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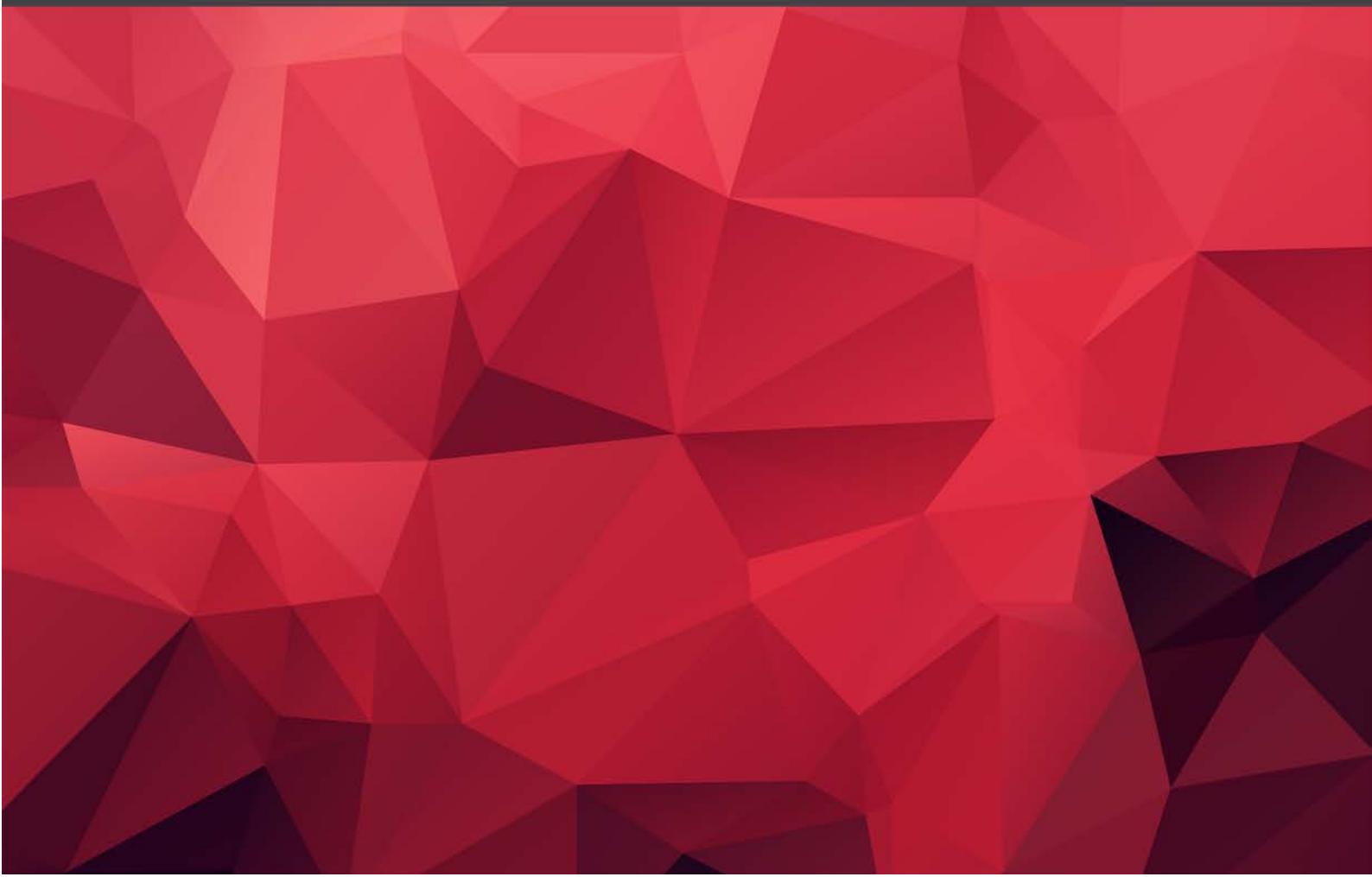
Auditor General for Wales

Medical Equipment Management – **Betsi Cadwaladr University Health Board**

Audit year: 2015-16

Date issued: October 2016

Document reference: 357A2016



The person who delivered the work was Charlotte Owen.

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Summary report

Introduction

1 Health bodies typically own and maintain thousands of items of medical equipment. Medical equipment can perform numerous functions such as diagnosis, prevention, monitoring, investigation and treatment. It is therefore vital that health bodies manage their medical equipment in such a way as to ensure patient safety and high-quality care. Medical equipment, as defined by the National Audit Office, includes all medical devices connected to patients as part of their treatment and care in hospital, and medical devices used for diagnostic and laboratory purposes.

2 Previous reviews by the Wales Audit Office have highlighted some concerns in relation to medical equipment in Betsi Cadwaladr University Health Board (the Health Board):

- our 2012 Structured Assessment highlighted the need for the Health Board to standardise procurement practices regarding equipment; and
- our 2014 work on Acute Medicines Management highlighted concerns with replacement of key equipment.

3 In addition, given the pressure on the discretionary capital budget within the Health Board, and high levels of backlog maintenance, there is a risk that the Health Board may be using outdated equipment and not taking sufficient action to mitigate this risk. In response to this, we undertook a local review, which examined the Health Board's approach to the management of medical equipment and sought to answer the question: 'is the Health Board managing its medical equipment effectively?'

Our findings

4 We concluded that day-to-day maintenance of medical equipment is reasonably well managed and there are effective, risk-based systems for prioritising capital spend. However, arrangements for low-cost equipment are less clear and the Health Board lacks a definitive medical equipment inventory.

5 The main findings are summarised below.

The Health Board has a clear structure for managing medical equipment but medical equipment does not have a high profile and oversight from independent members has reduced

6 The Executive Director of Nursing, Midwifery, Therapies and Health Sciences has overall responsibility for medical equipment whilst the Assistant Director of Therapies and Health Sciences (ADoTHS) provides leadership at director level. These arrangements cover both acute and community based services.

7 Although changes to operational structures at the Health Board have impacted on high-level planning, strategy and communication, the new structure also provides an opportunity to improve the arrangements for the management of medical equipment.

8 The Medical Devices Oversight Group (MDOG), chaired by the ADoTHS, sits within a clear and well-established structure and provides strategic direction for medical devices. There are clear reporting lines to this group, and membership covers a broad range and level of staff. The MDOG oversees the Medical Devices Capital Group and Medical Devices Locality groups, and is well informed. There is evidence that governance, safety and financial management issues relating to medical equipment are escalated through this structure as far as the Quality Assurance Executive (QAE), but exposure above this level is unclear.

9 Although a Medical Devices and Equipment Management Policy is in place, the supporting procedural documents are still at draft stage and a number of legacy policies are in use in the interim.

10 The Health Board's latest self-assessment against Standards for Health Services 16: Medical Devices, Equipment and Diagnostic Systems (SHS16) scored highly, with action underway to address areas for improvement in relation to training. Due to structural changes at the Health Board, independent members did not provide scrutiny of the self-assessment in 2015; the submission was instead reviewed by the ADoTHS. These arrangement changes removed the process of independent scrutiny and the opportunity for independent members to be directly involved in the oversight of medical equipment. The Standards for Health Services have now been replaced with Health and Care Standards, which do not require Independent Member scrutiny of the Health Board's self-assessment. Going forward, the review process will be delivered in line with the new Standards' requirements and Independent Member time will instead be focussed on higher risk areas.

The Health Board is developing arrangements to manage risks associated with medical equipment at an operational level but strategic risks are not always escalated quickly

11 Departmental risk registers include medical equipment risks and equipment-related incidents inform local risk registers. There is, however, limited focus on medical equipment within the corporate risk register. Historically, communication within the Health Board has not always been fully effective, causing delays in some key operational risks being recognised at a strategic level, such as the need to coordinate the replacement of the pharmacy robotic dispenser with the Ysbyty Glan Clwyd refurbishment works to avoid disruption to services. Although this risk was identified by Pharmacy in 2014 and recognised in 2015 by the MDOG, the dispenser was not included in the Discretionary Capital Programme until 2016.

12 The Health Board makes good use of the information it holds on risk to assess and prioritise bids for discretionary funding, but more broadly there is no collated source of all medical equipment risks. Such information would help QAE to be better informed of key medical equipment risks that cannot be managed locally so that the Health Board can take relevant action.

13 Staff training on medical equipment and the extent of user risks in relation to medical equipment are unknown due to incomplete training records. Untrained users of medical equipment are more likely to make errors, which can impact on patient care. In response, the Health Board has developed a new medical devices training policy that focuses on needs-based training. The policy aims to highlight problem areas and improve take up of training. However, training records are likely to remain an issue due to the reported limitations of the Electronic Staff Record (ESR) system. The recording and reporting of staff training data is impeded by inconsistent local use of ESR and the limitations of the system which have been highlighted in other forums nationally.

14 The Health Board communicates Medicines and Healthcare Products Regulatory Agency (MHRA) alerts and guidance well, and staff record medical equipment related incidents. There are also effective systems in place within the medical equipment group structure to identify potential trends in incidents, and to investigate and take mitigating action where necessary. This is an example of good practice which could be shared with other areas of the Health Board.

The Health Board uses its discretionary capital budget effectively to prioritise new and replacement medical equipment but for lower-cost items arrangements are less clear and there is no single inventory of all items

15 There are effective and transparent processes in place for capital purchases of medical equipment. Bids for discretionary funding are submitted annually and there is a clear process of prioritisation linked to clinical risk, enabling the Health Board to make best use of limited funds. Submissions set out upcoming requirements for both new and replacement equipment on a rolling five-year basis, facilitating forward planning. There are similar arrangements in place for the use of charitable funds, although funding available varies by site, potentially leading to inequity. The Health Board also has effective processes for dealing with emergency bids as a result of equipment failure.

16 There is a less strategic approach to the replacement of items below the capital threshold of £5,000. Whilst some items (e.g. infusion devices, defibrillators and beds) come under the ‘fleet’ category and are covered by the capital process, the Health Board has many items where acquisition decisions are made at departmental level and it is unclear whether departments are taking a risk-based approach to decision making. Although the Health Board has systems in place to regulate the acquisition of devices and there are processes in place to block orders

of non-standard items, it is unclear how effective these processes are and whether departments are able to bypass them, resulting in potential clinical risks.

17 There is no single inventory for medical equipment in the Health Board. The Health Board's asset register only captures capital items (i.e. those over £5,000) and the picture below £5,000 is less clear. The Electro-Biomedical Engineering Department (EBME) maintains a Hospital Engineering Management System (HEMS). This system provides the most complete inventory, but some devices, such as radiology and pathology equipment, are managed outside the core medical equipment arrangements and so are not included on HEMS. In addition, HEMS does not contain complete information on the monetary value of equipment, making it difficult to calculate replacement costs accurately. The Health Board estimated the cost to replace out-of-life equipment at 31 March 2014 at £22.5 million but this does not include equipment under £5,000. The lack of one source of complete inventory information makes it difficult to determine how much the Health Board is spending on medical equipment and what total upcoming replacement needs and costs are in relation to out-of-life equipment.

The Health Board has reasonably effective arrangements for the maintenance of medical equipment but its equipment library could be more effective and standardised across the Health Board by sharing good practice across sites

18 EBME uses HEMS to monitor the maintenance of equipment. Equipment is well managed, and despite an ongoing maintenance backlog, hospital staff report high levels of satisfaction with the service provided by the EBME department. The department has ISO 9001 accreditation and the external audit process found no failings. However, as not all equipment is recorded on HEMS there is a risk to patient safety if the Health Board does not know if all equipment below £5,000 is properly maintained or calibrated.

19 The equipment library service, which provides medical devices to wards and departments on a temporary basis, is an effective use of resources, although the service is managed differently at different sites, the range of equipment varies between sites and there is scope for standardisation.

20 The Health Board is in the process of standardising equipment across sites. Work is currently underway to standardise infusion pumps and defibrillators, following on from previous projects to standardise epidural pumps and beds, but there are opportunities to further standardise and rationalise equipment.

Recommendations

21 We make the following recommendations to the Health Board.

Exhibit 1: Recommendations to the Health Board

We make four recommendations to help improve policy and procedures by making sure they are all up to date. To explore the need and possible benefits of a single inventory for medical equipment. To look at whether there are benefits for a single approach to equipment libraries instead of three libraries. And to share the good practice we identified on risk and trend analysis more widely in the health board.

Recommendations	
Policies and procedures	
R1	Prioritise the completion of updated procedure documents to support the Medical Devices and Equipment Management Policy.
Medical equipment inventory	
R2	Scope the need for, and potential benefits of, a single inventory of medical equipment which brings together all the key data items and assesses clinical risk.
Medical equipment libraries	
R3	Explore the benefits of standardising the equipment library services across the three sites by bringing them under the same managing department.
Sharing of good practice	
R4	Share with the Quality and Safety Executive (QSE) the positive work being undertaken by medical equipment groups to identify potential trends in incidents. This is as an example of good practice which could be replicated elsewhere in the Health Board.

Appendix 1

Management response

Exhibit 2: Management response

All recommendations are accepted, and management describe a sensible staged approach to implementation. All actions should be completed by the end of 2017. The most important recommendation, to complete updating policies and procedures will be completed in risk order and totally by the end of June 2017. This is a well-structured and thoughtful response to our work.

Ref	Recommendation	Intended outcome/ benefit	High priority	Accepted	Management response	Completion date	Responsible officer
Policies and Procedures							
R1	Prioritise the completion of updated procedure documents to support the Medical Devices and Equipment Management Policy.	To remove the use of legacy documents and ensure staff have access to up to date procedural information.	Yes	Yes	The Medical Device Oversight Group has identified the following supporting procedures as being the initial priorities for development in the organisation:		Adrian Thomas/ Patrick Hill
					When things go wrong. Selection and Procurement. Commissioning.	31/01/17 31/01/17 31/01/17	

Ref	Recommendation	Intended outcome/ benefit	High priority	Accepted	Management response	Completion date	Responsible officer
Policies and Procedures							
R1	Prioritise the completion of updated procedure documents to support the Medical Devices and Equipment Management Policy.	To remove the use of legacy documents and ensure staff have access to up to date procedural information.	Yes	Yes	**Maintenance and Repair**	31/04/17	Adrian Thomas/ Patrick Hill
					User Training and Normal Use	31/04/17	
					Cleaning and Decontamination	31/04/17	
					Records and Instructions Disposal	30/06/17	
Medical Equipment Inventory							
R2	Scope the need for, and potential benefits of, a single inventory of medical equipment which brings together all the key data items and assesses clinical risk.	A single inventory of equipment could enable the Health Board to: • determine how much it is spending on medical equipment • provide a full picture of upcoming replacement needs and costs in relation to out-of- life equipment above and below £5000; • establish how many different variations of a single type of equipment are held by the Health Board to help identify the scale of potential risks and scope for rationalisation; and • gain assurance that processes in place to regulate the acquisition of devices are being followed and working effectively in relation to the purchase of items below £5000.			We will progress discussions regarding this and the potential benefits with the All Wales Medical Equipment Management Group and the Medical Physics and Engineers sub Committee of the Welsh Scientific Advisory Committee. The Wales Audit Office are also currently contacting Cardiff and Vale regarding their single inventory.	30/06/17	Adrian Thomas/ Patrick Hill

Ref	Recommendation	Intended outcome/ benefit	High priority	Accepted	Management response	Completion date	Responsible officer
Medical Equipment Libraries							
R3	Explore the possibility of standardising the equipment library services across the three sites by bringing them under the same managing department.	To provide staff using equipment libraries with a consistent level of service and range of equipment across sites.		Yes	We will review the equipment library provision across the Health Board and make recommendations regarding service provision on the major sites to the Executive Management Group.	30/05/17	Adrian Thomas/ Nigel Lee/ Bethan Jones
Sharing of good practice							
R4	Share with QSE the positive work being undertaken by medical equipment groups to identify potential trends in incidents. This is as an example of good practice which could be replicated elsewhere in the Health Board.	To highlight to QSE existing good practice so that it can be used to improve the identification of trends in incidents in other areas of the Health Board.	Yes	Yes	We will present this at the Quality, Safety and Experience Committee.	06/12/16	Adrian Thomas/ Patrick Hill

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