

Why patients need to understand the surrogate outcome

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# Talk outline

- Patient and Public Involvement (PPI) in general
- PPI in SPIRIT-CONSORT extension
- PPI panels in clinical research
- PPI panels in clinical trial design using surrogates
- Patient understanding of surrogates
- Final thoughts

# Google search: 'patient and public involvement research' 1 Jan – 31 March 2024



Health Research Authority

<https://www.hra.nhs.uk> › public-involvement › putting-p...

## Putting people first - embedding public involvement in ...

26 Mar 2024 — Excellent **public involvement** is an essential part of health and social care **research** and has been shown to improve its quality and impact. People's lived ...



UK Research and Innovation

<https://www.ukri.org> › opportunity › understanding-publ...

## Understanding public involvement in non-clinical research

26 Mar 2024 — **Public involvement**, comprising active collaborative partnerships between **researchers** and members of the public, **patients**, carers and communities, is an ...



National Institute for Health and Care Research

<https://www.nihr.ac.uk> › patient-engagement-service

## Engage with patients and the public to improve your ...

28 Feb 2024 — A service to help life science organisations collaborate with **patients** to improve the design and delivery of commercially-sponsored **research**.



BioMed Central

<https://researchinvolvement.biomedcentral.com>

## Research Involvement and Engagement: Home page

21 Mar 2024 — **Research Involvement** and Engagement is an interdisciplinary, health and social care journal focussing on **patient** and wider **involvement** and engagement in ...



National Institutes of Health (NIH) (.gov)

<https://www.ncbi.nlm.nih.gov> › articles › PMC10909615

## Patient and public involvement in the development ...

by E Sheldon · 2024 — **Patient and public involvement** in the development of health services: Engagement of underserved populations in a quality improvement programme for...



European Respiratory Society

<https://www.ersnet.org> › Events

## Virtual school on patient and public involvement in research

25 Jan 2024 — In this course, the attendees will learn what **patient and public involvement** in **research** is and the evidence which shows that it is effective.



The Lancet

<https://www.thelancet.com> › lanhl › article › fulltext

## Increasing patient and public involvement in clinical research

1 Feb 2024 — **Patient and public involvement** (PPI) can be a powerful tool in ensuring that **research** focuses on the most pressing needs of a population. Older adults, often ...



UK Research and Innovation

<https://www.ukri.org> › what-we-do › public-engagement...

## Public involvement and engagement – MRC

16 Feb 2024 — Collaborative **research** and **patient and public involvement** are all ways that **research** and innovation can be co-created with the public. Festivals, museums ...

# Public Involvement in development of Surrogate reporting guidelines

Key factors:

- .Safe space to talk** - rooted in our questions and concerns about surrogates
- .Good explanations of what it was about** - using metaphors, drawings, basic guides
- .Clear point of the discussion** - the benefits and risks of using surrogates, the uncertainties and the lack of clarity about what participants are told
- .The purpose of the meeting** - to improve the CONSORT/SPIRIT guidance
- .Recognising the contributions** made by people and recompense for time

# PPI panels in clinical research

Patient and public involvement is engagement in a study setting and involves conduct of research **'with'** or **'by'** members of the public rather than *'for'*, *'to'*, or *'about'* them.

Public engagement is crucial for trial planning and conduct and also translation of trial findings and increasing benefit for trial participants and the public.

Public engagement and informed consent are mutually supportive aspects aimed at the same goal: ensuring conduct of research in a respectful manner and maximising its social value.

# PPI panels in clinical trial design using surrogates

PPI representatives must understand the proposed surrogates

All parties must listen and understand each other's points and views

Surrogates are common and accepted in some areas, novel or controversial in others

Clarity on how well the surrogate predicts the target outcome and how robust the measures are

What is important to the patients?

What are the practical aspects?

What effects on consent (recruitment)?

What will be the future benefits for patients and the public?

# Patient understanding of surrogates

Patients must understand the surrogates used

Consent cannot be 'informed' without that understanding

# Research team & patient communication: 1

Patients must be informed in plain (lay) language what the surrogate endpoint is

Identify any web resources that may be helpful to give more information



# Research team & patient communication: 2

Clarify why the surrogate endpoint is being used  
e.g. faster approval of the intervention and  
subsequent future patient benefit

# Research team & patient communication: 3

Explain the uncertainty of how well the surrogate predicts the target outcome

# Research team & patient communication: 4

Explain that the trial size and duration of the intervention may not be sufficient to identify all the harms of the intervention

# PPI and the statistician

A good statistician will always be able to think like a patient