



PWYLLGOR ADNODDAU CYNALIADWY SUSTAINABLE RESOURCES COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	23 August 2021
TEITL YR ADRODDIAD: TITLE OF REPORT:	Investment in Clinical Equipment
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Andrew Carruthers Director of Operations
SWYDDOG ADRODD: REPORTING OFFICER:	Gareth Rees Deputy Director of Operations

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

Ar Gyfer Trafodaeth/For Discussion

ADRODDIAD SCAA SBAR REPORT

Sefyllfa / Situation

The purpose of this report is to provide the Sustainable Resources Committee with the information from the Strategic Medical Device Replacement report, previously presented to the Capital, Estates and Information Management & Technology Sub-Committee at its meeting on 21 July 2021.

The Committee is requested to receive the report and discuss key issues arising from the narrative and data provided.

Cefndir / Background

This report provides the Sustainable Resources Committee with the latest capital and associated strategic investment information relating to the Health Board's medical devices inventory position.

Highlights include:

- Overall investment into medical devices in 2020/21 totalled £4.67m
- The inventory currently consists of 31,405 devices
- The estimated replacement cost for the inventory is £91.82m
- Devices in service that are overdue replacement total 5,222 with an estimated replacement cost of £35.44m
- The age profile of devices in-service is improving – with an increase in newer items in service
- At current investment rates, the replacement cost of items overdue replacement will rise to £81m by 2031 – this will introduce significant clinical risk. Annual investment of £4-6m will hold the backlog figure at the 2021 position. To clear the backlog within 5 years would require an annual investment of £12m
- Investment into devices falling outside of the definition of capital totalled £2.06m in 2020/21 which marks a significant change in the funding provisions for medical devices

Asesiad / Assessment

The Strategic Medical Device Replacement report published in July 2020 outlined the overdue, current and future capital investment needs associated with medical devices. In light of COVID-19, this report followed several months of intense and rapid procurement intended to prepare the Health Board's existing hospital sites and additional field hospitals for the anticipated influx of COVID-19 patients. Such has been the level of medical device acquisitions, it had been anticipated that the report would describe the prevailing position. However, taking into consideration the level of activity that continued throughout the year, with hindsight, it perhaps should have been viewed as presenting an interim position.

The update provided in this report has been prepared on the understanding that the vast majority of acquisitions due to the pandemic have now been concluded. However, due to the level of continued activity, this report may need to be viewed as a snapshot when the 2022 version is presented.

Supporting Notes:

- Unless indicated otherwise, all data used in this report originates from a snapshot of the medical device inventory taken on 7th June 2021. It relates to devices that are known or believed to be either 'In-Use' or in 'Storage' and are assigned to one of the following Maintenance Overseers – Clinical Engineering, Estates, Hospital Sterilisation and Decontamination Unit (HSDU), Pathology or Radiology. The term 'Maintenance Overseer' refers to the department that has maintenance management responsibility for each type of device – their detailed responsibilities being defined within the recently revised Medical Device Management Policy (467).
- As a consequence of the inventory being managed by Clinical Engineering, a higher level of assurance can be provided that the information pertaining to the devices managed is current. At this time, the same level of assurance cannot be provided for a small number of pockets of devices as well as some devices managed by the other maintenance overseers in Pathology – the anticipated progress in resolving these issues continues to be hampered by on-going events.
- In terms of the split, 98% of all devices on the medical device inventory are identified as having Clinical Engineering as their maintenance overseer – this equates to 72% of the total estimated replacement cost.
- Estimated replacement costs are provided on an estimated basis and based on the list price including VAT at the time of purchase and have a notional annual uplift component based on an inflation figure of 2%. This standardised approach removes the vagaries of using the price paid for devices that often vary e.g. with/without VAT, differing levels of unrepeatably discount etc.
- Whilst some specialised medical devices might have a shorter or longer expected service life, regulatory bodies and suppliers generally consider that devices over 10 years old should not remain in service. Therefore, for the majority of devices, this service life is used as the nominal service life used within this report. It should be noted that while many devices will operate efficiently and safely well beyond 10 years, numerous factors can also combine to shorten the service life of individual devices.

Previous Position (July 2020)

Table 1 summarises the overall position/s as reported in previous reports and shows the quantity and estimated replacement cost of the medical devices on the inventory. Also shown is the number and value of these devices that had been identified as 'potentially' requiring replacement.

Table 1: Devices on Health Board inventory presented in previous years.

	Medical Devices* on Health Board Inventory		Medical Devices* identified as potentially Due/Overdue/Requiring Replacement	
	No. of Devices	Est. Replacement Cost (£m)	No. of Devices	Est. Replacement Cost (£m)
2020	28,975	£84.75	4,829	£28.80
2019	23,007	£77.45	4,341	£35.36
2018	22,439	£71.40	4,534	£22.30

*Status 'I' (In-Use) devices across all maintenance overseer groups.

Note 1. The modest increase between 2018 and 2019 was due to a combination of additional devices and general cleansing of the newly developed inventory. As reported in July 2020, the significant increase between 2019 and 2020 was almost entirely attributable to devices acquired for, and during, the early stages of COVID-19 preparations.

Capital and End of Year Investment

Far from an anticipated slowdown in medical device acquisition following the easing of the first COVID-19 wave, significant levels of funding for medical devices continued to be made available for the remainder of 2020-21 as shown in Table 2.

Table 2. Medical device funding in 2020/21.

Source of Funding	Est. Level of Funding (£m)
DCP - including End of Year	£2.21
Revenue stream (note 2)	£2.06
Charitable funds	£0.40

Note 2. All previous reports have called out the limited financial strategy for the replacement of devices deemed to be revenue by nature (i.e. below the capital £5k threshold). With the onset of the second COVID-19 wave, resources were made available for the acquisition of a range of 'revenue' medical devices as required by clinical services – ultimately these were used to replace old and/or Out Of Support (OOS) devices and will greatly assist in dealing with this often overlooked value group of equipment – see also Note 9.

Further to the funding sources identified in Table 2, additional medical devices were also acquired via alternative resourcing routes:

- Welsh Government (WG)/Department of Health (DoH) supplied devices. Early pandemic preparations led to medical devices acquired centrally for later distribution on a priority/need basis. As demand of these reserves lessened, a range of devices were offered to Health Boards across Wales.
- Directorate Funds. The pandemic resulted in lower than normal service activity across some directorates, which allowed for the release of some funding towards the procurement of replacement and/or additional devices.
- The funding and acquisition of devices through these one-off routes enabled funding previously planned for the same purposes to be redirected towards the replacement of other devices.

Current Position (June 2021)

Given the aforementioned funding and acquisitions, Table 1 has been updated to include the new position as of June 2021 – see Table 3.

Note 3. To fully appreciate all changes that recent events have had on the inventory, it is necessary to take a view of the entire pandemic period, which is best done by comparing the positions in July 2019 and June 2021.

	Medical Devices* on Health Board Inventory		Medical Devices* identified as potentially Due/Overdue/Requiring Replacement	
	No. of Devices	Est. Replacement Cost (£m)	No. of Devices	Est. Replacement Cost (£m)
Jun-21	31,405	£91.82	5,222	£35.40
Jul-20	28,975	£84.75	4,829	£28.80
Jul-19	23,007	£77.45	4,341	£35.36
Sep-18	22,439	£71.40	4,534	£22.30

*Status 'I' (In-Use) devices across all maintenance overseer groups.

Note 4. The quantity and value of devices shown in July 2020 include those devices provided to WG for the COVID-19 relief effort for India (see Note 6), whereas the June 2021 does not. The increases seen between July 2020 and June 2021 are in addition to the removal of these redistributed devices.

Table 4 details those devices on the inventory for which Clinical Engineering are assigned as the maintenance overseer. The impact of the pandemic on the quantity and value of devices this department manages can be seen below:

- 99% of the increase in the quantity of medical devices (detailed in Note 3) is attributable to devices for whom Clinical Engineering is the maintenance overseer;
- 90% of the increase in the value of medical devices (detailed in Note 3) is attributable to devices for whom Clinical Engineering is the maintenance overseer;
- Both are consistent with the nature of devices required to treat COVID-19 patients.

	No. of Devices	Est. Replacement Cost (£m)
Jun-21	30,705	£65.84
Jul-20	28,306	£60.58
Jul-19	22,370	£52.90

*Status 'I' (In-Use) devices with Clinical Engineering as their maintenance overseer.

Additional Devices

Despite many obstacles, the goal of adequately equipping Health Board sites and nine additional Field Hospitals to deal with any influx of COVID-19 patients was successfully achieved. Furthermore, the Health Board was fortunate to not experience the large numbers of patients being admitted to its sites as initially anticipated. Given this, and the easing of the second wave, the number of operationally ready Field Hospitals has gradually reduced.

The requirement to return the Field Hospitals to their former use, whilst ensuring the Health Board retains sufficient medical device stock to deal with any potential third wave (and/ or severe seasonal flu outbreak), necessitated an urgent need to acquire storage facilities. Therefore, the Health Board has secured a number of storage locations for the medium term.

Table 5 outlines the quantity and value of Clinical Engineering managed medical devices currently held at storage locations, and their status on the inventory, in addition to those in Table 4.

Table 5: Devices with 'other' status levels that have Clinical Engineering as their maintenance overseer.		
Status Level	No. of Devices	Est. Replacement Cost (£m)
Quarantine	2,074	£5.15
Received Not Accepted (RNA)	453	£0.95
Total	2,527	£6.10

Devices described as 'Quarantine' will include:

- New devices that have been acceptance tested but have yet to be deployed into service;
- New/used devices acquired for and/or returned from decommissioned Field Hospitals;
- Previously used devices that have been replaced by new devices but are being retained in the short-medium term in the event of any future surge e.g. intensive care ventilators, patient monitors and beds;
- In the short-medium term, a proportion of quarantined devices will be used to replace old stock, whilst others will be deployed in addition to existing stock and the remainder will be decommissioned.

Those devices described as 'Received Not Accepted' (RNA) are:

- Acquired devices that have been receipted but not fully acceptance tested by the relevant maintenance overseer;
- In the medium term, these RNA devices will replace old/OOS devices, whilst a minority will be deployed in addition to the existing stock where/should clinical need dictate.

Note 5. Neither the quantity nor value of any of the devices included in Table 5 have been included in any previous tables. Consequently, when they are deployed there will be a corresponding change to levels shown previously.

Redistributed Medical Devices

Due to the medical equipment procurement successes achieved by the Health Board as part of its pandemic response preparations, the Health Board was able to offer the following devices when approached by the Welsh Government in May 2021 for support to India:

- 50 x Continuous Positive Airway Pressure (CPAP) drivers;
- 450 x oxygen concentrators.

Additionally, the Health Board was able to offer 200 CPAP devices to Aneurin Bevan University Health Board (ABUHB) in summer 2020, who were experiencing significant front line COVID-19 patient demand.

Note 6. The medical device data presented in this report has been updated to reflect the redistribution of these devices – also see Note 4.

Table 6 illustrates the increase in the number of devices on the inventory and its subsequent impact on the estimated replacement cost.

Table 6: Inventory changes between July 2019 - 2021.

	Number of Medical Devices on Health Board Inventory			Estimated Replacement Cost of the Medical Devices on the Health Board Inventory.		
	No. of Devices	Increase since 2019	Increase since 2019 (%)	Replacement Cost (£m)	Increase since 2019 (£m)	Increase since 2019 (%)
Jun-21	31,405	8,398	37%	£91.82	£14.37	19%
Jul-20	28,975	5,968	26%	£84.80	£7.35	9%
Jul-19	23,007			£77.45		

Analysis of the data in Table 6 indicates:

- An overall increase of 8,398 devices – this increase being almost entirely attributable to the devices acquired to deal with COVID-19 and the necessity to increase bed capacity;
- This increase is in addition to those new devices that have already been deployed and the removal of old stock from service and clinical engineering inventory – also see Notes 4 and 6;
- As suggested in Note 5, once deployed, a proportion of the devices in Table 5 will impact on the quantity and value of ‘In-Use’ devices on the inventory.

Closer scrutiny of the inventory allows the In-Use devices to be categorised in terms of their natural capital (>£5k) and revenue (<£5k) definitions as per Table 7.

Table 7. Medical Devices (*In-Use*) currently on the Health Board Inventory.

Capital		Revenue		Overall	
No. of Devices	Est. Replacement Value (£M)	No. of Devices	Est. Replacement Value (£M)	No. of Devices	Est. Replacement Value (£M)
2,865	£64.81	28,540	£27.01	31,405	£91.82
9%	71%	91%	29%		

Despite numbering only 9% of the overall asset holding, those devices classified as being capital in nature account for >70% of the total value of the Health Board’s devices.

Table 3 showed the number of devices that remain in clinical use, but for a variety of reasons (mainly due to being past their expected service life) should be considered by the service as potentially being due or overdue replacement. Further investigation of these devices shows the split between capital and revenue devices as illustrated in Table 8.

Table 8: Devices (In-Use) identified as potentially Due/Overdue Replacement.

	Capital		Revenue		Overall	
	No. of Devices	Est. Replacement (£m)	No. of Devices	Est. Replacement (£m)	No. of Devices	Est. Replacement (£m)
2021	981	£30.56	4,241	£4.88	5,222	£35.44
2020	1,016	£23.48	3,813	£5.32	4,829	£28.80
2019	1,131	£30.07	3,210	£5.29	4,341	£35.36

Table 8 highlights several issues:

- Despite a decrease in the number of capital valued devices due for replacement in 2021, there is a significant increase (£7m) in their estimated replacement cost;
- Whilst the number of revenue valued devices due for replacement has increased, their overall replacement cost has fallen;
- The overall impact of these variations is that the number and replacement value of devices that potentially need replacing has now increased compared to the 2020 position;
- Analysis of Table 13 suggests one explanation for this change. In 2021, due to reaching their 10-year service life, several of the Health Board's Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) scanners now fall into the category of requiring replacement. Having a combined replacement value of approx. £7.7m, this appears to account for the unwanted reversal of the downward trend. This impact was not unexpected having been highlighted in the July 2020 report along with several additional HSDU devices that have also reached an age when they should be considered for replacement;
- Due to the high cost of each scanner, if funding is to be sourced internally, replacement of a single scanner would have the potential to consume an entire year's equipment allocation from the Discretionary Capital Programme (DCP). Therefore, a specific business case for funding would be required to be developed for WG consideration.

Note 7. As previously stated, the snapshot on which this report is based was taken in June 2021. Therefore, this paper may not capture/reflect imminent/planned activity. Examples that illustrate this relate to the aforementioned Radiology scanners:

- *A project to replace the MRI scanner at Withybush General Hospital (WGH) is currently underway with completion expected in the latter part of 2021;*
- *Funding has also been secured to replace the CT scanner at WGH as well as providing an additional system at Glangwili General Hospital (GGH);*

Given the level of funding involved with these projects, once complete, there would be a significant impact (reduction) on the overall value of devices shown in Table 8, which suggests that the previous downward trend is indeed continuing if somewhat currently disguised.

'Other' devices on the medical device inventory

All devices on the inventory are assigned to one of several status levels, the two yet to be described are 'Withdrawn' and 'Un-Located'. Whilst the former is self-explanatory, Un-Located refers to Health Board owned devices whose whereabouts cannot be established despite efforts to do so. Occasionally, devices previously categorised as "Un-Located" reappear after time and records are amended accordingly. However, the general trend and expectation is that there will be a small annual increase with Table 9 suggesting this is indeed the case.

As inventory development continues, and records are subject to regular scrutiny, greater assurance can be taken over the reliability of data, including which devices have not been located.

	No. of Devices	Est. Replacement Cost (£m)
Jun-21	4,750	£5.2
Jul-20	4,300	£4.4
Jul-19	3,200	£2.1

Further analysis of the data in Table 9 suggests:

- Of the 4,750 devices, 183 are deemed capital and 4,567 are revenue by accounting definition;
- The value of the capital devices is c.£2.4m and revenue c.£2.8m;
- Included in the capital devices are hoists, trolleys, ultrasound probes and scopes;
- An entire cross-section of devices is included in the revenue total.

Note 8. Inventory devices are given a status 'Withdrawn' when their removal or decommissioning has been witnessed and/or sufficient proof of said is provided. In instances where such proof has not been forthcoming, the assumption must remain that the devices are still in circulation but are unable to be located – thus "Un-Located". A significant proportion of devices date back several years prior to the current inventory and systems being introduced. It is expected that these devices have been removed from use albeit not documented as such and no longer exist in service.

Table 10 shows a breakdown of devices in terms of their capital/revenue definitions and age.

Year of Acceptance	Age	Capital	Revenue	Overall Quantity	No. as % of Overall Devices
2021	0	197	2,664	2,861	9.1%
2020	1	649	7,828	8,477	27.0%
2019	2	232	3,069	3,301	10.5%
2018	3	198	2,885	3,083	9.8%
2017	4	143	1,599	1,742	5.5%
2016	5	77	2,920	2,997	9.5%
2015	6	184	1,947	2,131	6.8%
2014	7	89	913	1,002	3.2%
2013	8	105	819	924	2.9%
2012	9	127	467	594	1.9%
2011	10	192	505	697	2.2%
2010	11	78	300	378	1.2%
2009	12	91	256	347	1.1%
2008	13	125	337	462	1.5%
2007	14	64	305	369	1.2%
2006	15	57	179	236	0.8%
2005	16	54	166	220	0.7%
2004	17	41	130	171	0.5%

2003	18	12	91	103	0.3%
2002	19	41	92	133	0.4%
2001	20	18	94	112	0.4%
>20 yrs.	20+	91	974	1,065	3.4%
Totals		2,865	28,540	31,405	100%

Entering the age profile data from Table 10 into graphical form produces Figure 1.

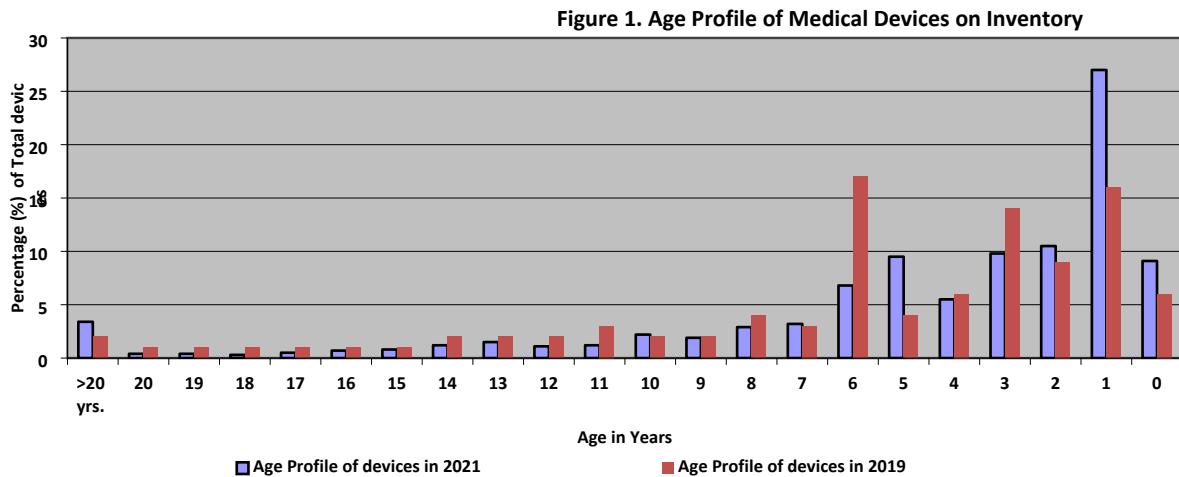


Table 10 and Figure 1 highlight:

- Whilst Figure 1 shows the number of devices >20 years old has increased (see also Table 11) when compared to the 2019 position, it also indicates a gradual improvement in the age profile of devices consistent with continued efforts to replace older/OOS devices that had been accelerated through revenue and COVID-19 initiatives;
- The increase in the number of new and/or accepted devices in 2020 as a result of the pandemic was such that it now represents 27% of the entire inventory;
- Given the majority of devices have an expected service life of 10 years, it is anticipated that in 2030, many devices will be at an age when they should be replaced – Table 12 concurs with this deduction;
- Despite only being midway through the year, devices acquired in 2021 already account for >9% of the inventory total, which suggests another significant number will be due for replacement in 2031;
- The continued cleansing of inventory data pertaining to the age and value of devices provides greater assurance in the accuracy of the overall device value and age profile portrayed within this paper – the flattening of the previous (2019 data) peak at 6 years reflects this;
- It is realistic to expect further improvements to the age profile once devices listed in Table 5 are deployed.

Table 11 shows the effect equipment replacement projects have had on the age profile of devices in clinical use across the Health Board.

- When expressed as a percentage of overall devices, the number and value of devices over 10 years old that remain in use is decreasing year-on-year;
- However, this positive reduction can be misleading due to the increase in overall device numbers, indicating that the overall number and value remains relatively stable;
- As above, the deployment of devices included in Table 5 are expected to have a positive effect on the age profile and thus the content of Table 11.

Table 11. Quantity, value and age profile of devices on the inventory over successive years.

	2018		2019		2020		2021	
	Qty.	Value (£m)	Qty.	Value (£m)	Qty.	Value (£m)	Qty.	Value (£m)
Devices on Inventory	19,424	£43.80	23,007	£77.50	28,975	£84.75	31,405	£91.82
Devices over 10 years old	4,234	£11.57	3,711	£24.20	3,536	£23.50	3,596	£22.84
	22%	26%	16%	31%	12%	28%	11%	25%
Devices over 15 years old	2,177	£4.99	1,530	£8.20	1,509	£8.90	1,804	£9.91
	11%	11%	7%	11%	5%	11%	6%	11%
Devices over 20 years old	849	£1.33	521	£2.30	507	£3.00	1,065	£3.45
	4%	3%	2%	3%	2%	4%	3%	4%

Using age and value data from the inventory, Table 12 shows the number and value of devices that will potentially require replacement due to age (if for no other reason) year-on-year over the next decade.

As previously noted, due to the intensified equipping programme that occurred in 2020 and the future financial impact of replacement in nine years' time, a significant challenge lays ahead. However, one mitigating factor which may offset the full impact of this is the transformation agenda and the proposal for a new hospital within the Health Board (although this should not be considered the primary plan).

Table 12. Year-on-year prediction of Devices that will potentially require replacement by capital & revenue

	Capital		Revenue		Overall	
	No. of Devices	Est. Replacement Value (£M)	No. of Devices	Est. Replacement Value (£M)	No. of Devices	Est. Replacement Value (£M)
2021	981	£30.56	4,241	£4.88	5,222	£35.44
2022	147	£2.66	705	£0.63	852	£3.29
2023	116	£2.12	1,240	£1.06	1,356	£3.18
2024	91	£3.04	1,252	£1.27	1,343	£4.31
2025	192	£4.83	3,446	£2.38	3,638	£7.21
2026	115	£2.39	2,930	£3.31	3,045	£5.70
2027	198	£3.01	1,330	£1.06	1,528	£4.07
2028	123	£1.85	2,288	£1.35	2,411	£3.20
2029	170	£2.47	2,542	£2.77	2,712	£5.24
2030	552	£8.70	6,102	£6.24	6,654	£14.94
2031	180	£3.19	2,460	£2.05	2,640	£5.24
	2,865	£64.82	28,536	£27.00	31,401	£91.82

Note 9. The historic issues associated with the replacement of old/OOS revenue devices resulted in the backlog of such devices increase annually – see Note 2. Appreciating the

service implications of allowing this trend to continue, the Health Board has committed to an annual allocation of £300k specifically for the replacement of such devices.

On further inspection of the devices included in the yearly totals used in Table 12, Table 13 illustrates some higher value, higher quantity and/or headline devices that would need to be considered for replacement over the coming years.

As highlighted previously, radiology scanners that are at the end of their service life and currently undergoing replacement are not covered by this report. The new equipment will feature as part of next year's annual update.

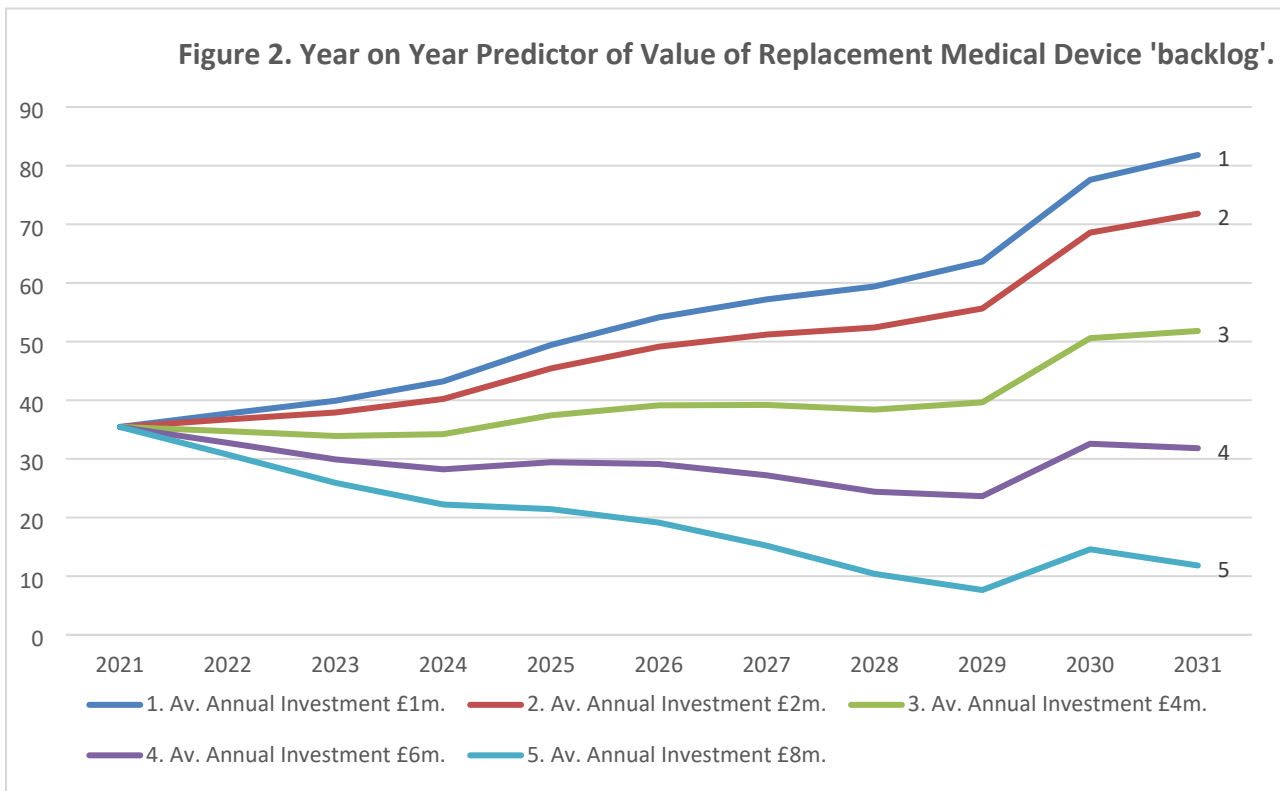
Table 13: Headline Examples of Devices & Values (£M) of devices anticipated to require Replacement.												
	Yr. 0	Yr. 1	Yr. 2	Yr. 3	Yr. 4	Yr. 5	Yr. 6	Yr. 7	Yr. 8	Yr. 9	Yr. 10	Totals
	2021	2022	2023	2024	2025	2026	2027	2028	2029	2030	2031	
Infusion Devices - BBraun					£0.34	£1.87						£2.21
Patient Monitoring	£2.40	£0.40	£0.52	£0.19	£0.13	£0.02	£0.64	£0.41	£0.15	£1.73	£0.40	£6.99
Sterilisers - HSDU	£0.10	£0.10	£0.10									£0.30
Theatre Tables	£0.12	£0.10			£0.20							£0.42
Visual Ultrasound	£1.45	£0.62	£0.11	£0.30	£1.50	£0.70	£0.80	£0.07		£0.29		£5.84
Anaesthetic Mc.	£0.29	£0.35	£0.28	£0.26								£1.18
Procedure Trolleys	£0.10		£0.04									£0.14
Scopes/Stacks	£1.00	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£0.30	£4.00
CT Scanners	£4.70											£4.70
MRI Scanners	£3.00				£1.32					£1.47		£5.79
Total for Headline devices above	£13.16	£1.87	£1.35	£1.05	£3.79	£2.89	£1.74	£0.78	£0.45	£3.79	£0.70	£31.57
Total for Devices Expected to Require replacement by the Year... (Table 10)	£35.40	£3.29	£3.18	£4.31	£7.21	£5.70	£4.07	£3.20	£5.24	£14.94	£5.24	£91.78
Balance	£22.24	£1.42	£1.83	£3.26	£3.42	£2.81	£2.33	£2.42	£4.79	£11.15	£4.54	£60.21

Tables 12 and 13 illustrate that the number and value of devices that the service should consider for replacement varies from one year to the next. Furthermore, the level of DCP available and directed toward replacement and additional medical devices varies likewise.

Given these annual fluctuations, and a starting position of the Health Board having a current backlog of c.£35m worth of devices, Figure 2 depicts the financial ramifications of various funding levels over the coming years.

- Line 1 in Figure 2 shows the effect on the value of the backlog if the Health Board spent an average of £1m per year. This level of investment would result in the current backlog increasing to £81m by 2031.
- Doubling the average annual spend to £2m, Line 2 shows that the backlog would continue to increase to £71m by 2031.
- Doubling the spend once again to an average of £4m, Line 3 shows the backlog will still be in the order of £51m by 2031.
- It is only through increasing the average spend to £6m per year (as in Line 4) that the backlog shows a modest fall from the current position of £35m to £31m.
- For a significant reduction in the backlog, an average annual investment of around £8m (Line 5) is required to see a fall to £11m by 2031.

Providing the Health Board was in a position to allocate £11.8m annually towards medical device replacement, the current backlog would be eliminated in 5 years i.e. 2026.



Regardless of the level of investment annotated, of note is the predicted hike in backlog in years 2030 and 2031, which is a direct consequence of the majority of COVID-19 acquired devices reaching the end of their expected 10-year service life.

Maintenance Arrangements for the Additional Devices

The July 2020 report highlighted the majority of devices acquired over the COVID-19 period as having one-year warranties, resulting in a new batch of equipment falling out of warranty each month and requiring appropriate and adequate maintenance arrangements putting in place. The importance of ensuring such maintenance is in place cannot be overstated given previous Health and Safety Executive (HSE) improvement notices and medical device incident in 2017.

Table 4 illustrated that the nature of COVID-19 acquired devices is such that their maintenance falls entirely under the remit of Clinical Engineering. Given acknowledgment that the Clinical Engineering service was at capacity pre-pandemic, the additional capacity needed to move these devices into clinical use was significant. This initially took all of the existing resource and continues to have a significant impact on all aspects of performance. Current capacity does not allow for the annual maintenance of the COVID-19 acquired devices to be absorbed by existing Clinical Engineering resources and therefore other arrangements will be required to address this imperative. The full implications of this are beyond the scope of this report, and a further report is currently in development that will explore the various options available to the Health Board to address this patient safety issue. Using unvalidated data suggests that the 9000 devices acquired during COVID-19 will generate a maintenance cost of £1.4m annually.

The revenue implications of equipping and/or acquiring new and additional devices for the service should not be dismissed or diminished during the procurement stage, as each acquisition has a recurring annual impact on revenue in order to meet statutory requirements.

Medical Device Inventory

Whilst cleansing, refinement and updating of the information held within the inventory happens on a daily basis, due to its dynamic nature, without disproportionate resources being dedicated to its upkeep, the notion of a 100% accuracy must be considered unrealistic. Confidence that the accuracy of the data within the inventory is increasing can however be taken from the previously mentioned changes in Figure 1.

Notable Medical Device Successes In the Past Year

Despite the challenges brought about by the pandemic, and in part due to the associated availability of additional funding in the area of medical devices replacement/acquisition/modernisation, the Health Board has and will benefit for years to come as a result of several initiatives including:

- Ventilators – replacement ventilators for OOS units at GGH that would have required DCP funding were sourced via WG/DoH – allowing the internal funding to be directed elsewhere;
- Beds – coincidentally, prior to the pandemic, the Health Board had embarked on a wide-ranging and costly bed replacement programme. Many of the beds acquired to equip the Field Hospitals are now in the process of being redeployed to both acute and community sites to replace those old/OOS beds that had previously been identified for replacement prior to the pandemic;
- Patient Monitoring at WGH – similarly, there was a phased project to update old/OOS patient monitoring pre-pandemic. Compatible devices acquired through WG/DoH all but negated the need for any Health Board outlay, and in so doing, brought the project to a close much sooner than would have been otherwise possible whilst saving the Health Board DCP approximately £400,000.
- Bariatric equipment – often required and regularly acquired via costly rental, a range of devices designed for this category of patient have been procured to meet growing demand;
- Patient Trolleys – a high proportion of the current stock of patient trolleys has been due for replacement for several years. A combination of trolleys acquired through COVID-19 monies and others provided by WG will allow many of the oldest trolleys to be withdrawn, motorised trolleys to be deployed where physically required (due to areas with ramps etc.) and achieve a level of standardisation across certain sites/areas;
- Hoists – the acquisition of a range of hoists will allow for the majority of OOS/oldest hoists to be replaced;
- Defibrillators – the July 2020 report highlighted the pressing need to replace the majority of defibrillators. The procurement of manual and automatic defibrillators will replace the OOS devices with modern replacements, complete with features not seen in Wales including CO2 monitoring and WiFi connectivity to facilitate reporting and analysis.

Future Medical Device Developments

Several additional projects are underway that will ultimately have a positive impact on patient safety and clinical outcomes whilst also replacing and modernising old/OOS devices:

- The aforementioned replacement of MRI and CT scanners at WGH and GGH;
- Vital signs monitors – a proof of concept project has been approved designed to look at standardising monitoring devices across all areas and using WiFi connectivity to automatically link in with the Electronic Patient Record (EPR). Being the first of its kind in Wales, the results of this project are expected to provide learning for similar future installations across Wales;
- BBraun WiFi Infusion Devices – despite on-going events, a joint Bevan Commission and Health Board project has been completed that demonstrated the advantages and need for such connectivity with this type of SMART infusion pump. Funding was secured

which will allow for the upgrading of the entire Health Board stock of over 1200 BBraun infusion pumps. On-going collaborative work with BBraun will see the Health Board continue to be the only Health Board in Wales to have Drug Libraries on all such infusion devices. The WiFi connectivity opportunity will also move the Health Board into an elite group within the UK;

- TriTech – the formation of this medical device research and innovation hub working alongside commercial and higher education partners is the first of its type in Wales and only the third of its kind in the UK.

Overall Conclusions.

- The pandemic continues to have a significant impact on matters relating to medical devices.
- Recurring resources within Clinical Engineering will be required to ensure adequate maintenance arrangements are established and implemented whilst the inventory remains at its current level of 31,405 devices with a replacement cost estimated at £91.8m
- The on-going development/cleansing of the inventory continues to identify devices not previously recorded and thus provides an increasingly accurate portrayal of devices owned/used by the Health Board.
- Improved record keeping is allowing greater assurance to be given that appropriate device management arrangements are in place.
- Consequently, improvements to the inventory will allow service leads to make improved informed decisions when planning service development and medical device replacement.
- Without significant and sustained investment in this area or a reduction in the number of devices in use, the Health Board should expect that the number and value of devices due/overdue for replacement will continue to increase to the potential detriment of patient, staff and organisational safety.
- Intrinsically linked to the increasing number and value of equipment on the medical device inventory is the increased resource requirements to ensure that appropriate maintenance arrangements are in place.

Argymhelliad / Recommendation

The Committee is requested to:

- note the extraordinary challenges that the COVID-19 pandemic has and continues to present to the medical device inventory;
- Consider the impact of sub-optimal funding for replacement medical devices;
- Take assurance from the improved governance of the management of an inventory that holds 31,405 medical devices.

Amcanion: (rhaid cwblhau)

Objectives: (must be completed)

Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	3.6 Receive assurances in respect of Directorate Performance against annual budgets, capital plans and the Cost Improvement Programme and innovation and productivity plans.
Cyfeirnod Cofrestr Risg Datix a Sgôr Cyfredol:	Central Operations Risk Register:

Datix Risk Register Reference and Score:	384 - Ability to fully comply with statutory and manufacturer guidelines for medical devices and equipment.
Safon(au) Gofal ac Iechyd: Health and Care Standard(s):	2.1 Managing Risk and Promoting Health and Safety 2.9 Medical Devices, Equipment and Diagnostic Systems
Amcanion Strategol y BIP: UHB Strategic Objectives:	4. Improve the productivity and quality of our services using the principles of prudent health care and the opportunities to innovate and work with partners.
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2018-2019	8. Transform our communities through collaboration with people, communities and partners

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	<ul style="list-style-type: none"> • MHRA Bulletin: Managing Medical Devices • MHRA Bulletin: Infusion Systems • NPSA alerts and incident profiles • Internal Datix incident reports • Business Planning and Performance Assurance Committee report - 30 June 2015 - Emerging Principles Underpinning Capital Schemes
Rhestr Termiau: Glossary of Terms:	Included within the body of the report
Partion / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Adnoddau Cynaliadwy: Parties / Committees consulted prior to Sustainable Resources Committee:	Capital, Estates and Information Management & Technology Sub-Committee

Effaith: (rhaid cwblhau) Impact: (must be completed)	
Ariannol / Gwerth am Arian: Financial / Service:	Financial impacts affecting capital requirements and potential revenue impacts are contained within the report.
Ansawdd / Gofal Claf: Quality / Patient Care:	Direct quality and patient impacts in terms of clinical governance and patient safety if matters are not addressed and remain unchecked.
Gweithlu: Workforce:	Not applicable

Risg: Risk:	Risks identified and noted in the risk register for Clinical Engineering. Internal control measures being put in place to ensure these significant risks are identified and assessed.
Cyfreithiol: Legal:	Legal issues arising from patient safety and organisational liabilities.
Enw Da: Reputational:	Adverse impact on reputation of the Health Board
Gyfrinachedd: Privacy:	Not applicable
Cydraddoldeb: Equality:	Not applicable