

# NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

## Final Appraisal Determination

### Pre-hospital initiation of fluid replacement therapy in trauma

#### 1 Guidance

This guidance covers the management of adults, children and infants with physical injuries as a result of trauma, in whom there is evidence of obvious or probable blood loss. It does not cover the management of isolated closed head injury. For the purpose of this guidance, it is assumed that basic life support and ongoing assessment of the trauma victim are taking place as appropriate. The requirement for cannulation is considered only within the context of pre-hospital intravenous fluid (IV fluid) administration.

- 1.1 It is recommended that in the pre-hospital management of adults and older children, IV fluid should not be administered if a radial pulse can be felt (or, for penetrating torso injuries, if a central pulse can be felt).
- 1.2 In the absence of a radial pulse (or a central pulse for penetrating torso injuries) in adults and older children, it is recommended that IV fluid should be administered in boluses of no more than 250 ml. The patient should then be reassessed, and the process repeated until a radial pulse (or central pulse for penetrating torso injuries) is palpable.
- 1.3 The administration of IV fluid should not delay transportation to hospital, but when given in accordance with 1.2 above, consideration should be given to administration en route to hospital.
- 1.4 It is recommended that when IV fluid is indicated in the pre-hospital setting, crystalloid solutions should be the routine choice.

- 1.5 There is inadequate evidence on which the Institute can base recommendations on when pre-hospital use of IV fluid in young children and infants following trauma is appropriate, or on the volumes of fluid to use. However, there is a broad consensus that transfer to hospital should not be delayed by attempts to administer IV fluid.
- 1.6 It is recommended that only healthcare professionals who have been appropriately trained in advanced life-support techniques and pre-hospital care should administer IV fluid therapy to trauma patients in the pre-hospital setting.
- 1.7 Training programmes for healthcare professionals should incorporate the above recommendations.

## **2 Clinical need and practice**

- 2.1 The term 'trauma' is used to describe injuries caused by external force through accidents, violence or acts of self-harm. Injuries are broadly categorised by the mechanism of injury. In penetrating injuries, the skin is breached by a sharp object such as a knife or glass, causing external and potential internal bleeding, and in blunt injuries, the skin is normally unbroken and the force of the injury damages the skin or internal organs.
- 2.2 Blunt and penetrating injuries may cause severe bleeding and subsequent reduction in blood volume (hypovolaemia), which can lead to hypovolaemic shock (circulatory failure as a result of inadequate blood volume). If uncorrected, hypovolaemia will initially lead to inadequate perfusion and oxygenation of tissues and will subsequently cause permanent damage to vital organs and multiple organ failure, which is one of the major causes of death in trauma patients.
- 2.3 Data from the Office for National Statistics on the causes of death in England and Wales in 2000 state that 15,462 deaths were caused by injury. The Royal College of Surgeons suggests that about 14,500 fatalities arose from 545,000

trauma admissions in the UK in 1988. Department of Transport Statistics for motor vehicle crashes in England and Wales in 1998 reported that there were about 320,000 injuries involving road vehicles and around 3400 deaths. Blunt injuries account for most of the trauma in the UK – there are about 10 times as many blunt as penetrating injuries.

- 2.4 Ambulance services across the UK differ in their composition and may comprise emergency medical technicians (EMTs) trained in basic life support (BLS), paramedics (emergency medical specialists) trained in advanced life support (ALS), or a combination of EMTs and paramedics. BLS involves establishing a clear airway, starting expired-air resuscitation in the absence of breathing, and starting external chest compression in the absence of a carotid pulse. ALS includes immediate procedures such as defibrillation, the administration of oxygen and cardioactive drugs, monitoring of the electrocardiogram, endotracheal intubation and setting up of an intravenous infusion in a large peripheral or central vein. The British Association for Immediate Care (BASICS) also provides a service of voluntary doctors who are qualified in emergency medicine and equipped to attend accident scenes. Cannulation and administration of IV fluid can be undertaken by doctors or paramedics trained in ALS and may be initiated at the accident scene, in the ambulance en route to hospital, or in the accident and emergency department.
- 2.5 Ambulance crews are usually the first healthcare professionals to attend an accident scene, where they assess the general physiological state of the patient to determine which pre-hospital interventions are needed. The evaluation includes an assessment of the degree of blood loss and whether bleeding is controlled or uncontrolled. This involves identifying possible sites of bleeding (which may be external or internal) and assessing whether there is a radial or central pulse. Other indicators of haemorrhage in adults are tachycardia, peripheral vasoconstriction and reduced blood pressure (if more than 750 ml of blood is lost). The severity of hypovolaemic shock in adults is

classified according to the volume of blood lost, from class I when it is less than 750 ml, to class IV when it is more than 2000 ml.

### **3 The technology**

- 3.1 Fluid replacement therapy (intravenous infusion of fluid) attempts to reverse the effects of hypovolaemia by increasing circulatory blood volume and blood pressure back towards normal, in order to maintain the perfusion of vital organs and to reduce the risk of death from multiple organ failure.
- 3.2 IV fluids used in the treatment of trauma patients are regulated as medicines, and are broadly classified as crystalloids, colloids, or combination fluids consisting of hypertonic saline with either starch or dextran. Paramedics may legally administer crystalloid and colloid solutions, including succinylated modified fluid gelatine, compound sodium lactate intravenous infusion, and sodium bicarbonate and sodium chloride infusions. Crystalloids are solutions of small ionic or non-ionic particles in water (salt or small sugars such as glucose), which pass through cell membranes into different body fluid compartments but over time become eliminated from the intravascular compartment. Fluid replacement with crystalloid solutions requires three to four times the volume of fluid to produce a given expansion in the intravascular compartment. Colloid solutions contain large molecules (molecular weight > 10kDa) of albumin, gelatins, polysaccharides or starch, which are unable to cross cell membranes, and remain in the intravascular fluid compartment for much longer. Smaller infusion volumes are required for fluid replacement with colloid fluids than with crystalloids.
- 3.3 According to manufacturers' list prices, the cost of crystalloid solutions is about £1–£1.80 per 500 ml unit, compared with about £4–£16.50 per 500 ml unit for colloid solutions, excluding VAT. The list price of HyperHAES (a combination fluid comprising hypertonic saline solution and starch) is £28 per 250 ml unit, which is higher than for other colloids. HyperHAES is intended for single-dose administration and may be followed by standard volume-

replacement therapy. Costs may vary in different settings because of negotiated procurement discounts.

- 3.4 There are two approaches to the timing of IV fluid replacement in trauma. One approach is to start IV fluid replacement in the pre-hospital setting; this may be done by paramedics or doctors trained in ALS, either at the accident scene or in the ambulance en route to hospital. Administration of IV fluid before arrival at hospital may reduce the risk of tissue and organ damage in patients with severe hypovolaemia and may improve survival. However, potential benefits from stabilising the patient before transportation should be balanced against risks associated with increased delays in reaching hospital and with the possibility that restoring the blood volume and increasing the blood pressure back towards normal may exacerbate haemorrhage. Initiation of fluid replacement en route to hospital confers any potential benefits of early fluid replacement while minimising time delays at the accident scene.
- 3.5 The other approach is to delay IV fluid replacement until patients arrive at hospital, where they receive definitive treatment for their injuries. Fluid may be administered before, or in conjunction with, the surgical management of haemorrhage. Delaying fluid replacement minimises time delay at the accident scene. Delaying fluid replacement is also believed to reduce the risk of re-bleeding caused by the mechanical disruption of blood clots and the dilution of clotting factors, which can occur, particularly when large volumes of IV fluid are administered.
- 3.6 The setting for the initiation of fluid replacement is the main focus of this appraisal; other issues, such as delayed hospital arrival and the efficacy of different fluid types, are subsidiary considerations.
- 3.7 A professional Consensus Statement on pre-hospital administration of fluid in trauma patients has been developed by representatives of the Faculty of Pre-hospital Care, the Faculty of Accident and Emergency Medicine, the Royal College of Surgeons of Edinburgh, the United Kingdom Military Defence

Forces, the Ambulance Service Association, BASICS, the London Helicopter Emergency Medical Service and researchers with an interest in pre-hospital care. There are also clinical guidelines, developed by the Joint Royal Colleges Ambulance Liaison Committee (JRCALC). Both of these documents recommend a cautious policy on IV fluid resuscitation.

- 3.8 In the absence of data on the audit and monitoring of the JRCALC guidelines for IV fluid replacement in trauma, it is difficult to establish current adherence to them.

## **4 Evidence and interpretation**

The Appraisal Committee (Appendix A) considered evidence from a number of sources (Appendix B).

### **4.1 Clinical effectiveness**

#### **Pre-hospital or hospital IV fluid replacement**

- 4.1.1 The Assessment Report identified randomised controlled trials (RCTs) and systematic reviews of RCTs that compared pre-hospital IV fluid replacement with withheld (no pre-hospital) fluid. Observational studies cited in the evidence base of the Consensus Statement and JRCALC guidelines were also critically appraised. Seven studies were identified: two RCTs comparing immediate pre-hospital IV fluid replacement with delayed replacement; two RCTs comparing the use of different volumes of fluid for IV fluid replacement; two systematic reviews of RCTs of IV fluid replacement in humans and animals; and one observational study.
- 4.1.2 One US trial randomised (according to day of the week) 598 trauma patients with penetrating injuries either to receive IV fluid before surgery (en route to hospital or in a trauma centre), or to have fluid withheld until surgical intervention at hospital. This was the most methodologically sound of all of the studies, with appropriate randomisation and protocol compliance, although the study population was not representative of the majority of trauma patients

in the UK, who have blunt injuries. Delayed IV fluid replacement was associated with a significant improvement in mortality until discharge (70% survival compared with 62%,  $p = 0.04$ ).

- 4.1.3 In a UK crossover RCT of 1309 trauma patients with mainly blunt injuries, paramedics were randomised either to withhold IV fluid until arrival at hospital (delayed fluid group) or to give pre-hospital fluids to those who would normally receive them (immediate fluid group), and the paramedics were 'crossed over' to the other protocol half way through the trial. The trial reported no statistically significant differences in mortality between groups (adjusted odds ratio, 0.93; 95% confidence interval, 0.58 to 1.49). However, poor adherence to the protocol meant that only about 10% more patients in the immediate fluid group received pre-hospital fluid than in the delayed fluid group.
- 4.1.4 Two US studies compared the effect of IV fluid volume administered after hospital arrival on patient mortality. The studies did not appear to take into account fluid administered before arrival. One RCT randomised 36 hypovolaemic patients to the rapid infusion system or to a conventional infusion system. The rapid infusion system administered IV fluid via one catheter, which resulted in a higher rate of fluid infusion in the first hour than conventional infusion but a lower total volume administered over 24 hours. There were no significant differences in mortality between groups (5/16 deaths with rapid infusion and 4/20 deaths with conventional infusion), but there was a trend towards fewer complications among survivors of the rapid infusion group. In the other RCT of 110 patients with uncontrolled haemorrhage, IV fluid was administered to achieve a target systolic blood pressure of 70 mmHg in the intervention group and more than 100 mmHg in the control group. Again, there were no differences in mortality between groups. However, interpretation of both studies was hindered by methodological limitations, including the absence of details of randomisation, concealment, compliance and differences in surgical interventions between groups.

- 4.1.5 One systematic review of RCTs comparing immediate and delayed IV fluid replacement included the four RCTs considered above and an additional two RCTs that did not meet the inclusion criteria for this appraisal because their focus was on blood transfusion.
- 4.1.6 Another systematic review of animal models of IV fluid replacement in uncontrolled haemorrhage reported an improvement in mortality associated with early replacement, but this was not statistically significant (risk ratio, 0.88; 95% confidence interval, 0.73 to 1.07). Early IV fluid replacement appeared to improve survival in severe haemorrhage but to increase the risk of death with less severe haemorrhage. It is not clear, however, whether the findings are relevant to humans.
- 4.1.7 A Canadian retrospective cohort study compared the effect of administering or withholding pre-hospital IV fluid in 360 patients with matched pre-hospital injury (PHI) scores. Pre-hospital administration of IV fluid was associated with a significant increase in mortality (adjusted odds ratio, 2.33; 95% confidence interval, 1.02 to 5.28). Despite the matching of the PHI scores of the two groups, there remained important differences in terms of age, injury severity score, mechanism and anatomical location of the injury, all of which are predictors of trauma-related mortality.
- 4.1.8 In summary, there was insufficient evidence to draw definitive conclusions about the effectiveness of pre-hospital or delayed IV fluid administration in trauma. Although the most methodologically sound RCT provided some evidence that in certain circumstances pre-hospital IV fluid resuscitation may be harmful, it is not clear how different subgroups would be affected.

#### **Advanced life support (ALS) versus basic life support (BLS)**

- 4.1.9 Studies that compared the effectiveness of ALS (where additional interventions including the administration of pre-hospital IV fluid may be performed) with BLS (where no pre-hospital IV fluid is administered) were considered as indirect information on the effectiveness of pre-hospital and

withheld IV fluid respectively. Six studies were identified: two systematic reviews, and the four observational studies that formed the evidence base of the Consensus Statement and JRCALC guidelines.

- 4.1.10 One of the systematic reviews contained just one RCT, in which 2045 trauma patients in three areas of England (covering urban, suburban and rural areas) were randomised to treatment by paramedics or EMTs. Although the study was designed as an RCT, the results were analysed as a cohort study because poor protocol compliance meant only 16 patients were successfully randomised. When data from all areas were aggregated, the study showed that attendance by paramedics was associated with a non-significant increase in mortality (adjusted odds ratio, 1.74; 95% confidence interval, 0.89 to 3.41) but there was substantial regional variation (odds ratio 3.1 in area 1 and 0.78 in area 3).
- 4.1.11 The other systematic review included 13 observational studies and two reports of one RCT. Of these studies, in terms of mortality, 3/15 favoured ALS and 12/15 supported BLS (overall unadjusted odds ratio 2.92, favouring BLS). Limiting the analysis to well-designed studies produced a crude odds ratio of 1.89 (favouring BLS to a lesser extent) but as confidence intervals were not stated it is not clear whether differences in mortality were statistically significant.
- 4.1.12 Four observational studies were cited in the Consensus Statement and JRCALC guidelines: two reported higher mortality in patients attended by paramedics, one favoured ALS and the other found that pre-hospital time did not affect survival. The results of these studies are included in the systematic reviews above. All the studies were critically appraised and were considered to have serious methodological flaws that increased the likelihood of bias, or to have controlled inadequately for confounding factors.
- 4.1.13 In summary, studies comparing ALS with BLS care of trauma patients provide insufficient evidence to demonstrate the benefit or harm of paramedic

interventions. There was a trend towards poorer outcomes with ALS but it is not possible to determine whether this is due to the delay associated with ALS, or to the additional procedures themselves, or because patients who have additional procedures may be more severely injured and have a poorer prognosis.

### **Intravenous infusion with different fluid types**

4.1.14 As a subsidiary issue, systematic reviews of the effectiveness of IV infusion with different fluid types in a variety of settings were assessed.

4.1.15 Ten systematic reviews of RCTs were identified that compared different IV fluid types: four reviews were general comparisons of crystalloid and colloid solutions; the other reviews compared more specific IV fluid types (for example, isotonic crystalloid versus colloid; albumin-based colloid versus non-albumin solutions; comparisons of different classes of colloid; and hypertonic crystalloid [with or without dextran] versus isotonic crystalloid). The four systematic reviews that were general comparisons of IV fluid types showed a potential trend towards crystalloids being more effective than colloids, although making general comparisons may have obscured the effect of individual crystalloid or colloid solutions. The Assessment Report concluded that there was insufficient evidence of benefit of a particular IV fluid because of clinical heterogeneity between studies (such as case-mix, additional interventions received, resuscitation protocols, amounts of IV fluid administered, and different types of colloids and crystalloids administered) and the fact that different types of patients were combined in the meta-analyses.

## **4.2 Cost effectiveness**

4.2.1 The Assessment Report identified two Health Technology Assessment reports of the cost effectiveness of pre-hospital IV fluid replacement from an NHS perspective.

- 4.2.2 The first study, published in 1998, assessed the cost and effectiveness of treatment of trauma patients by paramedics, compared with treatment by EMTs.
- 4.2.3 The additional cost of paramedic treatment (costs associated with trauma-related ALS training, salary and additional pre-hospital interventions) was presented per paramedic crew and per call out. The average unit cost of the ALS crew at £2.44 per minute was similar to the cost of a BLS crew at £2.43 per minute. There was an increase of £3 in the call out cost of an ALS crew (average of £81.08 per ALS call out) compared with a BLS crew call out (average of £78.02), because ALS crews spent more time at the scene. The total costs (pre-hospital and hospital costs combined) were also estimated. There was a non-significant increase of £22 in the average total costs for patients attended by a paramedic-crewed ambulance (£2231 per patient, compared with £2209 per patient attended by EMTs alone). Between 20% and 30% of the cost of paramedic training and salary was attributed to trauma. However, reductions in the level of trauma-related training had little effect on the overall cost of training.
- 4.2.4 The second study was conducted alongside an RCT (discussed in Section 4.1.3) in which paramedics were randomised to different resuscitation protocols (pre-hospital IV fluid versus no pre-hospital fluid) to evaluate the cost effectiveness of pre-hospital IV fluid therapy.
- 4.2.5 Although there was no difference in the median ambulance call-out time of 55 minutes, there was a 2-minute increase in the mean call-out time associated with pre-hospital IV fluid replacement. Costs were presented as initial costs (ambulance costs, consumables, and accident and emergency costs) and total costs (which also included inpatient costs). The cost of pre-hospital IV fluid replacement was higher (but not significantly higher) than that of delayed fluid replacement, by £3 in the initial phase of treatment (£419 compared with £416) and by £28 overall (£2706 compared with £2678).

4.2.6 The Assessment Report did not include an economic model because it was considered that there was insufficient evidence on the effectiveness of IV fluid replacement therapy to inform such a model, and because the additional costs associated with pre-hospital IV fluid therapy, such as consumables and paramedic training, were thought to be minor – particularly because paramedics would be required to stock IV fluid and to undergo training in cannulation and IV fluid administration for the treatment of non-trauma patient groups. Adherence to a conservative pre-hospital IV fluid policy could, however, increase ambulance efficiency to a small extent by improving response times.

### **4.3 Consideration of the evidence**

4.3.1 The Committee reviewed the evidence, including the views of experts, on the clinical and cost effectiveness of IV fluid administered in a pre-hospital setting. In its considerations, the Committee was mindful of the need to take account of the effective use of NHS resources.

4.3.2 The Committee considered that there was some evidence of benefit associated with delaying the initiation of IV fluid until hospital arrival.

4.3.3 The Committee considered the extent to which evidence from the most methodologically sound RCT, which demonstrated a benefit in delaying IV fluid resuscitation in penetrating injuries, could be generalised to blunt injuries. The Committee heard, however, that the trial was based on the administration of larger quantities of IV fluid than would now be considered appropriate, and that it was, therefore, difficult to generalise the results to current clinical practice. In the absence of high-quality evidence on effectiveness, the Committee considered that guidance should take into account professional consensus, although the Institute did not formally evaluate the Consensus Statement and JRCALC guidelines.

4.3.4 The Committee heard from experts that it would not be clinically appropriate to withdraw the use of IV fluid in a pre-hospital setting. The experts

emphasised that there was a small proportion of severely hypovolaemic trauma patients at high risk of immediate death who might benefit from pre-hospital initiation of IV fluid therapy; they explained that the aim of IV fluid in these circumstances is to prevent further circulatory collapse without attempting to restore circulating volume fully back to normal or to achieve normal physiology.

- 4.3.5 The Committee considered how these patients with severe hypovolaemic shock should best be identified and treated. The Committee heard that there are a number of physiological indicators of haemorrhagic shock such as pallor, tachycardia and capillary refill time, although the most readily available physiological measure was considered to be the absence of a palpable radial pulse. The Committee understood that presence or absence of a radial pulse has been used as an approximate guide to whether the systolic blood pressure is above or below 80–90 mmHg but that this is not fully validated. The Committee concluded, therefore, that IV fluid should be administered in the pre-hospital setting only if a radial pulse (or a central pulse, in penetrating injuries of the torso) is not palpable. The Committee was persuaded that in the presence of severe hypovolaemia, which is considered to be immediately life threatening, clinical judgement as to the best course of action would be required.
- 4.3.6 The experts further advised the Committee that consideration should be given to how well the haemorrhage is controlled. Haemorrhages can be described as controlled (for example, by external pressure applied to a wound), self-limiting (for example, bleeding from a closed femoral fracture), potentially uncontrolled (when the bleeding has stopped but might start again if the blood pressure increased, and the injury is at a site where applying pressure would not stop the bleeding), or uncontrolled. The Committee heard that the risks associated with administration of IV fluid are different for controlled and uncontrolled haemorrhage, and it may be difficult to distinguish between these types of haemorrhage in the pre-hospital setting. Patients with severe uncontrolled bleeding with circulatory collapse are at risk of immediate cardiac

arrest and death from extreme hypovolaemia/exsanguination. But the experts also highlighted that in patients with uncontrolled or potentially uncontrolled bleeding, vigorous fluid therapy may exacerbate bleeding by diluting blood clotting factors, reducing the concentration of circulating blood platelets, and by dislodging early clots forming at the site of haemorrhage. In patients with controlled or self-limiting bleeding, the infusion of IV fluid may help to restore tissue perfusion without exacerbating bleeding.

4.3.7 Taking these factors into account, the Committee considered that a pragmatic approach would be to withhold IV fluid if the signs of shock are not marked. If the signs of shock are more severe (as illustrated by an absent radial pulse) administering IV fluid may prevent extreme hypovolaemia with its risk of producing organ damage and cardiac arrest. The experts advised that giving small volumes in this situation (and repeating, if necessary) may keep the patient alive without unduly exacerbating the bleeding, even if the bleeding is uncontrolled or potentially uncontrolled. The Committee concluded that IV fluid should be administered according to the above criteria in boluses of no more than 250 ml and should normally be started en route to hospital to avoid delays at the scene. This agrees with the recommendations in the Consensus Statement; the revised JRCALC guidelines (due in 2004) are also expected to include this recommendation. The Committee also concluded that administration of the first bolus should be followed by reassessment and administration of further boluses until a radial pulse (or a central pulse in penetrating injuries of the torso) becomes palpable. The Committee was advised that good patient-handling techniques in pre-hospital care were essential to minimise the risk of continued haemorrhage before the administration of IV fluid.

4.3.8 The treatment of trauma in patients with isolated closed head injury was not considered in detail by the Committee because it fell outside the remit of this appraisal. However, the Committee heard from experts that consideration should be given to trauma patients with multiple injuries in whom both haemorrhagic shock and head injury might coexist. Altered consciousness in

trauma may be indicative of severe haemorrhagic shock or of head injury, and it may be difficult to distinguish between the two in the pre-hospital setting. There was concern that if IV fluid was withheld from trauma patients with multiple injuries including head injury, this might have a deleterious effect on the outcome of the head injury because of low perfusion of the brain. The Committee considered cautious administration of IV fluid (with 250 ml boluses titrated against the presence of a radial pulse, with reassessment) was appropriate for trauma patients with uncontrolled bleeding and concomitant head injury in the same way as other hypovolaemic trauma patients.

4.3.9 Experts advised that the guidance should take into account factors – such as the patient being trapped – that might delay arrival at hospital. The Committee concluded that there was inadequate evidence on which to base recommendations on the use of IV fluid in these circumstances. It was appreciated, however, that in these circumstances, other emergency procedures would be initiated that fall outside the remit of this guidance.

4.3.10 On the balance of the evidence on the relative effectiveness of crystalloid and colloid solutions administered in the pre-hospital setting, the Committee was persuaded that the merits of different IV fluid types should be based on cost and risk of adverse events. Crystalloid solutions are not associated with the hypersensitivity reactions seen in some patients when colloids are infused, and they are less expensive than colloid solutions. The Committee therefore considered intravenous infusion with crystalloid solutions to be the preferred option. On balance of the evidence on the relative effectiveness of different crystalloids, the Committee considered normal saline, which has the lowest cost, to be the favoured option.

4.3.11 Consideration was given to the use of pre-hospital IV fluid in young children and infants. The Committee heard from the experts that children, particularly those younger than 8 years, should be considered as a separate group because their physiology is different and different methods are needed to assess hypovolaemic shock. The experts advised that it would not be

appropriate to use the absence of a radial pulse or an increased heart rate, in isolation, as criteria to determine whether pre-hospital IV fluid should be administered. The Committee discussed in detail both the available evidence and the experts' views on the appropriate use of IV fluid in the pre-hospital setting for young children and infants. In the absence of adequate evidence and any professional consensus, the Committee considered that they were unable to make specific recommendations for this group. However, they concluded that transfer to hospital should not be delayed in order that IV fluid can be administered.

4.3.12 The Committee considered the issue of training for those administering pre-hospital IV fluid therapy, and concluded that only healthcare professionals with appropriate training in ALS techniques and pre-hospital care should administer IV fluid therapy to trauma patients in the pre-hospital setting.

4.3.13 The Committee noted that the information available on cost effectiveness was poor. The Committee considered the costs associated with the IV fluid used for pre-hospital administration to be minimal. It also considered that costs associated with paramedic training would be unchanged regardless of whether IV fluid is administered for trauma in a pre-hospital setting, because all paramedics should have undergone the necessary training as part of routine preparation for pre-hospital care. The Committee concluded that, although the costs associated with pre-hospital IV fluid administration were minimal, there was an opportunity cost to be considered in terms of potential improvements in response times, throughput, and overall efficiency as a result of longer call-out times when IV fluid therapy was administered.

## **5 Recommendations for further research**

5.1 It is strongly recommended that studies be undertaken to evaluate the appropriateness of pre-hospital IV fluid therapy, including consideration of specific patient groups, for example, young children and infants, and patients with blunt versus penetrating injuries. Assessment of different protocols for

pre-hospital care is essential in order to improve understanding of the risks and benefits of the use of IV fluids in this setting.

- 5.2 Validation studies are needed to assess the suitability of the absence of a radial pulse as an indicative marker of hypovolaemia.
- 5.3 It is recommended that studies be undertaken to compare the efficacy of blood volume resuscitation to different blood pressures.

## **6 Implications for the NHS**

- 6.1 Estimates of the numbers of trauma patients given pre-hospital IV fluid range from 8.6 to 65 patients per 100,000 population per year. The population of England and Wales is about 57 million, so pre-hospital IV fluid is likely to be administered to between 5000 and 37000 trauma patients annually.
- 6.2 The cost of IV fluid replacement therapy in the pre-hospital phase is primarily determined by the unit cost of the IV fluid and the cost of the ambulance crew. A small cost increase for ALS was observed in the economic studies, predominantly because more time was spent at the scene. There is also likely to be substantial regional variation in costs, according to unit costs of services across ambulance trusts.
- 6.3 Given the absence of reliable information on the current use and cost of pre-hospital IV fluids in people with trauma, it is difficult to quantify the likely cost of implementing the recommendations in Section 1. Limiting the use of pre-hospital IV fluid in the treatment of trauma patients would be unlikely to yield monetary savings within the ambulance service, but it could save time at the accident scene. This might release resources within the ambulance service – contributing to improved response times – and lead to small improvements in overall efficiency.

## 7 Implementation and audit

- 7.1 Ambulance trusts and clinicians who have been trained in ALS and pre-hospital care should review their current practice and policies to take account of the guidance set out in Section 1.
- 7.2 Any local adaptations of the JRCALC guidelines that refer to the pre-hospital initiation of fluid replacement therapy in trauma should incorporate the guidance.
- 7.3 To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C.
  - 7.3.1 IV fluid is not administered as part of pre-hospital management of an adult or older child if a radial pulse, or with a penetrating torso injury, a central pulse, can be felt.
  - 7.3.2 IV fluid in boluses of no more than 250 ml is administered if no radial pulse is palpable (or no central pulse is detected in the case of a penetrating torso injury), followed by reassessment, repeating the process until a radial (or central) pulse is palpable.
  - 7.3.3 If IV fluid is administered for the circumstances described in 7.3.1–7.3.2, it is initiated en route to hospital (excluding individuals who are not considered appropriate to move).
  - 7.3.4 When IV fluid is indicated in the pre-hospital setting, crystalloid solutions are the routine choice.
  - 7.3.5 Only healthcare professionals who have been appropriately trained in ALS and pre-hospital care administer IV fluid to people experiencing trauma in the pre-hospital setting.

7.3.6 Training programmes for healthcare professionals caring for people experiencing trauma incorporate the guidance in Section 1.

7.4 Local clinical audits could also include measurement of compliance with other relevant clinical guidance such as JRCALC guidelines and the Consensus Statement.

## **8 Related guidance**

8.1 There is no related guidance for this technology.

## **9 Review of guidance**

9.1 The review date for a technology appraisal refers to the month and year in which the Guidance Executive will consider any new evidence on the technology, in the form of an updated Assessment Report, and decide whether the technology should be referred to the Appraisal Committee for review.

9.2 The guidance on this technology will be reviewed in January 2007.

David Barnett

Chair, Appraisal Committee

November 2003

## **Appendix A. Appraisal Committee members and NICE project team**

### **A. Appraisal Committee members**

**NOTE** The Appraisal Committee is a standing advisory committee of the Institute. Its members are appointed for a 3-year term. A list of the Committee members who took part in the discussions for this appraisal appears below. The Appraisal Committee meets twice a month except in December, when there are no meetings. The Committee membership is split into two branches, with the chair, vice-chair and a number of other members attending meetings of both branches. Each branch considers its own list of technologies and ongoing topics are not moved between the branches.

Committee members are asked to declare any interests in the technology to be appraised. If it is considered there is a conflict of interest, the member is excluded from participating further in that appraisal.

The minutes of each Appraisal Committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

#### **Dr Sunil Angris**

General Practitioner, Waterhouses Medical Practice, Staffordshire

#### **Dr Darren Ashcroft**

Senior Clinical Lecturer, School of Pharmacy and Pharmaceutical Sciences, University of Manchester

#### **Professor David Barnett (Chair)**

Professor of Clinical Pharmacology, University of Leicester

#### **Dr Peter Barry**

Consultant in Paediatric Intensive Care, Leicester Royal Infirmary

**Professor John Brazier**

Health Economist, University of Sheffield

**Professor John Cairns**

Professor of Health Economics, Health Economics Research Unit, University of Aberdeen

**Professor Mike Campbell**

Statistician, Institute of General Practice & Primary Care, Sheffield

**Dr Mark Chakravarty**

Head of Government Affairs and NHS Policy, Procter and Gamble Pharmaceuticals (UK) Ltd, Egham, Surrey

**Dr Peter I Clark**

Consultant Medical Oncologist, Clatterbridge Centre for Oncology, Wirral, Merseyside

**Professor Cam Donaldson**

PPP Foundation Professor of Health Economics, School of Population and Health Sciences & Business School, Business School – Economics, University of Newcastle upon Tyne

**Professor Jack Dowie**

Health Economist, London School of Hygiene

**Dr Paul Ewings**

Statistician, Taunton & Somerset NHS Trust, Taunton

**Ms Sally Gooch**

Director of Nursing, Mid-Essex Hospital Services NHS Trust, Chelmsford

**Miss Linda Hands**

Clinical Reader in Surgery, University of Oxford

**Professor Robert Kerwin**

Professor of Psychiatry and Clinical Pharmacology, Institute of Psychiatry, London

**Ms Ruth Lesirge**

Lay Representative, previously Director, Mental Health Foundation, London

**Dr George Levvy**

Lay Representative, Chief Executive, Motor Neurone Disease Association, Northampton

**Dr Stephen Saltissi**

Consultant Cardiologist, Royal Liverpool University Hospital

**Mr Miles Scott**

Chief Executive, Harrogate Health Care NHS Trust

**Professor Andrew Stevens (Vice-Chair)**

Professor of Public Health, University of Birmingham

**Professor Mary Watkins**

Professor of Nursing, University of Plymouth

**Dr Norman Waugh**

Department of Public Health, University of Aberdeen

**B. NICE Project Team**

Each appraisal of a technology is assigned to one or more Health Technology Analysts and one Technology Appraisal Project Manager within the Institute.

**Eleanor Donegan and Zoe Charles**

Technical Leads, NICE project team

**Nina Pinwill (up to August 2003) and Dr Sarah Cumbers (from August 2003)**

Project Managers, NICE project team

## Appendix B. Sources of evidence considered by the Committee

A The assessment report for this appraisal was prepared by West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, The University of Birmingham:

- I Dretzke J, Sandercock J, Bayliss S, *et al.* The clinical effectiveness and cost effectiveness of pre-hospital intravenous fluids in trauma patients, July 2003

B The following organisations accepted the invitation to participate in this appraisal. They were invited to make submissions and comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD). Consultee organisations are provided with the opportunity to appeal against the Final Appraisal Determination:

I Manufacturer/sponsors:

- Baxter Healthcare
- Fresenius Kabi

II Professional/specialist and patient/carer group:

- Ambulance Service Association
- British Association for Immediate Care (BASICS)
- British Association for Accident and Emergency Medicine
- British Association of Paramedics

- British Trauma Society
- Department of Health
- Faculty of Pre-hospital Care
- Joint Royal Colleges Ambulance Liaison Committee
- Royal College of Anaesthetists
- Royal College of General Practitioners
- Royal College of Nursing
- Royal College of Paediatrics and Child Health
- Royal College of Physicians
- Royal College of Surgeons
- Royal Pharmaceutical Society
- The Faculty of Accident and Emergency Medicine
- Welsh Assembly Government

III Commentator organisations (without the right of appeal):

- NHS-Quality Improvement Scotland
- NHS Confederation
- NHS Purchasing and Supply Agency

C The following individuals were selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups. They participated in the Appraisal Committee discussions and provided evidence to inform the Appraisal Committee's deliberations. They gave their expert personal view on pre-hospital initiation of fluid replacement therapy in trauma by attending the initial Committee discussion and/or providing written evidence to the Committee. They were also invited to comment on the Appraisal Consultation Document:

- Dr Tim Coates, Senior Lecturer in Accident & Emergency/Prehospital Care, Royal College of Surgeons Trauma Committee
- Dr Tom Clutton-Brock, Consultant Anaesthetist, Royal College of Anaesthetists
- Mr Mark E Cooke, National Clinical Effectiveness Manager, Ambulance Service Association
- Mr Henry R Guly, Consultant in Accident and Emergency Medicine, Derriford Hospital, Plymouth
- Dr Peter A Oakley, Consultant in Anaesthesia and Trauma, University Hospital of North Staffordshire, Stoke-on-Trent, Past President of the British Trauma Society
- Dr Tina Sajjanhar, Consultant in Paediatric Accident and Emergency, Royal College of Paediatrics and Child Health, Representative on Joint Royal Colleges Ambulance Liaison Committee

## **Appendix C. Detail on criteria for audit of the use of pre-hospital initiation of fluid replacement therapy in trauma**

### ***Possible objectives for an audit***

An audit on pre-hospital initiation of fluid replacement therapy in people experiencing trauma could be carried out to ensure the following.

- Fluid replacement is used appropriately.
- Training programmes for people providing pre-hospital care for people experiencing trauma are consistent with the guidance.

### ***Possible patients to be included in the audit***

An audit on the first objective above could be carried out on the pre-hospital management of adults and older children who have physical injuries as a result of trauma (excluding those with an isolated head injury), over a reasonable time period for audit, for example 3 months. The audit could exclude individuals who are trapped or, alternatively, individuals who are trapped could be added as an exception to relevant audit criteria.

An audit on the second objective above could be carried out on training programmes currently being attended by ambulance staff or by other healthcare professionals who provide pre-hospital care to people experiencing trauma.

### ***Measures that could be used as a basis for an audit***

The measures that could be used in an audit of the use of pre-hospital initiation of fluid replacement therapy in trauma are as follows.

<b>Criterion</b>	<b>Standard</b>	<b>Exception</b>	<b>Definition of terms</b>
1. IV fluid is not administered if a radial pulse (or for a penetrating torso injury, a central pulse) can be felt	100% of adults and older children for whom a radial or central pulse can be felt	None	
2. IV fluid is administered as follows: a. a bolus of no more than 250 ml is used <b>and</b> b. a crystalloid solution is used	100% of adults and older children who are given IV fluid in a pre-hospital setting	None	Paramedics and other healthcare professionals trained in advanced life support (ALS) will need to agree locally on when solutions other than crystalloids are to be used (any exceptions to criterion 2b)
3. IV fluid is initiated en route to hospital	100% of adults and older children who are given IV fluid in a pre-hospital setting	A. If it is not considered appropriate to move the patient.	Paramedics and other healthcare professionals trained in ALS will need to agree locally the circumstances in which it is not considered appropriate to move the patient (with documentation for audit purposes).
4. The individual who is given IV fluid is: a. reassessed following administration of each bolus of fluid <b>and</b> b. given boluses only until a radial pulse (or for an individual with a penetrating torso injury, a central pulse) is felt	100% of adults and older children who are given IV fluid in a pre-hospital setting	None	Paramedics and other healthcare professionals trained in ALS will need to agree locally on what constitutes reassessment, and how reassessment is documented, for audit purposes
5. IV fluid is administered only	100% of adults and	None	Ambulance trusts will need to agree locally

by a healthcare professional who has been appropriately trained in advanced life support and pre-hospital care	older children who are given IV fluid in a pre-hospital setting		on what constitutes appropriate training, for audit purposes
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The measure that could be used in an audit of the training programmes for people providing pre-hospital care for individuals experiencing trauma is as follows.

<b>Criterion</b>	<b>Standard</b>	<b>Exception</b>	<b>Definition of terms</b>
1. The training programme for healthcare professionals is consistent with measures 1–4 above	100% of training programmes attended by staff employed by an ambulance or hospital trust	None	Trusts will need to agree to include basic training as well as continuous professional development sessions, for audit purposes.

## **Calculation of compliance**

Compliance (%) with the measures for audit of pre-hospital initiation of fluid replacement therapy described above is calculated as follows.

$$\frac{\text{Number of adults and older children whose care is consistent with the **critierion plus** number of adults and older children who meet any **exception** listed}{\text{Number of adults and older children for which the **measure** applies}} \times 100$$

Compliance (%) with the measure for audit of training programmes described in

above is calculated as follows.

$$\frac{\text{Number of training programmes whose content is consistent with the guidance}}{\text{Number of training programmes to which the **measure** applies}} \times 100$$

Ambulance and other relevant staff should review the findings of measurement, and use their judgement to review cases in which fluids have been administered. For example, if a radial pulse is barely palpable in an individual with severe tachycardia, pallor, reduced capillary return and clouded consciousness, the team may decide that it would be appropriate to administer a small aliquot of fluid and review carefully. The team should identify if practice can be improved, agree on a plan to achieve any desired improvement and repeat the measurement of actual practice to confirm that the desired improvement is being achieved.

