Hywel Dda University Health Board

Medical Devices

Final Internal Audit Report

January 2020

Private and Confidential

NHS Wales Shared Services Partnership

Audit and Assurance Services

Contents **Page**

Review reference:	HDUHB-1920-16
Report status:	Final Internal Audit Report
Fieldwork commencement:	22nd October 2019
Fieldwork completion:	26th November 2019
Draft report issued:	29th November 2019
Management response received:	11th December 2019
Final report issued:	27th January 2020
Auditor/s:	Ceri-Ann Corcoran
Executive sign off:	Andrew Carruthers (Director of Operations)
Distribution:	Gareth Rees (Deputy Director of Operations) Chris Hopkins (General Manager Operations – Improvement)
Committee:	Audit & Risk Committee

Audit and Assurance Services conform with all Public Sector Internal Audit Standards as validated through the external quality assessment undertaken by the Institute of Internal Auditors.

ACKNOWLEDGEMENT
NHS Wales Audit & Assurance Services would like to acknowledge the time and co-operation given by management and staff during the course of this review.

Disclaimer notice - Please note:

This audit report has been prepared for internal use only. Audit & Assurance Services reports are prepared, in accordance with the Service Strategy and Terms of Reference, approved by the Audit & Risk Committee.

Audit reports are prepared by the staff of the NHS Wales Shared Services Partnership – Audit & Risk Assurance Services, and addressed to Independent Members or officers including those designated as Accountable Officer. They are prepared for the sole use of the Hywel Dda University Health Board and no responsibility is taken by the Audit and Assurance Services Internal Auditors to any director or officer in their individual capacity, or to any third party.

1. Introduction and Background

The review of the management of medical devices within Hywel Dda University Health Board was completed in line with the approved 2019/20 Internal Audit Plan. The relevant lead Executive Director for the review was the Director of Operations.

2. Scope and Objectives

The overall objective of the review was to provide assurance that there are appropriate systems and processes in place for the management of medical devices so that all devices are appropriately managed and maintained.

The main control objectives reviewed were:

- There is compliance with health, safety and environmental legislation, regulation and guidance. Policies and procedures are in place and staff are aware of their responsibilities;
- Processes ensure that equipment and devices are maintained, cleaned and calibrated in accordance with manufacturer's guidelines, ensuring they are appropriate (risk assessed) for their intended use and for the environment in which they are used;
- Adequate reporting arrangements are in place for the escalation of risks;
- Timely reporting and management arrangements exist to address any device, equipment or system faults in use, including any alert or warning notices issued by appropriate agencies such as MHRA or device manufacturers;
- There is an inventory listing of medical equipment which is regularly maintained and reviewed (including additions, disposals, loans);
- An on-going programme of training and competence assessment covers staff and users; and
- Suitable and sustainable systems, policies and procedures are in place for medical device decontamination by competent staff in an appropriate environment.

3. Associated Risks

The inherent risk associated with medical devices is patient harm due to poorly managed devices.

OPINION AND KEY FINDINGS

4. Overall Assurance Opinion

We are required to provide an opinion as to the adequacy and effectiveness of the system of internal control under review. The opinion is based on the work performed as set out in the scope and objectives within this report. An overall assurance rating is provided describing the effectiveness of the system of internal control in place to manage the identified risks associated with the objectives covered in this review.

The level of assurance given as to the effectiveness of the system of internal control in place to manage the risks associated with Medical Devices is **Reasonable** assurance.

RATING	INDICATOR	DEFINITION
Reasonable assurance		The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

The overall level of assurance that can be assigned to a review is dependent on the severity of the findings as applied against the specific review objectives and should therefore be considered in that context.

The review highlighted the overall satisfactory management of medical devices across the Health Board. We noted the proactive approach taken by the Clinical Engineering Department in the implementation of the new inventory system that captures key information such as maintenance and calibration data, and adequate monitoring and reporting arrangements in place. In addition, policies and procedures in regard of medical devices have been produced.

However, two high priorities were identified during this review:

- The current system of identifying medical device alerts and safety notices does not provide assurance that all alerts are captured and addressed; and
- There is a lack of training coordination for clinical and nursing staff with the trainers not being informed of training undertaken by manufacturers within wards and departments, whilst there is no record or database of training for medical devices other than infusion pumps.

5. Assurance Summary

The summary of assurance given against the individual objectives is described in the table below:

		Assurance Summary*			
Audit Objective					
1	There is compliance with health, safety and environmental legislation, regulation and guidance			✓	
2	Processes ensure that equipment and devices are maintained, cleaned and calibrated				✓
3	Adequate monitoring and reporting arrangements are in place				✓
4	Timely reporting and management arrangements exist to address any device, equipment or system faults in use including any alert or warning notices issued by appropriate agencies such as MHRA or device manufacturers		✓		
5	There is an inventory listing of medical equipment which is regularly maintained and reviewed				✓
6	An ongoing programme of training and competence assessment covers staff and users		✓		
7	Suitable and sustainable systems, policies and procedures are in place for medical device decontamination			✓	

** The above ratings are not necessarily given equal weighting when generating the audit opinion.*

Design of Systems/Controls

The findings from the review have highlighted **two** issues that are classified as weaknesses in the system control/design for Medical Devices. These are identified in the Management Action Plan as (D).

Operation of System/Controls

The findings from the review have highlighted **two** issues that are classified as weaknesses in the operation of the designed system/control for Medical Devices. These are identified in the Management Action Plan as (O).

6. Summary of Audit Findings

The key findings are reported in the Management Action Plan at Appendix A.

OBJECTIVE 1: There is compliance with health, safety and environmental legislation, regulation and guidance.

The Health Board has in place a Medical Device Management Policy that is available to employees on the organisation intranet site. In addition, a number of supporting policies and procedures in regard of medical devices had also been publish.

We noted the Management and Distribution of Safety Alerts & Notices Policy review date had expired, whilst the following three policies and procedures were still in draft form:

- Purchase Acquisition of Medical Devices Procedures
- Maintenance of Medical Devices
- Safe use Operation of Medical Devices

We can also confirm that the Clinical Engineering (CE) Department have also setup shared folders on the network to all employees to access other sources of information in regard of medical devices including sets of work instructions, forms and ISO Standards.

See Finding 3 at Appendix A.

OBJECTIVE 2: Processes ensure that equipment and devices are maintained, cleaned and calibrated

The Clinical Engineering Department maintains a central log of medical equipment on the RAM5K inventory system. The RAM5K system allows the CE Department to record acceptance testing, repair and planned preventative maintenance (PPM).

The CE Department run a PPM schedule report every month that identifies medical devices that require maintenance and calibration reviews with a risk-based approach in order to focus on priority. A walkthrough test of a sample of medical devices listed on the RAM5K system confirmed that a valid and up-to-date calibration certificates had been retained on file.

No matters arising.

OBJECTIVE 3: Adequate monitoring and reporting arrangements are in place

Performance figures for PPM compliance across acute and community sites are regularly reported within the Integrated Performance Assurance Report submitted to the Business Planning and Performance Assurance Committee (BPPAC). Monitoring of performance figures are also reviewed at the Medical Devices Governance and Assurance Group.

We can also confirm that performance reports are also submitted to the Executive Team; whilst ad hoc reports have been submitted to other statutory committees of the Board.

No matters arising.

OBJECTIVE 4: Timely reporting and management arrangements exist to address any device, equipment or system faults in use including any alert or warning notices issued by appropriate agencies such as MHRA or device manufacturers

The CE Department are responsible for receiving and addressing alerts and safety notices received form agencies and device manufacturers. All alerts and safety notices are recorded on the RAM5K system.

The Health Board, as a registered member, receives alerts and safety notices from the Medicines & Healthcare products Regulatory Agency (MHRA) on weekly basis. In addition, alerts and safety notices are also received from device manufacturers. However, only alerts known to the CE Department are input onto the RAM5K system; whilst some manufacturers are not registered with the MHRA, resulting in some alerts or safety notices being missed by the Health Board.

This weakness in ensuring alerts and safety notices are identified and addressed by the Health Board was identified by the CE Department and recorded on the Corporate Risk Register (Risk ID: 384 & 387).

To mitigate the risks in ensuring all alerts and safety notices are identified and addressed by the Health Board, an evaluation exercise was undertaken proposing the introduction of an interactive web-based patient safety solution.

See Finding 1 at Appendix A.

OBJECTIVE 5: There is an inventory listing of medical equipment which is regularly maintained and reviewed

The RAM5K system retains all Health Board inventory listings of medical devices. A review of 40 medical devices across the four acute hospital sites was selected to ensure the items reconciled to the RAM5K system. We can confirm that a record for each medical device tested was retained on the RAM5K system and that the item and maintenance details accurately reconciled.

No matters arising

OBJECTIVE 6: An ongoing programme of training and competence assessment covers staff and users

Training of medical devices are currently split into two groups – technical and clinical. The Medical Devices Trainer and the Clinical Skills Trainer are responsible for managing the training of nursing and clinical staff, whilst the Principal Clinical Technologist and Medical Devices Coordinator are responsible for training CE staff.

Clinical Training

We can confirm that a database of employee training records for infusion pumps was being maintained. However, no databases of training for other medical devices were maintained.

We were informed by the Medical Devices Trainer and the Clinical Skills Trainer that in some instances the manufacturer will arrange training with wards and departments directly. In these instances, the Medical Devices Trainer and the Clinical Skills Trainer will not have any knowledge of the training being undertaken, unless informed by the ward or department, nor the quality of training delivered.

Ward and department managers are responsible for ensuring their staff receive the correct training and for maintaining staff training records. Due to only two trainers employed by the Health Board, a 'link trainer' approach has been implemented whereby a designated individual that has received the necessary training, then trains their colleagues within their ward or department. Link trainer documentation packs have also been produced to support this approach.

An analysis was undertaken by the Principal Clinical Technologist into the number of medical devices being reported as damaged for the period 13th September 2018 to 3rd November 2019 – see breakdown of number by acute site below.

- BGH – 155
- GGH – 239
- PPH – 98
- WGH – 109

Technical Training

We can confirm that a training matrix has been established for all technicians within the Health Board. Testing was undertaken on a sample of technicians and confirmed that the information recorded in the training matrix reconciled to training certificates retained in personal files.

See Finding 2 at Appendix A.

OBJECTIVE 7: Suitable and sustainable systems, policies and procedures are in place for medical device decontamination

All medical devices used by wards and departments must be cleaned before being returned to the inventory libraries that are based on each of the four acute sites. An 'Equipment Status' tag must be completed and accompany all returned items following their decontamination.

A sample of 20 decontamination tags was tested to ensure the 'Equipment Status' tags had been fully completed and the appropriate decontamination method had been applied as per the Decontamination Policy. Concluding testing, we noted:

- Two instances where the Ward/Dept. side of the tag had not been fully completed; and
- Five instances where the Clinical Engineering side of the tag had not been fully completed.

See Finding 4 at Appendix A.

7. Summary of Recommendations

The audit findings and recommendations are detailed in Appendix A together with the management action plan and implementation timetable.

A summary of these recommendations by priority is outlined below.

Priority	H	M	L	Total
Number of recommendations	**2**	**2**	**0**	**4**

Finding 1 – Patient Safety Alert System (D)	Risk
The current system of identifying alerts and safety notices does not provide assurance that all alerts will be captured and addressed by the Health Board that could impact patient safety.	Patient harm due to poorly managed medical devices.
Recommendation 1	**Priority level**
Management should put in place safeguards to ensure alerts and safety notices for all Health Board medical devices are fully captured.	**HIGH**
Management Response	**Responsible Officer/ Deadline**
The current procedure for the management of safety notices and alerts is under review. Following consultation it will be taken through Health Board processes for ratification and then implementation. The revised policy will ensure that the responsibility, for capturing all alerts received and actions taken is clear. With the introduction of the Once for Wales Concerns Management System which includes an alerts function, the Head of Quality and Governance has requested that an all Wales solution is considered. The Head of Quality and Governance will continue to the OfWCMS project to try and influence an all Wales solution. This will be done through the Programme Team and Programme Board.	Head of Quality and Governance March 2020

Finding 2 – Medical Devices Training (D)	Risk
There is a lack of training coordination for clinical and nursing staff with the trainers not being informed of training undertaken by manufacturers within wards and departments, whilst there is no record or database of training for medical devices other than infusion pumps.	Patient harm due to poorly managed medical devices.
Recommendation 2	**Priority level**
Management should review the current approach to medical devices training for clinical and nursing staff to ensure: • **all training is coordinated through a central point;** • **training provided by external parties can be quality assessed; and** • **training records can be accurately maintained.**	**HIGH**
Management Response	**Responsible Officer/ Deadline**
The medical device trainer is currently undertaking a mapping exercise to prioritise the training in accordance to high medium and low risk devices. The initial training plan will focus on the high risk to identify the specific trainers (including external parties); assess that they are delivering a quality assured programme and identify records of training. The trainers that deliver aspects of the mandatory training programme i.e. resuscitation and moving and handling are already recording device training onto ESR.	Director of Workforce & OD 30th April 2020

The work stream will also identify any gaps in provision of training. There is only one medical device trainer for the whole Health Board. At present, a large proportion of the time is dedicated to coordinating the cascade assessors' programme for infusion devices. There is currently no administrative support for the trainer. To ensure a timely delivery of all of the recommendations there will be a requirement to increase both trainer and administrative resources.	

Finding 3 – Finalisation and Review of Procedures (O)	**Risk**
We noted the Management and Distribution of Safety Alerts & Notices Policy review date had expired, whilst three policies and procedures were still in draft form.	Patient harm due to poorly managed medical devices.
Recommendation 3	**Priority level**
Management should ensure the identified medical devices policies and procedures are promptly reviewed and submitted for approval.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
The current procedure for the management of safety notices and alerts is under review. It will be issued for consultation early January 2020. Following consultation it will be taken through Health Board processes for ratification and then implementation.	Head of Quality and Governance March 2020

Finding 4 – Completion of Status Labels (O)	Risk
We noted seven instances (out of 20) where the 'Equipment Status' tags had not been fully completed.	Patient harm due to poorly managed medical devices.
Recommendation 4	**Priority level**
Clinical Engineering Department should ensure that 'Equipment Status' tags for all returned medical devices to the inventory libraries are completed by the returning and receiving officers.	**MEDIUM**
Management Response	**Responsible Officer/ Deadline**
The new decontamination tags were introduced over the past six months as part of our ongoing continuous improvement exercise. During the initial stages of introduction these tags were incomplete due to a new process being implemented. We have since communicated with the Assistant Director of Nursing Quality and Safety and all General Managers / Heads of Nursing that we will not accept any equipment into the department without the tags being completed correctly. All equipment librarians have also been informed and this process will be monitored within our quality system.	Deputy Director of Operations & General Manager Operations (Improvement) December 2019

Appendix B - Assurance Opinion and Action Plan Risk Rating

2019/20 Audit Assurance Ratings

 **Substantial Assurance** - The Board can take **substantial assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Few matters require attention and are compliance or advisory in nature with **low impact on residual risk** exposure.

 **Reasonable Assurance** - The Board can take **reasonable assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. Some matters require management attention in control design or compliance with **low to moderate impact on residual risk** exposure until resolved.

 **Limited Assurance -** The Board can take **limited assurance** that arrangements to secure governance, risk management and internal control, within those areas under review, are suitably designed and applied effectively. More significant matters require management attention with **moderate impact on residual risk** exposure until resolved.

 **No Assurance** - The Board has **no assurance** arrangements in place to secure governance, risk management and internal control, within those areas under review, which are suitably designed and applied effectively. Action is required to address the whole control framework in this area with **high impact on residual risk** exposure until resolved.

Prioritisation of Recommendations

In order to assist management in using our reports, we categorise our recommendations according to their level of priority as follows.

Priority Level	Explanation	Management action
High	Poor key control design OR widespread non-compliance with key controls. PLUS Significant risk to achievement of a system objective OR evidence present of material loss, error or misstatement.	Immediate*
Medium	Minor weakness in control design OR limited non-compliance with established controls. PLUS Some risk to achievement of a system objective.	Within One Month*
Low	Potential to enhance system design to improve efficiency or effectiveness of controls. These are generally issues of good practice for management consideration.	Within Three Months*

* Unless a more appropriate timescale is identified/agreed at the assignment.

Office details: St Brides
St David's Park
Carmarthen
Carmarthenshire
SA31 3HB

Contact details: 01267 239780