PWYLLGOR CRONFA ELUSENNOL CHARITABLE FUNDS COMMITTEE

DYDDIAD Y CYFARFOD: DATE OF MEETING:	28 November 2023
TEITL YR ADRODDIAD: TITLE OF REPORT:	Charitable funds request for the purchase of Neonatal Ventilators
CYFARWYDDWR ARWEINIOL: LEAD DIRECTOR:	Andrew Carruthers, Director of Operations
SWYDDOG ADRODD: REPORTING OFFICER:	Nick Williams-Davies (Service Delivery Manager, Acute Paediatric and Neonatal Services)

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

Ar Gyfer Penderfyniad/For Decision

ADRODDIAD SCAA SBAR REPORT

Sefyllfa / Situation

This report is being presented to the Charitable Funds Committee to consider and approve an application for £120,727.72 of charitable funding to support the purchase of four respiratory ventilators utilised within the neonatology settings at Glangwili and Bronglais Hospitals, prior to ratification to Board in its role as Corporate Trustee.

Cefndir / Background

There are currently five ventilators in use, four at Glangwili Hospital (GH) and one at Bronglais Hospital (BH) which are required to support infants with respiratory distress immediately after birth.

The following table shows the identity of the units and most importantly, the installation dates:

Site	Location	Brand	Model	Equipment No	Serial No	Status	Support Level	Installation Date
GGH	SCBU	SLE	5000	CE010875	52793	In Use	EXT	08/04/2009
GGH	SCBU	SLE	5000	CE010876	52794	In Use	EXT	08/04/2009
BGH	GWENLLIAN WARD	SLE	5000	CE004232	55156	In Use	EXT	11/01/2012
GGH	SCBU	SLE	5000	CE010873	56408	In Use	EXT	23/07/2014
GGH	SCBU	SLE	5000	CE010874	56409	In Use	EXT	23/07/2014

Noting the installation dates above, these ventilators require replacement due to the support and maintenance packages no longer being available due to the age of the machines.

PERIPrem Cymru

PERIPrem Cymru (Perinatal Excellence to Reduce Injury in Premature Birth) is a new Quality improvement (QI) project which has recently been launched in Wales with the aim to improve "best practice". Although it is not a statutory requirement to meet the standards that are set out in PERIPrem guidance, it is a clear and accepted opportunity to enhance the pathways and outcomes that are available to neonates. Hywel Dda University Health Board (HDdUHB) is actively participating in the scheme. One of the outcome measures of this project is the

utilisation of equipment to meet the "volume guarantee" standards that are a standard describe by the British Association of Perinatal Medicine (BAPM). BAPM standards are widely adhered to within neonatal units in Wales.

Volume Guaranteed (VG) ventilation, also known as Volume Targeted Ventilation (VTV), is known to be protective to the lungs of premature infants and lead to reduced rates of chronic lung disease, including reducing the need of the use of home oxygen. The use of VTV is an integral part of the PERIPrem All-Wales project - ensuring good perinatal optimisation of preterm infants, leading to improvements in survival and neurodisability.

With a national focus being applied to neonatal services through the PERIPrem quality improvement project, it is clear that where volume guarantee can be reliably achieved, neonatal babies will receive higher levels of care and intervention then currently available.

Asesiad / Assessment

Network and Standards

The neonatal team based at GH is part of the Wales Maternity and Neonatal Network. The Network strives to support infants and their families in the provision of high-level evidenced-based comprehensive medical intervention and care. It does this through a system of Special Care Baby Units (SCBU), High Dependency Units (HDU) and Paediatric Intensive Care Units (PICU).

In neonates who have severe respiratory distress at birth, there is a need to deliver oxygen via a ventilator which has the ability to operate a VG to ensure tidal volumes of oxygen are delivered in a controlled way. This enables ventilator support which minimises potential for lung damage (especially in pre-term infants) by reducing the potential for the over-inflation of the lung. Equally, the devices are able to ensure that sufficient inflation is maintained in order to maximise the benefits of ventilation and to bring stability to the patient's condition.

The neonatologists operating within the Network also observe the guidance as set out by the British Association of Perinatal Medicine (BAPM). The BAPM standards (supported by Welsh Network recommendations) advise how the delivery of VG should be applied.

The importance of VG ventilation provides clear benefits to neonatal babies as described below:

- found to maintain correct levels of carbon dioxide;
- known to reduce the risk of pneumothorax (causing a collapse of a lung) by a third;
- known to reduce intraventricular haemorrhage (bleeding around the ventricles within the brain) by half;
- reduces potential for barotrauma, known as "the bends", where air or gas pressures can cause the lungs to over-expand.

Current Equipment

Currently, the SLE5000 ventilator is in use within the state-of-the-art SCBU with four based at GH, and a fifth based in the stabilisation area in the maternity ward at BH. It is in these areas that the ventilators provide a critical function, providing the maximum level of intervention that can be offered to the youngest members of the Health Board's population, without needing to transfer the babies to other units in Swansea or further afield.

Of the five ventilators held within the neonatal service, two at GH are no longer able to be fully supported with a third at BH also at risk. This is due to a manufacturer declaration that they are ending support, meaning parts may no longer be available to repair a ventilator should a breakdown occur with the other two machines continue in service, which will also run out of support.

The neonatal lead consultants have reviewed the use of the equipment in order to ensure that this request is made as cost efficient as possible. For these reasons, the request is to support the replacement of four of the machines. Three will be based in GH to support the delivery of ventilatory support to twin babies and one simultaneous additional birth. The fourth will replace the outdated unit in BH to maximise the stabilisation that is provided to babies in that area, prior to repatriation to the SCBU.

Additional Issues Associated with Current Equipment

In addition to the clear quality improvement outcomes detailed above, and subject to the PERIPrem project, some further issues are emerging with recent reports from the neonatal lead consultants that the ability of the SLE5000 ventilator to deliver the specified VG levels of oxygen is not reliable, with instances of the devices delivering too high a volume of air – meaning the appropriate controlled volume delivery is not achieved.

The Cymru Inter-Hospital Acute Neonatal Transfer Service (CHANTS) is a dedicated resource that is deployed anywhere within the Network to enable safe transfer of neonates to Intensive Care Units, where required. CHANTS clinicians have also made verbal representations to the neonatal consultants that when operating across the South Wales corridor, HDdUHB is an outlier in terms of the type of ventilator if operates meaning there is potential for issues relating to familiarity when they are called to transfer from HDdUHB.

HDdUHB is now seen to be an outlier in terms of the use of the SLE5000 with all other units operating the SLE6000 model.

Finally, a Datix risk-register entry has been made, reference 1674 "Requirement to replace neonatal ventilators due to suboptimal function". This has an inherent and actual risk rating of 16 ('extreme').

Although support from the Charitable Funds Committee for the replacement of these machines would mitigate this risk, the overarching objective of this application is to improve the care and outcomes of neonatal activity requiring this type of intervention.

Benefits of Upgrade

In order to reduce the clinical risks identified above and to meet the objectives of the QI workstream, the devices require replacement or upgrade to the newer SLE6000 model. Purchase of the new devices will also have some additional benefits:

- The SLE6000 will provide both non-invasive (via a mask) and invasive (via tube into the trachea) ventilation. The SLE5000 is only able to provide invasive ventilation. This means that babies could be in receipt of higher levels of care via one machine than is currently offered.
- Delivery of non-invasive ventilation is currently provided via an additional Synchronised Inspiratory Positive Airway Pressure (SiPAP) machine. These devices are also no longer supported by the company due to age of the machines. Therefore, it is likely that in the near future these will also need replacing as they are no longer able to be serviced or repaired. However, if the SLE6000 is purchased, it will replace the need for

- the SiPAP device, reducing the amount of equipment at the cot side and also reducing the need for staff to utilise multiple machines during an episode of care.
- In addition to the SiPAP, a further oxygen device, Optiflow, is currently deployed in the care of these infants. The SLE6000 would make intervention far more straightforward, as it would replace both the SiPAP and Optiflow machines.
- As the SLE6000 would be able to provide all respiratory support, meaning respiratory circuits such as tubing would not need to be changed as frequently.
- SLE6000 machines are used across the Neonatal Network in the majority of the tertiary centres, providing an additional benefit of standardisation as an optimised level of intervention throughout the network meaning tertiary colleagues can provide a more bespoke advice to Health Board staff in the management of complex patients.
- Where deteriorating babies need an escalation in care, CHANTS clinicians attend
 Health Board locations to stabilise sick infants and then safely transfer them to definitive
 care. The clinicians are familiar with the SLE6000 ventilators and with these in use, the
 provision of the necessary patient care will be improved.
- Staff would also only require training on one piece of equipment rather than three, which would improve their confidence with the machine and improve training plans for the staff.

Summary

- VG is considered the recommended mode of ventilation and is advocated by BAPM, PERIPrem and the Wales Maternity and Neonatal Network. Currently the machines utilised do not reliably deliver this and by default, revert to less optimum modes of ventilation, placing the neonatal babies at significant clinical risk.
- In terms of quality improvement, PERIPrem has VG listed as an outcome measure and target to achieve. The Health Board will currently not meet this measure via the use of the older model ventilator.
- There is potential harm to babies from using non-VG modes, such as barotrauma, pneumothorax, and neurological haemorrhage, which will be addressed by utilising the functions of the SLE6000.
- The current machines, some of which are more than a decade old, no longer have adequate support or maintenance packages in place due to unavailability of certain mechanical parts and software. This raises clinical risks when continued to be used on the unit.
- The CHANTS transfer service has also raised concerns in relation to unreliability of the current machines in optimising ventilation prior to repatriation.

Recommended Solution

Given the significance of these issues and with the support of the Clinical Leads and the Practice Development team, in line with network recommendations, a trial of the newer SLE6000 has been performed in the GH neonatal unit. This is identified as the current default ventilator for neonatal care deliver across the south Wales corridor.

Following the success of the trial and whilst cognisant of the emerging clinical risks, it is proposed that five SLE6000 ventilators are purchased to replace the aging equipment and to provide an enhanced level of care through the newer machine, noting all the benefits and risks as highlighted.

Cost

Replacement of the four ventilators with the newer SLE6000 is subject to a multi-trust aggregation via the NHS Supply Chain. Under the terms of this process, the procurement of four new ventilators incur a cost of £120,727.72.

This includes a part-exchange reduction of £4,000, (£1,000 per device).

Revenue Consequences

There is no additional revenue cost associated with this equipment as they are replacements for the current ageing models. The annual maintenance contract costs are pending with the Service Delivery Manager and Assistant Finance Business Partner confirming that these will be covered from the existing revenue budget.

A Statement of Need (SON) has been completed and approved by Clinical Engineering, reference 2023-159.

Availability of Charitable Funds

There are sufficient charitable funds available within the Neonatal Paediatric Maternity Service to support the cost associated with this initiative:

Fund code	Fund name	Uncommitted balance as at 30.09.2023		
Neonatal				
T134	CARMS Special Care Baby Unit	£81,770.92		
T782	Carms Children's Services Neonatal	£64,202.42		
Paediatrics				
T355	CMW - Angharad Ward	£12,142.13		
T807	Ceredigion Children's Services	£6,412.13		
T516	PDT - WGH Ward 9 Fund	£25,198.61		
T921	Pembrokeshire Children's Services	£4,112.57		
T922	Pembrokeshire Children's Services £7,328.36 Children's Wards			
T780	Carms Children's Services	£78,059.46		
Maternity				
T713	GGH Obstetrics & Gynaecology	£8,319.22		
T754	Carms Community Midwifery	£49,045.43		
T867	Ceredigion Obstetrics & Gynaecology £3,152.73			
T868	Ceredigion Maternity Services	£12,744.79		
T925	Pembrokeshire Maternity & Gynaecology	£1,771.43		
Total		£354,260.20		

It is proposed that the funding contributions are as follows:

County	Value of contribution	Contribution from
Pembrokeshire	£15,090.96 (50%)	T516 PDT - WGH Ward 9 Fund
Carmarthenshire	£15,090.96 (50%)	T754 Carms Community Midwifery
Carmarthenshire	£60,363.86 (2 units)	T134 CARMS Special Care Baby Unit
	£30,181.93 (1 Unit)	T782 Carms Children's Services Neonatal

This funding application complies with the Charitable Fund eligibility criteria:

Equipment and consumables: Medical equipment for NHS patient care

This request for charitable funds is being made due to the significant pressures on the HDdUHB 2023/24 capital programme. Although this is replacement equipment, the purchase of this equipment falls within the charity's objectives with significant patient benefit outlined within the body of this report.

Argymhelliad / Recommendation

The Charitable Funds Committee is asked to **ENDORSE** and **RECOMMEND FOR APPROVAL** by the Corporate Trustee funding within the Neonatal Paediatric Maternity Service of £120,727.72 for the procurement of four new SLE6000 ventilators.

Amcanion: (rhaid cwblhau) Objectives: (must be completed)		
Committee ToR Reference: Cyfeirnod Cylch Gorchwyl y Pwyllgor:	6.1	Within the budget, priorities and spending criteria determined by the UHB as trustee, and consistent with the requirements of the Charities Act 2011 (or any modification of these acts), to apply the charitable funds in accordance with its respective governing documents.
	6.3	To ensure that the UHB policies and procedures for charitable funds investments are followed.
	6.19	Expenditure in excess of £50,000 will require the approval of the Charitable Funds Committee. Expenditure over £100,000 will require the approval of the Corporate Trustee.
Cyfeirnod Cofrestr Risg Datix a Sgôr	1	"Requirement to replace neonatal ventilators due
Cyfredol:	to sub	ooptimal function" Score= 16 (extreme)

Datix Risk Register Reference and Score:	
Parthau Ansawdd: Domains of Quality Quality and Engagement Act (sharepoint.com)	7. All apply
Galluogwyr Ansawdd: Enablers of Quality: Quality and Engagement Act (sharepoint.com)	4. Learning, improvement and research
Amcanion Strategol y BIP: UHB Strategic Objectives:	All Strategic Objectives are applicable
Amcanion Cynllunio Planning Objectives	Not Applicable
Amcanion Llesiant BIP: UHB Well-being Objectives: Hyperlink to HDdUHB Well-being Objectives Annual Report 2021-2022	4. Improve Population Health through prevention and early intervention, supporting people to live happy and healthy lives

Gwybodaeth Ychwanegol: Further Information:	
Ar sail tystiolaeth: Evidence Base:	https://executive.nhs.wales/networks-and-planning/maternity-and-neonatal-services/information-for-professionals/periprem-cymru-for-professionals/ https://www.bapm.org
Rhestr Termau: Glossary of Terms:	Included within body of the report.
Partïon / Pwyllgorau â ymgynhorwyd ymlaen llaw y Pwyllgor Cronfa Elusennol: Parties / Committees consulted prior to Charitable Funds Committee:	Deputy Director Operations NWSSP Procurement team Head of Hywel Dda Health Charities Directorate Finance Business Partner Clinical Engineering

Effaith: (rhaid cwblhau)	
Impact: (must be completed)	
Ariannol / Gwerth am Arian:	Included within the body of the report.
Financial / Service:	

Ansawdd / Gofal Claf: Quality / Patient Care:	Included within the body of the report, replacement of the ventilators will improve patient outcomes and minimise potential complications- and bring the service in line with national objectives and standards.
Gweithlu: Workforce:	No impact. To be included within team brief and all internal training & development will be supported by the in-house practice development team.
Risg: Risk:	Included in the body of the report. Investment will significantly mitigate risks.
Cyfreithiol: Legal:	Not applicable.
Enw Da: Reputational:	Positive reputational impact related to investment and improved outcomes for infants and their families. Potential for press release to support investment.
Gyfrinachedd: Privacy:	Not applicable.
Cydraddoldeb: Equality:	EqlA is not indicated for this proposal