

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Publication rate for funded studies from a major UK health research funder: a cohort study
AUTHORS	Turner, Sheila; Wright, David; Maeso, Rebecca; Cook, Andrew; Milne, Ruairidh

VERSION 1 - REVIEW

REVIEWER	Fujian Song Prof in Research Synthesis University of East Anglia Norwich, UK No competing interests declared
REVIEW RETURNED	08-Feb-2013

THE STUDY	Statistical methods not described. 1-2 sentences may be added.
GENERAL COMMENTS	The study question is defined as "assessing what percentage of HTA projects are published in the monograph series, and if they are not published what are the reasons?". I feel that the scope of the study was therefore too narrow, by considering only one format of publication (HTA monograph). I agree that the publication rate of the HTA programme has been much improved by HTA monograph series, but other ways of research dissemination may also be important or helpful. For example, NICE TARs are usually publicly accessible from NICE websites; and 7 of the 11 primary research projects without HTA monograph were published in journals. Therefore, I suggest that Turner and colleagues revise the manuscript by providing a more comprehensive dissemination profile of the included HTA projects in terms of journal publications and publically accessible reports.

REVIEWER	Swaroop Vedula Post-doctoral fellow Johns Hopkins University, USA I have no competing interests to declare.
REVIEW RETURNED	19-Feb-2013

THE STUDY	1. The reviews and studies included in this sample were conducted under contractual obligations to the sponsoring entity. This is unlike the situation for many other studies and systematic reviews, which are conducted by independent investigators or grantees under no contractual requirements to publish. 2. Criteria for assessing future publication are unclear. Also, this
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	<p>assessment seems pure speculation and its contribution to the scientific value of the paper is unclear.</p> <p>3. Mention in your methods what you were counting.</p>
RESULTS & CONCLUSIONS	<p>1. See my notes on figure 1 in items 5 and 7 under the section on comments to the authors.</p> <p>2. What is the basis for your conclusion that other research funders have scarcely reported on publication rates of studies they supported?</p> <p>3. What are the authors concluding?</p>
GENERAL COMMENTS	<p>1. Explain all acronyms the first time they are mentioned in the manuscript (e.g., NIH, NIC, NETSCC) in the text and the flow-chart.</p> <p>2. Why is the year 2002 of particular interest for sub-dividing the projects in your sample?</p> <p>3. Given that the authors commissioned to complete the projects were under contract obligations (as I understand from your write-up), why were the original authors not contacted to inquire about any publication and reasons for not publishing a report?</p> <p>4. When was the assessment by "LT" about whether the projects "will publish" or "will not publish" dated? What criteria were used for making this assessment?</p> <p>5. The last column in Figure 1 (boxes listed under the one labeled "Total NICE TAR" - $140+0+2+6+6$ is not equal to 148. It is unclear how one is supposed to count the numbers in these boxes so they add up to the totals? In the first column labeled "Primary research", adding 163, 2, 8, and 28 leads to the total of 201, and the last row of boxes add up to the previous one, 28. But the third column from the right - "Total HTA TAR" - the numbers to be added follow a different pattern because the last row must also be counted to add up to the total of 110. The different rules needed for counting different columns is confusing.</p> <p>6. The 52 projects that provided a draft final report (DFR) but no publication - the "staff expert in this area" who was consulted to determine whether there would be an eventual publication - was this expert an investigator on the projects? How would they know whether the projects will eventually be published?</p> <p>7. The explanation in paragraph on lines 3 to 7 of page 7 is confusing. What are the authors conveying here?</p> <p>8. Please clarify in figure 1 the origin of the "561 projects" specified on line 53 on page six (paragraph immediately following Table 1 in your manuscript). This information is available in Table 2, so at least refer to Table 2 at the appropriate location in the text. Also, why does adding 561 to the 52 shown in Table 1 not add up to your total of 628?</p> <p>9. On page 8, the authors concede that some of the projects in their sample were not part of the program they are trying to describe and evaluate. Why were the projects from "a previous funding stream" included in the study sample? The research question is muddled as a consequence, it seems.</p> <p>10. Table 4 - how is "insufficient quality" determined for the DFRs? Why should a "pilot" study not be eligible to have a published article and instead be limited to a monograph? Why were the studies with no available records not excluded from the study sample?</p> <p>11. How were the searches to identify any peer reviewed articles conducted? When were they conducted and which databases were searched?</p> <p>12. This seems to be a study on program evaluation. Did you have to obtain ethics approval?</p> <p>13. Can the authors comment upon access to data (for other investigators) from studies sponsored by the HTA program?</p>

REVIEWER	Prof Paul Glasziou, Bond University, Australia
REVIEW RETURNED	06-Mar-2013

RESULTS & CONCLUSIONS	The data could be better present
GENERAL COMMENTS	<p>This is a study of the publication rate of 628 research projects commissioned by UK HTA program showing a substantially higher publication rate than usual. It is novel as one of very few funder based assessments of publication, and an analysis of what might have led to the higher rate. Given the \$ Billions wasted in non-publication currently, this is an important start on ways to improve the problem. I would like to have seen a "survival curve" analysis of time to publication (but they say in the Discussion that this is underway). I would also have liked to have seen a more detailed analysis of the processes used to achieve this higher rate (their "3 elements" in the discussion), but these do not detract greatly from the overall findings.</p> <p>Some other specific comments:</p> <p>Page 9 : Table 3 would be much easier to read as a Figure, e.g. a bar graph (which could and should retain all the raw numbers but show the %s graphically).</p> <p>Page 10: There were 9 projects of "insufficient quality" which were not published as HTA, but 6 were published elsewhere. How was the "insufficient quality" judged? Was it the reporting or the design? And it is then that 6 were published elsewhere. Can this be explained a little more?</p> <p>Page 10: There is an implication that Pilot studies and feasibility might not be published, but they should still be publicly reported so that others do not waste their time and funds.</p> <p>Page 11: As I said above, Time to publication would be help in understanding and comparing these results with others.</p> <p>Page 11: Element 1 - "Monitoring". There is no mention of the HTA withholding 10% funds until the final results are submitted - could this be added. And other details of the monitoring process would help other funders attempting to emulate this.</p> <p>Page 11: The HTA journal. Do you have data on how many studies also published elsewhere? If this was very high, then it might suggest the HTA journal was not the crucial element.</p>

VERSION 1 – AUTHOR RESPONSE

Reviewer 2: Fujian Song, Prof in Research Synthesis, University of East Anglia, Norwich, UK

1) Statistical methods not described. 1-2 sentences may be added.

Action: One sentence added to text in Methods

"Each project was counted as one entity and the data were analysed by the calculation of percentages."

2) The study question is defined as "assessing what percentage of HTA projects are published in the monograph series, and if they are not published what are the reasons?". I feel that the scope of the study was therefore too narrow, by considering only one format of publication (HTA monograph). I agree that the publication rate of the HTA programme has been much improved by HTA monograph series, but other ways of research dissemination may also be important or helpful. For example, NICE

TARs are usually publicly accessible from NICE websites; and 7 of the 11 primary research projects without HTA monograph were published in journals.

Therefore, I suggest that Turner and colleagues revise the manuscript by providing a more comprehensive dissemination profile of the included HTA projects in terms of journal publications and publically accessible reports.

Action: The dissemination profile of the included HTA projects in terms of journal publications and publically accessible reports is beyond the scope of this project; however, another project is underway addressing these issues.

Text has been added to the Introduction:

“Authors are also encouraged to publish elsewhere to broaden dissemination of their findings, and there are other processes for the dissemination of Technology Assessment Reports”; and to the research recommendations: “and an investigation of the dissemination profile of HTA projects in terms of journal publications and publically accessible reports”.

Reviewer 3: Swaroop Vedula, Post-doctoral fellow, Johns Hopkins University, USA

The study

1) The reviews and studies included in this sample were conducted under contractual obligations to the sponsoring entity. This is unlike the situation for many other studies and systematic reviews, which are conducted by independent investigators or grantees under no contractual requirements to publish.

No action required

2) Criteria for assessing future publication are unclear. Also, this assessment seems pure speculation and its contribution to the scientific value of the paper is unclear

Action: Please see comments above and in response to reviewer 1 point 2.

Methods section page 5 text added:

“When projects publish in the monograph series the draft final reports go through an editorial review process which is conducted between the editors, reviewers and authors. Reports are published in the HTA journal series if they are of a sufficiently high scientific quality as assessed by the referees and editors¹⁰”.

“This judgement was made using the following criteria. If at the end of the editorial process the editorial board of the HTA journal had deemed the report to be of “insufficient quality” to publish, this report was recorded as “will not publish”. If a report has been deemed as of sufficient quality to publish this was recorded as “will publish”. Data for “published” “will publish” or “will not publish” was originally obtained in July 2012 and updated on 8th March 2013”.

3) Mention in your methods what you were counting.

Action: Text in methods amended: “Each project was counted as one entity and the data were analysed by the calculation of percentages”.

Results and conclusions

1) See my notes on figure 1 in items 5 and 7 under the section on comments to the authors.

Action: See items 5 and 7 below.

2) What is the basis for your conclusion that other research funders have scarcely reported on publication rates of studies they supported? What are the authors concluding?

Action: The sentence relating to this has been removed from the Discussion section of the manuscript.

Further comments

1. Explain all acronyms the first time they are mentioned in the manuscript (e.g., NIHR, NIC, NETSCC) in the text and the flow-chart.

Action: Text amended as requested. NIC should have read NICE, this was a typing error.

2. Why is the year 2002 of particular interest for sub-dividing the projects in your sample?

Action: This date was chosen as it allowed us to look at data for the last 10 years. (Data extraction was performed in 2012). Text in Methods section reads: "The data were further sub-divided into those projects where the commissioning process started within the last 10 years (i.e. after 2002)"

3. Given that the authors commissioned to complete the projects were under contract obligations (as I understand from your write-up), why were the original authors not contacted to inquire about any publication and reasons for not publishing a report?

Action: The original authors were contacted at the time when the reports were due. Records were kept of the correspondence; reasons for non-publication were clear from these records so no attempts to contact the original authors were considered necessary.

The one exception to this was one project commissioned in 1993 right at the start of the HTA programme twenty years ago. This file may have been lost in the transfer between offices.

Text has been amended in the last paragraph of Methods: "files which contained records of correspondence with the authors, at the time when the report was due"; and in Results: "For one project commissioned in 1993, we were unable to locate the paper files and so were unable to determine the reasons for non-publication".

4. When was the assessment by "LT" about whether the projects "will publish" or "will not publish" dated? What criteria were used for making this assessment?

Action: The original assessment by LT was performed in July 2012 and updated on 8th March 2013. Text in paragraph 5 of Methods amended to:

"Projects in this category were considered by a staff member (LT) with experience in editorial processes, detailed knowledge of the projects concerned and knowledge of editorial decisions. They designated projects as either "will publish" or "will not publish". This judgement was made using the following criteria. If at the end of the editorial process the editorial board of the HTA journal had deemed the report to be of "insufficient quality" to publish, this report was recorded as "will not publish". If a report has been deemed as of sufficient quality to publish this was recorded as "will publish". Data for "published" "will publish" or "will not publish" was originally obtained in July 2012 and updated on 8th March 2013."

5) The last column in Figure 1 (boxes listed under the one labelled "Total NICE TAR" - 140+0+2+6+6 is not equal to 148. It is unclear how one is supposed to count the numbers in these boxes so they add up to the totals? In the first column labelled "Primary research", adding 163, 2, 8, and 28 leads to the total of 201, and the last row of boxes add up to the previous one, 28. But the third column from the right - "Total HTA TAR" - the numbers to be added follow a different pattern because the last row must also be counted to add up to the total of 110. The different rules needed for counting different columns is confusing.

Action: This was a mistake the sizing of the box had not allowed all the text to be seen. It should have read DFR rec'd not published yet =8. The box has been re-sized. We have added additional boxes for the "will not publish" to try and make it clearer that the bottom row is not intended to be added to the total, but shows the split of those that "will" or "will not" publish.

We hope the confusion has been resolved by the changes made.

6. The 52 projects that provided a draft final report (DFR) but no publication - the "staff expert in this area" who was consulted to determine whether there would be an eventual publication - was this expert an investigator on the projects? How would they know whether the projects will eventually be published?

Action: This member of staff was not an investigator on the projects. She was a member of NETSCC staff with responsibilities for the editorial process. She had knowledge concerning where reports were in the editorial process. Text has been amended to say: "Projects in this category were considered by a staff member (LT) with experience in editorial processes, detailed knowledge of the projects concerned and knowledge of editorial decisions. They designated projects as either "will publish" or "will not publish". This judgement was made using the following criteria. If at the end of the editorial process the editorial board of the HTA journal had deemed the report to be of "insufficient quality" to publish, this report was recorded as "will not publish". If a report has been deemed as of sufficient quality to publish this was recorded as "will publish". Data for "published" "will publish" or "will not publish" was originally obtained in July 2012 and updated on 8th March 2013."

7. The explanation in paragraph on lines 3 to 7 of page 7 is confusing. What are the authors conveying here?

Action: The text has been amended to aid clarity:

"(NICE often requests TARs anticipating drug licencing, to inform future guidance, if subsequently the drug is not licensed, there is no need for a review, and NICE will cancel its request consequently there will be no publication)".

8) Please clarify in figure 1 the origin of the "561 projects" specified on line 53 on page six (paragraph immediately following Table 1 in your manuscript). This information is available in Table 2, so at least refer to Table 2 at the appropriate location in the text. Also, why does adding 561 to the 52 shown in Table 1 not add up to your total of 628?

Action: To clarify the data were updated in March 2013, at that time the total published monographs was 583. In figure 1 the sum of projects which have published (172+163+105+142 =582). Text has been amended: "In total 582 projects had published a monograph, 2 studies had no DFR and 13 studies had been discontinued (see Table 2)".

Using the updated data; the 582 (previously 561) published studies plus the 31 (previously 52) DFR received not yet published does not add up to 628 because this does not take account of the discontinued studies (13) or "no DFR received" (2).

The totals are:

Published studies =582

DFR received, not yet published = 31

Discontinued studies = 13

No DFR received = 2

Total =628

9) On page 8, the authors concede that some of the projects in their sample were not part of the program they are trying to describe and evaluate. Why were the projects from "a previous funding stream" included in the study sample? The research question is muddled as a consequence, it

seems.

Action: Apologies, we used incorrect wording here. The projects were part of the HTA programme, but they were commissioned at a time when the processes for commissioning were very different. Relevant sentences have been deleted from the text.

10) a) Table 4 - how is "insufficient quality" determined for the DFRs?

Action: The quality or "insufficient quality" of a DFR is determined by the editorial board for the HTA monograph journal series. The text has been amended in the Methods section:

"When projects publish in the monograph series the draft final reports go through an editorial review process which is conducted between the editors, reviewers and authors. Reports are published in the HTA journal series if they are of a sufficiently high scientific quality as assessed by the referees and editors".

"This judgement was made using the following criteria. If at the end of the editorial process the editorial board of the HTA journal had deemed the report to be of "insufficient quality" to publish, this report was recorded as "will not publish". If a report has been deemed as of sufficient quality to publish this was recorded as "will publish".

b) Why should a "pilot" study not be eligible to have a published article and instead be limited to a monograph?

Action: Text amended to say: "The judgement concerning whether a pilot study can be published as a "stand alone" monograph, or possibly together with another study as a combined monograph, is made by the editorial board".

All authors are encouraged to publish elsewhere in addition to a monograph; and in a situation where a pilot study was not to be published as a monograph the investigators would certainly be encouraged to publish elsewhere.

c) Why were the studies with no available records not excluded from the study sample?

Action: There were electronic records for all studies included in this sample. There was just one study for which there were no paper records. The study fulfilled the inclusion criteria for inclusion in this study. This study was never published, in this case the electronic records did not record why there was no publication and sadly there were no paper records as there were in other cases. Text amended to say: "For one project commissioned in 1993, we were unable to locate the paper files and so were unable to determine the reasons for non-publication".

11) How were the searches to identify any peer reviewed articles conducted? When were they conducted and which databases were searched?

Action: Searches were conducted in July 2012, using authors' names and key words. Databases searched were Medline and Google scholar. Text has been amended in the Methods section: "For projects where no DFR had been received a web search (searching Medline and Google scholar using authors' names and key words); and a search of internal records was conducted to see if the results of the studies had been published elsewhere."

12) This seems to be a study on program evaluation. Did you have to obtain ethics approval?

Action: No ethics approval was required. Text has been added to the title page:

"Study approval

This study did not require study ethics approval; it did not involve patients or clinical data."

13) Can the authors comment upon access to data (for other investigators) from studies sponsored by the HTA program?

Action: The focus of this paper is on the publication of research findings. We have stated in the introduction that all final reports (and the data they contain) are publically available via web.
Reviewer 4 Prof Paul Glasziou, Bond University, Australia

Page 9: Table 3 would be much easier to read as a Figure, e.g. a bar graph (which could and should retain all the raw numbers but show the %s graphically).

Action: Table 3 has been replace by Figure 2, a bar chart showing raw numbers and percentages

Page 10: There were 9 projects of "insufficient quality" which were not published as HTA, but 6 were published elsewhere. How was the "insufficient quality" judged? Was it the reporting or the design? And it is then that 6 were published elsewhere. Can this be explained a little more?

Action: Text in results section has been amended to say:
"Nine of the primary research studies where the DFRs received were of insufficient quality to publish as monographs, 6 of these projects had also published elsewhere in peer reviewed journals. Whether or not a draft final report is deemed to be of "insufficient quality" to publish is a judgement made by the editorial board of the HTA journal series. A monograph is expected to cover all aspects of the study concerned in detail (average word count approx. 50,000 words), in contrast journal articles are much shorter (approx. 3,000 words), less detailed, and covering only certain aspects of the study".

Also please see item 10 from previous reviewer.

Page 10: There is an implication that Pilot studies and feasibility might not be published, but they should still be publicly reported so that others do not waste their time and funds.

Action: Agreed. For HTA studies sometimes reports of pilot studies are combined with reports from full studies. Text has been amended to say: "The judgement concerning whether a pilot study can be published as a "stand alone" monograph, or possibly together with another study as a combined monograph, is made by the editorial board".

Page 11: As I said above, Time to publication would be help in understanding and comparing these results with others.

Action: Indeed it would, there is another project currently underway investigating this issue. Text in the Discussion reads: ". This work does not specifically consider the length of time to publication which is also pertinent¹²; however this question is being addressed in another study currently underway".

Page 11: Element 1 - "Monitoring". There is no mention of the HTA withholding 10% funds until the final results are submitted - could this be added. And other details of the monitoring process would help other funders attempting to emulate this.

Action: Some text added to discussion section which now reads: "Not only are the teams offered the opportunity and the space to publish studies in full, it is part of the contractual arrangement for funding and a proportion of funds are with-held until the report has been received".

Text in Discussion has been amended to say: "A robust monitoring process which assists with timely delivery, budgets, etc.; and which can anticipate which projects might fail and help to correct problems as they arise".

Page 11: The HTA journal. Do you have data on how many studies also published elsewhere? If this was very high, then it might suggest the HTA journal was not the crucial element.

Action: We do not have data on how many studies publish elsewhere, but all authors are encouraged to do so to maximise on dissemination of information. The role of the monograph is to provide authors with the space to give full descriptions of all aspects of the study e.g. full description of interventions etc. which may not be possible in shorter peer reviewed journal articles.

Some text added to discussion section: "Authors are also encouraged to publish in other peer reviewed journals to increase dissemination, however, the shorter length of these articles does not allow for the reporting of the detail presented in the monographs e.g. detailed descriptions of the intervention".

VERSION 2 – REVIEW

REVIEWER	Swaroop Vedula Postdoctoral fellow Johns Hopkins University I have no competing interests.
REVIEW RETURNED	04-Apr-2013

THE STUDY	The studies were conducted under contractual obligations, which makes the findings relevant to a portion of studies similar to what were included in the cohort described in the article.
GENERAL COMMENTS	<ol style="list-style-type: none"> 1. Capitalize first letter in the word "retrospective" under the "Design:" section in the abstract. 2. Capitalize "S" in "Scholar". Also, I believe that Google Scholar is a registered trademark and should be accompanied by the appropriate symbol (R) after the term. 3. Was Medline searched or Pubmed? If Medline was searched then please specify the platform that was used to search it (e.g., Ovid). 4. Spell out numbers less than 10. 5. Discussion section, first paragraph, last sentence - please clarify whether the acronym "NIH" mentioned in this sentence refers to the National Institutes of Health in the United States. 6. The last two paragraphs of the Discussion section seem a bit disparate, making the flow of this section seem choppy. A slight rearrangement of the ideas, with editorial support, may smoothen the flow.

VERSION 2 – AUTHOR RESPONSE

Reviewer: Swaroop Vedula
Postdoctoral fellow, Johns Hopkins University

1. Capitalize first letter in the word "retrospective" under the "Design:" section in the abstract.
Action: letter capitalised.

2. Capitalize "S" in "Scholar". Also, I believe that Google Scholar is a registered trademark and should be accompanied by the appropriate symbol (R) after the term.
Action: "S" in Scholar capitalised and symbol added.

3. Was Medline searched or Pubmed? If Medline was searched then please specify the platform that was used to search it (e.g., Ovid).
Action: text amended to say "searching Medline via Ovid, and Google Scholar®;"

4. Spell out numbers less than 10.

Action: numbers less than 10 spelt out and shown in tracked changes.

5. Discussion section, first paragraph, last sentence - please clarify whether the acronym "NIH" mentioned in this sentence refers to the National Institutes of Health in the United States.

Action: text amended to say "for the National Institutes of Health in the United States, after a median of 51 months"

6. The last two paragraphs of the Discussion section seem a bit disparate, making the flow of this section seem choppy. A slight rearrangement of the ideas, with editorial support, may smoothen the flow.

Action: this section has been amended using tracked changes and the text now reads:

"Interesting areas for future research could be: to compare the findings of this study which has used data from the HTA Programme with data from other funding streams or organisations, both within the UK and internationally. Additionally an investigation of the dissemination profile of HTA projects in terms of journal publications and publically accessible reports would be informative.

Recommendations for future commissioning would include funders making it a requirement for funded projects to publish reports of final findings; and for the funders to facilitate this process."