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Health and Care Research Wales

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

Using confidential health data to invite people to participate in research:

A Public Dialogue to inform UK policy

Alex Newberry

Welsh Government

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Disclaimers

This story is unfinished……

I'll try not to bore you……

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The bit you know…

Evidence has shown that research active hospitals have better patient outcomes, even for patients not on the research trial

But… embedding research activity in NHS care continues to be a challenge

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Motivating Questions

how do we balance the ability to work flexibly and innovatively to offer research options to patients, without infringing their expectations of privacy and confidentiality?

And…

Is inconsistent interpretation of information governance rules a barrier to effectively providing research as a care option to NHS patients?

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What we are and are not talking about…

General Data Protection Regulation (GDPR), Data Protection legislation

- *Lots of requirements, but mainly positive of enabling research*

Common Law Duty of Confidentiality

- information confided by an individual should not be used or disclosed further, except as originally understood by the individual, or with their subsequent permission
- sharing information in line with what they understand happens -or 'reasonably expect' - gives rise to concept of implied consent

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What we are and are not talking about…

Implied Consent

- Implied consent means that in certain situations, we don't need to ask for a patient's permission every time their health information is used for their care, because it's reasonable to assume they'd be OK with it
- Shorthand version: "for direct care purposes"

Implied Consent can apply to discussing individual's health information with colleagues to consider whether a research study is a potential care option for that individual

Implied Consent cannot apply to accessing or sharing an individual's health data for research where there would be no change to an individual's care

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'Research as Care Option'

- Research that involve testing a treatment, or a diagnostic procedure, or a preventive measure, **relevant to a patient's health** (i.e. a condition they have, or their susceptibility to illness, or their overall health)

- Can apply even when participation would not guarantee a benefit for those choosing to take part

Relevant circumstances:

- the research intervention is a treatment, or a diagnostic procedure or a preventative measure and there is uncertainty (equipoise) about the best care option for a patient or set of patients.
- the research involves comparison between one or more care options, or comparison of a care option with placebo, and patients will be allocated or randomised to a care option.
- the intervention is tested in a population that is intended as a future target population outside research.

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What needs clarifying?

When it is appropriate to rely on implied consent to identify and contact patients who may be eligible for research-as-care opportunities?

- What are the boundaries of implied consent?
  - Different people and organisations interpret and apply it in different ways
- What do the public ‘reasonably expect’ to be happening to their data?

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Our Approach

- Undertake public dialogue activity to get input on ‘reasonable expectations’ on our core question

  When it is appropriate to rely on implied consent to identify and contact patients who may be eligible for research-as-care opportunities?

- Engage with National Data Guardian and Health Research Authority to use dialogue findings as basis for new guidance

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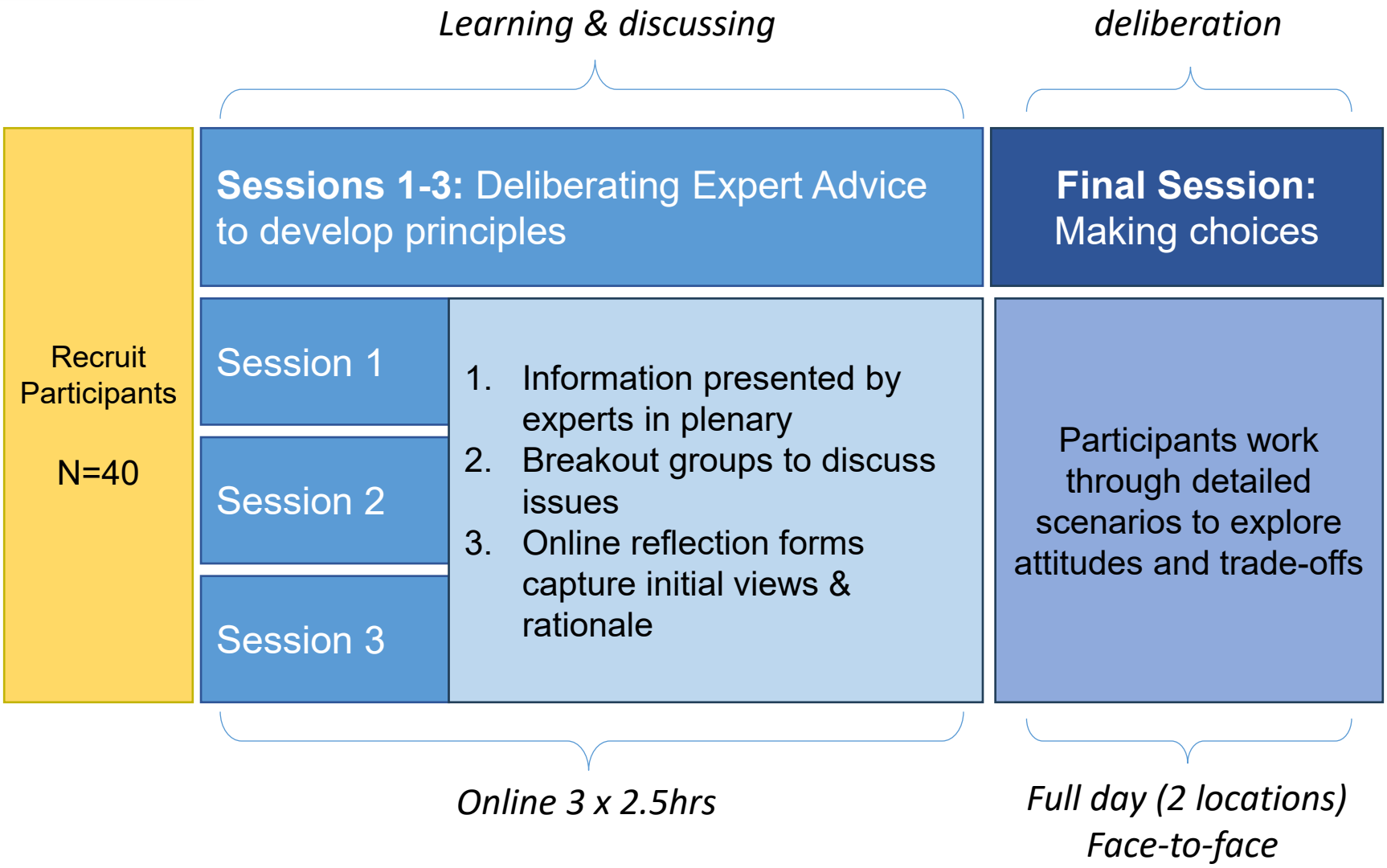
Dialogue Design



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Building the content

Basic structures of NHS Wales

What is a medical record, what information is in it, etc

How data is shared within & between organisations

How is data looked after in the NHS: rules & safeguards

What is health research

Research as a potential care option

Why might NHS staff share patient data with other staff & when does research options come into it

Who are the NHS staff, and how might they be involved with an individual's care

Types of research staff

Concept of implied consent

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Content agreed

Sessions 1-3: Deliberating Expert Advice to develop principles	
Session 1	The health system, Health data, medical records, safeguards
Session 2	Health research, ‘research as care’, implied consent
Session 3	Professionals involved in research as care, who might be accessing data & why, how the interpretation of rules is inconsistent

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Lacking spice!

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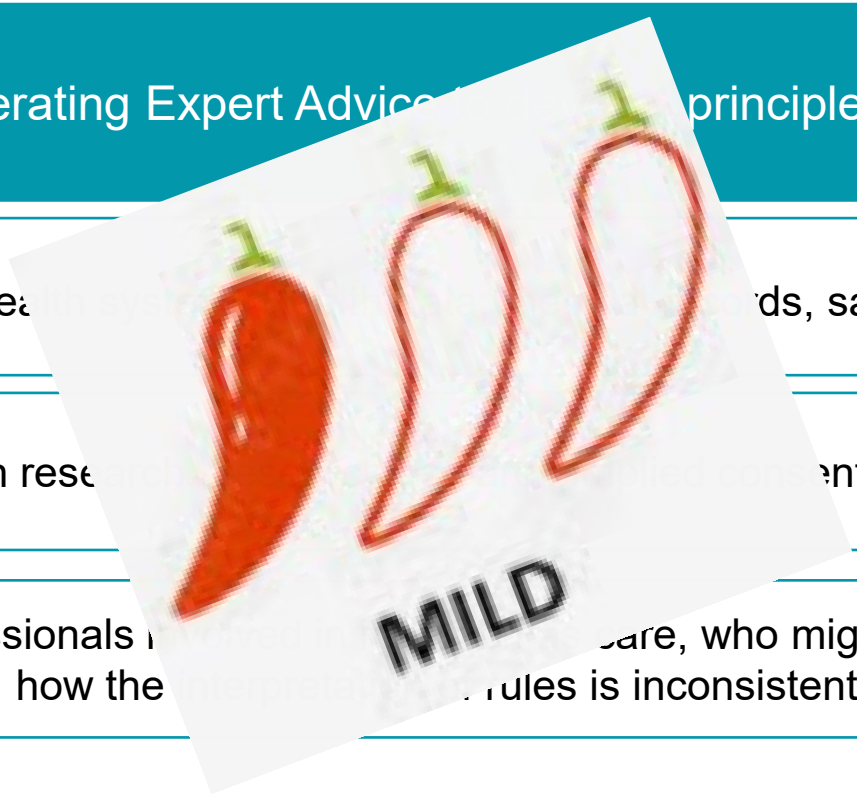
Session 1	The hea[illegible]rds, safeguards
Session 2	Health rese[illegible]ent
Session 3	Professionals [illegible]are, who might be accessing data & why, how the [illegible]rules is inconsistent



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Now with added spice!

Sessions 1-3: Deliberating Expert Advice to develop principles	
Session 1	The health system, Health data, medical records, safeguards
Session 2	Health research, ‘research as care’, implied consent Research doesn’t offer a ‘guaranteed’ benefit, role of placebos
Session 3	Professionals involved in research as care, who might be accessing data & why, how the interpretation of rules is inconsistent

Understanding Patient Data

NHS Health Research Authority

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Building the Scenarios

Creating nuanced scenarios to test incremental expansion of scope of implied consent

Primary care

GP sharing data with local GP cluster

Secondary care

Non clinical staff looking at records to support research as care options

Primary care

GP sharing data with national research network

Secondary care

Specialist services staff not seen by patients (e.g. genomics service staff)

Interesting variables to explore

Does perceived sensitivity of data impact views

Does perceived severity of condition impact views

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Building the Scenarios

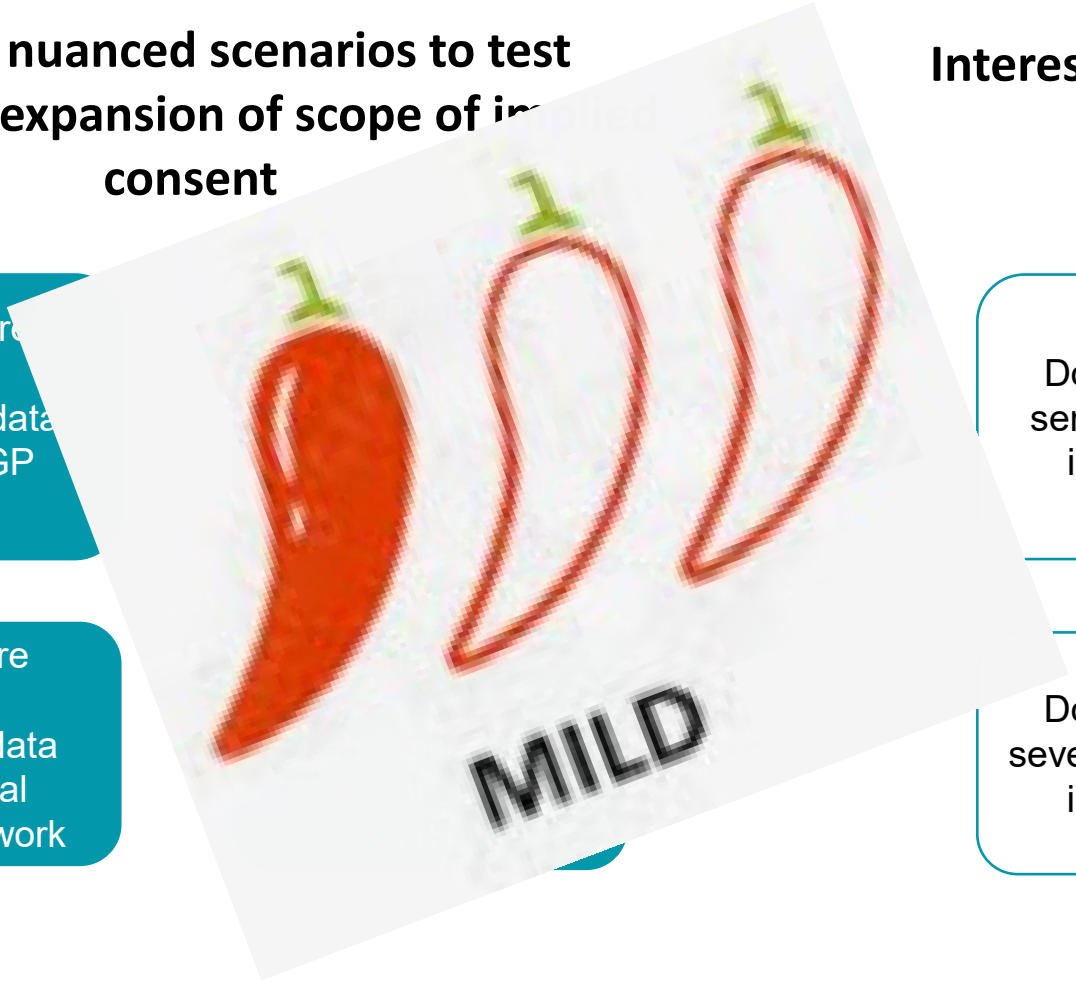
Creating nuanced scenarios to test incremental expansion of scope of i… consent

Primary car…

GP sharing data… with local GP cluster

Primary care

GP sharing data with national research network



Interesting variable to explore

Does perceived sensitivity of data impact views

Does perceived severity of condition impact views

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Final Scenarios

'Stretching' scenarios to test boundaries of implied consent for identifying and contacting individuals for research as care options

Scenario 1

1a. Data access within a GP cluster between health professionals
1b. Data shared with national primary care research network based in another NHS org
1c. Testing if access to data about a 'sensitive condition' changes comfort levels

Scenario 2

2a. Data accessed in hospital by non-clinical admin R&D staff to support care discussion.
2b. Testing if access to data when condition is less 'severe' changes comfort levels

Scenario 3

3. NHS Organisation working with University Trials Unit – data accessed by non-NHS staff

Scenario 4

4. Deployment of AI tool on all NHS Organisation patient data to match individuals to trials

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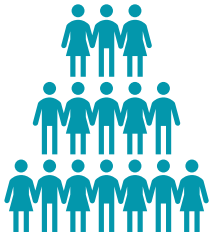
Delivery



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Sessions 1-3

Delivered April 2025

Session 4

Face to Face deliberation

Delivered 11 May 2025

Report being Drafted

Due 31 July 2025

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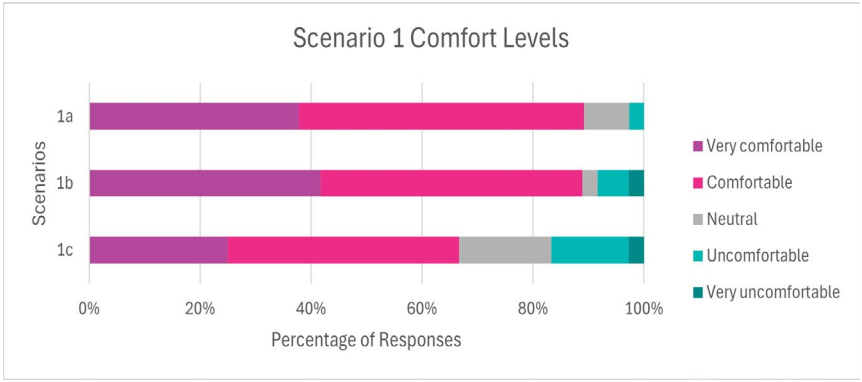
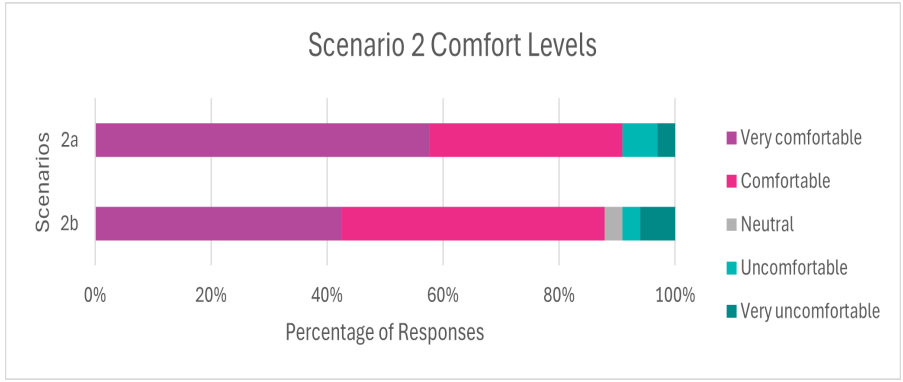
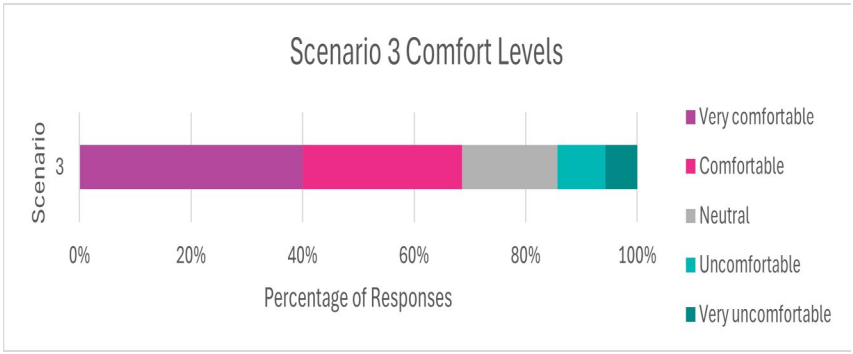
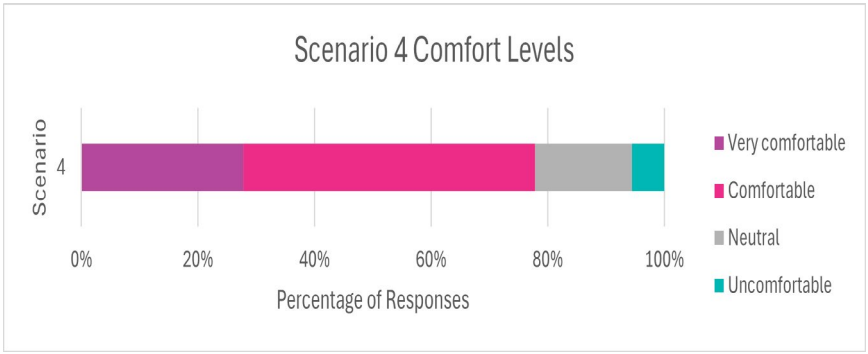
Teasing the results









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What's next…

Receive the report

Meet with National Data Guardian and Health Research Authority to discuss results

(hopefully) Develop guidance for NHS cross the UK