C.4 Guidance and Clinical Audit Timeline and Explanatory Notes

Introduction

This paper links to submission C.3 and takes the form of a timeline showing how the development and audit of guidelines relates to critical events. Following the timeline are explanatory notes on each topic and Appendix 1 lists associated papers which are provided in a separate binder.

Key issues to note in this paper are:

- the development of the various sets of Parenteral IV Fluid Therapy guidance;
- clinical audits of the use of the wallchart and other guidance; and
- the introduction of Regional Prescription and Fluid Balance Charts.

Timeline for Standards, Guidance and Clinical Audit

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
	1988	The Clinical Resource Efficiency Support Team (CREST) established
	1989	Northern Ireland Regional Audit Advisory Committee (NIRAAC) set up
	1995	Regional Multi-professional Audit (RMAG) Group created
STOP **Adam Strain died**	1995, November	
STOP **Claire Roberts died**	1996, October	
	1999	National Institute for Clinical Excellence (NICE) established

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
Lucy Crawford died	2000, April	
	2001, April	Best Practice – Best Care (BPBC) launched for consultation
	2001	Social Care Institute for Excellence (SCIE) established
Raychel Ferguson died	2001, June	
	2001, August	CMO asked for a group to be convened to collate evidence
	2001, September	Hyponatraemia **working group established** and first meeting held
Mr Leckey informed Dept of death of Adam Strain in 1995. Contact established with Dr Ed Summer , Great Ormond Street	2001, December	
	2002, March	Guidance completed and issued to all Trusts
Inquest into Rachel Ferguson's death	2003, February	
	2003, February	Publication of HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
Links identified between Raychel's and Lucy's deaths and the likelihood of it being hyponatraemia related	2003, March	

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
Conor Mitchell (aged 15) died in RBHSC after transfer from Craigavon Area Hospital. He had significant physical disability and epilepsy and was admitted with general malaise and vomiting. PM indicated cerebral oedema but not the underlying cause.	2003, May	
	2003, June	CREST publishes guidance and wallchart - Management of Hyponatraemia in Adults
	2004	NI Regional Review of Clinical and Social Audit. Report issued 2005
	2004	DHSSPS establishes formal links with SCIE
Inquest into Lucy Crawford's death – concluded that causes of death were cerebral oedema, dilutional hyponatraemia and excess dilute fluid.	2004, February	
	2004, March	CMO writes to Trusts for assurance that her guidance of 2002 and the CREST guidance of 2003 has been implemented
Inquest into Conor Mitchell's death.	2004, June	
	2004, July	Letter from Dr Miriam McCarthy, Medical and Allied, DHSSPS to Dr Jenkins, Antrim Area Hospital re

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
		updating guidance on the Prevention of Hyponatraemia in Children. Responses were then received and a meeting held leading to CMOs letter of November 2004.
	2004, August	CMO receives a report on a regional audit conducted in 2003-04 to examine adherence to the 2002 guidance on prevention and management of hyponatraemia
UTV Insight programme, *When Hospitals Kill*, broadcast.	2004, October	
Claire Roberts' parents contact RBHSC following the UTV Insight programme. Review of case undertaken by Prof Ian Young who considered that hyponatraemia may have played a part in her death.	2004, October	
Angela Smith MP announces public inquiry.	2004, November	
	2004, November	CMO requests that a regional fluid therapy working group is set up to revise the extant guidance. The group undertakes the task during 2005
Claire Roberts' death reported to Coroner.	2004, December	

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
	2005, April	Establishment of the Regulation and Quality Improvement Authority
Inquiry suspended to allow PSNI investigations to be completed	2005, October	
	2006, March	Launch of Quality Standards for Health and Social Care
	2006, 21 April	Acting CMO, Dr Carson, issues guidance produced by regional fluid therapy working group to Trusts
Inquest into Claire Roberts' death.	2006, April	
	2006, July	Department establishes formal links with NICE
	2006, July	NI Audit and Guidelines Implementation Project set up
	2007	Guidelines and Audit Implementation Network (GAIN) established
	2007, April	National Patient Safety Alert (NPSA) 22 issued to Trusts via Circular HSC (SQS) 20/2007 on 27 April 2007
	2007, September	Paediatric Parenteral Fluid Therapy Wallchart finalised
	2007, October	Addendum to Circular HSC (SQS) 20/2007 covering the Paediatric Parenteral Fluid Therapy Wallchart issued on 16 October 2007

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
	2008	Adult Hyponatraemia group established – chaired by Prof Ian Young
	2008, February	GAIN receive first application for funding for an audit of IV fluid use in hospitalised children and certain aspects of the proposed audit were queried
	2008, March	Poster Size Wallcharts issued to HSC Trusts
	2008, April	RQIA Review of compliance with NPSA 22
	2008, May	GAIN send approval letter with caveats in response to re-submitted proposal for audit of IV fluids in hospitalised children with Appendicitis or Bronchiolitis. Final agreement in July following discussions.
Inquiry Reconvened. Chairman announces that the Inquiry will no longer investigate the circumstances surrounding Lucy Crawford's death but would be including the deaths of Conor Mitchell and Claire Roberts	2008, May	
Formal revision of the Terms of Reference to remove Lucy Crawford's name	2008, November	
GMC finds doctor Jarlath O'Donahoe (Lucy Crawford case) guilty of serious	2009, November	

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
professional misconduct.		
Inquiry leases Banbridge Courthouse	2009, November	
	2010, February	GAIN issues guidance "Hyponatraemia in Adults (on or after 16th birthday)"
	2010, February	DHSSPS endorses NICE CG84 (Diarrhoea and Vomiting Due to Gastroenteritis in Children Under 5) for application in the HSC
	2010, February	Paediatric Parenteral Fluid Therapy Wallchart revised to clarify age limits in title and re-issued
GMC finds no evidence of former CMO (Dr Henrietta Campbell) being involved in "a deliberate cover-up."	2010, May	
	2010, May	RQIA follow-up review of compliance with NPSA 22
High Court hears case brought by Bridget O'Rawe (former director of corporate affairs in Sperrin Lakeland Trust) against the Impartial Reporter newspaper for alleging her involvement in a cover-up. Mr Justice Gillen reserves judgement.	2010, November	
	2011	Rollout of standardised adult and paediatric fluid balance charts in Belfast HSC Trust. (Work also developing in other Trusts)

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
	2011, June	First meeting of regional fluid chart group which agreed to design, test and implement standardised regional fluid balance charts for adults and children
	2011, August	Initial incomplete draft report of audit of IV fluid use in hospitalised children with Appendicitis or Bronchiolitis received by GAIN
	2011, September	Department publishes revised process for endorsement and implementation of NICE Technology Appraisals and Clinical Guidelines
	2011, September	CMO writes to Chief Executive of NICE on behalf of UK CMOs to request that NICE consider developing guidance on IV fluid use in children
	2011, October	CMO writes to co-chair of National Quality Board on behalf of UK CMOs to request NICE develop guidelines and quality standards for IV fluid use in children
	2011, December	"Snapshot" (or pilot) audit of position on IV fluid use in hospitalised children commissioned by Department
	2011, December	National Quality Board writes to CMO to advise that NICE will develop guidance on IV fluid use in children
	2012	Report of "snapshot"(or pilot) audit of IV fluid use in hospitalised children received by GAIN
	2012, December	Final report of audit of IV fluid use in children hospitalised with

CRITICAL EVENTS	DATE	STANDARDS, GUIDELINES AND CLINICAL AUDIT
		Appendicitis or Bronchiolitis received by GAIN
	2013, January	Department forwards Audit Reports to IHRD
	2013, April	Paediatric Parenteral Fluid Therapy Wallchart revised to take account of GAIN recommendation and re-issued
	2013, July	Paediatric Parenteral Fluid Therapy Wallchart further revised and re-issued with correct title (Version dated June 2013)
	2013	At Departmental request, GAIN commence design of further audit of compliance with Paediatric Parenteral Fluid Therapy Wallchart and also add on fluid balance charts following regional roll-out
	2013, August	Fluid balance charts introduced regionally and letter issued from CMO supporting their introduction. Prescription and Fluid Balance Charts and Training Package were attached.
	2013, August	CMO issues letter to HSC Board, PHA, Trusts and HSC Special Agencies advising that NICE is recruiting for members of guideline development group on IV fluid therapy for children and young people in hospital

Explanatory Notes

Clinical Resource Efficiency Support Team (CREST)
The Clinical Resource Efficiency Support Team (CREST) was established in 1988

under the auspices of the DHSS (NI) Medical Advisory Structure. Its formation was at the instigation of the medical profession because of concerns about the increasingly competitive pressures on scarce health service resources. It was felt that it was vitally important to continue to maintain the highest possible standards of quality while recognising the need to take account of economic constraints and improve the cost effectiveness of the service. The CREST group comprised 18 health care professionals from health and personal social services in Northern Ireland with an active interest in promoting clinical efficiency. The Chairman was Professor Gary Love (deceased), Emeritus Professor of Medicine at Queen's University, Belfast.

In pursuing its work the medical profession in Northern Ireland was invited to suggest specific target areas and CREST then operated by commissioning small sub-groups or task forces to address agreed topics.
The Convenor of CREST was Dr Glenda Mock, Senior Medical Officer, DHSSPS.
CREST had the following terms of reference:

1. To promote clinical efficiency in the health service in Northern Ireland while ensuring that the highest possible standard of clinical practice is maintained;
2. To identify examples of good clinical practice in Northern Ireland, throughout the United Kingdom and elsewhere;
3. To disseminate ideas, examples of good practice in Northern Ireland and other relevant information to health care professionals in Northern Ireland;
4. To consider ways of encouraging new initiatives including the commissioning of further research; and
5. To evaluate on an ongoing basis what effect, if any, the group's activities and deliberations are having on the use of clinical resources in Northern Ireland.

By the time it was amalgamated with two other organisations to form GAIN, CREST had produced 51 pieces of guidance and associated resources for the HSC.

Northern Ireland Regional Audit Advisory Committee (NIRAAC)

The Northern Ireland Regional Audit Advisory Committee (NIRAAC) was set up in 1989 as a sub-committee of the Northern Ireland Council for Post-Graduate Medical and Dental Education (now the Northern Ireland Medical and Dental Training Agency). It organised audit of the smaller medical specialties on a regional basis in order to facilitate peer review.

In general, a specialty with 10 consultant staff or less was considered a smaller specialty and there were around 25 of those specialties in the four main areas of laboratory medicine, surgery, medical specialties and dentistry at the time.

NIRAAC also arranged for clinicians to undertake external peer review of particular problem services in what were HSS Boards and advised on and supported the development of audit across Northern Ireland.

NIRAAC was chaired by Dr Tom Trinick and had a budget of £40k which was used to fund audit activity. Secretariat was provided by NIMDTA.

Regional Multi-professional Audit Group (RMAG)

The Regional Multi-professional Audit Group (RMAG) was created in 1995 under the auspices of the Management Executive to foster and encourage multi-professional audit to complement the already established uni-professional audit initiative.

Multi-professional audit is a process in which all relevant health and social care staff review and where necessary make changes to, the care and treatment they provide. Its primary aim is to improve the quality of care.

RMAG's Terms of Reference were:

1. To promote and co-ordinate the development of multi-professional audit in Northern Ireland;
2. To advise the HSS Executive on all issues relating to multi-professional audit including selection of regional topics for audit;
3. To act as an information resource and to develop a database of audit projects and examples of good practice to be shared between professions;
4. To advise on projects which should receive regional funding; and
5. To advise on education and training.

National Institute for Health and Care Excellence (NICE)

As of 1 April 2013, NICE is a Non Departmental Public Body tasked with producing national guidance on the promotion of good health and the prevention and treatment of ill health, as well as a new responsibility for developing guidance and quality standards in social care for England.

The Institute was established in 1999 as a Special Health Authority with the remit to promote clinical excellence and the effective use of resources for people using the NHS in England and Wales.

NICE produces a range of guidance including:

- *Technology Appraisals* where NICE determines whether or not a drug, medical device or surgical procedure should be funded by the NHS, based on its cost-effectiveness;
- *Clinical Guidelines* on the management of specific diseases and groups of patients;
- *Public Health Guidance* covers the promotion of good health and the prevention of ill health; and
- *Interventional Procedures Programme* assesses the safety and efficacy of new interventional procedures. England, Wales, Scotland and Northern Ireland are full participants in this programme.

Apart from the Interventional Procedures Programme, NICE guidance is written for implementation in England; it does not automatically apply in NI and requires review before endorsement for use in HSC.

The Department established formal links with NICE on 1 July 2006 whereby guidance (generally Technology Appraisals and Clinical Guidelines) published by the Institute from that date, would be locally reviewed for applicability to Northern Ireland and where appropriate, endorsed for implementation in the HSC. A new process for the endorsement, implementation, monitoring and assurance of NICE Technology Appraisals and Clinical Guidelines in NI came into effect on 28 September 2011, and is set out in circular HSC (SQSD) 04/11 which can be accessed via the Department's website at: http://www.dhsspsni.gov.uk/index/phealth/sqs/sqsd-guidance/sqsd-guidance-nice-guidance.htm.

Relevant policy and professional staff in the Department check each technology appraisal and clinical guideline to ensure that it is applicable to the legal and policy context in NI. When endorsed on the DHSSPS website there are links to any caveats explaining the relevant legal and policy context in NI. On rare occasions a particular section or all of a piece of guidance may be excluded from endorsement because it would be illegal in NI. It should be noted that NICE does not allow its actual guidance to be amended for example to include the NI legal and policy context.

The Department is currently reviewing the extant process in order to reduce bureaucracy and allow Trusts to begin implementation of NICE Guidance sooner. If agreed, a new circular will be issued to update and replace circular HSC (SQSD) 04/11.

The next development planned relates to public health and will be a process for the local endorsement, implementation, monitoring and assurance of Public Health Guidance. From preliminary work this process may be similar to that for Clinical Guidelines.

The Department has consulted the HSC and is reviewing responses on a new circular outlining a process for local participation in the Interventional Procedures Programme, as well as the dissemination of Interventional Procedure Guidance to the HSC and other relevant bodies.

In order to support the implementation of NICE guidance, the Department funds NICE to provide a NICE Implementation Facilitator to work in NI. The post has been filled since October 2012.

The NICE website gives more detail about its work:

www.nice.org.uk

Best Practice – Best Care (BPBC)

The Northern Ireland Executive's first Programme for Government included in its chapter "Working Together for a Healthier People", a commitment to put in place a framework to raise the quality of services provided to the community and tackle issues of poor performance. This Framework was set out in Best Practice – Best Care (BPBC) which was issued for consultation in April 2001. It focused on developing and disseminating clear service standards for health and personal social services, local accountability for the delivery of services and improving monitoring and regulation of services.

BPBC laid the foundations for a number of initiatives in standard setting including:

- The establishment of Safety, Quality & Standards Directorate within DHSSPS as a single, easily accessible source of the production and dissemination of standards and guidelines;
- The introduction of Service Frameworks;
- The establishment of formal links with NICE and SCIE and the subsequent process of departmental endorsement of NICE guidance for use in the HSC;
- The creation of the Guidelines and Audit Implementation Network (GAIN) as a single, regional body to facilitate regional audit and guideline development for the HSC; and
- The establishment of the RQIA and the suite of regulated services with corresponding regulations and minimum standards.

A summary of the responses to the consultation can be found at:

www.dhsspsni.gov.uk/bestpractice2002.pdf

Social Care Institute for Excellence (SCIE)

The Social Care Institute for Excellence (SCIE) is a charity which was established by Government in 2001 to improve social care services for adults and children in the United Kingdom. It achieves this by identifying good practice and helping to embed it in everyday social care provision.

SCIE works to:

- Identify and analyse knowledge about social care provision;
- Create and disseminate knowledge-based good practice guidance;
- Involve service users, practitioners, providers and policy makers in advancing and promoting good practice in social care; and
- Enhance the skills and professionalism of social care workers through tailored, targeted and user-friendly resources.

SCIE provides a range of products and services for the social care sector including:

- Practical guides on major issues in social care and social work;
- eLearning resources;
- An online Social Care TV channel;
- A database of good practice examples;
- Briefings on developing research;
- Self-assessment tools;
- A comprehensive database of information (Social Care Online);
- Tailored training and consultancy services;
- Implementation support;
- (From April 2013) senior partner in the NICE Collaborating Centre for Social Care.
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Formal links between DHSSPS and SCIE were established in 2004 and the Northern Ireland Practice Development Manager was introduced in February 2010.

SCIE's website provides more detail on its work:

www.scie.org.uk

Guidance issued to HSC – Prevention of Hyponatraemia in Children – March 2002
Following the death of Raychel Ferguson in 2001, the then CMO Dr Campbell discussed the case with the then Directors of Public Health and agreed that guidelines in respect of the use of IV fluids in children and the risk of hyponatraemia should be developed. In August 2001, CMO requested that a working group be set up under the chairmanship of the then DCMO Dr Paul Darragh to produce this regional guidance. Invitations were issued to: • Dr B Taylor, Royal Belfast Hospital for Sick Children; • Dr D Lowry, Craigavon Area Hospital; • Dr G Nesbitt, Altnagelvin Hospital; • Mr G Marshall, Erne Hospital; • Mr B McCallion, Royal Belfast Hospital for Sick Children; • Dr F Kennedy, Northern Health and Social Services Board; • Dr C Loughrey, Belfast City Hospital; • Ms E McElkerney, Ulster Hospital; • Dr P Crean, Royal Belfast Hospital for Sick Children; and • Dr J Jenkins, Antrim Area Hospital. Dr M McCarthy and Dr M Mark from DHSSPS were also part of the group. A smaller sub-group, chaired by Dr McCarthy was set-up to produce the guidelines and these were drafted and refined during the period from October 2001 to February 2002. The guidance was endorsed by CREST, although not issued under its banner. The guidance was produced in the form of an A2-sized wallchart. On 25 March 2002, Dr Campbell issued a letter to the service advising of the new guidance and stating that fluid protocols should be developed locally to complement the guidance and provide more specific direction to junior staff. The letter stated that the wallchart should be prominently displayed in all units that might accommodate children. The wallchart was issued by Dr Campbell the following day, the 26th March 2002.
HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003
The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 created the legal framework for raising the quality of health and social care services in Northern Ireland and extended regulation and

quality improvement to a wide range of establishments and agencies. The Order also introduced a statutory duty of quality to be placed on HSS Boards, HSS Trusts and some special agencies with regard to services they provide.

In April 2005, the Regulation and Quality Improvement Authority (RQIA) was established as a non-departmental public body of the DHSSPS as the regulator of health and social care services in Northern Ireland. RQIA has responsibility under Part III of the Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 to regulate (register and inspect) a wide range of services delivered by HSC bodies and by the independent sector. RQIA discharges its regulatory functions in accordance with the relevant statutory Regulations and the Minimum Care Standards published by DHSSPS.

CREST Guidance issued – Management of Hyponatraemia in Adults – June 2003

In June 2003, CREST issued guidance on the management of hyponatraemia in adults. The guidance, which had been developed by a sub-group under the chairmanship of Dr Clive Russell (a consultant physician, Tyrone County Hospital) was accompanied by a wallchart.

The guidance and wallchart can be found at:

www.gain-ni.org/images/Uploads/Guidelines/hyponatraemia_mainreport.pdf

www.gain-ni.org/images/Uploads/Guidelines/hyponatraemia_wallchart.pdf

This guidance was superseded when GAIN issued updated guidance in February 2010.

CMO writes to Trusts for assurance that her guidance of 2002 and the CREST guidance of 2003 has been implemented – 4 March 2004

On 4 March 2004, Dr Campbell wrote to the Chief Executives of Acute Trusts seeking assurances that the 2002 guidance on the prevention of hyponatraemia in children and the 2003 CREST guidance on management of hyponatraemia in adults had been incorporated into clinical practice and that their implementation had been monitored.

This was followed up by a reminder to Trusts who had not replied, by a letter from Dr McCarthy in November 2004.

CMO receives report on a regional audit carried out to examine adherence to the 2002 guidelines in the eight paediatric units in NI – August 2004

In August 2004, Dr Campbell received a report on a regional audit carried out to examine adherence to the 2002 guidelines in the eight paediatric units in NI.

The report was written by Dr Jarlath McAloon (then Consultant Paediatrician, Antrim Hospital) and Raj Kottyal (then Senior House Officer, Antrim Hospital). Dr McAloon presented these findings to SAC Paediatrics in October 2004.

Regional Fluid Therapy Working Group – 2004 - 2006

In July 2004, Dr Miriam McCarthy, Medical and Allied, DHSSPS wrote to Dr Jenkins, Antrim Area Hospital re updating guidance on the Prevention of Hyponatraemia in Children. Dr Jenkins and other copy recipients responded and a meeting was held to consider the way forward. As a result Dr Campbell requested in her letter of November 2004 that a working group be established to revise extant guidance. Following this, a Regional Fluid Therapy Working Group was set-up. This group was chaired by Dr McAloon and a new guideline was produced and sent to the Department in 2006.

Dr Ian Carson then acting CMO then circulated the new guideline on 21 April 2006.

DHSSPS later requested that the Regional Group review the revised 2006 Regional Guidance in light of NPSA Safety Alert 22 and this culminated in the 2007 revision that has since had minor amendments as set out below.

Northern Ireland Regional Review of Clinical and Social Audit – 2004

The NI Regional Review of Clinical and Social Audit was tasked with making recommendations to the Department on future arrangements for the support of clinical and social care audit in Northern Ireland to support the agenda set out in *Best Practice-Best Care*. A range of key stakeholders were involved in the review including NIPEC, the two audit bodies (NIRAAC & RMAG), DHSSPS and the NI Medical and Dental Training Agency.

The review, which was chaired by Dr David Stewart, reported to the Department in

January 2005. One of the key findings was the need for a single regional audit focus, in place of the two current committees – RMAG and NIRAAC. The review concluded that the different roles of the audit groups were unclear and led to confusion and fragmentation of effort. It recommended that a single regional audit focus would help to ensure more effective development of clinical and social care audit in Northern Ireland.

Quality Standards for Health and Social Care – 2006

The HPSS (Quality, Improvement and Regulation) (Northern Ireland) Order 2003 (the 2003 Order), introduced a statutory duty of quality on the services commissioned and provided by the (then HSS) Boards and Trusts. Post RPA, this statutory duty remains in place and in 2006 the Quality Standards for Health and Social Care were published.

The standards have five key quality themes:

- Corporate leadership and accountability of organisations;
- Safe and effective care;
- Accessible, flexible and responsive services;
- Promoting, protecting and improving health and social well being; and
- Effective communication and information.

The Quality Standards are used by RQIA in their assessment of the quality of care delivered by the HSC.

The standards can be found at:

www.dhsspsni.gov.uk/qpi_quality_standards_for_health___social_care.pdf

NI Audit and Guidelines Implementation Project – 2006

Following the NI Review of Clinical and Social Audit, CREST, NIRAAC and RMAG agreed, by June 2006 to work together to establish a single focus for regional audit - integrated with Northern Ireland clinical guidelines development.

The NI Audit and Guidelines Implementation Project was then established in July 2006, under the leadership of Dr Mock (Principal Medical Officer, DHSSPS) and with representation from CREST, the audit bodies, the Department and RQIA.

The aim of the project was to recommend future arrangements to support clinical efficiency and audit in the HPSS. Its objectives were to:

- Develop recommendations for an integrated structure and governance/organisational arrangements for the future development of clinical guidelines and the support of audit across the HPSS – to replace the current CREST and audit committees;
- Establish a framework and mechanisms to ensure that clinical and social care audit projects, guidelines development and implementation are undertaken effectively and deliver real service benefit; and
- Ensure the new group sits appropriately with Review of Public Administration structures and is linked appropriately to the DHSSPS (NICE) guidance process, RQIA and the educational bodies.

Establishment of Guidelines and Audit Implementation Network (GAIN) - 2007

GAIN was formally established as a partnership body of the Department in 2007. Standards and Guidelines Quality Unit provides sponsorship for GAIN which is housed in Castle Buildings and staffed by personnel on HSC terms and conditions.

GAIN receives programme funding of around £400k each year to carry out regional audit and produce local guidelines for the HSC where no such national (such as NICE) guidance exists.

GAIN is expected to comply with its Management Statement, Financial Memorandum and Statement of Purpose which can be found on their website at:

www.gain-ni.org/index.php/structure-and-governance/governance/governance-documents

GAIN aims to support achievement of high quality health and social care through:

- The development and dissemination of best practice clinical and social care guidance where important gaps have been identified;
- Audit to assure implementation of these and other guidance;
- The survey and reporting on user assessments of medical devices; and
- The provision of training for specific relevant skills.

GAIN is also involved in audit to support the implementation and monitoring of Service Frameworks.

Since its inception in 2007, GAIN has completed 21 guidelines and 42

audits.

Information about GAIN can be found on its website at:

www.gain-ni.org

Paediatric Parenteral Fluid Therapy Wallchart dated September 2007 (Revised 2010 and 2013)

Dr McAloon had chaired a group that produced guidance for IV Fluid Therapy in children which was sent to the Service in 2006. As a result of the recommendation in NPSA 22 that local guidance on the use of IV fluids in children should be issued, CMO asked the group to look again at their guidance and see if it needed to be updated in light of the NPSA guidance.

The new guidance was issued in the form of a wallchart to be placed in all areas where children may be treated in hospitals and the September 2007 version was sent out as an addendum to circular HSC (SQS) 20/2007 on 16 October 2007.

In November 2007, DHSSPS and NI Medical and Dental Training Agency representatives met to discuss related training issues.

Poster size Wallcharts were printed and forwarded to HSC Trusts in March 2008.

In 2010, the wallchart was revised to amend the title of the chart to "Parental Fluid Therapy for Children & Young Persons (aged over 4 weeks & under 16 years)". This was a clarification of the age limits.

In 2013, as a result of the findings of the GAIN audit in IV fluid use in hospitalised children, the wallchart was amended again to update the references to "plasma glucose" testing to "glucose" testing to reflect the fact that such tests could be done at the point of care rather than through a laboratory i.e. it was no longer routinely a plasma glucose test.

The charts were re-printed and re-issued to Trusts, but due to an error in the title, where the wording had reverted back to the 2007 version, had to be further re-issued in July 2013.

After the RQIA 2008 review, the Western HSC Trust sought clarification that the regional wallchart could be modified to reflect the IV fluids used as per the Trust policy. RQIA considered that the modified wording was appropriate in this circumstance. All Trusts except the Western HSCT received re-issued copies of the wallcharts in July 2013. The Western HSCT

received a pdf copy of the chart for them to modify and display on their sites.

GAIN Audits of IV Fluid Use in Hospitalised Children – 2008, 2011

In February 2008, GAIN received an application for funding for an audit of IV fluid use in hospitalised children. The proposal was submitted by Dr Mike Smith, Consultant Paediatrician at Antrim Area Hospital on the foot of the 2007 guidance for IV fluid use in children. Following consideration by the GAIN Operational Committee, GAIN wrote to Dr Smith with queries on some aspects of the application and asked him to resubmit his proposal addressing these issues. This was done and GAIN subsequently awarded funding of £16930 for the completion of the audit. GAIN wrote with a conditional approval of funding dependent on acceptance of the caveats in a letter dated May and following discussion the official approval is recorded as July 2008.

The audit focused on children hospitalised with appendicitis and bronchiolitis – two conditions that can pose a high risk of hyponatraemia. There were several delays with the completion of the audit due to long-term staff illness and the pressures of other clinical work (HSC staff carry out work on GAIN projects in addition to their clinical commitments and receive no personal financial redress for this).

When an initial but incomplete report was received in the Department in August 2011, it was decided to commission a further snapshot audit of compliance with the wall chart guidance on paediatric parenteral fluid therapy in children aged 4 weeks to 16 years cared for in non-specialist settings. The purpose of the audit was to assess the situation using the most up-to-date data and evaluate the position for children admitted with **any** condition requiring IV fluid as part of their treatment and not only those with appendicitis or bronchiolitis. As per the wall chart guidance, this audit excluded children cared for in specialist settings such as Intensive Care Units and those with liver, renal or cardiac diseases.

During this period and up until December 2012, work was ongoing on quality assuring and analysing the data of the original report and both reports were issued to the Inquiry in January 2013.

A query has been raised about the handling of cases with diabetic Keto acidosis as they should have been excluded since their treatment would have followed separate guidance. It is possible that this could have over estimated the issues encountered and is a factor to be considered in the design of the new planned audit.

Department endorses NICE Clinical Guideline No 84 – Diarrhoea and Vomiting Due to Gastroenteritis in Children Under 5 for application in Northern Ireland – February 2010

NICE issued this guidance in April 2009. Following the procedures in place at the time, the Department subjected the guidance to local scrutiny to ensure it met the conditions for endorsement in Northern Ireland.

The guidance was endorsed for application in Northern Ireland on 12 February 2010 including a caveat stating that "Where this guidance refers to the management of IV fluids, clinicians should apply the guidance in the wall chart on Parenteral Fluid Therapy for Children and Young Persons aged Over 4 Weeks and Under 16 Years."

The letter of endorsement can be found at:

www.dhsspsni.gov.uk/hsc-2010-01-cg84.pdf

The NICE guidance and supporting documentation can be found at:

http://guidance.nice.org.uk/CG84

The guidance was reviewed by NICE in 2012 and it was decided not to update the guidance at that point.

Development of GAIN Guidance - Hyponatraemia in Adults (on or After 16th Birthday) – February 2010

In 2008, a group was established to develop updated guidance in relation to Hyponatraemia in Adults.

The group was made up of HSC staff as below:

Chairman

- Professor Ian Young, Consultant Clinical Chemist, Belfast HSC Trust

Members

- Dr Peter Crean, Consultant Paediatric Anaesthetist, Belfast HSC Trust;
- Dr Kieran Fitzpatrick, Consultant Anaesthetist, Belfast HSC Trust;
- Dr Julian Johnston, Consultant Anaesthetist, Belfast HSC Trust;
- Dr Paul Loan, Consultant Anaesthetist, Northern HSC Trust;
- Dr Clodagh Loughrey, Consultant Clinical Chemist, Belfast HSC Trust;
- Professor Peter Maxwell, Consultant Nephrologist, Belfast HSC Trust;
- Dr Brian Mullan, Consultant Anaesthetist, Belfast HSC Trust;

- Professor Gary McVeigh, Consultant Physician, Belfast HSC Trust;
- Nicola Porter, Guideline & Audit Manager, GAIN.

The guideline can be found on the GAIN website at:

http://www.gain-ni.org/images/Uploads/Guidelines/Hyponatraemia_guideline.pdf

This guidance will be superseded when NICE issues its guidance on the topic. We expect this to be published in November 2013.

Development of NICE Guidance on IV Fluid Use in Children – September 2011 - present

Following a meeting of the four UK CMOs in September 2011, it was agreed that Dr McBride should write to the Chief Executive of NICE, Sir Andrew Dillon, to request that the Institute consider the development of UK guidance on IV fluid therapy for children. This letter was issued on 20 September 2011 and was followed up by a letter to Professor Sir Bruce Keogh, NHS Medical Director and co-chair of the National Quality Board, to bring the request to his direct attention.

On 29 December, Professor Sir Bruce replied to Dr McBride advising that the topic of IV fluids in children would be referred to NICE to take forward.

NICE is currently in the process of developing the guideline and expects it to be published by November 2015. This will produce consistent national best practice guidance. On 5 August, CMO wrote to the HSC advising that NICE were recruiting members to the guideline development group and encouraging participation from clinicians.

Further information on the development of the guideline can be found on the NICE website at:

http://guidance.nice.org.uk/CG/Wave0/655

Development of Fluid Balance Charts for Regional Use – 2011 - present

In March 2012, Dr Julian Johnston of the Belfast HSC Trust advised the Department of on-going work between Trusts to develop and regionally roll-out a unified fluid prescription and balance chart (one variant for adults and one for children). In 2011, a group had been convened to design, test and implement such charts on a regional basis.

It was anticipated that this unified chart would result in:

- Significant safety aspects to fluid prescribing and administration;
- A real benefit in reducing the incidence of Hyponatraemia;
- Safer prescribing for the young person in an adult ward;
- Safer transfer of patients between Trusts;
- Simpler, easier and better training of doctors and nurses province wide in fluid prescription practice; and
- Potential cost savings because there will be 2 charts instead of the 13+ in use at the time across Trusts.

Dr Johnston requested that a regional pilot of the charts be facilitated, a training package be developed for their use and a resource identified to cover the costs of funding the printing of the charts.

The development of the training package as well as the identification of the resources for the printing of the charts took place during 2012-13.

On 1 August 2013, CMO and CNO issued a circular to the HSC (HSS(MD)30/2013) endorsing the use of the charts and requesting that Chief Executives make resources available to allow for the roll-out of training for staff.

At Departmental request, GAIN commenced design of a new audit of compliance with wallchart guidance and also added use of new prescription and fluid balance charts - 2013

On the foot of the GAIN audits of 2008 and 2011 of IV fluid use in hospitalised children and as part of the Department's response to the recommendations contained therein, CMO requested that a new audit be designed by the key experts in GAIN to provide a large enough sample to look at detailed issues and covering all children within the scope of the guidance.

The planned prospective rolling audit is to commence as soon as possible but no sooner than 4 weeks after the regional prescription and fluid balance chart has been implemented in all Trusts. There are to be interim reports after 3 and 6 months' data collection as well as the full report at the end of the audit period (possibly about 1 year). If there are any significant emerging findings from the audit of practice which do not meet the standards identified they will be highlighted to Trusts and remedial action taken urgently.

The initial plan for the audit has altered since it was thought to be more useful to also

examine the quality and functionality of the new prescription and fluid balance charts. The parameters of the audit have not yet been settled, but it is anticipated that it would look at areas including the use of the correct prescription and fluid balance chart when children are cared for in an adult setting as well as staff performance in using the charts correctly.

18 September 2013

Appendix 1

Index of Associated Papers – Guidelines and Clinical Audit

Number		Date
1	Letter from John McGrath, DHSSPS to HSS Organisations re: Launch of Best Practice – Best Care: A Framework for Setting Standards, Delivering Services and Improving Monitoring and Regulation in the HPSS Consultation	11/04/2001
2	Letter from Dr Henrietta Campbell, Chief Medical Officer, DHSSPS to Chief Executives of Acute and Community Trusts re: Prevention of Hyponatraemia in Children	25/03/2002
3	Letter from Dr Henrietta Campbell, Chief Medical Officer, DHSSPS to Chief Executives of Acute and Community Trusts re: Prevention of Hyponatraemia in Children Posters	26/03/2002
4	The Health and Personal Social Services (Quality, Improvement and Regulation) (Northern Ireland) Order 2003	2003
5	Publication of CREST Guidance and Wall Chart – Management of Hyponatraemia in Adults	June 2003
6	Letter from Dr Henrietta Campbell, Chief Medical Officer, DHSSPS to Chief Executives of Acute and Community Trust re: Prevention and Management of Hyponatraemia	04/03/2004
7	Trust responses to Dr Henrietta Campbell's letter dated 04/03/2004	
8	Letter from Dr Miriam McCarthy, Medical and Allied, DHSSPS to Dr Jenkins, Antrim Area Hospital re: Guidance on the Prevention of Hyponatraemia in Children, and related responses	05/07/2004
9	Letter from Dr Jarlath McAloon, United Hospitals Trust to Dr Henrietta Campbell, DHSSPS – Findings from Prevention and Management of Hyponatraemia Guidance Regional Audit	02/08/2004
10	Letter from Dr Miriam McCarthy, DHSSPS re: Follow-up action in relation to Dr Henrietta Campbell's letter dated 04/03/2004	November 2004
11	Letter from Dr Henrietta Campbell, Chief Medical Officer, DHSSPS to Dr Jarleth McAloon, Consultant Paediatrician, Antrim Area Hospital commissioning the development of a Care Pathway for Fluid Management	05/11/2004
12	Final Report on the Northern Ireland Regional Review of Clinical and Social Care Audit	January 2005
13	Quality Standards for Health and Social Care – Supporting Good Governance and Best Practice in the HPSS	March 2006
14	Letter from Dr Ian Carson, Acting Chief Medical Officer, DHSSPS to HSS Trust Chief Executives issuing	21/04/2006

	Guidelines on the Prevention of Hyponatraemia in Children	
15	Letter from Dr Glenda Mock, Medical and Allied Branch, DHSSPS re: The Review of Clinical Audit and CREST	14/06/2006
16	Letter from Noel McCann, Director of Planning and Performance Management Directorate, DHSSPS to HSS Organisations re: Implementation of National Institute for Health and Clinical Excellence Guidance in the HPSS	30/06/2006
17	HSC (SQSD) 20/07 - Letter from Dr Michael McBride, Dr Norman Morrow and Mr Martin Bradley, DHSSPS to Health and Social Care Organisations re: National Patient Safety Alert (NPSA) 22	27/04/2007
18	HSC (SQSD) 20/07 Addendum - Letter from Dr Michael McBride, Dr Norman Morrow and Mr Martin Bradley, DHSSPS to Health and Social Care Organisations re: Paediatric Parenteral Fluid Therapy Wall chart - issued	16/10/2007
19	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to HSC Organisations re: The Establishment of Guidelines and Audit Implementation Network (GAIN)	19/10/2007
20	GAIN Funding Proposal from Dr Mike Smith seeking funding to carry out an audit on IV Fluid Use in Hospitalised Children Guidance issued in 2007	February 2008
21	Letter from GAIN to Dr Mike Smith re: application for funding for an audit of IV fluid use in hospitalised children – Returned to author with queries	February 2008
22	Letter from Dr Maura Briscoe, Office of the Chief Medical Officer, DHSSPS to HSC Organisations re: HSC (SQSD) 20/07 – NPSA Patient Safety Alert 2. Letter informs HSC Organisations that the 2002 Wall Chart will now be replaced	05/03/2008
23	RQIA Independent Review: Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children. Summary Report following Validation Visits to Trusts and Independent Hospitals throughout Northern Ireland	April 2008
24	Re-submitted GAIN Funding Proposal from Dr Mike Smith seeking funding to carry out an audit on IV Fluid Use in Hospitalised Children Guidance issued in 2007	May 2008
25	Letter from GAIN to Dr Mike Smith re: Successful funding application to carry out an audit on IV Fluid Use in Hospitalised Children Guidance issued in 2007(with caveats)	May 2008
26	Revised Paediatric Parenteral Fluid Therapy Wall Chart – Re-issued	February 2010
27	GAIN Guidance – Hyponatraemia in Adults (on or After 16th Birthday)	February 2010
28	HSC (SQSD) (NICE) 01/10 CG84 – Letter from Dr Michael Mc Bride, Chief Medical Officer, DHSSPS to HSC Organisations re: DHSSPS Endorsement of NICE Clinical	12/02/2010

	Guideline 84 (Diarrhoea and Vomiting Due to Gastroenteritis in Children Under 5) for application in the HSC	
29	GAIN Governance Documentation • Management Statement • Financial Memorandum • Statement of Purpose	02/07/2010
30	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to HSC Organisations re: RQIA Follow-up Review – Reducing the Risk of Hyponatraemia when Administering Intravenous Infusions to Children	16/08/2010
31	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to Sir Andrew Dillon, Chief Executive, National Institute for Health and Clinical Excellence re: Intravenous Fluids in Children. CMO requests that NICE consider developing guidance on IV fluid use in children	20/09/2011
32	HSC (SQSD) 04/11 - Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to HSC Organisations re: NICE Technology Appraisals and Clinical Guidelines – New Process for Endorsement, Implementation, Monitoring and Assurance in Northern Ireland	26/09/2011
33	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to Professor Sir Bruce Keogh, NHS Medical Director re: Intravenous Fluids in Children. Letter on behalf of UK CMOs to request NICE develop guidelines and quality standards for IV fluid use in children	07/10/2011
34	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to Chief Executives and Medical Directors of HSC Trusts Commissioning a snapshot Audit of Position on IV Fluid Use in Hospitalised Children.	06/12/2011
35	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to Professor Sir Bruce Keogh, NHS Medical Director re: Intravenous Fluids in Children. CMO acknowledges that NICE will develop guidance on IV fluid use in children	05/01/2012
36	GAIN Pilot Audit Report - Guidance on Parenteral Fluid Therapy for Children and Young Persons Aged Over 4 Weeks and Under 16 Years	December 2012
37	GAIN Report - Final report of audit of IV fluid use in children hospitalised with Appendicitis or Bronchiolitis received by GAIN	December 2012
38	Letter from Dr Paddy Woods, Deputy Chief Medical Officer, DHSSPS to Mr John O'Hara re: GAIN Audit Report on IV Fluid Use on Hospitalised Children in Northern Ireland	10/01/2013
39	Revised Paediatric Parenteral Fluid Therapy Wall Chart and letters issued to HSC Trusts	29/07/2013
40	HSS (MD) 30/2013 – Letter from Dr Michael McBride to HSC Trust Chief Executives re: Regional Fluid	01/08/2013

	Prescription and Balance Charts – Charts attached	
41	Letter from Dr Michael McBride, Chief Medical Officer, DHSSPS to Chief Executives of HSC Organisations re: NICE Guideline Development Group Members: IV Fluid Therapy for Children and Young People in Hospital. • NICE Scoping Document Attached	05/08/2013