Commissioned Review,

June to September 2016.

Review of the Blood Glucometry Investigations in Abertawe Bro Morgannwg University Health Board.

Establishing lessons learned.

Professor Angela Hopkins.

Abertawe Bro Morgannwg University Health Board

Review of Blood Glucometry Investigation.

Contents.

Appendices

1. Introduction and Terms of Reference.

Abertawe Bro Morgannwg University (ABMU) Health Board commissioned a review of the investigations, actions, processes and events associated with blood glucometry usage and recording.

The report provides findings, identifies lessons learned and includes recommendations to support continued learning.

The agreed purpose of the review was '*to review the actions taken and methodology used as part of the investigation into the blood glucometry events within ABMU. With an aim of determining whether there are lessons to be learned and revised procedures that can be set in place.*'

The full scope was broad and included a review of management, leadership and practice at all levels, which defines the culture in an organisation. The period under review extends from February 2013 to July 2016. The terms of reference are attached as appendix 1.

2. Summary of findings and Lessons Learned.

Commissioning the review demonstrates a commitment within ABMU to learn from events, to identify positive aspects from the response which followed and supports continuous improvement. There are aspects within the report which could provide learning on a broader scale across the nursing profession and across the NHS.

It was clearly evident from the interviews conducted and the documentation reviewed that the events associated with the blood glucometry investigation had a profound effect across ABMU, with the population served, for staff working within Princess of Wales Hospital and, in particular, with the nursing workforce at every level across the organisation.

The opportunity for individuals to critically reflect on past events within the framework provided by the review has resulted in a renewed focus on the achievements made, identified lessons which have been learned and afforded opportunities to further develop services, systems and processes for continued improvement in patient care and in support of staff employed within the organisation.

Positive outcomes identified during the review are outlined below.

A. The broad engagement with the public, patients and staff during the development of the values for the organisation has had a positive impact across Abertawe Bro Morgannwg University Health Board (ABMU)[1]

B. The approval of the Strategy[2] for quality & patient safety at the Board Meeting in January 2015 firmly outlines the objectives across ABMU.

C. A leadership team has been established in Princess of Wales Hospital (POWH), which has resulted in a sense of ownership amongst staff. The focussed team are engaging with patients, the clinical teams, providing scrutiny on the services provided with rapid feedback to empower and drive continuous improvement across the hospital[3]

D. The implementation of the 15 Steps Challenge[4] has provided a significant focus for action on complaints, concerns and incidents, supported by the implementation of concerns clinics and a focus on rapid resolution of issues.

E. The decision by the CEO to place Executive responsibility for Safeguarding children and adults with the Director of Nursing & Patient Services provides the expertise required in this vital area.

F. Significant learning from the Protection of Vulnerable Adults (POVA) process is evident at every level. In particular, training on thresholding POVA issues, training for staff on differentiation between POVA and professional issues and targeted training for Designated Lead Managers.

G. The governance of future internal assurance reviews (IAR) would be positively influenced following reflection on the blood glucometry IAR process, in particular, securing appropriate strategic assurance, oversight, management and learning.[5]

H. ABMU are seeking engagement with South Wales Police (SWP) to work in partnership to review approaches taken and to identify areas for learning through the stage of the police investigation[6]. An information sharing

[1] Interviewee 12, 16 and 14
[2] Our Quality Strategy for 2015-2018. Caring for each other, working together and always improving. ABMU (January 2015)
[3] Interviewee 12
[4] The Fifteen Steps Challenge – Quality from a patients' perspective. NHS Institute for Innovation & Improvement (2012)
[5] Interviewee 4, 10, 11 and 18
[6] Interviewee 4

protocol was developed jointly and approved for use in Autumn 2015.

I. The investigations undertaken for the internal disciplinary process were structured, robust and fully met the standards required in the ABMU policies and the requirements of the regulatory body when referrals have been made.[7]

J. An immense amount of structured, supportive professional development work has been undertaken, and continues, to assist nurses to maintain their skills and knowledge, to focus on professional delivery of patient care and to fulfil their registration requirements.[8] The input from Swansea University has been key in the approach taken.

K. The critical reflection completed by the registered nurses associated with the investigation has provided a focus for future professional actions and supported revalidation for the registrants.[9]

L. Evidence of significant improvement establishing the values, behaviours, professional standards and culture of the organisation has been provided in documentation provided and triangulated during a range of interviews.

M. Action has been taken to address aspects of the Point of Care Testing (POCT) governance, policy, protocols, training and updates.[10] This action will ensure completion of an annual review of POCT, production of an annual report which will be ratified by a reconstituted POCT Committee to ensure issues pertaining to POCT are clearly conveyed through a governance framework to provide assurance to the Quality & Safety Committee of the Board. *It is **recommended** that additional opportunities for a multidisciplinary approach to increase understanding, introduce safer systems and processes and to improve further are addressed.*

N. Significant improvements with the care of the diabetic patient in hospital has been reported in interviews[11]. This follows introduction of the ThinkGlucose[12] approach. The training which accompanied the introduction has been well received and widely rolled out to staff across the Health

[7] Interviewee 1, 9, 15 and 18
[8] Interviewee 3, 5, 9, 15 and 17
[9] Interviewee 9 and 18
[10] Interviewee 6 and 7
[11] Interviewees 3, 6, 8, 10, 18
[12] ThinkGlucose campaign. Introduced by NHS Institute of Innovation & Improvement, 2009 onwards across the UK

Board. Progress on unifying the policies, documents, charts and training associated with the care of diabetic patients in hospital across ABMU has been outlined[13]and must continue. *A review of the progress in this respect is* ***recommended*** *by the end of the current calendar year, to evaluate the documentation against exemplars and to ensure variation in policy and practice has been addressed.*

Additional points of learning are included in the marked boxes in the sections of the report.

3. Background.

3.1 Overview of the Princess of Wales Hospital (POWH).

The hospital is a major acute secondary care district general hospital (DGH) in one of the largest Health Boards in Wales. Around 160,000 people from the Bridgend area and locality receive health care at the hospital. A significant proportion of the staff employed at the hospital also live in the area served by POWH.

The hospital opened in 1985 and has a proud and loyal workforce who provide all the services associated with an acute DGH, in addition to providing specialist services, for example the cochlear implant service, for a much larger population across South and West Wales.

Following a period of organisational change POWH was established as one of six units within the ABMU management structures. The appointment of a Unit Hospital Management Team comprising a Unit Medical Director, Unit Nurse Director and Unit Senior Manager has been successfully completed.

In common with NHS providers across the UK, recruiting sufficient numbers of nurses, doctors and allied health professionals with the extensive range of skills and knowledge required, has been a challenge for POWH. However, the progress made marketing and recruiting in the last 2 years is positive for sustainability of high quality services. The appointment of new staff from all disciplines with different backgrounds and experiences brings a refreshing enhancement to the established workforce, many of whom have spent their entire careers in POWH loyally serving the local population.

[13] Interviewee 8, 12

3.2 The blood glucometry investigation.

The initial incident in POWH followed identification of an issue with the monitoring and recording of blood glucose measurements in a ward at the hospital. Following the initial raising of concerns a complex and wide ranging internal process ensued with a multi-agency Protection of Vulnerable Adults referral, an investigation by South Wales Police with a judicial process involving prosecution of individuals, the suspension from duty and referral of a number of nurses to the Nursing & Midwifery Council (NMC) with several subsequent disciplinary investigations and hearings. The initial incident focussed on one ward at the outset, but broadened to an investigation of individual nurses working on additional wards, predominantly in POWH. The trigger for the initial concern involved discrepancies between the recorded blood glucose measurements in individual patient records and the data uploaded from the ward based blood glucometry point of care testing equipment.

3.3 Methodology for the review.

The Terms of Reference were devised with the input from key staff within the organisation.

Professor Angela Hopkins was commissioned as the independent advisor to conduct the review. Her biography is attached as Appendix 2.

An initial scoping meeting was held on June 3rd 2016 by the Executive Director of Nursing & Patient Experience with Professor Hopkins where the methodology and scope of the review was established.

During June a comprehensive analysis of a range of policies, documents and reports pertinent to the period was conducted, together with a review of the actions initiated at each stage of the process within ABMU.

16 individuals were initially identified as vital contributors to the review to be contacted and invited to interview. Prior to interview, the individuals were provided with a series of questions relevant to their involvement in the processes surrounding the blood glucometry investigations. The field of interviewees included Directors of ABMU, nursing, medical, management staff, an external expert engaged at the time of the investigation, staff-side representative and members of the Internal Assurance Review Team.

In total, 20 individuals subsequently engaged in the process, with the majority of interviews being conducted between 4th and 8th July 2016. One participant

was accompanied to interview by a clinician who provided helpful information, which has been included within the overall review. Unavoidable delays occurred for some participants, resulting in responses being delayed until October 2016.

The interview questions provided a framework, but did not limit responses which would be helpful to the review. Interviews were scheduled for 90 minutes. An interim report with initial findings and seeking clarification on aspects from the review was forwarded to the Director of Nursing & Patient Experience on 15th August 2016, whilst the ongoing transcribing from interviews continued.

4.Involvement and Engagement.

It is commendable that the individuals invited to interview attended without exception. Each had prepared for the interview by considering the questions provided, many attended with supporting documents and evidence of actions taken as a consequence of learning and reflection from a complex and concerning time for all involved. To assist in the review all individuals consented to interviews being recorded and each received their taped transcript for amendment and approval, prior to submission to the independent advisor. There was a genuine focus on factual evidence and actions, a willingness to engage and to be part of supporting the identification of learning from the events, with a keenness to focus on the future in an organisation constantly striving to provide patient focussed high quality treatment and care.

5.Findings from the review.

5.1 Culture and Values

In both the information provided and the interviews conducted it was clear that the work across the Health Board to develop the values of the organisation has had a significant impact on the view that staff hold regarding ABMU. Establishment of the values has provided clarity on the purpose and responsibility of staff in their daily provision of all services across the organisation and has clarified the position the staff themselves hold as the most valuable asset of the Health Board. As the foundation of any learning organisation the production of the values, with wide engagement to develop them, has had a positive impact on the culture, the people and, as a result, on the services those people provide to the public.

During 2014/15 evidence from Board and Committee minutes provided an insight into the renewed focus on quality improvement, patient involvement and quality assurance within ABMU. The approval of the Quality Strategy at the Board meeting in January 2015 marked a key point for the Health Board, with quality objectives established to provide a framework for a focus on continuous improvement.

Clarity on the governance framework to the Quality & Safety Committee is ***recommended****.* Establishing the groups required to report to the Quality & Safety Committee and the arrangements for quarterly, bi-annual or annual reporting for the respective groups is necessary to secure the annual work plan for the committee and provide overall assurance to the Board. This aspect relates to the reporting arrangements for such groups as the Point of Care Testing Committee.

Learning Point 1. At a local level, the establishment of a Unit Hospital Management Team in POWH has been a significant enabler to securing high quality patient services, closer engagement with staff, robust accountability and assurance lines and a reported sense of ownership.

Learning Point 2. Information and the status of a range of critical indicators for safe, effective services and high quality care are provided in the Task Force Governance Update report which is scrutinised by the Unit Hospital Management team. The information is both provided from clinical areas and cascaded back to clinical areas in the report template. In interviews, it was clear the information in the report is widely assessed, shared and has become a tool for improvement in clinical meetings[14], ward Sisters meetings and across service delivery areas, providing a renewed focus on patient outcomes, patient experience and standards of care[15].

Learning Point 3. Extensive work has been undertaken in POWH building relationships to further focus on the multidisciplinary responsibilities for care of patients on wards, with mini teaching sessions at handover, in support of the more formal education and learning arrangements[16].

Learning Point 4. The implementation of concerns clinics was a significant step in listening and acting on patient and carer concerns. The engagement of the Community Health Council (CHC) in development and implementation of this

[14] Interviewee 12
[15] Interviewee 5 and 13
[16] Interviewee 5 and 12

approach was welcomed. It has been stated that the support from the CHC to initiate and evaluate the flexible visiting policy delivered significant benefits and their continued involvement is considered a vital component in the patient centred improvement focus.[17]

5.2 Incidents, complaints and concerns

It was clear from the documentation supplied and the subsequent interviews that much has already been learned in respect of early identification and action on issues of concern. One example is the management of complaints, concerns and incidents, considered under the 'Putting Things Right' (2011, revised 2014) guidance for Wales. Establishing this responsibility within the portfolio of a clinical Executive provides clinical oversight at the earliest stage to potential areas or services requiring additional focus, support or input. It is clear this focus has developed an improved working relationship with the Office of the Public Sector Ombudsman for Wales and the local Community Health Council.

Learning Point 5. In POWH a Patient Advocacy Liaison Service (PALS) was introduced in 2014 operating each day of the week. The impact has been positively evaluated by Swansea University and is a targeted improvement which is now being rolled out across the acute sites in ABMU. The different aspects of learning and the actions taken in POWH have resulted in a reduction in formal complaints and aligns with the recommendations in the review of concerns handling in Wales.[18]

Learning Point 6. The implementation of the '15 Steps Challenge' (NHS Institute for Innovation & Improvement, 2012) to provide oversight and scrutiny to all aspects of complaints, concerns and incidents, has provided a significant improvement to the process. The aspect of the 15 Steps Challenge involving review of ABMU complaints, concerns and incidents is provided by the most senior members of the organisation, under the leadership of the Chief Executive. This has provided one of the many opportunities now in place to triangulate information from clinical services. The approach identifies clinical areas or teams where members of the Board follow up with visits to meet staff, patients and carers, affords an opportunity to assess the clinical environments and identify areas for improvement and areas of best practice. This also provides a good opportunity for visibility and engagement of the

[17] Interviewee 4 and 18
[18] Review of Concerns (Complaints) handling within NHS Wales – 'Using the gift of complaints'. (WG, 2014)

Board members across a large Health Board and firmly connects the Board to the NHS services for which they are accountable.

5.3 Protection of Vulnerable Adults.

A change in the Executive team and the review of responsibilities in the portfolios of the Executives has afforded the Health Board the opportunity for reallocation of responsibilities and accountabilities associated with patient safety. Responsibility for Safeguarding children and adults, and in respect of the review, the Protection of Vulnerable Adults (POVA), has been moved to become a responsibility of the Executive Director of Nursing & Patient Experience. The role change provides the vital knowledge and experience required to oversee the provision and delivery of POVA from a post holder well versed in all aspects of Safeguarding, together with the requirements, regulations, procedures and provision of Safeguarding in accordance with the Social Services and Well-Being (Wales) Act, 2014. This in turn provides a corresponding assurance to the Board, and to partners engaged in the delivery of Safeguarding, on the efficacy and expertise of the Health Board to address a complex agenda.

In respect of the review, it is evident that at an early stage two POVA processes ran in parallel, which was in breach of the Safeguarding procedures[19]. Evidence from minutes and notes was provided of a clear breakdown in communication between the agencies involved, variation in the information shared at the meetings, attendees with differing levels of expertise and knowledge of safeguarding policy, procedures and protocols; all of which contributed to confused decision making with a loss of clarity on the actions to be followed. Decisions were reached and agreed in partnership in one meeting, with differing decisions reached in a separate meeting[20]. This was further corroborated during interviews[21]. In the evidence provided, including five separate sets of minutes from meetings held in February[22], June[23] and July[24] 2013 it is recorded that no evidence of harm to patients had been identified.

[19] Wales Interim Policy and Procedures for Protection of Vulnerable Adults from Abuse (Nov 2010. Revised, January 2013)
[20] Minutes of POVA strategy meeting February 11th 2013, Notes of meeting held on February 15th 2013, Minutes of meeting February 18th 2013 and Minutes of POVA strategy meeting February 19th 2013.
[21] Interviewee 7 and 17.
[22] ABMU minutes of meeting with SWP on February 15th 2013 and ABMU minutes of meeting to discuss management of concerns raised in relation to Ward 2, POWH on February 18th 2013.
[23] SWP minutes of meeting on June 4th 2013.
[24] SWP minutes of meeting on July 17th 2013.

Further, the risk of any future harm had been removed. This was corroborated by oral information provided at interviews.[25]

Robust initial investigations to assimilate and consider factual evidence is required to determine the appropriate route to be followed in these particular circumstances, whether an internal critical incident investigation is required, a review of professional issues, consideration of capability or competency issues and to assess any training, team, system or organisational factors which may require action.

Knowledge, understanding, capability and confidence in the assessment, evaluation and engagement at the earliest stage of a concern being raised is vital when the threshold for a POVA referral is being considered.

Learning Point 7. Safeguarding is everyone's responsibility, with training and awareness required for all staff across the Health Board and with partners also charged, alongside NHS healthcare providers, with a duty to protect vulnerable adults. Of particular relevance is the evidence regarding the provision of training in the Health Board over the last two years to those individuals required to engage in the role as Designated Lead Manager (DLM) at the point of a POVA referral, and required to engage with the agencies involved. The review of DLM staff has been undertaken and a mandatory training scheme introduced, with a clear commitment to sustain DLM selection, training and support[26]. In addition, the approach described for individuals engaging in POVA and in serious untoward incident investigations, to receive supervision from an experienced individual is a significant addition to the process, to increase learning and to build expertise and confidence in those charged with this responsibility[27].

5.4 Internal Assurance Review

An Internal Assurance Review Process (IAR) was established in 2013. A review team was appointed and protocols were developed for two different requirements for the team to deliver. No evidence has been presented of formal Terms of Reference for the IAR, the reporting arrangements required or the scope of the review. As a consequence, the review expanded without a formal structure and initially with only hand written records where cross referencing and tracking was not possible. There are no recorded minutes of

[25] Interviewees 1, 9, 11 and 12.
[26] Interviewee 9 and 18.
[27] Interviewee 9.

Terms of Reference being submitted to the Quality & Safety Committee of the Board for ratification. The review was conducted by a small team focussed on the blood glucose measurements for individual patients during their hospital stay, further clinical support was provided to establish if harm had been caused to patients.

Two protocols for use by the review team members were produced for the review[28], one states it is in draft.

Learning Point 8.

5.4.1 Strategic Oversight Group.

The learning from the IAR process has determined that a strategic oversight group would be formed for the purpose of approving Terms of Reference, to establish the scope of the investigation, agree robust reporting arrangements, to provide scrutiny and challenge and to further report to an appropriate Committee of the Health Board to provide assurance on the process, progress, actions and risks. The strategic oversight group would maintain a clear view of the totality of the issues, particularly important in an evolving investigation. The strategic oversight group would have responsibility for establishing the review team to fully meet the scope of the Terms of Reference, ensuring the team has sufficient resources to deliver against their responsibilities and access to expert advisors and support.

In the case of any investigation concerning clinical care the strategic oversight group should include the Medical Director for the clinical aspects, as the designated Caldicott Guardian when information sharing is likely to be a feature, and to consider any issues which arise regarding medical staff. The Director of Nursing & Patient Experience should be involved for the clinical and patient experience aspects, to oversee and advise on liaison with patients and families, and to consider any issues which arise regarding nursing staff. The Director of Human Resources should be involved to oversee the approaches being proposed for staff, to advise on employment issues and to provide a non-clinical perspective. The involvement of the Board Secretary is required to guide and oversee the governance arrangements and to compile the reports from the strategic oversight group to the Board Committee. The Director designated to liaise with police (which may be one of the officers identified

[28] No 1. Draft protocol for ABMU Health Board blood glucose meter investigation in relation to wards 5 & 20 in POWH (POVA investigation). No 2. Protocol for ABMU Health Board Blood Glucose Meter Review in relation to Ward 2 at POWH.

above) should also be a member of the strategic oversight group. Consideration should be given to the appointment of a legal advisor to the group, depending on the circumstances.

Learning Point 9.

5.4.2 Internal Assurance Review Team

It has been stated[29] that any internal assurance review team would, in future, have a senior member of the Human Resource Team and a balance of multi professional clinicians and managers to provide a fully rounded review, with perspective provided by all team members. The requirement for delineation between those engaged to investigate and those engaged in the internal review process has been described fully during the review[30].

Members of the review team should **not** have any prior involvement in the investigations of individuals or circumstances leading to the review, to maintain their integrity and to avoid any risk of predetermination or bias.

In situations where highly technical or specialised information is required for the review process, consideration should be given to appointing a suitable external individual to form part of the review team. This avoids compromising the integrity of the review or compromising individuals employed within ABMU who may have already significantly engaged in other aspects of the investigation. The involvement of a strategic oversight group in establishing the team, and considering the requirement for additional external expertise, is a vital aspect in the set up phase. This aspect has been acknowledged during the review.[31]

5.4.3 Terms of reference and methodology for the review.

In establishing the Terms of Reference and methodology for the review, particularly when considering the complex issues associated with the provision of clinical care, a specific time frame for the review should be established at the outset (e.g. the days of the inpatient episode). If the review assesses and evaluates investigations carried out on patients and care provided, careful consideration of the case mix of patients has to be a key component of the review scope. In this example, establishing the numbers of patients per ward requiring blood glucometry in a specific time period, the numbers of nurses

[29] Interviewee 1and 18
[30] Interviewee 1, 9 and 18
[31] Interviewee 1, 6, 9 and 18

competent and practicing point of care testing (POCT) within the same time period, and the frequency with which POCT is required per patient and per ward in a given time frame. These and other considerations would need to be set at the outset to establish a denominator against which delivery of care could be evaluated. Criteria, protocols or audit tools to be used in an internal review process should be developed according to available evidence, research or benchmark exemplars. These should be trialled at the outset, with the outcome being evaluated and tested for relevance, robustness and validity, before proceeding to their live application. There were many tools widely applied across NHS Wales at that time which would have supported development of the Terms of Reference and the methodology for the review. One example would be the Incident Decision Tree (7 Steps to Safety, National Patient Safety Agency, July 2004).

5.5 Suspension of Nurses from duty.

The Internal Assurance Review identified a large number of nursing staff with potential discrepancies between recorded blood glucose measurements in the patient record and those logged on the Precision Web system, the information technology system to which blood glucose point of care testing results were uploaded. It was established that a numerical value should be applied to the errors identified for individuals on which the decisions were to be made regarding suitability to remain active in post, or to be suspended from duty. It is recorded in interview[32] that the decision to suspend nurses with more than five errors, whilst referring those with five or less discrepancies through a capability process, was established by applying a professional and balanced judgement. It has not been possible to evidence where the decision making was tested and approved. It is stated within an undated document with no recorded author 'Nurse Suspensions', that suspensions in this context were ''*on the basis of professional judgement as to proportionate response.*'' A significant number of nursing staff suspensions followed, as did referrals to the Nursing & Midwifery Council (NMC), the regulatory body for nurses.

It is acknowledged that the circumstances at the time were unique, however, it is usual practice that the threshold for suspension should be based upon the individual circumstances of the case following an internal assessment of a range of evidence regarding the situation arising or the clinical incident, the character of the individual, record in post and any competence or concerns

[32] Interviewee 3 and 10

previously identified. Based on the information, a risk assessment should be undertaken by a senior professional lead and a senior Human Resource officer, as a minimum, before any decision on sanctions is reached.

Detailed in the Disciplinary Policy and Procedure (HB72, current version issued October 2014) at section 9.2 Initial Assessment, states, '*the fact finding assessment will involve discussing the alleged incident/misconduct with the employee as well as obtaining other preliminary pieces of information as necessary.'* In the evidence provided, across a significant number of suspensions of nurses, the aspect of the Policy at section 9.2 was not met. It has been recorded that it was not possible to discuss with staff the reason for suspension, to fact find or investigate the circumstances, due to the ongoing SWP criminal investigation.[33]

In addition, section 11, 'Alternatives to Suspension/Temporary Deployment During Period of Investigation', describes a range of possible alternatives to suspension. The aspect of the Policy at section 11 was not met. On the contrary, the document 'Nurse Suspensions' produced during the IAR process states '*any nurse identified as having 6 or more documented blood sugar readings that could not be located in EPOCS (abbreviated term to describe the IT data management system associated with blood glucometry) would be suspended from their duties.'* This disregards the ABMU policy statement.

In the case of registered nurses, compliance with The Code[34] is required. For the employer, reference to the relevant Nursing & Midwifery guidance[35] is recommended and for all, application of the organisations policies is essential.

As has subsequently been established by the Director of Nursing & Patient Experience, if professional issues emerge for nurses which may warrant action or sanctions the information should be referred to the professional lead at Executive level for a decision.

5.6 Liaison and engagement with South Wales Police.

[33] Interviewee 1, 7, 9, 15

[34] The Code. Professional standards of practice and behaviour for nurses and midwives. Nursing & Midwifery Council (2015)

[35] Advice and information for employers of nurses and midwives. NMC ( )

Evidence was provided which was triangulated and corroborated via interviews, revealing the lack of a robust governance process within the Health Board at the initial stage of involvement and engagement with SWP.[36]

One aspect of this, from the outset of the engagement with SWP, was the absence of a formal system of recording or a database within ABMU to identify and track information shared, documents released, oral communications, or a log of Health Board equipment that was removed. This situation was rectified at a later stage when a database was established. The governance, engagement and communication aspects were addressed following the appointment of a lawyer to act on behalf of the Health Board.

In addition, the Duty of Care of an employer to employees of the Health Board has emerged as a concern when considering interactions with SWP. A number of those interviewed described situations within busy acute wards and clinical areas where they or their teams were unexpectedly approached by officers of SWP requiring immediate provision of confidential information[37]. This introduces patient risk to the clinical environment, with individuals describing feeling intimidated, anxious and unsure on the actions to take, whilst also being distracted and drawn away from the supervision of staff and the delivery of patient care. The provision of clinical care under these conditions poses a risk to patients receiving health care and adversely affects the health and well-being of employees in the organisation.

5.7 Provision of information to the Board

It is evident from Board minutes and from interviews conducted that reports concerning the blood glucometry investigation were predominantly presented to the confidential, closed session of the Board meetings. Some reports were tabled, handed out at the commencement of the confidential Board meeting and immediately recalled at the close of the session.

The opportunity for Board members to analyse complex information is extremely limited in these circumstances. Providing scrutiny, challenge, consideration of risks and engaging in decision making is equally difficult when faced with factual, retrospective updates[38] pertaining to the number of nurse suspensions, or brief progress reports detailing the position with court cases and investigations. As a corporate body, the Board's role '*is to provide*

[36] Interviewee 4,10, 11
[37] Interviewee 6, 7, 11, 13, 17
[38] Interviewee 4 and 14

leadership of the organisation within a framework of prudent and effective controls which enables risk to be assessed and managed.' [39] Information and reports to the Board were restricted as a result of ongoing police investigations, which continued for years. Engagement with the regulators, Healthcare Inspectorate Wales (HIW) took place in May 2013[40], earlier involvement of the regulator would have provided another level of oversight in a complex matter.

5.8 Point of Care Testing (POCT)

In 2004 the Abbott Xceed Pro handheld system for blood glucometry was procured as the Point of Care testing system in wards, initially in Bro Morgannwg NHS Trust and was subsequently introduced across the Health Board. This product was widely used in the NHS across the UK and worldwide. The handheld devices were operated utilising a barcode system of individual identification (ID) supplied to nurses following an initial training programme when the system was installed, with training updates being provided if the individual requested this or if there had been a period of non-use of the system, normally associated with periods of maternity leave or long term sickness absence. In the majority of circumstances where absence from use of the system was not an issue, reactivation of the barcode ID followed annually when the system was assessed and demonstrated the individual remained a regular user.

The handheld devices were networked within ABMU to a centralised information technology system, the Precision Web Data Management System, also supplied by Abbott. The Precision Web system had various capabilities, including the ability to provide audit information, however, the capabilities of the system were not fully activated. Limited use was made of the audit facility in clinical management, care of the diabetic in hospital, to review the efficacy of the system at ward level, or to identify areas for staff training with the handheld devices.

The policy in place for POCT in 2013 'Governance Policy for Point of Care Testing' (Bro Morgannwg NHS Trust, 2006) states in the training section '*Refresher training will be required in the event of any break in service, any change in instrumentation, procedure, protocol or if quality controls show poor performance'.* From the point of procurement in 2004 up to the incident in

[39] 'The Pocket Guide to Governance in NHS Wales'. The Welsh NHS Confederation (2009)
[40] Interviewee 3

2013 the hand held devices were updated a number of times, but refresher training was not provided. Training and updates provide a further opportunity to reinforce the safety aspects, appropriate use in practice and to reinforce the professional responsibilities in the use of such equipment. Point of Care Testing (POCT) is increasingly seen in clinical areas and must be supported by a robust governance framework.

At present there is insufficient user involvement in POCT. A User Group exists, but is currently comprised of laboratory staff and the POCT support team. The policies, standard operating procedures (SOP), protocols and guidelines in place at the time of the incident were focussed on the equipment and maintenance required, for example, the equipment quality control aspects. It has been broadly acknowledged during interviews that the focus has to be on POCT in the context of a clinical environment and on its application in practice by clinical staff. Whilst the SOPs have been reviewed subsequently, it has been stated that clinical staff users at the bedside were not involved in that process.[41]

5.9 Referrals to the Nursing & Midwifery Council (NMC)

The NMC considers issues raised against registrants on a case by case basis, with due consideration of the individual circumstances of the case and previous conduct, competence or concerns. The situation in ABMU resulted in nurses being referred to the regulator by members of the public and by the Health Board. Referral to the NMC[42] is required for registered nurses who are the subject of a criminal investigation, in the case of five nurses, this applied in ABMU. However, additional nurses were referred to the NMC following suspension from duty on the basis of the denominator utilised in the IAR process. *Refer to section 5.5, paragraph 1.*

As a consequence of the ongoing police investigation, the normal process of an internal investigation to establish the facts, circumstances, professional and work records pertaining to the individual could not be conducted. Evidence, information and witness statements which are required as part of this process could not be collated. The search for evidence only began years later, resulting in complex disciplinary investigations.[43]

[41] Interviewee 6
[42] The Nursing & Midwifery Regulator for England, Wales, Scotland & Northern Ireland.
[43] Interviewee 9

The unprecedented situation which emerged during comparison of blood glucose measurements in patient records and the information stored on Precision Web resulted in fifty seven nurses being identified as having apparent errors of five or less as recorded on Precision Web, with a further sixteen nurses with more than five apparent errors. It has been reported in a number of interviews[44] the disbelief of nursing and medical colleagues, and by ward managers, when individual nurses were identified within this cohort as having allegedly omitted to record properly or to have made false recordings.

Given the number of nursing staff with allegedly serious practice concerns identified, it has been a challenge to establish whether sufficient consideration was given to broader issues associated with use of the equipment in practice, the clinical context in which the nurses were delivering care, whether professional practice issues in respect of contemporaneous record keeping[45] were considered, or whether the accuracy and capability of data storage in Precision Web was fully understood.

It has been acknowledged, that via the technical quality assurance processes conducted away from the wards, errors in practice had been identified at a much earlier stage with the blood glucometry,[46] such as the actions nursing staff were adopting to input patient identification numbers into the blood glucometers to obtain a blood glucose measurement for the patient. But the resulting action to the error recognition focussed on seeking an electronic 'fix' to the problems. Opportunities to address the errors with a professional practice focus, to provide updates on the equipment and links to the importance of accurate, timely record keeping in the clinical context were missed.

In terms of the stored data, evidence placed before the courts by two independent expert witnesses, and confirmed by an Abbott Precision Web support specialist, demonstrated that data which was downloaded into the error folder on the Precision Web system in ABMU had been removed or deleted, therefore the comparison between recordings on the wards and the stored data was not reliable.[47] However, decisions on referrals to the NMC were made on the basis of the remaining stored IT data in the system. The Health Board was unaware of the changes to data and to their extent.

[44] Interviewee 3, 7, 9, 12, 15, 17
[45] Record Keeping. Guidance for Nurses and Midwives. NMC (2009)
[46] Interviewees 6, 7
[47] Regina and Claire Cahill & Jade Pugh. Cardiff Crown Court, HHJ Crowther QC, October 14th, 2015.

5.10 Disciplinary investigations, process, findings and learning.

During September 2015 disciplinary hearings commenced for thirteen nurses against whom allegations had been made in respect of blood glucose measurements, as described in sections 5.5 and 5.9. The disciplinary processes concluded in August 2016.

The investigations which were conducted adhered to the relevant policy.[48] On reflection of the events, there was a missed opportunity for the timely investigation of the clinical context and professional practice amongst the staff who were found to have omissions in recordings lower than the numerical denominator threshold (<6). This would have provided more immediate opportunities to address any practice, policy or patient safety issues that may have required action.

For the registrants involved in disciplinary processes, full consideration of the policy, triangulated with evidence obtained in interviews[49] demonstrated a consistent, robust approach with full assessment of evidence presented, consideration of a range of other factors, including the individuals professional practice. Expert advice was sought and secured by the disciplinary panel members, as and when necessary, and the conduct of the hearings appears from the considered evidence to have been fair, equitable, professional and robust.

The findings at disciplinary clearly demonstrated that no harm had come to patients, the allegations of falsification of records in respect of the discrepancy between ward recordings and data stored in Precision Web was not proven. The disciplinary processes predominantly identified a root cause of failure to be poor compliance with contemporaneous record keeping standards. There were a number of mitigating circumstances identified, such as staffing resources and skill mix, in particular on night shifts, as well as identifying issues regarding the effectiveness and disconnect of the Point of care training to the clinical practice context.

Summary of the Professional Practice Findings

• In order to meet the acuity and care needs of patients, nursing staff adopted task focussed care and practice within the available staffing resources.

[48] Disciplinary Policy & Procedure. ABMU. Issued October 22nd, 2014.
[49] Interviewee 1, 9, 15

• Utilisation of the blood glucometry equipment required a staff bar code. Due to the impracticalities of the barcode system staff had widely adopted the practice of sharing barcodes to achieve blood glucose testing for patients.

• Staffing levels and skill mix of registered nursing staff, on night duty in particular, were reduced on some wards.

• A handover sheet was being used to record care during each shift with transcription at the end of shifts into the patient records – this does not meet the contemporaneous record keeping standards of the regulator.

• Registered nurses were recording the blood glucose measurements on behalf of their registrant colleagues.

• There were no Health Board nursing audits assessing record keeping, with insufficient scrutiny of patient records overall to identify poor recording keeping practices.

• Decision making on the threshold for suspension was based on numbers rather than professional practice principles, that falsification of/or failure to record once has the same burden of proof and professional implications within the NMC Code, irrespective of the number of times an action or omission has occurred.

The learning which emerged from the disciplinary hearings was extensive. To support continued learning for the profession and for the Health Board overall, learning themes were developed in real time, following each case hearing.

Learning Point 9. Professional Actions taken as a consequence of the Learning.

A programme focussed on continued professional development, contemporaneous record keeping, professional standards and compliance with the NMC Code of Conduct was implemented over two years ago in POWH, supported by Swansea University.

Through the ABMU Nursing & Midwifery Board the Director of Nursing & Patient Experience instigated a reflective learning approach, focussed on the aspects of professional issues outlined above. All nurses identified as having potential errors in the IAR process were required to undertake a reflection as part of their revalidation requirements. This approach supports learning, provides a valuable professional focus and evidence for revalidation[50] and is

[50] Revalidation, the new process for registration and to support safe, effective nursing practice. NMC, April 2016

much more likely to have a positive impact on improved practice than disciplinary sanction in isolation.

A programme of auditing[51] is in place across nursing teams with weekly audits in wards, under the leadership of the Ward managers and monthly audits at the senior nurse level, with sharing of outcomes, action plans and evaluations of improvements. An annual audit plan is in place.

A professional referral policy to the NMC has been developed, building on the Decision Making Tool recommended by the regulator, to provide assurance regarding future referrals for nursing staff to the regulator.

The correlation between levels of registered nurses and the patient safety environment of a ward has been widely researched.[52] In a large UK study of care left undone during nursing shifts, it was demonstrated that adequate documentation of nursing care was one of thirteen evaluated nursing practice elements in a shift which was left undone. The failure in record keeping was associated with low registered nursing levels per patient, as nurses prioritised direct patient care over record keeping.

The shortage of registered nurses at the point where the issues were identified in POWH was a matter of significant concern for many health care providers. Securing sufficient numbers of skilled registered nurses continues to be a National issue, with overseas recruitment and reliance on agency nurse staffing a common theme in Health Boards and Trusts across the UK.

In Wales, the value of sufficient registered nurses on acute medical and surgical wards has been acknowledged and resulted in the Nurse Staffing Levels (Wales) Act, effective from March 2016.

It was of particular note that throughout the investigations from February 2013 onwards that the focus remained on individual ward nurses, predominantly at Band 5 level. As part of the review, questioning has included whether other nursing or medical professionals, who might reasonably have been questioned regarding their supervision of the nurses and the management of patients on the wards, had been considered. In addition, when reliance on the information contained within the Precision Web data system was the only source for significant decision making regarding the professional futures of individual nurses, it is a serious concern that investigations did not extend to an independent questioning or check of the validity of the data, or

[51] Integrated Nursing Assessment Audit Tool. Revised June 2016.
[52] Ball J, Murrells T, Rafferty AM, Morrow E, Griffiths P. 'Care left undone' during nursing shifts: associations with workload and perceived quality of care. BMJQS, 2014, Vol 23, p 116-125.

extend to employees within the Health Board with access to amend, delete or restore information to the system and the authority to instruct third parties to attend and 'cleanse' the system.

It is clear from all the responses that the focus remained on individual nurses engaged in blood glucometry on the wards. *As a further point of learning reflection on this aspect should be considered within the Health Board.*

6.Recommendations.

Recommendation 6.1 (Refer to **N** in section2). Diabetic Patients in Hospital.

Review the progress with management of the diabetic patient in hospital. Evaluate whether the actions identified in the disciplinary processes[53], related to management of diabetic patients, have been implemented. **Action within four months from approval of the report.**

Recommendation 6.2 (Refer to section 5.1) Quality & safety Committee.

Review the governance framework for the Quality & Safety Committee to establish the groups required to report to the Committee. **Action within five months from approval of the report.**

Recommendation 6.3 (Refer to section 5.3) POVA.

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. **Action within six months from approval of the report.**

Recommendation 6.4 (Refer to section 5.6) SWP.

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

[53] Letter of September 2nd 2016 from Chair of the Disciplinary Panel to the Project Nurse Lead and Host Unit Nurse Director leading implementation of ThinkGlucose.

underway, including during criminal investigations. **Action within six months from approval of the report.**

Recommendation 6.5. Management of intellectual property, equipment, establishments and staff (Refer to section 5.6).

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. **Action within six months from approval of the report.**

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. **Action within six months from approval of the report.**

In addition, a Standard Operating Procedure should be developed, documented, approved and ratified, refer to 6.5.3 to 6.5.13 below. **Action within 3 months from approval of the report.**

Suggested inclusions for a new Standard Operating Procedure within ABMU

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.

6.5.4 Requests for information or for the release of equipment by the police should only be received via the nominated Director.

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.

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.

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.

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.

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 WiFi, raises significant data governance issues. A digitally signed copy of the data provided to the police should be retained.

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.

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.

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.

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.

<u>Recommendation 6.6 (Refer to section 5.8) POCT.</u>

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.**

A clinical review of Point of Care Testing management, governance and application in practice is required. Refer to 6.6.2 to 6.6.9 below. **Action within three months of receipt of the report.**

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.

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.

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.

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.

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[54] that in this case the police seized several

[54] Interviewee 2

blood glucometers, but these were not the only glucometers relevant to the case.

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[55].

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.**

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 required 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.**

Note : On completion of the report transcripts from a small number of individuals had not been returned following proof reading and approval. In

[55] Thimbleby, H. Cybersecurity Problems in a typical hospital (and probably in them all). Safety-Critical Systems Club (2017)

respect of those individuals, the report has been completed based on the draft transcripts and from notes taken by the author during interviews.

Professor Angela Hopkins.

October 14thth 2016.