Appendix 5D

Attitudes to and impact of the feedback of potentially serious incidental findings from UK Biobank’s imaging pilot study

TNS BMRB
Qualitative Research Findings

May 2015
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1. Executive Summary

1.1 Perceptions and understanding of the imaging study

- Consent for participation in the imaging study was almost ‘automatic’ for many given previous positive experiences. There was an additional sense of privilege in being invited to take part in the imaging study.
- Participants felt well-informed about the practical and ethical elements of the scanning process before they attended.
- Participants’ motivations to take part in the imaging study were largely altruistic. The potential to gain feedback on any incidental findings was perceived as a secondary benefit and did provide additional motivation to participate; however, there was minimal evidence of a misunderstanding that participation conferred a medical ‘health check’.
- Concerns at point of consent into the imaging study were very limited – in particular, consideration of potential downsides of the possibility of incidental findings notification was limited. However, a minority of participants weighed this decision heavily and were much more concerned overall about potential notification.
- Although participants were all happy with the consent process, there is scope to ensure more engagement at this stage to mitigate misunderstandings should incidental findings feedback be received.

1.2 Initial understanding and expectations of the feedback process

- There was limited understanding of the professionals involved in the scanning process and in the identification of incidental findings. However, participants did not feel they needed to know detail around this.
- Awareness of the technical difference in UK Biobank scans compared with clinical scans was low. This led to latent concerns and misinterpretations of incidental findings if reported.
• However, participants understood the implications of the scans being for research rather than clinical investigation and set their expectations around this.
• Serious findings were understood to mean cancer, aneurisms or critical heart conditions; participants did not consider non-serious or artefact outcomes to incidental findings, which meant these outcomes were often surprising.
• Expectations around the timescale of feedback were mixed. Six to eight weeks from scan to incidental findings notification was typically felt to be an acceptable time lag, although some had noted the two-week period cited by UK Biobank.
• UK Biobank need to be sure to communicate effectively around potential non-serious outcomes and to communicate the longest possible timeframes for providing feedback in order to manage expectations

1.3 Experiences of the scanning process

• UK Biobank staff were praised for being friendly and attentive, and the overall scanning process for being efficient and professional.
• A few isolated incidents raise concerns around UK Biobank staff effectively communicating with participants, being aware of how they are feeling and the impact of any comments they make.

1.4 Receiving feedback

• Participants were largely very satisfied with the way UK Biobank communicated with them around incidental findings. The letter received was felt to be appropriate in tone and language.
• Despite recognising the reassurance offered by UK Biobank, most participants receiving feedback immediately assumed they would be diagnosed with something serious; this caused high levels of short-term anxiety for some.
• There was a general preference for minimal detail in the letter to participants and an expectation that GPs receive full detail, including (where feasible) copies of the scans.
• Some issues with accuracy of information and timing of the letter were experienced, which heightened anxiety for participants.
• Participants noted that GPs displayed a proactive response to UK Biobank information, despite low awareness of the organisation and the study. However, where the GP response was considered less than ideal this did raise anxiety and could appear to hinder the progress of follow-up investigations.
• There are some opportunities for UK Biobank to improve the experience for participants through the provision of explicit information about the incidental findings process.
• There are also opportunities for UK Biobank to communicate more effectively to the medical community around the purpose and aims of the study, to aid its credibility.

1.5 Wider impacts of receiving feedback

• In general, levels of anxiety amongst family members in response to incidental findings notifications were low.
• However, there were a few examples of family members expressing high levels of worry and anxiety due to personality and/or not knowing enough about the UK Biobank study.
• Participants often reported wider positive impacts on lifestyle following receiving feedback on incidental findings. For example, being more active, eating more healthily and generally taking a more careful view of their health.
• In general, taking part in the imaging study has not negatively affected perceptions of UK Biobank, and in some cases perceptions have been strengthened.
Part I: Background and Introduction

2. Introduction

2.1 Background to the research

In 2014, UK Biobank launched an ambitious, multimodal imaging pilot study. The aim of the study is to create the world’s largest database of vital organ imaging scans to be used for research into the diagnosis and treatment of a wide range of diseases. The pilot stage so far has scanned over 3,800 of UK Biobank’s 500,000 registered participants, and there are plans to scan up to 100,000 participants over the coming years.

As part of pilot testing, UK Biobank needs to identify optimal procedures and protocols for research, including the most ethical and appropriate feedback mechanisms for incidental findings discovered during research. In some cases, these incidental findings can have serious health implications (e.g., brain aneurysms); in others, the findings turn out to be non-serious (i.e. not life-threatening) resulting in unnecessary clinical investigation by the NHS. UK Biobank cannot be responsible for the diagnosis of specific issues resulting from any incidental findings being identified.

How incidental findings should be managed – particularly for large-scale imaging research studies\(^1\) – is a matter of international dialogue and bioethical debate. Although many points of contention remain\(^2\), there are clear ethical issues to consider, as well as remaining research gaps. While sharing incidental findings has the potential to save lives, these findings

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\(^1\) For example, the German National Cohort study, which conducts 40,000 full-body MRI scans within the larger 200,000 person sample.

\(^2\) For example, see the 2012 Leuven Centre for Biomedical Ethics and Law literature review for a summary of divergent views in the academic community on how incidental findings should be most ethically handled. - *To tell or not to tell? A systematic review of ethical reflections on incidental findings arising in genetics contexts*, Gabrielle M Christenhusz, Koenraad Devriendt & Kris Dierick, 2012
can also cause distress and uncertainty if they yield false positives, identify conditions which lack effective treatment, or require costly or risky follow-up procedures. Likewise, although survey research consistently reports that the vast majority of participants in imaging studies express interest in receiving feedback about relevant incidental findings which arise, there is much less empirical evidence on the actual effects on participants, whether positive or negative, of receiving this kind of information.

Given the scale of the study being undertaken by UK Biobank, there was therefore a recognised need to address this evidence gap and assess experiences of participants taking part in the piloting phase of the study. The results of this research are intended to inform UK Biobank’s ethical decision-making process, and also to address any other underlying issues that may exist in relation to participant experience and understanding of the UK Biobank imaging study.

### 2.2 Research aims and objectives

This project had 4 specific aims:

1. Assess the attitudes of participants to receiving feedback of incidental findings and to track whether these change over time; also to assess initial understanding of feedback mechanisms and how this affects attitudes overall
2. To understand the impact on participants, their family and friends of receiving feedback
3. Assess the attitudes of radiographers and radiologists (involved in the feedback process) towards UK Biobank’s incidental findings feedback procedures
4. To inform the policy on feedback for the main phase of the imaging study.

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3 [http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf](http://bioethics.gov/sites/default/files/FINALAnticipateCommunicate_PCSBI_0.pdf)

4 The Royal College of Radiologists’ 2011 Report into the Management of Incidental Findings cites 95% of participants in the Rotterdam Scan Study, and 98% of participants in the Lothian Birth Cohort 1936 Study requesting feedback on incidental findings. In UK Biobank’s own 2012-2013 feedback survey of its participants, 92% said they would be happy to receive information on potentially serious incidental findings following an imaging assessment.
To achieve this, a research methodology was developed so as to separate general, knee-jerk expectations from considered views, and to explore how views differ upon reflection, upon experience of feedback versus pre-scanning, and upon the kind of outcome following investigation of the incidental finding.

The methodology used is detailed below.

2.3 Methodology

2.3.1 Overview

UK Biobank conducted their own quantitative research with participants and their GPs on the emotional and clinical impact on receiving feedback on incidental findings.

This report considers the feedback from a two-wave qualitative approach that was also conducted to understand a more nuanced, in-depth picture of the experiences of participants at different stages of the process.

Six main activities took place in relation to this qualitative research, separated in two waves:

Wave One:
1. **Two two-hour deliberative groups prior to scanning:** these assessed the attitudes of participants to the idea of receiving feedback, and understanding of feedback mechanisms and principles at point of consent. These participants had agreed to, but not yet undergone, the scanning process.
2. **16 90-minute one-to-one interviews with recipients of feedback:** these were held at the participant’s home, and gathered an in-depth picture of the journey each participant went through from point of sign-up to on-going or follow-up medical investigation since feedback on incidental findings was received.
3. **Six 30-minute one-to-one interviews with stakeholders:** we interviewed three radiographers and three radiologists who were involved in the feedback process to understand their initial views.

Wave Two:
4. **10 one-hour follow-up telephone interviews with wave one recipients of feedback:** these were held over the phone and
asked respondents to reflect further on their experience with UK Biobank, four months after our initial contact. The aim was to understand if thoughts or feelings had changed over that time, and to understand how any further medical investigation may have impacted on their views.

5. **Five additional 90-minute one-to-one interviews with recipients of feedback:** these were again held in home as in wave one, but involved five new respondents and were used to understand if findings from wave one still rang true with participants not previously consulted four months ago.

6. **Six 30-minute follow-up interviews with stakeholders:** the six stakeholders from wave one were re-consulted to understand if views had changed over time, and to feedback emerging qualitative findings so as to garner views on what these might mean for their work and for feedback procedures overall.

All discussion guides used for each stage of research are included in the appendices of this report.

### 2.3.2 Sample and recruitment

All participants for this research were recruited by TNS-BMRB’s in-house field team, supported by information provided by UK Biobank based on gaining informed consent from study participants.

All recruitment materials were pre-approved by the UK Biobank team. All materials made clear that participation in this research was optional, and that decisions to/not to participate would not affect participants’ relationship with UK Biobank or their participation status in the imaging research.

Full versions of all materials used to recruit participants are included within the appendices of this report.

**Deliberative groups**

For the deliberative groups, UK Biobank included a note regarding potential re-contact by TNS-BMRB in the imaging study invitation email. UK Biobank then sent a limited sample of contact details of individuals with upcoming imaging appointment times, and TNS-BMRB recruited
participants via an email contact letter. Formal written informed consent was obtained immediately prior to the deliberative group session.

Deliberative groups were recruited according to the Townsend score for affluence as per the table below:

<table>
<thead>
<tr>
<th>Group</th>
<th>Townsend score</th>
<th>Number of attendees</th>
</tr>
</thead>
<tbody>
<tr>
<td>One (&quot;affluent&quot;)</td>
<td>&lt;-2</td>
<td>10</td>
</tr>
<tr>
<td>Two (&quot;deprived&quot;)</td>
<td>&gt;0</td>
<td>11</td>
</tr>
</tbody>
</table>

The specific make-up of each of the groups was as per the table below:

<table>
<thead>
<tr>
<th>Group</th>
<th>Gender</th>
<th>Age</th>
<th>Townsend score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 – “Affluent”</td>
<td>Female</td>
<td>46</td>
<td>-4.608</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>67</td>
<td>-5.387</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>68</td>
<td>-5.657</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>74</td>
<td>-2.281</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>49</td>
<td>-4.608</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>54</td>
<td>-3.693</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>57</td>
<td>-2.817</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>64</td>
<td>-2.281</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>64</td>
<td>-4.057</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>67</td>
<td>-3.696</td>
</tr>
<tr>
<td>Group 2 – “Deprived”</td>
<td>Female</td>
<td>61</td>
<td>0.731</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>65</td>
<td>0.354</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>67</td>
<td>0.354</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>68</td>
<td>0.936</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>68</td>
<td>1.94</td>
</tr>
<tr>
<td></td>
<td>Female</td>
<td>70</td>
<td>7.758</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>55</td>
<td>2.933</td>
</tr>
<tr>
<td></td>
<td>Male</td>
<td>61</td>
<td>0.354</td>
</tr>
</tbody>
</table>
Both groups included one married couple each, which was considered to be appropriately representative of the UK Biobank imaging study sample.

**Feedback recipients**
Participants who had received feedback were recruited via a rolling sample of contact details for those having agreed to further contact, provided by UK Biobank from their quantitative survey data. TNS-BMRB then conducted telephone recruitment, sending on an ‘information and confirmation’ letter following initial verbal consent.

While no hard quotas were set for this sample, recruitment focussed on a mix of demographic criteria and a mix of potentially serious findings resulting from each imaging modality (i.e. brain MRI, cardiac MRI, whole-body MRI, whole body DXA, and carotid ultrasound).

A breakdown of participants recruited for wave one can be seen below. The third column shows responses to a question from UK Biobank’s six-week incidental finding questionnaire

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Townsend score</th>
<th>Has a doctor explained to you what this possible abnormality is or might be?</th>
</tr>
</thead>
<tbody>
<tr>
<td>55</td>
<td>Female</td>
<td>-1.049 (affluent)</td>
<td>I have been told that there is no abnormality</td>
</tr>
<tr>
<td>55</td>
<td>Female</td>
<td>5.412 (deprived)</td>
<td>Yes, I have been told that there is no abnormality</td>
</tr>
<tr>
<td>64</td>
<td>Female</td>
<td>3.394 (deprived)</td>
<td>I have been given a possible diagnosis</td>
</tr>
<tr>
<td>65</td>
<td>Female</td>
<td>-4.494 (affluent)</td>
<td>Other</td>
</tr>
<tr>
<td>68</td>
<td>Female</td>
<td>-4.717 (affluent)</td>
<td>No explanation</td>
</tr>
<tr>
<td>68</td>
<td>Female</td>
<td>-3.115 (affluent)</td>
<td>I have been given a possible diagnosis</td>
</tr>
<tr>
<td>71</td>
<td>Female</td>
<td>-2.349 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>Age</td>
<td>Gender</td>
<td>Townsend score</td>
<td>Has a doctor explained to you what this possible abnormality is or might be?</td>
</tr>
<tr>
<td>-----</td>
<td>--------</td>
<td>----------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>73</td>
<td>Female</td>
<td>1.315 (deprived)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>74</td>
<td>Female</td>
<td>-0.129 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>56</td>
<td>Male</td>
<td>0.83 (deprived)</td>
<td>Yes, I have been told that there is no abnormality</td>
</tr>
<tr>
<td>64</td>
<td>Male</td>
<td>1.862 (deprived)</td>
<td>I have been given a possible diagnosis</td>
</tr>
<tr>
<td>64</td>
<td>Male</td>
<td>-0.219 (affluent)</td>
<td>I have been given a possible diagnosis</td>
</tr>
<tr>
<td>67</td>
<td>Male</td>
<td>-2.208 (affluent)</td>
<td>Yes, I have been told that there is no abnormality</td>
</tr>
<tr>
<td>68</td>
<td>Male</td>
<td>-0.976 (affluent)</td>
<td>I have been given a possible diagnosis</td>
</tr>
<tr>
<td>68</td>
<td>Male</td>
<td>-4.108 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>76</td>
<td>Male</td>
<td>-4.009 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
</tbody>
</table>

For wave two, follow-up respondents were recruited to represent a range of different incidental finding outcomes according to UK Biobank’s categorisation including: finding found to be artefact; diagnosis considered non-serious; uncertain diagnosis; diagnosis considered serious. Those respondents re-recruited for wave two are indicated in grey in the table above. Where verbatim quotes are used from second wave interviews with repeat respondents within this report, they are referred to as “wave 2 follow-up.”

In addition, five new respondents were recruited at wave two, as per the table below:

<table>
<thead>
<tr>
<th>Age</th>
<th>Gender</th>
<th>Townsend score</th>
<th>Has a doctor explained to you what this possible abnormality is or might be?</th>
</tr>
</thead>
<tbody>
<tr>
<td>58</td>
<td>Female</td>
<td>-1.27 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>69</td>
<td>Female</td>
<td>-3.115 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>74</td>
<td>Female</td>
<td>-4.324 (affluent)</td>
<td>I have been given a definite diagnosis</td>
</tr>
<tr>
<td>75</td>
<td>Female</td>
<td>0.081 (deprived)</td>
<td>I have been given a definite diagnosis</td>
</tr>
</tbody>
</table>
Where verbatim quotes are used from second wave interviews with new respondents within this report, they are referred to as “wave 2 only.”

2.3.3 Analysis
An iterative and inductive qualitative analytical approach was undertaken for each wave of this research. This was a three-stage process, as described below.

Stage 1: Analysis began informally during fieldwork with researchers feeding back headline findings to each other as interviews were conducted, and continually updating thinking as research data was amassed. This allowed the whole fieldwork team to have a sense of emerging findings as they conducted interviews, meaning any areas of particular interest could be further pursued or probed in subsequent interviews.

Stage 2: A more formal analytical process then made use of set pro-formas, or frameworks, within which individual analysis of each session was set against the key research questions. Specific frameworks were developed for each element of research, in order to reflect its specific objectives, and these are included within the appendices. This enabled researchers to form initial overarching hypotheses and insights in relation to their own interviews, and to gain a read-across of all fieldwork insights.

Stage 3: The final stage of analysis brought all fieldwork researchers back together to discuss the main themes and insights from both stage 1 and stage 2 of the analysis. All frameworks were shared across the team and were used to identify the most salient reporting points. The overall structure of the report was also agreed within these sessions.

Each of these three stages of analysis was repeated for both wave 1 and wave 2 of fieldwork, with wave 2 building on the existing insights from wave 1. This ensured that recurring themes and insights were highlighted, as well as newly emerging ones.
Part II: Key Findings

3. Perceptions and understanding of UK Biobank research

This section briefly outlines research participants’ perceptions of UK Biobank, what they understood to be the key aims of the overall project and their reasons for taking part in the wider study, in order to set the context for the main focus of the report, which is around the impact of incidental findings.

3.1 Relationship with UK Biobank

All of the participants in this research had a long-standing relationship with UK Biobank. Most remembered initially signing up around five to eight years ago, and as such their perception of UK Biobank did not change over the course of this research.\(^5\)

Given the length of time since original consent, participants tended not to remember clearly how they came into contact originally with UK Biobank. Typically, participants reported a sense of altruistic duty driving their participation, expecting that 1) they had been invited because their data was needed, and 2) the research had the potential to benefit the wider public. They thus viewed it as a privilege to take part – clearly very committed to UK Biobank and believing in the benefit of its work. Participants reported a high level of trust between themselves and UK Biobank – every invitation to take part in a new study was accepted almost automatically, without extensive consideration. This is of obvious pertinence in relation to the willingness with which they took part in the imaging study.

"I understood ... all those years ago that it was not a one-off, you know, you were signing up for something which was going to be continuous. So, there’s a degree of commitment there.” [Deliberative group, “affluent”]

\(^5\) All participants were recruited between 2006 and 2010
3.2 Understanding of UK Biobank’s aims

There was typically an awareness that UK Biobank was developing a ‘data bank’ for research use. At times there were some misperceptions about the immediate uses of this database but in all cases it was clear to participants that the data they provided would be used by medical and scientific researchers to help further understanding of medical science. This was perceived as a very valuable objective.

"The overall thing is to provide data to improve the health of future generations." [Deliberative group, “deprived”]

Some participants, on reflection after having received feedback about an incidental finding, expressed a desire to know more about who UK Biobank were, how the organisation is funded, and what the research is being used for. Whether the incidental finding resulted in a positive diagnosis or not, participants were generally grateful to UK Biobank for giving them the opportunity to investigate something they otherwise would not have known anything about and, as a result, they often started to become more intrigued as to who and what the organisation was.

"If I could read a book about exactly what Biobank does, or what they’re going to do in 20 years’ time, I would be interested in that." [Female, received feedback, wave 2 only]

3.3 Motivations to take part

Altruism primarily drove participants to take part in UK Biobank research – far and beyond any other motivations. Participants liked feeling that they were contributing towards a beneficial future for others, even without any expectation of being able to see results from their contribution within their own lifetime.

"I might be dead before they have any detailed knowledge from it. But, I just take part in it because I think it’s a good thing to do." [Male, received feedback, wave 1]

Participants occasionally perceived feedback regarding the results of some measures taken on initial registration as an additional benefit – although
they also noted they knew this was not ‘the purpose’ of participation, and reported that it was not a key factor in their decision to take part.

“There were, sort of, twofold reasons – helping myself and helping others. ... They tell you when you’re coming out if there’s anything you need to watch.” [Female, received feedback, wave 1]

During follow-up research in the second wave of interviews, all participants expressed the same reasons as in wave one for wishing to continue with UK Biobank. In many cases, their motivation was stronger because they were so grateful to UK Biobank for having made them aware of an issue they would otherwise not have known about, and this added an extra sense of commitment and gratitude for the work being done.
4. Perceptions and understanding of the imaging study

This section explores: participant understanding of the aims of the imaging study; the consent process from a participant perspective; motivations and concerns at point of consent; and general perceptions and expectations in relation to imaging study involvement.

4.1 The consent process

At point of invitation to the imaging study – with high levels of trust in UK Biobank already established – participants tended to consent readily and without much consideration. Given years of involvement with the larger study, their default position was to take part unless there was a compelling reason not to.

“I got the letter for all these scans and I just thought why not really.” [Male, received feedback, wave 1]

“It’s a study! Sign me up!” [Female, received feedback, wave 1]

The detail participants were able to recall around the information they had received prior to consent (and their scanning visit) varied enormously. Their level of engagement with the information provided very much depended on personality type and preference for needing to know details. Some participants had read all the paperwork prior to consent, with one individual noting they had also visited the website and watched all the videos. Others had only skimmed it or relied on their partner to read it for them (e.g., if attending with their spouse). However, in all cases, participants felt well informed about what they were consenting to, and what to expect at point of scanning.

In most cases, participants recalled having received an email invitation, followed by a screening phone call once they had agreed to take part. This had been accompanied by a pack in the post, with information about the study, what to expect on the day and an explanation of the feedback procedure. Despite the varying degrees of engagement with this information, all participants understood that, should any incidental findings be identified, then they would be notified along with their GP
within a relatively short period of time. Section 5 below explores this understanding in more detail.

Some participants also used the screening phone calls to ask questions to clarify their understanding of what would happen at the scans. The friendly and informative responses they received in doing this contributed to already positive perceptions of UK Biobank, and helped participants feel “in safe hands”.

“I mean, they always send you enough information for you to make an informed decision as to whether you want to do it or not, and if you are not sure of anything they always give you the phone, you know, you are always welcome to phone them up and discuss it further.” [Female, received feedback, wave 1]

Most participants recalled being told what kind of scans they would have during the day, and most were well prepared for the length of time this would take. Those who were less clear about this tended to be those who were less concerned about knowing details and who had thus not closely read the information or asked any questions. They still felt as prepared as they needed to be prior to the scanning process; however, this is likely to also be helped by the existing level of trust they had in UK Biobank.

“I thought about it for a couple of days, not in a deep way, you know, ‘should I do this?’ [It was] whether I’ve got time to do it really because it did say I think it was three or four hours and I was busy, … but I thought ‘well, yes, I’ll just do it’.” [Male, received feedback, wave 1]

Overall, participants felt sufficiently prepared for the scanning process they were to undergo, based on the information they had been provided prior to attending. Those who wanted more detailed information were able to read it, and those who were less inclined towards detail felt they had enough from the information they had skim-read.
4.2 Perceived benefits of participation in the imaging study

Most participants were very aware of the imaging study’s pilot status – and so some felt even more privileged to be able to contribute. This sense of exclusivity further motivated consent.

Beyond this, a range of specific elements of the imaging study stood out at point of consent and further motivated participation:

- There was an awareness that the imaging aspect was particularly pioneering; this heightened interest, especially among those with medical or scientific backgrounds.
- Participants were interested in seeing the technology in action, and motivated to take part so they experience advanced medical technology (e.g., MRI scans) first hand.
- Some reported wanting to gain experience of the scanning process should they need to undergo scans relating to a genuine medical concern later in life. For some, the idea of having MRI or CT scans was an intimidating prospect because they feared claustrophobia. They felt that if they had already experienced it via the imaging study – in the absence of the additional stress relating to a potential medical problem – this would alleviate some of the anxiety of the situation should it arise in the future.

“I’ve always sort of had this slight nervousness about if I had to go in for one [MRI scan] for real. I thought well, here’s an opportunity to try it without even it mattering.” [Male, received feedback, wave 1]

Additionally, the possibility of notification of incidental findings was a stronger motivation for imaging study participation than for UK Biobank participation overall. Although participants were generally very clear that the scans were not clinical or diagnostic in nature, many nonetheless felt that any ‘major’ abnormalities would be likely to be picked up even in a research scanning context – and felt that finding out about any abnormalities, should they be identified, would be beneficial. Indeed, a number of participants referred to their research scanning as ‘a free health check’; one respondent even considered it ‘payment’ for his contribution and travel to the imaging centre.
"If I'm going to go through an MRI scan and all the rest of it, then that's my payment in a way. ... I'm not keen on the idea that you would do that to somebody, see something serious and then not tell them. ... I would have been less, very much less likely to do this scan thing in the first place." [Male, received feedback, wave 1]

"I did say to my wife, when they invited me to take part, 'they might find something’. I couldn’t afford to have a full medical check-up like that done privately, so for them to offer all those checks could be of benefit." [Male, received feedback, wave 1]

Radiographers also reported a high degree of interest in potential incidental findings during the scanning procedure itself. For example, they stated that participants often asked for reassurance during the scans that if anything was picked up they would be informed. Some participants reportedly asked about any unexpected findings immediately after scanning, opening questions with “I know I shouldn’t ask, but...”.

Altruism provided the strongest motivation for participation in the UK Biobank study overall, and in the imaging study specifically. However, despite participants knowing that the study was not clinical and was for research only, finding out about any incidental findings uncovered during the imaging study was a secondary motivation for many. There was evidence of minor misunderstanding that if nothing was found in the imaging study this equated to being given ‘a clean bill of health’. This may need further explicit clarification in informational materials.

4.3 Considering incidental findings

Low levels of concern
As outlined above, participants tended not to experience any concerns or hesitations about consenting into the imaging study – overall, or specifically in relation to concerns about potential incidental findings.

Participants who had already received feedback could not remember very clearly the procedure for providing consent in relation to incidental findings. They tended to remember ticking a box as part of the online questionnaire on arrival for their scans, but did not remember the detail of what was said. Most had not considered the potential of receiving
incidental findings in depth, and were not concerned by the procedures outlined.

“I think I was told that if they did find anything they would communicate with me and my GP. I think I had to sign to say that it was okay to tell my GP.” [Male, received feedback, wave 1]

“Do you know, I can't remember, because I just take it for granted that I'll do these things and I'll get stuck in.” [Female, received feedback, wave 1]

However, two factors are important to bear in mind here. It cannot be assumed that participants less familiar with UK Biobank would necessarily respond in a similar way to providing consent.

1. As previously discussed, the level of trust in UK Biobank was very high and so any pre-questionnaires and consent forms tended to be seen as formalities rather than important details participants needed to pay attention to.
2. It had already been made very clear to participants that they and their GP would be informed of any incidental findings, and this had acted as a secondary motivation to their taking part; they therefore took it for granted that this would happen.

This lack of engagement in the consent process, although not appearing to cause concerns by participants at this stage, could be an issue if participants afterwards felt they had been unnecessarily informed of an incidental finding that caused undue stress. This was noted by UK Biobank staff and radiologists, who were aware that it is an issue common to studies such as this where, despite the consent process being clear, participants often do not understand the full implications of it until it affects them.

Indeed, participants we spoke to within this research admitted that they were unable to think clearly on receiving the letter and only fully understood afterwards what had been the full implications of the consent they gave.
"You enter it knowing it might happen and it may not be anything, but your emotions take over." [Female, received feedback, wave 2 follow-up]

It may be helpful to provide a short video introduction or staff presentation to participants on arrival that explains the consent process and all its implications clearly, to aid engagement in and understanding of this.

**Concerns about receiving feedback**

Although most participants did not have initial concerns around receiving feedback on incidental findings, one participant deeply considered potential negative consequences.

This participant had been worried that, via participation, she may be alerted to early signs of untreatable conditions for which she had not yet experienced symptoms – specifically, Alzheimer’s disease. She felt that knowing about these kinds of conditions would actually make her life worse if she was not able to mitigate or resolve the identified problem.

However, upon considering all the possibilities and discussing it with her daughter, this participant understood that the scans being done would not be able to pick up on these kinds of diseases. She felt reassured by this and so believed that any information on incidental findings would, indeed, be beneficial.

"The previous [studies]: no problem. With this one, you do have to seriously think through, ‘do I want to be told?’" [Deliberative group, “deprived”]

**Interest in an opt-out procedure**

Despite all the participants in this research being very happy to consent to the feedback procedure, some did feel that this should not be a condition of taking part in the study. Although not typically a consideration at point of consent, those who had considered the
This was an issue raised in particular during the deliberative groups, and was also discussed with some depth-interview participants to understand the views of those who had received feedback. However, all but one participant who voiced this concern would not have wanted to opt out of hearing feedback if they had had the choice. The view that this option should be available came from a concern for other people, not themselves. It was felt to be unfair to exclude people from the study who may not have the same attitude to finding out about health issues as those interviewed within this research, particularly only once they had already travelled to the UK Biobank centre. Some also raised that the requirement to give consent to hearing feedback may even put some people off taking part, and would therefore skew the sample towards a particular attitude.

"It seems to be unclear. If you say you don’t want to know, are they not going to do it? I think you should be informed of that in advance, otherwise you’ve come a long way and you are going to go home without having been done. And I think that seems a bit, well, a waste of the participant’s time to say the least.” [Deliberative group, “affluent”]

The one participant who may have decided to opt out if he could have done was concerned that discovering and treating underlying health issues could affect the results of the research. He felt that the study ought to be able to retrospectively look at the progression of diseases in people; to treat something picked up in an early stage as a result of these scans would interfere with that process. Although he had given his consent to receive feedback, he claimed he would have opted out to receiving this on that basis had he been given the choice. This participant had not yet undergone the scanning.

On the other hand, some participants did raise some concerns that there was the possibility for people to regret opting out. For example, they

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6 This issue was raised both by deliberative group participants (who had opted into the imaging study, but not yet undergone scanning) and by some participants who had actually received incidental findings.
argued that people may change their minds once they had actually undergone scanning, or regret their decision should they be later diagnosed with a serious condition that may have been flagged via imaging study participation. Both participants and stakeholders raised concerns that there may also be negative outcomes for UK Biobank should these types of situations occur – or even that there may be legal ramifications.

Despite the opt-out option being raised by some as something that felt appropriate, participants all felt strongly that it was the ethical duty of UK Biobank to inform participants of any incidental findings from the study; there were therefore no issues with this principle at all. There was, however, a sense that in the interests of ensuring the process was fully consensual, they should be offered the genuine choice to receive feedback or not. Participants saw being able to take part in the study as an opportunity to “give back” and it did not sit comfortably with some that people should be denied that opportunity because of a difference in attitude towards knowing about their health.

Current UK Biobank protocol (and their recommendation for the main phase of the imaging study) is not to offer an opt-out option. However, if UK Biobank does consider offering an opt-out option of feedback, they should consider when and how this is communicated so that, if participants are unhappy or unsure about it, they are able to decide prior to coming along for the scanning. It may be also helpful to reiterate that UK Biobank’s obligation is to flag up potential abnormalities that may or may not be of a serious nature, and that it is participant choice as to whether to act on UK Biobank’s information. This highlights the element of choice for participants and maintains the ethical and legal obligations of UK Biobank.

### 4.4 Other concerns and hesitations

Other minor concerns expressed by a small minority of participants in relation to the imaging study were:

- **The risk of radiation** – one participant had questioned staff about risks associated with radiation, worrying that undergoing so many scans at once could carry health risks. However, she was reassured
by the information provided and decided she was still happy to take part. Other participants noted that they had been reassured by the information provided in their packs, citing the examples provided to illustrate the low levels of risk.

- **Unknown funding source** – although this was not of real concern to any of our participants due to their existing relationship with UK Biobank, some participants did make passing comments about not knowing who or what funded the organisation, and this was felt more strongly amongst those who had received feedback as they reflected on the experience. This suggests they may feel differently about the study if they discovered it was commercially funded. Concerns about funding provenance may be of greater concern to those less familiar with UK Biobank as an organisation.

It is worth noting again that these participants had already developed a high level of trust in UK Biobank, which is likely to have positively impacted on their willingness to take part and the degree of consideration they gave this decision. This was also flagged up by stakeholders interviewed at this stage.

It will be important to consider potential participants who do not have such strong existing relationships with UK Biobank when rolling out the full study. UK Biobank should ensure they provide clear information on who they are, what the imaging study is aiming to do, and what any associated risks may be.
5. Initial understanding of and expectations around the feedback process

This section outlines participants’ understanding of the principles and processes by which they would be notified of any incidental findings, highlighting any areas of potential ambiguity or misunderstanding.

5.1 Levels of understanding

It was clear to all participants that UK Biobank would notify them and their GP should any incidental findings be identified. The vast majority also understood that they would not hear back if nothing was found. One who had not yet been scanned had assumed participants would also be sent an "all-clear" notification, but was not unduly concerned on learning this was not the case. Participants recognised the general principle used in most medical tests that patients are only notified if results are positive, and so were satisfied that the same protocol was being used here.

"My assumption is nothing heard unless you are one of the few where they do notice something." [Deliberative group, “affluent”]

“They did warn me ... that they wouldn’t routinely disclose anything that was found in the test at all, in the scans.” [Male, received feedback, wave 1]

Detailed understanding of how the identification process worked was much more variable. This tended to vary according to how much information participants had chosen to read before coming to the scans; they tended to feel they knew and understood as much as they wanted to about the process at the time of scanning. Again, the underlying trust in UK Biobank is likely to play a part here.

However, despite this understanding, some concerns were expressed by radiologists that participants may not understand clearly enough that things could also be missed due to the nature of both the study and the scans themselves. They were concerned that this be clearly expressed to participants so that they did not interpret not hearing anything back as a
clean bill of health; the message still needs to be that if you have symptoms of any kind to go to the doctor to have a proper medical investigation.

5.2 Staff involved in scan review

Most participants had not given any consideration to who looked at the scans and how the decision was made as to whether feedback was necessary. For most, there was an assumption that adequately qualified staff would be involved, and they trusted staff would be able to spot anything that needed further attention.

This assumption was based on the fact that specialist machinery was being used and so qualified staff were necessarily involved. It was also partly based on previous experiences with UK Biobank where staff had always proved themselves to be professional and knowledgeable. This level of trust is similar to that placed in hospitals and GPs, particularly as the vast majority of participants had little or no medical knowledge. There was no anxiety or doubt around the qualifications of staff to assess the scans, and so no perceived need to enquire further around this process.

"I took it for granted that trained, fully qualified medics, medical people would be handling everything and would be following the normal ethics of clinical practice – which they did." [Male, received feedback, wave 1]

However, in a few cases these assumptions also led to the false expectation that ‘doctors’ would be looking at all the scans; many did not appreciate the triage system that is in place or that initial checks are made by technicians rather than trained medical practitioners. Those who had read more information assumed there must be some kind of triage process for practical reasons, and were aware that only around 10-15% of scans were expected to show up anything that required further investigation, but little consideration had been given to who was involved in this process. The assumption was, therefore, that this must always be ‘doctors’.
"I’d be surprised if that kind of anxiety was being created just on a technician’s say-so. I think they probably have some sort of radiologist or specialist level that it can be passed up the chain to." [Deliberative group, “affluent”]

It is worth noting that those who had read the literature in more detail and those who had better medical knowledge had a better appreciation of the different roles of radiographers and radiologists and were happy with the existing process. For the majority, however, there was not necessarily a clear understanding of the difference between a radiographer and a radiologist, and so learning about the specific process did not change their attitude or perceptions; they did not feel a need to know the different job roles.

"It was purely if the technician spotted it and they would then speak to a consultant, who if he agreed with them, they would then contact you. So, you knew it wasn’t just somebody picking something up, they had really looked at it." [Female, received feedback, wave 1]

UK Biobank staff themselves were happy overall with the current triage process by which scans are assessed and any potentially serious abnormalities identified. In general, radiographers felt happy with the process and had no concerns.

However, there were some concerns amongst more junior radiographers that they lacked the opportunity to develop and improve their skills through not getting any feedback on the referrals they made. They wanted to be told if the referrals they made had been approved by the radiologist or not, so that they could learn how to improve their accuracy. While there is an implication that a greater level of feedback from radiologists may be beneficial to the study for this reason, there is also the sense that it could imply a greater level of responsibility on radiographers, which would be ethically inappropriate. This was a concern expressed by radiologists.

"Once you educate them around how to identify an abnormality on a scan, you start to put the onus on them, and their college and most lawyers would not be very happy with that because it’s not what they do.” [Radiologist]
Radiologists raised another issue around communication that may be impacting the incidental findings process. Some radiologists were not accessing the contextual information or radiographer notes made available along with the scans they were sent to check. In these cases, there was a lack of awareness that these were indeed available to them, and it was mentioned how challenging it can therefore be to decide if there is a cause for concern and, on occasion, it had been impossible to tell what the radiographer had initially noticed on the scan. It is therefore important that all radiologists are fully aware of the supporting information available alongside the scans in order to aid accurate assessment.

5.3 Clinical versus research scanning

Despite understanding the difference in purpose, most participants were unaware of the technical differences between the research scans UK Biobank were conducting and any clinical scans that may be conducted at a hospital. In general, the assumption was that these were exactly the same. There was also low appreciation of the amount of additional data that would be taken into consideration in a clinical setting, where patients would be displaying symptoms. This lack of understanding led participants to believe that the scans they had could be diagnostic.

Furthermore, in some cases participants thought that the scans undertaken by UK Biobank as part of the research process were actually better than those conducted via the health services.

"It’s almost like the scan that was done on Biobank was more sophisticated than what a GP’s first line of intervention would be.”
[Female, received feedback, wave 1]

“They were very good. They were better than the NHS scans.”
[Female, received feedback, wave 1]

“All I remember was that the scanners were new ones and they were slightly wider than the NHS ones they use. ... The equipment all looked very modern so I assumed they were the best they could be.”
[Female, received feedback, wave 2 only]
This caused issues for some who later received feedback because it created the expectation that anything picked up on a UK Biobank scan was conclusive. This led to potentially undue stress if it turned out to be artefact, confusion around why further scans were needed and, in some cases, a sense that the NHS were unnecessarily spending money on repeating scans. There is potentially, therefore, a need for more clarity around the key differences in the types of scanning that are done within the study, as well as the conditions around them meaning it is impossible for them to be diagnostic (i.e. lack of medical history data, lack of detail/precision).

“I think possibly if they’d explained at the time more thoroughly that they weren’t the top scanners [I’d have been less worried about the letter].” [Female, received feedback, wave 2 follow-up]

Nonetheless, all participants understood that the aim of these scans was different to that of clinical scans, and this made a significant difference to their attitude. While they did not necessarily understand that the scans would be of lower resolution than clinical scans and that the majority would only be checked for technical quality, they did understand that they were not being carried out in order to look for anything specific. This meant that they were less concerned about the process overall and were happier for less specialist checks to be made. If the scans had been for the primary purpose of conducting a health check, there is likely to have been more concern around how they were being conducted and who was responsible for reviewing them afterwards.

“It’s not like going for an individual scan at the hospital. I would expect I think a quicker response from there. This was just a general thing rather than anything specific, you know.” [Male, received feedback, wave 1]

While there is an element of trust due to familiarity with UK Biobank at play here, UK Biobank’s clear communication around the non-clinical purpose of the study appears to have had a positive impact on participants’ overall perceptions and expectations. However, there could be a benefit to explaining clearly the three main reasons the scans are unable to diagnose conditions or to identify all abnormalities: 1) the resolution of the scans is not as high as in a clinical setting; 2) the
scanner is not being set to investigate any specific medical issue; 3) although some contextual information is viewed alongside the scans, access to full medical history data is not possible.

5.4 Notification of ‘potentially serious’ findings

Participants understood that they would only be notified of ‘potentially serious’ findings – and raised no concerns about this. When asked to provide examples of the kinds of findings that might be considered ‘potentially serious’, participants noted that they had interpreted this to mean issues such as tumours, aneurisms or serious heart defects. They reported that they would not expect to be notified about more minor issues such as suspected gallstones or arthritis.

“They can't tell you for every little thing, but I think if they do feel it's something sinister and something that does need addressing by the doctors etc. that's fine.” [Female, received feedback, wave 1]

“They did say it had to be serious, they wouldn’t inform you of things like a gallstone or things like that. It needs to be something reasonably serious.” [Deliberative group, “affluent”]

However, the expectation that followed from the above was that anything that participants were told about would be serious by default. While participants all understood that any findings they were notified about had the potential to be serious, they did not necessarily consider that they may be notified about findings that turned out to be non-serious. They acknowledged the word “potentially” but did not process this. This expectation was exacerbated by participants’ lack of understanding of the scanning equipment and normal process for diagnosis as described above.

Notification about incidental findings which turned out to be non-life-threatening had left some participants feeling relieved at a non-serious diagnosis but aggrieved at having been put through undue stress. Managing expectations prior to the scanning experience is therefore key to ensuring a better understanding of what incidental findings mean, thus reducing levels of stress on receiving notification.

“I wasn’t aware that there would be virtually nothing bad coming out of it.” [Female, received feedback, wave 1]
There is scope to improve communication prior to scanning so that participants have a better understanding of the range of potential outcomes, and the proportion of outcomes that turn out to be serious. Shifting the focus away from telling participants non-serious conditions they will not be told about and instead citing examples of potentially non-serious outcomes of incidental findings may be helpful in counteracting the negative bias that participants give to their understanding and expectations. This includes citing examples where the finding could be artefact due to technical issues or lack of contextual information.

5.5 Feedback timing

Consideration around how soon any feedback about potentially serious incidental findings would be received was relatively low. Some participants had read the information in detail and recalled that it cited a two-week period within which they would be informed; others had not seen or retained this information and had expectations of a much longer timeframe – such as six to eight weeks.

Due to the non-clinical nature of the study, and the fact that no specific investigation was being carried out, participants were relatively relaxed about the timeframe in which they would want to receive feedback. For most, six to eight weeks felt very reasonable; because they were not expecting to hear results, they did not anticipate an anxious wait. Participants also recognised the scale of the project for UK Biobank and so were forgiving in terms of the timescales they would expect.

“I think if I hadn’t received anything within 6 weeks I’d assume I wasn’t going to.” [Deliberative group, “deprived”]

However, where feedback had been provided more slowly than promised, this tended to raise concerns and frustrations. Although participants were not actively worried about receiving feedback, for those who had recalled the stated timeframe as two weeks there was a sense of relief once this period had passed with no communication. It then felt more distressing when they did receive a letter some weeks later.
"I got to four weeks after and I said ‘I must be alright because the Biobank haven’t written to me’. And then the next day or the next week Biobank wrote to me… and I thought ‘oh rats!’." [Male, received feedback, wave 1]

It is important that UK Biobank meet the expectations they set in communications around notification timeframes. It would be acceptable to inform participants of a longer timeframe for receiving feedback to ensure that this can always be met. This does not negate setting an internal target of two weeks, but allows more room for error without causing distress to participants.
6. Experiences of the scanning process

This section outlines participants’ expectations from the scanning process based on the information they received from UK Biobank, early concerns and questions, and their actual experience of the scanning.

6.1 Positive experiences overall

While some participants were a little nervous about the scanning, as mentioned previously, their overall experience of taking part was very positive.

The biggest practical concern for participants prior to scanning tended to be related to timetabling; a few mentioned that they had evening plans and they wanted to make sure they were not late for these. However, this caused no issues whatsoever and participants spontaneously mentioned that they were very impressed with the efficiency of the arrangements process.

Despite any prior nervousness, for the majority of participants taking part in this research, the scanning process itself caused no issues at all. UK Biobank staff were often spontaneously complimented on their friendliness, efficiency and professionalism throughout. Participants were impressed by the efficiency of the process – for example, the brief ‘waiting times’ between scans.

Participants described staff talking them through the process on arrival to make sure they were clear on what was going to happen and that they understood the procedure for receiving feedback. This was a useful experience that acted as further reassurance they were in safe hands, particularly for those nervous about some of the more claustrophobic scanners such as the MRI.

“They explained what they were doing, which I think is important.”
[Female, received feedback, wave 1]

Participants tended to report low understanding of what each of the scans was measuring; however, due to their high levels of trust in the process
and in the staff, this raised no concerns. For example, they tended not to ask questions prior to or after scanning procedures. There was a sense that participants’ altruistic motivations further reduced questions and concerns; the attitude was that ‘it’s not about me’, and focus on contribution to a ‘good cause’ reduced concern about individual experiences. Had the scans been taken in a clinical setting, participants may have been more inclined to ask questions and feel they needed more knowledge of what was happening.

“It didn’t really matter. It was just a series of things somebody else was going to do and all I had to do was lie there, sit there and do whatever it was really.” [Male, received feedback, wave 1]

6.2 Some unpleasant scanning experiences

However, there were isolated reports of participants not feeling sufficiently prepared for some of the scans, which could raise concerns or reduce the quality of the experience. One participant was distressed by the level of vibration during one of her scans as she had not been prepared for it. In this instance, just being told before the scan what to expect would have made a big difference to the participant.

“One of them, it mentioned noise; you would hear noise. It didn’t mention the juddering, and I found that a bit unnerving. ... I remember distinctly thinking that I’m not going to give in. I’m going to relax; I’m going to take deep breaths; I’m going to relax; I’m going to ignore it. But, I did find it unnerving.” [Female, received feedback, wave 1]

In another case, the participant had been alarmed by questions she was asked by the radiographer after her MRI brain scan. Although these were standard questions asked to all participants, this was not made clear and the participant worried that it meant something untoward had been spotted on her scan. This caused her some anxiety and when she received her feedback letter she immediately assumed it was an issue with her brain. In actual fact it was another issue, but these simple questions had caused her to worry about getting a letter unnecessarily.
While issues experienced during scanning sessions were relatively minor and not common, they do highlight the opportunity for UK Biobank staff to make sure they are adequately preparing and explaining situations that may make participants feel uncomfortable. Furthermore, they underline the importance of being sensitive to participants’ own circumstances, and understanding the potential impact of even routine questions. Ensuring that this process is fully explained in the initial briefing is key.
7. Receiving feedback

This section explores the experience of receiving feedback for participants and the impact of this on perceptions of UK Biobank. It also identifies areas where potential changes could be made to offer further reassurance.

7.1 Response to the feedback letter

Responses to receiving a letter relating to incidental findings varied to a large degree across the sample, from very pragmatic to very worried, according to personality. In many cases, however, participants tended to fear the worst and assume that their issue was of a serious nature – frequently worrying that a tumour of some kind had been identified. This anxiety occurred despite acknowledging the letter did state that there may not be anything to worry about.

“I mean, it's still that word 'potentially', but you tend to focus on the words 'serious' and 'life-changing or life-threatening' I think. I still remember it.” [Female, received feedback, wave 1]

Due to their concern about the possible worst-case scenario, most participants were quick to speak to their GP and book in an appointment. Those who were of a more pragmatic disposition wanted to know as soon as possible so that they could “get on” with following the appropriate course of action; they sometimes asked the doctor to explain over the phone before they saw them. Those who tended to panic more wanted to come to an exact diagnosis as soon as possible so that they could put their mind at rest.

There were no examples of participants not having taken the letter seriously, but there were some participants who had waited to take action due to planned events they did not want to spoil (e.g., family weddings or holidays). For example, one participant waited until he got back from his holiday before speaking to his GP or telling his family; assuming the incidental finding was serious, he did not want medical bad news to prevent him from going abroad.
Participants noted that their prior expectations that they would only be notified about potentially serious or life-threatening findings raised anxiety – and made it difficult for them to believe or trust the statement in the letter that findings may turn out to be non-serious. As previously discussed, participants typically did not consider that a finding may turn out to be positive but a non-serious issue, or that it may turn out to be nothing.

For some, where the letter had induced high levels of stress, there was some irritation with UK Biobank if findings did indeed turn out to be relatively benign; they felt UK Biobank had caused concern where there was no need to do so, or had even been misleading. This related strongly to misperceptions and misunderstandings both about the scanning process and the circumstances in which UK Biobank would send notification.

One participant was very annoyed because she felt the people checking the scan must have made a mistake, calling into question their professional credibility:

"Not knowing the difference between scarring – not that I know about scans - but not knowing the difference between some scarring and something that’s life-threatening. ... It said 'life-threatening’, so I was more than a little annoyed. ... All I can think is that maybe somebody who wasn’t very good at their job looked at that scan.” [Female, received feedback, wave 1]

While another was upset because she had ended up being diagnosed with something (a cyst) that UK Biobank had explicitly said would not warrant notification:

"It did say, 'if it’s a significant abnormality, we will inform you’. And it did actually say, 'if it’s an ordinary thing, if it’s a cyst, we will not inform you’. So, I think that was a misrepresentation." [Female, received feedback, wave 1]

However, in all cases participants were ultimately grateful for having had the opportunity to investigate fully, regardless of the outcome. Even where there was no serious finding, participants often appreciated the fact
that the feedback from UK Biobank had prompted their GP to conduct a full investigation, so they had peace of mind they were healthy in that area. Wave two follow-up interviews also revealed that participants who had been very upset during wave one had since changed how they felt and were now more understanding of UK Biobank’s position in informing them.

“I’d kind of forgotten about it, but now I do remember I was quite cross at the time, not cross, but worried and anxious. ... I do appreciate they [UK Biobank] are in a very difficult situation.” [Female, received feedback, wave 2 follow-up]

Despite sometimes negative experiences around receiving incidental findings notifications, most participants stated that they would take part in the scanning study again if they were invited.

As mentioned in section 4 above, there is the potential for UK Biobank to better prepare participants for the potential outcomes after receiving a letter, including the potential non-serious issues that may be identified as a result of incidental findings, and the reasons it is not possible to definitively classify any incidental finding from scans carried out of this nature.

**Level of detail in the letter**

Participants had received varying levels of detail within their letters, depending on the point at which they took part in the study. Some of the earlier participants had not received any detail at all in relation to the body area in which the incidental finding was found; later notification letters indicated the specific scan on which the abnormality appeared. While no-one expressed serious issues with the less detailed letters, it was generally felt to be preferable to be told the area of the body to which the finding related.

"If they write to you to say ‘we’ve found something’, they should tell you which area or what part of the body they have found something [in].” [Deliberative group, “affluent”]
"I think if it had just said 'we've found something wrong' and not been specific as to what area, I think that could be more worrying."
[Male, received feedback, wave 1]

However, this was under the assumption that the part of the body was accurately described. In some instances, there had been confusion around the specific area due to the scope of different types of scan, and this had caused distress to participants. This is discussed in more detail below.

Participants who had not yet had their scans disagreed on the level of detail they would want in their letter; some felt they should be given full details, whilst others felt that full detail should only be provided by a trained medical professional who knew how to interpret it. However, all participants who had actually received letters were happy with receiving less detail than their GP. There was a strong sense that it was much better to hear the details from their GP, who could explain to them what the implications were and answer any questions.

"Frankly, if I'm going to get some bad news like that, I would rather have it off the consultant who knows what he is talking about."
[Male, received feedback, wave 1]

Some reported that they also favoured less detail because it gave them less information to look up on the Internet – acknowledging that this kind of self-driven diagnostic activity was likely to cause worry and undue stress.

"If they'd started talking about lesions or gone into more technical terms then I think it may have made me more worried because I wouldn't understand the terms. So, for me, the information in the letter was spot on."
[Male, received feedback, wave 1]

"You can know too much about these things too early and then you increase your own anxiety by going and looking on the Internet."
[Male, received feedback, wave 1]

However, there were examples of when participants felt that more information in their letter would have been helpful to them. One participant was upset by the fact that her doctor knew it was not anything
serious and wondered why this could not have been put in her letter to reduce her level of anxiety. She was happy with her doctor having more detailed information than her, but would have liked to have known that it was not a serious finding in her case.

"Because the doctor knew it wasn’t anything ominous, I think I should have been given, not the same information, but more information. Even if it was a percentage thing like ‘we’re 95% sure it’s benign’.” [Female, received feedback, wave 2 follow-up]

It is of course possible that her doctor was making this assumption based on the additional contextual information he had from her medical records rather than any summation made to him by UK Biobank; however some radiologists within this research have suggested that in many cases it is possible to place this kind of likelihood on scans they see. It is therefore important for UK Biobank to consider how best to position the idea that incidental findings are likely to turn out to be non-serious. Including general proportions based on the pilot data, such as nine out of ten reports turn out to be non-serious, could be a resonant way to communicate this message if actual likelihood is not known for particular scans.

Overall, participants were happy for the letters not to include a sense of potential diagnosis. They tended to feel that it was not UK Biobank’s place to diagnose or make any clinical decisions based on potential issues identified. In this way, it would be inappropriate to tell participants more than the fact that there was a potential issue they would advise speaking to their GP about. The GP should then have the full information on which to base a decision around any further treatment or investigation.

"If I got a letter saying my left ventricle was functioning at 38%, I’d probably think I was on the verge of death. But, when the GP tells you that 40-50% is normal, it puts it into perspective doesn’t it? So, ... I think it reinforces the fact that the letter is appropriately written; and let the GP explain it in detail." [Male, received feedback, wave 1]

**Tone and language of the letter**

There were no issues raised at all by the tone or wording of the letter itself. On the contrary, all participants who received a letter felt it was
written in an appropriate and sensitive style, stating the facts without causing undue alarm.

"It was quite appropriate, it wasn't unnecessarily scary, it was just factual really, with the advice to contact my GP." [Male, received feedback, wave 1]

"It was well-worded, it was a gentle letter. I didn't come up with something and wonder what it is." [Male, received feedback, wave 1]

"So, that's sort of telling me not to worry too much as best you can. 'Your doctor will be able to advise you as to what actions or investigations are needed'. ... So, it's sort of smoothed over the edges." [Female, received feedback, wave 1]

Negative experiences of receiving the feedback letter
There were some isolated incidents where participants had not been satisfied with the communication they received regarding incidental findings. This related to perceived misinformation and delayed notification.

In one case, a female participant had been told that there was an issue on her cardiac scan, which she assumed was related to her heart. She was concerned about this but was not overly worried as it was not an issue she had any history of or symptoms relating to. However, on visiting her GP, he informed her it was an issue with her lung, which caused severe anxiety due to an existing family history of lung cancer. She was sent for immediate x-rays, but worried extensively while she was awaiting the results of these, making herself ill and suffering from IBS due to the associated stress.

Although knowing that the potential finding was related to her lung would have been likely to induce a high level of worry at whatever stage she was told about it, the participant reported that the perceived ‘misinformation’ from UK Biobank exacerbated her stress.

"I felt rather aggrieved with Biobank for sending a letter that said cardiac when it was pulmonary.” [Female, received feedback, wave 1]
In this participant’s case, the finding turned out to be non-serious. This was a relief, but there was a latent sense of having suffered unnecessarily due to the way in which the information was communicated to her by UK Biobank.

Similarly, one participant was informed about an abnormality on her abdominal scan, which she had interpreted to be her stomach, but it actually turned out to be her ovary.

“If it says an abdominal scan, you’re not really thinking an ovarian cyst; you’re thinking cancer of the stomach or the liver.” [Female, received feedback, wave 1]

While this may seem minor and open to interpretation, grievances such as this are exacerbated by the anxiety that is inevitably induced on receiving a letter. It is therefore very important that UK Biobank ensure accuracy at all times, or explain clearly the scope of each scan (i.e. the cardiac scan includes the heart, lungs, etc.) so that participants do not feel misinformed.

In another case, the participant had reportedly not received any communication from UK Biobank, and was first notified about the incidental finding once her doctor called her a month after her scans. This was concerning for two reasons: 1) she had assumed that nothing had been found because the two-week notice period had passed; and 2) she then went to see her doctor without knowing anything about what the issue was. She felt this was a difficult position to put both her and her doctor in, and it increased her anxiety around the situation. She noted that she would have liked to have visited her doctor fully prepared for what was going to be discussed.

“If you’re pre-warned, then it does sort of help, it doesn’t take away the fear completely but it does sort of partially help. If you know what you’re expecting then … [you can prepare yourself].” [Female, received feedback, wave 1]

In this participant’s case, her doctor had been given a copy of the letter that was meant for her in addition to his own more detailed version.
However, she did not receive this letter until a few days later, and this letter was dated two weeks later than the one received by her doctor. The first letter the participant saw in relation to the incidental finding was the GP’s version, which he showed her. This was a little alarming because of the level of technical detail it contained; however, due to the doctor being there to talk her through it, it was less distressing than it would otherwise have been.

“If they’d have sent them out at the same time, and if I’d have got that letter first, I think it would have put my mind at rest a little bit more. So, I’m annoyed with them that they didn’t do that.” [Female, received feedback, wave 1]

There was one further example of a participant who received her letter after being contacted by her doctor, also outside the two-week notification period. This was a little distressing for the participant as she had not had any information herself, had assumed all was fine, and when the letter did arrive, she recalled that it contained no detail relating to the area or scan in question. (However, on reflection she did not mind this as it gave her less information to worry about and research herself.)

While these specific incidents do appear to be anomalies occurring during the first few months of the project, there were a few additional instances where participants were notified significantly later than the specified two-week period. While this did not cause large concern for most, it is obviously undesirable and does not reflect well on UK Biobank. All these examples raise concerns around clerical issues that should be addressed to ensure that distress is minimised for participants.

It is important that UK Biobank set up appropriate expectations around timelines for incidental findings notifications and ensure a standardised approach to the information included in the letter. Ensuring that participants are notified with accurate information in a timely manner (e.g., within six weeks) is key. Participants would be comfortable with UK Biobank setting longer timeline expectations to reduce the risk of notifications falling outside this. Systems for ensuring GPs have received the letter before notifying participants need to be precisely managed to minimise distress in case GPs do get in touch with participants first.
7.2 Doctor response and follow-up

In the majority of cases, participants perceived that their GPs took UK Biobank’s notification seriously. Overall, GPs were very quick to schedule appointments to discuss the findings with their patients, and to set up further investigation to enable accurate diagnosis.

Participants sometimes expected that this swift action was based on GP perceptions of UK Biobank as a credible medical organisation. They were often surprised at how little doctors and hospitals knew about UK Biobank in reality; the majority had not heard of the organisation at all. Some participants felt that it would be better to inform medical professionals more about the work of UK Biobank. There was a sense that if doctors were more aware of UK Biobank then they would be more prepared for the information they received about incidental findings.

While in all cases GPs did act accordingly on the notification from UK Biobank, there were two examples of cases where participants did not feel they had been taken as seriously as they would have liked. In one case the participant felt that her GP was not interested in UK Biobank and thus was dismissive of the incidental findings notification – although a second doctor did take it more seriously. In another case, the participant was told by their GP that there was nothing to worry about, but was not satisfied with the level of investigation undergone to reach this conclusion.

There were also examples of cases where participants felt the communication between doctors and UK Biobank should have been better. Participants tended to assume that UK Biobank would send copies of the scans in question to GPs upon notification of the incidental findings. This was also felt to be the responsible course of action given the expense of the scans, which participants were keen to not be “wasted”.

“The crucial thing is, an MRI scan is a very expensive scan so it would be a crime to waste data. So our GP needs to be given the raw data and whatever interpretation has been made of it by the Biobank doctor.” [Deliberative group, “deprived”]

7 However, this is also clearly linked to participants’ misunderstanding around the kinds of scans being carried out as discussed in section 5
However, participants who had received feedback did not always think their GP had seen a copy of the scan, and in one case in particular this caused some issues in terms of follow-up and diagnosis. One participant spoke about a lot of correspondence between his GP, the consultant he was referred to and UK Biobank in trying to obtain his scans. The scans had not been sent to the GP, and the consultant had requested them directly from UK Biobank. However, the consultant was told that they could only release the images to the GP, so he had to write to the GP, who contacted UK Biobank on his behalf and sent on the scans. This caused a delay in the investigation of the issue, which the participant found frustrating. It was also very concerning for his partner as she was anxious to know what was wrong.

"I think that there would be no harm in telling the GP the results ... because the GP also has, you know, a duty of care." [Male, received feedback, wave 1]

"The procedure that took place for a month or five weeks after you got that letter was, to me, not as competent as it could have been ... and I think that was upsetting ... because I want to know if you’re going to keel over in two years’ time." [Partner of participant, received feedback, wave 1]

There was also one participant who believed that his surgeon was unable to obtain the scans from UK Biobank; he found it difficult to understand the reasons for this. He also described how it was difficult for NHS staff to understand what he was asking them to investigate because they had no knowledge of UK Biobank and no data to use as a start point.

"One of the slightly annoying things from the NHS point of view was here am I turning up at the NHS and having to tell the specialists and staff what the UK Biobank project is ... and you’re sort of walking in saying you have a relatively serious condition but no data. ... That is not the way the NHS likes to work." [Male, received feedback, wave 2 only]

One of the radiologists also commented that doctors’ lack of knowledge about UK Biobank could cause confusion within the medical community. He spoke about neurosurgeons he worked with not understanding why
patients had been sent to them, and thinking it must be from a private health scan.

"The neurosurgeons who I work with who’ve been sent cases are really quite confused by it – they didn’t know why this guy had had a scan, what was wrong with him?" [Radiologist]

There is therefore a sense that a small PR exercise within the medical community could be beneficial not only to ease any necessary follow-up for participants, but in particular to reinforce UK Biobank’s reputation.

Overall, communication between UK Biobank and GPs appears to have been effective, and GPs played a valuable role in swiftly meeting with participants and arranging follow-up investigations as necessary. However, it is important to ensure that as much detail is shared with GPs as possible to enable a smooth and swift follow-up investigation. UK Biobank may wish to invest some energy into PR within the medical community as a whole. This will also positively impact perceptions of UK Biobank’s efficiency amongst participants and doctors.
8. Wider impacts of receiving feedback

This section examines any other repercussions of having received feedback both for participants and their family. It also discusses any impacts on perceptions of UK Biobank for participants who received feedback.

8.1 Impact on family

In the majority of cases, family members and spouses were not adversely affected by their loved-one receiving the feedback letter. Participants typically reported that their spouse or family were very pragmatic and urged them to seek medical advice as soon as possible, but did not worry excessively. The fact they were removed from the process meant they could take on a supportive role.

“Nobody made an issue. I'm not saying they weren't worried, but no dramas or anything like that.” [Female, received feedback, wave 1]

“After my son had read that copy letter he said, 'oh, it's not as bad as I was expecting'.” [Female, received feedback, wave 1]

In some cases, however, family members were more concerned by the news from UK Biobank than the participants. This may be because of differences in personality, but also due to family members having a lower level of understanding of the UK Biobank study as they are less involved in it.

“It hit my wife as well just as hard because she probably was not really up to speed on understanding the issues.” [Male, received feedback, wave 2 only]

“[My wife] was very upset, but then ... my wife tends to be very emotional about lots of things in life and she obviously was ... crying, shouting ... you know, really upset.” [Male, received feedback, wave 1]
“My husband was very, very anxious for a couple of days and when I got into the car he burst out crying with relief. So, he was worried and holding it in.” [Female, received feedback, wave 2 follow-up]

“I think it was probably worse for my husband, but I think it always is for the onlookers.” [Female, received feedback, wave 2 only]

Some participants selectively told family members based on their anticipated reaction. Often this meant that only spouses were told, and children or other extended family were not informed until a diagnosis or course of action had become clear. Participants were mindful not to concern their families unduly, and did not like the thought of having to inform them of bad news.

In cases where the participant themselves had been very worried, this could compound the sense of worry for family members. They were naturally concerned about the meaning of the findings, but also worried about the welfare of their loved-one that was in a state of anxiety. The fact they were removed from the process could help them gain a different perspective, but it could also make them feel helpless. This contributed to a cyclical sense of anxiety throughout the family.

“I was basically thinking that I’d got a brain tumour. It’s as simple as that really. And I was planning my funeral. And of course, all the children knew I was going through it as well and I felt sorry for them because obviously it wasn’t good news for them either and they were worried during the time that I was worried.” [Female, received feedback, wave 1]

One participant was very worried during the investigation process, and this had induced stress-related IBS. Her husband was very worried about her as a result because he did not like to see her so anxious. In another case, the participant described how she had to remain strong for her husband during her own investigations because he had also become ill, increasing the level of anxiety within the family.

“My husband worries, so that meant I had to be stronger for him, so I couldn’t show that I was worried. ... He developed throat problems which he thought was cancer, so we had to see doctors about him.
He got very depressed so he had to go on anti-depressants, so I had to be strong for him.” [Female, received feedback, wave 2 only]

Despite these high levels of anxiety experienced within some families, the concern and anxiety expressed was in line with what would be expected if any potentially negative health issue were discovered, and it was often for a short time-period; there is no evidence that feedback from UK Biobank induced more anxiety than in a normal health-scare situation. In a few cases, there was indeed a serious issue that was discovered through this process, and here the participant and the participant’s family felt enormously grateful to UK Biobank. One man even described how it had brought him and his wife closer together.

There was also a sense that it was not seen as UK Biobank’s responsibility to support participants and their families in the event of incidental findings. For most, it was clear that UK Biobank were a research organisation and their ethical responsibility was to inform participants of anything that may be worth investigating, but that their responsibility did not go further.

“They’re there to research and report. They did their thing. They researched; they reported. It was then up to my doctor to do the supportive bit, which he did.” [Female, received feedback, wave 1]

“They just pass it on. Your doctor is always going to be your primary care giver. ... That's not what Biobank are there for. They are there as a research organisation.” [Female, received feedback, wave 2 only]

Despite this, it may be useful to produce a short “Guide for Families” or to suggest that participants ask family members to read existing information. This would help ensure that family members understand what their loved-one is taking part in so that they can be fully prepared and informed if there should be incidental findings feedback. This may help mitigate some of the unnecessary anxiety experienced in cases where no serious diagnosis was made.
8.2 Impact on lifestyle

In some cases, participants reported a positive impact on their lifestyle through having received feedback on incidental findings. In cases where serious conditions were diagnosed there was an obvious sense of relief and gratitude, but other side effects had also been noted.

“There are conditions that I had which I would classify as sort of ‘middle-aged anomalies’... chronic lower back pain and sleep apnoea being two of them, and suddenly over the months those have disappeared. So, in addition to having my heart condition fixed, the aneurism, all the other bits have been fixed.” [Male, received feedback, wave 2 only]

“I’m just relieved because I’d have no idea I’ve got one [aneurism]. ... It’s brilliant, otherwise I would be dead.” [Female, received feedback, wave 2 only]

Furthermore, in cases that resulted in non-serious outcomes, some participants also noted an improvement to their lifestyle, either due to recommendations from their doctor due to the non-serious underlying issue discovered, or just as a result of “taking stock” after having a health scare.

“It’s nothing more serious than hardening of the arteries, which has also made me react because I’ve decided to eat more healthily, do more exercise, and I’m doing it with purpose now so it’s been good in that way.” [Female, received feedback, wave 2 follow-up]

“In a sense, looking back on it afterwards, I’m glad that I thought it was something serious because it’s made me take a look at my life and check that I can do things, you know? I’ve been given another chance.” [Female, received feedback, wave 1]

“What I would like to say is that after all of this it is very, very nice to know that the only thing you have or they could find wrong with you is a slight abnormality in your heart muscle and that is a nice, comforting thing to know.” [Male, received feedback, wave 1]
8.3 Impact on perceptions of UK Biobank

Overall, feedback experiences around incidental findings did not adversely affect participants’ views of UK Biobank. Indeed, in the vast majority of cases it strengthened perceptions of the organisation as professional and ethical, and one participant said his daughter now also saw the organisation as more credible. All participants in the qualitative research would be happy to take part in future UK Biobank studies, and most were ultimately grateful for having had the opportunity to investigate potential health issues – even if the incidental findings resulted in a non-serious or artefact diagnosis.

“I think the whole process was worthwhile because that showed up, but equally something more serious could have shown up that I didn’t know I had, and, most things, the quicker you can get treatment the better the results, so a better prognosis.” [Male, received feedback, wave 1]

“I was very happy with my involvement with the project, I have no complaints about it whatsoever. The very fact that they flagged up something for which there is now an explanation, shows that there was something in that camera, that it wasn’t just another day out, that what they’re doing is real and legitimate, and I hope for them that it’s worthwhile.” [Male, received feedback, wave 1]

“I cannot stress how lucky I was this got picked up and diagnosed with Biobank because the endocrinologist thinks it may have been sitting there for a number of years and although I had commented on some of the effects, it is not easy to diagnose. I could have gone on for three to five years, struggling with the symptoms, without being diagnosed fully.” [Male, received feedback, wave 2 follow-up]

However, one participant claimed that though she was still loyal to UK Biobank she would not want to take part in an imaging study again, due to the amount of stress the incidental findings caused her. Although she claimed she was ultimately grateful the finding in her scan had turned out to be non-serious, she did not feel she would like to take part in the same kind of study again.
"I’m going to carry on with Biobank. I am, you know, because I said I would and I will. But, I was very, very angry about being put in a position where my health was affected by stress." [Female, received feedback, wave 1]

While this participant was not the only one to feel she had been subject to undue stress, others who were re-consulted in the second wave of interviewing had softened their perspective a little and no longer felt aggrieved by their experience. Indeed, the overwhelming sense was one of gratitude and continuing willingness to take part in further studies.

Although the overall perception of UK Biobank appears to remain very positive, it is important that the organisation makes clear to all participants the remit of the research and the processes behind incidental findings feedback.
9. Recommendations

Overall, the current principles and processes relating to the imaging study and the reporting of incidental findings are working well. The majority of participants expressed no issues causing undue distress within their experience, and were impressed with the handling by UK Biobank.

However, there are three key areas where improvements could be considered in order to ensure the study impacts least negatively on participants. These three areas are:

- Mitigating anxiety through communication
- Improving understanding of the study
- Improving logistics and overall experience

Each of these areas contains particular factors that this research suggests are important to take into account. Each is looked at below.

9.1 Mitigating anxiety through communication

Although low levels of lasting anxiety were noted overall, there are particular areas where poor communication and understanding in particular has led to unnecessary concern, and high levels of immediate anxiety. Addressing these areas would be likely to reduce levels of anxiety for participants receiving feedback on incidental findings.

- **Provide explicit examples of potential non-serious outcomes that could result from an incidental finding.** This has the potential to mitigate participants’ anxiety upon receiving notification letters and to reduce the risk of misunderstanding prior to this. Although all understood that findings were only “potentially” serious, the overriding message was that they would not be notified about non-serious issues. Providing examples of the kinds of non-serious outcomes that could result from incidental findings notification – such as the identification of cysts, abscesses or scarring – would be helpful to reinforce the lack of clinical clarity provided by the research scanning process. This has a different emphasis from providing information on conditions that participants will not be notified about. In fact, providing this information can
confuse the message and strengthen the perception in participants’ minds that anything they are notified about will certainly be serious.

- **Cite likelihood of incidental findings resulting in serious outcomes where possible.** Much of participants’ anxiety was caused around their lack of understanding that the notification letter was precautionary. Emphasising this further by providing percentage examples of the number of cases that are found to be serious on further investigation could help to reassure participants. Where possible, UK Biobank should also consider citing the actual likelihood of each case to result in a serious finding. However, care must also be taken not to suggest that no action should be taken, and the message that the participant is advised to seek further medical advice should still be made clear.

- **Ensure clarity around the reasons for IFs not being diagnoses.** Participants’ misunderstanding of the meaning of an incidental finding also stemmed from their misperception about UK Biobank equipment and their misunderstanding of the differences with clinical equipment and processes. Communication should make it clear in an easy-to-read format what the key differences are, to lower expectations that a diagnosis should be possible from UK Biobank scans. Namely, it should be made clear that:
  - UK Biobank scanners do not scan as high a resolution as clinical/diagnostic scanners
  - UK Biobank researchers are not following the clinical processes required to conduct specific diagnostic investigation
  - UK Biobank researchers do not have access to full medical records in reviewing the scans

- **Clearly communicate that not getting feedback does not imply a clean bill of health.** Although most participants implicitly understood this, there was some concern around this misperception. It is important to communicate the explicit message that the absence of a letter notifying participants of incidental findings does not equate to a clean bill of health and that participants should still always seek medical advice if they are experiencing any kind of symptoms. This will help to reinforce the
counter-message that notification of incidental findings also does not mean there is a conclusive health concern.

- **Consider creating a guide for families to aid understanding amongst those not directly involved.** Although most family members did not express undue concern in response to incidental findings feedback, there were incidents of accentuated anxiety and a sense of lack of clarity around exactly what the participant was taking part in. A short guide for families briefly explaining the process, what is meant by incidental findings and how family members could support the participant (e.g., by accompanying them to the doctor’s, remaining objective) may be helpful. It could help family members better understand the facts and therefore feel more able to provide the support needed, in addition to alleviating anxiety they may have picked up through participants’ own misperceptions or subjective interpretations. Alternatively, existing information could encourage participants to share information with their family members, such as via the website.

### 9.2 Improving understanding of the study

Despite the high level of engagement and positive perceptions of UK Biobank, most participants did not fully understand what the study was for or how it was being conducted. This same lack of knowledge extends to the medical community, many of whom have not previously heard of the organisation and are unaware of what it is aiming to achieve. While this did not create direct major issues, improving understanding of the study and of the organisation more broadly could not only improve the experience for participants, but also clarify the implications of incidental findings.

- **Provide clearer information and better examples to illustrate what the study is (and is not) for.** While misunderstandings about the extent of the study did not cause concern for participants, it did lead to some false expectations. It may be beneficial to explain more clearly that the data being provided may be used for myriad research projects that cannot yet be determined. This will help manage participant expectations around the level of
involvement of medical experts, and thus the kind of feedback that is likely and/or possible.

- **Provide information on funding streams.** The more involved participants become in UK Biobank, the more curious they become as to the funding source(s). Some scepticism around private and commercial finding is evident, and so being transparent and obvious about where the funding comes from and what it is intended for will not only help participants feel more ready to be part of the study, but will also help to manage expectations around differences with clinical scans.

- **Communicate to the medical community about UK Biobank’s aims and objectives.** Although most GPs did take the notification letter from UK Biobank seriously, some were a little dismissive, and some surgeons and consultants further down the line were confused as to where the referral had come from. In some cases, this resulted in a delayed or more drawn-out response than was perceived as necessary by participants. Doctors’ lack of knowledge about the study surprised many participants, who felt it should be better known within the medical community; this could undermine the perceived credibility of UK Biobank and/or the doctor in question. Ensuring the medical community has a better knowledge of the organisation, and the imaging study in particular, could help participants’ experiences and also improve perceptions and the credibility of UK Biobank overall.

- **Ensure all staff are referred to as “research staff”.** This is important to reinforce the message that the study is for research purposes not clinical or diagnostic. Many participants spoke about UK Biobank “doctors”, which exacerbates perceptions of medical diagnoses and procedures taking place. Simply being sure to refer to all staff, including radiographers and radiologists, as “research staff” could help to mitigate this further.

- **Emphasise participant choice at all stages of the study.** It remains important that participants always feel they have a genuine choice when taking part in the study. The requirement to opt-in to receiving feedback should be explicitly communicated early in the
sign-up process so that those who may feel uncomfortable about it do not risk coming along for their scans only to be turned away at consent. To clarify UK Biobank’s position further, it is important to reiterate the organisation’s role as a research body, responsible for notification of incidental findings only, and that it is the participants’ choice whether to take action following a notification. This may help address some of the concerns around participant choice raised in relation to including an opt-out option.

9.3 Improving logistics and overall experience

In addition to mitigating anxiety via communication and working on increasing awareness and understanding of the organisation’s and the study’s aims, there are also some areas for development relating to the logistics and overall participant experience.

- **Ensure participants are fully prepared for the scanning experience, including providing information on how the scans may feel.** Although it did not adversely affect participants’ overall experience of taking part in the study, there was some anxiety around knowing what to expect from the scans. Despite the information provided beforehand, some participants were not prepared for the level of noise or the physical sensations involved in each scan. This could be made clearer in communication materials. It is also important to ensure that all UK Biobank staff talk participants through how they may feel, to help them feel more relaxed.

- **Ensure UK Biobank staff are mindful of the impact of all comments made during the scanning process.** Most participants, while happy to take part, did not know exactly what to expect from the scanning experience; it was very unfamiliar to them. They are therefore likely to be in a heightened state of sensitivity and susceptible to feelings of discomfort. It is important that UK Biobank staff appreciate this and are mindful that any comments or questions may provoke more anxiety than is intended, even if these are routinely asked of all participants. Staff need to be sure to explain the reasons for everything they do and say during the scanning process so as not to cause undue concern, including asking routine questions.
• **Lengthen the notifications timeframe within which participants are told they will receive results.** Given that several respondents within this research did not receive feedback within the stipulated two-week timeframe, and that some rare cases still take up to six weeks to be referred, it would be advisable to extend the timeframe communicated to participants. The acceptable maximum timeframe as determined by participants is six to eight weeks. Setting an internal target of two weeks, but informing participants of a maximum six-to-eight-week timeframe, would help obviate any frustration around notifications after participants felt they had been given the ‘all clear’.

• **Ensure the timely notification of incidental findings to GPs and participants.** Although the majority of participants did receive notification before hearing from their GP, for the two cases where this did not happen some distress was caused. It is always possible that errors in the postal system may cause this kind of issue, and this is outside of UK Biobank’s control. However, it is important that UK Biobank do everything possible to mitigate the risk of participants receiving information too long after their GP. The process of ensuring GPs have the letter before participants so that they are able to refer to it during appointments needs to be rigorously managed to avoid any lapses.
Part III: Appendices

Appendix A: Current status of incidental findings follow-up

For most participants included in this qualitative research, the incidental findings identified had not been found to be serious issues. However, for some, underlying serious issues had been identified, and some were undergoing ongoing tests or awaiting test results.

The below table outlines the status of all participants receiving feedback on incidental findings who took part in this research, as of December 2014 or April 2015 as indicated.

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<th>Resp.</th>
<th>Area/scan affected</th>
<th>Action taken by GP</th>
<th>Diagnosis</th>
<th>Outstanding follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Lung</td>
<td>Chest x-ray following day</td>
<td>Inconclusive/ all clear</td>
<td>None – but participant wants to pursue (April 2015)</td>
</tr>
<tr>
<td>2</td>
<td>Lung</td>
<td>Consultant referral; further x-rays; operation</td>
<td>Haematoma</td>
<td>None (April 2015)</td>
</tr>
<tr>
<td>3</td>
<td>Heart</td>
<td>Consultant referral; follow-up scans and blood tests</td>
<td>Thickening of heart muscle</td>
<td>Drugs prescribed, some further monitoring to check dosage (December 2014)</td>
</tr>
<tr>
<td>4</td>
<td>Abdomen (ovary)</td>
<td>Consultant referral; ultrasound</td>
<td>Ovarian cyst</td>
<td>None (December 2014)</td>
</tr>
<tr>
<td>5</td>
<td>Lung</td>
<td>Consultant referral; follow-up scans over 1.5 months</td>
<td>Thickening of lung lining</td>
<td>None (April 2015)</td>
</tr>
<tr>
<td>6</td>
<td>Abdomen (ovary)</td>
<td>Private ultrasound</td>
<td>Ovarian cyst</td>
<td>Follow-up scan due in summer (April 2015)</td>
</tr>
<tr>
<td>7</td>
<td>Lung</td>
<td>Chest x-ray within a few days</td>
<td>All clear</td>
<td>None (December 2014)</td>
</tr>
<tr>
<td>8</td>
<td>Brain</td>
<td>Private consultant referral; follow-up scans within 2 weeks, then 3 months</td>
<td>Hardening of arteries</td>
<td>None (April 2015)</td>
</tr>
<tr>
<td></td>
<td>Location</td>
<td>Description</td>
<td>Diagnosis/Tests</td>
<td>Status</td>
</tr>
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<td>-----------------------------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
</tr>
<tr>
<td>9</td>
<td>Cardiac</td>
<td>ECG at surgery; heart scan at hospital</td>
<td>Suspected heart block – awaiting confirmed diagnosis</td>
<td>Still awaiting test results and diagnosis; follow-up appointment pending (April 2015)</td>
</tr>
<tr>
<td>10</td>
<td>Brain</td>
<td>None</td>
<td>Scars from previous concussion</td>
<td>Has had full medical check-up since with no issues being found (April 2015)</td>
</tr>
<tr>
<td>11</td>
<td>Abdomen</td>
<td>Blood test</td>
<td>Ovarian cyst; liver cyst (already known about)</td>
<td>None – but respondent wants further tests (April 2015)</td>
</tr>
<tr>
<td></td>
<td>(ovary and liver)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Brain</td>
<td>Consultant referral; follow-up scans over 3 months; surgery in March</td>
<td>Pituitary tumour</td>
<td>Ongoing tests to monitor impact and progress; MRI, CT scans; visual field checks; potential for hormone replacement drugs (April 2015)</td>
</tr>
<tr>
<td>13</td>
<td>Abdomen</td>
<td>Private consultant referral; colonoscopy within 10 days</td>
<td>All clear</td>
<td>None (December 2014)</td>
</tr>
<tr>
<td></td>
<td>(colon)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Cardiac</td>
<td>Consultant referral; x-ray within 10 days; chest clinic after 2 months</td>
<td>TB scarring on lung</td>
<td>None (December 2014)</td>
</tr>
<tr>
<td></td>
<td>(lung)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Abdomen</td>
<td>Consultant referral; blood tests; ultrasound plus follow-up 3 months later</td>
<td>Ovarian cyst</td>
<td>Follow-up ultrasound and blood tests in August (April 2015)</td>
</tr>
<tr>
<td></td>
<td>(ovary)</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>16</td>
<td>Kidney</td>
<td>Consultant referral; ultrasound; CT scan</td>
<td>Adrenal cyst/lesion in awkward place</td>
<td>Awaiting results of second scan (December 2014)</td>
</tr>
<tr>
<td>17</td>
<td>Cardiac</td>
<td>Instant consultant referral; ongoing monitoring and operation in February</td>
<td>Cardiac aneurism</td>
<td>Monitoring heart to identify next steps; potential physiotherapy (April 2015)</td>
</tr>
<tr>
<td>18</td>
<td>Cardiac</td>
<td>None – already knew about issue</td>
<td>Irregular heartbeat</td>
<td>None (April 2015)</td>
</tr>
<tr>
<td>19</td>
<td>Cardiac</td>
<td>Referred for blood tests and x-ray at walk-in clinic</td>
<td>Scarring on lung from previous radiotherapy</td>
<td>None (April 2015)</td>
</tr>
<tr>
<td></td>
<td>(lung)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>Abdomen</td>
<td>Referred for endoscopy</td>
<td>Hiatus hernia</td>
<td>None (April 2015)</td>
</tr>
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</tr>
<tr>
<td>21</td>
<td>Cardiac</td>
<td>Consultant referral; echo-scan followed by a 10-day stay in hospital having multiple scans; 9.5 hour surgery</td>
<td>Aneurism and friable myxoma</td>
<td>Awaiting check-up and then appointment with specialist (April 2015)</td>
</tr>
</tbody>
</table>
Appendix B: Deliberative group invite letter

Your views on feedback of a potentially serious abnormality from participation in UK Biobank’s imaging study

Dear [NAME],

You are receiving this letter because you have agreed to participate in UK Biobank’s imaging study. The purpose of this letter is to introduce an important piece of research being done by TNS BMRB for UK Biobank and to ask whether you would like to take part in the first phase of this project.

Who are we and what is this research about?

TNS BMRB is an independent research organisation which does work on behalf of a variety of public bodies, charities and government departments.

TNS BMRB has been asked by UK Biobank to find out about people’s views on what and how people are told about potentially serious abnormalities noticed during the scanning process. UK Biobank has asked us to conduct this work so that you can participate anonymously and can be completely honest about your views.

Our trained researchers will be talking to people both before and after they undergo their UK Biobank scans. We will discuss their attitudes to receiving feedback and their thoughts on the possible impact of feedback of potentially serious abnormalities on participants, family and friends. Currently, very little is known about the impact of receiving this type of information. This research will allow UK Biobank and other similar projects to improve their feedback procedures in the future.

What does participation involve?

We would like to ask you about your views on receiving feedback of potentially serious abnormalities that may be noticed on your scans during UK Biobank’s imaging study. Participation would involve attending a group discussion at the

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8 http://www.tns-bmrb.co.uk/home
imaging assessment centre in Stockport (near Manchester) on [DATE]. This is the same location that you will attend for your imaging assessment, about which you have already received information from UK Biobank. The group will have 10 participants, be led by one moderator and the discussion will last two hours.

**Do I have to take part?**

No. Participation in this research is completely voluntary, and your decision whether to participate or not will not affect your relationship with UK Biobank or your participation in the imaging study.

**Is this confidential?**

Yes. Everything you say to us will be confidential, you don’t have to talk about anything you don’t want to, and your identity will remain anonymous in the reports.

We plan to record the session so we can pay more attention to what the participants in the group say. It is also more accurate than taking notes. Only the researchers and the person who types up the notes will listen to the recording. Recordings will be held for one year, in case we need to listen again to prepare our report, and will then be destroyed.

We will put a summary of what everyone says in a report but we will not put any names in the report. It will not be possible for anyone outside the research team to know what you personally have told us.

**Can I claim travel expenses for attending?**

Yes, please do claim back any reasonable travel expenses (including standard train and bus fares, and mileage for car, motorcycle or bicycle journeys). A claim form will be handed to you at the end of your visit. It would help us if you attached your travel receipts.

There is ample free parking space at the centre. It is also within easy access of Stockport train station, where taxis (paid for by UK Biobank) are available. If you are registered as disabled, you can also claim travel expenses for a companion.

**Can I change my mind about taking part?**

Yes, at any time. Also, if there are any specific questions you don’t want to answer, that is fine – it’s completely up to you.
If you would like to take part in this research then please respond to this email and let us know what the best number to call you on is, and when you would like us to ring. One of the team members at TNS BMRB will then ring you to make arrangements.

If you have any questions at all then please contact Caitlin Connors at caitlin.connors@tns-bmrb.co.uk or by phone on 079 5603 2847.
**Consent for individuals to take part in research on:**
Feedback of potentially serious incidental findings from participation in
UK Biobank’s imaging pilot study

**DELIBERATIVE FOCUS GROUP**

**Please tick:**

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I understand what the research is about and that I am being asked to join a discussion session about feedback of potentially serious incidental findings from participation in UK Biobank’s imaging study.

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I give permission for the group discussion to be recorded so the researchers have an accurate record of the session.

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<th>Yes</th>
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I understand that my details will not be shared with anyone outside the research team and that my name will not be used in any research reports.

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I understand that I do not have to answer any question I do not wish to and that I can choose to leave the group at any time.
Appendix C: One-to-one interview recruitment script

Telephone script for depth interview recruitment following 6-week and 6-month questionnaire completion

Hello [NAME],

You are receiving this call because you have participated in UK Biobank’s imaging study. We understand that you have received feedback about a potentially serious abnormality noted on your scans during your imaging visit. You have also recently completed UK Biobank’s questionnaire on this topic and gave your permission for UK Biobank to re-contact you by telephone to explore further your experience of receiving this feedback.

The purpose of this call is to introduce this research, which is being conducted for UK Biobank by TNS BMRB, an independent research organisation. We also wish to ask whether you would like to take part in one or more face-to-face interviews with our team.

Who are we and what is this research about?

TNS BMRB is an independent research organisation which does work on behalf of a variety of public bodies, charities and government departments⁹.

TNS BMRB has been asked by UK Biobank to find out about people’s views on what and how people are told about any potentially serious findings discovered during participation in the imaging study. UK Biobank has asked us to conduct this work so that you can participate anonymously, and that you can be completely honest about your experience. UK Biobank wants to know what it is like for people in their imaging study to receive feedback so that they can develop the best feedback procedures possible. Currently, very little is known about the impact on participants, family or friends of receiving this type of information. This research will allow UK Biobank and other similar projects to improve their feedback procedures in the future.

⁹ http://www.tns-bmrb.co.uk
What does participation involve?

We would like to hear more about your experience of having received feedback about a potentially serious abnormality. The questions we would like to ask build on questions you answered in the questionnaire you recently completed.

Recruiter to pick correct script below depending on point of contact:

For participants recruited after the 6-week questionnaire:

If you choose to participate, we would like you to take part in two 90-minute interviews with one of our researchers:

- The first would be face-to-face, and can be arranged at your convenience between [DATES]. We are happy to conduct this in your home, or in another space which is convenient and comfortable for you.
- The second interview would be in [DATES] – again, at a time of your convenience. This interview would be conducted via telephone.

If your friends or family are available to participate in the interview as well and you are happy to take part, we would love to include them – to hear more about how the process affected them.

For participants recruited after the 6-month questionnaire:

If you choose to participate, we would like you to take part in a 90-minute interview with one of our researchers:

- The interview would be in [DATES] – at a time of your convenience. We are happy to conduct this in your home, or in another space which is convenient and comfortable for you.

Do I have to take part?

No. Participation in this research is completely voluntary, and your decision whether to participate or not will not affect your relationship with UK Biobank or your status in the imaging study.

Is this confidential?

Yes. Everything you say to us will be confidential, you don’t have to talk about anything you don’t want to, and your identity will remain anonymous.

We would like to record our conversation so we can pay more attention to what you are saying. It is also more accurate than taking notes. We will produce a transcript to help each researcher recall what was said during the interview.
After the interview, only the researcher and the person who types up the notes will listen to the recording.

We will put a summary of what everyone says together in a report but we will not say who has said what, or put any names in the reports. It will not be possible for anyone outside the research team to know what you personally have told us.

**Can I change my mind about taking part?**

Yes, at any time. Also, if you are interviewed by one of our researchers, if there are any specific questions you don’t want to answer, that is fine – it’s completely up to you.

Refrigerator: If participant would like to take part, email them 1) the written copy of this interview information, with written confirmation of their date and time of interview, 2) the contact details below so they can get in touch if they have questions, and 3) a copy of the consent form we will collect at point of interview.

Contact details: Jason Archer, TNS BMRB, 6 More London Place, London, SE1 2QY  
Jason.Archer@tns-bmrb.co.uk  020 7656 5773
Appendix D: One-to-one interview information letter

Your views on feedback of potentially serious abnormalities from participation in UK Biobank’s imaging study

Dear [NAME],

You are receiving this letter because you have agreed to participate in research that TNS BMRB is conducting for UK Biobank. We understand that you have received feedback about a potentially serious abnormality noted on your scans during your imaging visit.

This letter outlines some key information about what is involved in this next phase of research, and confirms when we have scheduled to see you.

Who are we and what is this research about?

TNS BMRB is an independent research organisation which does work on behalf of a variety of public bodies, charities and government departments.

TNS BMRB has been asked by UK Biobank to find out about people’s views on what and how people are told about any potentially serious findings discovered during participation in the imaging study. UK Biobank has asked us to conduct this work so that you can participate anonymously, and that you can be completely honest about your experience. UK Biobank wants to know what it is like for people in their imaging study to receive feedback so that they can develop the best feedback procedures possible. Currently, very little is known about the impact on participants, family or friends of receiving this type of information. This research will allow UK Biobank and other similar projects to improve their feedback procedures in the future.

What does participation involve?

http://www.tns-bmrb.co.uk
We would like to hear more about your experience of having received feedback about a potentially serious abnormality. The questions we would like to ask build on questions you answered in the questionnaire you recently completed.

Letter to include correct information below depending on point of consent and fill in the scheduled date/time/location of interview:

For participants recruited after the 6-week questionnaire:
You have agreed to take part in two 90-minute interviews with our researchers:
- The first would be face-to-face, and will be conducted at X TIME and DATE in LOCATION.
- The second interview would be in [DATES] – again, at a time of your convenience. This interview would be conducted via telephone. We will contact you in [DATES] to arrange a convenient time.

If your friends or family are available to participate in the interview as well and you are happy to take part, we would love to include them – to hear more about how the process affected them.

For participants recruited after the 6-month questionnaire:
You have agreed to take part in a 90-minute interview with one of our researchers. This interview will be conducted at X TIME and DATE in LOCATION.

Do I have to take part?
No. Participation in this research is completely voluntary, and your decision whether to participate or not will not affect your relationship with UK Biobank or your status in the imaging study.

Is this confidential?
Yes. Everything you say to us will be confidential, you don’t have to talk about anything you don’t want to, and your identity will remain anonymous.

We would like to record our conversation so we can pay more attention to what you are saying. It is also more accurate than taking notes. We will produce a transcript to help each researcher recall what was said during the interview. After the interview, only the researcher and the person who types up the notes will listen to the recording.
We will put a summary of what everyone says together in a report but we will not say who has said what, or put any names in the reports. It will not be possible for anyone outside the research team to know what you personally have told us.

**Can I change my mind about taking part?**

Yes, at any time. Also, if you are interviewed by one of our researchers, if there are any specific questions you don’t want to answer, that is fine – it’s completely up to you.

We will ask for your formal written consent when we come to interview you. A copy of the consent form is included below.

**What if I have further questions?**

If you have any questions please contact:

Jason Archer, TNS BMRB, 6 More London Place, London, SE1 2QY
Jason.Archer@tns-bmrb.co.uk  **020 7656 5773**


Consent for individuals to take part in research on:

Feedback of potentially serious incidental findings from participation in UK Biobank’s imaging pilot study

DEPTH INTERVIEWS

Please tick:

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<tr>
<th>Yes</th>
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<td><img src="yes1.png" alt="Yes" /></td>
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I understand what the research is about and that I am being asked to answer questions about feedback of potentially serious abnormalities from participation in UK Biobank’s imaging pilot study

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<tbody>
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<td><img src="no2.png" alt="No" /></td>
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I give permission for what I say to be recorded so the researchers have an accurate record of our conversation

<table>
<thead>
<tr>
<th>Yes</th>
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<tbody>
<tr>
<td><img src="yes3.png" alt="Yes" /></td>
<td><img src="no3.png" alt="No" /></td>
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I understand that my details will not be shared with anyone outside the research team and that my name will not be used in any research reports

<table>
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<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td><img src="yes4.png" alt="Yes" /></td>
<td><img src="no4.png" alt="No" /></td>
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</table>

I understand that I do not have to take part if I do not want to, and that my decision will not affect my status in the UK Biobank study

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td><img src="yes5.png" alt="Yes" /></td>
<td><img src="no5.png" alt="No" /></td>
</tr>
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</table>

I understand that I can refuse to answer any question or stop taking part at any time
Appendix E: Stakeholder interview invite email

Dear [NAME],

UK Biobank has commissioned TNS BMRB to undertake research on its feedback mechanisms for incidental findings discovered during participation in the imaging pilot study. This research will inform the policy on feedback for the main phase of the imaging study.

I am contacting you as TNS BMRB are looking to undertake two waves of telephone interviews with radiographers and radiologists who are involved in the feedback process. The first would be between [DATES] and the second would be in [DATES] – at times of your convenience. These interviews will last 30-45 minutes each and all views will be treated anonymously and confidentially. TNS BMRB are looking to understand your initial views on the feedback procedures so far, and also wish to feed back findings from their research with participants of the imaging pilot study to discuss what you think these findings might mean for your work and for the feedback procedures overall.

If you are happy to participate in these interviews please could you respond with dates and times that would work for you for the first interview, either by email at jason.archer@tns-bmrb.co.uk or if you could call Jason Archer (Research Executive) on 020 7656 5773 to discuss. TNS BMRB can then confirm a mutually convenient time/date to speak.

If you have any queries or require any further information please do get in touch with Jason. Similarly if you have any questions for UK Biobank then do get in touch directly.

Kind regards,

Steve
Appendix F: Deliberative group topic guide

Research objectives
1. Assess the **attitudes** of participants to receiving feedback of incidental findings and to track whether these change over time
2. To assess **initial understanding and experience of feedback procedures** and how these influence attitudes overall
3. To understand the **impact on participants, their family and friends** of receiving feedback
4. Assess the **attitudes of radiographers and radiologists** (involved in the feedback process) towards UK Biobank’s incidental findings feedback procedures
5. To **inform the policy on feedback** for the main phase of the imaging study.

This workshop aims to:
1. Understand initial experiences of consent and agreement to participate – and early understanding of and attitudes towards feedback procedures
2. Assess whether any further adjustments may be useful to help ensure informed consent
3. Explore early views on the potential benefits and downsides of being notified of incidental findings, and how participants would like this to occur

Questions to answer:

**Q1 What are people’s expectations about receiving feedback?**
What do they assume they would be told about? How do they feel about this? What do they see as the key potential harms and benefits?

**Q2 Do views change when they are provided with information about the type of feedback that they may receive?** Is this what they expected? How do they weigh up benefits of information provision against harms of false positives?

**Q3 What are people’s views about UK Biobank’s proposed process for providing feedback?** Does this match initial expectations? What do they see as benefits and drawbacks? Do they think UK Biobank has got the balance of benefits and harms right?
<table>
<thead>
<tr>
<th>Topic</th>
<th>Timing</th>
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<tbody>
<tr>
<td>Section 1: Welcome</td>
<td>5 mins</td>
</tr>
<tr>
<td>1.1 Welcome and introduction to research</td>
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<tr>
<td>- Thank for taking part in this part of research and explain</td>
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<tr>
<td>objective:</td>
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<tr>
<td>- TNS BMRB is an independent research agency commissioned to assess</td>
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<tr>
<td>procedures undertaken within UK Biobank’s approach, especially</td>
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<tr>
<td>relating to the information provided to you before and after</td>
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<td>imaging scans</td>
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<tr>
<td>- Explain confidentiality and anonymity:</td>
<td></td>
</tr>
<tr>
<td>- All responses are completely confidential and will remain</td>
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<tr>
<td>anonymous according to the MRS Code of Conduct and in line with</td>
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<tr>
<td>the Data Protection Act 1998</td>
<td></td>
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<tr>
<td>- No personal data is kept beyond the life of this project and no</td>
<td></td>
</tr>
<tr>
<td>information is passed on to third parties in any way</td>
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<tr>
<td>- Recording will take place on an encrypted device to ensure an</td>
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<tr>
<td>accurate record of the conversation; this is not shared with</td>
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<tr>
<td>anyone outside of the TNS BMRB project team, including UK</td>
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<tr>
<td>Biobank</td>
<td></td>
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<tr>
<td>- Your personal information is not passed on to UK Biobank in</td>
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<tr>
<td>relation to the findings from this interview</td>
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<tr>
<td>- TNS BMRB remain 100% independent and impartial and no elements</td>
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<tr>
<td>of your particular case can be affected by us</td>
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<tr>
<td>- Does anyone have any questions around the purposes of the project</td>
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<td>- Explain format – a mixture of small group and general discussions</td>
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<td>- Length of discussion approx. 2 hours</td>
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<td>- All participants are free not to respond to any questions where</td>
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<td>they feel uncomfortable, and participation is totally voluntary</td>
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<td>- Ensure all participants agree with format and procedures</td>
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before continuing
- Housekeeping: mobile phones, toilets, fire, etc.

### Section 2: Group introductions and icebreaker

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<th>2.1 Group introductions and icebreaker</th>
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<tr>
<td>• (Person by Person) To start with please introduce yourself saying your:</td>
</tr>
<tr>
<td>o First name</td>
</tr>
<tr>
<td>o Age</td>
</tr>
<tr>
<td>o What you do for a living</td>
</tr>
<tr>
<td>o What you like to do in your spare time</td>
</tr>
<tr>
<td>• (Group discussion) Tell me a bit about your family/who you live with, e.g.:</td>
</tr>
<tr>
<td>o Name and occupation of spouse/partner/flatmates</td>
</tr>
<tr>
<td>o Names/ages of any kids</td>
</tr>
<tr>
<td>o Things you like to do together</td>
</tr>
<tr>
<td>o Where you've been on holiday recently</td>
</tr>
</tbody>
</table>

**NB: these questions are important in establishing rapport and setting up trust with the participant**

*Moderator to explain we are first going to talk about the study more broadly and then go into more detail about their specific views and experiences*

### Section 3: Understanding of and attitudes towards UK Biobank and imaging study

<table>
<thead>
<tr>
<th>3.1 Early understanding of UK Biobank and imaging research</th>
</tr>
</thead>
<tbody>
<tr>
<td>• How they first heard about UK Biobank</td>
</tr>
<tr>
<td>o Explore channels – how became aware</td>
</tr>
<tr>
<td>o Explore views – what did they know, think and feel about UK Biobank as an organisation</td>
</tr>
<tr>
<td>• How they first heard about the study</td>
</tr>
<tr>
<td>o If directly recruited, views on the approach and why they thought they were being invited to take part in the project</td>
</tr>
<tr>
<td>o Information given on study – explore sources</td>
</tr>
</tbody>
</table>
3.2 Understanding of study aims and procedures

- Understanding of the UK Biobank study [if not covered above]
  - What is being done
  - What is the overall aim
  - How it is being done
  - What kind of data is collected
  - How is the data collected used
  - Benefits?
  - Any areas of confusion/concern/further questions? *(Moderator – to focus on research aims questions rather than procedural issues/practicalities).*

- How much did you know about the study before you signed up?
  - How did you find this information out?
  - What format was information provided in?
  - How easy/ hard was it to understand?
  - How much do you need to know about a study like this before taking part?

3.3 Motivations

- Why they agreed to take part in the project *(Moderator – do not probe, but listen out for any suggestion that respondents believed scans would be clinical/diagnostic)*
  - Probe: general interest, good cause, experience, medical history

- What factors did you consider when deciding whether to take part?
  - Probe: health issues, ethical issues, confidentiality, logistics, reputation, potential risks, potential benefits

- Did you talk to anyone else about taking part before you signed up?

- Are/were there any areas of concern or confusion? Why?

**Section 4: Initial understanding of and views on UK Biobank data collection and feedback procedures**

| 20 mins |
3.1 Initial expectations and understanding around imaging participation

- Based on the information you had when you signed up, what did you expect from taking part in the study?
  - What did you expect to happen at the scans?
  - What kind of communication did you expect before the scans?
  - What kind of communication did you expect after the scans?
  - How did you expect to feel before, during and after the scans?

If not explicitly mentioned during above conversation, then explore:

- Who do you think looks at your scan data? For what purpose? (Moderator to listen out for any misunderstandings re: research versus clinical scan examination)
- Had you thought about incidental findings/ were you concerned about this before?
- Were you aware of the procedures in place if any kind of incidental finding was found during the scan? (Moderator to provide explanation if necessary: Although the scan is for research purposes, it is possible that when your scan is reviewed that the radiographer or radiologist looking at your scan might see something on it that might affect your health or be important to know about. That is called an ‘incidental finding’.)
- What was your understanding of this procedure at the time? *Spontaneous, then probe:*
  - What kinds of findings would you be told about?
  - Why?
  - When (how soon after your scan)?
  - Who would be told?
  - How would you be told?
  - By whom?

- Did you receive any information about incidental findings and feedback procedures from anyone in the UK Biobank team? *(Spontaneous, then probe)*
  - In your consent forms?
  - Discussion with staff?
  - On the UK Biobank website?
### Section 5: Views on consent and feedback informational materials

**Moderator note:** play ‘feedback procedures video’ on UK Biobank website ([http://imaging.ukbiobank.ac.uk/](http://imaging.ukbiobank.ac.uk/)) and ask participants to note down 1) any key points of interest, 2) any questions or concerns.

**Moderator to then lead general discussion:**

- What are their (spontaneous) views on the process
  - Is this what they expected/understood when consenting?
  - Do they feel comfortable with the procedure overall?
  - Was anything confusing or hard to understand?
  - Would they have any questions or concerns?

- How do they feel about not receiving any results from the assessment visit, other than a few simple measures (e.g., blood pressure); why
  - Did being informed that scans are not intended for diagnostic use have any impact on their attitudes; why
  - Did being informed of advances that come out of research using UK Biobank have any impact on their attitudes; why

- How do they feel about scans being looked at to ensure their technical quality is adequate, rather than to identify particular clinical problems; why
  - How do they feel about scans not being routinely reviewed by specialists or other doctors; why
  - How do they feel about the fact that technical quality (e.g. resolution) may differ for different kinds of scans – e.g. abdominal scans are lower resolution than brain scans, so it may be more difficult to notice/assess potentially serious abnormalities

- Explain/reiterate: In the unlikely event that a potentially serious abnormality is confirmed to be present on a participant’s scan, UK Biobank will write to the individual and their GP within about two weeks of their visit, so that
the GP can make arrangements for further investigation if required

- What is their understanding of a ‘potentially serious abnormality’; how do they feel about this; why
- Who do they think should be involved in identifying potentially serious abnormalities; why
- What do they think they should be told at this time – what level of detail is important?
- What kind of information do they think their GP should be provided with? Would they expect this to be the same or different than the information provided in their own letter?

- **Do they think it makes sense to only notify people of potentially serious findings?** Why/why not?
  - What do they think would be the benefits/downsides of having a more/less restrictive criteria (e.g., notification of likely non-serious findings?)
  - Explore perceived relative costs and benefits for the participant/for the health service/for UK Biobank and the imaging study

- **Overall,** do they agree or disagree with any particular elements of the process – e.g. communication channels, timespan, etc.
  - What do they see as the benefits and drawbacks
  - If any concerns – what do they see as the potential negative impacts of any aspects of the feedback procedure that they disagree with?

### Section 5: Envisioning the feedback experience

<table>
<thead>
<tr>
<th>Moderator to lead brief discussion:</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Before seeing the video, had they considered that there might be any negative impacts of receiving incidental findings?</td>
</tr>
<tr>
<td>- Do they consider that there would be any positive impacts of receiving incidental findings?</td>
</tr>
</tbody>
</table>

*Moderator note: split group into 3 mini-groups and introduce the ‘scenarios’. Have each group nominate ‘readers’ for the scenarios, plus an overall ‘secretary’*
to take notes about the group’s discussion. Ask groups to read through the scenarios one by one, and then have 5 minutes’ discussion on what the scenarios made them think and feel, exploring:

- What kinds of issues or questions does this scenario raise for you?
- How do you think you would react in similar circumstances?
- If this was you, what kind of information would you want provided and why?
- How would you want that information provided?
- What kinds of questions would you have for your GP/for UK Biobank?
- If this was you, would this experience change your views about the overall feedback procedure? Do you think it would address your needs? Why/why not?

**Moderator to then lead discussion with the group as a whole – going case study by case study and asking each mini-group to feed back their thoughts and exploring the questions above. Moderator to explore variations in response depending on the different incidental findings ‘outcomes’.

### Section 6: The ideal process for providing feedback

Moderator to then lead general discussion with the group as a whole about what their ‘ideal’ feedback procedure would be, flip-charting the process proposed by respondents (what would happen; when; how). Throughout, probe to understand why they have proposed the procedure discussed.

### Section 7: Summary discussion and thank you

- Overall, what do they think are the key benefits and drawbacks of receiving feedback?
- Overall, what are the key principles to keep in mind for an ‘ideal’ feedback procedure, from their perspective?
- Do they have any other key thoughts to feed back to UK Biobank?

**Thank and close**
Appendix G: One-to-one participant topic guide (wave one)

UK Biobank Feedback Recipient Depth Interview
Topic guide v1

Research objectives
1. Assess the attitudes of participants to receiving feedback of incidental findings and to track whether these change over time
2. To assess initial understanding and experience of feedback procedures and how these influence attitudes overall
3. To understand the impact on participants, their family and friends of receiving feedback
4. Assess the attitudes of radiographers and radiologists (involved in the feedback process) towards UK Biobank’s incidental findings feedback procedures
5. To inform the policy on feedback for the main phase of the imaging study.

This interview aims to:
- To understand the impact of receiving incidental findings feedback on participants, their family and friends
- Understand what changes could or should be made to the feedback process to reflect participants’ views and needs

Questions to answer:
Q1 What were the positives and negatives of the experience of receiving feedback and any subsequent follow-up? What went well and could go better?
Q2 What was the impact of feedback – on participants? Friends? Family? How does this differ depending on the kind of feedback given, any outcomes (e.g., medically relevant versus false positives)?
Q3 Overall, what do findings against the above questions mean for any potential change to UK Biobank’s procedures – in terms of what is fed back and how this is done? Do participant expectations and the experience of those receiving feedback suggest that UK Biobank has got the balance of benefits and harms right? Why/why not?
Section 1: Introductions

1.1 Explanation of research
- Thank for taking part in this part of research and explain objective:
  - *TNS BMRB is an independent research agency commissioned to assess some elements of the procedures undertaken within UK Biobank’s approach, especially relating to the information provided to you before and after imaging scans*
- Explain confidentiality and anonymity:
  - *All responses are completely confidential and will remain anonymous according to the MRS Code of Conduct and in line with the Data Protection Act 1998*
  - *No personal data is kept beyond the life of this project and no information is passed on to third parties in any way*
  - *Recording will take place on an encrypted device to ensure an accurate record of the conversation; this is not shared with anyone outside of the TNS BMRB project team, including UK Biobank*
  - *Your personal information is not passed on to UK Biobank in relation to the findings from this interview*
  - *TNS BMRB remain 100% independent and impartial and no elements of your particular case can be affected by us*
- Interview will last around 90 minutes
- We may invite other family members to take part at specific moments if appropriate/relevant and you consent to this
- Respondent free not to respond to any questions where they feel uncomfortable
1.2 Respondent introduction

- To start with please introduce yourself saying your:
  - Name
  - Age
  - What you do for a living
  - What you like to do in your spare time

- Tell me a bit about your family/ who you live with, e.g.:
  - Name and occupation of spouse/ partner/ flatmates
  - Names/ ages of any kids
  - Things you like to do together
  - Where you’ve been on holiday recently

**NB: these questions are important in establishing rapport and setting up trust with the participant**

*Moderator to explain we are first going to talk about the study more broadly and then go into more detail about their specific experience*

<table>
<thead>
<tr>
<th>Section 2: Perceptions of UK Biobank study</th>
<th>20 mins</th>
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</table>

2.1 Attitudes towards UK Biobank

*Moderator note: the aim here is to bring out general views of the UK Biobank study and its procedures – not experiences of the imaging study yet*

- How did you first hear about the UK Biobank study?
  - Probe: recruited directly, through a friend, media channels

- What did you think about it when you first heard about it?
  - What did you find interesting about it?
  - Did you find anything concerning/ worrying about it?

- Have your views changed in any way now?
  - If yes, probe around how and why but don’t spend long on this as will be covering in more detail later on
- Do you feel it was the right decision to take part?
  - Briefly: why/ why not? (will be covering more later)

- Briefly: Overall, how would you say your experience so far has been?

- Do you know anyone else who has taken part?
  - Briefly: If yes, how has their experience differed to yours?

2.2. Understanding of the UK Biobank study

- (Briefly) What do you know about the UK Biobank study?
  - What is being done?
  - What is the overall aim?
  - How it is being done?
  - Benefits?

- How much did you know about the study before you signed up?
  - How did you find this information out?
  - What format was information provided in?
  - How easy/ hard was it to understand?
  - How much do you need to know about a study like this before taking part?

- What are the procedures that participants go through to take part in the study?
  - What is the sign-up process?
  - What information is provided?
  - What information is required?
  - What (if any) are the benefits of signing up to take part?
  - What (if any) are the risks to taking part?

- Briefly: Has your understanding of the study changed now compared to when you signed up? How?

- Briefly: Knowing what you know now, do you feel you had enough information about the study when you signed up?
2.3 Motivations

- What made you want to sign up for the UK Biobank imaging study?
  - Probe: general interest, good cause, experience, medical history
- What factors did you consider when deciding whether to take part?
  - Probe: health issues, ethical issues, confidentiality, logistics, reputation, potential risks, potential benefits
- Did you talk to anyone else about taking part before you signed up?

2.4 Expectations and understanding around feedback procedures

- Based on the information you had when you signed up, what did you expect from taking part in the study?
  - What did you expect to happen at the scan?
  - What kind of communication did you expect before the scan?
  - What kind of communication did you expect after the scan?
  - How did you expect to feel before, during and after the scan?
- How much have your expectations been met here?
  - Probe fully

*Moderator note: If not explicitly mentioned during above conversation ask:*

- Were you aware of the procedure if any kind of incidental finding was found during the scan?
- What was your understanding of this procedure at the time? *Spontaneous, then probe:*
  - What kinds of findings would you be told about?
Why?
By whom?
Who would be told?
How would you be told?
- Had you thought about it/ were you concerned about it before?

### Section 3: Feedback journey and experience

<table>
<thead>
<tr>
<th>3.1 Feedback journey</th>
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</thead>
<tbody>
<tr>
<td>Moderator to explain that we are now going to move on to talk about their experiences after the scan from receiving their letter to where they are now</td>
</tr>
</tbody>
</table>

- How long after your scans did you receive the letter informing you of incidental findings?
  - What do you think about this length of time?
  - Did you know to expect communication within this timeframe?
- What did the letter say?
  - About the finding?
  - About what to do next?
  - What did you think about the level of detail provided?
- What did you think of the way the letter was worded?
  - How would you describe the tone of the letter?
    - Probe: Friendly; informative; alarming; serious; reassuring; professional...
    - Was there anything you found difficult to understand?
- What did you understand from the letter?
  - Serious issue? Just a precaution?
- How did you feel when you received the letter?
  - Probe: thankful, reassured, scared, anxious, surprised, angry, etc.

*From this starting point, moderator to then walk through*
participant’s journey post-notification:

- What did you do next?
  - Probe fully around the steps taken following receipt of the letter and what they did, who they spoke to, what they discussed, and how they felt at each stage:
    - Contacting doctor (NB: some may have been contacted directly by their doctor)
    - Getting referral
    - Having further tests
    - Getting treatment
    - Further steps
- How did your doctor respond to the information in the letter/you coming to see them?
- What went well/less well? Did you have any concerns?
- Did you receive any conflicting information from UK Biobank and your GP/hospital?
- Did you look anything up yourself as a result of the letter, e.g. online?
  - If yes, what did you do, where did you go? What was the result of this?
  - How did this make you feel?
- What stage are you at now?
  - Are you awaiting any further tests/results/treatments?
    - How are you feeling about this?
    - Do you have any outstanding questions?
- How are you feeling now about having been notified about the incidental finding on your scan?
  - Probe: thankful, reassured, scared, anxious, surprised, angry, etc.

3.2 Impact on family

- Overall, what impact would you say receiving the letter has had on you and your family?
- How has it affected members of your family in
particular?

Moderator note: if appropriate and participant consents, invite members of the family into the discussion at this point and ask:

- What happened when X [respondent] received the feedback letter from UK Biobank?
- How did you feel?
- Did you know they were taking part in the study?
- Did you understand what the letter meant? Did you have any questions?
- Ask family member to talk through steps as above and probe on impact/ how they felt at each stage also

3.3 Response to potential outcomes

- Were you aware of the 4 different potential outcomes from having an incidental finding noted on your scan?
  - Finding judged to be artefact
  - Finding judged to be of a non-serious nature
  - Finding resulting in uncertain diagnosis and/or requiring longer term monitoring
  - Finding resulting in a diagnosis of a problem or illness considered serious according to Biobank’s definition
- If not, would it have been helpful to know about them? Why/ why not?
  - How would be the best way to communicate these to people?
- Do you know which category your issue would fall into?
  - What difference would knowing this have made to your experience?

Section 4: Response to other feedback 10 mins

Moderator to explain that we are doing wider research, including speaking to groups of participants who have signed up but not yet undergone the scanning process about what kind of information they would like to be included in the consent forms
they sign relating to discovering incidental findings

- Thinking back to when you signed up, what kind of information did you think you would like to hear about after your scans?
- Has this changed now and if so, how?

FOLLOWING DELIBERATIVE RESEARCH: FEEDBACK SOME OF GROUP FINDINGS AND GET A SENSE OF HOW THESE RESPONDENTS FEEL ABOUT THEM; DO THEY AGREE HAVING RECEIVED FEEDBACK FROM THEIR SCANS?

<table>
<thead>
<tr>
<th>Session 5: Improvements to process</th>
<th>10 mins</th>
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</thead>
<tbody>
<tr>
<td><strong>Overall,</strong> how do you feel about your experience of taking part in the study and receiving feedback relating to a medical condition?</td>
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<tr>
<td>o What has gone well and less well?</td>
<td></td>
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<tr>
<td>o How informed have you felt throughout?</td>
<td></td>
</tr>
<tr>
<td>o Should anything have been made clearer to you at any point? If so, what, when and how?</td>
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</tbody>
</table>

**Thinking about the whole process,** what improvements could be made to make it an easier experience for people taking part?

| o What information should be given at the start? |
| o What needs to be included in the consent form/ process relating to any incidental findings? |
| o What form should communication take before, during and after the scans? |
| o How much information should be shared with participants about their scan data? |
| o What role should your GP play in the process? How much information should they be given? |
| o Who else should be involved/ informed and how? |

**Knowing what you know now,** would you want to have been informed of anything differently?
Would you want any kind of different information?
Any other comments to add?

Thank and close
Appendix H: Stakeholder interview topic guide (wave one)

UK Biobank Incidental Findings
Stakeholder Discussion Guide Wave 1

Introduction (5 mins)

- Introduce yourself and TNS BMRB – an independent research agency
- Explain the purpose of the interview – to get a sense of UK Biobank radiologist and radiographer views on the current incidental findings feedback process
- Length: 30-45 minutes
- Recording – notes on the interview will be shared with the TNS BMRB research team; fully anonymised quotes may be used in reporting to the UK Biobank research team
- MRS guidelines – confidentiality and anonymity (any quotes will be attributed anonymously, please note any sensitive topics)

Introductions and general context (5 mins)

- Explore respondent’s current job role within UK Biobank
  - Length in post
  - Key tasks/responsibilities overall
  - Describe a typical day (or week)

- Explore respondent’s previous job history prior to UK Biobank
  - Research versus clinical roles?
  - If clinical – what do they find to be the key differences in how they approach their work at UK Biobank versus clinical imaging? 
    *Spontaneous, then probe for implications for how they perceive*
their responsibilities; how they read scans; how they respond personally to incidental findings

Views on feedback procedures (15 mins)

- Why they think volunteers partake in the project
  - Perceived and anticipated benefits
  - Perceived risks or downsides
  - Where they think participants source information about the study

- What they think participants assume they will be told about
  - Whether they think the inclusion of imaging has changed participants’ relationship with or expectations towards UK Biobank
  - Whether they think the consent process (that takes place at the UK Biobank imaging assessment centre) adequately informs participants in this regard
  - What they consider the key potential harms and benefits of feedback to be

- What are their (spontaneous) views on the process
  - Whether they feel it meets participants’ expectations

- How do they think participants feel about not receiving any results from the assessment visit – are they adequately prepared for this
  - Whether they think being informed of advances that come out of research using UK Biobank has any impact on participants’ attitudes

- Is there a perceived responsibility to identify particular clinical problems – if so, where does that responsibility lie
  - Whether they feel the current process meets ethical obligations
• How easy/difficult is it to classify an abnormality as ‘potentially serious’
  o Do they consider there to be any issues around this

• Overall – what seems to work well or not well?
  o Do they agree or disagree with any particular elements of the process
  o What do they see as the benefits and drawbacks
  o Do they think UK Biobank has got the balance of benefits and harms right
  o Do they agree to a standardised process, or should it be dependent on the nature of the potentially serious abnormality

Final reflections and close (5 mins)

• Overall, what do they think are the key benefits and drawbacks of receiving feedback for participants
• Overall, what do they think is working well and less well for radiographers and radiologists involved in providing incidental findings feedback
• Overall, what do they think are the key factors that UK Biobank need to bear in mind with regard to their feedback procedures
  o If they could change anything based on their experience supporting the imaging study, what would it be and why

Thank and close
## Appendix I: One-to-one participant topic guide (wave two)

### UK Biobank Feedback Recipient Depth Interview
**Topic guide v1**

### Research objectives

1. Assess the **attitudes** of participants to receiving feedback of incidental findings and to track whether these change over time
2. To assess **initial understanding and experience of feedback procedures** and how these influence attitudes overall
3. To understand the **impact on participants, their family and friends** of receiving feedback
4. Assess the **attitudes of radiographers and radiologists** (involved in the feedback process) towards UK Biobank’s incidental findings feedback procedures
5. To **inform the policy on feedback** for the main phase of the imaging study.

### This interview aims to:

- Gauge whether and how participants’ attitudes to receiving feedback changed over time
- Understand what changes could or should be made to the feedback process to reflect participants’ views and needs

<table>
<thead>
<tr>
<th>Section 1: Introductions</th>
<th>Approx timing</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 Explanation of research</td>
<td>10 mins</td>
</tr>
<tr>
<td>• Thank for taking part in this part of research and explain objective:</td>
<td></td>
</tr>
<tr>
<td>o <strong>TNS BMRB is an independent research</strong></td>
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</tbody>
</table>
agency commissioned to assess some elements of the procedures undertaken within UK Biobank’s approach, especially relating to the information provided to you before and after imaging scans

- Reiterate confidentiality and anonymity:
  - All responses are completely confidential and will remain anonymous according to the MRS Code of Conduct and in line with the Data Protection Act 1998
  - No personal data is kept beyond the life of this project and no information is passed on to third parties in any way
  - Recording will take place on an encrypted device to ensure an accurate record of the conversation; this is not shared with anyone outside of the TNS BMRB project team, including UK Biobank
  - Your personal information is not passed on to UK Biobank in relation to the findings from this interview
  - TNS BMRB remain 100% independent and impartial and no elements of your particular case can be affected by us

- Interview will last around 60 minutes
- Respondent free not to respond to any questions where they feel uncomfortable

1.2 Recap of first interview (for individuals interviewed at Wave 1 only)

- Reiterate some of the key points discussed in the first interview
  - General views and understanding of the UK Biobank study and its procedures
  - Motivations for signing up for the imaging study and factors considered when deciding whether to take part
  - Expectations and understanding around feedback procedures
  - Actual experience of receiving feedback and any subsequent follow-up
- Impact of feedback on them and their family
- Potential changes to UK Biobank’s procedures

Moderator to explain we are first going to talk about the study again more broadly and then go into more detail about their specific experience of any further follow-up care since last contact.

### Section 2: Perceptions of UK Biobank study

<table>
<thead>
<tr>
<th>2.1 Any change in views or understanding of the UK Biobank study and its (feedback) procedures?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Have your views of the UK Biobank study changed in any way since last contact?</td>
</tr>
<tr>
<td>- If yes, probe around how and why but don’t spend long on this as will be covering in more detail later on</td>
</tr>
<tr>
<td>• Do you still feel it was the right decision to take part?</td>
</tr>
<tr>
<td>- Briefly: why/ why not? (will be covering more later)</td>
</tr>
<tr>
<td>• Have you talked to anyone else about the study or your experience since last contact?</td>
</tr>
<tr>
<td>• Briefly: Has your understanding of the study or its feedback procedures changed in any way since last contact? How and why?</td>
</tr>
<tr>
<td>• Briefly: Knowing what you know now, do you feel you had enough information about the study when you signed up?</td>
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</tbody>
</table>

### Section 3: Journey since last contact

<table>
<thead>
<tr>
<th>3.1 Experience of any further follow-up care</th>
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<tbody>
<tr>
<td>Moderator to explain that we are now going to move on to talk about their experiences of any further follow-up care since last contact to where they are now</td>
</tr>
</tbody>
</table>
• What has happened in relation to the potential abnormality noted on your scan?
  o Probe fully around what they’ve done, who they’ve spoken to, what they’ve discussed, and how they’ve felt at each step in their journey – e.g.,:
    ▪ Further follow-up conversations with GP/other health care providers
    ▪ Getting referrals
    ▪ Having further tests
    ▪ Getting treatment
    ▪ Any definitive ‘diagnosis’?
    ▪ Further steps

• What stage are you at now?
  o Are you awaiting any further tests/results/treatments?
  o Are there any implications of what was found for your future health or health care?
  o How are you feeling about this?
  o Do you have any outstanding questions or concerns?

• Did you look anything up yourself at any stage, e.g. online?
  o If yes, what did you do, where did you go? What was the result of this?
  o How did this make you feel?

3.2 Impact on family
• Overall, what impact would you say receiving feedback has had on you and your family?
  o Probe on impact/how they felt at each stage also – especially in relation to any further follow-up care

3.3 Response to potential outcomes
Throughout, do you feel you have had adequate information about what the implications of the potential abnormality on your scan might have been?

Based on the 4 different potential outcomes from having an abnormality noted on your scan (discussed in first interview), do you now know which category your issue would fall into?

- Finding judged to be artefact
- Finding judged to be of a non-serious nature
- Finding resulting in uncertain diagnosis and/or requiring longer-term monitoring
- Finding resulting in a diagnosis of a problem or illness considered serious according to UK Biobank’s definition

Do you feel you understood that there could be multiple outcomes to being notified of a potentially serious abnormality on your scan?

- At point of consent?
- At point of receiving feedback?

What difference would knowing that were multiple potential outcomes from being notified of a potential scan abnormality have made to your experience?

### Session 4: Improvements to process

<table>
<thead>
<tr>
<th></th>
<th>15 mins</th>
</tr>
</thead>
</table>

Overall, how do you now feel about your experience of taking part in the study and receiving feedback relating to a medical condition?

- What has gone well and less well?
- How informed have you felt throughout?
- Was there anything you wanted more clarity on at any point? If so, what, when and how?
• Overall, knowing what you know now, how do you feel about the process by which you were notified of a potentially serious abnormality on your scan?
  o Letter content?
  o Letter wording and tone?
  o Level of detail?
  o GP and personal notification?

• Thinking about the whole process, what improvements could be made to make it an easier experience for people taking part?
  o What information should be given at the start?
  o What needs to be included in the consent form/process relating to any incidental findings?
  o What form should communication take before, during and after the scans?
  o How much information should be shared with participants about their scan data?
  o What role should your GP play in the process? How much information should they be given?
  o Who else should be involved/informed and how?

• Knowing what you know now, how do you feel about having been notified of the potential abnormality on your scan?
  o Are you glad this was done? Why/why not?
  o If you have changed your mind, why is this?

• Knowing what you know now, would you want to have been informed of anything differently?
  o Would you want any kind of different information?

• Do you think UK Biobank should notify participants about potentially serious findings?
  o Why/why not?
- Knowing what you know now, would you have consented to participate in the imaging research?
  - Why/why not?
- Any other comments to add?

Thank and close
Appendix J: Stakeholder interview topic guide (wave two)

UK Biobank Incidental Findings
Stakeholder Discussion Guide Wave 2

Introduction (2 mins)

- Introduce yourself and TNS BMRB – an independent research agency
- Explain the purpose of the interview – to feed-back experiences and views from the qualitative research with research participants, to understand what these might mean for their work and for feedback procedures overall
- Length: 30 minutes
- Recording – notes on the interview will be shared with the TNS BMRB research team; fully anonymised quotes may be used in reporting to the UK Biobank research team
- MRS guidelines – confidentiality and anonymity (any quotes will be attributed anonymously, please note any sensitive topics)

Revisiting discussion points from wave 1 (10 mins)

- Explore respondent’s current job role within (or relationship with) UK Biobank
  - Has role/relationship changed since last contact? If so, how and why?

  - *(Briefly)* Why they still think volunteers partake in the project
    - Perceived and anticipated benefits
    - Perceived risks or downsides

- What are their current (spontaneous) views on the feedback process
o Whether they feel it meets participants’ expectations
o Spontaneous, then probe on:
  ▪ Information given at the start
  ▪ Consent form/process relating to any incidental findings
  ▪ Communication before, during and after the scans
  ▪ Involvement of GP / the fact that they get more information than participants

o **Have their views changed at all since last contact? If so, why?**

- Overall – what seems to work well or not well?
  o Spontaneous, then probe on:
    ▪ Identifying particular clinical problems
    ▪ Classifying an abnormality as ‘potentially serious’
    ▪ A standardised process (vs. one dependent on the nature of the potentially serious abnormality)
  
  o **Have their views changed at all since last contact? If so, why?**

**Summary of findings from the deliberative groups and wave 1 depth interviews (15 mins)**

*Researcher to explain that overall, the current principles and processes relating to the imaging study and the reporting of incidental findings appear to be working well. The majority of respondents expressed no issues causing undue distress within their experience, and were impressed with the handling by UK Biobank. However:*

- Participants assumed that they would not be notified about non-serious issues; some felt aggrieved at having been put through undue stress when notification about an incidental finding led to a non-serous diagnosis
  o Explore implications for UK Biobank / staff members
  o Explore what they think could be done to alleviate undue stress
In a few cases misunderstandings about the extent of the study led to the false expectation that ‘doctors’ would be looking at all scans
  o Explore implications for UK Biobank / staff members
  o Explore what they think could be done to address misunderstandings

Doctors’ lack of knowledge about the study surprised some participants, who felt it should be better known within the medical community
  o Explore implications for UK Biobank / staff members
  o Explore what they think could be done to address this lack of knowledge

Despite participants knowing that the study was not clinical and was for research only, finding out about any incidental findings uncovered during the imaging study was a secondary motivation for participation for many
  o Explore implications for UK Biobank / staff members
  o Explore what they think could be done to address this (if anything)

For those who had recalled the stated notification timeframe as two weeks, there was a sense of relief once this period had passed with no communication; it then felt more distressing when they did receive a letter some weeks later
  o Explore their views on the current stated two-week notification timeframe and the implications for UK Biobank / staff members
  o Explore what they think could be done to address the misunderstanding that if nothing is found this equates to being given ‘a clean bill of health’

Participants had a very strong level of trust in UK Biobank due to previous positive experiences of taking part in studies; they tended to consent readily and without much consideration
  o Explore implications for UK Biobank / staff members
  o Explore what they think could/should be done differently with new participants

Explore whether they think any additional support or guidance for imaging staff would be useful
Final reflections and close (3 mins)

- Overall, what do they think are the key benefits and drawbacks of receiving feedback for participants

- Overall, what do they think is working well and less well for radiographers and radiologists involved in providing incidental findings feedback

- Overall, what do they think are the key factors that UK Biobank need to bear in mind with regard to their feedback procedures
  - If they could change anything what would it be and why

Thank and close
## Appendix K: Deliberative group analysis pro-forma

Pro Forma – 260126145 UK Biobank – Deliberative groups

<table>
<thead>
<tr>
<th>Group</th>
<th>Location</th>
<th>Other</th>
</tr>
</thead>
</table>

### Understanding of and attitudes towards UK Biobank and imaging study

#### Early understandings
- How they first heard about UK Biobank
- What did they know, think and feel about the organisation?
- What did they think the research was about and what did they think were its aims and objectives?
- What information were they given about the study?

#### Motivations
- Why did they want to take part?
- What did they see as the benefits?
- Did they perceive any risks or have any concerns? Did they speak to anyone about these?

#### The imaging study
- How did they hear about the imaging study?
- Why did they want to take part in this specifically?
- What did they see as the benefits and risks?
- What information did they have about this study?
- What did they understand to be the aims of the imaging?
### Initial understanding of and views on UK Biobank data collection and feedback procedures

<table>
<thead>
<tr>
<th>Initial expectations and understanding around imaging participation</th>
</tr>
</thead>
<tbody>
<tr>
<td>- What did you expect to happen at the scan?</td>
</tr>
<tr>
<td>- How did you feel about taking part?</td>
</tr>
<tr>
<td>- What information did you expect before or after the scans?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>How did you expect the feedback process to work?</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Were you aware of the incidental findings process?</td>
</tr>
<tr>
<td>- Who did you think would look at the scans and why?</td>
</tr>
<tr>
<td>- What was your understanding of how the procedure worked?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Information about the process</th>
</tr>
</thead>
<tbody>
<tr>
<td>- What information about the incidental findings process did you receive from Biobank?</td>
</tr>
<tr>
<td>- How did you receive this?</td>
</tr>
</tbody>
</table>

### Views on consent and feedback informational materials
Views on the process

- Is this what they expected?
- Do they feel comfortable?
- Is anything unclear?
- Do they have any concerns?

Do they have any feelings about not receiving feedback from the imaging study?

- Did this affect their attitude to the study and their participation in it?
- How do they feel about scans being looked at to ensure their technical quality is adequate, rather than to identify particular clinical problems
- How do they feel about scans not being routinely reviewed by specialists or other doctors?
- How do they feel about the fact that technical quality (eg resolution) may differ for different kinds of scans

Identifying a potentially serious abnormality

- What is their understanding of a ‘potentially serious abnormality’; how do they feel about this; why
- Who do they think should be involved in identifying potentially serious abnormalities; why
- What do they think they should be told at this time – what level of detail is important?
- What kind of information do they think their GP should be provided with? Would they expect this to be the same or different than the information provided in their own letter?
- Does it make sense to only notify people of potentially serious abnormalities?
Envisioning the feedback experience

Views on the process
- Before seeing the video, had they considered that there might be any negative impact of receiving incidental findings?
- Do they consider that there would be any positive impacts of receiving incidental findings?

<table>
<thead>
<tr>
<th>Scenario 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>What kinds of issues or questions does this scenario raise for you?</td>
</tr>
<tr>
<td>How do you think you would react in similar circumstances?</td>
</tr>
<tr>
<td>If this was you, what kind of information would you want provided and why?</td>
</tr>
<tr>
<td>How would you want that information provided?</td>
</tr>
<tr>
<td>What kinds of questions would you have for your GP/for UK Biobank?</td>
</tr>
<tr>
<td>If this was you, would this experience change your views about the overall feedback procedure? Do you think it would address your needs? Why/why not?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Scenario 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>What kinds of issues or questions does this scenario raise for you?</td>
</tr>
<tr>
<td>How do you think you would react in similar circumstances?</td>
</tr>
<tr>
<td>If this was you, what kind of information would you want provided and why?</td>
</tr>
<tr>
<td>How would you want that information provided?</td>
</tr>
<tr>
<td>What kinds of questions would you have for your GP/for UK Biobank?</td>
</tr>
<tr>
<td>If this was you, would this experience change your views about the overall feedback procedure? Do you think it would address your needs? Why/why not?</td>
</tr>
</tbody>
</table>
Scenario 3

- What kinds of issues or questions does this scenario raise for you?
- How do you think you would react in similar circumstances?
- If this was you, what kind of information would you want provided and why?
- How would you want that information provided?
- What kinds of questions would you have for your GP/for UK Biobank?
- If this was you, would this experience change your views about the overall feedback procedure? Do you think it would address your needs? Why/why not?

The ideal process for providing feedback

- What would the ideal feedback procedure look like, and why?
- What are the key principles?
Appendix L: In-home participant depth interview analysis framework (wave one and wave two)

<table>
<thead>
<tr>
<th>1.1 age</th>
<th>1.2 Respondent background</th>
<th>1.3 Respondent family</th>
<th>1.4 Other participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Note any information about what the respondent does/did for a living and whether they are retired, their hobbies and what they do in their spare time</td>
<td>Who the respondent lives with; any wider information about their friends/family</td>
<td>Do they know anyone else taking part? What has their experience been?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.1 Perceptions of Biobank</th>
<th>2.2 Sign up process to the study</th>
<th>2.3 Understanding</th>
<th>2.4 Motivations</th>
</tr>
</thead>
<tbody>
<tr>
<td>How did they first hear about the study? What were their initial perceptions of it?</td>
<td>How were they recruited? What sign up process did they go through? What information did they receive and what did they think of this?</td>
<td>What is their understanding of the aims, purpose, and benefits of the study? How did they find out about these?</td>
<td>Why did you want to take part in the study? Why did they want to take part in the imaging study specifically?</td>
</tr>
</tbody>
</table>
## 3.1 Perceptions of scanning

<table>
<thead>
<tr>
<th>3.2 Sign up process for scanning</th>
<th>3.3a Expectations around feedback procedures</th>
<th>3.3b Expectations around feedback procedures</th>
<th>3.3c Expectations around feedback procedures</th>
<th>3.4 Concerns</th>
<th>3.5 Scanning experience</th>
</tr>
</thead>
<tbody>
<tr>
<td>How did they first hear about the scanning aspect? What were their initial perceptions of it?</td>
<td>How were they invited? What sign up process did they go through? What information did they receive and what did they think of this?</td>
<td>Based on the information they had when they signed up, what did they expect from taking part in the study?</td>
<td>What was their understanding of the incidental findings procedure?</td>
<td>did they have any concerns about incidental findings or the procedure beforehand?</td>
<td>What was their experience of the scanning process at the Biobank centre? Did they have any concerns? Would they like to see any improvements to the process on the day? [only record if any problems arose or interesting improvement suggestions]</td>
</tr>
</tbody>
</table>

## 4.1a Receiving the letter

<table>
<thead>
<tr>
<th>4.1b Receiving the letter</th>
<th>4.2 Understanding the letter</th>
<th>4.3a Next steps - dr’s visit</th>
<th>4.3b Next steps - dr’s visit</th>
<th>4.4 Further steps</th>
<th>4.5 Outstanding action</th>
<th>4.6 Seeking information</th>
</tr>
</thead>
<tbody>
<tr>
<td>How long after the scan did they receive the letter? What did the letter say?</td>
<td>What did they think about the letter, tone, and level of detail? How did they feel when they received it?</td>
<td>What did they do next? How did they find the visit to the GP? How did the GP respond? (i.e. what was the problem/finding)</td>
<td>How did they feel about the fact their GP had more/different information to them?</td>
<td>Was any further action required? (scans, tests or treatment?) How did they feel about this?</td>
<td>What stage are you at now and is any further action required?</td>
<td>Did you seek any further information at any point? From which sources? (e.g. the internet, friend or relatives) How did this make them feel?</td>
</tr>
</tbody>
</table>

UK Biobank Imaging Pilot Study – Qualitative findings – TNS BMRB 2015
### 5.1 Impact on family
Who did they speak to and when? Has this had any impact on friends or family members?

### 5.2 awareness of outcomes
Were they aware of the 4 different potential outcomes from having an incidental finding? (artefact, non serious, uncertain, serious finding). Which category do they fall into? Would it have been helpful to know about these? Why?

### 5.3 Reflections
How do they feel now about having been notified about their incidental finding?

### 6.1 Improvements
What improvements do they think could have been made to the feedback process?

### 6.2 Desired information
Thinking back to when they signed up, what kind of information would they like to have had about incidental findings? What needs to be included in the consent forms?

### 6.3 Future
Has this changed their perception of Biobank and the study? Has it affected their willingness to take part in the future?

### 6.4 Other
## Appendix M: Stakeholder interview analysis framework

<table>
<thead>
<tr>
<th>1.1 Current role</th>
<th>1.2 Tasks</th>
<th>1.3 Job history</th>
<th>1.4 Key differences</th>
<th>1.5 Perceptions of Biobank</th>
</tr>
</thead>
<tbody>
<tr>
<td>Respondent's current role with Biobank; length in post</td>
<td>Key tasks and responsibilities; a typical day or week</td>
<td>Respondent's previous job history (any clinical or academic roles?)</td>
<td>What are the key differences between their current role and previous roles? (clinical / university roles versus this research project)</td>
<td>How did they hear about / become involved with the study? What were their initial impressions of the study? Have these changed / what are they now? Why did they get involved?</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.1 Motivations, risks/benefits</th>
<th>2.2 Feedback process</th>
<th>2.3 Views on the process</th>
<th>2.4 Harms and benefits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Why do they think volunteers take part in the study? What are the perceived benefits? Are there any risks for participants?</td>
<td>What do you think participants assume they will be told? How do they feel about not receiving any results? Where do they get information about the study from?</td>
<td>Their spontaneous views on the process. Does the process adequately inform participants?</td>
<td>What are the key potential harms and benefits of receiving feedback? Does it meet their expectations?</td>
</tr>
</tbody>
</table>
### 3.1 Identifying an abnormality
- What is the process for identifying an abnormality and informing the respondent? What is your role in this?

### 3.2 Easy/ difficult
- How easy/difficult is it to identify a potential abnormality? Are there any issues around this?

### 3.3 Working well
- What is working well in the process?

### 3.4 Working less well
- Are there any aspects of the process which are working less well? Are there any issues or concerns for you?

### 3.5 Serious
- How is serious defined and operationalised? Is there a formal process or is this left to your discretion?

### 4.1 Improvements/changes
- Are there any changes/improvements they would like to see to the current consent and incidental findings process?

### 4.2 Ideal process
- What would be the ideal process they would like to see in place?

### 4.3 Improvements
- Are there any changes/improvements they would like to see to the process for identifying abnormalities?

### 4.4 Ideal process
- What would be the ideal process they would like to see in place to identify abnormalities?

### 4.5 Other
## Appendix N: Follow-up participant telephone interview analysis framework (wave two)

<table>
<thead>
<tr>
<th>1.1 Age</th>
<th>1.2 Understanding of UK Biobank</th>
<th>1.3 Motivations for signing up</th>
<th>1.4 Expectations and experiences</th>
<th>1.5 Overall reflections</th>
</tr>
</thead>
<tbody>
<tr>
<td>What did the respondent understand about UK Biobank when they signed up to the imaging study. Note any gaps in understanding at this point</td>
<td>What made the respondent want to take part in the imaging study and if they took anything into consideration in doing so</td>
<td>How did their expectations meet with their experiences overall?</td>
<td>What has been the impact on them and their family and what lasting reflections do they have</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>2.1 Perceptions of Biobank</th>
<th>2.2 Perceptions of procedures</th>
<th>2.3 Motivations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any changes in views or understanding of UK Biobank since last interview and what has prompted this</td>
<td>Have perceptions or understanding of feedback procedures changed over time</td>
<td>Has their motivation to take part changed in any way, any regrets about it or any reflections on what has changed in relation to this</td>
</tr>
</tbody>
</table>
### 3.1 Recap of activity before first visit

<table>
<thead>
<tr>
<th>What had happened by the first interview visit, where were they up to and what were they waiting for</th>
</tr>
</thead>
</table>

### 3.1a Current stage

<table>
<thead>
<tr>
<th>What has happened since and where are they up to now? Anythig still outstanding or any diagnoses etc made</th>
</tr>
</thead>
</table>

### 3.1b Feelings/perceptions of follow up

<table>
<thead>
<tr>
<th>How they have felt about the activity that's happened at each stage and how this has changed over time from getting letter to now</th>
</tr>
</thead>
</table>

### 3.2 Personal impact

| Any indirect consequences of getting feedback eg finding out about other unrelated health issues, changes to lifestyle, attitudes etc |
| How family/ friends have reacted, impact on them |

### 3.2a Impact on family

### 3.3 Response to potential outcomes

| Knowledge and perceptions of potential outcomes at different stages. What would the value of knowing these beforehand? Impact of knowing them now (particularly where non-serious issue has caused stress) |

### 4.1 Overview

<table>
<thead>
<tr>
<th>Overall perception of UK Biobank's processes</th>
</tr>
</thead>
</table>

### 4.2 Improvements pre-scanning

<table>
<thead>
<tr>
<th>Any improvements necessary to UK Biobank's processes before the scanning</th>
</tr>
</thead>
</table>

### 4.3 Improvements post-scanning

<table>
<thead>
<tr>
<th>Any improvements to consent process, level of information provided at this stage etc</th>
</tr>
</thead>
</table>

### 4.4 Views on consent

<table>
<thead>
<tr>
<th>Any improvements to the experience and/ or processes</th>
</tr>
</thead>
</table>

### 4.5 Missing information

<table>
<thead>
<tr>
<th>Summarise any key information missing and what stage it should be shared</th>
</tr>
</thead>
</table>

### 4.6 Further reflections

<table>
<thead>
<tr>
<th>Any other comments around improvements to the experience and/ or processes</th>
</tr>
</thead>
</table>

### 4.7 Interviewer observations

<table>
<thead>
<tr>
<th>Anything to add from own personal observation during interviews, any issues that are really there lying underneath the surface etc</th>
</tr>
</thead>
</table>