

## Themed Call for proposals for health technology assessment research in the area of Healthcare Associated Infection

### Introduction

The remit of this NIHR Health Technology Assessment (HTA) programme Call is to promote high quality research on the effectiveness and broader impact of health technologies in the field of Healthcare Associated Infection (HAI).

### Definitions of Healthcare Associated Infection

Healthcare associated infections are infections that are acquired in hospitals or other healthcare settings or as a result of healthcare interventions. There are a number of factors that can increase the risk of acquiring an infection, but high standards of infection control practice minimise the risk of occurrence.<sup>1</sup>

### Remit of this Call

This call will consider research relating to healthcare associated infections associated with hospitals or occurring in the community, for example in primary care, in nursing homes or in community care. This call includes research on prevention, diagnosis and treatment and is not limited to specific patient groups or types of infection. Areas of interest might include, but are not exclusive to, the effectiveness of physical barriers (to infection); the evaluation of drugs and tests for diagnosis, monitoring or treating HAI; the use of rapid or point of care diagnostic tests; and information technology or management systems that change practice or help better manage antibiotic prescribing.

Proposals need to demonstrate the importance of the particular Healthcare Associated Infection to the NHS and must fall within the remit 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 it 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 Healthcare Associated Infection or prevention or an associated methodological question 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.

### The commissioning process

Outline proposals will be assessed first for importance to patients and the NHS, and then for scientific quality. Researchers whose proposals are shortlisted will then be asked to submit a full proposal for consideration. Funding decisions will be made at this stage. For the details of timings and dates please see the last section in this specification 'Making an application'.

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<sup>1</sup> [http://www.hpa.org.uk/infections/topics\\_az/hai/default.htm](http://www.hpa.org.uk/infections/topics_az/hai/default.htm)

Through a two stage process the Board will assess proposals against the following criteria:

1. The importance of the health problem (including any relationship to the Department of Health or NHS strategy and policy) or for methodological research the importance of the methodological problem.
2. The importance of the measured outcomes to patients and the NHS.
3. The possible range of effectiveness of the technology or the impact of the technology.
4. The 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, but on occasions other study designs may be appropriate, for instance in the evaluation of diagnostic tests. In all cases researchers should propose and justify their choice of study design. The HTA programme funds pragmatic clinical studies, not proof of concept studies and the technologies proposed for evaluation should already have had some assessment of efficacy. Studies should be adequately powered for clinically important outcomes and 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 or help clarify important questions for subsequent primary research.

#### Methodological research

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

### **Applicants should consider:**

#### **Networking**

The HTA programme particularly welcomes collaborative studies and encourages researchers making proposals for clinical studies (including clinical trials) 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. Please visit the UKCRN website for more details (<http://www.ukcrn.org.uk/index/networks.html>).

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### **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), Mental Capacity Act (2005).

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

All HTA-funded research teams are also expected to conduct their research in accordance with the Medical Research Council's Good Research Practice Guidelines.

<http://www.mrc.ac.uk/PolicyGuidance/EthicsAndGovernance/GoodResearchPractice/index.htm>

The MRC and the Department of Health have also devised a Clinical Trials Toolkit which applicants can view at <http://www.ct-toolkit.ac.uk/>.

### **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 (<http://www.invo.org.uk/>) 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 (<http://www.invo.org.uk/pdfs/Briefing%20Note%20Final.dat.pdf>)

Suggested guidance for grant applicants about involving the public in research (<http://www.invo.org.uk/pdfs/Guidelines%20April%202004.pdf>)

A Guide to Paying Members of the Public Actively Involved in Research ([http://www.invo.org.uk/pdfs/Payment\\_Guidefinal240806.pdf](http://www.invo.org.uk/pdfs/Payment_Guidefinal240806.pdf))

A Guide to Actively Involving Young People in Research: for researchers, research commissioners, and managers ([http://www.invo.org.uk/pdfs/Involving\\_Young\\_People\\_in\\_Research\\_151104\\_FINAL.pdf](http://www.invo.org.uk/pdfs/Involving_Young_People_in_Research_151104_FINAL.pdf))

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

([http://www.invo.org.uk/pdfs/guide\\_for\\_consumers.pdf](http://www.invo.org.uk/pdfs/guide_for_consumers.pdf))

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. We also recommend that all primary research projects appoint a dedicated project/trial manager. We have produced a generic job description which may help you with this. This is available through the HTA website <http://www.hta.ac.uk/investigators/governance.shtml>. 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/project/htapubs.asp>)

### **Making an application**

If you wish to submit an outline proposal in response to this call, complete the electronic application form and return it to either the HAI Themed Call, National Coordinating Centre for Health Technology Assessment, Mailpoint 728 Boldrewood, University of Southampton, Southampton SO16 7PX or email it to [htaprop@soton.ac.uk](mailto:htaprop@soton.ac.uk) by **23<sup>rd</sup> April 2008 1300h**. Applicants will also be asked to specify any competing interests at this point.

If the outline proposal is short listed by the board, investigators will be notified given a minimum of eight weeks to make a full proposal for consideration at a later board meeting.

***Outline proposals received after 1300 hours on 23<sup>rd</sup> April 2008 will not be considered.***

If you have any questions please contact

Themed Call Commissioning Team, NCCHTA, Mailpoint 728, Boldrewood, University of Southampton, Southampton, SO16 7PX. Tel: 023 8059 5621 (24 hour answer phone), Fax: 023 8059 5639, email:

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