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Evidence-Based Research

The project is supported by

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EUROPEAN COOPERATION IN SCIENCE & TECHNOLOGY

Funded by the Horizon 2020 Framework Programme of the European Union

Why do we need to incorporate end users' perspectives when planning new research?

Klara Brunnhuber

14th September 2022

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Evidence-Based Research

The first trial conducted under the **Nuremberg** Military Tribunals in **1947** became known as The **Doctors'** Trial, in which 20 physicians from the German Nazi Party were tried for crimes against humanity for the atrocious experiments they carried out on unwilling prisoners of war and civilians in occupied countries.

Nuremberg Code (1945-1946)

Set of ethical research principles for human experimentation

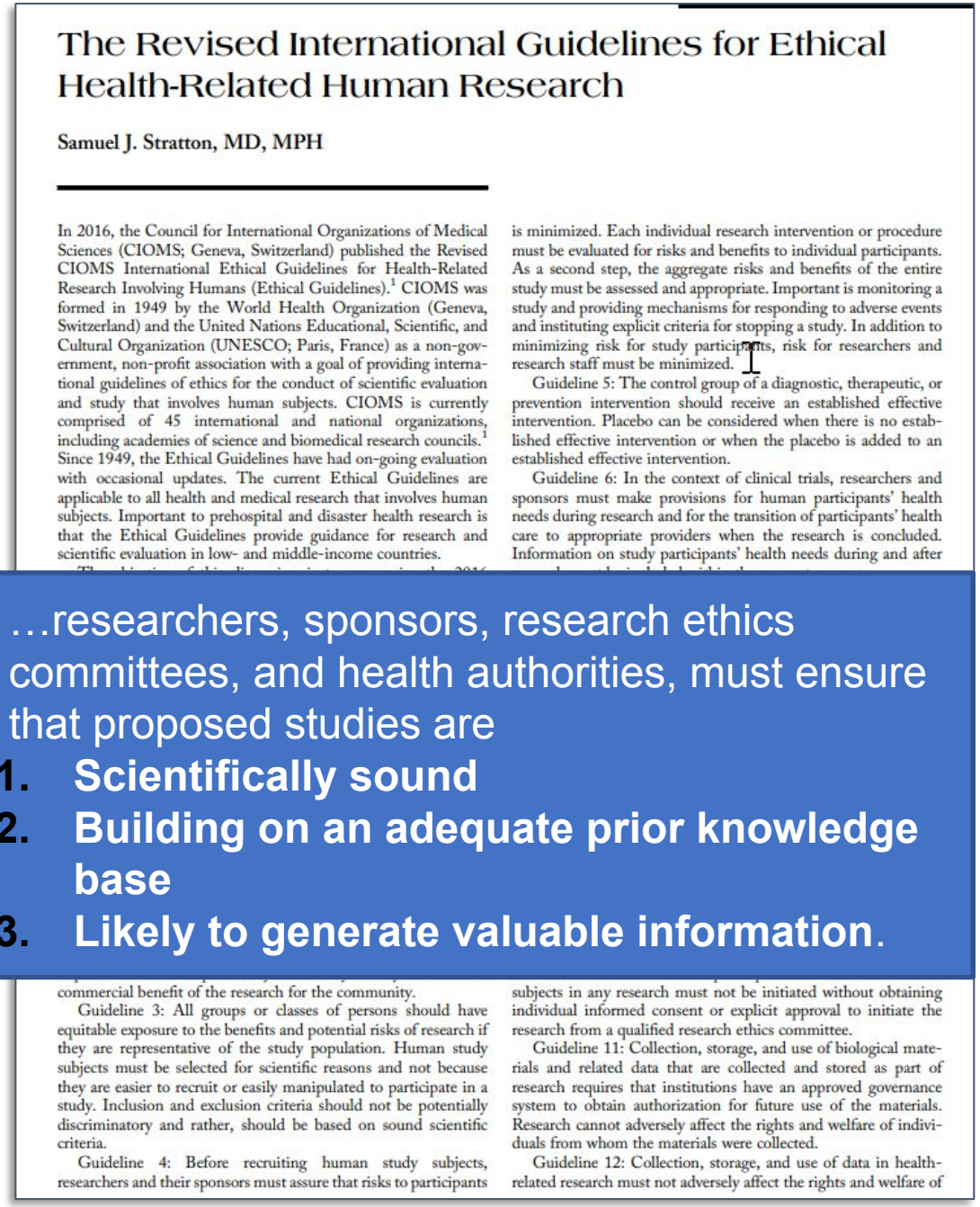
Principle 2. The experiment should be such as to yield fruitful results **for the good of society**, unprocurable by any other methods or means of study, and not random or unnecessary in nature.

Principle 3. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study **that the anticipated results will justify the performance of the experiment**.

International Guidelines for Ethical Health-Related Human Research
(first edition in 1949, last revised in 2016)

- **Guideline 1: Scientific and social value are the fundamental justification for conducting research that includes human subjects…**

The guideline defines the scientific and social value of a study as: «...generating the knowledge and the means necessary to protect and promote people's health»



The Revised International Guidelines for Ethical Health-Related Human Research

Samuel J. Stratton, MD, MPH

In 2016, the Council for International Organizations of Medical Sciences (CIOMS; Geneva, Switzerland) published the Revised CIOMS International Ethical Guidelines for Health-Related Research Involving Humans (Ethical Guidelines).[1] CIOMS was formed in 1949 by the World Health Organization (Geneva, Switzerland) and the United Nations Educational, Scientific, and Cultural Organization (UNESCO; Paris, France) as a non-government, non-profit association with a goal of providing international guidelines of ethics for the conduct of scientific evaluation and study that involves human subjects. CIOMS is currently comprised of 45 international and national organizations, including academies of science and biomedical research councils.[1] Since 1949, the Ethical Guidelines have had on-going evaluation with occasional updates. The current Ethical Guidelines are applicable to all health and medical research that involves human subjects. Important to prehospital and disaster health research is that the Ethical Guidelines provide guidance for research and scientific evaluation in low- and middle-income countries.

is minimized. Each individual research intervention or procedure must be evaluated for risks and benefits to individual participants. As a second step, the aggregate risks and benefits of the entire study must be assessed and appropriate. Important is monitoring a study and providing mechanisms for responding to adverse events and instituting explicit criteria for stopping a study. In addition to minimizing risk for study participants, risk for researchers and research staff must be minimized.

Guideline 5: The control group of a diagnostic, therapeutic, or prevention intervention should receive an established effective intervention. Placebo can be considered when there is no established effective intervention or when the placebo is added to an established effective intervention.

Guideline 6: In the context of clinical trials, researchers and sponsors must make provisions for human participants' health needs during research and for the transition of participants' health care to appropriate providers when the research is concluded. Information on study participants' health needs during and after

commercial benefit of the research for the community.

Guideline 3: All groups or classes of persons should have equitable exposure to the benefits and potential risks of research if they are representative of the study population. Human study subjects must be selected for scientific reasons and not because they are easier to recruit or easily manipulated to participate in a study. Inclusion and exclusion criteria should not be potentially discriminatory and rather, should be based on sound scientific criteria.

Guideline 4: Before recruiting human study subjects, researchers and their sponsors must assure that risks to participants

subjects in any research must not be initiated without obtaining individual informed consent or explicit approval to initiate the research from a qualified research ethics committee.

Guideline 11: Collection, storage, and use of biological materials and related data that are collected and stored as part of research requires that institutions have an approved governance system to obtain authorization for future use of the materials. Research cannot adversely affect the rights and welfare of individuals from whom the materials were collected.

Guideline 12: Collection, storage, and use of data in health-related research must not adversely affect the rights and welfare of

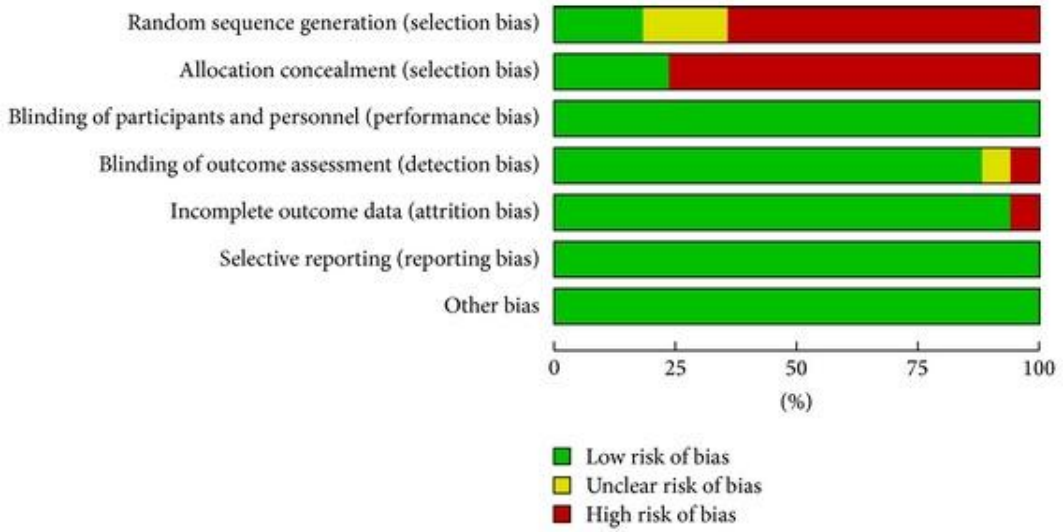
…researchers, sponsors, research ethics committees, and health authorities, must ensure that proposed studies are

1. **Scientifically sound**
2. **Building on an adequate prior knowledge base**
3. **Likely to generate valuable information**.

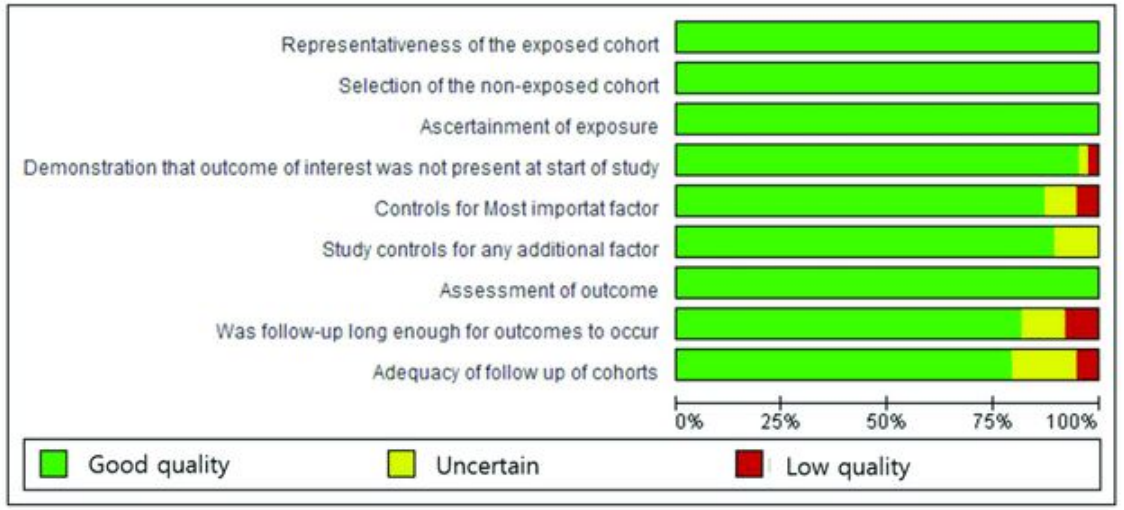
1. Scientifically sound studies:

1. Internal validity: Trustworthiness of results (and any causal relationship)

Risk of Bias tool for RCTs



Newcastle Ottawa tool for non-RCTs



2. External validity: Generalisability of results outside the study context

2. Building on an adequate prior knowledge base:

Considering earlier studies in a systematic and transparent way when justifying and designing new clinical studies:

- Minimises the number of redundant studies to be performed and published – avoiding the waste of time, resources and money
- Prevents patients from receiving unnecessary placebo, or treatment which is incorrect or suboptimal – avoiding the waste of health and life.

Placing new results in the context of earlier similar trials in a systematic and transparent way:

- Prevents new results of a single study overshadowing the real results (= based upon all similar trials including the new study)
- Prevents medical reversal (= the introduction of new interventions in the clinic without real effect)
- Prevents incorrect recommendations that further studies are still needed and hence the conducting of new redundant studies.

3. Generating valuable information - for???

End users: Individuals, communities or organisations outside of academia that will use or benefit from the results of research*

We prefer: End users = individuals, communities or organisations that will use or be affected by the results of research!

Key end users of health research include **patients, caregivers, and clinicians**

*Source: Australian Research Council. Engagement and Impact Assessment 2018–19. 2018. https://dataportal.arc.gov.au/EI/NationalReport/2018/pages/introduction/index.html?id=background. Accessed 06 Sep 2022.

Context:
The cha(lle)nging landscape of health research

Research agenda misaligned with the needs of and not reaching the population it is meant to serve:

- Often guided by vested researcher interests
- Research funding does not reflect the burden of disease on the population
- Difficult to recruit and retain adequate number of study participants
- Study results hard to disseminate to patients and to implement in clinical practice
- Publication bias: ‘Positive’ results more frequently published, as are studies written in English or conducted in native English-speaking countries
- And many more…

Interested in the Future of Research? Check out Elsevier’s future-scoping study at https://www.elsevier.com/research-intelligence/resource-library/research-futures

Context:
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- And many more…

One possible solution gaining momentum:

Two key drivers

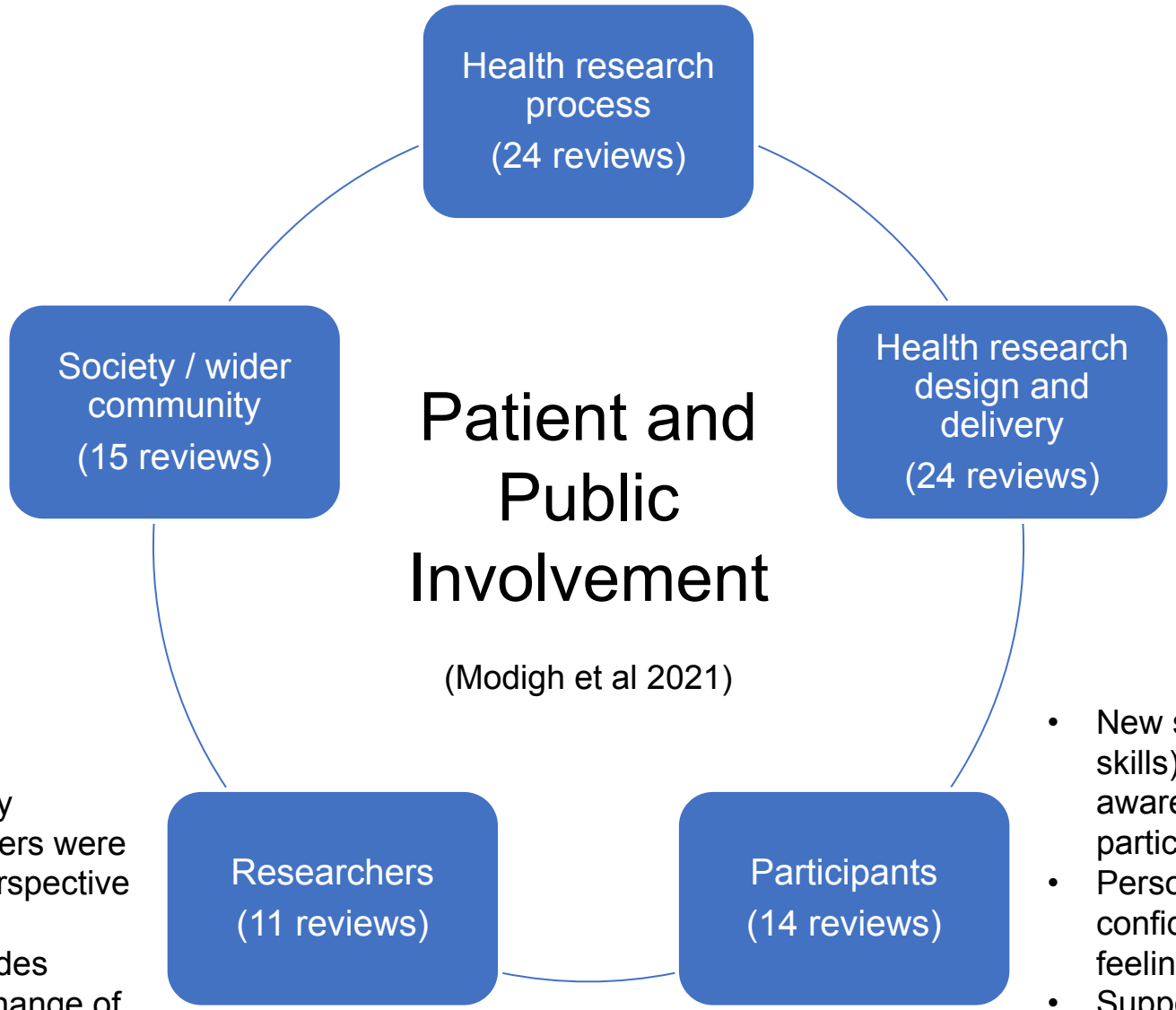
Ethical / moral argument: Manifestation of democratisation of research process: those who use and/or are affected by research should have a say in what and how it is done

Consequentialist argument: Expected benefits for research quality, efficiency, and impact (applicability of results to patients and translation into clinical practice)

Benefits mentioned in the literature

Improved identification of study topics and setting of research priorities

- Increased trust, acceptance, and credibility of the research
- More sustainable, population-appropriate and meaningful interventions, providing community perspectives
- New and improved services/practice changes (improved services for people with dementia and identified factors that should be considered in prevention programs)

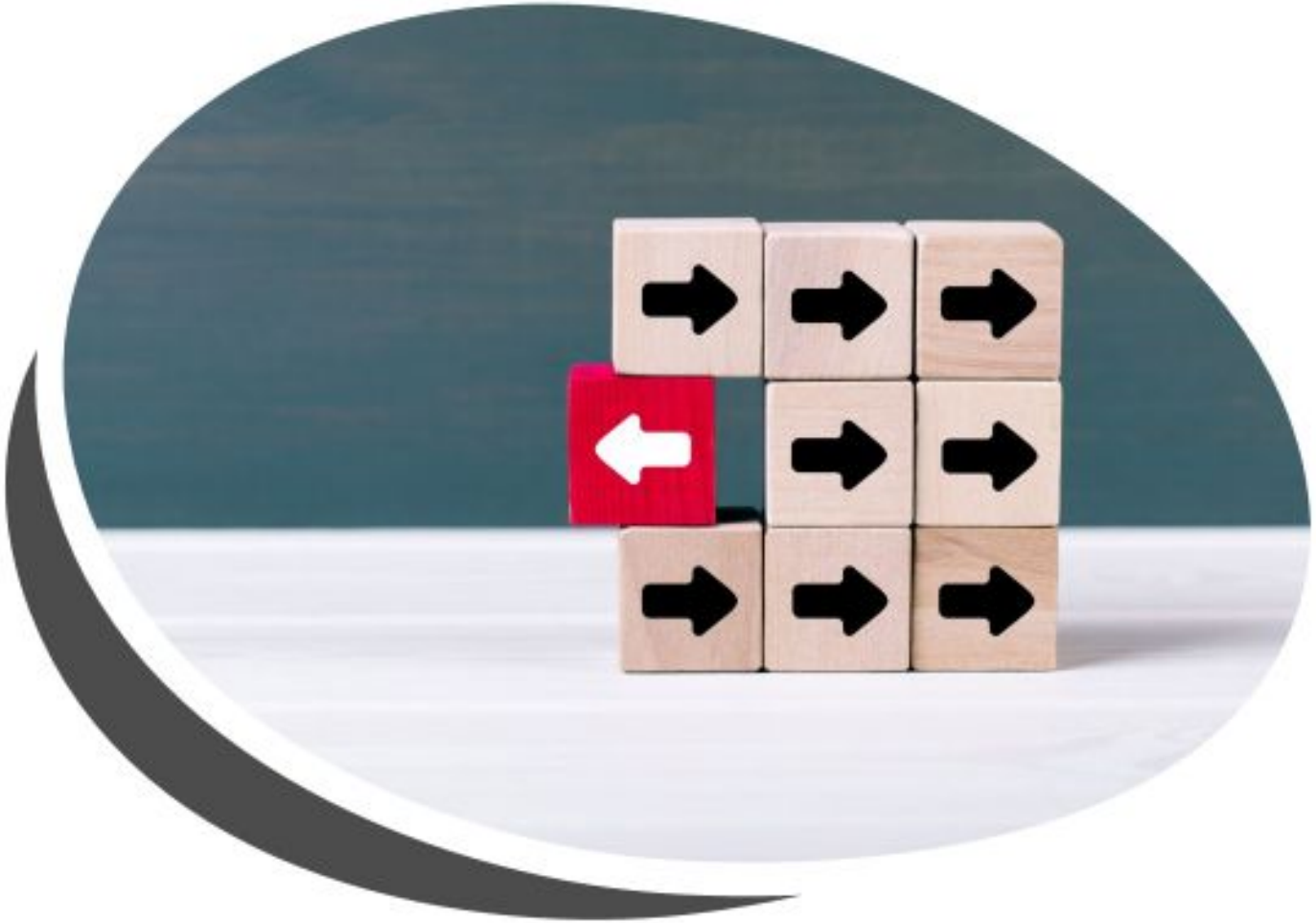


- Increased recruitment, response rates, and enrolment
- Contribution to data collection, dissemination and presentation of results, and the analysis of data
- Greater rigour in decision-making

- Increased knowledge and understanding of the community (identifying issues the researchers were not initially aware of, patient perspective
- Increased motivation
- Challenges to beliefs and attitudes (challenged prejudices and a change of expectations and assumptions on how to conduct research with adults with intellectual disability)

- New skills (research and teamwork skills) and knowledge (increased awareness of health issues and the participant's illness)
- Personal development: Increased confidence and self-esteem, and feeling empowered
- Support (giving and receiving) and friendship
- Joy and enjoyment (pride, feeling valued, and making a contribution)

So, the direction is clear - or is it?



Thank you

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Challenges and barriers to incorporate end users' perspectives in research and how to overcome them

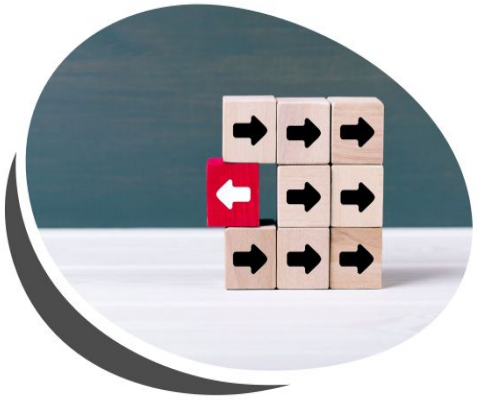
Hans Lund

14th September 2022

Manafo 2018 (A systematic review)

"Over the past 10 years, end-user involvement in health research has emerged as the next evolution in health research.

However, **limited knowledge about the clear role and extent of end-user involvement in health research and the lack of evidence of its impact have affected the uptake, implementation and ongoing development of end-user involvement**"



Manafo *et al. Health Research Policy and Systems* (2018) 16:5
DOI 10.1186/s12961-018-0282-4

Health Research Policy and Systems

REVIEW Open Access

Patient engagement in Canada: a scoping review of the 'how' and 'what' of patient engagement in health research

Elizabeth Manafo[1*], Lisa Petermann[1], Ping Mason-Lai[2] and Virgnia Vandall-Walker[2]

Abstract

Background: Over the last 10 years, patient engagement in health research has emerged as the next evolution in healthcare research. However, limited evidence about the clear role and scope of patient engagement in health

A number of researchers and end users have asked important questions

Russell et al. Research Involvement and Engagement (2020) 6:63
https://doi.org/10.1186/s40900-020-00239-w

Research Involvement and Engagement

COMMENTARY Open Access

The impact of public involvement in health research: what are we measuring? Why are we measuring it? Should we stop measuring it?

Jill Russell[1*], Nina Fudge[1] and Trish Greenhalgh[2]

Abstract

Jennifer Johannesen

MSc Bioethics – author of No Ordinary Boy

MATTERS of ENGAGEMENT

with Jennifer Johannesen and Emily Nicholas Angl

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Domecq et al. BMC Health Services Research 2014, 14:89
http://www.biomedcentral.com/1472-6963/14/89

BMC Health Services Research

RESEARCH ARTICLE Open Access

Patient engagement in research: a systematic review

Juan Pablo Domecq[1,2,5], Gabriela Prutsky[1,2,5], Tarig Elraiyah[1,5], Zhen Wang[1,5,6], Mohammed Nabhan[1,5], Nathan Shippee[1,5,6], Juan Pablo Brito[1,4,5], Kasey Boehmer[1,5], Rim Hasan[1,5,8], Belal Firwana[1,5,8], Patricia Erwin[1,7], David Eton[1,5,6], Jeff Sloan[1,5,6], Victor Montori[1,2,4,5,6], Noor Asi[1,5], Abd Moain Abu Dabrh[1,5]

Age and Ageing 2018; **47:** 801–809
doi: 10.1093/ageing/afy092
Published electronically 25 June 2018

Impacts of older people's patient and public involvement in health and social care research: a systematic review

JENNIFER N. BALDWIN, SARA NAPIER, STEPHEN NEVILLE, VALERIE A. WRIGHT-ST CLAIR

AUT Centre for Active Ageing, Faculty of Health and Environmental Sciences, Auckland University of Technology, Auckland, New Zealand

Overview of challenges

1. **Limited research on the issue**
2. **The role of end users**
3. **Implications for the research itself**
4. **Ethical aspects**
5. **Challenges for the end users while participating**
6. **Representation**

Based upon a number of systematic reviews evaluating end user involvement in research

1. Limited research on the issue

Research on the question of including the end users' perspectives in research

1. What is the beneficial effect of end user involvement? For society - For the research - For the end users
2. What are the harmful effects? For society - For the research - For the end users
3. How many involve the end-user perspective in their research?
4. How are the end users involved?
5. What are the researchers 'reasons' for including the end users' perspectives?
6. When in the research process should the end user be involved?
7. Etc.

Research on the questi
end users' perspectives

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   society - For the research - For
2. What are the harmful effects?
   For the end users
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4. How are the end users involve
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   perspectives?
6. When in the research process should the e
7. Etc.

"We are calling for a critical research agenda for end-user involvement such as:

1. considers end-user involvement not as an instrumental intervention, but a social practice of dialogue and learning between researchers and the public
2. explores how power relations play out in the context of end-user involvement in health research, what "empowerment" means and whose interests are served by it
3. asks questions about possible harms as well as benefits of end-user involvement, and whether the language of influence is useful or not."

Russell et al. Research Involvement and Engagement (2020) 6:63
https://doi.org/10.1186/s40900-020-00239-w

Research Involvement and Engagement

COMMENTARY Open Access

The impact of public involvement in health research: what are we measuring? Why are we measuring it? Should we stop measuring it?

Jill Russell[1*], Nina Fudge[1] and Trish Greenhalgh[2]

Abstract

Regarding “How many involve the end-user perspective in their research?”

A search for systematic reviews about end users’ involvement in research identified 107 SRs. Nine of these evaluated the prevalence of published research incorporating end users’ perspectives.

The median was: 1.75%!!!

Research on the question of including the tives in research

- Interviews
- Focus groups
- Surveys
- Study board
- Advisory council/panel/group
- Regular meeting with researchers
- Consultants
- Subjects of research
- Panels
- Co-creation / Partnerships
- Newsletter
- Online tools
- Public events
- Steering group
- User forum

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All methods assume the involvement of an individual or a group of individuals.

Not any other approach.
For example: use of Qualitative Evidence Syntheses and / or systematic reviews of surveys etc.

Research on the question of including the tives in research

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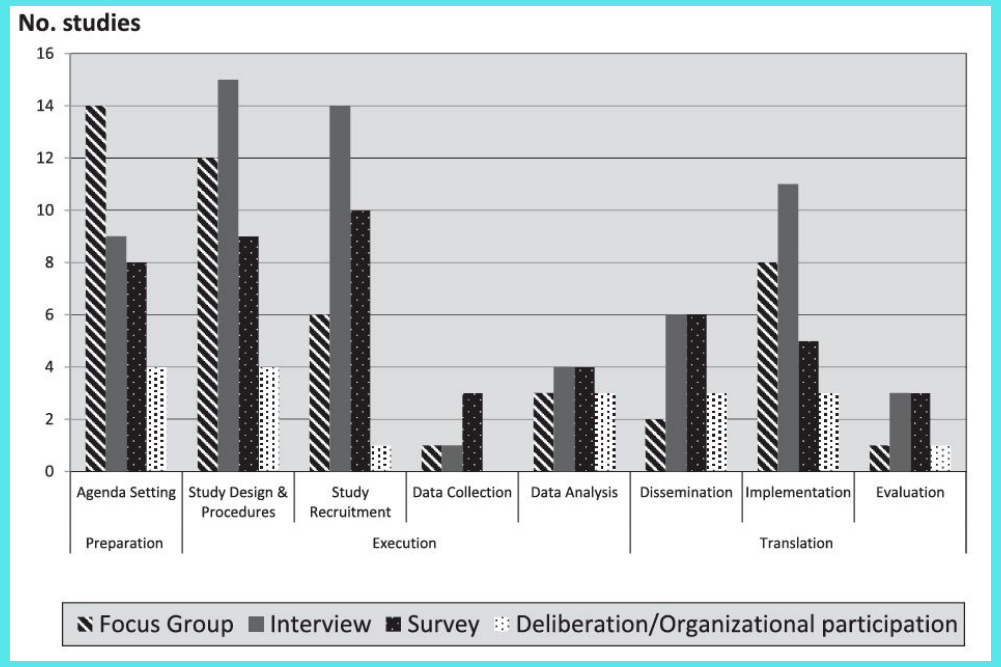
End user involvement:
It is a method not a goal!

Using a method as a goal limits the range of methods used for **incorporating end users' perspectives in research**



In all phases of research

3. How many involve the end-user perspect… …eir research?
4. How are the end users involved?
5. What are the researchers 'reasons' for including the end users' perspectives?
6. When in the research process should the end user be involved?
7. Etc.

2. **The role of end users**

Important factors to consider:

1. End users' actual competence in research
2. Unequal relationship
3. Hierarchy
4. End-user responsibility ("inclusion ladder")
5. Empowerment of end users
6. How to know / collect end users' perspectives, experiences, values, preferences, concerns?
7. Do end users know why researchers invite them?
8. Etc

3. **Implications for the research itself**

Consider the following threats

Factors that may affect the conduct and quality of the research:

1. Unclear goal of involving end users
2. Involvement takes extra time - prolongs the research process
3. Tokenism problem
4. Scope Creep problem
5. The end users' lack of competence can take an extra-long time and thus reduce quality

4. Ethical aspects

Consider the following treaths

As a research subject, there are clear rules for the conditions for participation in research.

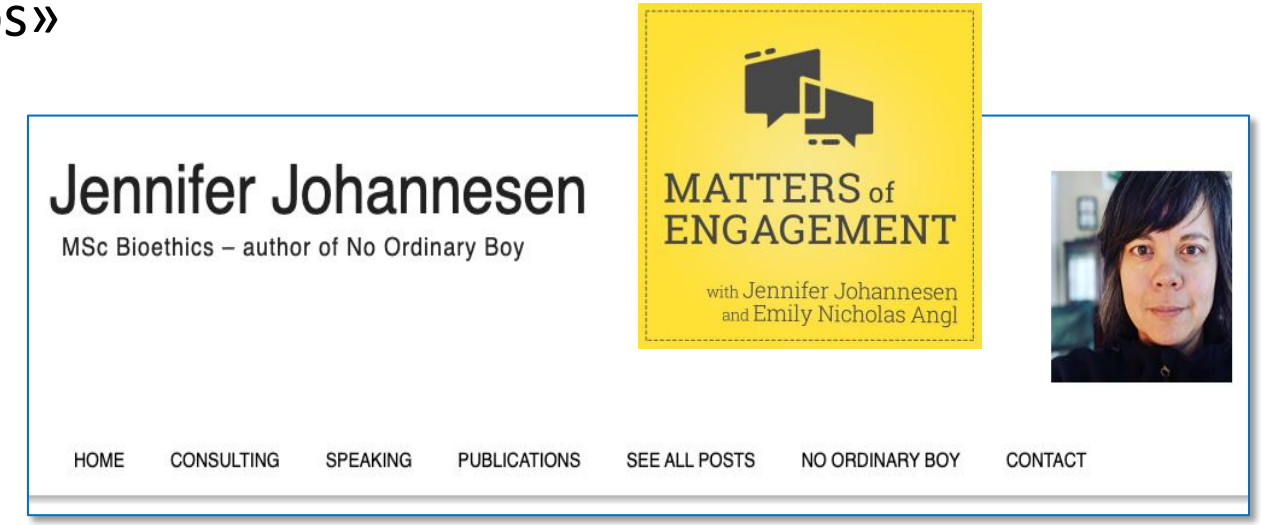
1. What are the ethical aspects of participating as a co-researcher?
2. Does involvement include REC (independent assessment crucial for good ethical assessment)?
3. What does the legislation say about the involvement of end users - both for researchers and for end users?
4. What are the ethics / ethical considerations related to Tokenism
5. What are the ethics / ethical considerations related to Scope Creep?

The ethical dimension

“As patient engagement programs continue with uncritical and enthusiastic support, health ethics must assess the risks and potential harms of such programs.

... the practice of patient engagement fundamentally changes the way we think about and conduct health research, the impact of which has unknown consequences for both the patient's well-being and the integrity of health research

... patient engagement is a major social experiment, and the involvement of patients in activities previously reserved for professionals disrupts the traditional nature of patient-healthcare relationships»



The ethical dimension

"As patient engagement … d enthusiastic support, health ethics m… ms of such programs.

… the practice of patient… the way we think about and conduct healt… nknown consequences for both t… ity of health research

… patient engagement is… nvolvement of patients in activities prev… upts the traditional nature of patient-healthc…

Ethically, we MUST make sure that the research is socially beneficial.

But we cannot implement this by creating new ethical dilemmas.

5.Challenges for the end users while participating

Consider these challenges

1. Intellectually challenging and time-consuming
2. Skewed-twisting of competencies (unequal relationship)
3. Locked in a contract - what if the end user is dissatisfied with the agreement?
4. It is difficult to navigate the different functions and roles that researchers have among themselves
5. Mismatch between expectations and actual roles
6. The discomfort of perhaps affecting research negatively
7. Many hours - what about expense coverage / salary? And what does it mean for the input quality if you are paid (does it give what the researchers want?)
8. Etc.

6. **Representation**

Consider these challenges

1. Can "lived experience" be representative?
2. Must there be a democratic process for selection? If so, who can you choose from?
3. How are the end users recruited? Those that the researchers know? The ones they have easy access to? Same end user in several different studies (professional end users)?
4. Advertising: who is responding to the ad?
5. Etc.

Possible ways to overcome these challenges and barriers

The common characteristics of most of these challenges

There is an assumption that specific, concrete individuals / groups of individuals must be identified and included.

But that is making one possible method the goal!

Our aim ...

... in incorporating end users' perspectives, experiences, concerns, values and preferences is to produce

Societal and relevant research

Further:

The process of obtaining end users' perspectives, experiences, concerns, values and preferences must be

Scientific, systematic, and transparent

and not random, opaque, and tokenistic

We suggest to use an evidence-based approach

Evidence-Based Research (EBR)

Research on research has shown that because researchers do NOT systematically review previous research in their field, wasteful and indifferent research is produced!

We have established an international organization (EBR Network) that seeks **to promote the use of a systematic and transparent approach when researchers justify and design new studies.**

We suggest to use an evidence-based approach (2)

But it is only one leg - the rationale and design of new studies must stand on 2 legs:

Research must be valuable: only carried out because there is a knowledge gap AND because there is a need among the end uses

It is time for the end users' perspective to be taken into account when research is planned, carried out and published.

Therefore …

Researchers MUST include the end-users' perspectives when planning, performing and disseminate research

- but it must be done in a scientific, systematic and transparent way.

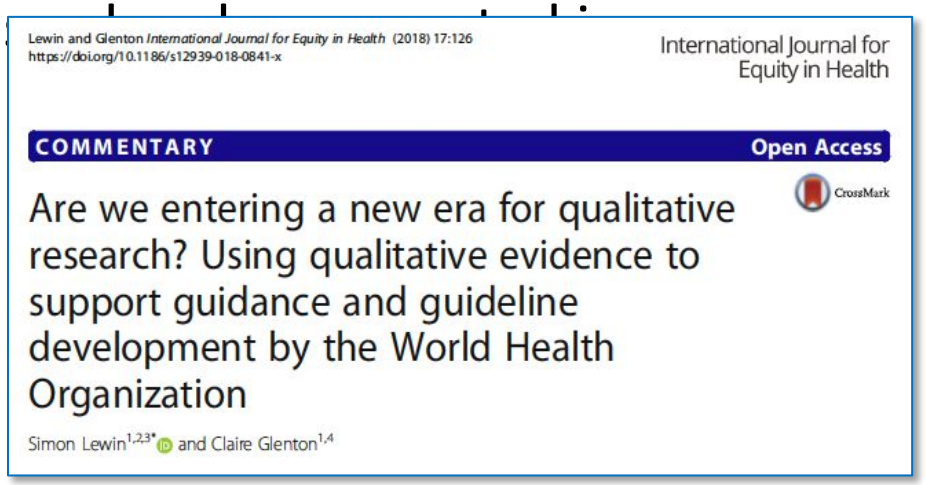
1st requirement

Scientific approach

End users need to inspire researchers to look at important and socially important issues. Researchers must know and be in dialogue with end users - continuously

Use of systematic overviews of previous similar research & qualitative studies that include the end users' perspective

"Qualitative systematic overviews enable the perspectives and experiences of several stakeholder groups from different contexts to be asse
systematic and transparent manner"


Lewin and Glenton *International Journal for Equity in Health* (2018) 17:126
https://doi.org/10.1186/s12939-018-0841-x

International Journal for Equity in Health

COMMENTARY Open Access

Are we entering a new era for qualitative research? Using qualitative evidence to support guidance and guideline development by the World Health Organization

Simon Lewin[1,2,3*] and Claire Glenton[1,4]

2nd requirement

Ethical involvement

It requires the development of legislation that ensures that end users are involved on an equal footing with the researchers themselves.

Perhaps REC can also look at the way end users are involved in planned projects, to ensure independent assessment.

Legislation must ensure that tokenism is avoided, but also that "scope creep" is avoided.

3rd requirement:
IF you need to involve individuals/groups, then

1. Have a clear purpose, role and structure to engage patients
2. Initiate and maintain partnerships between researchers and stakeholders
3. Take the time required to promote relationship building as the most critical component of establishing trust
4. Have a clear leadership from the lead researcher and / or broader culture of involvement
5. Promote the need for facilitation of cross-communication among all groups involved in the project
6. Optimize end-user perspectives across all phases of research
7. Ensure meaningful end-user influence on research by demonstrating the need for respect and support for end-users
8. Ensure adequate training for researchers and end users
9. Share and promote research learning, including evaluation efforts


Manafo et al. Health Research Policy and Systems (2018) 16:5
DOI 10.1186/s12961-018-0282-4

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Patient engagement in Canada: a scoping review of the 'how' and 'what' of patient engagement in health research

Elizabeth Manafo[1*], Lisa Petermann[1], Ping Mason-Lai[2] and Virgnia Vandall-Walker[2]

Conclusion

1. Involvement of end users is crucial for valuable research
2. End user involvement is not a goal but a method for performing relevant and important research
3. We must use a scientific approach to incorporate end users' perspectives in research: systematic reviews of qualitative studies
4. We must find solutions to the unanswered ethical challenges
5. We must show respect and consider the many practical challenges when we involve individuals / groups of individuals in research

Thank you

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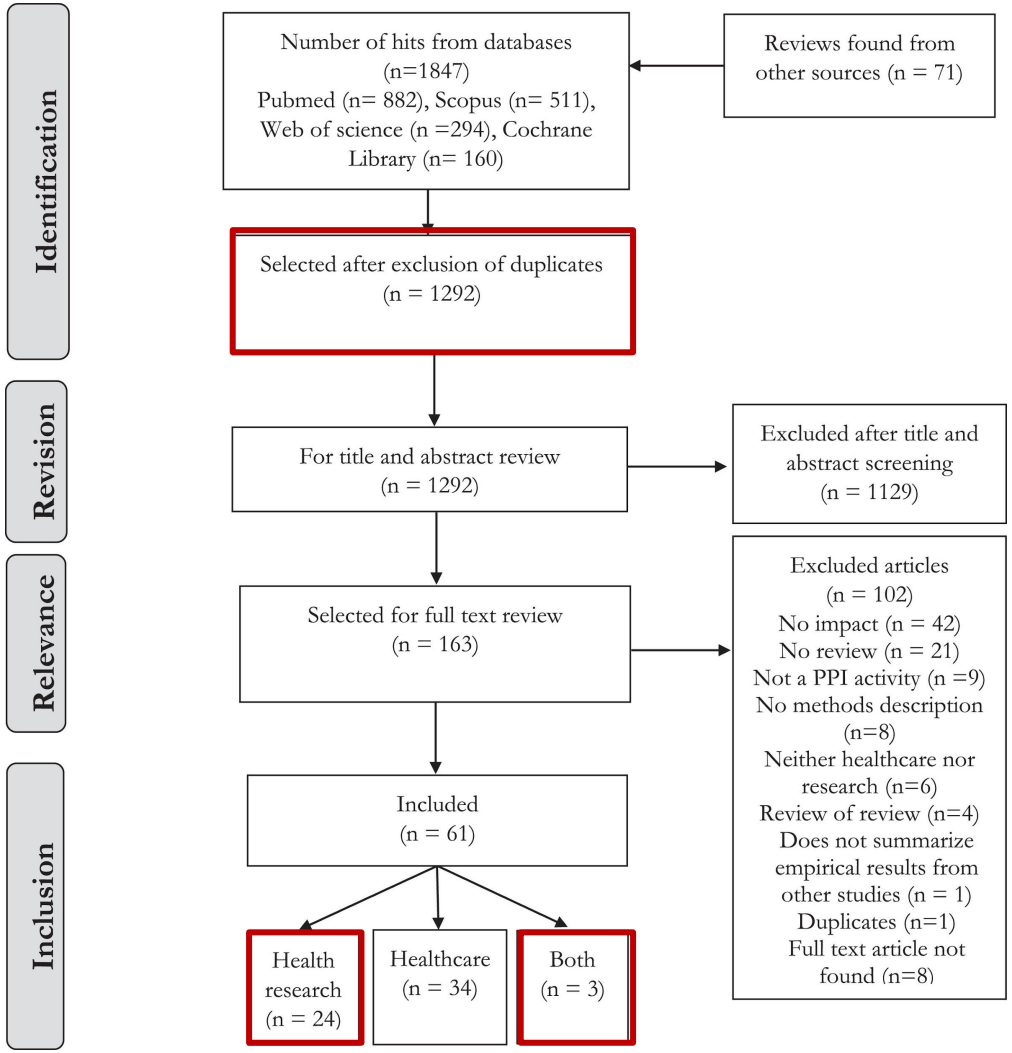
Funded by the Horizon 2020 Framework Programme of the European Union

What does the Evidence say? (Modigh et al 2021)

A scoping review of reviews on the impact of PPI in health research and healthcare:

- **Definition of PPI:** “Research being carried out ‘with’ or ‘by’ members of the public rather than ‘to’, ‘about’ or ‘for’ them”
- **Search date:** March 2020
- **Databases:** Web of Science, Scopus, Medline/Pubmed and Cochrane Library
- **Included studies:** English-language studies published from 2020 that reviewed the literature on the impact of PPI activities on health research and healthcare

What does the Evidence say? (Modigh et al 2021)



What does the Evidence say? (Modigh et al 2021)

Results:

- 888 studies included in 24 reviews for health research alone; 69 studies in 3 reviews for health research and healthcare

Country	% studies of 888 (health research alone)	% studies of 69 (health research & healthcare)
UK	54%	50%
USA	15%	26%
Canada	8%	6%
Australia	5%	4.5%
Netherlands	3%	4.5%
South Africa	2.5%	
India		3%
Other countries	12.5%	6%

Quality	# Health research alone	#Health research and healthcare
Significant deficiencies	10	2
Continued uncertainty about the evidence for impact	14	3
Overlap between two	7	2

Impact on	Number of reviews	Positive Impact	Negative Impact
Health research process	24	Improved identification of study topics and setting of research priorities	
Health research design and delivery	24	• Increased recruitment, response rates, and enrolment • Contribution to data collection, dissemination and presentation of results, and the analysis of data • Greater rigour in decision-making	• More time consuming and more costly • Scientific and ethical conflicts • Downgraded methodological standards
Participants	14	• New skills (research and teamwork skills) and knowledge (increased awareness of health issues and the participant's illness) • Personal development: Increased confidence and self-esteem, and feeling empowered • Support (giving and receiving) and friendship • Joy and enjoyment (pride, feeling valued, and making a contribution)	• Frustration • Powerlessness • Marginalisation • Distress • Demanding workload • Lack of control
Researchers	11	• Increased knowledge and understanding of the community (identifying issues the researchers were not initially aware of, patient perspective • Increased motivation • Challenges to beliefs and attitudes (challenged prejudices and a change of expectations and assumptions on how to conduct research with adults with intellectual disability)	• Power struggles • Experiences of the process being lengthy and demanding • Coordination challenges
Society / wider community	15	• Creating trust and acceptance of the research (increased trust, acceptance, and credibility of the research) • Keeping projects grounded and focused on benefits for the community (more sustainable, population-appropriate and meaningful interventions, providing community perspectives) • New and improved services/practice changes (improved services for people with dementia and identified factors that should be considered in prevention programs)	Inclusion of irrelevant community input