CURRENT POSITION

Contents

Introduction

8.1 In order to discover whether the many deficiencies uncovered by this Inquiry have been addressed, and to understand what the relevant statutory bodies have done and could still do to improve matters, I decided upon a different approach for inquiry. I convened forum sessions for opinion and discussion, with representatives from the Department of Health ('the Department'), the Belfast Health & Social Care Trust ('BHSCT'), the Health and Social Care Board ('HSCB'), the Public Health Agency ('PHA'), the Patient and Client Council ('PCC'), Action against Medical Accidents[1] ('AvMA') and others. Exchanges of opinion were encouraged from the evidence received, the agenda for discussion and questions arising. Participants were immune from criticism. Statutory bodies and others were asked for up-to-date position papers to detail current systems and problems. In particular, submissions were invited in respect of my more significant concerns, including the reporting and investigation of Serious Adverse Incidents ('SAI's'), the involvement of families, the handling of complaints and the introduction of a legally enforceable duty of candour. The responses and position papers received were shared with interested parties and are to be found on the Inquiry website.

8.2 Formulation of relevant recommendations is dependent upon an understanding of systems as they are today, notwithstanding that some problems appear constant. The Inquiry sought relevant up-to-date information and has attempted to note the changes occurring in the years since the deaths examined. Given the pace of procedural reform in the years since, this has been no easy task. For this reason this chapter of the Report is not to be understood as intending a comprehensive and up-to-the-minute account of the current position.

8.3 In Chapter 9 of this Report I set out my recommendations to strengthen and improve both practice and system. Although much has been achieved, much remains to be done. I recognise the obvious difficulties inherent in

[1] A UK charity offering independent advice and support to people affected by medical accidents.

translating recommendation into effective change and have come to believe that the best prospect for continued improvement rests with the focused involvement of families and a Health Service leadership which is zealous about learning from error.

8.4 Even brief analysis of this Report will reveal the recurrent themes so clearly marking the cases examined. I believe that the issues of competency in fluid management, honesty in reporting, professionalism in investigation, focus in leadership and respect for parental involvement to be the most obvious raised. They are also the most important because they are individually and collectively critical to learning from error.

8.5 Ultimate accountability for learning from error in the healthcare service rests with the Department and the Minister. The Department must ensure that, having issued standards, the policies of the 'arms-length' HSC organisations are compliant and quality assured. The key question is, as posed by Permanent Secretary Dr Andrew McCormick, "*How can we know if arms-length bodies are actually fulfilling the guidance and directions issued by the Department?*"[2] With so large and complex a system, quality assurance must come from active oversight, audit and review.

8.6 It is in this context that I have considered, in so far as I have been able, the steps taken by the Department and other statutory bodies to minimise the likelihood of recurrence. By drawing on the evidence received, weaknesses can be identified and recommendations made to further protect the patient interest. In this respect the evidence received and the frank views expressed during panel session discussions have been of real assistance.

Progress in hyponatraemia practice and guidance

8.7 In April 2007 the Department circulated 'Safety Alert 22' from the National Patient Safety Agency ('NPSA') about the risk of hyponatraemia to children receiving IV infusions.[3] The removal of Solution No. 18 from general use

[2] Dr Andrew McCormick T-15-11-13 p.10 line 21
[3] 330-167-001

was directed and warning posters placed in all paediatric units.[4] Trusts were instructed to develop local protocol[5] and audit their own compliance.[6] Alert 22 guidance was then issued by the Department in September 2007 as 'Parenteral Fluid Therapy (1 month – 16 years): Initial Management guideline'.[7] The BHSCT was able to confirm that Solution No 18 had been removed from all general areas where children were treated.[8]

8.8 The Regulation & Quality Improvement Authority ('RQIA') reviewed compliance with 'Safety Alert 22' in June 2008[9] and found it wanting. It reviewed and reported again in May 2010 on the 'Implementation of recommended actions outlined within NPSA Alert 22 throughout HSC Trusts and independent hospitals in Northern Ireland'[10] and concluded that compliance with Alert 22 had, by then, been substantially achieved and that there was good operational control of IV fluid administration to children. It concluded that clinicians were aware of the Guidelines and that nursing staff had received training in paediatric fluid administration. Notwithstanding, it made recommendations to consolidate progress. The Guidelines were amended in 2010[11] and the Department requested the Northern Ireland Medical & Dental Training Agency ('NIMDTA') provide the relevant training for medical undergraduates and junior doctors.[12]

8.9 There were also Guideline and Implementation Network ('GAIN')[13] audits in 2012[14] and 2014 measuring adherence with the IV fluid guidance developed from Alert 22.[15] The 2012 report found that the IV fluids in use were compliant with recommendations even if some further improvement

4 303-026-350
5 330-135-002
6 330-167-002
7 303-059-817
8 330-134-001
9 303-058-776
10 303-031-415
11 303-060-818 - Guidance on Parenteral Fluid Therapy for Children & Young Persons (Aged over 4 weeks and under 16 years)
12 330-152-003
13 GAIN was established as a partnership body of the Department in 2007.It works closely with the Department's Standards and Guidelines Quality Unit. It receives programme funding to conduct regional audits and where necessary produce local guidelines for the HSC.
14 333-165-001
15 303-060-818

was required to achieve 100% overall compliance. Progress was maintained in 2013 with a revised 'Regional Fluid Balance and Prescription Chart for Children and Adults' and the wall chart for 'Parenteral Fluid Therapy for Children and Adults (aged over 4 weeks and under 16 years)' was updated in September 2014.

8.10 GAIN conducted a follow-up audit in 2014 "*to examine whether the administration of IV Fluids to children and young people (aged over 4 weeks and under 16 years) is safe and meets quality standards.*"[16] Overall compliance was again found to have improved but adherence was not yet 100%. Nonetheless and importantly it found "*that the prescription of fluid type, particularly to those deemed to be at particular risk of developing hyponatraemia was always found to be appropriate…*"[17] and that "*young people being cared for in an adult ward appear to have received the same standard of care as children being cared for in paediatric wards.*"[18]

8.11 However, the report did make some recommendations concerning regularity of assessment and the proper completion of documentation. The HSCB/PHA then published further guidelines for use with the chart in 2015 and BHSCT issued its own 'Policy for recording fluid prescriptions and balance charts.'[19]

8.12 GAIN recommended additional hospital auditing of IV fluid management in children. To that end a Paediatric IV Fluid Audit Improvement Tool ('PIVFAIT') has now been devised and introduced to all HSC Trusts to provide local assurance in relation to the administration of IV fluids to children and young people.[20]

8.13 National Institute for Health and Care Excellence ('NICE') has since published 'Clinical Guideline NG 29'[21] for 'Intravenous fluid therapy for children and young people in hospital' which received the endorsement of

16 403-011-009
17 403-011-003
18 403-011-006
19 401-001an-001
20 401-001ao-001 & 404-001i-011
21 404-001e-001

the Department in September 2017.[22] The regional Fluid Balance and Prescription Chart for children and young people has now been revised in line with NG 29[23] and amended wall charts detailing parenteral fluid therapy for those aged over 4 weeks and under 16 years have been circulated for display in all areas where such patients are treated. Trusts have been requested to disseminate these charts and, given their regional importance, have been required to formally advise the Department as to anticipated dates of implementation and assure HSCB/PHA as to implementation. BHSCT intermittently updates its 'Policy for Recording Fluid Prescription and Balance Charts.' It is due for further review in 2018.

8.14 The Chief Medical Officer ('CMO') has requested the RQIA undertake 'a snapshot review/audit' of paediatric IV fluid practice. Such a review will examine the implementation of NG 29 together with the effectiveness of the wall-charts, Fluid Balance & Prescription Charts ('FB&PC's') and PIVFAIT. RQIA has indicated that the review "*will take place in spring 2018*".[24]

8.15 This may be timely because, in November 2017 the RQIA published an 'Unannounced Hospital Inspection Report - Royal Belfast Hospital for Sick Children – 3-5 May 2017'.[25] Whilst generally reassuring it did identify some ongoing deficiencies. It specifically recommended that "*assurance audits should be carried out to ensure fluid balance charts are appropriately completed in line with best practice.*"[26] It also noted a lack of clear nursing leadership.[27]

8.16 It is clear that very considerable professional attention has been devoted to protecting children undergoing fluid therapy and significant progress has been made. However, there can be no room for complacency because total patient safety cannot be assured. I consider that such therapy must therefore always be subject to scrutiny, which is why I recommend that all

22 403-001-001 & 404-001k-001
23 403-001-006
24 404-002b-008
25 403-028-001
26 403-028-038
27 403-028-014

children's wards should have a senior lead nurse to provide the active leadership necessary to reinforce nursing standards and to audit and enforce compliance with guidance.

Training in fluid management and the prevention of hyponatraemia

8.17 In 2015 the HBSC/PHA assimilated all up-to-date regional IV fluid guidance and training packages into one document to ensure consistency in both competency assessment and training. The 'Competency Framework for Reducing the Risk of Hyponatraemia'[28] specifies that "*All prescribers caring for children are required to be competent in prescribing IV fluids appropriately and safely.*"[29] Competency in fluid management is reliant upon training.

8.18 Within Belfast, the current BH&SCT induction process for relevant trainee doctors requires that they provide "*evidence of completion of the BMJ Learning Module on Hyponatraemia.*" [30] The British Medical Journal ('BMJ') e-learning module 'Reducing the risk of Hyponatraemia when administering intravenous fluids to children'[31] is designed to teach "*the dangers of hypotonic fluids in children, and how to diagnose and treat acute hyponatraemic encephalopathy*" and is based on the 2015 NICE guidelines. It usefully incorporates four clinical case studies referencing the regional paediatric fluid balance chart. Whether this training is sufficiently focussed on paediatric fluid prescribing has recently been questioned by foundation doctors at RBHSC.[32] The RQIA has recommended that BHSCT review and improve the induction programme to ensure training is appropriate.[33]

8.19 Importantly present learning is available to all medical staff in Northern Ireland, just as most of the required training material is now available on-line. In terms of continuing professional education, the Competency Framework requires that "*all staff… should revisit the module, once every*

28 403-006-001 (reviewed September 2017)
29 403-006-006
30 http://www.belfasttrust.hscni.net/about/Inductionfortraineedoctors.htm - Point 3
31 http://learning.bmj.com/learning/module-intro/hyponatraemia.html?moduleId=5003260
32 403-028-019
33 403-028-020

three years as a minimum. Evidence of completion should be submitted… during annual appraisal."[34] Relevant training presentations are also posted on the BHSCT intranet, including 'How to prescribe IV medicine infusions on a medicines kardex and/or daily fluid balance and prescription sheet'.

8.20 It is recognised that these programmes are for doctors in Northern Ireland as opposed to those clinicians who have trained outside the UK (as was the case with some doctors treating Raychel at Altnagelvin and both Raychel and Lucy at the Royal Belfast Hospital for Sick Children ('RBHSC'). The General Medical Council ('GMC') has sought to address this issue and continues to scrutinise the content and quality of induction and continuous professional development programmes.

8.21 With regard to the training of nurses in fluid management, Professor Hanratty found that the RQIA reviews brought focus to both training and practice. She noted a "*flurry of activity to include training and policy development…evident from the number of new documents and training materials during 2008/09.The universities have included sessions in pre-registration programmes. In-service training records demonstrate that nurse managers are requesting training sessions on the topic. Discussions with nurse managers indicate that there have been shared learning sessions on both hyponatraemia and record keeping attended by junior doctors and nurses.*"[35]

8.22 Professor Charlotte McArdle, the Chief Nursing Officer ('CNO'), stressed that training is now within the undergraduate programme and that the Northern Ireland Practice & Education Council for Nursing & Midwifery ('NIPEC') is conducting a quality assurance review of the paediatric fluid management training course. Within the Trusts, and as early as 2010, the Southern Health & Social Care Trust ('SHSCT') developed a nursing

[34] 403-006-005
[35] 308-004-086

Competency Framework 'For the Prescription, Administration, Monitoring and Review of IV Fluids for Children and Young People.'[36]

8.23 There is additional ongoing education by way of induction programmes, shared learning and continuing professional development. BHSCT has introduced both an e-learning module and specific 'awareness' training for all RBHSC nursing staff, with a 'Hyponatraemia – How to complete a Paediatric Fluid Balance Chart'[37] module. It can be accessed on the BHSCT intranet. I would recommend that all Health & Social Care ('HSC') Trusts ensure that relevant nursing staff access such e-learning.

8.24 A repository of HSC resources relating to hyponatraemia has been made available on the PHA website at www.publichealth.hscni.net/directorate-nursing-and-allied-health-professions/nursing/central-repository-hsc-resources-relating.[38] This webpage brings together both regional and national guidance relating to hyponatraemia, including links to NPSA Patient Safety Alert 22, BMJ e-Learning module, competency framework, regional wall chart, FB&PC and associated training, RQIA reports, GAIN audit reports, NG29 and advice on how to prescribe IV medicines.

Some progress in matters of clinical relevance

8.25 Just as poor record keeping emerged as a recurrent theme in the cases examined by this Inquiry, so too was it identified as an issue in 5 out of 11 public healthcare Inquiries during the period 2003-08.[39] It was therefore very important that the CNO should have launched a 'Recording Care Project' ('the Project') to raise the standard of nursing records. The project has been extended to encompass all acute paediatric wards in Northern Ireland. Through a process of audit, benchmarking and professional review[40] the Project has successfully demonstrated improvement in specific areas of practice. In conjunction, NIPEC has actively supported

36 330-016-004
37 401-001an-003
38 401-002i-001
39 330-022-025
40 330-018-001

improvement and developed tools for audit. The Department has promoted benchmarking through its 'Essence of Care' programme. The Nursing and Midwifery Council ('NMC') issued updated and detailed guidance on 'Record Keeping' in 2010[41] and the BHSCT has since published 'Good Record Keeping – a Simple Guide' with Guideline posters.[42]

8.26 Also of relevance is the recent development by the HSC Safety Forum (Paediatric Collaborative) of a standardised Physiological Early Warning Scores System ('PEWS') to assist in the early identification of deterioration in the child patient and to encourage the timely escalation of concern. A regional protocol has been agreed for its use.[43] The same collaborative has also worked with parent representatives to design a safety poster 'You Know Your Child Best' to encourage greater parental collaboration in care. In 2014 a small multi-disciplinary group within RBHSC instituted the practice of daily PICU Safety Briefings. This innovation has proved useful and the practice has now been adopted within other clinical areas of RBHSC including Allen Ward.

8.27 Notwithstanding, the RQIA unannounced inspection of RBHSC in 2017 found "*…completion of paediatric early warning scores was not always present. Robust systems to assure that best practice is followed are not in place and …limited documented evidence of communication with parents…*"[44] Whilst improvement has been achieved, shortcomings in documentation and communication persist. Rigorous audit must become routine.

8.28 In developing its 'Strategy for Paediatric Healthcare Services (2016-2026)' the Department specifically recognised some important interdependencies between paediatric services and other healthcare services, for example access to laboratory and diagnostic services, anaesthetic services and intensive care.[45] Focus on interaction is important for patient safety and

41 330-020-053
42 401-001an-001
43 401-001s-001
44 403-028-014
45 403-020-013

the identification of systemic weakness. It is encouraging that it should inform strategy.

8.29 Importantly, the Department Strategy has also made it a Key Strategic Objective that "*every child who is admitted to a paediatric department should be seen by a paediatric practitioner at ST4*[46] *or equivalent (including advanced children's nurse practitioner)*[47] *within four hours of admission and by a consultant within 24 hours of admission*"[48] It is Departmental intention that this very important objective be kept under review. I consider it should also be subject to routine audit.

Age appropriate care

8.30 In 2012 RQIA carried out a Baseline Assessment of the Care of Children under 18 Admitted to Adult Wards in Northern Ireland[49] and found that in 2009-2010, 3,933 children aged under 18 were cared for on adult wards. Whilst these patients were mostly adolescents and could, on occasion, be justifiably cared for in an adult setting, the figures are nonetheless disquieting given what was disclosed by Conor Mitchell's case. The RQIA Report noted inconsistent age limits for admission onto paediatric wards and recommended regional agreement in this regard.

8.31 In 2012 HSCB issued guidelines on 'Delivering Age Appropriate Care'[50] to ensure that children up to their sixteenth birthday would almost always "*be cared for in a paediatric environment.*"[51] All HSC Trusts must satisfy the HSCB Director of Commissioning as to compliance with this important patient care requirement.[52] However, difficulties have been experienced with physical infrastructure, staffing levels and the lack of available beds.[53] Some Trusts have indicated that they are '*working on it*'[54] and the RQIA has

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46 Assessment by ST4 or equivalent within 4 hours of admission means that in practical terms there should be a St4 practitioner or higher, resident in the hospital.
47 Advanced nurse practitioner, staff grade or associate specialist doctor or doctor in training at ST4 or higher.
48 403-020-041
49 260-003g-001
50 401-001i-001
51 401-001i-001
52 401-001a-018
53 403-028-028
54 401-001a-018

suggested that BHSCT "*work with key stakeholders to address these issues*".[55]

8.32 There remains inconsistency between HSC Trusts as to the age limit for paediatric admission to hospital. The RBHSC admits children up to 13 years on to the paediatric medical/surgical wards and up to 14 years from the emergency department. Most other regional hospital paediatric units in Northern Ireland admit up to the 16th birthday. Recognising that some clinical conditions necessitate flexibility, the Department has now made it a key strategic objective within the Paediatric Strategy that "*Children (from birth up to 16th birthday) should usually be cared for by the paediatric team in paediatric settings, and those aged 16-17 years should be managed in age-appropriate settings within either paediatric or adult settings. In all cases, children and young people should have treatment and care delivered to them in an age-appropriate environment*"[56]

8.33 The HSCB Commissioning plan for 2016-2017[57] requires that HSC Trusts make effective arrangements to ensure that children and young people receive age-appropriate care and that the regional upper age limit for paediatric services of 16th birthday is implemented. Trusts are required to demonstrate how the upper age limit of 16th birthday is actually operated in practice and those arrangements in place to ensure that children admitted to hospital up to their 16th birthday are cared for in an age-appropriate environment, by staff with paediatric expertise and with input from paediatricians where necessary.[58] The new Children's Hospital to be built in Belfast is planned to provide care for children up to the age of 18 years.[59]

8.34 This is an important patient safety issue and clearly not one that has been forgotten. HSCB and PHA have established forums with both professional and managerial representation to discuss just such issues arising in paediatric service provision. HSCB and HSC Trusts must continue to

55 401-028-029
56 403-020-036
57 403-021-001
58 403-021-053
59 403-020-014

pursue solutions. I recommend that HSC Trusts should publish their policy and arrangements for ensuring that children admitted to hospital are cared for in age-appropriate settings and the RQIA should review progress on implementation of the regional guidelines.

Importation of external guidance

8.35 Given the relative size of Northern Ireland it is important that it learns from the experience of other healthcare systems. To that end, the Department has maintained contact with the former NPSA and has arranged with the Health Care Quality Improvement Partnership to share in the Confidential Inquiries programme. In 2006 the Department introduced procedure to review and endorse healthcare guidance and patient safety alerts from NICE and NPSA.

8.36 External guidelines and NCEPOD Reports are received by the Department for consideration and the Department directs HSC Trusts to implement recommendations as appropriate and within stated periods. Confirmation of implementation is almost always required. In 2007, the CMO instituted the HSC Safety Forum to assist Trusts in the implementation of patient safety recommendations. It is for the HSCB to assess the implementation and provide assurance to the Department that the HSC Trusts have acted as required.[60]

8.37 The Department created the Guideline and Audit Implementation Network ('GAIN') in 2007 by amalgamating CREST, the Regional Multi-Professional Audit Group and the Northern Ireland Regional Audit Advisory Committee. GAIN has an important scrutiny and quality improvement role through auditing. It promotes good practice by publishing the results and facilitating the implementation of regional guidelines. It also promotes operational standards not yet covered by NICE. Importantly, GAIN also trains HSC staff in clinical audit and systematic review.

[60] 401-002w-012

8.38 BHSCT also has a Standards and Guidelines Committee to ensure the timely implementation and monitoring of external guidance.[61] It was this committee that responded to NPSA advices by issuing policy on 'the administration of IV fluids to children aged from one month until the 16th birthday'.[62] The BHSCT has also formed a Therapeutic Review Steering Group to audit compliance with NICE.[63] These systems ought to allow the BHSC Trust Board assurance that external guidelines are both implemented and monitored.

8.39 The Department identified external evidence of good practice as a "*key driver for change in paediatric healthcare service provision*"[64] in its 'Strategy for Paediatric Healthcare Services Provided in Hospitals and in the Community (2016-2026)'[65] In November 2011 the Department announced the development of a ten-year strategy 'Quality 2020' to raise standards, measure improvement and transform culture. Coincidently, much work has also recently been completed in England relevant to the 'Quality 2020' project which will prove of considerable assistance.[66]

8.40 In October 2016 the Department launched a ten year 'transformation' programme 'Health and Wellbeing 2026: Delivering Together' which encompasses the concept of a Regional Improvement Institute.[67] A 12 month progress report on this initiative was published in October 2017.[68]

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61 332-039-001
62 This was written by Drs Crean and Steen.
63 332-025-007
64 403-020-014
65 403-020-001
66 Care Quality Commission Briefing: Learning from serious incidents in NHS acute hospitals, June 2016; Care Quality Commission Review: Learning, candour and accountability, December 2016 PHSO Review: Quality of NHS complaints investigations: Government response to the Committee's First Report of Session 2016-2017; House of Commons Public Administration and Constitutional Affairs Committee: Will the NHS never learn? Follow-up to PHSO report 'Learning from Mistakes' on the NHS in England, 31 January 2017; National Quality Board: National Guidance on Learning from Deaths, first edition March 2017.
67 404-002b-002
68 403-025-001

Serious Adverse Incidents

8.41 Consideration of the reporting and investigation of Serious Adverse Incidents ('SAIs') has been central to the work of this Inquiry.

8.42 The Department issued the first regional guidance for SAI management in 2004. This was consolidated by 'Reporting and Follow-up on Serious Adverse Incidents' in March 2006.[69] Further advices followed on 'How to Classify Adverse Incidents and Risk'[70] and additional procedure was then introduced to promote learning from SAIs[71] and guidance with templates for incident investigation reports was published in September 2007.[72] Individual trusts then introduced their own protocols.[73]

8.43 Overall, Departmental strategy was set out in 'Safety First: A framework for sustainable Improvement in the HPSS' (2006)[74] which emphasised the objective of an open and fair culture within HPSS. The promotion of adverse incident reporting together with improved investigation and sharing of learning were accorded particular importance in this context.

8.44 In 2013 the Department published 'Investigating Patient or Client Safety Incidents' outlining the Memorandum of Understanding entered into with the Coroners Service and the Health and Safety Executive for Northern Ireland in relation to liaison arrangements for joint or simultaneous SAI investigations.[75]

8.45 Responsibility for the management and follow-up of SAIs was transferred in 2010 from the Department to HSCB and PHA working collaboratively with RQIA. The HSCB/PHA became responsible for monitoring Trust responses to adverse incidents and providing assurance to the Department on the application of procedure. Importantly, it became responsible for ensuring that Trusts were implementing recommendations from SAI reviews. The

69 330-061-001
70 330-062-001
71 330-063-001
72 330-133-065
73 330-133-042
74 333-117-001
75 403-013-001

HSCB published an 'Assurance Framework' to formally articulate the quality assurance available to Trust Boards.

8.46 A regional system for the reporting of all SAIs to the HSCB was established and a 'Procedure for the Reporting and Follow-Up of SAIs' was issued by HSCB to all Trusts in 2010. It was reviewed and revised in 2013[76] and again in November 2016.[77] It remains under 'continuous review.' The Procedure outlines a process which, if followed, would answer many of the concerns raised by the findings of this Inquiry.

8.47 The Procedure and guidance are informed by the NPSA 'Being Open Framework' (2009) and the Health Service Executive 'Open Disclosure National Guidelines' (2013) and are expressly based on the principles of openness, responsibility to share learning and necessity to continually review both reporting and investigation. In order to provide regional consistency it provides clear procedures for reporting, reviewing and the implementation of learning. It sets out necessary definitions, roles and responsibilities. There are model SAI notification forms and forms for use in both 'interface' incidents[78] and 'never events'.[79] Criteria are given for proportionality in investigation and provision is made for the involvement of families and 'lay people'. There is guidance on post-incident debriefing, independence in investigation, root cause analysis, significant event audit, Datix coding forms, joint investigations and timescales. The form and content of an Incident Review Report and Action Plan are set out. Guidelines and checklists for engagement with families are appended. Completion of these checklists is mandatory. Advice is given on meeting a family after a death and examples of open communication are helpfully appended. The Guide for HSC Staff on 'Engagement/Communication with the Service User/Family/Carers following a serious adverse Incident' is attached and updated to November 2016.[80] Guidelines to ensure best

76 401-001au-001
77 403-003-001
78 An incident which has occurred in one hospital but which is identified in another.
79 https://www.health-ni.gov.uk/sites/default/files/publications/health/HSC-SQSD-56-16.pdf
80 403-003-075 - Developed by HSCB, PHA, PCC and RQIA

practice are given and truthfulness, timeliness and clarity are emphasised. Assistance for families is suggested and details are given of the help available from the PCC. An information leaflet designed to advise families about the SAI process is now available.[81]

8.48 The Procedure introduced the role of the HSCB 'Designated Review Officer' ('DRO') to oversee Trust SAI procedures, scrutinise findings and identify regional learning.[82] The DRO, in the case of a child death where fluid mismanagement or nursing failure is suspected, would be a Consultant in Public Health who would work with a Nurse Consultant and a Pharmacist.[83] A new practice protocol for DROs was issued in April 2017.[84]

8.49 The terms of reference for an investigation, timescales for reporting, extent of family involvement and identity of those investigating must all be agreed with the DRO. The DRO will then consider the SAI report and, if content with both investigation and recommendations, will formally conclude the SAI process. The DRO consults other relevant organisations including RQIA to ensure that reasonable action has been taken to reduce the risk of recurrence and that learning of broader implication has been disseminated. Thereafter further action is to be monitored by the Trust itself.

8.50 Workshops were organised to discuss implementation of the new SAI process attended by governance leads from HSCB/PHA, the six HSC Trusts and the Department.[85] HSCB also organise SAI follow-up exercises with checklists for systematic monitoring.

8.51 HSCB/PHA seeks to maintain focus on the central problem of learning from SAIs with a weekly HSCB Senior Management Team review of Trust SAI reports and healthcare related Coroner's reports. Regular and formal liaison is maintained with other relevant organisations including RQIA, NIMDTA and NIPEC. 'Learning Reports' on SAIs are published bi-

81 401-001aa-001
82 331-009-001
83 331-013-002
84 http://insight.hscb.hscni.net/information-for-designated-review-officers-dros/
85 404-001j-007

annually.[86] The most senior level of management is involved so as to provide assurance. In an attempt to enhance learning from less serious incidents, a project within the 'Quality 2020' programme is examining different methods of sharing the analysis of investigation.[87]

8.52 The Regional SAI Review Group considers individual SAI investigations and decides if further action is necessary. Specific advice can be given Trusts by way of a 'Learning Letter'. Notwithstanding "*judicious use*" of learning letters, the Review Group still "*issues around one learning letter a month.*"[88] Thereafter it requires appropriate assurance that the trust has acted as required.[89]

8.53 SAIs, complaints and the reports of the regional SAI review group are considered by the HSCB/PHA Quality Safety and Experience Group which seeks to identify broader regional concerns. Although RQIA does not receive acute hospital SAI reports it does provide two members of the HSCB Regional Adverse Incident Steering Group which also reviews a selection of investigation reports to assure appropriate scrutiny of themes, trends, practice and learning. Thereafter, the Safety Quality and Alerts Team ('SQUAT') implements and quality assures the Alerts, Guidance and Learning Letters arising from SAIs.

8.54 HSCB/PHA have developed a newsletter, in addition to other channels of regional communication, to disseminate SAI learning to all levels of healthcare staff. 'Learning Matters' is accessible on line.[90] Learning is also shared through SAI regional training events, Trust SAI workshops, Regional Governance Leads workshops, good practice letters and the implementation of specific recommendations. HSCB also publishes standardised hospital mortality rates benchmarked against rates in

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86 401-001n-001 & 404-001j-001
87 404-002b-001 – 'Testing methods to learn from adverse incidents.'
88 Dr Carolyn Harper T-14-11-13 p.42 line 24
89 Dr Carolyn Harper T-14-11-13 p.45 line 5
90 The 5th edition of Learning Matters, April 2016 covered, amongst other topics, the Prescription of IV Fluids. http://www.publichealth.hscni.net/sites/default/files/Learning_Matters_Issue_5.pdf page 4

England. These would appear to indicate that death rates in Northern Ireland are comparable to or lower than those in England.

8.55 Whilst many of the deficiencies and vulnerabilities exposed in the course of this Inquiry have thus seemingly been addressed by changes in guidance, practice and procedure, it must nonetheless be observed, that the ultimate effectiveness of the learning derived from SAIs remains largely unknown.

HSC Trust SAI process

8.56 HSC Trusts have now developed individual protocols to guide reporting, review and learning from adverse incidents. All were found to be comparatively up-to-date when listed in the Regional Learning System Project Report in May 2015.[91] Nonetheless there was clear disparity as and between the HSCT Trusts in relation to the breadth and depth of policy and guidance. Development of procedures for more uniform adoption across HSC Trusts was therefore recommended in the interests of regional consistency.[92] The Department advised in November 2017 that "*work is ongoing to develop and agree regional adverse incident guidelines and procedures for adoption across the HSC.*"[93] I consider this to be work of great importance.

8.57 It is to be noted that BHSCT procedures are both comprehensive and subject to oversight. The Trust approved its 'Serious Adverse Incident Procedure' in 2016.[94] Within the RBHSC every child death is to be assessed and in each instance of unexpected death, a SAI investigation is initiated and the families advised. The Trust in such circumstances will meet with the Medical Officer from the Coroner's Office to examine the potential for shared learning and all such deaths are discussed at the monthly Morbidity and Mortality meeting. The Procedure provides for family input and feedback with opportunity given to discuss concerns and make contact with a bereavement co-ordinator. The BHSCT Coroner Liaison

91 401-002w-026
92 401-002w-009
93 404-002b-002
94 401-001ab-001

Office collaborates with the Bereavement Co-ordinator to support families involved with inquests.

8.58 BHSCT has also set out a 'Board Assurance Framework'[95] incorporating SAI procedures, complaints, patient experience and the processes for the identification and dissemination of learning. It is encouraging that the Assurance framework specifically references "*the three landmark reports in 2013 on quality and safety in the NHS (Francis Report, Keogh Review and the Berwick Report) all recommended the development of an organisational culture which prioritises patients and quality care above all else…*"[96]

8.59 The RBHSC has an Assurance Sub-Committee and a Governance Group reviewing SAIs, complaints, audit, quality improvement and policy. In addition BHSCT has established specific responsibility groups to consider, supervise and provide assurance. These include the SAI Group, Claims Review Group, Complaints Review Group, Outcomes Review Group, Standards and Guidelines Committee, Safety and Quality Steering Group, Safety Improvement Team, Strategic Group for Quality, Improvement and Development, Deteriorating Patient Group, External Reports Review Group, Patient and Public Involvement Group, Quality Improvement Strategy Group, Learning from Experience Steering Group, Patient and Client Experience Working Group and the Bereavement Fora.

8.60 The Department has instituted an 'Early Alert System' whereby Trusts can notify the Department directly of incidents for immediate attention. The Permanent Secretary said "*that happens quite regularly…that's normal practice now.*"[97]

8.61 Importantly, I have now been assured that all deaths in the RBHSC are "*reviewed irrespective of whether there have been any concerns about the quality of care*"[98] Whilst ostensibly reassuring, it must be observed that the same was misleadingly claimed in relation to RBHSC at the time of the

95 401-001aw-001 (2016-17)
96 401-001aw-011
97 Dr Andrew McCormick T-15-11-13 p.16 line 2
98 Mr Colm Donaghy T-12-11-13 p.9 line 9

deaths of Adam, Claire and Lucy. Their deaths were not reviewed. Notwithstanding that review meetings are now minuted, they are not recorded.[99] Given the value of accurately recording clinical response to patient death and given the very modest cost, I would recommend that all such reviews be digitally recorded.

Adverse incident database

8.62 Each Trust maintains its own adverse incident database using DATIX risk management software to record and manage relevant information about incidents, claims, complaints, risks, alerts, inquests and requests. However, it was reported that even though the same software is used, different Datix adverse incident classification codes are employed by different HSC Trusts.[100] The resultant inconsistency in classification[101] means that the system cannot constitute a conventional database or permit easy regional analysis.

8.63 The Department chairs a Regional Information Group which exercises oversight of data standards and has an ICT Implementation Plan.[102] It has recognised that "*much remains to be done in order to have a truly connected and e-enabled service.*"[103] Presumably to that end and in response to the May 2015 recommendations of the 'Regional Learning System Project Report',[104] it has recently carried out a 'scoping exercise' to "*review and agree datasets, including classifications within services and then regionally to ensure consistency of reporting.*"[105]

8.64 If it has not already done so, it should act with despatch to fully merge data and intelligence so as to permit scrutiny of overall performance and the identification of emerging patient safety issues. HSC organisations should synchronize electronic patient safety incident and risk management

99 Mr Colm Donaghy T-12-11-13 p.69 line 7
100 401-001a-022
101 323-037f-001
102 403-020-052
103 403-020-052
104 401-002w-044
105 404-002b-002

software systems, codes and classifications to enable plain oversight of regional patient safety information.

Familiar problems

8.65 Notwithstanding that SAI reporting is mandatory, it would be unwise not to assume that there is still under-reporting. There are a number of obvious explanations for non-reporting, including failure to recognise the SAI, poor understanding of how and what to report and time pressures. However, individuals fear blame and the system is not proof against avoidance and manipulation. The SAI Procedure presents a number of critical decision making points open to 'subjective interpretation' and the exercise of 'discretion'. These include whether to report, who should investigate, what the investigation should pursue, the appropriate level of investigation and whether the level of investigation should be raised in response to evidence.

8.66 Notwithstanding considerable efforts to change hospital culture, familiar problems persist. For example the RQIA review of 2008 found "*little evidence of a reporting culture for incidents relating to intravenous fluids and hyponatraemia.*"[106] The HSC Staff Survey of 2012 reported that "*only 42% of staff agree that their organisation does not blame or punish people involved in errors, near misses or incidents*."[107] The PAC reported that "*Whistle blowers still face real problems in speaking out … a 'culture of fear' still exists in many parts of the HSC sector*"[108] The NIAO reported in 2014 that "*given the experience of the Turnaround Team in the Northern Trust and the RQIA inspection findings in the Belfast Trust, the culture within HSC bodies is still one of concern.*"[109] The Regional Learning System Project Report of May 2015[110] noted staff reporting "*that they would be concerned that there would be a risk to their professional reputation or registration as a result of reporting and that they might be blamed.*" Indeed clinicians

106 303-030-382
107 403-016-064
108 403-018-006
109 403-016-067
110 401-002w-001

themselves acknowledged in 2015 that "*When dealing with SAIs there is a culture of blame which needs to be changed.*"[111]

8.67 In April 2014 the Minister, responding to criticism of the Health Service, instructed HSC Trusts to review their handling of all SAIs reported between 2009 and 2013. As a part of this 'look-back exercise' the Minister requested that the RQIA scrutinise each of those reviews. It did so and reported in December 2014.[112]

8.68 In general terms, its review was rigorous and its findings encouraging. However during the exercise, Trusts uncovered cases which should have been classified and reported as SAIs but which were not. Included was one death which required retrospective notification to the Coroner.[113] Amongst other specific issues identified and relating to SAI management was difficulty experienced in obtaining independent expertise for the more complex investigations and staff who wished "*to examine potential legal issues with their advisors before becoming involved in an investigation.*"[114] The RQIA report was provided to Sir Liam Donaldson to inform his subsequent review of HSC governance arrangements.

8.69 Current guidance indicates that an SAI investigation will take up to twelve weeks depending on the seriousness and complexity of the case. More significant cases reviewed by root cause analysis may take longer with the agreement of the DRO. HSCB advise that "*in most instances SAI reports will have been finalised by the time the Coroner investigation is underway. However, the timing of SAI reviews and Coroner investigations may mean that it is a draft SAI report that is available to the Coroner. Any future review of the SAI procedure will continue to emphasise timeframes.*" [115]

8.70 It is reassuring that there will continue to be an emphasis on timeframes because when investigative journalists[116] filed a Freedom of Information

111 403-017-013
112 401-003b-001
113 401-003e-044
114 401-003e-039
115 404-001a-004
116 http://www.thedetail.tv/articles/healthcare-investigations-face-serious-delays

request of HSC Trusts as to the "*longest time periods taken to complete SAIs within their catchment areas?*" responses indicated that some SAI reviews by BH&SCT took up to 3 years to complete. Whilst the quality of investigation remains the paramount objective, timeliness is important for both learning and public confidence. The Department is aware that there is scope for improvement and has asked GAIN to advise on the basis of an "*examination of good practice on SAIs (or SIs) elsewhere in the UK and internationally.*" Notwithstanding, it remains most probable that improved resources and training could improve the efficiency of investigation.

8.71 In order to obtain assurance that current SAI procedures are working, continuous audit and review is required of reporting, investigation, analysis and response. In order to measure the engagement of Trust Boards, the involvement of families and the effectiveness of remedial action, it will be necessary to monitor practice. Since late 2015 RQIA has conducted unannounced inspections of acute hospitals in order to assess the quality of services. The report of its 2017 inspection of RBHSC gives valuable insight. Such inspections are an important development and because I believe that there should be additional and increased external monitoring of the entire SAI process, I would propose that the scope and remit of the RQIA be extended to encompass this important work.

Adverse incident investigation

8.72 The work of this Inquiry has shown that vulnerabilities in patient care systems are more likely to be the cause of a SAI than individual error. For that reason, I consider that improvement in investigation would be meaningfully assisted by further and advanced training in Root Cause Analysis. This would intensify the search for the underlying and interconnected causes of adverse incidents rather than fuelling fears of individual blame.

8.73 Investigation is sensitive to human input and the oversight provided by individual DROs may not always be consistent. Accordingly the independence of investigators is essential to achieve satisfactory

investigation and ensure that it is seen as such. I consider that the most serious AIs should therefore be investigated by wholly independent teams from outside Northern Ireland because, as Dr Carson on behalf of RQIA observed, "*Northern Ireland is quite a small community, everybody has worked with everybody else at some stage or another..*"[117] Mr Peter Walsh, Chief Executive of AvMA, thought that would add a "*tremendous amount to the process*"[118] so that there could be "*no perception of, let alone real, conflict of interest.*"[119] I agree and believe that it would engender public confidence in the findings. An investigation team, independent of individuals, Trusts, the HSCB and the Department, would be able to investigate all parts of the Northern Ireland healthcare system without any taint of conflict of interest. Such an approach might be pursued with the newly established Healthcare Safety Investigation Branch from England. Collaboration could prove instructive for all concerned.

8.74 The wisdom of involving families in review and investigation has been amply confirmed by evidence before this Inquiry. Parents are experts in respect of their own children and often close observers of the care given. Ms Slavin had real understanding of the nature of Adam's renal problems, Mrs Crawford was an eye witness to a key event, Ms Mitchell was the first to voice concern about Conor,[120] Mr Roberts' attention to detail identified an overdose and Mr and Mrs Ferguson could have accurately described the deterioration of their daughter's condition. In addition, all could have given invaluable advice about how not to communicate. In terms of reviewing care and contributing to improved patient safety the value of their potential contribution was too obvious not to have been actively pursued.

8.75 Whilst I was assured by Dr Carolyn Harper, Executive Medical Director of PHA, that there is increasing involvement of families at all stages of the investigation process,[121] I nonetheless make several recommendations to

117 Dr Carson T-13-11-13 p.17 line 3
118 Mr Peter Walsh T-11-11-13 p.82 line 16
119 Mr Peter Walsh T-11-11-13 p.83 line 22
120 087-002-020
121 Dr Harper T-14-11-13 p.46 line 5

ensure that families are accorded all proper respect and managed for the potential they offer. Indeed, some families may even wish to maintain involvement after the conclusion of an investigation in order to satisfy themselves fully that lessons have been learned. Such might make a further and valuable contribution.

Translation of learning into improvement

8.76 Systems designed to translate learning from SAIs into improved practice were said to have been strengthened in recent years. In 2012, the PHA advised the Department that all trusts had confirmed "*robust systems in place for the dissemination of learning from adverse incidents.*"[122] However, what was wanting was reliable evidence about the current monitoring and effectiveness of these systems. This issue lies at the heart of the Inquiry's work and the requirement of families to know that the tragedy of their child's death cannot happen again.

8.77 In October 2012 the Northern Ireland Audit Office reported on 'The Safety of Services Provided by Health and Social Care Trusts.'[123] It noted the absence of a monitoring system to collate patient safety information from across the HSC service and concluded that the regional sharing of 'lessons learned' was not as structured or as comprehensive as it could be. The Comptroller and Auditor General told the Northern Ireland Public Accounts Committee in November 2012 that "*the Department still lacks a reliable means of tracking the progress of health and social care services in improving the safety of those receiving care or in holding service providers accountable for minimising preventable harm.*"

8.78 Inability to demonstrate effective dissemination of learning from the SAI process is not a problem unique to Northern Ireland. The House of Commons Public Administration Select Committee received evidence in

122 330-057-001
123 403-026-001

2014-15 that the "*failure to learn from incidents and disseminate lessons has been a longstanding weakness of the NHS.*"[124]

8.79 In 2013 RBHSC attempted to address this issue by publishing a strategy indicating by means of flow-chart the distribution of relevant learning within the Children's hospital. In 2016 BHSCT introduced its 'Policy for Sharing Learning' particularising the communication of learning and providing templates for dissemination.[125] It encompasses learning from complaints, mortality reviews, audit, litigation and SAIs. The SAI Review Board provides evidence to the Assurance Committee that risks revealed by the process are addressed. Importantly the Policy describes a regional process for information sharing through HSCB as well as the Department and proposes a central repository of learning on the intranet.

8.80 The Department has commissioned two regional studies from GAIN[126] to specifically examine the learning extracted from SAIs involving the death of a patient.[127] Both exercises are to be pursued in partnership with HSCB and the HSC Trusts.

8.81 I have sympathy with the busy clinician working in the pressurised Health Service who is expected to learn rapidly from the dissemination of guidance. Given that corrections to clinical care are not always straightforward or intuitive, it follows that clinicians may require time and space to consider, discuss and assimilate learning from SAIs. I consider it proper that such should be provided within contracted hours.

8.82 In addition, Trusts do not appear to be obligated to provide assurance to the families of victims of clinical mismanagement that lessons have been learned or that that learning is practiced. It is in this context that the work of a Child Death Overview Panel could be important. Such a panel is comprised of individuals from a range of different organisations and professions. It specifically considers the anonymised details of death,

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124 403-027-049
125 401-001at-001
126 Now conjoined with RQIA.
127 401-003i-001

howsoever caused, to determine whether learning exists such as might prevent another death. The introduction of this process in Northern Ireland under the Safeguarding Board for Northern Ireland has proved problematic[128] and the Department and PHA may now assume responsibility.[129] This would enable additional oversight and the potential for additional assurance that lessons have indeed been learned.

8.83 Trusts should publish current policy on learning from SAI deaths (especially child deaths) and thereafter not only publish the detail of all such deaths but also what has been learned from them.

Family involvement

8.84 The Permanent Secretary said he believed "*very strongly that the best chance we have of securing sustained improvement is through very open involvement …making it easier for patients and families to be…aware ...and to feedback views…*"[130] and the CNO, Professor McArdle, said "*… we all believe that the patient's voice has to be front and centre in everything that we do.*"[131]

8.85 In 2009 the Department published standards for 'Improving the Patient and Client Experience' in an attempt to define appropriate respect, attitude, behaviour and communication. This was very necessary because, as the evidence confirmed, shortcomings in communication fuel suspicion.

8.86 BHSCT developed a 'Being Open Policy – saying sorry when things go wrong'[132] to encourage open disclosure to patients and families involved in adverse incidents. It emphasises that healthcare professionals must understand that good communication engenders trust and that openness is important. In December 2014 the policy was made available as an e-learning module. It advises on communication with patients and families and emphasises quick and open disclosure so that transparency is

128 404-002h-001 Jay Report 2016 – 'A Review of the Safeguarding Board for Northern Ireland'
129 404-002b-004
130 Dr Andrew McCormick T-15-11-13 p.72 line 5
131 Ms McArdle T-15-11-13 p.65 line 4
132 332-027-001 & 401-001ad-001 - 2011/2014 and revised 2015

understood. Specific guidance is given for sharing information with additional advices on 'being open' in the event of a death. It carries links to the Ombudsman's 'Guidance on Issuing an Apology'. The Trust Board is charged with promoting both it and a policy known as 'Involving You' which seeks to enhance 'user' involvement.[133]

8.87 Notwithstanding, difficulties continue to surround the problem of communication with patients and families in the context of SAIs[134] and HSCB/PHA has produced further guidance (2015) in the form of a checklist to guide and monitor engagement with patients and families. Notwithstanding, it must be recognised that a list does not equip staff to manage difficult conversations with empathy and credibility. Successful interaction at times of distress is difficult, which is why training is critical to ensure the skills and awareness necessary to adequately inform a family and engage with it in the process of investigation and learning.

8.88 Whilst Dr Harper of PHA stressed that medical training has advanced in recent years "*particularly in the aspect of communication skills and interpersonal skills*"[135] and that communication training is now given all trainee clinicians, Dr Anthony Stevens, Medical Director of BHSCT conceded that "*there are real areas particularly round engagement with families, where we recognise we've still got a great deal to do.*"[136] It is in this context that I recommend that training in communication skills be accorded enhanced priority.

8.89 I believe that there is also scope for the experience of patients and families to be heard within the Department. I believe that this is a deficiency and one which should be addressed.

133 332-013-001
134 348-010d-001
135 Dr Harper T-14-11-13 p.58 line 3
136 Dr Stevens T-12-11-13 p.95 line 20

Complaints

8.90 In 2009 the Department issued 'Complaints in HSC: Standards & Guidelines for Resolution and Learning' to replace the 1996 HPSS Complaints Procedure and established a HSC Complaints Policy Liaison Group in 2011. Departmental policy now requires involvement of the complainant and encompasses advocacy services and staff training. Complainants can get independent advice from the PCC and are now advised of their right to refer their complaint to the Ombudsman.[137] The Department has tried to secure patient engagement through community exercises, such as '10,000 Voices' and 'Family and Friends Test.' Policy on complaints continues to evolve.

8.91 HSCB has sought to improve the content of feedback to complainants and has held annual 'Complaint Learning Events'[138] with 'patient-centred' advice for healthcare professionals coupled with specific guidance on communication and bereavement support. Learning materials are also available on the HSCB intranet and there is an Annual Complaints Report.[139]

8.92 Actual complaints are used as the basis for learning. In one instance, a family complained about poor communication in the context of a relative's deterioration and death. In consequence the Trust provided specific training to the staff on the proper conduct of such difficult and timely conversations.[140] Mr John Compton, Chief Executive, of HSCB also described a seminar where patients recalled good and bad experiences for the benefit of clinicians which resulted in "*interplay between them and the staff about what would make it better*".[141] These are important initiatives in

137 Who, unlike his predecessor the NI Commissioner for Complaints, can now publically report the outcome of complaint investigation. Public Services Ombudsman Act (Northern Ireland) 2016 - http://www.legislation.gov.uk/nia/2016/4/contents/enacted
138 401-001b-001
139 401-001e-001 & 404-001c-001 & 404-001d-001
140 404-001c-009
141 Mr Compton T-14-11-13 p.31 line 17

feedback and learning and represent an approach which is obvious and should be encouraged.

8.93 The HSCB is responsible for reviewing HSC Trust response to complaints in order to identify trends. It makes regular performance reports to the Department. It advises on the numbers and categories of complaints together with response times and learning outcomes. HSCB reported on the 'Process for Evaluation of Complaints in HSC: Standards and Guidelines for Resolution and Learning' in 2011 and concluded that, whilst HSC organisations do learn from complaints, there is a need to advise staff and patients of that learning. The HSCB/PHA Annual Quality Report 2014-2015 noted that "*Service user feedback has demonstrated that further work is required to promote the visibility and accessibility of the Complaints Process.*"

8.94 HSCB subsequently produced an updated 'Policy for HSCB staff on the management of complaints' in April 2016. It set out revised standards and guidelines promoting accessibility, advocacy services, appropriate investigation, involvement of lay persons, independence of experts, opportunities for shared learning and speedier resolution. It provides flow-charts to detail procedures. The 2016 HSCB Policy explains that "*The operation and effectiveness of the HSC Complaints Procedure will be monitored continuously. A Regional Complaints Group…has been established and will meet on a quarterly basis to consider analysis of information pertaining to…HSC Trust complaints…the Regional Complaints Group will identify what learning should be cascaded regionally to ensure policies and practices are amended as a result of complaints.*"[142] Auditing of complaints handling has been introduced.[143]

8.95 The PCC is the main healthcare 'consumer' organisation in Northern Ireland. It has responsibility for representing the interests of the patient and for supporting public involvement in decisions about care. The PCC has no

[142] 403-004-013 to 014
[143] 404-001c-005

power to investigate complaints but has a statutory duty to assist those who wish to make a complaint. It has a permanent seat at the monthly meetings of the HSCB board responsible for oversight of HSC complaints.[144] All HSC Trusts are required to publish annual reports on complaints and submit them to the PCC. The PCC also publishes an annual report on complaints. In 2015-16 it reported that "*families and carers do not feel that they are being kept adequately informed about the progress of their treatment and care*".[145]

8.96 The Northern Ireland Commissioner for Complaints[146] also reports annually and has recorded the growing numbers of healthcare related complaints. In 2014/15 he referred "*to an underlying issue in many complaints, being a breakdown in trust between the patient/family and the HSC organisation*"[147] and expressed concern that all but one of the complaints received by him of complaint mismanagement was upheld.[148]

8.97 Independent Advocacy services have an important role in communication and in connecting the experience of patients and families to the improvement of care. The RQIA has included a Review of Advocacy Services for Children and Adults in its 2015-2018 review programme.[149]

8.98 BHSCT introduced its 'Policy and Procedure for the Management of Complaints and Compliments' in 2010[150] indicating appropriate responses and time frames. A Complaints Review Group assured the investigation, analysis and follow-up from complaints. However, in order to more effectively involve the complainant and investigate the complaint, BHSCT introduced a largely revised 'Policy and Procedure for the management of Comments, Concerns, Complaints & Compliments' in 2017.[151] Emphasis is placed on effective communication, with appropriate meetings, agreed

144 Mr Compton T-14-11-13 p.9 line 9 & p.11 line 8
145 403-008-011
146 Now the Ombudsman
147 401-001e-015
148 401-001e-016
149 401-003d-015
150 332-014-001
151 404-003b-001

agendas and recording. Specific requirements are given as to roles and responsibilities, the complaint investigation process and the types of resolution possible and responses to be given. Not only is outcome monitored for pattern but it is also measured for efficiency, learning and complainant satisfaction.

8.99 Given the problems of trust and communication which still seem to undermine the investigation of complaints, Mr Walsh, urged me strongly to the view that there ought to be standards for complaint investigations which should include the early involvement of the family.[152] I agree and consider that there should be a charter to particularise the rights of the family or patient in relation to complaints and further that those Trusts, which have not already published their responsibilities to families in respect of complaints, should do so now. Clarity about the process can only assist. Information encourages inclusion and families and patients should always be included in the investigation of patient safety issues.

8.100 Complaints present a valuable source of insight into patient safety problems and should be analysed as such. I am advised (as of November 2017) that "*the Department has commenced, in liaison with HSC Trusts, the piloting of the use of Healthcare Complaints Analysis Tool…for more meaningful analysis and comparison of data from complaints within and across Trusts.*"[153] This could prove of considerable benefit for both individual Trusts and regional learning.

The Duty of Candour

8.101 Of all the themes emerging from the evidence to this Inquiry, the most disquieting has been the repeated lack of honesty and openness with the families. In his report on the Mid Staffordshire NHS Foundation Trust Public Inquiry, Robert Francis QC found the same problem. In consequence, he recommended that a statutory duty of candour be imposed in situations where it was suspected or believed that death or serious injury had been

152 Mr Peter Walsh T-11-11-13 p.8
153 404-002b-003

caused to a patient by an act or omission of a healthcare organisation or its staff. He proposed that in such circumstances the patient or family should be informed of the incident and given an explanation. He believed furthermore that the duty of candour should be imposed on registered healthcare professionals, NHS healthcare organisations and private providers.

8.102 Since then there has been a prolonged debate as to whether those recommendations should be implemented in their entirety, whether the duty should apply to both individuals and organisations and exactly what the threshold definition of harm should be. In England a statutory duty has been enacted for organisations but not for individuals and in Wales the position has not progressed beyond White Paper proposals. In Scotland, a duty of candour will come into force in April 2018 but will differ from the English model in minor but significant respects.[154]

8.103 In Northern Ireland, Jim Wells MLA (then Minister for the Department), informed the Assembly on 27th January 2015 that "*a statutory duty of candour will be introduced in Northern Ireland. There should be no ambiguity in respect of my expectation regarding the crucial elements of patient safety, which are openness and transparency.*"[155]

8.104 The Department advised that in November 2017 it "*continues to develop policy to support the introduction of a statutory duty of candour in Northern Ireland. Initial comparisons of the approaches adopted in other jurisdictions and a workshop with HSC colleagues has highlighted a number of issues which require further consideration before we will be in a position to take our proposals to Minister, including definitions of harm, apologies etc. There is learning to be had from the experience of colleagues in other jurisdictions and we are examining the evidence presented during the associated Parliamentary sessions and the difficulties/successes of implementing their legislation to further inform our options. The Department will need to*

154 http://www.legislation.gov.uk/asp/2016/14/contents/enacted
155 http://data.niassembly.gov.uk/HansardXml/plenary-27-01-2015.pdf page 2

consider the introduction of a statutory duty that is straightforward and brings value to existing principles of openness and transparency and the individual duty of candour."[156]

8.105 Whilst the issues involved are not straightforward and there are matters for legitimate debate, the unfortunate truth to be drawn from this Inquiry is that there are too many people in the Health Service who place reputation before honesty and avoidance of blame before duty. All that is required is that people be told honestly what has happened and a legally enforceable duty of candour for individuals will not threaten those whose conduct is appropriate. The duty was not imposed upon clinicians in England on the basis that they are already placed under an 'ethical duty' of honesty by their professional organisations. I consider that such an argument would be stronger, had the evidence to this Inquiry not revealed obvious weakness in the call of 'ethical duty'.

8.106 Whilst Mr Walsh did indicate some recent improvement in levels of openness towards families, he believed that that improvement had not been consistent. It is to encourage consistency in openness and to avoid any ambiguity in expectation that I endorse the Francis recommendations.[157] I recommend that a duty of candour attach to individuals as well as organisations in the event of death or serious harm and that criminal sanctions should apply.

8.107 It will be necessary to provide specific guidance on implementation and compliance. The duty should be entrenched by Trust Directors appointed with specific responsibility for candour. Procedures should be audited, not only by HSC Trusts but also by the RQIA. It will be necessary for a regulatory body, such as the RQIA, to undertake enforcement. There should be willingness to prosecute in cases of serious non-compliance.

156 404-002b-009
157 Recommendations 181-183

Whistleblowing

8.108 Patient safety is the concern of everyone working in the Health Service and accordingly it must be the duty of everyone to raise patient safety concerns. However, because it has been found necessary to encourage whistleblowers, the Department has directed that Trusts develop policies enabling staff to raise concerns about questionable practice.[158] The RQIA issued guidance for whistleblowers and published its 'Review of Whistleblowing Arrangements in Health and Social Care in Northern Ireland' in September 2016.[159] It made eleven recommendations, seven of which the Department maintains "*are either fully implemented or on target to be implemented*" as at November 2017.[160] This impetus should be maintained. In every hospital there should be real or virtual individuals to whom concerns can be taken easily and without formality. There should be training and the system should be as responsive as possible.

Appraisal of clinical performance

8.109 The Department has developed procedures to address concerns about poor medical performance. 'Maintaining High Professional Standards' gives guidance for managing under-performance and allows Trusts access to the National Clinical Assessment Service. This complements recently introduced professional revalidation for practicing doctors.[161] There is now a statutory duty[162] to ensure that doctors undergo regular appraisal, that action is taken in respect of any lack of fitness to practice and that relevant concerns are referred to the GMC. The re-validation process became operational within the BHSCT by 2013 and has since been extended to the rest of Northern Ireland. It considers feedback from colleagues and feedback from patients.[163] The GMC has appointed a Liaison Advisor in Northern Ireland to assist with formal referrals to the GMC. Whilst the

158 403-019-001
159 401-003x-001
160 404-002b-003
161 332-030-001
162 http://www.legislation.gov.uk/nidsr/2010/9780337981302/body
163 Dr Michael McBride T-15-11-13 p.28 line 19

overall number of recent referrals has been too small to reveal trends, the procedure itself provides additional quality assurance.

8.110 Management of poor nursing performance is now also the subject of process and protocol.[164] Each Trust has disciplinary and capability procedures and can make referral to the NMC.[165] All nurses are required to undergo annual appraisal with their line manager.

Leadership

8.111 Evidence received by this Inquiry revealed numerous failings in leadership. These included failure to supervise nursing staff, consultant failure to direct care or give leadership in the event of unexpected death, failure of those in governance to demonstrate appropriate behaviour, failure of Directors of Nursing to provide visible leadership, failure of a HSC Trust Chief Executive to accept responsibility for the quality of care given children in his hospital and failure by the Department to hold the Health Service to account in respect of the quality of care or secure the timely introduction of clinical governance. Such attitudes and behaviours influence hospital cultures.

8.112 Building a culture where the natural response to error is to learn from it, is therefore very much the responsibility of leadership at every level. Change in culture will take time and expert leadership. Leadership has now been exercised by the Department in setting the direction of quality improvement. The Directors of each HSC Trust now have the major role to play in achieving the appropriate learning culture within each organisation. The best leadership is critical and there should be investment in the best.

8.113 The Permanent Secretary observed that "*leadership is not about position, it's about behaviours that drive each individual to do the right thing all the time…*"[166] I believe that to achieve the 'right thing' that there should be visible leadership at every level of an organisation. Leaders at all levels and especially at Board level must not be inaccessible. They should do

164 332-033-004
165 332-038-001
166 Dr Andrew McCormick T-15-11-13 p.99 line 7

more than appear on the occasional senior management 'walk-round'.[167] Senior managers should be observable to the 'front-line' encouraging learning and discouraging blame. They should welcome concerns and give feedback on improvement. They should demonstrate confidence in transparency by commending staff who speak out. They should communicate in the clearest terms that it is safe to raise concerns.

8.114 Clinical leadership should encourage those who care for patients to improve their care. Senior clinicians should be role models. They should challenge defensiveness and ensure that every opportunity for improvement is taken.

8.115 The BHSCT has introduced a 'Clinical Engagement and Leadership' programme and a 'Leadership Attributes Framework.' The Department published a HSC Collective Leadership Strategy in October 2017.[168] Whilst such initiatives respect the broad importance of leadership, I believe that there is nonetheless a pressing necessity to strengthen leadership at each and every level. I recommend that improvement in leadership now be accorded the utmost priority.

Death certification

8.116 Both the Luce Review (2003) and the Shipman Inquiry (2003) considered issues of death investigation and certification and made recommendations for Northern Ireland. Recognising the problem of inaccuracy in certification,[169] the Department issued guidance for both completion of the Medical Certificate of Cause of Death ('MCCD') and notification to the Coroner in 2008. The Coroner's Service published a 'Best Practice' guide in 2009 and appointed a Medical Officer to assist the coroner in identifying issues of clinical concern. Notwithstanding, the senior Coroner had to ask

167 401-001ag-001
168 403-024-001
169 338-012-001

the Board and the CMO in 2014 to remind doctors of their duty to notify the coroner of all deaths which might be SAI related.[170]

8.117 Within the BHSCT there was no systematic way of collecting details of MCCDs or notifications to the Coroner for the purposes of review. It was therefore difficult to assure that every death and certification had been clinically scrutinised. Accordingly, and at the instigation of the Department, a Death Certification Implementation Working Group was established to improve assurance of the certification process.

8.118 In 2016, the Department issued comprehensive, detailed and step-by-step guidance on the 'Child Death Reporting Process'[171] and the BHSCT in turn adopted clear policy on 'Actions Following a Patient's death' with advice on what, when and how to report to the coroner. Updated training has been provided to all junior doctors to ensure a proper understanding of the responsibilities attaching to completion of the MCCD. Further training programmes are being developed. The MCCD has been re-designed to collect additional information enabling audit and improved assessment of medical compliance with statutory obligation.[172]

8.119 In April 2017 the CMO then issued further guidance on reporting child deaths.[173] Child deaths in hospital are to be recorded by means of the Regional Mortality and Morbidity Review System ('RM&MRS')[174] which standardises procedures and permits review of all hospital deaths and death certificates.

8.120 The process means that all child deaths in hospital are recorded by means of a step-by-step computerised procedure on the RM&MRS. The consultant will particularise and certify the details as accurate. The system will generate the MCCD or a clinical summary where the death is to be referred to the coroner. The consultant must record all contact with the Coroner's

170 401-002d-001
171 401-001av-001
172 401-002b-017
173 404-002e-001
174 401-002h-001

Office and cite an identifying reference provided by the Coroner's Death Reporting Team. If the death meets SAI criteria the consultant must initiate the SAI process. The consultant must then forward the case to the designated Mortality and Morbidity ('M&M') lead for discussion and review at the next M&M meeting. SAI investigation reports will be listed for the next M&M meeting which will thus review all child deaths and any completed SAI investigations occurring since the previous meeting. The M&M lead will cause a multi-disciplinary review of the clinical history, cause of death, avoidable factors, discussions with the Coroner, lessons learned and actions required.

8.121 All child deaths must be reviewed within 12 weeks. This includes those deaths reported to the Police Service of Northern Ireland ('PSNI') or the Coroner as well as those investigated as an SAI or subject to post-mortem. This is to ensure that learning is disseminated as soon as possible. Should it appear to a M&M meeting that a case should be reported as a SAI or to the Coroner, then this must be done immediately. Only when the M&M has completed its review and each step of the process has been completed can a child death notification form issue. It is sent to the Trust governance team and/or audit unit and served on the HSCB/PHA.

8.122 The RM&MRS will thus routinely collect information from certificates, reports to the coroner, consultant reviews, mortality meetings, inquest findings, action plans, learning reports and other relevant sources.[175] The information will be consolidated and made available for scrutiny. The system provides a means to assure that the process of certification can be relied upon and that notifiable deaths are reported to the coroner. The information, if properly interpreted, should provide reasonable assurance to public and Trust board members alike, that such deaths in their hospitals as do result from unsafe care are identified, analysed and learned from.

8.123 Implementation of the system was complete by March 2017. In November 2017 there were reported to be "*over 150 teams across the 5 HSC Trust*

[175] 401-002r-006

hospitals using the system with a recording rate of over 80%". HSC Trusts were said to be "*establishing mechanisms to ensure they oversee/monitor outcomes from the M&M process.*"[176] This is a most valuable development and its operation and effectiveness should be subject to regular internal and external audit.

8.124 Notwithstanding the advances inherent in this system, I would nonetheless recommend the appointment of an Independent Medical Examiner, at least until such time as the RM&MRS has proven its reliability. A Medical Examiner can reconsider the consultant input and the MCCD, and with full access to the medical records, can pursue queries with the certifying doctor and the family of the deceased. The Examiner can refer uncertain cases to the coroner for further investigation and assist in the important task of pattern recognition.

Issues of coronial involvement

8.125 A most important part of the Coroner's role in relation to deaths associated with clinical mismanagement, is the power to alert relevant authority to the potential to prevent further fatality.[177] The Coroner can do this by way of a formal report made pursuant to Rule 23(2) of The Coroner's (Practice and Procedure) Rules (Northern Ireland) 1963.

8.126 However, the Department advised that "*… there is no standardised approach to how [Rule 23] reports are made. In some cases correspondence is addressed to the Minister, on other occasions information is provided for the Chief Medical Officer or some other senior officials, and in some instances there is no mention that the referral is being made under Rule 23(2).*"[178] In recognition of the weaknesses of such an approach the Department indicated that it would seek agreement on standardising referral of Rule 23 Reports.

176 404-002b-006
177 303-052-715
178 401-002r-005

8.127 The Coronial Service has indicated that Rule 23 Reports are now sent to the Department with a requirement that it respond giving both proposed action and timetabling. Copies of the report and response are sent to other interested parties to stimulate appropriate action.[179] The Coroner will then seek assurance from the Department and HSC Trust that learning has indeed been, or will be, put into practice. This feedback is important. It was these channels of communication that the Coroner regretted were not available to him following the Inquest into Adam's death.

8.128 Furthermore, the Coronial Service has confirmed in that "*Work is underway to ensure that there is proper feedback and follow up to Rule 23 Reports taking account of best practice in other jurisdictions*".[180] Additionally, inquest findings which may have implications for health care are forwarded by the Coroner's Office to HSCB where they are reviewed through the SAI process. These procedures are detailed in HSCB 'Paper on communication Pathways between the Coroner's Office, PHA and HSCB.'[181] Additional measures have been agreed enabling the Coroner's Medical Officer to notify healthcare authorities of emerging trends.

Disclosure of relevant documents to the Coroner

8.129 The right to assert entitlement to legal privilege in respect of certain documents and so withhold them from a coroner's investigation into a health care related death, highlights a tension between transparency and important legal principle. A coroner has no power to order the production of documents and HSC Trusts are under no general legal duty to disclose relevant expert opinions to the Coroner. This is notwithstanding obligation to assist the coroner and the fact that such reports are publically funded. Nor is a Trust under any duty to advise the Coroner that such experts could be called to give evidence at inquest. Furthermore, an organisational duty

179 401-004a-002
180 401-004a-002 August 2016
181 401-001f-001

of candour might not necessarily obligate disclosure because it would relate to factual information rather than an expert expression of opinion.

8.130 Whilst the Department maintains "*a presumption in favour of disclosure as a matter of general principle, the matter of whether to claim privilege is one for a Trust to consider based on its own legal advice,*"[182] the CMO nonetheless expressed the view that "*it should never be the case that we have information in relation to the circumstances and death of a patient which is not shared fully, frankly and openly with the coroner to inform and assist him in his investigations and determination of the cause of death.*"[183]

8.131 BHSCT is said to share all such reports with the Coroner.[184] I believe that is the preferred approach. However, and in order to acknowledge the claims of both transparency and privilege, I would recommend that HSC Trusts claiming privilege in respect of a document relevant to the proceedings of an inquest, should inform the Coroner as to both the existence and nature of the document.

8.132 The Department should, in any event, issue guidance to HSC Trusts on the approach it would wish adopted.

Regular external review

8.133 Cumulatively, the measures introduced over recent years have very significantly reduced the risk of harm to children and young people receiving IV fluids. Additionally where a SAI does occur, there are greatly improved mechanisms to identify it, investigate it, learn from it and reduce the risk of recurrence. That so much has been done, taught and published and that so many more SAIs and complaints are reported, all confirm that the Health Service environment has most definitely been transformed since the period under review.

182 333-342-011
183 Dr Michael McBride T-15-11-13 p.79 line 14
184 Mr Colm Donaghy T-12-11-13 p.81 line 20

8.134 Whilst I am able to conclude that lessons have been learnt, I cannot conclude that all risk of recurrence has been eliminated. Given that the provision of health care is an immense and complex task, I can only agree with Dr Carson when he observed "*one can never give full assurance that full compliance will ever be achieved.*" [185]

8.135 Accordingly, it remains critical to keep building upon the very real progress made and to further undermine the remnant culture of clinical defensiveness. To that vital end, future progress should be subject to regular external review.

[185] Dr Carson T-13-11-13 p.47 line 10