CHAPTER 1 Research Approach

1.1 Introduction and research design

The aim of this study is to assess the impact of the NIHR HTA Programme during the period 2003 to 2013, including the health and economic impact of the programme and other impacts on policy, practice and research. The Commissioning brief suggests that the study takes a case study approach, analysing the impact of a sample of HTA projects conducted over the period 2003-2013. We would see this as the core of this study, but would suggest that this may not be sufficient to capture the range of impacts resulting from the HTA programme. We propose a wider approach, aiming to explore the full range of impacts resulting from HTA research across the programme, including the impacts resulting from the programme itself, not just as a body of individual projects. Therefore, we see this project as consisting of two elements:

1. Analysis of the impact of the HTA programme as a whole
2. Analysis of the impact of a sample of individual HTA projects

To analyse the impact of the HTA programme as a whole, we propose to:

1. Conduct interviews with NIHR and wider organisations to understand the impact of the HTA programme on their practice. This will cover:
    a. 'Customers' of HTA research, such as NICE and the National Screening Committee (NSC), to understand how the programme supports their work and the impact it has overall
    b. Other research funders (e.g. MRC, Wellcome Trust) to understand the impact the HTA programme has on them. For example, to add value in medical research, Chalmers et al (2009, 2014) suggest that systematic reviews should be conducted before a new clinical trial is funded. The HTA acts as an exemplar of this practice, and we would like to see how this, and other elements of the HTA programme, has impacted on the policy and practice of other research funders.
2. Conduct a bibliometric analysis of the HTA programme. This would consist of two elements:
    a. Analysis of the academic impact of the studies published through the HTA programme using citation analysis
    b. Analysis of citations of HTA work on clinical guidelines to help understand the impact of the programme on policy and practice
3. Conduct a survey of PIs on all HTA funded research over the period. This would use a modified version of the survey used by RAND Europe to support universities in identifying their impact for REF 2014 submissions.

To analyse the impact of a sample of HTA projects we propose to conduct detailed payback case studies. However, expand upon the range of impacts captured through the payback model to also capture wider societal benefits, drawing on the impact categories used in the REF 2014 assessment. We would also, where possible and relevant, include economic analysis of the impacts of the individual studies. Where appropriate this could be integrated with the economic analysis of clinical trials in the HTA programme already conducted. We have costed this proposal based on twelve case studies being included in the analysis. However, we also include a unit price per case study for additional case studies if NIHR would prefer a larger sample.

These tasks are laid out in the project scheme in Figure 1 below, and the tasks are mapped against the key study questions in Table 1. In addition, we would draw on the findings of our current project looking at the impact of the HTA programme using an

economic analysis approach, and incorporate those findings into this work as appropriate.

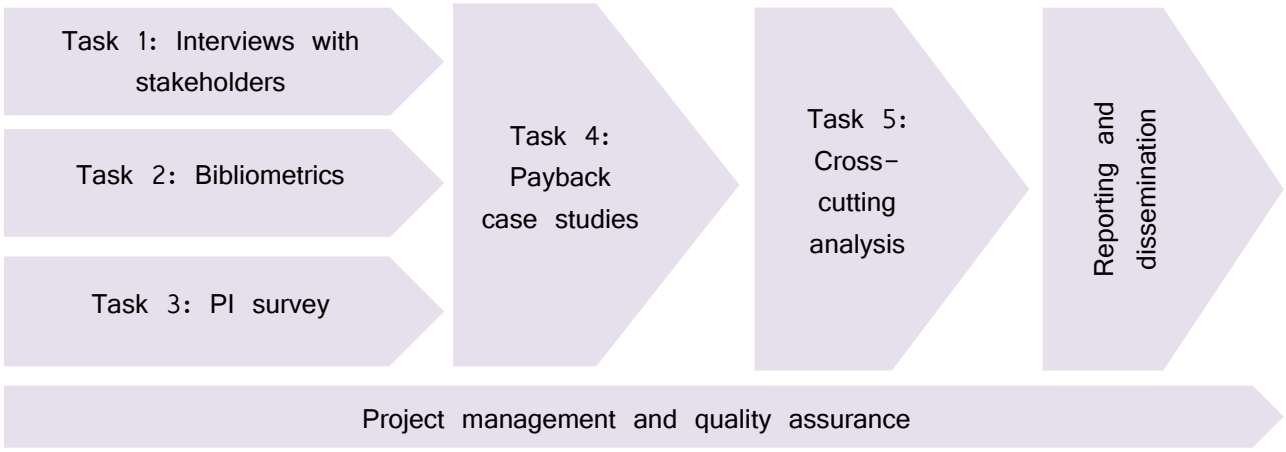

Figure 1: Project schema

Table 1: Mapping tasks to key study questions

Question	Source
What broad impacts on policy, practice, health, the economy and society more widely and research have resulted from the HTA programme as a whole over the period 2003-2013?	Task 1: Interviews with Stakeholders Task 2: Bibliometrics Task 3: PI survey
What is the impact on policy, practice, health, the economy and society more widely and research of the HTA programme at a project level, looking at a sample of projects over the period 2003-2013 in detail?	Task 4: Payback case studies
What actions can the HTA programme take to help maximise its impact on policy, practice, health, the economy and society more widely and research in the future?	Task 5: Cross-cutting analysis

1.2 Research Plan

Task 1: Interviews with key experts

The purpose of this task is to understand the broad impact of the HTA programme on the medical research funding and policy landscape. Interviews are generally flexible and can thereby cover a wide range of factors and topics, thus they will allows us to get a broad perspective of the value that HTA research may bring. The interviews will cover the following groups:

- 'Customers' of HTA research, such as NICE and the National Screening Committee (NSC), but also patient groups (e.g. the James Lind Alliance),

- Other medical research funders such as the MRC and the Wellcome Trust
- Agencies outside the UK with a similar remit to the HTA (e.g. PCORI in the US)
- NHS representatives

Interviewing customers of HTA research as well as funder groups will help to establish how the HTA programme supports their work and the impact it has overall. For example, to add value in medical research, Chalmers et al (2009, 2014) suggest that systematic reviews should be conducted before a new clinical trial is funded. The HTA acts as an exemplar of this practice and we would like to see how this, and other elements of the HTA programme, have impacted on the policy and practice of other research funders.

We will also use these interviews to explore the areas of research that the HTA has supported, and whether there may be areas that they have not supported which would have been beneficial. As well as the interviews, we may be able to further investigate this question by looking at UKCRC coding records of successful and unsuccessful applications for HTA funding. Subject to the HTA being able to provide the relevant data, we will look at the feasibility of using this, or other methods to analyse the areas of research funded (and not funded) alongside the findings from the interviews.

Interviews will conducted by telephone and will take approximately one hour. Questions will be open ended and the protocol will be flexible to allow the interviewer to focus on the most relevant questions for that particular stakeholder. A semi-structured approach will ensure that interviewers cover a consistent range of issues in each interview but also allow the particular context and circumstances relevant to the different groups to be discussed. We expect to conduct around 8-10 interviews with relevant representatives from the groups mentioned. RAND Europe has good contacts with research funders and policy makers in the biomedical sector and we expect to be able to straightforwardly identify and recruit relevant people for interview.

Interviews will be written up and key findings from each extracted and mapped against the key study questions. One team member will then review findings across the interviews and prepare an overview of the perspectives of these different groups on the HTA programme, and its impact on their work. This will be reviewed by all team members involved in conducting interviews to ensure completeness. .

Task 2: Bibliometric analysis

The purpose of this task is twofold:

1. To give an overview of the academic quality and breadth of the research produced by the HTA programme
2. To understand the impact of HTA research on policy through citation in NICE clinical guidelines

Although the production of academic knowledge is not the primary purpose of the HTA programme, this is one of the contributions that it makes which we would like to capture. The measure of citation on guidelines in particular is useful as it provides a proxy measure of the impact of the work on policy. However, it should be noted that may not take into account Technology Assessment Reviews which form an important part of the support provided to NICE by the programme, and this will be considered alongside the analysis of the guidelines citation data.

RAND Europe has significant expertise in using bibliometrics to support research funders. Working collaboratively with the Centre for Science and Technology (CWTS) in the Netherlands, we have delivered a series of regular bibliometric assessments on

the English health research system that have supported the allocation of over £1bn of research funds into centres of excellence and faculty. We have also conducted a range of bibliometric analyses for research funders internationally. We are aware of the number of well-known limitations to bibliometric analysis and that the results will need to be used within that context, and for that reason the analysis is intend to inform (not substitute) the wider qualitative analysis proposed in this study.

Analysis will cover both the publications in the Health Technology Assessment Journal and wider publications resulting from HTA-funded research. The HTA journal is covered by the Web of Science since 2004, so we propose to limit this analysis to the period 2004-2013 to make sure the analysis is robust. We will identify wider publications resulting from HTA funded research using two methods. Firstly, we will look at funding acknowledgements. Since August 2009 Web of Science records include the funding acknowledgements (FA) of scientific publications (whenever available).We will collect all publications carrying a FA to the HTA programme, considering all possible variants of the wording of the acknowledgement in the identification of the FA. This will give us a sample of publications resulting from HTA research for the period 2009-2013. In addition to this, we will identify publications that are included in NETSCC records and those highlighted on the project pages of the NIHR Journals Library website. Although, again, this will not provide a comprehensive list of all publications resulting from HTA funded research, bringing together these two sources should give a large sample of the wider publications supported by HTA-funded research. It should also be noted that publications with the highest visibility and impact are more likely to be those included in the NETSCC records and NIHR Journals Library website. Therefore, we intend to focus the analysis on publications in the HTA journal for the period 2004-2013, supplemented by a sample of the wider publications resulting from HTA funded research covering those publications either listed on the relevant project pages on the NIHR journals website, held in NETSCC records, or those from the period 2009-2013 which acknowledge HTA funding.

The analysis of the academic quality and breadth of the research produced will focus on the following indicators:

- **Number of publications** (P) in international journals of the unit of analysis in the period;
- **Number of citations received** by P during the entire period, excluding self-citations;
- **The average number of citations** without self-citations per paper;
- **Percentage of publications not cited by others** (in the given time period;
- **The mean field normalized citation score** (MNCS); the actual number of citations (without self-citations) divided by the expected number of citations on a paper basis. Here, the expected number of citations is based on the world-wide average citation score without self-citations of all similar papers belonging to the same field (journal subject category). In this way, a field normalized score is calculated for each paper. Next, the MNCS indicator is computed for each unit of analysis, by taking the average of these field normalized citation scores for individual papers. A value above 1 indicates that the mean impact for the unit is above world average whereas a value below 1 indicates the opposite.
- **The mean normalized journal score:** the average citation impact of the journals in which the papers appeared. The indicator is calculated based on the same principles as the MNCS. It shows whether the publications originating from the unit of analysis were published in top or in sub-top (in terms of citation impact) journals.

- **Number of highly cited publications** (i.e. in the top 10% of publications, normalised by field) in international journals of the unit of analysis in the period;
- **The percentage of highly cited publications**, which is the percentage of publications that are among the top 10% of the citation distribution for similar papers belonging to the same fields (as defined by journal subject categories).

In addition, an analysis of the breadth of fields covered by the research will be produced, analysing the fields of the journal in which research is published (looking at the sample of publications outside of the HTA journal), and the fields of the journals in which this research is cited.

Impact on policy will be investigated through an analysis of the number of citations of publications resulting from HTA research on the 23 clinical guidelines published by NICE in 2013-14. The most recent guidelines are selected since the majority of the HTA research portfolio over the period being studied would have been available to inform panels in developing these guidelines. Earlier guidelines may have missed out on important evidence from the period being analysed since the research evidence was not yet published. The reference data from the guidelines will be extracted using a Perl script which has been developed in-house by RAND. This produces an Excel spreadsheet of reference data which will be cleaned and then matched against publications resulting from the HTA programme identified as described above, using some matching algorithms already available at CWTS. This would provide a lower bound on the number of publications resulting from the HTA programme which are cited in guidelines due to the fact that the papers identified in the Web of Science will be a subset of all publications resulting from the HTA programme as described above. However, it will give an indication of the level of impact of the HTA programme as a whole on the policy-making process, supporting the wider analysis through the survey and case studies.

Task 3: PI Survey

The purpose of this task is to obtain an overview of the range of impacts of the work funded through the HTA programme. We intend to use a survey approach based on the *ImpactFinder* survey developed by RAND Europe and used most recently to support universities in understanding their breadth of their impact and to identify case studies for the REF 2014. The *ImpactFinder* survey is an online survey designed to identify research impacts on policy, practice, health, the economy, the environment and society more widely. It consists of just over 300 individual Yes/No questions that explore a wide variety of benefits and impacts to which a piece of research may have contributed. However, not all questions need to be answered by the participant, as the questions are built in a hierarchical fashion and secondary and tertiary questions are only revealed if any of the circa 50 primary, 'top-level' questions is answered in the affirmative. This structure increases the effectiveness of the tool as it combats one of the key issues with many survey approaches, which is burden on the participants. *ImpactFinder* is a tool which was originally developed by RAND Europe for the UK Arthritis Research Campaign (now Arthritis Research UK)[1] and UK universities.[2] It also provided the conceptual underpinning to the UK Medical Research Council E-Val[3] system and subsequent Researchfish[4,5].

[1] Wooding et al (2009). *Mapping the Impact: Exploring the Payback of Arthritis Research*. RAND Europe, Cambridge (MG-862-ARC).

[2] http://www.rand.org/randeurope/research/projects/impactfinder.html

[3] Medical Research Council (2010). Outputs, outcomes and impact of MRC Research: Analysis of MRC e-Val Data. Available at:

In this context, the survey would be adapted to also include impacts within the research system, through the development of new knowledge and research tools and techniques, through capacity building and through the targeting of future research. The survey would also be tailored to the type of research conducted through the HTA programme, such that irrelevant questions are excluded. However, a breadth of areas of potential impact will be retained in the survey, which is largely structured around those impacts discussed in the REF2014 materials which cover a broader range of areas than the payback framework since it is covering a wider range of research areas, not just the biomedical sciences. This could be beneficial, allowing a better understanding of the impact of HTA research taking a broad definition of impact as understood in the REF 2014, and hence capturing a wider range of potential societal impacts. However, this will be balanced with the need to reduce burden on the researchers participating in the survey. The survey will be sent by email to the PIs of all HTA studies commissioned since 2003. The survey will remain open for three weeks initially, with the option to extend for an additional week if necessary to increase the response rate. NIHR will be asked to supply names and email addresses for all PIs to be included in the survey. It may be beneficial for NIHR to be involved in contacting PIs to improve the survey response rate, and this can be discussed at the project inception meeting.

The output of the survey will be quantitative (e.g. the number of HTA studies claiming a particular type of impact), but will also be visually presented. It is possibly to create a 'map' of the results of the survey which can give a sense of the breadth of the impacts resulting from the HTA programme. This approach can also demonstrate the areas in which the HTA programme is likely to be having the most impacts, based on the number of projects noting an impact in that area. The survey results will be analysed to provide a description of the range of types of impact the programme is having, the frequency with which impacts are occurring within particular areas, and the extent of the impacts in those areas. The results will also be used to support the selection of case studies as described below.

Task 4: Payback case studies

The purpose of this task is to determine the returns from the NIHR HTA Programme from 2003 to 2013 through use of the payback framework developed by Buxton and Hanney (1996).[6] This framework will be used to measure the payback from the HTA programme in a systematic way. The main objective of this approach is to determine the wider impact of research through multidimensional categorisation of the benefits from HTA research.

The payback framework has two main components, a set of payback categories for classifying impacts from the case studies and a logic model of the research process, as shown in Figure 1. This study will use the five standard payback categories: knowledge production, research targeting and capacity building policy and product development, health sector benefits and broader economic benefits. However, in addition we will supplement this final category to incorporate wider societal benefits drawing on the approach used in the REF2014 assessment. This category would

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http://www.mrc.ac.uk/consumption/groups/public/documents/content/mrc008191.pdf [Last Accessed 27th February 2013].

[4] https://www.researchfish.com/

[5] Pollitt et al (2011). Project Retrosight: understanding the returns from cardiovascular and stroke research: methodology report. RAND Europe, Cambridge (TR-925-RS).

[6] Buxton and Hanney (1996). How can payback from health services research be assessed? Journal of Health Service
Research and Policy 1:35–43.

capture other benefits resulting from the research such as environmental benefits or cultural benefits. Clearly, these would potentially contribute to economic benefits and this will be described where appropriate. As such, this category will be termed broader economic and societal benefits. These categories will be used to classify the outputs and outcomes of the HTA Programme. The categories reflect the objectives of the HTA Programme and can include quantitative as well as qualitative descriptions of impact. For example, where feasible, we would include some economic analysis of the benefits of the research in particular case studies, matching this to the economic analysis approach used in the current ongoing work by RAND Europe.

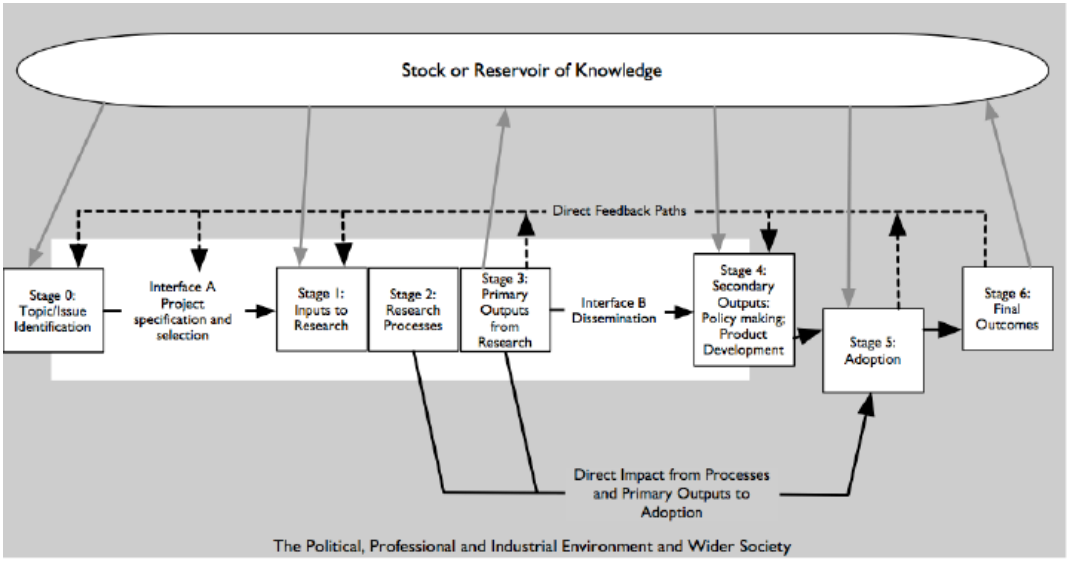

Figure 2 Payback Logic Model. Source: Buxton and Hanney (1996) [7]

We propose to conduct twelve case studies, and the proposal is costed with this in mind. However, additional case studies can be added to the sample at a unit cost of £8,000 per case study if a larger sample is preferred. The unit of analysis for the case studies will be individual HTA projects. Given that time is needed for research to be translated into impact we will focus on older studies in this analysis. Case studies will be selected from projects which have a final report published in the HTA journal in 2010 or earlier. Case studies will be selected through analysis of the survey results. We will aim to select a sample of case studies that show high impact in different areas. The survey sections correspond loosely to the payback categories, so we would look to include studies which have a high impact as reported in the survey in each of the payback categories. In addition, we would include case studies covering research in a range of different fields, and covering both primary and secondary research. Raftery and Powell[8] classified NIHR journal library publications for the period 1997-2012 into seven research fields: screening and diagnostics, pharmaceuticals, surgery, devices, mental health, methodology and other. They also classified publications into RCTs, other primary research, NICE TARs, and evidence synthesis. We would select a sample that covered all of these types of research, and a number of different research fields. Clearly, with a sample of twelve case studies, it will not be possible to cover all of these different classifications systematically. Therefore, our approach will be as follow:

1. Identify case studies which have a high level of impact in each payback category area based on the survey results (5 categories). At least two case

[7] ibid

[8] Raftery, J. and Powell. J,. (2009) Health Technology Assessment in the UK. Lancet 382, 1278-85. Supplementary appendix.

studies to be selected from each of these. Note that it is likely that some case studies will have a high level of impact in more than one payback category.
2. Group these into the type of research (RCTs, other primary research, NICE TARs, and evidence synthesis). Ensure at least two from each of these groups are selected.
3. Select randomly from the sample to meet these two requirements.
4. Map studies selected for the research field (screening and diagnostics, pharmaceuticals, surgery, devices, mental health, methodology or other). Ensure that the sample selected covers a spread of at least four of these areas and no more than four in any one field. If necessary, reject some of case studies selected and replace with new random selections until an appropriate mix is obtained.

In addition to these selection criteria, we will consider including case studies for which the PI has been both a successful and an unsuccessful applicant to the HTA programme. This will allow us to also reflect on the application process and the added value that the HTA programme provides from the perspective of failure as well as success. The HTA will provide information on PIs who fit this category.

Once we have identified the twelve case studies, we will gather data from two main sources: document review and interviews, Interviews will be conducted with the PI for the study at a fairly early stage to establish the key impacts of the study, the publications resulting from the study, and the relevant stakeholders for further interviews. This will then be supplemented by analysis of relevant documents, including published papers and reports, guidelines and policy documents, systematic reviews and meta-analyses, project records such as end of grant reports and, if available, original proposal documentation, and CVs of project team members. As well as verifying and expanding upon information from interviews, this will be used to identify key informants for further interviews. Interviews will be conducted with members of the project team, and research users such as policy makers, practitioners and patient representatives. Interviews will be semi-structured and will use a protocol tailored to the payback framework, An example protocol used for a previous study[9] is provided in Annex A. The protocol used in this project would follow a similar format, matching the stages of the payback framework logic model, but would focus more on capturing the range and nature of the impacts, as well as the success factors for these impacts. It would be tailored to the type of research conducted in the HTA programme and the UK context. Interviews will be conducted by telephone and will be recorded, subject to permission from the informants. Recordings will be confidential and for the use of the team only. We anticipate conducting approximately five interviews per case study, each lasting approximately one hour. The interviews in turn will support the identification of further relevant documentation for analysis. All participants will be given the opportunity to review the final case study and make comments, and will be given the opportunity to request that any quotations attributed to them included in the case study are anonymised or removed.

In each of the case studies, we will analyse the initial and long-term outputs and outcomes of HTA research, including translation of the research findings into the knowledge base or clinical practice. Through key informant interview, we will explore possible attribution problems by asking the studies' principal investigators and other key stakeholders what would have happened in the absence of the HTA research. In particular, the payback case studies will focus on the health and economic outcomes

[9] The protocol provided was used in the Mental Health Retrosight study conducted by RAND Europe. Wooding et al (2013) Mental Health Retrosight: Understanding the returns from research (lessons from schizophrenia): Policy Report. RAND Report RR-325-GBF; Guthrie et al. (2013) Mental Health Retrosight: Methods and Methodology Report. RAND Report RR-292-GBF

of the research. Where possible, quantitative as well as qualitative estimates of the economic benefits will be included in the case studies. The economic benefits of the HTA programme can be assessed by analysing four main types of economic benefits: cost savings from cheaper treatments or technologies that reduce the number of patients needing treatment, gains from improvement in "human capital" resulting from a healthier workforce, gains to the economy from product development that results in increased employment and sales and intrinsic gains from the improved health of society.[10] Application of the logic model from Buxton and Hanney's (1996) payback framework will allow us to breakdown the input, process and output relationships from the HTA programme. The economic assessment will then consider the economic impact resulting from each of the stages in the payback model. The economic evaluation will consist of four steps: identifying the relevant research making the impact, valuing that research, accurately ascribing the impact of the research and valuing the economic benefit.[11] Where feasible, this will be compared and integrated with the economic analysis of a sample of HTA projects currently being conducted by RAND Europe.

The final results of each case study will be presented in a standard template using the payback framework to enable comparability across the set. A cross-cutting qualitative analysis of all of the case studies will allow us to identify the key impact mechanisms associated with HTA research. It will also allow us to identify success factors, that is, things that support the successful translation and implementation of the findings of HTA research. These will be investigated through a qualitative analysis of the different stages of the translation process across studies and through an internal workshop with all case study authors

Task 5: Cross-cutting analysis

The purpose of this task is to synthesise the findings from the previous tasks and to produce a set of findings detailing the extent and nature of the impact of the HTA programme, and suggestions for future actions to maximise that impact.

The synthesis stage will consist of mapping findings across tasks to the key study questions and discussing conclusions and implications across the study team. The mapping exercise will draw on the payback categories to synthesise evidence and observations from the different tasks using a matrix as illustrated below. We have mapped into this matrix the tasks from which we expect the evidence to be identified, but we will be open to evidence from all tasks across all cells of the matrix. Task leads will map data from those tasks into the cells, and this will be shared with the whole project team for input and comment. In addition, we would draw on the findings of our current project looking at the impact of the HTA programme using an economic analysis approach, and incorporate those findings into analysis where appropriate. The team will then meet for a day long internal workshop to discuss the key findings and implications of the evidence identified across tasks.

Impact category	**Evidence of impact of HTA programme as a whole**	**Evidence of impact of specific HTA funded research projects**	**Observations on how impact can be maximised in the future**

[10] Buxton et al (2004). Estimating the economic value to societies of the impact of health research: critical review. Bulletin
of the World Health Organization, 82: 733-9.

[11] Buxton et al (2004). Estimating the economic value to societies of the impact of health research: critical review. Bulletin
of the World Health Organization, 82: 733-9.

Impact on knowledge creation	Task 2: Bibliometrics Task 3: PI survey	Task 4: Case studies	Task 4: Case studies
Impact on research targeting and capacity building	Task 1: Interviews with other funders Task 3: PI survey	Task 4: Case studies	Task 1: Interviews with other funders Task 4: Case studies
Impact on policy and product development	Task 1: Interviews with research users Task 3: PI survey	Task 4: Case studies	Task 1: Interviews with research users Task 4: Case studies
Impact on health and the health sector	Task 1: Interviews with research users Task 3: PI survey	Task 4: Case studies	Task 1: Interviews with research users Task 4: Case studies
Impact on the economy and wider societal benefits	Task 3: PI survey	Task 4: Case studies	Task 4: Case studies