

Feedback of Incidental Findings during the Imaging Pilot Study

By

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Introduction

- The purpose of the imaging pilot is to demonstrate feasibility for the main phase – this specifically includes assessing the feasibility of the Incidental Findings Protocol (IFP)
- Incidental Findings are “findings observed during the imaging assessment visit which are incidental to its purposes”

UK Biobank's existing feedback policy

- Three separate forms of feedback (from the original assessment visit)
 - Routine reporting of selected measures (that would have been impractical to conceal)
 - Feedback of potentially serious incidental findings detected during the assessment visit
 - No reporting of findings from subsequent research
- Rationale for a more detailed protocol for imaging is due to the potential significance and frequency of the incidental findings arising from imaging

Development of imaging incidental findings protocol (ICF)

- Reviewed the existing literature and visited the main population-based imaging research projects (MESA, Icelandic Heart Study and SHIP/GNR)
- Extensive dialogue with leading clinicians, the RCR, expert ethicists, our funders and UK Biobank's EGC
- Legal advice from leading clinical negligence counsel

Strategic factors behind the IFP

- Best practice, taking into account
 - Nature of the research project
 - Imaging protocols
 - Context of the participant visit
 - Information provided to participants
- Likely nature of the serious incidental findings themselves
- Interests of the participant, balancing the potential benefits and the potential harm from the feedback of incidental findings

Contextual factors behind the IFP

- Participants attend in a non clinical setting with no specific research hypothesis
- Consent form and information materials very explicit (about the IFP)
- Images are taken for research purposes (not diagnostic)
- Generation of serious incidental findings is partly dependent on the area of the body being scanned
- Public expectations about imaging often (significantly) exceed the diagnostic ability of the scans
- Feedback will not necessarily result in a positive outcome for the participant
- Assess the impact on the wider healthcare system

The IFP in full

“During the process, radiographers may notice incidental findings, some of which could be potentially serious (i.e. those that indicate the possibility of conditions which, if confirmed, carry a real prospect of significantly threatening life span, or of having a substantial impact on major body functions or quality of life). If such findings are confirmed to be potentially serious by the imaging centre radiographer, the scans from the imaging modality concerned will be flagged for reporting by a consultant radiologist or other appropriate specialist. If the reporting radiologist/specialist confirms a potentially serious finding then UK Biobank will inform both the participant and their GP.”

Evaluation of the IFP

- Evaluation of participant's understanding of their consent to the imaging assessment
- Evaluation of the impact of the feedback of serious incidental findings
- Evaluation of the process of detecting serious incidental findings

For the first 1,000 participants

- Discreet study to compare the frequency of serious incidental findings that have been flagged by radiographers and referred for reporting by a radiologist, as against
- A formal review of all images by radiologists or other specialists

What we have found to date

- Approx. 3,000 participants have been invited and over 1,000 have accepted
- 200 participants have been scanned
- 170 of these scans have been reviewed by the radiologists
- Radiologist review: 30 potentially serious incidental findings (0 Head, 16 Heart, 17 Abdomen)
- Radiographer review: 26 have been referred by the radiographers, of which 5 have been considered as potentially serious incidental findings by the radiologists

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