

Witness Statement Ref. No. 295/1

NAME OF CHILD: Claire Roberts

Name: Sean O'Hare

Title: Dr.

Present position and institution: Retired, previously Head of Pharmacy and Medicines Management
Belfast Health and Social Care Trust

Previous position and institution:

[As at the time of the child's death]

Director of Pharmaceutical Services, Pharmacy Directorate- Royal Group Hospitals Trust (the "Royal")

Membership of Advisory Panels and Committees:

[Identify by date and title all of those between January 1995 - September 2012]

See Attached

Previous Statements, Depositions and Reports:

[Identify by date and title all those made in relation to the child's death]

OFFICIAL USE:

List of previous statements, depositions and reports attached:

Ref:	Date:	

IMPORTANT INSTRUCTIONS FOR ANSWERING:

Please attach additional sheets if more space is required. Please identify clearly any document to which you refer or rely upon for your answer. If the document has an Inquiry reference number, e.g. Ref: 049-001-001 which is 'Chart No.1 Old Notes', then please provide that number.

If the document does not have an Inquiry reference number, then please provide a copy of the document attached to your statement.

(1) Please state your qualifications as at 1996 (and kindly provide a copy of your Curriculum Vitae). B.Sc., Ph.C., M.Sc., Ph.D., M.R.Pharm. S. M.P.S.N.I.

(2) Please describe your career history before you were appointed as Clinical Director.

Previously Chief Pharmacist Ulster Hospitals, Principal Pharmacist Purdysburn Hospital. Staff Pharmacist Masserereene Hospital Antrim and Muckamore Abbey Hospital

(3) Please provide any and all information regarding your work commitments in the Royal and/or the Royal Belfast Hospital for Sick Children ("RBHSC") from the date of your appointment to 1996.

See attached Job Description

(4) Please describe the role, function and accountability of your post as at 1996, including those individuals to whom you reported, and who reported to you.

See attached Job Description

(5) Was there a written job description for your post in 1996? If so, please provide copy of the same.

See attached Job Description

(6) Please identify your predecessor and successor in post.

Predecessor Mr Robert Markwell M.Sc., M.P.S.N.I.

Successor Mrs Rhona Fair M.Sc., M.P.S.N.I.

(7) Please provide any and all information in relation to the following (in 1996):

(a) Where, how and in what manner drugs were stored within the Royal/RBHSC, including who was responsible for managing the same

Bulk Drugs were stored in Locked Medicines Cupboards and in Locked Medicines Trolleys at ward level. The design of which was specified by regulation. In certain circumstances certain drugs, which were liable to be used in emergencies, in for example Theatres, Emergency Departments and intensive care units were kept readily available under the supervision of Sister in Charge.

- (b) The process and system in place for dispensing drugs within the Royal and particularly to the RBHSC, and from there onto individual wards, with particular reference to the Allen ward**

All dispensing was undertaken in the main Hospital Pharmacy located in the main block of the Royal Victoria Hospital located adjacent to the Caves Restaurant and under the Cardiology wards. The department was accessible only by Pharmacy staff using a controlled access system.

- (c) How and in what way such dispensing was carried out, in what manner and by whom**

All dispensing was undertaken by pharmacy assistants, qualified pharmacy technicians and registered pharmacists. All dispensing was double checked prior to leaving the department for its destination. Controlled Drugs, as specified by the Misuse of Drugs Act, were dispensed only by registered Pharmacists and delivered separately.

- (d) Whether the RBHSC had its own pharmacy/drug store and, if so who was responsible for the same, how did it operate, and how was the pharmacy/drug store accessed by clinicians/nurses (specifying which).**

Each ward within the RBHSC would have had Bulk Ward Drug Stores kept in locked medicines cupboards as prescribed by regulation and medicines in current daily use kept within locked medicines Trolleys as prescribed by regulation. These drugs were issued by pharmacy to each specific ward solely for use within that specific ward. The legislation clearly stated that the responsibility for the keys of both Drug Cupboards and Medicines Trolleys resided with the Sister or Nurse in Charge of that specific Ward. Medical staff did not have keys to drug supplies.

- (e) Whether the drugs Midazolam and Phenytoin would have been stored within this pharmacy/drug store and if so, in what quantity and under the supervision of whom**

Supplies of both Midazolam and Phenytoin could well have been stored within a ward in the prescribed Medicines Cupboards and/or Medicines Trolleys provided these drugs were prescribed for an individual patient on that ward and/or the drugs would have had a reasonable expectation of being used within a ward which contained children whose medical condition would have required either of the drugs to alleviate symptoms e.g. fitting.

- (f) If the RBHSC did not have its own pharmacy, the process which needed to be followed by clinicians/nurses to obtain drugs, including all steps and paperwork involved, and where such drugs were obtained and from whom**

Clinicians cannot order drugs from pharmacy. The ordering of drugs is the responsibility of the Sister/Nurse in Charge of the individual ward. Drugs are ordered by the appropriate Sister/Nurse in Charge in a book specifically supplied by pharmacy to individual wards. The issue of such books is recorded in pharmacy and these are only supplied on the requisition on a previous book and such requisition must be signed by the Nurse in Charge and the Signatory must be a nurse whose name appears in the National Register. In addition some wards operate a "top-up" system where bulk supplies i.e. drugs which would normally be kept on a ward for the treatment of multiple patients e.g. paracetamol.

This system is either operated by registered nursing staff or by registered pharmacy technicians. In either case the "bulk" order must be signed by a nurse whose name appears in the National Register. Upon receipt in Pharmacy the orders are assembled and checked for accuracy prior to dispatch to the individual ward. The transportation is undertaken by pharmacy staff or in 1996 some orders would have been transported by porters based in RBHSC.

- (g) Whether the RBHSC had its own drugs stores, with particular reference to Allen Ward, and if so how where they stocked, supervised and managed and by whom**

Each ward /Theatre would have medicines cabinets, as specified by regulation. These would normally contain Bulk supplies; in addition medicines Trolleys also specified by regulation are used in each ward for those drugs currently prescribed for the specific coterie of patients occupying beds. Both cupboards and Trolleys are required to be locked and the keys are under the control of the Sister/ Nurse in Charge of the ward. Additionally at the completion of each medicine round the Trolley must be locked to a wall to ensure that it is not removed from the ward. The Department of Health specifies in regulation all these requirements for the storage of Drugs in Hospitals

- (h) What records were kept, and by whom, in relation to the dispensing of drugs for prescriptions, providing copies of all such records pertaining to the Allen Ward on 21st, 22nd and 23rd October 1996**

Where such dispensing was undertaken at ward level, Nursing staff would record this on a form specifically for each individual patient and this would be retained with the patient notes. Where such dispensing was undertaken in Pharmacy the completed prescription would be recorded on the pharmacy computer and the hard copy retained for the requisite time as specified by regulation.

- (i) What system was in place for monitoring, auditing and reviewing (for accuracy or otherwise) prescription calculations and dosages**

Pharmacy had no input for such a system at ward level. All prescriptions for "take home" medicines dispensed in pharmacy were clinically checked, for appropriateness, by a registered pharmacist

- (j) The role, function, responsibilities and accountability of Paediatric Pharmacists (naming any such persons who held the role in 1996)**

There were no Paediatric pharmacists in the Royal Hospitals in 1996. The pharmacy staffing complement for the Royal Hospitals was the lowest of any tertiary care teaching hospital in the United Kingdom. Sheffield Children's Hospital, which is approximately the same size as RBHSC had I believe 7 clinical pharmacists. The staffing levels had improved greatly by my retirement but are still substantially less than equivalent sized Hospitals elsewhere in the U.K

- (k) The system in place for the reporting of any adverse incident, near misses or errors in respect of prescription calculations and dosages, providing copy of the same in respect of the RBHSC in 1996**

The only system of which I am aware would have been the national reporting system or

"Yellow Card" which clinicians are asked to complete if there is an adverse effect to a drug.

- (l) Whether the drugs Midazolam and Phenytoin were dispensed to the RBHSC/Allen ward on 21st, 22nd, 23rd October 1996 and if so to whom, and in what quantity**

I am unable to answer this as it would require access to the pharmacy computer system in RGH. This question should be addressed to the Head of Pharmacy in RVH

- (m) Whether any records were taken and kept in respect of the dispensing of the drugs Midazolam and Phenytoin to the RBHSC/ Allen ward on the 21st, 22nd and 23rd October 1996, providing copies of the same. If not, please explain why not.**

See answer to (l)

- (n) Whether it was possible that 120mg of Midazolam was dispensed to the RBHSC/Allen ward on the 21st, 22nd, 23rd October 1996 and, if so, please describe the number of boxes/ampoules this would constitute and whether the dispensing of such a large quantity would have required any particular procedure to have been followed**

See answer to (l)

- (o) If there was no dispensing of these drugs to the RBHSC/Allen ward over this period, please answer questions (k)-(m) in respect of any drug store contained within the RBHSC/Allen ward**

See answer to (l)

- (p) Please provide any and all guidance or protocols in place in 1996 governing the storage, dispensing, prescription, dosage calculation, administration and audit of drugs in the Royal and the RBHSC, and the reporting of errors/near misses in relation to the same**

The guides and protocols would have followed the document issued by the Department of Health and Social Services

"Storage Administration and Handling of Drugs"

The current edition and possibly previous editions would be available from DHSSPS

- (8) Please provide any further comments you may wish to make.**

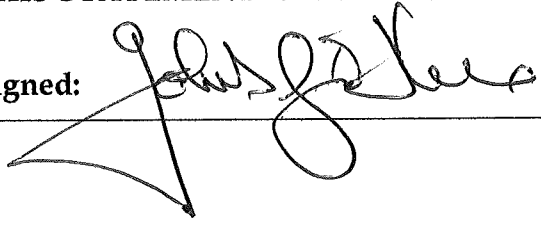
None.

- (9) Please identify any further relevant documents or materials.**

None.

THIS STATEMENT IS TRUE TO THE BEST OF MY KNOWLEDGE AND BELIEF

Signed:

A handwritten signature in black ink, appearing to read "John J. Lee". The signature is written in a cursive style with a large initial "J".

Dated:

12/11/2012

CURRICULUM VITAE

NAME: Dr J D G O'Hare

PRESENT POSITION: Former Head of Pharmacy and Medicines Management
Belfast Health and Social Care Trust (now retired)

DEGREES : B.Sc., Ph.C., M.Sc., Ph.D.,

APPOINTMENTS

1978 Co-opted member of the Eastern Health and Social Services Board Area Pharmaceutical Advisory Committee.

1979 – 1987 Appointed to the main Committee of the Central Services Agency for the Central Supply of Drugs and Dressings.

1979 – 1989 Appointed to the Advisory Panel, to the main Committee of the Central Services Agency for the Central Supply of Drugs and Dressings.

1979 – 1990 Honorary Secretary, Eastern Health and Social Services Board, Area Pharmaceutical Advisory Committee.

1981 – 1984 Sponsorship organiser and member of the Planning Committee for the United Kingdom Guild of Hospital Pharmacists Weekend School in the University of Ulster, Coleraine 1984.

1982 – 1984 Nominated by the Eastern Health and Social Services to membership of Health Education Forum for Northern Ireland.

1983 Selected by the Pharmaceutical Society of Northern Ireland as speaker on Pre-Registration Training in hospitals at the first seminar for tutors.

APPOINTMENTS (Cont'd)

- 1984** Lecturer at the Guild of Hospital Pharmacists (NI) Group meetings on the Future of Hospital Pharmacy.
- 1986 – 1994** Nominated by the Pharmaceutical Contractors Committee to membership of the Central Pharmaceutical Advisory Committee.
- 1986 – 1991** Appointed member of the Eastern Health and Social Services Board Management Development Team.
- 1986** Elected Vice-Chairman of the Guild of Hospital Pharmacists Northern Ireland Group.
- 1987 – 1988** Elected Chairman of the Guild of Hospital Pharmacist Northern Ireland Group.
- 1988 – 1989** Participant in the Associate Training Programme for General Management
- 1989** Co-opted to the Council of the Pharmaceutical Society of Northern Ireland.
- 1989 – 1995** Nominated by the Pharmaceutical Contractors Committee to membership of the National Appeals Panel of the Family Health Services Directorate of the Management Executive.
- 1989 – 1995** Nominated by the Pharmaceutical Society of Northern Ireland the membership of the Pharmacy Practice Committee of the Eastern Health and Social Services Board.
- 1989** Member of Infection Control Committee of the Royal Hospital.
- 1989** Member of the Drug and Therapeutics Committee of The Royal Hospitals.
- 1990 – 1997** Elected member of the council of the Pharmaceutical Society of Northern Ireland.
- 1993 – 1997** Appointed Chairman of Ethics and Law Committee of the Pharmaceutical Society of Northern Ireland.
- 1993 – 1997** Nominated member of the Postgraduate Pharmaceutical Education and Training Committee for Northern Ireland.

APPOINTMENTS (Cont'd)

<u>1994 – 1995</u>	Trustee nominated Governor of St Bernard's Primary School, Belfast.
<u>1994 – 1995</u>	External Assessor for AMSPAR GP Practice Management Course, Belfast Institute for Further and Higher Education.
<u>1995 -</u>	Department of Education Nominated Governor of St Bernard's Primary School, Belfast.
<u>1998 -</u>	Chairman – Northern Ireland Computer Users Sub-Group.
<u>1997 -</u>	Member of the UK Paediatric Chief Pharmacists Group.
<u>1989 -</u>	Member of the Association of Teaching Hospital Chief Pharmacists.
<u>2000 -</u>	Member of the Regional Group on the Prescribing of Specialist Drugs for Northern Ireland.
<u>2000 -</u>	Member of the Prescribing Task Group of the North and West Locality Consortium Total Purchasing Pilot.
<u>2006 -</u>	Member of the Regional Group on Therapeutic Tendering.
<u>2006 -</u>	Chair of the Regional Group on the prescribing of Specialist Drugs for Northern Ireland.
<u>2008-</u>	Head of Pharmacy and Medicines Management Belfast Health and Social Care Trust