



NHS Research & Development

The HTA programme

**The Principles Underlying the Work of the National
Coordinating Centre for Health Technology Assessment**

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The Principles Underlying the Work of the National Coordinating Centre for Health Technology Assessment

All aspects of determining priorities and commissioning research and research related activity will be conducted according to the underlying principles of probity, openness and accountability.

1 *The purpose of this paper*

This paper sets out the ways in which the HTA programme in general and the NCCHTA in particular try to work according to the three crucial public service values probity, openness and accountability. It does not cover the contractual arrangements between the Department of Health and those commissioned to do research on behalf of the programme.

2 *Framework of values*

2.1 In January 1994 the Secretary of State for Health published national codes of conduct and accountability for the NHS. In the Secretary of State's codes three crucial public service values were identified:

Accountability - Everything done by those who work in the NHS must be able to stand the test of parliamentary scrutiny, public judgements on propriety and professional codes of conduct.

Probity - There should be an absolute standard of honesty in dealing with the assets of the NHS; integrity should be the hallmark of all personal conduct in decisions affecting patients, staff and suppliers, and in the use of information acquired in the course of NHS duties.

Openness - There should be sufficient transparency about NHS authority activities to promote confidence between the NHS authority or trust or its staff, patients and public.

2.2 Though the above values were defined for the NHS, the NCCHTA should adopt them, and use them; to ensure that high ethical standards are maintained at all times in all its work.

3 *Identifying possible topics for assessment by the HTA programme*

3.1 Arrangements have been adopted to ensure that no one source - in particular those associated with the NCCHTA and parties to its contract with the Department of Health - has excessive influence in the identification of potential research topics.

3.2 The arrangements for identifying future topics for research include:

- 'open channel' webform on the NCCHTA website for public and professionals to submit suggestions at any time
- topics coming from central sources such as the National Specialist Commissioning Advisory Group, National Service Frameworks and the National Institute for Health and Clinical Excellence
- capturing research recommendations from systematic reviews commissioned by the R&D programme or published in the Cochrane Library and horizon scanning reports
- scanning data bases and journals
- developing links with external organisations including other NIHR programmes, NICE Collaborating Centres, Clinical Research Networks and the National Screening Committee.

3.3 In addition the Affiliate Programme consults key groups such as: Royal Colleges and Societies; service users; commissioners (Primary Care Trusts); Health Authorities and health service managers.

4 *Prioritisation*

4.1 Suggestions identified or submitted are considered by one of four HTA advisory panels. The panels meet three times per year. NCCHTA carry out an initial sifting of potential topics in consultation with the Programme Director and Panel Chairs. If the panel's senior lecturer or researcher has a particular interest (e.g. likely to submit an application; financial) in a topic, the Panel Chair or another senior lecturer should decide on the priority given to the topic before the finalised list of topics goes forward to the panel. Panels may call for vignettes or, in exceptional circumstances, expert papers on short-listed topics, for a final decision at a subsequent meeting. Panel papers will indicate the source of suggestions and the scientific, clinical and policy work lying behind them.

- 4.2 Decisions on which topics should be recommended are made as a result of open debate within panels, followed usually by a vote and further debate. Panel members are asked to make difficult decisions in the absence of adequate evidence and there is scope for concern about the conscious or unconscious distortion of those decisions by members with strongly held views. The following help to reduce this:
- preparation of vignettes by NCCHTA staff
 - the role and responsibilities of the Panel Chair
 - the presence of observers e.g. Department of Health; MRC; NCCHTA staff.
- 4.3 The HTA advisory panels also play a role in prioritising outline proposals received through the HTA Clinical Trials (HTACT) route.
- 4.4 Arrangements for the appointment of panel members and chairmen have been drawn up and clear terms of reference are available.
- 4.5 Panel members have a responsibility to declare appropriate interests, such as financial, career or similar gain that might be anticipated by themselves or people closely associated with them should the research topic ultimately be advertised. At the panel meetings:
- at the start of the discussion about topics the Panel Chair reminds members that if they have declarations to make they should do so but that they will not be reminded at the introduction of each topic. Any declarations are formally recorded in the minutes
 - a system of reminding, declaring and recording interests at the vignette discussion stage is in place, with the Panel Chair reminding members of the need to declare any relevant interests each time a vignette is introduced
 - at the start of the discussion of the relevant clinical trial proposal panel members are required to declare any interests. Any panel member who is a named applicant on a proposal being discussed is required to leave the room for the discussion and not to score the proposal in the subsequent vote. If a panel member recognises a proposal as being from their own or another department within their organisation, they are required to declare a potential interest and not participate in the discussion or score the proposal.
- 4.6 Where a Panel Chair has a competing interest in a topic for which a vignette is due to be discussed or in a clinical trial proposal, not only is this declared and minuted but the Chair will be passed to an appointed Deputy Chair for the relevant discussion.

- 4.7 Finally, it should be noted the role of the panels is merely to suggest topics for future research. It is the HTA Prioritisation Strategy Group (see below, 4.9) that makes the final decision. The Programme Director, Chair of the Prioritisation Strategy Group, is accountable to the Department of Health Director of R&D.
- 4.8 It is also recognised that there is scope for unconscious bias in the vignettes prepared by the NCCHTA. They are written in a very short time (typically 3-4 days), on the basis of a search of Medline, the Cochrane library and other databases; and of input from experts in the field. The experts who contribute to the preparation of the vignettes are documented on each vignette with a note of why they have been approached kept on file. The researchers who prepare the vignettes and the senior lecturers who oversee them are fully aware of the scope for bias and try to reduce this.
- 4.9 Declaration of interests within the NCCHTA: a system to declare possible competing interests (financial and research) of researchers and senior lecturers supporting vignette production is in place. The senior lecturer on behalf of themselves and the panel researcher complete a form which is tabled at the pre-meeting with the Panel Chair. The Chair is briefed at this pre-meeting and alerts the panel to any relevant interests when a particular vignette is under discussion. Copies of the declaration of relevant interest forms are kept on file for future reference.
- 4.10 The HTA Prioritisation Strategy Group (PSG) is responsible for oversight and approval of topics recommended for research by the panels and oversight and approval of HTA clinical trials prioritised by the panels/mini-panels. It also has a role in managing the pool of project applications recommended for funding by the HTA Commissioning Board but not yet commissioned. This process involves matching the costs of recommended projects to available funds, balancing topic importance and urgency as advised by the panels with the scientific quality of applications as advised by the HTA Commissioning Board.
- 4.11 PSG is chaired by the Programme Director with the rest of the membership consisting of the four Panel Chairs, the Chair of the HTA Commissioning Board/HTA Clinical Trials Assessment Board and the Chief Executive Officer of NCCHTA. The four panel senior lecturers attend PSG as observers. Clear terms of reference for PSG are available and members have a responsibility to declare appropriate interests. PSG has agreed to adopt differing approaches to the declaration of competing interests according to which of its roles it is fulfilling:

- when considering and approving topics recommended for research by the panels PSG will adopt the “panels approach” to conflicts of interest. The chair will remind members to declare any possible conflicts of interest and these will be minuted
- when considering and approving HTA clinical trials prioritised by panels/mini-panels and managing the pool of project applications recommended for funding by one of the HTA Boards, PSG will adopt the “commissioning approach” to conflicts of interest. This is set out in detail below in sub-paragraph 5.16.

4.12 A list of all topics and proposals prioritised by the HTA programme is readily available on the HTA website.

5 **Commissioning**

5.1 The process of turning priorities into research projects is overseen by a number of Boards:

- the HTA Commissioning Board (HTACB)
- the HTA Clinical Trials Assessment Board (HTACTAB)
- ad-hoc HTA Assessment Boards convened for specific Themed Calls
- the NIHR Methodology Panel

and in particular the Chairs of these Boards/panel.

(for the purposes of the rest of this section the term Board is used in general to apply to any of the Boards or Panel listed above)

5.2 In undertaking this task the Boards are guided by the following principles:

- *quality* - in advice to applicants, selection of referees and HTACB members, and commissioned work
- *openness* - all decisions being transparent and justified
- *equity* - all applicants being treated similarly
- *efficiency* - using limited staffing resources as efficiently and effectively as possible
- *importance* – taking into account the likely level of national priority for particular topics

5.3 There are four distinct routes by which proposals to undertake research are received:

- by open advertisement inviting the submission of outline proposals (for primary research) or full proposals (for evidence synthesis)
- by ongoing submission of outline proposals through the HTA Clinical Trials response mode

- occasionally, by direct invitation to one or more institutions (in the event that the Programme Director, the relevant Panel Chair and the relevant Board Chair agree that only a limited number of institutions have the necessary expertise in a particular topic area)
- occasionally, and subject to approval by the Programme Director, by direct invitation to one of the teams contracted to the DH to provide Technology Assessment Reports to the HTA programme (see below, section 8)

- 5.4 Technical queries relating to advertised topics are referred to the panel senior lecturer by the relevant Commissioning Manager. These are queries of a technical nature, requiring clarification of the brief rather than advice on the content of an application, and it is acceptable for panel senior lecturers to handle these queries whether or not they have a particular interest (financial or research). NCCHTA does not give advice on the content or quality of an individual bid or an application to another party as this would be unfair to other bidders.
- 5.5 Arrangements for the appointment of Designated Board Members and Associate Members, and their roles and responsibilities have been drawn up so that a clear constitution exists and clear terms of reference are available. Designated Board Members also have a responsibility to declare appropriate interests.

Referees

- 5.6 A system has been set up to allocate external referees to particular topics independent of the academic staff of the NCCHTA. This ensures that in the substantial majority of instances selection of referees is by administration staff, though on occasion judgement has to be exercised to involve academic staff.
- 5.7 It is inevitable that there will be occasions when referees selected are associated with the research institutions of applicants. A conflict of interests, real or potential, occurs when:
- a referee is from the same department as the applicant
 - a referee is closely associated with the applicant in a personal, professional or volunteer role.
 - there are close links with a private or commercial interest.
- 5.8 The normal policy is to err on the side of caution, avoiding the selection of referees with institutional links where possible. A referee is not chosen if there is a conflict of interest as described in the bullet points above.

Evidence Synthesis

- 5.9 All full proposals are considered by three Board members, who are appointed by the Commissioning Manager to act as Designated Board Members for that topic. The Designated Board Members draw up a shortlist of successful full proposals to be taken forward for further consideration by the Board.
- 5.10 The full proposals received from short-listed applicants are then assessed by the Designated Board Members, once the proposals have been the subject of external refereeing by, if possible, at least four referees. Final selection of one or more proposals is then made at a meeting of the relevant Board.

Primary Research

- 5.11 Outline proposals are required for primary research topics. Once these are received they are considered by three Designated Board Members, who are appointed by the Commissioning Manager, with a short-list of applicants being invited to submit full proposals being agreed at a Board meeting. Exceptionally, on request by Designated Board Members, outline proposals will be reviewed by at least four referees, before being considered. The short-listed applicants are then invited to submit full proposals which are considered in a similar manner to the outline proposals - that is they are subject to review by, if at all possible, at least four referees, before being considered by the identified Designated Board Members, whose views are considered at a Board meeting. The only variation to the above procedures should be where action has been explicitly agreed by the Programme Director, the Chair of the relevant Board or the Panel Chairs.

Methodological Research

- 5.12 The NIHR Methodology Panel requires full proposals, and these are handled in the same way as Evidence Synthesis full proposals as described above in sub-paragraphs 5.9 - 5.10.
- 5.13 Following consideration of outline and full proposals at a Board meeting, there will in some instances be the need for the NCCHTA staff to request additional information, clarification or reworking of proposals. In such instances the Board may agree that follow up action can be reviewed and agreed by the Designated Board Members and Chair of the Board. In such instances the required actions should be included in appropriate records of Board meetings, and action taken or agreed by the Chair should be reported to the next meeting of the Board for ratification.

- 5.14 If the Programme Director agrees that only a limited number of institutions have the necessary expertise in a particular topic area, full proposals may be invited by direct invitation to one or more institutions. The submitted full proposals are then handled as described above in sub-paragraph 5.11.
- 5.15 It is inevitable that there will be occasions when members of the Board are associated with the research institutions of applicants, or applications. A conflict of interests, real or potential, occurs when:
- a group member's own application is being considered for funding
 - a group member is from the same department as the applicant
 - there are close links with a private or commercial interest
 - there is a close professional collaboration
- 5.16 A conflict of interest may also occur where a group member is in a different department but from the same institution as the applicant. If in doubt about a potential conflict of interest members should seek the advice of the Chair of the relevant Board. If a conflict of interest actually arises, members are asked to (i) declare their interest in such situations, (ii) ensure that they take no part in the discussion and selection of such applications, (iii) leave the room when such proposals are considered at Board meetings, for the duration of discussion, and until action has been agreed. This applies equally to the Chair of the Board and where a conflict arises, the Chair will leave the room and pass the Chair to an appointed Deputy (usually the Deputy Chair or HTA Programme Director) for the relevant discussions. The minutes of the meeting should record decisions about a conflict of interests and any withdrawals for particular items. In order to support this action the staff of the NCCHTA will provide a written report for each appropriate agenda item identifying the departments and institutions involved in putting forward proposals for consideration.
- 5.17 In addition to the above procedures for handling potential conflicts of interest at Board meetings when operating in 'commissioning' mode, the NIHR Methodology Panel will also function as a topic prioritisation panel and when operating in such a mode will follow the procedures set out above in sub-paragraph 4.4.
- 5.18 Funding recommendations agreed by the HTA Boards are ratified by the HTA Prioritisation Strategy Group (see above, sub-paragraph 4.9).
- 5.19 Details of public minutes of the Board meetings and of all projects funded by the HTA programme are readily available on the HTA website.

6 Contracts

- 6.1 NCCHTA is responsible for the drafting of HTA project contracts, which are sent for final signature to the Research and Development Directorate (RDD). The contract wording is a standard DH template and may not be altered without prior reference to RDD. NCCHTA has developed a detailed framework, agreed with RDD, for the preparation of the contracts. This includes:
- procedures for handling standard contracts
 - how to handle fund with changes and resubmitted proposals
 - contract variations and amendments
 - a comprehensive list of items that NCCHTA check in the resources sections of the proposals

7 Monitoring and Assessment

- 7.1 Operational procedures for monitoring approved contracts and assessment of draft reports have also been adopted that ensure:
- for primary research projects, the formation of Trials Steering Committees with an independent chair responsible to the HTA Programme Director, and where the function of such a committee is appropriate, formation of Data Monitoring & Ethics Committees
 - regular review of progress
 - progress and monitoring visits are undertaken on an agreed basis
 - appropriate handling of requests for extension of contracts
 - final reports are refereed
 - arrangements for appointing referees are made explicit
 - editors have oversight of final reports
 - authors sign a declaration of interests form before final reports are published
- 7.2 To minimise editors' potential conflicts of interest, it has been agreed that:
- Editors should not be allocated reports where the first author is employed by the Editor's institution.
 - If, subsequently, a first author moved to the Editor's institution, the Editor would notify NCCHTA so that a co-editor could be appointed.
 - An Editor should not edit a report where any of the authors are within their unit of assessment for RAE purposes.

- 7.3 For all requests for more time, additional funds and funded time extensions, a standard

request form is required before the request can be considered. All such requests are assessed on an individual basis, but within the context of the impact on the HTA programme as a whole and providing the appropriate evaluation of value for money, relevancy and timeliness. The NCCHTA monitoring team follows agreed procedures, involving the panel senior lecturers and Programme Director depending on the nature of the request. The panel senior lecturers are required to declare any relevant interests and a record of these is kept on the project file.

8 *Commissioning Technology Assessment Reports (TARs) on behalf of the HTA programme and NICE*

- 8.1 NCCHTA, on behalf of the HTA programme, has responsibility for the commissioning of the TAR teams at the Universities of Aberdeen, Birmingham, Exeter, Liverpool, Sheffield, Southampton and York. The contracts are between the DH and the TAR teams' host university, but monitored by NCCHTA. The main, but not sole, customer for the TAR work is the National Institute for Health and Clinical Excellence (NICE). Outputs from the TAR contract are published in the HTA Monograph series, subject to meeting the usual quality criteria for such publication.
- 8.2 NCCHTA is aware of the concerns about the potential for the TAR teams to influence the NICE appraisal process to further personal or departmental aims at the expense of conducting the commissioned TAR in an impartial manner. Similar concerns exist for the reports commissioned for the HTA programme. As for the HTA programme's work, the tasks of topic identification/prioritisation and commissioning are clearly separated. NCCHTA is not responsible for identifying or prioritising NICE's work programme. However, several Consultant Advisers, employed by NCCHTA, are members of one or more of NICE's Consideration Panels. Ultimately the Secretary for Health approves the list of topics for referral to NICE.
- 8.3 It is clearly the case that TAR teams have expertise and particular interests in many areas – that is why the teams have been contracted to be involved in this work. Not all potential competing interests would constitute an absolute bar to a team being allocated a particular topic, but to demonstrate probity the teams are required, in advance of being allocated topics from the NICE list and in respect of all TAR team members, to declare any potential specific or non-specific competing interests at the personal or departmental level. At this stage declarations of competing interest are sought in respect of all topics listed. The teams will also be required, from notification of allocation until all work on the subsequent final report has ceased, to refrain from bidding for any future work that would lead to the creation of a competing interest

- 8.4 Similar declarations of competing interest (specific/non-specific; personal/departmental) are required at the point of commissioning, this time relating only to those topics allocated to each team. Finally, the teams are asked to make author-specific declarations of competing interests on submission of their protocols and reports.
- 8.5 In advance of the topic allocation stage the teams submit written declarations of topic preference and potential competing interests as described above in sub-paragraph 8.3. The allocation of the topics to the teams is then agreed at a meeting or teleconference chaired by the HTA Programme Director and attended by the NCCHTA Executive Director, Senior Programme Manager and Programme Manager and, if appropriate, HTA Commissioning Board Chair. The allocation will take into account: the teams' potential competing interests; the teams' expressed preferences and how these interact with each other; the balance of work to be allocated to each team taking into account the potential size of the topics and the NICE delivery timetable; the number of contracted TARs per team per financial year.
- 8.6 The teams are formally commissioned by NCCHTA, on behalf of the HTA programme. The standard pro-forma for protocol and final report contain a section for declaration of competing interests.
- 8.7 One of the TAR teams is co-located, with NCCHTA, within the Wessex Institute for Health Research and Development, University of Southampton. Safeguards have been put in place to ensure that there is no opportunity for the allocation of topics to the teams to be influenced by other parts of the Wessex Institute for Health Research and Development. The overriding principle is to separate the key administrative commissioning decisions from academic work so that academic staff have no influence on such decisions.
- 8.8 The TAR Editors are asked to declare any potential competing interests and are not allocated editorial work originating from their own academic centres. If, subsequently, a first author moved to the Editor's institution, the Editor would notify NCCHTA so that a co-editor could be appointed. In the event of potential competing interests the HTA Programme Director will decide whether the editorial role can be undertaken by one of the TAR Editors or whether the HTA Programme Director should take on this responsibility for certain reports.

- 8.9 The TAR Editor holds editorial control of the description of any potential competing interests within the published monograph.
- 8.10 In January 2004, a new HTA Programme Director, who is also a member of a TAR team, was appointed. It was felt that this might raise concern about potential conflicts of interest which Professor Tom Walley might have between his HTA Programme Director responsibilities and his role within the Liverpool Reviews and Implementation Group, University of Liverpool. However, there are various safeguards in the HTA process which help to ensure that no one individual (including the HTA Programme Director) could unduly influence any allocation decisions. In particular, it has been agreed that decisions about the allocation of TARs and particularly the TAR unit value of those allocated to the Liverpool Reviews and Implementation Group, University of Liverpool would be counter-signed by the Department of Health (RD3), since it is the contract holder for the TAR contract.
- 8.11 NCCHTA have checked with the Department of Health (RD3) to see whether these measures are adequate and they have confirmed that they are satisfied with the safeguards in place, but have asked NCCHTA to keep this under review.

9 *Operating framework*

- 9.1 As a publicly funded organisation the NCCHTA must ensure that at all times business is conducted as efficiently and effectively as possible, and that proper stewardship of its activities on behalf of the Department of Health is achieved. Accounting, tendering, employment practices, identifying and recommending research organisation/individuals to be contracted to undertake reviews and research must be undertaken to the highest professional standards.
- 9.2 Those with the greatest opportunities to influence the work of the HTA programme, and to whom these standards apply include:
- the staff of the NCCHTA based at the University of Southampton and
 - the Chairs and members of the advisory panels; the HTA Commissioning/Assessment Boards; the HTA Prioritisation Strategy Group and the NCCHTA Steering Group.
- 9.3 A key element of the standards of operation adopted by the NCCHTA is the separation as far as possible of responsibility for the identification of topics and their prioritisation on the one hand; and their commissioning on the other. This should safeguard the key principle that the academic departments that make up the NCCHTA should be free to

bid for and undertake research, particularly research funded by the R&D strategy and the HTA programme.

10 The NCCHTA and its associates

- 10.1 It is recognised that all the staff of the NCCHTA and the associated staff of its parent body (the Wessex Institute for Health Research and Development or WIHRD) are at times in positions where they may have, or may be seen to have, the opportunity to exercise undue influence in the identification of potential research institutions/organisations, or in the award of contracts. The NCCHTA will ensure it undertakes all activities in accord with the above guidance, and the public service values identified in, and at the beginning of, this paper.
- 10.2 Taking into account the safeguards built into this paper, it is essential that the expertise of the academic departments associated with the NCCHTA are able to bid freely and in an unimpeded way to undertake HTA research via the open advert route, the response-mode HTA Clinical Trials route or via direct tender.
- 10.3 In 2005 the HTA Programme Director and the DH agreed a process to enable WIHRD and NCCHTA staff to submit proposals for HTA funding. The purpose of this route is to allow the HTA programme to efficiently commission research relevant to developing HTA, whilst ensuring probity. It is a two stage process of assessment of the importance of the topic by the NCCHTA Steering Group (including the HTA Programme Director and a DH representative) followed by a direct tender to applicants to submit a full proposal for consideration by the HTA Programme Director and Chair of the HTA Commissioning Board.
- 10.4 Additionally, the panel senior lecturers should be permitted to bid for work arising from the panel for which they work, and submit bids via the response-mode and direct tender routes. It is in everyone's interests that R&D is of the highest quality for the NHS and Wessex Institute for Health Research and Development academics should not be barred from such research simply on the grounds of geographical location.
- 10.5 Arrangements have therefore been adopted within the NCCHTA's Southampton office to ensure a clear segregation of activity between administrative work/programme management and clinical activity. A clear code of conduct is in place to ensure that there is no opportunity for the HTA programme's research, or selection of research applicants, to be influenced by other parts of the Wessex Institute for Health Research and Development or Departments of Southampton University. The overriding principle

is to separate the key administrative commissioning decisions from academic work so that academic staff have no influence on such decisions.

11 Data Protection

11.1 The NCCHTA follows the Wessex Institute for Health Research and Development Policy on Information Technology. This covers the protection of both computerised and non-computerised data. In summary, all staff must ensure that they do not store, on electronic medium or on paper, data of a personally identifiable nature without valid, authorised reasons. Where it is essential to hold this type of data, it must be password protected, with the individual password known only to the data holder.

12 Freedom of Information

12.1 The NCCHTA is based in the School of Medicine at the University of Southampton and manages the HTA programme on behalf of the Department of Health. As such the programme's annual report and research findings are incorporated into the **DH Freedom of Information publication scheme**. NCCHTA makes information about the HTA programme available to the public, in electronic and printed form: the full text and executive summaries of all published work of the programme; information explaining how the programme works; the project costs and grantholder details of all contracts awarded under the HTA programme; other publications such as updates, bulletins, newsletters and annual report. Requests should be made in writing to the Information Manager, NCCHTA at the following address: Information Manager, NCCHTA, Mailpoint 728, Boldrewood, University of Southampton, Southampton, SO16 7PX. Fax: 023 8059 5639. Email: hta@soton.ac.uk.

13 Conclusion

13.1 The NCCHTA and all those involved in the activities of identifying, selecting and awarding contracts for reviews and research will do so in a manner which preserves their integrity, and does not lead to justified criticisms of inefficiency, bias or personal gain.

13.2 Working methods that are not only honest but are seen to be honest are needed for the integrity of the programme. There is also the subsidiary purpose of ensuring that the academic departments that make up the NCCHTA are free to bid for and undertake research, particularly research funded by the R&D strategy and the HTA programme.

NCCHTA, March 2007