

# Insight Report: Online public involvement session on the use of the Wynn Database for Metabolic Research

Halle Johnson, Ian Godsland, Nick Oliver, Maria Piggin, Parizad Avari, Desmond Johnston. On behalf of the NIHR Imperial Biomedical Research Centre.

Correspondence: [publicinvolvement@imperial.ac.uk](mailto:publicinvolvement@imperial.ac.uk)

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## Background

The [Wynn Database](#) comprises 29,245 records of metabolic information (e.g. blood pressure, blood sugar, insulin levels, weight etc) for 13,848 individuals which were recorded between 1965 and 2000 by Professor Victor Wynn's group, working initially at the Department of Metabolic Medicine, St Mary's Hospital Medical School and then at the Wynn Institute of the National Heart and Lung Institute. Data within the Wynn Database has been acquired from many different contexts including healthy volunteers, oral contraceptive users, coronary heart disease patients, heart failure patients, obesity clinic patients, and diabetes patients.



As the data within the Wynn Database were collected many years ago, at a time where it was not the norm to ask people what they would want to happen to their data in the long-term, much of the data within the database has limited or no consent for future use.

Researchers at Imperial College, London, who have preserved and currently manage the Wynn Database have been exploring opportunities to use the data for further research. The team have undertaken steps to achieve the relevant approvals and have recently been granted Health Research Authority (HRA) ethics approval and provisional approval from the HRA's Confidential Advisory Group (CAG) to use the data.

One of the conditions of approval from the HRA CAG was for the team *“to undertake further patient and public involvement, to discuss the acceptability of the proposed use of confidential patient information without consent”*.

## Purpose

A public discussion meeting was convened for the purpose of undertaking public involvement<sup>1</sup> to ascertain the acceptability of using data, which was unconsented for future use within the database, and to obtain public views on next steps for the database, including how this database may be used to inform further research in an appropriate and acceptable way.

## Session overview and agenda

An online discussion was hosted on Thursday 29 July 2021 (5pm to 6.30pm) via Zoom Pro and was attended by 18 members of the public who broadly represented the demographics and patient groups of individuals whose data is within the Wynn Database (see Appendix 1 for demographics). The online session was led and included presentations by three members of the Wynn Database team (Dr Ian Godsland, Wynn Reader in Human Metabolism; Professor Nick Oliver, Wynn Chair in Human Metabolism; Professor Desmond Johnston, Professor of Clinical Endocrinology). Facilitation support

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<sup>1</sup> 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”- NIHR INVOLVE - <https://www.invo.org.uk/find-out-more/what-is-public-involvement-in-research-2/>.

was also provided by two members of PERC and a Clinical Research Fellow from the Department of Metabolism, Digestion and Reproduction.

The aim of this particular online session was to:

- Introduce the use of patient data in research (including concepts of consent, anonymisation and data linkage)
- Introduce and provide an overview, of the Wynn Database (25 mins)
- Give attendees an opportunity to ask questions (15 mins)
- Facilitate small group discussions about the following questions (45 mins):
  - a. For what kinds of research would it be acceptable to use the Wynn database, where all those whose data it holds can't be asked to consent for their data to be used as part of further research?
  - b. We have plans to establish a Data Access Committee (with public representation) who will check that requests to use the data for research purposes are appropriate and for public benefit. Do you have any suggestions on how else can involve patients and the public within this work?

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. A PERC staff member was available to assist those who had technical difficulties during the small break out room discussions.

## Attendee recruitment

For this online meeting we wanted to involve patients and members of the public who represented the patient groups within the Wynn Database. Due to the rapid nature of the call, to involve relevant individuals, an email invite was disseminated through the following routes:

- Through existing contacts and patient groups linked to Professor Nick Oliver (Wynn Chair in Human Metabolism) and presenter at the session including:
  - Imperial College, London Diabetes Technology Group; and
  - The Guy's and St Thomas's diabetes peer support group.
- Through the VOICE North West London Research Involvement Network

Please see **Appendix 2** for further details on recruitment, event registration and technical requirements of the Zoom call.

## Key Insights Summary

Attendees of the discussion session on the 29 July 2021, provided helpful insights into their perceived acceptability of the use of data without consent for future use within the Wynn Database for further research.

Overall, attendees were accepting of the use of unconsented data within the Wynn Database for further research. Attendees noted that a dataset such as the Wynn Database '**doesn't come around too often**' and felt that it could '**potentially cause harm not to use it**' and highlighted its potential to **improve patient quality of life, advance science and understanding of disease**, and increase **opportunity for collaboration**. However, critical to proceeding with its use was the need for the research being undertaken to have clear **patient and public benefit, for the database to be secure, for the data to be properly anonymised and have restricted access, or for a consent process to be in place for third parties**.

However, attendees also noted concerns relating to the potential for **unintentional harm due to lack of consent** and how **generalisable research findings from the Wynn Database may be for current and future patients as tests, measurements and treatments may not now be relevant**.

Attendees agreed that further involvement of patients and the public would be necessary to **minimise unintentional harm**, to **ensure research being undertaken was for patient and public benefit**, to provide **ongoing review as to the ethical appropriateness** of research and to **inform decision making and consent processes relating to the Wynn Database**. Key to these aspects was ensuring that patients and the public were **involved meaningfully, provided with adequate support and those involved represented diverse groups**.

Reflecting on how the Wynn Database team should communicate and engage further with patients and the public, it was suggested that **feedback should be provided at all stages** from updating, linking, and using the Wynn Database to feeding back any research findings and should be **shared across multiple channels**. Some attendees who had taken part in research previously noted the **frustration of not receiving any feedback as to the findings of the study** they had been involved in and also being unable to find relevant publications relating to the research following participation. Efforts should also

be made to **reach under-represented groups** and **those who would benefit most from the potential findings** from the Wynn Database.

### Breakout room Discussions

Insights raised during the breakout room discussions have been themed under the two questions posed in the breakout rooms and briefly summarised below:

*For what kinds of research would it be acceptable to use the Wynn database, where all those whose data it holds can't be asked to consent for their data to be used as part of further research?*

Following the initial introduction to the Wynn Database, attendees considered in what ways they felt it would be acceptable for the Wynn Database to be used for further research. The responses captured attendees' personal perspectives on the future use of the Wynn Database for research, the benefits of the using the Wynn Database as well as any concerns and considerations for future use. Responses are themed and summarised below.

#### *Patient and public perspectives on the use of the Wynn Database for future research:*

Many attendees were in favour of proceeding with use of the Wynn Database for future research:

- I'm pretty relaxed about the use of the data really
- probably, people would have liked their data being used in this way,
- I know the data is, is totally anonymized so I haven't got any qualms about it being used.
- I actually do agree that if data is already there, we should use it
- if I was long gone, I'd be fine with that sort of data being used and even if I was still alive really
- my starting point is very much why wouldn't you use this data and exactly as others have said, it kind of seems a sensible thing to do and there's not really a very good reason why anyone could object to that
- coming back to the overall consent problem that you're facing, in my mind, everything points to it being not a huge problem you know

With some attendees also highlighting that from their perspective the perceived benefits outweighed the potential risks:

- what harm is actually caused by using it, it's like balance that against the harm these diseases inflict on people on a daily basis.
- I think what we also need to balance up is the potential harms that could be unintentionally created if we don't use this data

And others commenting that they believed consent to continue further research using this database was implied:

- it's like when you pass away do you want to donate your organs, I always tick everything except for my eyes but I don't know if that will be acknowledged, because I'm going to be dead anyways if that happens. So, but knowing that it will go to research or be used for somebody else who could benefit. But even if I didn't, I'd hope my body would be used for research or, you know, future studies.
- as a very young diabetic, you know, people are always wanting to take blood for various research projects or they're asking questions and even from when I was, you know, a child the idea of either not consenting, or saying, at some point, you can't use my information anymore, it didn't occur to me at any point.
- I think that by taking part in a research study or a project, you're ultimately... it's almost like its implied consent to do whatever the researchers see fit with the data that they collect

For many, future use of the Wynn Database was dependent on the research activity undertaken being for patient and public benefit:

- I'm quite happy for it all being used for the benefit for the future, good health for people who will benefit from it
- I want this information to be used for the benefit of others and not to be hindered in its use really
- as long as it is for the sake of science and for the benefit of people

It was also relevant that the risk of unintentional harm was minimal, due to diligence of going through appropriate approval processes:

- there's also the sort of the presentational and PR issue which I think is probably, you know, almost in some ways as important that you know you've been through exercises for the study for instance you know to get patient views and that you know it's been through all the committees and stuff

However, others did not feel that it was appropriate to use the data while some individuals whose data was within the database were still alive:

- much as I hate to say this, unless new consent can be obtained, I feel the use of the data for research outside of the area of original consent shouldn't be allowed. I don't feel anonymizing the data should nullify the original consent/agreement. However, once participants are no longer alive, I would not have the same objections.

#### *Potential benefits of the use of the Wynn Database*

Throughout the breakout room discussion attendees highlighted a number of perceived benefits of using the Wynn Database for future research, these are summarised below:

##### **a) To improve quality of life for patients**

- a lot of the people who've lived with some of these illnesses, they would have felt how overbearing sometimes it is and how difficult it is. So, to use the data to help advance things, I think we really are fine about it

- Personally, to me. I don't care what information is used, as long as I get something out of it that will get rid of this horrible disease for all of us. It is a pain being a diabetic
- Can be used to the advantage of people living with all the conditions we have to put up with and hopefully improve outcomes for them in the future.
- what we can learn from this might actually make people's lives better.
- using the data unpicks opportunities that affects millions and millions of people around the world.

**b) To extend research into other areas of health**

- To use it as a pilot study for more health issues.
- Lupus and really all autoimmune diseases
- If the database could not only just be for diabetes but be used in other things like, you know, the age-related menopause knows that aspects as well as the diabetes and cancer and heart condition

**c) An existing and unique resource**

- I think it's really important to use this data, because it's an enormous database system of so many people's records
- You know this longitudinal data, it doesn't often come along, that we can get this kind of resource.
- I think there's lots to learn if data is already there. And we can replicate it. Not just replicate it, but can we learn from it and do something with it.
- I was on lipid lowering [medication] since diagnosis in the 70's. So, a lot of the patients will be too. It's [the Wynn Database] not that out of date really.

**d) To answer current unknown questions and advance science**

- I go to my diabetes appointment, and I've seen other consultants for heart issues, and you know, so often, they will say, "well I just don't know, and the only way we will know about the impact of this really will be with time".
- To look retrospectively at what's already happened, is there a repeating pattern that we can create, again, the same results from what happened previously. Have we changed in any way in our society, our culture, our demographics, has that impacted on the results of our health from previous years to current age?

- Will the Wynn Database research be able to look back to when people got diabetes and when people first noticed it, and what the reaction was, and how do they think they got it?
- e) To advance understanding of interaction of diseases**
- The crossover of the impact and the interrelationship between type one diabetes and other autoimmune conditions, that is, particularly where I think something like this could be of benefit.
  - Looking at that interrelationship between those different diseases and what you might learn from risks of x y and z, if this is the case then this might be the proportion or their real relative risk for later disease
- f) Opportunity to foster collaboration**
- There has to be some understanding that in today's world, Imperial works with the NHS and that they might work with AstraZeneca [pharmaceutical companies], through partnership working. And that isn't the wrong way around because the NHS can't afford to deliver on some of these activities
  - Linking to other data sets like charity sort of datasets you see Diabetes UK, British Heart Foundation, and the Juvenile Diabetes Research Fund (JDRF)

However, many attendees considered that the use of the Wynn Database for future research to be conditional on the following:

**a) Access restrictions and/or consent processes for third-party and private sector**

- I think the interface between public and private, is becoming more and more blurred and I don't know the answer in terms of the distinction between working with a pharmaceutical company using an anonymized database, feels like that's more justifiable than other areas of the spectrum where maybe parts of the NHS have been fully kind of externalised
- I think the caveat of protecting it from full access into the private sector is probably a good idea, but you know working with drug companies I don't see a problem with, as long as they don't have direct access to the database.
- As long as it is non- profit

**b) Proper anonymisation of data**

- There are people who have concerns, and partly those concerns are about security, and about making sure that pseudonymized data, remain pseudonymized.
- When the data are anonymised, I can't see why they can't be used for any research that will benefit public health and a better understanding of disease processes.

**c) Ensuring data security**



- We know that security-wise, that there are security breaches that happen at times
- It just doesn't help that you keep hearing in the newspapers all the time data breaches, and, you know, not necessarily intentional, but you know unintentionally it has been happening as well, so it doesn't assure people.
- I am quite sort of keen to protect my own data I have to say, I am not very easy about sharing information easily.
- I'm aware that actually issues around primary care data at the moment that will cause people some unease

Attendees also expressed concerns about the future use of the Wynn Database for research which are set out below and themed:

**a) Issues around consent and contact**

- If some of the youngest participants as you said are like seven or eight, it's the parents who have made the decision. So, for your youngest ones, those might be harder to do without actually speaking to them because it wasn't their personal opinion
- The key ethical thing for me is does the lack of consent, lead to harm and nothing that I've heard today suggests that it would, however if there is a bit of conceptual possibility that that might be the case, then I think, it doesn't mean it's a blocker, but we've got to kind of consider what the implications of that might be
- If NHS digital is matching the records to the current patient records, it could be possible to write to them to say, your historic data is being used if you got a problem with that, let us know. I'm not actively suggesting that I can see that is a whole world of pain, potentially, but I'm not sure it's entirely true to say it's totally impossible.

**b) Generalisability of the data**

- Since the 60s, and right through to the completion of the Wynn database, healthcare, people's general health treatments for heart disease for diabetes for cancers, they've massively changed, they've massively improved, so are we sure that the data that is being collected in the Wynn database is actually going to be as useful for everything, as we're perhaps expecting it to be.

*We have plans to establish a Data Access Committee (with public representation) who will check that requests to use the data for research purposes are appropriate and for public benefit. Do you have any suggestions on how else can involve patients and the public within this work?*

Attendees also considered the establishment of a data access committee and other opportunities for patients and the public to be involved and engaged in the activity associated with the Wynn Database. Responses focused on the acceptability of public representation on a data access committee, the intended purpose of such a committee and considerations required to set up such a group. Attendees also discussed wider communication and engagement strategies including relevant platforms for communication and strategies for reaching under-represented groups. Responses are themed and summarised below.

Attendees felt that the establishment of a data access committee was an important aspect of governance of the Wynn Database and associated requests to undertake future research using its data:

- Good idea.
- I think it is a brilliant idea
- Sounds like another sensible idea
- Oversight of future requests is important, not just for this dataset here and now, but for the precedent it might set.

Commenting further on the potential role of the public representatives on the committee, attendees highlighted the following:

- public representation is extremely important to prevent such a committee turning into a collection of like-minded individuals i.e., an "echo chamber". Professionals ultimately do have to be accountable to members of the public and the wider society.
- I agree with some checks and balances, but then, you know, part of me doesn't want to hinder the science really

#### *Considerations of setting up the committee:*

##### **a) Ensure diverse representation**

- They will not necessarily represent everybody's views. I'd like to see in this PPI future representation that different kinds of people with different concerns
- A wide pool of PPI reps would be best

- It's important to make different groups of people accessing this PPI group
  - I wonder how the public representation would be selected. What would the ratio of people involved in research/use of data vs public representation be?
- b) Patient and public need to be involved meaningfully in decision-making process**
- Will the Data Access Group have teeth? It's very good to put on paper, processes, and governance but I fear that the public needs to have representation but also the independence to challenge, and if it says no, it means no
  - If we're going to have governance and involvement of the public, that the public are not seen as a token gesture to be on that board or part of that conversation, it needs to have evidence that the public are also allowed to have that influence
  - Medical directors don't have all the answers. People living with the condition have a lot of answers, and people living with the condition give the best honesty about it in terms of going forward because they're already invested in trying to get better every day.
  - Would their voices really have an impact?
- c) Provide adequate support for those involved**
- It's so easy to be overwhelmed by people participating they're really expert patients and then you kind of feel ah well I didn't understand it, and I don't feel like I can ask this question or whatever everybody seems very enthusiastic.
  - There needs to be some kind of way of allowing people to understand the information you're presenting, i.e., supporting people who may not be used to that kind of environment or a data access committee to be supported to be part of that
  - I'd consider it essential for them all to have a full briefing on that role before being appointed.
- d) Involve people in formulating research ideas**
- [In response to asking whether patients/public should have the opportunity to put forward possible research questions/ideas which the Wynn Database may be able to answer] people might feel more ownership and actually also more engaged in actually what happens to the data currently and actually feel more willing to participate in research going forward. I think it'd be really good idea.

### *Communication and Engagement with the Wynn Database:*

- a) Be engaging**
- It has to be applicable to the person.

- You want it to be engaging, eye catching, connected to good resources to fulfil what you need

**b) Communicating findings and feedback**

- Patients and the public need to be kept informed that historical longitudinal data (their data) is kept over many decades and has potential benefits for many years to come.

**c) Use multiple channels**

- Not everyone has access to virtual means
- Important to provide access not just online but different ways of reaching people not just going on websites but trying to find other forums that actually, this can be presented like balance magazine, Diabetes UK annual conference, and JDRF and their various publications as well
- You do need to maybe make some sort of effort to contact people perhaps who have forgotten digital means of responding, but don't know if you can do some things through the hospital to contact patients attending clinics
- Writing on notice boards in outpatient clinics, via social media channels, the NHS Choices website, the NHS app, and via the BBC and other news websites under "health".
- look at patient groups and PCNs (primary care networks)

**d) Reaching under-represented groups**

- It's pretty hard and the obvious route is through the clinical side, if there's a relevant finding to them then it can be discussed with them by their clinician
- By "boots on the ground" not trying to do it digitally
- Don't underestimate that in this room of eight you might have 100 connections of people that you could be reaching out
- There are already existing networks within London, for example, and you can engage with the leads of those groups

## Appendix 1: Demographic of public attendees

**Table 1: Demographic characteristics provided during event registration for discussion group (N=18)**

Characteristics	n (%)
<b>Age (in years)</b>	
Mean (range)	49 (31- 81)
<b>Age groups (in years)</b>	
18-24	0 (0.0%)
25-34	1 (5.6%)
35-44	3 (16.7%)
45-54	3 (16.7%)
55-64	5 (27.8%)
65+	4 (22.2%)
Prefer not to say	0 (0.0%)
Not provided	2 (11.1%)
<b>Gender</b>	
Female	10 (55.6%)
Male	7 (38.9%)
Non-binary/Gender Variant	1 (5.6%)
Prefer not to say	0 (0.0%)
<b>Ethnic group</b>	
<b>White</b>	
English/Welsh/Scottish/Northern Irish/British	11 (61.1%)
Irish	1 (5.6%)
Gypsy or Irish Traveller	0 (0.0%)
Other White background	1 (5.6%)
<b>Mixed/Multiple Ethnicity</b>	
White and Black African	0 (0.0%)
White and Black Caribbean	0 (0.0%)
White and Asian	1 (5.6%)
Other Mixed/Multiple background	0 (0.0%)
<b>Asian/Asian British</b>	
Indian	3 (16.7%)
Pakistani	0 (0.0%)
Bangladeshi	0 (0.0%)
Chinese	0 (0.0%)
Other Asian background	0 (0.0%)
<b>Black/African/Caribbean/Black British</b>	
African	0 (0.0%)
Caribbean	0 (0.0%)
Other Black/African/Caribbean background	0 (0.0%)
<b>Other</b>	
Any other ethnic group	1 (5.6%)
Prefer not to say	0 (0.0%)

## Appendix 2: Event registration and Zoom call set-up

### *Attendee recruitment*

For this online meeting we wanted to involve patients and members of the public who represented the patient groups within the Wynn Database this included individuals with lived experience (as a patient or carer) of cardiovascular risk factors (high blood pressure, obesity), diabetes, cancer and/or heart disease. Due to the rapid nature of the call, to involve relevant individuals, an email invite was disseminated through the following routes:

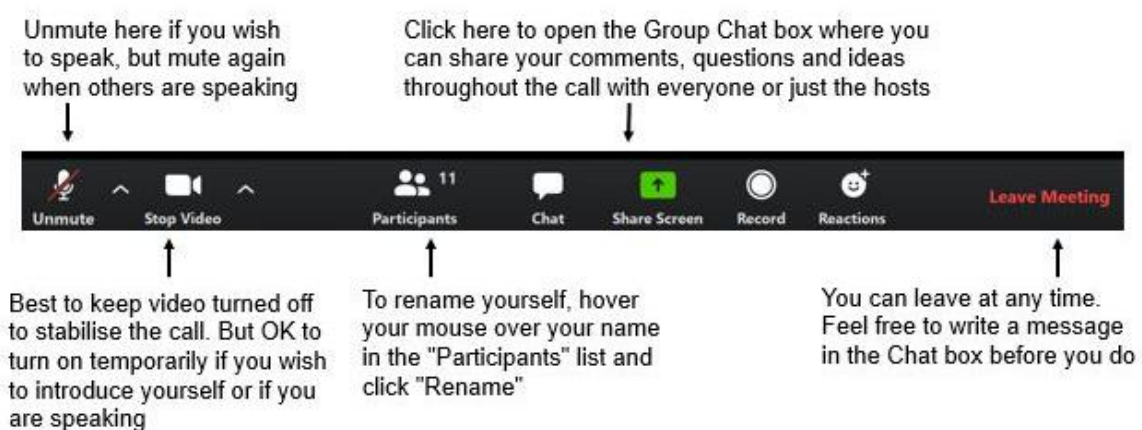
- Through existing contacts and patient groups linked to Professor Nick Oliver (Wynn Chair in Human Metabolism) and presenter at the session including:
  - Imperial College, London Diabetes Technology Group; and
  - The Guy's and St Thomas's diabetes peer support group.
- To individuals with relevant lived experience within the VOICE North West London Research Involvement Network

### *Event registration*

Attendees were asked to register for the call via an Imperial Qualtrics form, which included providing some basic demographic details. Twenty-seven individuals registered for the call who were given direct access to the Zoom call by the Imperial Patient Experience Research Centre Team.

### *Zoom call technical requirements and troubleshooting*

Zoom is a relatively easy platform to use, both from the attendee and facilitator perspective. Attendees may not have had much experience with Zoom, so supporting troubleshooting, where the team can, is a key component to ensuring that participants can join the call and feel included in the work.



The team shared a holding slide that provided attendees with tips on how to navigate and use Zoom and also did a quick run through of these once the meeting began.

The team set all facilitators up as co-hosts, which supported attendee management as well as troubleshooting. Each breakout room had a second co-host who helped with facilitation of the breakout room and manage attendees' questions.

Co-hosts were able to record breakout rooms to their local computers and use the notes and audio recordings after the call to write notes. This is useful to provide a record of what was discussed and supports rapid collation of the key insights, comments, and questions.

### Appendix 3: Questions asked by attendees following the presentation

- Will the database become a sellable asset to private interest?
- Is there any reason why some of the data needs to be identifiable for research purposes.
- How is the Wynn Database used with existing/current studies at Imperial?
- Do you know what proportion of individuals whose data is within the database are now deceased or are still alive?
- Can we ask those still alive if they consent directly?
- What's the age range of the participants in the database?
- Are there plans for an independent ethical steering group available to address requests to use the data?
- For those who may have died but who went through other hospitals not part of the Wynn database, will you be able to link it with other datasets via the NHS no. e.g via Hospital Episode Statistics etc?
- I'd imagine researchers would be very keen to access this database- will due consideration be given to their participation in PPIE for ongoing checks to avoid possible bias?

#### Comments:

- I would imagine that the research question relating to age-associated changes in insulin sensitivity would be of great benefit
  - In response: Agree and links to cancer
- I imagine many of those that originally took part in the research and lived with chronic illness would support the use of their data to assist others in the future