Open Call for expressions of interest in the area of Emergency Medicine, Pre-hospital Care and Trauma

Introduction

The remit of the NIHR Health Technology Assessment (HTA) programme with this Call is to promote high quality research on the effectiveness and broader impact of health technologies in the topic areas of trauma, emergency medicine, and pre-hospital care.

Remit of this Call

The main focus of this call is the emergency phase of the management of patients with urgent conditions, especially trauma. This includes pre-hospital care, hospital treatment and the first one to two days of management. We also wish to include research on prevention within this call; that is the assessment of technologies to prevent accidents, injuries or the need for treatment in the emergency department. Drugs used in the treatment of trauma or other emergencies are eligible for evaluation in this call, but drugs to prevent accidents or injuries are not a priority.

While the priority of this call is on the care of injuries, the programme will consider applications for research into the emergency care of other conditions.

Proposals must fall within the <u>remit</u> of the HTA programme*. Normally the HTA programme funds projects which include cost-effectiveness as an outcome, however here the focus is being broadened and so cost-effectiveness may not be applicable in every case. Nevertheless, as a minimum, proposals must include an evaluation of the effectiveness of a health technology in terms of urgent care or prevention (or associated methodological questions) and have patient centred outcomes.

* Health Technology is an internationally recognised term that covers any method used to promote health, prevent and treat disease and improve rehabilitation or long-term care. The HTA programme undertakes research for the benefit of patients and the NHS. 'Technologies' in this context are not confined to new drugs or equipment, but include procedures, devices, tests, settings of care, screening programmes and any intervention used in treatment, prevention or diagnosis.

Expressions of interest invited

The following types of proposed research are invited; primary research (RCTs or other studies), evidence synthesis and methodological studies. Please note that without an initial expression of interest potential applicants will not be able to progress to submitting an outline proposal at a later

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stage. Applicants may submit more than one expression if considering work in a variety of areas. We are looking to fund individual components of research and not programmes of work through this Call.

The Board will assess against the following criteria.

1. Importance of the health problem (including its relationship to government/NHS strategy and policy). For methodological research this will be the importance of the methodological problem.

- 2. The importance of the measured outcomes to patients and the NHS.
- 3. The possible effectiveness range technology or impact of the technology.
- 4. Current evidence base.
- 5. Current use of the technology or method and its likely diffusion.
- 6. Views of those working in and using the NHS.
- 7. Scientific quality.
- 8. Value for money.

Further guidance on submission

Primary research

The HTA programme is supportive of a staged approach to some research and the need to design a proposal to first answer one question before subsequent research should start. We expect that the usual pre-requisite for a clinical trial would be a high quality systematic review. The most suitable primary study design is often a randomised controlled trial. Other study designs may be appropriate, for instance in the evaluation of diagnostic tests. The HTA programme funds pragmatic clinical studies; not proof of concept studies; technologies being evaluated should have had some assessment of efficacy already. The studies should be adequately powered using clinically important outcomes. Researchers should specify and justify the comparator. The eligibility criteria for participants should be wide, and representative of the UK population.

Evidence synthesis

Proposals for evidence synthesis topics are welcome where they are likely to make a major impact on patient care.

Methodological research

Proposals for methodological studies are welcome. There are many areas where the methods for undertaking clinical trials and observational studies within an urgent care setting are poorly developed, or inadequate. There may be difficulties in applying methods developed in other fields to an urgent care setting.

Applicants should consider:

Networking

It is expected that clinical studies (including clinical trials) funded from this call will be conducted Please visit the **UKCRN** website through а research network. for more details (http://www.ukcrn.org.uk/index/networks.html). Although some proposals may be suitable for the topic specific networks it is envisaged that the majority will need to link to the NIHR comprehensive research network (NIHR CRN). The network role is to provide support for clinical research in the NHS, providing infrastructure through the allocation and management of NHS service support costs.

Ethical, Legal and Social Issues

All those involved in research must adhere to the strictest ethical and legal standards. Ethical, social and legal issues must be considered in relation to all stages of the research cycle. Applicants are asked to consider documents such as the MRC Ethics Guide: Medical research involving children; (DH 2004), Seeking Consent (DH 2001), Direction of Travel for Urgent Care (DH 2006), Mental Capacity Act (2005).

Applicants should follow the Medical Research Council's Good Clinical Practice guidelines (<u>http://www.mrc.ac.uk/Utilities/Documentrecord/index.htm?d=MRC002416</u>) when planning how studies, particularly RCTs, will be supervised.

Public involvement

The HTA programme recognises the increasing active involvement of members of the public in research and would like to support research projects appropriately. The HTA programme encourages applicants to consider *how* the scientific quality, feasibility or practicality of their proposal *might* be improved by involving members of the public. Research teams wishing to involve members of the public should include in their application: the aims of active involvement in this project; a description of the members of the public (to be) involved; a description of the methods of involvement; and an appropriate budget. Applications that involve members of the public will not, for that reason alone, be favoured over proposals that do not but it is hoped that the involvement of members of the public will improve the quality of the application.

INVOLVE (<u>http://www.invo.org.uk/</u>) is a key organisation for promoting public involvement in research, in order to improve the way that research is prioritised, commissioned, undertaken, communicated and used. By doing so, it is hoped that such research will be more relevant to the public's needs, more reliable and more likely to be used. INVOLVE have published a number of documents aimed at researchers seeking to involve the public in their research:

Involving the public in NHS, public health, and social care research: Briefing Notes for Researchers

Suggested guidance for grant applicants about involving the public in research

A Guide to Paying Members of the Public Actively Involved in Research

A Guide to Actively Involving Young People in Research: for researchers, research commissioners, and managers

INVOLVE also produce a useful publication aimed at members of the public wishing to get actively involved in research (other than as a trial participant):

Getting Involved in Research - a Guide for Consumers

Researchers should also use this as a resource for advice on involving the public in research.

Required expertise

HTA is a multidisciplinary enterprise. It may need to draw on the expertise and knowledge of clinicians and of those trained in health service research methodologies such as health economics, medical statistics, study design and qualitative approaches. HTA expects applicants to engage a qualified Trial Manager for appropriate projects. Applicants will need to show a commitment to team working and may wish to consider a collaborative approach between several institutions.

Timescale

There are no fixed limits on the duration of projects or funding and proposals should be tailored to fully address the problem. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed within a reasonable time. For further examples of the type of portfolio the HTA programme currently funds please visit our website (http://www.hta.ac.uk/ProjectData/3_publication_listings_ALL.asp)

Making an application

If you wish to submit an expression of interest in response to this call, complete the electronic application form and return it to the National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, Southampton SO16 7PX by 8th May 2007 1300 h by email to <u>htaprop@soton.ac.uk</u>.

Please note that applicants may submit more that one expression of interest if required. Without an initial expression of interest applicants will not be able to progress to the next stage.

Shortlisted applicants will be notified by mid June 2007 and asked to submit an outline application for considered by an assessment board with a deadline of early September 2007. If the outline proposal is acceptable and shortlisted by the board , investigators will be given a minimum of eight weeks to submit a full proposal for consideration at a later board in 2008.

Expressions of interest received after <u>1300 hours</u> on 8th May 2007 will not be considered.