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Ms Bernie Conlon
Secretary to the Inquiry into Hyponatraemia
Related Deaths
Arthur House
41 Arthur Street
BELFAST BT1 4GB

Your Ref: BC-0227-16

Our Ref: LIT 0477/08/DMcC

Date: 19 July 2016

Dear Ms Conlon

RE: SCHEDULE OF QUESTIONS TO THE DEPARTMENT OF HEALTH

I refer to the above matter and to your letter of 22 June 2016 addressed to Catherine Rodgers of this office.

Please find attached response to the schedule which is now forwarded on behalf of the Department.

I trust this is in order.

RECEIVED
20 JUL 2016
INQ-4591-16

Yours sincerely

Des McCann

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Enc

HE1/16/50009

INQUIRY INTO HYPONATRAEMIA-RELATED DEATHS

Questions for Department of Health

July 2016

Question 1

i. What steps have been taken to implement the recommendations in the Donaldson report in relation to complaints and SAIs?

In respect of the recommendation that more independence should be introduced into the complaints process, a series of initiatives are being taken forward with the HSCB, HSC Trusts, Ombudsman's Office and PCC to enhance and improve the HSC Complaints Procedure (see progress section below). In relation to Serious Adverse Incidents, a series of actions to review the procedure and are listed in the progress section below.

ii. What progress has been made to date?

The following progress has been made:

- The Department has promoted greater use of Independent Lay Persons throughout the HSCB and Trusts.

- The Department has encouraged better engagement/communication between HSC staff and complainants. Several Trusts are carrying out work to improve their quality and tone of the correspondence.

- The HSCB has been asked to carry out research on the length of time taken to resolve complaints, particularly those that take more than 20 days.

- The HSCB and Trusts have been signposted to the Ombudsman's best practice guidance on apology and the use of the guidance has been promoted.

- The Department is exploring with HSCB and HSC Trusts some reshaping of the system of adverse incident reporting, analysis of adverse incidents in aggregate and on a sampling basis to enhance learning from less severe events and improving the reporting process to address under-reporting and make it easier for staff to report and to make analysis of the data.

- Work is ongoing with the HSCB and HSC Trusts to co-ordinate the necessary changes to the Serious Adverse Incident process in relation to the investigation of cases involving mental health patients to make sensible changes to the rules and timescales for investigating incidents involving the care of mental health patients.

- Deaths of children from natural causes are no longer classified as Serious Adverse Incidents. The Department has introduced a new regional process for recording and reviewing child deaths which includes a multidisciplinary review of all child deaths at Mortality and Morbidity (M&M) meetings as the prime method of scrutiny.

- A computerised Regional Mortality and Morbidity Review System is being developed to support the review of all child deaths at multidisciplinary Trust M&MR meetings in the Belfast HSCT and is to be introduced to all other Trusts by March 2017. If the circumstances of a child death meet the definition of a SAI, the death will continue to be reported and investigated in accordance with the SAI process.

- The HSCB has been asked to amend the SAI process to include notification of Never Events as part of the SAI process. The Department has considered the English Never Event List and confirmed that there is existing guidance in place in NI which addresses all of the issues identified in the List. Since NI has an integrated health and social care system, the HSCB was instructed to carry out an examination of current SAI data on social care incidents to identify if there are any which should be considered for inclusion in the proposed HSC Never Events List. The HSCB also

worked with Trusts to seek views on potential areas for inclusion. It was concluded that the list already includes three areas which also refer to social care settings. The HSCB has recommended that there are no additional social care-specific incidents which should be added to the proposed list of Never Events.

- In support for the implementation of a Never Events list. The Department has asked the Quality 2020 Implementation Team (led by the HSCB/PHA) to lead on the development of a HSC Operational Standard for invasive procedures using the National Safety Standards for Invasive Procedures (NatSSIPs) as a basis with the objective of reducing reoccurrence for the three main events - wrong site surgery, wrong implant/prosthesis and retained foreign object post-operation as a Q2020 task.

- The Department has promoted better engagement/involvement of people and their relatives in the SAI process. The HSCB/PHA introduced a new checklist in February 2015 to monitor engagement/involvement and this data is published every six months in the HSCB/PHA SAI Learning Report. It has shown good progress although 100% will not be achievable as some people will elect not to participate in the process, a next of kin or contact may not be available and some people may be too unwell to take part.

Question 2

i. Was this guidance issued?

The Department is continuing to explore with stakeholders the interface of complaints/litigation processes to ensure that engagement with patients, clients and families can continue as appropriate through the complaints process should legal/litigation proceedings proceed in parallel.

ii. If so, what steps have been taken to ensure that the guidance is followed?

There is no formal guidance currently in place in respect of the complaints/litigation interface however stakeholder engagement is proceeding with the aim of further guidance being issued as appropriate.

Question 3

i. What is the current position in relation to this Review of 'measuring and monitoring patient and client experience'?

A scoping exercise has been carried out to review the current position in relation to measuring and monitoring patient and client experience and this will form the basis for addressing the Programme for Government (PfG) draft outcome 5 "Improve the quality of the healthcare experience".

The scoping exercise engaged with all HSC Trusts including the Ambulance Service, Patient Representatives and the Patient Client Council alongside their Patient Forum. Putting baseline information in place and establishing regular monitoring arrangements will form part of the data development agenda for PfG. Any work on Patient/Client/Healthcare experience will be co-designed and co-produced with patients/clients and citizens of NI as well as staff within the HSC.

Question 4

i. What is the current position with the development of a system to 'draw all AIs together across Northern Ireland' for purposes of assessing trends and lessons learned?

In December 2014, Professor Sir Liam Donaldson submitted his report "The Right Time; The Right Place: An expert examination of the application of health and social care governance arrangements for ensuring the quality of care provision in Northern Ireland" to the Department. The report was published on 27 January 2015.

Recommendation Seven of the Donaldson Report is concerned with the establishment of a Patient Safety Institute for Northern Ireland. This recommendation outlines eleven key functions on which the Institute should concentrate although other recommendations are also linked to the establishment of such an Institute. A particular focus of the body would support system transformation, building on the range of quality improvement and patient safety initiatives currently ongoing in the HSC which the proposed Institute should harness. This includes harnessing greater learning from Adverse Incidents and Serious Adverse Incidents.

This functional, analytical approach was appropriate in the context of the Donaldson Review however the broader context is that the health and care system is operating less than optimally and is in need of transformation. Transformation requires a system architecture which goes beyond analytics to establishing the necessary enablers for action.

Therefore, on 12 November 2015 in a speech to the Faculty of Medical Leadership and Management, the then Minister, Simon Hamilton, set out his vision for an Improvement Institute for Northern Ireland . The Institute would lead and provide support for a three-year rolling programme of projects ("A Northern Ireland Safety Programme") based on the eleven key Patient Safety functions outlined by Donaldson in Recommendation 7 of his report. The programme would identify evidence based quality improvements to prevent/reduce levels of 'avoidable' patient/service user harm and ensure sustained regional implementation, improvement and learning to build safety resilience into the health and social care system.

Organisational models and funding for the establishment of an Improvement Institute are currently being explored by the Department.

Question 5

i. Is any consideration being given to the professions being required to report adverse incidents and near misses?

The quoted guidance from the medical and nursing regulator covers the point in a number of passages (para 4(b) and 25).

For the Department's part its focus is on organisations (predominantly its ALBs). Where the Department puts in place guidance for an activity such as adverse incident reporting, it is for those organisations to put in place processes to ensure that their employees (whether members of regulated professions or not) are supported in complying to the fullest extent possible.

Departmental and pharmacy representatives from Northern Ireland have been appointed to a Rebalancing Programme Board, chaired by Ken Jarrold CBE.

The programme has a number of objectives which includes creating a defence for pharmacists, if they make inadvertent dispensing errors, from criminal sanction under the provisions of the Medicines Act 1968, subject to the meeting of certain conditions (The Pharmacy (Preparation and Dispensing Errors) Order 2016).

The possibility of criminal prosecution, as provided by the sanctions in the Medicines Act 1968, for inadvertent dispensing errors has long been a source of concern for pharmacists. The development of proposals for mitigation has been a priority for the Programme Board as the under-reporting of errors leads to a loss of the opportunity to learn from such errors and this in turn impacts patient safety.

In relation to dentistry:

- The General Dental Council (GDC) was one of the eight regulators that signed the 'Openness and honesty - the professional duty of candour' in June 2015. A consultation closed on new GDC guidance on the duty of candour in December 2015, though guidance has not yet been published. T he GDC's

main standards, 'Standards for the Dental team' has principle number 8 as "Raise concerns if patients are at risk" and some of the underlying standards relate to putting patients' safety first; taking action promptly if patients are at risk; encourage and support the raising of concerns; and that procedures are in place for this purpose. These therefore represent an ethical responsibility to report incidents. The responsibilities defined under principle 8 impact on the individual as a GDC registrant and apply at a UK-wide level.

- The minority of the dental profession works in a Trust environment either through the Community Dental Service or Hospital Dental Service and I assume there are Trust governance processes in place to require the reporting of adverse incidents and near misses. This responsibility impacts on the individual as an employee and there may be some regional variation in the requirements and processes.

- The majority of dental care and treatment is carried out by the significantly larger independent general dental practitioner workforce and they do not have a similar responsibility as they are not employees of an HSC organisation. Previous guidance circulars issued by DHSSPS have been developed from the perspective of Trusts and therefore it is not directly transferable to primary care independent contractors. Responsibility for the alert and AI/SAI process now rests with HSCB. The HSCB internal audit process has recently raised the fact that whilst the HSCB offers training to practices and requires an annual declaration on the number of incidents occurring, there is no legislative or regulatory requirement for general dental practitioners to do so. They have asked that the Department considers whether the Regulations can be amended to make the reporting of adverse incidents a requirement. They could be changed but the difficulty at present is that with the uncertainty of the HSCB the process for future reporting is not known.
- Standard 14 of the Minimum Standards for Dental Care and Treatment is relevant. - "The dental service has an ongoing risk management programme to ensure your safety. Any adverse incidents or near misses are reported through the appropriate route and followed through." The difficulty though is

that there does not appear to be a formal mechanism to do so, either through the previous DHSSPS circulars or the GDS Regulations, and this would be likely to contribute to under-reporting. Again, if guidance on the process was to be promulgated, we would have to be conscious of the proposed changes to the HSCB and that the process would have to change and require further guidance.

The Northern Ireland Social Care Council is the regulatory body for social care in Northern Ireland. The Standards of Conduct and Practice for Social Workers does include a requirement to report adverse incidents and near misses. Para 1.12 of the Standards of Practice states that social workers must report any adverse events, incidents, errors and near misses that are likely to affect the wellbeing of service users or carers. In addition the Standards of Conduct require social workers to:

- Bring to the attention of your employer or the appropriate authority, without delay, resource or operational difficulties that might get in the way of the delivery of safe practice;
- Inform your employer or an appropriate authority, without delay, where the practice of colleagues or others may be unsafe or adversely affecting standards of care; and
- Being open and honest with people if things go wrong, including providing a full and prompt explanation to your employer of what has happened.

Question 6

i. Please provide the relevant statistics since November 2013 to date.

There have been 15 confidentiality clauses contained in the settlements of medical negligence cases taken against health authorities here over the last three years which represents 2% of all settled cases. The Department recognises that there may be occasions where such clauses are unavoidable but these should only be in

exceptional circumstances. Confidentiality clauses are only inserted where the plaintiff or co defendant request it. It is never requested by the HSC body.

ii. **Please provide a copy of the guidance**.

Copy attached

HSC(F) 08-2016 -
FD(DFP) 02-16 Respor

See Document 401-002c

iii. When was the guidance issued?

The guidance was issued 14 January 2016.

iv. How is adherence to the guidance being monitored?

HSC bodies have to seek Departmental authority to use confidentiality clauses.

Question 7

i. What is the position in relation to the RQIA review of the operation of Whistle blowing?

RQIA's review of HSC whistle blowing policies was undertaken in the latter half of 2015/16 and included not only a review of the extant policies but engagement with staff to find out the level of awareness and any barriers which exist. A draft report has been shared with the Department for factual accuracy checking. Upon receipt of the final report the Department will consider the specific recommendations made. In addition to implementing those recommendations, a further stage of the work will

involve the Department reviewing the effectiveness of RQIA's whistle blowing policy and that of other designated bodies under the Public Interest Disclosure legislation

Question 8

i. What actions are being taken by the Department to ensure that the Trusts are adhering to its policy in whistle-blowers?

As above in Question 7

Question 9

i. What liaison has there been between Department of Health and Department of Justice about improving the Health Service through the issue of Rule 23 reports following Inquests and the sharing of SAI reports for Inquests?

There has been no direct liaison between the Department of Health and Department of Justice in respect to Rule 23 Reports. However the Department of Health does, on occasion, receive correspondence from the Coroner's Office regarding Rule 23 referrals and responds accordingly to each on an individual basis.

If requested, HSC Trusts provide copies of SAI reports to the Coroner's Office. Trusts will also consider a referral to the Coroner if further information comes to light as a result of an SAI investigation.

ii. Is any further liaison under active consideration?

The Department of Health will be liaising further with the Coroner's Office to ensure consistency of handling of Rule 23 reports by both the Coroner's Office and the Department.

iii. Are there any plans to bring the NI legislation in line with England and Wales or for amendments in any way?

Legislation in this matter is a responsibility for the Department of Justice (DoJ). This has been passed to the Department DoJ and they will respond directly to the Inquiry on this issue.

Question 10

i. Has the Department issued any guidance or direction to Trusts about circumstance when it should not exercise its right to claim privilege on expert reports in the context of Coroners Inquests?

The Department of Health has not issued any guidance to Trusts in this matter.

Question 11

i. In light of this report what steps has Department taken to monitor accuracy of coding?

Accuracy is monitored regionally through data quality reports which are run monthly and published as part of the clinical coding timeliness report. The data quality reports currently are looking at basic coding errors to ensure that these are amended and the foundations for accuracy are built on.

Audits are carried out on trainee coders' work six months after completion of the National Clinical Coding Standards Course. This audit highlights early in the coder's career if they are having problems and allows an action plan to be put into place to bring this coder's accuracy level up to what is expected.

Audits have been carried out in the following areas: Obstetrics; Paediatrics; Palliative Care; Mortality Audit; Progressive Haematological cancers (carried out as part of a UK wide audit) and Termination of Pregnancy.

From 2016 a broad based audit will be held annually across all trusts and sites. The audit will look at the following specialities: obstetrics, general medicine and general surgery. The schedule for this audit was agreed by the Strategic Clinical Coding Group.

Ad hoc audits are carried out when errors are brought to the Regional Teams attention or errors are highlighted when carrying out analysis of information.

The Regional Clinical Coding Team created and introduced the use of a unique identifier on PAS for each coder in Northern Ireland. The unique identifier was created to allow the regional auditors to identify which coders had made errors during audit so that the reason for the error could be assessed and a recommendation made to address it. The unique identifier could also be used by the trusts to monitor throughput of staff and to also ensure errors in coding are identified and amended.

Trusts should be running regular internal audits to ensure accuracy.

The Regional Helpdesk ensures that diagnoses or procedures that have no guidance or the standards are difficult to understand are clarified and guidance is provided for all clinical coders across NI to assist in producing accurate coding. For 2015 there were 284 queries dealt with from multiple stakeholders.

Regional Clinical Coding Accredited Auditor – all audits are carried out by an accredited clinical coding auditor who annually attains their UK licence to audit. The auditor attends the UK Auditor Forum annually to keep up with developments within clinical coding in relation to audit and the implementation of new audit methodology. This ensures that clinical coding audits carried out in Northern Ireland are comparable with coding audits carried out in other parts of the UK as the same methodology is used.

Question 12

i. **Please provide information on number of reports to the Coronial service from all Trusts over past 10 years.**

HSC Trusts do not currently collate information on the number of cases discussed with, or reported to the Coroners Service. Section 7 of the Coroners Act 1959 places a duty on every medical practitioner to notify the Coroner of the facts relating to a death, if the deceased died directly or indirectly from any cause other than natural illness or disease for which the deceased had been seen and treated within the previous 28 days.

The Regional Mortality and Morbidity Review System (RMMRS) will however record all details of contact with, or referral to, the Coroners Service, for deaths in hospital. This will include the name of the doctor making contact with the Coroner, the time and date when contact was made and the agreed outcome of the discussion (i.e. the issue of a Medical Certificate of Cause of Death, a pro-forma, or a Coroner's investigation).

The RMMRS will also have the facility to provide the Clinical Summary of the case for the Coroner in a more efficient manner in cases where a Coroner's investigation is to take place. Additionally, RMMRS will provide a mechanism for ensuring that the outcome of any Coroner's investigations i.e. following post-mortem reports or inquests, are reviewed at multi-disciplinary Mortality and Morbidity Review meetings. This will ensure that learning lessons from Coroner's investigations are discussed by, and disseminated to, the appropriate front-line staff dealing directly with patient safety and care.

Question 13

i. Please provide copy of that letter.

Letter of 2 April 2014 which was addressed to the Chief Executive of the HSCB and copied to CMO.

MM01062014 - John Leckey - SAIs.PDF

See Document 401-002d

ii. The response to the Coroner.

Response to Coroner 18 April 2014

Letter to John Leckey - SAIs and Re

See Document 401-002e

iii. Any subsequent correspondence issued to the Trusts by the CMO?

Subsequent Correspondence issued to Trusts

Letter to Trust Chief Executives and Medic

See Document 401-002f

Question 14

i. Please provide a copy of the letter dated 25th February 2015?

DHSSPS RESPONSE TO AGY.123.2015.pd

See Document 401-002g

Question 15

i. Has this Working Group reported?

ii. If so, is the report available?

The Death Certification Implementation Working Group (DCIWG) was established in October 2013 to take forward, following approval from the Executive, the implementation, review and evaluation of a series of enhancements to the existing assurance arrangements for death certification (Option 1).

This option was approved following a recommendation from an Inter-Departmental Working Group which was established to consider the findings of the 3rd Report of the Shipman Inquiry and the Luce Review. One of the primary recommendations from these was that there should be independent scrutiny of all deaths by a Medical Examiner, prior to burial or cremation.

The Option 1 enhancements are:

- Adding the GMC number of the certifying doctor and the Health & Care number of the deceased to the existing Medical Certificate of Cause of Death

- Improving death certification training for registered medical practitioners and including this as part of doctor appraisal

- Developing a set of system standards and improved guidance for death certification

- Establishing a mechanism to facilitate review of compliance with standards and guidance on certifying death across organisations

- Building on learning from other established death reporting systems; and

- To undertake an analysis of MCCD completion by hospital based doctors under current governance arrangements.

The Medical Certificate of Cause of Death now contains specific fields for the certifying doctor to confirm their GMC Number, print their name and confirm the Health and Care Number of the deceased. Periodic quarterly audits of this information are now taking place and this provides greater assurance that medical practitioners are complying with their statutory requirements.

Updated training has been provided to all Junior Doctors to ensure that they are fully aware of their responsibilities when completing a Medical Certificate of Cause of Death or making referrals to the Coroner and work is ongoing to develop a new training package for all medical grades. This work is being taken forward in conjunction with QUB and NIMTDA.

The Department is also currently revising its guidance on Death, Stillbirth and Cremation Certification.

Additionally, the development of the Regional Mortality and Morbidity Review system is being taken forward by DCIWG as an integral part of Option 1 enhancements. It is anticipated that the system will be fully implemented by April 2017.

Work is on-going to fully implement the enhancements under Option 1 and once completed, an evaluation will be prepared for the Executive to determine if the introduction of an Independent Medical Examiner here (Option 2) is necessary.

Question 16

i. What was the outcome of the pilot scheme?

The BHSCT 'Mortality & Morbidity Review System' system was piloted in the Mater Infirmorum in August 2012 and rolled out across the Belfast Trust in May 2013. The system, which is still currently in operation, allows for the:

a) Recording of details from all patient deaths entered onto the Medical Certificate of the Cause of Death or notified to the Coroner; and

b) Review by a Consultant, followed by,

c) Examination and scrutiny, in detail, of avoidable factors or areas of learning and subsequent actions associated with the patient's death by,

d) 'Ward based' multidisciplinary (M&M) clinical teams and units, aimed at identifying the causes of harm, learning and thus avoiding the repeating of harm.

In April 2014, the then Minister in a statement to the Assembly, gave the go-ahead for a Regional Mortality and Morbidity Review System (RM&MRS) to be rolled out across all five HSC Trusts.

A technical specification for the RM&MRS, based on the functionality of the BHSCT system, with further modifications and enhancements, was developed and agreed. In February 2016, the outline business case was approved, giving agreement for the development of the RM&MRS within the Northern Ireland Electronic Care Record (NIECR).

ii. What system has now been implemented?

Development of the electronic system is currently underway and it is anticipated that the system will be fully implemented and operational across all HSC Trusts by April 2017.

Question 17

i. Is this 'audit' the audit carried out by GAIN and published on 8 August 2014?

This was a statement made by CMO Dr McBride and reflected the intention at the time that an audit would be undertaken to measure qualitative and quantitative data in respect of compliance with the guidance on fluid management for children and young people. GAIN was asked to undertake this audit. However, following Dr McBride's statement, it was brought to the Department's attention that the guidance would require updating in order to reflect revised Advanced Paediatric Life Support guidance. Some other changes were also suggested by clinicians. To that end, Dr McBride wrote to the clinical leads who had led the development of the wallchart guidance and fluid balance and prescription charts and requested that they reconvene their working groups to make the appropriate changes to their documents. Revised wallcharts were issued to Trusts on 1 July 2014 and on 30 September 2014 Dr McBride wrote to Trust Chief Executives advising that the fluid balance and prescription charts had been revised.

Given the plans to revise the wallchart guidance, Dr McBride wrote to GAIN on 17 January 2014 to request that they postpone the planned audit of compliance until such time as the revised wallchart guidance and fluid balance and prescription charts had been produced. However, GAIN responded with a proposal that they perform the audit as an accurate Spring 2014 snapshot of the care of children receiving IV fluids in Northern Ireland. The modifications to the wallchart and FP&B chart did not affect the relevance of the audit. The CMO agreed with this proposal and the GAIN audit was published in August 2014.

The audit recommended the development of a dedicated tool for local audit of IV fluids in children and young people. A Paediatric IV Fluid Audit Implementation Tool (PIVFAIT) has been under development in the intervening period and has been piloted in the Belfast HSC Trust. Comments on the tool have been received from other trusts and have been considered in a final refinement of the tool before it is

issued by CMO. In issuing the tool, CMO will ask for results to be shared with him initially so the Department can keep abreast with quality and safety in this area.

Question 18

i. Please provide any documents available explaining the full procedure for the implementation of the RM & MRs?

A copy of the technical specification document has been provided which outlines the full M&MRS process.

FINAL V 2 1 RMMRs Requirements Specification document.pdf See Document 401-002h

ii. What training will staff be provided with for these RM & MRs reviews?

Guidance for the Regional Mortality and Morbidity process has been drafted for issue to all HSC Trusts. The guidance provides comprehensive advice and support in relation to the M&M process encompassing the recording, reviewing, monitoring and analysing of hospital deaths at Specialty Mortality Review and Patient Safety meetings. This guidance document will be adopted and implemented by all Trusts.

Funding has been made available to all HSC Trusts for the recruitment of a RM&MRS Implementation Facilitator (IF) for a 6 month period. The IF will provide expert advice on the RM&MRS to managers, clinicians and other professionals during the implementation and roll-out and support users and managers on all aspects of system operation. There is also a NI ECR Implementation Lead based in each Trust, who will provide advice and support on a day-to day basis.

The RM&MRS will be tested on the Mater Hospital site before roll-out commences on a Trust by Trust basis.

iii. Will the consultant reviewing the death be the consultant involved in the care?

The consultant involved in the care of the individual will be expected to review the information recorded on to the RM&MRS, including details contained on the Medical Certificate of Cause of Death if not completed by them initially. The information being reviewed will include the background details on the patient covering the description of the admission and diagnosis, past medical history, medications, their clinical course and any procedural details, surgery or investigations. The consultant must sign-off the review confirming that they are in agreement that the details recorded are complete, accurate and correct.

There will then be a peer review of the death by a multi-disciplinary M&M team, which includes the consultant involved in the care. These peer review teams are to be large and varied enough to ensure robust challenge and review of practice. They will also include the medical and nursing staff involved in the care of the patient, together with other relevant staff members who may have been responsible for the treatment and care of the patient i.e. AHPs, Pharmacists etc.

The peer review team will consider the details of the case and the care that was provided to the deceased. The primary function of the review is to identify any learning lessons or avoidable factors in each case. Those learning lessons and their associated actions will be recorded within the NI ECR patient record.

This method of scrutiny is designed to enable clinicians and managers at any level in the Trust to understand and learn from the underlying conditions that lead or contribute to death or harm to patients so as to improve the management and quality of care.

iv. Will the M&M Review Meetings be minuted?

Specialty Mortality Review and Patient Safety meetings, of which the M&M review is a part, will be minuted.

Question 19

i. Can the Department confirm that these figures show that the Hyponatraemia guidelines were not being followed adequately?

GAIN was commissioned by CMO in February 2014 to undertake an audit of the administration and recording of IV fluids in children and young people. The audit was designed to examine whether the administration of IV fluids to children and young people was safe and met quality standards.
The audit found that in all cases examined the fluid prescription was appropriate.

There were areas for improvement in respect of recording – particularly regarding glucose monitoring where there was evidence of monitoring in 62% of cases. However the report does not therefore extrapolate that the monitoring did not take place – just that there was no evidence of recording.

With regards to 100% compliance, the report states "*A view was taken that for many of these performance criteria, the aim must be for* 100% compliance ***and absolute perfection***".

It is widely acknowledged that "absolute perfection" whilst desirable is often never achieved. The audit found compliance levels of 97%, 94%, 95% and 92% in key areas such as patient identifiers and the testing, sampling and monitoring of urea and electrolytes at key points.

The report noted that further work is required to improve the totalling of fluid input, output and overall balance.

Question 20

i. What (if anything) has been done or is proposed to be done to implement any of these recommendations particularly for a single daily chart for a DFBC?

As indicated in the answer to question 14, in the summer of 2014 one single daily fluid prescription and balance chart for children was introduced throughout Northern Ireland. A visually similar chart was also introduced regionally for use in adults.

On publication of the GAIN report in August 2014, CMO wrote to Trust Chief Executives enclosing the report and requesting each organisation's plan to implement the recommendations of the report.

Each trust responded with its plans to implement the recommendations. These plans outlined the action underway in each organisation to improve practice in the areas covered by the audit.

Furthermore a paediatric audit IV Fluid improvement audit tool (PIVFAIT) is currently in the last stages of refinement before it is rolled out to Trusts. This audit tool has been designed to allow trusts to self-evaluate the quality of IV fluid prescription, recording, monitoring & administration and was piloted in the Belfast Trust. Other trusts were given the opportunity to comment on the draft tool and these comments have been considered producing a refined final tool for regional introduction.

Question 21

i. **Why is a facility provided for local modification *"from what has been regionally agreed"?***

There is and has NOT been any facility provided for local modification to the FP&B chart.

ii. **What did the development of the regionally agreed position disclose as the likely requirement for such modification?**

There was a request to insert one pre-printed line onto the chart – this request was refused.

iii. How will the Department monitor and/or keep under review any risk from the 'deviation'?

The charts are printed, produced and stocked as regional items.

iv. What steps were taken to ensure that the revised charts were distributed and the training delivered *"to facilitate their introduction across the HSC"?*

The charts are stock items available to and used by all hospitals in NI.

There is a central repository for HSC resources relating to hyponatraemia held on one website within the PHA.

http://www.publichealth.hscni.net/directorate-nursing-and-allied-health-professions/nursing/central-repository-hsc-resources-relating- See Document 401-022i

v. What procedures are in place for the Department to know what has been done since 2014 and is currently being done about adherence to the revised wall chart guidance?

Local Trust audits and regionally the PIVFAIT tool described above.

Question 22

i. Please provide a copy of the review referred to.

Please see attached documents detailing:

1. NIPEC Quality Assurance **Framework** for DHSSPS Commissioned Practice Development and Education Programmes (Non NMC Registered or Recorded) Non-NMC Monitoring. July 2013. Provider QUB; course - ***Nursing Care of the Critically Ill Child***

2. NIPEC Non NMC QA **Monitoring Progress Report** 2013-2014. QUB for: ***Nursing Care of the Critically Ill Child.*** June 2014.

3. NIPEC Quality Assurance **Framework** for DHSSPS Commissioned Practice Development and Education Programmes (Non NMC Registered or Recorded) Non-NMC Monitoring. June 2014. Provider CEC; course **- *Fluid***

Management in Children & Young People (from 1 month to age up to 16 years only)

4. NIPEC Non NMC QA **Monitoring Progress Report** 2014-2015. Provider CEC; course - ***Fluid management in Children & Young People*** (from 1 month to age up to 16 years only). June 2015.


Fluid Management progress report 11Ju


doc completed QA progress report Care 26jun14


doc final report Fluid Manage


doc QUB final report QA report Critically ill

See Documents 401-002j to 401-002m

Question 23

i. Please provide a copy of *'piece of work'* referred to and evidence of the continuing work being done by the CNO & NIPEC.

Please see the attached NIPEC document, 'Activities and outcomes for recording care 2009-2016' that provides a summary of the activity, outcomes, resourcing, barriers and enablers experienced through seven years of regional work streams, delivering successfully on a strategic imperative to improve person-centred record keeping practice.

The document has links or embedded documents in to enable ease of access to relevant evidence.


outcomes for recording care 09 to 1

See Document 401-002n

Question 24

i. How often has that actually happened since November 2013?

HSC organisations are required to speak to a senior officer in the Department about a potential Early Alert. The senior officer may be a Chief Professional officer, Policy

Director, Deputy Secretary or Permanent Secretary. Following the initial contact HSC organisations must send a formal Early Alert notification to a central email inbox within 24 hours of making contact. A total of 95 Early Alert notifications were received by the Department in 2013, 151 in 2014 and 158 in 2015. A copy of the Early Alert guidance, which has already been provided to the Inquiry, can be accessed at https://www.health-ni.gov.uk/sites/default/files/publications/dhssps/HSC%20%28SQSD%29%2010-10.pdf See Document 401-002o

ii. How do they define a 'serious' SAI as distinct from simply an SAI?

There is no difference between these. The definition of a Serious Adverse Incident (SAI) is outlined in the guidance which can be accessed at - http://www.hscboard.hscni.net/download/PUBLICATIONS/policies-protocols-and-guidelines/Procedure-for-the-reporting-and-followup-of-Serious-Adverse-Incidents.pdf. See Document 401-002p

There are three levels of investigation for an SAI. The investigation will be conducted at a level proportionate to the complexity of the incident under review.

Question 25

i. Are these early alerts assessed for trends, if so who does it and where is that reported?

The purpose of the Early Alert system is to ensure that the Department (and thus the Minister) receive prompt and timely details of events (these may include Serious Adverse Incidents), which may require urgent attention and possible action by the Department. Early Alerts are forwarded to the relevant policy leads in the Department for consideration.

Question 26

i. What has happened about this? Are there any reports from the Regional Learning Project Team on it?

The report of the Regional Learning System Project was issued to the HSC on 26 August 2015.

ii. How will the differences between the Trusts be managed?

In December 2014, Professor Sir Liam Donaldson submitted his report "The Right Time; The Right Place: An expert examination of the application of health and social care governance arrangements for ensuring the quality of care provision in Northern Ireland" to the Department. The report was published on 27 January 2015.

Recommendation Seven of the Donaldson Report is concerned with the establishment of a Patient Safety Institute for Northern Ireland. This recommendation outlines eleven key functions on which the Institute should concentrate although other recommendations are also linked to the establishment of such an Institute. A particular focus of the body would support system transformation, building on the range of quality improvement and patient safety initiatives currently ongoing in the HSC which the proposed Institute should harness. This includes harnessing greater learning from Adverse Incidents and Serious Adverse Incidents.

This functional, analytical approach was appropriate in the context of the Donaldson Review however the broader context is that the health and care system is operating less than optimally and is in need of transformation. Transformation requires a system architecture which goes beyond analytics to establishing the necessary enablers for action.

Therefore, on 12 November 2015 in a speech to the Faculty of Medical Leadership and Management, the then Minister, Simon Hamilton, set out his vision for an Improvement Institute for Northern Ireland. The Institute would lead and provide support for a three-year rolling programme of projects ("A Northern Ireland Safety Programme") based on the eleven key Patient Safety functions outlined by

Donaldson in Recommendation 7 of his report. The programme would identify evidence based quality improvements to prevent/reduce levels of 'avoidable' patient/service user harm and ensure sustained regional implementation, improvement and learning to build safety resilience into the health and social care system.

Organisational models and funding for the establishment of an Improvement Institute are currently being explored by the Department.

Question 27

i. Have the milestones for the work of the Regional Learning System Project Team (set out at 348-010-005) been met?

The milestones set out in 348-010-005 were met by May 2015.

ii. Have recommendations for the future development of a Regional Learning System that were due at the end of September 2015 been made?

The recommendations were made in the final report of the Regional Learning System Project. The report was issued to the HSC on 26 August 2015.

iii. If so, where are they? If not, when will they be issued?

Recommendation Seven of the Donaldson Report is concerned with the establishment of a Patient Safety Institute for Northern Ireland. This recommendation outlines eleven key functions on which the Institute should concentrate although other recommendations are also linked to the establishment of such an Institute. A particular focus of the body would support system transformation, building on the range of quality improvement and patient safety initiatives currently ongoing in the HSC which the proposed Institute should harness. This includes harnessing greater learning from Adverse Incidents and Serious Adverse Incidents.

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Organisational models and funding for the establishment of an Improvement Institute are currently being explored by the Department.

Question 28

i. How (if at all) is this criticism by the Royal College of Anaesthetists being addressed?

Datix is a highly configurable and flexible system which can be tailored to suit the needs of individual HSC Trusts. The majority of HSC Trusts either have or are working towards implementation of DatixWeb. This web based version allows for incidents to be input to the system by the reporter at local level and by using a Dashboard module, allows users to easy access to standardised tables, graphs and other pictorial methods of displaying live data with very little knowledge required of the system.

The system can be set up with standard reports for users however these dashboards can be re-designed to meet the user's individual requirements. Dashboards are displayed at login and require no action from the user. They can include graphical pivot charts or listing reports and relate to live data within the system.

Whilst access to Datixweb allows users to conduct their own searches and run reports, HSC Trust Datix administrators can run regular reports for staff and provide ad hoc reports on request.

Question 29

i. Is the OECD's assessment to be factored into this 'reform'?

If the Ministerial announcement referred to was the one that was made on 4 November 2015, there are some significant passages that highlight the approach that has determined how these reforms are being taken forward. The clearer, sharper accountability will encompass organisations fulfilling their statutory duty of quality. The approach adopted pre dates publication of the OECD report by three months, but it proved a useful affirmation of that approach and is being factored into the reform programme.

Question 30

i. How is cooperation under that legislation in respect of SAIs and children being addressed, given the requirement at s.2 on arrangements and s.3 on the adoption of a strategy?

The relevant Government Departments, HSCB and Trusts cooperate to promote the well-being of children, including their physical and mental health. All SAIs relating to children are notified to senior managers from both the PHA and the HSCB who agree the most appropriate person to lead and co-ordinate the SAI management and follow up with the relevant reporting organisation; this includes all HSC organisations and will also apply to independent Community and Voluntary sector organisations

which are contracted by a HSC organisation. SAI reviews relating to maternity, children and young people, are considered by a team including midwifery, specialist public health nursing, medical consultants, child and family health and social care services, GPs and may also include participation from other agencies as deemed appropriate having regard to the incident and services involved. Reviews will include input from service users and /or their representatives to contribute to the identification of effective learning to improve the health and well-being of children young people and their families.

Governance arrangements include multi-agency forums that meet regularly where SAIs and learning from SAI reviews is considered and actions agreed to improve uni-disciplinary and multi-agency practice. The learning and recommendations from SAIs will be brought, as relevant and appropriate, into other strategic arenas concerned with and responsible for improvements to services for children's health and well-being.