Commissioned report to the HRA

Modifying IRAS question A51 to reflect publication and dissemination best practices

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Summary

An estimated 85% of all biomedical research is wasted through non-publication, selective publication, and poor reporting of research. Two solutions to these issues are requiring that all research on human participants be disseminated and encouraging the use of recognised reporting guidelines that specify which crucial information is needed for a fully reported study. The Health Research Authority (HRA) is in an excellent position to help researchers understand their obligation to publish study results clearly and accessibly. As part of the HRA's commitment to the transparency and quality of health research, it commissioned the EQUATOR Network to investigate whether and how the HRA can prompt researchers to disseminate their research in an accessible form to better reflect current demands on research dissemination. The focus of this investigation was IRAS question A51, "How do you intend to report and disseminate the results of the study?"

We collected public comments from all relevant stakeholders in the HRA in an online survey, 1 August – 30 September 2016. 654 usable responses were received, with around 90% of respondents agreeing that IRAS A51 should be modified. Around 75% of respondents felt that the HRA should use the ethics approval process to promote the use of reporting guidelines. A modified version of IRAS question A51 was presented for comment, which included sub-questions about planned use of data sharing and reporting guidelines. Around 65% of respondents supported the modified version as presented, with many comments on how it could be improved. Comments focused on offering researchers a wide range of dissemination options beyond traditional publishing and clarifying any minimum required response, such as whether the HRA considers data sharing compulsory.

Preliminary results and a modified version of A51 were discussed at the HRA Transparency Forum on 8 December 2016. There was general support for the modified question, with comments that the question should signpost affected researchers to their legal obligations under the upcoming EU Clinical Trials Regulation, or any related guidance.

We recommend that the HRA modify IRAS question A51, piloting any changes with a representative sample of stakeholders. We propose a new question version based on respondent comments, with an expanded dissemination list, a question on whether data sharing is planned, and a question on whether reporting guidelines may be used. Gold standard responses are unlikely to be helpful, except where study types are affected by statutory requirements. We recommend that the HRA use the IRAS Guidance Notes to make clear that this question concerns intent, that data sharing is not compulsory but does have ethical issues that should be considered in study planning, and that reporting guidelines are not compulsory but are useful. We also recommend that the HRA consider education and training for research ethics committees and researchers on good publication practice.

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Introduction

Every new well-conducted study contributes to our existing medical knowledge. New findings either refute or confirm our current understanding, or add completely new information that will be refuted or confirmed by further research work. This evolution of our body of knowledge is an important dynamic process necessary for advancing patient care.

Withholding information from the knowledge pool by not publishing a study or by only publishing a portion of a study (e.g., only those outcomes with statistically significant results) seriously distorts the available literature and misleads researchers and clinicians. Publishing a study does not guarantee that researchers will not be misled, as many research articles do not contain all of the important information that users of research evidence need to properly evaluate the methods and findings.

The loss of knowledge resulting from non-publication, selective publication, and poor reporting has three critical consequences:

- We repeat studies that have already been done but were never published due to disappointing results. These unnecessary extra studies expose more participants to unnecessary risks
- We determine patient care using the biased selected information available, which may expose patients to less effective or even harmful treatments
- We waste the funds and human effort invested in the lost research

It is estimated that up to 85% of all biomedical research is wasted through such issues (Chalmers and Glasziou, 2009). However, there are two clear actions that can prevent the above problems and strengthen the reliability of the available evidence (Glasziou et al, 2014):

- Require the publication of all studies conducted on human participants
- Strongly encourage the use of recognised reporting guidelines that specify the crucial information needed for a fully reported study when writing up. Guidelines include CONSORT for randomised trials and STROBE for observational studies, and are available at www.equator-network.org.

Major forward-looking funders already recognise the value of reporting guidelines and the EQUATOR portal. For example, the *MRC Policy on Open Research Data from Clinical Trials and Public Health Intervention Studies* (MRC, 2016) stipulates that studies should be published using reporting guidelines and links to the EQUATOR portal. The NIHR Journals Library (NIHR Journals Library, 2016), *Wellcome Open Research* (Welcome Open Research, 2017) and *eLife* (eLife, 2017) all require authors to adhere to reporting guidelines and also link to the EQUATOR portal.

The Health Research Authority (HRA) is in an excellent position to help researchers understand their obligation to publish their study results clearly and accessibly. The EQUATOR Network was commissioned by the HRA to investigate whether and how the HRA can prompt researchers to disseminate their research in an accessible form to better reflect current demands on research dissemination. The focus of this investigation was the Integrated Research Application System (IRAS) question A51: How do you intend to report and disseminate the results of the study? The format of this question as of March 2017 is shown in Figure 1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

Figure 1: IRAS question A51, as of March 2017.

Research ethics committees (RECs) use the answer to IRAS question A51 to assure themselves that a dissemination plan exists and that it is appropriate and proportionate to the study type. However, there is a belief at the HRA that the current question may be insufficient for these goals. There is at present little guidance for both researchers and RECs regarding what can be considered a proportionate and appropriate answer to this question.

The objectives set for the EQUATOR Network by the HRA were as follows:

1. To review, consult on, and propose a new question set to replace IRAS question A51 (How do you intend to report and disseminate the results of the study?) to better reflect current demands for research dissemination
2. To develop a proposal for HRA standards for the issues covered. These HRA standards may suggest a recommended response to IRAS question A51. This recommended response should appear in text above the question, with a request that applicants defend any deviation from the standard.

To meet these objectives, we conducted an informal Call for Comments on whether there was public support for the HRA to modify IRAS question A51 to better promote good current research dissemination practices. Using the public comments gathered, we propose a modified version of question A51 for the HRA to consider.

Methods

Survey

Survey design

The survey text and questions were approved by the HRA, and are shown in Appendix A. The survey was hosted on SurveyMonkey (SurveyMonkey Inc, San Mateo, California, USA, www.surveymonkey.com). The survey front page indicated that "Your responses will be anonymous, no individual respondents will be identified, and the data will only be reported in an aggregated form. You are under no obligation to complete this survey and can end your involvement at any time. We will receive all of the responses that you enter even if you exit the survey early, but you can edit your responses while in the survey." Our contact details were given at the beginning and end of the survey.

The nine questions asked are shown in Table 1. Only general demographics questions were asked: country location and role with the research community. No question was compulsory, so

respondents could answer a subset of questions if they wished. Respondents could use the 'Prev' button to return to previous responses and edit them. Response rates were not tracked.

Table 1: Online survey questions and answer formats

Question	Question text	Answer format
1	Please indicate your role (tick all that apply).	Checkbox of key stakeholders and free text for other
2	Please indicate your location.	Checkbox for UK countries and free text for non-UK
3	From your professional experience, what information do you need about a research study to understand it, assess how good and reliable it is, and use its findings in your practice (tick all that apply).	Checkbox of all documents related to a study, and free text comments
4	Are you familiar with research reporting guidelines, such as CONSORT for reporting randomised trials or STROBE for reporting observational studies, which can be accessed from www.equator-network.org?	Yes/No checkbox
5	Do you believe that using reporting checklists that prompt researchers to report key information in sufficient detail is useful for increasing the completeness and value of research publications?	Yes/No/Unsure/Other checkbox and free text comments
6	Some funders in the UK (e.g., NIHR) require compliance with recognised reporting guidelines. Should the HRA use the ethical approval process as an opportunity to encourage the use of these guidelines?	Yes/No/Unsure/Other checkbox and free text comments
7	The HRA finds it complicated to monitor whether researchers have published their studies. What could the HRA consider doing to ensure research is reported well and is published?	Free text comments
8	Thinking about the current A51 question and the proposed three new questions, do you 1. Agree that A51 needs changing and think that the proposed three questions should be used as presented 2. Agree that A51 needs changing, but with modifications of the proposed three questions or something completely different 3. Disagree that A51 needs changing 4. Not sure	Checkbox options and free text comments
9	Please use this box for any further comments, ideas, suggestions or concerns	Free text comments

Recruitment

We aimed to reach all stakeholders in the research ethics process: REC members, the research community, funders, journal editors and publishers, industry and patients. We used a convenience sample, advertising the survey through:

- EQUATOR and HRA Twitter feeds – daily to weekly tweets
- HRA REC newsletter – appeared twice
- HRA IRAS partners – emailed as deemed appropriate by HRA representatives
- EQUATOR contacts list, including journal editor mailing list – emailed twice
- Advertisement on the Patients Active in Research Thames Valley patient and public involvement recruitment site (https://patientsactiveinresearch.org.uk) – open for the survey duration

All advertising text was approved by the HRA. The email invitation text is shown in Appendix B and a representative Twitter advert is shown in Appendix C.

The survey was open 1 August 2016 – 30 September 2016. There were no restrictions on responses from the same IP address and no other attempts to prevent duplicate responses.

Data analysis

Data cleaning was performed to remove unusable responses and tidy free text responses for demographics. No adjustment for representativeness was done.

The cleaned dataset was uploaded to Nvivo 11 (NVivo qualitative data analysis software; QSR International Pty Ltd. Version 11, 2017). Closed-ended questions were uploaded as case classifiers. Open-ended questions were used for coding theme nodes. 'Country' uploaded as open-ended and coded as case nodes, to allow responses with more than one country listed.

We did not remove duplicate IP addresses.

Thematic analysis (Braun and Clarke, 2006) was conducted in Nvivo 11 on all five open-ended questions. The dataset was read through repeatedly. This showed that the same general ideas were repeated across the open-ended questions, regardless of what the question was actually asking. The same set of theme codes was therefore used across all five questions.

We started by coding themes in the answers to the question "Please explain your answer about the proposed A51 changes (agree, agree with changes, disagree, unsure)". We then applied these theme codes to the full set of answers to the question "Any other comments", adding themes as needed. Finally, we went through each respondent's full answer set, recoding the two questions above and also coding themes within the remaining three questions, "How can the HRA monitor compliance with ethical dissemination?", "Are reporting guidelines useful?" and "Should the HRA encourage the use of reporting guidelines?". Coding continued until no new themes emerged.

Once initial coding was complete, the set of codes were read repeatedly and duplicate codes removed. Codes were then grouped into general themes.

The question "Additional documents to understand a study" was coded separately, using the same structure.

Study reporting was done with guidance from relevant reporting guidelines, such as CHERRIES (Eysenbach, 2004).

Discussions with Transparency Forum

The proposed IRAS question A51 was modified using feedback from the online survey and discussed by the HRA Transparency Forum on 8 December 2016. The absent Transparency Forum members were given the option to send their comments via email.

Results

Proposing a new question

The modified IRAS question A51 tested in Question 8 is shown in Figure 2. A preamble reiterating the importance of research dissemination was added to the question. The question was then split into three:

A51-1 dealt with intended routes for dissemination. A comprehensive list of options was presented, and the option 'none' removed. Ambiguous options like 'other publication' were removed. One 'other' box with compulsory free text was added.

The old dissemination option regarding raw data was removed, and in its place A51-2 created. This sub-question raised the issue of data sharing. Many journals now require data sharing at the point of article submission. However, data sharing has ethical implications, so preliminary plans for sharing should be considered at the research planning stage.

A51-3 promotes the HRA transparency mandate, by steering researchers towards reporting guidelines at the planning stage. Reporting checklists should ideally be consulted when planning a study, so that all crucial study details have been considered before the study begins. This prevents difficulties in using the checklists at the writing stage.

Not publishing the results of your study is unethical and breaches the Declaration of Helsinki.

Please indicate how you are going to make your study findings (i.e., your methods and results) publicly available by ticking all of the following that apply

- Research protocol published in a peer-reviewed scientific journal
- Research protocol freely available online, either published open access or a version deposited in an open-access repository
- Article(s) reporting the study in peer-reviewed scientific journals
- Article(s) freely available online, either published open access or a version deposited in an open-access repository
- Full study report available to funders
- Full study report freely available online
- Submission to regulatory authorities
- Research registry (e.g., in a trial registry)
- Other (please specify)

Do you intend to provide access to your study data? ***The HRA supports data sharing where possible. If you plan to share patient data, please indicate how you will anonymise and aggregate the data, if relevant***

- Yes – please describe your data-sharing plans, including who can access the data and how (free text box):
- No – please explain why your study data are unsuitable for sharing (free text box):

What reporting guidelines do you intend to follow when reporting your study or when depositing samples and data into biobanks and repositories? If you are unsure, please use the EQUATOR Network's database of guidelines (www.equator-network.org) to find the correct reporting guideline for your research study type.

Figure 2: Modified IRAS question A51 tested in Question 8 of the online survey

Survey

The survey was open for two months and gathered 735 responses. Data cleaning was done in a pragmatic manner. We removed 80 responses with only role and/or location, and one other response with only a single answer, for question 3 (which documents do you need to understand a study). We created new 'role' classifications, using the free text comments under the 'Other' response: research governance, educator, researcher (no experience level given), expert REC member non-clinical, lawyer, communications specialist, ethicist, PPI advisor/manager, research nurse, industry, and none. We also tidied the free text comments in the 'countries' designation, converting all into sentence case and standardising how 'USA' was entered (US, USA, and United States were all used)

After data cleaning, we were left with 654 usable responses.

Demographics

Figure 3 shows the spread of roles that survey respondents selected or indicated in free text comments. Around 18% (118/654) respondents indicated that they were involved in RECs in some capacity (four respondents selected two REC categories each).

About two-third of respondents (447/654) were located in the UK, with 385 respondents in England, 31 in Wales, 26 in Scotland, 4 in Northern Ireland, and 1 indicating with free text that they were located in the UK, without giving a more specific location. One respondent did not give their location. The remaining one-third of respondents (206/654) were located across 39 countries,

including, for example, the USA (40/654), Canada (23/654), and Germany (23/654). The full breakdown is given in Table 2.

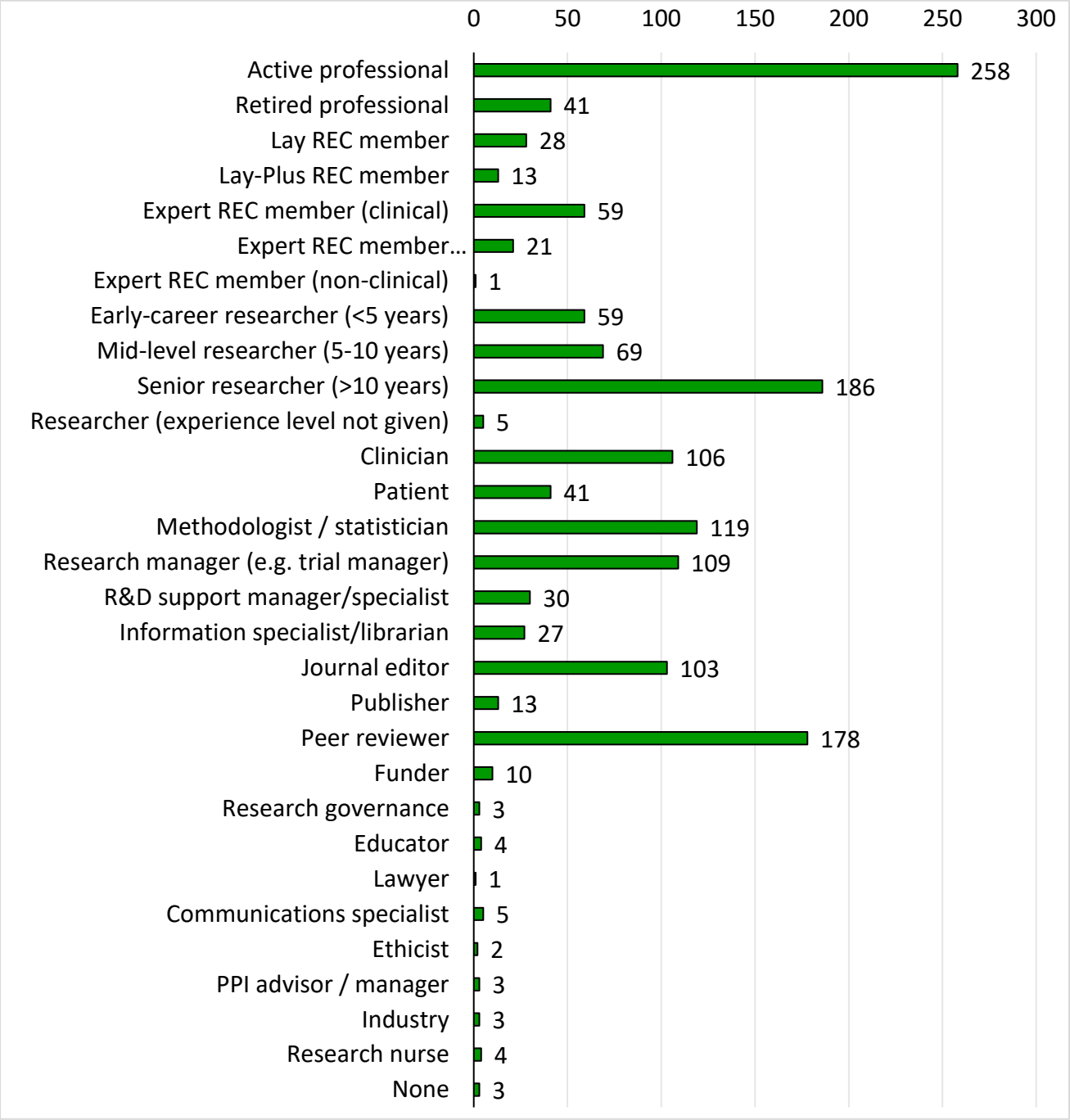

Figure 3: Roles selected by survey respondents (n=654). Multiple responses were allowed.

Table 2: Country mentioned in free text comments to survey question 2. UK numbers are collated from free text comments, as well as those selecting one of the four UK nations from the check boxes. Three respondents used general categories 'Europe' and 'South East Asia'. Numbers do not add up to number of respondents (654), as one respondent listed two countries.

Country	Number of references in free text comments	Percentage of respondents mentioning this country (n=654)
Australia	16	2.4%
Austria	3	0.5%
Brazil	5	0.8%
Canada	23	3.5%
Colombia	2	0.3%
Croatia	4	0.6%
Czech Republic	1	0.2%
Denmark	11	1.7%
Europe	2	0.3%
Finland	1	0.2%
France	8	1.2%
Germany	23	3.5%
Greece	3	0.5%
Iceland	1	0.2%
India	2	0.3%
Indonesia	1	0.2%
Ireland	2	0.3%
Italy	9	1.4%
Japan	1	0.2%
Korea	1	0.2%
Mexico	1	0.2%
Netherlands	10	1.5%
Nigeria	2	0.3%
Norway	3	0.5%
Peru	1	0.2%
Philippines	2	0.3%
Poland	1	0.2%
Romania	5	0.8%
Serbia	1	0.2%
Singapore	2	0.3%
South Africa	1	0.2%
South East Asia	1	0.2%
Spain	8	1.2%
Sri Lanka	2	0.3%
Sweden	1	0.2%
Switzerland	4	0.6%
Thailand	1	0.2%
Turkey	1	0.2%
UK	447	68.3%
Ukraine	1	0.2%
USA	40	6.1%

Venezuela	1	0.2%
None	1	0.2%

Promoting reporting guidelines in the ethical approval process

Question 4 asked whether respondents were familiar with reporting guidelines. Of 651 respondents who answered this question, 508 (78%) said yes and 143 (22%) said no. Of 446 UK respondents who answered this question, 321 (72%) said yes and 125 (28%) said no. Of 117 REC respondents who answered this question, 71 (60.7%) said yes and 46 (39.3%) said no.

Question 5 asked whether reporting guidelines are useful. Of 650 respondents who answered this question, 534 (82.2%) said yes, 13 (2.0%) said no, 57 (8.8%) were unsure, and 46 (7.1%) selected 'Other'. Of 445 UK respondents who answered this question, 371 (83.4%) said yes, 7 (1.6%) said no, 45 (10.1%) said not sure, and 22 (4.9%) said other. Of 117 REC respondents who answered this question, 100 (85.5%) said yes, 3 (2.6%) said no, 10 (8.5%) said not sure, and 4 (3.4%) said other.

Question 6 asked whether the HRA should use the ethical approval process as an opportunity to encourage the use of reporting guidelines. Of 647 respondents who answered this question, 486 (75.1) said yes, 31 (4.8%) said no, 92 (14.2%) were unsure, and 38 (5.9%) selected 'Other'. Of 443 UK respondents who answered this question, 324 (73.1%) said yes, 28 (6.3%) said no, 61 (13.8%) said not sure, and 30 (6.8%) said other. Of 118 REC respondents who answered this question, 92 (78.9%) said yes, 7 (5.9%) said no, 11 (9.3%) said not sure, and 8 (6.8%) said other.

What documents are useful for understanding a study?

Question 3 asked respondents about the information about a study that they need access to so that, in their professional experience, they can understand it, assess how good and reliable it is, and use its findings in their practice. The results are shown in Table 3. Comments reiterated many of the document types and mentioned full sets of data.

Table 3: Information types selected by respondents as being crucial for understanding and assessing a research study.

Information type	Number of responses	Percentage of respondents answering this question (n=651)
Scientific rationale for the study, ideally based on a robust literature review	592	90.9%
Detailed description of the study methods	620	95.2%
Study results (reporting on every prespecified outcome)	605	92.9%
Adverse effects information and how it was collected	516	79.3%
Study funding	431	66.2%
Conflict of interest	493	75.7%
Links to the trial or study registration	350	53.8%
Links to the protocol	463	71.1%
Links to the intervention materials (e.g. manuals, questionnaires)	394	60.5%

Links to the annotated data	187	28.7%
Links to other key study documents (e.g. case report forms)	241	37.0%
Other documents that, in your professional experience, are needed to understand a research study, assess how good and reliable it is, and use its findings in your practice	111	17.1%

Monitoring dissemination and publication

Question 7 asked for ideas for ways the HRA could promote good research reporting and publication, and to monitor whether dissemination had occurred. Any comments made about monitoring across all free-form questions were collated. In general, comments about the need for monitoring were made across all questions, whereas specific suggestions for how to monitor were made only in answer to Question 7.

The general comments regarding monitoring focused on the idea that any changes to IRAS A51 should be made with a purpose and that the HRA should follow up to see whether researchers put their plans into action. Some commentators queried whether monitoring is in fact within the HRA's remit, or whether this is the responsibility of the funder or sponsor.

Respondents suggested that the HRA could monitor dissemination plans by working with funders and sponsors to collect dissemination or by requiring researchers to report any dissemination to the HRA. Some suggested only triggering study end after dissemination has been confirmed, as an incentive. Respondents suggested that the HRA could also collect dissemination information itself, by using the HRA approval number as an identifier in publications or by collecting information from other databases, such as OpenTrials, ResearchFish, and study registries. Some suggested that the HRA set up a dedicated monitoring team.

Some commentators went beyond monitoring and made suggestions regarding how the HRA could enforce researchers reporting back to the HRA on the progress of their plans or enforce the following of dissemination plans. The most common suggestions were to put in place funding penalties, either withholding final payments or affecting future grant funding applications, or to withhold ethical approval of new studies.

Proposed changes to IRAS question A51

Question 8 asked what respondents thought about the proposed modifications to question A51. Of 614 respondents who answered this question, 399 (65.0%) selected "agree that A51 needs changing and think that the proposed three questions should be used as presented", 154 (25.1%) selected "Agree that A51 needs changing, but with modifications of the proposed three questions or something completely different", 19 (3.1%) selected "Disagree that A51 needs changing", and 42 selected "Unsure" (6.8%). Of the 419 UK respondents who answered this question, the breakdown was 268 (64.0%) in agreement, 108 (25.8%) in agreement but with modifications, 14 (6.9%) in disagreement, and 29 (3.3%) unsure. Of the 114 REC respondents who answered this question, the breakdown was 73 (64.0%) in agreement, 28 (24.6%) in agreement but with modifications, 7 (6.1%)

in disagreement, and 6 (5.3%) unsure. In all cases, around 90% of respondents agreed that IRAS question A51 needs changing.

The broad themes raised in comments across the survey about whether IRAS A51 should be changed and the proposed changes were

- General impressions about making a change and how to implement it
- Suggestions for changes in wording
- Issues surrounding data sharing
- Support for encouraging reporting guidelines, but concerns about their use
- Concerns about how specific research types should answer the question
- Concerns based around misconceptions about reporting guidelines, the publication process, and the HRA's remit

The subthemes within theme are presented below.

General impressions about making a change and how to implement it

As can be expected with 90% of respondents agreeing that IRAS question A51 should be changed, there was support for making a change in the comments. The new question set was described as more specific and thorough, and as likely to improve dissemination and transparency, reduce reporting bias, and prompt researchers to plan these aspects of their study early on. The old question set was described as passive and a tick box exercise.

Those opposing the changes described the ethical approval process as already too burdensome. The changes were described as beyond the HRA's remit and the new question set was described as patronising and accusatory. Some felt that the HRA needed to monitor the answers to the existing question better, rather than making changes to the information collected.

There were also suggestions to pilot any changes.

Suggestions for rewording

Suggestions for rewording focused on the introductory paragraph, dissemination routes, and intent. Comments on the introductory paragraph were either strongly in favour or strongly against the mentions of the Declaration of Helsinki and the responsibility to publish.

Respondents suggested adding books, conference outputs, patient and public dissemination, lay summaries, dissemination targeting policy makers, and updated study registry entries to the list of options. There was support for removing the simple 'no dissemination planned' option, although others felt that including this option with a required comment would be helpful for RECs, as full explanations would be gathered. Respondents pointed out that reports to funders and the HRA, which were included in the modified question, cannot always be considered dissemination, as these reports are often confidential.

Respondents felt that RECs should enforce a minimum requirement for this question, focusing on dissemination and/or publishing of the results summary. Many commentators were concerned that the question text make clear that a dissemination plan is indeed only a plan, and that this question was about intent, rather than what would definitely occur.

Issues surrounding data sharing

The proposed sub-question on data sharing drew many comments. Those in favour of asking about data sharing wanted researchers to be clear that data sharing requires informed consent. Commentators suggested prompting researchers to explain how they planned to de-identify data and whether they planned to use aggregated or individual data.

Those against asking about data sharing in IRAS had a range of concerns. Some felt that the research planning stage is too early in the research process to think about data sharing, as data sharing can only be planned when the data has been collected and analysed. Some were against data sharing at all, citing anonymity breaches. Some were concerned that data sharing is not appropriate for all data types and studies, so that if the question were included, an indication of what is appropriate and proportionate was required.

Finally, many commentators were concerned that data sharing as a concept is still very new. They called for clear guidance for researchers on what was expected of them. Some suggested that the field is too new for the HRA to endorse data sharing.

Support for encouraging reporting guidelines, but concerns about their use

The proposed sub-question on reporting guidelines also drew many comments. Those in support of asking about reporting guidelines suggested offering a list of common reporting guidelines to choose from, using the study type collected in the IRAS form to suggest an appropriate reporting guideline, and allowing more than one reporting guideline to be chosen.

Those hesitant or against asking about reporting guidelines here felt that reporting guidelines should not be compulsory and were concerned about study types that do not have a recognised reporting guideline. Some respondents preferred a simple signpost to the EQUATOR Network rather than asking researchers to select a reporting guideline, as this stage of the study was considered too early to plan which reporting guidelines may be used. Some respondents felt that reporting quality is journals' and sponsors' responsibility, not the HRA's responsibility.

Respondents who mentioned the inclusion of biobanks in this question suggested it be removed, as they found it confusing alongside reporting guidelines.

Concerns about how specific research types should answer the question

Commentators were concerned that the modified version of IRAS question A51 did not make it clear that not all dissemination routes were suitable for all study types. Comments were made in particular about qualitative research, student research, and commercially sensitive research

Commentators concerned about qualitative research pointed out that it is difficult to publish protocols for this kind of research. Qualitative research also has challenges when considering data sharing, as the level of detail collected in long interviews, for example, is very difficult to truly anonymise.

Commentators concerned about student research pointed out that it is not always suitable for publishing. Some commentators pointed out that student research is held to a different standard

(proportionate review) to other research, while other commentators questioned whether this was a good thing. Again, student research was connected with difficulties in data sharing.

Commentators who mentioned commercial phase I studies were split, with some insisting that such research should not be compelled to publish and others insisting that even commercial research should disseminate results, at least in part.

Concerns based around misconceptions about reporting guidelines, the publication process, and the HRA's remit

Many of the comments made within the survey indicated common misconception that could be used as a starting point for REC and researcher training.

Respondents indicated that they believed that journals routinely do not publish negative research, unexpected results, and small studies. However, many journals encourage the publishing of this kind of work. Some respondents also showed that they believed that dissemination and publishing are the same thing. This contrasts with the extra dissemination routes suggested by other respondents, which were generally not traditional publishing routes.

Some respondents were concerned that suggesting reporting guidelines would constrain the methods used in research studies. This is a common misconception, that reporting guidelines tell you how to do your research.

Some respondents expressed confusion over what the HRA's remit is.

Modifications to question as a result of survey

The overall positive nature of the comments led us to make small changes to each question, but to keep the three proposed questions.

Proposed A51-1: We added the suggested dissemination routes and made it clear that not every dissemination route would be suitable for every study type. We reinstated a 'none' option, now 'not suitable for public dissemination', with required explanation.

Proposed A51-2: We modified the question preamble to make clear that data sharing has ethical issues and must be covered in informed consent, so needs to be thought about at the research planning stage. We also made clear that HRA does not require data sharing.

Proposed A51-3: We added the most common reporting guidelines as a checkbox selection. We also removed mentions of biosharing.

The modified A51 taken forward to the Transparency Forum is shown in Figure 4.

The Declaration of Helsinki states that "Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports". Whether and how the results of a study are disseminated is an ethical consideration.

As part of your regulatory requirements, you are likely to submit full study reports or research summaries to your funder, sponsor, and/or the HRA. As not all of these documents will be made available to the scientific community and wider society, they are not sufficient for dissemination or publication of your work.

How are you planning to report and disseminate the methods and results of your study to the scientific community and wider society? *Tick all of the following that apply to your study. Not every dissemination route will be proportionate or appropriate for every study*

- Research protocol published in a peer-reviewed scientific journal
- Research protocol made freely available through another online venue
- Article(s) reporting the study in peer-reviewed scientific journals
- Book or book chapter
- Thesis or dissertation
- Full study report (as submitted to funder, for example)
- Study registry entry with updated results summary (e.g., clinicaltrials.gov)
- Conference presentation
- Lay summary for study participants
- Lay summary for the wider public
- News article or press release
- Other (please specify) [FREE TEXT BOX]
- Not suitable for public dissemination (Please explain why) [FREE TEXT BOX]

Some funders and journals now encourage the sharing of deidentified participant data, which can have ethical implications. Do you plan to provide access to your study data to anyone beyond your study team and collaborators?

- Yes – please describe your data-sharing plans, including how you will obtain consent from your participants and how you will anonymise your data [FREE TEXT BOX]
- No – please explain why your study data are unsuitable for sharing [FREE TEXT BOX]

Reporting guidelines help achieve complete reporting of studies by giving a minimum list of information that should be commented on in your study publication. The HRA encourages their use. Which reporting guidelines, if any, do you intend to follow when reporting your study? If you are unsure, please use the EQUATOR Network's database of guidelines (www.equator-network.org) to find the correct reporting guideline for your research study type. *Tick all that apply*

- SPIRIT (protocols for trials)
- PRISMA-P (protocols for systematic reviews)
- CONSORT (randomised controlled trials)
- STROBE (observational studies)
- CARE (case reports)
- TREND (non-randomised trials)
- PRISMA (systematic review of trials)
- MOOSE (systematic review of observational studies)
- SRQR (qualitative research studies)
- CHEERS (economic evaluations)
- SQUIRE (Quality improvement studies)
- Other (please specify)
- None

Figure 4: Modified IRAS question A51 discussed at the HRA Transparency Forum on 8 December 2016.

Discussion with Transparency Forum

The survey results and modified proposed new IRAS question A51 were presented to the HRA Transparency Forum for comment on 8 December 2016. Forum members in general expressed support for the changes to the question. They reiterated the need for gold standards for each kind of research and for clear guidance notes for researchers and RECs. Attention was drawn to new EU guidance on required dissemination routes for clinical trials, due for implementation in 2018. Recommendations were made to use the study type entered into IRAS to remind researchers of their minimum dissemination requirements under the EU Clinical Trials Regulation.

Discussion

The EQUATOR Network undertook to present modifications to IRAS question A51 that would promote the HRA's mandate to support transparent, ethical research. EQUATOR undertook a public call for comments on the existing question and on proposed changes that would explicitly state researchers' obligation to disseminate their work, expand the dissemination routes listed, draw attention to data sharing, and draw attention to reporting guidelines as a tool for transparent reporting. The public call for comments drew 645 usable responses, of which 90% of respondents supported modifying IRAS question A51. Further modifications based on the public call for comments were presented at the HRA Transparency Forum, where they received support.

Most survey respondents knew what reporting guidelines were and considered them to be useful. Question 3 was included as a check, to see whether respondents' answers as to the usefulness of reporting guidelines matched up with the kinds of information they said they needed access to in order to understand and assess a study. Most respondents agreed that information routinely asked for by reporting guidelines, like full outcome reporting, detailed methods, adverse events, and conflicts of interest, is indeed necessary for judging a study. Comments indicated support for drawing attention to reporting guidelines and signposting researchers to the EQUATOR Network. However, respondents were hesitant about the HRA making reporting guidelines compulsory.

Public comments indicated support for drawing attention to data sharing. Some were concerned that the research community has not yet reached a consensus on data sharing, as it has done with trial registration, and that it is premature to include data sharing in IRAS. Others drew attention to the ethical implications of data sharing and how it should be reflected in consent forms. Whether or not data sharing should be encouraged is not the issue; if a researcher plans to data share, then that researcher should consider the ethical implications of data sharing when they plan their study.

Respondents suggested an enhanced list of dissemination routes that went well beyond traditional publication. Some were concerned that the HRA make clear that not all options were suitable for all kinds of research, and that researchers would not be penalised for selecting a subset of options. In particular, respondents were worried that there be options suitable for student research.

Both respondents and the Transparency Forum were concerned that any changes made to the dissemination options list reflect the requirements set by funders and statutory guidance. In particular, those conducting clinical trials should not be given information that conflicts with statutory guidance.

Limitations

As the online survey was run over the UK summer holiday period, potential respondents may have been missed despite the two-month period and multiple reminders. Public comments were only sought using an online survey, which may have skewed the responses. We also did not check the representativeness of the sample reached through the online survey, and received replies from only 118 REC members. However, this project was a first step to gauge whether there is any public support for a change to IRAS question A51. The large total number of responses with coherent themes across the stakeholders reached indicates that there is indeed at least some public support for making a change to the question. If the HRA moves forward with this project, then any agreed-upon wording will need to be tested with a representative sample of HRA stakeholders, using a variety of formats.

It is possible that the routes through which the survey was disseminated would have skewed heavily towards those who already knew about the EQUATOR Network, and therefore had a pre-existing interest in transparency and the use of reporting guidelines. Conversely, if respondents had a limited background knowledge of issues resulting from non-publication and incomplete publication of research, then the background information provided in the survey could have influenced their responses. We assume that international respondents were obtained exclusively through EQUATOR's channels, whereas REC members would have been contacted primarily through HRA channels. Answers to Questions 4, 5, 6, and 8 were similar across all respondents, UK-based respondents, and REC respondents. Again, if the HRA decides to move forward with this project, widespread piloting of a modified IRAS question A51 will be needed.

Recommendations

There is support from all stakeholders for changes to IRAS question A51. Stakeholders support a more detailed list of dissemination options that goes beyond publication. The question should make clear that not all dissemination routes are required for all study types, and examples should be given in guidance notes for both researchers and RECs. In particular, the expanded dissemination option list gives options that are suitable for student research, and guidance notes should explicitly mention what can be considered proportionate and appropriate for this kind of research. RECs should treat the option 'not suitable for public dissemination' with great care.

Stakeholders support signposting to reporting guidelines and drawing attention to data sharing at the research planning stage. However, the question should make clear that these are not compulsory. Again, clear examples should be given in guidance notes for both researchers and RECs.

Any wording change to IRAS A51 should be made with the new EU Clinical Trials Regulation or any similar replacement legislation in mind, and should explicitly signpost affected study types to their statutory requirements.

Final proposed new question

Our final recommendation for wording changes to IRAS question A51 is shown in Figure 5.

The Declaration of Helsinki states that "Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports". Whether and how the results of a study are disseminated is an ethical consideration.

As part of your regulatory requirements, you are likely to submit full study reports or research summaries to your funder, sponsor, and/or the HRA. As not all of these documents will be made available to the scientific community and wider society, they are not sufficient for dissemination or publication of your work.

How are you planning to report and disseminate the methods and results of your study to the scientific community and wider society? *Tick all of the following that apply to your study. Not every dissemination route will be proportionate or appropriate for every study*

- Research protocol published in a peer-reviewed scientific journal
- Research protocol made freely available through another online venue
- Article(s) reporting the study in peer-reviewed scientific journals
- Book or book chapter
- Thesis or dissertation
- Full study report (as submitted to funder, for example)
- Study registry entry with updated results summary (e.g., clinicaltrials.gov)
- Conference presentation
- Lay summary for study participants
- Lay summary for the wider public
- News article or press release
- Other (please specify) [FREE TEXT BOX]
- Not suitable for public dissemination (Please explain why) [FREE TEXT BOX]

Some funders and journals now encourage the sharing of deidentified participant data, which can have ethical implications. Do you plan to provide access to your study data to anyone beyond your study team and collaborators?

- Yes – please describe your data-sharing plans, including how you will obtain consent from your participants and how you will anonymise your data [FREE TEXT BOX]
- No – please explain why your study data are unsuitable for sharing [FREE TEXT BOX]

Reporting guidelines help achieve complete reporting of studies by giving a minimum list of information that should be commented on in your study publication. The HRA encourages their use. Which reporting guidelines, if any, do you intend to follow when reporting your study? If you are unsure, please use the EQUATOR Network's database of guidelines (www.equator-network.org) to find the correct reporting guideline for your research study type. *Tick all that apply*

- SPIRIT (protocols for trials
- PRISMA-P (protocols for systematic reviews)
- CONSORT (randomised controlled trials)
- STROBE (observational studies)
- CARE (case reports)
- TREND (non-randomised trials)
- PRISMA (systematic review of trials)
- MOOSE (systematic review of observational studies)
- SRQR (qualitative research studies)
- CHEERS (economic evaluations
- SQUIRE (Quality improvement studies)
- Other (please specify)
- None

Figure 5: Final modifications to IRAS question A51 proposed by the EQUATOR Network to the HRA on the basis of public comments and Transparency Forum feedback.

Gold standard responses

Part of this project was to explore the possibility of creating a set of minimum responses or gold standard responses that could be used to prefill IRAS question A51. However, we suggest that gold standard or minimum responses for questions A51-1 and A51-2 are not possible for most study types.

Gold standards for A51-1

The purpose of IRAS question A51 is to provide information for RECs so they can assure themselves that there is a robust dissemination plan in place. That plan should indicate that researchers have considered all forms of dissemination, not just traditional publication, so that the findings are contributed meaningfully to the scientific, clinical and patient communities and the public, as needed. The plan should be proportionate and appropriate to the kind of research study and to whether the research will be undertaken by a student, for example. The plan should also follow any legal requirements (e.g., in clinical trials), funder requirements (e.g., compliance with reporting guidelines and data sharing plans), and the general requirements of good publication practice, such as the international guidelines for authors developed at the second World Conference on Research Integrity (Wager and Kleinert, 2011) and the ICMJE guidelines (ICMJE, 2016).

There are 13 broad study types to choose from in IRAS question A7, with multiple sub-classifications within those types possible. Student research can refer to a simple 3-month clinical rotation project or to a four-year doctoral research project. It is not practical to develop a study-type specific gold standard response to question A51-1 for each possible category of research that is both proportionate and appropriate to all studies within that category. Any minimum response that could apply across all studies within a category would be so minimal as to be unhelpful.

Instead, we propose that the HRA use the IRAS guidance notes and other education channels to provide illustrative examples of what it expects and to encourage researchers to think beyond traditional publication when writing their dissemination plan. We also propose that the HRA provide RECs with training on how research can be disseminated and under what circumstances ‘no public dissemination’ can be accepted.

The clear exception is studies that fall under the EU Clinical Trials Directive and Regulation or similar legal directive. For these studies, we suggest that the HRA either use the study type to generate a minimum response or a pop-up box reminding researchers that of the relevant legal requirements for results disclosure and dissemination that must be followed.

Gold standards for A51-2

There can be no appropriate minimum or gold standard answer for question A51-2, as the HRA has no official policy on data sharing. Instead, guidance notes should be used to remind researchers that if they choose to data share, then they must consider ethical issues such as informed consent and anonymity.

Gold standards for A51-3

We recommend that the HRA explore the possibility of prefilling answers or presenting a pop-up box with suggested minimum answers for proposed question A51-3, on choosing a reporting guideline, as shown in Table 4. The text of the question should make clear that these guidelines are not compulsory.

Table 4: Suggested prefilled answers to proposed question A51-3

Study type selected in IRAS question A7	Minimum response to IRAS question A51-3
Case series / case note review	CARE
Case control	STROBE
Cohort observation	STROBE
Controlled trial without randomisation	TREND
Cross-sectional study	STROBE
Database analysis	STROBE
Epidemiology	STROBE
Feasibility/pilot study	CONSORT
Laboratory study	None
Metanalysis	PRISMA
Qualitative research	SRQR
Questionnaire, interview or observational study	STROBE
Randomised controlled trial	CONSORT

Proposed notes for the IRAS Guidance

We recommend that the HRA update the IRAS Guidance Notes for researchers as follows:

1. Make clear that not all dissemination routes are necessary for all study types. Instead, proportionate and appropriate routes should be selected.
2. Include examples of proportionate and appropriate answers for different study types, in particular commercial research, student research and qualitative research, as these were the kinds of work that survey respondents expressed the most concern about.
3. Make clear that data sharing is not compulsory. Instead, as data sharing has ethical implications, researchers should at minimum be thinking about whether they might choose to share data and if so, whether their informed consent process is sufficient.
4. Make clear that the use of reporting guidelines is not compulsory.

Proposed notes for REC members

We recommend that the HRA provide guidance notes for REC members reiterating all points that researchers require clarity on:

1. Not all dissemination routes are necessary for all study types. Instead, proportionate and appropriate routes should be selected.
2. Include examples of proportionate and appropriate answers for different study types, in particular commercial research, student research and qualitative research.

3. Data sharing is not compulsory. However, as data sharing has ethical implications, researchers should at minimum be thinking about whether they might choose to share data and if so, whether their informed consent process is sufficient.
4. The use of reporting guidelines is not compulsory.

Proposed areas for training and education

We recommend that training be developed for researchers and REC members to support the changes to IRAS question A51 and the IRAS Guidance Notes. This training should cover the purpose of IRAS question A51, the purpose of a research dissemination plan, dissemination possibilities, and the consequences of not disseminating work. It should also cover the changing research publication landscape, publication requirements, and the consequences of poor publication practice for further use of research.

This call for comments indicated misconceptions about the publication process and the HRA's role that are common across all stakeholders. We recommend that the HRA consider either signposting towards existing training or commissioning its own training on good publication practice, to address misconceptions regarding dissemination of negative results and regarding how reporting guidelines can be used. Research publication and dissemination is a crucial element of any research study and not doing it properly or at all has major ethical implications for the study's participants and for society as a whole. We also recommend that the HRA consider a publicity campaign making clear what its remit is, as many stakeholders expressed confusion.

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Appendix A: Survey text

Welcome!

We are part of the EQUATOR Network and are conducting a project that aims to increase the transparency and completeness of future published research. We would like to invite you to help us in this effort by completing this short online survey.

This project has been commissioned by the UK's Health Research Authority (HRA), who has tasked the EQUATOR Network with carrying out a call for comments to inform future HRA policies on research reporting and dissemination.

The survey focuses on how to modify the current question A51 on the IRAS ethics application [link to www.myresearchproject.org], 'How do you intend to report and disseminate the results of the study', to ensure researchers understand the full extent of their commitment to responsibly share their research findings.

We estimate that the survey will take about 10 minutes to complete. Your responses will be anonymous, no individual respondents will be identified, and the data will only be reported in an aggregated form. You are under no obligation to complete this survey and can end your involvement at any time. We will receive all of the responses that you enter even if you exit the survey early, but you can edit your responses while in the survey.

If you have any queries, please email us at iveta.simera@csm.ox.ac.uk or jennifer.de-beyer@csm.ox.ac.uk.

Thank you very much in advance for your consideration and your time.

With kind regards,
Dr Iveta Simera, Dr Jennifer de Beyer, and Prof Doug Altman

UK EQUATOR Centre, Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

The **EQUATOR Network** [link to www.equator-network.org] is an international programme established in 2006 and hosted by the University of Oxford. It focuses on increasing the completeness, reliability, and value of health research publications. We provide free online resources that help to achieve this aim, including reporting guidelines that guide researchers when writing up their studies.

The **Health Research Authority** [link to www.hra.nhs.uk] was established in December 2011 to protect and promote the interests of patients and the public in health research, and to streamline the regulation of research. Many members of the public want the opportunity to participate in research. We make sure that health research involving them is ethically reviewed and approved, that people are provided with the information they need to help them decide whether they wish to take part, and that their opportunity to do so is maximised by simplifying the processes by which high quality research is assessed. In doing this, we will help to build both public confidence and participation in health research, and so improve the nation's health.

The **Integrated Research Application System (IRAS)** [link to www.myresearchproject.org] is a single system for applying for permissions and approvals for health and social care / community care research in the UK. It helps researchers to meet regulatory and governance requirements. IRAS captures the information needed for relevant approval from a number of UK review bodies, including many ethics committee bodies. It is maintained by the HRA.

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Question 1

Please indicate your role (tick all that apply):

- Active professional
- Retired professional
- Lay REC member
- Lay-Plus REC member
- Expert REC member (clinical)
- Expert REC member (methodologist – statistician)
- Early-career researcher (up to 5 years of research experience)
- Mid-level researcher (with 5-10 years of research experience)
- Senior researcher (with more than Y years of research experience)
- Clinician
- Patient
- Methodologist
- Research manager (e.g. trial manager, study co-ordinator, etc.)
- R & D support manager / specialist
- Information specialist / librarian
- Journal editor
- Publisher
- Peer reviewer
- Funder
- Other - please describe:

Question 2

Please indicate your location:

UK – England

UK – Wales

UK – Scotland

UK – Northern Ireland

Other – please indicate country:

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Every new well-conducted study contributes to our existing medical knowledge. Withholding information from this knowledge pool by not publishing a study or by only publishing a piece of a study (e.g., only those outcomes with statistically significant results) seriously distorts the available literature and misleads researchers and clinicians. Even publishing is not enough, as many published research articles do not contain all of the important information that users of research evidence need to properly evaluate them.

The loss of knowledge resulting from non-publication, selective publication, and poor reporting has three critical consequences:
1. We repeat studies that have already been done but were never published due to their disappointing results. These unnecessary extra studies expose further participants to unnecessary risks
2. We determine patient care using the biased selected information available, which may expose patients to less effective or even harmful treatments
3. We waste the funds and human effort invested in the lost research

There are two clear actions that can prevent the above problems and strengthen the reliability of the available evidence:
1. Require the publication of all studies conducted on human participants
2. Strongly encourage the use of recognised reporting guidelines that specify the crucial information needed for a fully reported study when writing up. Guidelines include CONSORT for randomised trials and STROBE for observational studies, and are available from www.equator-network.org.

Thinking about this information, please answer the following 7 questions.

Question 3

From your professional experience, what information do you need about a research study to understand it, assess how good and reliable it is, and use its findings in your practice (tick all that apply):

- Scientific rationale for the study, ideally based on a robust literature review
- Detailed description of the study methods
- Study results (reporting on every prespecified outcome)
- Adverse effects information and how it was collected
- Study funding
- Conflict of interest
- Links to:
    - Trial (study) registration
    - Protocol
    - Intervention materials (e.g. manuals, questionnaires)
    - Annotated data
    - Other key study documents (e.g. case report forms)
- Other – please specify:

Question 4

Are you familiar with research reporting guidelines, such as CONSORT for reporting randomised trials or STROBE for reporting observational studies, which can be accessed from www.equator-network.org?

- Yes
- No

Question 5

Do you believe that using reporting checklists that prompt researchers to report key information in sufficient detail is useful for increasing the completeness and value of research publications?

- Yes
- No
- Not sure
- Other – please specify

Question 6

Some funders in the UK (e.g., NIHR) require compliance with recognised reporting guidelines. Should the HRA use the ethical approval process as an opportunity to encourage the use of these guidelines?

- Yes
- No
- Not sure
- Other – please specify

Question 7

The HRA finds it complicated to monitor whether researchers have published their studies. What could the HRA consider doing to ensure research is reported well and is published? (free text box)

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Question 8

The **Integrated Research Application System (IRAS)** [link to www.myresearchproject.org] is a single system for applying for permissions and approvals for health and social care / community care research in the UK. It helps researchers to meet regulatory and governance requirements. IRAS captures the information needed for relevant approval from a number of UK review bodies, including many ethics committee bodies. It is maintained by the HRA.

The current IRAS A51 question does not sufficiently reflect the current demands on research reporting and dissemination. It reads:

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- Peer reviewed scientific journals
- Internal report
- Conference presentation
- Publication on website
- Other publication
- Submission to regulatory authorities
- Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- No plans to report or disseminate the results
- Other (please specify)

We propose replacing question A51 with the following three questions, to gather more meaningful information:

Not publishing the results of your study is unethical and breaches the Declaration of Helsinki.

Please indicate how you are going to make your study findings (i.e., your methods and results) publicly available by ticking all of the following that apply

- Research protocol published in a peer-reviewed scientific journal
- Research protocol freely available online, either published open access or a version deposited in an open-access repository
- Article(s) reporting the study in peer-reviewed scientific journals
- Article(s) freely available online, either published open access or a version deposited in an open-access repository
- Full study report available to funders
- Full study report freely available online
- Submission to regulatory authorities
- Research registry (e.g., in a trial registry)
- Other (please specify)

Do you intend to provide access to your study data? ***The HRA supports data sharing where possible. If you plan to share patient data, please indicate how you will anonymise and aggregate the data, if relevant***

- Yes – please describe your data-sharing plans, including who can access the data and how (free text box):
- No – please explain why your study data are unsuitable for sharing (free text box):

What reporting guidelines do you intend to follow when reporting your study or when depositing samples and data into biobanks and repositories? If you are unsure, please use the EQUATOR Network's database of guidelines (www.equator-network.org) to find the correct reporting guideline for your research study type.

Thinking about the current A51 question and the proposed three new questions, do you:

- Agree that A51 needs changing and think that the proposed three questions should be used as presented
- Agree that A51 needs changing, but with modifications of the proposed three questions or something completely different (please specify below)
- Disagree that A51 needs changing
- Not sure

Please use the box below to elaborate on your answer. In particular, please tell us how you would like to see the proposed questions modified, if relevant, and why you do or do not agree that A51 needs changing.

Question 9

Please use this box for any further comments, ideas, suggestions or concerns (free text box)

[Next page button]

Thank you very much for your help!

To edit any responses, please press the 'Prev' button. Once you are happy with your responses, exit the survey by pressing the 'Done' button. You will no longer be able to edit your responses after you exit the survey.

This survey will close on 30 September 2016.

If you have any queries, please email us at iveta.simera@csm.ox.ac.uk or jennifer.de-beyer@csm.ox.ac.uk.

[Survey end]

Appendix B: Email invitation sent by the EQUATOR Network

We are part of the EQUATOR Network and are conducting a project that aims to increase the transparency and completeness of future published research. We would like to invite you to help us in this effort by completing a short online survey and passing it on to any relevant contacts: https://www.surveymonkey.co.uk/r/HRA_IRAS_A51

This project has been commissioned by the UK's Health Research Authority (HRA), who has tasked the EQUATOR Network with carrying out a call for comments to inform future HRA policies on research reporting and dissemination.

The survey focuses on how to modify the current question A51 on the IRAS ethics application, 'How do you intend to report and disseminate the results of the study', to ensure researchers understand the full extent of their commitment to responsibly share their research findings. We are particularly interested in the views of the UK-based medical research community, including but not limited to researchers, clinicians, patients, journal editors, and funders.

We estimate that the survey will take about 10 minutes to complete. Your responses will be anonymous, no individual respondents will be identified, and the data will only be reported in an aggregated form. You are under no obligation to complete this survey and can end your involvement at any time. We will receive all of the responses that you enter even if you exit the survey early, but you can edit your responses while in the survey.

If you have any queries, please email us at iveta.simera@csm.ox.ac.uk or jennifer.de-beyer@csm.ox.ac.uk.

Thank you very much in advance for your consideration and your time.

With kind regards,
Dr Iveta Simera, Dr Jennifer de Beyer, and Prof Doug Altman

UK EQUATOR Centre, Centre for Statistics in Medicine, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS), University of Oxford

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Appendix C: Representative Twitter advert for the online survey