Do patients and the public trust researchers with their health data?

Report of a 2019 workshop

Avril Kennan[1], Caitriona Dunne[2], Edel Murphy[3]

1. CEO, Health Research Charities Ireland (HRCI)
2. Head of Advocacy, Fighting Blindness & HRCI member
3. Programme Manager, PPI Ignite, NUI Galway

hrci.ie

About HRCI and its members

Health Research Charities Ireland (HRCI), previously known as the Medical Research Charities Group (MRCG), is the national umbrella organisation of charities active in medical and health research, together representing over 1 million Irish patients. Through support and advocacy, we represent the joint interests of our 37 members, working to improve health and prevent illness through research. We also run the Irish Health Research Forum, bringing together all stakeholders to improve health research in Ireland. It is our core belief that today's health research is tomorrow's healthcare.

Background

Since GDPR and the Health Research Regulations 2018 came into being, there has been much discussion and debate about the interpretation and implementation of the regulations in the context of health research. With some exceptions, such as the inclusion of patients and their representatives at Irish Health Research Forum events, most of the discussion, has been restricted to researchers and policy makers. In order to further expand the conversation to include patient and public perspectives, Health Research Charities Ireland (at the time called the Medical Research Charities Group) and PPI Ignite, NUI Galway hosted a workshop at the 4th National Public and Patient Involvement (PPI) Conference, in May 2019

The workshop entitled 'Should Researchers be Trusted with your Health Data?' was targeted at patients, carers and members of the public. It was a one-off workshop with a small group of people and therefore it is just an indicator of views that might be more widely held. The presence of a small number of researchers and industry representatives was very useful in stimulating discussion but the focus at the workshop was on the views of patients and members of the public. The findings from the workshop form the basis of this report.

Workshop overview

Participants

There were eight participants at the workshop, which included: 3 patients or carers, 2 members of the public, 2 researchers and 1 industry representative.

Structure

Fictional case studies were initially discussed to allow participants to consider and share their views on the practical and ethical issues of sharing health data for the purposes of research. These addressed a range of topics including the consent process, the re-consent of patients, the involvement of industry in research, the risks and benefits of clinical research, genomics and rare diseases.

Participants were then asked to vote on which information items they would most like to see in a patient information leaflet, at the time of consenting for their data to be used for research. Finally, they wrote postcards to policy makers expressing their hopes for research and for how they wish their data to be treated.

Recommendations

The workshop findings guided us in formulating the following recommendations:

1. All involved in health research should recognise that **views on consent are very personal** - there is no one single patient perspective in relation to the use of personal health data for research.
2. A **public information campaign** on health research is essential, in order to ensure an Irish public that is supportive of health research and understands the role of consent.
3. The **use of health data for commercial purposes** can be an issue for patients and therefore more education and transparency about the research process in its entirety are essential.
4. The requirement for **patients to give their personal time to a consent process** should be recognised and every effort made to facilitate them.
5. **Online, accessible and tiered information** on research projects should be provided as standard, to cater for varying degrees of interest in the research and the plans for data protection.
6. The **potential harm that re-consent could cause patients** needs to be carefully balanced with the need to keep patients informed about the uses of their health data and should be addressed on a case-by-case basis.
7. **Patient involvement** at all stages of the research process will be helpful in off-setting and managing potential issues relating to data protection and health research.
8. **Additional efforts to capture patient and public perspectives on health research and data protection are necessary**. It will be particularly important to understand of the views of particular patient populations, in order to guide decision-making in different fields of research.

The findings in more depth

As might be expected at a health research conference, participants at the workshop were broadly supportive of health research and recognized its value to their own lives and the wider population. This was particularly so in the case of those participants who are living with illness.

Views on the use of health data and consent

- Some participants expressed surprise that **compliance with the legislation which was in place at the time of consent,** for research which began prior to the Health Research Regulations, was no longer sufficient.
- For a number of the participants, the **sharing of their data with commercial companies** was a red line issue. This position waivered for some however, after discussion about the role of the healthcare industry in developing healthcare interventions.
- Concerns around the challenges of **truly anonymising data from rare disease patients** were raised.
- Some were **frustrated at the notion that they would be asked for reconsent** for the use of the data agreed to many years' prior while others felt that research had moved on to such a degree that they would **no longer be comfortable with their data being used without their re-consent**.

- The risk of **worry or upset being caused to patients and their families through re-consent** was highlighted by participants.
- Some participants expressed a concern with the idea of **people outside their care team accessing their data**, with one particularly prescient observation that, if they as a patient didn't even have access to their own health records, why should anyone else?
- Others were very happy for their **health data to be seen by anyone connected with the research**, with appropriate protections in place, in order to benefit their health and the health of others.

Views on the process of obtaining consent

- Some participants (but not all) had some **concerns over needed to read very long documents** as part of the consent process, feeling that it was disingenuous and based on a need to legally protect the research institutions.
- Others stated **a desire to be given in-depth information** about the research.
- All agreed that if it is necessary for the consent documentation to be long, then **sharing it with the patient in advance of the appointment** would be useful, to allow time to reflect on it.
- Participants suggested that it would be valuable to have an option of reviewing the documents in an **online accessible format**, with the option to **click and expand on aspects of interest**.
- The group suggested that if patients need to more than a few minutes of their personal time on the consent process, then **advance notice should be given**, in order for them to make the necessary arrangements e.g. car-parking.
- Participants felt that a request for **consent for research should ideally not happen on the same day as a diagnosis**, in order to give time to come to terms with the diagnosis.
- In relation to the use of their data for future research purposes, some participants felt that a **simple, granular consent would be appropriate**. This would include the following options: 1. broad consent for all future ethically-approved research, 2. consent to be approached again for future research or 3. no consent for the use of their data for future research.
- Some participants expressed concern about consent in **the case of people with reduced capacity or children**. Children, in particular older children, should have the option of expressing their own views on the privacy of their health data and to re-visit previous consent given on their behalf by their parents or guardians.

What information is important in a consent process?

As part of the workshop, participants were informed that when considering participating in health research they should always be provided with some core information, including details of the research, their contribution to it, risks and benefits and their rights in relation to the research. See the full list of core information participants were informed they should always be provided with in Appendix 1.

They were then asked: 'if you were participating in research, what other information would be most important to you as part of the consent process?' and given a list of items to vote on. Their compiled responses are provided in Table 1.

Table 1. **Patient and carer** votes (N=5) and **researcher and industry representative** votes (N=3), when asked 'if you were participating in research, what other information would be most important to you as part of the consent process?' (participants had six votes each and could allocate more than one vote to any one item). *The items receiving notes are provided in the footnote.*[1]

Ranking by patient/public	Information item	Ranking by researcher/ industry
1st (6 votes)	Description of what measures will be put in place to protect the **confidentiality of your data**.	Not ranked
2nd (4 votes)	Whether you will be informed of the **results of the research.**	Joint 4th (2 votes)
Joint 3rd (3 votes)	Whether you will be **advised of any finding from the research that could impact on your health**.	Not ranked
Joint 3rd (3 votes)	**Details of every possible future use of your data (and samples)** for research purposes.	Joint 1st (3 votes)
Joint 3rd (3 votes)	**Length of time your data will be kept** and arrangements for it to be archived or destroyed.	Joint 4th (2 votes)
Joint 3rd (3 votes)	Details of **who to contact with questions or complaints** in relation to the research.	Not ranked
Not ranked	Details of **who provides the funding for the project**.	Joint 1st (3 votes)
Not ranked	Details of the **approval by a Research Ethics Committee**	Joint 1st (3 votes)

[1] The items which received no votes from either patients/public or researchers/industry representatives

1. **Whether there is any intended follow-up contact** with you, as part of the current or future research.
2. A detailed description of any **planned genetic tests**.
3. **Identification and contact details** for all people with responsibility for your data i.e. the researcher in charge, the data processors, the data controller, the data protection office.
4. Details of **any person who will have access to your personal data**.
5. Information on **financial implications to you and whether any of your expenses will be covered**.
6. Details of whether the results of the research will be used for **commercial purposes**.
7. **Whether the personal data will be sent out of Ireland** and, if so, to where and why.

In their own words

Following the discussions at the workshop, participants wrote postcards to policy makers, stating their hopes for research and for how their data should be treated. These are their words:

My hope for research is to make life easier for people with similar illness to benefit from our contribution, especially through PPI and clinical trials. Please keep my health data confidential – ***a patient/carer***

My hope for research is that it contributes to the improvement in quality of life for everyone. Please ensure my health data is used ethically in perpetuity – ***a patient/carer***

My hope for research is that research is used for the good of all, access to better health regardless of ability to pay. I want my health data anonymised and used for good. Not shared indiscriminately – ***a patient/carer***

My hope for research is that it will benefit the health of the individual and community; that my input to what is important to actively research is taken into consideration; that it is not an end in itself. Treat my health data with respect and always seek my consent when my data is to be used – ***a member of the public***

My hope for research is that it be used ethically for the greater good. Please ensure my health data is not exploited for monetary gain. Thank you – ***a member of the public***

My hope for research is that it addresses questions of importance and is guided by the patient voice. Please use my health data to improve healthcare in Ireland in any way. Share it – ***a researcher***

My hope for research is to improve the health and healthcare of Ireland. Please use my healthcare data for research! – ***a researcher***

My hope for research is that it changes the way we provide healthcare to enable better targeted treatments for complex diseases. Please use and protect my data – ***an industry representative***

Acknowledgements

The HRB Primary Care Clinical Trials Network, who, with PPI Ignite at NUI Galway, organize an annual PPI Conference, provided the opportunity for this workshop. We would also like to thank Fighting Blindness for their contribution to the report in the form of co-author Caitriona Dunne. Finally, we give grateful thanks to all participants at the workshop for lively discussion and for sharing their honest views.

Appendix 1

Prior to voting on the information they would like to be provided to them as part of a consent process, participants were informed that when considering participating in research they should always be provided with the following core information:

- A plain language explanation of the **purpose of the Research**
- Details of the **types of data (and samples) that will be collected** and how they will be used in the research.
- Details of the expected **duration of your participation, any procedures involved** and possible **benefits or risks.**
- **A statement that your participation is voluntary,** your consent is **informed** and that a decision not to consent will have **no adverse consequences** on your medical care.
- **Information on your right to withdraw your data** and how to do that, if you change your mind about participating.

Health Research Charities Ireland (HRCI)
Digital office Centre
12 Camden row, Dublin 8, Ireland
T 353 1 479 3234
E avril@hrci.ie
www.hrci.ie

The HRCI is supported by pobal government supporting communities, Rialtas na hÉireann Government of Ireland, HRB Health Research Board