HDRuk
Health Data Research UK

Exploring public perspective on enabling acces to regional health data to support COVID-19 vaccine safety research –

Data and Connectivity National Core Study - Patient and Public Involvement and Engagement (PPIE)

Exploring public perspectives on enabling access to regional health data to support COVID-19 vaccine safety research

PPIE Workshop

Introduction

In Spring 2021 reports of blood clotting disorders associated with some COVID-19 vaccines began to emerge, especially in people under 40 years of age. These reports led to national immunization committees recommending specific age restricting policies for these vaccines.

To better understand these blood clotting disorders and any link to COVID-19 vaccines, several groups of researchers in the UK are currently analysing national, linked datasets, including hospital admissions, primary care (GP data) and vaccination status.

However, to rapidly identify possible cases of individuals attending hospital with blood clotting disorders possibly linked to COVID-19 vaccines, there is an unmet need for researchers to have access to rapid (near real time) hospital admissions data, including laboratory test results.

Rapid hospital admissions data is not currently available in national datasets. This data would also need to be linked to other key datasets, such as vaccine status, to help research.

 A group convened by the Data and Connectivity National Core Study at HDR UK are now working with three regions across England to investigate whether linked data sets available at regional level can provide information currently lacking from national data, and in a timelier fashion.

HDRUK is working with the following 3 regional organisations:
- o   CIPHA, which is based in Liverpool
- o   Barts Health NHS Trust, which is based in East London
- o   PIONEER, which is based in Birmingham

These three regions were chosen because these organisations had already started work to tackle this problem.

These three regions are the initial area of focus and this work is looking to be expanded to all regions across the UK in the future and used for different urgent health data research needs.

Workshop

We invited members of the public to participate in a workshop to understand public perspectives in making regional, linked health data available for research use, to support vaccine safety research and to consider examples and situations that go beyond vaccine safety.

We promoted this workshop across HDR UK patient and public networks, as well as working with OneLondon and CIPHA to engage patients and the public from their networks. We had 38 people register to attend the workshop, and 18 people attended on the day.

Ahead of the workshop we provided a pre-read document for participants to provide as much background and context as possible. This is to ensure rich discussion and effective use of time during the workshop.

At the beginning of the workshop, we asked attendees (via online tool '*Slido'*):

How comfortable are you with your routine health data being securely linked to other data sets (such as vaccination), anonymised, then being made available for approved research use?

Attendees answered:
- Very comfortable: 68%
- Somewhat comfortable: 21%
- Unsure: 5%
- Not comfortable: 5%

We spent the first 30 minutes of the workshop as a whole group. We presented background and overview to HDR UK, Data and Connectivity and the aims of the Acute Admissions Task and Finish Group. We also provided insight into why we wanted to involve the public and what we hope to understand from the public.

To ensure that attendees understood the pre-read and would be able to contribute to discussion we provided a summary on why rapid acute admissions data is needed for important vaccine safety research and an outline of key current and future research questions.

Attendees were divided into three breakout rooms, allocated into regions. Though due to uneven participant numbers per region, each breakout room this was only loosely allocated via region. Each breakout room had a region and content lead, as well as a PPIE facilitator. This ensured that region and content experts were on hand to answer any technical questions.

The breakout room facilitators each asked the same questions:

- *What are your initial reactions to this work?*
- *What do you need to know to be confident that the work is transparent, secure and trustworthy?*
- *What do you think about anonymised datasets being made available to researchers outside the region?*
- *What organisations would you be comfortable/uncomfortable with accessing this data?*

- *What do you think about additional data linkages from national data sets (such as vaccination status data) being made to routine health data which is held about you regionally to support this project and other urgent pandemic research?*
- *Uses of the data beyond a Covid focus? E.g., complications of new drugs, rapid assessment of new diseases or infections*

Themes

The following themes emerged from the workshop discussion:

Public benefit

The baseline for acceptability is that all research, data access, linking and sharing must be for the benefit of patients and the public. While it was identified that there are risks to this type of work, there was a strong consensus that the benefits outweigh the risks. This can be assisted by ensuring that appropriate safe guards are in place.

The perceived benefit to the public meant that attendees were supportive of this project being scaled up across the UK. Another clear theme that emerged alongside was the support overall of the public, if it meant that the NHS was benefiting. This is because the public see a clear link between benefit to the NHS and benefit to the public.

The role of the patient/public

Discussion around how much responsibility is with patients and the public to be actively seeking to find out about how their data is being used, or if researchers need to be providing that information more freely.

This did raise conversations between researchers and public contributors about how this would realistically work – given the amount of research happening, and that data is anonymised.

An agreed outcome was that involving patients and the public in the development of communications and engagement plans is vital to adequately ensuring the public is informed. This helps to build trust and transparency.

Additional data linkages

There were categorically no concerns around additional data linkages from national data sets (such as vaccination status data) being made to routine health data support this project and other urgent pandemic research.

There was also broad support for data to be joined up nationally if that was of best interest to research and outcomes.

As well, uses of the data beyond COVID-19 was supported, and it was felt that the learnings from COVID-19 should be used in other areas moving forward.

Recommendations

There was strong support and keen interest for this project and for the work to be scaled up, as long as the benefits to the public, NHS and researchers are clear. Detailed plans should be developed and delivered to communicate the project to the public. It was felt that the onus should not be with the public to be researching how their data is being used (as it is an almost-impossible task).

Involving patients and the public in a communications and engagement plan would be a beneficial next step in ensuring that patients and the public continue to be involved in a meaningful way to shape the project. They are best placed to advise on how to communicate to the public and identify priorities.

Next steps

This workshop to hear and understand public perceptions to this work, and the subsequent report will be useful in helping to inform the proposal to NHS England for scale up. This report will form part of a larger proposal and will provide a clear basis demonstrating support from the public.

Furthermore, this report will be used to help inform the regional development of Trusted Research Environments.

Finally, as mentioned above developing a communications plan, with patient and public involvement, is a key priority following this workshop.

Workshop evaluation

Particpants were asked to complete an evaluation survey post workshop. Respondents highly rated the communication, including pre read document, in the lead up to the workshop. As well, they were positive regarding the format of breakout rooms to give ample opportunity for discussion. Respondents were extremely positive rating the speakers giving high scores out of five.

Some participants felt that there was not enough time for discussion, and that the session could have been longer. As well, some felt as though the scope of the session could have been widened. This demonstrates the interest of patients and the public to be involved in this work and again highlights the benefits of a strong communication plan.

Appendix

Pre-read document: <u>available here</u>

Workshop agenda: <u>available here</u>

Workshop notes

Initial reactions:

- Don't see any problem with sharing data across regions
- Condition must be that it's secure
- Not happy with 'regionalisation' - feels that it should be a national approach
- Keen for data to be joined up nationally
- Some concern with the lack of data actually held by hospitals
- Generally don't see a problem however concerns arise if there are occurrences where it is easier to identify an individual patient (for example, ebola situation)
- As long as there is NHS benefit only, not industry.
- It is important to gain public trust through communication with different communities.
- Well needed project
- Time information is through, it's lost its value
- UK slow to respond to vaccine
- Speedier we can have reliable data is good for all research
- Timely as benefit to patients takes a long time
- Need to refute negativity so it doesn't affect all data research
- People may not want their name or to be contacted
- Think about those in public eye
- Critical factor is security of data
- How do you inform the public about security as many don't even know data is being collected about them?
- Safeguards are in place to prevent unauthorised use

What would you need to know to be confident that the work is: trustworthy, secure, transparent

- Trustworthiness starts at a basic level, e.g. is patient data accurate and reliable
- Data should remain within 'the NHS system', i.e. only be available to the NHS and those with accreditation to be able to utilise it
- Question who authorises this project? i.e. research ethics committee for the project?
- Helpful for the public to understand and be reassured about how their data is being kept secure
- Guidelines for protecting privacy and honouring confidentiality
- Fairly relaxed attitude towards data sharing as recognise that your priority is patient safety
- Need to recognise that there are groups of people that have concerns around this

- Emphasising the fact that this project is using de-identified data, that in itself is reassuring, but recognise that not everyone feels the same
- Transparency: good to publish findings and outputs; to know the research is being done
- Transparency: reassurance that the findings and outputs aren't pushed out for commercial gain
- Trade-off: don't spend loads of time writing up papers for the public when you could be using the time for the research (should be a balance)
- Accountability: don't want the research to disappear into a black hole and not be seen again. Shortish, interim reports might be the compromise
- We have to accept that there will be breaches, no matter how good restrictions are: it is a possibility, and therefore someone has to be responsible.
- When attending health appointments health care workers have a role in developing trust
- Trust can also be gained via faith groups, regardless of faith
- False information dealt with quick accurate information
- "I'll trust it if it's accurate"
- Delays in access to data can lead to mistrust
- Support for linkage but in terms of accessing – what is the process.
- People need to understand it to trust it
- Some people are against national data transfer and worry about anonymity
- Concern around security of data e.g., care.data
- Public education to be done
- Be clear on safeguards on how to ensure security
- Shouldn't be complacent
- Public education and organisations sharing protocols in an accessible way is essential
- Having an audit trail
- When you are transparent, make sure it's accessible
- Publish all decisions and updates on projects too

What do you think about anonymised datasets being made available to researchers outside the region?

- Very comfortable with this
- *PARTICIPANT QUOTE: "If I'm living here, and you're doing research there, I want to be able to get the benefit."*
- Are we just using this for research or are we using it to support the medical profession?
- Researchers should have the fullest access to data to support their research
- Don't have an issue with this, but not knowing or understand is a potential issue
- Expectations are important – why must I (the patient/public) have to go looking for information – why cant I be informed? Is it feasible to expect to be told?
- Useage isn't a concern, but important to know who, what where, when and why
- It would be good to know in advance and good to know impact/outcome afterward
- Sharing information as to how data is used builds trust – we can use the COVID experience
- Good to have national data infrastructure
- Benefits outweigh risks in terns of data outside region

What organisations would you be comfortable/uncomfortable with accessing this data?

- What about the private healthcare sector? Are they 'entitled' to the data?
- Concern is around selling the data, the data going to insurance companies so that they can set premiums, etc.
- Pharma companies an important area: is it a good thing for them to have access to the data? (Yes, but needs to have much more control than, say, the NHS)
- I just want to know that the NHS gets value and doesn't sell it cheaply
- Some members of the group are less comfortable with industry but overall are happy with the approach
- Need to talk to people who have concerns to better understand their concerns
- Community engagement is important as you're unlikely to have people who are skeptical attend these workshops

What do you think about additional data linkages from national data sets (such as vaccination status data) being made to routine health data which is held about you regionally to support this project and other urgent pandemic research?
- 100% this should be happening
- Can't see anything other than good out of this
- Not a concern – although it could depend upon size of region/issue being researched
- Need to be clear on how to opt-out
- Vaccine centre didn't record opt-out
- Does hospital records have opt-out
- If there are wider databases, ensure accuracy and consistency of data

Uses of the data beyond a Covid focus? E.g. complications of new drugs, rapid assessment of new diseases or infections

- Very positive – participants were really clear that it should be used to benefit public health and care outcomes
- There is real opportunity in COVID in which public perception and understanding of health data is at a high and there are positive putcomes, which could be used in other areas.
- Quality of care using more detailed data available in hospitals
- Complications of new drugs (currently done for cancer drugs but difficult for others)
- rapid assessment of new diseases or infections