

**National Institute for Health and Clinical Excellence**

**IV Therapy – Clinical Guideline and Quality Standard  
Scope Consultation Table  
14<sup>th</sup> June 2011 and 5<sup>th</sup> July 2011**

| <b>Type</b> | <b>Stakeholder</b>  | <b>Order No</b> | <b>Section No</b> | <b>Comments</b><br>Please insert each new comment in a new row.  | <b>Developer's Response</b><br>Please respond to each comment   |
|-------------|---|-----------------|-------------------|--|---|
| SH          | Royal Liverpool and Broadgreen University Hospitals Trust | 1.0             | General           | There is a tendency to overload patients on surgical wards who become unwell but who remain haemodynamically stable with normal MEWS score – which tends to make matters worse so that patients eventually need resuscitation. Junior doctors need clarity about when patients needs resuscitation level fluids as opposed to maintenance fluids. This fits in with “recognising sick patients”. They also need clear guidelines about when and how to carry out a fluid challenge safely. | Thank you for your comment. The guideline development group will consider the issues raised as part of the evidence review. |
| SH          | Faculty of Intensive Care Medicine                        | 2.0             | 2.1               | The epidemiology addresses the relevant issues.  | Thank you for your comment.   |
| SH          | Faculty of Intensive Care Medicine                        | 2.1             | 2.2               | Standardisation is important – I agree.  | Thank you for your comment.   |
| SH          | Faculty of Intensive Care Medicine                        | 2.2             | 3.1               | Inclusions and exclusions are sensible.  | Thank you for your comment.   |
| SH          | Faculty of Intensive Care Medicine                        | 2.3             | 3.3.1 c d e       | The key issues are important- this is a massive undertaking and it is clear that there are many issues here that have failed to be resolved over many years – hence a more general and less specific approach may be sensible when it comes to specific fluids.  | Thank you for your comment.   |
| SH          | Faculty of Intensive Care Medicine                        | 2.4             | 3.3.1f            | Emphasis needs to be on the more basic clinical assessment and developing thresholds for escalating monitoring requirements. I think this section implies that and certainly more advanced   | Thank you for your comment.   |

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|      |                                    |          |            | monitoring requirements are excluded in 3.3.2 e   |  |
| SH   | Faculty of Intensive Care Medicine | 2.5      | 3.3.2 f    | A very sensible and pragmatic approach – no additional comments.  | Thank you for your comment.  |
| SH   | Faculty of Intensive Care Medicine | 2.6      | 3.5        | Economic aspects are likely to be difficult as there is a real paucity of information currently available and this needs to be addressed so developing a 'system' for collecting relevant economic data needs to be a fundamental part of the project.  | Thank you for your comment. The cost effectiveness review of a NICE guideline follows a set process described in the NICE technical manual, which can be found on the NICE website following this link <a href="http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp">http://www.nice.org.uk/aboutnice/howwework/developingniceclinicalguidelines/clinicalguidelinedevelopmentmethods/GuidelinesManual2009.jsp</a> |
| SH   | NHS Kidney Care                    | 3.0      | General    | Very much agree with the rationale and need for this document. The 2009 NCEPOD report into AKI (Adding Insult to Injury) also highlighted inadequacies in fluid resuscitation for people with AKI   | Thank you for your comment and information.  |
| SH   | NHS Kidney Care                    | 3.1      | General    | Agree about the importance of including the high risk groups and in particular those with acute kidney injury. It might be worth expanding this slightly to include patients at risk of AKI – since appropriate fluid management may prevent AKI in this population.  | Thank you for your comment. We believe that prevention of AKI is implicit in the guideline development.  |
| SH   | NHS Kidney Care                    | 3.2      |            | Training should include not just prescribing but also monitoring of fluid and electrolyte status. The latter is very much a multidisciplinary task, involving nurses and health care assistants for example. Fluid assessment is something that all healthcare workers should have competencies in (albeit at different levels of competency) | Thank you for your comment. The monitoring of fluid and electrolyte status will be covered in the guideline.   |
| SH   | NHS Kidney Care                    | 3.3      | 3.3        | Fluid balance assessment should account for non-prescribed fluids (e.g. oral fluids)  | Thank you for your comment. The guideline is for intravenous fluid therapy. Administration of oral fluids is outside the scope of this guideline but it is anticipated that this will be considered as part of the evidence review related to monitoring and assessment in section 3.3.1f of the scope.  |

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| SH   | NHS Kidney Care                                 | 3.4      | 3.3f            | Serum lactate is an important marker of tissue perfusion and can be helpful in fluid assessment. Probably more useful than chloride, which is not a very helpful marker clinically, though can be useful in diagnosing acid/base disturbances.           | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | NHS Kidney Care                                 | 3.5      | 3.3f            | Creatinine measurements for fluid assessment should consider changes in creatinine, not just a single value (As per the main classification schemes for acute kidney injury)   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | NHS Kidney Care                                 | 3.6      | 3.3f            | Serial measurements of patient weight are often far more useful than input/output charts in assessing fluid balance – and is correlated with risk of in hospital mortality   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | NHS Kidney Care                                 | 3.7      | General         | Should emphasise the multidisciplinary aspects of fluid management. The guideline should be about how trusts can prevent some of the fluid related deficiencies in basic care flagged up in the recent Health Ombudsman and Patient Association Reports. | Thank you for your comment and information. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | National Critical Care Network Lead Nurse Forum | 5.0      | 2.1.D           | Needs evidence base and referencing  | Thank you for your comment. Section 2.1 d is intended to be an introduction to the guideline scope, not a full evidence review. We do not usually reference statistics in line with the NICE house style structure of a scoping document.  |
| SH   | National Critical Care Network Lead Nurse Forum | 5.1      | 3.1.1.          | To include emergency situations or high risk groups here   | Thank you for your comment. The populations considered within this guideline include high risk groups and those attending hospital for emergency surgical or medical care. This does not include emergency situation outwith the hospital setting as prioritised by the remit from the Department of Health. |
| SH   | National Critical Care Network Lead Nurse Forum | 5.2      | General and 3.5 | We note the absence of a pharmacist from the guideline development membership list. A suitably experience pharmacist would be able to provide  | Thank you for your comment and information. A clinical pharmacist will be recruited to the guideline development group. The guideline will only consider   |

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|      |             |          |            | <p>input to the group on formulation and prescribing issues.</p> <p>The range of commercially available solutions is limited, and recommendations in the past have included solutions that require compounding on an individual basis. This raises issues of safety (eg NPSA potassium, and injectable alerts), as well as cost. 'Special' solutions are more expensive than the routine commercially available preparations.</p>  | <p>the role of licensed intravenous fluids in developing its recommendations. The guideline development group may choose to make recommendations related to non-standard infusions on consideration of the evidence related to the prescribing of intravenous fluids in section 3.3.1a of the scope.</p>   |
| SH   | BDA         | 6.0      |            | No comments  | Thank you for your comment.  |
| SH   | BSPGHAN     | 6.1      |            | <p>A guideline is required to review the principles of prescribing intravenous fluids (IVFs) to the acutely ill child.</p> <p>Evidence: The historic approach of administering hypotonic IVFs results in a high incidence of hospital-acquired hyponatremia in children.</p> <p>A guideline is necessary for children and infants to give advice on requirements and types of fluids.</p> <p>Evidence: there is varied practice on adjusting sodium composition and fluid rate to prevent disorders in serum sodium or volume status from occurring.</p> <p>References<br/> 1] <a href="#">Curr Opin Pediatr.</a> 2011 Apr;23(2):186-93. Intravenous fluid management for the acutely ill child.<br/> <a href="#">Moritz ML, Ayus JC.</a><br/> 2] <a href="#">Arch Dis Child.</a> 2007 Jun;92(6):546-50. Epub 2006 Dec 15.</p> | <p>Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area</p> |

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|      |             |          |            | Fluid therapy for children: facts, fashions and questions.  |   |
| SH   | BSPGHAN     | 6.2      |            | A guideline needs to be prepared to allow for different age groups to allow for special case of newborn infants, where rational parenteral fluid therapy must take into account large insensible fluid losses, adaptive changes of renal function in the first days of life and the fact that neonates do not tolerate prolonged periods of fasting.          | Thank you for your comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area              |
| SH   | BSPGHAN     | 6.3      |            | Mention of recent reviews to include special cases where subcutaneous and intra osseous routes for rehydration are employed   | Thank you for your comment. This guideline will cover intravenous fluid therapy. Subcutaneous and intra osseous routes for hydration are outside the scope of this guideline.   |
| SH   | BSPGHAN     | 6.4      |            | The adult guideline includes management of special cases such as renal insufficiency. The adult guideline does not include management of individuals with diabetic ketoacidosis or with marked dehydration. These are areas that are important to consider inclusion in a guideline for children so that paediatricians have access to these recommendations. | Thank you for your comment. Diabetic ketoacidosis and marked dehydration is outside the scope of this guideline. NICE has developed guidance on the management of IV fluids in its diabetes portfolio of guidance <a href="http://www.nice.org.uk/CG15">http://www.nice.org.uk/CG15</a> .<br><br>We are unable to include the management of IV fluid therapy in paediatrics as the Department of Health remit for this guideline was for adults only. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in |

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|      |                                |          |                            |  | relation to the specific need for children's guidance in this area..   |
| SH   | The Renal Association          | 7.0      | General                    | This guideline will tackle a very important clinical area that is poorly appreciated at present.   | Thank you for your comment.  |
| SH   | The Renal Association          | 7.1      | 2.2a                       | There continues to be a significant knowledge gap in the prescription of intravenous fluids. There needs to be consideration for how this can be improved at undergraduate and postgraduate level.   | Thank you for your comment. The guideline development group will be made aware of this information during the guideline development.   |
| SH   | The Renal Association          | 7.2      | 2.2b                       | There needs to be a unification of fluid prescribing charts. Fluid prescribing needs to take on the same importance as drug prescribing. The prescription charts need to be linked more carefully with the fluid balance chart.  | Thank you for your comment. The guideline development group will be made aware of this information during the guideline development.   |
| SH   | The Renal Association          | 7.3      | 2.2d                       | Intravenous fluids should not be prescribed without the patient being examined. Daily weights are often a more accurate way of ascertaining a patient's fluid balance. Fluid balance charts are currently very poorly completed and therefore inaccurate.  | Thank you for your comment. The guideline development group will be made aware of this information during the guideline development.   |
| SH   | The Renal Association          | 7.4      | 3.1.2b                     | I think that patients with chronic kidney disease (but not including dialysis patients) should be included as this is a group which is at risk of developing AKI if not evaluated properly.  | Thank you for your comment. Patients that will be included in the guideline are detailed in section 3.1.1 "Groups that will be covered" and 3.1.2 "Groups that will not be covered"  |
| SH   | National Patient Safety Agency | 8.0      | 2.2.1<br>Need for Guidance | <p>There is need for a multidisciplinary approach to this guidance scope to cover prescribing, preparation of non-standard infusions in clinical areas, administering and monitoring intravenous fluid therapy.</p> <p>It is not sufficient to focus only on prescribing and monitoring issues within this guidance and assume all the other processes will be conducted safely in practice. The NPSA has evidence that unsafe</p> | <p>Thank you for your comment. The scope includes training and education in prescribing of IV fluids (see section 3.3.1a). The inclusion of processes other than prescribing and monitoring were not prioritised as areas as per the remit from the Department of Health (see section 3.3.2).</p> <p>The guideline will only consider the role of licensed intravenous fluids in developing its recommendations. The guideline development group</p> |

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|      |             |          |            | <p>infusion therapy results from poor practice of the health care team and not just prescribers. The evidence includes patient safety incident reports involving infusion therapy arising from all steps of the medicine use process</p> <p>For example</p> <p>Prescribing infusion fluids that are not commercially available and where there are no formally agreed procedures for preparing these products in clinical areas.</p> <p>Some recent national guidelines have been issued that recommend specific infusion solutions which are not commercially available to the NHS. This can lead to confusion, mis-selection, preparation errors and delays in treatment. (e.g. NHS Diabetes. Preoperative management of adults with diabetes undergoing surgery and elective procedures: improving standards 2011).</p> <p>The NPSA has identified a number of serious patient safety incidents related to fluid overloading, and is pleased the proposed CG will be addressing this in a context where the counter-balancing risk of dehydration can also be considered. The CG may need to extend to the systems that allow good monitoring of prescribed fluids, e.g. access to weighing scales for bedfast or hoist –dependant patients to detect fluid overloading and avoidance of 'repeat prescriptions' of IV fluids out of hours.</p> <p>The scope should include guidance intended to</p> | <p>may choose to make recommendations related to non-standard infusions on consideration of the evidence related to the prescribing of intravenous fluids in section 3.3.1a of the scope</p> <p>The guideline development group will be considering the evidence related to monitoring of fluid status. We will ensure that the guideline development group are aware of your comments when formulating the appropriate clinical questions</p> <p>The guideline development group will consider the evidence relating to assessment including serial weights.</p> |

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|      |                                |          |            | <p>minimise the following risks:</p> <p>Errors in the preparing non-commercially available infusion fluids in clinical areas using concentrated electrolyte solutions containing for example potassium, calcium and phosphate containing products.</p> <p>Errors in administering infusion fluids. Over infusion leading to fluid overload and cardiac failure, too rapid infusion of potassium containing infusion leading to cardiac arrest. Guidance on the use of infusion pumps and infusion pumps with dose error reduction software for clear fluid and electrolyte therapy. Drug – infusion incompatibilities.</p> <p>Failure to safely monitor fluid and electrolyte therapy. The role of all clinical staff preparing and administering infusion fluids to also monitor therapy as well as the that of the prescriber.</p> <p>Links to the following NPSA guidance.</p> <ul style="list-style-type: none"> <li>• Patient Safety Alert 1. Safer use of potassium chloride infusion. 2002</li> <li>• Patient safety Alert 20. Safer use of injectable medicines. 2007</li> <li>• Design For Patient Safety. A guide to the labelling and packaging of injectable medicines. 2008.</li> <li>• Design for Patient Safety. A guide to the design of electronic infusion devices. 2010.</li> </ul> |  |
| SH   | National Patient Safety Agency | 8.1      |            | Many prescribers (and staff who prepare, administer and monitor) do not know the constituents of the many different types of intravenous replacement   | Thank you for your comments and information.<br><br>A clinical pharmacist will be recruited to the guideline |

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|      |             |          |            | <p>therapy.</p> <p>Guidance is required to minimise the risks associated with the use of hypotonic and hypertonic infusion fluids</p> <p>There is a need for a standardised approach to the clinical assessment of patients and the preparation and administration of intravenous fluid therapy in the NHS. This guidance represents a major opportunity to improve patient safety.</p> <p>The scope should consider the following guidance from Australia:</p> <ul style="list-style-type: none"> <li>• Australian Commission on Safety and Quality in Healthcare. National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines</li> </ul> <p>The use of unlicensed special infusion fluids vs infusion fluid prepared in clinical areas should also be included in the scope.</p> <p>The scope of both the draft scope in addition to the new topics identified above requires the expertise of a senior hospital pharmacist on the NICE review panel. The inclusion of a Clinical Pharmacologist on the review panel is no substitute for a Pharmacists' knowledge of clinical pharmaceuticals, the commercial availability of infusion products and other technical, practical and legal issues associated with the use of infusion therapy.</p> | <p>development group.</p>                              |

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| SH   | National Patient Safety Agency | 8.2      | Management<br><br>3.1 Additional key issues that need to be covered: | <p>1) The safety and effectiveness issues of using infusion fluids that are not commercially available, including the use of unlicensed specials – infusions vs those prepared in the clinical area</p> <p>2) The safe preparation of non standard infusion fluids in clinical areas including a standardised labelling of IV additives.</p> <p>The safe administration of infusion fluids including guidance on using infusion pumps and pumps with dose error reduction software, drug-infusion solution incompatibilities</p> | <p>1) Thank you for your comment. The issue of preparation, labelling, software and drug infusion solution incompatibility is outside the scope of this guideline.</p> <p>2) The guideline will only consider the role of licensed intravenous fluids in developing its recommendations. The guideline development group may choose to make recommendations related to non-standard infusions on consideration of the evidence related to the prescribing of intravenous fluids in section 3.3.1a of the scope.</p> |
| SH   | National Patient Safety Agency | 8.3      | 3.4 Main outcomes  | c) adverse events and patient safety incidents relating to fluid and electrolyte imbalance.  | Thank you for your comment. The outcomes listed are examples suggested for questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review. The guideline development group will finalise the list and we will include your suggestions in the options that we will consider.   |
| SH   | National Patient Safety Agency | 8.4      | 4.1.1 Quality standards that will be considered                      | <p>Essential topics that need to be included in this section:</p> <p>1) The preparation of non-standard infusions in clinical</p> <p>2) Administering and intravenous fluid therapy</p>  | <p>Thank you for your comment.</p> <p>The guideline will only consider the role of licensed intravenous fluids in developing its recommendations. The guideline development group may choose to make recommendations related to non-standard infusions on consideration of the evidence related to the prescribing of intravenous fluids in section 3.3.1a of the scope.</p> <p>The guideline will address the types, volume and timings of intravenous fluid therapy.</p>  |
| SH   | Edwards life sciences          | 9.0      | All  | We agree with the proposed Scoping document.   | Thank you for your comment.   |

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|      |                            |          | sections   |   |   |
| SH   | Resuscitation Council (UK) | 10.0     | 2.1 b      | Losses of RED blood cells – as opposed to other types of cells in blood   | Thank you for your comment. We have amended the scope to read “red blood cells”.  |
| SH   | Resuscitation Council (UK) | 10.1     | 2.1 d      | Inappropriate fluid therapy is commonly documented as being responsible for patient harm in patients admitted to ICUs – as opposed to ‘rarely documented’   | Thank you for your comment. We do not agree that the scope wording needs to be amended.   |
| SH   | Resuscitation Council (UK) | 10.2     | 2.1 e      | The correct term is Emergency Department - not Accident and Emergency   | Thank you for your comment. We have amended the scope wording.  |
| SH   | Resuscitation Council (UK) | 10.3     | 2.2 a      | In our experience of teaching ‘most’ prescribers do not know the constituents of the fluids they prescribe – as opposed to many.  | Thank you for your comment. We do not agree that the scope wording needs to be amended.   |
| SH   | Resuscitation Council (UK) | 10.4     | 3.1.2 e    | Given that patients with sepsis are included in the scope, many of these same patients will require vasoactive drugs. We strongly support the inclusion of patients requiring or receiving inotropic and vasoactive drugs. This will be the case for those groups of patients who do not respond to fluids alone.                                 | Thank you for your comment. The inclusion of people receiving vasoactive therapy is outside the remit of this guideline. The guideline scope is limited to the general medical and surgical populations and not including ICU patients.                               |
| SH   | Resuscitation Council (UK) | 10.5     | 3.2 a      | We think the NHS hospitals inclusion is invalid - many NHS patients are now treated in ‘private hospitals’ and independent treatment centres. I think this guidance is equally important for all hospitals in the UK and the scope should not be limited. This is probably an issue for all NICE guidance.  | Thank you for your comment. NICE’s remit is to provide guidance only for healthcare where NHS healthcare is provided or commissioned and we are limited by this. However, people providing healthcare in other settings may find the guideline beneficial.            |
| SH   | Resuscitation Council (UK) | 10.6     | 3.3.2e     | When writing this guidance there will clearly be patients who require more than basic monitoring to assess their fluids need – also advanced monitoring techniques are excluded there does need to be statements requiring identifying patients who need advanced monitoring techniques/ higher levels of care to assess and guide fluid therapy. | Thank you for your comment. Whilst we recognise that advanced monitoring techniques are required for the care of some patients, we do not consider this appropriate to include in the guideline as there is a need to prioritise the areas we cover in the guideline. |
| SH   | Resuscitation Council (UK) | 10.7     | 3.4 c      | I assume this includes organ failures (including pulmonary oedema and renal failure)  | Thank you for your comment. Patients with chronic kidney disease stage 1, 2 and 3 will be included.   |

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|      |  |          |            |  | Patients with pulmonary oedema will also be included. Patients that will be included in the guideline are detailed in section 3.1.1 "Groups that will be covered" and 3.1.2 "Groups that will not be covered". |
| SH   | Resuscitation Council (UK)                           | 10.8     | General    | Many patients can take oral fluids (or enteral via nasogastric tubes) even after major surgery. Intravenous fluids are often prescribed when not necessary – this does not have the same emphasis as lack of prescribing of fluids in the scope.   | Thank you for your comment. The guideline development group will take this into account when reviewing the evidence.   |
| SH   | Resuscitation Council (UK)                           | 10.9     | General    | It is not clear whether scope will specifically address relative risks of allergic reactions to different fluids (e.g. anaphylaxis to colloids)  | Thank you for your comment. The scope is not intended to be an exhaustive list of the guideline scope. The guideline development group will consider adverse events when reviewing the evidence in this area.  |
| SH   | Sheffield Teaching Hospitals<br>NHS Foundation Trust | 11.0     | 3.1.1      | Consider inclusion of adult patients who are at risk from refeeding problems when starting artificial nutrition support as described in NICE CG 32. This patient group may need intravenous fluids with potassium, magnesium or phosphate. These patients are poorly managed due to a lack of national guidance on the management of refeeding syndrome  | Thank you for your comment. The Guideline Development Group will consider this information when developing the guideline.  |
| SH   | Sheffield Teaching Hospitals<br>NHS Foundation Trust | 11.1     | 3.3.1 f)   | Clinical biochemistry labs in different hospitals have their own set up for what electrolytes to include in routine blood tests. For example, U&Es mean different things to different labs and there should be some national agreements on what electrolytes should be included in blood tests. I think U&Es should have Na, K, Cr, Ur, Cl, HCO <sub>3</sub> . In my institution, Cl and HCO <sub>3</sub> have to be requested separately and it took me 2 yrs and 6 mths to get it changed. | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |

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| SH   | Sheffield Teaching Hospitals<br>NHS Foundation Trust       | 11.2     | 7.7.1      | <p>Need to consider the NCEPOD report from June 2010 – <b>A Mixed Bag</b> which mentioned intravenous fluids in patients receiving parenteral nutrition.</p> <p>Need to consider the recommendations in the <b>'British Consensus Guidelines on Intravenous Fluid Therapy for Adult Surgical Patients' GIFTASUP.</b></p>  | Thank you for your comment and information.   |
| SH   | Sheffield Teaching Hospitals<br>NHS Foundation Trust       | 11.3     | 3.1.2b     | It may be relevant to include pregnant women who need IV therapy that is not birth related (those with acute illnesses – e.g. swine flu) or at least to state that their IV care should be the same as others presenting with same infections.  | Thank you for your comment. Whilst the treatment of pregnant women is outside the remit of this guideline, some of the general principles could be extrapolated to this population. |
| SH   | Sheffield Teaching Hospitals<br>NHS Foundation Trust       | 11.4     | 4.1.1d     | How to monitor IV fluid balance should not be over prescriptive. For example in some areas of the Trust all patients having 4 hourly normal saline have to have 125mls documented hourly. This is time consuming and can lead to errors elsewhere in a busy acute ward (and nurses may document 125mls without actually checking). The whole 500mls can be documented at the end of the infusion. Sick patients requiring fluid challenges etc have their fluids documented as they receive them as the fluids are given in short time frames and this can be reflected on fluid balance chart. | Thank you for your comment. The guideline group will be reviewing the evidence relating to the appropriate monitoring of fluids.  |
| SH   | United Kingdom Clinical<br>Pharmacy Association<br>(UKCPA) | 12.0     | General    | UKCPA recognises and congratulates NICE on attempting to undertake a broad examination of the area, rather than trying to very narrowly define one aspect in one small population   | Thank you for your comment.   |
| SH   | United Kingdom Clinical<br>Pharmacy Association            | 12.1     | General    | It is not clear why there is no pharmacist on the guideline development group. Indeed it is clear that  | Thank you for your comment and information. A clinical pharmacist will be recruited to the guideline  |

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|      | (UKCPA)  |          |            | very few pharmaceutical issues have been discussed. Pharmacists and pharmaceutical issues will be crucial if the NICE guidance is to have any impact. Pharmacists are increasingly available on wards and used as a source of information about many drugs including fluids. EQUIP clearly identifies that the availability of tailored information at the point of prescribing is vital for safe prescribing. Pharmacists provide this information to most junior doctors for a significant portion of prescribing, including fluids.                       | development group.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) |          | General    | In addition, pharmacists understand the market and licensing issues, and this knowledge will be required to avoid the unconsidered recommendation of a non-licensed fluid composition. A group which includes the appropriate expertise, including a pharmacist, will be able to make this decision.   | Thank you for your comment. A clinical pharmacist will be recruited to the guideline development group.                           |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.2     | General    | There is no discussion of the support that pharmacy can offer and how commonly used fluids should be readily available in the clinical area. If they are not readily available this is to minimise risk in that the fluids are not usually used and staff will be unfamiliar with them. Sudden introduction of new fluids and strengths is associated with additional hazards to staff and patients. It also raises the question of whether the patient may receive better care in another area (such as critical care) and a transfer should be considered. | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline. |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.3     | General    | To limit confusion pharmacy will only stock a selection of products so terms such as dextrose / saline Dextrose / saline may have a different interpretation in paediatrics (0.9% sodium chloride and 5% dextrose) from adults (0.18% sodium chloride and 4% dextrose) - see NPSA alert, or in   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline. |

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|      |  |          |            | specialist clinical areas.   |  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.4     | General    | Abbreviation such as D/S, D5W and N/S are potentially misleading. It should be recommended that abbreviations be avoided to reduce the risk of patient harm.   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.5     | General    | Will the treatment of alcoholics be discussed with reference to fluid and electrolyte shifts and their management?   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline. The guideline scope has prioritised populations for inclusion that addresses the very general needs relating to IV fluid management in hospitals as identified within the remit of the Department of Health. |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.6     | General    | Will there be discussion of refeeding syndrome or will there be signposting to nutrition guidelines?   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline. Where appropriate the guideline may cross refer to other related NICE guidance.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.7     | General    | Particular mention could be made of potassium containing maintenance fluids in compliance with the NPSA alert on Strong potassium. Local choices will have been made according to specific patient cohorts and clinical choices in individual hospitals. Specific NICE recommendation will cause significant re-negotiation of long term contracts, market distortion, educational needs and complex change management initiatives with associated risk of errors. | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.8     | General    | Licensed and unlicensed dilutions of other medications may need to be changed in order to achieve target fluid balance. Notably large volumes for antibiotics or parenteral nutrition.   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association         | 12.9     | General    | There is no consideration of hyperchloraemic acidosis and the consideration of balanced salt   | Thank you for your comment. The guideline development group will review the evidence relating  |

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|      | (UKCPA)  |          |            | solutions.  | to monitoring and assessment of IV fluids.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.10    | 2.1b       | <p>Consideration should be given to assay of fluid outputs in order to rationalise decisions about fluid input.</p> <p>Fluid replacement may also be required where there is no 'apparent' fluid loss eg, vasodilation in sepsis and 3<sup>rd</sup> space losses intra-operatively. In such circumstances fluid resuscitation is needed but the fluid 'loss' is not quantifiable.</p> | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.11    | 2.1d       | Education, clinical choices and handling of fluids is generally given a low priority. One of the key factors is regular review of what has been given (rather than what has been prescribed) and a clear plan for the next 24 hours (or more frequently if patient is dynamically unwell).  | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.12    | 2.1d       | Education should raise awareness of the influence of glucose solutions (with/without insulin) on electrolyte shifts - potassium, magnesium, calcium and phosphate.  | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.13    | 2.2b       | Attention should be drawn to the frequency of basic arithmetic errors in fluid balance charts. Charting has many practical issues – separate sheets are lost and separated from main prescription.  | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.14    | 2.2b       | There is a considerable need for education on the causes of acute renal failure, especially pre-renal failure.  | Thank you for your comment. The guideline development group will be made aware of this information when developing this guideline.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.15    | 2.2b       | There is poor understanding of serum creatinine, reporting units and normal ranges.   | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.16.   | 2.2d       | There is a need for a user friendly tool for regular assessment of maintenance or fluid challenge – describe each.  | Thank you for your comment. The guideline development group will be made aware of this information when developing the guideline. If appropriate, the guideline development group will |

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|      |  |          |                  |   | work with the NICE implementation team to produce this.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.17    | 3.1.1e           | Careful consideration should be given to the organisational impact of extrapolating religious beliefs in ways that may not have been originally intended (Gelofusine for Hindus, and only Gelofusine & starches for Jehovah's witnesses).   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.18    | 3.1.2d           | If DKA is to be excluded it should be noted that this is often poorly managed and there should be signposting to latest guidelines.   | Thank you for your comment. Diabetic ketoacidosis is outside the scope of this guideline. NICE has developed guidance on the management of IV fluids in its diabetes portfolio of guidance <a href="http://www.nice.org.uk/CG15">http://www.nice.org.uk/CG15</a> .       |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.19    | 3.1.2e           | Inotropes have been excluded but will the relationship between vasodilators/constrictors and fluid requirements be discussed?   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.20    |                  | Will there be discussion of the avoidance of prescriptions for fluids and frusemide? Except in hypercalcaemia or when combining plasma expanders and diuretics (for redistribution).  | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.21    | 3.3.1c           | It is important not to cluster all starches together as differences can be significant. Exclude old data about Hespan that is no longer used.   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.22    | 3.3.1c           | Will albumin be considered separately from other colloids, particularly with reference to differences between 20% and 4.5/5%  | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in relation to crystalloids and colloids.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.23    | 3.3.1c<br>3.3.1d | When recommending type of crystalloid/colloid to use, consider which products are commercially available and readily obtainable from wholesalers. Therefore not compromising care due to insufficient supply to meet demand.<br>The cost of the products must also be considered when making a first line recommendation. | Thank you for your comment. The costs of IV fluids from an NHS perspective will be included. Considerations for product availability is beyond the scope of economic evaluation but will be considered by the guideline development group when recommendations are made. |
| SH   | United Kingdom Clinical                              | 12.24    | 3.3.1f           | Will there be discussion of the use of arterial blood   | Thank you for your comment. The guideline  |

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|      | Pharmacy Association (UKCPA)                         |          |            | gas analysis to manage electrolytes?  | development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.25    | 3.3.1f     | Urinary sodium should only be undertaken if no diuretic and need to compare with plasma osmolality.   | Thank you for your comment. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.26    | 3.3.2a     | Will there be discussion of the broad differences between central and peripheral fluid administration. This is crucial for potassium containing fluids.   | Thank you for your comment. The route of administration is outside the scope of this guideline.  |
| SH   | United Kingdom Clinical Pharmacy Association (UKCPA) | 12.27    | 3.3.2e     | If invasive monitoring of fluid status is to be excluded, will there be guidance on when to consider invasive monitoring or a recommendation to move the patients to critical care areas that specialise in this?   | Thank you for your comment. Invasive monitoring is outside the scope of this guideline. We are unable to make specific recommendations without reviewing the necessary evidence.   |
| SH   | British Association of Critical Care Nurses          | 13.0     | General    | I've read and reviewed the consultation scope. It appears appropriate in context, the range of areas appears to be broad ranging but at the same time generic to the majority of hospitals.   | Thank you for your comment.  |
| SH   | British Association of Critical Care Nurses          | 12.29    | 3.3.1.(f)  | Perhaps rather than talk about pulse, blood pressure and temperature charts you should mention the National Early Warning Score chart which is being developed by the Royal College of Physicians in conjunction with key stakeholders and which we understand will be published in the next few months | Thank you for your comment and information. The guideline development group will consider this information when reviewing the evidence in this area.   |
| SH   | British Association of Critical Care Nurses          | 12.30    | 4.2 & 3.5  | Two sections with the same title?   | Thank you for your comment. Section 3 presents the areas of the clinical guideline and Section 4 the areas to be covered in the quality standard. Economic aspects will be considered in both the clinical guideline and the quality standard. |
| SH   | Department of Health                                 | 13.0     |            | No substantive comments   | Thank you for your comment.  |
| SH   | Royal College of Paediatrics and Child Health        | 14.1     | 3.1.1      | The College believes this document does not justify the exclusion of children from the scope of the guidance.   | Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only.                                   |

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|      |             |          |            | <p>Children need higher water and electrolyte intakes than adults making them more susceptible to perturbations as a result of illnesses such as gastroenteritis that are common in children and can cause fluid and electrolyte imbalance. Most of the issues raised in sections 2.1 and 2.2 apply to children but there is additional concern that changes in fluid and electrolyte can be more rapid than in adults so inadequate fluid resuscitation in the emergency department increases the risk of developing acute kidney injury (AKI). Furthermore, the consequence of inappropriate intravenous fluid management in children with established AKI can lead to significant morbidity such as hyponatraemic seizures. Conversely, appropriate management of intravenous fluid and electrolyte therapy can lead to more rapid recovery from illness, avoidance of significant morbidity and a shorter duration of hospitalisation.</p> <p>Section 3.1.1 (e) recognises the specific consideration for older people who have particular challenges for managing fluid balance. Children also have challenges and this justifies their inclusion in the guidance.</p> <p>The College, along with the British Association for Paediatric Nephrology and the British Society of Paediatric Gastroenterology Hepatology &amp; Nutrition, strongly believes the principles for intravenous fluid replacement in children is the same as in adults and consequently that patients less than 16 years of age should be included in this guidance.</p> | <p>The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area</p> |

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|      |   |          |            | <p><b>Reference</b><br/>GA Pearson. Fluid, electrolyte and acid-base disturbance. In: Forfar and Arneil's Textbook of Paediatrics (6<sup>th</sup> ed). Churchill Livingstone; 2003. pp 583-598.</p>   |   |
|      | Royal College of Paediatrics and Child Health | 14.2     | 3.1.1      | <p>We believe a guideline is needed to review the principles of prescribing IV fluids to acutely ill children and infants. The historic approach of administering hypotonic IV fluids results in a high incidence of hospital-acquired hyponatremia in children.</p> <p>A guideline is needed to advise on the requirements and types of fluids in children and infants; there is varied practice on adjusting sodium composition and fluid rate to prevent disorders in serum sodium or volume status from occurring.</p> <p><b>References</b></p> <p>1. Moritz ML, Ayus JC. Intravenous fluid management for the acutely ill child. Curr Opin Pediatr. 2011 Apr;23(2):186-93.</p> <p><b>Fluid therapy for children: facts, fashions and questions. Arch Dis Child. 2007 Jun;92(6):546-50. Epub 2006 Dec 15.</b></p> | <p>Thank you for your comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area</p> |

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| SH   | Royal College of Paediatrics and Child Health | 14.3     | 3.1.1      | A guideline covering different age groups is required, in particular covering the special case of newborn infants, where rational parenteral fluid therapy must take into account large insensible fluid losses, adaptive changes of renal function in the first days of life and the fact that neonates do not tolerate prolonged periods of fasting. | Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area |
| SH   | Royal College of Paediatrics and Child Health | 14.4     | 3.1.1      | The same issues covered in sections 2.1 and 2.2 apply to children. They have the same range of clinical situations as listed in these two sections. Paediatricians, Emergency Department staff and surgical teams face exactly the same challenges in children as those seen in adults.  | Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area |
| SH   | Royal College of Paediatrics and Child Health | 14.5     | 3.1.2      | The document should specify whether total parenteral nutrition is excluded.  | Thank you for your comment. The role of parenteral nutrition will be considered within the context of total IV fluid therapy management.  |
| SH   | Royal College of Paediatrics                  | 14.6     | 3.3.1 a    | Prescribing intravenous fluids for children is complex   | Thank you for you comment and information. We are   |

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|      | and Child Health                              |          |            | as they may range in weight from a few kilograms to adult size. While paediatricians do receive training in prescribing fluids, sick children often present to Emergency Departments and the staff they encounter may not have had appropriate training in prescribing intravenous fluids for children. The inclusion of children in this guidance will improve the initial care of sick children presenting to emergency departments without paediatric cover. | unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area  |
| SH   | Royal College of Paediatrics and Child Health | 14.7     | 3.3.1 a    | The only difference in prescribing IV fluids in paediatric and adult populations is that in paediatrics, fluids are prescribed as mls per kg. We do not think this is a reason to exclude children. Any specific recommendations regarding increasing or decreasing IV fluids in certain situations should be described as percentage changes.  | Thank you for your comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area |
| SH   | Royal College of Paediatrics and Child Health | 14.8     | 3.3.1 c-e  | Inclusion of children in the guidance will help bring consensus to the topic of the relative merits of crystalloids and colloids in acutely ill children, an issue that remains contentious in paediatric practice and one that continues to be subject to variation in practice.   | Thank you for your comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the   |

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|      |   |          |            |   | Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area   |
| SH   | Royal College of Paediatrics and Child Health | 14.9     | 3.3.1 f    | If children are included in the guidance it is important to include measurement of weight as an essential component of monitoring during intravenous fluid therapy.   | Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. We would like to draw your attention to the National Quality Board engagement exercise on the core library of topics commencing on the NICE website in August. You may wish to submit comments to this process in relation to the specific need for children's guidance in this area |
| SH   | Royal College of Paediatrics and Child Health | 14.10    | 3.3.1.g    | We think this guideline should make special reference to covering IV fluid management in situations likely to be associated with SIADH (syndrome of inappropriate ADH). SIADH is ubiquitous and can be caused by a myriad of wide ranging conditions from pneumonia, cancers (not only lung), COPD, CNS infection, drugs, post operative surgery, etc., with patients being looked after by many different hospital teams (medical and surgical). It would be a missed opportunity if the | Thank you for your comment. This guideline includes all hospitalised patients. The guideline development group will consider this information during the development of the guideline.  |

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|      |   |          |            | guideline is not used to create awareness of the potential development of SIADH and how to prevent potential iatrogenic deaths due to injudicious IV fluid prescribing.  |  |
| SH   | Royal College of Paediatrics and Child Health | 14.11    | 3.4        | We think that morbidity should be listed as a main outcome. For example, reduced renal function as a result of under prescribing, pulmonary oedema, cerebral oedema and CNS impairment as a result of overprescribing and or poor fluid / electrolytes monitoring.   | Thank you for this information. The outcomes listed are examples suggested for questions that we expect the guideline to answer. The list is not exhaustive and will be tailored to each evidence review. The guideline development group will finalise the list and we will include your suggestions in the options that we will consider.                          |
| SH   | Royal College of Paediatrics and Child Health | 14.12    | General    | Mention of recent reviews needs to include special cases where subcutaneous and intra osseous routes for rehydration are employed.   | Thank you for your comment. This guideline is for IV fluid therapy. Subcutaneous and intra osseous routes for rehydration are outside the scope of this guideline.   |
| SH   | Royal College of Paediatrics and Child Health | 14.13    | General    | The draft scope includes management of special cases such as renal insufficiency, but does not include management of individuals with diabetic ketoacidosis or with marked dehydration. These are areas that are important to consider for inclusion so that paediatricians have access to these recommendations.                    | Thank you for your comment. The management of people with diabetic ketoacidosis or marked dehydration is outside the remit of this guideline. NICE has developed guidance on the management of IV fluids in its diabetes portfolio of guidance. <a href="http://guidance.nice.org.uk/CG15">http://guidance.nice.org.uk/CG15</a>                                      |
| SH   | Royal College of Paediatrics and Child Health | 14.14    | General    | A useful document is the NPSA Central Alert System (CAS) reference NPSA/2007/22 published in 2007: Reducing the risk of hyponatraemia when administering intravenous infusions to children (March 2007): <a href="http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59809">http://www.nrls.npsa.nhs.uk/resources/?EntryId45=59809</a> | Thank you for you comment and information. We are unable to include the management of IV fluid therapy in paediatrics at this time as the Department of Health remit for this guideline was for adults only. The areas included in the final scope have been prioritised based on the remit provided by the Department of Health and the development time available. |
| SH   | Royal Pharmaceutical Society                  | 15.0     | General    | We are very concerned to note that there is no pharmacist included in the membership list of the guideline development group. In our view it is vital that a pharmacist is included. We are aware that   | Thank you for your comment and information. A clinical pharmacist will be recruited to the guideline development group.  |

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|      |                              |          |            | <p>there are two recent examples, the Guidelines on Intravenous Fluid Therapy for Surgical Patients (GIFTASUP) and the Guidelines for the Perioperative Management of Patients with Diabetes, to which there seems to have been no pharmacist input, with the result that routine use of fluids was recommended which aren't and are unlikely ever to become readily available as licensed or even as unlicensed products. Compliance with these guidelines therefore requires routine addition of concentrated potassium solutions to infusions in clinical areas, creating an avoidable risk to patient safety and contravening NPSA guidance. Inclusion of a pharmacist with expert knowledge of intravenous fluid therapy would avoid such issues occurring with the NICE guideline.</p> <p>We would also like to highlight the Injectable Medicines Guide, website which is now widely in use across the UK and is quality checked by UKMI. This website is coordinated by pharmacists and it is vital that this expertise is included and referred to during guideline development.</p> |   |
| SH   | Royal Pharmaceutical Society | 15.1     | 3.2        | <p>Out of hospital and community use should also be included in the scope. Community services, e.g. community hospitals and community nursing, include managing Long Term Conditions out of the acute care setting and the use of injectable therapies to support this care which may include iv fluids. Iv/sc fluids administered within community hospitals and similar settings often help to keep a patient out of the acute hospital trust so any guidelines should be able to acknowledge this. In this context, consideration of issues such as regulatory status and availability of recommended fluids is especially critical.</p>   | <p>Thank you for your comment and information. We are unable to include the management of IV fluid therapy in community settings at this time as the Department of Health remit for this guideline was for hospital only.</p> |

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|      |                              |          |            | Treatments are in future expected to be moved out of hospitals and it is therefore important that the safety issues in Community Health Services are considered in advance rather than not including them at this stage and addressing problems after incidents start to occur.  |  |
| SH   | Royal Pharmaceutical Society | 15.2     | 3.5        | Whilst the cost of currently available fluids is minimal, that of less commonly used and unlicensed Specials can be 3-5 times greater. Similarly recommendations for use of unlicensed fluids or those that which would require bedside manipulations poses risk of errors and patient safety hazards. Any economic analysis that fails to take these issues into account will be flawed. If these factors are to stay excluded from Scope, this should be noted in 3.3.2. | Thank you for your comment. We agree. The guidelines development group will consider both issues in the economic evaluation. In the event that the influence of potential human error on health outcomes cannot be formally included in the economic analysis due to lack of information, this issue will be considered by the guideline development group informally. |
| SH   | Royal Pharmaceutical Society | 15.3     | 1.2        | To be meaningful, Quality Standards must take into account the issues of availability and regulatory status of recommended fluids.   | Thank you for your comment. The guideline development group will be made aware of this information during the development of the guideline and quality standard.   |
| SH   | Royal Pharmaceutical Society | 15.4     | 2          | The Need for Guidance identifies risks in the care pathway from prescribing to monitoring but excludes consideration of risks highlighted in NPSA Guidance and by the Never Events Framework, shown to be associated with product selection, bedside manipulation and administration. If these factors are to stay excluded from Scope, this should be noted in 3.3.2.   | Thank you for your comment and information. The guideline development group will be made aware of this information during the development of the guideline.  |
| SH   | Royal Pharmaceutical Society | 15.5     | 3          | Issues associated with the choice of route of administration - peripheral vs central - should be identified  | Thank you for your comment. The route of administration will not be covered within the guideline as this was not prioritised as a key issue within the remit from the Department of Health.  |

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| SH   | Royal Pharmaceutical Society | 15.6     | 3          | Many pharmaceutical issues have not been identified in the draft scope. We have referred to some of them specifically in previous comments. Others such as packaging and labelling availability and supply, the range of fluids stocked in clinical areas, storage capacity, the risk of selection errors, drug/fluid compatibility & stability issues, are all inter-related and impact directly on cost, patient safety and quality of care. We suggest again that in order to ensure that these are given properly informed consideration, a clinical pharmacist should be recruited to the guideline development group at the outset. If these issues are to remain excluded this should be noted in 3.3.2, If this is the case, however, we believe the guidelines may be seriously flawed. | Thank you for your comment. A pharmacist will be recruited to the guideline development group.<br><br>The remit from the Department of Health is to produce a guideline on Intravenous fluid therapy. The areas of packaging, labelling and availability and supply and storage capacity have not been prioritised for inclusion in the final scope. |
| SH   | Royal Pharmaceutical Society | 15.7     | 3.1.2      | Given the rising incidence of diabetes, we question whether exclusion of patients with diabetes will compromise the economic analysis  | Thank you for your comment. Diabetes is excluded because NICE guidance for diabetic ketoacidosis and diabetes mellitus patient subgroups already exist in the NICE diabetes portfolio.<br><a href="http://guidance.nice.org.uk/CG15">http://guidance.nice.org.uk/CG15</a>  |
| SH   | Infection Prevention Society | 16.0     | General    | I think the scope for this guidance has encompassed the area to be focussed on   | Thank you for your comment.  |
| SH   | Infection Prevention Society | 16.1     | General    | It does not state that it will consider / cover mental health settings. Mental Health patients are at risk of many of the issues raised here due to poor hydration, and obviously IV therapy would be last resort. It would be good to seek some guidance as to whether there is a role for IV therapy as being available and in what format within mental health settings, as this is not universal across providers. Opinions vary with time and personnel, but as a part of an organisation considering using this option, it would be good to seek some evidence base and opinion as to if this is considered to be a good move,   | Thank you for your comment. This guideline is intended for use in all NHS settings. The guideline will produce general principles that may be extrapolated to other populations.   |

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|      |                              |          |            | and if yes, some of the safety considerations around this practice in mental health settings.   |  |
| SH   | Infection Prevention Society | 16.2     | General    | It is recognised that the guidelines do not cover infection and prevention of potential infection relating to intravenous fluid therapy and the management of devices used to provide this treatment in patient care. Perhaps this group felt that this was outside the remit of their expertise. Nevertheless reference to the publications around the management of these devices and their role in intravenous therapy should be made. For example, EPIC, Patient Safety/Care bundles, APIC Guidelines 2009 and CDC guidelines 2011. | Thank you for your comment and information. Infection prevention and IV fluid devices have not been prioritised for inclusion in this guideline as the briefing paper from the Department of Health that supported the remit identified that there is a need to address the general principles of intravenous fluid therapy. This was endorsed by attendees at the Scoping Workshop for this guideline. As such the areas you highlight have not been prioritised for inclusion in the final scope. You may be interested to note that NICE is currently developing public health guidance on healthcare associated infections <a href="http://www.nice.org.uk/guidance/phg/advicehealthcareassociatedinfections.jsp">http://www.nice.org.uk/guidance/phg/advicehealthcareassociatedinfections.jsp</a> |
| SH   | Infection Prevention Society | 16.3     | General    | I think there should be some mention of 'insensible loss' and its importance in fluid balance, particularly for patients in heart failure & renal failure who have a difficulty handling excess fluids anyway. I think there should be some mention on how to assess a pt's insensible loss and how to apply the principles when estimating fluid over-load or dehydration. Further things that would increase a pt's insensible loss such as hyper-ventilating, hyper-pyrexia etc  | Thank you for your comment. The guideline development group will consider this as part of the evidence review related to monitoring IV fluids.   |
| SH   | Infection Prevention Society | 16.4     | General    | NICE should produce 'fluid balance chart' templates and guidance on how to use them to go with this guidance! So that consistency occurs across the country!  | Thank you for your comment. The production of a fluid balance chart is outside the scope of this guideline. However, if during development, there is a need for a template, the guideline development group will discuss this with the NICE Implementation team.   |
| SH   | Baxter Healthcare            | 17.0     | General    | Baxter Healthcare is pleased to comment on the draft scope for the development of NICE Guidelines and quality standards for Intravenous Fluid Therapy   | Thank you for your comments.   |

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|      |                          |          |                 | and would like to congratulate NICE on the thorough scope. We welcome the development of these guidelines and look forward to their implementation.   |   |
| SH   | Baxter Healthcare        | 17.1     | 3.1.1e          | Would NICE please clarify which particular religious groups are referred to in this point and which fluids would require special consideration? Baxter has received an official statement from the Jehovah's Witness organisation in relation to this subject which is attached for your information. | Thank you for your comment and information. The specific groups that may have cultural or religious needs will be identified by the guideline development group at the beginning of development.  |
| SH   | Baxter Healthcare        | 17.2     | 3.1.2f          | Please could NICE clarify the exclusion of patients with burns from these guidelines; are NICE planning to have separate guidelines for the treatment of patients with burns?   | Thank you for your comment. The management of people with burns was not prioritised for inclusion as there is a need to address within the limited development time frame the general principles relating to IV fluid management in hospitals identified within the remit from the Department of Health |
| SH   | Baxter Healthcare        | 17.3     | 3.2a            | Would NICE consider also including the emergency ambulance service within the scope?  | Thank you for your comment. We are unable to include the management of IV fluid therapy in emergency ambulance as the Department of Health remit for this guideline was for IV fluid management in hospital only.   |
| SH   | Baxter Healthcare        | 17.4     | 3.3.1a          | We welcome the inclusion of the training and education in prescribing IV fluids within the scope. Would NICE please clarify which healthcare professionals and at what level this training will be targeted?  | Thank you for your comment. The guideline development group will consider training and education during development.  |
| SH   | Baxter Healthcare        | 17.5     | 3.3.1c, d and e | Would NICE consider re-wording the "crystalloids compared with crystalloids" differentiator to "balanced crystalloids compared with unbalanced crystalloids?"   | Thank you for your comment. We do not agree that the wording requires amendment.  |
| SH   | Baxter Healthcare        | 17.6     | 3.3.1c, d and e | Could NICE clarify the parameters by which these solutions will be compared? For example ionic composition, pH, presentation.   | Thank you for your comment. The guideline development group will consider this information during the development of the guideline.   |
| SH   | Royal College of Nursing | 18.0     | General         | The Royal College of Nursing welcomes proposals to develop this guideline. It is timely. The draft  | Thank you for your comment.   |

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|      |   |          |            | scope seems comprehensive.  |  |
| SH   | Royal College of Nursing                          | 18.1     | General    | We are pleased to see the cross reference to acute kidney injury.<br>We presume that this includes oral fluids – the guideline should indicate that where appropriate these should be first choice.<br>We consider that oral fluids should be included so that appropriate use of IV fluids is included as a risk assessment.   | Thank you for your comment. The guideline is for intravenous fluid management. Administration of oral fluids is outside the scope of this guideline but it is anticipated that this will be considered as part of the evidence review related to monitoring and assessment in section 3.3.1f of the scope. |
| SH   | Royal College of Nursing                          | 18.3     | 3.4 c      | Coagulation should be included as some fluids have been renowned to affect coagulation.   | Thank you for your comment. The guideline development group will be made aware of this during the development of the guideline.  |
| SH   | Royal College of Nursing                          | 18.4     | General    | Nurses would welcome this proposed work to support excellence in practice.  | Thank you for your comment.  |
| SH   | Wrightington Wigan And Leigh NHS foundation Trust |          | General    | Weight / size of patient – In paediatrics we use weight to determine amounts of fluid. When I began working with adult medics I was astonished that there is no size factored into calculation of fluid requirement. A 40 kg frail elderly patient will receive as much fluid as an 80 kg 30 year old – typically 3 litres per day. This practise was identifiable as a cause of heart failure in the former group. There is no clear agreement amongst medics of a size related calculation of fluid requirement. It seems crucial to any document dealing with iv fluids to have an agreement on how much fluid a patient should receive on a daily basis. To my reading, this does not exist, even without the added complication of size. | Thank you for you comment and information. The guideline development group will consider this evidence as part of the assessment of IV Fluid requirements.   |
| SH   | Wrightington Wigan And Leigh NHS foundation Trust |          |            | Use of a single iv fluid – in terms of patient safety, and potentially other benefits, a single manufactured solution is better than multiple bag regimes. Typical patterns are Saline / 5% Dextrose / 5% Dextrose with or without potassium. A single fluid such as  | Thank you for your comment. The guideline development group will be made aware of this information during the guideline development.   |

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|      |   |          |            | Please insert each new comment in a new row.   | Please respond to each comment  |
|      |   |          |            | hartmanns is preferable in terms of continuous sugar and electrolyte delivery, but also in terms of predictable iv fluid provision.  |   |
| SH   | Wrightington Wigan And Leigh NHS foundation Trust |          |            | IV fluid pumps – in our own Trust we found that patients who had iv fluids as a “gravity feed” were much more likely to have very inaccurate fluid delivery – mistakes were much more likely. In terms of a quality standard, should we consider how fluids are delivered, if we are going to produce the safest practise? | Thank you for your comment and information. The administration of IV fluids via pumps is outside the scope of this guideline. The areas that have been prioritised for inclusion in the final scope related to types, volume and timings of intravenous fluid therapy will help to inform the quality standard. |

**These organisations were approached but did not respond:**

3M Health Care Limited

Alder Hey Children's NHS Foundation Trust

Alder Hey Children's NHS Foundation Trust

Association for Clinical Biochemistry

Association of British Health-Care Industries

Association of Clinical Pathologists

Association of Surgeons in Primary Care

Association of Surgeons of Great Britain and Ireland

Bard Limited

Barnsley Hospital NHS Foundation Trust

Blackpool Teaching Hospitals NHS Foundation Trust

BMJ

British Association for Immediate Care

British Association for Parenteral & Enteral Nutrition (BAPEN)

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British Medical Association (BMA)  
British National Formulary (BNF)  
British Pharmaceutical Nutrition Group  
British Psychological Society, The  
Burton Hospitals NHS Trust  
Cambridge University Hospitals NHS Foundation Trust (Addenbrookes)  
Care Quality Commission (CQC)  
Clatterbridge Centre for Oncology NHS Trust  
College of Emergency Medicine  
Connecting for Health  
Deltex medical  
Department for Communities and Local Government  
Department of Health Advisory Committee on Antimicrobial Resistance  
and Healthcare Associated Infection (ARHAI)  
George Eilott Hospital Trust  
Gloucestershire Hospitals NHS Trust  
Gloucestershire LINK  
Great Western Hospitals NHS Foundation Trust  
Haemophilia Society, The  
Healthcare Improvement Scotland  
Healthcare Quality Improvement Partnership  
Heart of England NHS Foundation Trust  
Humber NHS Foundation Trust  
Intensive Care Society  
ITP Support Association, The  
Lancashire Teaching Hospitals NHS Foundation Trust  
Letterkenny General Hospital

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London Ambulance Service NHS Trust  
Medicines and Healthcare Products Regulatory Agency (MHRA)  
Ministry of Defence (MoD)  
National Treatment Agency for Substance Misuse  
NCC - Cancer  
NCC - Mental Health  
NCC - National Clinical Guideline Centre (NCGC)  
NCC - Women & Children  
NETSCC, Health Technology Assessment  
NHS Clinical Knowledge Summaries Service (SCHIN)  
NHS Direct  
NHS Plus  
NHS Sheffield  
NHS Western Cheshire  
NICE - CHTE for info  
NICE - CPHE  
NICE - CPHE Methodology - Simon for info  
NICE - Guidelines - GC, HE, Tech Lead  
NICE - Guidelines HE for info  
NICE - IMPLEMENTATION CONSULTANTS (ALL)  
NICE - IMPLEMENTATION CO-ORDINATION for info  
NICE - PPIP  
NICE - R&D for info  
North Tees & Hartlepool NHS Foundation Trust  
North West London Perinatal Network  
Nottingham University Hospitals NHS Trust

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Pharmacosmos  
Public Health Wales  
Rotherham NHS Foundation Trust  
Royal Berkshire NHS Foundation Trust  
Royal College of Anaesthetists  
Royal College of General Practitioners  
Royal College of General Practitioners Wales  
Royal College of Midwives  
Royal College of Obstetricians and Gynaecologists  
Royal College of Paediatrics and Child Health  
Royal College of Pathologists  
Royal College of Physicians London  
Royal College of Psychiatrists  
Royal College of Radiologists  
Royal College of Surgeons of England  
Royal Free Hospital NHS Trust  
Royal Society of Medicine  
Scottish Intercollegiate Guidelines Network (SIGN)  
Social Care Institute for Excellence (SCIE)  
Society for Acute Medicine  
Vifor Pharma UK Ltd  
Welsh Assembly Government  
Welsh Cancer Services Coordinating Group  
Welsh Scientific Advisory Committee (WSAC)  
Wirral University Teaching Hospital NHS Foundation Trust  
York Teaching Hospital NHS Foundation Trust

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