ABM University Health Board	
Date of Meeting: 1st February 2018 **Name of Meeting: Quality & Safety Committee** **Agenda item: 4.3**	
Subject	**Blood Glucometry/Lessons Learnt Report Update**
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Approved by & Presented	Angela Hopkins Interim Director of Nursing and Patient Experience

1.0 Situation

This paper is to provide the Quality and Safety Committee with a further update on the agreed Action Plan in relation to the Blood Glucometry/ Lessons Learnt Report action plan. The last update was reported to Quality & Safety Committee in August 2017.

2.0 Background

The Quality and Safety Committee received an action plan on the Blood Glucometry/ Lessons Learnt report conducted for Abertawe Bro Morgannwg University (ABMU) Health Board with the last update report at the August 2017 Committee and it was agreed for a further update to be provided to the February 2018 committee.

3.0 Assessment

The Action Plan has been updated to reflect the progress made against the recommendations of the report. Four actions had been completed, and were presented to the August 2017 Quality & Safety Committee. The update on the current position is as follows;

- A further seven additional actions have been achieved since the last update to the Quality and Safety Committee in August 2017, this now means that twelve of the actions have been completed (Green status).
- There are fifteen actions with an Amber status, one of which refers to the management of Diabetic patients in Hospital, thirteen relating to Intellectual Property, Equipment, Establishments and Staff and one relating to Point of Care Testing Recommendations.
  The outstanding amber actions and projected timescales are summarised below;
- One action relates to the management of Diabetic patients a new draft In-Patient Diabetes Policy has now been drafted, and is expected to be ratified, by the end of February 2018.
- Thirteen actions relate to the management of intellectual property, equipment, establishments and staff. The Head of Digital records and Information Assurance within the Health Board is addressing these. A Data Protection Policy has been rewritten and a Police Disclosure Procedure produced these are expected to be fully completed by the end of March 2018, with the majority having completion dates of 31st January 2018.

- The one remaining action relating to Point of Care, a draft Terms of reference (TOR) has been developed, which proposes a review of the current system; the TOR will be discussed in the next Point of Care Committee on the 7th February 2018. Following agreement appropriate reviewers will be approached to undertake this work.

All actions are expected to be completed by the end of March with the exception of one relating to the Point of Care, which is expected to be completed by the end of April 2018.

There will be a final update to the Quality and Safety Committee in June 2018 on the progress of all actions against the recommendations of the report.

4.0 Recommendations

The Quality & Safety Committee is asked to:

- Note the contents of this report

Blood Glucometry Action Log

Created in March 2017

Recommendation Number	Action	Lead	Monitoring method	Progress	Timeline			Completed
					Length of time from report	Original Deadline	Expected completion date	
6.1	**Diabetic Patients in Hospital** Review the progress with management of the diabetic patient in hospital. Evaluate whether the actions identified in the disciplinary processes , related to management of diabetic patients, have been implemented	Singleton Delivery Unit Senior Management Team as hosts	Action Plan in place	Reporting to The Quality and Safety Forum on completed action plan. The Charts have been reviewed and new Charts are currently in the process of being implemented. The Draft In-Patient Diabetes Management Policy was considered in October's Nursing Midwifery Board, comments have been received and the policy updated. The policy will be taken to the Think Glucose Implementation Group on the 26th January 2018 and Nursing Midwifery Board February 14th for ratification.	Within 4 months	July 2017	14th February 2018	
6.2	**Quality and Safety Committee** Review the governance framework for the Quality & Safety Committee to establish the groups required to report to the Committee.	Christine Morrell, Director of Therapies and Health Science Hamish Laing, Executive Medical Director Rory Farrelly, Director of Nursing and Patient Experience Jan Worthing, Service Unit Director, Singleton Hospital	Review of Governance framework and group has already been completed and reported to Quality and Safety Committee	Completed October 2016	Within 5 months	August 2017	30th June 2017	
6.3	**Protection Of Vulnerable Adults** A multiagency review of the blood glucometry investigation, from the POVA referral point onwards, should be organised to establish learning for all the agencies involved. To increase learning across Wales it is recommended that the findings are shared with the National Independent Safeguarding Board, established in 2016, under The Social Services and Well-being (Wales) Act.	Rory Farrelly, Director of Nursing and Patient Experience	Multi agency learning event has been completed initiated by SWP and completed on 23rd February 2017	Themes from the learning event will be shared at the Western Bay Adult Safeguarding Board on 24th of April 2017 with a recommendation to share with national independence safeguarding boards	Within 6 months	September 2017	30th April 2017	
6.4	**South Wales Police** The Health Board should engage at the most senior level with South Wales Police (SWP) to review specific aspects of the blood glucometry investigation related to ABMU and SWP. This is in addition to the learning in partnership outlined in recommendation 6.3. An agreed approach and protocols should be developed, in partnership, following the joint specific learning from the blood glucometry investigation. Both SWP and ABMU have statutory responsibilities which they must be able to discharge fully whilst any investigation is underway, including during criminal investigations.	Paul Roberts, Chief Executive Steve Combe, Director of Corporate Governance		A meeting was held between the HB and senior officers of South Wales Police to agree the need for the lessons learnt event.	Within 6 months	September 2017	30th July 2017	
6.5	**Management of Intellectual Property, equipment, establishments and staff**							
	6.5.1 The Health Boards Data Protection and Confidentiality Policy (HB51, 2010) should be urgently revised and include more robust information regarding the Release of Personal Data in relation to Crime and Taxation (Section 29, Data Protection Act 1998) and in full consideration that Caldicott principles apply to information held on both patients and staff.	Hamish Laing, Executive Medical Director		The Health Boards Data protection policy has been rewritten and is being presented to IGB Committee in January 2018	Within 6 months	September 2017	31st March 2018	
	6.5.2 The Information Technology (IT) Strategy should be revised, taking into consideration issues identified within the report relating to POCT, networks and supporting databases, to protect the Health Board from Caldicott breaches. External validation of the strategy should be considered with a clear timetable for Board assurance on the 'milestones' of external test and challenge to ensure long term effectiveness and reliability of POCT and potentially other IT based systems.	Hamish Laing, Executive Medical Director		NWIS have commissioned an external validation of the IT security in ABMU and the Consultant leading the output has concluded his interviews in ABMU NHS Trust. Draft report has been received January 2018, comments provided. Awaiting final report February 2018	Within 6 months	September 2017	28th February 2018	
	6.5.2 In addition, a Standard Operating Procedure should be developed, documented, approved and ratified, refer to 6.5.3 to 6.5.13 below.	Hamish Laing, Executive Medical Director		The new Police procedure is on the agenda for IGB on the 13th of December. this has been approved will be ratified in audit committee 23rd January 2018.	Within 3 months	June 2017	31st January 2018	
	6.5.3 One individual at Director level within the Health Board should be the lead officer to engage with SWP in any future investigations.	Kate Lorenti, Acting Director of Human Resources		Identify the point of contact with South Wales Police to discuss matters should events of this nature occur again. To determine if previous processes have been reviewed in order to learn lessons. . Point of contact agreed as Director of Human Resource		June 2017		
	6.5.4 Requests for information or for the release of equipment by the police should only be received via the nominated Director.	Hamish Laing, Executive Medical Director		This will be covered in the police disclosure procedure which is being ratified in Audit Committee on January 23rd		June 2017	31st January 2018	
	6.5.5 Access to Health Board premises and to staff on duty should only be via a request to the nominated Director, with appropriate notification to staff regarding the level of access agreed by the Director.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.6 The lead Director should consider early notification to Welsh Government, to the health regulators (HIW) and to the Medicines and Healthcare Products Regulatory Authority (MHRA), in circumstances where that is both advisable and necessary.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.7 A formal written process must be used to determine the specific information required by SWP to enable them to fulfil their lawful duty. The purpose of the request must be submitted by the police, to support the Health Board in determining whether information can or should be released.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.8 Access to Information Technology (IT) systems should be by court order to ensure a full and proper record is provided of the explicit IT section to be interrogated. This would provide absolute clarity regarding the information accessed and downloaded, together with the security arrangements which will apply.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.9 The seizing of confidential data must be properly managed. Transferring patient and staff data on unencrypted storage devices or media, such as USB sticks, CD's or Wi-Fi, raises significant data governance issues. A digitally signed copy of the data provided to the police should be retained.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.10 A database should be established at the outset of any investigation to record the police request, the detail of the request, the outcome of the assessment of the request in ABMU and to record the specific pages of any and all copies of documents or records released. The database should also include emails transmitted or telecommunications where information is shared.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	

	6.5.11 Access to the database should be managed and restricted, as advised by the Information Governance lead and approved by the Caldicott Guardian, with oversight from the nominated Director. The database provides an information log, an audit trail of activity for the Health Board and would meet the requirements of the Data Protection Act	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.12 It should be clearly stated within the Standard Operating Procedure the controls and safeguards ABMU requires to be in place for the storage and management of confidential patient and staff information remaining with SWP, including information which they hold on USB, CD, Wi-Fi or other data storage devices.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
	6.5.13 The Standard Operating Procedure should be explicit regarding the Health Boards requirements for the safe return of all information, with proof of secure deletion of copies and an agreed process for the return of all property and equipment belonging to ABMU.	Hamish Laing, Executive Medical Director				June 2017	31st January 2018	
6.6	**POCT Recommendations**							
	6.6.1 Notification to the Medicines and Healthcare Products Regulatory Agency (MHRA) is recommended, if this has not yet occurred. This is to notify the known and recorded POCT user errors identified during the disciplinary investigations, together with the risk identified to networked systems from data deletion and data loss. Immediate action.	Christine Morrell, Director of Therapies and Health Science	Pathology	No data deletion or loss identified, no operational errors were identified with the meter. No evidence that data can be deleted from the system. Precision Web provides an audit trail of testing. Not an MHRA reportable issue.	Immediate	June 2017	30th March 2017	
	6.6.2 POCT must be supported by a robust training programme which is focussed on POCT in practice with the professionals required to engage as part of patient care delivery, with update training provided prior to introduction of new versions of the hand held ward based devices.	Christine Morrell, Director of Therapies and Health Science	Point of Care Testing Committee	Training programme in place since 2004. Staff training records and access to own staff bar codes is evidence of this. there are extensive detailed written training records for individual staff members documenting this. In addition all staff complete a competency assessment and a tick list to agree that aspects of training were understood and accepted. Recommendation already in place. All staff trained in Blood Glucometry on PCX in 2004, further clinical based training provided in 2009 with upgrade to PXP and again in 2012 when use of ketone strips on PXP meter was agreed. Training discussions undertaken and a proposal has been made to include clinical competence assessments at ward. Proposal discussed and endorsed at POCT meeting and to .be taken forward for discussion on practical aspects of implementation via Think Glucose.			30th Sept 2017	
	6.6.3 POCT must operate with adequate clinical Standard Operating Procedures (SOP), with a clear focus on the provision of care at the bedside. The SOPs should be placed on the agenda for the POCT Committee for approval and ratification. The procedures should be developed with users of the handheld devices to identify aspects which may impede clinical delivery and to ensure the technical aspects within the SOP are kept to a minimum with the information in language relevant to the users at ward level.	Christine Morrell, Director of Therapies and Health Science	Point of Care Testing Committee	There are SOPs for all POCT meter operation – all versions are document controlled via Q Pulse which a requirement for CPA & UKAS accreditation. Recommendation therefore already in part in place. However they were not written in conjunction with operators. Pathology are required to produce SOPs to ISO accreditation standards, these were not necessarily user friendly for nurses, and therefore we have now introduced a User SOP that sits along the ISO version. SOPs should be reviewed and commented on by nursing staff, the current glucose meter SOP is also on COIN. Discussed at POCT committee and agreed by Units for implementation at next meeting- to be taken forward via Think Glucose			30th Sept 2017	
	6.6.4 A properly constituted POCT Users Group should be formed. This must include clinical staff users of the equipment. Members of this group should be involved in procurement of equipment, testing, risk and benefit analysis to include the impact assessment on activity and workload within ward areas.	Christine Morrell, Director of Therapies and Health Science	Point of Care Testing Committee	Multidisciplinary POCT Committee in place, but attendance from users was poor. To be refreshed to reflect new unit structures. Review of TOR of POCT testing Committee to ensure appropriate clinical representation and attendance, clinical leadership and Exec Lead. Membership review complete with unit representatives identified. Clinical leadership provided by Laboratory medicine Clinical Director and Vice Chair form Primary Care. Unit Attendance at meetings to be reported in annual reports. Full review of terms of reference complete and review of governance document to inclusion of new All Wales Guidance as well as these recommendations. Completed by 23 October ahead of UKAS inspection of laboratory medicine in November 2017. Closed at POCT committee 9 November			30th Oct 2017	
	6.6.5 When new tenders are invited to replace POCT devices, users should be involved in the process to ensure that where there is a choice between equally accurate and precise devices, the equipment procured is the most user-friendly device suited to delivery of patient care at the bedside. Procurement should significantly focus on the practical application in the clinical context, professional practices required to obtain tests and results, and support the provision of good quality care.	Christine Morrell, Director of Therapies and Health Science	Point of Care Testing Committee	Nursing staff have always been included in all meter procurement process. This was the case in glucose meter procurement process, in 2004 & 2014. During the 2004 tender the meters from both companies tendering were trialled on CCU in POW and there was a preference for the Abbott meter._ABMU HB follow the strict guidelines for tender process. The cost of the glucose meter tender dictated on both occasions that it was an OJEU tender, on both occasions more than one company tendered, users trialled the equipment and there was a multidisciplinary group that decided on the outcome. Recommendation already in place			April 2017	
	6.6.6 All POCT equipment must be managed with an up to date inventory, which takes account of both planned and free movement of devices around the hospital. It has been noted that in this case the police seized several blood glucometers, but these were not the only glucometers relevant to the case.	Christine Morrell, Director of Therapies and Health Science	Point of Care Testing	. Precision Web tracks all movement and changes of glucose meters in ABMU HB and provides a full audit trail. Movement of meters is tracked by this system. The police investigation focused on one ward and all meters were seized from this ward none were missing. Recommendation already in place			April 2017	
	6.6.7 Standard Operating Procedures must be developed and documented that stipulate access rights and authority levels to the system supporting POCT. These should be developed for all Information Technology staff, for the POCT team and all other personnel with a requirement to access, monitor, manage or troubleshoot with the system. This should include all clinical staff who administer or correct errors in records (which is required in using Precision Web). Manipulation of information, including deletion and reinstatement of data, or instructing manufacturers or supporting other parties to access information belonging to the NHS, should be strictly governed, managed through SOPs and overseen by appropriately senior leads within the Health Board to avert Caldicott breaches and mitigate against cybersecurity issues .	Christine Morrell, Director of Therapies and Health Science	Information Governance IM&T, POC Team, Abbott	IM&T have the overall administrative rights to all software systems that reside upon their servers. Manipulation of information, including deletion and reinstatement of data, or instructing manufacturers or supporting other parties to access information belonging to the NHS. Data cannot be manipulated, or deleted or reinstated to knowledge of POCT.			April 2017	
	6.6.8 The current Abbott blood glucometry systems as used in ABMU has weaknesses which this review has considered. It is essential that an external validation of the system (including SOPs and the system in clinical practice) is undertaken with urgency, to test robustness and reliability for continued clinical use. The tender for an external validation should be put in place within three months from approval of the report.	Christine Morrell, Director of Therapies and Health Science	Exec Lead	Pathology oversees the management & governance of POCT equipment and supports safe application of its use where the POCT kit is applied for by clinical areas using POCT business case arrangements. Responsibility for correct application of POCT sits with clinical areas. Developing Draft Terms of Reference for review of current system and seeking appropriate reviewers. The Draft Terms of Reference will be discussed in the next POCT on the 7th February.2018			April 2018	

	6.6.9 In support of greater understanding of issues associated with the blood glucometry system it is recommended that all staff investigated, together with those staff involved in the investigations, the case note reviews, internal assurance review process and in the management of the Precision Web system, should be r**equired to read the report prepared by Professor Thimbleby for the court,** together with the Judge's ruling, and complete a written reflection on the contents. It is also recommended that Professor Thimbleby is invited to engage in a filmed recording for educational purposes and to inform the Board on the findings which were presented to the courts. Action within 3 months from approval of the report.	Christine Morrell, Director of Therapies and Health Science	Exec Lead	POCT advise that Professor Thimbleby was asked to review the Abbott meters and Precision Web by ABMU HB in 2013 by Steve Coombe, POCT manager was asked to meet with him and Steve Coombe to explain the operation of the meter. There was also a visit arranged to Singleton Hospital where POCT coordinator (LP) showed him the system in working practice on a ward. Professor Thimbleby did not report any concerns in 2013. Subsequently Professor Thimbleby became an expert witness for the defence. June 2017 .'Angela Hopkins presented a lessons learned talk which was attended by Clinical Director of Laboratory Medicine who produced feedback and a reflective report in regard to Professor Thimblebys report			June 2017	