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Review of Clinical Equipment – **Velindre NHS Trust**

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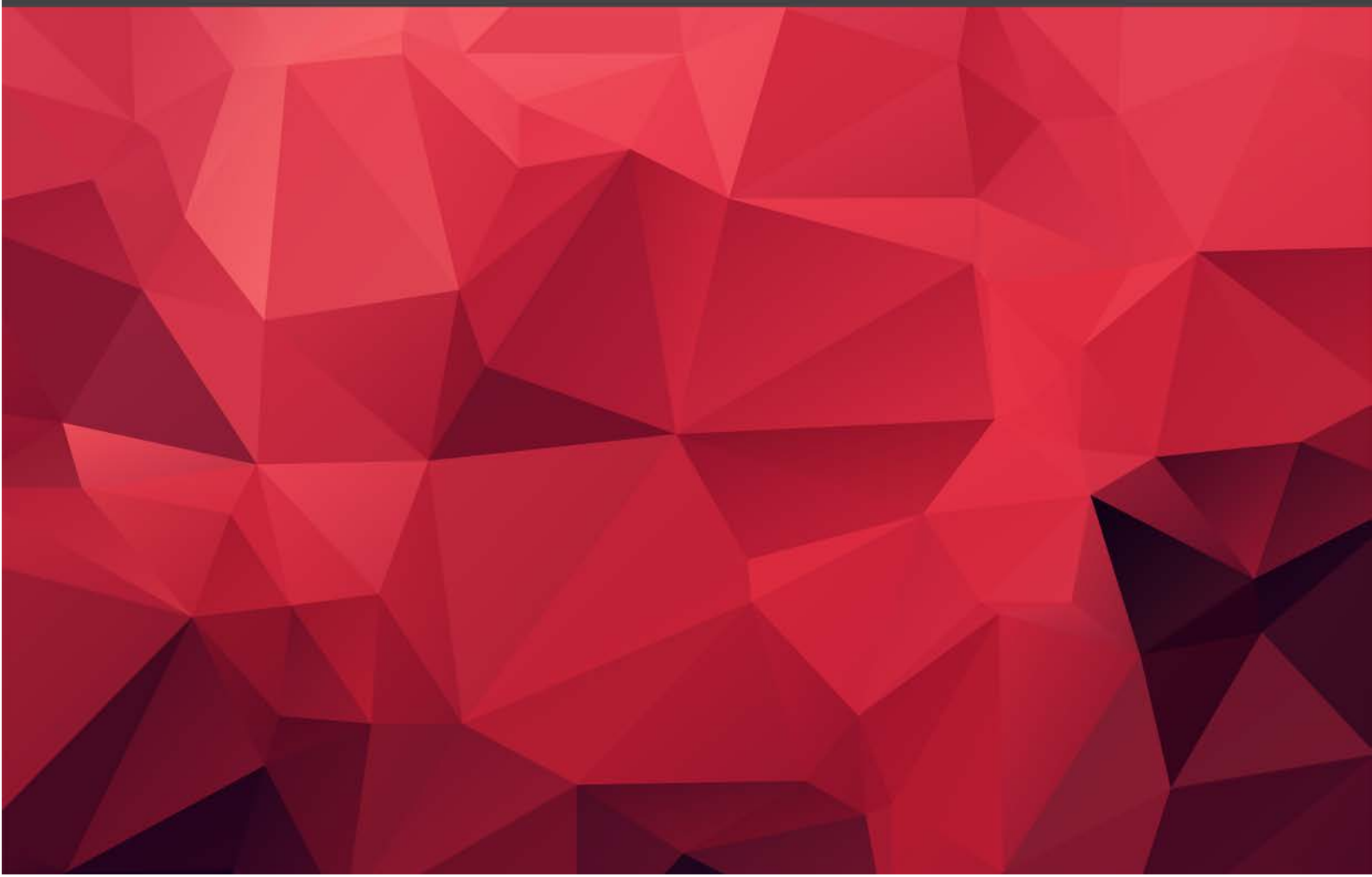

The work was delivered by Philip Jones.

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Detailed report

Background

1 Velindre NHS Trust (the Trust) owns and maintains thousands of items of clinical equipment. By clinical equipment, we mean ‘any equipment connected to patients’. The term covers a broad range of products which are used for the diagnosis and treatment of disease, monitoring of patients, and includes assistive technologies. In the case of the Welsh Blood Service, this meaning extends to laboratory equipment and equipment used in blood donation clinics.

2 It is vital that health bodies manage their clinical equipment in such a way as to ensure patient safety and high quality care. Effective management of clinical equipment should also ensure value for money.

3 Discussions between the Wales Audit Office and the Trust highlighted the cost of maintenance contracts for clinical equipment. Maintenance contracts are the second highest value item of non-pay expenditure at the Velindre Cancer Centre.

4 We undertook a local review to assess whether the Trust is managing its clinical equipment effectively now and for the future. In order to answer this question, we examined whether the Trust has:

- effective corporate arrangements for managing clinical equipment;
- adequate management information about clinical equipment; and
- effective operational arrangements for managing clinical equipment.

5 As well as reviewing arrangements for managing clinical equipment at the corporate level, we also looked at arrangements in the Velindre Cancer Centre Division and the Welsh Blood Service Division. We examined information and interviewed staff from departments within both divisions.

Key findings

6 Our overall conclusion is that the Trust could strengthen its strategic approach to clinical equipment and operational arrangements and improve its management of risks with a dedicated software system. We have set out the main reasons for this conclusion in the paragraphs below.

Operational arrangements

7 The Trust does not have a Trust-wide clinical equipment inventory, cannot readily identify maintenance costs and could improve the procurement of equipment. We came to this conclusion because:

- the Trust does not currently have a Trust-wide dedicated software system for clinical equipment, but is procuring one;
- the Trust has a medical devices policy but needs to ensure that associated policies are kept up to date;
- procurement skills vary between divisions, staff need to be trained in drafting business cases and the governance of procurement could improve; and
- the Trust has localised arrangements in place to monitor and maintain clinical equipment, but cannot centrally quantify maintenance expenditure.

Corporate arrangements

8 Clarifying the role of executive leads, managers and a key working group would strengthen corporate arrangements for clinical equipment. We reached this conclusion because:

- senior executive lead and management responsibilities for clinical equipment are not described in detail;
- the Trust has devolved day-to-day operational responsibility for clinical equipment to department managers and has recently taken a step forward by appointing a medical devices officer; and
- the Medical Devices Working Group could be an important part of clinical equipment management arrangements, but its remit needs to be clarified.

Managing risks

9 The absence of dedicated clinical equipment software hinders the Trust's ability to audit, manage risks and monitor training compliance, although arrangements are in place to issue safety alerts and learn from incidents. We reached this conclusion because:

- Velindre Cancer Centre highlighted a number of risks associated with the absence of a dedicated clinical equipment software system two years ago;

- the absence of a dedicated software system for clinical equipment hinders corporate monitoring of maintenance requirements and information on performance is fragmented;
- although the Welsh Blood Service holds staff training records, the Trust's ability to monitor compliance with training is hindered because Velindre Cancer Centre's staff training records are fragmented; and
- the Trust has arrangements in place to issue safety alerts and share learning from incidents.

Recommendations

10 As a result of our work, we make the following recommendations in relation to clinical equipment, targeted at minimising risks and maximising value for money.

Exhibit 1: recommendations

Recommendations	
R1	**Executive lead arrangements.** Whilst there are executive lead responsibilities in relation to clinical equipment allocated to key individuals, we found that those responsibilities were not set out in detail and were primarily focused on patient safety. The Trust should strengthen and clarify corporate leadership arrangements, and ensure that executive lead responsibilities for clinical equipment are extended beyond patient safety.
R2	**Operational management arrangements**. We found that the Medical Devices Working Group suffers with intermittent attendance, its remit is not clearly understood by staff and its fit in relation to procurement, with other forums, is unclear. The Trust should review the terms of reference of the Medical Devices Working Group, and clarify the group's purpose, ensuring it is in the best position to influence the management of clinical equipment across the Trust.
R3	**Operational management arrangements**. The Medical Devices Officer was new to their substantive role at the time of our audit, after being on secondment to the role for the two previous years. We found that the post holder's ability to focus fully on their new role was hindered by the need to fulfil duties relating to their former role. We think that the Trust should establish a clear and prioritised work programme for the Medical Devices Officer. The programme should prioritise progressing the introduction of the software system for clinical equipment, and establishing an audit/monitoring regime.

Recommendations	
R4	**Record management**. We found that the absence of a software system for clinical equipment was hindering the Trust's ability to: • manage and monitor equipment maintenance, • identify staff training compliance and needs, • collate and report performance information; • manage risks; and • identify the costs of maintenance. The Trust should prioritise the introduction of a Trust-wide software system for clinical equipment. The Trust should ensure that the implementation of the system is fully planned, including establishing clear executive support, the operational requirements to populate the system, staff training requirements and a review mechanism to ensure successful implementation.
R5	**Procurement**. We found that there was variability in the procurement skills of the two divisions, and whilst there were signs that while the culture was improving at Velindre Cancer Centre, there was more that could be done. The Trust should ensure that; a. staff involved in equipment procurement at the Velindre Cancer Centre, have the necessary knowledge and expertise to prepare business cases; b. it considers how to further strengthen clinical equipment procurement arrangements; such as the identification of a lead for procurement with clinical and technical knowledge to add to the process; and c. it reviews the terms of reference of forums responsible for the governance of procurement, to identify and eliminate any overlaps or gaps in responsibilities (such as for the consideration of the renewal of maintenance contracts).
R6	**Audit, risk management and learning**. We found that the Trust does not routinely audit compliance at Velindre Cancer Centre with all areas of the Medical Devices and Equipment Policy, and that corporate monitoring of compliance with regulations and equipment warranties is difficult. The Trust should: a. establish a programme of audit at Velindre Cancer Centre to ensure compliance with the Trust's Medical Devices and Equipment Policy, and any other relevant regulations or policies; b. identify the performance information needed to enable corporate monitoring of clinical equipment, and how to report this in a meaningful and coherent way; and c. carry out a review of the Hospira pump issue highlighted in this report, to identify any learning from the way the issue was dealt with that could be used to improve and inform the way the Trust responds to similar scenarios in the future.

The Trust does not have a Trust-wide clinical equipment inventory, cannot readily identify maintenance costs and could improve the procurement of equipment

The Trust does not currently have a Trust-wide dedicated software system for clinical equipment, but is procuring one

11 The Trust does not have a Trust-wide dedicated software system for clinical equipment management. The Medical Equipment Management Review for Velindre Cancer Centre, 2013[1] recommended that such a system should be put in place.

12 Currently there are numerous spreadsheet inventories held by departments within the Velindre Cancer Centre. The spreadsheets provide an inventory of equipment, planned maintenance programmes, and staff training records. They contain information in different formats so the Trust cannot readily access one consistent inventory of clinical equipment, for either the Velindre Cancer Centre or Trust-wide.

13 The Welsh Blood Service has its own divisional asset inventory, the Q-Pulse[2] Asset database. Q-pulse is used to record information relating to clinical equipment, including details of maintenance and any associated cost, along with information on the scope of use and operational status.

14 Cardiff and Vale University Health Board's Clinical Engineering Department is responsible for the maintenance of some of the Velindre Cancer Centre's clinical equipment. Trust staff told us that they do not have electronic access to a list of the Trust equipment maintained by the Clinical Engineering Department at Cardiff and Vale University Health Board. This means that the Trust can only access this information by request.

15 At the time of our fieldwork, the Medical Devices Working Group (paragraph 52) was preparing a business case for a dedicated software system for clinical equipment management, with the aim of procuring it before April 2018. The intention was that such a system will be implemented and managed by the Medical Devices Officer. Originally, the system was to cover the Velindre Cancer Centre only, despite the recommendation for a Trust-wide solution (paragraph 12). However, towards the end of 2017, the Welsh Blood Service expressed an interest in using the Trust-wide system (in addition to the Q-Pulse system already used by

[1] Clin Eng Consulting Ltd, **The Medical Equipment Management Review for Velindre Cancer Centre**, 2013. The review examined clinical equipment responsibilities, policies, and inventory arrangements within the division.

[2] Q-Pulse is an electronic quality management system to help document compliance and risk management processes.

the division). The business case may need to be reviewed to consider any specific requirements for the Welsh Blood Service.

16 The Welsh Blood Service currently uses Q-Pulse to address regulatory requirements and ensure robust processes are in place. Whilst they recognise that a Trust-wide system may be advantageous to the Trust as a whole, it would introduce additional unbudgeted cost on top of the current system which the Welsh Blood Service would continue to use. They suggested an assessment of costs and benefits against competing priorities.

17 The Trust was unable to provide evidence that here has been meaningful planning for the implementation of the software, despite the intention to buy a system in the coming months. The Medical Equipment Management Review of 2013 (footnote 1) pointed out that the implementation would be a considerable undertaking. The implementation of the system will require;

- the leadership of an executive who is in a position to ensure that divisions and their departments participate fully;
- effective divisional director involvement so that they are aware of the implications of the project and will in turn ensure that departmental managers engage in the project;
- a robust project management approach, led by the Trust's Medical Devices Officer;
- the identification of operational staff resources to assist in the necessary work to populate the system with data;
- training for all Trust staff who will need to use the system; and
- a review mechanism to ensure successful implementation.

18 The Trust needs to ensure there is clear executive support for the planning and implementation of the software system for managing clinical equipment.

The Trust has a medical devices policy but needs to ensure that associated policies are kept up to date

19 The Trust approved the latest version of the Trust's Medical Devices and Equipment Policy in April 2017. The policy reflects the requirements of the Medicines and Healthcare products Regulatory Agency's **Managing Medical Devices – Guidance for Healthcare and Social Services Organisations**[3].

20 The aim of the policy is to ensure that whenever clinical equipment is used it is:

- suitable for its intended purpose;
- used in accordance with the manufacturer's instructions;

[3] Medicines and Healthcare products Regulatory Agency, **Managing Medical Devices – Guidance for Healthcare and Social Services Organisations**, April 2015.

- maintained in a safe and reliable condition, with associated records kept; and
- disposed of appropriately at the end of its useful life.

21 The policy is comprehensive and covers the life-cycle of equipment, including acquisition, maintenance, decontamination and disposal. The policy also covers responsibilities, record keeping, audit requirements, incident management and the management of responses to clinical equipment alerts.

22 The Welsh Blood Service has a local medical devices policy, which was written in support of the Trust policy. It is also based upon **Managing Medical Devices – Guidance for Healthcare and Social Services Organisations**, produced by the Medicines and Healthcare products Regulatory Agency. It is managed through the division's formal Document Control system which ensures regular review (every two years). The next review is due in November 2018.

23 Our work did not include a detailed review of all of the Trust's policies on clinical equipment, although we saw evidence that a range of policies are in place in both the Velindre Cancer Centre and the Welsh Blood Service. As mentioned above, the Welsh Blood Service utilises a formal Document Control system to help manage its local policies as part of its Quality Management System. However, at Velindre Cancer Centre, in the absence of consistent arrangements, there is a risk that the Trust is not doing enough to ensure that all of their policies are kept up to date.

24 At interview we were told that the Medical Devices Regulation 2017[4] has extended previous requirements to include in-house development of clinical equipment, whether hardware or software, which were previously excluded. This has potential implications for all staff involved in this type of work, for example, doctors developing application software. There is a transition period until 2020 for compliance and the guidance is currently in 'draft for comment'. We were told that at the time of our review that the Trust needed to ensure that the implications of the change are clearly communicated to staff.

[4] A European Union regulation covering clinical equipment, which came into force in 2017.

Procurement skills vary between divisions, staff need to be trained in drafting business cases and the governance of procurement could improve

The culture of procurement varies by division and there is a need for further training for staff responsible for drafting business cases

25 The Medical Devices and Equipment Policy with the Trust's Standing Financial Instructions sets out a framework for the procurement of clinical equipment, and the responsibilities of the procurement team.

26 Purchases under the value of £25,000 are handled by operational services of the Trust, and purchases above that value are referred to the NHS Shared Service Partnership's Local Procurement Team. Contracts above the value of £100,000 require the Trust's Board's approval. When the Trust identifies a need to procure, high value items are included in the capital investment plan and the Integrated Medium Term Plan. Business cases are developed by the departments, and prioritised through the divisional senior management teams. The Trust Capital Planning and Delivery Group manages and co-ordinates the monitoring over all capital schemes.

27 The Trust is supported by the NHS Wales Shared Services Partnership Local Procurement Team which includes a head of procurement and a procurement lead. Procurement staff told us that the support function provided via the shared service model needs to be aligned to better fit the diversity of the products and patient care provided by the divisions at Velindre Cancer Centre.

28 The Trust told us that the procurement skills are more developed in the Welsh Blood Service than at the Velindre Cancer Centre. This is in part because the Welsh Blood Service previously had a staff member to provide dedicated procurement support, whereas Velindre did not. The remainder of the support is provided by the NHS Wales Shared Services Partnership Local Procurement Team. However, we were told that staff expertise and understanding are variable, particularly at the Velindre Cancer Centre. Whilst we were told that there are signs of improvement at the Velindre Cancer Centre, we were also told that some staff do not have the required level of skills or training to draft a robust business case. Some business cases are sometimes over or under-specified. This affects the procurement process and leads to frustration where the staff do not get the outcome they required.

29 The Trust recognises that further guidance on drafting business cases is required. The Trust did provide some training on the Trust's standing financial instructions 18 months before our fieldwork. All heads of departments at the Velindre Cancer Centre and the Welsh Blood Service were invited, along with staff involved with drafting business cases for goods and services. The Trust would benefit from repeating the procurement training and ensuring that all staff needing this training attend. At interview it was suggested that the appointment of a lead nurse for

procurement could also help, by providing a combination of clinical and procurement expertise. However, it would also be worth considering a broader role providing the required clinical and technical expertise to procurement exercises. Such a role would also help the Trust to ensure business cases are more robust.

30 The Trust has established a clear strategy for clinical equipment required for the Transforming Cancer Services programme[5]. Velindre Cancer Centre has agreed a Clinical and Information Management Technology Equipment Strategy which sets out the approach for the provision of clinical equipment and information technology for the new hospital. The strategy sets out an appraisal process for equipment items, including the potential for transferring existing equipment and purchasing new equipment, and includes risk appraisal of the options. Staff leading the planning arrangements for the Transforming Cancer Services project would like procurement staff to be embedded into project implementation teams. This would help ensure good communication and increase responsiveness. However, they are concerned about the national shortage of procurement staff, and the impact this might have on the project.

The governance of procurement could be strengthened

31 The Trust's Capital Planning and Delivery Group oversees the management and co-ordination of all capital schemes. The group is chaired by the Director of Finance; we were told that there was limited clinical representation attending this group, potentially leading to the under-representation of views of clinical staff.

32 Procurement issues are also reported to the Planning and Performance Committee. Neither the Capital Assets Group nor the Planning and Performance Committee considers the work of the other group in relation to procurement. At interview, we were told that both forums are focussed on patient safety and service delivery but less focussed on the technicalities of procurement. In addition, while there is a forum at the Welsh Blood Service to discuss maintenance contracts, there is no equivalent at Velindre Cancer Centre. Procurement staff told us they regard this as a shortcoming in the existing arrangements and suggested that a single forum for contracting would be beneficial. At the time of our fieldwork, procurement representatives were also concerned that a planned review of the Velindre Cancer Centre Planning and Performance Group could diminish the involvement of procurement.

[5] Transforming Cancer Services is a programme being managed by the Trust to respond to increasing demand for cancer services across South East Wales. The plans include building a new cancer centre (hospital) in Cardiff, and providing more services closer to patients' homes by creating a satellite radiotherapy unit and further integrating their services with hospitals in the region.

The Trust has localised arrangements in place to monitor and maintain clinical equipment but cannot centrally quantify maintenance expenditure

The Trust was unable to provide a centrally collated breakdown of internal and external maintenance expenditure

33 The Trust's clinical equipment is maintained through a combination of internal resources and external maintenance contracts with private companies and Cardiff and Vale University Health Board's Clinical Engineering Department.

34 In order to comply with equipment warranties, many manufacturers require that equipment be maintained either by the manufacturer or by a recognised third-party provider. Therefore, this is a major fixed determinant of the budget required for external maintenance over a number of years. The predicted life-span of a piece of equipment does present the opportunity for longer-term projections of cost and future budget planning.

35 Department managers are responsible for operational contract management. The Local Procurement Team supports the monitoring of contracts when requested, and resolves any issues arising.

36 Whilst the Welsh Blood Service in the main relies on external contracts for the maintenance of its clinical equipment, Velindre Cancer Centre relies on both external and internal maintenance. Velindre Cancer Centre is the main user of internal maintenance resources. These include Velindre Cancer Centre's Medical Physics Department engineers, who maintain linear accelerators[6], and the Trust's Estates Department, which has responsibility for the maintenance contract for hoists and medical gas pipework.

37 The Trust's corporate finance team maintains records of expenditure on all external maintenance contracts, although they were unable to provide us with a centrally collated breakdown of external maintenance budgets and costs. The Trust was also unable to provide us with budgets and expenditure specifically on internal maintenance.

Velindre Cancer Centre and the Welsh Blood System have arrangements in place to monitor, maintain and decontaminate clinical equipment

38 It is a requirement that individual departments within the two divisions ensure that procedures to monitor, maintain and decontaminate clinical equipment are in place to comply with warranty requirements and standards set by the Medicines and Healthcare products Regulatory Agency and the International Organisation for Standardisation.

[6] Linear accelerators are used to treat organs or parts of the body by delivering high energy x-rays or electrons to the region of the patient's tumour.

39 Velindre Cancer Centre's Medical Physics Department's planned maintenance schedule is developed in the autumn for each coming year. This forward planning allows manufacturer visits to be booked and any modifications to be agreed where the maintenance is undertaken by external parties. For all planned maintenance, a set of regular checks and individual modules are printed for completion on the day, this enables concurrent work by a number of engineers to speed up the process.

40 The Velindre Cancer Centre Medical Physics Department provided us with a description of their internal maintenance processes for linear accelerators (see footnote 5). Engineers follow guidelines in flow charts held in the Q-Pulse system which provides documentary control with compliance with ISO 9000[7] standards. This process helps engineers decide what checks need to be made, and actions to take before the equipment returns to clinical use.

41 Velindre Cancer Centre's radiation therapy and associated equipment is tested by the Medical Physics Department to ensure equipment accuracy. Clinical equipment breakdowns and associated faults are recorded in the Medical Physics Department's Breakdown Logbook, and where appropriate, the equipment's logbook. The information is manually added to the department's Breakdown Logbook, on a monthly basis. The Trust also uses an application called Slack (for smart phones and computers), that allows updates on current faults to be logged and the solution to be recorded for future reference.

42 The Welsh Blood Service operates Q-Pulse, a quality management system incorporating the principles and guidance of the Medicines and Healthcare products Regulatory Agency's Good Manufacturing Practice[8]. All equipment that requires maintenance is subject to a maintenance contract. The contracts are recorded in the Q-Pulse system along with details of planned preventative maintenance and emergency maintenance. The system helps to ensure that all critical equipment is regularly cleaned and decontaminated, as required by manufacturers' instructions, and in accordance with Trust procedures. All critical measuring and test equipment is calibrated. The Welsh Blood Service told us that relevant procedures for monitoring, maintenance and decontamination are in place and, as a consequence, holds a Blood Establishment Licence, granted by the Medicines and Healthcare products Regulatory Agency.

[7] ISO 9000 quality management standards help organisations document compliance with statutory and regulatory requirements related to a product or service.

[8] Good Manufacturing Practice is the minimum standard that a medicines and medical products manufacturer must meet in their production processes.

Clarifying the role of executive leads, managers and a key working group would strengthen corporate arrangements for clinical equipment

Senior executive lead and management responsibilities for clinical equipment are not described in detail

43 The Trust is similar to other health bodies, in that corporate arrangements for clinical equipment have developed slowly. The development of arrangements has been driven by the needs of the individual departments, rather than being a top-down process. During our fieldwork, we heard numerous concerns about the absence of a corporate Trust-wide focus on clinical equipment.

44 The Executive Director of Nursing and Service Improvement is the lead executive for the management of clinical equipment across the Trust. The Quality and Safety Manager and the Health and Safety Manager also have Trust-wide responsibilities for clinical equipment. However, the Trust told us that the two managers' responsibilities are primarily focussed on the quality of patient care, but their clinical equipment responsibilities are not described in detail.

45 The Welsh Blood Service has a Head of Quality Assurance and Regulatory Compliance. Their role includes providing leadership for the development of effective systems to ensure safe services and to fulfil regulatory requirements, including safe operating procedures, risk management, business continuity and the management of clinical equipment. This role is regarded as crucial in ensuring that effective clinical equipment management arrangements are in place.

46 There is no equivalent senior post providing the same type of expertise at the Velindre Cancer Centre. Staff at the Velindre Cancer Centre told us that leadership is not always forthcoming to help manage and resolve issues relating to clinical equipment. The case study in Appendix 2 outlines a situation which staff told us about.

47 The Trust's Medical Director does not have any direct responsibility for clinical equipment. In interview, they told us that in their view, it could be helpful if their role was more formally involved to provide an additional executive management Trust-wide oversight of clinical equipment management.

The Trust has devolved day-to-day operational responsibility for clinical equipment to department managers and has recently taken a step forward by appointing a medical devices officer

48 The Velindre Cancer Centre's and Welsh Blood Service's directors are responsible for ensuring that appropriate equipment management and reporting structures are in place. Day-to-day operational responsibility for clinical equipment has been

devolved to department managers within the two divisions. Departmental managers are responsible for ensuring the safe operation and maintenance of clinical equipment. They must ensure compliance with statutory requirements and regulatory standards. The extent of their responsibilities is clearly defined. They are supported by NHS Wales Shared Services procurement staff, the Trust Medical Devices Officer and the ward leads and ward safety officers.

49 The Trust appointed a Medical Devices Officer in November 2017 to strengthen oversight of clinical equipment across the Trust and to provide support where operational issues arise in relation to clinical equipment. The Medical Devices Officer reports to both the Head of Medical Physics at Velindre Cancer Centre and to the Trust's Health and Safety Officer. This role was established as result of a recommendation to the Trust as part of the Medical Equipment Management Review (footnote 1). The role previously existed as a fixed term two-year appointment from July 2015, although it has taken four years to get a substantive post in place.

50 At the time of our fieldwork, the Medical Devices Officer was newly appointed to the role, but had been on secondment to an equivalent position for the previous two years. The Medical Devices Officer previously held an equipment maintenance role at the Velindre Cancer Centre. The Trust has already recognised the need to ensure that the Medical Devices Officer is able to concentrate on the broader corporate requirements of his role. In response, the Trust backfilled a member of staff to the maintenance role formerly held by the Medical Devices Officer. The Medical Devices Officer works one day a week at Trust headquarters, and the remaining time on fulfilling the practical requirements of the role at the Velindre Cancer Centre. Nevertheless, there is still concern that the right balance has not yet been facilitated.

51 Senior corporate staff told us that they recognise the need to develop a clear work programme for the Medical Devices Officer, to prioritise his activities and reinforce the Trust-wide nature of the role.

The Medical Devices Working Group could be an important part of clinical equipment management arrangements, but its remit needs to be clarified

52 This Medical Devices Working Group has existed for many years and reports to the Trust's Quality and Safety Committee. Whilst the group has a Trust-wide remit, it devotes most of its time to Velindre Cancer Centre. This suggests the group may not be fulfilling its remit in relation to the Welsh Blood Service or the NHS Wales Informatics Service. While the Medical Devices Working Group is the Trust's only group dedicated to clinical equipment issues, it has a low profile. We spoke to a number of people who were either unaware of the group, or were unsure of its purpose.

53 The remit of the Medical Devices Working Group includes the:

- identification and management of procurement issues;
- identification and management of issues with medical devices in use, including responding to regulatory agency alerts[9];
- receiving incident reports relating to medical devices and providing recommendations on preventing reoccurrence; and
- developing guidance on clinical equipment selection, procurement and management.

54 Some staff are under the impression that the Medical Devices Working Group's remit covers Velindre Cancer Centre only. This may in part be because the chair of the group is the Head of Medical Physics at Velindre Cancer Centre, and the group devotes most of its time to this division.

55 However, it is unclear how the group's procurement remit fits in with other groups. Each division has its own capital planning group and a performance and planning committee. Business cases for new equipment are considered by divisional groups before going to the local senior management teams for prioritisation.

56 The Trust told us that attendance at the Medical Devices Working Group's meetings is a problem. Some members decide whether to attend depending on the content of the agenda. Cardiff and Vale University Health Board clinical engineering representatives no longer attend the meetings, although they are responsible for maintaining some clinical equipment in the Velindre Cancer Centre. This diminishes the potential impact of the group as a forum to share experience, concerns and good practice.

57 It is likely that the potential of the Medical Devices Working Group is not being realised. It would be beneficial to review the terms of reference and consider whether there is a need to reinforce the group's Trust-wide role. The terms of reference should clarify the purpose of the group's procurement responsibilities, and how they relate to the remit of the other groups and committees discussed in paragraph 55. The Medical Devices Working Group needs to be better represented at the Board's committees to help raise its profile and communication of issues discussed at meetings. Attendance problems need to be addressed, by reviewing the existing membership and by reinforcing the importance of the group's role.

[9] The Medicines and Healthcare products Regulatory Agency is an executive agency of the Department of Health in the United Kingdom which is responsible for ensuring that medicines and medical devices work and are acceptably safe.

The absence of dedicated clinical equipment software hinders the Trust's ability to audit, manage risks and monitor training compliance although arrangements are in place to issue safety alerts and learn from incidents

Velindre Cancer Centre highlighted a number of risks associated with the absence of a dedicated clinical equipment software system two years ago

58 An entry in the Velindre Cancer Centre divisional risk register identified a risk first noted in December 2015, highlighting a risk to patients and staff from clinical equipment that is not identified, managed and maintained properly. It points to the absence of an equipment software management system to support these activities. This impedes the ability to provide assurance that risks are being mitigated effectively at departmental level.

59 A risk assessment carried out by the Trust in 2015 said that the absence of a comprehensive clinical equipment software management system caused problems in the Velindre Cancer Centre in relation to:

- accessing an accessible and comprehensive equipment inventory;
- ascertaining the current maintenance status of all equipment;
- establishing which departments are responsible for each item of equipment;
- difficulties in locating equipment for essential maintenance and safety notices;
- the absence of documented controls in relation to clinical equipment operation, maintenance and decontamination;
- auditing compliance of the clinical equipment policy;
- the management of staff training records;
- ensuring the calibration[10] of equipment; and
- the absence of monitoring of the life-cycle of clinical equipment.

60 However, the Welsh Blood Service uses the Q-Pulse system, and we were informed that it is therefore compliant with the points listed in paragraph 59. The Welsh Blood Service has advised that it utilises Q-Pulse for monitoring maintenance requirements. Information on equipment failures and issues are reported via Datix and investigated where necessary.

[10] Equipment calibration is a process to maintain accuracy. Calibration involves checking, by comparison with a standard, the accuracy of a measuring instrument, and, if required, making adjustments to align the instrument with the standard.

61 One of the main conclusions to be drawn from this risk assessment is that ensuring a systematic approach across the Trust, and in particular within the Velindre Cancer Centre, is much harder in the absence of a dedicated software management system. For example, the Trust was not able to comply with a recent Freedom of Information request about infusion pumps due to the absence of a comprehensive set of records. The Trust told us that if a clinical equipment software management system had been in place, in this instance they would have been able to comply with the request. The Welsh Blood Service is confident that it would be able to provide comprehensive records if a Freedom of Information Request was received.

The absence of a dedicated software system for clinical equipment hinders corporate monitoring of maintenance requirements and information on performance is fragmented

62 The Trust does not routinely audit compliance at Velindre Cancer Centre with all areas of the Medical Devices and Equipment Policy, although this was identified as a risk in 2015 (paragraph 59). At the time of our fieldwork, the Health and Safety Manager was drafting an audit framework questionnaire to help address the audit gap, although we did not see it. The intention is that the Medical Devices Officer will facilitate the audit and report its findings to the Medical Devices Group.

63 The Welsh Blood Service has an established audit programme which encompasses maintenance, cleaning and validation of equipment to provide assurance that there is regulatory compliance. Any non-conformities are formally recorded, actioned and monitored via Datix and are only closed out on satisfactory completion following review by the dedicated Quality Assurance Systems Audit team. Instances of non-compliance with audit/metrics are reported to the Welsh Blood Service Quality Review Group and any issues/concerns are reported quarterly, to the Welsh Blood Service Quality Systems, Standards and Governance Board.

64 The Trust does monitor compliance against a number of statutory and regulatory standards that apply to clinical equipment. We highlighted in paragraph 12 that information on equipment maintenance contracts is held by the departments and divisions. The absence of a single Trust-wide clinical equipment inventory to store maintenance information makes it difficult to audit compliance with warranty and regulatory requirements. The risk assessment in 2015 highlighted the difficulties the Trust has with ascertaining the current maintenance status of all equipment and the absence of documented controls in relation to clinical equipment operation, maintenance and decontamination. Again, the Welsh Blood Service has its own arrangements, and does monitor compliance in relation to its equipment.

65 As part of our document review, we looked at a small sample of records including:

- linear accelerator uptime (footnote 5) – the extent to which each device was available for use;

- dosimetry records from radiological equipment – indicating whether the dose provided was accurate, and associated information such as corrective actions;
- a breakdown log book – which recorded a range of information associated with equipment breakdowns, including the time the case was opened and closed;
- a sample of equipment calibration records;
- a sample of radiation protection certificates[11]; and
- a staff training log.

66 However, because information was presented as a series of separate documents, rather than collated in to a meaningful report of performance, we found it difficult to draw any conclusions from the information. Performance data is produced at departmental level, and the absence of a mechanism to draw together this information, means that corporate monitoring and oversight are difficult.

Although the Welsh Blood Service holds staff training records, the Trust's ability to monitor compliance with training is hindered because Velindre Cancer Centre's staff training records are fragmented

67 The Trust Medical Devices and Equipment Policy sets out responsibilities for identifying and addressing staff training needs. The policy sets out that that the departmental managers will identify which staff are able to use each device following successful completion of a programme of training. This might include setting up a device, preparing for its use, checking the device and decontamination where appropriate.

68 The Welsh Blood Service delivers a continuous training programme for individual staff in relation to equipment which is subject to the requirements of the Medicines and Healthcare products Regulatory Agency. The division maintains its own training records. Currently, each Welsh Blood Service department has a separate specific staff training matrix, there are plans to adopt the 'Training' feature in Q-pulse in late 2018. This would remove the requirement for separate departmental training matrices in that division.

69 Engineers in the Velindre Cancer Centre Medical Physics Department undergo supervised training. The engineers also attend training courses run by manufacturers, usually following new equipment purchases. The department maintains its own spreadsheet inventory of training courses attended by staff, with the attendance dates and copies of course certificates.

[11] Any person wishing to act as a Radiation Protection Adviser must, under the Ionising Radiations Regulations (IRR99), fulfil a number of requirements to hold a certificate.

70 However, we only saw limited evidence to demonstrate compliance with clinical equipment training requirements in Velindre Cancer Centre. Staff equipment training records (both maintenance staff and staff using equipment) are held separately by individual departments. Therefore, the Trust said it is difficult to collate Trust-wide training compliance records, an issue highlighted in the risk assessment carried out in 2015 at Velindre Cancer Centre (paragraph 59).

71 We are not aware of any Trust review to identify whether clinical equipment training requirements are being fully identified, monitored and fulfilled. The provision of a central software system would mean that staff training records could be easily accessed. This would help ensure that training is kept up to date and would make auditing easier.

The Trust has arrangements in place to issue safety alerts and share learning from incidents

72 Effective management of risks associated with clinical equipment helps ensure patient safety and the operational delivery of clinical services. It requires robust recording and monitoring, and processes to learn from incidents.

73 The Trust Medical Devices and Equipment Policy sets out the responsibilities of divisions, their departments, professional users and the procurement team for clinical equipment. This includes activities which help to mitigate the risks associated with clinical equipment.

74 The Trust Medical Devices and Equipment Policy specifies that the Quality and Safety Manager is the Trust's lead for the Health and Care Standards, including the issuing safety notices, alerts and other such communications. The Quality and Safety Manager retains the responsibility for this process, but the Medical Devices Officer leads the process within the Velindre Cancer Centre on behalf of the Quality and Safety Manager.

75 The Medical Devices Officer establishes which departments need to be made aware of alerts and notices, and ensures that appropriate action is taken and who needs to be notified. The officer provides a report to the Medical Devices Working Group for discussion and agreement of the actions required to respond to safety alerts and notices, and the actions required.

76 The Medical Devices Officer sets out the actions required to relevant divisional patient safety groups, and meets with the two ward safety champions in Velindre Cancer Centre on a regular basis. The ward safety champions cascade safety notices to ward staff.

77 The Medical Devices Officer told us that where clinical equipment recalls apply to equipment managed by the Trust's stores, it is easier to manage. However, for equipment procured via the NHS Shared Service Partnership or provided by a charitable source, the Trust has less assurance that recalls and safety notices are managed safely, because the link between the manufacturer and the Trust is not as direct as is the case for Trust-purchased equipment.

78 The Trust uses DATIX[12] to record notifications of clinical equipment incidents. This triggers an alert to relevant staff to enable them to consider issues arising from incidents and any learning to be shared. The Welsh Blood Service is signed up to the Medical and Healthcare products Regulatory Agency alert system for device bulletins so that any issues can be acted upon in a prompt manner.

79 The Trust's Organisational Learning Sub-Committee was previously the forum where incidents, such as those relating to clinical equipment, were raised and discussed. However, following the suspension of this sub-committee, the Quality and Safety Group at Velindre Cancer Centre and the Quality Systems Standards and Governance Board at the Welsh Blood Service consider incidents and the appropriate response. The Medical Device Working Group also considers any equipment or device issues associated with reported incidents. Escalations are reported to and considered by the Trust's Quality and Safety Committee.

80 However, the Trust needs to consider whether it is taking all opportunities to learn from experience relating to the management of clinical equipment. The case study in Appendix 2 sets out a scenario where the Trust could take the opportunity to learn from the management of a safety issue relating to clinical equipment, and identify whether the Trust's response in similar scenarios could be improved.

[12] Datix software used for incident reporting and risk management.

Appendix 1

Audit methodology

The scoping work in advance of our review of Clinical Equipment took place at Velindre NHS Trust between June and July 2017. The review took place between November 2017 and February 2018. Details of the audit approach are set out in Exhibit 2.

Exhibit 2: audit methodology

Methodology
Scoping work. In order to scope the review we met with the: • Executive Director of Nursing and Service Improvement (Trust) • Health and Safety Manager (Trust) • Head of Medical Physics, Velindre Cancer Centre • Compliance Manager, Welsh Blood Service • Medical Devices Officer (Trust) **Main phase interviews.** During our fieldwork we interviewed the: • Medical Devices Officer (Trust) • Quality and Safety Manager (Trust) • Medical Director (Trust) • External consultant on clinical equipment • Estates manager (Trust) • Head of Quality Assurance and Regulatory Compliance, Welsh Blood Service • Procurement manager for the Trust, NHS Shared Services Partnership • Trust IT managers • Velindre Programme Director for Transforming Cancer Services, and the Velindre Planning and Performance Director (joint interview) • Director of the Welsh Blood Service • Director of Cancer Services, Velindre Cancer Centre • Radiotherapy Services Manager, Velindre Cancer Centre • Head of Clinical Engineering, University Hospital of Wales • A small number of Trust users of clinical equipment. **Documents.** We requested the following documents: • Audit schedule of clinical equipment • Health and Safety Committee reports relating to clinical equipment • Spreadsheet listing external reviews and reports relating to clinical equipment • Examples of contingency plans relating to clinical equipment • DATIX equipment summary report • Transforming Cancer Services information relating to clinical equipment • Diagram/explanation of governance and assurance arrangements • The finance team's report into value for money from equipment warranties • Recent minutes of the Clinical Oncology Sub-Committee of the WSAC • Information relating to internal distribution of medical devices alerts

Methodology

Data. We also requested data to inform our work, including:

- Current inventories of existing equipment
- Data on the performance, safety and effectiveness of existing equipment
- Data on the performance of teams involved in clinical equipment management
- Data on the budget and expenditure on clinical equipment management

Appendix 2

Case study on issues related to Hospira infusion pumps

Exhibit 3: Case study about Hospira infusion pumps

The Trust uses pumps manufactured by Hospira. The pumps are used to administer chemotherapy to patients. In 2012, the manufacturer discovered that there was a risk that part of the pump might break and lead to an incorrect dose of chemotherapy drugs being administered to the patient. Regulatory authorities in Europe and the United States stopped the sale of the pump and instructed the manufacturer to modify it. The CE safety mark was withdrawn while corrective measures were developed. However, there was no requirement to withdraw existing pumps from use.

The Trust's pumps did not develop the problem discovered by the manufacturer, and the Trust established a protocol to increase its monitoring of the pumps to mitigate any potential risks. Whilst the manufacturer developed corrective measures, a number of the Trust's Hospira pumps came to the end of their lifespan for other reasons, and thus the number of available pumps reduced. It became necessary for the Trust to reorganise a number of clinics. In November 2013, the Trust added the risk caused by a shortage of pumps to the corporate risk register. In May 2017, the Trust reported on the risk register that the Trust was down by 23 pumps (a reduction of 20%).

The manufacturer took more than a year to develop a solution and at that point proposed a deal to replace existing pumps with a new version free of charge (rather than fix the existing pumps). The Trust decided to go out to tender to see if an alternative CE marked pump could be found. During our interviews, we were told that it was unclear why the decision to source a pump from an alternative manufacture was not made sooner, given the challenges in sustaining a sufficient number of pumps to deliver services.

After the Trust went out to tender, the process was challenged by one of the companies that submitted a bid. As a result of the challenge, the procurement exercise was delayed. At the time of our fieldwork, the procurement process was still ongoing.

The Trust took a number of measures to ensure the availability of a sufficient number of pumps for operational needs. Risk logs were maintained and our understanding is that there have been no incidents of individual harm, although some patients may have had their appointments reorganised. However, some staff questioned whether there had been sufficient leadership demonstrated to resolve the situation, and sufficient support for staff having to manage the complications that arose.

Whilst some staff groups have subsequently reflected on some of the aspects of the situation to see what lessons could be learned, there has not been a full evaluation of the issues that arose, and how the situation was managed. Such an exercise could look at the decisions that were made; whether the right people were involved in managing the situation; why the option of a direct replacement free of charge was not implemented; whether alternative pumps could have been procured earlier; the procurement process; and whether there was clear leadership. The learning could help to inform changes in the way that clinical equipment and similar scenarios are managed in the future.

Source: Wales Audit Office fieldwork

Appendix 3

The Trust's management response to the recommendations

Exhibit 4: management response

Ref	Recommendation	Intended outcome/benefit	Priority	Accepted (yes/no)	Management response	Completion date	Responsible officer
R1	**Executive lead arrangements.** The Trust should strengthen and clarify corporate leadership arrangements, and ensure that executive lead responsibilities for clinical equipment are extended beyond patient safety.	Robust and clearly articulated executive responsibilities for clinical equipment.	High	Yes	The Trust will review the corporate leadership arrangements for clinical equipment to ensure that executive lead responsibilities for clinical equipment are extended beyond patient safety.	31 October 2018	Executive Director Nursing & Service Improvement
R2	**Operational management arrangements.** The Trust should review the terms of reference of the Medical Devices Working Group, and clarify the group's purpose, ensuring it is in the best position to influence the management of clinical equipment across the Trust.	The purpose and remit of the Medical Devices Working Group is clearly understood by staff. The Medical Devices Working Group is able to influence the management of clinical equipment across the Trust.	High	Yes	The Trust will review the terms of reference of the Medical Devices Working Group, ensuring it is in the best position to influence the management of clinical equipment across the Trust.	31 October 2018	Executive Director Nursing & Service Improvement & Head of Medical Physics & Director WBS
R3	**Operational management arrangements.** The Trust should establish a clear and prioritised work programme for the Medical Devices Officer. The	The Trust's Medical Devices Officer is able to concentrate on their new role, and prioritise key requirements.	High	Yes	The Trust will establish a 12 month clear and prioritised work programme for the Medical Devices Working Group which will then be reflected in the work	30 November 2018	Head of Medical Physics Service Directors

Ref	Recommendation	Intended outcome/benefit	Priority	Accepted (yes/no)	Management response	Completion date	Responsible officer
	programme should prioritise progressing the introduction of the software system for clinical equipment, and establishing an audit/monitoring regime.				programme for the Trust Medical Devices Officer. Priorities in the programme will include the implementation of the new software system, an audit programme and a monitoring regime. **Comments:** The work programme for the Medical Devices Working Group will include the production and oversight of the implementation plan for the new software system for clinical equipment. The role of the Medical Devices Officer is to support the Group to deliver against these objectives. The implementation of the new software will be based upon a phased approach across the Trust. This will ensure existing systems and processes are not destabilised and resources can best utilised.		
R4	**Record management.** The Trust should prioritise the introduction of a Trust-wide software system for clinical equipment, ensuring that the implementation of the system is	A Trust-wide software system for managing clinical equipment, providing the Trust with easy to access clinical equipment	High	Yes	The Trust will develop an implementation plan to ensure that the new software system for clinical equipment is fully planned.	30 November 2018	Head of Medical Physics Service Directors

Ref	Recommendation	Intended outcome/benefit	Priority	Accepted (yes/no)	Management response	Completion date	Responsible officer
	fully planned, including establishing clear executive support, the operational requirements to populate the system, staff training requirements and a review mechanism to ensure successful implementation.	management information.			The plan will consider and incorporate: • roles and responsibilities, including clear executive support • operational requirements to populate the system • staff training requirements • review mechanism to ensure successful implementation.		
R5a	**Procurement.** The Trust should ensure that staff involved in equipment procurement at the Velindre Cancer Centre, have the necessary knowledge and expertise to prepare business cases.	Staff with the necessary skills and expertise to draft robust procurement business cases.	Medium	Yes	The VCC will make further training provision for staff involved in equipment procurement in order to develop their competence and expertise when preparing business cases.	31 January 2019	Director Velindre Cancer Centre
R5b	**Procurement.** The Trust should consider how to further strengthen clinical equipment procurement arrangements; such as the identification of a clinical lead for procurement to add informed clinical knowledge to the process.	Clinical expertise input into the drafting of clinical equipment procurement business cases.	Medium	Yes	The Trust will review the current clinical equipment procurement arrangements in order to improve the robustness of clinical equipment business cases. **Comment:** The role of 'clinical lead' within the procurement of clinical equipment process will be considered as part	31 March 2019	Service Directors Head of Procurement

Ref	Recommendation	Intended outcome/benefit	Priority	Accepted (yes/no)	Management response	Completion date	Responsible officer
					of the review of current arrangements. However, the Trust will also consider other areas where expert knowledge will strengthen the procurement process. For example, the role of a 'technical lead' or other appropriate advisory roles.		
R5c	**Procurement.** The Trust should review the terms of reference of forums responsible for the governance of procurement, to identify and eliminate any overlaps or gaps in responsibilities.	Appropriate governance oversight of procurement of clinical equipment.	Medium	Yes	The Trust will review the terms of reference of forums responsible for the governance of procurement, to identify and eliminate any overlaps or gaps in responsibilities.	31 March 2019	Service Directors Head of Procurement
R6a	**Audit, risk management and learning**. The Trust should establish a programme of audit at Velindre Cancer Centre to ensure compliance with the Trust's Medical Devices and Equipment Policy, and any other relevant regulations or policies.	Trust-wide management assurance regime to monitor compliance with the Trust's Medical Devices and Equipment Policy, and any other relevant regulations or policies.	Medium	Yes	The Trust will establish a programme of audit at Velindre Cancer Centre to ensure compliance with the Trust's Medical Devices and Equipment Policy, and any other relevant regulations or policies.	31 January 2019	Director Velindre Cancer Centre Head of Medical Physics
R6b	**Audit, risk management and learning**. The Trust should identify the performance information needed to enable corporate monitoring of clinical	Trust-wide performance information to inform corporate monitoring of clinical equipment.	Medium	Yes	The Trust will review the current arrangements for monitoring the performance of clinical equipment at a corporate level and will identify the performance information	31 March 2019	Executive Director Nursing & Service Improvement

Ref	Recommendation	Intended outcome/benefit	Priority	Accepted (yes/no)	Management response	Completion date	Responsible officer
	equipment, and how to report this in a meaningful and coherent way.				needed to enable corporate monitoring of clinical equipment, and how to report this in a meaningful and coherent way.		Head of Medical Physics
R6c	**Audit, risk management and learning**. The Trust should carry out a review of the Hospira pump issue highlighted in this report, to identify any learning from the way the issue was dealt with that could be used to improve and inform the way the Trust responds to similar scenarios in the future.	Improved management of clinical equipment and responding to safety concerns.	Medium	Yes	Undertake a review of the Hospira pump issue highlighted in the Wales Audit Office report, to identify any learning from the way the issue was dealt with that could be used to improve and inform the way the Trust responds to similar scenarios in the future	31 March 2019	Executive Director Nursing & Service Improvement Executive Director Finance

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