Insight Report: Online public Involvement session on the views of patients living with Inflammatory Bowel Disease (IBD) in relation to a Multiomic phenotyping of IBD

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Contents

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Background

The National Institute for Health Research (NIHR) currently funds 20 Biomedical Research Centres (BRCs) across England. These are collaborations between world-leading universities and NHS organisations that bring together academics and clinicians to translate lab-based scientific breakthroughs into potential new treatments, diagnostics, and medical technologies. The Imperial BRC is a collaboration between Imperial College, London and Imperial College Healthcare NHS Trust and is currently funded until November 2022. It has 12 research themes, 4 of which are cross cutting. The Gut Health theme is one of these 12 themes.

To assist with a project being undertaken by this theme, the Imperial Patient Experience Research Centre (PERC), a core facility of the Imperial BRC facilitated an online discussion session to gain the perspectives of inflammatory bowel disease patients (IBD) who are on treatment for IBD about current research being undertaken by Dr Robert Perry and Dr Sharmili Balarajah (working in the Imperial BRC Gut Health theme) as part of a multiomic phenotyping of IBD research project.

Public Involvement is defined by the NIHR as "research being carried out '**with**' or '**by**' members of the public rather than '**to**', '**about**' or '**for**' them"[1]

"Public" includes patients, potential patients, carers and people who use health and social care services as well as people from specific communities and from organisations that represent people who use services. Also included are people with lived experience of one or more health conditions, whether they're current patients or not.

Approach and purpose

Public involvement is considered a crucial component of all BRC research projects. As part of this online session the research team wanted to understand the following from individuals with lived experience of IBD in order that this could shape and improve this project:

- Whether they felt that their current IBD treatment plan has been individually tailored to them? What personal information they thought IBD clinicians should take into account when designing treatment plans?
- If during the course of this research, the researchers discovered a non-invasive stool test which could diagnose/monitor IBD, would they prefer this to an endoscopic test (such as colonoscopy)?

Call overview and agenda

An online discussion was hosted on Tuesday 16th July 2022 from 5.30pm to 7pm via Zoom Pro.

The aims of this particular online session were to:

[1] https://www.nihr.ac.uk/documents/briefing-notes-for-researchers-public-involvement-in-nhs-health-and-social-care-research/27371#:~:text=NIHR%20defines%20public%20involvement%20in,that%20influences%20and%20shapes%20research.

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1. Introduce and explain the purpose of the multiomic phenotyping of IBD project and its timeline
2. Give attendees an opportunity to ask questions (15 mins)
3. Facilitate small group discussions in Zoom break-out rooms about the following questions (45 mins):
    - Whether they felt that their current IBD treatment plan has been individually tailored to them? What personal information they thought IBD clinicians should take into account when designing treatment plans?
    - If during the course of this research the researchers discovered a non-invasive stool test which could diagnose/monitor IBD, would they prefer this to an endoscopic test (such as colonoscopy)?

An introduction was provided to the project and attendees were given an opportunity to ask questions (see **Appendix 2**). As a result of the number of attendees on the day, it was decided that two break - out rooms were not required and therefore the attendees all joined the same conversation hosted by the two researchers and a public involvement facilitator from PERC.

Attendee recruitment

Efforts were made to bring together members of the public who had lived experience of IBD and who were currently on treatment for this. This was undertaken by disseminating the opportunity through Guts UK, Crohn's and Colitis UK as well as through gastroenterology clinics at Imperial College Healthcare NHS Trust. Although 14 individuals were expected to attend, 7 individuals attended the session (see **Appendix 1** for demographics).

Feedback

Following the session, attendees were sent an anonymous online feedback form to comment on ways the session could be improved and to give any additional views on the questions posed in the session (see **Appendix 3**). Comments relating to the questions discussed in the session were integrated into the Key Insights summary.

Payment

In accordance with NIHR payment guidance, participants were paid £42.50 for their time including a £5 contribution to Wi-Fi/data for accessing a virtual meeting.

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Key Insights Summary

Insights raised during the discussion have been themed under the questions posed and are summarised below.

Whether they felt that their current IBD treatment plan has been individually tailored to them? What personal information they thought IBD clinicians should take into account when designing treatment plans?

Attendees' **who felt that their current IBD treatment plan had been individually tailored to them** included:

- having received a number of different treatments since diagnosis but **being able to choose to have infusions at a hospital on a weekend** to suit other life commitments
- having various treatments over 20 years including immunosuppressants, pouch surgery which failed and then an ileostomy but considered they had **lived a normal life and** thought that diet and advice from a dietician had had a significant positive impact.
- being **happy not to be confused with too much choice of treatment** and (after a multidisciplinary team had discussed the options without them present) was given a choice of having treatment at home or at the hospital
- when **treated contemporaneously for breast cancer,** this limited the treatment they could have in order that the breast cancer treatment was safe

Attendees' who **felt that their current IBD treatment plan had not been individually tailored** to them included:

- feeling like they were **"on a ladder" or "jumping through hoops"** and no matter how serious their symptoms were, there is one process where you are put on a treatment and if you don't respond you move to the next one and so on
- being put on a treatment when it was known that they wouldn't "get on with it" but there was a need to **"tick the box" to be able for them to receive a biologic at a later stage**.
- **short terms solutions not being helpful** where prescriptions for one month were provided e.g. Omeprazole
- the **practical aspects of receiving a treatment being overlooked** e.g., attending hospital for treatment at times when may not be convenient as people have other commitments including work, family and social lives
- **feeling pressured to choose the right treatment** when provided with a list of options (and undertake their own research on these treatments) without knowing which one might be optimal for them and suggested that the use of genomics would take away the pressure and anxiety of choosing the wrong treatment.

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- Most treatment options are **infusions.** A need was expressed for biologics to be delivered in tablet or oral liquid form (or subcutaneous patch) due to the **ease of delivery method** and which would remove the requirement to have to go into the hospital for an infusion

Attendees' who felt that their **current IBD treatment plan had not been individually tailored to them to begin with but had improved over time** included:

- an attendee with Crohn's disease whose treatment plan previously meant spending a lot of time going to hospital for methotrexate injections, then following surgery being asked which drug they would like to go on next and could now **inject their medication at home** and not have to take time off work which had previously been an issue
- an attendee with colitis had been on steroids for years after having been **put on 'whatever had not yet been tried',** then had a panniculectomy which was transformative but has recently developed pouchitis and is back on steroids but isn't yet sure if the treatment is individually tailored.
- an attendee considered they were only getting individual treatment now **after 2 years because they demanded follow up appointments, tests and referrals** including an endoscopy and stool tests. They had attended A&E nine times in six months because they didn't know what else to do. They had also been told to manage their condition with specific diets e.g., the low FODMAP diet but not being given any guidance about how to do this properly or with a dietician providing advice. This had also led to their relationship towards food having changed as a result of the amount of focus put on diet as a way to manage IBD.
- one attendee expressed **the need for clinicians to ask patients to define what personalised treatment and treatment success means to them** so they can work towards that rather than automatically referring to scales for test results e.g., faecal calprotectin. It was noted that even when faecal calprotectin is normal, they still had symptoms.

The **impact of COVID** had made it more difficult to get **referrals** for one attendee including a referral for ovarian cancer due to the overlapping symptoms with IBD. However, one attendee had experienced **more interaction with clinical staff over COVID** albeit over the phone. One attendee was thankful that COVID had meant they had **"dodged" their colonoscopy** which results may mean being taken off their current treatment which is working for them. There is only one other treatment option left (following having had surgery for Crohn's which then returned) and should this not work this impacts family life especially as they have a limited support network.

Attendees suggested the following personal information should be taken into account when designing treatment plans:

- the **severity of someone's IBD**

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- which **medication might be optimal for a particular patient** e.g. if a genomic analysis could be undertaken to predict which medication might work best this would take away the anxiety of choosing the wrong medication.
- the patient's **medical history** and particularly the history of carcinoma
- someone's **personal or family genetic history** as one attendee had a family history of colitis which was dismissed and also had a genetically driven breast cancer
- **practicality of infusion treatments** for patients including timings of these around their work, family and social life and their delivery methods as some people don't like needles and others find it hard to take tablets

If during the course of this research the researchers discovered a non-invasive stool test which could diagnose/monitor IBD, would they prefer this to an endoscopic test (such as colonoscopy)?

Broadly, the attendees had a **positive response to a non-invasive stool test** replacing an endoscopic test to diagnose and manage IBD **subject to**:

- the **practicality of having the test** and how far you would have to travel to take it
- the **reliability and specificity of the test** to diagnose and monitor their specific condition e.g., one attendee's Crohn's disease is in the small intestine for which they usually have a small bowel MRI and they weren't sure a stool test could replace this
- **whether other factors could bias the results of a stool test** e.g., an infection, if someone is on proton pump inhibitors, recently had a colonoscopy or handed in the stool sample the day of the colonoscopy
- whether a non-invasive stool test **would work for someone with an ileostomy** and if the test would be correctly calibrated in this situation e.g., it would be difficult to decide whether someone had diarrhoea unless they knew what someone's "normal" looked like

Attendees noted that even though endoscopy/colonoscopy were not comfortable, and the preparation was not pleasant, they would still like to have these for:

- **reassurance of having had a thorough investigation** as the patient can see what the clinician is seeing on the screen, the results are provided instantly (which is not the same for current stool tests), and they can have a discussion about the results at the time
- the purpose of **monitoring bowel cancer** and removing polyps and having them tested
- diagnosis as it was thought that this required **looking at the lining of the intestines** to see how deep the inflammation is and clinicians needed imaging to be able to see this.

Other non-invasive options discussed were **pill cams** as these only require swallowing something and **ultrasounds** to monitor small bowel Crohn's which are not available at all hospitals. It was also suggested that a **better bowel preparation** could be invented. One attendee did not mind having an endoscopy once every 3 years as this was also needed to monitor a hernia.

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Appendix 1: Demographics of attendees

Table 1: Demographic characteristics provided during event registration for discussion group (N=7)

Characteristics	**n (%)**
Age (in years)	
Mean (range)	45 (27-76)
Age groups (in years)	
18-24	0 (0.0)
25-34	2 (28.6)
35-44	2 (28.6)
45-54	1 (14.3)
55-64	1 (14.3)
65 – 74	0 (0.0)
75+	1 (14.3)
Prefer not to say	(0.0)
Gender	
Female	5 (71.4)
Male	2 (28.6)
Prefer not to say	0 (0.0)
Ethnic group	
White	
English/Welsh/Scottish/Northern Irish/British	5 (71.4)
Irish	0 (0.0)
Gypsy or Irish Traveller	0 (0.0)
Other White background	1 (14.3)
Mixed/Multiple Ethnicity	
White and Black African	0 (0.0)
White and Black Caribbean	0 (0.0)
White and Asian	0 (0.0)
Other Mixed/Multiple background	0 (0.0)
Asian/Asian British	
Indian	1 (14.3)
Pakistani	0 (0.0)
Bangladeshi	0 (0.0)
Chinese	0 (0.0)
Other Asian background	0 (0.0)
Black/African/Caribbean/Black British	0 (0.0)
African	0 (0.0)
Caribbean	0 (0.0)
Other Black/African/Caribbean background	0 (0.0)
Other	

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Arab	0 (0.0)
Any other ethnic group	0 (0.0)
Prefer not to say	0 (0.0)

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Appendix 2: Questions asked by attendees during the session

Questions asked and answered during the introduction to the research project are set out below:

Q: Are you doing research into genetics?

A: To see whether there may also be genes that are linked with failure of predict response and disease severity is still very much an area where there's a lot of uncertainty. We don't know enough about it to be able to use it to provide useful clinical information at the moment. We have got lots of research projects going on at the moment. I don't know if you've heard of the IBD Bioresource for example, where they're collecting samples. But like Rob said, with our research at the moment, we're in the stage where we're still collecting samples and we've got onto the bit where we're looking at things in detail and analysing those samples

Q: Have you got a specific hypothesis or area of interest?

A: So in terms of response to treatment, looking at IBD patients as a whole, there has been some research that identified certain bacteria which might predict that someone might respond better to treatments. Those studies are quite small and sample sizes but quite a small one. We're trying to replicate what they've done, but also try to identify other factors. Other things other than just the treatment that you're on to see if there's anything that transpires from that. I suppose the concept of multi omics is all about big data. So it's about doing a lot in each of the areas and combining them to provide more accurate information than you'd get if you just looked at one area.

Q: I just wanted to check in regards to looking at commonalities and sequencing. I've been going through a lot of different diagnosis and referrals and some of them do tend to link to women's health and gynaecology being linked with pelvic floor and I'm just wondering if you're looking at that as well?

A: Anyone that we recruit to our study, we also take more general health information about them as well so that we could hopefully spot any other links with other conditions, and to try and get an idea of whether there are particular links with inflammatory bowel disease or particular things that may influence and damaging bowel disease and see if we will also look at other medical problems which may well be relevant.

Q: What kind of sample sizes you were working with?

A: We've recruited about 35 patients. Like I said, we're looking at different cohorts. So the aim would be to get at least 50 in each cohort, which is a little bit ambitious and it's a bit niche because there are other confounding factors that you might have to exclude initially, because those can also affect the omic kind of analysis. So that's where we are at the moment, but we've still got another year or so to recruit. So we're hoping to really push that forward now that COVID hopefully isn't so much of an issue. Multiple stuff is going on lots of time points, it’s not just a one-off set of sample collection, you're also getting samples as they start a treatment and as they respond and don't respond to it.

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Q: In America, they put you on the strongest drug first?

A: There is some debate about what the best treatment approach is and there are studies ongoing at the moment to try and answer that question as to whether in some patients starting off with the strongest drug first is the best way to effectively kind of switch off the disease process and get things under control quickly. You wouldn't want to put everyone on the strongest drugs because whilst all these are generally pretty safe medication all medications do have some theoretical side effects and possible long term risks. So you wouldn't want to give everyone the strongest drug when you know that some patients are okay on the milder drugs. So again, this comes back to this idea of the more personalised medicine. Ideally, what we'd like is some sort of biomarker that you could test someone and say your disease is likely to become severe or be treatment resistant and therefore, for you we'll give you the strongest one first rather than starting with meslazine and thiopurines and taking a long time to get to the stronger biologics. So that's a very much an ongoing debate in IBD treatment at the moment.

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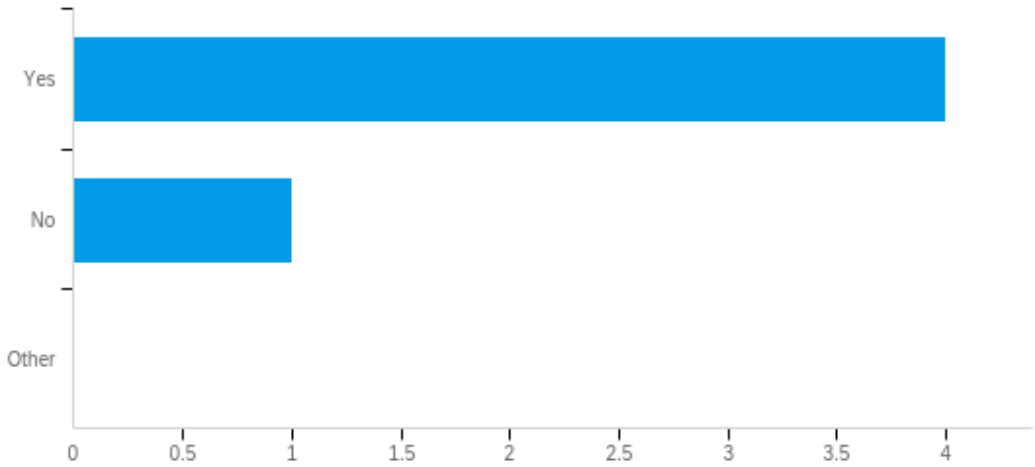
Appendix 3: Post- session feedback from attendees (n=5/7)

In the post -session anonymous feedback form emailed to attendees, they were asked practical questions about the session including how they rated it, their motivations for joining and which parts they liked the most. Respondents were also asked if they had any further responses to the questions posed in the breakout rooms and these responses have been consolidated with those provided in the breakout rooms above in the Key Insight Summary above.

Question 1: Is this the first time you have joined an Imperial College, London or Imperial College Healthcare NHS Trust event in person or online?



#	Answer	%	Count
1	Yes	80.00%	4
2	No	20.00%	1
5	Other	0.00%	0
	Total	100%	5

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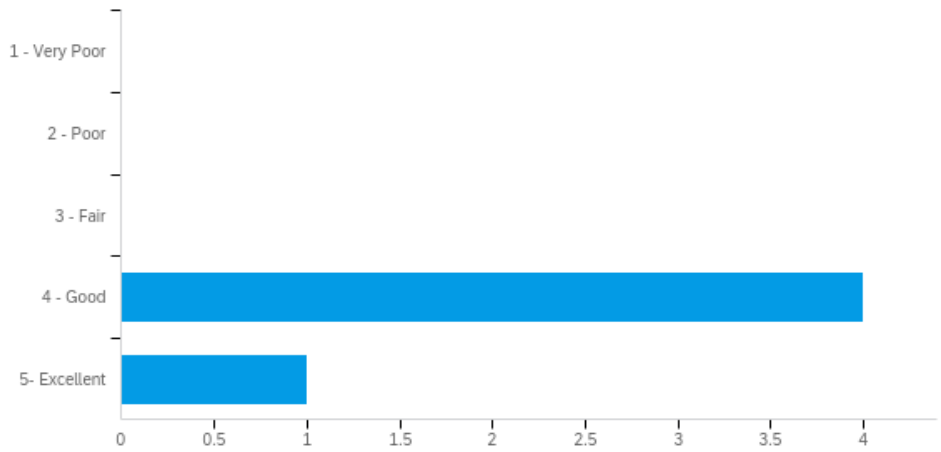
Question 2: On a scale of 1-5, how would you rate the session?



Please tell us why you chose this rating
Clear explanation. Interesting and articulate respondents.
Seem to broad a group of participants to be useful
Well run, everyone got to speak and kept to time
I enjoyed that the session was on Zoom instead of in person. It wasn't too long. I liked the layout - information and then questions.
Staff leading the session were great.

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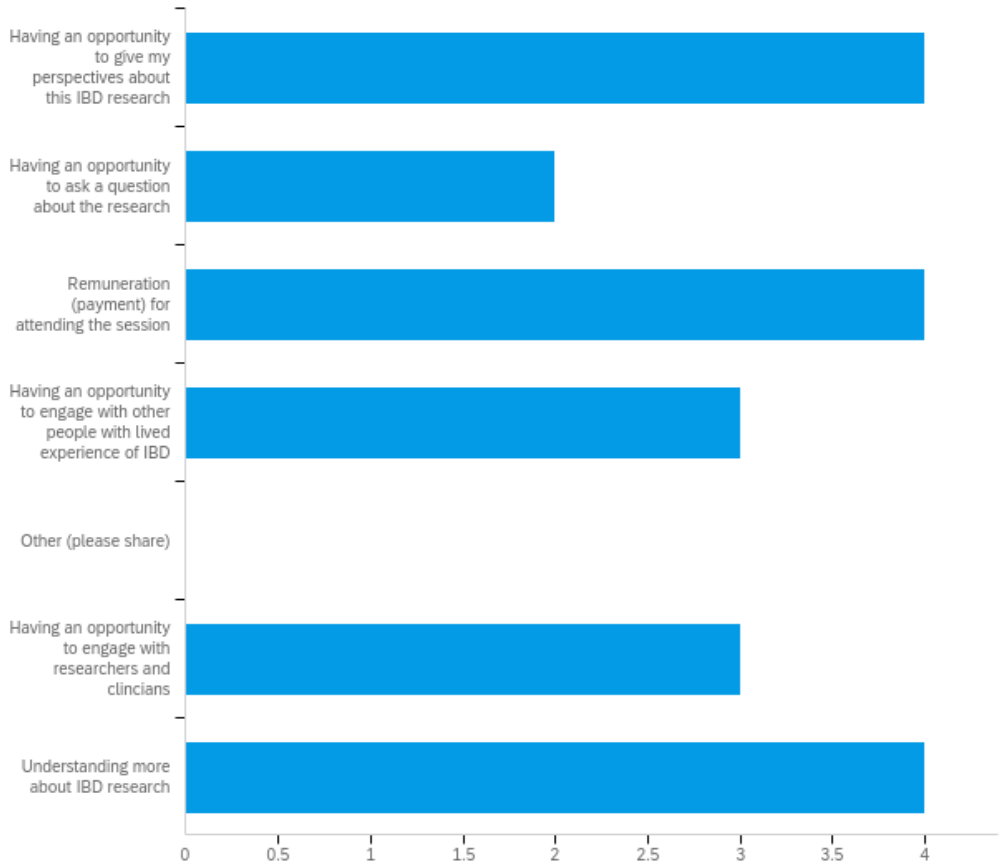
Question 3: Please tell us your main motivations for attending the session? [Feel free to choose more than one]



#	Answer	%	Count
1	Having an opportunity to give my perspectives about this IBD research	20.00%	4
3	Having an opportunity to ask a question about the research	10.00%	2
4	Remuneration (payment) for attending the session	20.00%	4
5	Having an opportunity to engage with other people with lived experience of IBD	15.00%	3
6	Other (please share)	0.00%	0
7	Having an opportunity to engage with researchers and clinicians	15.00%	3
8	Understanding more about IBD research	20.00%	4
	Total	100%	20

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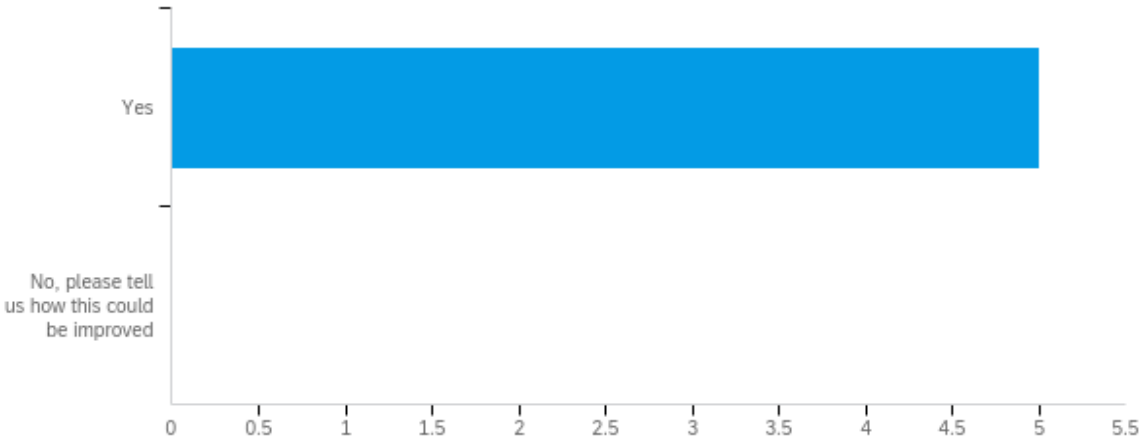
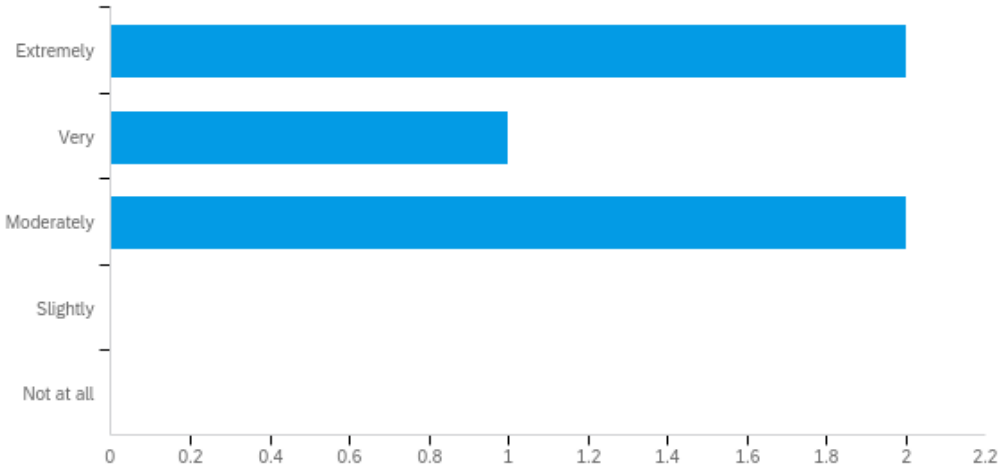
Question 4: Did you find the presentations easy to understand?



#	Answer	%	Count
1	Yes	100.00%	5
2	No, please tell us how this could be improved	0.00%	0
	Total	100%	5

Question 6: How informative did you find this session?



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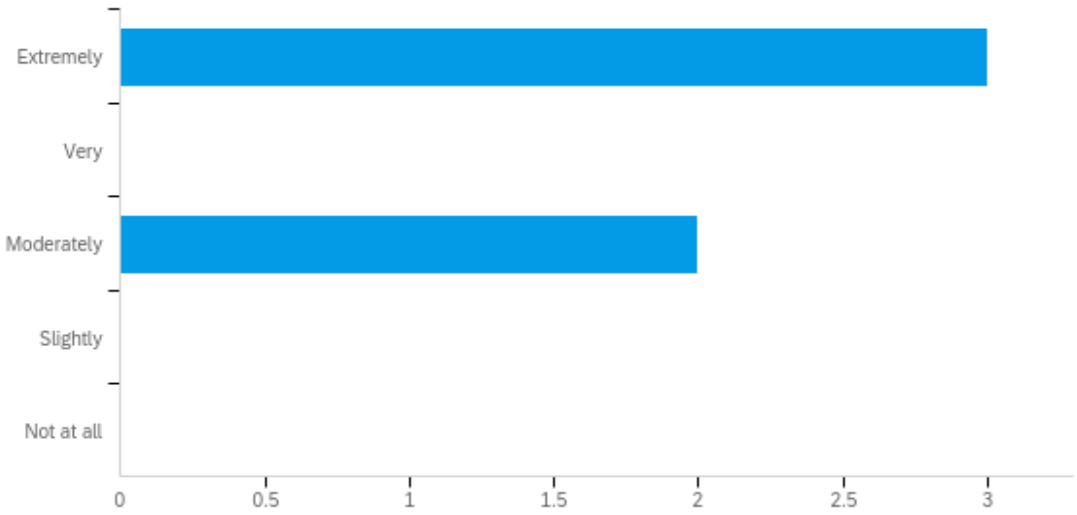
#	Answer	%	Count
1	Extremely	40.00%	2
2	Very	20.00%	1
3	Moderately	40.00%	2
4	Slightly	0.00%	0
5	Not at all	0.00%	0
	Total	100%	5

Question 7: How likely are you to attend a session like this again?



#	Answer	%	Count
1	Extremely	60.00%	3
2	Very	0.00%	0
3	Moderately	40.00%	2
4	Slightly	0.00%	0
5	Not at all	0.00%	0
	Total	100%	5

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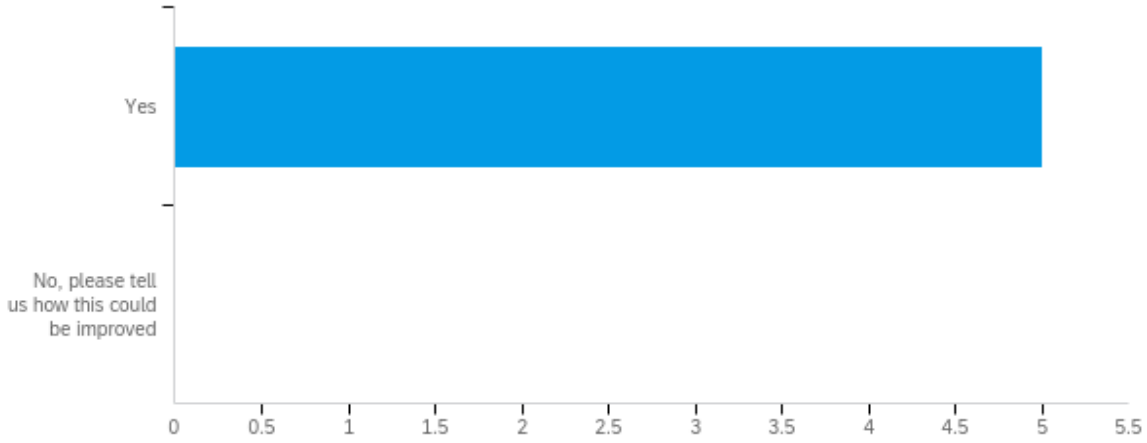
Question 8: Do you think you were provided with sufficient information about the session prior to attending?



#	Answer	%	Count
1	Yes	100.00%	5
2	No, please tell us how this could be improved	0.00%	0
	Total	100%	5

Question 9: In the breakout rooms you were asked the following questions. If you didn't get a chance to answer these at the time or would like to add anything else, please respond below.

These responses have been included in the Key Insights Summary above

Question 10: Is there anything else you would like to share about the session?
Pace was about right and researchers were very patient listening to off-topic answers
NA

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