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Guidance on Involving the Public in Health Data Research

This guidance document is for researchers involving the public in health data research.

Section A: Background

a) What is public involvement?

i. "Public involvement" is defined by the National Institute for Health Research (NIHR) as the public being actively involved in specific research projects or research in general to help shape the research. Research is carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them.

ii. "Public" is defined as "patients, potential patients, carers and people who use health and social care services as well as people from organisations that represent people who use services. This does not include the perspectives of the public and the perspectives of people who have a professional role in health and social care services."

b) Why involve the public in health data research?

i. The involvement of the public in research has been mandated by the NIHR for many years.

ii. It is considered a democratic right (in light of the fact that taxpayers fund most research). Being accountable and transparent about the research that is taking place is a part of this.

iii. It is ethically appropriate i.e. where stakeholders are affected by something, they have an ethical right to have a say in it

iv. Given that health data is often used without individuals' explicit consent, involving the public is critical to ensure that research carried out using this data is transparent, trustworthy and acceptable.

v. You get a better outcome if you involve those who have insight/lived experience of the condition. This insight can be used to make your research better, more relevant and impactful.

Section B: How to involve the public in developing a health data research project?

Set out below are suggested ways to involve the public in your health data research divided into the different stages of the research cycle (See Appendix A):

1. **Identifying and prioritising research**
   a) It is essential that a research topic is important for those affected by the condition and the general public (where appropriate), as well as for the researcher. The "Identification and Prioritisation" stage of research (see **Appendix A**) should be informed by those with lived experience of the condition in question.

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b) Although there are established methods of identifying and prioritising research topics (e.g. the Dialogue Model or James Lind Alliance Priority Setting Partnerships), these can be time and resource consuming, and may not always be appropriate. See some suggested alternatives below.

c) If the research affects a subset of the public (e.g. what effect does COVID 19 have on those being treated with immunosuppressants?), then it would be appropriate to have input from patients/carers of those on the relevant immunosuppressants. Please see **Appendix B**: "How to find people to involve" for more information.

d) If the research question could potentially impact a much larger proportion of the public e.g., testing and adapting a risk prediction tool to determine whether a patient should be admitted to ICU and what the likely outcome will be, then general members of the public without specific lived experience could be asked about this as they could potentially end up in ICU.

e) **Suggested ways to involve the public in identifying/prioritising research questions**, or to check the relevance of already identified research questions, include:

i. Undertaking an online poll:

- of members of the public asking them to prioritise research questions which could be answered using the data (or currently available data) which are relevant to the general population (use VOICE if this is available to you or Twitter)

- of specific groups e.g. those on immunosuppressants through charities or patient organisations and their Facebook groups or online forums, members of community groups through establishing contacts in these groups and third sector groups

i. Citing previous research projects which identified that patients/public considered the question to be a priority (including research questions identified as a priority through a James Lind Alliance Priority Setting Partnership.

ii. Having conversations with members of the general public/patients/family members/carers of those affected by the research question. Please see **Appendix B: "How to find people to involve"** for more information

2. **Designing your research project**

When designing your project, patients/public could inform the following:

a) **the inclusion/exclusion criteria for categories of data** to be included in the analysis, for example, does the age range need to be restricted or can it be wider?

b) **outcome measures.** For example, mortality may have been identified as a primary outcome measure, however, patients and the public may consider that morbidity is relevant to them, and this could be included as a secondary outcome measure. Talking to those affected by a condition can be very valuable in ascertaining what is important to them and may even identify something they are aware of from their lived experience which a researcher may not have thought about which is relevant to the research.

c) **The lay summary for either an application for funding or to help communicate your research plans.** In order to make a start on a draft lay summary, you might want to:

    i.   use The Up-Goer 5 Text Editor. This website is based on the premise that in order to be successful in communicating scientific knowledge, you should be able to distil the main concepts into a statement that only uses the ten thousand most commonly used words.   This website allows you to type in your statement and flags words that are not on the list and also lists these common words.

    ii.   Read the INVOLVE Make it Clear guidance

You should then ask a member of the public to read your draft lay summary to ensure that it really is in plain language and understandable.

3.   Managing your research project

a) Public involvement in research governance is expected by funders like the NIHR. A health data research project may not have a management committee overseeing it alike a trial steering committee, however, if there are management/steering group meetings for the project, then having a patient/member of the public take part in these can help to keep the research relevant and grounded and inform questions which arise from the patient/public perspective.

4.   Analysing the data

a)   It is possible to involve the public in data analysis and set out below are some ways in which the public can do so:

- **By checking the validity of conclusions and assumptions which inform the data analysis.** It is important for these conclusions and assumptions to be based on the values and current behaviour of the public which may change over time. This information will not always be available from scientific publications or may not be current, so checking conclusions and assumptions with people from relevant groups of the public affected by your research is important e.g. do people taking immunosuppressants usually take any other kind of medication which may affect how COVID 19 might affect them.
- **By ensuring that emerging themes and trends are interpreted from the public perspective as well as from the scientific viewpoint.** By way of example, perhaps some people taking immunosuppressants might have stopped taking them when the pandemic started as they were concerned these made them more susceptible to becoming severely ill from COVID 19 and this may have impacted the analysis. The public can also provide personal narratives to compliment or rebut trends and patterns in the data.
- **By enriching and improving the quality of the 'Discussion' about the results.** For example, the public may be able to provide a reason for an outlier in the data. This could be something to do with their medical condition or their behaviour that may have affected the results about which a researcher is not aware.

- **By engendering acceptance of the results of the research/modelling used and improved model validation by the public.** Being transparent and open about the methodology used to obtain the results can build trust in the research.
- **By identifying unanswered questions for future research.** At this stage members of the public can help advise on future research questions arising from trends and patterns identified in the data analysis which might require future exploration through looking at other data sets, linking data, or through a follow-up qualitative study to better understand trends identified in the data.

5. **Dissemination of the study results**

a) If public involvement is not possible at any other stage of the research cycle, there are very few research projects where it is not possible to involve members of the public in communicating the results in plain language to relevant groups

b) A scientific publication is rarely read (and able to be accessed) by the public who want (and are entitled to) know the outcome of research.

c) If results are not published or disseminated because they are not what was expected or are negative, there is a risk of other research repeating the same study and contributing to "waste research".

d) Sharing research results appropriately is part of being transparent and accountable about research (which is usually carried out with taxpayer money). It is essential to share research results with:

- the research participants where possible (without whom the research could not have taken place). These may only be the key findings and will not jeopardise the ability to publish these.
- those affected by, or those who will/may benefit from the research
- specific populations about which the research concerns e.g. those on immunosuppressants if the research question concerns the impact of COVID 19 on those patients. There may be a Facebook group or patient group forum through which you could disseminate a plain language summary of results.

e) **Suggested ways in which patients and the public can assist with the dissemination of research results:**
- By reviewing your dissemination plan. Although ideally you will have planned your dissemination strategy at the design stage of the research, this may need to be reviewed again when you are ready to disseminate the results to ensure the plan is still relevant, comprehensive and appropriate. The public can help you decide how to communicate the results for maximum impact. Members of the public can advise you on the most appropriate/accessible ways to share and communicate results with the public/patients/relevant populations. They can also advise on appropriate mediums for dissemination e.g. infographic, video.

- By developing and/or reviewing plain language summaries of results so they are clear and accessible to the research population e.g. information on NHS or GP websites, a

video, in different languages. Use the website [Up-Goer 5 Text Editor](link) to ensure your summary is plain language before you ask patients/members of the public to review it.

- Inviting members of the public to speak about your research results (with you) to those affected by the research question. This is a very impactful way to show the public's support for the research (as they will ideally be from groups who would directly benefit from the research).

- Giving members of the public an active part in writing up the research findings, e.g. developing publications (as a co-author) for open-access peer-reviewed journals, developing online content including infographics and videos, creating/reviewing leaflets for waiting rooms or community centres which explains the research

- By linking you to their contacts and networks of patient/public/community groups to whom the results can be disseminated, and which may be able to facilitate/fund follow on research e.g. charities.

6. **Implementation of the research findings**

a) Depending on the research, it may be that the public can play a role in implementing research results. For example:
   i. the public can inform any consequential changes to NICE guidelines
   ii. the power of the patient voice can be utilised to lobby a payer/regulator to change and/or implement a new service/device/therapy/intervention.

7. **Evaluating the impact of public involvement**

a) The public can assist you to evaluate the impact of public involvement (on the project and on the people involved (including researchers and public contributors). This can be done through:
   i. recording short and long term impacts from both researcher and public contributors' perspectives
   ii. by researchers' completing the Imperial Patient Experience Research Centre's Public Involvement Planning and Impact Tool. Please contact PERC for more information.
   iii. populating a [Public involvement Log (adapted by PERC)](link) throughout the project in order to be able to report impact to funders and the public contributors involved in the project.

Section C: Further public involvement in research resources and training

The Imperial Patient Experience Research Centre (PERC) has many resources to assist researchers with public involvement in research.

Please see our Rough Guide to Public Involvement for more information generally including information about addressing underrepresentation in research and the training and support of public contributors.

Please see our Public Involvement in Research Resource Hub for more information, examples and template documents (to use for public involvement including role descriptions).

Training

Please see our Public Involvement Training page for information about our free Public Involvement in Research course as well as other courses for researchers and members of the public.

Crohn's and Colitis UK Charity: Public Involvement Training – for members of the public

This training course is made up of an introduction, three modules, and a quiz.

- Module 1 has a good introduction or refresher on Public Involvement in Research.
- Module 2 covers Public Involvement in Health Data Research, including sitting on committees and explanations of terms.
- Module 3 covers Practical Examples of Public Involvement including Data Access Committees and Steering Committees.

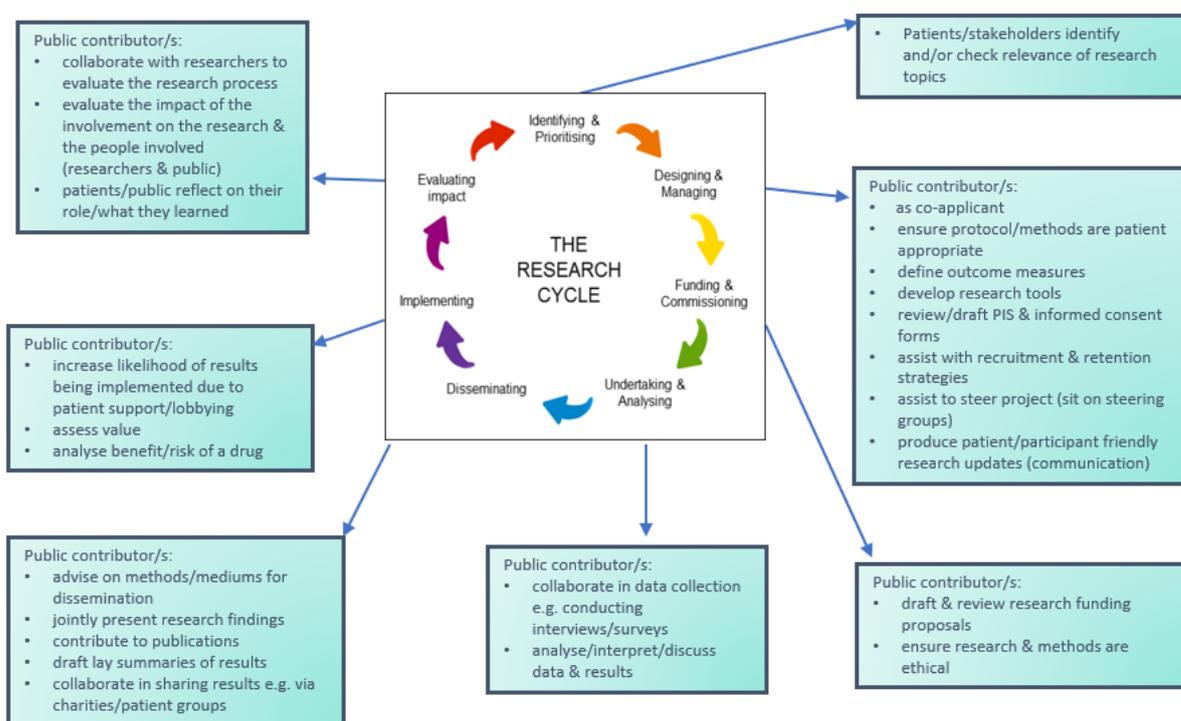There is a short quiz at the end which when passed provides a certificate.

Blog

Please see our blog with case studies of different types of research where the public have been involved.

Contact

Please email publicinvolvement@imperial.ac.uk

Appendix A

The NIHR refers to seven stages of the research cycle. For reference, we have included a diagram below which gives examples of ways that the public (defined above in Section A) can be involved at different stages of the research cycle. Not all of the examples in the diagram will be relevant for health data projects.

Public contributor/s:
- collaborate with researchers to evaluate the research process
- evaluate the impact of the involvement on the research & the people involved (researchers & public)
- patients/public reflect on their role/what they learned

- Patients/stakeholders identify and/or check relevance of research topics

THE RESEARCH CYCLE

Identifying & Prioritising
Designing & Managing
Funding & Commissioning
Undertaking & Analysing
Disseminating
Implementing
Evaluating impact

Public contributor/s:
- as co-applicant
- ensure protocol/methods are patient appropriate
- define outcome measures
- develop research tools
- review/draft PIS & informed consent forms
- assist with recruitment & retention strategies
- assist to steer project (sit on steering groups)
- produce patient/participant friendly research updates (communication)

Public contributor/s:
- increase likelihood of results being implemented due to patient support/lobbying
- assess value
- analyse benefit/risk of a drug

Public contributor/s:
- advise on methods/mediums for dissemination
- jointly present research findings
- contribute to publications
- draft lay summaries of results
- collaborate in sharing results e.g. via charities/patient groups

Public contributor/s:
- collaborate in data collection e.g. conducting interviews/surveys
- analyse/interpret/discuss data & results

Public contributor/s:
- draft & review research funding proposals
- ensure research & methods are ethical

(INVOLVE Briefing note eight: Ways that people can be involved in the research cycle)

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Appendix B

Finding people to involve.

a) PERC can provide you with further advice and possibly connect you to local public panels/contributors/community leaders/groups who have relevant lived experience or wish to be involved in public involvement in research.

b) As involvement has been carried out virtually during the pandemic, this has allowed some people who may not have been able to be involved previously, to do so, making public involvement more accessible to many.

c) **If you are a health care professional** (and/or know other health care professionals) who have access to patients/carers/family members, utilise these connections to invite people who might be interested in shaping/ informing your research to be involved. This does not require ethics approval as it is for public involvement not for participation in research.

- In a non-pandemic environment, we would suggest putting a poster up in an outpatient clinic inviting patients to get involved. Approaching people directly about being involved in research will obviously have to be done very sensitively and will depend on the health of the patient.
- If a patient has been very ill, they may not remember this time very well so having their carers and family members involved in the research may provide wider perspectives (even if the carers and family members were not permitted to be in the hospital with their loved one whilst they were unwell).

d) **If you don't have access to patients or know anyone who does**, you could attempt to get in touch with patients with relevant lived experience in other ways for example:

- Through connecting with patient or community groups affected by your area of research. We recommend doing this early (not just when you are applying for funding) so you have time to build trust and a relationship with them. Remember they are likely to have limited capacity and resource so will need time to be able to plan to work with you (and possibly funding).

- PERC maybe able to put you in touch with people with lived experience of your research area through their mailing list, the VOICE platform or their Young People's Advisory Network (17 to 25 years)

- Utilising other social media platforms e.g. Twitter and Instagram (this may be a preferable way to access young people).

Diversity is very important for public involvement. Although you don't need to "sample" patients for public involvement, you should actively seek out and involve people of different ages and from a variety of diverse backgrounds in order to be as representative as possible of your research population. These include people from groups from all the protected characteristics under the Equality Act 2010:

- Geographical location
- Age
- Disability
- Gender reassignment

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- Marriage and civil partnership
- Pregnancy and maternity
- Ethnicity
- Religion or belief
- Sex
- Sexual orientation
- Socioeconomic status
- Access to health or social care

Read more about diversity and inclusion in public involvement here:

https://www.nihr.ac.uk/documents/strengthening-our-commitment-to-equality-diversity-inclusion-and-patient-and-public-involvement-and-engagement-ppie/24697

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