CASE RULING:
ENGLAND & WALES

Case citation:
***R v Cahill; R v Pugh* Ruling 14 October 2014**

Name and level of the court:
Crown Court at Cardiff

Case numbers:
T20141094 and T20141061

Date of ruling:
14 October 2015

Trial Judge:
HHJ Crowther QC

This is a Ruling by HHJ Crowther QC on a matter of evidence at the trial of two nurses in 2015. The judge determined that the evidence was unreliable and was therefore excluded. As a result, the prosecution offered no evidence and the nurses were discharged. The facts of this case and its importance are set out in Stephen Mason and Daniel Seng, editors, *Electronic Evidence* (4th edition, Institute of Advanced Legal Studies for the SAS Humanities Digital Library, School of Advanced Study, University of London, 2017), 9.90 – 9.95.

England & Wales; digital evidence; glucose testing; handheld device; Electronic Patient Record; efficacy of evidence

IN THE CROWN COURT AT CARDIFF

REGINA

AND

CLAIRE CAHILL

JADE PUGH

RULING

Subject to any agreed amendments between Counsel as to CH15/CH20 derivation and to comparison with the oral judgment.

OVERVIEW

1. Claire Cahill and Jade Pugh were in 2012 and 2013 nurses working on Ward 2 of the Princess of Wales Hospital, Bridgend. It is a specialist stroke unit. One of the side effects of stroke is that it can disturb diabetes control; another is that cognition and awareness may be affected, and make a sufferer less likely to recognise the symptoms of poorly controlled blood sugar.

2. Accordingly, regular glucose testing is an essential part of the care of such patients.

3. Glucose testing at the PoW is undertaken by nurses using a handheld device, the Abbot Precision Xceed meter. There were three such meters assigned to ward 2. After a blood sugar reading is taken, it is noted for the ward's paper record and stored in the handheld device until the device is docked and the reading is uploaded to the hospital's database, known as PrecisionWeb. Ultimately, the data will populate the patient's Electronic Patient record.

4. It is said against these two defendants that they fabricated blood sugar readings – Ms. Cahill in respect of six patients and Ms. Pugh in respect of four.

5. In support of this contention, the Prosecution point to the fact that the paper readings – nor any broadly similar in terms of time, date or result – find any echo on the Xceed meters or on the hospital's database.

SUBMISSION

6. The submission is made, effectively jointly, that the prosecution should not be allowed to rely on the database evidence. The evidence is, submit Miss Brimelow QC and Mr. Rutherford QC, fundamentally unreliable. It should be excluded either under s.78 or, if it is hearsay, under the provisions of the 2003 Act.

7. I have heard evidence on the voire dire from Phillip Starling, Principal Investigator at the ECRI Institute, an

independent, not for profit healthcare services research agency; from Nick Reece, a PrecisionWeb support Specialist employed by employed by Abbott Diabetes Care; and from Professor Harold Thimbleby, a professor of Computer Science at Swansea University. I have taken into account statements from Dr. Dr Neil Carpenter, Principal Scientist for Abbott, from Christine Hopkins, Point of care Co-Ordinator at PoW, and from Debbie Boulton, an Intelligence Analyst with the police.

8. Dr. Carpenter submitted reports which dealt with the glucometers themselves. In summary, he concluded: that each meter tested was fully functional, that the recording of data was accurate, and that downloads matched the recorded data under controlled conditions (both to a controlled isolated system and to PrecisionWeb). While interrupted docking may result in PrecisionWeb not receiving all latest test results the meter would not flag any data as uploaded, and guidance to rectify that would be given to the user. While there were error codes logged, the presence of error codes does not mean a meter is not performing in accordance with specification.

9. Mr. Starling drafted a series of reports. He dealt with further analysis of the glucometers. He noted that the system in place at PoW did not require a nurse to scan a valid patient ID before taking a blood test; the requirement was that the nurse would identify themselves, then submit a second identity reading from a barcode. Were the nurse so minded, they could scan their own ID twice. This would result in a test that could not be found by searching patient ID in EPR, PrecisionWeb or the glucometer and arose because PoW had not implemented the full features of PrecisionWeb. That was, said Mr. Starling, a reason why tests made by such a user might have "disappeared", and that is a more credible explanation for the defendants' cases than failure of the glucometer, which is a robust piece of equipment. He confirmed that incomplete download did not result in data loss though had found an instance in the literature of fouled data when glucometers were almost simultaneously docked; that error had been patched by Abbott, but the patch had not been implemented by PoW.

10. Mr. Starling also considered data that had been provided on a CD-ROM CH15. This exhibit was created by Nick Reece and is described as "a *.csv file of data selectively exported from the actual precisionWeb database". There were 131,087 data records of which 130,978 were blood glucose readings. Starling concluded that data was transferred from the glucometers to PrecisionWeb without observable error but underlined that without access to PrecisionWeb, rather than the selective export, ECRI could not exclude other possibilities raised.

11. Professor Thimbleby undertook a step by step analysis of the data flow. After docking, an analysis of the results transferred takes place in the hospital database system. Results which are in the expected form are sent to the PrecisionWeb database. Results which are not as expected as sent to a "reject" folder. PrecisionWeb then sends data to Conworx, essentially an interface with the hospital's electronic patient records. The CD-ROM CH15 did not include all data stored by PrecisionWeb and was in a format which made it impossible to determine its correctness and authenticity.

12. Professor Thimbleby's concerns about correctness and Mr. Starling's reservations about completeness of data led to the prosecution disclosing a further exhibit, CD1, which was said to be the entirety of the PrecisionWeb system. This was dealt with in evidence.

13. Mr. Starling confirmed that the primary data is that which is held on the device itself – the glucometer. It is not editable on the device and data sets have been protectively downloaded. There are no concerns about correct transfer to Precision Web.

14. So far as the database was concerned, Mr. Starling had checked CH15 against CD1 and found no discrepancies. The results sets from the glucometers appeared in both CD1 and CH15.

15. Mr. Starling accepted that the database system rejects certain readings, resulting in apparent loss – IP non recognition might have this effect, or, as he had

said in his reports, double scanning of an operator ID – and further accepted that the Abbott technician Mr. Reece had attempted to integrate rejected readings into the PrecisionWeb prior to any download having been made.

16. As to the operation of the glucometer, Mr. Starling accepted that premature removal of the blood testing strip would initiate a shut down which may or may not have been earlier than the operator would expect, dependent on the machine's settings. If a reading had not been displayed prior to shut down it was unlikely that the reading had been recorded in the device memory.

17. Ms. Brimelow asked: Would you agree that in order for there to be complete reliance on your analysis, the full database needs to be considered – the full original database ? and he replied "yes, I would consider it is fundamental – we requested this and it was not forthcoming and the content of CH15 was provided in lieu". Mr. Starling agreed further that access to the whole database would have given a wealth of further detail, not available to him in his analysis. He had been reassured in late September to receive CD1, which was not identical to CH15 but incorporated subsequent changes; however, those changes were auditable. They had checked the reliability by comparing the databases against each other.

18. Mr. Starling was asked what happened to "bad" data, the rejects, and he said he didn't know; he had not been provided with any detail. CD1 did not include the reject folder. In any event, his role had not been to consider the entire system looking for bad data. He had no knowledge of the role of the "reject folder". He said that folder had been "kept in darkness", but he agreed that malformed records do and have occurred and manual intervention is then required to recover them. He had not known that the entire system needed rebooting regularly, and confessed to some surprise as a system of this nature should not need regular reboots. The (admittedly) underpowered central server might have been a reason for that. When asked "can software failure lead to loss of data?" he replied "In this circumstance I do not know enough to fully answer your question. It is potentially possible."

19. Mr. Starling was asked whether it was reasonable in his judgment to infer that the missing data – the defendants' absent readings – might be somewhere else, within the unseen complete system, and he said "it may indeed be elsewhere. In general terms our testing was not relating to missing records but to efficacy of the process". He said he had no idea whether data had been reliably transferred through the later Conworx system or other systems in the data flow.

20. Professor Thimbleby gave evidence, and accepted that the glucometers themselves were likely reliable, and that CH15 and CD1 matched to a significant extent; however, CH15 and CD1 were not the complete content of the system: the reject folder was absent.

21. At this point Mr. Clee QC produced CH20, a download of the reject folder. Professor Thimbleby had not seen that before; neither had Mr. Starling, and he was not re-examined on it.

22. At this point, the hearing was adjourned for Mr. Starling and Professor Thimbleby to consider jointly what was, to just about everyone concerned in the case, fresh material, although it had been part of the early service of the case. I pause to note that that the failure to recognise the importance of CH20 by all parties is at least regrettable; and further, to remark that whoever did uncover CH20 is an unsung hero of this case deserving congratulation.

23. After two days, a joint report was prepared on the reject folder CH20. The reference to the time it took is to underline the scope of the task and not to complain about speed. It notes

> i. the data contains details of 18,546 rejected tests
>
> ii. none of the results matched the "missing" data, using a search methodology similar to that which had been employed by the police
>
> iii. statistical analysis of the data, particularly an odd distribution of failed tests, does not

support the contention that the data is complete and in fact suggests loss or deletion of data

iv. analysis of filenames suggests multiple deletion has taken place

v. the presence of empty XML files suggests a technical problem, as such files are forbidden.

24. The joint conclusions of Mr. Starling and Professor Thimbleby were

i. that while there were no patient tests on CH20 that could align with the missing patient records, the logic processes that generate the reject files are unknown, and so further investigation with Abbott would be necessary to determine if any files were actually missing;

ii. the distribution of the data very strongly suggests some form of manipulation and suggests that CH20 has lost significant amounts of original data, and it is not possible to countenance an explanation consistent with the data being reliable;

iii. the files within CH20 are not consistent with a uniform or complete sample.

25. The Prosecution called Mr. Reece, who had come to help PoW when it faced problems in 2013. He came at the instance of Christine Hopkins, who later created CH15 in July 2013. The purpose of his evidence was to deal with the point raised by the experts as to the processes that generate the reject files; but Mr. Reece was unable to help with that, it being beyond his expertise. He was able to assist to some extent with the alteration of the database, as he had restored reject files to the main database and then prepared the download CH15. He also allowed, when questioned by Ms. Brimelow QC, that he had not undertaken the download in any sort of forensic or supervised way, because he was at that stage unaware of any investigation. He had gone to PoW as there were difficulties with the system. It was running on an underpowered server and needed regular rebooting. Because he had not been asked to undertake a forensic exercise, he did not make notes or records of what he had done, but it was, he said, everyday work and uncomplicated. He remembered being asked to search for specific operator IDs in the system but could not remember the IDs for which he searched and nor say if he found matches.

26. He was asked what would lead to rejection of results by the system, and replied that IP address changes certainly would. The hospital is a large concern with a server that reallocated IP address to its PCs; that reallocation required PrecisionWeb routinely and regularly to reinterrogate the system to match IP addresses; uploads before the reinterrogation and identification of addresses to PCs would result in failure.

27. Mr. Reece did not know whether upload during reboot of the system would result in failures; that was a matter for Abbott's technical team.

28. Mr. Reece would not comment on the joint experts' report; it was more technical than his knowledge allowed.

SUBMISSIONS AND ANALYSIS

29. Miss Brimelow QC, who has led these submissions for the defence in a way I have found helpful, reminded me in submissions that ECRI and Mr. Starling did not dispute that CD1, the PrecisionWeb data dump, was not complete. The Prosecution's original argument that CD1 was an answer to criticism does not hold water. Professor Thimbleby has shown that the chain has various breaks where the data can be lost. None of the data now relied on is original; it was all made after human intervention by Nick Reece and he has no real recollection of what he was asked to do, what ID codes he was asked to consider, and did not note it at the time. All the material is at best edited. CH20 has lost significant amounts of data: but there is no way to tell whether the missing files were reintegrated into the PrecisionWeb database, in which case the Prosecution case might have force, or simply deleted, in which case it would not. I should exclude the evidence as being more prejudicial than probative or I should consider it hearsay because of Reece's intervention, and unreliable hearsay.

30. In his submissions Mr. Clee QC asked me to consider whether CH20, the reject data, and any limitations on CH15, the originally disclosed PrecisionWeb sample, were overtaken by CD1; the lately-served source data which had led Mr. Starling to say that CH15 was validated. The answer to that question is no; because the original download data flow from the glucometer splits into two streams. One stream leads to a tank, PrecisionWeb, from which CH15 and CD1 were drawn, and one leads to the reject folder CH20, which the evidence tells me is, to continue the analogy, an open pool, which may well be susceptible to evaporation and seepage. While CD1 may validate CH15 – Professor Thimbleby thinks not, and it may not be an issue that needs to be resolved – unless the contents of both PrecisionWeb and the reject folder are known, it cannot be said with certainty whether an absence in the electronic patient record shows that a reading was not uploaded, or whether it was taken in and filed as a reject.

31. As Mr. Rutherford QC has it: "are the Crown in a position to show that the omissions are not or were not ever in that reject folder?" If not, then the evidence relating to the searches of the hospital databases are, it seems to me, only partly relevant, and what is more their adduction in evidence would serve only to suggest to the jury a conclusion they could not draw – namely, that absence in the searches meant those results had never been in PrecisionWeb or the reject folder. Mr. Clee QC suggests that the jury can decide whether to accept or reject the evidence of the experts. Notwithstanding the familiar terms of the standard direction on expert evidence, namely that it is ultimately a matter for the jury to decide, given the highly technical nature of the field and given the degree of agreement between the experts, I regard that suggestion as unrealistic and faintly desperate.

32. It follows that my ruling is that the adduction of the evidence of searches of CH15, CH20 and CD1 would be more prejudicial than probative and I exclude it under s.78.

33. What that means for the case as a whole is a matter for the Prosecution. If it regards the glucometers as a complete and accurate record of tests taken on ward 2 then it will choose, subject to any submissions made, to proceed. If it does not, then this case will end and two points need to be made:

i. first, I have found it striking that the expert evidence had been that PoW could have implemented features of the PrecisionWeb database that would have ensured that patient IDs were always associated with glucose tests, which would have reduced the scope for rejects and made audit of the results a far simpler task;

ii. second, the investigations that led to this decision have been made over the last two weeks, the jury having been sworn. The importance and relevance of CH/20 did not become clear until this time. It was the analysis of that exhibit, the rejected results file, in depth and at speed by Mr. Starling and Professor Thimbleby, that led them to the unanimous view that the database's integrity could not be proved. But this could have been dealt with at an early stage. It matters because enormous expense has been incurred in trial preparation – hundreds of hours of time spent by experts, by the investigators, by lawyers. It matters because Court time has been used to make enquiries that should have been made before, with a knock on effect on other cases waiting to be tried. It matters because two women have been facing a trial that should have been ready earlier and it matters because families of the patients involved will have had their upset prolonged.

HHJ CROWTHER QC