National Institute for Health and Care Excellence
IV fluid therapy in children
Scope Consultation Table
22 July – 27 August 2013

Type	Stakeholder	Order No	Section No	Comments Please insert each new comment in a new row.	Developer's Response Please respond to each comment
SH	Association for Clinical Biochemistry	1	3.1c	Other conditions include liver disease	Thank you for your comment, liver disease has been added to the list of examples.
SH	Association for Clinical Biochemistry	2	3.1e	Brain complications may be caused by correcting an electrolyte imbalance too rapidly.	Thank you for your comment. This has been included in section 3.1 e.
SH	Association for Clinical Biochemistry	3	3.2a	A good example of education on iv fluids in children is available on BMJ-Learning online, see comment 10 below.	Thank you for your comment.
SH	Association for Clinical Biochemistry	4	4.3.1a	Central hospital laboratory or ward based POCT assessment to cover serum, plasma or whole blood tests and serum/plasma/urine osmolality measurements.	Thank you for your comment. We agree that this is an important consideration and this has been included in 4.3.1.a).
SH	Association for Clinical Biochemistry	5	4.3.1b c,d	Consider use or avoidance of saline with glucose, glucose only and hypertonic saline	Thank you for your comment. We have included two reviews that compare the use of glucose with 0.9% or 0.45%saline with saline alone. We are not aware of hypertonic saline being used in current practice

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					and as such, this has not been included in the current guideline scope.
SH	Association for Clinical Biochemistry	6	4.3.2b	Another example is high calcium influencing renal water reabsorption	Thank you for your comment. Section 4.3.2. b) has been amended.
SH	Association for Clinical Biochemistry	7	4.5.2c	Consider POCT and central laboratory methods	Thank you for your comment. We agree and section 4.3.1 a) has been amended to clarify this.
SH	Association for Clinical Biochemistry	8	4.5.3j	Adding magnesium and potassium together to saline	Thank you for your comment. This has been clarified to highlight that we will be considering the addition of potassium only.
SH	Association for Clinical Biochemistry	9	4.5.6u	Include further laboratory testing	Thank you for your comment. This will be considered when developing the protocol for this question.
SH	Association for Clinical Biochemistry	10	4.5.7	Discuss use of BMJ Learning module on iv fluids for children http://learning.bmj.com/learning/module-intro/reducing-risk-hyponatraemia-administering-intravenous-fluids-children.html?locale=en_GB&moduleId=5003358	Thank you for your comment. Evidence on the use of existing training and education materials may be considered when developing the review protocol on training and education of healthcare professionals.
SH	Association of Anaesthetists of Great Britain and	1	Q1	Complex methods to calculate maintenance fluids are more likely to be associated with error. A simple bedside method of calculating fluid maintenance, with routine monitoring of fluid balance and electrolytes is most likely to be safe and effective.	Thank you. Your feedback will be helpful when the GDG discuss the results of the findings from the review on "What are the most clinically and cost effective methods

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	Ireland				for assessing, monitoring and reassessing fluid intake and output to detect hypovolaemia and dehydration?"
SH	Association of Anaesthetists of Great Britain and Ireland	2	Q2	Fluid management changes in the first few days of life, after ADH levels have fallen and the post-natal diuresis has occurred (i.e. the stress response associated with delivery has receded).	Thank you for your comment. We are aware of physiological differences in babies within the first 72 hours of life however, Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Association of Anaesthetists of Great Britain and Ireland	3	Q3	It does not seem logical to exclude term neonates <2 weeks of age from the scope of the guideline, particularly as many children with congenital abnormalities undergo surgery during this time. Conversely, premature neonates, particularly extreme premature and very low birth weight infants <1000g have special requirements associated with immaturity, and it is logical to exclude these infants from the scope of the guideline.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Association of Anaesthetists of Great Britain and Ireland	4	Q4	Routine monitoring of fluid and electrolyte balance is an important aspect of safety in IV fluid administration. Blood tests are unpleasant for children, and daily weights, particularly in the post-operative period, may not be comfortable for the child. Signs of fluid	Thank you for your comment. Your feedback on the importance of considering the patient when making recommendations will be particularly helpful when the GDG discuss the results of the review on

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				overload may be quite subtle (e.g. facial puffiness), and best detected by those familiar with the child. It would be helpful to identify how often children should be weighed and blood electrolytes should be measured, and to identify methods of monitoring electrolytes that are cost effective, accurate and most acceptable (least painful) for the child. It would be helpful to explain to children, their families or carers why these procedures need to be undertaken, and to engage them in these processes.	"What are the most clinically and cost effective methods for assessing, monitoring and reassessing fluid intake and output to detect hypovolaemia and dehydration?". Issues relating to patient/carer information have not been prioritised by stakeholders during development of the scope. However, a lay version of the guideline will be available on publication of the guideline and should be of use to patients and their parents and carers.
SH	Association of Anaesthetists of Great Britain and Ireland	5	3.1b General	There is no mention of surgery. Surgery represents a distinct clinical situation when there is a marked stress response and very high levels of ADH (a situation analogous to that after birth). There are specific requirements for intravenous fluid, electrolytes and glucose in the intraoperative period, that differ from those in the immediate postoperative period or other times of acute illness in children. It would be helpful to consider fluid requirements during the intraoperative period, in order that	Thank you for your comment. The guidelines' recommendations will be cross cutting and are likely to be relevant to children in the intra-operative phase.

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				manufacturers produce the range of intravenous fluids required, specifically relating to the glucose content of intravenous fluids.	
SH	Association of Anaesthetists of Great Britain and Ireland	6	3.1d	It is important to emphasise that errors in fluid prescribing or administering intravenous fluids can result in imbalances in electrolytes and blood glucose in normal children.	Thank you for highlighting this. We have amended the text to highlight that children with problems with liver or kidney function are a specific group who may be at risk.
SH	Association of Anaesthetists of Great Britain and Ireland	7	3.2a	Prescribers are not always aware of the specific physiology associated with various conditions in children, and as such, many fluid prescriptions provide too little or too much fluid or electrolytes to restore or maintain fluid balance.	Thank you for your comment, section 3,2a has been amended.
SH	Association of Anaesthetists of Great Britain and Ireland	8	3.2b	Whilst acknowledging that monitoring of fluid and electrolyte balance is often sup optimal, it would be helpful to also acknowledge here that blood tests in children can be painful or distressing to the child.	Thank you for your comment, the text in 3.2b has been amended to reflect this.
SH	Association of Anaesthetists of Great Britain and Ireland	9	4.1	It would extremely helpful to include IV fluid requirements in the intraoperative period as a specific condition. Glucose requirements in the intraoperative period differ compared to other times due to the intense stress response associated with surgery. The need for manufacturers to develop fluids	Thank you for your comment. The guidelines' recommendations will be cross cutting and are likely to be relevant to children in the intra-operative phase.

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				specifically for the intraoperative period was highlighted in a consensus statement from European paediatric anaesthetists (Sumpelmann R et al, European consensus statement for intraoperative fluid therapy in children. Eur J Anaesthesiology 2011 28: 637-9)	
SH	Association of Anaesthetists of Great Britain and Ireland	10	4.1.1	It would be helpful to include all babies born at term. Children undergoing surgery need specific consideration with respect to glucose requirements, as identified above. In infants and babies, balanced crystalloid/normal saline solutions containing 1-2% glucose may be required during the intraoperative period, whilst balanced crystalloid/normal saline solutions containing 5% glucose may be required at other times.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term. We will examine glucose requirements in the review, including evidence on surgical patients. The GDG will decide whether these patients should be considered separately during this review, however the general scope for this guideline is to be cross-cutting rather than to go into detail for specific patient groups. .
SH	Association of Anaesthetists of Great	11	4.1b	It would be helpful to include children undergoing surgery, as described previously.	Thank you for your comment. The guidelines' recommendations will be cross cutting and are likely to be relevant to children in the intra-

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	Britain and Ireland				operative phase.
SH	Association of Anaesthetists of Great Britain and Ireland	12	4.1.2b	It would be helpful to include fluid requirements in the period immediately after birth as this is a common time for children to require IV fluid therapy. Premature infants, particularly extreme premature infants and very low birth weight infants represent a different clinical situation, and it would be reasonable to exclude this group.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Association of Anaesthetists of Great Britain and Ireland	13	4.3c	The type of fluid to offer should read 'normal saline compared with balanced crystalloids', 'half normal saline compared with balanced crystalloids'. An additional category should be included 'normal saline with glucose compared to balanced crystalloid with glucose'. Balanced crystalloid solutions with glucose are not routinely manufactured in the UK, but are available elsewhere.	Thank you for your comment. This has been amended. We have also included an additional comparator of 'balanced crystalloids compared with balanced crystalloids with glucose'.
SH	Association of Anaesthetists of Great Britain and Ireland	14	4.3.2f	Labelling of fluids in an important safety issue. For instance, failure to identify that a bag of 0.9% saline contained 5% glucose led to the death of a patient (the fluid was used as a flush solution for an arterial line; the pressure bag for the solution obscured the wording '5% glucose'). (Hartle et al Article in preparation. Anaesthesia 2013).	Thank you for your comment. Unfortunately, labelling of fluids has not been prioritised for inclusion in the current guideline by stakeholders. However, when developing recommendations on the training and education of healthcare professionals, we may consider any

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				Similarly, volume resuscitation using a crystalloid solution containing 5% glucose would result in very high blood glucose levels. If fluids are not clearly labelled, NICE recommendations for fluids containing different concentrations of dextrose in different clinical situations may result in an increased number of accidents described.	aspects relating to labelling of fluids.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	1	Q1 response	Calculation of fluid requirements should be as simple as possible. The use of body weight is the most practical way of doing this. It is reproducible and universally understood. We conclude that methods outside of those suggested should not be considered. However given the increasing problem of obesity in our anaesthetic population a simple method of factoring this in could be considered.	Thank you for your comment. Section 4.3.1 of the scope states that assessment, monitoring and reassessment of fluid and electrolyte status will be considered and this will identify whether body weight of body surface area is the most effec tive means of calculating fluid requirements and we will gather evidence on the use of these methods.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	2	Q2 response	The consensus is that most of the physiological changes characterised in the immediate peri-natal period for the term neonate are complete within 72 hours. However it is recognised that this is not absolute and would be complicated further by the inclusion of premature babies within this scope. We support the proposal that this guideline should be	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.

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				limited to term neonates with the proviso that it should NOT be limited to neonates over 2 weeks of age (see response to Q3 below).	
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	3	Q3 response	We have received very strong feedback from Council members that to provide guidelines for term neonates yet to exclude term babies less than 2 weeks of age is illogical. We recognise that profound physiological changes take place within the first few days of life that require specific consideration with respect to fluid management; the evidence for this should be fully explored such that the final guideline provides complete guidance for all term babies from birth. We recognise that very separate management protocols may have to be described for term babies within the first few days of life, the first week and the remainder of the neonatal period. This would provide complete guidance those in the DGH environment who may receive younger neonates for resuscitation and stabilisation prior to transfer to the tertiary centre and also those in the tertiary centre, whose needs are for complete evidence based perioperative fluid management guidance. We recognise that this will make the research and development of the guideline more complicated but conclude that all term neonates should be included in this guideline. We agree with the proposal to exclude all pre-term neonates from this guideline. The needs, particularly of those more extreme premature babies are complex	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.

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				and beyond the scope of this guideline. Guidance on the use of TPN would also add complexity and should be excluded from the guideline.	
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	4	Q4 response	We feel that the educational needs of parents and carers are paramount and the provision of information to the lay population is integral to this guideline. This should include an evidence-based summary on the recognition of the signs of dehydration, the initial management and when to call for help.	Thank you for your comment. Issues relating to patient/carer information have not been prioritised by stakeholders during development of the scope. However, a lay version of the guideline will be available on publication of the guideline and should be of use to patients and their parents and carers.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	5	General	The need for a nationally agreed Intravenous fluid prescription chart is emphasised.	Thank you.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	6	General	We feel that this is a real opportunity to ensure that the calculation of fluid requirements, the choice of fluid and the administration and monitoring thereof should be made as simple as possible to help avoid error.	Thank you for your comment.
SH	Association of Paediatric Anaesthetists	7	3.1 p.1	There needs to be recognition that the administration of IV fluids is a "relatively uncommon event" and as such decisions to start and/or continue administration	Thank you for your comment. We agree I principle with this, however, given the lack of incidence data

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	of Great Britain and Ireland		Epidemiology	should be carefully considered on the basis of risk vs. benefit.	available, we have not amended the introductory text.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	8	3.2b p.3	The need to recognise that children are relatively difficult to assess and monitor particularly with respect for the need to assess urine output accurately and the difficulty associated with a need to take repeated blood samples should be recognised within this section. This may well have a bearing on the final recommendations.	Thank you for your comment, the text in 3.2b has been amended to reflect this.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	9	4.1.1b p.4 Population	Given our comments regarding the need to include all term neonates we suggest that the neonate within the first 72 hours of life should have specific consideration. Section 4.1.2 may require rewriting if this is the case.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	10	4.3.1b p.5	Consideration could be given to the use of hypertonic saline during resuscitation and maintenance.	Thank you for your comment. However, we are not aware of this fluid being used in current practice and as such, this has not been included in the current guideline scope.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	11	4.3.1c and d p.5	Consideration should be given to the comparison of Ringers Lactate with other crystalloid solutions. The use of balanced solutions containing 1% and 2% glucose should be included in the scope. Currently they are not routinely available from UK	Thank you for your comment. The use of Ringer's lactate will be considered in Section 4.3.1 c), where we have considered balanced crystalloids. '.

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				manufacturers but their use in continental Europe is increasing and the evidence for their use is becoming available.	We have also included review questions that compare the use of glucose with normal or half saline with saline alone.
SH	Association of Paediatric Anaesthetists of Great Britain and Ireland	12	4.3.1 p.5	The specific context of fluid replacement in the surgical child warrants separate consideration. Pre, intra and postoperative fluid requirements may be complex, especially in the sick child.	Thank you for your comment. The guidelines' recommendations will be cross cutting and are likely to be relevant to children in the intra-operative phase.
SH	Baxter Healthcare Ltd	1	General	Baxter Healthcare welcomes the opportunity to comment on the draft scope of the Intravenous fluid therapy in children guidelines. We would like to congratulate NICE on highlighting the urgent need to acknowledge intravenous fluid therapy as prescription only medication. In particular, with the imminent publication of clinical guidelines for IV fluid therapy in adult hospital patients, this is a good opportunity to align standards of care. IV fluid therapy merits the same considerations and documentation as pharmaceutical agents, with the need to establish the most appropriate type, composition and volume of intravenous fluids in these patients for maintenance, replacement and redistribution.	Thank you for your comment.
SH	Baxter Healthcare Ltd	2	4.1.1a	The groups that will be covered by the guideline are "Babies born at term, infants, children and young people older than 2 weeks of age and younger than 16 years." Would NICE consider including weight	Thank you for your comment. The recommendations are likely to be dictated by how the authors of the papers classify their patient groups

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				recommendations as well as chronological age? This is important, in particular for teenage children as they may be approaching the size and weight of adults.	and therefore, where this is appropriate, we will consider including weight recommendations.
SH	Baxter Healthcare Ltd	3	4.3.1b	Under the types of intravenous fluid to be considered for resuscitation it states "normal saline" and "half saline". Would NICE consider clarifying these terms by substituting these for "0.9% sodium chloride" and "0.45% sodium chloride" throughout the scope, rather than at the end of the document only?	Thank you for comment. We agree and this has been amended throughout.
SH	Baxter Healthcare Ltd	4	4.3.1	In light of the NPSA safety concerns of the risk of hyponatraemia with hypotonic solutions, would NICE consider the inclusion of solutions containing 0.18% sodium chloride to demonstrate it has been considered and allow the GDG to formally comment on its use?	Thank you for your comment. The use of 0.18% sodium chloride will not be considered within the guideline,as its use is contraindicated in children and young people under 16 years, as outlined in the NPSA Safety Alert 'Reducing the risk of hyponatraemia when administering intravenous infusions to children' (2007).
SH	Baxter Healthcare Ltd	5	General	An important issue in the management of paediatric patients undergoing IV Fluids Therapy is that of potential over hydration and hyponatreamia. The use of a volumetric pump can provide more accuracy, consistency and predictability of fluid administration. The use of gravity administration sets increases the risk of inaccurate fluid delivery and increases the administrative burden for nursing staff	Thank you for your comment. The scope states in Section 4.3.1 that we will be including the 'management of hypernatraemia and hyponatraemia'. The use of devices for the provision of intravenous fluids in children was not included in the scope as it was felt that there were other areas

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				who must accurately record volume delivered. We are aware that volumetric pumps are routinely used for younger children and babies, however the scope covers patients up to the age of 16 who may be on a general ward. Although we are aware that the method of administration for IV fluids are outside the scope for this guideline, would NICE consider the delivery of IV fluids via a volumetric pump to be included for all those under 16 years of age to minimise both the risk of over hydration and hyponatraemia?	where clinical practice varied which should be prioritised for this guideline.
SH	Department of Health	1	General	No Comment	Thank you.
SH	Medicines and Healthcare product Regulatory Agency	1	3.2a	As the scope states, clinicians' awareness of the constituents of intravenous fluids and their correct use may be suboptimal. It is therefore very important that the final recommendations can be translated into everyday clinical prescribing decisions for intravenous fluid solutions that are available in NHS hospitals	Thank you for your comment, we agree.
SH	Medicines and Healthcare product Regulatory Agency	2	3.2c	To minimise the risk of dosing errors or inappropriate use of certain fluid solutions by healthcare professions with varying expertise, the review should lead to streamlining of prescribing practices in paediatric wards across the UK. Specific recommendations should cover how frequently IV fluid replacement should be monitored and reviewed by trained healthcare professionals.	Thank you for your comment. We will address how frequently intravenous fluid replacement should be monitored in the review question "methods for assessing, monitoring and reassessing fluid intake and output to detect hypovolaemia and dehydration", as

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					outlined in Section 4.5.
SH	Medicines and Healthcare product Regulatory Agency	3	4.1	We are concerned that the guidance 'will not include recommendations relating to specific conditions'. We consider that it would be valuable to identify specific conditions where different considerations apply, particularly in areas where other relevant guidance exists. This review could be an excellent opportunity to identify paediatric areas where guidelines for IV fluids therapy should be developed.	Thank you for your comment. The aim of the guideline is to provide cross-cutting recommendations that apply to a range of conditions that result in fluid and electrolyte imbalance. The evidence will include patients with a range of conditions, such as gastroenteritis and sepsis. Recommendations relating to fluid requirements in specific conditions can be found in related NICE guidance, as outlined in Section 5.
SH	Medicines and Healthcare product Regulatory Agency	4	4.1.2b and c)	It is not clear why neonates and premature babies are to be excluded from the review.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term and those premature babies who have reached a corrected age equivalent to term. However, we felt that it is appropriate for the guideline to exclude premature babies from the guideline (see Section 4.1.2) as there

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					are specific complex management considerations for these babies.
SH	Medicines and Healthcare product Regulatory Agency	5	4.3.1b	The benefit-risk balance of hydroxyethyl starch products for fluid replacement is being reviewed at a European level. The final European position is expected in Autumn 2013. Within the UK the MHRA, acting on advice from its independent expert group, the Commission on Human Medicines (CHM), has suspended the licences of hydroxyethyl starch and issued a recall of these products. The decision to suspend the licences for these products was taken on the basis that: i) Evidence from randomised controlled clinical trials shows that the use of hydroxyethyl starch, when compared to crystalloids, is associated with an increased risk of mortality and renal replacement therapy or renal failure in patients with sepsis and in the critically ill. ii) There is a lack of evidence to provide reassurance that these risks are not present in other clinical settings such as surgery, trauma and burns patients. iii) There is little evidence that hydroxyethyl starch provides any clinically relevant benefit over crystalloids in any setting The suspension in the UK will last until a definitive	Thank you for your comment and for highlighting this document. We are aware of the current decision by the MHRA. As noted in Section 4.3.1, the guideline will consider synthetic colloids which may or may not include starches, depending upon the outcome of the work by the MHRA.

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				position is reached in Europe. At that point the EU decision will be binding on all member states. Further details can be found in the Drug Safety Update (DSU) bulletin on the MHRA's website: www.mhra.gov.uk/Safetyinformation	
SH	Neonatal & Paediatric Pharmacists' Group	1	3.1e	It is important that "hypotonic" is appropriately defined within the body of the guideline. 0.45% sodium chloride and 5% glucose is defined as "isotonic" but this is a misleading statement. In relation to cellular tonicity it is hypotonic.	Thank you for your comment. This will be defined during development of the guideline, when developing the pre-defined review protocols.
SH	Neonatal & Paediatric Pharmacists' Group	2	4.1.1a	We strongly believe that term neonates should be included in this guideline. The care of neonates is not limited to the Neonatal Unit in many organisations. During certain peak periods, the majority of paediatric hospital inpatients will be neonates who will require some intravenous fluid support. Neonatal fluid management in the later period (from 5days of life) differs only in the volumes that are administered. It is common practice to administer 120-150ml/kg/day of fluid (intravenous or enteral) to neonates. This would then be reviewed to 100ml/kg for the first 10kg at one month of age. We believe that the use of "paediatric" fluids in neonates is safe from 5 days of age, as long as sufficient care is taken with blood glucose monitoring.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Neonatal &	3	4.1.2b	As mentioned above we would encourage NICE to	Thank you for your comment.

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	Paediatric Pharmacists' Group			include term neonates <14 days old in this guidance	Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Neonatal & Paediatric Pharmacists' Group	4	4.1.2c	Is this a typo? Should this be babies born who are less than a post-conceptional age of 36 weeks? We support the exclusion of premature neonates. However, it is important that guidance is given on fluid management in neonates. This should include ex-premature neonates who are discharged from neonatal care e.g.at 36 weeks post-conceptional age, who then require paediatric in-patient support. In some cases these infants will be several weeks old.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term and those premature babies that have reached a corrected age equivalent to term.. Therefore section 4.1.2 has been amended to clarify that the guideline will exclude babies born prematurely.
SH	Neonatal & Paediatric Pharmacists' Group	5	4.3.1a	We strongly support the inclusion of monitoring of weight as a measure of fluid requirement and fluid assessment. We are less sure of how frequent calculation and reassessment of body surface area may affect that. Changes in surface area in smaller children are commonplace and of dubious significance and our concern is that the use of Body Surface Area as a measure of dosing is likely to require frequent dose changes and adjustments in electrolytes which is a significant risk in the in-patient setting, without any clear benefit.	Thank you for your comment on the risk of measuring body surface area in children. We agree that practical considerations are important and these will be considered by the GDG when developing recommendations on the use of body surface area or body weight to calculate fluid and electrolyte requirements. Thank you for comment on albumin. Your feedback will be shared with

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				We would also welcome guidance on the management of fluids in children who are obese. Should ideal body weight be used rather than actual body weight? If so – in which patients? We would suggest that you include albumin in your laboratory investigations. Albumin plays an important role in maintaining the water balance between the extracellular and intravascular compartments, and is also an important contributor to acid:base balance. pH, bicarbonate and chloride alone are useless without some mention of albumin and the "Strong Ion Gap" when considering acidosis associated with fluid management. We note that this section includes assessment, monitoring and reassessment of various parameters. We feel it is important that guidance is provided on the need for, and frequency of, regular monitoring and review of fluid balance and electrolytes in the clinical situation – for example in children who are being managed post-operatively. We would also urge NICE to consider the practicalities of the calculation of fluid and electrolyte requirements in children when developing guidance.	the GDG when designing the review strategy on "What are the most clinically and cost effective laboratory-based methods to assess, monitor and reassess fluid and electrolyte status?" Thank you for your comment on the need for, and frequency of, regular monitoring and review of fluid balance and electrolytes in the clinical situation. This will adequately be addressed as part of this guideline, as outlined in Section 4.3.1.
SH	Neonatal &	6	4.3.1b	We commend you to include balanced colloids in your	Thank you for your comment.

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	Paediatric Pharmacists' Group			assessment.	
SH	Neonatal & Paediatric Pharmacists' Group	7	4.3.1g	We are pleased to see that you intend to cover the issue of training and education needs of healthcare professionals. This needs to cover not just Paediatricians and Paediatric Anaesthetists but other doctors such as adult surgeons/anaesthetists etc. who may need to prescribe fluids for children regularly in non-specialist hospitals and can be a source of errors. For example we are aware of children treated in adult environments due to bed pressures who have been on inappropriate fluids, and errors have occurred when non paediatricians have prescribed for children. We would also be keen to see this education and training requirement expanded to include other professionals such as nurses and pharmacists working in specialist and non-specialist areas.	Thank you for your comment. Section 4.3.1 g) highlights that we will be considered the training and education of all healthcare professionals.
SH	Neonatal & Paediatric Pharmacists' Group	8	General	Please do not refer to "normal" and "half normal" saline as these terms are without scientific basis and obsolete. When referring to saline, please phrase as 0.9% sodium chloride. Likewise, when referring to half-saline or half-normal saline please refer to 0.45% sodium chloride.	Thank you for your comment, this has been amended throughout.
SH	Neonatal & Paediatric Pharmacists' Group	9	4.4c	How do you define "Adverse Events"?	Thank you for your comment. The review protocol will include a more explicit list of adverse events.

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SH	Neonatal & Paediatric Pharmacists' Group	10	4.5.2d	Please refer to our comments in 4.3.1.a	Thank you. Please see our responses to your previous comments.
SH	Neonatal & Paediatric Pharmacists' Group	11	4.5.4k	We are unsure what NICE mean by "What is the most clinically and cost-effective rate of administration for routine maintenance"? There will be no single rate of administration as there is in adults, because you are already assuming that weight or BSA will be used to determine fluid volume to administer. We suggest that this is redefined as "What is the most clinically and cost-effective method to calculate routine maintenance volume."	Thank you for your comment. This will be covered by the questions outlined in 4.5.2.
SH	Neonatal & Paediatric Pharmacists' Group	12	4.5.4 (general)	You do not mention the clinical or cost-effectiveness of administering glucose containing sodium chloride with additional potassium chloride. There is an enormous cost differential between a bag of 0.45% sodium chloride with 5% glucose, and a bag of 0.45% sodium chloride with 5% glucose and 10mmol of potassium. This is an enormous cost pressure to the NHS as child-appropriate potassium-containing maintenance fluids are in the main unlicensed specials and thus command a premium. We would encourage NICE to consider the availability and cost effectiveness of potassium containing fluids bearing in mind that it is preferable to use ready made bags containing potassium where this is possible. This	Thank you for your comment. A question on the comparator of crystalloids with or without added glucose or electrolytes has been added to Section 4.5.4. The use of ready made bags compared with added glucose or electrolytes will be considered by the GDG.

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				is important in view of the fact that in the non-acute ward setting it is difficult to obtain, and potentially dangerous to use, concentrated potassium ampoules to add to non-potassium containing bags of fluid. We would encourage NICE to include a recommendation advocating the use of ready to use bags of IV fluids containing potassium where possible. We strongly suggest that NICE include these issues in their economic assessment.	
SH	Neonatal & Paediatric Pharmacists' Group	13	4.5.7	We are pleased to see that one of the review questions is to consider the training and education needs of healthcare professionals. This needs to cover not just Paediatricians and Paediatric Anaesthetists but other doctors such as adult surgeons/anaesthetists etc. who may need to prescribe fluids for children regularly, particularly in non-specialist hospitals and this can be a source of errors. We would also be keen to see this education and training requirement expanded to include other professionals such as nurses and pharmacists.	Thank you for your comment. We agree and this question covers the training and education of all healthcare professionals.
SH	Neonatal & Paediatric Pharmacists' Group	14	General	NPPG has concerns that the scope is not tight enough and reviewers may struggle to come to meaningful decisions. There is a paucity of "evidence" pertaining to fluid management in children, with much of our custom and practice extrapolated from adult studies.	Thank you for your comment. We will include evidence from adult studies for reviews where there is a lack of evidence in the direct population and it is deemed appropriate by the GDG.
SH	Resuscitation	1	4.1	In resuscitation terms, it is important that the pre-	Thank you for your comment. The

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	Council (UK)			hospital environment is considered. It is possible that much of the advice intended for in-hospital use is also appropriate for the pre-hospital environment but it will be important to identify which is and is not applicable	guideline covers the provision of intravenous fluids in hospital settings. Recommendations on the provision of replacement intravenous fluids in pre-hospital settings can be found in NICE Technology appraisal 74 'Pre-hospital initiation of fluid replacement therapy in trauma'.
SH	Resuscitation Council (UK)	2	4.1.1	The 2 week limit is a little arbitrary. The physiological changes at birth that require special consideration are most marked in the 1st 72 hours of life. In resuscitation terms, once a neonate has been discharged from neonatal care, the paediatric life support guidelines are applied, irrespective of age. It would be useful if the same criteria were used here.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term.
SH	Resuscitation Council (UK)	3	4.3.1b	Hypertonic saline is advocated for resuscitation in some circumstances. It would be helpful to evaluate any paediatric evidence for this fluid.	Thank you for your comment. However, we are not aware of this fluid being used in current practice and as such, this has not been included in the current guideline scope.
SH	Resuscitation Council (UK)	4	4.5.3	(i) is particularly important. A difficult subject but "Are different fluids required for different resuscitation circumstances" is an important clinical question requiring an answer	Thank you for your comment. The use of different fluids for different resuscitation circumstances may only be considered if the evidence for the resuscitation reviews show this.

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SH	Royal College of Paediatrics and Child Health (RCPCH)	1	General	We are pleased that the comments made at the scoping workshop have been heard.	Thank you.
SH	Royal College of Paediatrics and Child Health (RCPCH)	2	4.3.1.	We think that the scope needs to define further which groups of patients who need IV fluids are going to be included; e.g. gastroenteritis, bronchiolitis, pneumonia and other respiratory conditions, sepsis and within this group CNS sepsis/encephalitis, trauma patients, etc. We think all these categories of patients would need to be included. There is also a need to define whether children known to have chronic conditions such as kidney problems, liver problems, etc. are going to be included or specifically excluded. This is more problematic and it may be best to leave out children with chronic kidney disease perhaps also leave out liver and some endocrine problems. However, for example, if a girl on thyroxine who is stable, develops one of the above intercurrent acute illnesses it should be possible to manage her fluids as per any other previously fit child.	Thank you for your comment. The evidence will include patients with a range of conditions that result in fluid and electrolyte imbalance. As a result, the findings will be applicable to a range of conditions. Thank you for highlighting which patient groups the recommendations may not be relevant for. We will discuss with the GDG which patient groups are to be excluded when developing the review protocols for each question.
SH	Royal College of Paediatrics and Child	3	4.1.2b	We are concerned that the term 'babies aged 14 days or less' will not be included as this represents a rather arbitrary age cut-off.	Thank you for your comment. Section 4.1.1 has been amended following feedback from stakeholders and it has been agreed

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	Health (RCPCH)				that the guideline will include all babies born at term.
SH	Royal College of Paediatrics and Child Health (RCPCH)	4	4.3.1b	We believe the scope should consider the use of hypertonic saline in "small volume" resuscitation, e.g. in head injury.	Thank you for your comment. However, we are not aware of this fluid being used in current practice and as such, this has not been included in the current guideline scope.
SH	Royal College of Paediatrics and Child Health (RCPCH)	5	4.3.1f	We believe the scope should consider the use of hypertonic saline in management of hyponatraemia in patients with hyponatraemic seizures.	Thank you for your comment. The management of hyponatraemia resulting from poor intravenous fluid provision will be considered as outlined in 4.3.1 f).
SH	The British Association of Paediatric Nephrology	1	General	Comments submitted through RCPCH	Thank you.
SH	The Paediatric Intensive care society	1	General	No comment	Thank you.
SH	The Royal College of Anaesthetists	1	3.1e	There was no support from our expert group of five consultant paediatric anaesthetists that fluid therapy should be based on body surface area rather than body weight.	Thank you for your comment. Section 4.3.1 of the scope states that assessment, monitoring and reassessment of fluid and electrolyte status will be considered and this will identify whether body weight of

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					body surface area is the most effective means of calculating fluid requirements and we will gather evidence relating to the use of these methods.
SH	The Royal College of Anaesthetists	2	3.2a	We agree that there is a need for standardised training packages to ensure consistency of approach in fluid prescribing by practitioners from all specialties. This consistent approach should begin at the undergraduate level.	Thank you for your comment. Section 4.3.1 g) highlights that we will be considered the training and education of healthcare professionals.
SH	The Royal College of Anaesthetists	3	3.2b	We agree with the comments on the variability of recording fluid and electrolyte status. Standardisation should be encouraged. Regular measurement of body weight should be added to the data set for all patients receiving iv fluids.	Thank you for your comment.
SH	The Royal College of Anaesthetists	4	3.2c	We support the standardisation of clinical assessment of fluid and electrolyte status as a starting point but need to emphasise that a 'one size fits all' approach should not prevent the necessary flexibility of prescribing required for some sub-groups of patients e.g. renal failure, cardiac dysfunction, short gut syndromes, metabolic disorders.	Thank you for your comment. We agree it is important that the assessment form is applicable to a range of patient groups however, we as cross cutting guideline this has not been specified in the scope. We will keep this in mind when developing the recommendations.
SH	The Royal College of Anaesthetists	5	3.2d	Same comments on use of BSA versus body weight as in 3.1 (e)	
SH	The Royal College of	6	4.1.1a	We suggest that the lower age range for the guideline should adhere to the widely recognised definition of	Thank you for your comment. Thank you for your comment. Section 4.1.1

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	Anaesthetists			the neonatal period – 44 weeks post conceptual age would be our recommendation. At the upper age range a flexible and pragmatic approach needs to be emphasised. Many younger teenage children are anatomically and physiologically adults and may be safely and appropriately managed using adult fluid management regimens. We would also wish to see the guideline address maintenance fluid requirements in the intraoperative period as these will vary significantly from the non-surgical requirements due to increased evaporative losses e.g. from. open body cavities.	has been amended following feedback from stakeholders and it has been agreed that the guideline will include all babies born at term. We recognise the difficulty health care professionals may experience when they have they have teenage children who may be anatomically and physiologically close to being an adult. Where possible, we will consider whether we can provide recommendations based on the weight range of the patients Recommendations within the guideline are cross-cutting and likely to be applicable to intraoperative care.
SH	The Royal College of Anaesthetists	7	4.2a	Unsure why the guideline should only be applicable to NHS hospitals and not include those in the independent sector.	Thank you for your comment. NICE guidelines are developed for use within the NHS however, independent settings are welcome to adopt the recommendations where appropriate.
SH	The Royal College of Anaesthetists	8	4.3.1a	This should emphasise frequent assessment of fluid and electrolyte status with a minimum frequency of once every 24 hours (and more frequently if the	Thank you for comment. We will consider the optimum frequency of assessment when considering the

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				patient is physiologically unstable).	evidence identified in this review.
SH	The Royal College of Anaesthetists	9	4.3.1b	In light of the recent published evidence on adverse outcomes associated with their use, we assume that the use of starch solutions will not be considered in development of these guidelines.	Thank you for your comment and for highlighting this document. We are aware of the current decision by the MHRA. As noted in Section 4.3.1, the guideline will consider synthetic colloids which may or may not include starches, depending upon the outcome of the work by the MHRA.
SH	The Royal College of Anaesthetists	10	General comment on 'Clinical management'	We recommend that the guideline group consider the delivery of iv fluid therapy including the advisability of using volumetric devices particularly in younger children and infants.	Thank you for your comment. The use of devices for the provision of intravenous fluids in children was not included in the scope as it was felt that there were other areas where clinical practice varied which should be prioritised for this guideline.
SH	The Royal College of Anaesthetists	11	4.4	Adverse outcomes will need to be clearly defined; obvious areas for inclusion are hypo- and hyper-natraemia. Length of stay in hospital should only be included when directly affected by adverse fluid management issues. Quality of life – might wish to consider whether iv fluid therapy was indicated and whether the preferred and safer, enteral route could have been used.	Thank you for your comment. We will generate a more explicit list of adverse events when the review protocols are discussed with the GDG. Thank you for comment on when to include length of stay in hospital. We will consider then when designing the review protocols with the GDG.

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					Quality of life data will be extracted wherever possible. However, capturing details on whether a preferred and safer, enteral route could have been used instead of intravenous fluids is outside the remit of this guideline.
SH	The Royal College of Anaesthetists	12	4.5	All the review questions should be considered for their emphasis on patient safety as well as 'clinical and cost effectiveness'.	Thank you for comment. Safety and/or adverse events will be considered in each of the reviews. In addition, as outlined in Section 4.5, we included have a review question "What key components need to be documented to ensure safe prescribing and improved fluid balance recording?".
SH	The Royal College of Anaesthetists	13	4.5.6	Management of hypo- and hyper-natraemia is a huge topic and in our view outside of the remit of a guideline focussing on fluid therapy.	Thank you for your comment. We have clarified that this will cover the management of hypernatraemia and hyponatraemia resulting from poor intravenous fluid use.
SH	The Royal College of Nursing	1	General	No comment	Thank you.

These organisations were approached but did not respond:

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3M Health Care UK

Addenbrookes Hospital

Alder Hey Children's NHS Foundation Trust

American Medical Systems Inc.

Barnsley Hospital NHS Foundation Trust

British Association For Paediatric Nephrology

British Association of Paediatric Endoscopic Surgeons

British Medical Association

British Medical Journal

British National Formulary

British Nuclear Cardiology Society

British Psychological Society

British Specialist Nutrition Association

BSPGHAN

Capsulation PPS

Care Quality Commission (CQC)

Central London Community Health Care NHS Trust

Childhood Eye Cancer Trust

counselling for prisoners network

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Covidien Ltd.

Croydon Health Services NHS Trust

Croydon University Hospital

Deltex Medical

Department of Health, Social Services and Public Safety Northern Ireland

East and North Hertfordshire NHS Trust

East Kent Hospitals University NHS Foundation Trust

Ethical Medicines Industry Group

Five Boroughs Partnership NHS Trust

Gloucestershire Hospitals NHS Foundation Trust

Guidelines and Audit Implementation Network

Health Quality Improvement Partnership

Healthcare Improvement Scotland

Herts Valleys Clinical Commissioning Group

Lanes Health

Leicester Royal Infirmary

Luton and Dunstable Hospital NHS Trust

Masimo Corporation

Medicines and Healthcare products Regulatory Agency

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Meningitis Research Foundation

Ministry of Defence

National Childbirth Trust

National Clinical Guideline Centre

National Collaborating Centre for Cancer

National Collaborating Centre for Mental Health

National Collaborating Centre for Women's and Children's Health

National Institute for Health Research Health Technology Assessment Programme

National Patient Safety Agency

National Treatment Agency for Substance Misuse

Newcastle upon Tyne Hospitals NHS Foundation Trust

NHS Barnsley Clinical Commissioning Group

NHS Connecting for Health

NHS Cumbria Clinical Commissioning Group

NHS Direct

NHS England

NHS England Greater Manchester

NHS MEDWAY CLINICAL COMMISSIONING GROUP

NHS Plus

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NHS Sheffield

NHS South Cheshire CCG

NHS Wakefield CCG

NHS Warwickshire North CCG

NICE TLOC GDG

Nordic Pharma

North and East London Commissioning Support Unit

North of England Commissioning Support

North West London Perinatal Network

Nottingham City Council

Oxfordshire Clinical Commissioning Group

Primary Care Pharmacists Association

Public Health England

Public Health Wales NHS Trust

Public Health Wales NHS Trust

Royal College of General Practitioners

Royal College of General Practitioners in Wales

Royal College of Midwives

Royal College of Obstetricians and Gynaecologists

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Royal College of Pathologists

Royal College of Physicians

Royal College of Psychiatrists

Royal College of Radiologists

Royal College of Surgeons of England

Royal Pharmaceutical Society

Scottish Intercollegiate Guidelines Network

Sheffield Childrens Hospital

Sheffield Teaching Hospitals NHS Foundation Trust

Smith & Nephew UK Limited

Social Care Institute for Excellence

South London & Maudsley NHS Trust

South West Yorkshire Partnership NHS Foundation Trust

Staffordshire and Stoke on trent NHS Partnerships

Stockport clinical commissioning group

Stockport NHS Foundation Trust

Suffolk County Council

The African Eye Trust

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The Patients Association

Trauma Audit & Research Network

UK Clinical Pharmacy Association

University Hospital Birmingham NHS Foundation Trust

Welsh Government

Western Sussex Hospitals NHS Trust

Wigan Borough Clinical Commissioning Group

York Hospitals NHS Foundation Trust

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