Newborn Genomes Programme: Pilot
Public Standing Group on Ethics

Workshop 2 findings and pilot review

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Introduction

This document provides a summary of the Pilot Public Standing Group objectives and process.

It reports on the discussions at the second workshop about how to communicate the Newborn Genome Programme.

It looks at what the Pilot Standing Group members think about the future of the group and concludes with HVM's thoughts on the Group and where it could go next.

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1. Pilot public standing group aims & objectives

Aims & objectives

Genomics England would like to understand:

1. How the Standing Group's views **can be fed into wider discussions on ethical issues** faced by the study, including discussions by the Newborn Genomes Programme's Ethics Working Group
2. How to **bring in a diversity of public perspectives** to inform the ongoing ethical design of the study
3. **The support, resources, and materials that group members need** in order to tackle the ethical issues and questions raised by the study
4. What the **optimal methods of working** are for the Group – e.g., whether organising online or in-person meetings work best

Outcomes

The expectation is that, at the end of the Pilot Public Standing Group on Ethics' three meetings, Genomics England will have answers to these points. These answers will help Genomics England to determine whether the Group should:

a. Continue in a similar form: e.g., the same group of people, meeting 4-6 times in a year
b. Continue in a different form: e.g., a different group of people meeting more or less frequently
c. Be limited to three pilot meetings only (i.e., not continue)

2. Pilot public standing group process & membership

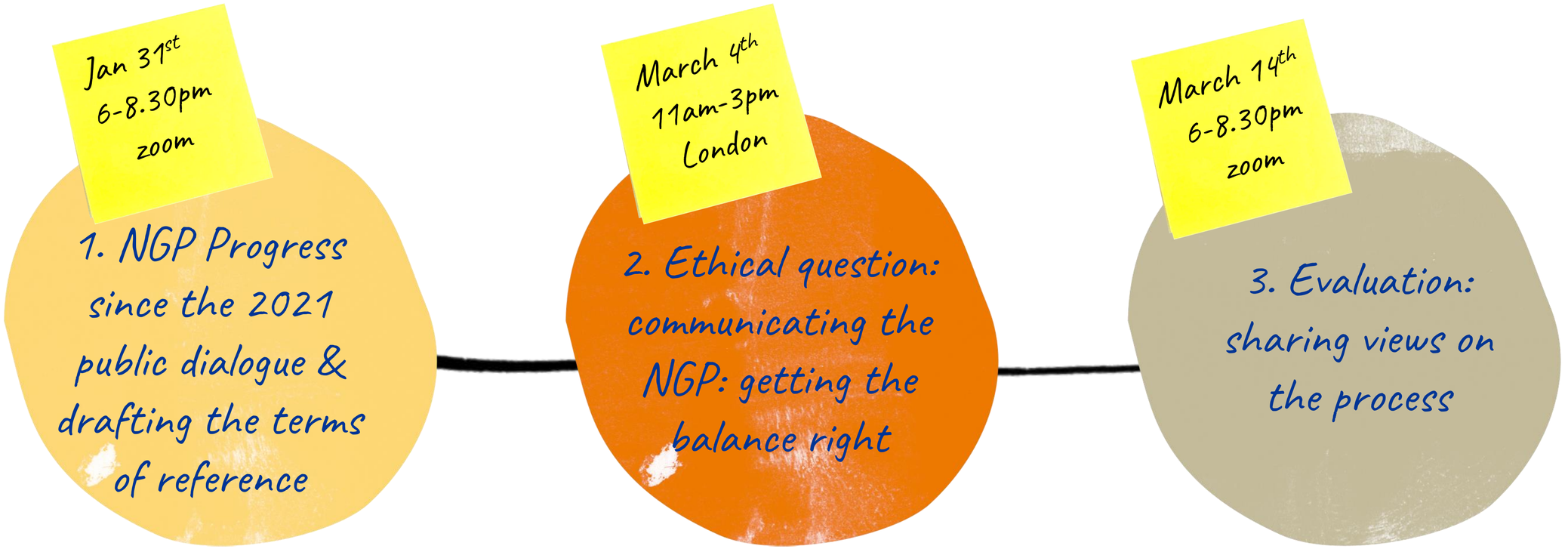
Standing group member profile

HVM contacted 64 participants from the 2021 public dialogue living in England to invite them to express interest in the public standing group.
22 replied and 18 took part. We actively recruited a larger proportion of younger people to ensure we heard from people who may be potential parents.

Gender:	Women: 10 Men: 7 Non-binary: 1
Age:	20-30yrs: 6 31-40yrs: 5 41-50yrs: 3 51yrs+: 4
Ethnicity:	Asian/Asian British: 4 Black African/Caribbean British: 3
	Mixed multiple ethnic: 3 White: 8
Status:	Mix of parents, pre-children and no children

The Process

Three meetings: the first and third on zoom and the second face to face in London. The first provided an update on the Newborn Genome Programme since the 2021 dialogue and gathered views on a draft terms of reference. The second explored questions around communication or the NGP and the third meeting gathered views on the standing group process.



Friends House, March 4th 2023

3. Workshop 2 findings

Questions & topics in workshop 2

How should we strike a balance between ensuring parents are as informed as they need/want to be…

…while not overloading them at a time when they have a lot of other potential things on their plate?

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How should we approach ongoing communications…

… to all families who take part in our research study?

Should we…

- Send an annual email update on progress with our study?

For the babies who take part, should we…

- Establish an opportunity for them to assent to continue being part of the study? If so, what age should we do this?
- Contact them again at age 16 to ask them to consent to continue, or withdraw from the study?

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How should we accommodate the fact that people will have different communication needs and preferences…

…when we have to roll this out at scale with limited resources?

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We also discussed how Genomics England should communicate the NGP study when it starts.

Why be part of the panel?

At the start of the meeting, we asked members why they said yes to being in this pilot… their reasons included:

- Having “the science bug”
- Having a sister who is a paediatrician with an interest in genetics
- Thinking of having a baby in the next two years and their partner who is wary of WGS for newborn screening
- Intrigued by the “moral and ethical issues” – asking questions such as “how far could this go, what could it mean for society”
- Being encouraged that the 2021 dialogue had influenced the NGP and wanted to help influence again
- Having friends with genetic conditions who could have been helped with earlier interventions
- Having children with sickle cell disease and unsure why one is frail and the other stronger

“For a majority of us, we’re in an office job where perhaps you’re not doing what you would do if money were no object, so it’s nice to do something where you could contribute in some way meaningfully.”

Post-screening result communication: the right balance?

Balance is best achieved by offering choice

For all those involved in the NGP study

- Having a choice of how to access information about the NGP was seen by all groups as the best way to get the balance of too much or too little information right.
- During the consent process, members thought parents should be offered a ‘push’ or ‘pull’ approach.
- Push would be offering twice yearly email updates on what the Study has achieved so far, significant milestones and benefits
    - a year felt too little - you would forget about the Study, twice a year felt like a happy medium to keep people interested and motivated in staying part of the Study.
- Pull would be offering a portal where Study participants (and the wider public) could access up to date information on how the Study is progressing and what research is accessing the National Genomic Research Library (NGRL).

“You tell people where it is and they can just go and look as opposed to going ping. ping, ping, ping.”

- Some participants also envisaged the portal having a log-in feature for Study participants to see what research their child’s data is contributing too. The participants understood that this would be at a study level in the short/medium term, but hoped to be able to see research involvement at an individual level at some point in the future.
- Sharing information about the research that is being done using the Newborn genome data was seen to be a useful ‘primer’ to help parents potentially be willing to take part in future research.
- Members hope that post screening communication is not just written, but could include drop-in sessions / webinars at particular milestones e.g. 1 year in, 10,000 babies screened etc. to help meet people’s different communication preferences.
- As well as information on the Study’s progress and research, members wanted a portal to include guidance to parents on how/when to tell their children about their role in the NGP. They thought this would help to pave the way for the children to consenting (or not) for themselves.

Post-result communication: the right balance?

For those with a condition suspected diagnosis

- Workshop discussions around communicating with those who have received a ‘condition suspected’ screening result naturally focused on the impact of receiving this diagnosis.
- Members expected medical information on the condition provided directly by specialist clinicians, signposting to support from parents/charities who share this condition and guidance on the familial implications of this condition at the point of diagnosis (if/how to inform other family members).
- Sensitivity was the key for communications about the Study to this group: they asked how parents with a child with a diagnosed condition would they feel about a newsletter that was all about the NGPs successes? Could this be insensitive, or could it be a ray of hope?

> *“If it’s parents whose child has been flagged as like conditioned suspected, and then they go on to be diagnosed with something they might not want to receive annual letters with, like success stories of like how amazing the programme has been. I mean, they might. People will be different, they might be happy.”*

- Members thought it likely that parents would want to focus on the condition and any relevant research specific to that condition rather than other Study information.
- They wondered if a tailored approach to communication might be possible, even to the extent of providing a named contact who could offer future research opportunities, so parents know that any communication is coming from a trusted source.

Communicating about assent and consent

Important to prepare the ground, but age of maturity is tricky

- Members talked about the importance of equipping parents to talk to their children about their involvement in the NGP.
- The NGP ‘Portal’ was seen as a logical place to provide guidance and age appropriate materials to encourage and help parents to discuss the NGP with their child/ren. They thought it was also important to explain why perhaps older siblings had not been screened in this way.
- Members also took a more macro view, saying how the education system should be gearing up to expand how genomics is taught in schools to provide a grounding for children to understand genetics and research. They feared that without this, a covid-style conspiracy theories could proliferate.
- In terms of communicating with older children to seek assent, many members felt that age of responsibility varied very widely (comparing mature 8 year olds with immature 17 year olds), but could see the practicality of an age such as 16, provided parents had been equipped to communicate beforehand, as described above.

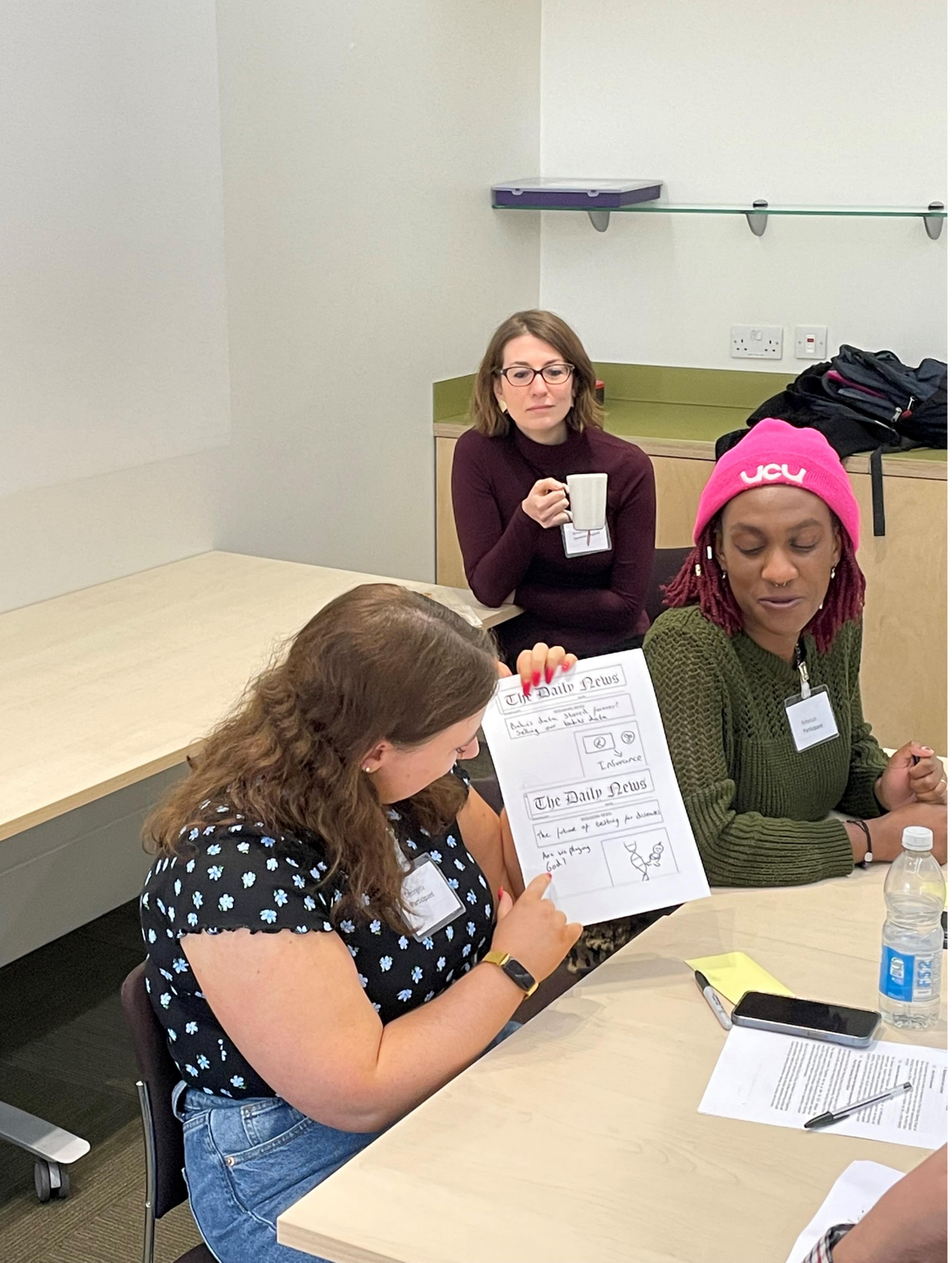
Communicating about research stemming from the NGP

The nature of research needs to be communicated

- Members thought about the nature of research and how it needs to be communicated with those participating in the NGP study.
- The dynamic nature of research: that its not static, that opportunities to take part are likely to be time limited and that outcomes are not certain.

"The other thing we talked about was the language that's actually used. If you talk about research, it's research opportunities. Opportunity is really lovely. positive word is rather than just research which is flat, dead and possibly clinically scary."

"I think you need to define the framework at the beginning, because I think it's if you went that we talked about an opportunity, very valuable opportunity, but it's not something that's just there as a tap. You can give you can dip in. You can dip out. I think there needs to be a commitment. I think that's incredibly important. So there's there's a buy in you like you've got the opportunity to do this."



The Daily News

The afternoon of the workshop started with a headline generation exercise.

Members were asked to pen positive and negative headlines about the launch of the Newborn Genome Programme and the discuss what Genomics England would need to do to prepare for these headlines.

The exercise demonstrates that Members have a strong sense of the thorny ethical and controversial waters that the NGP Study may face as it prepares to launch.

Challenging headlines and responses

Designer Baby' Headlines:

Are they genetically modifying our babies?

Are we paving the way to universal soldiers and blue eyed blonds?

Little babies for repair

Are we playing God?

→ Steady and consistent focus on the core purpose of the NGP: earlier diagnosis of babies with treatable genetic conditions.

Affordability Headlines:

How can the NHS afford this? Investment in our future or waste of money?

→ Clarity that the Study budget is Government, not NHS and how in the long term, when rolled out it could save money by preventing expensive, ongoing treatment for life long conditions.

'For the few, not the many' Headlines:

The 'lucky few' why were these locations chosen?

Born at the wrong time? The children who miss out because of timing

Families with genetic conditions feeling excluded/overlooked

→ Choice of locations made clear upfront. Availability of other access points to the genomics medicine services beyond the NGP.

Selling our children's data for big pharma gain Headlines:

A private company is paying for access to the data is like a headline that could be made alarming

Wider climate of profit: at its heart the NGP is a good thing, but it exists in a political landscape where private profit is felt to be more to the fore than public good. *"the market and the economy, as opposed to social welfare and public health. And so then under that kind of government it doesn't make me so confident about this"*

→ Life science industry paying for data, assurances on affordability of resulting treatments for the NHS.

Positive Headlines

A world first

- Most of the positive headlines created by Members focused on the ‘world first’ status of the NGP Study.
- Many found this a strong message and point of pride for the UK, particularly given that they perceive countries such as the USA and China as normally dominating innovation in the gene tech space.

Principles for communication

Members share three main principles to guide NGP communication

- **Transparency**: *"If there's not a clear reason to withhold the information, we should tell people because if you keep it hidden then it creates space for people to like, create some mad ideas."*

- **Inclusive:** *"Like what people did with the vaccine roll out – involving local community leaders - if you're concerned about certain groups having lower uptake than others - aside from just, hearing about it on the news or in leaflets - take it to local community groups."*

- **Keep focused on the original purpose:** *"People could get swept up a lot and talk about like budgets and like how it's going to happen and what could happen with people's data and lose sight a little bit of the original purpose of the programme, which is to benefit the babies who would be found with conditions."*

Communicating to the wider public

What questions will communications with the wider public need to answer?

Short term:

- How and why were the study sites chosen?
- Will all babies born at those sites be eligible or will they be selected somehow? If so, why?
- What is the cost of the study and where is the budget coming from?
- How will data be kept safe and secure?
- How and why will the life sciences industries access the data and will the benefits of their access be shared?

Medium/longer term:

- Can the NHS cope with a nationwide screening programme of this kind? Staff already under pressure, low satisfaction ratings currently for the NHS…

4. Pilot member views on the future of the standing group

Workshop 3

In the third and final Pilot Standing Group workshop, we shared a summary of the process with Members and asked for their thoughts on how a Standing Group on Ethics might work with Genomics England in the future and if the current group should stay the same or include others…

Pilot member recommendations

How to bring in a diversity of public perspectives to inform the ongoing ethical design of the study

- Retain the current members to capitalise on their knowledge of the Programme.
- Add more sceptical voices to the membership.
- Review the diversity of the group and add members as needed.
- Support new members with programme information to ensure a level playing field of member knowledge.

> *"I feel that you now have a well informed diverse committed group of people that can and will, only add value to the pilot."*

> *"I believe this is more valuable than having to start from scratch with an unknown group."*

Pilot member recommendations

The optimal methods of working for the Group

- When the options of how Genomics England might work with the Group were explained, Members favoured a responsive over a regular approach to when they meet, to provide timely input to the programme as it develops.
- However, they said that a responsive approach needs to be supported by regular communications to keep members informed and engaged, e.g. a six month silence would make people feel detached and undervalued.
- They support being involved in a range of ways: gathering views via email, surveys, zoom and face to face meetings.
- Face to face meetings were seen to be important as both a trust building exercise between members and between members and Genomics England and for discussing complex and controversial topics. 1-2 times a year is sufficient.
- They hope to see continued support for the group to bring in and share their personal experiences and perspectives to enrich the discussions (e.g. sperm donor mother).

5. HVM Conclusions

HVM Conclusions

Many members of the Group have expressed support for the Study to explore the merits of WGS for newborn screening.

However this support for the concept, should not be seen as ‘going native’.

The workshop 2 discussions around how to balance communications stimulated mostly practical considerations, but this stemmed from the nature of the question rather than participants ability to consider ethical issues.

In fact more ethical issues emerged from the ‘news headline’ exercise.

During these discussions, participants have raised ethical and societal issues such as ‘fairness’ (think of who will feel left out of this programme: older siblings, surrounding locations etc), ‘value’ : why spend millions to identify a relatively small number of cases? ‘honesty’: is this really about benefiting life science industry rather than the public’s health?

And when asked for feedback on the process, several Members raised topics they thought an ethics group should consider, such as if and how to share genetic results with wider family members and whether it is right to exclude certain parents/situations from the NGP Study.

HVM Conclusions

Our conclusions from working with this Pilot Group is that they are committed but still questioning. This makes them a reliable source of insight when given meaningful ethical questions to consider.

We believe a future Public Standing Group on Ethics should involve at least half/three quarters of the current group, but be supplemented by more sceptical participants, potentially drawn from the Research Access Public dialogue and/or from the Basis Social Ethnic Minority Community Leader engagement. Our thinking here is that these are groups will have a similar level of understanding for the NGP.

Starting from scratch, with an entirely new cross section of the public would need time and resource to bring them to an understanding of the NGP. It is highly likely that this new group would land in the same place as the current group in terms of having broadly positive attitudes to the concept.

There is a clear appetite for a ‘responsive’ rather than ‘regular’ approach to working with Genomics England on ethical questions. But this needs to be supported by:

1. A clear understanding of how their views are being considered alongside other inputs.
2. Consistent communication to maintain interest and involvement.