Witness Name: Sarah Louise Davies
Statement No.: 1
Exhibits: SLD/1 - SLD/4
Dated: 15/05/2024

THIRLWALL INQUIRY

WITNESS STATEMENT OF Sarah Louise Davies

I, Sarah Louise Davies, will say as follows: -

Personal details

1. My name is Ms Sarah Louise Davies.

Career and employment

2. Following an undergraduate degree in Chemistry at the University of Oxford (2005-2009, First Class), I completed my three year pre-registration Clinical Scientist training from my base at Wythenshawe Hospital (Band 6, from September 2010 to August 2013). This included an MSc in Clinical Biochemistry at the University of Manchester (2010-2012, Distinction) and shorter rotations in several hospitals including Stepping Hill, Royal Bolton and Alder Hey Children's Hospitals. In August 2013, I began working at a Band 7 level within Liverpool Clinical Laboratories in Liverpool University Foundation NHS Hospital Trust, first as a Higher Specialist Trainee Clinical Scientist (Aug 13-Apr 15) and then as a Senior Clinical Scientist (Apr 15-Apr 17). Since April 2017 I progressed to a Principal Clinical Scientist role (Band 8A) within this organisation, and in September 2021 started studying for a five year professional doctorate as part of the Higher Specialist Scientific Training programme (University of Manchester). I have been a member of the Association for Laboratory Medicine since 2010, I have been registered with the Health and Care Professionals Council as a Clinical Scientist since 2013 I&S and have been a Fellow of The Royal College of Pathologists since November 2020. My job role within laboratory medicine is varied (e.g. research, quality, education) and the analytical and clinical specialisations I have developed are in areas that are not relevant to this case (e.g. lipids and adrenal pathology). However, the aspect of my job role that is most relevant to this case from 2016 is the Duty Biochemist function. When covering the Duty Biochemist rota, I clinically review and authorise results

back to the requesting clinician (electronically and/or via paper reports). Results that require more immediate clinical attention are verbally communicated by telephone according to clinical judgement and/or departmental policies and procedures.

Child L

3. I conform that the statement that I provided to Police on 04/11/2021 [INQ0001252] summarises my actions relating to communication of the insulin and C-peptide results obtained in Liverpool Clinical Laboratories on a sample from Countess of Chester Hospital from Child L (collected on 09/04/16, received in Liverpool on 11/04/16, analysed in a batch on 13/04/16, communicated verbally by telephone to the Duty Biochemist in the Chester Biochemistry Laboratory at 09:38 on 14/04/16, insulin 158.4 mU/L/1099 pmol/L, C-peptide 264 pmol/L; see INQ0001175, INQ0001176]. I was the only person at Liverpool Clinical Laboratories to communicate these results externally to our laboratory. There is no evidence (telephone log) that Liverpool Clinical Laboratories were requested to expedite analysis on this sample (at the time insulin and C-peptide samples were not analysed on receipt but for efficiency were frozen to be run in larger batches each week. Urgent analysis was possible but had to be explicitly arranged with the laboratory). Although a glucose result was not provided by the Chester Laboratory, and therefore full interpretation of the insulin and C-peptide results was not possible in Liverpool, I wanted to flag the results to the clinical team. This is because the clinical details stated 'hypoglycaemia' and so I felt that the results may be inappropriate in this context and would need further clinical follow-up. When glucose is low, the normal response is for the body to decrease insulin and C-peptide in an attempt to increase the glucose to normal levels. Thus, a high insulin in a patient with low glucose is inappropriate. If the inappropriately high insulin is being made by the body, then C-peptide should also be inappropriately high. But if the inappropriately high insulin is from exogenous insulin (e.g. insulin injection), then the C-peptide will be low (often fully suppressed). Thus, C-peptide is a marker of whether the insulin is being produced by the body. The insulin and C-peptide reference intervals we provide in our laboratory are for patients with a normal glucose, and insulin / C-peptide results should always be interpreted alongside a glucose measured at the same time, as well as the clinical history. It is not uncommon for clinical details to state 'hypoglycaemia' when the glucose is not low enough on that particular sample to be considered hypoglycaemic, which is why we need to

check that the glucose measured at the same time is in the hypoglycaemic range rather than relying on the clinical details alone. In addition, we do not have the full clinical history in the laboratory (e.g. patient/family member medications, symptoms, renal function, etc), particularly when samples are referred from another laboratory since we cannot access their clinical notes. Thus, ultimate responsibility for follow up of results lies with the doctor that requests a test since they have the full clinical information. The laboratory can flag potentially abnormal results for more rapid review by the clinical team, and have a clinical advisory service that is available by telephone if interpretive support is required for any results. In our laboratory, there are no prescribed limits for telephoning insulin/C-peptide results (this is a clinical judgement made based on the concurrent insulin/C-peptide/glucose results, and clinical information that we can access). With samples that we receive from other laboratories, it is not practically possible to communicate results directly to the requesting clinician unless we receive an explicit request to do so from the referral laboratory/clinical team. For example, we often so not have the name or contact details of the requesting clinicians. Thus, our standard practice is to communicate results to the laboratory that sent us the sample so that they can make a decision on how or who to communicate the results to. Thus, I verbally communicated results to the Duty Biochemist in the Chester laboratory; this telephone communication route is standard for results requiring prompt clinical attention and I wanted to speak to the Duty Biochemist as there was some nuance to the message. According to our laboratory protocol, I documented a short summary of the result communication in the electronic telephone log [INQ0001175, INQ0001176]. I documented that these results were communicated to Shirley (Bowles) but did not record what she said in response. There was a requirement in our laboratory for all investigations for suspected exogenous insulin administration to be sent to Guildford, but there was no indication that this was suspected clinically from the clinical details on the sample we received or the telephone log of the conversation. No assessment of insulin or C-peptide assay interference was performed in our laboratory.

4. Further extracts from the medical record [INQ0001169] were not provided for comment at the time of my Police statement on 04/11/2021. However, from this it appears that the glucose was not available on specimen I&S; a comment that 'INTERPRETATION OF INSULIN LEVEL DEPENDS ON GLUCOSE' was

immediately added (14/04-09:38) to the result I communicated by the Chester Duty Biochemist. There is a note that 'GLUCOSE RESULT UNDER FLUORIDE OXALATE TUBE NUMBER 030824' but from the information that I can see I don't know whether sample I&S was collected at the same time, or what the glucose result on this sample was. There is also an automated flag on specimen I&S that the CPEPTIDE/INS ratio is low (L) at 0.2 (reference interval 5.0-10.0); this reference interval is consistent with the C-Peptide:Insulin entry in the Liverpool Laboratory handbook at the time (and in May 2024). In other words, the C-peptide is lower than you would expect based on the insulin and the reason for this would need further investigation. I can infer nothing further from the excerpts from the clinical record. [INQ0001169] does not include details of any verbal correspondence between the Chester Duty Biochemist and the clinical team looking after the patient, but I do not know the process for this in Chester and this information may be stored elsewhere and is beyond the scope of our laboratory involvement.

Process and communication of results

5. Since 2015-2016, insulin and C-peptide tests have been reviewed (circa 2020) as part of a complete review of our test repertoire. This was part of a project where we transitioned onto a single laboratory information management system across Liverpool Clinical Laboratories in Liverpool University Hospitals NHS Foundation Trust. We have a test set for capturing glucose results provided by external laboratories. Insulin:C-peptide ratios are not calculated routinely on all requests in our laboratory IT system. Following the transfer of laboratory services into a new hospital building with new analytical equipment (around August 2022), insulin and C-peptide samples are now analysed as soon as they are received in the laboratory. In April 2024, we have changed from paper to email result reporting to Chester Biochemistry laboratory to ensure that results/comments are fully and accurately returned to Chester Biochemistry Laboratory. A Clinical Scientist has been tasked with reviewing insulin/C-peptide clinical authorisation (with supporting educational meetings as required). Laboratory handbook entries for insulin and C-peptide are currently under review. Clinical judgement is still required to determine which results to communicate and the best way of doing this on a case-by-case basis.

6. When there is a suspicion of exogenous insulin administration, then this is a safeguarding issue. If possible, it is best for a Clinical Scientist from the laboratory to speak directly to the clinician to obtain more clinical information/context and make arrangements for samples to be sent to Guilford laboratory. The clinician has the most complete clinical information and have ultimate responsibility for following-up any abnormal results or safeguarding concerns.

7. In the laboratory, our improvement efforts are most usefully directed towards improving test utilisation/interpretation and communication of abnormal results. We can support the clinicians to get results quickly to detect deliberate insulin injection and help them to interpret the results that are obtained in these investigations.

Statement of Truth

I believe that the facts stated in this witness statement are true. I understand that proceedings may be brought against anyone who makes, or causes to be made, a false statement in a document verified by a statement of truth without an honest belief in its truth.

Personal Data

Signed: _____

Dated: 15/05/2024