Health Technology Assessment Programme

NHS National Institute for Health Research

HTA no 17/71

Treatment of new onset atrial fibrillation in the ICU

Introduction

The aim of the HTA Programme is to ensure that high quality research information on the effectiveness, costs and broader impact of health technology is produced in the most efficient way for those who use, manage, provide care in or develop policy for the NHS. Topics for research are identified and prioritised to meet the needs of the NHS. Health technology assessment forms a substantial portfolio of work within the National Institute for Health Research and each year about fifty new studies are commissioned to help answer questions of direct importance to the NHS. The studies include both primary research and evidence synthesis.

Research Question:

In adults in the intensive care unit who develop new onset atrial fibrillation, how do current treatment strategies compare in effectiveness?

1. **Interventions:** Any, to include pharmacological agents including anticoagulation, as well as non-pharmacological interventions such as fluid and electrolyte management and electrical cardioversion. Timing of different interventions should also be included.
2. **Patient group:** Adults admitted to ICU (not to include post cardiac surgery patients) who then develop new onset atrial fibrillation (AF). Applicants to define the clinical condition of new onset AF in the ICU and how it differs from AF in other settings. Applicants to then justify baseline subgroups.
3. **Setting:** Adult intensive care.
4. **Study design:** Scoping review of best available evidence and observational study using routinely available data to compare the effectiveness of current treatment strategies and to identify future primary research priorities.
5. **Important outcomes:** Restoration of normal rhythm; rate control; survival at 30 days; research recommendations.

NHS decision problem to be addressed by this research:

Management of new onset atrial fibrillation (AF) in the intensive care setting lacks specific guidelines and practice varies considerably. Risk factors for new onset AF include sepsis, rapid changes in fluid status and previously undiagnosed ischemic heart disease and paroxysmal AF which are distinctively different from the risk factors for chronic AF.

Whether or not to try to control heart rate (with drugs) or restore sinus rhythm (with drugs and/or electrical cardioversion) is still unclear. Prompt control of heart rhythm may be desirable in order to improve circulatory stability and to reduce the risk of adverse events such as emboli, but anti-arrhythmic drugs have well-known side effects and may also be ineffective in this setting. Electrical cardioversion can also restore AF to a normal rhythm, but it is unclear if this is effective in the critically ill. Rate control can be undertaken with digoxin or more usually now with beta-blockers or calcium channel blockers.

A scoping review of best available evidence together with analysis of routinely collected data will help to identify the direction for future research so that evidence based guidelines can be established for this currently under served population.

Making an application

The NIHR Health Technology Assessment Programme is funded by the NIHR, with contributions from the CSO in Scotland, Health and Care Research Wales, and the Public Health Agency in Northern Ireland.

If you wish to submit a stage one application against this topic, complete the on-line application form at www.nets.nihr.ac.uk/funding/hta-commissioned and submit it on line by **30 November**. Applications will be considered by the HTA Funding Board at its meeting in **January 2018**.

IMPORTANT: For stage one applications, if shortlisted, investigators will be given a minimum of **eight weeks to submit a full proposal**. The full proposal will be considered at the Funding Board in **May 2018.**

In line with the government's transparency agenda, any contract resulting from this tender may be published in its entirety to the general public. Further information on the transparency agenda is at: http://transparency.number10.gov.uk/#

Applicants are recommended to seek advice from suitable methodological support services, at an appropriate stage in the development of their research idea and application. It is advisable to make contact at an early a stage as possible to allow sufficient time for discussion and a considered response.

The NIHR Research Design Service (http://www.rds.nihr.ac.uk/) can advise on appropriate NIHR Programme choice, and developing and designing high quality research grant applications.

Clinical Trials Toolkit

Researchers designing or undertaking clinical trials are encouraged to consult the Clinical Trials Toolkit (www.ct-toolkit.ac.uk). This NIHR resource is a website designed to help researchers navigate through the complex landscape of setting up and managing clinical trials in line with regulatory requirements. Although primarily aimed at those involved in publicly funded Clinical Trials of Investigational Medicinal Products (CTIMPs), the Toolkit will also benefit researchers and R&D staff working on trials in other areas, who will find useful information and guidance of relevance to the wider trials environment.

Applications received electronically after 1300 hours on the due date will not be considered.

Please see GUIDANCE ON APPLICATIONS overleaf.

Should you have any queries please contact: htacommissioning@nihr.ac.uk
Telephone: Commissioning Board 02380 595510

Guidance on applications

Methods

Applicants should demonstrate knowledge of current research in the field and of systematic review methods and state how these would apply to the question posed. Valid and reliable methods should be proposed for identifying and selecting relevant material, assessing its quality and synthesising the results. Guidance on choice of appropriate methods is contained in NHS CRD Report *Systematic Reviews: CRD's guidance for undertaking reviews in health care (third edition)* (www.york.ac.uk/inst/crd/index_guidance.htm). Where established Core Outcomes exist they should be included amongst the list of outcomes unless there is good reason to do otherwise. Please see The COMET Initiative website at www.comet-initiative.org to identify whether Core Outcomes have been established. Where policy implications are considered, the emphasis should be on assessing the likely effects of a range of policy options open to decision makers rather than a judgement on any single strategy. Where epidemiological modelling or economic evaluation is required, the range of uncertainty associated with the results should be assessed. In the assessment of cost-effectiveness, further data collection may be required to estimate resource use and costs. If there is evidence that the ratio of costs and benefits may differ between readily identifiable groups, applicants are encouraged to state how they will identify these differences. Where relevant, researchers should explore the effect of the intervention in relation to health inequalities.

Cochrane

Applicants wishing to produce and maintain a Cochrane systematic review from a HTA commissioned systematic review should make the case in their proposal. This will need to include the approval of the relevant Cochrane Review Group (www.cochrane.org). Any additional costs associated with the initial preparation of a Cochrane review should be included in your project proposal. Maintenance costs cannot be met.

Diagnostics and Imaging

In evaluating diagnostic and imaging techniques, the emphasis of the HTA Programme is to assess the effect on patient management and outcomes (particularly where changes in management can be shown to have patient benefits). Improvements in diagnostic accuracy, whilst relevant, are not the primary interest of this commissioned research programme. Applicants should justify where they consider improvements in diagnostic accuracy to be relevant to these objectives. Where there is poor evidence to link diagnostic improvements to patient benefits, part of the research may be to assess the effects of such changes on patient outcome.

Public involvement in research

The HTA Programme recognises the benefit of 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 *could* be improved by involving members of the public. Examples of how this has been done for health technology assessment projects can be found at www.nets.nihr.ac.uk/ppi. 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.

Updating

It is the policy of NETSCC, HTA that all search strategies undertaken as part of evidence synthesis/secondary research projects must not be more than 12 months out of date when the draft final report is submitted. We expect that most projects will manage to bring their searches up to date prior to analysis and writing up. As research funders we are aware that exceptional circumstances can apply that would not allow this to be case but this must be the exception rather than the rule and will be assessed on a case by case basis. The expectation is that projects funded by the HTA Programme will deliver information that is both relevant and timely.

In addition, in order to inform decisions on whether and when to update the review, researchers will be expected to give some indication of how fast the evidence base is changing in the field concerned, based on the nature and volume of on-going work known at the time the review is completed. Applicants should note that they will not be expected to carry out any future updating as part of the contract to complete the review.

Communication

Communication of the results of research to decision makers in the NHS is central to the HTA Programme. Successful applicants will be required to submit a single final report for publication by the HTA Programme. They are also required to communicate their work through peer-reviewed journals and may also be asked to support NETSCC, HTA in further efforts to ensure that results are readily available to all relevant parties in the NHS. Where findings demonstrate continuing uncertainty, these should be highlighted as areas for further research.

Timescale

There are no fixed limits on the duration of projects or funding. However, there is a pressing need within the NHS for the information and so the research would normally be expected to be completed as soon as possible – however it is for applicants to justify the duration and costs proposed.