

Assessing Public Attitudes to Health Related Findings in Research

April 2012

Assessing Public Attitudes to Health Related Findings in Research

Commissioned by the Wellcome Trust and the Medical Research Council,
conducted by Opinion Leader

April 2012

Contents

1. Executive summary	3
2. Introduction	6
3. Main findings	12
3.1 Understanding of attitudes towards, and participation in, medical research	12
3.2 The benefits and harms of receiving feedback	22
3.3 When health related findings should and should not be fed back	31
3.4 How health related findings should be addressed within the consent process	46
3.3 Mechanisms for the feedback of health related findings	56
4. Discussion and conclusion	65
5. Glossary of terms	68
6. Appendices.....	70

1. Executive summary

Introduction

During research involving human participants, researchers may find something that has direct significance for a participant's health, revealing an undiagnosed disease or an increased risk of illness, for example. These health related findings may be relevant to the research question (a 'pertinent finding') or completely unrelated (an 'incidental finding'). Health related findings can be of varying severity and may occur during different types of research involving human participants, including imaging and genetic studies.

The Wellcome Trust and the Medical Research Council commissioned Opinion Leader to undertake this study to find out more about public attitudes to the feedback of health related findings. This will help inform the development of any 'principles' for researchers about the feedback of health related findings.

Objectives

The overall aim of this study was to explore public attitudes towards health related findings in research. Its four core objectives were to:

- investigate the general public's attitudes towards the feedback of health related findings to individual participants and how they view the potential advantages and disadvantages of feedback; (Section 3.2)
- identify which factors are seen to be most important by the general public when deciding if health related findings should be fed back to individual participants, for example the severity of the medical condition and whether or not it is treatable; (Section 3.3)
- explore the general public's opinion on how the feedback process should be managed, including identifying preferred feedback routes (Section 3.4 & 3.5); and
- explore the views of research participants and those affected by particular conditions and establish if, and how, these vary from the views of the general public (explored throughout).

Methodology

This study was undertaken across the UK in 2011 and 2012. The qualitative phase included eight extended focus groups with the general public and 20 in-depth interviews with research participants and people affected by medical conditions. The quantitative phase consisted of a survey of 1,105 members of the public.

Discussion and conclusion

The findings of this study have implications for the feedback of health related findings in research. In developing policy, the following issues should be considered alongside other factors, such as the impact on research and legal implications that may influence the approach to feedback:

- **Participants showed overwhelming support for the return of health related findings to research participants**, particularly where a condition is serious and treatable. Researchers should therefore consider the feedback of findings when designing and setting up a study to ensure that potential research participants have the information they need to decide whether to take part in a study.
- **Respondents viewed the consent process as a critical point for potential participants to receive information on health related findings before agreeing to take part in**

research. It is therefore essential that information on feedback is presented clearly and in an accessible form that members of the public are able to understand.

- **Respondents valued the role of health professionals or those they had an existing relationship with in the feedback process and it was seen as important that those receiving feedback have sufficient information and access to follow up.** Researchers should take these factors into account in designing the feedback process and ensure that those receiving feedback have sufficient information and access to follow up advice.
- **This study showed that public understanding about medical research is weak.** It is important that the results of this study are considered within the context of the low level of understanding of the process of medical research, particularly where they are to be used to inform policy development. This finding also has important implications for how researchers communicate with research participants, particularly to avoid a gap developing between participants' expectations and their experience of taking part in research.

Further research in a number of areas would enhance the evidence base for policy decisions on the feedback of findings to individuals. This should encompass a wider range of stakeholders, including those who have had findings returned to them and health professionals.

Summary of findings

The public's understanding of, attitudes towards and participation in medical research

(Section 3.1)

- Participants had different perceptions of medical research. In the qualitative phase of the study, largely negative spontaneous connotations were observed, with dominant associations around drug trials and testing on humans and animals. There was a more positive feeling towards medical research within the quantitative research, with three quarters of the survey respondents saying that the advantages of medical research outweighed the disadvantages.
- The study found that trust in those conducting research varied substantially. Medical doctors and scientists working in universities were considered most trustworthy and those working for pharmaceutical companies least trustworthy.
- This study showed that there were weak levels of public understanding about who conducts medical research and what it involves.
- When asked about potential motivations for participating in medical research, focus group participants tended to focus on individualistic gain such as the fee received for taking part. However, those affected by medical conditions had a more advanced understanding of research and what it involved. Their motivations for participation tended to be less individualistic and more focused on contributing to scientific advances.

The benefits and harms of receiving feedback (Section 3.2)

- There was a general perception that the benefits of feeding back health related findings outweighed the harms.
- Spontaneously cited benefits of feedback can be grouped around two categories: benefits to the health of participants, e.g. early detection of a condition, awareness of the risk of developing a condition and psychological preparation, and benefits to relatives, e.g. family members being prompted to seek screening, allowing decisions to be made about whether or not to have children and, again, psychological preparation.
- Participants were asked to weigh the advantages and disadvantages of the feedback of findings both before and after considering further information on the potential benefits and harms. Opinion that the advantages outweighed the disadvantages was completely unchanged between these questions.

- Issues around the clinical relevance* and the accuracy of findings, which play a large part in the disadvantages of providing feedback, are complex, with participants finding them difficult to understand. Further work would therefore be useful to explore whether a more detailed examination of the potential harms or disadvantages of feedback to the individual has an impact on attitudes.

When health related findings should and should not be fed back (Section 3.3)

- Among those sampled there was a very a strong desire to receive feedback on health related findings.
- The qualitative research tested 12 variables that may have affected attitudes towards whether findings should be fed back. Of these variables, severity and treatability had the strongest influence over whether participants thought the findings should be fed back.
- More people thought that clinically trained researchers were obliged to feedback health related findings compared to researchers who were not clinically trained.

How health related findings should be addressed in the consent process (Section 3.4)

- Respondents thought that participants should receive information on how health related findings would be handled in a study to help them make an informed decision about taking part. This information was seen as a critical part of the consent process. It is therefore essential that information on the management of feedback is presented clearly and in an accessible form that members of the public are able to understand.
- Eight in ten respondents felt that in studies where feedback was going to be given research participants should be given a choice whether or not to receive feedback.
- Generally participants felt that there may be situations where it would be acceptable for an individual's preference to not receive feedback to be overridden, for example if the condition involved could potentially impact others, such as an infectious disease. They thought it was far less acceptable where a potential condition was found that could directly harm the participant.

Mechanisms for the feedback of health related findings (Section 3.5)

- Face-to-face discussion was identified as the preferred way of receiving feedback on a finding. The nature of the condition had some impact on the preference for different channels of feedback, for example where a condition is life threatening and not manageable it was seen as a lot less acceptable to feedback via channels that were not face-to-face.
- Participants generally wanted to receive the result from someone with medical knowledge and expertise, who could ensure the finding was followed up appropriately: usually a GP or a specialist healthcare professional.

* Clinical relevance is how well established the link is between the finding and a specific condition within medical literature. For example, some genetic patterns have been associated with conditions but not proved to be causal and are therefore not clinically relevant.

2. Introduction

2.1 Overview

This report presents the findings of a programme of research carried out among the general public by Opinion Leader on behalf of the Wellcome Trust and the Medical Research Council (MRC).

The research programme comprised:

1. **Qualitative research**, involving eight general public extended focus groups held in London, Cardiff, Belfast and Glasgow. (Conducted 11-13 October 2011 in London and 18-19 October 2011 in Belfast, Cardiff and Glasgow.)

In addition ten **in-depth interviews** were conducted face-to-face with individuals affected by conditions and another ten in-depth interviews were conducted with individuals who had participated in medical research. (Conducted October 2011.)

2. A large-scale **quantitative online survey** of attitudes, opinions and behaviour among 1,105 members of a nationally representative panel. (Conducted 23-30 January 2012.)

A further boost was conducted with non-internet users via a series of **hall tests**. The hall test participants answered the same online questionnaire as the main sample and were assisted (where required) by an interviewer.

This report draws together the findings from the qualitative and quantitative stages in the research programme.

2.2 Background and objectives

Background

During research involving human participants, a finding may be made that has direct significance for the participant's health, revealing an undiagnosed disease or an increased risk of illness, for example. These health related findings may be relevant to the research question (a 'pertinent finding') or completely unrelated (an 'incidental finding'). Health related findings may result from different types of research involving human participants, including imaging and genetic studies.

The most appropriate way to manage health related findings in research is currently a topic of intense debate, and the management of the feedback of health related findings varies widely among research organisations and disciplines. The issue is further complicated by a lack of clear UK guidelines in this area. The Royal College of Radiologists has published guidance for research imaging that say that "within available resources, research centres should endeavour to have in place mechanisms for detecting and providing appropriate medical advice when incidental findings are detected".[†] A similar consensus document has not been produced for any other disciplines.

The Wellcome Trust and the MRC are gathering a range of evidence to inform the development of 'principles' to guide researchers about the feedback of health related findings for researchers. This includes looking at the range of factors that could influence whether findings are fed back, such as

[†] Royal College of Radiologists. Management of Incidental Findings Detected During Research Imaging. London: The Royal College of Radiologists; 2011.

the ethical and legal implications, the impact on research and the views of professionals and the public. There is limited evidence on public or participant attitudes to the reporting of health related findings. The Trust and the MRC commissioned Opinion Leader to undertake this study to address this evidence gap. The 'principles' will take into account these findings on public attitudes and seek to balance these with other factors, including the views of researchers in different fields, health professionals, ethicists and lawyers.

Objectives

The overall aim of this research was to improve understanding of public attitudes towards health related findings in research, to inform those working in this area. The four core objectives for this research were to:

- investigate the general public's attitudes towards the feedback of health related findings to individual participants, including how they view the potential advantages and disadvantages of feedback;
- identify which factors are seen to be most important by the general public when deciding if health related findings should be fed back to individual participants, for example the severity of the medical condition and whether or not it is treatable;
- explore the general public's opinion on how the feedback process should be managed, including identifying preferred feedback routes; and
- explore the views of research participants and those affected by particular conditions on the above topics and establish if, and how, these vary from the views of the general public.

2.3 Methodology

Scoping stage

A period of two to three weeks was set aside to conduct a rapid evidence review of the relevant research that has been published and undertake in-depth interviews with stakeholders. The rapid evidence review included research already conducted by the Trust to ensure that no overlap occurred. During this stage the Opinion Leader research team also conducted five in-depth interviews with experts in the field, two in-depth interviews with individuals who were affected by particular conditions and two in-depth interviews with individuals who had participated in medical research. These interviews were used to further contribute to our understanding of the area and the issues involved and to highlight areas that were seen by the experts, those with conditions and research participants to be of particular importance in the field. The interviewees were also asked if there were any particular areas that they felt may need further exploration in research. The information collected in the scoping phase contributed to making the research materials as meaningful and relevant as possible.

It was agreed during project inception that scenarios would be used in both the qualitative and quantitative stages of the research as they are an accessible way to present complex information to the general public and they provide scope to explore a wide range of different factors/variables at play. Due to the importance of the scenarios, considerable time was spent on their development, working closely with the Trust, the MRC and their stakeholders to develop and refine them throughout the scoping stage.

Qualitative methodology

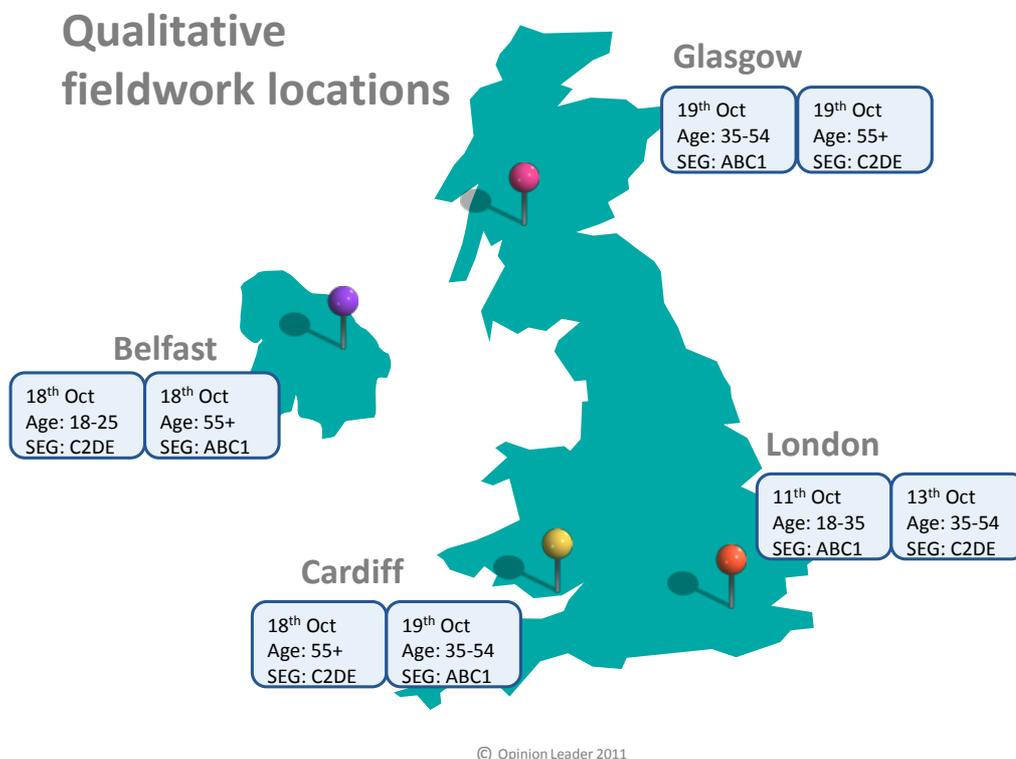
Firstly, eight extended focus groups, each comprising 10 people, were held in London (11 & 13 October 2011), Cardiff (18 & 19 October 2011), Belfast (18 October 2011) and Glasgow (19 October 2011) to give a very broad sweep of the UK. The complexity of the issues involved in this project presented a challenge in terms of research with the general public in that they might not

fully understand the issues involved, or that they might present only an immediate ‘gut’ reaction, without having the opportunity to fully explore the issue. To avoid these outcomes, extended groups of 2 to 2.5 hours were conducted, in which deliberative techniques were used. Extended groups are ideal when the concepts involved are quite complex and opportunity needs to be given to digest them or there are many issues to be debated. They also allow the opportunity to divide and mix people up into smaller break-out groups to debate issues.

Participants were recruited face-to-face by Opinion Leader recruiters in streets, at people’s homes, and at community centres. The following quotas were set to ensure the overall make-up of the groups was broadly representative of the national population: gender, ethnicity, socioeconomic group and age. Groups were divided by age – with three groups held with 18 to 34 year olds, three groups held with 35 to 54 year olds and two groups with those over 55 years – and socioeconomic group.

Figure 1 provides an overview for the locations, demographic make-up and dates of the eight extended focus groups.

Figure 1



Secondly, 10 face-to-face in-depth interviews were conducted with individuals affected by certain medical conditions. They were conducted in parallel with the extended groups and participants were recruited from a list of organisations provided by the Trust and using a free-find method through Opinion Leader’s network of recruiters. The interviewees were:

- Five individuals affected by genetic disorders
- Two individuals affected by cancer
- One individual who has epilepsy
- One individual who has diabetes
- One individual who has cardiomyopathy.

Thirdly, in parallel with the extended groups, 10 face-to-face in-depth interviews were conducted with research participants. A list of research studies was provided by the Trust and the research studies then provided contact with individual participants. The studies included:

- Physiological studies
- Genetic studies
- Treatment trials
- Cohort studies
- Psychological experiments.

The purpose of the 20 in-depth interviews was to explore the greater understanding and different perspectives these groups may have relating to feedback management. For example, those who have already been involved in a trial may be expected to have a clearer understanding of some of the processes involved in giving consent, although this varies from trial to trial. Typically research participants had received feedback from the studies they had taken part in, in formats that ranged from an official letter to a researcher telling them their results verbally during the research. Feedback also varied from confirming that the participants' results were within a 'normal' range to the discovery of a potentially dangerous abnormality.

It was also hypothesised that those affected by a condition would have a more in-depth understanding of the clinical implications of that condition, and could therefore relate this understanding to their view on feedback. Those affected by conditions who had also participated in research had experienced a range of feedback procedures, including receiving no feedback at all as a policy of the study, receiving feedback of some results or only receiving feedback on results that indicated a potential harm to the participants' health. Some had also only received feedback from the research in the form of the final publication of the results.

Quantitative fieldwork

The qualitative component of the work was followed by a wider quantitative survey to explore different issues around health related findings. Before embarking on the quantitative phase, a findings workshop was held with the Trust in which insights from the scoping and qualitative stages were drawn together to create a draft questionnaire. Key stakeholders identified by the Trust and the MRC were also involved as advisors during the questionnaire development stage. The survey was tested in a pilot stage, with a sample of respondents being re-contacted and interviewed about their understanding of the survey questions they had answered and the ease with which they could navigate through the survey.

An online methodology was selected as this allowed sufficient time to present scenarios to explore, and gave the respondent opportunity to consider and respond to them. The representative sample was obtained through Toluna, a leading global online market research company with a global panel community of 4 million members in 42 countries, including around 500,000 members in the UK. Members are recruited to the Toluna community from a broad array of online and offline approaches that best represent the online community as a whole in each country. Members regularly update their profiles, ensuring that the sample answering the questionnaire is relevant to the demographics and additional quotas set. Toluna's quality procedures are in full compliance with ISO standards for market research access panels.

A large enough sample was interviewed to allow for analysis of whether there are any differences in opinions between key demographic groups. Fieldwork was conducted during 23-30 January 2012.

The questionnaire was administered online and an additional 100 surveys were completed by internet non-users via a series of hall tests.

Hall tests are a form of quantitative data collection where respondents complete a questionnaire in a public space or venue after being recruited face-to-face on the street. Recruitment is conducted to strict quotas using 'screener' questionnaires to ensure that the sample interviewed is representative of the target population on certain pre-defined variables. In this case, respondents were selected on the basis that they did not have access to the internet in their homes or regularly use the internet at other locations. In addition to this, quotas were also set on age and gender to be representative of the offline population of the UK (i.e. those who do not have access to the internet).

The hall test participants answered the same online questionnaire as the main sample and were assisted (where required) by an interviewer. In total 1,105 online questionnaires were completed, 100 of these were completed in hall tests by non-internet users. Quotas set for the main sample were gender, age and geographical location of the respondents based on latest available UK Census data. Quotas for the boost sample were set on gender, age and socioeconomic group, based on the UK population of non-internet users.

Once fieldwork was completed, the data was then combined and weighted to be representative of the UK population based on latest available UK Census data. Weighting was applied on gender, age, geographical location and socioeconomic group.

Limitations of the methodology

The methodology used hypothetical scenarios to present complex information on health related findings in an accessible way. However, these scenarios produce 'imagined' reactions that may be very different to how the individual would react when faced by the actual scenario. While the study therefore tells us what participants think that they would like to happen in response to these scenarios, it cannot be assumed that this is what they would decide when faced by the same scenario in real life.

The qualitative research used extended focus groups to explore the views of the participants. In this situation the group discussion shapes individual views. A positive aspect of this is that the discussion encourages participants to think deeply about the issues and form considered views. However, others in the group and the group dynamic will also influence participant views and it cannot be assumed that an individual would have come to the same opinion in a one-to-one discussion.

All qualitative and quantitative research materials were designed to be as accessible as possible for the public, using language that is easy to understand. However, the study demonstrated a limited understanding of medical research among participants, including who conducts it and how research processes work, and therefore the findings should be interpreted accordingly.

2.4 Reporting

In the graphs and tables used for the quantitative results, the figures quoted are percentages. The size of the sample base from which the percentage is derived is indicated. Note that the base may vary – the percentage is not always based on the total sample. Caution is advised when examining responses from a general public sample of less than 100, or when comparing responses between small sample sizes of less than 100 in each case. Also, please note that all sample sizes are subject to 'margins of error', which are outlined in the appendices. The percentage figures for any sample size or sub-group need to differ by a certain number of percentage points for the difference to be statistically significant. This number will depend on the size of the sample and the percentage finding itself – as noted in the appendices. Where an asterisk (*) appears, it indicates a percentage of less than 0.5 but greater than zero. Where percentages do not add up to 100% this can be due to a variety of factors – such as the exclusion of 'Don't know' or 'Other' responses, multiple responses or computer rounding.

2.5 Acknowledgements

We would like to thank Dr Beth Thompson, Dr Anna Wade, Katherine Littler and Halina Suwalowska of the Wellcome Trust for all their help and assistance in developing and delivering this study. We would also like to thank the following, who provided valuable input and peer-review of materials during the project:

Dr Tom Booth, Professor Dian Donnai, Dr Catherine Elliott, Professor Erica Haines, Dr Matthew Hurles, Professor Graeme Laurie, Professor David Lomas, Dr Ultan McDermott, Dr Madeleine Murtagh, Dr Anna Middleton, Dr Christine Patch, Professor Martin Richards, Professor Nazneen Rahman and Professor Joanna Wardlaw.

Thank you also to the Avon Longitudinal Study of Parents and Children, Genetic Alliance UK, the National Cancer Research Network and the Centre for Functional MRI of the Brain who spent time and effort putting us in contact with research participants.

And of course, a large thank you to the 1,209 members of the public who participated in the study.

3. Main findings

3.1 Understanding of attitudes towards, and participation in, medical research

Background and summary of findings

To introduce participants to some of the issues that would be considered by this study, the first questions in the qualitative and quantitative research asked about medical research generally. In the quantitative research, this approach also enabled an individual's attitude towards feedback of health related findings to be compared to their views on medical research in general.

Medical research generated largely negative spontaneous connotations in the qualitative phase of the study, with dominant associations around drug trials and testing on humans and animals. However, there was a generally more positive response towards medical research within the quantitative research. Spontaneous associations placed more emphasis on finding cancer cures or cures for other illnesses and three quarters of the survey respondents said that the advantages of medical research outweigh the disadvantages.

Most people surveyed had never participated in any type of medical research, but for those who had, the most common type of participation was completing a questionnaire or providing a sample of blood or tissue. When asked about future likelihood of taking part in research, more respondents answered that they were "certain to participate" in different types of research than "certain not to participate", with the exception of testing a new drug or treatment, where the opposite was true. In the focus groups, views on motivations to participate in research focused on individualistic gain e.g. payment for taking part or a cure for a condition that they or a family member may have. However, those affected by conditions had a more advanced understanding of medical research and what it involved. Their motivations tended to be less individualistic and more driven by a desire to contribute to scientific understanding.

Among those taking part in this study there was a poor understanding of what medical research consists of and who conducts it, for example limited distinction was made between medical research and the routine provision of healthcare services. The findings of this study should be considered in light of this limited understanding of medical research among many survey respondents and focus group participants. This should also be borne in mind when communicating with research participants about feedback.

The study showed that medical professionals were most trusted to conduct medical research with human participants, but revealed mistrust of the motivations of pharmaceutical companies. This may reflect the lack of understanding around medical research generally and specifically the essential role the industry plays in bringing drugs and other treatments to market.

3.1.1 Perceptions of medical research

Medical research generally generated quite negative spontaneous connotations within the qualitative research. There was limited understanding as to what medical research consisted of, with the dominant ideas being of drug trials and animal testing. These drug trials were seen to involve risk and participants were concerned about consequences of taking part in the trials. There was also limited understanding as to who conducted research beyond the perception of pharmaceutical companies, with groups referring to 'research companies' spontaneously and continuing to use this term despite being informed of other bodies or organisations who carried out research. However, those affected by conditions had a more advanced understanding of medical

research, giving a broader range of types and purposes of studies, and with a deeper understanding of what is involved in many types of research. They were also more aware of the sometimes exploratory nature of research, acknowledging that science was not certain and there was not always going to be a definite outcome. Those who had previously participated in medical research, although a varied group, did have less 'knee jerk' reactions to medical research and their ideas of research were shaped by their own experience.

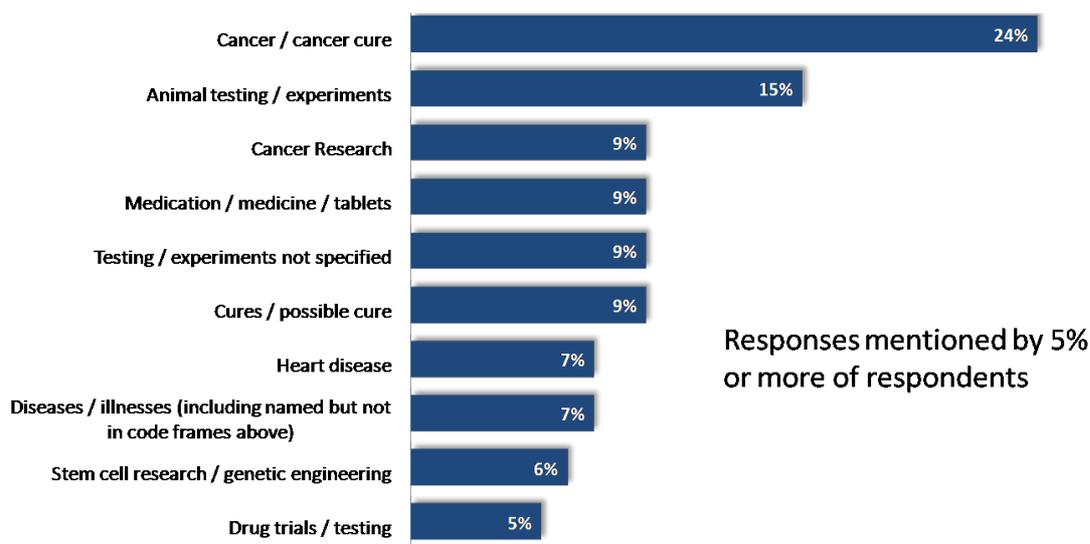
When asked about their unprompted perceptions of the phrase 'medical research' in the online survey, respondents gave a variety of responses. The most common association was 'cancer', 'cancer cure' or 'cancer research', which were mentioned by 24%, 9% and 9% respectively. The other key response was 'animal testing or experiments', given by 15%. Responses generally resonated well with the spontaneous connotations observed in the qualitative research. However, quantitative participants, whilst still citing similar negative associations, tended to be more likely to make positive associations than the qualitative respondents.

Just over a fifth (22%) could not think of any associations with the phrase 'medical research', which indicated fairly low awareness. Most associations increased with age, with younger people (18-34) being consistently least likely to mention most things related to medical research and most likely to say that 'nothing in particular' came to mind in response to medical research (17% compared to 14% overall and 4% among those aged over 65). Those who did not have a long term health condition and those who had never participated in medical research were also more likely than average to say that 'nothing in particular' came to mind in response to medical research (16% and 20% respectively). This finding supported the assertion from the qualitative research that those affected by conditions had a more advanced understanding of medical research and what it involved.

Figure 2 shows responses given by 5% or more of respondents in the online survey. The full list of responses is available in the data tables, available on request.

Figure 2

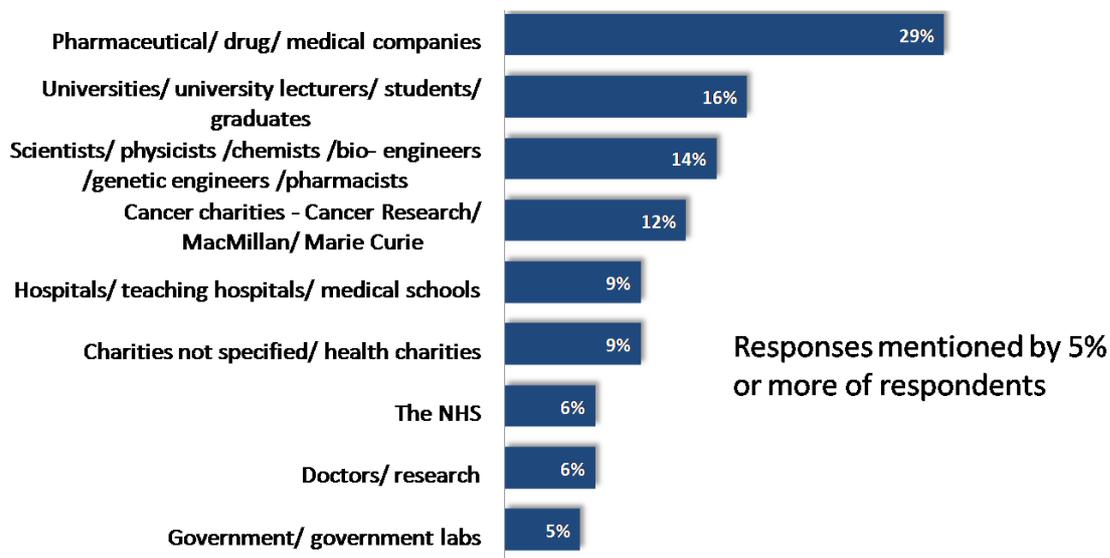
Perceptions of medical research



Q1. What two or three things come to mind, if anything, when you think of 'medical research'? . Base: All Respondents (1105)

Figure 4

Who conducts medical research?

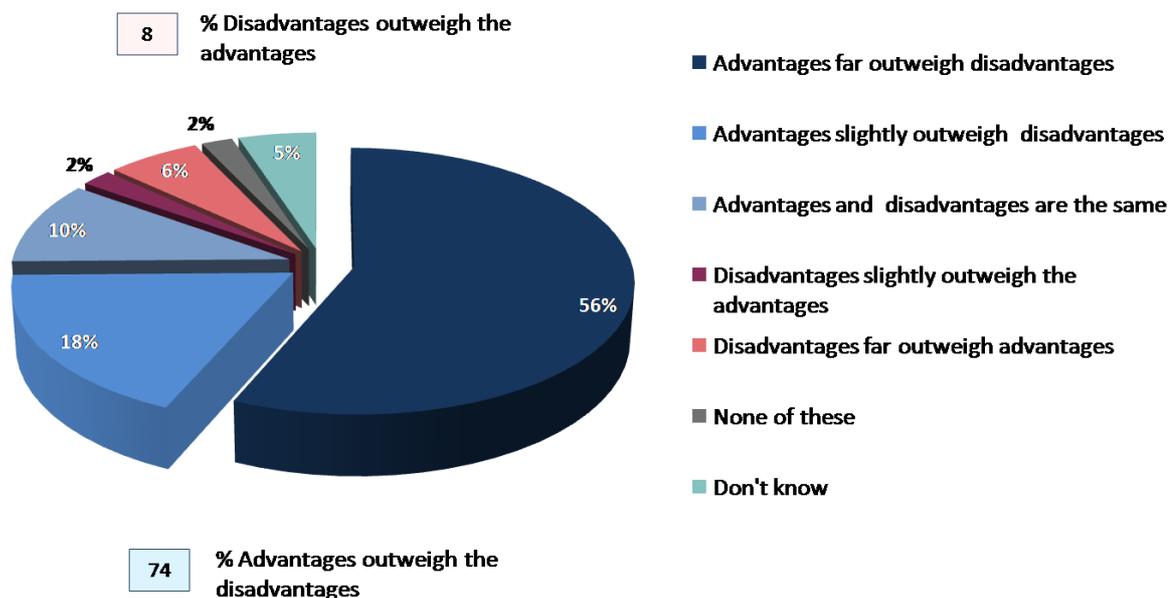


Q2. Which types of people or organisations do you think conduct medical research? Base: All Respondents (1105)

The advantages of medical research were seen by respondents to outweigh the disadvantages by far. As shown in Figure 5 below, just under three quarters (74%) felt the advantages of research outweighed the disadvantages, compared with only 8% who said the opposite. One in ten said that the advantages and disadvantages were about the same. The quantitative findings indicated a more positive general predisposition towards medical research than was suggested in the qualitative stage. This suggested that whilst initial connotations might well be negative e.g. 'animal testing', 'human guinea pigs' and 'profiteering by pharmaceutical companies', there is also a view that medical research is an important activity, the benefits of which, such as 'curing illnesses', outweigh these harms or risks.

Figure 5

Opinions on Medical Research



Q3. Which, if any, of these five statements most closely reflects your own opinion about medical research? Base: All Respondents (1105)

Sub-group differences

Uncertainty about the benefits of medical research was higher among women than men, with 11% of women saying the disadvantages outweighed the advantages compared with 5% among men (8% overall). In keeping with most of the findings discussed in the report so far, those in the highest socioeconomic group (AB) were most likely to be positive about medical research, with 82% saying advantages outweighed disadvantages, while the lowest socio-economic group (DE) were least likely (69%) to say this. Similarly, those in poorer health (74%) were more likely than those in good health (68%) to be positive about the benefits of medical research. Perhaps not surprisingly, previous participation in medical research had a strong influence on perception that advantages of medical research outweighed its disadvantages. Specifically, 78% of those who had previously participated felt that the advantages outweighed disadvantages, compared with 70% of those who had never previously participated in medical research.

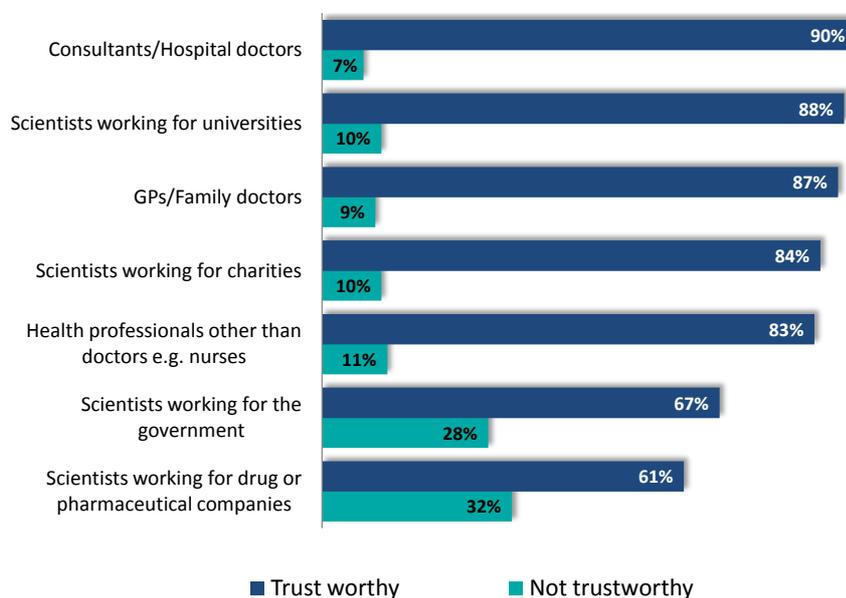
3.1.3 Trust in those who conduct medical research

The majority of the respondents felt that the various types of people involved in medical research which were asked about in this survey were trustworthy in terms of conducting medical research with human participants. However, the size of this majority did vary a little. As shown in Figure 6, consultants and hospital doctors were the most trusted with 90% saying they were trustworthy and only 7% saying that they were not. They were closely followed by scientists working for universities (88% trustworthy, 10% not trustworthy), and GPs/family doctors (87% trustworthy, 9% not trustworthy). Scientists working for charities and the government (seen as trustworthy by 84% and 67% respectively), were more trusted than their counterparts working for pharmaceutical companies (seen as trustworthy by 61%). However, it is worthy of note that almost three in ten (28%) said that scientists working for the government were not trustworthy, which is similar to the proportion who said the same about scientists working for pharmaceutical companies (32%).

This chimes well with the qualitative findings, where there was a deep mistrust of pharmaceutical companies' motivations among participants. A view that frequently emerged was that participants would not trust individual findings made and fed back by a company, as the company may be trying to get them to buy medication that they produced. General lack of trust in pharmaceutical companies may reflect a lack of understanding about the important role that these companies play in medical research. The qualitative research showed that trust in medical research practitioners is based on perceptions of their knowledge and expertise, which helps to explain why consultants and GPs (medical expertise) and universities (scientific expertise) were seen as most trustworthy in terms of conducting medical research among human participants.

Figure 6

Q4. Trustworthiness of those conducting medical research with human participants



Q4. The following is a list of some types of people who conduct medical research. For each one, please state to what extent you consider them to be trustworthy or not in terms of conducting medical research with human participants. Base: All Respondents (1105)

10

Sub-group differences

Trust in those who conducted medical research generally increased with age, mirroring the findings for general attitudes towards medical research. For example, younger people (aged 16-24) were least likely to say consultants or hospital doctors are trustworthy in conducting medical research (81%), significantly less likely to say this than the average (90%) and those aged over 45 (93%). This pattern held true for the different individuals who conduct medical research, with the exception of scientists working for government or pharmaceutical companies, where there were no age differences in perceptions of trustworthiness. Socioeconomic grade was a factor in perceptions of trustworthiness of some medical research practitioners and not others. For example, higher socioeconomic respondents (AB) were significantly more likely than lower socioeconomic respondents (DE) to say that scientists working for charities, drug companies, the government and universities are trustworthy in conducting medical research with human participants. Health professionals including GPs, hospital doctors and consultants were equally trusted across social grades.

Those who felt that the advantages of medical research outweighed the disadvantages were consistently more likely to trust all medical research practitioners than those who felt the opposite. For example, 91% of those who were positive in this way about medical research said GPs were trustworthy to conduct medical research with human participants, compared to 75% of those who felt the disadvantages of medical research outweighed the advantages.

As one might expect, those who had participated in medical research in the past were significantly more likely than those who had not to say they trust most types of medical research practitioners. For example, 63% of those who had participated in the past trusted scientists working for pharmaceutical companies, compared to 58% among those who had not (61% overall). The types of medical research practitioners where there were no differences in this respect were GPs and health professionals who are not doctors.

3.1.4 Participation in medical research

The qualitative research showed that when discussing potential motivations for participating in research there was an emphasis on individualistic gain e.g. payment for taking part, those with a condition trying to find a cure, or healthy participants taking part in research on a condition that a friend/family member has. This finding appears to contradict some of the existing empirical literature reporting that altruism is a key motivation for participation. However, this view has also been challenged by other recent research.[‡] This difference in findings may partly be explained by the fact that qualitative stage respondents typically had no experience of taking part in medical research. Consequently, the answers they gave were based on speculation of motivations rather than drawing on real life experiences.

Those in the qualitative stage affected by conditions had a more advanced understanding of medical research, citing a broader range of types and purposes of studies, and showing a deeper understanding of what is involved in many types of research than those not affected by conditions. They were also more aware of that research can sometimes be exploratory in nature, acknowledging that science was not certain and there was not always going to be a definite outcome. Their motivations to take part in research were less individualistic with a greater emphasis on contributing to medical understanding. Medical research participants who took part in the qualitative phase were a very varied group of individuals. They differed in age by up to 40 years, and were socially diverse. For example, participants had varied educational backgrounds: one participant had learning difficulties and another had English as a second language. They had participated in different types of studies – genetic, physiological and scanning – and had different reasons for taking part, including financial reasons, access to treatment, general interest, research being a last resort, and being signed up since birth. In the qualitative research, few clear findings emerged that were specific to the research participants and that were different to the groups or individuals affected by conditions.

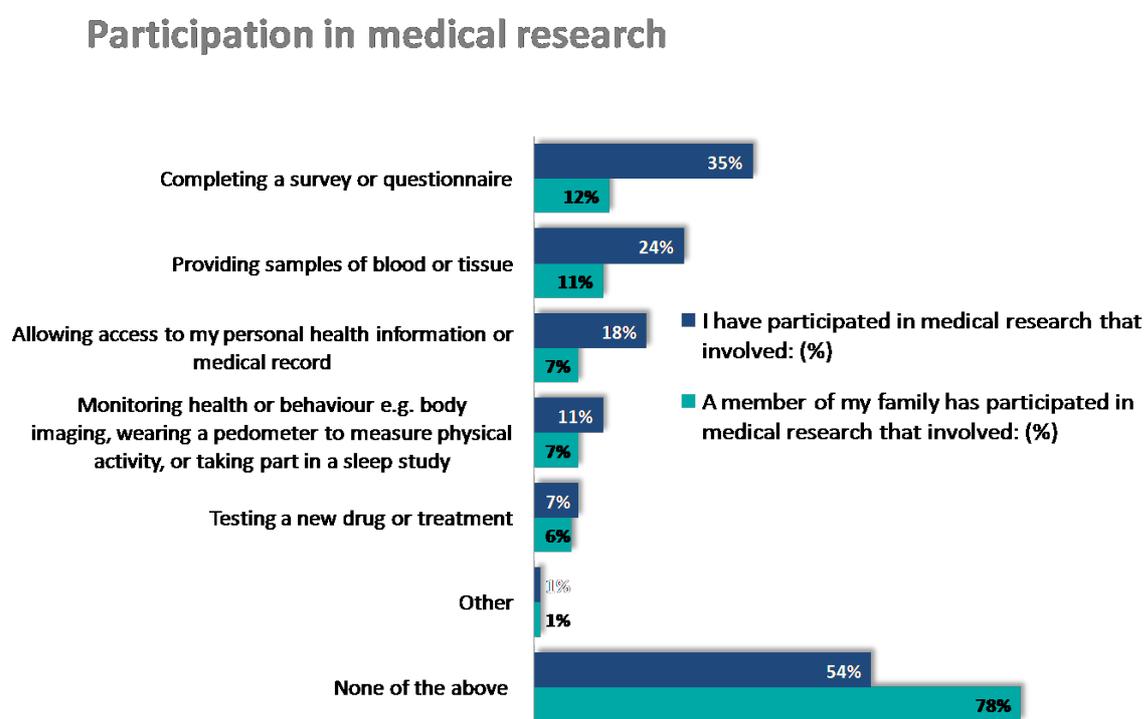
The majority (54%) of survey respondents had never participated in any type of medical research. Just over a third (35%) of respondents had participated in medical research that involved the completion of a questionnaire, a quarter (24%) had provided samples of blood or tissue for the purposes of medical research and just under one in five (18%) had allowed access to their personal health information or medical records (Figure 7). It is important to note that this information on research participation has not been independently verified and therefore is it not possible to account for participants who may, for example, have confused research and a clinical test.

[‡] Hallowell N et al. An investigation of patients' motivations for their participation in genetics-related research. *J Med Ethics* 2010;36:37–45.

Sub-group differences

Men were consistently more likely than women to say they had participated in medical research, as were those in the highest social grades (AB) compared with the average for the sample and those in lowest social grades (DE). Participation did not vary across age groups for most types of medical research, except that likelihood of having completed a questionnaire and provided samples of blood or tissue increased with age. For example just 19% of those aged 16-24 had provided blood or tissue for medical research compared with 44% of those aged over 65. Similarly those with long-term health conditions were consistently more likely to have participated in medical research than those who did not. However, this may be linked to the fact that those with long-term health conditions were also more likely to be in the older age categories, so there may have been substantial overlap with the proportion of older participants who said they had participated in medical research. Those who do not have children are more likely to have participated in medical research than those that do have children.

Figure 7

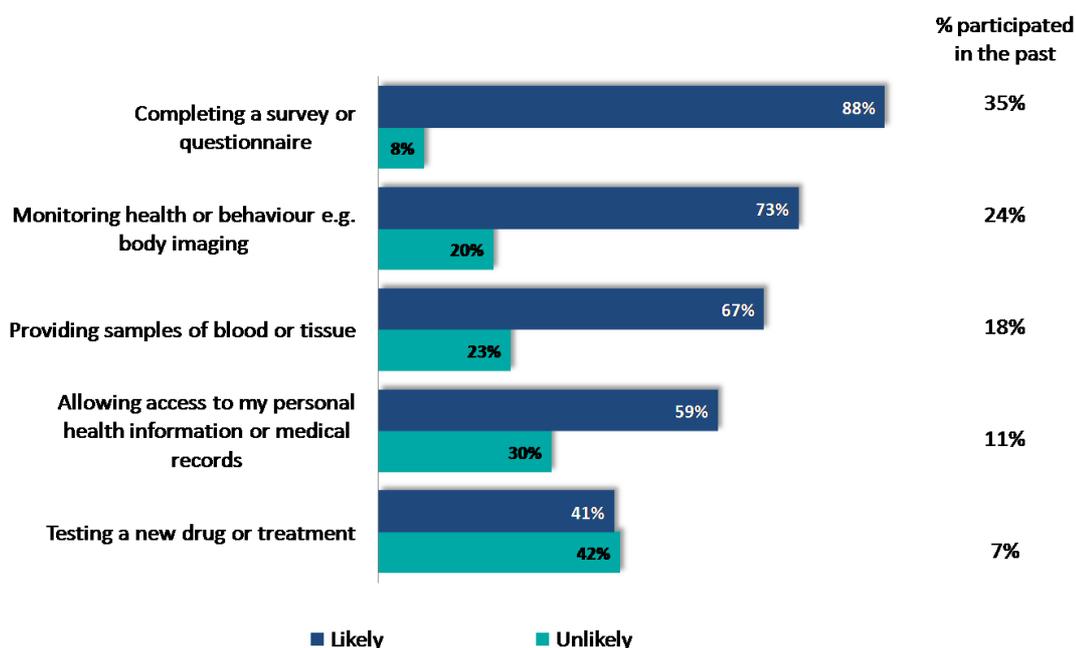


Q5a. Which of the following types of medical research have either you, or a member of your family, participated in? Base: All Respondents (1105)

As shown in Figure 8, the majority of respondents said that they were more likely to participate in medical research of a less invasive nature. For example, just under nine in ten would be likely to complete a questionnaire (8% would be unlikely) and just under three-quarters (73%) would have been prepared to subject themselves to monitoring of their health or behaviour (20% unlikely). However, this proportion reduced where participation involved greater levels of intrusion, such as giving a blood or tissue sample (67% likely, 23% unlikely) and testing a new drug treatment (41% likely, 42% unlikely). Allowing personal health information or medical records to be used for medical research sits in between these two extremes, with 59% likely and 30% unlikely to do so.

Figure 8

Likelihood of participation in medical research



*Q5b. How likely would you be to participate in each of the following types of medical research, if you were given the opportunity to do so ?
Base: All Respondents (1105)*

Respondents' likelihood of participating in certain types of medical research in the future corresponded closely with the types of medical research that they reported to have been involved with in the past. This suggested that respondents found the idea of participating in some types of research more palatable or acceptable than others (see Figure 9). The proportion of those who said they were 'certain to' participate was often one in five or lower, possibly suggesting an understandable degree of caution in basing this decision on limited information. Nevertheless, the proportion saying they were 'certain to participate' was almost always significantly greater than the proportion who said they would be 'certain not to'. The exception to this was testing a new drug treatment, where the reverse was true.

Figure 9

Q5b. How likely would you be to participate in each of the following types of medical research, if you were given the opportunity to do so? MULTICODE (base = 1005)	Certain to	Certain not to
Completing a survey or questionnaire	42%	3%
Monitoring health or behaviour e.g. body imaging, wearing a pedometer to measure physical activity, or taking part in a sleep study	21%	6%
Providing samples of blood or tissue	18%	6%
Allowing access to my personal health information or medical records	16%	9%
Testing a new drug or treatment	6%	14%

The quantitative findings on participation in medical research substantiated the qualitative findings. The respondents generally appeared to find some types of research more appealing than others, with the less invasive types of medical research generating the most positive responses around past and future participation.

Sub-group differences

Sub-group differences for likelihood of participation in medical research mirrored those for previous participation. Men, those in higher social grades (AB), those with long-term health conditions, and those who did not have children were more likely to say they would participate. Likelihood of participation also increased with age, from its lowest in the 16-24 group to its highest among those aged over 55. An exception to this pattern was likelihood of testing a new drug or treatment, where there were no significant differences by social grade or whether the individual had children or not. Another exception was allowing personal health information or medical records to be used, for which there were no significant sub-group differences in likelihood of participation.

3.2 The benefits and harms of receiving feedback

Background and summary of findings

Sometimes during medical research involving people, researchers can discover findings that relate specifically to an individual participant's health. For example, they could find out in the course of the research that a participant has a particular disease. These findings are defined as 'health related findings' and the majority of the qualitative and quantitative research was dedicated to exploring participants' views on these.

Health related findings may be identified as part of the aims of the research – 'pertinent findings' – or they may be 'incidental findings' that are unrelated to the aims.

This study showed that there was a general perception that the benefits of feeding back health related findings outweighed the harms, with almost eight in ten of the survey respondents of this opinion. Spontaneously cited benefits can be grouped around two categories: benefits to the participant themselves and benefits to their relatives. Many, but not all, of the perceived benefits assume that follow up support or care will be available after a finding is fed back to a research participant.

Spontaneously mentioned drawbacks of feedback included: shock and worry; hypochondria; findings that are later found not to be real (or 'false positives'); health insurance being affected; and the risk that information fed back would not remain private.

Perceptions of possible reasons why health related findings should or should not be fed back were explored. The most important reasons to feed back findings were deemed to be if the condition could put others at risk and if steps could be taken to manage or treat a condition. The most important reason not to feed back findings was that the results may be incorrect, unclear or inaccurate. Consistent with findings that there was an overwhelming desire for feedback, respondents considered the reasons why health related findings should be fed back to be far more important than the reasons why they should not be fed back. Further work to explore perceptions of the disadvantages of feedback would be useful.

Definition of health related findings

This research defined health related findings as those discovered during research with human participants that relate specifically to an individual participant's health. For example, researchers could find out in the course of a research study that a participant has a particular disease. This broad definition included both incidental and pertinent findings and findings of varying severity, and therefore enabled the research to probe a range of attitudes and perceptions without pre-judging these. Participants spontaneously discussed both the reporting back of findings that might have negative implications for their health, as well as findings that indicated that they were healthy or had nothing to be concerned about. However, the scenarios used throughout the research focused on findings that had negative implications for the health of an individual.

The concept of 'feedback' was not explicitly defined in this research but focused on the initial delivery of information about a finding to an individual. The study considered the mechanism of feedback and, to some extent, the further support that an individual might need once they have received feedback.

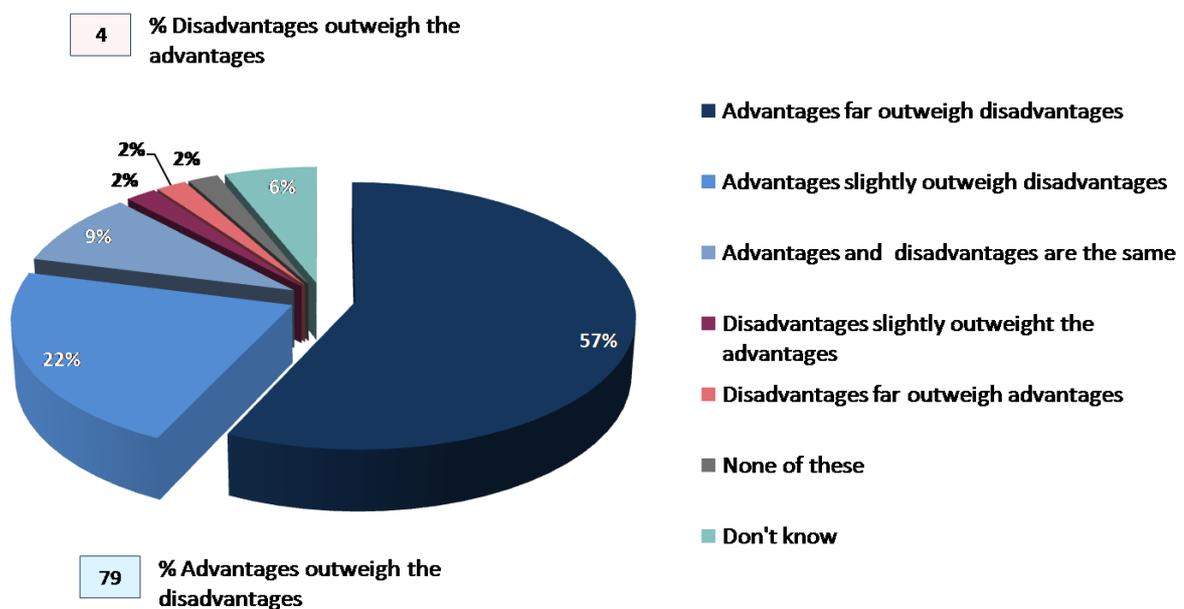
3.2.1 The balance between the benefits and harms of feeding back health related findings

The study showed that there was a general perception that the benefits of feedback outweighed the harms in both the qualitative and quantitative stages of the study. The shock and longer term worry of feedback was appreciated, but not thoroughly considered, and perceived as being far outweighed by the benefits of feedback.

The advantages of feeding back health related findings were seen by survey respondents to far outweigh the disadvantages. As Figure 10 shows, just under eight in ten (79%) felt the advantages of this outweighed the disadvantages, compared to only 4% who said the opposite. Just over a fifth (22%) said that the advantages and disadvantages were about the same. This supported the general perceptions found in the qualitative research.

Figure 10

Overall opinions on feeding back health related findings



Q8. Which, if any, of these five statements most closely reflects your own opinion about feeding back Health Related Findings in medical research to participants? Base: All Respondents (1105)

Sub-group differences

Many of the significant sub-group differences in respondents' perceptions on this issue mirrored those found for perceptions of the advantages versus disadvantages of medical research. For instance, men (84%) were more likely than women (75%) to say that the advantages of feeding back health related findings outweighed the disadvantages. In keeping with most of the findings discussed in the report so far, those in younger age groups were least likely to be positive, with 68% saying the advantages outweighed the disadvantages compared with the highest proportion of 88% among those aged over 55. Similarly, those who had a long-term health condition (84%) were more likely than those who did not (77%) to be positive about the advantages of feeding back health related findings. This resonates well with the qualitative research, where those with existing

conditions were generally particularly positive about receiving feedback as it provided them with information on their condition and reassurance about their health generally.

Perhaps not surprisingly, previous participation in medical research and future inclination to do so was associated with a perception that advantages of feeding back health related findings outweighed the disadvantages. Specifically, 84% of those who had previously participated felt that the advantages outweighed disadvantages, compared with 75% of those who had never previously participated in medical research. 82% of those likely to participate in any medical research felt the advantages outweighed the disadvantages, compared with 53% of those who said they were not likely to participate. Finally, those who did not have children in their household (82%) were more likely than those who did (75%) to be positive about the benefits of feeding back health related findings relative to the disadvantages.

3.2.2 Exploring the benefits and harms of feeding back health related findings

Within the qualitative groups and in-depth interviews the definition of health related findings, and the various contexts in which they might occur, were explained to the participants. Following this, participants engaged in a detailed discussion of the various potential benefits and drawbacks of feeding back. The key findings are summarised below:

Benefits for the health of the participant:

- Early detection of a condition
 - More effective treatment and management of a condition
- Awareness of the risk of developing a condition
 - Lifestyle changes to reduce risk (which may also improve general well-being)
 - Monitoring allows earlier diagnosis e.g. regular screenings and self-examinations
- Psychological preparation
 - End-of-life arrangements
 - Preparation for a decline in quality of life

“Gives you time to get treatment if it's possible, or to make arrangements...Allows you to make an informed decision, so you give yourself an element of control...and life changing - you might become inspired to go rock climbing or something.”

Focus group participant, Cardiff

“You may have a condition where you can prevent further problems by your lifestyle...You diet, or do not drink too much...You know, prevent other things.”

Focus group participant, Glasgow

Benefits for relatives of the participant:

- Psychological preparation
 - End-of-life arrangements
 - Family can be vigilant for development of symptoms and manage accordingly

For genetic findings that may be present in other family members or inherited by the participant's children, there were additional perceived benefits:

- Family members prompted to seek screening
 - Earlier diagnosis of heritable conditions
- Allows decisions to be made about whether or not to have children
 - Couple may decide not to have children

- Children of the participant may decide to not have their own children

“You’ve got the choice then to respond...and for your family to be aware also, if maybe there’s a possibility it’s hereditary, or there’s maybe a female carrier or a male carrier with an illness.”

Focus group participant, Cardiff

“After the initial shock it would be like ‘I need to put things in place, there are three kids there that need to be looked after’.”

Focus group participant, Glasgow

Benefits cited by people affected by conditions:

- Feedback provides information on condition
 - This helps to confirm the type of condition that they have and allows them to identify with others affected by the same condition
 - More information means they may be more empowered to seek treatment
 - Knowing the origin of the condition may alleviate concerns that they were responsible for it i.e. that it is due to genetics and not lifestyle
- Reassurance
 - Some of those with conditions also considered that feedback on health related findings could show that everything is fine. In this case, it was felt that findings would be fed back to the participant which gave a positive indication they were healthy
- Finding out that they have additional conditions means they may be able to participate in other studies
 - Contributing to further advances

“It’s to do with your sense of identity as well, I think. So, I had that test done to find out exactly what form of muscular dystrophy I’ve got and the genetic mutation.”

Person with condition

“Things are going on and you just have no idea because you get up every day and you have aches and pains but, you know, you’re still breathing and getting on with things so for me the benefits is knowing that there is nothing going on.”

Person with condition

Drawbacks cited by qualitative participants:

- Shock and worry
 - Exacerbated by not knowing what to do with the information and how to act
 - Depression or fatalistic behaviours e.g. smoking, drinking, poor diet
- Hypochondria
 - Obsessing about health, with any small sign of illness becoming a concern
- False positives
 - Resulting in unnecessary worry
- Health insurance companies may request individuals to disclose information about their health
 - Could impact on insurance premiums

- Lack of privacy of any feedback

“It might create unnecessary worry which potentially could lead on to psychosomatic illnesses. You think you’re ill, you’re going to be ill.”

Focus group participant, Cardiff

“You’re suddenly dropped right in at the deep end and that’s a massive thing to try and overcome.”

Focus group participant, London

Drawbacks cited by qualitative participants with an existing health condition:

- Feedback relating to heritable conditions may provoke blame towards oneself or relatives
- Genetic findings could indicate mis-attributed paternity of a child
- One person felt that she had enough to worry about already and did not want the extra burden of feedback

“I mean there are certain things that are only related to like ethnic groups and that and it could be that somebody has it, it could split a family up. Truth will out sort of thing.”

Person whose child has a condition

“I think that I’ve got enough on my plate without needing to know anything else that I can do nothing about.”

Person whose child has a condition

Due to the diversity of the research participants’ responses, no consistent findings emerged that related only to this group. However, a drawback worth noting for one of the parents of a young participant was the guilt they felt because they were receiving a lot of health information on their one child involved in the research but not for their other children not involved in the research.

“I might feel a bit like a bad mother in the fact that my other two that weren’t part of the [long term study]. What did I miss in their growing up which [the study] has actually picked up in [my daughter].”

Research participant

From the findings from the qualitative stage, a comprehensive list of possible reasons why health related findings should or should not be fed back to participants who take part in medical research was drawn up. This was presented to survey respondents, who were asked to indicate how important they believed each reason to be. The order in which the pro and con arguments were discussed was alternated between surveys so that half of the sample saw pros first and half saw cons first. The individual reasons within each list were also rotated between interviews so that the order was varied.

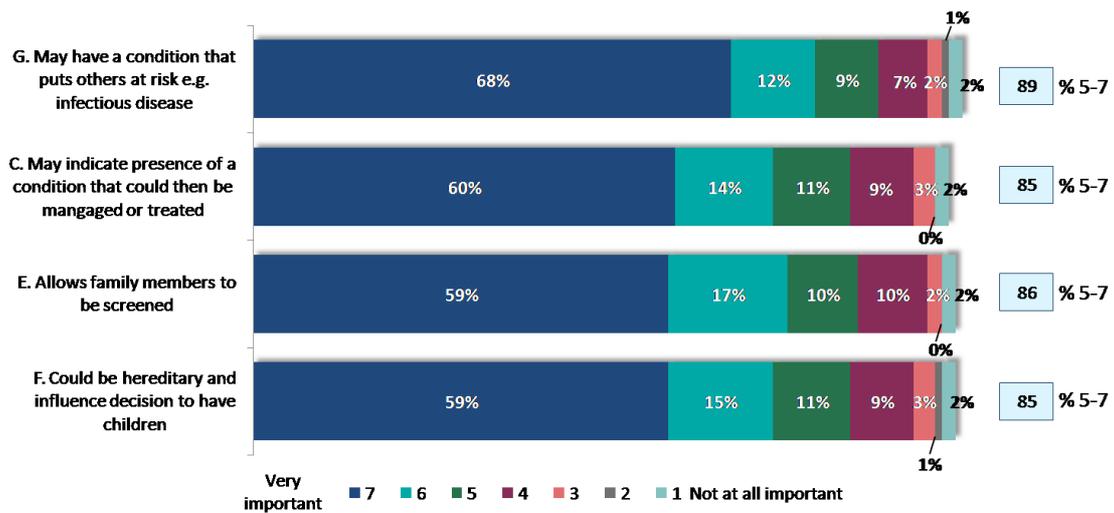
Over eight in ten survey respondents thought that each of the reasons why health related findings should be fed back were important (Figure 11a). Looking at the numbers of respondents who chose the highest rating of importance (7 on the scale), more differentiation between the scenarios is possible. For example, respondents were significantly more likely to rate “They may indicate the participant has a condition that puts others at risk” as very important, compared with all other potential reasons why health related findings should be fed back. The reason least likely to be rated as very important was “Participants should be able to access information about their health”, as displayed in Figure 11b.

Sub-group differences

Sub-groups more likely to place importance on reasons for feeding back health related findings mapped onto those most in favour of feeding back generally – older age groups, those with long-term health conditions and previous and potential medical research participants.

Figure 11a

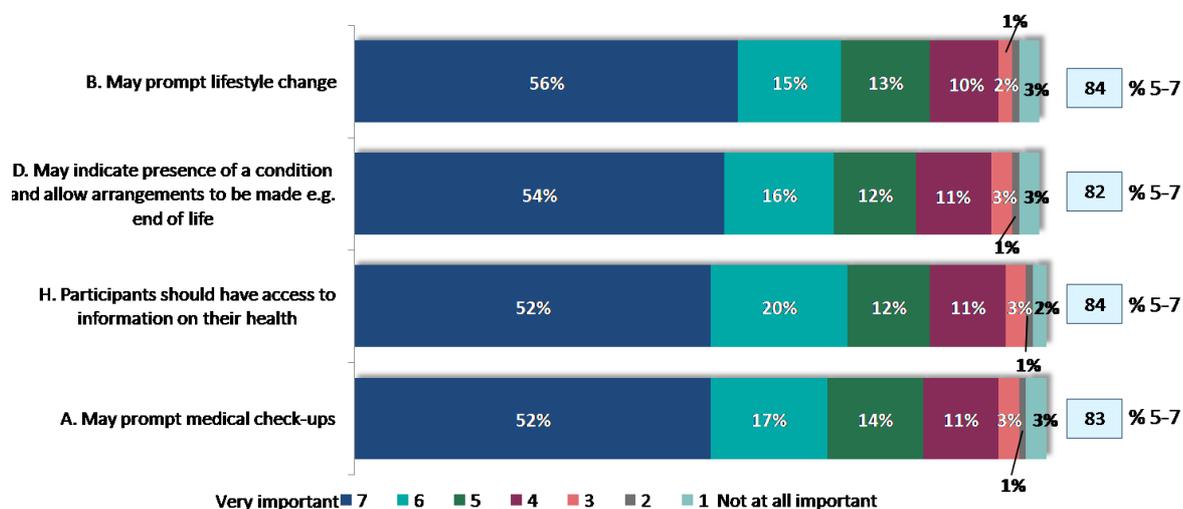
Importance of reasons why HRFs should be fed back to participants (part 1)



Q12. Below are some possible reasons why Health Related Findings should be fed back to participants who take part in medical research. Please indicate how important you believe each of these reasons are with 1 being not at all important and 7 being very important. Base: All Respondents (1105)

Figure 11b

Importance of reasons why HRFs should be fed back to participants (part 2)



Q12. Below are some possible reasons why Health Related Findings should be fed back to participants who take part in medical research. Please indicate how important you believe each of these reasons are with 1 being not at all important and 7 being very important. Base: All Respondents (1105)

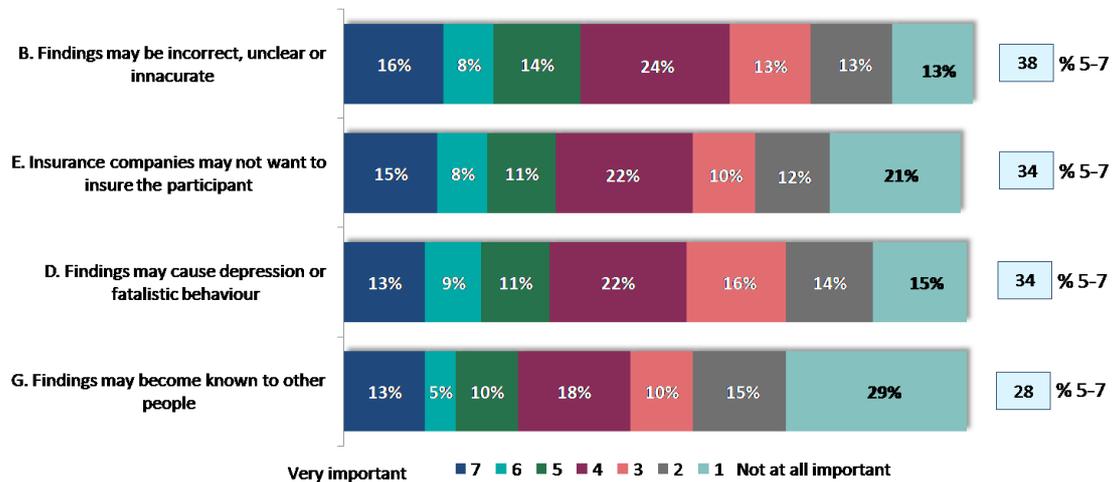
The relative importance placed on the potential benefits of feeding back health related findings corresponded well to the potential benefits identified by the qualitative research. Specifically, the early detection of a condition (or the risk of developing a condition) that may need treatment was a key motivator so the person (and their family) can seek appropriate medical care and begin to make adjustments in their lives.

Respondents generally placed much less importance on reasons not to feed back than on reasons to feed back. This reinforces the positive stance towards feeding back health related findings generally shown throughout this study. The reason that respondents considered most important was that “the results may be incorrect, unclear or inaccurate”, which was cited by 38% as important (Figure 12a). Two reasons why health related findings should not be fed back were significantly less likely to be rated as important than other reasons, and these were: “findings could have implications on a person’s lifestyle” (25% important) and “findings may become known to other people” (28% important), as shown in Figure 12b.

Those who were negative overall about medical research and those who said they were unlikely to participate in medical research in the future were both most likely to rate reasons for not feeding back as important. There were no other significant patterns in sub-group differences in ratings for the reasons for not feeding back.

Figure 12a

Importance of reasons why HRFs should not be fed back to participants (part 1)



Q13. Below are some possible reasons why Health Related Findings should not be fed back to participants who take part in medical research. For each reason please indicate how important you believe each of the reasons are with 1 being not at all important and 7 being very important. Base: All Respondents (1105)

Figure 12b

Q13. Importance of reasons why HRFs should not be fed back to participants (chart 2)



Q13. Below are some possible reasons why Health Related Findings should not be fed back to participants who take part in medical research. For each reason please indicate how important you believe each of the reasons are with 1 being not at all important and 7 being very important. Base: All Respondents (1105)

It was hypothesised that after reviewing the lists of the potential pros and cons of feeding back health related findings to medical research participants, respondents in this survey might have formed a different view on the relative advantages versus disadvantages of feeding back health related findings to the one which they generated spontaneously. To this end we asked the same question about how respondents weighted the advantages of feedback compared to the disadvantages again after they rated the various pros and cons for importance. As shown in Figure 13 below, opinion on the relative balance between advantages and disadvantages of feeding back health related findings did not change. This indicated that in the context of this survey, the initial finding – that the respondents saw the advantages of feeding back as significantly stronger than the disadvantages – was robust. However, further research would be beneficial to probe in more detail understanding and perceptions of the disadvantages of feedback.

Figure 13

Opinions on feeding back health related findings, before vs. after reviewing pros and cons

Statement	Q8 (%)	Q14 (%)	% point change
The advantages of feeding back Health Related Findings to a participant far outweigh the disadvantages	57	57	-
The advantages of feeding back Health Related Findings to a participant slightly outweigh the disadvantages	22	21	-1
The advantages and disadvantages of feeding back Health Related Findings to a participant are about the same	9	10	+1
The disadvantages of feeding back Health Related Findings to a participant slightly outweigh the advantages	2	2	-
The disadvantages of feeding back Health Related Findings to a participant far outweigh the advantages	2	2	-
None of these	2	2	-
Don't know	6	6	-

Q8. Which, if any, of these five statements most closely reflects your own opinion about feeding back Health Related Findings in medical research to participants? Base: All Respondents (1105)

Q14. Which, if any, of these five statements most closely reflects your own opinion about feeding back Health Related Findings in medical research to participants? Base: All Respondents (1105)

3.3 When health related findings should and should not be fed back

Background and summary of findings

Among researchers, health professionals and the ethics community, there has been significant debate around when the benefits of feeding back health related findings would be sufficient to outweigh the potential harms, and which variables determine this. Some principles are beginning to emerge from this debate, for example that findings should only be reported back when they have important and well-understood health implications for the participant and when the participant has indicated that they would want to receive such feedback.[§] Both the qualitative and quantitative phases of this study explored the public's perspectives on this issue.

Among those sampled there was a very strong desire to receive feedback on health related findings. The study explored a number of different factors or variables that may affect attitudes towards whether findings should be fed back. Of these variables, severity and treatability had the strongest influence on views towards feedback, with widespread agreement that findings related to conditions that are severe but manageable should be fed back. Opinions were most divergent around whether feedback should be provided on conditions that are severe but not treatable or manageable.

There is very limited empirical evidence on the views of research and healthcare professionals and the ethics community on the factors that affect feedback. However, the findings of this study appear highly consistent with the emerging view appearing from professionals: that feedback is appropriate where it indicates a condition that is both severe and treatable or manageable, since these possibilities offer the greatest potential to be acted on for the benefit of the participant.

While the majority of participants demonstrated a strong desire to receive feedback in a variety of scenarios presented to them, there was also a recognition that some individuals may prefer not to receive feedback at all.

These findings are consistent with the limited evidence available that suggests that most research participants would want to be informed of findings. For example, 90 per cent of research participants responding to a survey in the US in 2005 said that they would want incidental findings communicated to them.** In a survey in the Netherlands, majorities of 66% to 88% of the respondents would 'probably' or 'definitely' like to be informed if they had a gene mutation themselves in particular scenarios.††

Within the qualitative stage there was an overriding feeling from respondents that researchers should feed back health related findings to participants and that it was a participant's *right* to receive this feedback as it pertains to their bodies and health.

"[The scenario character] has volunteered to be part of the study he has a right to know what they have found."
Research participant

[§] Fabsitz RR et al. Ethical and practical guidelines for reporting genetic research results to study participants. *Circ Cardiovasc Genet* 2010;3:574–80. <http://circgenetics.ahajournals.org/content/3/6/574.full>

^{**} Kirschen MPet al. Subjects' expectations in neuroimaging research. *J Magn Reson Imaging* 2006;23:205–9.

^{††} Bovenberg J et al. *Always Expect the Unexpected*. Nijmegen, Netherlands: Centre for Society and Genomics; 2009. pp. 24–32.

“It’s all about choice isn’t it...if you’re going to say in extreme cases you should just pass a law that says doctors shouldn’t tell patients, that’s effectively people playing god, you’re deciding that person, you’re not giving that person choice, what we’re actually saying is about choice, people making choices in your life.”

Focus group participant, London

There was recognition, however, that sometimes a participant may not *want* feedback. Whether a participant would want feedback or not was seen as being strongly linked to the participant’s personality. The participants in the qualitative stage identified two main personality types with reference to feedback preferences:

- Those that wanted to know everything about their health in order to manage it or prepare for potential poor health. This type of person would want to be given feedback irrespective of the type or severity of the condition.
- Those that believed that ignorance is bliss and would not want to receive feedback as they would not want to worry needlessly.

“It’s individual how people can handle the truth because they can make it be the end and it’s not, in their minds.”

Focus group participant, Cardiff

“It makes me feel like I’ve got more control over my body perhaps. I like to think I’m quite aware of what I eat, what I drink, what I do to keep fit and to keep healthy. Some people might not care.”

Research participant

3.3.1 External variables that could influence the desire for feedback

Twelve variables, which had been identified in the scoping phase, were introduced and tested across the eight scenarios used in the qualitative stage. Each scenario was a realistic situation in which health related findings may have been detected; variables were introduced sequentially once the participants had familiarised themselves with the initial scenario.

The 12 variables, and the groups they were categorised into, are outlined in Figure 14 below:

Figure 14

Variable	Explanation
The condition	
Severity	The degree to which the identified condition is life threatening or debilitating.
Treatability	The extent to which the condition can be treated, managed or cured completely.
Risk of condition	Where the finding relates to disease risk rather than an actual disease, for example a genetic pattern: this is the chance of the condition occurring given the finding identified. If the condition is highly likely to occur, the finding is thought to be high risk.
The result	
Clinical relevance or validity	How well established the link is between the finding and a specific condition within medical literature. For example, some genetic patterns have been associated with conditions but not proved to be causal and are therefore not clinically relevant.
Accuracy or analytical validity	How accurate the finding is based on the instruments and procedures used to measure them. For example, in some scanning studies the images produced are well below the quality used for clinical diagnosis.
Pertinent versus incidental	Whether the finding was related to the main aim of the research study, or if it was a finding that was completely unrelated to the main research aim.
The methodology of the study	
Setting of research	Where the research took place, for example in a university, private pharmaceutical company venue or medical setting such as a hospital or health centre.
Consent	What the individual had been told during the consent process about feedback of health related findings, and if they had requested not to have findings fed back.
Secondary research	When research is being conducted by a secondary research team, not the team responsible for the initial data collection and analysis.
Time elapsed since samples or data collected	How long after the initial data or samples are collected that the findings are fed back.
The 'right not to know'	Whether a participant who has decided not to receive feedback has an absolute right not to be told about a finding. This included exploration of whether the 'right not to know' could be overridden in certain circumstances, for example where the condition could have potential impacts on individuals other than the participant.
The participant	
Age of participant	To what extent the age of the participant affects views on feedback. For diseases that develop in later life, the participant's age will affect the time between a finding being made and the likely onset of disease.

The quantitative stage also included some, but not all, of these variables, focusing on those variables that appeared to have the most influence on attitudes, or that could have a high impact on feedback procedures.

➤ The condition: treatability and severity

Within the qualitative stage the two most influential factors when considering whether to feed back health related findings to participants were the severity and treatability of the condition. There was a clear relationship between these two variables and how certain respondents were about the necessity to feed back health related findings to the participant.

If the health related finding could indicate the presence of a condition that was potentially **severe** and could also be **treated**, e.g. blood pressure or a potentially cancerous lump that could be removed, there was consensus that feedback should be given.

“We thought she should know, we couldn’t think of a reason why not. The reason why she should know is that it’s potentially fatal and perfectly treatable.”

Focus group participant, Glasgow

If the health related finding was a condition that was perceived as **not severe** it was still felt, in principle, that feedback should be given. This was in line with the overriding view that researchers should feed back health related findings to participants as it was the participant’s right to know.

“Yeah [Parkinson’s is] much more serious than eczema, I mean yeah it’s more important to be told about Parkinson’s but I think still the general principle holds.”

Focus group participant, London

Despite the overarching view of the importance of feedback, in cases where the condition was not severe it was acknowledged by respondents that the speed and urgency with which the feedback needed to be given was of less importance than the more severe conditions.

“I still think it’s important to feed it back but it doesn’t have the same implications if Thomas [the character in the scenario] doesn’t find out this week as opposed to in three weeks’ time, he’s not going to suddenly die from his eczema.”

Person affected by a condition

If the condition was less severe it was also thought by some that the potential negative impacts of feeding back findings could be less than if dealing with a severe condition.

“It’s not like – well eczema doesn’t seem that bad, it’s not like very severe is it? In that sort of sense it can be, I guess, but it doesn’t sound that severe so I don’t think that there’s going to be many disadvantages to letting him know.”

Research participant

Where the implications of health related findings were severe and the condition was untreatable or terminal, e.g. Parkinson’s disease, participants were divided in their preference for feedback and there was a lot less certainty about whether it would be beneficial for the participant to receive feedback. One view held was that participants who received findings indicating a severe and untreatable condition could experience psychological distress, and potentially suicidal feelings. An opposing view was that having such knowledge allowed participants to research potential new treatments for the condition, and also gave them and their family time to prepare emotionally and financially for the progression of their condition.

“So say there is no cure by the time I get to 50 at least I know that if I’m not able to look after my kids that somebody else can look after them, they’re financially secure, that everything’s in place should I not be capable or able.”

Focus group participant, Belfast

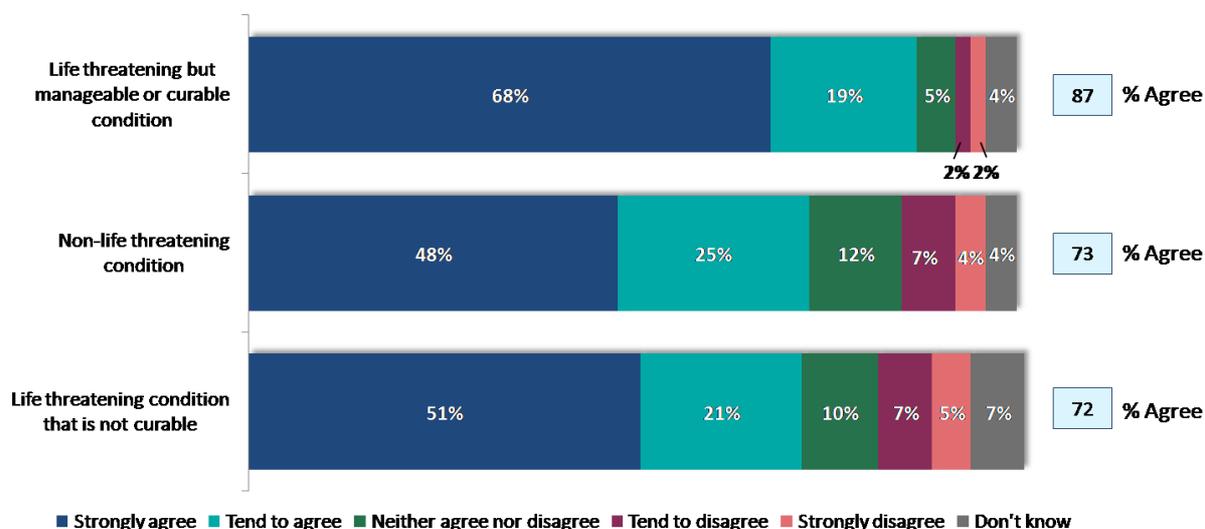
The quantitative results supported the qualitative findings in showing that the majority of respondents believed that health related findings should be fed back to participants in the majority of cases. The results also gave further information on the important relationship between the two variables *treatability* and *severity*, which were found to have a strong influence on respondents’ view of whether to feed back health related findings to a participant.

Genetic health related findings

When considering feedback from genetic research, 87% of respondents agreed that they would want to have findings fed back if researchers found that they had a genetic pattern linked to a life threatening condition which was manageable or curable. However, as Figure 15 shows, this dropped to 73% agreement if the condition was not life threatening and 72% agreement if the condition was life threatening but not curable.

Figure 15

Preference for feedback if genetic patterns were found that linked to conditions of varying severity



Q9. Imagine that you personally took part in some medical research where your genes were analysed. To what extent do you agree or disagree that you would want to be told if the researchers found: a genetic pattern linked to a... Base: All Respondents (1105)

Significantly more people did not know if they wanted feedback for a condition that was life threatening and did not have a cure, compared to those conditions that were not life threatening or conditions with a cure (7% compared to 4% and 4% respectively). These results may indicate the difficulty of balancing the potential harms with the potential benefits when feeding back the findings for serious conditions that are not treatable.

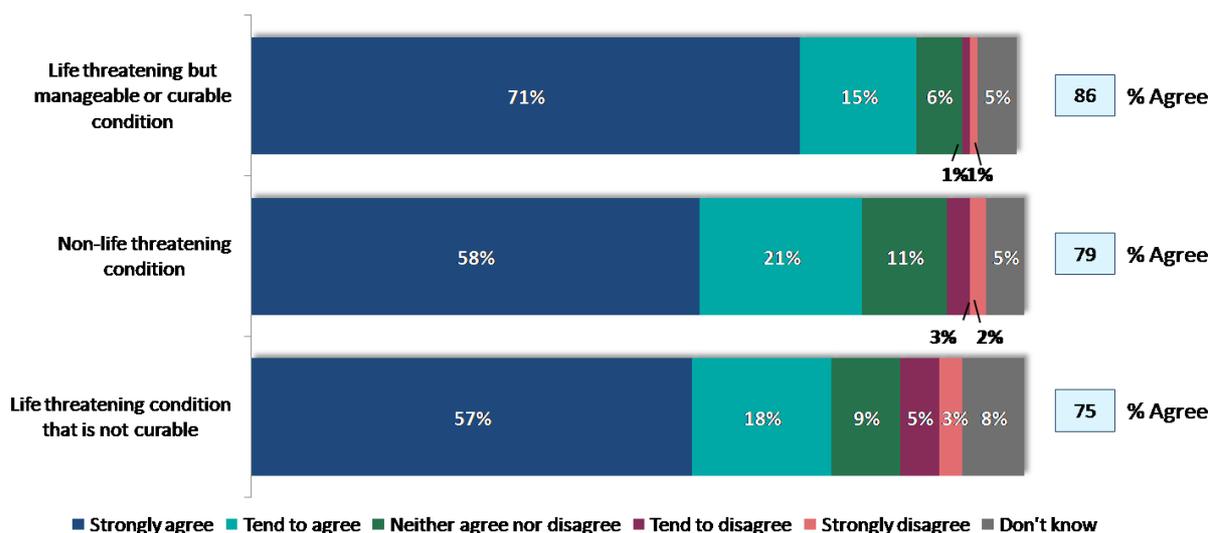
Feeding back findings to the parents of children under 16

Participants were asked to imagine a situation in which they could receive feedback from a genetic study in which their child had taken part. The trend in the findings mirrors that for personal feedback, with the desire to have findings fed back greatest where the findings were linked to a condition that was life threatening but manageable or curable (86% agreed). For conditions that were not life threatening, 79% of respondents wanted the findings fed back, whilst only 75% of respondents wanted feedback on a life threatening condition that was not curable.

The most significant difference between feedback preferences for respondents *themselves* and preferences for their *children* was the desire to get feedback on conditions that were not life threatening. Whilst 73% of respondents agreed they would like feedback if it was found that *they* had a genetic pattern that was linked to a condition that was not life threatening, 79% would want to know if this pattern had been found in their children.

Figure 16

Preference for feedback if genetic patterns were found in respondents' children that linked to conditions of varying severity



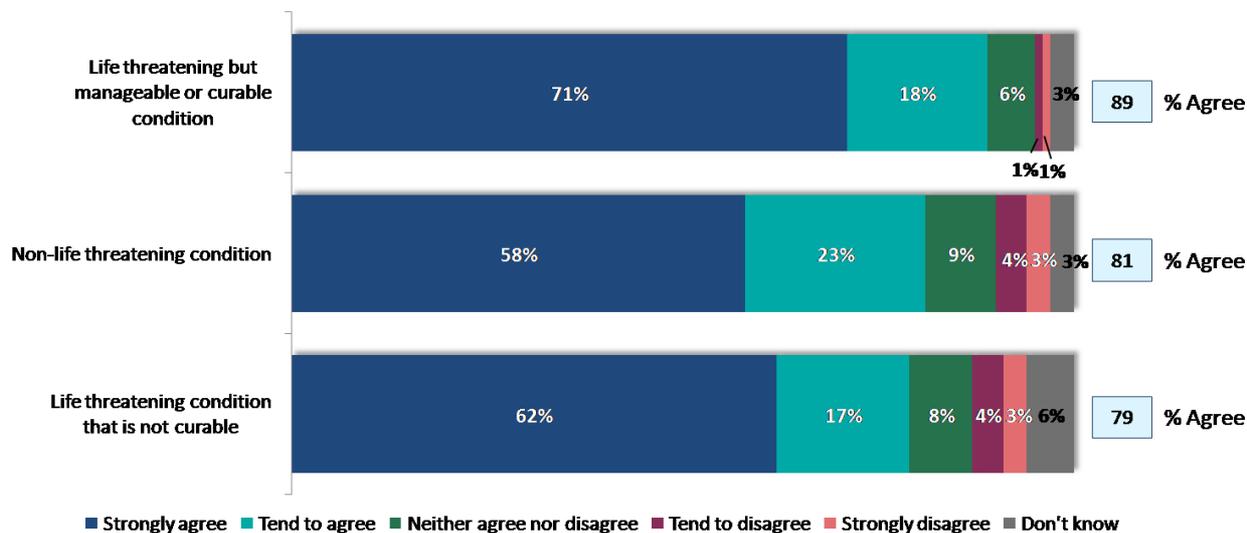
Q10. If you were a parent or guardian of a child under the age of 16, who was taking part in some medical research, to what extent do you agree or disagree that you would want to be told if the researchers found that your child had a genetic pattern linked to ...
Base: All Respondents (1105)

Scanning studies

The severity and treatability of a condition also have a strong influence on the desire for feedback from scanning studies. Again, feedback was most popular for a condition that was life threatening but manageable or curable, with 89% of respondents agreeing they would want feedback about such a finding (Figure 17). In comparison, 81% of respondents agree they would want feedback on a finding that may indicate they had a condition that was not life threatening and 79% of respondents would want feedback on a finding that may indicate they had a condition that was life threatening but not curable.

Figure 17

Preference for feedback if a scan identifies a “lump” with consequences of varying severity



Q11. If you personally took part in some medical research which involved scanning, to what extent do you agree or disagree that you would want to be told if the researchers found a lump that may suggest you have a... Base: All Respondents (1105)

As with genetic research, the proportion of respondents who did not know if they would want feedback from scanning research was highest when asking about a life threatening condition that was not curable (6% compared to 3% and 3%).

Differences between genetic and scanning feedback preferences

When comparing the respondents' views on feedback in genetic studies with views on studies that involved scanning (Figure 18) it is interesting to note that the percentage of the respondents who wanted feedback is higher in the scanning studies than the equivalent condition type in the genetic studies. This could, in part, be due to the greater certainty that people ascribe to results from scanning studies. Within the qualitative stage the language used by respondents implied they believed it would be easy to identify abnormalities within scans. They also expressed the belief that all abnormalities which were spotted would be checked by a doctor. If survey respondents held similar beliefs, they may have assumed that any health related findings delivered from a scanning study would have less chance of being incorrect than those from a genetic study, lowering the risk of the result being a false positive and causing needless worry.

Figure 18

	Genetic	Genetic for child	Scanning
Percentage wanting vs. not wanting feedback			
Life threatening but manageable	87 vs. 4	86 vs. 2	89 vs. 2
Not life threatening	73 vs. 11	79 vs. 5	81 vs. 7
Life threatening and not manageable	72 vs. 12	75 vs. 8	79 vs. 7

Sub-group differences

Across all three study types (genetic study for individual, genetic for child and scanning study) those who believed that the advantages of medical research outweighed the disadvantages of medical research were significantly more likely to want health related findings fed back to them for all categories of condition (not life threatening, life threatening and curable, and life threatening but not curable). Those who said they were likely to take part in research were also significantly more likely to want health related findings fed back to them across all study types and categories of condition.

Interestingly, a difference in feedback preference between those who had *actually* participated in research and those who had not only occurred for the study where feedback would be given for a child. In this situation, those who had taken part in research previously were more likely to want feedback about their child for conditions that were not life threatening or life threatening and curable. However, there was no difference in feedback preference for life threatening conditions with no cure between those with research experience and those without.

Within the three study types, an association emerged between the age of respondents and their feedback preference. Within the scanning study an older age was associated with an increased desire for feedback across all categories of condition. Within the genetic study on a child, this association only held for conditions that were life threatening and curable or that were not life threatening. For example, 72% of 18-24 year olds would like feedback when a condition was not life threatening, compared to those over the age of 45, of whom 83% would want feedback. Within the genetic study where the participant imagined they would be taking part, an older age was associated with a greater preference for feedback only if the condition was life threatening and curable.

Whether a respondent had a long-term health condition or not also had a relationship with preference for feedback about study results that were linked to certain types of conditions. For the scanning and genetic studies where the individual was taking part in the study, rather than their child, the presence of a long-term health condition increased the likelihood of the individual wanting feedback for conditions that were life threatening but manageable. For example, 92% of people with long-term conditions wanted feedback from the scanning study compared to 88% of those without, if the findings were linked to a conditions that was life threatening and curable. For the genetic study on a child, those with long-term health conditions were more likely to want feedback on a condition that was not life threatening than those who do not have a long-term health condition.

➤ The condition: risk

If a health related finding indicated that an individual was at risk of developing a condition, the level of risk associated with developing the condition could be a key moderator in whether respondents wanted health related findings to be fed back. Variation within responses to different scenarios and between individuals was so great that only general principles around risk could be drawn from the discussions.

The overarching principle is that there is a large lack of understanding around risk, in terms of both semantics and statistics.

Semantically, people hear the word 'risk' and think that it means something substantial and serious. 'Risk' as a concept is perceived as opposed to 'no risk', rather than being viewed as a scale along which different degrees of risk can be placed. When presented with a 'risk' it was rarely compared to the risks for which everyone is exposed e.g. being involved in a traffic accident or developing cancer.

Statistical understanding of risk was also poor. Mathematical and statistical understanding varied greatly among individuals. For those with a poor understanding, answers were given to questions on risk without fully comprehending the risk and its implications. For example, without a good grasp of probability it is difficult to assess either the absolute risk to an individual or their relative risk compared to the general population, and understand what these might mean in terms of impact to the individual.

➤ The results: clinical relevance

The concept of clinical relevance or validity was difficult for people to understand. The concept of genetics is very abstract to those with little experience of it and participants found it difficult to distinguish between an established causal link, e.g. high blood pressure and the increased risk of stroke, and an association between a genetic pattern and a condition that has not been shown to be causal.

With this caveat, respondents felt that findings should be fed back even if not clinically certain, as it was felt that the participant had the right to know information about themselves. By receiving health related findings, regardless of clinical relevance, it was thought that the participant would then have the choice to follow up the findings if they deemed it necessary. This demonstrates the lack of understanding about this issue, since follow up would not be possible for a finding of uncertain clinical meaning, and these results must therefore be considered in this context.

It was acknowledged, however, that feedback of findings that were not clinically relevant may worry people unnecessarily if they were the type of person who does not deal well with this type of uncertain information.

"It depends whether she was told at the beginning [if she would receive feedback on findings that were not clinically certain], but I'd like to think she would be told that but also reassured that it might not mean anything bad."

Research participant

To prevent researchers from having to make decisions on the feedback of results that are not clinically relevant, respondents stressed that the consent form should clearly state whether such findings would be fed back or not so that the participant is aware from the start of the study.

Unsurprisingly, among those affected by genetic conditions there was a higher level of awareness of the nature of genetics than the general public. Those individuals affected by syndromes without a name often hoped for any form of information despite being fully aware of the limits of some genetic findings.

“Because in my position [the condition] doesn’t have a test, so you never – it’s just a clinical diagnosis and it’s done by discounting everything else that it could possibly be.”
Person affected by a condition

➤ **The results: accuracy**

There was consensus among participants that if a result was not guaranteed to be accurate, for example it was not diagnostic standard, but had identified a potential health related finding then a retest should be carried out. If the participant had to be involved in this retest, e.g. a participant had to have another scan or sample taken, respondents felt it was essential to inform the participant of why this retest was being conducted. If a retest could be conducted without the involvement of the participant e.g. a blood sample needed to be retested, respondents felt the participant should not be informed of the potential health related finding as this could cause unnecessary worry. It was felt that results should be given to the participant once an accurate result had been achieved, which the participants assumed would be after the retest. This oversimplification reflects some lack of understanding about the complexity and practical difficulties associated with the process.

“I think putting me in that sort of situation, I’m looking at a computer, it’s flashed up on the screen, I’d say ‘Oh, right, yes better tell them’. Yes I would be inclined to say ‘Right we need to run another scan, this is what we feel, it may be nothing but you want to have peace of mind and so do we, let’s have another look’.”
Research participant

➤ **The results: pertinent vs. incidental**

Differences between pertinent and incidental findings were not considered an important variable by respondents. The fact that the finding could affect the individual’s health was the most important consideration.

“The fact that one study was looking for them and the other wasn’t, I’m not sure is relevant once you find them.”
Research participant

“It’s like leaving your car in to get fixed, maybe it’s got a flat wheel and you leave it in and it gets fixed and there’s something in the steering and they don’t bother to tell you they just fix the wheel. You would like to know.”
Focus group, Belfast

The significance of the differences was not always appreciated, a sentiment felt so strongly by some people that they could not appreciate why the question was even being asked.

“I just don’t see why you wouldn’t give it. If you’re going to give out variable 1 [pertinent finding] why wouldn’t you give out variable 2 [incidental finding]? It doesn’t make any logical sense to me.”
Focus group, Cardiff

➤ **The methodology of the study: setting of the research**

The setting in which the study was carried out was not seen to influence whether health related findings should be fed back, but it did influence confidence in the clinical relevance and accuracy of the result. If the study was carried out in a hospital it was assumed that doctors and nurses would be carrying out the research and the results from a hospital were trusted as clinically relevant and accurate.

Students were believed to carry out most of the research in a university setting. It was felt that the results from studies carried out in a university should be fed back to participants but that the participant may then want to have it retested in a medical setting.

“From a university point of view, I’m not saying university students aren’t competent, I think the level of trust is slightly lower than a hospital, a hospital would be your standard level of trust.”

Focus group participant, London

Within a pharmaceutical company, researchers and scientists in the research department were believed to carry out the studies. There was, however, a deep mistrust of such companies’ motivations. It was frequently stated by respondents that they would not trust the feedback from a pharmaceutical company as they may be trying to get the participant to buy medication produced by the company. Participants therefore expected to seek a second opinion from their GP to validate any result given by a pharmaceutical company.

“If it’s a pharmaceutical company, they’ve got a vested interest and all that and you can’t exactly take, I mean even if they say, ‘Yeah, you’ve got blood pressure,’...what kind of advice they would give you and if they did give me advice, it’s the same thing, I don’t know if I’ll take it 100% face value.”

Focus group participant, Glasgow

“The pharmaceutical company would be sort of way down here because of their hidden agenda but that doesn’t mean that you can’t trust them it just means that it should always be backed up by your health care official.”

Focus group participant, London

Research participants and those affected by conditions also expressed the view that setting had little influence on whether a health related finding should be fed back. The only difference in viewpoint emerged around their understanding of research in a university. Those research participants and individuals affected by conditions who had had contact with specialist departments in universities had a greater appreciation of the scientific expertise of some universities and therefore had greater trust in their results.

➤ **Methodology: right not to know**

The preference of individuals not to receive feedback was discussed, particularly in terms of whether there are situations in which an individual’s preference may be overridden, for example, where there are potential harms to others that could result from not disclosing the finding. The outcomes of this discussion are discussed in section 3.4, as are the outcomes of the importance of consent.

Two other variables related to the methodology of the medical research were discussed:

- whether the study was being undertaken by the research team who had recruited the participant and collected the data or samples or by a secondary researcher
- the amount of time elapsed between a participant joining a study and the identification of a potential finding.

These issues are discussed in ‘Mechanisms for the feedback of health related findings’, below (Section 3.5).

➤ **The participant: Age**

There was consensus that the age of the participant did not affect whether health related findings should be fed back. In one group it was suggested that someone aged 90 years old should not be

told about blood pressure, but they subsequently changed their mind after discussing it with the group. Another individual questioned whether a young person should be told they have a high risk of Parkinson's disease due to its late onset. However, others believed that the sooner the individual is told the better as they have more time to prepare.

"No, age makes no difference at all."
Focus group participant, Belfast

3.3.2 Exploring different scenarios

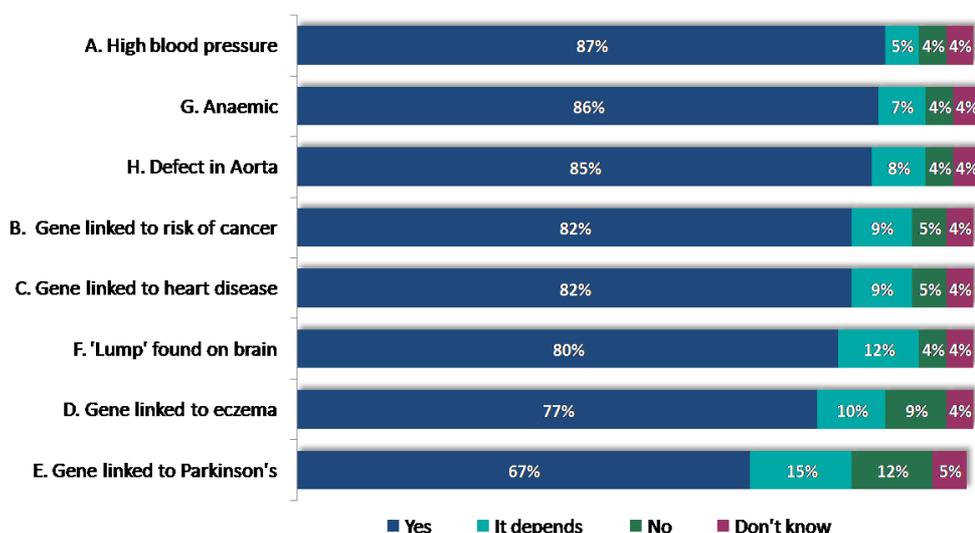
Within the survey, respondents were also asked whether feedback should be given in various scenarios focusing on a range of specific conditions. The scenarios included different settings in which the study took place, and different types of studies e.g. large scale studies, genetic studies, scanning studies. The results, again, supported the qualitative findings' emphasis on the importance of treatability and severity.

As displayed in Figure 19, the conditions for which respondents thought feedback was most necessary were those conditions that were described as having severe consequences or impacts on a person's life and for which changes could be made to reduce the impact. For example, feedback was seen as most important for high blood pressure, a condition which if left untreated can lead to increased risk of a heart attack, kidney disease or stroke, with 87% of respondents stating this finding should be fed back. This was followed by anaemia, a condition that causes breathlessness and tiredness, with 86% of respondents believing this should be fed back, and a major defect in a participant's aorta (aneurysm) which could burst, with 85% of respondents thinking researchers should feed this back if detected. All three conditions can be managed to substantially reduce the risk of damage occurring.

As well as having large impacts on the participants' lives and being manageable, the condition was already present in all three cases. This contrasted to the genetic conditions where a particular pattern could only suggest predisposition for the development of a particular disease. As shown in section 3.3.1, more respondents also had preference for feedback in scanning studies than in genetic studies. This chimes with the result for this question where there was a feedback on a defect in the aorta (identified in a scanning study) has the third highest preference for feedback.

Figure 19

Feedback preferences for a range of scenarios



Q6. The following is a list of scenarios involving Health Related Findings in medical research. For each one, putting yourself in the shoes of the participant, please state whether or not you would like the Health Related Finding in question to be fed back. In each case the Health Related Finding is highlighted in bold. Base: All Respondents (1105)

Sub-group differences

For all eight scenarios, those who believed the advantages of medical research outweighed the disadvantages were more likely to feel that feedback should be given to the participant than those who thought the disadvantages outweighed the advantages.

For all scenarios, apart from the scenario involving a genetic link to Parkinson's, age had a strong influence on feedback preference with a general trend for those over 35 years to be more positive towards the delivery of feedback than those under 35. For example, in the scenario on **blood pressure** a higher percentage of those aged 35 and above agreed that feedback should be given compared to those under 35. The extreme difference in view can be seen by looking at both ends of the spectrum with 72% of those aged 18-24 years having felt that feedback should be given compared to 90% of those aged over 65 years.

Participation and likely participation in research also had a strong relationship to feedback preference, with those who had taken part in research or were likely to take part being more likely to feel that feedback should be given in each scenario. For example, within the blood pressure scenario 90% of those who had participated in research stated that feedback should be given compared to 84% of those who had no experience of research. A more striking difference is seen between those who were and those who were not likely to take part in research in the future, with 90% of those who were likely to take part in research feeling feedback should be given in this scenario compared to 65% of those who were not likely to take part in research.

Those with long term conditions were also more likely to want feedback in every scenario given. For example, in the anaemia scenario, 91% of those with such a condition wanted feedback compared to 84% with no long term condition. For this scenario those who had taken part in research were more favourable to feedback, as were those who were likely to volunteer for research in future.

3.3.3 Understanding of obligations of researchers to feed back

The legal obligations of UK researchers to feed back health related findings are not entirely clear. We used this study to explore respondents' attitudes towards and perceptions of the duties of researchers.

The overriding feeling in the qualitative research was that researchers *should* be obliged to give health related feedback and that individual feedback was a participant's right. There was recognition, however, that sometimes a participant may not want feedback – whether you did or not was a personal choice.

“It's individual how people can handle the truth because they can make it be the end and it's not, in their minds.”

Focus group participant, Cardiff

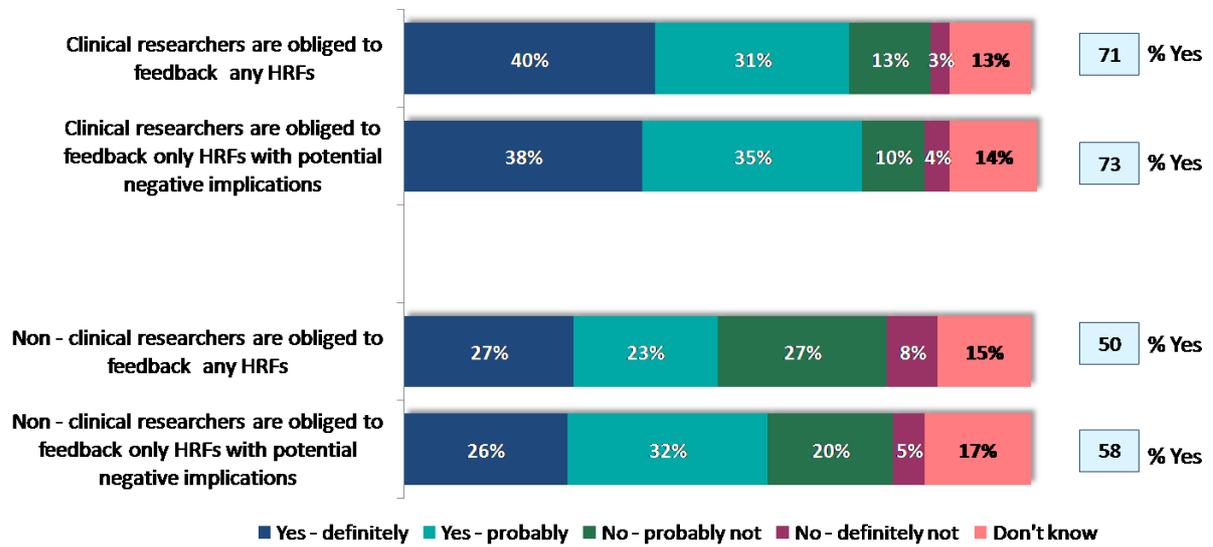
The survey sought to build on the qualitative findings by gauging respondents' perceptions of what obligations they thought researchers *actually* have when they make a finding about a participant's health. Respondents were asked to review the obligations that researchers might have in four different situations. Before responding, respondents were informed that medical researchers fall into two categories – those trained as doctors (clinical researchers) and those who are not (non-clinical researchers) – and were provided with a definition of 'health related findings'. As shown in Figure 20 below, respondents perceived that there were much stricter obligations placed on clinical researchers compared with non-clinical researchers: 71% believe that clinical researchers are obliged to feed back any health related findings they observe, whilst just 50% believe that non-clinical researchers have the same obligation. There is also a significant link between the type of health related finding and the extent to which people feel that there is currently an obligation to feed back. For both clinical and non-clinical researchers, a greater proportion of people believe that researchers are obliged to feed back health related findings with negative implications, rather than simply any health related findings.

Sub-group differences

In terms of sub-group differences, the oldest age group (over 65) were consistently more likely than other age groups and the average to say that they were definite about researchers having an obligation to feed back. This was also true for lower social grades (C2 and DE) compared to higher social grades (AB and C1). Scottish respondents were more likely than those from other regions to say that researchers 'definitely' have these obligations across the four scenarios.

Figure 20

Perceptions on obligations of researchers to feedback



Q7. For each of the statements below, please state as far as you are aware what obligations you think researchers currently have when they make a finding about a participant's health Base: All Respondents (1105)

3.4 How health related findings should be addressed within the consent process

Background and summary of findings

The consent process involves providing potential research participants with the information they need to decide whether to take part in a study, and the formal decision about whether they take part. The consent process could be a useful tool in communicating with potential participants about health related findings and we therefore used this study to explore views about consent and health related findings.

Focus group participants felt very strongly that medical research participants should be clearly informed about what would and would not be fed back as part of the consent process, with this echoed by around seven in ten survey respondents. Integrating information on health related findings into the consent process was perceived to enable the individual to make an informed choice about whether they wanted to take part in the study or not.

Eight in ten respondents felt that research participants should be given the choice of whether to receive feedback or not in studies where feedback could be given. The study probed the views on whether a decision not to receive feedback could be overridden. Focus group participants often saw it as acceptable to override an individual's preference to not receive feedback if the condition involved could potentially impact on others e.g. a contagious disease. However, it was not deemed acceptable to override the participant's preference if a condition was found that could potentially harm the participant, despite the difficult situation this poses for the researcher. This sentiment was echoed to some degree in the quantitative research, where seven in ten people thought it acceptable to override the participant's preference to protect others, and half thought it acceptable to override the preference to protect the individual.

3.4.1 The importance of the consent process

Throughout all focus groups and in-depth interviews carried out in the qualitative stage there was a strong belief that participants should be clearly informed about what would and would not be fed back at the start of the process as part of the consent process. This would then give them the personal choice as to whether they would want take part in the research and also allow them to consider, where the choice was available, if they would want feedback were health related findings identified.

“So at the end of the day once you’ve signed that you don’t want feedback or you do want feedback...it’s a personal choice.”

Focus group participant, Belfast

“For the participants, overwhelmingly it’s about their own individual opinions, their own individual decision and whether that be the decision to not know at all, if that’s the case, or whether it be the decision to make your own mind up after being told all the information they can give you.”

Research participant

The consent process was seen as needing to include a number of crucial pieces of information.

1) What will and will not be fed back to the participant

- Will incidental and pertinent findings be fed back, or only pertinent findings?
- Will the participant be informed about all conditions or only those of a certain severity or treatability?

- Will only clinically relevant findings be fed back?
- Above what risk threshold will a finding be reported back? e.g. if a genetic pattern is found that is associated with a 5% or 50% chance of developing a condition, will these both be fed back?

2) How feedback will be given if a health related finding is identified

- Who will feed back the finding?
- In what format will feedback be given? e.g. face-to-face, via letter.

3) Validity of results

- To what extent will any findings be accurate?
- Are there any other methodological issues that may affect results?

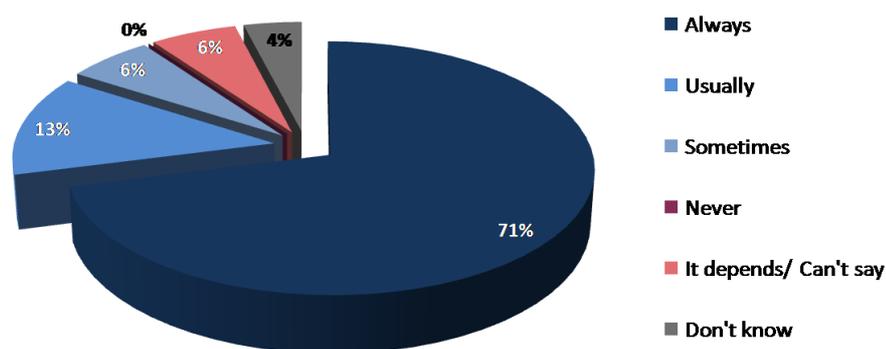
4) When the choice of the participant will be overridden

- In which situations will a participant's stated preference not to receive feedback be overridden?

Respondents in the quantitative stage of the study also felt that it was important for the feedback process to be specified in the consent process. As Figure 21 shows, just over 7 in 10 respondents felt that information on the feedback process for health related findings should *always* be covered as part of the consent process. In contrast to the qualitative findings, in which there was almost universal support for always including the information in the consent process, 13% of respondents thought that the information should usually be covered and 6% thought it should sometimes be covered. There was also more uncertainty within the quantitative research around the coverage of this information, with 6% responding 'it depends/can't say' and 4% not knowing.

Figure 21

The extent to which information on whether HRFs would be fed back should be included in the consent process



Q15. To what extent should information on whether or not researchers would feedback Health Related Findings to participants be covered as part of the consent process in medical research studies? Base: All Respondents (1105)

Sub-group differences

There was a strong relationship between people's age and the support for covering feedback procedures during the consent process. There was a steady increase in preference for covering feedback procedures in at least some cases (always, usually or sometimes) from younger to older, with 82% of 25–34 year olds thinking feedback should be covered compared to 95% of over 65s.

Those who had experience of research, or whose family had been involved in research, felt the information should be covered in at least some cases to a far greater degree than those who had not. 94% of those who had taken part in research themselves, and 93% of those whose family had taken part, believed it necessary to cover the information in at least some cases, whilst only 86% of those with no research experience held this view. An even greater difference could be found between those who were likely to participate in research, of whom 92% would have liked the information covered in at least some cases, compared to 75% of those not likely to take part in research.

3.4.2 Attitudes to approaches for feedback

Two main approaches to feedback were spontaneously discussed within the qualitative stage: compulsory feedback of health related findings to participants and no feedback being given.

Compulsory feedback was the preferred approach out of the two, with some focus group participants raising this spontaneously as a way to avoid the researchers facing difficult dilemmas around whether to feed back or not. It was also mentioned that this method gave participants an element of choice as they could choose not to read the information despite receiving it, but this was clearly based on assumptions about how the feedback would be delivered.

“I think if you have information and you choose to ignore it, it’s surely better than having no information to ignore. At least if you take that letter and throw it in the bin then fortunately the conscience has been taken away from the people that did the research.”

Focus group participant, London

However, some people did not like the concept of having no choice in receiving results. There was a belief that compulsory feedback could prevent people from taking part in medical research in the first place, and an approach was advocated that gave the participant the choice to have results fed back or not.

“I think everything should be explained and like you said if you don’t want to know what it is or what’s going to be the findings then you have the choice, not that you don’t want to take part in it but you don’t want to know, and that’s my prerogative, it’s my problem if I’ve got something that’s horrible and you’ve found it out and I don’t want to know but it’s still my decision and I should have that ability to say no.”

Focus group participant, Cardiff

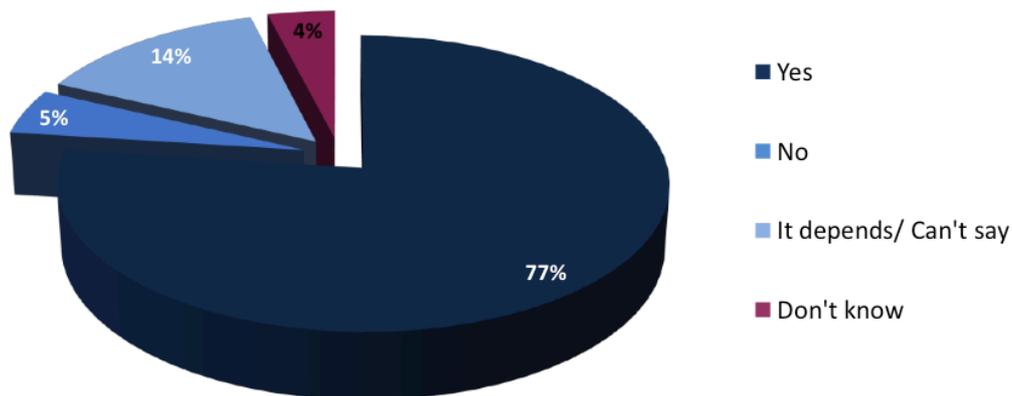
The groups discussed the approach of giving no feedback to participants at all. This approach was typically disliked, but the extent to which this was disliked was reduced when possible reasons for this approach were explained (see 3.5.5 for further discussion of this point).

Survey respondents also strongly believed in the importance of choice about receiving feedback. 77% believed that participants should be given the opportunity to decide whether to receive feedback in studies where feedback could be provided, whilst 14% of respondents answered either that they could not say or that it would depend, and 8% said they did not know (Figure 22). Although this emphasis on personal choice chimes with the qualitative research, participants in the qualitative stage were more favourable towards the approach of *always* providing feedback. It may be, however, that the compulsory feedback mechanism was still seen as providing choice as the individual can simply choose not to read the result. This difference between the qualitative and quantitative findings may also have occurred due to the discussions that took place in the qualitative stage around the potential difficulties for the researcher of knowing whether to feed back or not. These discussions could have led the qualitative participants to feel that a compulsory feedback mechanism was the easiest method of feedback whilst those who answered the questionnaire were not so familiar with the dilemmas of a researcher such as cost and time

implications of feeding back and the emotional impact of not feeding back a finding they know is present in a participant.

Figure 22

In studies where feedback will be provided, should participants be given the opportunity to decide whether or not to receive feedback?



Q16. In medical research studies where feedback will be provided, should participants be given the opportunity to decide whether or not to receive feedback on Health Related Findings? Base: All Respondents (1105)

Sub-group differences

Belief that individuals should have the choice to receive feedback increased steadily with age. Of those aged 18–24 years, 61% felt that a choice should be offered, with this percentage rising steadily across age bands to 89% of those who are over 65 years holding this view. Those with a long-term health condition also felt more strongly that a choice should be given, with 83% answering yes, compared to 75% of people without a long-term health condition.

Although there was no difference in views on choice of feedback between those who have and have not participated in research, a difference was present between those who were likely to participate in research and those who were not, with 80% of those who were likely to participate advocating choice compared to 63% of those not likely to participate in research.

3.4.3 Overriding participants' feedback preferences

As mentioned previously, one piece of information that was felt to be crucial in the consent process was if, and when, a participant's preference not to receive feedback could be overridden. There was a strong consensus that if an individual has chosen not to receive feedback at the beginning of the research then this should be respected. The distress this could cause to the researcher was acknowledged, but was seen as less important than maintaining the participant's right not to know. There were certain situations, however, in which it was seen as acceptable to override the participant's right not to know. Situations where this was acceptable included cases where withholding information could present a risk to other people's health, e.g. the presence of an infectious disease (such as HIV) or when a participant held a job that meant the condition could endanger others (such as a bus driver who had a lesion in the brain that suggested they had epilepsy).

“It’s the same as epilepsy isn’t it and stuff, if you have an epileptic fit you’re not allowed to drive so that’s a duty of care to the public and that sort of thing so I think there is a need at times to obviously do that I think to protect other people as much as yourself obviously.”

Focus group participant, Cardiff

Respondents emphasised that situations where the ‘right not to know’ could be overridden must be highlighted clearly in the consent process so that participants understand when and if their preferences could be overridden. Only one individual questioned the right to override individual preference, stating that everyone could pose a risk to others by driving, or walking down the road.

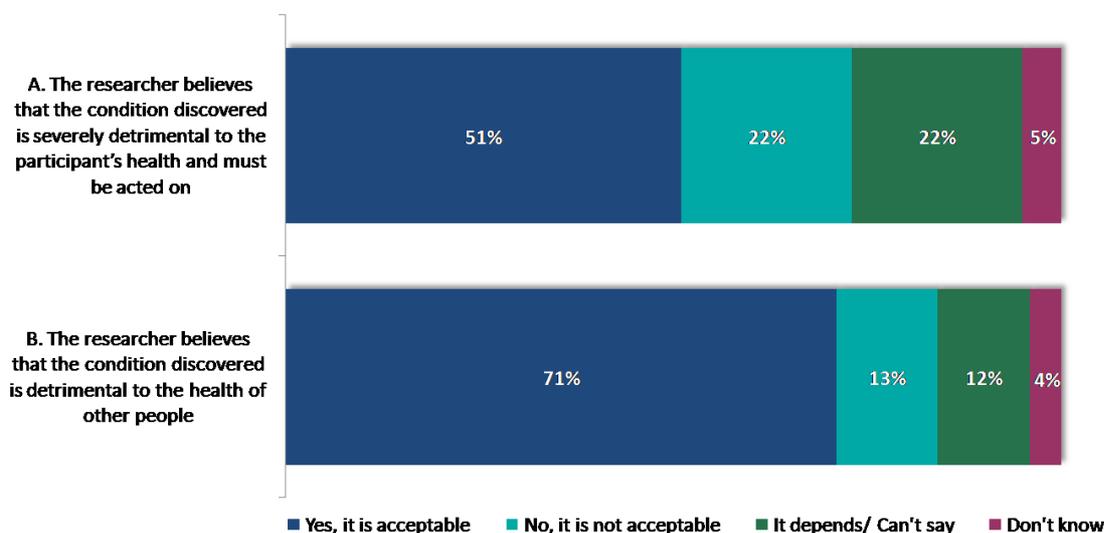
Within the quantitative stage these views were explored and it was generally felt to be more acceptable to override an individual’s preference not to receive feedback if this was to protect the health of others rather than to protect the participant themselves. As shown in Figure 23, just over 7 in 10 people (71%) felt it acceptable to override feedback preference if the condition discovered would be detrimental to the health of others, whilst just over half of people (51%) felt this to be acceptable if the condition was severely detrimental to the participant’s own health. There was a great deal more uncertainty around the decision to override a preference for the health of the participant, with 22% of people answering that they couldn’t say or that it would depend, compared to 12% in cases where the condition would affect others.

These results were consistent with the respondents’ views on the importance of different of reasons why health related findings should be fed back to participants. As discussed in section 3.2, people felt that the most important reason for feeding back a finding was that the participant may have a condition that puts others at risk e.g. an infectious disease. The second most important reason was that it could indicate that the individual has a condition which could be managed and treated.

These results also echo the qualitative results, in which respondents were supportive of overriding feedback preferences to protect others. The qualitative participants, however, were far less tolerant of overriding preferences to protect the participant, instead focusing on the right of the individual to have their initial choice respected.

Figure 23

Situations in which it is acceptable to override a participant's preference to not receive feedback



Q17. If a participant has told researchers that they do not want to receive feedback on Health Related Findings, please state, for each of the following circumstances, whether or not this request should be overridden by researchers. Base: All Respondents (1105)

Sub-group differences

Those who said they were likely to participate in research thought it more acceptable to override this preference in situations where the participant's health is at risk, with 54% finding it acceptable, compared to 36% of people who were unlikely to take part. It is interesting that those who were likely to take part in medical research were more supportive of a participant having the right to choose to have feedback or not, as discussed above, but were also more supportive of this right being overridden to protect the participant. Those who had participated in research, or whose family had, also thought it more acceptable to override preferences in this situation (55% and 57% respectively) compared to those with no research experience, of whom only 48% thought it acceptable.

Views on overriding a participant's preference to protect others contained greater sub-group differences. Those over the age of 35 believed it to be more acceptable to override a preference for this reason than those aged under 35. Individuals with long-term health conditions also saw overriding preferences in this situation to be more acceptable than those with no such conditions (79% vs. 67%). An individual's view on the advantages of medical research also had a relationship with support to override a participant's preference if it could put others in danger, with 76% of those who thought the advantages of medical research outweighed the disadvantages seeing it as acceptable compared to 63% of those who held an opposing view.

As with views on overriding preference for personal protection, those who had participated in research were more favourable to overriding the participant's preference for the protection of others compared to those with no experience in research (76% vs. 67%). Likelihood of participating in research also had a positive relationship with believing it to be acceptable to override preferences in this situation.

3.4.4 Managing consent

Within the qualitative stage, there was an exploration of how feedback procedures could be best explained in the consent process. The overwhelming response was that information needed to be clear and comprehensible, irrespective of the method in which the information was delivered.

For most participants the preferred method of delivery of this information was through a combination of written material and discussion with a researcher or medical professional. It was felt by the majority of participants that simply providing written material was not sufficient. This written material, including the consent form, could potentially contain a large amount of potentially complex information and it was thought that some people may have difficulties reading and understanding written material. Further, participants agreed that many people do not read written information presented to them in other contexts.

“We’re reading it but we’re not reading it if you understand what I mean you know, we’re not thinking of the consequences, oh yeah that’s right, oh yeah I’ll tick that.”

Focus group participant, Cardiff

“How many people read all the ins and outs of what’s on the disclaimer? They go ‘Oh yes doctor’ and sign it.”

Focus group participant, Belfast

“You’d have to read through it because everyone just signs things without reading them.”

Focus group participant, London

It was felt that there was a need for discussion alongside the consent form which would give the researcher or medical professional the opportunity to highlight to the potential participant any significant or complex issues regarding feedback e.g. issues around clinical relevance. This approach would also give the participant an opportunity to ask questions to those involved in running the research which, again, could help increase understanding of the feedback process.

The need for some form of participant-researcher discussion was strengthened by findings from the qualitative research showing that respondents have poor understanding of concepts such as clinical relevance and risk, both of which are likely to be important factors in researchers’ consideration to feed back findings.

Although a discussion was seen as necessary, some participants also wanted to be given a booklet explaining the feedback procedure and other information on the research which they could take away with them to read and keep for reference.

“I like to keep it and have it in front of me and then read that. Because you can’t always remember what they’re telling you at the time and then you’ll go back and then ‘What did they say about such and such?’ and it’s nice to be able to refer back to it.”

Person with experience of research

Concerns arose that a participant may change their mind about receiving feedback or not during the process of the study itself. To overcome this they suggested a two point consent process in which participants in a study are asked if they want feedback at both the beginning of the study and then again at the end of it, or in the case of long-term studies during the study itself.

“It may be, and we will talk to you about it again in three months’ time...People aren’t auditable. They evolve. They change. The things that happen to them over their lives make them different.”

Person with experience of research

3.5 Mechanisms for the feedback of health related findings

Background and summary of findings

At present, studies that do feed back health related findings often do so in different ways. The mechanism chosen often depends on practical factors, such as whether any of the research team are clinically trained or whether additional staff, such as GPs or specialists, can be involved. This part of the research explored public attitudes towards different feedback mechanisms.

Face-to-face feedback is the preferred way of receiving feedback on a finding. The nature of the condition has some impact on the preference for different channels of feedback, for example where a condition is life threatening and not manageable it was seen as a lot less acceptable to feed back via channels that are not face-to-face.

Participants generally wanted to receive the result from someone with medical knowledge and expertise and who could ensure the finding was followed up appropriately: usually a GP, specialist or consultant. However, those with research experience had a preference for feedback from a member of the research team, as they valued the participant-researcher relationship that had been established through the study. Those affected by conditions tended to prefer feedback from specialists as these specialists had the appropriate knowledge and expertise in their conditions, in comparison to their GP or other health professionals.

Participants were asked to consider large scale studies that may encounter logistical difficulties in providing feedback but that offer important contributions to society's understanding and development of medical knowledge. Focus group participants acknowledged the difficulties of providing feedback in some settings and felt that it could be acceptable not to give feedback in these studies, but only if the participants had been made aware of this before they joined the study. This finding was supported by the quantitative research, which found that more people agree that it is acceptable not to feed back in large scale studies than thought it unacceptable. However, responses varied depending on the extent to which the societal benefits of these studies were emphasised in the question.

3.5.1 How feedback should be delivered

The respondents expected that the process for feedback would vary depending on the nature of the health related finding. Typically, however, there was preference for verbal feedback, particularly face-to-face feedback. Face-to-face feedback was seen as especially important when feeding back findings that were linked to conditions of a more severe nature and those that are severe and untreatable.

"For something that intense you would expect somebody face-to-face."

Focus group participant, Glasgow

"Surely it depends how serious it is, you know if it's life threatening they would get you in straight away wouldn't they."

Focus group participant, Cardiff

"Like if someone says a lump, a lump can be nothing but people might read lump and hear cancer and then it might just be a lump so it has to be fully explained."

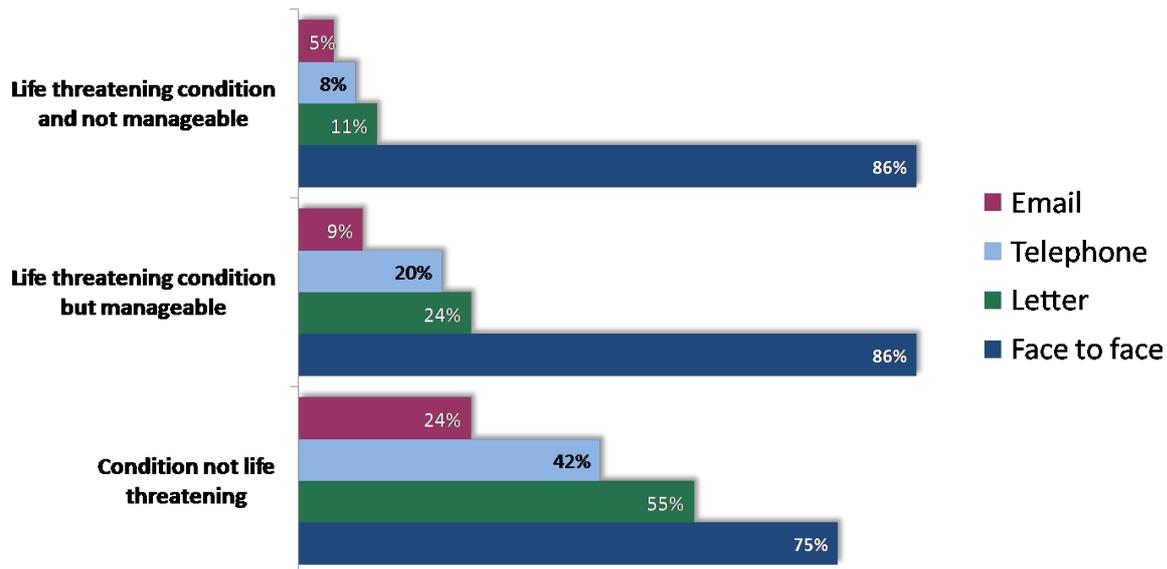
Focus group participant, London

As found in the qualitative stage, there was an overwhelming preference for face-to-face feedback among survey respondents. Such feedback was particularly valued when it was about conditions

that were life threatening, with 86% of respondents finding verbal feedback acceptable for life threatening conditions, whether manageable or not (Figure 24). This figure dropped to 75% when asking about feedback related to conditions that were not life threatening. Feedback via letter was the second most acceptable form of feedback across all types of condition followed by telephone, with email being seen as the least acceptable form of feedback.

Figure 24

Preferred channels of communication (top four answers)



Q18 a – c. Through which, if any, of the following channels and individuals is it acceptable to receive initial feedback on a potential Health Related Finding relating to a condition that is not life threatening/ life threatening but manageable or curable/ life threatening and not curable. Base: All Respondents (1105)

As conditions became more manageable and less severe, it was more acceptable to feed back by channels other than face-to-face. For example, for a life threatening condition that was not manageable only 11% of respondents felt it acceptable to feedback by letter, compared to 24% of respondents seeing feedback by letter as acceptable for a life threatening and manageable condition, and 42% seeing feedback by letter as acceptable for a condition that is not life threatening.

Sub-group differences

Older people were more likely than younger people to state that they found face-to-face feedback acceptable. This association was present across all three categories of condition shown in Figure 24. Those over 65 were also less favourable to receiving feedback through a channel that was not face-to-face.

Respondents who felt the advantages of medical research outweighed the disadvantages of research were more likely to say that they thought face-to-face feedback was acceptable compared to those who say the disadvantages outweighing the advantages. Similarly, those likely to take part in medical research were also more likely to say face-to-face feedback was acceptable compared to those unlikely to take part in research. These associations held across all three categories of condition.

Those of a higher social grade (AB) were also more favourable towards face-to-face feedback than any of the other social grades. There were no significant differences in preference between social grades for feedback delivered in any other way.

3.5.2 Who should give the feedback

Respondents wanted the feedback to be delivered by someone with whom they had an existing relationship, or someone who had relevant medical knowledge and expertise. For those within the focus groups this individual was usually a medical practitioner (when in hospital) or a GP, as both were perceived to be trustworthy, knowledgeable and, in the case of a GP, familiar. A medical professional was also seen to be in an ideal position to direct the participant to the relevant specialist or counsellor. These findings are consistent with the quantitative findings on trust in those undertaking research, which found that medical practitioners, including GPs, were seen as particularly trustworthy.

“Doctors have years of training on how people are going to react and deal with their emotions, the steps to take, tell them what to do next, what they should do.”

Focus group participant, Belfast

Individuals who had taken part in research expected that results would be fed back to them by a member of the research team rather than their GP, and preferred this method having built up a relationship with these researchers. Some individuals with conditions also wanted a member of the research team to feed back as they appreciated that there could be an existing participant-researcher relationship.

“Whoever you saw on that day...I think it's better if it's a familiar face...so maybe one of the technicians who took it on that day...so you don't just have a random person telling you.”

Research participant

“I think just so that you're not having a continuous churn and I think having those kind of relationships if you've got one person who, you know, maybe you've got a research nurse who's working on her Master's degree, she's going to be really motivated to make sure that she does see all the patients that she needs to and that she does get informed consent and she'll follow it through.”

Person affected by condition

Other individuals affected by conditions stated a preference to have the specialist who initially referred them to the study to feed back findings. The specialist was seen to have the knowledge and expertise to explain the findings and their implications to the individual with the condition. ^{‡‡}

“I would prefer to go to [my specialist]...because in my case it would be research of cancer, so it would go to my oncologist first and foremost, rather than the doctor [GP].”

Person affected by condition

Most people spoken to were in favour of having their results fed back automatically to their GP to keep them informed. It was recognised by some participants, however, that some people may not want their GP informed about certain results as this could cause stigma.

^{‡‡} It is important to note that often in the interviews with individuals with conditions the hypothetical health related findings they discussed were related, in some way, to the condition they had e.g. they spontaneously discussed the finding of a genetic condition, when they had multiple sclerosis caused by a particular genetic sequence.

"I think there's cases, I can imagine there's cases where you wouldn't [want results fed back to your GP], that's why there's private clinics about."

Focus group participant, Glasgow

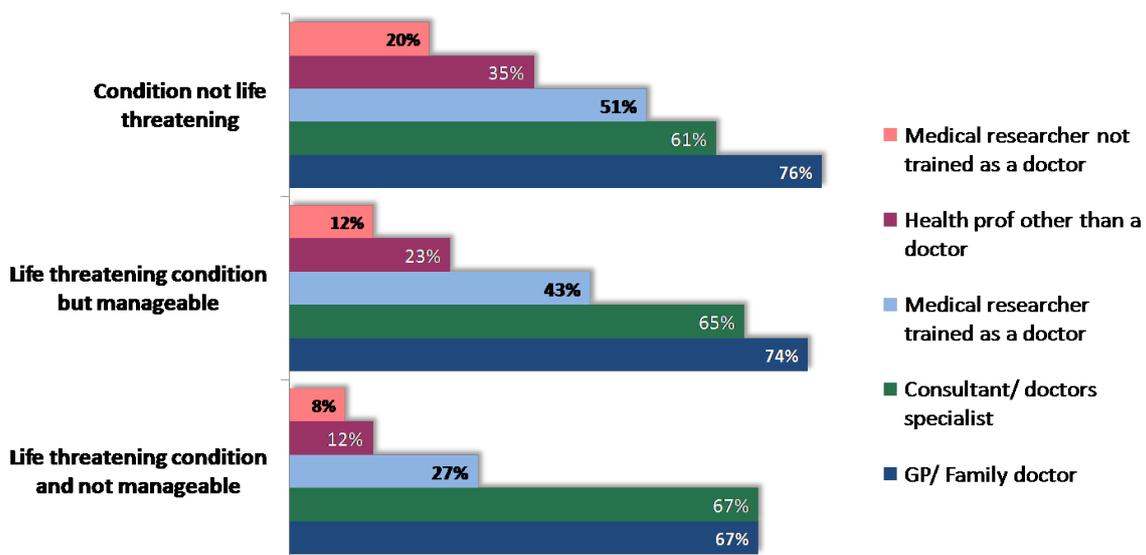
Feedback by health professionals could create a substantial burden for the National Health Service. This burden was recognised by participants in the qualitative stage with respect to the extra workload that feedback could cause for their GP, if all results were fed back through the GP. There was little recognition, however, of the extent to which feedback procedures, and treatment of identified conditions, could impact on the wider NHS resources e.g. health professionals' time and the cost of additional treatment and medication.

The quantitative findings echoed the findings from the qualitative groups with GPs the preferred individuals to give feedback on conditions, whether life threatening (74%) or not (76%), and being joint preferred with specialists to give feedback on conditions that were life threatening and not manageable (67%) (Figure 25). Specialists were the second most preferred individuals to give feedback on conditions that are life threatening but manageable (65%) or not life threatening (61%). Researchers who were trained as doctors were generally seen as less acceptable than GPs or specialists but were seen as more acceptable than a health professional who was not a doctor. The least acceptable person to provide feedback was seen as a medical researcher not trained as a doctor.

These results chime with the results from the qualitative research in which the general public wanted either their GP or a medical doctor to feed results back to them. Medical qualifications, knowledge and expertise were valued as they equipped the health professionals to provide feedback in an informed and practised manner. It is worth noting, however, that the preferences expressed by the general public in the qualitative stage differed considerably to those preferences expressed by research participants and those with conditions.

Figure 25

Preferred individuals to give the feedback (top five answers)



Q18 a – c. Through which, if any, of the following channels and individuals is it acceptable to receive initial feedback on a potential Health Related Finding relating to a condition that is not life threatening/ life threatening but manageable or curable/ life threatening and not curable. Base: All Respondents (1105)

Sub-group differences

There were quite striking differences in feedback preference between different age groups. Those over 65 had a consistently higher preference for GPs to feed back findings compared to other ages, and they also found feedback from any other individual less acceptable than any other age group did. For example, 73% of over 65s thought that feedback from a GP would be acceptable for a life threatening condition that is not manageable but only 35% of them thought feedback from a specialist would be acceptable.

At the other end of the age spectrum, those aged 18–24 were less likely than older age groups to want findings fed back by a GP if they were about a life threatening condition, irrespective of whether it was manageable or not.

Specialists were deemed more acceptable by higher social grades (A, B and C1) than by lower social grades (D and E), for all three categories of condition. For conditions that were life threatening and manageable or not life threatening there was a preference for the GP to deliver feedback to individuals who are working full time, compared to those not working or working part time. It could be hypothesised that this was due to the convenience of fitting a visit to the GP into a working day compared to a hospital appointment.

Those who were likely to take part in medical research generally found feedback more acceptable from all of the individuals listed compared to those who were not likely to take part in medical research. The only exceptions to this relationship were when the feedback concerned conditions that were life threatening and not curable. In this situation there was no significant difference between those likely to take part in research and those who were not with regard to how acceptable they felt it would be to accept feedback from a medical researcher not trained as a doctor or a health professional such as a nurse.

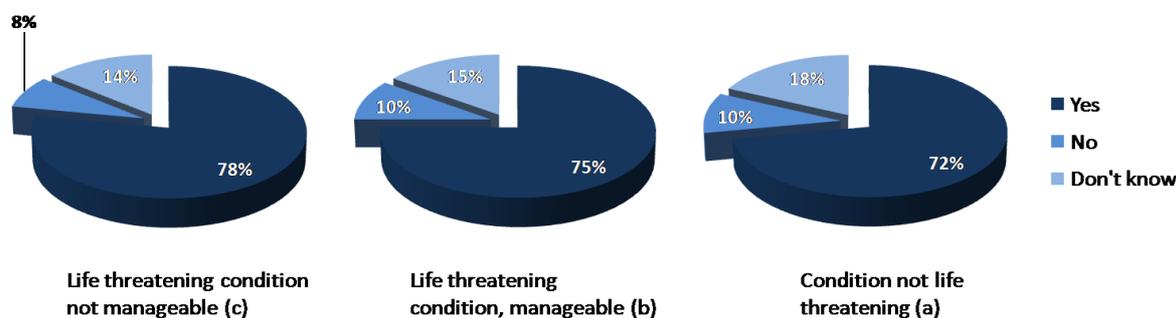
For feedback on conditions that were life threatening but manageable there were two additional sub-group differences. Those who had a long-term condition were more favourable towards having feedback from a GP, with 79% saying this was acceptable, compared to 73% of those who did not have a long-term condition. Also more favourable towards GP feedback were those who thought the advantages of medical research outweighed the disadvantages (77% compared to 67% of those who believed the disadvantages outweighed the advantages).

Feeding back health related findings to GPs

In addition to feeding back to the research participant, informing the participant's GP of the finding was generally seen as a good idea where the GP was not providing the initial feedback. Across the three categories of condition asked about, an average of three quarters of respondents wanted findings to be fed back to their GP (Figure 26). It was seen as most desirable to feed back findings to a GP if the findings related to a life threatening condition which was not manageable, with 78% of respondents wanting feedback in this case. For life threatening conditions that were manageable, 75% of respondents wanted findings to be fed back to a GP, with this percentage falling to 72% for conditions that were not life threatening. Respondents were least sure about their GP being informed of the findings where these were linked to a condition that was not life threatening, with 18% of respondents being unsure if they would want such findings fed back to their GP.

Figure 26

Feeding back health related findings to the participant's GP



Q28 c. In this situation would you want your GP to be told? Base: All those who initial choice of feedback is not through GP (387)
Q28 b. In this situation would you want your GP to be told? Base: All those who initial choice of feedback is not through GP (301)
Q28 a. In this situation would you want your GP to be told? Base: All those who initial choice of feedback is not through GP (259)

Sub-group differences

Older people wanted their results fed back to their GP more than younger people. This relationship was present across all three condition categories. Those with long-term health conditions wanted findings fed back to their GP more than those without a long-term condition.

Those who had participated in research themselves, or had family members who had participated, wanted findings on conditions that are not life threatening fed back to their GP more than those who had no experience in research. Over three quarters (78%) of those who had experience of medical research would have liked their findings returned to their GP if they were linked to conditions that were not life threatening, in comparison to 64% of those with no research experience.

3.5.3 Secondary research

Some research studies may, with the participant's consent, share individuals' data with other research studies. These 'secondary' research studies often receive data where information on the participant's identity, such as their name, has been removed and replaced with a code.

In the qualitative research, whether research was using primary or secondary data was not considered to be a significant variable in whether to feed back health related findings. Logistical difficulties of feeding back were acknowledged but these were seen as being easily solved by feeding back the result through the GP.

It was widely believed that data could be easily shared between a GP and researchers, and that a patient's medical files follow them from their GP to hospital and through any medical treatments they have. This belief highlights some lack of understanding around the practical difficulties of sharing data in the clinical setting and in identifying the participant's GP.

"Yeah, just to me it's just part of...the duty of care I think...Aye, I just think if they moved you would still be able to track them because your files go with you."

Focus group participant, Glasgow

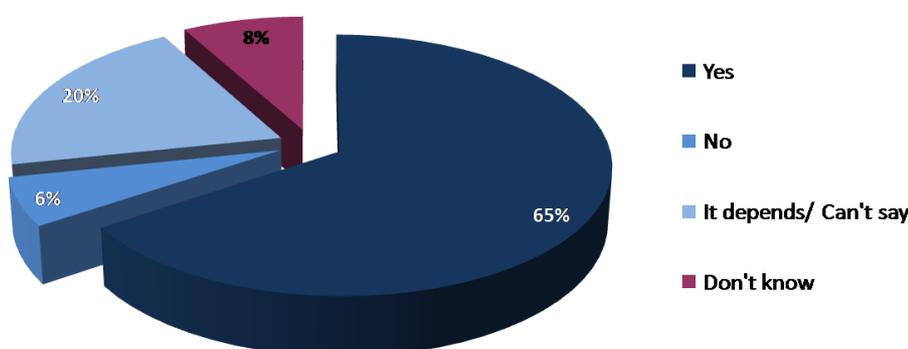
“And then obviously it would be fed back through research staff, then through to the biobank and then finally to the GP.”

Focus group participant, Belfast

The majority of survey respondents (65%) thought that health related findings from secondary studies should be fed back to participants. However, one fifth of respondents thought that it depended on the situation and 6% thought that findings should not be fed back. This contrasted with the qualitative research in which the public were aligned in their view that findings should always be fed back.

Figure 27

Should researchers working with secondary data report HRFs to the original research team?



Q20. If medical researchers are working with anonymous data or samples that they have obtained from other research teams, should they report individual Health Related Findings to the original research team who collected the data or samples? Base: All Respondents (1105)

Sub-group differences

The belief that findings should be fed back from secondary research generally increased with age. For example, younger people (aged 16-24) were least likely to say it should be fed back (55%) and older people (55 and older) were most likely to say this (72%). People who were likely to participate in medical research were more likely to say that feedback should be given (68%) compared to those with no intention to take part in research (42%). General views towards medical research were also related to these responses, with 73% of people who believed the advantages of medical research outweighed the disadvantages agreeing feedback should be given, in comparison to 58% of those who held the opposite view.

3.5.4 Time elapsed since the participant agreed to take part in the study

Some research studies and related secondary studies may take place many years after the participant has agreed to take part and provided data or tissue samples. This means that health related findings could be made a long time after participants last had contact with the researchers. This study therefore explored whether the public would want findings to be returned to them after a potential time delay.

In the qualitative phase, the public were divided over whether there should be a cut-off point after which time feedback would not be given. One view was that it was reasonable to have a cut-off point as individuals would not want results from a study that they participated in a long time previously.

"I think it's however long they feel is relevant...but you're right, I mean you wouldn't want someone chasing you around telling you what you may or may not have for 20 years."

Focus group participant, London

An opposing view was that, irrespective of time elapsed, it was still the participant's right to know if any health related findings had been identified.

"We thought no number of years can make a difference."

Focus group participant, Glasgow

The difficulties of re-contacting individuals after a long period of time were acknowledged (e.g. change of address) but, as with the issue of feeding back from secondary research, it was thought that these difficulties could be overcome by the researcher sending the findings to the participant's GP or hospital. It was also suggested that they could be tracked using their NHS number.

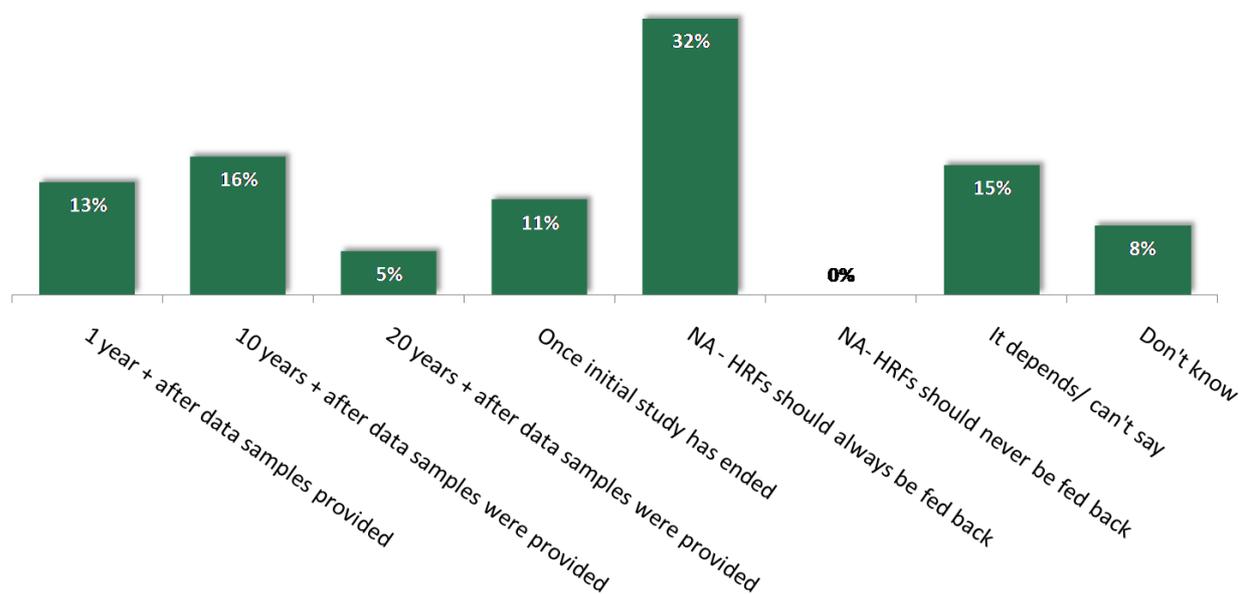
"They could phone the hospital, so they like pass the message [of the finding] onto them."

Research participant

In the quantitative phase, views were divided on whether a cut-off point should be established after which no feedback would be given (Figure 28). 45% of respondents felt that some form of cut-off point should be established, with 32% disagreeing and believing that health related findings should always be fed back to the participant irrespective of the time elapsed since initial participation. The view that findings should not be fed back at all was not supported by anyone. The question was not clear cut to some people, with 15% responding either that it would depend or that they could not say, and 8% stating that they did not know.

Figure 28

Q19. Time after which health related findings should no longer be fed back



Q19. At what point in time after initial participation, if any, should Health Related Findings no longer be fed back to participants? Base: All Respondents (1105)

Of those who stated a preference for a cut-off point, a 10 years cut-off point was most popular, with 16% of respondents choosing this option, followed by a one year cut-off point preferred by 13% of the population. Having the cut-off point at the completion of the individual study was the preferred option for 11% of respondents, with the least popular cut-off point being 20 years.

Sub-group differences

There was a clear distinction in opinion between those over 65 and those under 65 with regard to findings always being fed back. On average, 35% of those aged up to 65 supported the statement that findings should be fed back after any length of time. This contrasts to only 7% of over 65s who held this belief. Those who believed the advantages of research outweighed the disadvantages were also likelier (36%) to support findings always being fed back than those who felt the disadvantages of medical research outweighed the advantages (29%). People who were likely to take part in medical research preferred the option that findings would be fed back after any length of time more than those who weren't likely to take part did (34% vs. 20%). Conversely, 20% of those who were not likely to take part in research preferred the option of having a cut-off point at the completion of the study, while only to 11% of those who were likely to take part held this view.

Participation in medical research only had an influence on preference for the 10 year cut-off point option: those who had experience of research, whether individual or through family members, had a higher support for this option than those with no experience. Specifically, 21% of people who had taken part in research and 23% of those whose family had taken part in research preferred this option in contrast to 12% of people who had no experience of research.

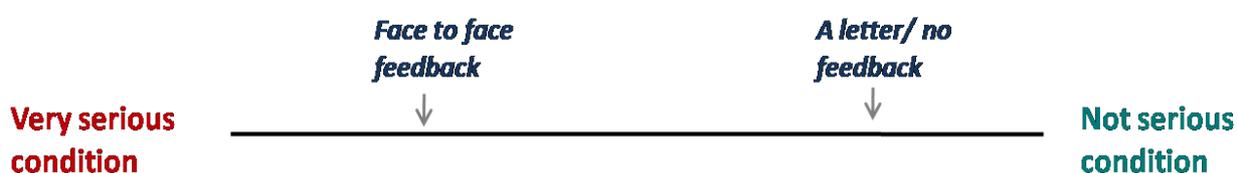
3.5.5 Feedback processes in large studies

Large medical research studies are important for developing understanding about health and disease. Large scale research could encounter logistical issues, such as finding people when they have changed address, and cost barriers to feeding back health related findings.

In the qualitative stage, participants acknowledged the logistical difficulties involved in providing feedback in large studies.

There was discussion among respondents as to whether, in this situation, it was acceptable to give no or limited feedback for conditions of any severity. When it was explained that the cost saved by not providing face-to-face feedback could lead to medical developments or increased robustness of studies, participants suggested that a tiered feedback system could be introduced whereby serious results are fed back face-to-face, but for less serious conditions a letter could be sent out. This system is demonstrated in Figure 29.

Figure 29



"As long as the people that need to be informed are getting informed when there's something wrong, but if it's all okay there's no need."

Focus group participant, Belfast

"If there's something in a huge huge study and I think for something that's life threatening like when you were saying that you've got a gene that may or may not and they wasn't sure, maybe that probably isn't a need to feed that back, but if you came across someone with the what did you call it, the aortic, yeah then that I think you would need to feed that back."

Focus group participant, London

An alternative view was that it was acceptable not to provide feedback for such large scale studies, but only if the participants had been made aware that they would not receive feedback before they signed up.

"I think it's just impractical sometimes and it would make it prohibitively expensive to do a lot of the trials and really like the quality of healthcare would suffer as a result and I don't think that that's worth it for like feeding back to the individual. I think it's better to just kind of let them know it's not a diagnostic test, you need to go to your health centre if you've got problems."

Research participant

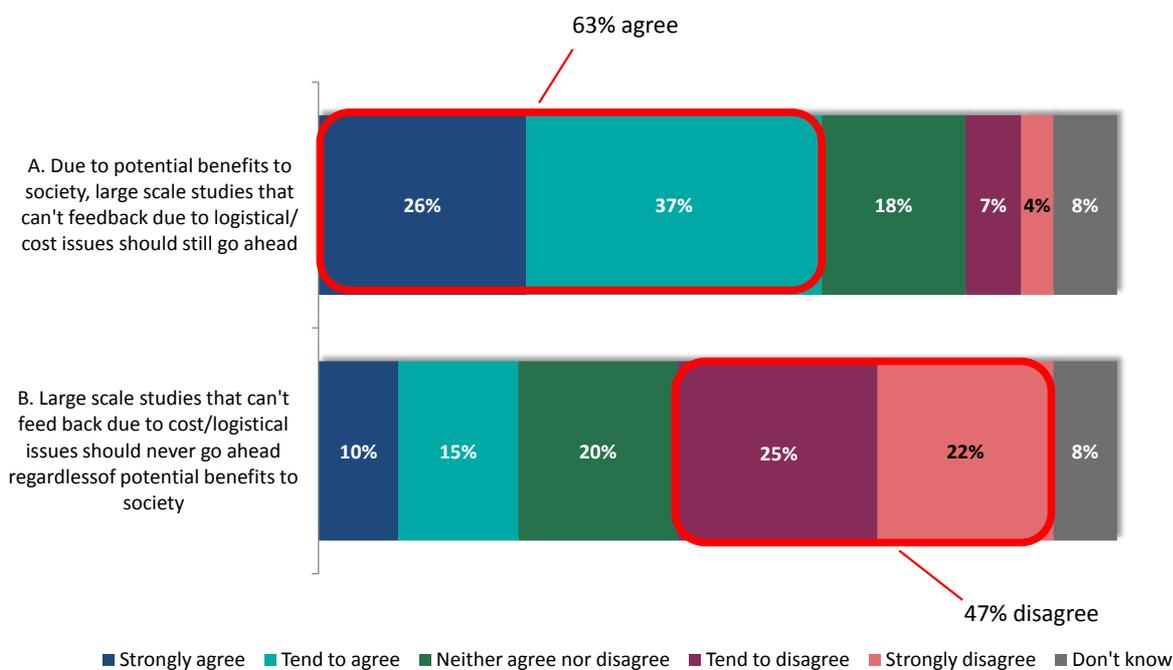
"I think that in that case [with no feedback] you've just got to say, on the consent form, there is absolutely no way that we can provide feedback on this regardless of whether it's minor or major feedback, and let the patient make their own mind up."

Person affected by condition

When the issue of feedback in large scale studies was addressed in the quantitative phase, over six in ten people agreed that due to the potential benefits to society, large scale studies that cannot feed back due to logistical or cost issues should still go ahead. This contrasts with just over one in ten who think that these large scale studies should not go ahead if they cannot provide feedback. However, respondents' views on the balance between the societal benefit of these studies and the personal loss of feedback to the participant appeared to shift depending on which aspect of the equation was placed first in the question. As Figure 30 displays, when the potential benefits to society of large scale research were presented first in the question, and lack of feedback was then explained (statement A), 63% of respondents agreed that large scale studies which provide no feedback should still go ahead. However, if the explanation of lack of feedback was stated first and public benefits were then mentioned (statement B), only 47% of respondents thought that large scale studies should still go ahead. This could have significant implications for how the absence of feedback is explained to potential participants when they are given information on a study.

Figure 30

Opinions on the benefits and costs of feeding back on large scale studies



Q21. To what extent do you agree, or disagree with the following statements: Base: All Respondents (1105)

Sub-group differences

The belief that large scale studies should continue despite lack of feedback was held most strongly by those in higher socioeconomic grades (A and B). Seven in ten people in these grades agreed with statement A whilst six out of ten people in other socioeconomic grades (C1, C2, D and E) agreed. The same pattern occurred with statement B, with those in socioeconomic grades A and B having higher levels of disagreement with the statement, indicating higher levels of acceptance for large scale studies with no feedback.

Acceptance of such large scale studies was also higher among those with no children in their household. 67% of those with no children in the household agreed to statement A compared to

58% of those with children. This sentiment was replicated for statement B, with 53% of those without children disagreeing in comparison to 35% of those who had children in the household.

Individuals with long-term health conditions were more favourable to statement A than those with no health conditions (70% vs. 60% agreeing) and were also more unfavourable to statement B (53% vs. 45% disagreeing), although the difference in opinion was less for this statement. This difference in view could have partly been due to the potential direct benefits that individuals with long term conditions feel they could get from large scale medical research in relation to their condition. The acceptance of large studies with no feedback was greater among those who had participated in research compared to both those who had family who had participated in research and those who had no research experience. Acceptance of such studies was also higher among those who were likely to participate in research compared to those who said they were not likely to.

4. Discussion and conclusion

The findings of this study on public attitudes have implications for the feedback of health related findings in research. In developing policy, the following conclusions should be considered alongside other factors – such as the impact on research and legal implications – that may influence the approach to feedback.

1. Consider the feedback of findings to individuals during study planning

Participants showed overwhelming support for the return of health related findings to research participants, particularly where a condition is serious and treatable. Researchers should therefore consider the feedback of findings when designing and setting up a study to ensure that potential research participants have the information they need to decide whether to take part in a study, and to ensure that appropriate mechanisms can be put in place to support the feedback of findings.

In considering whether findings will be fed back to individuals and the processes used to do this, researchers should take into account the views of the public and seek to balance these with other factors, such as feasibility and the views of health professionals.

Researchers should consider the feedback of findings to individuals when designing and setting up studies and cohorts. This should include thinking about whether and how feedback would be provided.

2. The importance of consent, transparency and clear communication

Respondents viewed the consent process as a critical point for potential participants to receive information on health related findings before agreeing to take part in research. This information could include:

- whether any findings will be fed back
- what factors would determine whether a specific finding would be fed back, for example only findings that are clinically relevant and indicative of a condition that is both serious and manageable
- limitations of any feedback provided, for example in the accuracy of the findings
- whether a participant can indicate a preference not to receive feedback and, if so, whether there are any circumstances in which this 'right not to know' could be overridden
- how feedback would be provided if a finding is identified, for example who would provide the feedback and how it would be delivered.

Respondents considered that this information would help potential participants make an informed decision about taking part in research. It is therefore essential that information on feedback is presented clearly and in an accessible form that members of the public are able to understand.

A common view in the qualitative research was that it was acceptable for feedback not to be provided if research participants had understood that this was the case from the outset. Information on why feedback would not be given, for example that findings would not be sufficiently accurate or that the study would not be able to go ahead at all, would help potential participants decide whether to take part.

Information on the feedback of health related findings should be provided to potential research participants before they decide whether to take part in research.

3. Establishing appropriate processes for feedback

Respondents generally recognised that those involved in the research may need to make some decisions on their behalf, for example, whether it was appropriate to feed back a finding or not. To maintain public trust it is therefore important that robust mechanisms are in place to support the decision-making process on feedback in individual cases.

Where findings were to be fed back, respondents valued the role in the process of health professionals or those they had an existing relationship with. It was felt that the route through which feedback was provided should be appropriate to the severity of the finding. Participants in the qualitative research did not want to receive feedback without further support and information to understand the implications of the finding and how they should act upon it. Researchers should take these factors into account in designing the feedback process and ensure that those receiving feedback have sufficient information and access to follow up advice.

Formal and clear processes should be established where findings are to be fed back. These should support decision-making about whether to return a potential finding, establish the nature of the feedback process itself, and ensure that those receiving feedback have sufficient support to act upon it.

4. Limited understanding of medical research

This study showed that public understanding about medical research is weak. For example, participants' expectations and perceptions of the obligations of non-clinical researchers do not correspond with law and some current practice. It is important that the results of this study are considered within this context.

The low level of understanding has important implications for how researchers communicate with research participants, particularly to avoid a gap developing between research participants' expectations and current practice in a study.

Researchers should take into account the low level of public understanding of research when designing materials and consent forms. Research studies and cohorts should provide clear and accessible information to those thinking about taking part in research and those who choose to participate.

5. Further research

This study has highlighted a number of areas that would benefit from further research to enhance our understanding of attitudes towards feedback. This would enable a more sophisticated balancing of the different factors that should be taken into account around the feedback of findings.

Further research, particularly exploring the areas set out below, would enhance the evidence base for policy decisions on the feedback of findings to individuals:

- The substantial financial and time implications of feeding back findings may have negative impacts on research, potentially meaning that fewer studies can go ahead. Involving health professionals in the feedback process is likely to increase the burden on the health service. **How do the public balance or prioritise these potential societal costs with the strong desire for individual feedback?**
- In the context of this study, respondents valued the advantages of feedback over the disadvantages. However, the issues around clinical relevance and the accuracy of findings are complex and the public found these issues difficult to understand. Further work would therefore be useful to explore **whether a more detailed examination of the potential**

harms or disadvantages of feedback has an impact on the strong desire for it to be provided to participants.

- The study showed that more respondents favoured there being a cut-off point, after which findings would no longer be returned, than favoured being able to receive findings over an indefinite period of time. This study did not consider whether views on the timescales for feedback would be affected by scientific or medical developments, for example when the clinical meaning of a gene pattern is unknown at the time the study is conducted, but is later found to be strongly associated with a serious disease. Further research would therefore be valuable on **how the public perceive the impact of scientific or medical developments that change the way a finding is interpreted on feedback.**

Research with certain types of individual would provide further evidence and a useful assessment of the similarities and differences between the views of the general public and the specific groups, including the following:

- This study examined qualitatively the views of 10 individuals who had taken part in research. It would be useful to extend this analysis to **explore the views of individuals who have participated in different types of research, including those who have participated for a fee, in further detail.** This research could examine research participants' perceptions of whether or not they expect to receive feedback and compare this to the conditions in their original consent.
- Understanding the **views of research participants who have had findings fed back to them** would provide useful context for understanding the results of this piece of work by providing further evidence on the practical implications of feedback.
- The feedback of findings will need to take into account the views of the public and those of health professionals. It would therefore be useful to **understand better the views of health professionals on feedback and explore what has shaped their views.**

5. Glossary of key terms

Accuracy/Analytical validity: How accurate the findings are based on the instruments and procedures used to measure them. For example, in some scanning studies the images produced are well below the quality used for clinical diagnosis.

Anaemia: A condition which means that a person's blood cannot carry as much oxygen as it should, which causes tiredness and breathlessness.

Aorta: The largest artery in the body, starting from the heart and extending down to the abdomen. The aorta distributes oxygenated blood to all parts of the body.

Clinical researcher: A researcher who is a trained doctor and who may well do their research within the health service.

Clinical relevance/validity: How well established the link is between a finding and a specific condition within medical literature. For example, some genetic patterns have been associated with conditions but not proved to be causal and are therefore not clinically valid.

Consultant: A senior medical doctor who has completed their entire specialist training and has been placed on the register for their chosen speciality.

Eczema: A condition that causes the skin to become itchy, red, dry and cracked. It is a long-term, or chronic, condition.

Gene: Segments of DNA that provide information for the body to build or do something. A parent passes on genes to their offspring.

Gene pattern: Different forms or variants of a gene that a person might have. Some patterns are associated with a risk of developing a disease.

Genetic: Associated with genes or DNA.

Hall test: A form of quantitative data collection where respondents complete a questionnaire in a public space or venue after being recruited face-to-face on the street. Recruitment is conducted to strict quotas using 'screener' questionnaires to ensure that the sample interviewed is representative of the target population on certain pre-defined variables.

Health professional: A person who works in the health service, identifying, preventing or treating illness or disability. This includes doctors and other in the medical profession, such as nurses, physiotherapists and speech and language therapists.

Health related findings: Findings discovered during research with human participants that relate specifically to an individual participant's health e.g. researchers could find out in the course of a research study that one participant has a particular disease.

Incidental finding: A finding that is not related to what the main research study is looking at, e.g. if a study scanning the liver to look at fat levels on the liver detects a possibly harmful lump.

Non-clinical researcher: A researcher who is not trained as a doctor but who has undertaken training as a scientist or researcher and who may well work outside of the health service.

Parkinson's disease: A non-curable neurological condition that causes the body to shake and can have other effects such as pain and tiredness.

Pertinent finding: A finding that is related to what the main research study is looking at, e.g. if a study looking at patterns in genes associated with a particular disease finds such a pattern in a participant.

Qualitative research: Research focusing on understanding the nature of phenomena and their meaning, rather than how often they occur. It tends to have the following characteristics: direct face-to-face contact between researchers and those being researched and in-depth examination of small-scale samples.

Quantitative research: Research focusing on the incidence and statistical relationships of variables. It tends to have the following characteristics: use of structured questionnaires with standard questions; little face-to-face contact between respondents and primary researchers, with the questionnaire being administered by trained interviewers; use of large samples and results subjected to statistical analysis.

Research participant: A volunteer in a research study.

Scenario: An imagined situation or sequence of events.

Secondary research: When research is being conducted on data that was collected by a primary research team and not the team conducting the further analysis.

Socioeconomic group (SEG): Social classification based on the occupation of the highest earning individual in the household. Groups range from the highest, A, through B, C1, C2 and D to E, the lowest.

Statistical significance: The likelihood that a finding or a result is caused by something other than chance. This is usually set at less than 5% probability, meaning that the result is at least 95% likely to be accurate (or that this result would be produced by chance no more than 5% of the time).

Variable: A factor that is subject to change, and that, in conjunction with other variables, explains overall change of a situation or object.

6. Appendices

Appendix 1: Discussion guides.....	71
Appendix 2: Scenarios	72
Appendix 3: Focus group quotas and scenario allocations.....	74
Appendix 4: Quantitative survey topline results	76
Appendix 5: A guide to statistical reliability.....	77

Appendix 1: Discussion guides

The discussion guides used in the qualitative stage are available on request. Three different topic guides were designed for the extended groups, the interviews with individuals affected by conditions and the research participants. All three guides cover the same general themes; however, the guide for the extended groups are longer due to the longer length of the session itself. The guide for the groups also includes additional group activities to encourage discussion from the participants.

The guides for the interviews with individuals affected by conditions and research participants were similar to each other in structure and length. The main area of difference between the two was in the introduction sections in which the interviewees' personal experiences are discussed.

Appendix 2: Scenarios

Scenarios were used in the project as they are an accessible way to present complex information to the general public. They were a good platform for discussion and probing of individuals' opinions, and could also be varied in different aspects, giving scope to explore a wide range of factors/variables.

The development of the scenarios was key to the success of the project. It was important for the scenarios to contain concrete examples of situations to allow participants to understand and engage fully with the topic and to foster debate and discussion around the issue. However, it was also crucial to ensure that the findings would not relate solely to the concrete situations that were presented in the scenarios and could feed into broader recommendations on the area as a whole.

The scenarios were informed by the scoping stage of the project, which had highlighted variables that could potentially have an impact on the public's view on when, if and how to feed back health related findings to a participant. Following the scoping stage a brainstorm was conducted with members of the Opinion Leader project team and Wellcome Trust staff. From this brainstorm, a grid was drawn up, ensuring each of the variables was covered within a scenario and that the scenarios also included variation in terms of participant type (healthy or with a condition), gender, setting of the research study and the type of findings discovered (physiological, genetic, images).

The table below displays the variables included in each scenario.

Scenario	Intro	1	2	3
Participant type	Healthy	Condition	Healthy general population study	Healthy (individual study)
Gender	Male	Female	Male	Female
Findings	Physiological	Genetic	Genetic	Genetic
Setting	Health centre	Hospital	Research facility	Hospital
Variable 1	Setting	Incidental vs. pertinent	Severity	Certainty of risk
Variable 2	Age	Clinical validity - (probing on certainty)	Analytical validity	Impact on others
Variable 3		Consent level	Treatability	

Scenario	4	5	6
Participant type	Healthy (individual study)	Healthy (biobank)	Healthy
Gender	Male	Female	Male
Findings	Image	Physiological	Image
Setting	University	Health centre	University
Variable 1	Analytical validity (with probing around setting)	Secondary research	Right not to know
Variable 2	Risk of false positives	Time after data collected	Effect on others
Variable 3			

The initial scenarios were drafted and were then reviewed by a steering group of experts to ensure both scientific accuracy and that the situations were as true to life as possible. To allow easy use of the scenarios in the groups and interviews, a booklet was designed with the scenarios and probes for each scenario. The participants had a similar booklet without the variables (e.g. effect on others) named at the top of each scenario.

An activity built into the groups and the interviews was for two or three scenarios to be read through and the questions on that scenario answered. Within the groups, the individuals were given time to write their answers into the booklet in breakaway groups. These answers were then discussed in the main group. Within the interviews the questions were answered verbally.

The scenario booklets used are available on request.

Appendix 3: Focus group quotas and scenario allocations

Quotas

- The following quota matrix was designed for the qualitative stage extended groups:

Location	London		Cardiff		Belfast		Glasgow	
Group	1	2	3	4	5	6	7	8
Age	18-35	35-54	55+	35-54	18-35	55+	35-54	55+
SEG	ABC1	C2DE	C2DE	ABC1	C2DE	ABC1	ABC1	C2DE
Ethnicity	At least 3 BME	At least 3 BME	At least 2 BME	At least 2 BME	Attempt 2 BME	Attempt 2 BME	At least 2 BME	At least 2 BME
Gender	5 men 5 women							
Involved in market research in last 6 months	None							
Involvement in scientific activity*	Maximum 2 activities per person							
Taken part in any medical research in the last 3 years	Maximum 3 people							
Long-standing illness, health problem or disability	Maximum 2 people							

* Involvement in research included any of the following:

- | | |
|--|------------------------------------|
| - Been a member of a science org in the last 5 years | - I am a scientist |
| - Have (ever) worked as a scientist or engineer | - I am an engineer |
| - Have science or engineering degree | - Member of a science organisation |
| - Have studied science to A Level | - Have taught a science subject |
| - Have studied science to degree level | |

- No quota matrices were used for the groups with conditions but we aimed to have, and achieved, differences among the sample in the following variables:
 - Severity of the condition
 - Type of condition (long-term versus short-term)
 - Nature of the condition (e.g. genetic disorder, cancer, diabetes, heart disease) (we did not include those with mental conditions)

- No quota matrices were used for the groups with research participants but we aimed to have, and achieved, differences among the sample in the following variables:
 - Type of research they had participated in (long-term, one-off)
 - Nature of the research study (physiological, genetic, imaging)

Scenario allocations

The scenarios were allocated to the extended groups to ensure that different demographic groups gave their views on the same scenarios. The scenarios were also allocated to each set of depth interviews to ensure that they were evenly distributed between groups

Within each group the introduction scenario was used, followed by two other scenarios, the allocation of which is shown below:

Groups

Location	London		Cardiff		Belfast		Glasgow	
Group	1	2	3	4	5	6	7	8
Age	18-35	35-54	55+	35-54	18-35	55+	35-54	55+
SEG	ABC1	C2DE	C2DE	ABC1	C2DE	ABC1	ABC1	C2DE
Scenarios	Intro	Intro	Intro	Intro	Intro	Intro	Intro	Intro
	1	2	3	1	4	5	5	6
	5	6	4	6	2	3	1	3

Within each interview the introduction scenario was used, followed by one other scenario, the allocation of which is shown below:

Participants affected by conditions

Participant	1	2	3	4	5
Scenarios	Intro	Intro	Intro	Intro	Intro
	1	2	3	4	5

Participant	6	7	8	9	10
Scenarios	Intro	Intro	Intro	Intro	Intro
	6	1	2	3	4

Participants who have taken part in research

Participant	1	2	3	4	5
Scenarios	Intro	Intro	Intro	Intro	Intro
	1	2	3	4	5

Participant	6	7	8	9	10
Scenarios	Intro	Intro	Intro	Intro	Intro
	6	5	6	1	2

Appendix 4: Quantitative survey topline results

- The questionnaire was administered online and a boost was conducted with internet non-users via a series of hall tests. The hall test participants answered the same online questionnaire as the main sample and were assisted (where required) by an interviewer.
- 1,100 online questionnaires were completed. 100 of these were completed in hall tests by internet non-users.
- Quotas set for the main sample were gender, age and geographical location of the respondents based on latest available UK Census data. Quotas for the boost sample were set on gender, age and socioeconomic group, based on the UK population of internet non-users.
- Once fieldwork was completed the data was then combined and weighted to be representative of the UK population based on latest available UK Census data. Weighting was applied on gender, age geographical location and socioeconomic group.
- The base size of the data is 1,105 unless otherwise stated.
- Where figures do not sum to 100% this may be due to computer rounding, multiple codes or the exclusion of “don’t know”.
- All figures represented by a * indicates that responses were given but that the responses did not equal up to 1%.
- The full quantitative topline results are available on request.

Appendix 5: A guide to statistical reliability

The decision on sample size generally depends on the accuracy with which you want to measure views, as well as the available budget. Our achieved sample size of 1,105 provides robust overall findings and allows survey results from key social and demographic sub-groups to be considered in isolation (provided we have a minimum sub-group size of c.100 for that sub-group). The table below shows the possible variation that can be anticipated because a sample, rather than the entire population, is interviewed. As indicated, sampling tolerances vary with the size of the sample and the size of the percentage results. For example, on a question where 50% of the people in a sample of 1000 respond with a particular answer, the chances are 95 in 100 that this result would not vary by more than 3 percentage points, plus or minus, from a complete coverage of the entire population using the same procedures.

Sample size	Approximate sampling tolerances applicable to result at or near...		
	10% or 90% \pm %	30% or 70% \pm %	50% \pm %
100	6	9	10
300	3	5	6
600	2	4	4
900	2	3	3
1,105	2	3	3

The requirement for larger sample sizes is also affected by the need to compare findings for specific sub-groups. The table below provides an indication of the tolerances that will apply when comparing data based on two sub-group samples. It shows that the larger the sample size the more accurate you can be in determining whether a difference between two groups is statistically significant.

Sample sizes being compared	Approximate sampling tolerances applicable to result at or near...		
	10% or 90% \pm %	30% or 70% \pm %	50% \pm %
100 and 100	8	13	14
300 and 300	5	7	8
500 and 500	3	5	6

