Managing evaluation research on behalf of the National Institute for Health Research

Obesity Themed Call Briefing Event

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Dr Ruairidh Milne
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7 October 2009
Agenda

► 10:30 Introduction to the Event
► 10:35 Background to the Themed call
► 11.00 Successful research proposals
► 11.30 The application process
► 12.00 Questions to panel
► 12.30 Lunch
Previous HTA programme Themed Calls

- Diagnostic tests and test technologies
  February 2009

- Healthcare associated infection
  April 2008

- Emergency medicine, pre-hospital care and trauma
  May 2007

- Medicines for children
  October 2005
The Obesity Joint Themed Call in Context

- NIHR Obesity Research Strategy (December 2008)
- ‘Healthy Weight, Healthy Lives’ (January 2008)
  A cross-government strategy for England
Overview of NETSCC

- NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC)
- Manages evaluation research on behalf of the National Institute for Health Research
- Supports scientific quality in all aspects of the research management process
The Translational Pathway

INVENTION
- Basic Research
- Development Pathway Funding
- Efficacy & Mechanism Evaluation

EVALUATION
- Invention for Innovation
- Biomedical Research Centres
- Biomedical Research Units
- Patient Safety and Quality Research Centres
- Research for Innovation, Speculation & Creativity
- Research for Patient Benefit

ADOPTION
- Health Services Research
- Programme Grants for Applied Research
- Public Health Research
- Service Delivery & Organisation
- Health Technology Assessment

DIFFUSION
- NHS Purchasing & Supplies Agency
- National Institute for Health & Clinical Excellence
- NHS Evidence
- NHS Institute for Innovation & Improvement
- Strategic Health Authorities
- Primary Care Trusts
- NHS Providers

This pathway covers the full range of interventions - pharmaceuticals, biologicals, biotechnologies, procedures, therapies and practices - for the full range of health and health care delivery, prevention, detection, diagnosis, prognosis, treatment, care.
NIHR Public Health Research programme

► Purpose and Remit
The PHR programme evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability and wider impacts of non-NHS interventions intended to improve the health of the public and reduce inequalities in health.

The scope of the programme is multi-disciplinary and broad covering a range of public health interventions.

► History
The PHR programme was launched in Autumn 2008.

► Contact PHR
For more information and to apply for funding visit www.phr.nihr.ac.uk
The predicted annual budget is £10m by 2011/12

The PHR Programme offers 2 funding workstreams: Commissioned and Researcher-led

<table>
<thead>
<tr>
<th>Types of Research</th>
<th>Who defines the question?</th>
<th>Frequency Per year</th>
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<tbody>
<tr>
<td>Commissioned</td>
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<tr>
<td>Non-NHS Primary research Evidence synthesis</td>
<td>PHR programme</td>
<td>As required</td>
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<tr>
<td>Researcher-led</td>
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<tr>
<td>Non-NHS Primary research Evidence synthesis</td>
<td>Researcher</td>
<td>Continuous with 3 closing dates</td>
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</table>
Purpose and Remit

To deliver information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS.

History

Since its inception in 1993 the HTA programme has invested over £280m in more than 800 research projects.

Health Technology Assessment: 2008 impact factor places it in the top 10% of medical & health related journals.

Contact HTA

For more information visit www.hta.ac.uk.
The predicted annual budget by 2011/12 is £88m

The HTA programme offers 3 funding workstreams:

<table>
<thead>
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<th>Types of Research</th>
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<th>Frequency Per year</th>
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</thead>
<tbody>
<tr>
<td>Primary research</td>
<td>HTA programme</td>
<td>4 calls</td>
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<tr>
<td>Feasibility &amp; pilot</td>
<td></td>
<td></td>
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<tr>
<td>Evidence synthesis</td>
<td></td>
<td></td>
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<tr>
<td>Theme from HTA</td>
<td>Theme from HTA programme</td>
<td>1 call</td>
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<tr>
<td>Question from researcher</td>
<td>Question from researcher</td>
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<tr>
<td>Evidence synthesis</td>
<td>NICE</td>
<td>Direct referral to</td>
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<td>On-contract teams</td>
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Commissioned

Clinical evaluation

Researcher Led

Themed Calls

NICE Guidance
Obesity Joint Themed Call Process

Obesity Joint Themed Call
Opens 10 November 2009 - Closing date 20 January 2010

Application to HTA programme
Board meeting
Notification of outcome
Full proposal deadline
Notification of outcome

OR

Application to PHR programme
Board meeting
Notification of outcome
Full proposal deadline
Notification of outcome
Successful research proposals - overview

- General observations
- Remit of the two programmes
- Specification document
- What the boards will look for
- What you can do
General observations

- Needs-led research programmes: scientific quality and need for research
NIHR Evaluation, Trials and Studies Coordinating Centre

Scientific quality

Need for research (importance)
Need for research (importance)

How much will...

- Decision makers
  - in the NHS
  - outside the NHS
- Patients
- Public

benefit from this research?
Need for research

- Central to both programmes
- Picked up in both application forms
- Both programmes have specific processes for assessing need and importance as well as scientific quality
General observations

- Needs-led research programmes: scientific quality and need for research
- Obesity evaluation research
- Must be within remit of HTA or PHR: evaluation with an interest in cost-effectiveness, that could inform decision-makers
Remit of the two programmes

▶ **HTA**: produces high quality research information about the effectiveness, costs and broader impact of healthcare treatments and tests for those who plan, provide or receive care in the NHS

▶ **PHR**: evaluates public health interventions, providing new knowledge on the benefits, costs, acceptability & wider impacts of non-NHS interventions intended to improve the health of the public & reduce inequalities in health
Not sure which programme?

► Who will fund the intervention? Where will it be delivered once fully developed?
► HTA, not PHR:
  ► Screening programmes
  ► Interventions delivered by midwives or health visitors or community pharmacists; or through prison health services
► If in doubt, ask NETSCC
Specification document – eligibility (1)

► Participants: Adults and/or children in whom the intervention might be of value.

► Interventions or Tests: Those which prevent obesity or identify, diagnose, or treat people who are obese or overweight. Both programmes are interested in research which may lead to a reduction in health inequalities.

► Setting: Any: either the wider community or the NHS (e.g. hospitals or primary care, community NHS settings such as pharmacies or health promotion services, etc)
Specification document – eligibility (2)

Study Design:

► Well-designed evaluation studies, including randomised controlled trials, pilot and feasibility studies, and evidence syntheses

► Pilot and feasibility study proposals should come with an overview of the definitive study, and a clear plan of how the preliminary study will inform it. The definitive study should also be within the remit of 1 of the two programmes.
Outcomes: For HTA

- Eligible studies should have a primary outcome of a measure of obesity/overweight for a minimum of 1 year.

- Among their outcomes, investigators should report weight (kg) in adults or BMI centile in children, at baseline & 1 year, or another widely reported outcome to allow later meta-analysis & indirect comparisons.

- Cost effectiveness should normally be assessed.
Outcomes: For PHR

- Eligible studies should normally have a primary outcome of a measure of obesity/overweight for a minimum of 1 year or a well validated surrogate.

- Among their outcomes investigators should report weight (kg) in adults or BMI centile in children, at baseline & 1 year, or another widely reported outcome to allow later meta-analysis and indirect comparisons.

- Cost effectiveness should normally be assessed.
What the Boards will look for – assessment of need

- Clear research question
  - PICO
- Size of the problem
- Place of the technology in the care pathway (HTA)/intervention in overall context (PHR)
- Thorough summary of current research
- People (patient) centred outcomes
What the Boards will look for – assessment of need also in terms of:

► How does this proposal relate to other relevant research e.g. SRs?
► How would the proposal fit into the HTA and PHR portfolio?
► How does the proposal relate to NICE guidance?
What the Boards will look for – assessment of scientific quality

- Sample size/effect size
- Outcomes
  - Include a measure of obesity/overweight (or well validated surrogate in PHR)
  - Also weight or BMI centile for later meta-analysis
  - Cost effectiveness
- Systematic reviews
- Developed interventions where possible
- Comparators
  - Best alternative, TAU, placebos
- Teams
- Value for money
What the Boards will look for – feasibility

► Not over-complex
► Recruitment rate
  ► Centres
  ► Eligible participants
  ► Participant consent
  ► Participant follow-up
► Experience, track record
► Sustainability, e.g. maintaining equipoise, burn-out, etc
What the Boards will look for – clarity and presentation

► English for mixed audience
  ► Clinical, methodologists, patient and public
  ► Tell the story well for the non-expert
  ► Plain English summary
  ► Follow the writing guides here, not just in the publication.

► Visible headings
  ► (e.g. sample size, outcomes, technologies)

► White space – enough paragraphs

► Flow diagrams
  ► CONSORT type – sufficient detail
  ► To explain complex interventions
What can you do?

► Ask for advice from NETSCC – esp eligibility and remit

► Speak to active PHR & HTA researchers (esp CTUs) & to Research Design Services (England)

► Offer to peer-review so you can see how others write a grant application

► Stick to the remit

► Scientific quality and need for the research

► Make your case

► Avoid pitfalls

► Fill in the form

And finally

Good luck!
Obesity themed call application process

Dr Andrew Cook, NETSCC Acting Director, Public Health Research programme
Aims:

► Brief introduction to each programme.
► Talk though the application process for each programme.
► Introduce you to each programmes application form.
Overview of the Public Health Research programme:

► non-NHS public health interventions
► new knowledge on the benefits, costs, acceptability and wider impacts of interventions intended to:
  ► improve the health of the public
  ► reduce inequalities in health
► variety of research designs
► does not fund intervention costs.
Overview of the Health Technology Assessment programme:

► Evaluates the effectiveness of a health technology in a real life NHS setting.
► Looks at fully defined and developed technologies.
► Assesses clinically important outcomes that matter to patients and that measure health gain.
Electronic application forms and guidance notes available from the 10 November 2009 on each programmes websites:

www.phr.ac.uk/fundingopportunities/obesity.asp
www.hta.ac.uk/fundingopportunities/obesity.shtml

Deadline for submitting electronic applications is the 20 January 2010 by 1pm.
Application process:

- Outline proposals received 20 January 2010.
- Those in remit considered by relevant programme boards.
- Applicants will be informed whether their proposal has been shortlisted or rejected in July 2010.
- Those shortlisted will be asked to submit full proposals.
- A minimum of 8 weeks will be given to applicants to complete full forms.
- Full proposals will be considered by relevant programme boards during October/November.
- Applicants will be informed of the Board outcome in January 2011.
Obesity themed call

The NIHR Health Technology Assessment (HTA) and Public Health Research (PHR) programmes are launching a joint themed call for obesity evaluation research. This call is a response to the Strategic Co-ordination of Health Research, which has prioritised obesity for further research and Healthy Weight, Healthy Lives: A cross-government research and surveillance plan for England was published in 2008.

Research proposals to this call must be within the remit of the HTA or PHR programme. Both programmes focus on evaluation, with an interest in cost-effectiveness. The research should be designed to inform NHS and/or public health decision-makers.

The HTA programme evaluates interventions in the NHS and the PHR programme evaluates public health interventions delivered in other settings. NETSCC can help researchers to identify which programmes to apply to, or may allocate proposals between the programmes when they are submitted.

This call will close on the 26 January 2010 by 1pm

Remit of call

More information about the remit of the obesity themed call is available in the joint specification document.

How to apply

Download the guidance notes for submitting a proposal to the PHR programme.

Access the outline proposal e-form for the PHR programme.
Obesity

The NIHR HTA programme is funded by the NIHR, with contributions from the CSO in Scotland and WORD in Wales.

The NIHR Health Technology Assessment (HTA) and Public Health Research (PHR) programmes are launching a joint themed call for obesity evaluation research. The Office for the Strategic Co-ordination of Health Research has prioritised obesity for further research and Healthy Weight, Healthy Lives: A cross-government research and surveillance plan for England was published in 2008.

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The HTA programme evaluates interventions in the NHS and the PHR programme evaluates public health interventions delivered in other settings. NETSCC can help researchers to identify which programmes to apply to, or may allocate proposals between the programmes when they are submitted.

If you would like to receive emails updating you on this call please complete the registration form.

Call opens

This call will open on Wednesday 10th November 2009. Application forms will be available on the HTA and PHR programme websites from that date.

Deadline for submission

Applications should be submitted electronically and the deadline for receiving all applications is 1pm on Wednesday 20th January 2010.

Remit of call

More information about the remit of the obesity themed call will soon be available from the NETSCC website.
NIHR Health Technology Assessment Programme

HTA programme Obesity Themed Call Outline Proposal

Eligibility

Introduction

Lead Applicant

Project Details

Proposed Research

Project Justification

Section D: Justification

Team Expertise

Joint Applicants

Collaboration

Appendix

Attach and Submit

Eligibility

Items marked * must be completed

The NIHR Health Technology Assessment programme is funded by the NIHR, with contributions from the CSO in Scotland and WQRf in Wales.

* In which country of the United Kingdom (UK) are you based?

* What is the setting for your proposed research?

Within the NHS includes, for example, pharmacies or health promotion services in care or community primary care settings such as:

- England
- Scotland
- Wales
- Northern Ireland
- Other
Section C: Project Details & Justification

Items marked * must be completed.

Project Details & Justification

Please note: The Programme Advisory Board will use only this section (Section C) of the form to assess the public health importance of the proposal. You must complete this section of the form in an anonymised format - there must not be any information that enables any individual, team or institution associated with your application to be identified.

1. What is the main research question? (in one sentence, 280 character limit - approx 40 words)
Please refer to the guidance notes for detailed information on what is required in this section.

   Word Count: 0

2. Describe the intervention being evaluated. Please include (1) what the intervention is (2) the setting in which it will be delivered for the project and, if different, when implemented (3) who will deliver the intervention (4) who will fund the intervention costs. (2800 character limit - approx 400 words)
Please refer to the guidance notes for detailed information on what is required in this section.
PHR Obesity Themed Call Outline Proposal

Section C: Project Details & Justification - cont.

Items marked * must be completed

Project Details & Justification

5. Please state why the research questions are important now for improving the health of the public, and will they address inequalities in health?
(1700 character limit - approx 250 words)

6. Summary for the Non-Expert (1700 character limit - approx 250 words)
Please refer to the guidance notes for detailed information on what is required in this section.
Section D: Justification of Project Proposed

Items marked * must be completed

Justification of Project Proposed

1. Specification of research question:
* Please state in one sentence the research question to be addressed.

Word Count: 0

2. Importance of the health problem to the NHS:
* Please describe the frequency of the health problem in the population and its impact on patients and the NHS. Include a description of the population (e.g., adults/children) in whom the intervention might be of value.

Word Count: 0

3. A description of the technology and its possible effect on health status:
* Include a description of current and/or projected use of the technology(ies), with approximate costs. Interventions/tests should prevent obesity or identify, diagnose or treat people who are obese or overweight.
Summary of Project

1. Please give a summary of the evidence explaining why this research is needed now
(3500 character limit - approx 500 words)

Word Count: 0

2. Summary of Project
Please provide a summary of your proposed research using the headings listed in the guidance notes. If appropriate to your study, you can also submit a flow diagram with your application (as a .pdf file) illustrating the study design and the flow of the participants. (3500 character limit - approx 500 words)
Section E: Team Expertise

Items marked * must be completed

Team Expertise

1. Please provide a clear account of the team assembled and the skills and expertise each member will provide. (3000 character limit - approx. 430 words)

Word Count: 0

2. Please provide details about any related (planned or active) grants held by any member of your research team in this or similar research areas. You should include a clear explanation of how the research being proposed in this application will fit. (3000 character limit - approx. 430 words)
Section G: Partner Collaboration

Items marked * must be completed

**Partner Collaboration**

1. Please say with which partner organisations you intend to link for this research - for example: local government, voluntary organisations, research networks. (3000 character limit - approx 430 words)

2. What role will these organisations have in the research proposed? (2500 character limit - approx 360 words)
Section C: History of Proposed Research

Items marked * must be completed

**History of Proposed Research**

1. Will this research be supported by any other funding body?  
   - YES  
   - NO

2. Has this or any related application been submitted elsewhere?  
   - YES  
   - NO

3. Is the research likely to lead to patentable or otherwise exploitable results?  
   - YES  
   - NO

4. Do you or any of the other joint applicants have a conflict of interest?  
   - YES  
   - NO
**Section I: Nominated referees**

Items marked * must be completed.

<table>
<thead>
<tr>
<th>Nominated referees</th>
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<tbody>
<tr>
<td>Please provide details of three suitable experts who would be prepared to act as a referee should you be invited to submit a full proposal. You should only include details of individuals you have contacted and who are prepared to undertake a review of your proposal if requested.</td>
<td></td>
</tr>
</tbody>
</table>

1. **First nominated referee**
   - **Surname**
   - **Title**
   - **Forenames**
   - **Job Title**
   - **Discipline**
   - **Department**
   - **Organisation**
   - **Reason for suggesting this potential referee (250 character limit - approx 35 words)**
   - **Email Address**
   - **Telephone**
   - **Has this person agreed to referee, if requested, and for their details to be submitted to and stored in the PHR programme's database to process proposals?**
     - Yes
     - No

2. **Second nominated referee**
   - **Surname**
   - **Title**
   - **Forenames**
   - **Job Title**
   - **Discipline**
   - **Department**
   - **Organisation**
   - **Reason for suggesting this potential referee (250 character limit - approx 35 words)**
   - **Email Address**
   - **Telephone**
   - **Has this person agreed to referee, if requested, and for their details to be submitted to and stored in the PHR programme's database to process proposals?**
     - Yes
     - No
Section G: Network Collaboration

Network Collaboration

Please say with which of the UK Clinical Research Networks (http://www.ukcrn.org.uk) you intend to link for this research:

Please list any benefits you may have identified from working with the network(s):

Word Count: 0
PHR Obesity Themed Call Outline Proposal

Submit the Form

* Items marked with an * must be completed

**Attachments**
Attach supporting documents

**Submit**
When you are ready to submit the form click "Submit." Submitting the form may take a few seconds.
Call opens 10 November 2009.

Closing date 20 January 2010 by 1pm.

www.phr.ac.uk/fundingopportunities/obesity.asp

www.hta.ac.uk/fundingopportunities/obesity.shtml
Further Information

► For general information on NETSCC and our work
  ► email info@netscc.ac.uk or visit www.netscc.ac.uk

► HTA - NIHR Health Technology Assessment programme
  ► email hta@hta.ac.uk or visit www.hta.ac.uk

► PHR - NIHR Public Health Research programme
  ► email info@phr.ac.uk or visit www.phr.nihr.ac.uk
Questions

www.phr.ac.uk/fundingopportunities/obesity.asp

www.hta.ac.uk/fundingopportunities/obesity.shtml