may be classified

they carry the required CE marking.	MHRA and are being used within the organisation.	developed which may be medical devices. Meeting held with the Head of Informatics to discuss.	as a medical device and further advice is being sought where required. Informatics advised that although CSIMS is not currently a medical device, it has the potential to be classified as a device in the future.
All medical devices used by the organisation should be CE marked.	There is a risk that a medical device may be in use but not be CE marked.	Directorates have been asked to identify whether medical devices used in local areas are CE marked.	Slow progress due to time pressures within services or staff not being in the office to undertake checks in non-clinical areas.

GAP ANALYSIS – Summary of new/additional requirements of the MHRA Guidance

MHRA Recommendation	**Current status**	**Gaps identified**	**Actions to be taken**	**Lead Executive**
There is a director or board member with overall responsibility for medical device management.	It was agreed at BET that Executive Director of Public Health Services/Medical Director would retain responsibility for the management and	None		Executive Director of Public Health Services/Medical Director

The management structure for medical devices should have clear lines of accountability up to board level.	governance of medical devices and the Executive Director of Quality, Nursing and Allied Health Professionals would be responsible for the governance of the corporate medical devices register. N.B The current procedure on the management of medical devices states that the Executive Director of Public Health Services/Medical Director is the Board's nominated Director responsible for ensuring compliance with the Medical Devices policy and procedure.			
Healthcare organisations should establish a Medical Devices	There is currently no organisational wide medical devices	A lack of a corporate oversight for the	Terms of reference to be drafted. Membership of group to be considered.	Executive Director of Public Health

Management Group to develop and implement policies across the organisation.	management group in place.	management of medical devices.		Services/Medical Director
The Medical Devices Management Group should undertake an audit of the organisation's performance on medical device management.	There is currently no organisational wide medical devices management group in place.	There is currently no organisational wide medical devices management group in place.	Consideration to be given to this once the need for a medical devices group has been reviewed.	Executive Director of Public Health Services/Medical Director
Medical Device Safety Officers (MDSO) should be appointed.	There are no Medical Device Safety Officers in place, however the current medical devices procedure states that the Head of Estates and Facilities is Public Health Wales' nominated Medical Devices Liaison Person and is responsible for ensuring the reporting of adverse incidents relating to medical devices.	There are no Medical Device Safety Officers in place, but a nominated Medical Devices Liaison person is in place.	Consider and review current arrangements.	Executive Director of Public Health Services/Medical Director

There should be a device management policy in place to help ensure that the risks associated with the use of medical devices are minimised or eliminated.	A medical devices policy and procedure was approved by the Quality, Safety and Improvement Committee in November 2018 and is due for review in November 2021.	The policy and procedure need to be reviewed to ensure they comply with guidance from the MHRA.	It is recommended that the Medical Devices Management Group review the current policy and procedure to ensure that it complies with the new guidance from the MHRA.	Executive Director of Public Health Services/Medical Director
Organisations should have a policy in place (or other mechanism) for the acquisition and selection of devices (policy for procuring medical devices).	The procedure on medical devices refers to the acquisition and selection of devices.	It is not clear whether the current policy and procedure complies with new guidance from the MHRA.	It is recommended that the Medical Devices Management Group review the current policy and procedure to ensure that it complies with the new guidance from the MHRA. Any local policies should also be reviewed by the group.	TBC
The MHRA recommends that a training policy should be developed by the medical devices management group.	There is no specific overarching training policy for the use of medical devices.		The need for a specific training policy should be considered by the medical devices management group.	TBC
Organisations should have mechanisms in place to distribute	Public Health Wales has an up to date Alerts policy in place.	Review current policy to ensure it complies with	Review Alerts policy in due course.	Executive Director of Quality, Nursing

safety notices and MHRA safety information.		MHRA recommendations.		and Allied Health Professionals