PWYLLGOR CYLLID FINANCE COMMITTEE

| DYDDIAD Y CYFARFOD: DATE OF MEETING: | 23 March 2021 |
|--|---|
| TEITL YR ADRODDIAD: | Investment in Medical Device Equipment to meet Audit |
| TITLE OF REPORT: | Requirements and reduce Risk of Harm |
| CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR: | Huw Thomas - Director of Finance |
| SWYDDOG ADRODD: | Chris Hopkins, Head of Clinical Engineering, Innovation & |
| REPORTING OFFICER: | Research. |

Pwrpas yr Adroddiad (dewiswch fel yn addas) Purpose of the Report (select as appropriate)

Er Gwybodaeth / For Discussion

ADRODDIAD SCAA SBAR REPORT

Sefyllfa / Situation

Every year the Clinical Engineering Department undertakes a review of the status of medical devices currently being utilised within the Health Board (HB). On the back of these annual reviews and in line with audit requirements, it was determined that a number of medical devices required replacement, or additional medical devices needed to be purchased in order for the HB to be compliant with both audit and patient safety requirements.

The purpose of this paper is to justify the case for investment in medical equipment in order that the HB may ensure compliance with statutory and audit requirements, thus reducing the risk of potential harm to both staff and patients. The additional investment will enable greater resilience in service provision through possession of sufficient resource in terms of available equipment.

This paper will illustrate areas where investment has been made and the rationale supporting the decisions.

Cefndir / Background

Medical devices are defined as any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/ or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purposes of :

- Diagnosis, prevention, monitoring, treatment or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- Investigation, replacement or modification of the anatomy or of a physiological process;
- Control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means.

There are c.31,000 medical devices within the HB, with an estimated replacement cost of c.£85m and an annual recurring maintenance cost of c.£8.5m (10% of purchase value). These range from small hand-held devices; such as syringe drivers or infusion pumps, to larger pieces of equipment;

such as intensive care ventilators and (ultimately) Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scanners.

There are currently a number of medical devices which have passed their prescribed useful life, yet are still in operation throughout the HB; ranging from smaller items, such as medical gas equipment to larger pieces of equipment, such as paediatric beds. There are also a number of items that are required to maintain, or to be used with, other medical equipment; these have also been documented below.

The last report of this type to Capital Estates and Information Management and Technology (CEIM&T) Sub-Committee in July 2020 outlined overdue, current and future capital and revenue investment needs - principally where medical devices were concerned. This detailed review of the medical device inventory followed the theme of previous reports produced following a serious incident in 2017. These reports were the first to furnish the HB with insight into strategic medical equipment replacement requirements, based upon a significant evidential platform.

Table 1 identifies the number of devices that the HB should have considered as being potentially Due/ Overdue/ Requiring Replacement from an age/ technical perspective (as at July 2020):

| Table 1. Medical Devices (In-Use) identified as potentially Due/ Overdue/ Requiring |
|---|
| Replacement. |

| | Capital | | Revenue | | Overall | |
|------|---------|-------------|---------|-------------|---------|-------------|
| | No. of | Est. | No. of | Est. | No. of | Est. |
| | Devices | Replacement | Devices | Replacement | Devices | Replacement |
| | | (£m) | | Cost (£m) | | Cost (£m) |
| | | | | | | |
| 2020 | 1,016 | £23.48 | 3,813 | £5.32 | 4,829 | £28.8 |
| | | | | | | |
| 2019 | 1,131 | £30.07 | 3,210 | £5.29 | 4,341 | £35.36 |
| | | | | | | |

CEIM&T - July 2020

From Table 1:

- Devices defined in terms of revenue the number identified as potentially requiring replacement had increased by 603 from the previous year. Despite this rise, the estimated replacement cost had only seen a relatively small increase of £30k – this being largely accounted for by lower cost devices being identified and on-going cleansing work.
- Overall replacement costs have fallen by £6.56m.
- While the welcome fall in the number and value of capital devices requiring replacement can
 be attributable to recent efforts and the availability of capital funding, no similar revenue
 stream existed and (as highlighted in previous CEIM&TSC reports), the number of
 'Revenue' devices identified continued to grow.

Items* procured in order for the HB to be able to de-risk certain outstanding actions as per audit requirements and improve patient care provision include:

Wi-Fi batteries for infusion pumps – These were due for replacement within one year. They are required to support drug library updates and to prevent medication errors.

Vital signs monitors – These monitors take measurements of the body's most basic functions. The four main vital signs routinely monitored are; body temperature, pulse rate, respiration rate and blood pressure. Current records indicate that the age of some monitors in use is in the region of 12-25 years (useful expected life is 10 years). One record suggests an item in excess of 40 years.

Non-Invasive Blood Pressure monitors – These monitors allow the recording and measurement of blood pressure via a non-invasive system. Within the HB, they are required for use in acute and community services (including the Heart Failure service) – at present staff either do not have a device or there is a need to replace unsuitable existing devices.

Bariatric chairs, trollies, recliners and commodes – These pieces of equipment are larger than average chairs, trollies or commodes and are able to cope with heavier loads; some are suitable for a seated weight of up to 50 stone. Following a recent audit, it was concluded that there was insufficient resource within the HB for potential patient requirements. Purchase of equipment will also reduce current rental costs, which are circa £300k every 6 months.

Portering chairs – Again following a recent audit it was concluded that there was an insufficient number of usable chairs for the transportation of patients within acute sites.

Suction regulators - A suction regulator is a medical device that converts the high-pressure vacuum that is supplied by the Hospital central vacuum system to a safe level for use on a patient. While most of the equipment currently in operation within the HB is of unknown/ indeterminable age, it has passed its recommended usage life.

Mattresses at Bronglais General Hospital (BGH)— Hybrid power mattresses and dynamic mattresses use air cells which inflate and deflate alternately, powered by a pump/ control unit. Following an audit of equipment levels, it was determined that there was insufficient supply held onsite.

Paediatric beds – These are designed for infants, toddlers, and young children who are patients in healthcare facilities. Current beds do not comply with latest entrapment guidance at either Glangwili General Hospital or BGH.

RFID for acute and field sites – Radio Frequency Identification (RFID) is a wireless system comprised of two components: tags and readers. The reader is a device that has one or more antennae that emit radio waves and receive signals back from the RFID tag. These have been designated as required for all new assets at both acute and field hospital sites and will support the Scan 4 Safety rollout across Wales.

Scales for Oxford hoists – These are digital scales, which are microprocessor controlled, digital weighing devices designed for use with Oxford Hoists. There are approximately 70 Oxford Hoists in use throughout the HB without scales.

Portable suction units (Laerdal) – The Laerdal Suction Unit (LSU) is a portable, powerful and highly reliable suction unit designed for optimal preparation in emergency situations. Most of the equipment currently in operation within the HB has passed its recommended usage life.

*A detailed listing of units ordered and associated costs is provided in the financial table within the assessment.

Assessiad /Assessment

Based on the above data, it has been determined that there is an urgent need for procuring approximately £1.842m of medical equipment due to items being classed as obsolete due to age, or due to items integral to providing patient care not being present at some of the sites throughout the HB. The following table itemises the current spend on medical equipment for the HB as part of this piece of work:

| Description | Site/s | De-risking of item or Improvement of service | Qty. | Actual Total Cost (inc VAT) |
|--|-----------------|--|-------|--------------------------------|
| Wi-Fi Batteries for Infusion Pumps | All | Improvement | 1,100 | £330,000 |
| Monitor - Vital Signs | BGH | De-Risk | 20 | £35,100 |
| | GGH | De-Risk | 33 | |
| Monitor - Vital Signs | PPH | De-Risk | 8 | £78,960 |
| | WGH | De-Risk | 10 | |
| Danima Davida | WGH | De-Risk | 4 | C10.070 |
| Pacing Boxes | PPH | De-Risk | 4 | £19,078 |
| AED - Defibrillators | All | De-Risk & Improvement | 69 | £91,009 |
| Patient Trolleys | GGH | De-Risk | 16 | £53,222 |
| NIBP Monitors | Community | De-Risk | 100 | £10,000 |
| | PPH | De-Risk | 50 | |
| Oxygen Single Flowmeters | GGH | De-Risk | 100 | £9,716 |
| | Pembs | De-Risk | 46 | |
| Entonox Demand Valves | GGH | De-Risk | 22 | £6,065 |
| | Ceredigion | De-Risk | 12 | |
| Entonox Demand Valves | Pembs | De-Risk | 26 | £7,538 |
| | Pembs | De-Risk | 24 | £36,287 |
| Suction Regulators | GGH | De-Risk | 120 | |
| - | PPH | De-Risk | 100 | |
| Suction Regulators | Ceredigion | De-Risk | 20 | £1,588 |
| Paediatric Beds | GGH & BGH | De-Risk | 14 | £26,460 |
| | BGH | De-Risk | 15 | £9,088 |
| | GGH | De-Risk | 15 | £9,088 |
| Hybrid Power Mattress & Pump | PPH | De-Risk | 15 | £9,088 |
| | WGH | De-Risk | 15 | £9,088 |
| RFID - asset tracking for Medical Devices | Field Hospitals | Improvement | | £107,826 |
| RFID - asset tracking for Medical Devices | All Acute | Improvement | | £133,630 |
| | BGH | De-Risk | 1 | £2,448 |
| Automated Lateral Transis - Costs | GGH | De-Risk | 1 | £2,448 |
| Automated Lateral Turning System | PPH | De-Risk | 1 | £2,448 |
| | WGH | De-Risk | 1 | £2,448 |
| Cushion | BGH | De-Risk | 10 | £6,204 |
| | GGH | De-Risk | 15 | £9,306 |
| | PPH | De-Risk | 11 | £6,824 |
| | WGH | De-Risk | 14 | £8,686 |
| | BGH | De-Risk | 15 | £27,898 |
| Dynamic Mattresses | GGH | De-Risk | 15 | £27,898 |
| | PPH | De-Risk | 15 | £27,898 |

| | WGH | De-Risk | 15 | £27,898 |
|---|-----------|--------------------|-----|----------------|
| Tourniquet x 5 | WGH | De-Risk | 5 | £15,455 |
| Tourniqueex5 | BGH | De-Risk | 80 | £68,256 |
| | GGH | De-Risk | 50 | £42,660 |
| Portable Suction Units | PPH | De-Risk | 10 | £8,532 |
| | WGH | De-Risk | 80 | £68,256 |
| NIBP Monitors | Community | De-Risk | 200 | £20,000 |
| Monitor - Vital Signs | WGH | De-Risk | 18 | £24,953 |
| RFID - asset tracking for Medical | WGH | Improvement | 16 | 124,933 |
| Devices | All | • | | £108,257 |
| | GGH | De-Risk | 25 | £29,880 |
| Scales for Oxford Hoists | PPH | De-Risk | 15 | £17,928 |
| Scales for Oxford Holses | WGH | De-Risk | 15 | £17,928 |
| | BGH | De-Risk | 15 | £17,928 |
| | GGH | De-Risk | 40 | £23,440 |
| Portoring Chairs | PPH | De-Risk | 20 | £11,720 |
| Portering Chairs | WGH | De-Risk | 20 | £11,720 |
| | BGH | De-Risk | 20 | £11,720 |
| | GGH | De-Risk | 40 | £4,200 |
| Oxygen Bottle Holder for Manchester | PPH | De-Risk | 20 | £2,100 |
| INN | WGH | De-Risk | 20 | £2,100 |
| | BGH | De-Risk | 20 | £2,100 |
| | GGH | De-Risk | 50 | £850 |
| | PPH | De-Risk | 25 | £425 |
| Opt.951 - IV Pole | WGH | De-Risk | 25 | £425 |
| | BGH | De-Risk | 25 | £425 |
| | GGH | De-Risk | 40 | £5,480 |
| | PPH | De-Risk | 20 | £2,740 |
| Orthopaedic Leg Rest and its Support | WGH | De-Risk | 20 | £2,740 |
| | BGH | De-Risk | 20 | £2,740 |
| | GGH | De-Risk | 40 | £1,760 |
| Plastic Document Holder on Rear of | PPH | De-Risk | 20 | £880 |
| Chair | WGH | De-Risk | 20 | £880 |
| | BGH | De-Risk | 20 | £880 |
| | GGH | De-Risk | 10 | £9,520 |
| Manchester Heavyweight Portering | PPH | De-Risk | 5 | £4,760 |
| Chair | WGH | De-Risk | 5 | £4,760 |
| 5 | BGH | De-Risk | 5 | £4,760 |
| | GGH | De-Risk | 2 | £1,920 |
| 20" Single Deticat Lee Herritage | PPH | De-Risk | 1 | £1,920 £960 |
| 39" Single Patient Use HoverMatt - Box of 10 | WGH | De-Risk | 1 | £960 |
| 50% 01 10 | BGH | De-Risk | + | £960 |
| | | De-Risk De-Risk | 1 | |
| , | GGH | | 2 | £3,648 |
| HoverMatt 39" Double Coated | PPH | De-Risk | 1 | £1,824 |
| | WGH | De-Risk | 1 | £1,824 |
| | BGH | De-Risk | 1 | £1,824 |
| | GGH | De-Risk | 2 | £7,188 |
| Battery pack for HoverJack | PPH | De-Risk | 1 | £3,594 |
| | WGH | De-Risk | 1 | £3,594 |

| HB Total ordered spend on medical equipment as at 10.02.21 | | | | £1,842,024* |
|---|-----|---------|-----|-------------|
| Bariatric Chairs/ Trollies PSU for Bbraun Infusion Devices | WGH | De-Risk | 20 | £360 |
| | PPH | De-Risk | 20 | £360 |
| | GGH | De-Risk | 40 | £720 |
| | BGH | De-Risk | 20 | £360 |
| | BGH | De-Risk | 55 | £23,880 |
| | WGH | De-Risk | 55 | £23,880 |
| Pariatric Chaire / Trolling | PPH | De-Risk | 55 | £23,880 |
| | GGH | De-Risk | 110 | £48,300 |
| | BGH | De-Risk | 1 | £3,594 |

^{*}Figure does not include an additional c.£160k worth of orders yet to be placed or in progress. These include; Doppler machines (for both foetal and vascular usage), additional bariatric recliners and trollies, Baby lifeline training equipment, ICU ceiling panels, docking stations and cylinder trollies. All of these items are expected to be ordered in the next few weeks.

- The total value committed on de-risking items is £1.12m
- The total value committed on improvement of patient provision is c.£725k

Summary of Benefits against the preferred way forward

The benefits from investment will be:

- An increased level of safety for both staff and patients resulting from use of appropriate upto-date equipment;
- A reduction in clinical incidents due to the removal of obsolete medical equipment;
- The ability to address and then close off risks with regards to audit requirements;
- Mitigation of any potential enforcement action, (previous enforcement action received c.1998).
- A reduction in costs relating to repairs of medical devices, as all equipment will be under warranty for 1 year, so there will be a non-recurrent benefit in the region of c.£90k.
- Increased capacity on the wards due to sufficient equipment being available.

Argymhelliad / Recommendation

The Finance Committee is asked to note the expenditure incurred during the year on medical equipment below the capitalisation threshold, which has been submitted to the Executive Team for approval, and which will be noted in the Financial Report to the Board.

| Amcanion: (rhaid cwblhau) Objectives: (must be completed) | |
|--|---|
| Cyfeirnod Cofrestr Risg Risk Register Reference: | Risk 384 (Score 8): Ability to fully comply with statutory and manufacturer guidelines for medical devices and equipment. |
| Safon(au) Gofal ac lechyd: Health and Care Standard(s): | Safe Care: Standards 2.1 Managing Risk and Promoting Health and Safety |
| | Standard 2.9 Medical Devices, Equipment and Diagnostic Systems Effective Care: |
| | Standards 3.1 Safe and Clinically Effective Care |

| Amcanion Strategol y BIP: UHB Strategic Objectives: | To improve the productivity and quality of our services using the principles of prudent health care and the opportunities to innovate and work with partners. To deliver, as a minimum requirement, outcome and delivery framework work targets and specifically eliminate the need for unnecessary travel & waiting times, as well as return the organisation to a sound financial footing over the lifetime of this plan |
|---|---|
| Amcanion Llesiant BIP: UHB Well-being Objectives: | Support people to live active, happy and healthy lives |

| Gwybodaeth Ychwanegol: Further Information: | |
|---|---|
| Ar sail tystiolaeth: | Evidence is included within the report. |
| Evidence Base: | |
| | |
| Rhestr Termau: | Explanation of terms is included within the report. |
| Glossary of Terms: | · |
| Partïon / Pwyllgorau â ymgynhorwyd | Details included within the report/ bid. |
| ymlaen llaw y Pwyllgor Cyllid: Parties | · |
| consulted prior to Finance Committee | |

| Effaith: (rhaid cwblhau) Impact: (must be completed) | |
|--|---|
| Ariannol / Gwerth am Arian: Financial / Service: | Significant opportunity exists in relation to a standardised approach to equipment replacement. |
| Ansawdd / Gofal Claf: Quality / Patient Care: | Mitigate potential harm to patients through the use of ageing equipment. |
| Gweithlu: Workforce: | Safeguard our workforce by providing the required equipment to support Health and Safety at Work |
| Risg: Risk: | Risks are described in the report. |
| Cyfreithiol: Legal: | Potential litigation from sustained harm to patients and staff caused by use of ageing equipment. |
| Enw Da: Reputational: | Potential risk of reputational damage to the HDUHB through legal challenges from utilisation of ageing equipment. |
| Gyfrinachedd: Privacy: | Not applicable |
| Cydraddoldeb: Equality: | If systems are not robust there is a potential that patients will be harmed through the use of ageing equipment. |