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Think Ethics Public Dialogue Findings Report

NHS
Health Research Authority

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1 Executive Summary

Background

The response to the COVID-19 pandemic in 2020 and 2021 led to research ethics review for treatments and vaccines taking place in record time without cutting corners. In the wake of this experience, the Health Research Authority (HRA) set up Think Ethics to explore what elements of ethics review in the pandemic could be kept and built on. The aim of Think Ethics is to make ethics review of health and care research more innovative, efficient and trusted.

Independent research ethics review ensures that the rights and wellbeing of people taking part are at the heart of all research. It aims are to reassure the public that health and social care research is designed and carried out in a way which responds to their needs, enables them to make informed choices about whether to take
part and ensures they are treated fairly.

The HRA commissioned Hopkins Van Mil to design and deliver a rapid public dialogue to inform the Think Ethics programme. The key questions discussed were:

- What are the most important questions to ask to ensure that research is ethical?
- What is the right process for ethical review?
- Who should be involved in the ethics review process?

Methodology

Forty-six public participants from a wide UK demographic took part in the public dialogue over two weeks in January 2022. The samples for ethnic minority and lower socio-economic groups were boosted to ensure their perspectives were heard. A small number of participants were recruited who had experience of healthcare research.

The dialogue took place online, using one 1 ½ hr webinar, three 2 ½ hr - 2 ¾ hr Zoom workshops and online homework tasks.

FIGURE 1: DIALOGUE PROCESS

Key Findings

Participant journey

Most participants began the dialogue process never having heard of the HRA and with little or no awareness of the existence of the research ethics review service and research ethics committees (committees). As they learnt about the HRA's role and the purpose of committees, there was a widespread sense of surprised relief that health and care research is being assessed to ensure the interests of participants are designed into studies. Surprised relief developed into strong praise for research ethics review. Particularly praiseworthy in participants' eyes is the independence of committees, in that they are not part of the research study team, their combination of both professional and lay perspectives and the thorough scrutiny that ethics committees focused on health and care research provide.

Dialogue participants emphasise the value that committees bring to particularly complex research, where study participants are putting their lives and wellbeing into the hands of researchers. As this report shows, to ensure that committees have the capacity to focus on this high stakes research, many think that some non-interventional research such as patient surveys, could be ethically reviewed through other means.

Many participants said that before they took part in the dialogue they assumed that the COVID-19 vaccines were developed so quickly that any sort of ethics review would have been jettisoned in the interests of speed. Hearing that ethics review had in fact taken place was a surprise. They think that if more people had known about the role that research ethics review played, vaccine scepticism would have been lower.

Headline findings

Headline findings from the dialogue show:

- **There is widespread support for alternative ethics review methods:** Participants discussed alternative methods of ethics review, including researcher self-assessment, expert staff review and review by accredited institutions. Diversifying methods of review is important to participants to give committees more time to focus on complex research studies and to ensure research is not held up unnecessarily. Participants think that committees should review the most complex and challenging health and care research, such as some interventional research where the risks and benefits are high and research without precedent.

- **Calls for more diverse committee membership and research participation:** It matters that ethics committees are diverse, inclusive and cover a wide range of backgrounds and lived experience in order to make more informed decisions on ethics. Compensating committee members, increasing the rotation of committee members and a jury-style system of membership are seen as ways of achieving

this. Furthermore, an ethical feature of research is that participants are drawn from diverse backgrounds so that they can better reflect the whole population affected by whatever is being researched.

- **A desire for increased HRA visibility to build trust in health and care research:** There are universal calls to increase the visibility of the HRA and its equivalents in the Devolved Administrations and the ethics review service. This is seen as building public trust in research and advancements in health and care. Participants also believe that this democratises ethics, by making it better known and understood and so increasing the range of people involved in the ethics review service. It is possible that had the research ethics service been better known across society before the pandemic, there may have been less uncertainty about the safety and efficacy of the COVID-19 vaccines. In light of this, the HRA may want to broaden their ambition from 'Think Ethics' – which encourages the research community to think about ethics at every stage of the study process – to also 'See Ethics' to ensure that ethical consideration is visible to society to build trust in research.

- **Ongoing monitoring of ethics, beyond approval is desirable:** There is a need provide reassurance to research participants and the wider public that once ethics approval is received the ethical features of research are being adhered to through the research study. This includes publishing results and beyond. Participants feel that researchers should be held accountable in a meaningful way, independent of the study, throughout each stage of the research. They believe that the ethical delivery of research needs to be monitored and assessed, rather than just being 'green lit' before the research begins.

Summary of conclusions

Drawing on our analysis of the public dialogue, our experience in public dialogue both during and before the pandemic, and the context in which the dialogue took place, we share here three main conclusions. These conclusions apply most particularly to ways in which the ethical review of complex health and care research which carries some risk to the participant should evolve in the future.

1. The trust expressed by participants in a research ethics committee with professional and lay membership that is focused on health and care research and that is independent of the research study. This trust stands in stark contrast to the distrust and disappointment we have heard in other public dialogues about other sectors of society, notably politicians and some sections of industry. It was striking to hear how strongly participants value a system of ethical review that has the characteristics of independence, dedicated focus and collective professional and public participation. However, future trust is dependent on greater efforts to involve a more diverse range of society in ethics review. This matters because research affects everyone in society and it therefore needs to be informed by a diversity of thought and experience.

2. There is a concern that as science and technology become ever more sophisticated and pushes at the boundaries of what is possible and what is ethical, committees should not be overburdened. They should be allowed to focus on complex and unprecedented research and not have their attention diverted by more routine research that does not need such comprehensive scrutiny.

3. HVM observed among participants an ambition for research and its ethical delivery to be better understood and more widely embedded in society. This is expressed through calls for a wider range of organisations to be involved in the ethical review of research, particularly for research that may be more routine and less interventional. It is also expressed through the desire for the ethics of research to be monitored and assured over time, rather than just at the point research is about to start. Furthermore, participants are keen for research priorities to be identified by public and patients (rather than the preserve of government, industry and researchers) and to see opportunities to take part in research and research results more widely publicised.

2 Introduction

2.1 Context

The purpose of research ethics review is to ensure the safety, autonomy and dignity of health and social care research participants is protected. In the last twenty years Research Ethics Committees (committees) have moved from being hosted across the NHS, each working to local processes and standards, to a UK-wide service co-ordinated by the Health Research Authority. Committee members are a mix of professional and lay members who bring a range of professional and lived experience and volunteer their time.

During the COVID-19 pandemic, the Research Ethics Service[1] reviewed COVID-19 research in a tenth of the time taken in normal times without comprising on ethical standards and provided expert advice to researchers. The ambition is to learn from the pandemic and the HRA set up the Think Ethics Review programme (Think Ethics) with this purpose.

The aim of Think Ethics is to maintain safety and quality whilst redesigning the research ethics service to be more innovative, efficient and trusted:

- clear and concise study information designed with and for patients and study participants
- fast, proportionate review focused on key ethical issues in a consistent way
- a rewarding experience for diverse, skilled and committed members
- a streamlined and user-friendly service, attracting world-leading health research in the UK.

The dialogue took place almost two years in to the COVID-19 pandemic and in the wake of the omicron variant, which made its presence felt in December 2021. At this time, 34million people in the UK had received booster or third vaccines and pandemic measures such as face-mask wearing and proof of vaccination status were still in place (mandatory masks in England were dropped on 27th January, the day before our final workshop). As well as the ongoing health, social and economic impact of the pandemic, the news headlines were also dominated by reported parties in Downing Street during lockdown, which may have broken social distancing laws in place at the time. This was the backdrop to the discussions – a strong awareness of how quickly health treatments can be developed and some distrust of a political system that didn't seem to adhere to its own rules.

[1] https://www.hra.nhs.uk/about-us/committees-and-services/res-and-recs/

2.2 Dialogue purpose

The HRA commissioned deliberative research specialists Hopkins Van Mil (HVM) to design and deliver a public dialogue to gain understanding of what people know about research ethics review and to discuss these key questions:

- What are the most important questions to ask to ensure that research is ethical?
- What is the right process for ethical review?
- Who should be involved in the ethics review process?

The HRA will use the findings to inform:

- How different pathways of ethics review could be used to ensure that research is reviewed in a more proportionate way
- How to improve the consistency of how committees review studies
- How to improve patient and public involvement in the develop of information for study participants and focus ethics review on what matters most to those participants.

2.3 Dialogue process

Forty-six participants recruited from across the UK took part in the dialogue process over two weeks in January 2022. The samples for ethnic minority and lower socio-economic groups were boosted to ensure their perspectives were heard. A small number of participants were recruited who had experience of healthcare research, but most had not participated in healthcare research.

The dialogue process included online tasks, a 1 ½ hr webinar and three 2 ½-2 ¾ hour online workshops. Before attending the introductory webinar, participants completed a questionnaire asking them what they know about health and care research and committees, and they watched videos about the dialogue purpose and format. Each workshop was a mix of presentations, question and answer sessions and facilitated small group discussions of seven or eight participants.

During the process a range of speakers, either live or on film, gave different perspectives on health and care research, research ethics and the process of ethical review. The specialist speakers included members of committees, clinical and pharmaceutical researchers, public contributors, research participants and HRA staff who support committees. Participants also reviewed different types of research, including clinical trials for new drugs; genetic research; staff interviews; patient questionnaires; observational research; consented tissue studies and emergency research.

Further information on how the public dialogue was designed and delivered is included in Appendix 1. This includes the materials used, who the specialists were and what they presented, as well as details of the public dialogue participants.

2.4 About this report

The findings in this report are drawn from an analysis of workshop transcripts and homework space (Recollective) responses. In our qualitative reporting terms such as ‘a few’, ‘several’, ‘some’ or ‘many’ are used to reflect areas of agreement and difference. These should be considered indicative rather than exact.

HVM builds theories from what we have heard rather than having a preconceived hypothesis to test. Throughout the process the HVM coding, analysis and writing team has maintained a rigorous approach and held frequent sense-checking sessions to mitigate against researcher bias. Public dialogue is a qualitative methodology, findings do not demonstrate statistically representative analysis. We present the subtleties and nuances of participants’ views, concerns, hopes and aspirations so that they can inform the HRA’s Think Ethics programme.

The transcriptions do not attribute comments to named individuals. Small group discussions involved a mix of participant backgrounds: gender, ethnicity, age, socio-economic group. This means that where our findings draw out differences by ethnicity, they are based on Recollective responses.

It is important in any dialogue process that the report reflects the voices of participants. As such we have used quotations taken from transcripts to emphasise main points. Some quotes have been edited to remove repeat or filler words. We have made no other edits, so as not to distort speakers’ meaning.

3 Public dialogue findings

3.1 Awareness of the HRA, health and care research and the role of ethics and ethics review

Few participants were aware of the HRA before the dialogue and many had not heard of Research Ethics Committees when asked in the pre-webinar questionnaire. Whilst no participants mentioned the HRA in response to the question 'who is involved in health and care research', most identified a broad range of organisations and roles that include the NHS, clinicians, universities, charities, pharmaceutical and other medical, health and care companies, general public and patients and also government, with a few mentions of politicians (likely related to the government involvement in COVID-19 vaccine and treatment developments).

When participants think of types of health and care research, what comes to mind includes new ways to diagnose and treat both physical and mental health conditions; improving health and care services; understanding the prevalence of conditions; health trends and dealing with big societal issues such as an aging society. Only a few mentioned COVID-19 in this context: one on COVID-19 and care homes, the other on how the health service moves on after COVID-19. None mentioned the COVID-19 vaccine at this point.

As participants learnt about and discussed the existence and role of the HRA, there was a clear sense of surprised relief that such a body exists and that it is seeking to evolve to meet society's expectations and to learn lessons from how research into COVID-19 was accelerated.

It seems HRA approval is constantly evolving getting better and continuously striving to do better which makes me feel happy.

At the beginning of the dialogue, participants discussed what makes research ethical. The role of ethics in its widest sense was explored. Ethics is seen as walking a tightrope: keeping in step with social norms and attitudes and at the same time looking towards the future such as the implications of scientific advances and their impact on humanity. As will be seen, participants discussed keenly the importance of quality of life to the patient/participant versus the perceived tendency for science to focus on life expectancy.

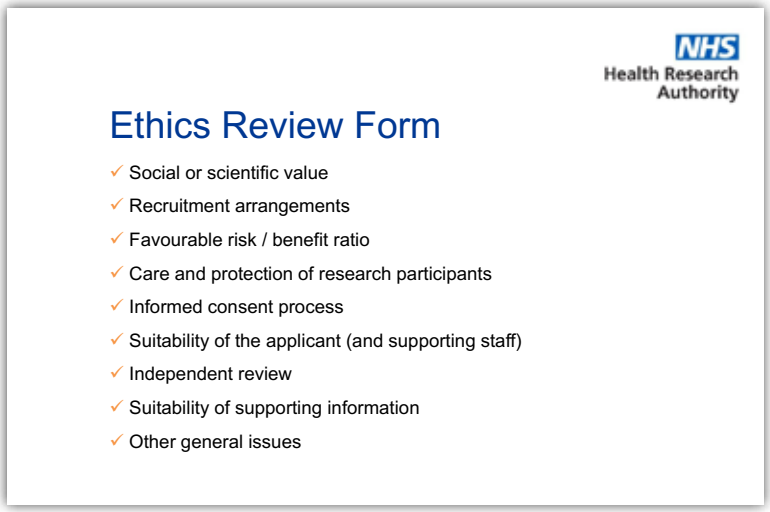
I would say, in 2022, there's never been a more important time for trials to be ethical. When we were all young, we thought that there would be robots going about or we could live to 140. As science gets better and things progress, there are going to be things that people will come up with, 'We can help you live to 140,' but, at the end of the day, is that ethical? Do we want robots? Ethics will become more and more important as people get more advanced.

In the early stages of the dialogue, some participants questioned why ethics reviews are necessary when they see themselves living in a society that has developed more comprehensive legal and regulatory safeguards to defend human rights, deter prejudice and protect the vulnerable.

However, as participants developed their understanding of the wide range of types of research, and that ethics in this context of research means a focus on participant interests, ethical review is seen to have an essential role in ensuring that research that is trusted and beneficial to society.

3.2 Research ethics review: questions that matter

FIGURE 2: CATEGORIES ON THE LEAD REVIEWER FORM



The previous section explored participant views on the process of reviewing the ethics of health and care research. This section focuses on the questions that participants think are important to ask to help ensure that research studies have participants' and the wider public's interests at heart. Dialogue discussions on this topic were prompted by questions on what makes research ethical and on which of the categories on the lead reviewer form (see fig2) mattered most.

Participants say that the type of research will determine which questions matter most. For example, the risk/ benefit ratio will be highly important for interventional research e.g. randomised controlled drug trials, but of lower importance for surveys. All questions are seen to have merit. The questions in the section below are ordered in the importance that participants identified and each section includes examples of specific questions that participants expect the ethics review process to ask.

Everything, again, is important. It's just in a different context isn't it? That's what's amazed me about what these Committees actually do is all points need to be considered but considered in different balances depending on what the research subject actually is. So, because you're not looking at maybe necessarily risk ratio being as high or people needing specific care and protection as much as you would a seriously ill patient, but you still have to weigh those up to come up with your end ethical decision.

3.2.1 Social and scientific value of research

Widespread agreement is expressed by participants that the first question asked of research should be does this research have social or scientific value? If the answer is no - then the research is not worthwhile. Proposals should clearly explain why the research is necessary for the good of society and how it will add value.

Participants feel it is important for a research proposal to clearly outline the overall purpose and the expected outcomes of the research. The intended outcomes should be realistic. To this end the proposal should explain what the mechanisms for change could be. It should be able to explain how the research findings will be used and by whom - and how this could then reasonably lead to the expected outcomes or benefits. One participant gave an example of a research study and how he would articulate its social and scientific value:

We are studying male depression as suicide is a leading cause of death in men. We hope that at the end of the study we will understand how to recognise, diagnose and treat depression in men quicker, and save lives.

Participants also suggest that considering the moral, political and economic implications of any research should be part of the ethical review process. The consequences of the research could be damaging or negative - and it is felt necessary to ensure that a research proposal has considered these.

Participants feel it is important to ask whether the research will be duplicating research that already exists or add value. Participants argue that rather than carrying out additional research on areas already heavily researched – it feels more ethical to focus resources on research into areas that are less known about, or receive less attention (e.g. rare conditions, mental health and male fertility).

A key ethical priority for participants is that the research proposal should outline the expected benefits of the research findings to wider society. It is important for a research proposal to be transparent about: what groups and individuals in society are most likely to experience those benefits; how many people are likely to benefit; and when those benefits are likely to transpire (e.g. short or long term benefits).

Participants view the health and wellbeing of patients and public as the most important or valuable type of benefit of any health and care research. This includes improving the quality of care patients receive, improving the life expectancy and quality of life of patients, and increasing knowledge around health conditions, treatments and research.

Some participants feel that it will be more ethical if patients and the public can input into decision making about what research to carry out. Their assumption is that decisions on what to research are based on government and organisational priorities. They are particularly struck by the presentation that spoke about how patient involvement in research flipped the focus from life expectancy to quality of life.

Ideally, it [research] would all be patient led so patients with conditions would be saying, 'We want research in this area.' And then people would fund that. But in reality it's the other way round. It's often government priorities or a research organisation that might have things that they want research.

Examples of specific questions that participants expect the ethics review process to ask:

Objectives and outcome questions for the ethics review to consider:

- Have the overall purpose and expected outcomes been clearly outlined?
- Are the stated outcomes of the research realistic?
- Has the proposal explained how the findings will be used and what the mechanisms for change will be?
- Have the possible political, moral and economic implications of the research findings been considered?
- Does the research duplicate other research or add value?

Benefit questions:

- Has the research proposal outlined the expected benefits of the research findings to wider society and been transparent about who may benefit, how many may benefit, and when?
- Have the public and patients had the opportunity to feed into decision making about the research question and objectives?

3.2.2 Benefits and risks for participants

Following on from demonstrating the social and scientific value of research, participants feel that a clear understanding of the risk benefit ratio is the next most important ethical issue for a research study to consider, and for the ethics committee to review.

For me, one of the things maybe is that I would want to know for sure that the benefits outweigh the risk or the harm. That it's open and transparent of what the balance is there.

Most participants understand that risk cannot be completely eliminated. In fact some mentioned that they would not trust research that implied that all risks had been eliminated. Instead what is important is to ensure that all potential risks and harms have been identified, including providing evidence that lessons learnt from previous research have been taken on board. Types of risk include physical and mental health and wellbeing for the research participant and family, financial benefits and risks, as well as the benefits and risks to wider society. Research proposals must then demonstrate they have done everything possible to minimise any risks.

Participants feel that a research proposal has to provide evidence that it will lay out the risks and benefits clearly for potential participants in an accessible manner. Transparency about the risks and benefits is of utmost importance in order to ensure potential research participants understand what the possible
implications are.

Understanding the risks and benefits includes having a clear understanding of the short, medium and long term risks and benefits. A risk that participants often highlight as being particularly important to spell out to research participants is the long term side effects. This includes the physical, mental, wellbeing side effects of any research - particularly in relation to drug trials. They feel it is also essential to have mechanisms in place to monitor the long term side effects that might materialise for research participants.

A significant question for an ethics committee is whether the benefits of the research taking place outweigh the risks to participants. This has to include the benefits to wider society, the benefits to research participants, but also the risks involved if the research does not take place. The COVID-19 vaccine studies were highlighted as an example. When calculating the risk benefit ratio – the risks of not developing a vaccine had to be considered.

Participants ask what risk probability is acceptable and if acceptable levels of risk can change depending on the context. For example – participants wonder whether the acceptable level of risk could be substantially higher if the potential benefits are really high, or if the risks of doing nothing are particularly high - for example with COVID-19 vaccine studies.

With COVID we had to get it [the vaccine] out as quick as possible because this infectious pandemic disease was killing people. If it was a 35% chance it wouldn't work, would they have still done it or would they have just carried on for years and years until they basically got it down to 5%?"

Another question is whether the acceptable level of risk should be lower in relation to research studies involving children or other vulnerable groups. Throughout, participants recognised that the context of the health condition or setting is essential to determine an ethical risk/benefit ratio.

Participants emphasise the importance of ensuring that a research study has clear protocols in place that explain what will happen if harm does come to a research participant as a result of taking part in the research. It is seen as necessary that if harms or risks come to pass – that support and aftercare is provided – and in some cases further compensation. Participants think it is unethical if when a research participant consents to taking part in research and has acknowledged the potential risks - that this then means they are not supported, cared for or compensated if they came to pass. Some participants are concerned about whether accepting payment of any sort for taking part in research could prevent a research participant from holding a research study responsible if any harms happened.

I would just be worried, if you're getting paid for it and something [bad] happened, they'd turn round and go, 'Well, we paid you money. That's a shame. Sorry to hear that.

Examples of specific questions that participants expect the ethics review process to ask:

Risk benefit ratio questions:

- Are the risks and benefits clearly laid out for potential participants in an accessible manner?
- Are the short, medium and long term risks and benefits understood?
- Does the design demonstrate that risks have been minimised and that the research is safe? Have research studies used learning from past studies?
- What is the risk benefit ratio? Do the benefits significantly outweigh the risks?
- What risk probability is acceptable? Does the acceptable level of risk change depending on the context?
- What systems and protocols are in place for when a potential risk materialises and a research participant suffers harm? Will research participants receive support and aftercare if they are harmed in any way due to taking part in the research?

3.2.3 Informed consent

Following the social and scientific value and risk/benefit ratio, assessing the consent process is seen as seen as a particularly important element of any ethics review process. Some see the ethical review of risks and benefits and informed consent as inextricably linked. Participants emphasise the need to ensure that research studies obtain informed consent. In order for research participants to meaningfully consent - they have to be provided with enough information to fully understand all aspects of the research study relevant to them. This requires open and honest communication between the researcher and the study participant.

It's really important that the patient totally understands the process, what's involved, and the benefits and the risks. So, actually, risk and benefits and informed consent I would say are equal.

Not only should the information be communicated clearly and in an accessible format - but participants feel that a research study is responsible for checking that research participants fully understand the information that they are provided with. This should include providing some participants with extra support if needed - for example with a translator if English is not their first language.

Participants say that research studies should always make it clear that consent can be withdrawn at any time (both during and even after the research is complete). Research studies should have a clear opt out process in place. Research participants should be able to withdraw for any reason – and without having to give that reason. Research studies should ensure research participants do not feel pressured or coerced to remain within the study if they no longer feel happy or comfortable about their participation.

There should be an exit strategy. Basically if you feel that you're being mistreated or anything that you can always leave, that you're not going to be held against your will or legally bound to anything.

Participants are interested in how a research study finds out whether potential research participants have the capacity to consent (for example participants referred to vulnerable people, children or individuals with severe mental health issues). They argue that research involving these groups requires extra scrutiny around the consent process.

Examples of specific questions that participants expect the ethics review process to ask:

Informed consent questions:

- Does the research study fully explain to research participants what the process of taking part will involve, including all the possible risks and benefits?
- Is this information communicated in an accessible way that can be easily understood by all research participants?
- Is consent an ongoing process? Can participants withdraw consent at any time?
- How will the research study assess capacity to consent?

3.2.5 Supporting information: communication and transparency

Honest and transparent communication with research participants has already been noted as a key prerequisite for obtaining informed consent. Participants raise a number of points about what honest and transparent communication should look like throughout the life of the research study and beyond. These are summarised here.

Participants refer to the importance of supplying research participants with all the necessary information - and not holding anything back. One participant phrased it as ensuring information included 'the good and the bad'.

I did a medical trial for whooping cough... What wasn't told to us in the [information] pack about what's going to happen, was that every visit, the person who got the whooping cough up their nose had to give [significant amounts of] blood. I'm sure it probably was in the information somewhere, but it wasn't necessarily in laypeople's terms... Because I believed them to be ethical, I was like, 'Wow, you can really sneak something by somebody if you wanted.'

The amount of time that research participants or potential participants are given to take in all the information is seen as important. Research participants need to have time to process the information in order to make meaningful decisions about whether to participate or not - to consider how it might affect them, as well as having time to ask questions. The importance of active, two-way communication rather than passive information giving is emphasised.

Dialogue participants feel strongly that any form of communication with research participants must be clear and accessible. This means using plain English language and laypeople's terms that are easy to understand. It is important to avoid using technical language or sector specific jargon. Information should be available in a variety of forms that meet different communication needs (e.g. via email, in the post, braille, large print, translated)

Participants expect a research study to communicate with research participants on an ongoing basis - not just beforehand when they want to persuade them to participate, but throughout the study and even once it is completed. This includes providing participants with updates about what is happening during periods of the research where the research participants might not be directly involved.

Research studies should check in and ask research participants how they are finding the experience and if anything could be done to improve it. Researchers should also ask for feedback from research participants once the study is complete – to gather learning and improve future studies from an ethical point of view.

A common theme is the need to share research findings with both research participants and the wider public. Findings should be written up in an accessible format so that they can be easily understood by participants and members of the public. Participants suggest using a user-friendly website and publicising the existence of any publicly available information about the research.

Participants argue that publishing the findings of research helps to ensure that it is more accountable and easier for other members of the public, including professionals, academics, and relevant organisations, to scrutinise the research process – including the ethics. It will also provide learning around ethical research for others considering doing research in similar areas.

Examples of specific questions that participants expect the ethics review process to ask:

Questions that matter about communication:

- Will the information communicated to research participants be complete?
- Are participants given enough time to absorb and reflect on the information?
- Will all communication use plain English?
- Will communication be available in a range of languages?
- Is participant communication ongoing?
- Will the study seek feedback from participants about their experience?

Questions on transparency:

- Will the research findings be shared with research participants?
- Will the research findings be shared with the public?

[transparency and communication] is about building trust. I think it also means it doesn't give anybody any surprises, there's a greater understanding if something goes wrong, so you'll get more support, because you've all been on that journey all the way through and there's been no secrecy, or there's been nothing hidden.

3.2.6 Care and protection of research participants

Participants strongly agree that the care and protection of research participants is highly important and a cornerstone of research ethics. They feel it is important for a research study to indicate how they will safeguard research participants and protect them from harm. A research study should also identify the needs and rights of research participants and explain how it intends to meet those needs and respect their rights. This means ensuring research participants are treated fairly, with dignity and respect.

In order to ensure that all participants can take part in research meaningfully - a research study must ensure it removes any potential barriers and is able to support a wide range of needs. This includes making sure that those with physical or learning disabilities can take part and ensuring the study can provide support to any participants who have any mental or physical health needs. Participants also spoke about how anxiety and stress can prevent research participants from taking part in research or can impede their level of engagement. Ensuring that participants feel comfortable and at ease when taking part in research is seen as essential.

Participants care about the confidentiality process. Participants think that a research study should clearly outline how it will ensure no one taking part can be identified by external parties. They also feel that if a study is able to provide research participants with assurances about confidentiality and the anonymisation of data – that this will lead to more open, comfortable and meaningful input or engagement.

Participants believe that an ethical research study should consider the possible impact of taking part on research participants, not just during the study but in the longer term once a study has finished. There should be a process in place for checking in on research participants after the study has finished - and for providing any after care to meet any longer term needs.

A strong theme to emerge from the discussions is the need for an independent body or forum that research participants can take any ethical concerns or questions to during the study. A key suggestion made was that research participants are provided with the direct contact details for someone that is independent from the research team - who they can easily reach out to in order to voice concerns or make a complaint. Several reasons for this were given, including that research participants might not feel comfortable voicing their concerns to the researchers themselves and may fear that doing so could jeopardise their place on the study.

The participant may not want to upset the researcher, or risk their place on the study by voicing their concerns to the person running it. The researcher might be blinded by the results they are trying to achieve and therefore be incapable of assessing the feedback given to them...Because of these reasons and more, there should be a body dedicated to the hearing out, evaluating and protecting participants. A body which is independent and separate from those involved in the actual research project.

Examples of specific questions that participants expect the ethics review process to ask:

Key questions that matter about the care and protection of research participants:

- Does the research proposal include a safeguarding policy?
- How will the researchers make participants feel comfortable?
- How will the study support any additional needs that some research participants may have?
- How will the study ensure that confidentiality is maintained?
- Has the study considered the longer term impacts of taking part in the study, and will it provide longer term support and after-care?
- Do research participants have access to an independent body that can address any ongoing concerns or questions for the duration of the study?

3.2.7 Recruitment arrangements and research participant diversity

Participants believe that if research findings are intended to benefit all of society, then it is necessary to recruit a sample of research participants that is representative of the whole population who experience the condition/care process that is being researched. This means the sample must include participants from every demographic group in society.

They often referred to examples that they had heard or read about, or had seen within one of the homework videos, where research samples do not include sufficient numbers of participants from ethnic minority groups. Participants emphasise that the resultant lack of data around ethnic minority groups means that research findings often do not consider the particular needs, backgrounds or context of these groups. This consequently can lead to certain groups in society not trusting research findings or believing that the findings are relevant to them. COVID-19 vaccine and maternal health research were both mentioned as key examples.

Participants argue that research ethics review should assess that the recruitment strategy is designed in such a way that it can reasonably be expected to recruit the intended sample. Participants want to know that research studies will commit to recruiting a representative sample rather than settling for a convenient one.

Recruiting research participants from black and minority ethnic groups is noted as being particularly challenging – especially due to there being a lot of justified distrust amongst these communities around health research (several participants cited the Tuskegee Syphilis study[2] and the homework video around research from ethnic minority perspectives).

As such, participants emphasise the importance of including strategies within the recruitment process aimed at building trust amongst distrustful or seldom heard groups in society and encouraging them to take up opportunities to get involved in research. It is important for the ethics review to assess whether the recruitment strategies are appropriate and will not exclude certain groups. Participants suggest that ethics committees look out for certain strategies like:

- being transparent about who the intended beneficiaries of the research findings are; and (where true) providing reassurances that the intended beneficiaries of the research will include all groups represented by the research sample (including ethnic minority groups);
- working with trusted gatekeepers who are better placed to explain, answer questions and reassure potential participants;
- offering compensation (thank you payments) to research participants - in order to encourage participation and make it more feasible for a representative group in society to give up their time to take part in the study;
- and following up with research participants on a regular basis before, during and after a study - to ask for feedback about their experiences and for suggestions on how to improve the process.

The role of gatekeepers (for example, clinicians, parents and carers) in recruitment was discussed. This is deemed as particularly important when recruiting children and young people – who are seen as a group completely reliant upon gatekeepers to take part in research because they are least likely to find out about opportunities on their own. It is important to participants that research studies ensure a fair and robust approach to recruitment, for example making sure that the professionals they work with to recruit children and young people do not simply pick the children they prefer.

Participants are interested in how a research study makes sure it doesn't just recruit participants who really want to take part or often tend to take part in research. Participants also argue for the importance of informing participants who do not qualify to take part in research about the reasons why they weren't chosen. This is to avoid resentment and an unwillingness to engage in future research studies.

[2] https://www.cdc.gov/tuskegee/timeline.htm

Come back to them and explain to them why they weren't selected, so there's an understanding. Maybe their disease is too far gone or it's not the specific one that they're treating or there's something different but not to just say, 'No,' and that's it. To come back and inform them, 'This is why we made the decision,' and then they can be informed of what the reason for it.

Examples of specific questions that participants expect the ethics review process to ask:

Key questions that matter about recruitment:

- Is the recruitment strategy designed in such a way that it can reasonably be expected to recruit the intended sample?
- Does the recruitment process include targeted strategies to help encourage potential participants from groups most likely to distrust the research process to take part? Strategies to look out for could include being transparent; offering compensation; working with trusted gatekeepers; and asking for feedback on an ongoing basis.
- How are gatekeepers used to recruit research participants?
- How does the study ensure that their biases do not affect the recruitment process?

It would also be about making sure that you weren't excluding people by the way that you recruited, so if you go to a particular hospital that has, for example, a very white, middle class cohort of patients then you're excluding a large proportion of the population if you only use those hospitals.

Underlying many questions on the recruitment process is the principle of transparency. Participants feel it is important for a research study to be clear and upfront about its recruitment approach. Participants say that the answers to these questions will help ascertain whether a recruitment approach is fair, robust, appropriate and representative. They should therefore be considered by ethics review. The questions participants want to see considered in the ethics review process are:

- What is the rationale behind the sample? Is it random or targeted and why?
- How large is the sample size and will it be statistically robust?
- How have decisions been made about the eligibility criteria for each quota?
- Is the recruitment process able to address issues around selection bias?
- How does the study ensure a fair selection process when too many people apply?
- Is there a process in place to provide feedback to individuals who apply but aren't selected?

3.2.8 Suitability of the applicant (researcher) and participant

Whilst the categories for ethical review include the suitability of the applicant, participants think it is important to consider the suitability of the research participant too. Participants raise a number of key considerations for assessing the suitability of both research participants and researchers.

From an ethical standpoint, participants feel it is important to ensure that research participants are well prepared, know what to expect and are emotionally equipped to take part in the study. This is particularly the case if the research involves people from vulnerable groups or involves activities or any engagement that could be distressing or painful.

I know obviously we can't speak for every eventuality, but just making sure that the person is as stable enough as they can be for that sort of research.

Some participants argue that research studies should have a process in place to verify that research participants are eligible to take part and definitely meet the necessary sample criteria. Participants do not feel it is ethical to simply take a potential participant's word for it, particularly if the research sample is focused on individuals with a specific condition.

Participants refer to the need for a process to ensure participants are taking part for the right reasons. This is seen as particularly important when research participants are being financially compensated for their time and participation. The concern isn't so much that people might just take part for the money - but more that the financial reward might convince people to take part even when they might not be able to honour the necessary commitments or might not be aware of what is actually being asked of them.

Determining the suitability of the research team is seen as important for to assessing their competency and trustworthiness to carry out the research ethically. Establishing the incentives or motives of any organisation or company carrying out research is seen as important from an ethical point of view. Participants want to know what any organisation or company is going to get out of the research. The motives behind why any research is taking place should be completely transparent. This enables any conflict of interest to be assessed and any improper influence monitored.

Knowing that the experts or the scientists or whoever is conducting this research has a background of understanding the topic, understanding what they're researching, that would give me confidence, as to someone who doesn't understand the topic, doesn't have an interest in the topic. It would be less likely that they would be able to conduct it ethically.

Some participants suggest that any research being carried out with the primary purpose of increasing profits, rather than helping improve people's lives, does not feel ethical. Connected to this, participants also think that the review process should look at the funding sources for a research study in case there is a conflict of interest there. Participants argue that considering who is funding the research should be reviewed because the funder can impact many aspects of the study: the objectives; its transparency; the decisions made about who will ultimately benefit from the research; and how research findings might be used/disseminated.

Examples of specific questions that participants expect the ethics review process to ask:

Questions that matter about participant suitability:

- How does the study ensure research participants are well prepared, know what to expect and are emotionally equipped to take part in the study?
- Is there a process in place to verify that research participants are eligible to take part?
- Is there a process in place to ensure participants are taking part for the right reasons?

Questions that matter about researcher suitability:

- What are the qualifications and experience of the research team?
- What is the research team's track record with research and what is their reputation in the field?
- What are the motives of the researchers/ research organisation for carrying out this research?
- What are funding sources? Is there a conflict of interest?

The category of 'Other general issues' was not discussed in detail during the dialogue.

3.3 Process and methods of ethics review: appropriate diversification and the need for ongoing review

In the webinar and first two workshops, the dialogue focused on committees: who should sit on them and the most important questions to ask. In the final workshop, participants considered alternatives to committees for some types of research studies. These alternative methods of review are:

- **Researcher self-assessment:** a researcher could use a self-assessment and triaging tool developed by the HRA. If the tool indicates that the study can go through a self-assessment route, they would conduct the review themselves and if the study meets the approval criteria, they would be considered to have an approved study. Alternatively, the HRA could specify that self-assessment approval would

only be allowed for certain types of studies that are carried out by 'delegated' researchers. This means that researchers have undergone pre-specified training or can show significant experience in research ethics.

- **Expert staff:** HRA staff with the appropriate training and expertise could review studies against an agreed set of criteria or an agree code, and those that are classed as needing a committee review will be passed onto Research Ethics Committees.

- **Accredited or approved institutions:** the HRA would delegate approval for certain types of study to institutions who satisfy a pre-specified set of standards. Institutions could review studies where there is no material ethical concerns based on an agreed set of criteria. They could also review sub-studies of clearly defined umbrella programmes which have gone through ethics review. If this type of review were to be set up, the HRA would establish an audit process to check compliance.

At first, some participants shared concerns about the prospect of moving some studies out of committees to other methods of review. But towards the conclusion of the dialogue there was widespread support for appropriate diversification. Benefits include giving committees more time to focus on complex studies and speeding up the delivery of research by channelling some non-interventional and common methodology studies to alternative routes. Participants want to know the 'who and how' for deciding the ethical review route and ensuring a more diverse system isn't 'gamed' by researchers and doesn't lead to greater bureaucracy. If alternative methods are used, participants expect clear and robust training, guidance and ongoing monitoring of reviewers as self-assessors, expert staff or accredited/approved research institutions. They want assurance that oversight of research ethics won't be lost if a wider range of ethical review routes are used.

Learning from the speed of ethical review of COVID-19 vaccines and treatments is highly valued by participants. They see opportunities for non-interventional research and research with precedent to be reviewed by alternative methods. They also see that the need for speed has to be balanced with maintaining thorough reviews of more ground-breaking, interventional research. Speed of review in this latter case could undermine trust in the research.

Some fear that a non-committee process may miss things and therefore be less trusted by the public. Fears are also expressed that alternative methods would lack a diversity of perspectives. A diversity of methods may also make it harder to have comprehensive oversight of research studies, lead to greater bureaucracy and cause inconsistencies in ethical review.

If we now moved them out of that realm and put it into others, it's the regulation of that and whether we then need to have four different bodies that regulate each one of those bodies.

Most participants support diversification and the HRA is seen as a trusted arbiter of which method of review is appropriate for a study.

I would be comfortable with someone like the HRA being the judge who decides this research meets this precedent, therefore it doesn't need to go to a REC review or this case doesn't meet any other precedent that has been set and therefore it does need to go to an ethics committee review.

The follow sections look at each method of review, current and proposed, and the perceived strengths and weaknesses of each.

3.2.1 Committees

Most participants had not heard of research ethics committees before the dialogue, but felt surprised relief that they exist. Many said they and people they know assume that the COVID-19 vaccine must have skipped this and other review/testing processes to be approved and available so swiftly. When they heard about the fast track approach to ethics approval, some doubted the sustainability of this speed and intensity of COVID-19 reviews.

Committees are seen as the gold standard as a method for thorough ethics review, but, unprompted, participants stress the importance of diversity (see section 3.4) and question the achievability of this given the amount of detailed work and time involved and lack of compensation.

The features and benefits of the committee method of review are seen to be its:

- range of professional and lay perspectives and expertise, less likelihood of bias
- focus on health and care research
- recruited to be independent
- public trust: seen as a rigorous gate keeper, not likely to miss anything,
- essential for new, challenging research.

A school Board of Governors was a wide, diverse group who came together for the benefit of the school, so you're looking at a group who for the benefit of the health of the nation, for the benefit of developing research, it's developed in a timely manner, and in a safe manner.

The weaknesses of committee reviews are seen to be:

- Lack of membership diversity means some perspectives are not being heard.
- Are they overburdened? Is too much being asked of committees? Could mistakes in judgement happen as a result, or loss of membership?
- A risk of groupthink if members stay on committees for too long.

Feel free to spend less time/mental energy on things for which there are existing precedents! Committees should focus on the new, the challenging and the controversial.

Participants see committees as the central pillar of an ethical review process. This belief is founded on their characteristics of independence from the research study, diversity of thought and focus. Participants want to see committees focusing on the most challenging research, where patient risk or societal expectations are uppermost.

3.2.2 Researcher self-assessment

Researcher self-assessment is seen as suitable for non-interventional research, such as interviews and some observational research. Researchers would need guidance from the HRA, and their study should be reviewed internally by senior, appropriately experienced colleagues.

The weaknesses of researcher self-assessment are seen as:

- a system that may be open to abuse, as researchers may game the system and design studies to enable self-assessment.
- potentially open for researchers to focus only on the science and neglect the participant
- lacking a diversity of perspectives and not being independent

If you move some of the studies to self-assessment, then people might have a vested interest. Even if that's unconscious in the result.

The strengths of researcher self-assessment of research ethics are seen as:

- allowing committees to focus on more complex studies
- increasing the number of people involved in and knowledgeable about ethics review, making it part of the culture of research
- speeding up research and increasing the number of studies overall

If you've got people signing off their own work, you're upskilling them potentially and raising compliance on a wider scale, because the more people have to do it, the more they have to be trained and generally then that should raise the level of compliance around ethics more widely.

3.2.3 Expert staff and accredited institutions

Expert staff and accredited institutions tend to be favoured as methods of ethics review. This is particularly the case when the research has some element of complexity or specialism, but has precedents and the expert/institution has expertise in that field of research.

The strength of expert staff review is seen as the expert having specialist knowledge of the field of research, patient interests and/or the healthcare area. Participants think it may be a weakness that, unlike a REC whose sole focus is on research ethics review, would this be the sole focus on the expert staff? If not, could that slow the process and reduce the quality and thoroughness of the review?

Accredited institutions are often spoken of in similar terms and considered suitable for similar types of study as 'Expert staff' review. Their strengths are seen as expertise in the field of research, patient interests and/or the healthcare area, diversifying the range of those qualified to review ethics and help the review system be more efficient.

If the institutions can be trained up to apply the HRA rules and ethics standards within their organisation, then they can effectively perform the same function but with less people involved.

The weakness of accredited institutions is that they are seen as unlikely to have the diversity and lay membership of a REC.

3.2.4 Alternative methods of review: participant ideas

As well as discussing the current and potential methods of ethical review, participants spontaneously put forward other methods. Some suggested a jury-style system, where it is a civic duty to serve on an ethics committee. This is seen as having the benefits diversifying REC membership and increasing public awareness and interest in health and care research. This suggestion is indicative of the high value that participants put on the research ethics review process, giving it equal status with the importance of the jury process in our criminal justice system.

You'd be invited to join, you'd then be given information about what goes on. You'd be told you'd be compensated for time off work and you are part of something that's very important. You have to really think about it ...you've got someone's life in your hands.

Other participants thought about alternative methods to take away the more routine or administrative aspects of a committee's workload. They think that artificial intelligence could be used to streamline the more administrative aspects of ethics review. Whilst they do not want AI to replace human deliberation, they think it could ease the burden from committees by checking the more straightforward aspects of research applications.

There's a place for the artificial intelligence in this scenario but in a limited capacity, should I say, not all the way through.

3.2.5 Ongoing ethical review

Participants look beyond the decision of the REC, to the research being carried out. They express strong opinions about the need to monitor research studies on an ongoing basis to ensure they continue to adhere to the ethical practices set out in their proposal. They feel that researchers should be held accountable in a meaningful way throughout each stage of the research.

Once a research project has been approved then we're all really trusting that the researcher and teams in charge will uphold the ethics they put forward in their proposal and I don't think that's good enough. No one can predict the challenges that might crop up of course but we can't just leave it to good faith.

It is important to participants that there is a specific auditing process in place to monitor adherence to ethical practices whilst a research study is being carried out. They feel uncomfortable with an approach that relies on trusting researchers to maintain high ethical standards after they have received ethics approval from the REC.

Participants like the idea of an ongoing ethical review body that could step in and intervene and even shut down research studies if they are made aware of any unethical practices. They argue that an audit process of this nature would also build public trust in research.

Participants do not specify who should be responsible for this ongoing oversight role, but the general consensus is that it should be an independent body that is completely separate from the research team and any organisation directly associated with the research.

Participants understand that an ongoing review process would require a lot of resources. Suggestions for less resource intensive alternatives include a system of random spot checks. Participants think that if all researchers know their study could be randomly reviewed, they would be more motived to carry out their research in an ethical way throughout the whole study.

If there were audits that were made public, then that would give everybody more confidence in the way research was being conducted.

3.4 REC membership – an inclusive approach

The questions that matter to participants have been explored in the previous section. In this section we focus on what participants feel is important about the membership of committees and why.

3.4.1 Inclusive and diverse membership

First and foremost it is important to share the widespread agreement participants express on the need for REC members to represent society, to be diverse and to cover a wide range of backgrounds and lived experience. Participants feel this is essential in any consideration of the ethics of research. It matters to participants because they feel that ethics is never entirely clearly defined, a yes or no answer. It requires thought and consideration from a range of perspectives and if committees can achieve this it will improve the decisions involved in ethical review and help to build trust in the process.

Having people of different sexualities, gender identities, ethnicities, backgrounds, disabilities and so on involved in analysing the ethics would probably give me more trust into considering if research is ethical, or not.

Across the dialogue groups, participants emphasise that ensuring REC membership is inclusive and diverse will be a visible demonstration that that health and care research, and researchers, consider this to be important. It is a strongly held belief amongst participants that actively broadening REC membership will underscore the fact that health research covers a very wide range of subjects, something they feel needs to be well understood by society. As such participants want to know that people from across society, with a diversity of thought, a broad range of experience, and from diverse backgrounds are bringing their views of the ethical dimensions of the research to bear.

Participants set out a number of proposals for improving the diversity of committee membership. Spontaneously participants include in this compensating REC members for their time. In their view this will ensure people are able to be involved whatever their financial position. A perception was expressed by many that the current REC membership

is likely to comprise people who are affluent and have available time and resources. They worry this might restrict membership to a few relatively privileged people.

I imagine it's all retired people that are quite wealthy, they're the only ones that can afford to do this for free. I might be wrong, but I would imagine that it doesn't meet diversity guidelines and that a number of social classes or ethnic groups aren't properly represented as a result.

This reflects participants concern that those in lower paid jobs, or who have limited resources due to household commitments would be unable to contribute as a REC member.

We can all keep talking about diversity, but if you're working a minimum wage job, 9 to 5, you probably can't really afford to do that much voluntary work, and therefore you don't get the representation that you might want.

Payment for people's contribution is also seen as important in recognising the responsibility members have and demonstrate that REC members' time is valuable and valued. However, some participants want to ensure that the term 'compensation' rather than 'payment' is used. For these participants there is a distinction to be made, that being a REC member is not a job, but it is an important societal role which needs to be recognised.

Paid or compensated perhaps, maybe. That's a term you could use perhaps, as opposed to being paid like a job. It's not a job is it, it's something else, it's time out. It's quite a responsible position to have for however long it would take. You need people from all backgrounds, all socio-economic backgrounds and maybe that would be a way of having those people on board.

A few participants do not agree with either payment or compensation. They express concern that some might only do it for the money and this would be unethical in and of itself. But many more feel that it is essential step in making committees inclusive.

Participants also propose that the HRA should establish recruitment criteria for committees to actively look for a diverse membership. This would set out that committees are looking for people who have been underrepresented to date and why it is important to gain a diversity of views on what is ethical and what is not in health research. Linked to the criteria set, participants also want the benefits of REC membership to be promoted in ways which are tailored to appeal to specific groups. This might include showing to those who are under represented currently that this is an important way of giving back to the community you live in. Equally they see it as a benefit that REC members have the prestige of doing an important job for society.

I guess it'd be very prestigious to be on the committee. That kind of thing would look good on your CV. I would say that being on the committee itself would be rewarding, because it is quite a prestigious position to be in.

3.4.2 The skills and experience required of a REC member

Whilst diversity and lived experience are essential, participants are also concerned that REC members can understand the material that is shared with them. For many across all groups this means that REC members might need to have higher levels of educational attainment; for some it means that the material provided by research teams is in language that can be clearly understood, whatever the technical background or knowledge of the members.

I would like to know that (REC members) have been given the best information and are the best possible people to make those decisions. When we're talking about serious subjects, we perhaps need a bit more in-depth knowledge and study.

A concern emerges here that REC members might not understand what they are reviewing and therefore not propose ethical approval. This, they feel, is an important risk, which could mean that a research study which could bring important opportunities for society is not taken further.

Do we run the risk of a study not being passed that could have had massive benefit to society as a whole because we have people on a committee that don't have the depth of understanding of what's submitted to them?

Equally, participants say that they want new perspectives brought into ethical review – a diversity of thought as well as experience. This includes ensuring that REC members don't all think in the same way and committees include, for example, people who think laterally, visually, imaginatively and/ or critically. Participants want to avoid ethical reviews becoming a rubber stamp because everyone in the committee has the same way of thinking, one that only matches the established views of the health research community. Such an approach would draw people who bring their specialist knowledge, common sense, moral judgements and lived experience. Such experience could include having:

- Good analytical skills
- Suitable experience and intelligence
- The ability to digest a lot of information
- The strength of character to stand up for what they believe is ethical, defend their own positions in discussion, and not be led by the 'clever' people in the room.

Participants stress that lay experience is necessary but that committees must also include those with professional expertise for example: researchers; health and social care professionals; ethicists and faith leaders; philosophers; human rights professionals; lawyers. Including a range of expertise gives reassurance to dialogue participants that the ethical review process is robust and effective and can, therefore, be trusted.

I'm going to trust the people who (because of their) formal education, lay people with a good standard of understanding, street smart, whatever that is, I'm going to trust them to say, 'this research is valid, it is ethical'.

3.4.3 Expectations of REC membership

It is essential to participants that REC members demonstrate independence from the research being conducted. It matters to participants to minimise bias and ensure people don't have vested, including financial, interests when considering the ethics of any research programme.

I would say the people who had a financial interest in it. If you owned a company or you had any financial interest in the product or the outcome of the research you shouldn't be on the committee.

Participants want to ensure that REC members are people who will act with integrity and in the interests of society. They contrast this with people who might hold extreme or harmful views and would not bring independent thought to the process.

This leads many participants to the idea that a vetting process should be in place to exclude people from Committees who might act against society's interests, including those with a criminal record. Background checks, DBS checks and psychometric testing are suggested as possible methods for checking people's suitability for REC membership. This comes with a recognition that this isn't necessarily easy to achieve.

It's a very difficult subject isn't it. How do you know that someone has society's best interests at heart? Do you do a test for that? A lot of people thought the GP Harold Shipman was doing the best for his community and that didn't turn out to be the case.

Other expectations include ensuring that REC members have the time available and won't be overwhelmed by what is required. Participants want those who become involved as REC members to be clear about their responsibilities and be prepared to be the 'eyes and ears' of all of those who might be affected by a research programme and protect their interests.

The fact that participants place a great deal of importance on who is a REC member demonstrates the value they place on ethical review as a whole. Participants stress the essential requirements of ensuring a diversity of thought, background and experience; and that people have, or are given, the skills necessary to approach their task with the seriousness it deserves. This all contributes to their view that ethical review is important and will be trusted by a society if it is shown to have taken in to account different opinions from people appropriately selected from across society.

4 Considerations for the Think Ethics Programme

This section draws together the strongest recommendations put forward by participants, both at the conclusion of the dialogue and themes that emerged during the process.

4.1 Increase visibility to build trust

During the dialogue, participants' awareness and appreciation of the HRA and ethics review process transformed from almost zero to high praise. The praise grew from hearing about the committees, that they include lay as well as professionals, their independence, the time they spend on scrutiny and the work that researchers do to prepare for ethics review – including early public/patient involvement.

At the end of the dialogue, making the HRA's work better known was the most frequent recommendation. Suggestions to increase visibility include a portal to access research summaries and REC decisions. On the basis of the dialogue discussions, it is reasonable to suggest that had the HRA and the REC process been better known across society, there may have been less uncertainty about the safety and efficacy of the COVID-19 vaccines. In light of this, the HRA may want to broaden their ambition from 'Think Ethics' – which encourages the research community to think about ethics at every stage of the study process – to also 'See Ethics' to ensure that ethical consideration is visible to society to build trust in research.

I'd never heard of the HRA until we started this, so maybe to come out of the shadows somewhat and let people know they exist and the work that they're doing in protection of participants, and also to maybe have a new idea, have a public portal or a portal whereby a snapshot of reviews and studies are posted, and feedback on the decisions that were made, and feedback on the results of the study, so those interested parties have a place to go to.

Share what you do, across a wider spectrum of media, so that everyone has a better understanding about research.

4.2 The questions that matter most for research to be ethical

Drawing on their own knowledge of research and reviewing the examples shared in the dialogue, participants say that context matters when deciding which are the most important questions for ethical review. Having looked across the categories of questions asked, all are seen to be relevant and important. Some are of greater importance in terms of determining the merits of the research objective itself, before more practical considerations are developed and reviewed: notably: Does the research have social and scientific value and what is the risk/benefit ratio?

4.3 Expert channelling of research to appropriate ethics review methods

There is widespread support among participants for the HRA to direct different types of research to different methods of review.

The committee method is seen as the gold standard for review, but participants want committees to focus their time and energy on research with little or no precedent and research where the risks to the research participant need careful consideration.

Research with a consistent track record and non-interventional research are examples of candidates for other review methods. Participants want the HRA to build and administer a process to ensure that studies are reviewed appropriately and that researchers don't 'game' the system by designing studies to go down the least scrutinised route.

Participants also expect the HRA to provide training, guidance and oversight for the alternative methods of researcher self-assessment, accredited institutions or expert staff review. There are also expectations that any risk of loss of oversight through using diverse methods of review is mitigated.

We talked about a system of precedents, much like a court case might often be decided against a precedent that has been previously set by another judge and in that case I would be comfortable with someone like the HRA being the judge who decides this research meets this precedent, therefore it doesn't need to go to a REC review or this case doesn't meet any other precedent that has been set and therefore it does need to go to an ethics committee review.

4.4 Research and ethics review that is diverse and inclusive

Participants talk about the HRA and ethics review coming out of the shadows. Coming into the light means looking at how to ensure that a breadth of backgrounds and life experience are included in the ethics review process to build trust in it and the way health and care research is conducted.

A diverse and inclusive REC membership recognises that research covers a very wide range of subjects and with people that bring a diversity of thought, a broad range of experience and come from diverse backgrounds, are bringing their perspectives to bear. Some dialogue participants believe that many research samples are not representative. They express the hope that a more representative committee may increase scrutiny of this aspect of the research design and lead to greater public confidence in the representativeness of research.

The idea of compensation for REC members emerged spontaneously in several groups. It is supported as a way of achieving diversity and ensuring that membership is not just the preserve of those who have the financial means to take part. Other suggestions include less time intensive time commitment such as being involved with sub-committees that review less complex research and increasing membership rotation (i.e. serving less than four years to ensure a wider range of perspectives). If the HRA and research ethics committees become better known in society, it is likely that who they do and don't involve will be more widely scrutinised.

Pay people for the work they do, and you will have a more diverse group as a result of it

Diversity diversity diversity! Everyone included race sex differently abled everyone!!!

4.5 Ongoing monitoring of research ethics

Participants feel strongly that there is a need to provide reassurance that once ethics approval is received, the ethical features of research are being adhered to. Participants say that researchers should be held accountable in a meaningful way, independent of the study, throughout each stage of the research. This is particularly for research where the risk/benefit ratio for the participant is an important factor.

So whilst there is high praise for the role that committees play at the start of the research process, there are equally high expectations for the ongoing review of ethics and an expectation that the HRA lead the development of this in the future.

I was thinking that if they were able to get more powers to just ensure that the guarantees that were given by the researchers are being followed up, rather than waiting for something to go wrong on an annual report coming out saying, 'This is where it's gone wrong.' An awful lot can happen inside a year. So it's just that they would have powers to, not do it on them all, but if the researchers know that there could be more follow-ups, they may be more likely to ensure that the guarantees that they've given to the committee are going to continue.

5 Summary of conclusions

Drawing on our analysis of the public dialogue, our experience in public dialogue both during and before the pandemic, and the context in which the dialogue took place, we share here three main conclusions. These conclusions apply most particularly to ways in which the ethical review of complex health and care research which carries some risk to the participant should evolve in the future.

1. The trust expressed by participants in an independent and dedicated research ethics committee with professional and lay membership. This trust stands in stark contrast to the distrust and disappointment we have heard in other public dialogues about other sectors of society, notably politicians and some sections of industry. It was striking to hear how strongly participants valued a system of ethical review that had the characteristics of independence, dedicated focus and collective professional and public participation. However future trust is dependent on greater efforts to involve a more diverse range of society in ethics review. This matters because research affects everyone in society, and it therefore needs to be informed by a diversity of thought and experience.

2. The concern that as science and technology become ever more sophisticated and pushes at the boundaries of what is possible and what is ethical, committees should not be overburdened. They should be allowed to focus on complex and unprecedented research and not have their attention diverted by more routine research that does not need such comprehensive scrutiny.

3. HVM observed among participants an ambition for research and its ethical delivery to be better understood and more widely embedded in society. This is expressed through calls for a wider range of organisations to be involved in the ethical review of research, particularly for research that may be more routine and less interventional. It is also expressed through the desire for the ethics of research to be monitored and assured overtime, rather than just at the point research is about to start. Furthermore, participants are keen for research priorities to be identified by public and patients (rather than the preserve of government and researchers) and to see opportunities to take part in research and research results more widely publicised.

6 Acknowledgements

The creation and delivery of this Think Ethics Dialogue was a truly collaborative process. The HVM team would like to acknowledge and thank all those who gave their time, energy, knowledge and experience. This includes the dialogue participants who so richly contributed to and engaged with the discussions in an intensive process. It also includes all those who supported and challenged us to create a public dialogue that participants found enlightening, inspiring and worthwhile and which we hope gives useful insights to inform the Think Ethics programme:

HRA Project Team:

Juliet Tizzard, Director of Policy and Partnerships, HRA*
Naho Yamazaki, Head of Policy and Engagement, HRA*
Nicola Gilzeane, Engagement Manager, HRA

Think Ethics Dialogue Advisory Group:

Andrew George, Non-Executive Director, HRA*
Della Ogunleye, Public Contributor and member of the HRA's Public Involvement Network
Joanne Doleman, Senior Research Governance manager, Wellcome Sanger Institute; REC lay member*
Louise Vale, Public Contributor and member of the HRA's Public Involvement Network
Lynn Laidlaw, (Chair), Patient researcher, Public Contributor and member of the HRA's Public Involvement Network*
Susan Kohlhaas, Director of Research, Alzheimer's Research UK

Stakeholder Interviewees:

Andrew Toft & Fiona Watt, Senior Research Policy Manager, Chief Scientist Office, Scottish Gov
Christopher Cannaby, Senior Clinical Operations Manager, MSD
Mary Dixon-Woods, Director, THIS Institute
Rasha Al-Lamee, Clinical Senior Lecturer, Imperial College
Simon Kolstoe, Bioethics and University Ethics Advisor, University of Portsmouth

Dialogue Speakers:

* Also dialogue speakers

Bob Philips, Senior Lecturer and Honorary Consultant in Paediatric Oncology Hull-York Medical School and Centre for Reviews and Dissemination University of York
Charlotte Allen, Quality & Performance Manager, HRA
Mark Sheehan, Oxford Biomedical Research Centre Ethics Fellow
Sheuli Porkess, Founder & Director, Actaros Consultancy Limited
Sue Harrison, Lay REC Committee Chair
Clive Collett, Senior Policy Manager, HRA

Appendix 1 Methodology and process

The HRA and HVM project team worked collaboratively with the Dialogue Advisory Group to design the dialogue process.

A1 A deliberative process

To introduce the methodology, it is worth setting out why the public dialogue approach was chosen for this project. Public dialogue is not a 'we tell you this and you tell us what you think about it' information exchange. Dialogue works when participants interact on a level playing field with specialists in this case REC members and those with experience of public involvement in research, researchers, academics and HRA staff. Speakers gave presentations and answered questions from participants. In addition, observers from the Dialogue and Think Ethics advisory groups attended sessions, some of whom also responded to participants' ad-hoc queries during small group discussions.

This specialist evidence is then viewed through the lens of participants' own lived experience, leading to rich and powerful insights.

In a public dialogue citizens come together, with sufficient time to reflect, to:

- Learn about the issue
- Talk with, not past, each other
- Consider diverse points of view
- Discover key tensions and values
- Spark new ideas

This leads to an understanding of what people value, what they see as benefits and harms, their trade-offs and redlines and, in this case, the areas they consider important when reviewing the ethics of health and care research.

We used a consistent group of HVM facilitators in all dialogue workshops. Each small group comprised no more than seven participants working with one facilitator. Facilitators followed workshop process plans designed in discussion with the Project Team.

A2 Recruiting the public dialogue participants

A total of 46 participants were recruited and retained to the dialogue. HVM worked in collaboration with the specialist recruitment company, Roots Research, using a recruitment screener to ensure dialogue participants broadly reflected the demographics the UK population. Sampling was done for age, ethnicity, gender, life stage, disabilities and socio-economic group. The sample was boosted for minority ethnic groups and those at lower ends the of socio-economic scale to ensure voices that may be less frequently heard were well represented in the dialogue.

We excluded those who had taken part in qualitative research in the previous twelve months. Participants were given a cash honorarium/shopping voucher (according to preference) to recognise the time committed. This is standard in public dialogues and means people are not excluded because of their financial circumstances.

The recruitment process ensured that of the 46 participants, a maximum of 8 had taken part in health research previously or knew someone who had. We excluded people who are/have been Research Ethics Committee members or support staff; people who work in frontline NHS roles (e.g. doctors, nurses, allied health professionals); Health Research Authority staff and family members and researchers (academic and industry) who have applied for research ethics approval.

Table 1 Demographics of dialogue participants

46 Participants	
Gender	
Male[3] Female Non-Binary	19 27 0
Age	
18-30 31-40 41-50 51-60 61-70 71+	7 12 10 7 7 3
Ethnic Minority	
Yes No	12 34
Disability / Chronic Condition	
Yes No	23 23
LGBTQ+	
Yes No	11 35
Children	
Yes No	23 23

[3] 4 of the 5 recruited participants who dropped out were male.

Employment status	
Full Time	13
Part Time	8
Self-Employed	4
Homemaker	1
Retired	10
Student	2
Unemployed	8
Social Economic Grade	
A/B	8
C1-C2	25
D/E	13
Health/Social Care research	
Yes, I have taken part	3
Yes, Someone I know has taken part	5
No	38
Location	
London	3
Northern East/West	2
Yorkshire	2
East Midlands	2
West Midlands	4
South East	6
East of England	2
South West	3
Scotland	8
Wales	7
Northern Ireland	7

Digital inclusion is an essential part of recruitment for an online dialogue. No one who wished to participate in the dialogues was excluded because they did not have the hardware, software or technical knowledge to attend an online workshop. Before the dialogue process began, HVM ran a 'tech support' session in which people could run through, in an informal way, how to use the key elements of Zoom, Recollective and the online voting tool Menti. We opened the workshop 15 minutes before each session so that participants could check their technology was working. Each workshop also had a dedicated tech support team member to get people back online if they lost their connection and find solutions for loss of sound or visuals.

It has been key to HVM's process during the pandemic to ensure everyone in the dialogue feels safe and able to discuss matters of emotional and ethical significance in the online space. To enable this the 'Welcome pack' and introductory videos distributed in advance of the dialogue to all participants included guidance on who to contact if they wanted to ask any questions about the research process.

A3 Designing the dialogue

The questions we asked, the speakers we invited and the stimulus materials we shared were identified and developed with the guidance and insight of the eight stakeholders we interviewed, the Dialogue Advisory Group and the HRA project team.

A4 What did participants do?

For all participants the dialogue involved four main elements:

- An emailed welcome pack & introductory videos and pre-webinar questionnaire
- Four online events: an introductory webinar and three workshops
- An online space to view new materials such as videos and review the presentations and summaries of other groups' discussions from the workshops, ask further questions and add additional comments in participants' own time;
- Online polling during the workshops (Menti) to ask for quick reactions and/ or to sum up how participants feel about an issue.

Process summary

Webinar:
Welcome and purpose of dialogue
Dialogue process overview
Speaker: What is Health and Care research
Speaker: Approving research and ethics committees
Q&A

Homework 1:
Watch short animation on HRA approval process
Read responses to questions answered after the webinar
Respond: If you are taking part in a health or care study, what would you want to know before taking part?
Watch short animation on taking part in research & answer this question: One thing you'd like to research in health/care?

Workshop 1:
Welcome back
Small group discussion 1: Put yourself in the shoes of people/organisations involved in research: What do they get out of research?
Speaker: What is 'research ethics'?
Speaker: Patient involvement in research design
Speaker: REC member perspective
Q&A
Small group discussion 2: What would give you confidence that research is ethical?

Homework 2:
Read other groups 2 key points & comment on similarities/differences
Responses to unanswered questions
Watch video on minority ethnic research perspectives
Watch video on REC member perspective (Sue Harrison)

Workshop 2:
Welcome back
Speakers: Research applicant perspectives: commercial & clinical
Q&A
Small group discussion: Q1: Thinking of research ethics committees: create your ideal committee. Q2: Thinking about the other stages of research (visual in Jamboard) e.g. designing research, research in action, reporting on research: what's important to consider at these stages to ensure that research is ethical?

Homework 3:
Read summaries from other groups
Talk to two friends/family members: If they were taking part in a health research study: what would they want to know?
Review research study snapshots we'll be discussing in Workshop 3

Workshop 3:
Welcome back
Speaker: Categories to review ethics of research
Speaker: Alternatives to review by committee e.g. self assessment etc
Small group discussion 1: which of the categories presented are most important / least important/or unnecessary/ anything missing? Which method of ethics review would be proportionate/ sensible for the types of research we have been discussing. What are the implications of moving some studies out of committee review?
Small group discussion 2: Thinking about all we've discussed today and during the dialogue, what recommendations do you want to make to the HRA to help them make health and care research more ethical and to improve ethics review.

Interaction with specialists is an essential element in public dialogue, providing participants with insight into the different perspectives on a topic. In this dialogue we worked with a range of specialists who contributed to the dialogue in the following ways:

- Presenting live during workshops;
- Filmed interview watched as an activity between workshops
- Answering participants' questions;
- Explaining key concepts and terms.

This interaction meant a lot to participants who told the dialogue team that they had learnt a great deal from this process of presentation and discussion.

The small group discussions of seven or eight participants were facilitated by the HVM team who recorded the sessions with participant permission and took visible notes using Jamboards. Following workshop 1, small groups were mixed to ensure a diversity of views were heard.

A4 Analysis and reporting

The Zoom dialogue workshops generated over 30 hours of audio recordings. These were transcribed and analysed by the HVM team using NVivo software together with:

- Visible notes captured by facilitators on Jamboards
- Data from the online space reflective tasks that participants completed in between each workshop
- Results of the online Menti polling questions used live during workshops.

HVM applies grounded theory to our analysis of public dialogue deliberations. We build theories from what we have heard rather than having a preconceived hypothesis to test. Throughout the process the HVM coding, analysis and writing team have maintained a rigorous approach and held frequent sense-checking sessions to mitigate against researcher bias. Public dialogue is a qualitative methodology, findings do not demonstrate statistically representative analysis. For this reason and because the transcriptions are anonymised, our analysis does not draw out if some perspectives were more prevalent by age, gender, socio-economic group, location, ethnicity etc. We present the subtleties and nuances of participants' views, concerns, hopes and aspirations so that they can inform the next steps in the consideration of UK land use.

[4] A full list of speakers can be found in the acknowledgements section on page 34

Appendix 2 Participant feedback on taking part in the public dialogue

Very interesting couple of weeks. I very much enjoyed discussing the topics raised and being able to contribute to the discussion and voice my opinions

I have absolutely loved taking part in this, it's been mind blowing and very informative. You should be so proud of yourselves and what you do, more people should hear about you. Thank you for giving me the opportunity to be a part of it!

I was so nervous about taking part as I know I'm not a person who asks a lot of questions and can be quite reserved and most is the people in my teams were so clever and chatty and asked amazing questions but it's good to have a diverse range of people on these types of research and I did ask some questions and tried my hardest to take part in discussions when I felt it was out my comfort zone. I feel proud of myself for taking part as it was a thought provoking exercise with tough questions but as [they] said there were no right or wrong answers

Thank you so much for allowing me to participate in this project. I have thoroughly enjoyed it and learned a lot. It was a joy to meet such a diverse group of people and to share our thoughts and opinions

Thank you and your Team for the opportunity you gave us to take part. It was a great experience, and I learnt so much.

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