Complete Summary

GUIDELINE TITLE

Pre-hospital initiation of fluid replacement therapy in trauma.

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Pre-hospital initiation of fluid replacement therapy in trauma. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jan. 28 p. (Technology appraisal; no. 74).

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

Blunt and penetrating trauma that may result in hypovolaemic shock

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Treatment

CLINICAL SPECIALTY

Emergency Medicine

INTENDED USERS

Emergency Medical Technicians/Paramedics
Nurses
Physician Assistants
Physicians

GUIDELINE OBJECTIVE(S)

To assess the effectiveness and cost-effectiveness of pre-hospital initiation of fluid replacement therapy in trauma patients

TARGET POPULATION

Patients with blunt or penetrating trauma in whom there is evidence of obvious or probable blood loss

INTERVENTIONS AND PRACTICES CONSIDERED

Pre-hospital initiation of fluid replacement therapy

MAJOR OUTCOMES CONSIDERED

- Clinical effectiveness
- Cost-effectiveness

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases
Searches of Unpublished Data

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Note from the National Guideline Clearinghouse (NGC): The National Institute for Health and Clinical Excellence (NICE) commissioned an independent academic centre to perform a systematic literature review on the technology considered in this appraisal and prepare an assessment report. The assessment report for this technology appraisal was prepared by the West Midlands Health Technology Assessment Collaboration (see the "Companion Documents" field).

Search Strategy

The primary question addressed by this review is how effective intravenous (IV) fluids are in the resuscitation of hypovolaemic trauma patients with no head injury in a pre-hospital setting. Preliminary scoping searches suggested that high quality randomised controlled trial evidence directly addressing this question was unlikely to be sufficient to provide an unequivocal answer to this question. The guideline

developers therefore decided to look at evidence from other settings that may be generalisable to the pre-hospital setting.

Two separate search strategies were used: a highly sensitive search strategy, designed not to miss any relevant studies, was developed to identify studies relating to the use of fluids in a pre-hospital setting (immediate versus delayed fluids, different volumes, or speed of infusion), and a more specific search strategy was used to identify additional randomized controlled trials (RCTs) of fluid administration in other settings (e.g. after admission to hospital), as tens of thousands of studies would have otherwise been identified. Full search strategies are listed in Appendix 3 of the assessment report.

Databases

The following electronic databases were searched: the Cochrane Central Register of Controlled Trials (Issue 1, 2003), MEDLINE (OVID, 1966-2003), EMBASE (OVID, 1980- 2003) and the Science Citation Index (1980-2003).

Strategy

Text and MeSH terms relating to the population (e.g. trauma, hypovolaemia), the intervention (e.g. IV fluid, fluid resuscitation) and the setting where applicable (e.g. pre-hospital, emergency) were combined with filters for randomised controlled trials. There were no language restrictions.

Citation Searching, Handsearching

In addition, citation lists of relevant publications (included studies and reviews) were checked and the Journal of Trauma, Injury, Infection & Critical Care was hand searched for the years 1998 (volume 44) - 2003 (volume 54 (2)) inclusive.

Unpublished Data

Unpublished data were sought by contacting organisations and individual experts, and by checking research registers of ongoing trials and other relevant web sites (list of web sites searched in Appendix 1 of the assessment report). Data from the industry and other submissions were checked for relevant published and unpublished studies.

Additional Questions

A. What is the effect of basic life support (BLS) versus advanced life support (ALS) on patient outcome?
B. What is the effect of fluid replacement for different types of injuries (e.g. blunt, penetrating) on patient outcome?
C. What is the effect of different types of fluid (e.g. different crystalloids or colloids or crystalloids versus colloids) on patient outcome?
D. What is the effect of fluid replacement in paediatric trauma patients?
E. How accurate are paramedics at diagnosing hypovolaemia in trauma patients at the scene and can this affect patient outcomes?

F. Is there evidence on whether naturally occurring physiological shock mechanisms have a protective effect? How does fluid resuscitation interact with these mechanisms?

In order to identify the evidence base concerning additional relevant issues relating to fluid replacement, search strategies were developed to identify systematic reviews relating to these issues. Search filters for reviews were combined with relevant MeSH terms and text words.

The following databases were searched: Cochrane Library (Issue 4, 2002), MEDLINE (OVID, 1966-2003) and EMBASE (OVID, 1980-2003). There were no language restrictions.

Individual randomised controlled trials were not systematically sought.

Observational Studies

A separate systematic review of observational studies was ruled out at the protocol stage as these would not have informed the question adequately due to the intrinsically confounded nature of the study designs. However, some observational studies are frequently cited. Therefore, for the purpose of providing an adequate appraisal of current policy, all observational studies cited in the Consensus Statement or Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines were retrieved and critically appraised.

Inclusion and Exclusion Criteria

Primary research question: Immediate versus delayed fluid replacement or differential volume replacement in a pre-hospital or other setting

Inclusion Criteria

Study design: Randomised controlled trials

Population: Patients of any age with haemorrhagic hypovolaemia resulting from trauma

Intervention: Immediate or early fluid replacement (pre-hospital or other setting)

Comparator: Delayed or no fluid replacement (pre-hospital or other setting); different volume of fluid given (pre-hospital or other setting); fluids given at different speed (pre-hospital or other setting)

Exclusion Criteria

Study design: Observational studies

Population: Randomised controlled trials* with primarily:

- Head injured patients

- Patients with burns
- Patients with septic shock

Intervention/Comparator: Randomised controlled trials comparing different types of fluids; randomised controlled trials comparing blood or blood products to other fluids

* Studies were not excluded if they had mixed populations providing the majority were patients with haemorrhagic hypovolaemia resulting from trauma.

The inclusion and exclusion criteria were applied independently by two reviewers to all identified citations, and any disagreement resolved by a third reviewer. Where a decision on inclusion or exclusion could not be made on the basis of title or abstract, the full study was retrieved.

Inclusion Criteria for Systematic Reviews for Additional Research Questions

Systematic reviews of primary evidence of any study design that addressed the questions outlined above. Two reviewers independently assessed reviews for their relevance.

NUMBER OF SOURCE DOCUMENTS

Four randomized controlled trials and 14 systematic reviews were included in the report

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Data Extraction Strategy

All identified relevant randomized controlled trials (RCTs) were data extracted independently by two reviewers onto prepiloted data extraction forms. Data on study characteristics, population characteristics, setting, details of intervention and comparator, any additional treatment given and outcomes were extracted.

The primary outcome of interest was mortality, although data on short-term and long-term morbidity and quality of life was also extracted.

Quality Assessment Strategy

Randomised Controlled Trials

In order to assess the internal validity of the study, the following quality criteria were checked: method of randomisation, unit of randomisation (patients or paramedics); concealment of allocation; follow-up and intention-to-treat analysis; amount of crossover between allocated treatments; similarity of baseline characteristics and comparability of other care received. Blinding was also documented, although it was not considered to be an important quality criterion as individuals administering the treatment cannot be blinded; patients are unlikely to be aware of the different treatment strategies; and the primary outcome of interest (mortality) is unlikely to be influenced by knowledge of a certain treatment.

Systematic Reviews

The following checklist was used to appraise the identified systematic reviews. Summaries of outcome data were limited to mortality.

- Main characteristics (population, intervention, comparator, outcomes)
- Date of completion of searches
- Search strategy (databases used, language restrictions, citation searching, handsearching)
- Types of studies included (RCTs only, observational studies included)
- Inclusion and exclusion criteria (clearly defined, applied by more than one reviewer)
- Data extraction (performed independently by more than one reviewer)
- Quality assessment (was it performed, what were the criteria)
- Quantity of studies identified
- Synthesis of results (were results pooled, was clinical or statistical heterogeneity assessed, sub-group analyses)
- Direction of effect
- Potential publication bias
- Summary (key findings and validity)

Observational Studies

Observational studies were appraised in terms of the following criteria:

Checklist for appraisal of observation studies

- Study design (prospective, retrospective)
- Patient sample (e.g. consecutive, random)
- Baseline characteristics
- Potential selection biases (leading to differences in patient groups being compared)
- Adequacy of analysis and explicit consideration of confounders

- Consistency of conclusion with results of study

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Considerations

Technology appraisal recommendations are based on a review of clinical and economic evidence.

Technology Appraisal Process

The National Institute for Health and Clinical Excellence (NICE) invites 'consultee' and 'commentator' organisations to take part in the appraisal process. Consultee organisations include national groups representing patients and carers, the bodies representing health professionals, and the manufacturers of the technology under review. Consultees are invited to submit evidence during the appraisal and to comment on the appraisal documents.

Commentator organisations include manufacturers of the products with which the technology is being compared, the National Health Service (NHS) Quality Improvement Scotland and research groups working in the area. They can comment on the evidence and other documents but are not asked to submit evidence themselves.

NICE then commissions an independent academic centre to review published evidence on the technology and prepare an 'assessment report'. Consultees and commentators are invited to comment on the report. The assessment report and the comments on it are then drawn together in a document called the evaluation report.

An independent Appraisal Committee then considers the evaluation report. It holds a meeting where it hears direct, spoken evidence from nominated clinical experts, patients, and carers. The Committee uses all the evidence to make its first recommendations, in a document called the 'appraisal consultation document' (ACD). NICE sends all the consultees and commentators a copy of this document and posts it on the NICE website. Further comments are invited from everyone taking part.

When the Committee meets again it considers any comments submitted on the ACD; then it prepares its final recommendations in a document called the 'final appraisal determination' (FAD). This is submitted to NICE for approval.

Consultees have a chance to appeal against the final recommendations in the FAD. If there are no appeals, the final recommendations become the basis of the guidance that NICE issues.

Who is on the Appraisal Committee?

NICE technology appraisal recommendations are prepared by an independent committee. This includes health professionals working in the NHS and people who are familiar with the issues affecting patients and carers. Although the Appraisal Committee seeks the views of organisations representing health professionals, patients, carers, manufacturers and government, its advice is independent of any vested interests.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

The Assessment Report identified two Health Technology Assessment reports of the cost effectiveness of pre-hospital intravenous (IV) fluid replacement from a National Health Services (NHS) perspective.

See Section 4.2 of the original guideline document for a detailed discussion of the cost-effectiveness analysis.

METHOD OF GUIDELINE VALIDATION

External Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Consultee organizations from the following groups were invited to comment on the draft scope, Assessment Report and the Appraisal Consultation Document (ACD) and were provided with the opportunity to appeal against the Final Appraisal Determination.

- Manufacturer/sponsors
- Professional/specialist and patient/carer groups
- Commentator organisations (without the right of appeal)

In addition, individuals selected from clinical expert and patient advocate nominations from the professional/specialist and patient/carer groups were also invited to comment on the ACD.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

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.

- 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).
- 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.
- The administration of IV fluid should not delay transportation to hospital, but when given in accordance with the recommendation above, consideration should be given to administration en route to hospital.
- It is recommended that when IV fluid is indicated in the prehospital setting, crystalloid solutions should be the routine choice.
- 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.
- 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.
- Training programmes for healthcare professionals should incorporate the above recommendations.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations concerning clinical effectiveness are supported by four randomized controlled trials and 14 systematic reviews.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Appropriate use of pre-hospital initiation of fluid replacement therapy to reduce the risk of tissue and organ damage and improve survival in trauma patients

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

Implementation and Audit

- Ambulance trusts and clinicians who have been trained in advanced life support (ALS) and pre-hospital care should review their current practice and policies to take account of the guidance.
- Any local adaptations of the Joint Royal Colleges Ambulance Liaison Committee (JRCALC) guidelines that refer to the pre-hospital initiation of fluid replacement therapy in trauma should incorporate the guidance.
- To measure compliance locally with the guidance, the following criteria could be used. Further details on suggestions for audit are presented in Appendix C of the original guideline document.
    - Intravenous (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.
    - 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.
    - If IV fluid is administered for the circumstances described in the two points above, it is initiated en route to hospital (excluding individuals who are not considered appropriate to move).
    - When IV fluid is indicated in the pre-hospital setting, crystalloid solutions are the routine choice.
    - 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.
    - Training programmes for healthcare professionals caring for people experiencing trauma incorporate the guidance.
- Local clinical audits could also include measurement of compliance with other relevant clinical guidance such as JRCALC guidelines and the Consensus Statement.

IMPLEMENTATION TOOLS

Audit Criteria/Indicators
Patient Resources
Quick Reference Guides/Physician Guides

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Patient-centeredness
Timeliness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

National Institute for Clinical Excellence (NICE). Pre-hospital initiation of fluid replacement therapy in trauma. London (UK): National Institute for Clinical Excellence (NICE); 2004 Jan. 28 p. (Technology appraisal; no. 74).

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2004 Jan

GUIDELINE DEVELOPER(S)

National Institute for Health and Clinical Excellence (NICE) - National Government Agency [Non-U.S.]

SOURCE(S) OF FUNDING

National Institute for Health and Clinical Excellence (NICE)

GUIDELINE COMMITTEE

Appraisal Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Committee Members: 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

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

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.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) format from the National Institute for Health and Clinical Excellence (NICE) Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- Pre-hospital initiation of fluid replacement therapy in trauma. Quick reference guide. London (UK): National Institute for Health and Clinical Excellence

(NICE); 2004 Jan. 2 p. (Technology appraisal 74). Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

- The clinical effectiveness and cost-effectiveness of pre-hospital intravenous fluids in trauma patients. Assessment report. West Midlands Health Technology Assessment Collaboration, Department of Public Health and Epidemiology, The University of Birmingham; 2003 Jul. 138 p. Available in Portable Document Format (PDF) from the NICE Web site.

Print copies: Available from the National Health Service (NHS) Response Line 0870 1555 455. ref: N0430. 11 Strand, London, WC2N 5HR.

Additionally, Audit Criteria can be found in Appendix C of the original guideline document.

PATIENT RESOURCES

The following is available:

- Starting replacement fluid therapy for people with serious injuries before reaching hospital. Understanding NICE guidance - information for the public. London (UK): National Institute for Health and Clinical Excellence (NICE); 2004 Jan. 10 p. (Technology appraisal 74).

Electronic copies: Available in Portable Document Format (PDF) from the National Institute for Health and Clinical Excellence (NICE) Web site.

Print copies: Available from the Department of Health Publications Order Line 0870 1555 455. ref: N0370. 11 Strand, London, WC2N 5HR.

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

NGC STATUS

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