PERSONAL REFLECTIONS ON PROFESSOR HAROLD THIMBLEBY'S REPORTS ON BLOOD GLUCOMETRY AT THE PRINCESS OF WALES HOSPITAL, BRIDGEND

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This personal reflection is written as a consequence of Professor Angela Hopkins' report and its recommendations, in particular part of recommendation 6.6.9 that "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 casenote reviews, internal assurance review process and in the management of the PrecisionWeb 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". Although I have not been investigated, involved in the investigation, the casenote review, internal assurance review process nor am I involved in the management of the PrecisionWeb System, I am the Clinical Lead for Laboratory Medicine, which encompasses the POCT team in ABMU Health Board, and in that capacity I take ultimate responsibility for the actions of the POCT team and its members. I have read the two reports prepared by Professor Thimbleby but so far have not been given a copy of the Judge's ruling.

Professor Thimbleby has produced two reports, the first of which entitled "**Design Review of Abbott Precision XceedPro etc, Princess of Wales Hospital, Bridgend**" was apparently commissioned by ABMU Health Board and is dated 23rd August 2013. This report is 4 pages long. The second report, dated "Friday, 21st August at 16:00" with no year given, though I believe this was 2015, is entitled "**Technical Review of Patient Data Recording at the Princess of Wales Hospital**". This report is 112 pages long and is marked "Confidential – Final Draft". I note that this report was prepared at the request of the defence of two nurses in Cardiff Crown Court and has not been redacted, i.e. it has been circulated with the names of Health Board staff and patients clearly readable. It is worth noting that both of these reports comment on the historical use of the Precision XceedPro meter and PrecisionWeb Database, which were in use at the Princess of Wales Hospital during 2012 - 2013 at the time of events that were in contention. Both Precision XceedPro and PrecisionWeb started to be phased out progressively from July 2014. At present ABMU Health Board uses the new "Freestyle Precision Pro Glucose Meters" and a database called "Freestyle PrecisionWeb". The two reports were clearly written two years apart, for two separate purposes and have a different focus. The first report focuses on performed tests, which have not been recorded in the notes. This is in contrast to the second report, which concentrates on recorded results on paper for which there is no record in the device or database.

In the first report ("**Design Review of Abbott Precision XceedPro etc, Princess of Wales Hospital, Bridgend**") I read with interest Professor Thimbleby's suggestions for improving the design of the (now no longer used) XceedPro meters and PrecisionWeb Database. Many of these suggestions are helpful but as Professor Thimbleby himself notes in the final section of the first report, "whether or not these obvious suggestions are *really* good ideas in actual clinical practice of course requires empirical investigation". In this context I note a suggestion that users of POCT equipment be given the option of recording in the patient's notes that "measurement taken but not recorded on paper notes" or "see device logs" rather than forcing an actual numerical entry. The risk with this approach is that it "normalises" not recording glucose measurements, and considering that POCT glucose measurements have to be known in order to enable clinical staff to improve patient safety by having instant access to the patient glucose levels, there is a risk that this approach would institutionalise poor practice and compromise handovers from nurses between shifts (e.g. if data that was relevant to patient care was not available). Having said that, Professor Thimbleby has clearly thought about this very deeply and made a number of proposals for device design that ought to make "post completion errors" less likely. I welcome this and note that Professor Thimbleby states in his first report that "a corollary of the opportunities to fix the design open to an interested manufacturer is that improved procurement processes in the Health Board could also have picked up the design issues and chosen a different device that was more appropriate for the intended use, and/or it could have been aware of the design issues and may have chosen to manage risks differently". This implies that the author believes that there were better systems that were overlooked during procurement, but it is my understanding this is not so. Furthermore, the culture of an organisation is predominantly determined by its leadership and not by the design of the equipment its staff use. In other words, while Professor Thimbleby's constructive suggestions are welcome, device design is not the only factor in determining a culture in which bad practice appears acceptable, and the critical issue here is: Proper clinical governance arrangements are the way to ensure correct use of equipment – better design would be helpful but is no substitute for this.

Professor Thimbleby's second report ("**Technical Review of Patient Data Recording at the Princess of Wales Hospital**"), written for the defence of two nurses, is completely focused on results that have been recorded on paper but for which no equivalent could be found on the instrumentation or database. This is in contrast to the first report, which focussed on performed tests which had not been recorded in the notes. The second report makes many important and relevant points. For example, it is correct to say that audit of the Precision Web Database to ensure its suitability for criminal prosecution was not regarded as a priority within the Health Board. The focus of the POCT team was very much on the clinical uses of the Precision XceedPro meters and the PrecisionWeb Database. The main purpose of the latter was to ensure that there was a record of near patient blood glucose

measurements and that these could be incorporated in electronic patient records (page 28).

Likewise it is not controversial to point to “poor staff ID management” (page 48). Professor Thimbleby points out (Page 54) that there was a significant amount of “double tapping” where an operator, having already entered their barcode ID as the tester, subsequently enters their barcode ID as the patient. I would agree that this indicates poor practice (rather than equating to criminal behaviour). Professor Thimbleby points out (page 70) that “XceedPro seems perfectly adequate for clinical use” and correctly states that “at a hospital that performed audits, the discrepancies would have been discovered immediately – and would be treated as a nurse training issue”. Furthermore, he confirms (page 75) that “drift into failure is *not* a problem of individual character, but a problem of management (Dekker, 2001)”.

Professor Thimbleby expresses concern about the movement of meters (pages 59-62 and pages 109-110). Since all the meters were part of an integrated ABMU-wide system, where a meter is docked should be irrelevant but that it is docked is absolutely essential. If some meters were not docked or failed to complete uploading, this clearly could compromise the live PrecisionWeb Data. Results and patient ID and times etc should however still be correct even if they were uploaded in the “wrong” Wards. It is worth noting that deficiencies in data due to insufficient or faulty docking would be expected to affect results from all nurses using the equipment equally.

In a section on poor clinical practices (**10.4** page 75) Professor Thimbleby suggests “that POW management decided that such practices were not clinically relevant”. I have no direct knowledge of any such decision or even discussion involving the management of clinical areas that use Point of Care Testing equipment in Princess of Wales Hospital, but it is the case that managerial staff in such clinical areas did not engage sufficiently in POCT matters and it is possible that this contributed to an atmosphere in which such practices were tolerated.

Professor Thimbleby repeatedly refers to the PrecisionWeb Database as being “unreliable” and to data that he believes has been “manipulated”, “deleted”, “lost” and “corrupted”. In making these assertions he cites differences (which he documents very clearly) between data that was presented to him by South Wales Police and evidence quoted by ECRI, South Wales Police and Christine Hopkins. These differences must be explicable. The key to their significance is in the explanation as to how they arose. It appears that these differences have been relied upon to infer that data is unreliable, missing, manipulated, edited, deleted etc, so that no inference can be drawn on the absence of an electronic record. It should however be noted that the Health Board (facilitated by IM&T and under the supervision of the Caldicot Guardian) provided South Wales Police with one single download of the Precision Web Database. It appears that Professor Thimbleby and indeed ECRI were

provided with downloads from the “original” download, whereas Christine Hopkins relied on using the live PrecisionWeb Database. The facts as I understand them are capable of being interpreted as suggesting that differences in the data (which there undoubtedly were, and which were clearly documented by Professor Thimbleby) between what was available to himself, ECRI, Christine Hopkins and South Wales Police are a consequence of data handling by South Wales Police and not a reflection on the integrity or otherwise of the original live PrecisionWeb Database.

While Professor Thimbleby makes many valid points, some of his observations do not support his assertions. For example, he refers to the problem of multiple nurse identities (**6.6** page 10) where some nurses have several roles within the hospital, for instance acting also as a bank nurse. While this undoubtedly happens, any nurse acting in different capacities within one or any of the hospitals in ABMU still has the same badge and ID in terms of POCT access, i.e. a nurse working on a Ward who helps out in the Emergency Department still uses the same ID and badge.

On page 12 Professor Thimbleby asserts that “the administrator of PrecisionWeb can delete data and make changes to data (see Abbott Document EDMS024878 Revision 002 page 8, 11th November 2014)”. He also states (on page 14) that “people can interactively provide or change data. PrecisionWeb, the user interface to the database, allows changes (see Abbott Document EDMS024878 Revision 002 page 8, 11th November 2014)”.

It is not difficult to see how, in the context of a criminal case, the mere possibility that “evidence” had been tampered with would lead to a collapse in the case. As a direct consequence of consideration of Professor Thimbleby’s report, the ABMU POCT team has approached Abbot for a copy of Abbott Document EDMS024878 Revision 002 page 8, 11th November 2014, to which Professor Thimbleby refers, though at the time in contention i.e. 2012 – 2013, the relevant manual was the Abbott PrecisionWeb User’s Manual QC manager 3.0 from 2009. Unfortunately I have not had access to Abbott Document EDMS024878 Revision 002 page 8, 11th November 2014, and contact with Abbott indicates that they are unaware of and unable to supply a copy of this document. I wonder whether this may have been a court document/exhibit associated with the court case. Perusal of the Abbott PrecisionWeb User’s Manual QC manager 3.0 from 2009 (<u>after</u> reading Professor Thimbleby’s second report) indicates that it appears possible to change operator ID, patient ID, the lot number of QC, QC level (high or low), lot number of a strip and result type (control or patient) in the live PrecisionWeb system. However, it appears that no change can be made to the actual result, time & date of measurement, or the serial meter that the result was measured on. The POCT team members and myself were unaware of the Edit features as none of the POCT team had attempted to modify data. I am indebted to Professor Thimbleby for providing the impetus for this functionality to become apparent.

However, in spite of reading and re-reading Professor Thimbleby's report and studying the relevant parts of the Abbott PrecisionWeb User's Manual QC manager 3.0 from 2009, it remains far from clear to me that patient results can be deleted from PrecisionWeb. Regardless of what can or cannot be done within the live PrecisionWeb database, there is no doubt whatsoever that prior to acquaintance with Professor Thimbleby's second report and at the time in question, all POCT team members who are PrecisionWeb administrators were completely unaware that data could be amended in the live PrecisionWeb database. They were unaware of this functionality and they did not realise they had access to edit records, and this had not been covered in the Abbott training. Furthermore, the Abbott PrecisionWeb User's Manual QC manager 3.0 from 2009 confirms that there is a comprehensive audit trail in the live PrecisionWeb database of any changes made, which are also associated with an alarm that must be acknowledged.

The suggestion that a barcode from a Kleenex box could be used as an ID on an XceedPro is erroneous – an XceedPro would not accept the number coded from a Kleenex box because of formatting issues. On page 26 (**8.13 **Data was uploaded but was modified**) Professor Thimbleby states that "…. it is impossible to tell if data is deleted from the database for any reason (if a row of data is deleted, it is simply not there and leaves no trace)". If this applied to the live PrecisionWeb Database this would be a very serious matter in terms of reliability of the data it contains. Professor Thimbleby, however, appears to be referring to the CD with which he was provided by South Wales Police rather than the live PrecisionWeb database to which he had limited access.

The suggestion that there may be more than one database (page 27 **8.16 **There may be more than one database**) is not consistent with the facts. Although there are different hospitals within ABMU Health Board, the POCT service to them acts as a single integrated service and all POCT devices used within the ABMU hospital service were linked to the same PrecisionWeb Database. On page 34 Professor Thimbleby writes that "according to the Police, Davies has patient ID W0029395. The database has a field called "patient name" but it is unused at POW, so the database cannot confirm whether W0029395 is in fact Davies". While it is the case that at the time in question the PrecisionWeb Database was not linked to a data feed with patient identities, there is a very clear correlation between hospital numbers and the identities of the patients concerned. The handling of all patient data, including Blood Transfusion records etc, is utterly dependent on the hospital number correctly identifying individual patients and the absence of a feed for the "patient name" field in the database does not detract from that. On page 85 Professor Thimbleby quotes the "Abbott Precision XceedPro – PXP Operation Training Glucose Test" dated September 2010, which says "do not remove PXP from its docking station when the "communication turner" is turning as this may cause data loss". Subsequently Professor Thimbleby says that "here "data loss" hopefully may not be permanent if the XceedPro records that the docking was prematurely terminated. Abbott do not

specify". It is in fact the case that data was not lost in this situation – the fact that docking was interrupted was shown on the display and all data that was in the process of being transferred was uploaded when the Precision XceedPro was next docked. Also, the process of docking did not delete data from the meter, so that data remained on the Precision XceedPro after docking.

Notwithstanding these issues, Professor Thimbleby does correctly make many valid points and has successfully called into doubt the Prosecution's assertion that the absence of electronic evidence of results that were recorded on paper was the consequence of fabrication. Reading his two reports has confirmed my own view that the prosecution of members of the nursing staff at Princess of Wales Hospital was a mistake. However, this is not because of the view that deficiencies in the PrecisionWeb Database diminished the chance of a successful prosecution, but rather because, as Professor Thimbleby has pointed out, this matter concerns poor practice rather than criminal behaviour. Poor practice has its origins in the "culture of disdain" for POCT, which is led from the top. For some time now there have been deep concerns about the clinical governance of POCT in ABMU (ably summarised in a letter written in December 2016 by Dr Charles Percy, previous Clinical Lead for POCT in ABMU, to Professor Hamish Laing, Medical Director) with attendance at the POCT Committee very poor, with more or less no user representation, including Senior Nurse Managers in ABMU. User involvement in POCT is essential as it is the users who operate the equipment on a daily basis. While the POCT team provides training in how to use POCT equipment properly, the task of ensuring that good practice is adhered to is an issue for the management of the relevant service, and the persistent poor attendance record at POCT Committee meetings by Senior Nurse Managers demonstrates a degree of disengagement over a prolonged period. Professor Hopkins' report (which recommended reflection on Professor Thimbleby's reports) provides an opportunity for this deficiency and the systemic cultural problems it has brought in its wake to be addressed.

It is worth noting that while Professor Thimbleby outlined many ways in which data could theoretically not be present or detected electronically for blood glucose measurements that were recorded on paper, such discrepancies were not noted in audits that continued for a period of nearly three years after the events in contention became public. As I mentioned at the commencement of this written reflection, ABMU has moved from the Precision XceedPro and PrecisionWeb to the new Freestyle PrecisionPro and Freestyle PrecisionWeb systems. There are some significant differences, including the fact that the new meters are "wireless" and upload data to the Freestyle PrecisionWeb Database in real time. The actual or potential difficulties surrounding docking operations highlighted by Professor Thimbleby have therefore been addressed in the newer system. Likewise it has been possible to configure staff ID barcodes to require 12 digits, which means that these cannot be "confused" with patient IDs (not even the 10 digit NHS number). There have also been significant developments in the degree and nature of nurse

training, with the ABMU-wide implementation of “Think Glucose”, which brings together Laboratory and Nurse Specialist staff in the training of glucose meter POCT users. It is hoped that the newly appointed Director of Therapies and Health Sciences in ABMU (Christine Morrell) will help to further develop high level Executive interest in POCT matters and I warmly welcome the suggestion that Christine Morrell be invited to Chair the POCT Committee on a regular basis. This clearly demonstrates the commitment of senior management in ABMU Health Board to full engagement in POCT matters and together with Professor Thimbleby’s conclusion and Professor Hopkins’ recommendations provides an opportunity for a comprehensive review of clinical governance arrangements and improvements in the management and practice of POCT in all clinical areas making use of it.