IBD BioResource genetic feedback

a conversation between participants and researchers

Workshop report

December 2023

contents

1 Executive summary

Research into the genetics of common, complex conditions generates findings that are both pertinent to the subject of the study and those related to a range of other genetic conditions.

On November 20th 2023, 15 NIHR IBD BioResource participants, 6 gastroenterologists and 3 genetics researchers joined members of the Wellcome Connecting Science Engagement and Society team at the Wellcome Genome Campus in Cambridgeshire. The purpose of the workshop was to inform a helpful and reassuring process for how the NIHR IBD BioResource shares genetic feedback related to additional findings with the study participants who have opted in to receive it, and to provide learnings for the wider field of genomic research into common, complex conditions.

Additional findings are not those directly related to IBD, but to a range of other specific, rare, and treatable genetic conditions that could be identified in the course of genome sequencing. These conditions are drawn from the Genomics England 100,000 Genomes project list of additional findings and include bowel, breast and ovarian cancer pre-disposition as a result of single gene mutations and familial hypercholesterolaemia.

The one day workshop[1] involved a mix of presentations, Q&As and facilitated small group discussions and activities. **Wellcome Connecting Science** worked with the **Sanger Institute Human Genetics team** and the **NIHR IBD BioResource** to commission **Hopkins Van Mil** to design facilitate and report on the workshop.

Participants hopes for receiving additional feedback as part of the IBD BioResource programme were that:

- The process starts with re-consent for receiving additional findings because participants may well have forgotten that they had signed up to receive them;
- It increases personal health knowledge, in a tailored way;
- The feedback sharing process is managed by a central resource;
- There is a clear timeline for the feedback process;
- Additional genetic conditions could be included in future feedback from the IBD BioResource and that more broadly, genomic health screening becomes mainstream in the NHS.

[1] See appendix for **agenda** and facilitator **process plan**.

Participants concerns about receiving additional feedback included:

- Health system capacity and connections: can NHS services cope with the numbers of people receiving information about a genetic risk? Is the IBD BioResource planning to share feedback in partnership with the NHS? Will support be available when results are shared?

- How feedback information will be shared: will risk of a genetic condition be communicated clearly and without causing alarm, how will false positives be dealt with and what if someone has already been diagnosed with the condition on which they have just received feedback?

- Consequences of receiving feedback: how receiving genetic information would affect health insurance for them or family members, potential impact on people's mortgages or employment, would feedback go on medical records?

- Data: how secure is it, who has access?

Discussions at the workshop generated the following important considerations for the design of the additional findings feedback process:

1. **Updates on the condition of concern: IBD**

   Returning additional genetic feedback to IBD BioResource participants should go hand in hand with providing an update on the status of the IBD BioResource programme and its findings. Helping to prevent, treat and cure inflammatory bowel disease are the main motivations for joining the study.

2. **Managing expectations for what genetic feedback is available**

   Some workshop participants had the attitude of 'tell me all, even if not treatable, so I can keep any eye on things'. There needs to be clarity on the limited number of genes being screened for and why these genes were chosen.

3. **Where can the process be tailored to individual circumstances?**

   Participants are hopeful that choice will be designed into the feedback process. For example, choosing to receive feedback, but at a later date; choosing to only receive feedback on some genes/conditions and not others.

4. **Be mindful of the interest in bowel cancer as part of the 13 genes**

   The additional genetic findings will include conditions that are of particular interest to people with IBD, especially bowel cancer. Particular care will be needed on how this is communicated to a patient population some of whom may have had parts of their colon removed or have been told there is a link between their specific type of IBD and bowel cancer.

5. **Use a range of tools to make the information accessible**

   Feedback that promotes comprehension through providing contextual information on the conditions, visual aids to explain risk and supporting materials to educate people on uncertainty. Include risk 'benchmarks' so that results are comparable with the general and IBD populations.

6. **A process that doesn't leave participants waiting anxiously for results and follow up**

   Participants expect each stage to be conducted within weeks of each other rather than stretched over several anxiety-inducing months, with support in between provided through website FAQs and a helpline.

7. **Information received from the most appropriate sources**

   The IBD BioResource is seen to be the most appropriate information provider for re-consent and no additional findings. For contact on the need for a confirmatory blood sample the NHS – acknowledging the link to the IBD BioResource – is most appropriate as this carries trust and provides the bridge between research and clinical findings. For the return of genetic results for a variant, the NHS speciality should be the lead communicator.

8. **A clear appetite for more involvement with the IBD BioResource in the future**

   During the workshop conversations IBD BioResource participants demonstrated an appetite for more involvement in its work and also in deciding what is researched in the future.

2 Foreword

Genomics has huge potential to improve our understanding of many common diseases such as inflammatory bowel disease (IBD) and, ultimately, our ability to improve the ways they can be diagnosed and treated – or possibly even predicted and prevented. Research into these conditions also raises complex questions about how we collect, share and use genomic information. Wellcome Connecting Science conduct empirical research and enable public dialogue on the social and ethical questions associated with genomics and genomics research. In this project, Wellcome Connecting Science worked with the National Institute for Health and Care Research (NIHR), IBD BioResource and the Human Genetics team at the Wellcome Sanger Institute to enable a dialogue between research participants and researchers and particularly to address the question of what to do with 'additional' findings generated in the course of genomics research.

The IBD BioResource is a national platform that aims to recruit 50,000 patients with Crohn's disease or ulcerative colitis to expedite research into these conditions and help develop new and better therapies. In collaboration with researchers at the Wellcome Sanger Institute, it is exploring the genetic factors that predispose people to developing IBD. In the process however, it is generating information which relates not only to IBD, but also to a range of other 'additional' conditions that may be identified while analysing whole genomes or exomes.

It is essential to understand how to return additional genetic findings in a way that is supportive and helpful to participants, and considerate of the context in which research is conducted. Programmes such as Genomics England's 100,000 Genomes Project have begun to develop and test processes for doing this. They have proposed a list of 14 genes within which 'mutations' (which are abnormalities of the genetic sequence) powerfully predispose to corresponding medically treatable or preventable conditions such as high cholesterol levels and rare forms of bowel or breast cancer. This list provides a starting point for additional findings for which there is a strong case for feeding back results to research participants. Amid the expansion of genomics research, however, it is essential that the research community continue to build on the work of the 100,000 Genomes Project and develop approaches to the return of additional findings that acknowledge the specific contexts in which the research was done and specific concerns of the research participants. Dialogues such as the one reported here are a central part of this, ensuring that the future of genomics research and its interface with clinical care reflects the interests and values of all those involved.

We would like to thank all the BioResource participants, clinicians, researchers and expert speakers who took time to join the workshop and share their experience and expertise.

3 Workshop aims and approach

Workshop purpose and objectives

The purpose of this workshop with Inflammatory Bowel Disease (IBD) BioResource participants, clinicians and researchers is to inform how the NIHR IBD BioResource shares genetic feedback related to additional findings with the participants who have opted in to receive it. These findings are not those directly related to IBD, but to a range of other specific, rare, and treatable genetic conditions that could be identified in the course of genome sequencing.

The focus is on creating a helpful and reassuring process for feedback on whether participants are at an increased risk of most of the specific rare, treatable genetic conditions included in the Genomics England 100,000 Genomes[2] project list of additional findings[3]. These conditions are:

- Lynch syndrome (linked to an increased risk of bowel, womb and ovarian and other cancers)
- Bowel cancer pre-disposition as a result of single gene mutations
- Breast and ovarian cancer predisposition as a result of single gene mutations
- Other rare cancer predispositions
- Familial hypercholesterolaemia

The workshop objectives were to:

- Involve IBD BioResource participants, clinicians and researchers in a genuine exchange where they learn about each other's hopes, concerns and interests about feedback from genetic tests for wider health conditions.
- Ensure all event participants have a shared understanding of the background and purpose of BioResource and learnings from other relevant genetic studies to inform their discussions on how best to feedback results of genetic tests for wider health conditions.
- Create a space for BioResource participants, clinicians and researchers to discuss the genetic data generated from participants and what happens to it.
- Ensure the outputs of the event reflect the values and interests of all participants.
- Inform further work between Bioresource and the IBD patients/community.
- Understand the points to consider for large-scale bioresources considering the return of additional findings.
- To share learnings with other research programmes who are considering sharing additional genetic findings with study participants.

[2] **www.genomicsengland.co.uk/initiatives/100000-genomes-project/additional-findings**

[3] The 100K project also included carriers of Cystic Fibrosis, however BioResource does not plan to include this in feedback because BioResource participants opted in to find out if they are at 'increased risk of rare genetic disease'. Being a CF carrier is relevant to family planning.

Workshop participants and format

On November 20th 2023, 15 IBD BioResource participants, six gastroenterologists and three genetics researchers gathered at the Wellcome Genome Campus in Cambridgeshire for the one day workshop.

In the weeks leading up to the workshop, invitations to express interest in taking part were sent by the IBD BioResource Research Co-ordinators to BioResource participants who had opted in to receive additional feedback. Workshop participants were chosen to achieve a cross section of people with IBD, with a range of age, gender, ethnicity, type of IBD (Ulcerative Colitis and Crohn's) and location. Clinicians and scientist participants were recruited through the network of collaborators of the IBD BioResource and its associated clinical network. Several observers from IBD BioResource, Wellcome Connecting Science and the Our Future Health programme were also present to listen in on the conversations.

The social research agency Hopkins Van Mil was commissioned to design, facilitate and report on the workshop.

The 24 participants formed four small mixed groups, each with a Hopkins Van Mil facilitator. The workshop involved a mix of plenary presentations, Q&As, small group discussions and micro-group tasks[4].

9:30	Arrival and refreshments
10:00	Welcome and introductions
10:20	Small group discussion 1: • Introductions : your connection to the IBD BioResource • Expectations for the day
10:40	Presentations on • Genetics in the IBD BioResource • BioResource feedback of additional findings • Genomic Medicine Service
11:00	Small group discussion 2: • Questions for the presenters
11:15	Break
11:30	Question and answer session

11:45	Small group discussion 3: • Your experiences of receiving and delivering health and research information/results
12:45	Lunch
13:30	Presentations on • Learnings from the 100K Genomes Project • Q&A
14:00	Small group discussion 4: • What matters when developing guidance for how genetic feedback is shared?
14:55	Break
15:10	Reflections on the day and next steps
15:30	Thank you and goodbye

[4] See appendix for the full workshop **process plan**.

The day started with welcomes from the IBD BioResource Chief Investigator Miles Parkes and Wellcome Connecting Science's Head of Research and Dialogue, Richard Milne.

In the first small group discussions participants introduced themselves and their connection to the IBD BioResource and shared their expectations for the day.

The four groups came back together to hear three short presentations from specialists in the fields of IBD, genetic medicine and genetic feedback.

- **A reminder of the purpose of the IBD BioResource and the genetic feedback element**
  Carl Anderson, Head of Human Genetics and Senior Group Leader Wellcome Sanger Institute, Co-PI of IBD BioResource

- **IBD BioResource's current thinking on the feedback of additional genetic findings**
  Hannah Knight, Clinical Feedback Lead, NIHR BioResource

- **An introduction to the NHS Genomic Medicine Service**
  Dr Sarah Bowdin, Consultant in Clinical Genetics, East Anglian Medical Genetics Service National Specialty Advisor for Genomics, Genomics Programme, NHSE

This was followed by discussions in small groups to generate questions for a subsequent question and answer session.

Following the Q&A, participants returned to their small groups to talk about their experiences of receiving and delivering health and research information and results.

After lunch, participants heard two presentations that shared learnings from Genomics England's 100K Genomes Project:

- **Setting up the return of additional findings**
  Ana Juett, Programme Manager SW Genomic Medicine Service Alliance

- **A study of participant experiences in the 100,000 Genomes Project**
  Melissa Hill, Senior Social Scientist and Research Genetic Counsellor. North Thames Genomic Laboratory Hub

Most of the afternoon was spent in groups of twos or threes made up of either patients or clinician/researchers. Each used a feedback template to guide their conversations and capture their thoughts on what matters most when developing guidance for sharing genetic feedback. Highlights from these conversations were then shared when the four small groups re-formed.

The workshop ended with Miles Parkes sharing reflections on what he and the IBD BioResource team had heard and how the findings would shape the design and roll out of feedback in the coming months.

About the report

This report was written by Hopkins Van Mil drawing on the flipchart notes captured by facilitators, the templates on guidance for feedback completed by workshop participants and on AI transcriptions of the workshop recordings.

In this report the term ‘pertinent findings’ refers to findings related to IBD. The term ‘additional findings’ refers to findings that are not directly related to IBD, but to a range of other specific, rare, and treatable genetic conditions identified in the course of genome sequencing.

4 Workshop findings

The report begins by looking at the context of inflammatory bowel disease and participants' experiences of diagnosis and treatment. For many, this is their predominant health condition and additional genetic findings – if any – will be received as an additional risk factor to cope with.

The following section reports on participants' previous experiences of receiving health information and test results. The report then turns its attention to the delivery of additional genetic results: the hopes and fears for this process and suggestions for how the communication process should work: the information to be shared, by who and how.

Participant experiences

People with IBD signed up to the IBD BioResource research study with the hope of helping to progress research into the causes and treatment of inflammatory bowel disease.

The return of additional genetic findings (not specific to IBD) to this group of people will need to take into account their IBD, their health status and related hopes and concerns. This first section of the report looks at the experiences IBD participants shared about living with the condition and how this needs to be borne in mind when designing the additional feedback process.

IBD: the experience of a diagnostic odyssey

During the course of the workshop, BioResource participants shared their experiences of being diagnosed and living with IBD. Some spoke about the diagnostic odyssey they had experienced until they received a confirmed diagnosis of Ulcerative Colitis (UC) or Crohn's. The moment of diagnosis, as described by some participants, was quite distressing. Participants spoke of being told they had an incurable condition and then finding the prescribed treatment had uncomfortable side effects.

> *I found the clinicians to be very cold, they basically said, 'You've got this, there's no cure.' When I told them about the nausea the meds were giving me, they just said, 'You have to ride it out.' I've just been trying to survive ever since.*

Positive experience of IBD research study participation and support by specialist nurses, but lack of information about the research landscape

Some participants spoke positively about being involved in IBD research studies for new treatments. They said they experienced attentive care during these studies, but when they ended, they felt less supported by their standard NHS care.

> *When I was in the research study, I would email a Dr and get a reply within 24hrs. Back in the NHS I sometimes need to go to A&E to get help.*

Some participants particularly praised the IBD nurses in their clinics for being an excellent source of information. However, others spoke about feeling on their own with their condition and feeling in the dark about any new research – genetic or otherwise – or new developments in IBD care.

> *I'm not sure why there isn't more information on preventative messages, or information on diet.*

> *No information is given on research or new developments, that's why you turn to Google and Facebook groups, but you don't know how trustworthy that information is.*

Importance of an update on IBD research progress from the BioResource, alongside additional genetic findings

When considering how to communicate additional feedback to this cohort of BioResource participants, it is important to recognise the strong appetite for an update on the IBD BioResource's progress in understanding which genes are linked to IBD. There is also high interest in whether there are any genetic connections between IBD and other health conditions.

Workshop participants recognised that the additional findings are just that - 'additional' to IBD - but they see the return of these results as a relevant opportunity to share feedback on the research programme as a whole.

> *Where are the IBD BioResource with 'cracking the egg' – finding the link between Crohn's, UC and genetic risk?*

High interest in bowel cancer and cholesterol risk

One area of heightened interest for the participants is for results on genetic risk for bowel cancer. They want to see this area of genetic feedback handled with particular care, regardless of a higher or lower risk result. Participants pointed out that some IBD BioResource participants may have had part of their colon removed. Careful consideration needs to be given to how these people might react to being told they are at risk of bowel cancer.

> *IBD surgery may mean people have had their colon removed. It's important to personalise information. Does that mean they're not at any risk? People may disregard an 'increased risk' finding if it isn't explained properly.*

> *I'd like to know anything they can tell us on the risk of bowel cancer as associated with IBD and the genetic risk of the Big C more generally.*

JAK[5] Inhibitors are an oral treatment for Crohn's and UC, which some research studies have found have the effect of increasing levels of cholesterol in some patients. Some participants thought this would be relevant if a genetic risk of familiar hypercholesterolaemia was returned.

Throughout the workshop discussions, participants spoke about how the return of additional feedback should be mindful that people with IBD are highly aware of possible links to other illnesses.

> *Because it's not out of the blue, just tell us how it is -don't beat around the bush. Honesty!*

To help set the scene for discussions on returning additional feedback, we asked workshop participants to share their experiences of receiving information from health tests and research.

Poorly planned communication: medication and treatment notifications coming out of the blue before formal diagnosis

Negative experiences of receiving information and results were often caused by poorly planned and delivered communication. Some participants spoke about being distressed by receiving notifications of their medications and treatment out of the blue, before their diagnosis of IBD had been confirmed.

> *I got this text message, 'your steroids are ready to collect' and a second one about surgery. I didn't know I needed steroids or surgery, I hadn't been told by a person or anyone that I needed these. Then I got letters from the clinic a couple of weeks later confirming my diagnosis and that I would need surgery. It was a bit shocking.*

[5] Janus kinase inhibitors.

Other participants said that they did not receive results from routine tests. They had found this alarming at first but had become used to this; no results meant no change or action needed.

Having to repeat the results of tests to multiple clinicians is a strong frustration and a sign for participants that hospital departments are not connected to each other.

> *You have to explain over and over again about your situation.*

After receiving a diagnosis, some participants said they didn't feel fully informed about their condition, their treatment regime, what support is available or what research is taking place. For example, one participant said that they hadn't realised that they were supposed to take their medication regularly rather than in response to symptoms.

Mixed views on the increasing use of digital channels and apps to share test results: quick and effective vs lacking human touch

The increasing use of digital channels to return results, such as Addenbrooke Hospital's MyChart and University College Hospital London's MyChart patient portals, was welcomed by several participants. They like how quickly results are shared and how they use plain English descriptions.

> *I get my results within four hours, sometimes even before I'm back home from hospital.*

But other participants feel the human touch is lacking with the use of online mechanisms to provide feedback.

Catering for different attitudes to risk: tell me everything vs only what's necessary and actionable now

During the discussions, participants reflected on the difference between receiving information on a definitive diagnosis or test result versus receiving information on the risk of a condition. They feel that how individuals deal with risk feedback was important to factor into the process design. Risk can cause anxiety and uncertainty for some, while others see any additional information about their health as empowering and adds to their ability to be vigilant and proactive about their health.

During this discussion, the tables were turned and clinician and researcher participants were also asked to share their experiences of delivering feedback and results from research and health tests to patients and study participants.

Importance of an empathetic approach tailored to different preferences

Clinicians spoke about sharing day-to-day care results which could be good or bad news. They said the way they shared results was guided by how they would want to be treated in the same situation. They also said that they took into account how different patients have different information needs.

> *It depends on the patient, some want to know everything relevant about their situation, others don't want that.*

A constant factor in communicating results was being clear about what the treatment pathway is, the options and their pros and cons.

Lack of time and training for providing feedback

Some clinicians spoke about the pressures on clinics and not having the time needed to share results of diagnosis or other test results in a tailored way to the patient. Clinicians also said that they hadn't received enough training in how to deliver feedback. Some clinicians spoke about how it was important to be humble about how much knowledge on the condition of IBD that they actually had – that so much is still unknown.

Approaches to additional feedback

The presentations in the morning of the workshop gave participants the following information on genetics and the IBD BioResource's plans for additional feedback:

- What a genome is and how it is sequenced
- What additional findings are
- The 13 genes included in the feedback
- A draft process for sharing additional feedback (Fig. 1)
- The structure and services offered by the NHS Genomic Medicine Service

With this information in mind, participants discussed their hopes and concerns about receiving additional feedback.

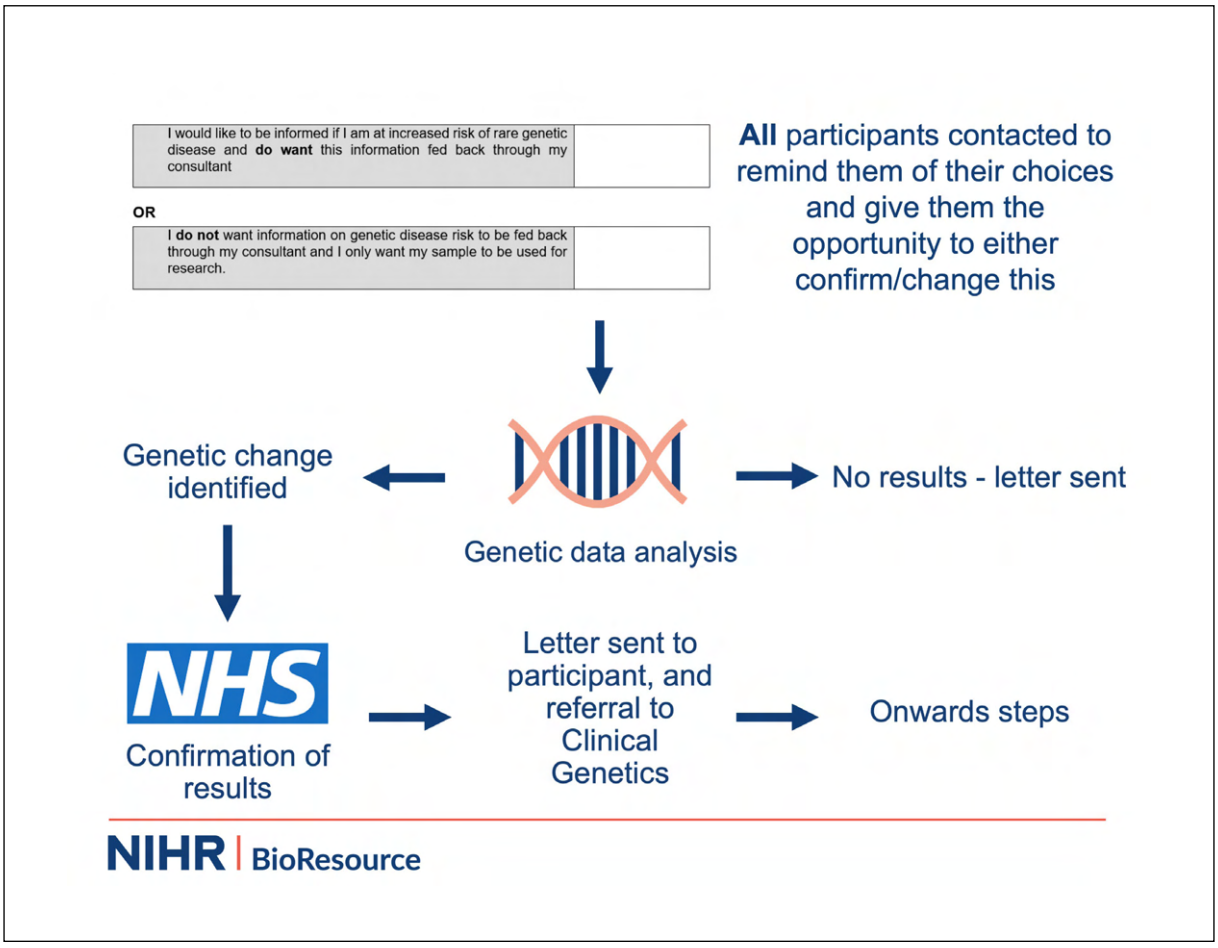

Figure 1. Presentation slide with a draft process for sharing additional feedback. Credit: Hannah Knight, NIHR BioResource.

Hopes for receiving additional feedback as part of the IBD BioResource programme

Hopes for receiving additional feedback touched on individual health benefits, the clarity of communication, the consistency of the process, the opportunity to learn more about research into IBD and that this is not just a one off piece of genetic feedback.

That re-consent is requested

- Participants agree that re-consent will be vital to the additional feedback communication process. Many couldn't remember if they had consented or not, or indeed that they had signed up to the IBD BioResource, with some taking part in several research studies.

An opportunity to receive information on the wider IBD BioResource research programme and what this means for its participants

- Participants would like information that reminds them of the goals of the IBD BioResource, progress made and future direction of IBD BioResource to be included in communication about additional findings, for example when re-consent is requested.

> *What about new discoveries? Do people within the IBD BioResource have front row seats to find out more about these – for example more information, new treatments?*

Increase personal health knowledge, in a tailored way

- Some participants welcomed the opportunity to receive additional genetic feedback and wanted as much information as possible to help inform decisions about their health, 'a full read out' of your genetic data, while recognising that some people would want more limited information that was immediately relevant and actionable.

That the feedback sharing process is managed by a central resource

- The preferred model for several participants is a central resource which talks to the patient and gets confirmatory testing. Only once this is done is the information sent on to the regional resource. There is the concern that if the feedback is all handled locally it won't be a priority.

> *I think there is a place for centrally managed feedback. Don't rely on local services which may not be reliable.*

For a clear timeline for the feedback process

- The prospect of receiving health information can be a cause of anxiety for some people. Workshop participants hope that the timeline for when feedback will be shared will be clear and detailed about each stage. For example if you have been asked to provide a blood sample of a confirmatory test, when will be result be available?

For additional conditions to be included in the future

- As knowledge about human genetics increases, some participants hope that a wider range of conditions could be included in future additional feedback.

For genomic screening to become mainstream

- Receiving information about genetic risk for conditions is seen as an important privilege by some participants. They hope that this is something that is available across the population in the future.

> *I'd like to see a future where everyone gets access to this screening information, not just those who are signed up to a BioResource.*

Concerns for receiving additional feedback as part of the IBD BioResource programme

The most frequently voiced concern about sharing additional genetic feedback was about the NHS' capacity to cope with the numbers of people who will be referred after they have received feedback for a higher genetic risk for heart disease or cancer.

Other concerns include not being able to understand the level of risk and its implications, that there won't be a clear pathway to NHS care, that results will affect health insurance and mortgage applications and how to personalise feedback to people's circumstances.

Health system capacity and connections

- All of the small groups raised questions about how NHS services can cope with the numbers of people receiving information about a genetic risk for serious health conditions such as heart disease and cancers.

- Participants want reassurance that IBD BioResource is planning to share feedback in partnership with the NHS and that support will be available when results are shared.

  Does the NHS have capacity to see people who may be at risk of 'additional' conditions and how long will it take to be seen?

  How well docked into the NHS is all this? Given how stretched the NHS is and regional differences in provision e.g. of genetic counselling?

- NHS Genetics facilities: Are they consistent across the country? Some participants were concerned about how follow up care after receiving feedback for genetic risk will differ by area, will people in some areas be better served than others?

- Concerns went beyond capacity to include questions about how well linked IBD BioResource is to the NHS. Is there a risk that patients can't follow a path to care?

Recontact: Confirmatory testing and being lost in the system?

- Participants highlighted the stage of the confirmatory NHS blood test if a genetic change is identified from the IBD BioResource sample as needing particular care when designing the feedback process. They flagged that the individual would need reassurance. Clinicians asked how they should manage patients' potential desire for additional tests (e.g. screening) while waiting for the results of the retest?

  Is there a budget for this? Who does the follow up? What if it is outside current guidance?

- Participants want to know how the additional findings feedback process would account for people whose contact details had changed e.g. change of home or email address.

- In a similar vein, there is a desire to know what IBD BioResource will do with people who don't reply to the communication checking for consent to receive additional findings.

Delivering feedback: communicating risk, dealing with false positives and late feedback

- All workshop participants, clinicians, people with IBD and researchers are concerned about how genetic risk will be communicated.

  It is important to be clear before having these conversations that we know what we can and can't say definitively about the results. We have to be clear and translate what the results mean, including what is uncertain/not sure.

- Some warned against taking a 'ticks and crosses' approach to sharing results that could imply that a genetic finding means you will definitely get cancer, for example. They feel this approach does not take into account the fact that these genes are not 100% predictive.

- A few participants asked how the feedback process could avoid or deal with the delivery of false positive genetic feedback.

- In some of the small groups, participants raised concerns about feedback coming too late for people to act on, particularly information relating to cancer risk. They thought it was important to factor in this kind of scenario when planning how to return higher genetic risk results.

> *What do we do about patients who have been diagnosed, but who could have been given feedback earlier? How will that be handled? For example, you've already got stage 4 breast cancer and then you get feedback from the BioResource that you have the BRCA gene? That could result in some anger from the patient.*

Consequences of receiving feedback

- All the small groups thought it would be important to address questions and concerns people might have about how receiving genetic information would affect health insurance they or family members have. These concerns were also shared for their potential impact on people's mortgages or employment. Would feedback go on medical records?

- Participants thought it would be important to allay people's concerns about being given genetic information that they can't do anything with. They thought it was important to emphasise that all the conditions have care pathways.

Data: how secure is it, who has access?

- Participants thought it would be important to address concerns people may have about how their genetic data is handled, how secure it is and who has access to it. Some wanted assurance that another party wouldn't know more about your health than you did.

> *I want to know as much as YOU know (researcher clinician). I'm best placed to know what information will be useful*

Guidance on communication

To help ensure that the feedback of additional findings takes place in a way that is reassuring and clear to IBD BioResource participants, workshop participants discussed four main points of communication:

1. **Checking consent for receiving feedback**
2. **Organising the confirmatory blood sample for those with genetic changes identified**
3. **Returning results to those with no genetic changes identified**
4. **Returning results to those with genetic changes identified**

The suggestions for information to include at each point, from who and through what format are drawn from the afternoon paired group work and the subsequent small group discussions. These discussions were prompted by templates that asked participants to write down what information, what format and from what source feels relevant, appropriate and reassuring.

1. Checking consent for receiving feedback

From who: **IBD BioResource**

As the programme that has committed to deliver additional findings, all participants believe that IBD BioResource is the most suitable source for this communication about re-consenting for additional feedback.

Format: **In writing: letter or email**

Given the amount of information to convey, the request for consent and the number of people being contacted, a letter or email is seen as most suitable. Given the quantity of information and to avoid sending something with several pages, some information, such as the IBD BioResource update, could be provided as links. Some participants said a copy of this letter should be sent to the IBD clinician and Principal Investigator.

Content: **More than a consent check**

This first step in the process of sharing potential additional findings is essential. Participants thought it should be more than just a short and simple ‘consent’ check. It should also be a reminder of the IBD BioResource programme and its progress to date. It should also be clear

on which conditions are covered in the feedback, that it is about 'risk' rather than 'diagnosis' and that all the conditions are treatable by the NHS. Finally it should also include information on what happens to the information if genetic changes are identified: including if it is put on NHS medical records, shared with your GP and impact on family members, private health insurance, mortgage applications and employment.

Reminder about the IBD BioResource and what it is

- Several participants said that the invitation to take part in this workshop came out of the blue for them as they had forgotten that they had signed up to be involved in the IBD BioResource, so a reminder is important.

- A clear, concise description of the IBD BioResource: its purpose, objectives, scale, funders and duration.

Update on IBD BioResource progress with IBD research and findings

- Information about the status and outcomes of the IBD BioResource:
  - Have markers of disease risk, severity and treatment response been identified?
  - How many participants have been involved in IBD research projects?
  - What research has been conducted/what their outcomes are using the IBD BioResource.
  - Information on how patients can influence the research being done.

Pertinent and additional results

Participants would like to receive feedback about both pertinent and additional results. There is a strong desire to understand the conditions they currently live with and understand what steps they can take for themselves. There was a realisation that they were less likely to receive information about pertinent results, as the percentage is so small.

Participants discussed what information might be useful for example, information about the IBD genetic landscape. This conversation was triggered by a participant who has had a cancer diagnosis and has Crohn's, and wanted to understand if there is a relationship between the two.

Reminder of previous consent for additional feedback: option to receive or opt out

- Reminder that participants previously agreed to receive additional feedback and that they can choose to receive them or not.

- A few participants thought it would be important to have the option to seek re-consent at each stage: at the initial re-consent check, when a confirmatory sample is requested and before additional feedback is shared.

- Who to contact to confirm consent and by when?

What additional findings are: risk not diagnosis; not linked specifically to IBD: genes being sequenced and related conditions

- The feedback is not linked specifically to their IBD condition and that is information on risk for a condition not diagnosis.

- What genes and conditions the additional feedback will be on, that they are in line with the Genomics England 100K Genomes project.

- Some workshop participants thought that there should be the option to choose which genes/conditions they would like feedback on e.g. just metabolic and not cancer.

That all conditions linked to the 13 genes have an NHS treatment pathway

- General reassurance needed at this point, with more information provided if a genetic change is identified.

- Clarity needed that this is not a full report on your entire genetic sequence – during the workshop several participants spoke about a wish to 'know everything'.

Timeline and key stages for the additional feedback process

- Visual timeline for when, from who and how feedback will be delivered, including the potential need for a confirmatory blood test.

- What the role of the IBD BioResource and the NHS and others would be through this timeline.

Information on whether this is a 'one off' return of additional findings or if there will be future additional feedback for conditions as new genetic information emerges

- It is important to clarify whether this is a one-off opportunity to receive additional feedback through the IBD BioResource or the first of several waves of feedback.

- If the first of several, seek consent for being contacted if further additional genetic feedback is available in the future.

> *I'd like to know that I'll be kept informed as new discoveries are made with this genetic data, if there are new tests, if there is any new information on this subject.*

Genes are just one of many factors that affect your health

- It is important to be clear that genes are just one of many factors that affect your health: diet, exercise, environment, mental health, etc.

Implications for family members if genetic change is identified

- It is important to be clear that an individual's genetic information may be relevant to family members. This may be a consideration for choosing to receive feedback.

> *What about my family? I think the feedback would need to come with advice on how to share the information I'd received with my family if there are repercussions for them.*

2. Organising the confirmatory blood sample for those with genetic changes identified

Workshop participants recognised that being told about the need for a confirmatory blood sample could cause anxiety. Those who discussed this point felt that the time gap between notification of the need for a second blood sample and the return of results should be as short as possible.

From who: **NHS / NHS Genomic Medicine Service**

Workshop participants want to minimise the steps needed to organise the confirmatory blood test. They believe the written request should refer to the IBD BioResource but be from the part of the NHS /NHS GMS who will provide direction on how the test will be done and deliver results.

> *We'd rather NHS requested extra sample to confirm findings than a letter saying IBD BioResource needs extra sample to give to NHS to confirm something. It feels safer being under NHS care when being told something might be wrong.*

Format: **Written, either email or letter**

Content: **Brief and to the point**

Participants felt that this communication should be brief and to the point and contain the following information:

Why a retest is needed

- That a retest is needed because you may have a genetic variant that may increase the risk of condition x.

Why the previous blood sample cannot be used

- The difference between a blood sample analysed for research purposes vs one analysed for clinical results

How the blood test will be done

- How to arrange the blood test e.g. with GP surgery, health hub, local hospital, etc.

How long it will take to return the results, by who and next steps

- The time gap between requesting the blood test and returning clinical results should be as small as possible (days/weeks rather than months)

3. Returning results to those with no genetic changes identified

Participants were very happy to learn that 'negative' (or no identifiable genetic changes in the genes looked for) results would also be returned. There was widespread agreement that the terms 'negative and positive' should be avoided because of their confusing connotations.

From who: **IBD BioResource**

Format: **Written email or letter**

Most participants are content that this information of no genetic changes identified was suitable to be sent via letter or email, provided there are links to answer any follow up questions.

Content: **Clarification**

They felt that this should contain the following information:

No genetic changes found among the 13 tested

- Be clear up front that no genetic changes were found among the limited sample of genes tested.

This does not mean that you have 'no risk' of these or other conditions

- Be clear that whilst these gene changes weren't identified, there are many other causes of these health conditions, genetic, lifestyle etc. This is not a clean bill of health.
- Continue to participate in screening and do not ignore symptoms.

Information on if a retest is available in the future as information about genetics changes

- Indicate whether this is a one off test or if there are future opportunities to receive further additional feedback.

Links to sources of further information

- Reminder of the genes and conditions screened for.
- How the test is done – research findings vs clinical results.
- What to do if you have a concern re your family history and have tested negative.

4. Returning results to those with genetic changes identified

This is seen as the most sensitive moment in the return of feedback process. Participants stressed the need for a multi-stage approach which should include written, telephone and face to face contact.

From who: NHS speciality for the genetic variant identified e.g. cancer or cardiovascular specialist

At first, some participants thought of their IBD clinician as the source of additional genetic findings results. This is because for many they are the clinician that knows most about their medical history. However, this preference quickly shifted towards a clinical team that specialises in the variant identified, such as a breast cancer specialist. This would be a more immediate pathway to understanding the risk, further screening and treatment options.

Format: A streamlined flow of:

1. Letter/email with result
   ↓
2. Follow up phone call to answer immediate questions and discuss next steps
   ↓
3. Face to face appointment for further tests/treatment discussion

Most participants favour this flow of information; however a few had a preference for a telephone call. The table below illustrate the pros and cons discussed by one of the small groups:

Letter	Phone call
• Prefer something I can refer back to • Phone call relies on signal, timing, getting caught off guard at work • Letter could also be sent digitally on an online health record e.g. MyChart	• Immediately ask questions • Reassurance • More personal • Letter/email feels impersonal with same template
Both agree we want to be able to talk to someone about the findings as soon as possible.	

Content: Information, next steps and guidance

Conversations on the information needed when returning results about genetic changes focused on these main points: risk and accuracy of results; immediate next steps for physical and emotional support; guidance on if/how to share results with family members.

Risk level and accuracy of result

To minimise anxiety and alarm and give confidence in the result, participants said how important it is be clear on the level of risk, the confidence in the result and that this is risk information, not a diagnosis.

- Clear language and a visual representation are seen to be important: e.g. name the gene variant.
- Reiteration that the result is for 'risk' not diagnosis.
- Risk stratified as low / medium / high.
- The quality of the evidence that supports linking this gene variant to the condition.
- Population incidence of the condition in a. general population and b. IBD population.

Next steps

Immediately after receiving information about a genetic variant, there should be information on what to do next, who to contact and the timeline.

- Further screening and treatment if necessary: how and when you will be referred into the relevant speciality: both clinical and counselling e.g. you are likely to be seen by x month.
- Links to patient facing material on relevant conditions to help answer questions and empower people to ask questions.
- Counselling offer: the feedback might affect your reproductive decisions if you receive it prior to deciding to have children.
- Next steps for treatment and timings.

Implications for family

Information should be available to say that the genetic nature of the results mean that family members may need to be aware and possibly screened.

- Provide links to Plain English advice on risk, how to tell family members and what the testing and treatment pathways are.

Personalising results?

What if a result of an increased risk of colon cancer is returned to someone who has had their colon removed? Participants wanted to know if it would be possible to personalise the results in a way that reflected people's personal medical history.

5 Conclusions and looking forward

Key findings for the future

The workshop raised some key points that should be carried into the design of the feedback process and implications for wider IBD BioResource communication and involvement.

1. **Updates on the condition of concern: IBD**

   It is clear that returning additional genetic feedback to IBD BioResource participants should go hand in hand with providing an update on the status of the IBD BioResource programme and its findings. Helping to prevent, treat and cure inflammatory bowel disease are the main motivations for joining the study. Providing an update on progress should be included in the first contact to re-confirm consent.

2. **Managing expectations: some want more information than the current list provides**

   Some workshop participants had the attitude of 'tell me all, even if not treatable, so I can keep any eye on things'. There needs to be clarity on the limited number of genes being screened for and why these genes were chosen.

3. **Where can the process be tailored to individual circumstances?**

   Participants are hopeful that choice will be designed into the feedback process. For example, choosing to receive feedback, but at a later date; choosing to only receive feedback on some genes/conditions and not others.

   Participants are also concerned about delivering potentially serious genetic risk feedback without any knowledge of the individual's medical history (e.g. BRCA gene identified in someone who already has breast cancer). Consideration is needed for how this can be factored in to returning results in way that reassures rather than alarms and confuses.

4. **Be mindful of the interest in bowel cancer as part of the 13 genes**

   The additional genetic findings will include conditions that are of particular interest to people with IBD, namely bowel cancer. Particular care will be needed on how this is communicated to a patient population some of whom may have had parts of their colon removed or believe there is a link between IBD and bowel cancer.

5. **Use a range of tools to make the information accessible**

   Feedback that promotes comprehension through providing contextual information on the conditions, visual aids to explain risk and supporting materials to educate people on uncertainty. Include risk 'benchmarks' so that results are comparable with the general and IBD populations.

6. **A process that doesn't leave participants waiting anxiously for results and follow up**

   Participants expect each stage to be carried out within weeks of each other rather than over several anxiety-inducing months, with support in between provided through website FAQs and a helpline.

7. **Information received from the most appropriate sources**

   IBD BioResource are seen to be the lead information provider for re-consent and no additional findings. For contact on the need for a confirmatory blood sample the NHS – acknowledging the link to the IBD BioResource – is most appropriate as this carries trust and provides the bridge between research and clinical findings. For the return of genetic results for a variant, the NHS speciality should be the lead communicator.

8. **A clear appetite for more involvement with the IBD BioResource in the future**

   During the workshop conversations IBD BioResource participants demonstrated an appetite for more involvement in its work and also in deciding what is researched in the future.

6 Appendices

Feedback and testimonials

In the feedback forms returned by 14 IBD BioResource participants and six clinicians/ researchers most spoke highly of their workshop experience.

For **IBD BioResource participants** the key take-aways from the workshop were:

- Being reminded what the IBD BioResource is.
- Understanding what the additional findings are.
- Feeling that the patient views are valued and taken into account.
- Contributing to hopes that genetics could play an increasing role in how chronic diseases are treated.

  Actually learning about the possible 'additional findings', named diseases that might be found to have higher risks. Also - learning from the research side about issues with NHS integration, sharing findings, and their concerns. It is nice to know they are thinking about these things and they care.

For the **clinician/researchers**, the key take-aways from the workshop were:

- Understanding the diversity of patient views on what information should be provided and by who.

  Patient/participant viewpoints are hugely diverse. Most want as much information as possible but understand the challenges to delivering it.

- Appreciating the patient desire for results delivered clearly – and crucially – in a timely manner.

- Spending time with patients in a way that allowed all parties to share their views.

When asked for final thoughts on the workshop and the discussion topic, participants wrote about how pleased they were to take part in a workshop like this. Several wanted more opportunities like this in the future.

One participant said that it would have been better if there had been an earlier workshop that explored the IBD findings from BioResource so far. They felt that this was of the greatest interest to people with IBD and by leaping to a workshop on additional findings, it felt that an opportunity had been missed to address people's headline health concern.

> *As a participant who has IBD my main interest in any research is what is known and being found out new about my disease. I think a session would have been helpful on what researchers know now and where it is going.*

Another participant emphasised how important the re-consent contact point is in the additional genetic feedback process. An opportunity to promote the work of the IBD BioResource.

> *I think there is a really valuable opportunity coming up when participants are contact to confirm their consent. So much could be done! Promote the website, the newsletter! Remind people what they signed up to!*

A researcher came away from the workshop with a greater sense of patients' strong appetite for news on research.

> *I got a better understanding of what they want to know and I do acknowledge they want to know more often news on research about their disease than we probably do at the moment.*

IBD BioResource participant

Tell us about your experience of taking part in the IBD BioResource workshop on November 20th.

I had a great experience at the IBD Dialogue event. It was very informative, especially from a science/lab tech perspective. Engaging with clinicians, researchers and research participants was surprisingly easy and the feedback that individuals gave was broad and very in depth. The guest speakers were brilliant and managed to squeeze huge amounts of information into short speeches which kept the day interesting while informative at the same time. It was of great interest to me to learn and understand the process of how samples are turned into data and how that data is used for research. The most inspiring aspect of the event was that non-clinical guests (like myself) felt comfortable to share experiences and thoughts without feeling looked down upon, this made the day much more engaging and enjoyable.

What three words describe the day for you?

Fascinating, informative, worthwhile

Would you encourage other patients/clinicians/researchers to take part in a workshop like this in the future? Why?

I would highly encourage others to take part in future events both clinical and non-clinical, the type of event is beneficial to all and I was surprised by the huge amount of ideas that people shared.

Clinician/researcher participant

Tell us about your experience of taking part in the IBD BioResource workshop on November 20th.

This was the first workshop of this type I had taken part in, it was so interesting to hear the perspectives of IBD BioResource participants as well as other clinicians. Each aspect of the workshop drilled down on what was most important to our patients, and how all our hopes, fears and aspirations for IBD research outcomes fit in the 'real' world of the NHS. The running of the workshop was superb – no time for dilly-dallying or waxing lyrical about our favourite gripe – each person was given time to voice their thoughts and explore implications of the research. Really excellent experience, and something I would encourage clinicians/clinician researchers to do.

What three words describe the day for you?

Deep-dive, exciting, perspective-altering

Would you encourage other patients/clinicians/researchers to take part in a workshop like this in the future? Why?

Yes! It was great to hear the perspectives from our patients and as a clinician, this has made me really consider how I broach implications of research, but also allied to this, how I broach unexpected findings in general. As a researcher, it is imperative we understand the implications of disseminating our work, how and when we do it, but also the impact it has.

Genetics research participant

Tell us about your experience of taking part in the IBD BioResource workshop on November 20th.

I felt privileged to have the opportunity to have an open discussion with both patients and gastroenterologists, the former is something I do not have the chance to experience often enough. It was an engaging event, that made me realise of the plurality of opinions within the patients community.

What three words describe the day for you?

Engaging, openness, knowledge-based

Would you encourage other patients/clinicians/researchers to take part in a workshop like this in the future? Why?

I definitely would do so It allows for direct feedback and insights, from the patients, about our research and provides the best reminder of why we are carrying out this work and who it's for.

Agenda

IBD BioResource genetic feedback: a conversation between researchers and participants

Monday 20th November 2023 10am-3.30pm

Hinxton Hall Conference Centre, Wellcome Genome Campus, Hinxton, Cambridgeshire, CB10 1RQ

9:30	Arrival and refreshments
10:00	Welcome and introductions
10:20	Small group discussion 1: • Introductions : your connection to the IBD BioResource • Expectations for the day
10:40	Presentations on • Genetics in the IBD BioResource • BioResource feedback of additional findings • Genomic Medicine Service
11:00	Small group discussion 2: • Questions for the presenters
11:15	Break
11:30	Question and answer session
11:45	Small group discussion 3: • Your experiences of receiving and delivering health and research information/results
12:45	Lunch
13:30	Presentations on • Learnings from the 100K Genomes Project • Q&A
14:00	Small group discussion 4: • What matters when developing guidance for how genetic feedback is shared?
14:55	Break
15:10	Reflections on the day and next steps
15:30	Thank you and goodbye

Process plan

IBD BioResource genetic feedback: a conversation between researchers and participants
Monday 20th November 2023 10am-3.30pm

Aim and objectives of the event

The aim of this event is to help shape how the NIHR inflammatory bowel disease BioResource gives feedback to its participants. The specific focus is on creating helpful and reassuring feedback to those who have opted in to receive information on whether they are at an increased risk of the specific rare treatable genetic diseases included in the Genomics England 100,000 Genomes project.

The objectives are to:

- Involve both IBD BioResource participants and researchers in a genuine exchange where they learn about each other's hopes, concerns and interests about feedback from genetic tests for wider health conditions.
- Ensure all event participants have a shared understanding of the background and purpose of BioResource and learnings from other relevant genetic studies to inform their discussions on how best to feedback results of genetic tests for wider health conditions.
- Create a space for researchers and BioResource participants to discuss the genetic data generated from participants and what happens to it.
- Understand the points to consider for large-scale bioresources considering the return of additional findings.
- Ensure the outputs of the event reflect the values and interests of all participants.
- Inform further work between Bioresource and the IBD patients / community.

Event team

Host: Miles Parkes

Lead Facilitator LF: Suzannah Kinsella

Facilitators: Henrietta Hopkins, Jamie Hearing, Hally Ingram

Event Support: Richard Milne, Christine Patch, Hollie Rowland

Emotional Support: Christine Patch, Hannah Knight

Video/Photography: Lauren Robarts, Colin Ramsey, Mark Danson

Speakers

Carl Anderson, Head of Human Genetics and Senior Group Leader Wellcome Sanger Institute, Co-PI of IBD BioResource

Hannah Knight, Clinical Feedback Lead, NIHR BioResource

Sarah Bowdin, Medical Director, East Genomic Laboratory Hub

Ana Juett, Programme Manager SW Genomic Medicine Service Alliance

Melissa Hill, Senior Social Scientist and Research Genetic Counsellor. North Thames Genomic Laboratory Hub

Participants

16-17 IBD BioResource participants

10 researcher/clinicians

Observers

Arzoo Ahmed, Our Future Health

Laetitia Pele, Hazel Davies

Time	Agenda	Process	Who?	Process tools	Expected outcomes
8:30-9:30	Set-up	Room set up – cabaret style • 4 tables for 10 people – well spaced apart to enable participants to hear each other in the small groups. Mixed researcher & BioResource participants + F on each table • 4 x flip charts & (pre-written flip sheets HVM) • 4 x facilitation kits (HVM) • Projector/screen, speaker box, laptop loaded with films/ PPs and with access to Mentimeter • Chairs/side tables for observers/speakers • Wifi sign-in • Welcome table – registration list, name badges (first name & role), research sign in, photography/filming/ recording permission sign-in (WCS) • Menti QR code/ number code printed on each table (HVM) • Coffee, tea, fruit, snacks available	TBC + HVM Team	PP Slides Facilitator packs Flip Charts	Project team set up and ready
9:30-10:00	Participant check-in	Event Support, Host & Facilitation Team to greet participants as they arrive LF to speak to any observers/speakers present – refreshments available	ES, Host, LF & Fs	Name Badges	Participants feel welcomed & interested in the day to come
10:00-10:10 (10 mins)	Welcome & introduction to the event and purpose of the day	Warm welcome to this event & its purpose: Wellcome Connecting Science & Miles Parkes Introduction to the day • Housekeeping: fire, loos, phones etc • Agenda • Who's in the room • Guidance e.g. welcome a range of perspectives, how we capture what's said, reporting, sharing health experiences: keep in confidence etc. • Photography, filming & recording	Richard M Miles LF: Suzannah	Intro PP	People are clear: Why they are here, who is in the room, who they will be working with. What we will be doing together today.

Time		Agenda	Process	Who?	Process tools	Expected outcomes
10:10-10:20 (10 mins)		Menti questions set 1	**Participants asked to get menti.com on their phones. Fs to assist any participant as needed** Share the code / QR code. LF to share screen with 'hide results' QM1: Share something about yourself QM2: My understanding of the BioResource and its work is (Multi-choice range) is (Very well informed to Non-existent) QM3: I am confident that BioResource will share information about genetic risk in a helpful and reassuring way (Multi-Choice Range) Strongly Agree – Strongly Disagree In each case LF to share results when more than 12 are in	LF	Menti.com	Getting to know each other and rooting ourselves in the topic today.
10:20		Participants turn into their groups				
10:20-10:40 (20 mins)	10:20-10:30 (10 mins) 10:30-10:40 (10 mins)	Small group introductions & hopes / expectations for the day	F welcomes everyone to the small group. Asks each participant in turn to introduce themselves: • Name & where you are from • Briefly tell us about your connection to the IBD BioResource RECORDER ON **Q1: Given the purpose of today – creating helpful and reassuring feedback on genetic risk of wider health conditions – what are your hopes and expectations for the day?** Prompts to be used as necessary: • E.g. greater understanding of BioResource • Learning about genetic data and how it's produced • Learning from other research studies etc • One thing we'd really like to hear about in the BioResource intro coming up (agree 1 point to feedback) RECORDER OFF	F	Flip Charts Capture key hopes & expectations on flip charts	Small groups get to know each other Shared understanding of hopes for the day
10:40		Participants turn into main space				

Time		Agenda	Process	Who?	Process tools	Expected outcomes
10:40-11:00 (20 mins)	10:40-10:45 (5 mins)	BioResource, IBD Research & Genomics Background & Context	LF welcomes everyone back together Asks each of the 4 small groups to share one thing they'd like to hear about in the BioResource introduction LF Introduces x3 'lightning presentations' on IBD BioResource / Genomics in healthcare: incorporating small groups 'one thing' points.	LF	PP Slides / Presentation materials	Increased understanding of the BioResource, IBD research & Genomics
	10:45-10:50 (5 mins)		**Presentation 1: Genetics in the IBD BioResource and how it may generate additional findings (incorporating 'one thing' small group feedback)**	Carl Anderson		
	10:50-10:55 (5mins)		**Presentation 2: BioResource: feedback of pertinent and additional findings: current situation & genes on the Genomics England 100K list.**	Hannah Knight		
	10:55-11:00 (5 mins)		**Presentation 3: Role of Genomics /genetics in healthcare: Genomic Medicine Service**	Sarah Bowden		
11:00		Participants turn into their small groups				
11:00-11:15 (15 mins)		Question development	RECORDER ON **Q2: What questions or reflections do you have on the presentations about IBD BioResource and Genomics?** Prompts to be used as necessary: • E.g. what genetic information is fed back? • How the genetic data is analysed? • Security of the data? • Connection between IBD BioResource and Genomics England? • How positive test results are followed up? Choose 2 to share + participant volunteer RECORDER OFF	F	Flip Chart Write 2 questions to share on flipchart	Questions raised about
11:15-11:30 (15 mins)		Break – refreshments available – speakers able to see the questions from each group written on the flips				
11:30-11:45 (15 mins)		Plenary Q&A Session	RECORDER ON LF asks each small group in turn to share their questions: aim to respond to x1-2 questions per group Invites responses from speaker panel RECORDER OFF	LF Speaker panel		Questions answered

Time		Agenda	Process	Who?	Process tools	Expected outcomes
11:45		Participants turn into their small groups				
11:45-12:45 (60 mins)	11:45-12.00 (15 mins)	Experience of receiving and delivering health & research information/ results	RECORDER ON **Q3: Everyone: What has been your experience of receiving information/results about your health or genetics?** Prompts to be used as necessary: • E.g. from blood tests/scans/investigations/genetic testing (NHS/ ancestry.com etc)/ health research studies • What has been good about the information? What has been poor? • Timing/clarity/information/follow up support etc	F	Flipchart	Experiences of designing and receiving health data feedback shared
	12:00-12:10 (10 mins)		**Q4: Researchers/Clinicians: What have you learnt from preparing feedback to share with study participants?** Prompts to be used as necessary: • E.g. what's worked well: why? What's worked less well, why? • Clarity vs information overload • Informing vs alarming?			
	12:10-12:25 (15 mins)		**Q5: What (if any) individual feedback of genetic results would you like to receive? Why? Why not?** • What would good communication of this information look like? Received from who, what information, how would it be delivered?			
	12:25-12:40 (15 mins)		**Q6: What concerns do you have about receiving this information?** Prompts to use as necessary e.g.: • Accuracy? • Linking with other specialities e.g. gastroenterology – oncology? • Lack of follow up /support? • Implications for family members? • Insurance implications RECORDER OFF			
12:40		Participants turn into the main space				
12:40-12:45		Lunch instructions	Lunch instructions shared	LF	PP Slide	

Time		Agenda	Process	Who?	Process tools	Expected outcomes
12:45-1:30 (45 mins)		Lunch break – reminder to return promptly at 1:30				
1:30-1:35		Reminder of Agenda	Shares agenda reminder for the afternoon	LF	PP Slide	
1:35-2:00	1:35-1:40 (5 mins) 1:40-1:45 (5 mins) 1:45-2:00 (15 mins)	Presentation & Q&A	LF Introduces Speakers RECORD **Presentation 4: Setting up additional findings return in the 100K Genomes project** **Presentation 5: Experiences of 100K Genomes project participants with the return of additional findings** Q&A: LF invites participants to share questions & reflections on learnings from other studies	 Speakers: Ana Juett Melissa Hill	Presentation	Learnings from other studies with genetic feedback elements
2:00		Participants turn into their small groups				
2:00-3:00 (60 mins)	2:00-2:40 (40 mins) 2:40-3:00 (20 mins)	Drafting guidance	F introduces paired exercise and checks in on pairs/3s during the session: **Part 1: Work in pairs/3s, separate groups of researcher/ clinicians & IBD BioResource participants:** Using what you've heard today and your own thoughts and experiences, design a draft guide for feeding back on results of test for risk of rare genetic disease: • What information should it include? Must have / nice to have? • Who would it be from? • What format? E.g. Email, telephone call, letter, other? • How would it differ if the results were negative (lower genetic risk) or positive (higher genetic risk)? • What is important about the IBD context to consider? **Part 2: Small group reforms: Pair/3s feedback on key points from their first draft guide with the rest of the small group** • What are the differences between the researcher clinicians' drafts and the participants? • Small group to select 3 key points about designing guidance on feedback to share with the group: participant volunteer	F	Guide template Pair/3 group lists Find space in the room to work in pairs/3s.	Points shared on important considerations for sharing guidance

Time	Agenda	Process	Who?	Process tools	Expected outcomes
3:00-3:15 (15 mins)	Break – refreshments available & participants encouraged to review and add further ideas to - each other's key points for guidance				
3:15-3:25 (10 mins)	Menti.com	**Participants asked to get menti.com on their phones/ another tab on their device. Fs to assist any participant as needed** Share the code / QR code. LF to share screen with 'hide results' QM3: My understanding of the BioResource and its work is (Multi-choice range) is (Very well informed to Non-existent) QM4: I am confident that BioResource will share information about genetic risk in a helpful and reassuring way (Multi-Choice Range) Strongly Agree – Strongly Disagree QM5: One piece of advice to the team as they design participant feedback on genetic risk…		Menti.com	Understand any shifts in understanding & attitudes
3:25-3:30 (10 mins)	Reflections on the day & next steps	Host reflects on the day, key points heard, learnings to take forward, sharing report of the event, piloting feedback etc. Reflections/questions from participants **Group Photo** Thanks everyone for coming & safe journey home	Hosts: Miles & Richard LF		Next steps understood

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