



UNIVERSITY OF  
LIVERPOOL

A wide-angle photograph of the University of Liverpool campus. The central focus is the large, ornate red brick building with a prominent clock tower and spire. To the left is a modern glass-fronted building. In the foreground, a paved plaza with people walking and sitting on benches is visible. The sky is blue with scattered white clouds.

**The purpose and justification for  
public involvement in health  
research: ethical and legal  
perspectives**  
**Dr Lucy Frith**

# Outline

1. Examine the terminological ambiguities that underlie the use of different terms like public and patient involvement (PPI), user engagement etc.
2. Consider the conceptual foundations of the justifications of PPI
3. Make an argument that PPI should be seen as a form of democracy

- Many of these arguments apply to PPI in health care in general, i.e. service redesign, service delivery and policy
- But I shall concentrate on the research domain in this talk



# Background

- There has been considerable growth in the use of PPI in research structures internationally.
- In the UK, The National Institute of Health Research (NIHR), from its launch in 2006, had a firm commitment to PPI in the research process: As Professor Dame Sally Davies said, 'The National Institute for Health Research aims to ensure that all our research projects have active public involvement right from the start.' (quoted in Staley,2009:4)
- In the US, initiatives such as the Patient Centred Outcomes Research Institute (PCORI) require all grants to have an 'engagement plan' for how they are going to involve the public and the Strategy for Patient-Oriented Research (SPOR)
- Canada aims to engage patients as partners and encourage greater focus on patient-identified priorities (CIHR, 2014).

# Definitions

- There is no consensus over how PPI should be defined
- Underpinning these terminological ambiguities are conceptual ambiguities
- This is partly as public participation in decisions in medical research spans a wide area and what constitutes 'engagement' or 'involvement' is contested.

- Broadly can be defined as some form of ‘lay’ contribution to the research process
- However such broad definitions are unhelpful
- ‘PPI operates as an empty signifier, intermittently populated with whatever policy ideas of citizen engagement are a la mode.’ (Madden & Speed, 2017)

# Terminology

Two sides to this:

The WHO side:

Stakeholders; public; citizens; community; patients; users; consumers

The WHAT side

Participation; involvement; engagement; co-production

# Who?

Stakeholders; public; patients; users; consumers etc.

Who is a stakeholder – how is that defined?

Has been argued that public and patients should be seen as different

Are patients consumers?



# Stakeholders

Who is a stakeholder?

Do we want those to be involved who have a stake in the process?

Or do we want impartiality?

What about powerful stakeholders?

Only those affected directly?

# Patients and public

These two terms are often used interchangeably, but it has been argued that they should be distinguished.

This can be done in various ways

Sheehan et al: Patient involvement:

‘taps into the unique insights and expertise that patients and those who are closely connected to them have by virtue of their experiences in order to improve research, care or policy.’

Whereas public involvement is based on people acting like a jury,

‘The public is consulted precisely because it is considered “non-expert” about the issue at hand and can therefore bring independence to ethically, politically and economically charged discussions of important public policy.’

# Consumers or patients?

Boote et al (2002), for example, considers two different models of PPI, the consumerist model and the empowerment model and argues that they have different theoretical underpinnings:

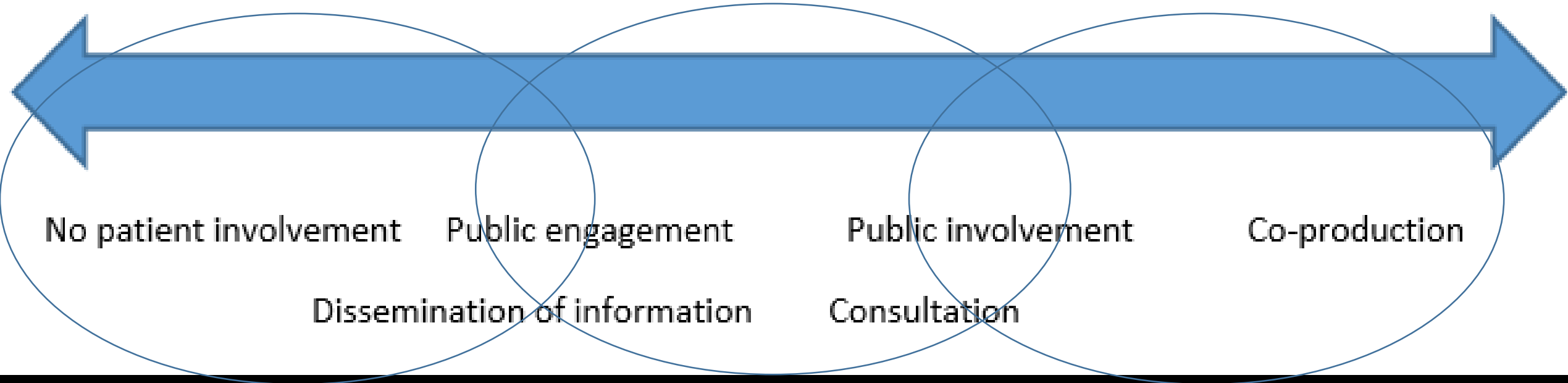
‘Consumerist models stress satisfaction and value-for-money, while empowerment models are political concepts based on control and accountability’ (Boote et al, 2002).

This calls into question what the key objective in involving patients should be:

‘Is it fundamentally about increasing the quality and user satisfaction of the end product (i.e. based on the consumerist model), or does it relate more to the empowerment of users and the democratisation of the research process? (p223)

# The what?

- Moving from dissemination - informing the 'public' about science and medical research
- To engagement
- To involvement
- To co-production
- And beyond?



No patient involvement

Public engagement

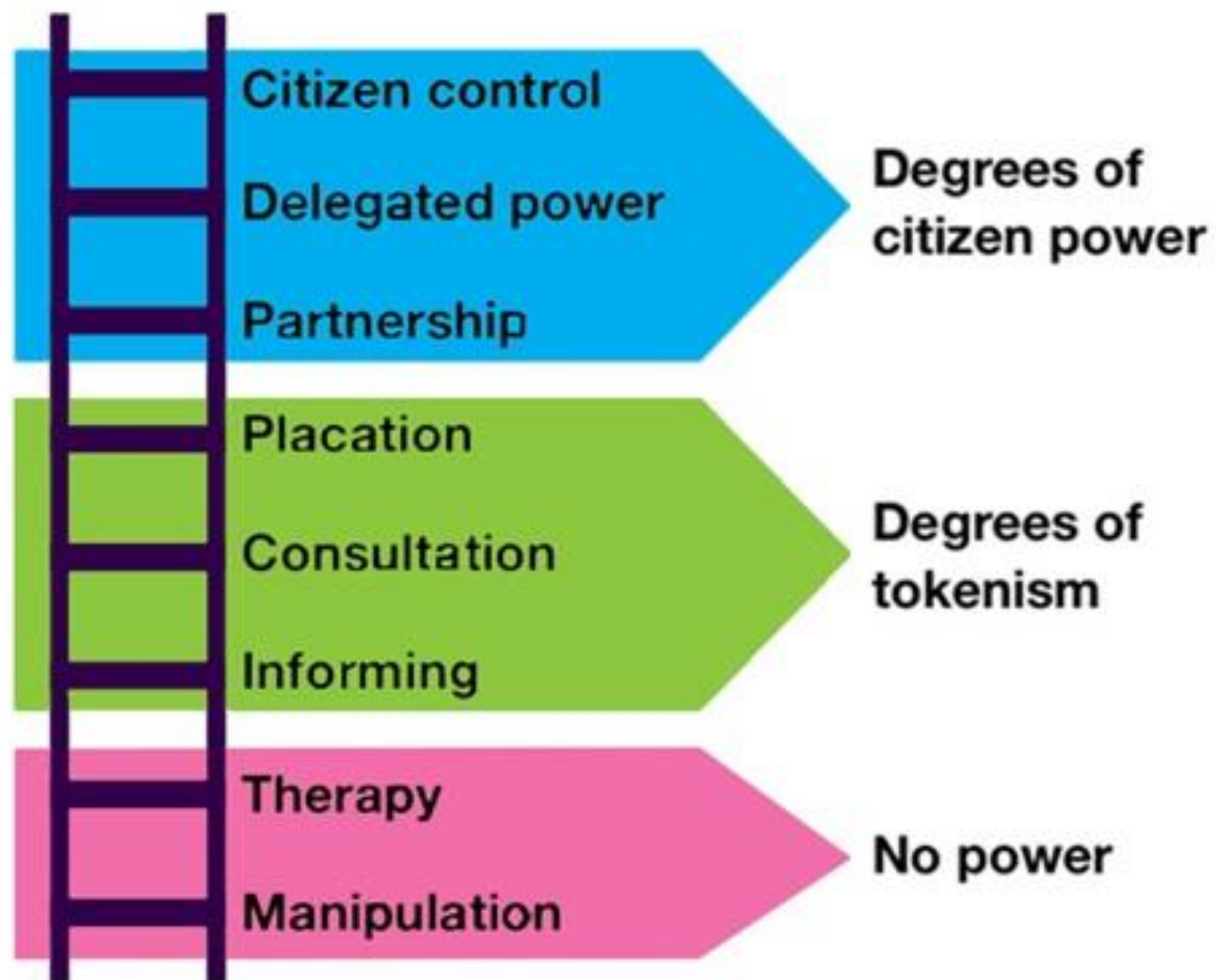
Public involvement

Co-production

Dissemination of information

Consultation

## Arnstein's Ladder of Public Participation







# INVOLVE

INVOLVE defines public involvement in research as ‘research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them.’

INVOLVE’s definition includes notions of active contribution, rather than just consulting or passive receiving of information.

Moving PPI towards co-production:

‘Co-production is a way of working that involves people who use health and care services, carers and communities in equal partnership; and which engages groups of people at the earliest stages of service design, [research] development and evaluation.’

Coalition for Collaborative Care

# Justifications for PPI

# What function does, and should, PPI perform?

Embedded in these questions of how to define PPI are different conceptions of the justifications for the practice

Jenny Popay's MRC project looked at this and found three types of value:

'(1) normative perspectives on PPI, which consider involvement as an end in itself, for example, rights and empowerment;

(2) substantive perspectives which consider the consequences of PI, for example, quality and relevance; and

(3) process-related values associated with good involvement, for example, robust decision-making.' (Snape et al, 2014:2)

These can pull in different directions



# Justifications

There are a number of different types of justifications for PPI in research that it can: improve the quality of healthcare; make research more relevant to users; make the decision-making process more inclusive and democratic; and empower patients and the public

The accounts that explicitly consider the underpinning theoretical justification of stakeholder engagement generally divide these into two, broad, categories:

- promoting intrinsic values that should underpin healthcare research and healthcare more generally (i.e. trust and transparency) and;
- instrumental values (i.e. improving research and consequently health outcomes and reducing inequalities).

# What do lay contributor do?

One way to approach this is to think about what lay contributors are called upon to do.

By making explicit the role PPI contributor is called on to play, we can better assess if those are reasonable expectations and the possible conflicts and tensions inherent in PPI.

Beresford (2007) lists these as:

- Identifying the purpose and potential benefits of research
- Identifying the focus of research and research question(s)
- Commissioning research
- Seeking, obtaining and controlling research funding
- Designing the research
- Undertaking the research (as researcher, interviewer, etc)
- Managing/controlling the research
- Collating and analyzing data
- Producing findings
- Writing up and producing publications/outputs
- Developing and carrying out dissemination policies
- Deciding and undertaking follow up action
- Being on advisory boards,
- A co-applicant on a grant
- Part of a reference panel made up of public contributors and researchers



# Lay contributor as expert

- They bring a different form of expertise and experience from the standard professional and technocrat views, from what can be termed 'credentialed knowledge and expertise'
- This can
  - give a richer more qualitative perspective on health,
  - introduce different values into the proceedings (Bruni et al, 2008) and,
  - challenge the authority of the medical professionals.
- Justified in terms of epistemic democratic considerations (i.e. Mill) and epistemic injustice (Fricker, 2007)
- Deliberative democracy – which view points do we want and need?

# Lay contributor as decision-maker

- Reducing the democratic deficit in modern life
- PPI as co-production – so should take decisions
- Conceptualising them as a form of ‘mini-public’ – a way of generating considered opinions
- However, there are a number of questions with this aspect of the role of the PPI contributor
- If PPI is conceptualised as an emerging form of non-electoral representation and what gives this type of representation legitimacy:
  - how are representatives authorised to act and,
  - how they are, and should be, held accountable?

# PPI as a mechanism to democratise the research process

- I argue, (Frith, forthcoming) that, at their root, justifications for PPI in health care is based on some form of democratic commitment.
- Although, as noted, it is often claimed that there are two categories of justification for engagement, intrinsic and instrumental, a form of democratic commitment also motivates these seemingly instrumental concerns.

# Part of trends in democratising health research

- That healthcare and health research specifically is an area that should be subject to some kind of democratic decision-making is a relatively new phenomenon, and has become central to health policy internationally.
- This is part of a wider trend of widening democratic engagement beyond the ballot box.
- Democratisation will be used here to mean the ways that democracy in health research is furthered or promoted
- Democracy is defined here broadly to mean the various ways the public can interact, be involved in and influence decisions and practices in healthcare research (Archiebugi & Held, 2011).

# Democratising research

This allows us to consider how different aspects, processes and policies related to PPI in research improve or reduce their democratic quality – how far they democratisation health research.

Democratisation is not an absolute category, there can be degrees of democratisation, it is a process and democratic quality can be improved incrementally by adjusting existing procedures and institutional structures (Stevenson, 2016), as well as radically instituting new systems.

- Without this commitment to democratising health research by involving a wider group of 'others' into the research process, either in the form of the public and/or patients, the very idea of having PPI falls apart.
- Most of the functions of PPI, such improving research by making it more sensitive to users' needs, getting different lay perspectives and ensuring research addresses the right priorities could be fulfilled, arguably, in more efficient ways. Data on patient or public views could be gathered more comprehensively, for example, through large-scale surveys, and patients' preferences explored more extensively in-depth qualitative work.
- Public contributors are more than research participants and subjects, they are more than a way of generating data or knowledge on a specific topic, their role and the associated processes of involvement are ways to attempt to make health research more democratic.



Ways forward

# Should we aim to democratise health research?

- The rationale for democratising the research process has been questioned, although as Beresford notes this is, 'frequently not made explicit in formal academic and research debate.' (2007:2 )
- There are a number of positions articulated here pragmatic ones, that the public will not understand research and therefore not be able to make a meaningful contribution
- They are unlikely to be sufficiently diverse or be able to represent all groups of patients, therefore the activity is meaningless
- It might be argued that if non-scientific expertise was entirely privileged this could raise concerns about scientific integrity for example (van Bekkum & Hilton, 2014).

- Or more fundamentally that research teams are made up of people with relevant expertise and membership of research teams is not usually decided democratically.
- Therefore, there is no reason why the public should be involved as this is not an area that we need to consider through a democratic lens.

# Moving towards democratisation?

- Research probably will never and can never be fully democratic – if indeed any system is – the goal is to make it more democratic and to determine the appropriate operational parameters of this.
- This is, in part, to determine how these processes can be done better and also to consider when this might be extended too far.

# Moving towards clarity?

Conceptual clarity can improve practice by:

- Making explicit the function of PPI and develop activities that further these goals and minimise conflicts that can sometimes result from different perceptions of the rationale for PPI (Dean, 2017, Wilson et al, 2018).
- Provide a firmer basis for assessment of how practices meet these ends, as ways to assess and measure the impact of PPI are generally under developed (Mockford et al, 2012).
- The lack or limited explication of underpinning theory can make evaluation challenging, as it is often unclear exactly what the PPI activity was meant to achieve.

# Practical suggestions

- Need theoretical clarity that can be translated into clear roles, with clear remits
- It is hard
- Challenges everyone
- Takes time
- Needs adequate resourcing
- The right kind of support (mentoring, shadowing, community of PI reps) and, possibly, training
- Not piecemeal, needs to be sustained
- Support of the whole system – organisational buy in, become a ‘way of doing things’ throughout the NHS



## Or....

- John - I am ticking a box. And I am going back to basics and I want, the hospital trust to define what exactly they want from volunteers, what exactly they want from patient reps.
- Jane - A box that requires to be ticked...
- John - Yes I am a box. I have been ticked....I was merely a tick in a box that said you have to have a patient rep.