CARDIFF CROWN COURT

B E T W E E N:

Regina

(R)

-and-

Jade Pugh & Clare Cahill

Experts' Joint Statement on Matters Agreed and/or Disagreed

The Experts,

Mr Philip Starling, on behalf of the Prosecution ('PS')

Professor Harold Thimbleby, on behalf of the Defendants ('HT')

have been appointed by their respective parties as experts in the field of Health Technology Information Systems, Medical Devices and Health Informatics.

Introduction

This Joint Statement on Matters Agreed and/or Disagreed in regard to Part 35 12 (3) CPR, which the Court has directed the Experts are to produce, represents the best understandings and consensus that **PS** and **HT** have been able to reach in the time available for reporting.

Data has only been released for the experts very recently. **HT** and **PS** respectfully request the Court to refer definitively to their final analyses, conclusions and opinions as will be provided in their respective Expert Reports or statements as may be reviewed or revised in the light of the recent releases of data or other evidence.

AGREEMENT ON THE ISSUES FOR EXPERTS

The terms of reference for HT and PS differ, and this list of agreements says nothing about issues that are outside the overlapping concerns of the experts. HT and PS are experts and they will agree on or may have valid differences of opinion and interpretation on issues that are not listed in this document.

For clarity, ECRI's initial terms of reference (ToR) are:

1. *"A national hazards and recall search which will determine if the medical product Abbott Precision Xceed Pro blood glucose meter has ever been the subject of any safety and functional notices that may be relevant to the case. This will include conduct the MHRA and international data as well as any peer reviewed literature that may have relevance to the case.*

2. *Conduct a review of the data captured from the 3 devices serial numbers XP0833A0098323, XP0920A0156125, XP1232B0512166 for accuracy.*

3. *Examine the 3 devices; serial numbers XP0833A0098323, XP0920A0156125, XP1232B0512166 to determine functional accuracy*

4. *Comment on the possibility of the loss of data/drop off from the glucose meters as explained in the report of Dr Neil Carpenter (Abbott)*

5. *Evaluation of the examinations conducted to date by Abbott employees, Princess of Wales hospital staff (Christine Hopkins) and police (DC Gareth Owen)."*

The three devices pertinent to the PS review are as follows:

XP1232B0512166 (Police Exhibit Reference: CH/1)
XP0920A0156125 (Police Exhibit Reference: CH/2)
XP0833A0098323 (Police Exhibit Reference: CH/3)

It should be noted that several further points of investigation arose during the above investigation.

- A Review of the Reports completed by Professor Thimbleby completed 23/08/2013 for ABMU.
- A report addressing requests for clarification concerning the definition of error codes.
- A review of a report generated by professor Harold Thimleby dated 21/08

PRELIMINARY ASSESSMENT OF AND CURRENT POSITION

ON AGREED ISSUES

<u>Issue 1:</u> Did the Exhibit CH/15 data supplied to each expert contain the same files for examination purposes?

1. We have compared our CH/15 data files (POWH 01.01.12 - 31.03.13.csv) and they are identical. It appears the CH/15 CDs themselves did not contain identical data, but the key file (POWH 01.01.12 - 31.03.13.csv) was identical.

<u>Issue 2:</u> Did either expert have access to the source data from the Precision Web database for analytical purposes prior to the production of expert reports that have been generated and submitted to date?

2. We did not have full access to data at the time of report production by either expert.

3. The data provided on September 30 has some differences this is likely due to data reconciliation carried out by Nick Reece per his statement, see 8 below

4. The CSV files previously supplied in CH/15 and the September 30th data have differences for explainable reasons such as point 8 below.

5. We consider that the previous lack of availability for examination purposes of any full original backup of the PrecisionWeb database opens to question the accuracy of some of data comparisons previously carried out. Such limitations are detailed in our previous expert reports in that exhibit CH/15 is not original source data.

6. Source data access has previously been requested and has not been forthcoming prior to production of the current reports produced by both expert witnesses to date.

7. We have not had a proper definition of the file ABM29092015PrecisionWeb.bak (the database of 30 September) supplied to both experts. We note that Christopher Dancer (witness statement of 30/9/150 describes it as QCM3 which we believe was used (and may still be used) by Princess of Wales prior to XceedPro/PrecisionWeb use.

8. We know from Nick Reece's witness statement that the original data (recently supplied Sept 30th) we have seen contains changes such as reconciled records that could not be automatically added due to for example miss-identification. These records are held for review by human operators this is normal and is tracked in a database table. Because of Nick Reece's actions we know that CH/15 was not exactly the data in use at Princess of Wales prior to May 2013.

9. We are agreed that we do not know enough about the (remaining) contents of the reject folder data. Nick Reece should be able to say.

<u>Issue 3:</u> Was the Precision Web system implemented with the full range of reporting functions enabled?

10. Apparently not. If the full range of reporting functions had been implemented and used as such, we believe the problems would not have occurred and/or would have been detected immediately and rectified as a normal procedure. (Without more information, we cannot tell whether they were not implemented or were implemented and not used fully.)

11. All reporting functions were in principle available to the staff according to the local security settings for those staff.

12. Additional reports could be/could have been built and added to the system by Abbot Diabetes Care staff.

Issue 4: The impact of implementing the Precision Web system without 'True ID' being implemented

13. The implementation of the Precision Web System and failing to implement "TrueID" Patient Confirmation has led to a situation where inappropriate information could be entered into the patient identity field and that this would not be automatically or readily detected. PrecisionWeb, unable to reconcile these tests, would await human intervention to reconcile them to the correct ID before passing the record to another system.

14. Had a system such as TrueID have been implemented then the miss-identification rate of patients could have been reduced significantly. Had standard features in PrecisionWeb been enabled and managed (e.g., with TrueID), the incidence of relevant errors could have been automatically reduced to very low figures (to almost zero according to an American study published in Journal Of Pathology Informatics referred to above) and in due course with appropriate management intervention down to zero or close to zero.

15. The US Baystate Health System conducts over 300,000 POC glucose tests annually using approximately 2,400 operators/nurses* in 6 hospitals**. They used Abbot PCx POC meters with post-test validation (pre onward data transfer to LIS, Finance and other systems) of the Patient ID. Due to a need for zero patient ID error rates the organization moved to XceedPro/PrecisionWeb and enabled TrueID where patient ID verification was carried out on the XceedPro itself before testing in an attempt to reduce the error rates to zero. This reduced their error rate from 61.5 (old System) to 3 per month.

16. The PrecisionWeb system at the Princess of Wales covers a larger number of Hospitals and community care facilities, 15 in all (according to data later supplied to both Experts). Also 50% more patient tests were carried out system wide between 01/01/2012 and 30/03/2013 than quoted in the BayState system study. This suggests that if TrueID were enabled a similar scale of ID Error reduction could be expected.

    * Journal Of Pathology Informatics; Alreja G, Setia N, Nichols J, Pantanowitz L. Reducing patient identification errors related to glucose point-of-care testing. J Pathol Inform [serial online] 2011 [cited 2015 Oct 1];2:22. Available from: http://www.jpathinformatics.org/text.asp?2011/2/1/22/80718

    ** http://www.baystatehealth.org.

Issue 5: The database is incomplete?

17. Neither ECRI Institute nor Professor Thimbleby have had access to the full source data and hence this is a conclusion that cannot be reliably suggested at this time.

18. The September 30th database does not change this problem (whether the database is incomplete) for the defence. However ECRI had a differing ToR examining record transfer from the XceedPro devices to PrecisionWeb.

~~18.~~19. The format of the CH/15 data and statements made on the provision of that data confirms that it was never the entirety of the PrecisonWeb database.

~~19.~~20. The recent SQL backup data also appears to be incomplete (though we think it is a complete backup of PrecisionWeb's current data), however ECRI and HT agree that "completeness" of the data is impossible to ascertain from the data alone.

~~20.~~21. There is no disagreement between the Experts that malformed (e.g., misidentified) records do and have occurred and that manual intervention (not by a nurse) is then required to recover them.

~~21.~~22. HT asserts the data we have seen to date implies it and/or the systems and/or the processes are not of an overall adequate quality to be used as a reliable basis for court evidence. ECRI has not seen the additional systems, but both ECRI and HT can say is that it appears that no Admission Discharge Transfer information (ADT) is present which suggests there is no connectivity to the hospital's HIS system which degrades the quality.

PRELIMINARY ASSESSMENT OF AND CURRENT POSITION

ON DISAGREED ISSUES

Issue 6: Is the Xceed Pro blood glucose measurement system reliable in the context of evidence in possession of the experts?

~~22.~~23. ECRI Institute's examination of the XceedPro devices at the Princess of Wales Hospital demonstrated the technology was reliable during testing and that data transfer occurred correctly. This conclusion is based on the confirmation of the operation of the processes by testing *in situ* and its effects upon the data upload process. Also examination the data transferred between that held in each device and the PrecisionWeb database as represented by CH/15 data and latterly confirmed through the provision of a backup of the database from the hospital

~~23.~~24. From Page 69 of the last defence report it is suggested that 1000s of examples of an action were required to prove reliability. On that basis uploading 5000+ records over 3 devices should be an acceptable level of proof that the upload process is reliable.

~~24.~~25. HT's view however is that successfully uploading *these* 5000+ records unfortunately allows us to infer little about records that failed (or might have failed) to upload and/or be recorded on PrecisionWeb or transferred through PrecisionWeb to the hospital's systems. PrecisionWeb is designed to put aside malformed records.

~~25.~~26. HT argues that whether or not 5000+ records were uploaded says nothing about errors earlier than the XceedPro records; also, successful "uploading" does not determine what PrecisionWeb and any manual intervention does with the data.

~~26.~~27. Additional to the above this is an annex 3 registered device. These are not critical medical devices as suggested by the defence, under which would place it as an annexe 2 or 1 device. Thimbleby and ECRI agree that the 'Critical' classification should only relate to Error Levels not to the device.

~~27.~~28. In relation to the use of MAUDE etc. In terms of Safety and Hazard reports ECRI reported no applicable events for this version of the XceedPro. As an Annex 3, CE registered device Abbott hold a quality file from which they have disclosed the only reported issue which was determined by the UK Notified Body, The Medicines and Healthcare Products Regulatory Agency (MHRA), to 'not require' further action. As such this confirms that the system has no notices as determined by examination of all data sources available to ECRI worldwide. This report was also copied to the US Federal Drug Administration (FDA).

~~28.~~29. The MAUDE Database was not and should never be used in isolation, as per this quote from the FDA's MAUDE Search Screen. "MDR [medical device reporting] data alone cannot be used to establish rates of events, evaluate a change in event rates over time or compare event rates between devices. The number of reports cannot be interpreted or used in isolation to reach conclusions about the existence, severity, or frequency of problems associated with devices."

~~29.~~30. HT's view is that the *Journal Of Pathology Informatics* article proves that MAUDE is not recording large numbers of events (an average of 61.5 per month is reported in the paper) relevant to this case.

~~30.~~31. ECRI's view is that relying on a single item or even 2 items of peer reviewed literature from a single healthcare institution is not adequately representative of significant evidence that large numbers of events

relevant to this case are prevalent. A systematic of this review of this manufacturer's technology would be required to underpin this assertion.

Issue 7: Was the Precision Web system implemented with the full range of audit functions enabled?

~~31.~~32. PrecisionWeb has to our knowledge simple audit logging systems for patient records, Instruments, operators and disposables/reagents.

~~32.~~33. These audit records are made automatically and cannot be adjusted by the system users. Their function appears to be implicit and not requiring configuration.

~~33.~~34. These data can be reported upon in the User Interface.

~~34.~~35. These are not controlled documents. Where the defence expert and ECRI disagree is that HT argues these reports would themselves need to be controlled documents if they are/were to be used as reliable evidence.

~~35.~~36. In any case, we cannot tell if use was made of such reports.

Issue 8: The appearance of 'Critical Errors in the data and their implication in terms of device functionality

~~36.~~37. HT drew attention to the error message analysis carried out by ECRI (Report 4 of 5) and the presence of 'Critical', particularly software errors. ECRI consulted with Abbott on the definitions and the effects of these errors and reported on the results of this line of questioning. Specifically the software errors which, according to ADC, are intended to ensure the integrity of a copy of the operating software loaded into the device's Random Access Memory: a failure of such a test would lock out the device and enforce a restart, reloading the device firmware. This is a 'Watchdog' process to ensure correct performance. The test is carried out every 30 seconds.

~~37.~~38. ECRI also questioned the outcome if such an error was found while a measurement was in progress and this was stated by ADC as being indeterminate.

Issue 9: Were the XceedPro Blood Glucose measurement devices subject to regular planned preventative maintenance

~~38.~~39. The Precision XceedPro glucometers (apart from minimal user maintenance) are not designed to be serviced according to statements made by Abbot Diabetes Care. The 'health' of each device is heavily monitored and devices not conforming to enforced performance checks are automatically removed from the patient measurement process.

~~39.~~40. Devices that fail the diagnostic monitoring checks are returned to ADC and replaced. According to ADC devices replaced in this way are disposed of after diagnostics and do not return to hospital service.

~~40.~~41. HT's view is that terminological distinctions between service/repair/maintenance are irrelevant. We are agreed that when there are problems, the devices are removed from the ward for "maintenance" or "servicing." Exactly what happens to them is irrelevant to the fact that they disappear from a ward and are either "serviced/repaired/maintained" or "replaced" with other instruments, either from Abbott or from stock.

~~41.~~42. We do not know whether there is a regular planned maintenance schedule, but in itself this makes little difference.

Issue 10: What constitutes an error in uploading data?

42.43. ECRI's definition of a failure to upload a record is different from that of the defence expert. ECRI's definition is that a record transferred from the glucometers to the database in its entirety as added to the device is correctly uploaded. The difference can be explained by the terms of reference given to ECRI. The failure to implement a function that would improve the data input quality however is not a failure of the device/data system itself.

43.44. HT's view is that the end-to-end flow of data from an XceedPro to its final use is the key data quality question, and that in this sense errors do occur: is the data uploaded *to the end* of the dataflow? PrecisionWeb may be functioning correctly in its own terms in discarding malformed or other erroneous data (e.g., with bad or unauthorised IDs etc), but this is effectively a "failure to upload" when it occurs and is not rectified manually.

45. HT agrees with ECRI's view that "failure to implement a function that would improve the data input quality however is not a failure of the device/data system itself," but it is a severe limitation (if not called an actual failure) of the whole Princess of Wales system to manage the data appropriately. (HT notes that "failure to implement" is meant by ECRI as a failure of the hospital to configure or use a feature, not a failure of the manufacturers to implement a feature so it was not available for use.)

PRELIMINARY SUMMARY VIEWS

PS's summary views are as follows:

~~44.~~46. The testing of the XceedPro Devices at Princess of Wales Hospital demonstrated that in 5000+ instances that we had both device and database data for, patient records were correctly transferred according to our definition with consideration to our terms of reference and that no errors could be determined to have prevented a reading displayed on the XceedPro display from being uploaded, e.g., a software error.

~~45.~~47. That early provision of the PrecisionWeb database backup should have been fulfilled as it would have excluded any doubt relating to content and traceability. It would also have made data processing significantly easier.

~~46.~~48. The ECRI Terms of Reference provided by South Wales Police were adhered to during the review of the devices and data. It should be noted this prevented ECRI from exploring in detail how data was managed beyond the PrecisionWeb system (ConWorx etc.) and restricted ECRI to confirming the operation of the 3 devices CH/1 to CH/3 and their interoperability with PrecisionWeb. However it is understood that the ToR's were generated at a point in time during a complex investigative process.

~~47.~~49. That providing a more robust barcode to identify patients could have reduced user frustration with the system lessening the use of the "Double Scanning" workaround.

~~48.~~50. That when identified (on another data system for Blood Gas Machines) that the Hospital investigated the issue of double scanning of patient IDs.

~~49.~~51. PrecisionWeb is designed containing a system to prevent double scanning (when configured and used as intended) it appears reasonable to not provide an in built report/alert for this specific case.

~~50.~~52. The Data transfer from PecisionWeb to Conworx is apparently indirect, via a flat file transfer. Had the LIS Transfer to ConWorx been direct Alarms would have been present to alert system users to faulty patient IDs.

~~51.~~53. As stated previously within this document ECRI does not agree that the single cited *Journal of informatics* article referenced above adequately demonstrates 'large numbers of events' are occurring internationally that are relevant to this case.

HT's summary views are as follows:

~~52.~~54. The dependability of end-to-end dataflow from an XceedPro through the dock, through PrecisionWeb, through middleware and back to the EHR has been called into question. The PrecisionWeb database is a small part of this process and we are agreed it does not include all data that may be uploaded from XceedPros.

~~53.~~55. The database content exhibits serious management issues that have and had not been addressed.

~~54.~~56. The forensic handling of data seems to have been poor. Without adequate forensic audit trails (whether from within POW or the Police) it is impossible to pinpoint where failure(s) to manage data occurred. However, the failure to manage data appears to have had no clinical consequences. Because of Nick Reece's actions (point 8 above) we know that CH/15 was not the data in use at Princess of Wales prior to May 2013.

~~55.~~57. Because it may take 2 days for data to go end-to-end there is no contemporaneous use for the final data.

~~56.~~58. We currently have no idea whether data is reliably transferred through Conworx and other systems in the dataflow.

~~57.~~59. The data, known processes (e.g., inventory of XceedPros, auditing of data, etc), and in particular the low quality of data in PrecisionWeb that has been made available to the Experts to analyse taken together imply that the database and other electronic information was managed in a way that makes it unreliable for use as evidence.

~~58.~~60. PrecisionWeb's manual says it should not be used for diagnostic purposes; and HT's view is that for the present case, that evidential use of XceedPros/PrecisionWeb is a harder criterion even than that, and one that it has failed to meet (irrespective of whether it is satisfactory for its intended clinical use). Put another way: that the XceedPros/PrecisionWeb work as specified or design is not the same question, and is not as strict a question, as whether data obtained from them is reliable.

~~59.~~61. HT's view is that had high integrity software techniques been used throughout the dataflow, the Experts may have been in a position to say that the PrecisionWeb data was a faithful representation of that part of the system. While XceedPro/PrecisionWeb is undoubtedly an industry standard product and apparently working to its specification, unfortunately it is taking it beyond its specification to expect to use it (or the data it manages) as reliable evidence.

SIGNATURES OF EXPERTS

We agree that this document is an accurate record of our respective views concerning the issues in our overlapping ToRs, and of current points of agreement and disagreement between us about this matter.

Professor Harold Thimbleby	**Mr Philip Starling** ***ECRI Institute***
INSERT DATE	**INSERT DATE**
(6 October 2015)	(6 October 2015)