NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

HEALTH AND SOCIAL CARE DIRECTORATE

QUALITY STANDARD CONSULTATION

SUMMARY REPORT

1 Quality standard title

Intravenous fluid therapy in children and young people in hospital

Date of Quality Standards Advisory Committee post-consultation meeting:
22 June 2016

2 Introduction

The draft quality standard for intravenous fluid therapy in children and young people in hospital was made available on the NICE website for a 4-week public consultation period between 26 April and 24 May 2016. Registered stakeholders were notified by email and invited to submit consultation comments on the draft quality standard. General feedback on the quality standard and comments on individual quality statements were accepted.

Comments were received from 8 organisations, which included service providers, national organisations, professional bodies and others.

This report provides the Quality Standards Advisory Committee with a high-level summary of the consultation comments, prepared by the NICE quality standards team. It provides a basis for discussion by the Committee as part of the final meeting where the Committee will consider consultation comments. Where appropriate the quality standard will be refined with input from the Committee.

Consultation comments that may result in changes to the quality standard have been highlighted within this report. Comments suggesting changes that are outside of the process have not been included in this summary. The types of comments typically not included are those relating to source guidance recommendations and suggestions for non-accredited source guidance, requests to broaden statements out of scope, requests to include thresholds, targets, large volumes of supporting information, general comments on the role and purpose of quality standards and requests to change NICE templates. However, the Committee should read this summary alongside the full set of consultation comments, which are provided in appendix 1.

3 Questions for consultation

Stakeholders were invited to respond to the following general questions:

1. Does this draft quality standard accurately reflect the key areas for quality improvement?

2. Are local systems and structures in place to collect data for the proposed quality measures? If not, how feasible would it be for these to be put in place?

3. Do you have an example from practice of implementing the NICE guideline(s) that underpins this quality standard? If so, please submit your example to the NICE local practice collection on the NICE website. Examples of using NICE quality standards can also be submitted.

4. Do you think each of the statements in this draft quality standard would be achievable by local services given the net resources needed to deliver them? Please describe any resource requirements that you think would be necessary for any treatment. Please describe any potential cost savings or opportunities for disinvestment.

Stakeholders were also invited to respond to the following statement specific questions:

1. For draft quality statement 4: This statement is published in the IV fluid therapy in adult's quality standard 66. Is this an area for quality improvement for children and young people as well?

4 General comments

The following is a summary of general (non-statement-specific) comments on the quality standard.

- Clarity needed over the population, QS title refers to children and young people but some of the statements are relevant for neonates.
- Highlight the terms defined in the introduction e.g. resuscitation.
- Query over the term 'competencies' and the different requirements needed by staff depending on how often they treat children and young people.

Consultation comments on data collection

- Stakeholders highlighted that resources for data collection may not be available in all trusts.
- Important to ensure that any data is retrieved in a meaningful manner to allow benchmarking and demonstrate measures in improvements.

5 Summary of consultation feedback by draft statement

5.1 Draft statement 1

Children and young people receiving intravenous (IV) fluid therapy have their fluid balance and electrolyte status assessed.

Consultation comments

Stakeholders made the following comments in relation to draft statement 1:

- There is no reference to how often electrolytes should be checked.
- Estimating body weight can be difficult and suggest including how to estimate body weight to ensure consistency.
- The use of a standard chart is important and including examples would be helpful.
- The reference of the standardised fluid balance chart in the rationale and commissioner audience descriptor is confusing.
- Electronic prescribing, charts and notes already capture the information that would be included in the standardised charts.
- Audit measures could be the number of children who have serum sodium levels outside normal range.
- It would be useful to identify which measures from the definitions were not being captured for example daily blood sampling and if this correlates with morbidity.

5.2 Draft statement 2

Children and young people receiving IV fluids for fluid resuscitation are not given hypotonic fluids or glucose-containing fluids.

Consultation comments

Stakeholders made the following comments in relation to draft statement 2:

- Statement should be phrased in the positive rather than the negative to encourage the correct use of the right fluid.
- Felt this was already standard practice and therefore queried whether it should be a statement.

- Rationale highlights the late signs of hyponatraemia but should it also reference the earlier signs including headache, nausea, vomiting
- Statement could be audited with ease.

5.3 Draft statement 3

Children and young people receiving IV fluids for routine maintenance are not given hypotonic fluids as the initial fluid.

Consultation comments

Stakeholders made the following comments in relation to draft statement 3:

- Statement should be phrased in the positive rather than the negative to encourage the correct use of the right fluid.
- The statement does not allow for exceptions for example those with rare inherited metabolic disorders who may require high levels of glucose (10%).
- The use of glucose containing solutions is embedded in paediatric practice for maintenance and glucose may be delivered in an isotonic or hypotonic solution. While there is no evidence to support the use of glucose for routine initial maintenance in most children it is accepted that this practice is likely to continue.
- Rationale highlights the late signs of hyponatraemia but not the earlier signs including headache, nausea, vomiting.
- Helpful if data collection could capture glucose usage as well as the use or otherwise of hypotonic solutions.

5.4 Draft statement 4

Hospitals have an IV fluids lead who has overall responsibility for training, clinical governance, audit and review of IV fluid prescribing, and patient outcomes.

Consultation comments

Stakeholders made the following comments in relation to draft statement 4 and consultation question 5:

- Agreed that this statement was an area for quality improvement for children and young people.

- An IV fluid lead is crucial for training, education, governance and the delivery of coordinated local audit and quality improvement activity.
- IV fluid leads will already exist in many hospitals for adults but for children's hospitals it would be an invaluable addition.
- An IV fluid lead must be held by a person with expertise in child health that may or may not be the same as the adult lead.

6 Suggestions for additional statements

The following is a summary of stakeholder suggestions for additional statements.

- Stakeholders queried why pre-mixed fluids were not discussed and felt this was an important area for patient safety and cost-effectiveness.

Appendix 1: Quality standard consultation comments table – registered stakeholders

ID	Stakeholder	Statement number	Comments[1]
1	Baxter Healthcare Ltd.	General	Baxter Healthcare Limited welcomes the opportunity to respond to the NICE consultation on draft quality standards for intravenous fluid therapy in children and young people in hospital. We feel this is an opportunity to further strengthen the quality standards in order to drive judicious and appropriate use of IV fluids in these vulnerable patients.
2	Department of Health	General	I wish to confirm that the Department of Health has no substantive comments to make, regarding this consultation
3	NHS England	General	I wish to confirm that NHS England has no substantive comments to make regarding this consultation.
4	Resuscitation Council (UK)	General	Although the document title is 'Intravenous fluid therapy in children and young people in hospital', some of the quality improvement areas are for newborns and term neonates. We think it needs explicit clarity exactly who this is for.
5	Resuscitation Council (UK)	General	This is rather generic and suggests that 0.9% saline should be used exclusively for replacing on-going losses. Maybe add 'for initial replacement of on-going losses' to 1.5.3 and 'Base any subsequent fluid prescriptions on electrolyte and glucose concentrations of both the plasma and the fluid losses. Specialist advice may be necessary' to 1.5.4.
6	Resuscitation Council (UK)	General	Consent is currently rarely or never obtained for fluid therapy (except for blood products) so these statements create the potential for medic-legal confusion unless there is a major change in practice
7	Royal College of Nursing	General	This is to inform you that the RCN has no comments to submit to inform on this quality standard consultation at this time.
8	Royal College of Paediatrics and Child Health	General	We feel this is a very useful and timely quality standard; however, did the team take into consideration recent research evidence on the dangers of high chloride levels in critically ill adults (http://www.ncbi.nlm.nih.gov/m/pubmed/25293535/?i=2&from=mortality%20fluid%20levels%20adults%20chloride)
9	Royal College of Paediatrics and Child Health	General	We feel that the document needs to be more explicit in stating if the quality standards apply to neonates in addition to "children and young people" or not. From the supporting evidence given it is implied that neonates are included within the scope of these standards, however from a teaching perspective most trainees will seek out specific neonatal standards and therefore it needs to be clear if these do or do not apply. If these quality statements are not intended to apply to neonates, this needs to be made apparent with a clear definition of what the lower applicable age is.
10	Royal College of Paediatrics and Child	General	This section appears intended to define the terms "maintenance fluids," "replacement fluids" and "resuscitation fluids." It would be helpful to clearly state this at the start of each paragraph. This would allow a person reading through the

[1]PLEASE NOTE: Comments received in the course of consultations carried out by NICE are published in the interests of openness and transparency, and to promote understanding of how quality standards are developed. The comments are published as a record of the submissions that NICE has received, and are not endorsed by NICE, its staff or its advisory committees.

ID	Stakeholder	Statement number	Comments[1]
	Health		quality standards to refer back to these definitions with clarity. A subheading or placing the terms in bold in each paragraph would be sufficient.
11	Royal College of Paediatrics and Child Health	General	From an educational point of view the term "competencies" here is unhelpful as it implies the specific acquisition of competencies in a competency based training programme and would be better worded as "competence". It should be recognised here that the training and level of competence required to manage IV fluid therapy in neonates, children and young people is different to that required for adults. Staff who do not have specific training in children's health, for example adult nurses in an Emergency Department or junior doctors rotating through a paediatric placement, will have additional education needs to those who regularly see children.
12	Royal College of Paediatrics and Child Health	General	We think it would be worth clarifying that this doesn't apply to neonates.
14	Sheffield Children's NHS Foundation Trust	General	The suggestion on page 7 footnotes 1 + 2 to seek formal informed consent and document is impractical and confusing for families and patients. Sheffield Children's NHS Foundation Trust has an over-arching policy on the use of unlicensed drugs and fluids that allows their reasonable use, where required
15	Sheffield Children's NHS Foundation Trust	General	There is no very clear point at which point of age or weight (ideal or actual) one should stop prescribing per kilo, and prescribe in a more 'adult' format. Clarity on this would be appreciated
16	Baxter Healthcare Ltd.	Question 1	We agree that the standards reflect the key areas for adequate and appropriate IV fluid prescribing in children and this standard highlights what clinicians should already be considering when prescribing to these vulnerable patients (with the exception of quality statement 4 – fluid lead). Please refer to our answer below to question 5.
17	Baxter Healthcare Ltd.	Question 2	We are unable to ascertain if adequate local systems and structures are in place to collect data for the proposed quality measures. However, it is equally important to ensure that any such data in any collection system is retrieved in a meaningful manner to allow benchmarking and demonstrated measures in improvements.
18	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Question 2	The quality measures for these statements rely heavily on local data collection. Resources for comprehensive high quality data collection may not be available in all Trusts.
19	Baxter Healthcare Ltd.	Question 3	We do not have such examples but we would recommend that NICE encourages both adult and children units in hospitals to submit and share examples of fluid charts, implementation plans and similar tools both during the consultation period and subsequently. This would allow hospitals to implement best practice and a quality improvement process.
20	Baxter Healthcare Ltd.	Question 4	As the quality statements included in this Quality Standard reflect what current ideal practice should be, local

ID	Stakeholder	Statement number	Comments[1]
			resources and services should already be in place.
22	Baxter Healthcare Ltd.	Draft statement 1	Quality statement 1 recommends “actual or estimated daily body weight” to be assessed. Body weight is often difficult to estimate and the estimate can vary greatly from the actual body weight. Baxter would suggest that NICE considers inclusion of further recommendations in quality statement 1 on how estimate body weight measurements can be standardised to ensure consistency.
23	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Draft statement 1	We are happy to note that a standardised fluid chart is proposed as means of improving quality in delivery and monitoring of IV fluid therapy and we see this as a key area in quality improvement. It would be helpful if example chart(s) were provided to support this or at least links to specimen charts in current use around the UK that conform to the comprehensive notation specified in the NICE guideline and in these standards. Collection of data would be dependent on local audit and we are unable to comment whether this capacity exists within individual Trusts and Health Boards.
24	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Draft statement 1	There is a comprehensive list of clinical observations and measurements on p9 and p10. Daily weighing is required which will not always be achievable for example in children the day after major surgery or for some children on PICU. Daily blood sampling is also needed to complete the assessment and this may be challenging in smaller infants and children and so information gathered to inform subsequent fluid prescription may be incomplete. It would be useful if audit activity was able to capture these episodes and determine if there was a correlation with morbidity. Another useful audit measure would be the number of children who have serum sodium levels outside the normal range especially the proportion of those less than 135 mmol/l and try to further refine the recommendations based upon any correlations with certain locally agreed fluid regimes.
25	Resuscitation Council (UK)	Draft statement 1	Although in agreement with all of this, daily weight and electrolyte measurements are not generally performed in most children’s wards and there needs to be some encouragement for staff to do them. We agree that a standard fluid balance and prescription chart would be a useful vector for this
26	Royal College of Paediatrics and Child Health	Draft statement 1	Assessment of fluid balance and electrolyte status • Resource requirements – a nationally produced combined fluid prescription and balance chart. The assessment and monitoring information in our trust is currently spread over a fluid balance and prescription chart. The QS refers to a ‘standard chart’ – it would improve patient care across regions/nationally is this was standardised. • Local systems – Robust audit practice in place but not currently auditing this data – again, a standardised audit tool would help.
27	Royal College of Paediatrics and Child Health	Draft statement 1	I agree entirely with the principle that children on iv fluids should have an assessment of fluid balance and electrolytes. However I think the wording of this statement gives for potential confusion in interpretation for the following reasons: • The rationale states that a ‘standard chart ..used to prescribe fluids and record fluid and electrolyte status’. The advice for commissioners states they should seek evidence of a ‘standardised fluid chart’. Therefore the purpose of the ‘standard chart’ is described in 2 different ways and this will cause confusion for those trying to follow this

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			guidance. My own opinion is that the former ('standard chart ..used to prescribe fluids and record fluid and electrolyte status') is impractical. The usual practice is to record all blood results in one place and to move away from this to have some blood tests apart from others may bring unforeseen hazards for patient care. Lastly, many hospitals have moved to electronic prescribing, charting, and notes. NICE guidance should reference this fact. • There is no guidance on how frequently electrolytes should be checked. The practice in my own hospital is for all children on iv fluids to have daily blood tests whilst they remain on maintenance fluids. I am not certain what the evidence base is for such guidance but I do believe NICE should advise practitioners on this key recommendation.
28	Sheffield Children's NHS Foundation Trust	Draft statement 1	Agreed with using Holliday Segar formula exclusively, especially as other calculations come up with erroneous results at higher weights
29	Baxter Healthcare Ltd.	Draft statement 2	The rationale for quality statement 2 and 3 highlights the consequences of hyponatraemia as brain swelling and neurological complications which are late signs of hyponatraemia and life threatening. Should clinicians be advised to look for the earlier signs of hyponatraemia in the rationale such as headache, nausea, vomiting, confusion, irritability, lethargy and reduced consciousness thus preventing the life threatening later signs?
30	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Draft statement 2	Both Statements 2 and 3 phrased in the negative – the statement is "not to give". A more positive and empowering Statement would be "to give". E.g. QS 3 (p14) would be better if it read" C and YP receiving IV fluids for routine maintenance are given isotonic fluid as the initial fluid." Audit data would then capture a positive not a negative. The statement would encourage the use of the correct fluid, not the use of an otherwise incorrect fluid.
31	Royal College of Paediatrics and Child Health	Draft statement 2	Fluid type for IV fluid resuscitation • Standard local practice. • Could be audited with ease. • I would hope that this is already standard practice (and therefore question whether it should be a QS although appreciate that it is vital that we get it right so understand why included)
32	Baxter Healthcare Ltd.	Draft statement 3	The rationale for quality statement 2 and 3 highlights the consequences of hyponatraemia as brain swelling and neurological complications which are late signs of hyponatraemia and life threatening. Should clinicians be advised to look for the earlier signs of hyponatraemia in the rationale such as headache, nausea, vomiting, confusion, irritability, lethargy and reduced consciousness thus preventing the life threatening later signs?
33	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Draft statement 3	Both Statements 2 and 3 phrased in the negative – the statement is "not to give". A more positive and empowering Statement would be "to give". E.g. QS 3 (p14) would be better if it read" C and YP receiving IV fluids for routine maintenance are given isotonic fluid as the initial fluid." Audit data would then capture a positive not a negative. The statement would encourage the use of the correct fluid, not the use of an otherwise incorrect fluid.

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34	Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	Draft statement 3	The use of glucose containing solutions is embedded in paediatric practice for IV fluid maintenance and glucose may be delivered in an isotonic or hypotonic solution. While there is no evidence to support the use of glucose for routine initial maintenance in most children it is accepted that this practice is likely to continue. It would be helpful if data collection could capture glucose usage as well as the use or otherwise of hypotonic solutions.
35	Royal College of Paediatrics and Child Health	Draft statement 3	Fluid type for routine maintenance • Resource requirements – A source of plasmalyte with glucose in a 500ml bag would be helpful! • We have had an education meeting as a department to discuss the evidence (I can email if helpful)
36	Royal College of Paediatrics and Child Health	Draft statement 3	• The recommendations in statement 3 are appropriate for the majority of paediatric patients, in whom IV fluids are given primarily for fluid and electrolyte loss. • We are concerned that the QS does not allow for exceptions in patients with rare conditions, in whom routine maintenance IV fluids are given for other purposes. In patients with Inherited Metabolic Disorders, IV fluids are given primarily to prevent or reverse catabolism when they cannot tolerate their prescribed enteral emergency feed. • These patients are prone to developing life-threatening metabolic decompensation during acute illnesses. One of the cornerstones of managing these patients is the enteral emergency feed which is given during any childhood illness, and which contains a high concentration of glucose to promote anabolism and prevent or reverse catabolism. If the enteral emergency feed is refused or vomited, patients are at high risk of developing acute life threatening decompensation, and urgent admission to hospital for IV administration of glucose-containing fluids is mandatory. It is essential for the fluids to contain plenty of glucose – 10% if given peripherally. • Many of these patients go on to require a substantial sodium load, in the form of sodium bicarbonate, sodium benzoate, sodium phenylbutyrate or other drugs. Hyponatraemia is extremely rare in patients with inborn errors of metabolism admitted for IV fluids to prevent catabolism. In contrast, hypernatraemia is much commoner. • For these reasons, we recommend 10% glucose 0.45% saline as the usual IV fluid in our patients. This recommendation is included in online guidelines, which are reviewed at least annually by representatives from each of the main UK metabolic centres (www.bimdg.org.uk/site/guidelines.asp). They are widely used & we encourage people to report any problems that are encountered: nobody has ever reported hyponatraemia when this fluid is used in the prevention of metabolic decompensation.
37	Sheffield Children's NHS Foundation Trust	Draft statement 3	Broad agreement with move away from hypotonic solutions for maintenance fluids. To treat 0.45 % NaCl (+/- 5%dextrose) as a specialist fluid for use in specific patients.
38	Sheffield Children's NHS Foundation Trust	Draft statement 3	Broad agreement with including dextrose in maintenance fluids. Again with the exception of specific conditions eg DKA and neurosurgical patients
39	Baxter Healthcare Ltd.	Draft statement 4	Mirroring the adult guidelines we believe an IV fluid lead would add value as it would establish a single point of contact with overall accountability for IV fluid therapy within an institution.
40	Joint response by	Draft	This is an important and powerful statement and we fully support its inclusion. The identification of an IV fluids lead is

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	Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists	statement 4	crucial for training, education and governance and the delivery of coordinated local audit and QI activity. Robust programmes of data collection for all the Quality Statements should flow from the appointment of a Lead within each institution. We note that this is a Quality Standard for the adult guideline and that as such guideline Leads should already exist in many hospitals. In hospitals with adult and paediatric practice, paediatric activity could be included in an existing brief. In paediatric hospitals this would be an invaluable initiative. However NICE should be aware that Trusts are clamping down on SPA time and doctors are less willing to do the work for no recompense. It may be difficult to find clinicians willing to take on this role unless Trusts use a more flexible approach to SPA time for doctors.
41	Royal College of Paediatrics and Child Health	Draft statement 4	We believe this is an area for quality improvement. Our commenter has a prescribing lead, an antimicrobial steward etc but nobody (whole dept. takes responsibility) who oversees this aspect of prescribing.
42	Royal College of Paediatrics and Child Health	Draft statement 4	This is an important statement which I believe is an area for quality improvement in children as well as in adults.
43	Royal College of Paediatrics and Child Health	Draft statement 4	Quality statement 4 is as applicable to children and young people as it is to adults and should be included in the quality standards. This role must be held by a person with expertise in child health. This may or may not be the same person who has the IV fluids lead role for adults and will depend on the expertise of that individual. The individual holding this role should be able to appreciate that fluid management in neonates, children and young people is different to adults and that staff, particularly junior doctors rotating through a paediatric placement will have specific education needs depending on their previous experience. It should be highlighted that education needs should be met before or immediately after starting a role which involves the prescribing of IV fluids to neonates, children or young people.
44	Sheffield Children's NHS Foundation Trust	Additional statement	As per briefing document - why were pre-mixed fluids e.g. Plasmalyte not mentioned or discussed. Data we have seen from other children's hospitals would support use of these mixtures from a patient safety and cost-effectiveness point of view

Registered stakeholders who submitted comments at consultation

- Baxter Healthcare Ltd.
- Department of Health
- Joint response by Association of Paediatric Anaesthetists of Great Britain and Ireland and Royal College of Anaesthetists
- NHS England
- Resuscitation Council (UK)
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Sheffield Children’s NHS Foundation Trust