NIHR Health Technology Assessment (HTA) Programme Webinar

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Webinar overview

• Introduction to the HTA Programme
• Funding opportunities highlights for:
  – 17/14 Zoledronic acid to reduce fractures in patients with alcoholic liver disease
  – 17/17 Management strategies for pilonidal disease
• Tips for success and commonly made mistakes
• Questions
The NIHR HTA Programme supports research that is immediately useful to patients, clinical practice, and policy or decision makers.

HTA research is undertaken when evidence exists to show that a technology can be effective.

The purpose of an HTA study is to establish the clinical and cost-effectiveness for the NHS in comparison with the current best alternative(s).

A study may also investigate uncertainty around a technology’s place in the existing care pathway.
Maximising the potential impact of health research funding

Questions relevant to users of research?

- High priority questions addressed
- Important outcomes assessed
- Clinicians and patients involved in setting research agendas

Appropriate research design, conduct and analysis?

- Studies designed with reference to systematic reviews of existing evidence
- Studies take adequate steps to reduce biases - e.g. unconcealed treatment allocation

Efficient research regulation and delivery?

- Appropriate regulation of research
- Efficient delivery of research
- Good re-use of data

Accessible, full research reports?

- Studies published in full
- Reporting of studies with disappointing results

Unbiased and usable reports?

- Trial interventions sufficiently described
- Reported planned study outcomes
- New research interpreted in the context of systematic assessment of relevant evidence

Adding Value in Research framework
HTA will not support

- Phase 2 or earlier trials
- Research on non CE marked medical devices
- PhD research
- Proposals currently pending with another research funder
Commissioning cycle

Establish research area of uncertainty, importance to NHS and study design

You are here!
Commissioned call deadline

3rd August 2017, by 1pm

17/14 – Zoledronic acid to reduce fractures in patients with alcoholic liver disease

17/17 - Management strategies for pilonidal disease

Why are we highlighting these studies?
Important areas, advertised before
The board has not supported previous applications
**17/14 Zoledronic acid to reduce fractures in patients with alcoholic liver disease**

**Question:** Does administration of zoledronic acid to patients admitted to hospital with alcoholic liver disease (ALD) reduce the incidence of fractures and is it cost effective?

**Intervention:** Zoledronic acid, applicants to define and justify dose.

**Patient group:** Patients with ALD and increased fracture risk (according to a validated tool e.g. FRAX® or QFracture).
- Applicants should define thresholds for inclusion
- Exclude patients already receiving a bisphosphonate

**Setting:** Secondary care.

**Control:** Usual care. Other aspects of best supportive care such as vitamin D and mineral supplementation, advice on exercise and interventions to reduce alcohol consumption same in all study groups.
Study design: An efficient pragmatic randomised controlled trial, making use of routine NHS data to capture outcomes. An internal pilot phase is needed to demonstrate willingness of participants to be randomised, willingness of clinicians to recruit patients, and retention rates. Applicants should define criteria for progression to the main trial. Stratification according to age and duration of liver disease should be considered.

Important outcomes: Fractures resulting in health service contact.

Other outcomes: Cost effectiveness, adverse events.

Minimum duration of follow-up: 24 months.
17/17 Management strategies for pilonidal disease

**Question:** In patients with symptomatic pilonidal sinus disease, what are the optimal management strategies and what types of disease are better treated with which intervention?

**Intervention:** Curettage with/without fibrin glue, phenol injections, surgery and other interventions used for the management of this condition for primary wound closure.

**Patient group:** Patients with a symptomatic pilonidal sinus that applicants think are suitable for interventional management (applicants to define and consider how they will account for severity of disease).

**Setting:** Secondary care.
17/17 Management strategies for pilonidal disease


A cohort study (including a pilot phase with clear stop/go criteria to identify which treatment groups will be included and to ensure that sufficient numbers can be recruited to each group), qualitative study, and consensus process working with clinicians and patients (such as recommended by IDEAL framework).

Study should:

(i) develop a consensus regarding the sub-groups of patients for whom the various interventions may be suited;

(ii) describe the intervention techniques;

(iii) include an assessment of which outcomes are most valued by patients, and are there particular interventions that patients would rather avoid;

(iv) describe appropriate comparators for the interventions to be tested against in any future randomised controlled trial.
Important outcomes: Consensus views from the community for the management of the disease and recommendations for further research. Applicants should consider stratifying outcomes by severity of disease.

Other outcomes: Healing rates; time to recurrence; need for further procedures; overview of patient views and experiences.

Minimum duration of follow-up: Sufficient to inform a consensus view of the community, to be justified by the applicants.
Tips for success

Andrew Cook, Consultant Advisor
Address the brief

- Keep to the spirit of the brief
- Cover all the key points in the commissioning brief
- Make sure you carefully justify any deviations
Give sufficient details

• But not too much!
• Space is limited – especially in the first stage – choose your words carefully
• Keep your response succinct
• Do not exclude any key areas or issues

• The board may ask for further details or clarifications for the full application, if your application is shortlisted
Include public and patients

Public and Patient involvement (PPI) matters to the NIHR

– Embed in your study at early stage
– Consider how public & patients involved in
  • Study design / application
  • In the study itself

Clarify how public and patients will be involved

How will PPI benefit the research?
• include rationale, activity and training
Get the right team

• multidisciplinary
• practitioners and academics
• demonstrated experience
• includes public / patients
Use available support / resources

- **Research Design Service (RDS)** provides design and methodological support to health and social care researchers across England.

- **INVOLVE** is our national advisory group supporting active public involvement in NHS, public health and social care research.

- **Clinical Trials Units (CTUs)** provide specialist expert statistical, epidemiological and other advice and coordination to undertake successful clinical trials.

- Clinical Research Networks (**CRN**) across the UK to support development and delivery of clinical studies.
Consider value for money

• We will fund a study to answer an important question
• However, we will consider
  – overall value of the proposal
  – opportunity cost of not funding something else
Carefully cost the proposal

- Sorting out the budget takes **time**!
- Ensure costs addressing the health issue are **justified**
- Be **realistic** & use plausible FTE rates
- First stage – headline costs
- Full application - **detailed breakdown**
- **Board understand that costs may change**
- Full applications **scrutinised** by finance team

Account **appropriately** (use AcoRD) for
  - research costs
  - NHS treatment costs (excess CRN)
  - NHS support costs
Ensure the proposal is feasible

• Design fits NHS Context
• Timing and timeline – future relevant to NHS?

• Develop a REALISTIC recruitment plan: Think about
  – Study sites, eligible patients, patient consents, follow-up, adequate retention of participants, expectations of service providers/patients
  – & make contingency arrangements as difficult to control

• Leave enough time for study set up and co-applicants to sign
  – ethics and research governance approvals
  – Recommended 8 months from ‘fund with changes’
Think about presentation

• Simple English for mixed audience
  – Although experts involved in the decision
  – Tell the story for the non-expert
  – Clear plain English summary

• Use visible headings
• And paragraphs

• A flow diagram can support your study design
• CONSORT diagrams are essential for trials

• PROOF-READ SUBMISSIONS CAREFULLY!
Common Pitfalls

• **Avoid contradictory** accounts – Board feedback
• Don’t Repeat Yourself
• Incorrect / inconsistent **numbers** e.g. sample size
• Justify where potential overlap with **study in progress**
• **Insufficient detail**, or muddled detail – esp. methods
• **Gaps** in expertise on the **research team**
• Avoid excess **acronyms**
  – explain where included
Consider pathways to impact

- Who are your main stakeholders?
  - Commissioners
  - Providers
  - Health care professionals
  - Patients and public

- How will you share learning rapidly/effectively?

- Consider working with stakeholders to develop your dissemination plan

- Be creative and plan to target all audiences (not just publications - movie, website, social media)
… for your full proposal

• You will be invited to submit full proposal, if shortlisted
• Your application will be reviewed by external reviewers and the board.

• You will get feedback on your first stage proposal
• Respond to every point.

If you disagree with board / reviewer comments
• Set out and justify your opinion.
• DO NOT ignore them!!
Get involved

• Suggest future research topics / areas of uncertainty

• Sign up to reviewer development scheme - feedback and regular opportunities to get involved on a panel

• Professional and public / patient reviewers always needed - develop your skills and knowledge base

• Apply for Panel member/Board member roles - advertised regularly on our website

• Join our mailing lists for programme and funding bulletins

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Questions?