HSC Public Health Agency
Research and Development

NHS SCOTLAND
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Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Make it public. Transparency and openness in health and social care research

MakeItPublic

The need for a new strategy

Why transparency is important?

The UK has a thriving health and social care research environment. More and more of us are taking part in research studies, and donations to medical research charities are on the rise. This research translates into better care for patients, as well as the wider economy.

Scientific and medical publishing has become more accessible over recent years and new initiatives are driving towards research findings being ever more freely available. However, even where a research publication is not hidden behind a paywall, it is not necessarily written in a way that patients and the public can understand. The people who take part in research studies should have an opportunity to know about the findings, to value the contribution they have made.

Transparency about what research is going on, and what its findings are, is important for patients and the public. It builds trust and accountability. It's also essential for professionals. It avoids duplication of effort and enables findings to be used to develop new and better treatments for patients and service users. It also helps improve the quality of research.

When research is carried out openly and transparently, everyone benefits:

- patients and the public can see what research is taking place and access clear information about the results
- patients, service users and carers know about research that is relevant to them, giving them the opportunity to join studies
- health professionals, commissioners, researchers, policy makers and funders can use research findings to make informed decisions.

What role does the Health Research Authority (HRA) play?

There are many different people and organisations involved in research: clinicians and scientists carrying out research; patients, services users and carers helping to design and then taking part in research projects; funding bodies such as the National Institute for Health Research (NIHR) and the many medical research charities; pharmaceutical and technology companies; research registries; regulators like the HRA and Medicines and Healthcare products Regulatory Agency (MHRA); staff in universities and NHS organisations and clinical research organisations managing and co-ordinating research projects; and all those involved in disseminating and publishing research findings. These people and organisations make up a huge national effort to make the UK a great place to do and be involved in research.

Whilst we all have a part to play in making sure that research takes place in an open and accountable way, it makes sense that the HRA is the lead organisation for transparency. That's because we review, in partnership with the devolved administrations, all health and social care research studies involving people, their tissue and their personal data - around 5000 studies each year – before they begin. We also set national policy for the conduct of research, laid out in the UK Policy Framework for Health and Social Care Research.

Why do we need a strategy?

The UK Policy Framework describes how the different people and organisations involved in research are responsible for making it transparent. Other legislation describes the requirements for particular types of research, such as the EU Clinical Trials Directive, regulating the safety and effectiveness of medicines.

However, whilst transparency has improved over recent years, particularly in commercial pharmaceutical research, we know that practice doesn't match the requirements and expectations. This is particularly so in non-commercial research, sponsored by universities and NHS organisations. The House of Commons Science and Technology Committee, during its 2017/18 inquiry into research integrity, focused on this issue of lower rates of reporting research results amongst non-commercial research. In its report, published in October 2018, the committee called on universities and NHS organisations to improve their performance.

The committee also called on us, the HRA, to play a more active role in making this change happen. It set us a challenge to move away from encouraging best practice and instead to drive improvements. That's what the strategy is all about. We have brought together a group of experts from different aspects of the research endeavour – the Research Transparency Strategy Group - to help us develop plans and proposals for consultation.

About the consultation

Rather than publish a draft strategy and then seek comments on that draft, we want the public and research professionals to have more influence over the development of the final strategy. We have worked with the Research Transparency Strategy Group to develop the overall vision and what we see as HRA's mission in delivering that vision, as well as a series of commitments. We'd like views about how some of those commitments will work in practice and what are the right measures to bring about lasting change.

To gather views, we're running an online survey and holding a series of open workshops across the UK. We're also seeking views from patient groups and Research Ethics Committees and the approvals staff who support them.

What we will do after the consultation

Once the consultation has closed, we will review the feedback we have received and incorporate it into the final strategy, which we expect to publish later in 2019. We will also publish a plan for implementing the strategy, working in partnership with key organisations to maximise its effectiveness.

Our vision for research transparency

Our vision is that:

Trusted information about health and social care research studies is publicly available for the benefit of all

Why is this important?

Research in the UK should be visible to all so that:

- patients and the public can see what research is taking place and access clear information about the findings
- patients, service users and carers can join studies
- health professionals, commissioners, researchers, policy makers and funders can use research findings to make informed decisions.

This will enhance public trust in research evidence and enhance public accountability.

The HRA's research transparency mission

As the body overseeing health and social care research on behalf of the UK, our research transparency mission is to champion openness in health and social care research in the UK. We will achieve this by working in partnership across the research system to set the national ambition and drive improvements.

To achieve the mission, HRA will:

- make transparency easy
- make compliance clear
- make information public.

Whilst the HRA is the lead organisation on research transparency, many players across the health system also have an important part to play. We will work together to make sure that we achieve our common vision.

Make transparency easy by:

- Setting policy which is effective and achievable
- Being clear about what we expect of sponsors and researchers, and what they can expect of us
- Supporting good practice through guidance, learning and clear communication
- Enabling a high quality, interoperable research approvals system.

Make compliance clear by:

- Monitoring sponsors' and researchers' transparency performance
- Giving sponsors and researchers feedback on their transparency performance
- Sharing best practice and celebrating improvement
- Flagging up individual studies where transparency information is overdue
- Sharing performance data with funders and others
- Setting our own performance targets and reporting on progress.

Make information public by:

- Maintaining an easily accessible public record of health and social care research in the UK, providing visibility about individual studies from the time they start to publication of full results
- Sharing data between the HRA and funders, other regulators and registries to enable good public information
- Promoting the use of plain language for lay audiences.

What the strategy covers

Types of research

This strategy covers health and social care research taking place in the UK which involves people, their tissue or their personal data. Information about research studies of this kind should be made public.

The initial focus of this strategy is on clinical trials. These are research studies that test the safety and effectiveness of patient interventions such as medicines, medical devices, surgical techniques, public health measures and behavioural therapies (for more detail, see our transparency information). We will consider other types of research, such as observational studies and questionnaires, at a later stage.

Types of transparency

Research transparency refers to:

- registration (making it public that a study has started)
- reporting results (making it public what the study has found)
- feeding back to participants (informing those who took part what the study has found), and
- sharing study data and tissue (enabling further research).

All of these types of transparency are important. However, the initial focus of this strategy is on registration, reporting results and feeding back to participants. We believe that these are the priority areas for the HRA. Others in the research system are best placed to continue to enable appropriate sharing of study data and tissue.

The different players involved in research

Everyone involved in research, from funding bodies to publishers, has a part to play in promoting transparency and openness in health and social care research. However, this strategy focusses primarily on researchers and research sponsors.

Research sponsors are organisations which take on overall responsibility for the research project. This includes ensuring appropriate arrangements are made for registration, reporting results and feeding back the study findings to participants. In commercially-funded research, the sponsor is the funder. In non-commercial research (government or charity funded), the sponsor is normally the university or NHS organisation which employs the chief investigator.

Researchers, in particular the chief investigator, are responsible for the overall conduct of a research project. This includes adhering to the arrangements for registration, reporting results and feeding back to participants agreed with the sponsor.

For more information, see the UK Policy Framework for Health and Social Care Research.

Our plans and proposals

This consultation describes the HRA's plans for realising our research transparency mission. We are keen to hear your views about them, so that our final strategy is bold but feasible. Our plans and proposals fall into three categories:

Changes we will make

These are changes that we have already decided to make. We have either started the work or will start soon. In the survey, we ask you to help us to prioritise these changes and make any suggestions for additional activities.

Changes we plan to make

These are areas where we plan to make changes but are seeking views about how to do that. We present a number of different approaches and ask for your views. This will help us to get the strategy right.

Changes we could make

These are further changes we could make if individual research sponsors do not fulfil their transparency responsibilities. We'd like to hear your views about them.

Changes we will make

Supporting good practice and making compliance easier

We have already decided to make a number of changes to support good practice and make compliance easier. We plan to:

- be clearer about what we expect of sponsors and researchers at the different stages of the process
- develop new learning packages to support them
- share best practice and celebrate improvement
- make it clear what information from applicants we will make public and what we will share with others
- introduce automated reminders for researchers and sponsors to submit transparency data and to view the status of their studies
- give sponsors and researchers feedback on their transparency performance.

In the survey, we ask you to help us prioritise these changes and make any suggestions for additional activities.

Making transparency performance clear

We want to make it clear when researchers and sponsors are not making their research public. To do that, we plan to:

- flag up individual studies where transparency information is overdue
- share transparency performance data with funders, other regulators and registries.

In the survey, we ask you for feedback about these changes and any suggestions for additional activities.

Sharing the results of research studies with the people who took part

We want to make sure that the people who take part in a study can access the research findings in a format they can understand. This respects participants and acknowledges their contribution.

To ensure better feedback to participants, we have already decided to:

- change the question we ask applicants from whether they will share study results with participants to how and when they will share them (where appropriate)
- ask sponsors to submit a lay summary of the study results to the HRA (no longer than 12 months after the end of the study), which we will then publish.

In the survey, we ask you to make any suggestions for additional activities.

Changes we plan to make

Making sure all clinical trials are registered

Information about each clinical trial should be made public before the first patient is recruited, unless the sponsor has permission to delay this to a later stage. This is called registration. Clinical trials of medicines are automatically registered on the EU Clinical Trials Register. However, despite it being a condition of approval, around 30% of clinical trials of medical devices, surgery, public health and behavioural interventions are not registered (BMJ Open). We want to fix this.

We expect sponsors to register their study before recruitment begins (unless they request a deferral), which can happen a few months after they seek approval. We do not ask them to give us the details when they do register. For the majority (around 90%) of sponsors we know that reminding them to register is effective.

In our survey, we seek views about the most reasonable and appropriate ways that we could ensure registration of all clinical trials:

- Researchers must register their study before seeking approval. The advantage of this would be that 100% of studies are registered (except those with a deferral). However, the disadvantage would be that those studies which are not approved would have been registered.
- The HRA supplies data about clinical trials directly to a registry. The advantage of this would be that 100% of studies are registered (except those with a deferral) and the sponsor has less to do. The disadvantage is the cost of building the systems to send the data to a registry.
- The HRA becomes a registry itself. The advantage of this would be that there is no need to build the systems to send the data to a registry. The disadvantage would be that it may duplicate the work of existing registries.

Monitoring sponsors' and researchers' transparency performance in clinical trials

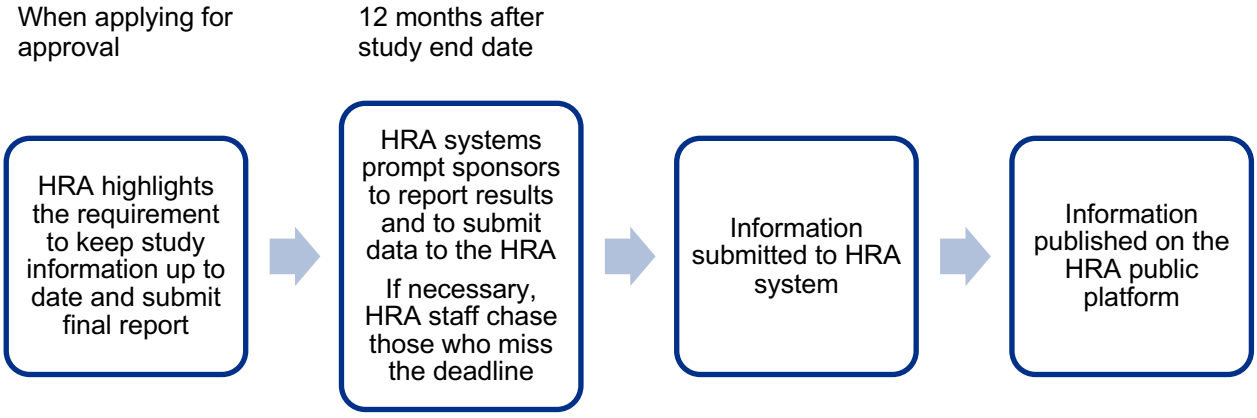
It is important that the results of individual clinical trials are shared publicly. Publishing results in a peer-reviewed journal isn't always achievable or accessible to the public. As a minimum, the record in the registry should be kept updated as the study progresses, including adding a summary of the results.

Whilst it is a legal requirement for clinical trials of medicines, around 25% of UK sponsors do not report results on time (data from EU Trials Tracker). For other types of clinical trials, where there is no legal requirement, the reporting rate is likely to be lower. We plan to change our processes for all clinical trials to address this challenge.

Currently, applicants seeking approval from the HRA for their research are asked how they will disseminate the results of the study, including to the people who took part in it. On approval, they are told that they must submit a final report within 12 months of the end of the study. However, there is no defined dataset for this and current resources don't allow us to chase overdue reports.

We plan to make it clearer to applicants at the time of study approval that they should send us a final report 12 months after the study has ended. We will also take a more proactive approach to prompt sponsors to keep their study information up to date and to submit final reports. We will publish information we receive on the public platform or provide a link to information held in a registry or publication. Some of this activity will require additional funding.

The process would look like this:



In the survey, we ask to what extent these steps will improve the reporting of results from clinical trials. We also ask for suggestions about what else we could do.

Changes we could make

We believe that the plans and proposals in this strategy will bring about significant improvements in research transparency. However, we have developed some possible further steps we could take for dealing with individual sponsors who do not fulfil their research transparency responsibilities.

We are not seeking views about detailed measures at this stage, as we are keen to hear your views about the approaches we could take. If we decide to pursue specific measures based on the feedback we receive, we will formally consult on them.

Taking actions under existing legislation

If a sponsor fails to fulfil their transparency responsibilities, we could:

- publish an annual ‘transparency league table’ highlighting individual studies which have information that is overdue
- take into consideration the extent to which they have fulfilled their transparency responsibilities in relation to their previous studies, when reviewing new studies for approval.

Action that would need a change in legislation

- Fining sponsors with very poor transparency compliance rates

In deciding whether to take these actions, we need to consider not only what could be effective, but also what is reasonable. We would also only take action once sponsors had had a reasonable opportunity to comply or to make a case for why they were unable to comply.

In the survey, we ask to what extent these actions would be appropriate.

Things that might make it difficult to be transparent

Researchers and sponsors have told us about things that make it difficult to comply with transparency requirements. Some of them are wider cultural or institutional factors and others are practical hurdles. Here are some examples:

- Limitations in the EU register make it hard to report results about certain types of clinical trials of new medicines
- Delays in the system for updating records on the EU register mean that results still appear to be outstanding when they are not
- Difficulties in reporting the results of trials because trial staff have left the sponsor organisation
- Lack of resources and clarity about responsibilities in sponsor organisations to adequately monitor and fulfil transparency requirements
- Lack of clarity about the transparency requirements for different types of studies
- Institutional pressures to publish in a peer-reviewed journal and apply for further research funding, rather than fulfilling transparency responsibilities on existing studies.

We are not saying that these reported difficulties are acceptable reasons for failing to fulfil transparency responsibilities. However, we want to understand the difficulties so that we can help to address them where possible – and we are already working on that in some areas. We also want to make sure the changes we make are feasible for sponsors and researchers.

In the survey, we ask for views about these difficulties and for suggestions about what else makes it difficult to be transparent. We also ask for feedback about what could make it easier.

How can you respond?

The strategy is not final. We want to hear your views about our different options for improving transparency performance across the research system. The consultation is open between 17 June and 6 September 2019.

Respond to our survey

Give us your views at www.hra.nhs.uk/makeitpublic

Attend one of our consultation workshops

London: Tuesday 16 July

Manchester: Thursday 25 July

Cardiff: Wednesday 31 July

Belfast: TBC

Edinburgh: TBC

For more information, and ticket booking, visit www.hra.nhs.uk/makeitpublic

After the consultation has closed, we will finalise the strategy, taking into account the feedback we have received, and publish a plan for implementing it.

Who's behind the strategy?

This strategy has been developed by the Research Transparency Strategy Group, who have worked with HRA staff to develop ideas and proposals for consultation. The Group is chaired by Professor Andrew George, non-executive Board member of the Health Research Authority. The members of the group are:

Marise Bucukoglu, Head of Research Governance, University of Edinburgh

Professor David Edwards, Professor of Paediatrics and Neonatal Medicine, Kings College London

Dr Cham Herath, Director of Healthcare and Medical Affairs UK, AstraZeneca

Dr Simon Kolstoe, University of Portsmouth and research ethics committee chair

Sile Lane, Head of Campaigns, AllTrials

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Dr Marina Parry, Senior Research Associate at UCL Cancer Institute

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Members of HRA staff working with the Group are:

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