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THE MANAGEMENT OF MEDICAL EQUIPMENT PROCEDURE

Introduction and Aim

The aim of the Medical Equipment Management Policy and this associated Procedure is to ensure that Cardiff and Vale UHB provides the most effective Medical Equipment support the delivery of high quality patient care and deliver the best possible health and financial outcomes. The Medical Equipment Management Policy sets minimum standards which are applicable across all sectors of the UHB's healthcare services and includes Medical Equipment which is deployed by partner organisations and contractors to care for UHB patients and service users. It also enshrines through Medical Equipment selection criteria strong alignment to UHB started and the overarching principles of prudent healthcare.

This Procedure has been developed so as to facilitate the consistent application of the Medical Equipment Management Policy, as part of an overarching governance framework. It expands on the 15 governance principles established by the Medical Equipment Management Policy and describes in detail the UHB's Medical Equipment Governance Framework. The In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure has been developed to assure compliance with relevant legislation, standards and guidance in relation to in-house design and manufacture of medical devices (including software) put into service within the UHB.

Objectives

The Medical Equipment Management Policy establishes a clear framework within which the UHB can;

- Effectively and actively manage its Medical Equipment so as to reduce risk,
- Meet its legal obligations to comply with legislation,
- Meet its governance obligations, both clinical and financial,
- To the requirements of the relevant Health and Care Standards,
- Demonstrate that it is taking account of MHRA guidance,
- Meet external accrediting body quality standards covering Medical Equipment

Scope

This Procedure applies to all of Cardiff and Vale UHB staff in all locations including those with honorary contracts. It covers all Medical Equipment used by Cardiff and Vale UHB services irrespective of whether the Medical Equipment is owned, loaned, leased or used by external service providers commissioned by the UHB.

Equality Impact Assessment	An Equality Impact Assessment (EqIA) has been completed and this found there to be a positive impact.
Documents to read alongside this Procedure	Cardiff and Vale UHB Policies: o Decontamination of Reusable Medical Devices Policy o Safe Use of Ionising Radiation Policy o Safe Use of Non-Ionising Radiation Policy o Waste Disposal Policy Provision and Use of Work Equipment Regulations (PUWER), 1998 Medical Device Regulations 2002 (as subsequently amended). Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, January 2021 Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health

	institution (IPEM January 2021) Yellow Card | Making medicines and medical devices safer (mhra.gov.uk)
Approved by	Quality, Safety and Experience Committee
Accountable Executive	Director of Therapies and Health Science.
Author(s)	*Head of Clinical Engineering / Deputy Director of Therapies and Health Science.*

Disclaimer

If the review date of this document has passed please ensure that the version you are using is the most up to date either by contacting the document author or the Governance Directorate.

Summary of reviews/amendments

Version Number	Date of Review Approved	Date Published	Summary of Amendments
2	15/09/2015	25/09/2015	The Policy and Procedure are disaggregated. Greater clarity on Medical Equipment life cycle management principles including more robust governance of the procurement of Medical Equipment and strengthened alignment to UHB strategy Significant specific amendments include: • Roles, responsibilities and lines of accountability are transparent. • There are more robust governance arrangements covering the procurement of Medical Equipment. • The procedures explicitly cover the activities of the Artificial Limb and Appliance Services hosted by Cardiff and Vale UHB.
3	25/03/2020	15/04/2020	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure in response to likely delay of publication of updated MHRA guidance until after the MDR 2017 full implementation date of 26th May 2020. The Policy and Procedures will be further updated following publication of pending updated MHRA guidance.
4	17/03/2021	04/04/2021	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure in response to the publication of Best-practice guidance for the in-house manufacture of medical devices and nonmedical devices, including software in both cases, for use within the same health institution (IPEM January 2021) and likely

			introduction of Medical Devices (Amendment etc.) (EU Exit) Regulations 2020 during 2021.
5	02/03/2022	14/04/2022	Review and interim update by UHB MEG of the UHB Medical Equipment Management Policy / UHB Management of Medical Equipment Procedure / UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure pending the outcome of the MHRA consultation on medical device regulation in the UK and subsequent introduction of new legislation.

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1. INTRODUCTION

1.1 This Procedure covers the life cycle management of all Medical Equipment (including Software as a Medical Device) in use at Cardiff and Vale University Health Board (UHB) irrespective of the source of funding for the equipment or whether it is owned, loaned, leased or used by commissioned service providers. This includes Medical Equipment provided under managed service contracts. It also covers the use of Medical Equipment by contractors to deliver UHB commissioned clinical services to Cardiff and Vale UHB's patients and service users. For the purposes of this Procedure, 'Medical Equipment' refers to medical devices (including software) that aid diagnosis, monitoring, treatment and rehabilitation in relation to medical conditions (some examples of which are given in Appendix 2). As a defined term, MEDICAL EQUIPMENT is placed in SMALL CAPITALS throughout the rest of this Policy.

1.2 Equipment management encompasses the whole life cycle process that applies to all MEDICAL EQUIPMENT from critical evaluation, selection procurement, commissioning, training, use, maintenance, repair, upgrade, decommissioning through to final disposal (Appendix 1).

1.3 Inappropriate management of MEDICAL EQUIPMENT at any stage of its life will lead to increased risks (unintended harm to patients, harm to professional users, statutory regulatory non-compliance, Welsh Risk Pool indemnity etc.) and poor value for money.

1.4 Therefore, relevant legislation, standards and guidance including Health and Care Standards, requires the UHB to have in place a Policy and Procedures to cover this activity.

1.5 This Procedure has been developed so as to facilitate the consistent application of this Policy, as part of an overarching governance framework and will be kept under review.

1.6 The philosophy of the Policy and associated Procedure is that there must be co-operation and collaboration between Clinical User Departments, Clinical Engineering, NHS Wales Shared Services Partnership (NWSSP) Procurement Services and other relevant parties in order for the UHB to maximise the benefits and minimise the risks of its use of MEDICAL EQUIPMENT. A slogan that has been suggested and modified by the Medical Equipment Group (MEG) for use in this context is;

"Choose it right; Buy it right; Use it right; Keep it right"

1.7 PROFESSIONAL USERS and END USER. These terms are used in Policy and Procedures and have the following meaning;

PROFESSIONAL USERS: Professionally qualified health care workers who use MEDICAL EQUIPMENT as part of their job.
END USERS: Patients or clients of the UHB or their carers, who use MEDICAL EQUIPMENT in the treatment or care of themselves or those whom they look after

2. POLICY AND PROCEDURE STATEMENT

Cardiff and Vale UHB aims to provide the most effective MEDICAL EQUIPMENT to support the delivery of high quality patient care and deliver the best possible health and financial outcomes. This is to be achieved by managing MEDICAL EQUIPMENT effectively and efficiently in order to reduce risk, meet all statutory regulatory requirements, ensure that all staff and, where appropriate, patients know how to operate the equipment safely and ensure that equipment is maintained to its optimum standard. To this end, the following principles will be applied:

2.1 MEDICAL EQUIPMENT must be selected taking account of the following factors:

- fitness for purpose as judged against a duly considered specification which references, where appropriate, NICE and other national evidence-based standards,
- future proofing in terms of both predicated demand and technology evolution including the impact of known disruptive technologies in that clinical sector,
- prudent healthcare principles; Medical Equipment must be selected to support the minimum appropriate intervention agreed on the patient pathway,
- strategic alignment including national, regional and local clinical service planning where the selection and procurement of MEDICAL EQUIPMENT may be a strategic enabler for change,
- known risks to sustainable delivery of high quality and affordable clinical services,
- best life cycle value for money including whole life revenue costs (consumables, maintenance, training etc.)
- demonstrable clinical benefits to deliver outcomes which matter to patients and service users,
- standardisation with other similar types of equipment already in use,
- the training needs of users of the equipment,
- the needs of the UHB as a teaching / training organisation and a leading research and development organisation, to include needs highlighted by strategic partnerships,
- maintenance implications, i.e. cost of maintenance, warranty terms, availability of in-house technical support, quality of support from the supplier etc.
- reliability, based on experience in this UHB and other organisations,
- any need for decontamination of the equipment and the availability of suitable decontamination facilities at the UHB,

- any implications for the UHB's IT infrastructure,
- any Estates enabling works,
- Medicines and Healthcare Products Regulatory Agency (MHRA) safety alerts, safety standards, Health & Safety Regulations and other relevant regulatory requirements and external quality accreditation standards and guidance,
- the UHB's Standing Orders, Policies and procedures.

Whilst user preference or supplier preference based on past experience are key considerations they must not take primacy over the factors listed above. As a principle the UHB must never adopt MEDICAL EQUIPMENT where there is evidence that is unreliable, but the issue of unplanned MEDICAL EQUIPMENT downtime should be discussed with suppliers and included as contractual performance indicators. The critical evaluation and selection phase is pivotal to ensure that the UHB achieves its objectives of delivering prudent healthcare and reducing waste, variation and harm. Therefore the MEG will support this phase to ensure a degree of impartiality and transparent decision making when selecting MEDICAL EQUIPMENT for use within the UHB. CEDAR provide access to contemporary critical assessments of novel MEDICAL EQUIPMENT and Medical Technologies and must be included in the evaluation phase for any MEDICAL EQUIPMENT which is new to the UHB.

2.2 In planning for the replacement of MEDICAL EQUIPMENT the following equipment criteria should be considered. Is the existing MEDICAL EQUIPMENT:

- worn out beyond economic repair,
- damaged beyond economic repair,
- unreliable,
- clinically or technologically obsolete,
- supported on 'best endeavours' as spare parts are no longer available,
- unable to be cleaned effectively prior to disinfection/sterilisation.

If replacement needs are identified then the availability of better alternatives on a regional or national network level should be considered rather than 'like for like' replacement. This may also enable health system level pathway or service redesign.

2.3 Procurement of will be undertaken via NHS Wales Shared Services Partnership (NWSSP) Procurement Services, in collaboration with the user, Clinical Engineering, the Health & Safety Department, the Estates Department and others as required.

2.4 There must be a site visit and survey carried out before any item of MEDICAL EQUIPMENT that will be fixed to the floor, ceiling or to a wall is ordered to ensure that there is sufficient space to use and maintain the equipment in a safe and effective manner, and that all necessary enabling works can be

undertaken. This site visit must be undertaken in collaboration with the UHB's Estates Department.

2.5 Certain types of MEDICAL EQUIPMENT, as designated from time to time by the Medical Equipment Group (MEG), will be 'owned' and managed corporately through the Medical Equipment Loan Service.

2.6 Before submitting a requisition for MEDICAL EQUIPMENT of capital or revenue value, Directorates and Clinical Boards must seek advice from Clinical Engineering (or the Rehabilitation Engineering Unit in relation to the Artificial Limb and Appliance Service (ALAS)) to confirm that all aspects of clinical risk, standardisation, technical specifications and maintenance arrangements are taken into account at the start of the procurement process.

2.7 MEDICAL EQUIPMENT (whether purchased or on loan) must not be put into clinical use until it has been commissioned by the appropriate technical department or, in approved cases, by the supplier. For equipment manufactured, modified or repaired in-house please refer to the UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure.

2.8 Appropriate maintenance arrangements must be considered and agreed before MEDICAL EQUIPMENT is put into clinical use. Where appropriate, external maintenance contracts will be technically monitored by the UHB's Clinical Engineering Department.

2.9 PROFESSIONAL USERS must have received appropriate training and be competent, before MEDICAL EQUIPMENT is put into clinical use.

2.10 END USERS of MEDICAL EQUIPMENT must be appropriately trained and given suitable written instructions before equipment is issued to them.

2.11 Records of all MEDICAL EQUIPMENT as designated from time to time by the Medical Equipment Group (MEG) will be kept on a database held and maintained by the UHB's Clinical Engineering Department.

2.12 The UHB's Clinical Engineering Department will hold a database of all MEDICAL EQUIPMENT PRIORITISED by risk to inform the UHB's Medical Equipment replacement programmes.

2.13 Disposal of MEDICAL EQUIPMENT must be done in consultation with the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) and adhere to UHB waste disposal policies and protocols.

2.14 The Policy and Procedures applies to all acquisitions of MEDICAL EQUIPMENT from whatever source, e.g. directorate budgets, capital allocation, capital schemes, Welsh Government, National Service Frameworks, lease, loan, voluntary organisations, endowment funds, in-house manufacture, etc.

2.15 This liability extends to all MEDICAL EQUIPMENT brought onto UHB premises by external contractors. The same level of assurance must be provided through contractual arrangements for MEDICAL EQUIPMENT used to deliver subcontracted or hosted clinical services for the population served by the UHB.

2.16 Issues regarding Ultrasound MEDICAL EQUIPMENT should first be raised with the Ultrasound Clinical Governance Group (UCGG). Issues can then be escalated to the Medical Equipment Group (MEG) where deemed necessary by UCGG chair.

For further details and explanations, see Appendix 3 of this Procedure.

3. AIM

The aim of this Procedure is to provide a clear framework within which the UHB can;

3.1 effectively and actively manage its MEDICAL EQUIPMENT so as to reduce risk,

3.2 meet its legal obligations to comply with legislation,

3.3 meet its governance obligations, both clinical and financial,

3.4 respond to the requirements of the relevant Health and Care Standards[14],

3.5 demonstrate that it is taking account of MHRA guidance

3.6 meet external accrediting body quality standards covering MEDICAL EQUIPMENT.

4. OBJECTIVES

4.1 To establish a robust Procedures to underpin the Medical Equipment Management Policy , to cover the evaluation, selection, procurement, commissioning, maintenance, use and disposal of the UHBs MEDICAL EQUIPMENT.

4.2 To ensure that the true life-cycle costs, including maintenance costs, consumable costs and other revenue costs are taken into account in the selection process.

4.3 To ensure that PROFESSIONAL USER training and where applicable, END USER training are considered as part of the process.

4.4 To ensure robust competence assessment programmes are available for all MEDICAL EQUIPMENT USERS.

4.5 To ensure best value for money in the overall management of the UHBs MEDICAL EQUIPMENT assets.

4.6 To ensure predictable and well understood systems are available to support consistent and auditable capital MEDICAL EQUIPMENT procurement activities.

5. ROLES and RESPONSIBILITIES

5.1 The Excecutive Director of Therapies and Health Science is the Executive Director with responsibility for MEDICAL EQUIPMENT.

5.2 The Assistant Director of Therapies and Health Science is the UHB lead for MEDICAL EQUIPMENT.

5.3 The Medical Equipment Group (MEG) is responsible for maintaining and reviewing the Medical Equipment Management Policy and Procedures.

5.4 The Medical Equipment Management Policy and this Procedure will mainly impact on the activities of Clinical Board teams, Clinical Directors, Directorate Managers and Clinical Teams when they are considering the management and use of MEDICAL EQUIPMENT and the procurement of new MEDICAL EQUIPMENT. The MEG will oversee a network of Medical Device Safety Officers (MDSOs) who will have delegated responsibility for the implementation of the standards for the management of MEDICAL EQUIPMENT contained within the Medical Equipment Management Policy and Procedures.

5.1 The UHB's Head of Procurement for NHS Wales Shared Services Partnership will ensure that all MEDICAL EQUIPMENT is procured in keeping with UHB policies and standing instructions. Procurement Services will have a UHB 'gatekeeper' function and bring all requests for MEDICAL EQUIPMENT to the attention of the Executive Director of Therapies and Health Science and the MEG to ensure that the correct authorisation pathway has been followed before proceeding to purchase (Appendix 6).

5.2 The UHB's Head of Discretionary Capital and Systems will coordinate and log any capital MEDICAL EQUIPMENT ordering activities including projects or schemes.

5.3 The Assistant Director of Planning, Capital, and Estates & Operational Services holds the capital budget and ensures that all capital MEDICAL EQUIPMENT replacement or development proposals are within allocated budget.

5.4 All capital MEDICAL EQUIPMENT requests have to be agreed by the Major Capital Group. The Executive Director of Planning provides final signed authorisation to any capital purchase request.

5.5 This hierarchical capital MEDICAL EQUIPMENT procurement process will be coordinate and signed off using the "Project Outline for Major Capital Medical Equipment Replacement" template (Appendix 5). A deputising subgroup of the MEG will be convened to sign urgent MEDICAL EQUIPMENT purchases in the absence of the Executive Director or Deputy Director for Therapies and Health Science.

5.6 Clinical Engineering (or the Rehabilitation Engineering Unit in relation to ALAS) will monitor the application and implementation of the Medical Equipment Management Policy and Procedures.

6. RESOURCES

6.1 There are no changes to the resource implications resulting from the revision of the Medical Equipment Management Policy and Procedures.

7. TRAINING

7.1 The Medical Equipment Management Policy and Procedures requires that the users of MEDICAL EQUIPMENT are appropriately trained and competent in the correct and safe use of the equipment (see 2.8 and 2.9). This is particularly important for MEDICAL EQUIPMENT which due to type, or mode of use, presents higher risks. The UHB has already identified infusion devices in this category and put in place a specific policy dealing with such equipment. On behalf of the UHB, the Medical Equipment Group (MEG) will continue to identify further UHB wide training needs and put in place mechanisms to meet them.

8. IMPLEMENTATION

8.1 Medical Equipment Management Policy and Procedures should be implemented following approval by Medical Equipment Group (MEG) and the UHB's Quality, Safety and Patient Experience Committee.

9. AUDIT

9.1 The Policy and Procedures will be monitored by the Medical Equipment Group (MEG).

9.2 The application of the Policy and Procedures will be audited by the Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS).

10. DISTRIBUTION

10.1 The Policy and Procedures will be available via the UHB Intranet and Internet Sites. Where staff do not have access to these resources the line manager must ensure that they are aware of the contents where appropriate.

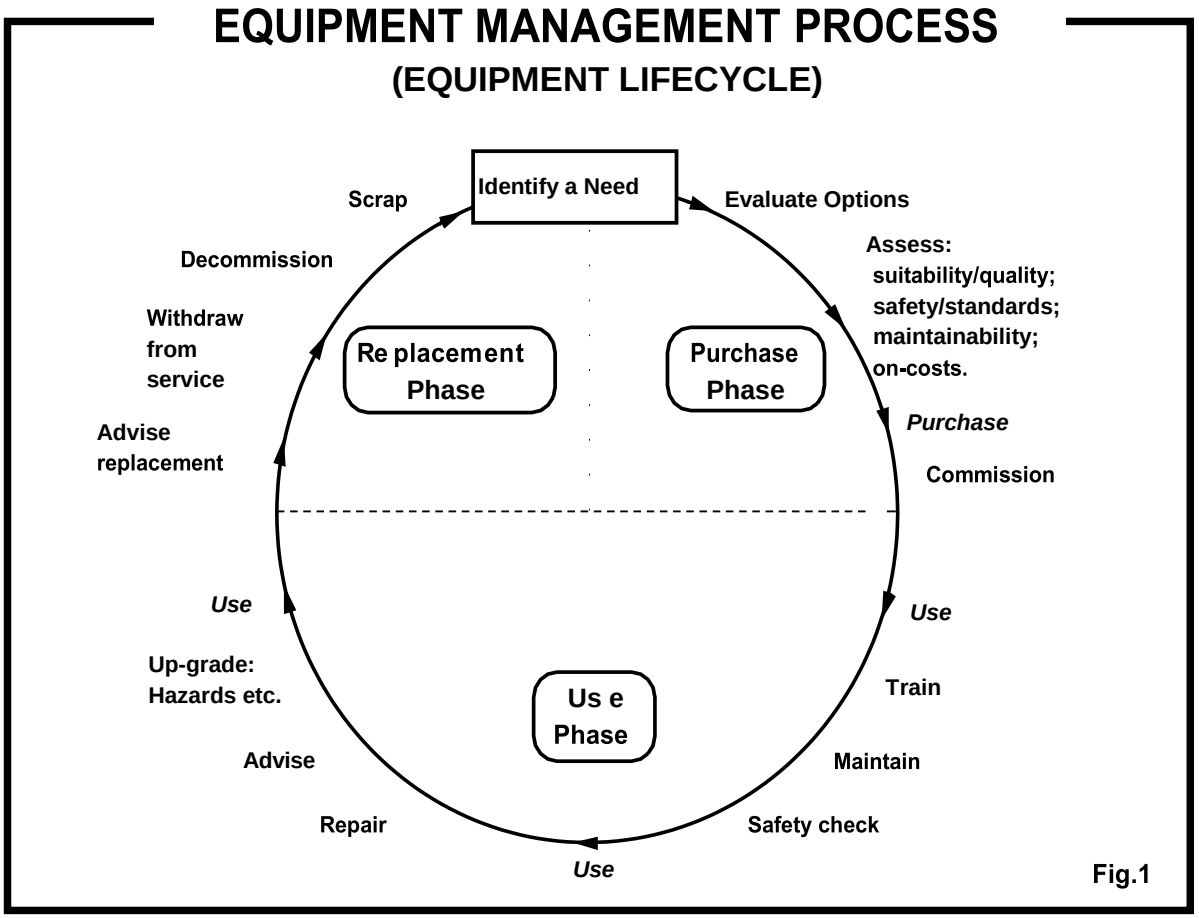
11. REVIEW

11.1 The Policy and Procedures will be reviewed to reflect any changes in guidance or legislation. As a minimum it will be reviewed 3 years after the date of approval.

Appendix 1

Equipment life cycle management can be defined as:

"A life-cycle approach to the critical evidence based evaluation, purchase, use, maintenance, and disposal of equipment."[7, 8]



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Appendix 2

EXAMPLES OF MEDICAL EQUIPMENT

Anaesthetic machines Apnoea Monitors Audiometers **B**lood Flow Meters Blood Pressure Monitors **C**ardiotacographs **D**efibrillators Dialysis Equipment Diathermy **E**CG Monitors EEG Equipment Electronic Assistive Technology Electro-Surgical Units Endoscopes **F**eed Pumps Foetal Monitors **I**nfant Incubators Infant Radiant Warmers Infusion Pumps ➢ Ambulatory ➢ Anaesthesia ➢ Patient Controlled Analgesia (PCA) ➢ Syringe ➢ Volumetric ➢ ICU/ITU Central Station and Monitoring Equipment	**L**asers **N**erve Stimulators NIBP Machines **P**atient monitors Patient Hoists Patient Plinths Posture and Mobility Equipment (including wheelchairs) Pressure Transducers Prosthetics and Orthotics Pulse Oximeters **S**urgical diathermy Surgical Saws Suction apparatus **T**elemetry Equipment Temperature Monitors Treatment Couches / plinths **U**rology Equipment **V**entilators Vital Signs Monitors **W**eighing Scales for patients
*This list of types is NOT exhaustive and is given as guidance only. Contact the UHB's Clinical Engineering Department at UHW or the Rehabilitation Engineering Department at ALAS for detailed advice.	

Appendix 3

Procedural advice to support the implementation of the Medical Equipment Management Policy.

Choosing the right equipment for the right prudent intervention:

Critical Evaluation

The CEDAR service at UHW supports decision making in healthcare by providing information and recommendations on:

•Emerging health technologies

•Medical devices

•Diagnostic tests

•Healthcare interventions

CEDAR representatives form part of the core membership of the MEG. CEDAR provides access to contemporary assessments of novel MEDICAL EQUIPMENT and Medical Technologies. CEDAR must be consulted before making decision to adopt MEDICAL EQUIPMENT or Medical Technologies which are new to the UHB

Specifications

Equipment suitability for the job required can best be determined by careful consideration and preparation of a technical specification. In many cases Clinical Engineering (or the Rehabilitation Engineering Unit in relation to ALAS) is in a position to provide advice on the options available and assist in the preparation of the specification.

Standardisation

If like for like technology replacement is being considered, e.g. another patient monitor or another pulse oximeter, then the need for standardisation of equipment to a restricted range of types throughout the UHB **must** override the personal preferences of individual users. The prudent benefits given by standardisation are a significant contribution to the reduction of clinical risk, the effectiveness of user training and the cost of procurement and maintenance.

Training

The costs of and arrangements for training both PROFESSIONAL USERS and technical maintenance staff need to be taken into account. Significant savings can be made if training arrangements are agreed as part of the procurement process. Robust training and competence programmes and competence assessment must be a critical dependency of implementation plan. This will ensure that all clinical and safety risks associated with the introduction of new medical technology are appropriately managed.

At times there may be a requirement to procure equipment to meet the training obligations of the UHB. Examples would be additional defibrillators for the Resuscitation Department's training programme, or a teaching attachment for endoscopy equipment.

Maintenance Implications

Maintenance implications of the procurement of new equipment are often overlooked. If same or similar equipment is procured then maintenance implications are minimised. In addition, experience gained regarding the overall reliability and performance of and support for various equipment types will inform decisions about which equipment to continue buying.

When new types of MEDICAL EQUIPMENT are being considered then the maintenance implications need to be considered and arrangements agreed at an early stage and any negotiations carried out with the potential supplier before the procurement order is finalised. Significant clinical and operational risks arise when the first time maintenance implications are thought about is as the equipment fails for the first time.

Reliability

Previous experience with the same or similar equipment from a given manufacturer or with a given manufacturer's equipment in general may be advantageous when making decisions. Networking with colleagues in other Health Boards, Trusts and Shared Service partner organisations can be helpful as can reference to guidance publications from the NICE Medical Technologies Evaluation Programme. Whilst MEDICAL EQUIPMENT which is known to be unreliable must never be adopted by the UHB, previous experience must be considered in the round with other MEDICAL EQUIPMENT life cycle criteria. Failure to do so may stifle innovation, depart from agreed prudent health care principles, fail to deliver outcomes that matter to patients and may not provide the best value for money option.

Decontamination

Some types of MEDICAL EQUIPMENT e.g. endoscopes, will require decontamination after each use. Some models may be more easily and effectively decontaminated than others. Some equipment may need highly specialised decontamination facilities and this may add significantly to the cost of a new purchase. These issues must be considered with expert advice from the UHB's 'Decontamination User' (Hospital Sterilisation and Decontamination Unit (HSDU) Manager), the Authorising Engineer (Decontamination) (Senior Decontamination Engineer, NHS Wales – Shared Services Partnership - Facilities Services, (NWSSP-FS, AE(D)) and the UHB's Decontamination Group. Please see Cardiff and Vale UHB's 'Decontamination of Reusable Medical Device Policy' for detailed advice.

Impact on the IT infrastructure

Some MEDICAL EQUIPMENT is networked either locally within a unit e.g. a Coronary Care Unit, or UHB wide, e.g. a Radiology Information System. Telemetry systems may interfere with wireless IT networks. All such

implications need to be considered prior to purchase and discussed with the UHB's IM&T and Clinical Engineering departments.

Impact on existing Estate.

If Medical Equipment is not 'plug and play' and requires modifications to the fabric of buildings, then enabling works can be costly and contribute significantly to overall project costs. Detailed project costs must be viable in advance of nay decision to purchase Medical Equipment. A Project Outline for Major Capital Medical Equipment Replacement template must be completed in collaboration with the Estates department.

Whole life costs

The whole life cost of equipment can be significantly altered if the costs of disposables are included. This is particularly so for infusion devices. Conversely, the nature and quality of disposables may affect the performance of the equipment. These clinical and technical issues need to be taken into account as part of the procurement process.

Regulations

CE/UKCA marking of all Medical Devices 'placed on the market' under the Medical Devices Regulations 2002 (as subsequently amended) is a legal requirement. However, problems arise with equipment supplied not being marked or marked but exhibiting characteristics that raise concerns. It is therefore prohibited for the UHB to purchase/loan and then put into use MEDICAL EQUIPMENT that is not CE/UKCA marked without explicit agreement from the UHB's Medical Equipment Group which may be granted under exceptional circumstances, for example, in line with a formally agreed MHRA humanitarian exemption together with agreement from the Welsh Risk Pool.[1]

Any urgent requests for the exceptional use of non-CE/UKCA marked devices (including for research purposes) may be made to the Chair of the UHB'S Medical Equipment Group who, in consultation with the Clinical Board Medical Devices Safety Officers and having received all relevant assurances, may take Chair's action to allow use under specific conditions.

Suppliers are required to submit a Pre-Procurement Questionnaire (PPQ). This is then reviewed by a technically competent person in the NWSSP Procurement Service prior to raising the purchase order.

Risks

Purchasing MEDICAL EQUIPMENT without due regard to the standards articulated in the Medical Equipment Management Policy can put patients at risk e.g. purchasing a non-standard anaesthetic machine. Indiscriminate purchase of equipment e.g. not taking account of expensive disposables or installation costs can put the UHB at financial risk.

Standing Orders

The UHB has in place Standing Orders regarding such things as limits above which formal tenders must be issued. Standardisation to limited lists may lead to prospective procurements of certain types of equipment exceeding these limits and presents the opportunity for tendering and thus cost reduction.

Replacement Criteria

The replacement status of all MEDICAL EQUIPMENT should be continually reviewed. In many cases, the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) will be in a position to review and provide advice based on one or more of the criteria given. Any application for funds to replace equipment will be strengthened by clear arguments based on these criteria. Advice must be sought from CEDAR to determine whether contemporary critical assessments of MEDICAL EQUIPMENT or Medical Technologies are available.

Formal Procurement Arrangements

NWSSP Procurement Services have the responsibility to raise procurement orders and the expertise to advise on issues around Standing Orders, EC rules for large procurements, leasing options etc. NWSSP Procurement Services will work collaboratively with the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) and the user departments to ensure that the principles of this policy are applied to the best advantage of the UHB.

Medical Equipment Loan Service Equipment

The UHB has established a Medical Equipment Loan Service with equipment libraries at UHW and University Hospital Llandough. For infusion pumps and defibrillators the UHB has already developed mechanisms to decide on the restricted range to be procured. Further consultative work will be carried out to extend the standard types agreed. (National Audit Office (NAO) Report, Recommendation 16)[2]

Requisitioning equipment through Clinical Engineering

Clinical Engineering (or the Rehabilitation Engineering Unit in relation to ALAS) have the expertise to deal with or advise on most of the issues raised above and the experience to co-ordinate all the factors that should be considered. They are in a position to take an overview of the reliability, suitability and performance of most devices based on the fact that they have contact with all users in the UHB of particular types of equipment.

Unless Clinical Engineering is involved on every occasion (other than in relation to ALAS), the opportunities for standardisation, cost saving, arranging appropriate maintenance, training etc. are likely to be lost with consequent risk to the UHB.

Commissioning new equipment

MHRA advice is clear that all MEDICAL EQUIPMENT should go through an appropriate acceptance check procedure.[3] In addition, MHRA guidance[3] states that all devices on loan from manufacturers should be subject to a written agreement which defines the device management requirements, responsibilities and liabilities (noting that delivery receipt and pre-use procedures for loan device should be the same as those for purchased device, unless otherwise specified in this written agreement). Technical support for most MEDICAL EQUIPMENT is provided by one of the Clinical Engineering teams

and they will carry out the commissioning process in most cases. They are in a position to advise in all cases. In certain situations the most appropriate arrangements are for the supplier to carry out the commissioning but input from a UHB technical team is still required so that equipment is logged on asset registers, safety test results recorded etc. User instructions will be issued as part of the commissioning process. There is also detailed specialist advice on commissioning decontamination equipment contained in the UHB's Decontamination of Reusable Medical Devices Policy.

If MEDICAL EQUIPMENT is manufactured in-house, or modified in any way, in addition to being required to demonstrate compliance with the relevant legislation, standards and guidance, the UHB takes on all of the associated civil law risks. Such activities must only be carried out in accordance with the UHB In-house Adaption, Modification, Manufacture and Repair of Medical Equipment Procedure.

If such in-house manufactured or modified equipment is passed on to other organisations e.g. another UHB, then they are likely to have been 'placed on the market' under the Medical Devices Regulations 2002 (as subsequently amended) in which case advice must be taken from the UHB Medical Equipment Group prior any such activity.

Maintenance of MEDICAL EQUIPMENT

Maintenance of all work equipment is a statutory requirement.[4] The details of maintenance arrangements will depend on the nature of the equipment and the risks posed to employees and others who might be affected. Poorly maintained MEDICAL EQUIPMENT may pose a risk to the UHB's employees but more likely a risk to patients. Clinical users have a responsibility to ensure that maintenance arrangements are in place. Agreement on the arrangements and on the funding of those arrangements must be made before equipment goes into use. It should be noted that with some equipment there will be routine maintenance requirements even in the warranty period. The manufacturer's warranty will not cover these, just as routine servicing on a new motor car is not covered by the warranty.

Detailed guidance has been issued by the MHRA[3] covering this and all other aspects of equipment management. This includes a recommendation that cannibalising old equipment is not an acceptable option for acquisition of equipment. The National Audit Office (NAO) Report[2] also provided opinions on best practice. This includes consideration of sharing maintenance with external suppliers, regularly reviewing contracts for value for money and reviewing preventive maintenance schedules in the light of experience and risk assessment.

The UHB also has to demonstrate that it is meeting the requirements of the Health and Care Standards[5]. The requirements of this policy are designed to ensure that these issues are addressed and agreed at an early stage. It is unacceptable for Directorates to assume that the relevant technical support team can simply take on the maintenance of additional equipment without any additional resource.

A register of maintenance providers for various types of MEDICAL EQUIPMENT is given in Appendix 4. This is current but is subject to change as more effective

methods of equipment maintenance become available. The UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) is always available to give advice.

Training Issues: PROFESSIONAL USERS

Training in the proper and safe use of work equipment is also a statutory requirement.[6] Regulation 9 of the Provision and Use of Work Equipment Regulation (PUWER) [3] states that,

'Every employer shall ensure that all persons who use work equipment have received adequate training for the purposes of health and safety, including training in the methods which may be adopted when using work equipment, any risks such use may entail and precautions to be taken.'

The extent and level of training can be proportionate to the risks to patients and employees. The obligation to provide adequate training extends not only to those who use work equipment but also to those supervising or managing them. An assessment of competence must form part of MEDICAL EQUIPMENT training programmes.

For these reasons, PROFESSIONAL USERS must not put MEDICAL EQUIPMENT into use unless they have had appropriate and adequate training and an initial assessment of competence and an on-going programme of competence assessment.

Training Issues: END USERS

The END USERS of equipment may be patients or carers. When the UHB issues equipment for use by END USERS the same legal principles outlined above apply, as well as a duty of care liability. Therefore, it is vital that appropriate training is given and that the equipment is accompanied by suitable written instructions. If possible these should be agreed with the manufacturer of the equipment but in any event must be peer reviewed and signed off by a responsible person. An assessment of competence must form part of MEDICAL EQUIPMENT training programmes. For End Users this could be a visual assessment of use following training.

MEDICAL EQUIPMENT inventory data base

Inventory information regarding all assets of Medical Equipment (other than in relation to ALAS) are held on the UHB's Clinical Engineering Department's data base which is accessible UHB wide in read only form. Departments that have holdings of equipment not on the Clinical Engineering data base must establish their own systems. The UHB is working towards a single data base for all MEDICAL EQUIPMENT including those items under £5,000 in value which are not assets.

Disposal of Equipment

Before MEDICAL EQUIPMENT is disposed of it is important that it is recorded on the database as having been removed from service. In addition, new

regulations coming into force and the attendant risk to the UHB of not complying mean that certain component parts of equipment e.g. VDU screens, batteries, may need to be made safe or removed and disposed of separately. This requires technical knowledge and facilities. Therefore the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) must be consulted prior to disposal and the Capital & Asset Management must be informed to update the UHB's Asset register.

Application of the Policy and Procedures to all MEDICAL EQUIPMENT Acquisitions

All the long term implications of controlling and making use of MEDICAL EQUIPMENT apply whatever the source of funding. Therefore the Medical equipment Management Policy and Procedure must be followed for all MEDICAL EQUIPMENT purchases.

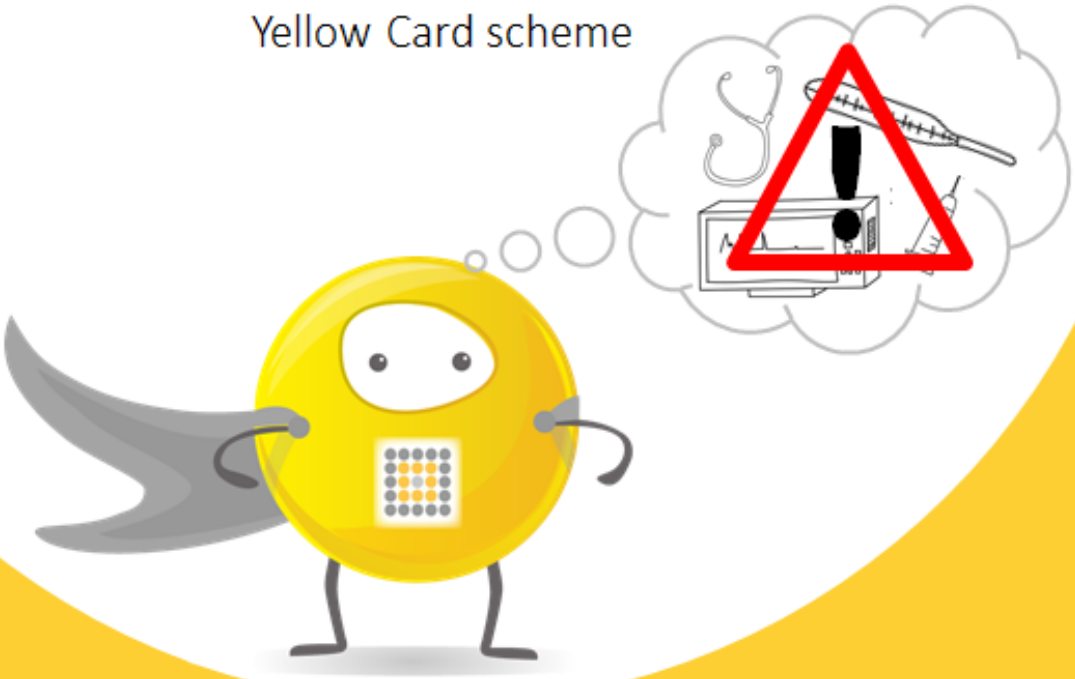
Medical Equipment – Incident Reporting

It is vital that all incidents involving MEDICAL EQUIPMENT are reported appropriately via both the internal Datix reporting system and the MHRA Yellow Card reporting scheme (please see below). The UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS) should also be informed so that appropriate action can be taken which may include referring the incident to the MHRA (NB – only equipment managed by Clinical Engineering will be reported to the MHRA by Clinical Engineering, therefore, all other equipment should be reported to the MHRA directly by those raising/managing the internal Datix report). Internal Datix incident reports must always be completed to include the 'medical equipment' flag in order that Clinical Engineering are alerted to the incident. All equipment that is the subject incident reporting should be taken out of service and quarantined pending an investigation further advice on which may be obtained from the UHB's Clinical Engineering Department (or the Rehabilitation Engineering Unit in relation to ALAS).

Equipment and accessories including disposable items must be retained securely for examination during an investigation. Information regarding MEDICAL EQUIPMENT incidents will be collated and reviewed at MEG meetings.

Problem with a medical device?

Did you know you can help make medical devices (including disposable items) safer by reporting suspected problems to the Yellow Card scheme



Examples of problems to report

- Faulty brakes on a wheelchair
- Faulty batch of test strips for a blood glucose meter test giving wrong readings
- Unclear labelling or instructions on the device
- Unsafe design
- Quality issues that impact safety

To report

- Visit **mhra.gov.uk/yellowcard**
- Use the free app

iPhone Android

For further information about the Yellow Card scheme go to **www.awttc.org/YCCWales** or contact Yellow Card Centre Wales on:

Phone: 029 2074 5831 **E-mail:** CAV_YCCWales@wales.nhs.uk

For more information or support please contact Clinical Engineering on 029 20745678

YCC Wales
Yellow Card Centre Wales
Canolfan Cerdyn Melyn Cymru

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Medicines & Healthcare products Regulatory Agency

Appendix 4

Register of maintenance providers for MEDICAL EQUIPMENT

Type of MEDICAL EQUIPMENT	Maintenance arrangements through:
General MEDICAL EQUIPMENT • Patient monitors • Infusion devices • Defibrillators • Blood pressure monitors • Pulse oximeters • Foetal monitors • Infant incubators • Infant warmers • Physiotherapy equipment (electronic) • Surgical diathermy • Temperature measuring equipment • Patient warming equipment • etc.	Clinical Engineering Technical Services
Anaesthetic equipment • Anaesthetic machines • Patient ventilators • Suction equipment • Oxygen therapy equipment • Nebulisers • Medical gas and suction flowmeters and regulators etc.	Clinical Engineering Technical Services
Dialysis equipment	Clinical Engineering – DTS
Patient handling equipment • Treatment couches and plinths • Patient trolleys • Chiropody equipment • Wheelchairs for short term loan/ transfers • Patient hoists • Operating tables	Clinical Engineering – Mechanical Engineering Clinical Engineering – Mechanical Engineering Clinical Engineering – Mechanical Engineering Contract via Estates Services
Radiology equipment • X-Ray equipment • CT equipment • MRI equipment	Contact Radiology Department

<u>Other imaging equipment</u> • Gamma cameras • Ultrasound scanners • Lasers	 Contract; first line Medical Physics Contract; first line Medical Physics Contract; first line Medical Physics
<u>Disability equipment</u> • Posture and Mobility equipment (including wheelchairs) • Prosthetics and Orthotics • Electronic Assistive Technology	 ALAS ALAS ALAS
<u>Laboratory equipment</u>	Contact Laboratory Medicine Directorate.
If there is any doubt please contact the Clinical Engineering Department at UHW or the Rehabilitation Engineering Department at ALAS.	

Appendix 5

CAPITAL MEDICAL DEVICE BIDDING PROCESS

Appendix 6

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

CAPITAL MEDICAL DEVICES BIDDING FORM

(Medical, Laboratory & Imaging Devices)
Please c*omplete and submit electronically*

BID FOR

Number of items Date bid was submitted

Clinical Board
Department/Specialty
Project Lead/Contact
Email Phone
Alternative Contact
Bid Amount £ (excl. VAT and Revenue Costs)

Have you contacted Procurement, your Clinical Board's MDSO[1] and Clinical Engineering to discuss this bid?

1. Statement of Need

Provide a short summary pitch or attach an SBAR of why the equipment should be purchased i.e. Statement of Need.

- *What does the equipment do?*
- *What are the issues with the current equipment? E.g. age, reliability, fit for purpose.*
- *What are the benefits of the new equipment?*
- *Are there Local and National drivers for change?*
- *How does the new equipment support delivery of WG, UHB, Point of Care Testing Policy, Clinical Board and Partner Organisation(s) objectives and priorities e.g. Audits, IMTP, Medical Equipment Management Policy etc.*

2. Primary reason for Bid

- ☐ Routine replacement
- ☐ Standardisation of equipment
- ☐ Expiry of lease arrangements
- ☐ Unreliable and/or maintenance support withdrawn
- ☐ Equipment failed or no longer fit for purpose
- ☐* Newer equipment saves its extra cost within in a specified time-frame
- ☐ New or additional equipment

*Please provide evidence/calculations of cost savings in section 1

3. Risk scoring

Please refer to Risk Assessment and Risk Register Procedure

Is this risk captured on the Department, Clinical Board or Corporate Risk Register? Yes ☐ No ☐

Please attached the risk assessment in the box below,

The UHB's template can be found here

Highlight the largest risk* of the **old equipment/current situation**:

*This should be the risk score on the risk register

Likelihood (1-5)	**x**	**Consequences** (1–5)	**=**	**Risk**
	x		=	

4. Details of equipment being replaced (if appropriate)

If you have a detailed equipment replacement plan or list of identified equipment attach this instead, indicating which items are to be replaced and the original funding source.

Extend the table as necessary.

Manufacturer	Model	Age (yrs)	Asset Number*	Who services/ maintains the equipment?
				Choose an item.
				Choose an item.

*Preferably the Asset Number, B or R Number. Provide the serial number if the other numbers are not available.

5. Disposal of existing equipment

Equipment should be disposed of through Clinical Engineering. Alternative routes must be agreed.

Clinical Engineering ☐
Manufacturer (of existing or new equipment) ☐
Other (please specify)

	Yes	**No**	**Approximate amount**
Are there decommissioning or disposal costs for the old equipment?	☐	☐	£

s there confidential information stored on the **old** equipment e.g. patient ata? Yes ☐ No ☐

6. Medical Device being Considered

1. Device Details

What category is the equipment?

Medical ☐
Laboratory ☐
Point of Care Testing (POCT) ☐*
Imaging ☐

Ionising ☐
Non-ionising ☐

*Consideration of POCT equipment must be signed off through POCT's procedure

Approved By	**Role**	**Evidence of Approval****

**Add the email (drag and drop) containing the approval

Who will own the equipment?

Please list all departments if equipment numbers will be divided.

Will this equipment be regularly used by users outside of the department which owns it? Yes* ☐ No ☐

*if **YES**, Who will pay for recurring costs? E.g. maintenance, consumables etc.
Please seek appropriate authorisation from the clinical board and head of finance, Section 8.

2. Quotation Examples

Provide at least two quotations of equipment that would meet the identified requirements

Option	Preferred Option	Manufacturer / Supplier	Model	Quote for one item Excl. VAT	Total Cost Excl. VAT	Quote**
A	☐			£	£	
B	☐			£	£	

*Highlight the preferred option and preferably add reasoning to the Risk Assessment, Appendix A

What is the lead time for delivery of the equipment? ..... Months

Is this equipment or a similar type that is not being replaced, already used in your area or elsewhere in the UHB? Yes* ☐ No ☐

***If Yes**, please specify where:

Has an equipment trial been undertaken? Yes ☐ No ☐

Will the new equipment require changes to consumables? Yes ☐ No ☐

New consumables ☐

Consumables no longer required ☐

3. Estates and Infrastructure

Does the equipment require Estate-enabling works? Yes* ☐ No ☐

Equipment may require construction work which includes supplying utilities.

If Yes, have you contacted Estates to discuss feasibility and costs? Yes ☐

Will the purchase require space reallocation or reconfiguration? Yes ☐ No ☐

Newer equipment may have a larger floor-footprint than older equipment such that it may not fit in the space previously used for that equipment.

4. I.T. Network and Data

Can the equipment be connected to a network? Yes ☐ No ☐

Will the equipment be connected to a network? Yes* ☐ No ☐

***If yes, have toy contacted the relevant team (IT or PACS) to discuss feasibility and costs** Yes ☐

Initial Cost **Annual Cost**

Networking setup/ management £ £

Central data storage/ server £ £

oes the new equipment store confidential information? Yes ☐ No ☐

an the new equipment output patient identifiable information via a port e.g. USB, Ethernet etc.)? Yes ☐ No ☐

5. Maintenance

Who will maintain the equipment?

		Annual Cost
Clinical Engineering	☐	£
ALAS	☐	£
Manufacturer or Supplier	☐	£
Third-party maintenance service	☐	£

6. User Training

What training is required to use this equipment?

Manufacturer ☐

UHB-led training ☐

What department/service provides this training? .....

ost of training £ ..... Per ..... places

low many staff require training (approximately)? .....

7. Decontamination

this equipment is new to the UHB, have you contacted HSDU nd/or IP&C to discuss feasibility and costs? Yes ☐

oes the UHB have the facility to effectively decontaminate this quipment? Yes ☐ No* ☐

If NO, please explain approved decontamination plan with additional costs

8. Radiation Safety

Does the equipment use any of the following?

	Yes	No	Approval required	Approved by	Evidence of Approval
Ionising radiation	☐	☐	Radiation Protection Advisor	.....	
Ultrasound	☐	☐	Ultrasound Protection Advisor	.....	
Laser technology	☐	☐	Laser Protection Advisor	.....	
MRI	☐	☐	MRI Protection Advisor	.....	

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7. Estimated Cost Summary

Total Cost of Medical Device* £

Additional Capital Costs* £

Total Cost of Bid* £

*Prices excluding VAT

Include any quotations for equipment, 6.2 Quotation Examples

1. Revenue Impact/ Annual Costs

These costs are the responsibility of the department that has agreed to pay for recurring costs and requires authorisation by the respective Clinical Board's Head of Finance.

What are the expected annual financial changes (revenue)?

	Increase	Neutral	Decrease	Approximate amount
Staffing costs	☐	☐	☐	£
Training cost	☐	☐	☐	£
Consumable costs	☐	☐	☐	£
Maintenance costs (**AFTER** warranty period)	☐	☐	☐	£
Other Costs	☐	☐	☐	£
Service Income	☐	☐	☐	£

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8. Authorisation

Proposal Completed By	Role	Date

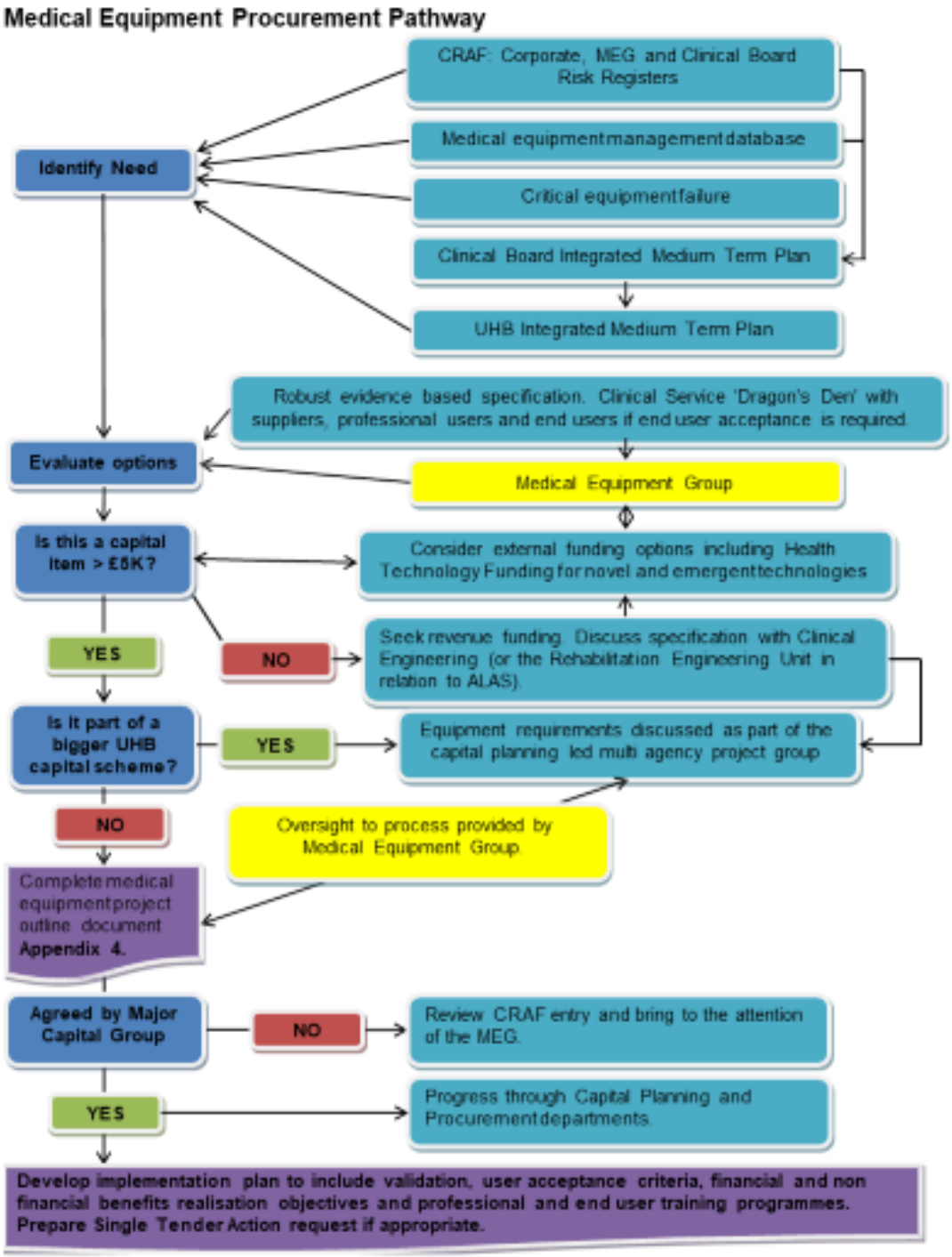
Clinical Board Authorisation	Role	Date

Clinical Board Head of Finance Authorisation	Role	Date

MDSO Authorisation	Role	Date

Executive Authorisation	Role	Date

Appendix 7


Medical Equipment Procurement Pathway
CRAF: Corporate, MEG and Clinical Board Risk Registers
Medical equipment management database
Identify Need
Critical equipment failure
Clinical Board Integrated Medium Term Plan
UHB Integrated Medium Term Plan
Robust evidence based specification. Clinical Service 'Dragon's Den' with suppliers, professional users and end users if end user acceptance is required
Evaluate options
Medical Equipment Group
Is this a capital item > £6K?
Consider external funding options including Health Technology Funding for novel and emergent technologies
YES
NO
Seek revenue funding. Discuss specification with Clinical Engineering (or the Rehabilitation Engineering Unit in relation to ALAS).
Is it part of a bigger UHB capital scheme?
YES
Equipment requirements discussed as part of the capital planning led multi agency project group
NO
Oversight to process provided by Medical Equipment Group
Complete medical equipment project outline document Appendix 4.
Agreed by Major Capital Group
NO
Review CRAF entry and bring to the attention of the MEG.
YES
Progress through Capital Planning and Procurement departments.
Develop implementation plan to include validation, user acceptance criteria, financial and non financial benefits realisation objectives and professional and end user training programmes. Prepare Single Tender Action request if appropriate.

REFERENCES

[1] Medical Devices Regulations 2002 (as subsequently amended)

Medical Devices are defined as follows and include a huge range of devices from sticking plasters to MRI scanners. The definition also encompasses disposables such as syringes, and accessories such as electrocardiograph leads:

A medical device is defined as:

Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

— providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations, …

An 'accessory for a medical device' are regulated as if it is a medical device.

[2] National Audit Office, *The Management of Medical Equipment in NHS Acute UHBs in England,* HC 475Session 1998-99, HMSO, London, 1999

[3] Managing Medical Devices, Guidance for healthcare and social services organisations, MHRA, April 2015

[4] Health and Safety at Work Act 1974

- Provision and Use of Work Equipment Regulations (PUWER) 1998

[5] Health and Care Standards, Welsh Government, January 2021

[6] Keay, S. *Policy for Parenteral Infusion Pumps Issue 2.0* Cardiff and Vale NHS UHB, Policy No 77, Cardiff, August 2003

[7] McCarthy J.P., *Health Service Equipment Management; the Engineers View* Presented to a Welsh Medical Technology Forum Seminar; *Medical Devices - the User's View.* Treforest, South Wales, October 1994

[8] McCarthy J.P., *Equipment Management: A Current Perspective* Presented to an NHS conference; *The Way Ahead for Equipment Procurement in the NHS,* Eastwood Park, June 1998