Establishing the effectiveness of complex health promotion interventions: Shining light on alternatives

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Establishing the effectiveness of complex health promotion interventions: Shining light on alternatives

Part 2 – The three ‘E’s

1. Evidence
2. Ethics
3. Epistemological markers

Part 2 – The three ‘E’s

1. **Evidence**
2. Ethics
3. Epistemological markers

Evidence

- Why do we need ‘evidence’?
- What constitutes ‘evidence’?
- How does/should the research context affect our notion of ‘evidence’?
- How does the research cycle shape our ideas of ‘evidence’?

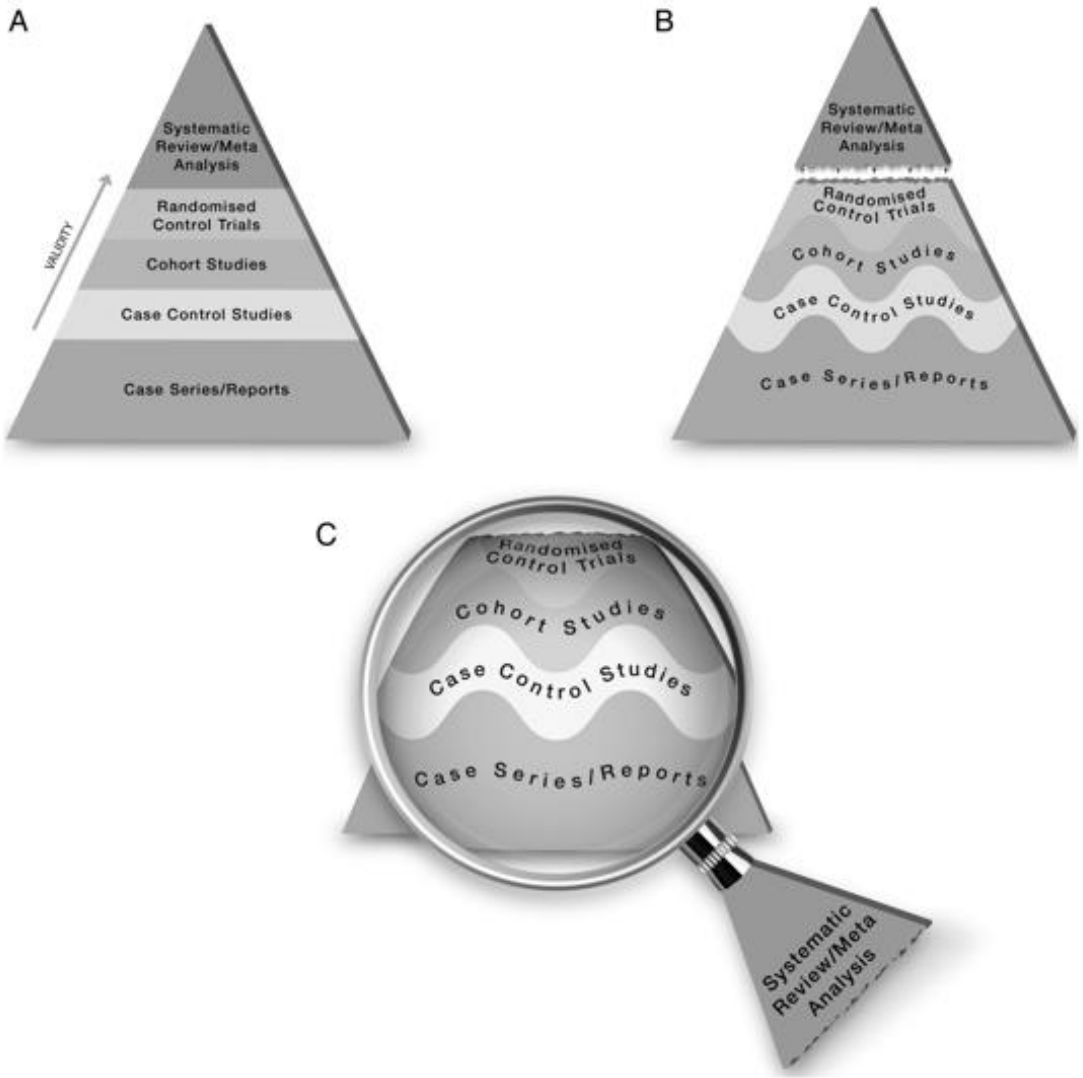
Why do we need ‘evidence’?

- To optimise the use of scarce resources
  - Workforce
  - Funding
  - Time
- To inform decision-making
- To minimise the impact of bias
- Any other suggestions?

The nature of ‘evidence’

- Different professional groups place value on different types of evidence
- The biomedical model of health has shaped our practices
- How can we challenge - or adapt to - this paradigm?

The proposed new evidence-based medicine pyramid.



M Hassan Murad et al. Evid Based Med 2016;21:125-127

The GRADE Framework

Certainty	What it means
Very low	The true effect is probably markedly different from the estimated effect
Low	The true effect might be markedly different from the estimated effect
Moderate	The authors believe that the true effect is probably close to the estimated effect
High	The authors have a lot of confidence that the true effect is similar to the estimated effect

Table 1. GRADE certainty ratings

https://bestpractice.bmj.com/info/toolkit/learn-ebm/what-is-grade/

The GRADE Framework

Certainty can be rated down for:	Certainty can be rated up for:
• Risk of bias • Imprecision • Inconsistency • Indirectness • Publication bias	• Large magnitude of effect • Dose-response gradient • All residual confounding would decrease magnitude of effect (in situations with an effect)

Table 2. Reasons rate certainty in evidence up or down

The GRADE Framework in PH

Specific challenges related to:

(i) complexity of public health interventions

(ii) choice of outcomes and outcome measures

(iii) ability to discriminate between different types of observational studies

(iv) use of non-epidemiological evidence

(v) GRADE terminology

(vi) the GRADE and guideline development process

Rehfuess & Akl 2013 https://link.springer.com/article/10.1186/1471-2458-13-9

The GRADE Framework in PH

Table 3 Comparison of "simple" and "complex" interventions

	"Simple" interventions	"Complex" interventions
Population	Sick population seeking care	Healthy general or at-risk population
Intervention	Individual-level intervention	Population- and/or individual-level intervention
	Single component	Multiple interacting components
	"Reactive" treatment through medication or surgery or clinical prevention	"Proactive" prevention through behaviour change and/or technical intervention and/or policy
	Implementation in healthcare setting	Implementation in household, community or policy setting
Comparison	No intervention or alternative intervention through treatment/surgery	"Business as usual" in several sectors
Outcome	Shorter causal pathway	Longer causal pathway
	One or a small number of health outcomes	Multiple health outcomes and broader societal consequences
	Usually impact after short lag period	Usually impact after long lag period
Delivery of intervention	Delivery through health sector	Delivery through multiple sectors
Contextual effects	Variation between healthcare providers (individuals, institutions)	Variation between providers of different intervention components in multiple sectors
	Patient preference and compliance	Large cultural and behavioural variation

"Simple interventions" tend to show more of the characteristics in the left column while "complex" interventions tend to show more of those in the right column.

Rehfuess & Akl 2013 https://link.springer.com/article/10.1186/1471-2458-13-9

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A ‘three level discrimination’

1. Interventions that are difficult to study through RCTs, as described by the “inverse evidence law”, are less likely to be the subject of a primary evaluation or a systematic review

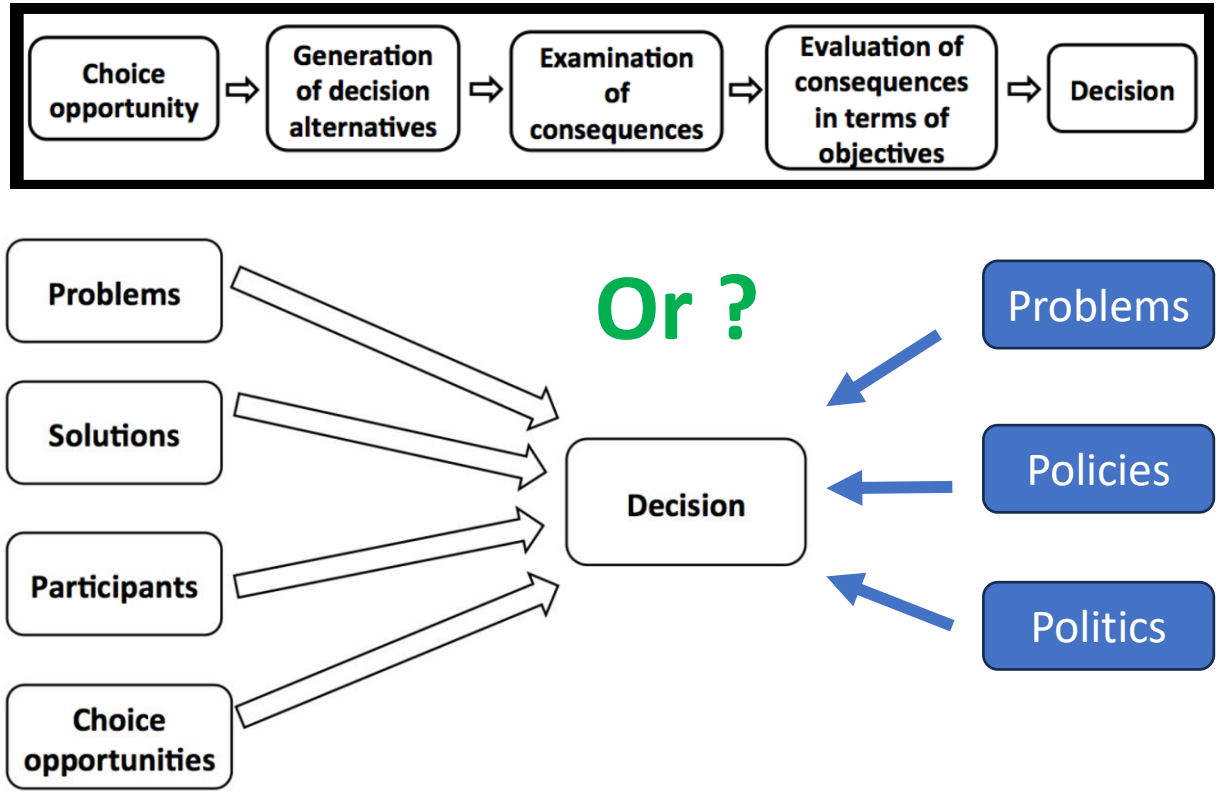
   IEL - There tends to be greater quantity and better-quality evidence for simple interventions directed at individuals compared to complex interventions directed at populations

2. Systematic reviews often search the literature only for randomised designs, dismissing as ‘noise’ much of what others would consider to be the signal
3. When evidence is graded, all observational studies start off as ‘low quality’, independent of the greater/lesser internal validity of the specific study design

Rehfuess & Akl 2013 https://link.springer.com/article/10.1186/1471-2458-13-9

Evidence-based policymaking – fact or fiction?

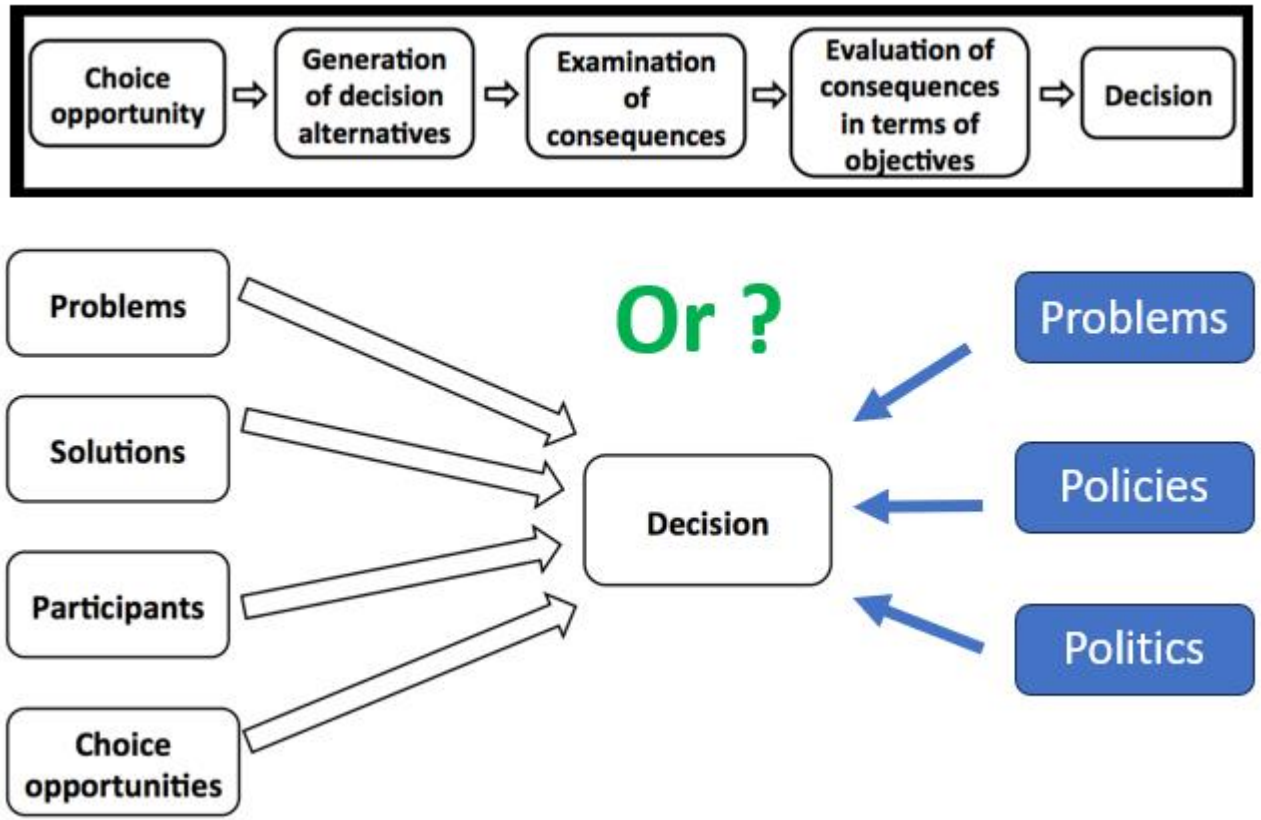
- There are scholarly models of evidence-based policymaking, including…
  - ‘Garbage can’ model (Cohen et al, 1972)
  - Multiple streams (Kingdon, 1984)



https://medium.com/10x-curiosity/organisational-decision-making-the-garbage-can-model-8541ea2b5036

Evidence-based policymaking – fact or fiction?

- There are many influences on policymakers and funders, of which evidence is only one
- Others include:
  - Ideology
  - Morality
  - Telling a good story
  - Any other examples?



Evidence-based policymaking – fact or fiction?

- Does evidence inform decision-making about health-related programmes?
- An example from healthcare (spoiler: it's complicated…)

Evidence-based policymaking – fact or fiction?

Research shapes policy: but the dynamics are subtle

Robbie Foy, Louise Locock, Sarah Purdy, Catherine O'Donnell, Nicola Gray, Tim Doran and Huw Davies

Major policy initiatives such as the Quality and Outcomes Framework (QOF) in the national contract for UK general practitioners might variably be informed by evidence at their inception, implementation and subsequent evolution. But what evidence gets admitted into these policy debates—and what is left out? Using QOF as an example, this article demonstrates what an analysis of the relationship between policy and the associated research can tell us about the underlying policy assumptions and about the role of evidence in policy debates.

Keywords: Evidence; policy; Quality and Outcomes Framework (QOF); research discourse.

Public Money & Management – January 2013
https://doi.org/10.1080/09540962.2013.744869

Quality & Outcomes Framework

- Targeted list of indicators that primary care doctor contractors can achieve to get remuneration
  - Register-keeping (81 points)
  - Clinical (401 points)
  - Public health (160 points)
  - Quality improvement (74 points)

QOF – Public Health examples

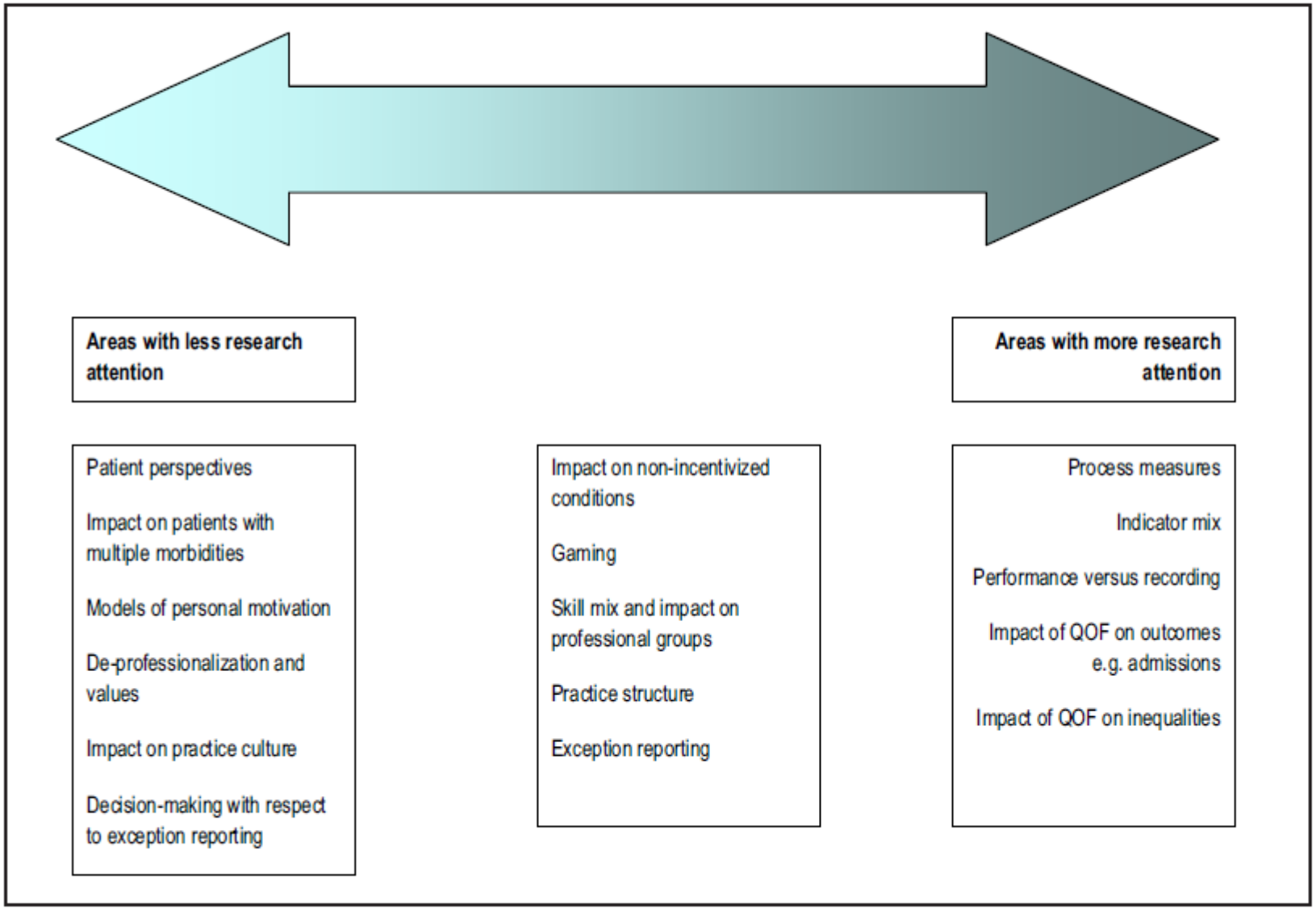
- Blood pressure
- Obesity
- Smoking
- Vaccination
- Cervical screening

Vaccination and Immunisations (VI)	Points	Thresholds
VI001. The percentage of babies who reached 8 months old in the preceding 12 months, who have received at least 3 doses of a diphtheria, tetanus and pertussis containing vaccine before the age of 8 months	18	89-96%
VI002. The percentage of children who reached 18 months old in the preceding 12 months, who have received at least 1 dose of MMR between the ages of 12 and 18 months	18	86-96%
VI003. The percentage of children who reached 5 years old in the preceding 12 months, who have received a reinforcing dose of DTaP/IPV and at least 2 doses of MMR between the ages of 1 and 5 years	18	81-96%
VI004. The percentage of patients who reached 80 years old in the preceding 12 months, who have received a shingles vaccine between the ages of 70 and 79 years	10	50-60%

Evidence-based policymaking – fact or fiction?

- ***Consensual*** – Broad agreement among policymakers and researchers about the issues of concern – making technical adjustments to improve service delivery & outcomes
- ***Contentious*** – Researchers may be on the sidelines and maintain a critical stance
- ***Paradigm-challenging*** – Researchers take a stance outside the orthodoxy and challenge established ways of thinking

Figure 1. Research discourse in relation to the Quality and Outcomes Framework.



Research discourse

"As so often with new policy, roll out of QOF occurred before evaluation. Thus, the context in which the QOF was negotiated precluded any prior testing of effects. Researchers, constrained by this, could subsequently only play 'catch-up' by undertaking quasi-experimental evaluations, which are prone to bias, difficult to interpret and hence provide questionable evidence on effectiveness."

"Research supply-side issues also provide some explanation for the patterning of the research discourse around the QOF. Earlier research on specific **quantitative issues** around impact was facilitated by core DH funding and drew upon readily available data generated by the payment system. In contrast, for example, **qualitative research** challenging some of the assumptions about the mechanisms and benefits of the QOF took longer to emerge, partly because of the time needed to acquire the necessary resources to establish studies and to collect and analyse the data."

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Research Discourse

"There are lessons from this example for other policy developments, such as new commissioning arrangements in healthcare, changes to the benefits system and the prospects for criminal justice system reform, or for international policy responses to challenges like climate change or drug trafficking. Above all, this analysis cautions against the legitimizing rhetoric of evidence: when policy advocates make claims that policies are informed by evidence ***we should ask not only which evidence has shaped the policies, but also what of the evidence that has not.***"

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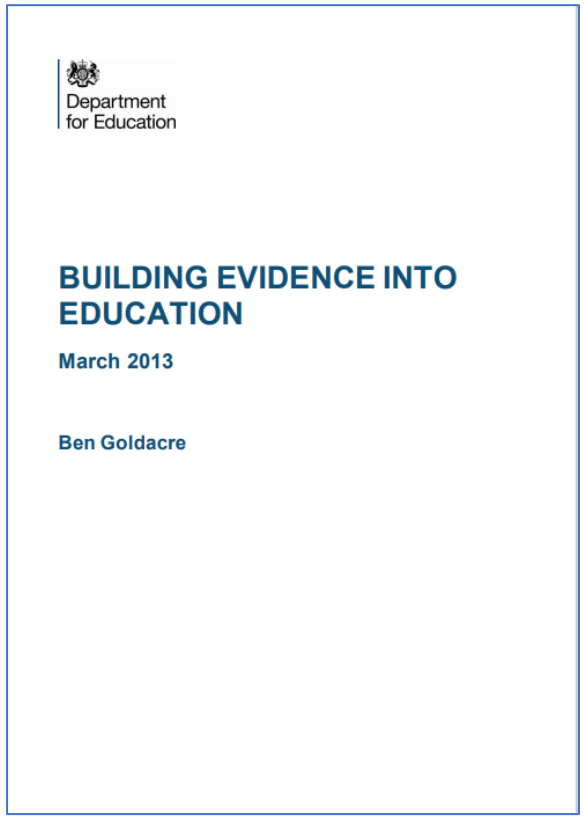
Evidence - Disciplinary Culture Clash?

- The culture and type of evidence valued in different disciplines is key to this issue

- An example is a Govt-backed ‘call to action’ to educators in England from a medical doctor, Ben Goldacre, in 2013
- The author of ‘Bad Science’

https://assets.publishing.service.gov.uk/media/5a7a219140f0b66eab999f4f/Building_evidence_into_education.pdf

Evidence - Disciplinary Culture Clash?



Department for Education

BUILDING EVIDENCE INTO EDUCATION

March 2013

Ben Goldacre

Building evidence into education

I think there is a huge prize waiting to be claimed by teachers. By collecting better evidence about what works best, and establishing a culture where this evidence is used as a matter of routine, we can improve outcomes for children, and increase professional independence.

This is not an unusual idea. Medicine has leapt forward with evidence based practice, because it's only by conducting "randomised trials" - fair tests, comparing one treatment against another - that we've been able to find out what works best. Outcomes for patients have improved as a result, through thousands of tiny steps forward. But these gains haven't been won simply by doing a few individual trials, on a few single topics, in a few hospitals here and there. A change of culture was also required, with more education about evidence for medics, and whole new systems to run trials as a matter of routine, to identify questions that matter to practitioners, to gather evidence on what works best, and then, crucially, to get it read, understood, and put into practice.

I want to persuade you that this revolution could - and should - happen in education. There are many differences between medicine and teaching, but they also have a lot in common. Both involve craft and personal expertise, learnt over years of experience. Both work best when we learn from the experiences of others, and what worked best for them. Every child is different, of course, and every patient is different too; but we are all similar enough that research can help find out which interventions will work best overall, and which strategies should be tried first, second or third, to help everyone achieve the best outcome.

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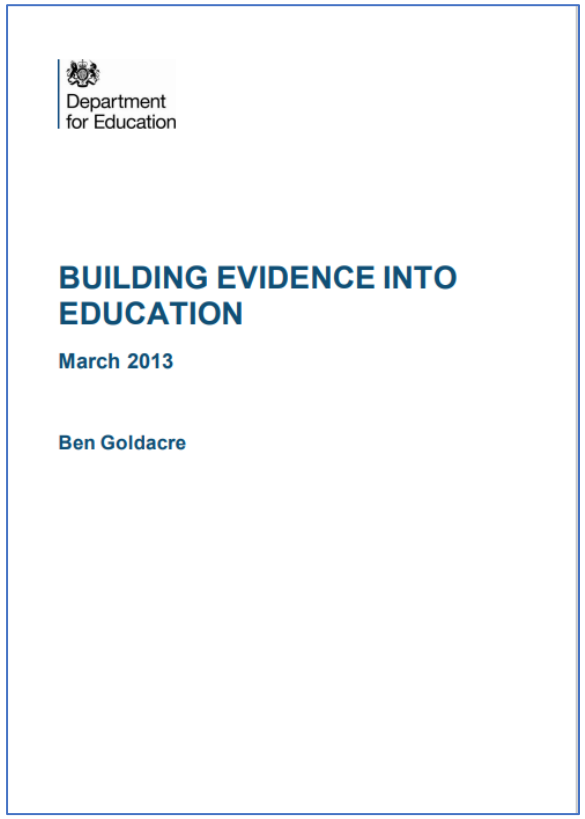
https://assets.publishing.service.gov.uk/media/5a7a219140f0b66eab999f4f/Building_evidence_into_education.pdf

Evidence - Disciplinary Culture Clash?



Department for Education

BUILDING EVIDENCE INTO EDUCATION

March 2013

Ben Goldacre

"…Gathering good evidence requires a culture shift, extending beyond a few individual randomised trials. It requires everyone involved in education to recognise when it's time to honestly say 'we don't know what's best here'. This isn't a counsel of despair: in medicine, and in teaching, we know that most of what we do does some good (if we're not better than nothing, then we're all in big trouble!). The real challenge is in identifying what works the best, because when people are deprived of the best, they are harmed too. But this is also a reminder of how inappropriate certainty can be a barrier to progress, especially when there are charismatic people, who claim they know what's best, even without good evidence."

https://assets.publishing.service.gov.uk/media/5a7a219140f0b66eab999f4f/Building_evidence_into_education.pdf

Evidence-based practice

- Gordon Guyatt – Father of EBM
- There is a tension between the population you serve and the person in front of you
- “How would you explain the options to a teen?”
- “I’d tell them a story…”

The power of storytelling

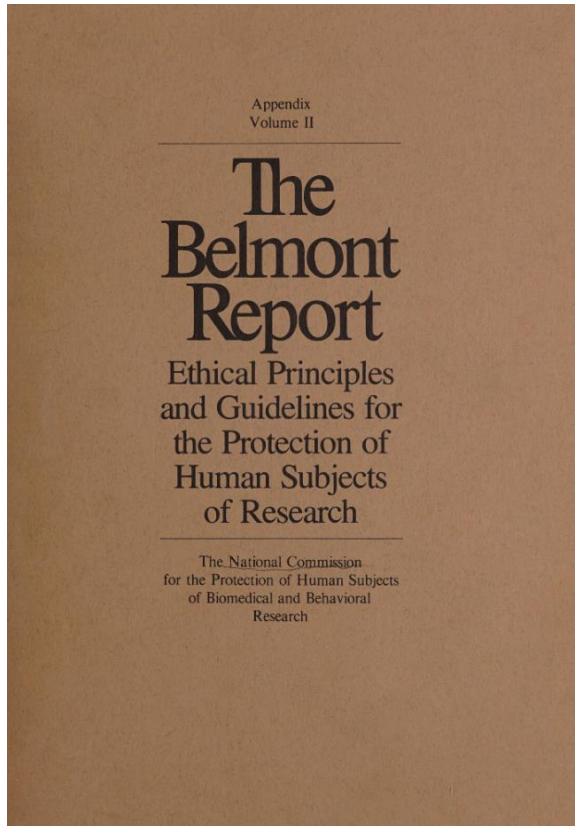
- We make sense of our lives by our narratives
- Important for all people – funders and policymakers are not immune
- How can the personal narratives relevant to evaluation of health promotion interventions be captured?

Part 2 – The three ‘E’s

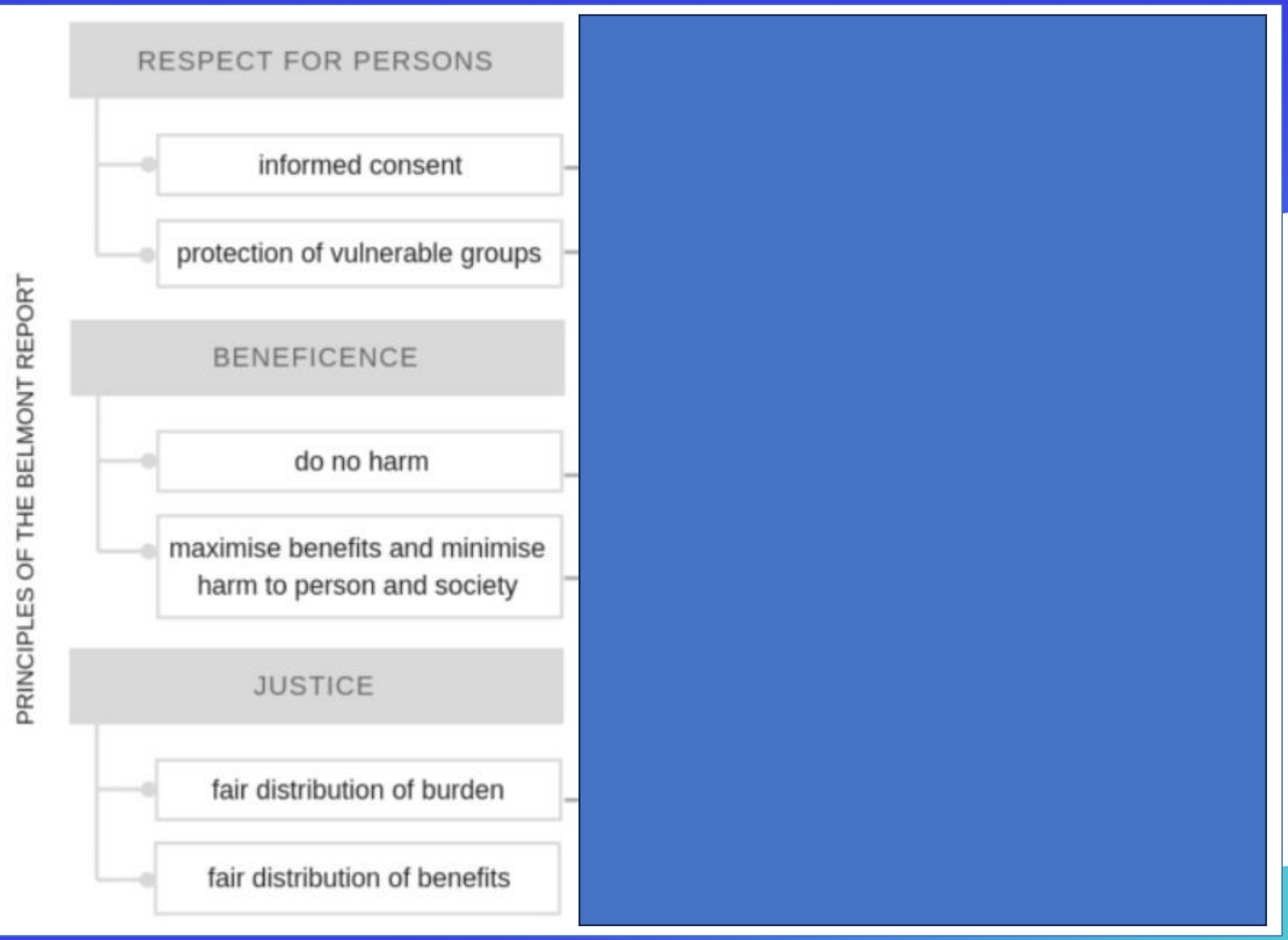
1. Evidence
2. **Ethics**
3. Epistemological markers

Ethics, and the Research Cycle

- Published in the USA in 1979
- Basis of research ethics on human subjects
- Prompted by the Tuskegee Syphilis Study
- Established the Office for Human Research Protections



https://wellcomecollection.org/works/r2dc7uuy



Anabo et al, 2019 https://link.springer.com/article/10.1007/s10676-018-9495-z

Ethics (and other parts of the Research Cycle…)

"Although statements of principle and codes of practice have symbolic importance, **doing practical ethics requires engagement with underlying arguments and concepts, and also with the details of everyday practice**. Simple prescriptions cannot suffice because every situation is different. Examining ethical questions requires **a conversation: a process of reasoning back and forth** between differing views of the good society and different exercises of practical wisdom and experience. It requires **openness among all parties to be transformed in the exchange**."
(Carter et al., 2012)

https://link.springer.com/content/pdf/10.1007/BF03391661.pdf

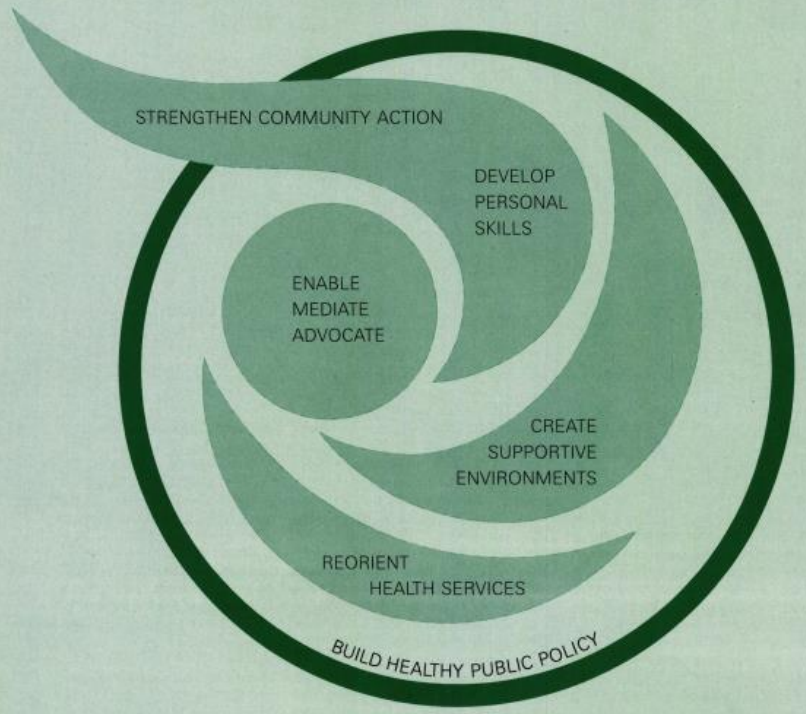
Ethics (and other parts of the Research Cycle…)

"On one hand, the **ethical frameworks employed often have their historical roots in academic medical trials where harm might be quite likely**. This has led to a framing of ethics as being mainly about risk **rather than rights and opportunities**...
In addition, it is critical to move beyond viewing ethics approval as something that researchers **have to 'get through'** before projects can start. We need ethics that can be extended and developed to handle more **iterative and dynamic ways of involving young people in research and service development**."
(Hagell, 2022)

https://ayph.org.uk/wp-content/uploads/2022/03/AYPH_EthicsBriefingPaper_March22.pdf

OTTAWA CHARTER FOR HEALTH PROMOTION

An international conference, jointly organized by WHO, Health and Welfare Canada and the Canadian Public Health Association, drew up this Charter for action to achieve Health for all by the year 2000 and beyond



A COMMITMENT TO INTERNATIONAL HEALTH ACTION

Photo WHO/Y. Pouliquen

More than 200 participants from 38 countries met in November 1986 in Ottawa to exchange experiences and share knowledge of health promotion. The conference stimulated an open dialogue among health workers, politicians, academics and representatives of governmental, voluntary and community organizations. The charter they drew up reflected their individual and collective commitment to the common goal of Health for all by the year 2000.

Health promotion is the process of enabling people to increase control over, and to improve, their health. So action for health promotion puts health firmly on the agenda of policy makers in all sectors and at all levels. Joint action by many sectors of society will ensure healthier public services, and cleaner and more enjoyable environments.

Consequently, the participants to the Ottawa Conference pledged themselves – among other things – to advocate a clear political commitment to health and equity in all sectors; to respond to "the health gap" within and between societies by tackling inequities in health; and to recognise health and its maintenance as a major social investment and challenge. ■

Photo WHO/T. Farkas

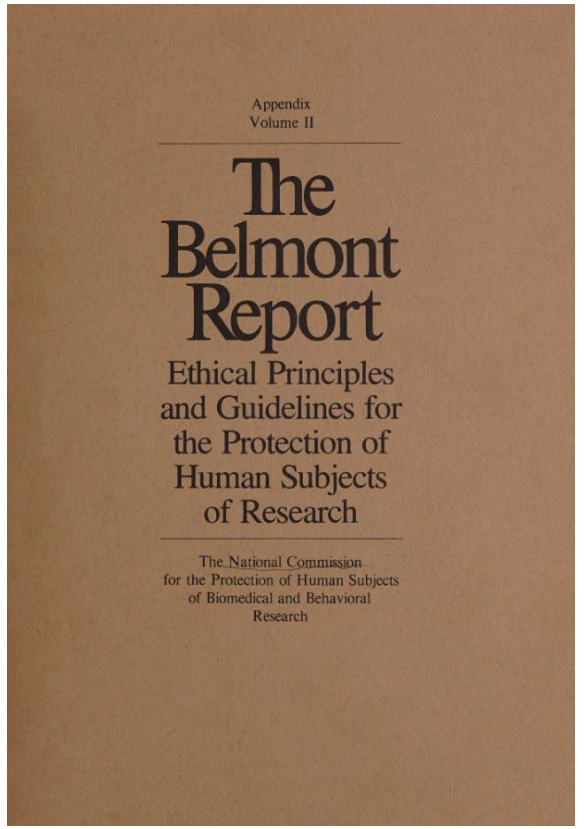
Good health must be actively promoted in the community, in the classroom, among "high-risk groups".

Photo WHO/T. Farkas

https://www.who.int/publications/i/item/WH-1987

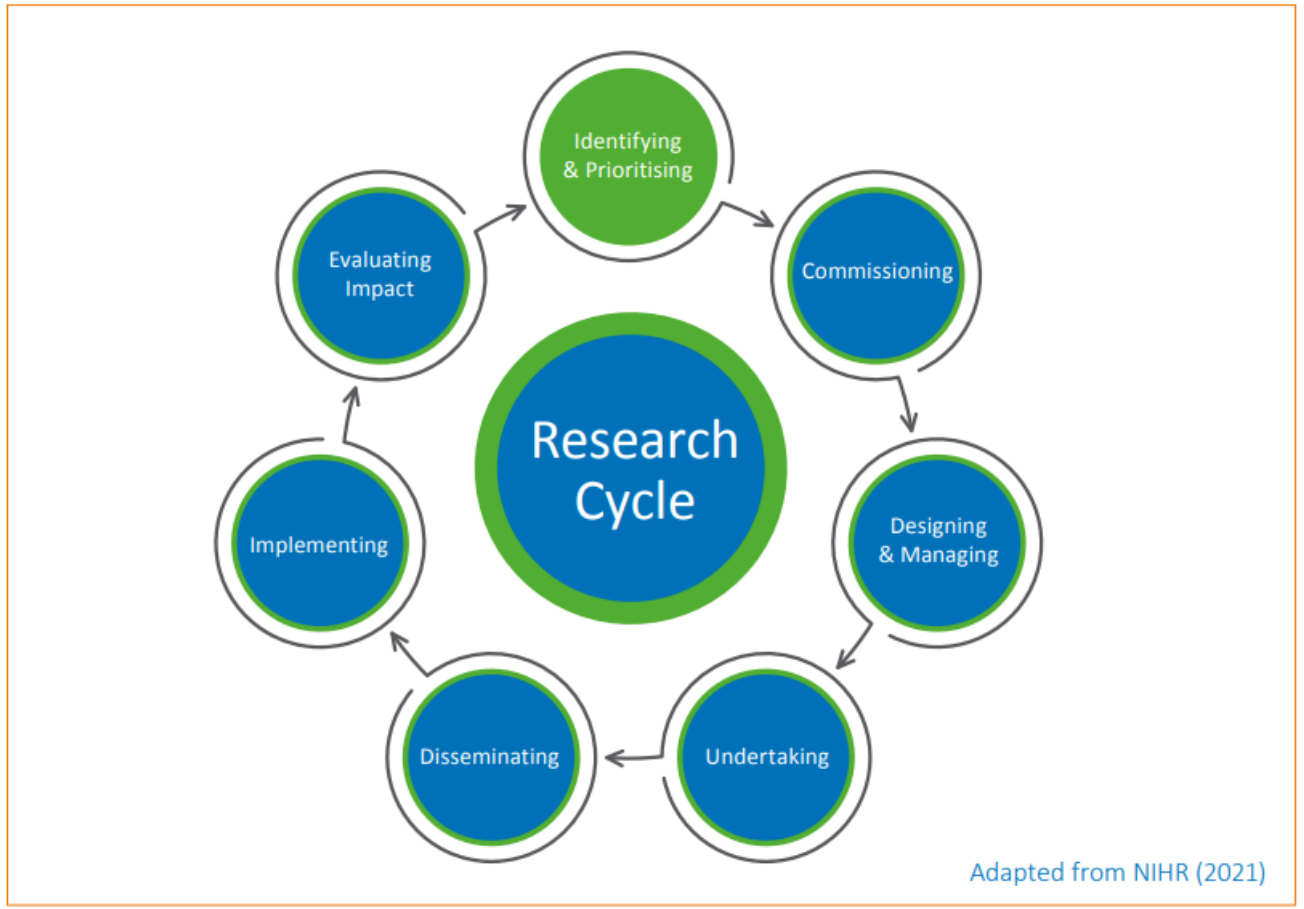
Ethics, and the Research Cycle

- Our research ethics systems originate from trials of medicines and therapies
- Are they fit for purpose for studies that are not RCTs?
- There will be examples of innovation
- Do we need further evolution?



Other parts of the Research Cycle

- What gets funded?
  - What is their agenda?
- Who is in the team?
  - Multidisciplinary?
  - What skills do we have?
  - User representation?
- What is our hypothesis?
- Where will we publish it?
  - Some journals do not publish qualitative research!
  - Word count vs mixed methods

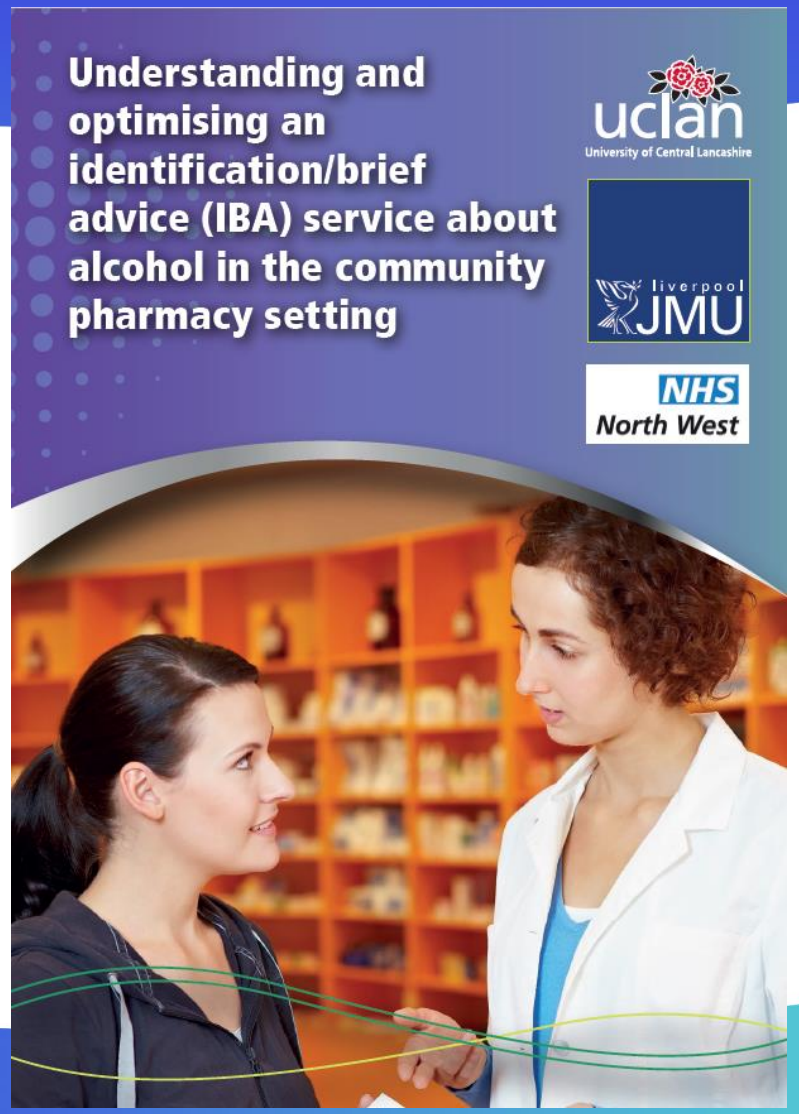


Adapted from NIHR (2021)

2 NIHR (2021) Briefing notes for researchers – public involvement in NHS, health and social care research

My experience

- Brief intervention about alcohol in community pharmacies
- Multidisciplinary team
- Funding from the commissioner



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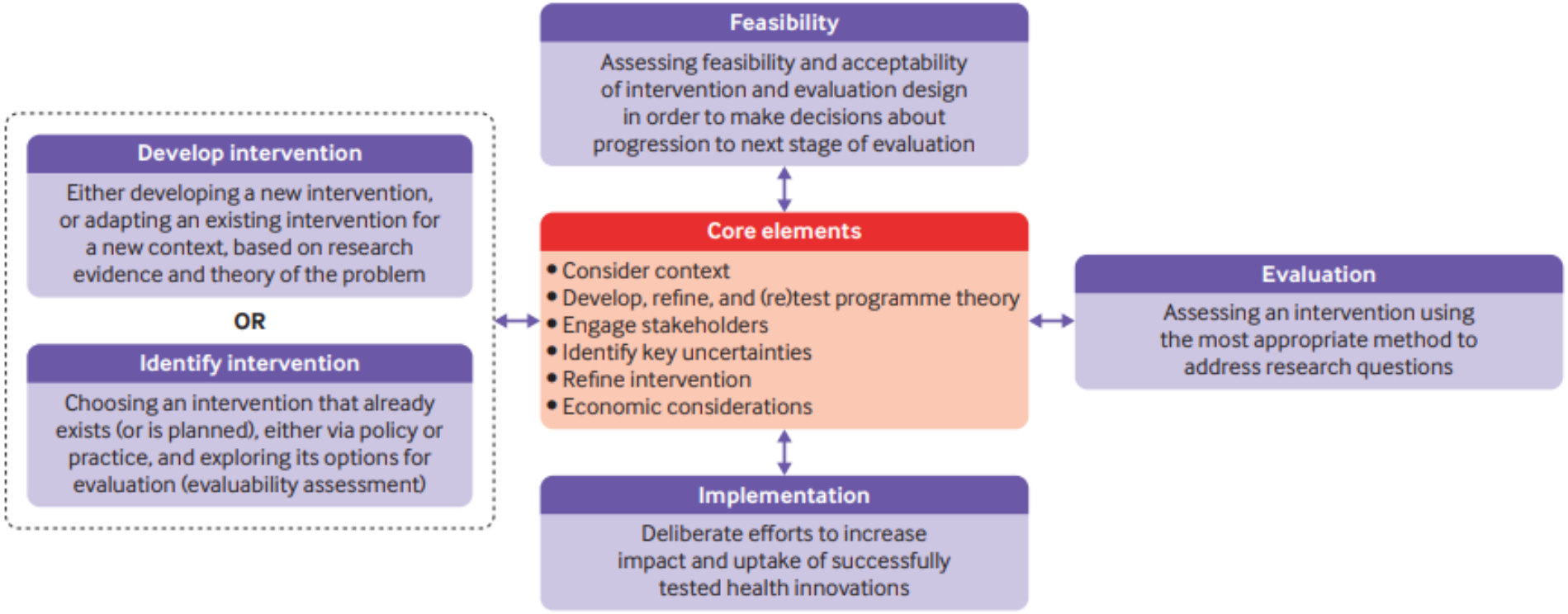
MRC Framework for Complex Interventions



https://www.bmj.com/content/374/bmj.n2061

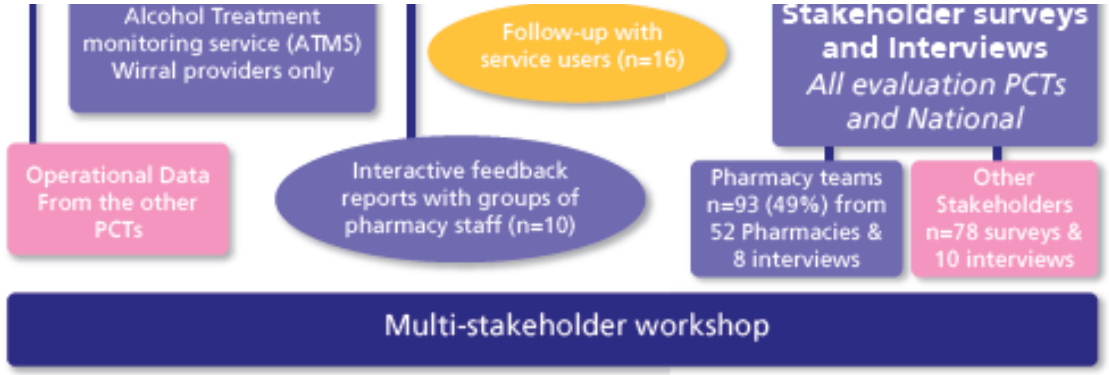
MRC Framework for Complex Interventions

Evaluation Design

Aims

1. To characterise, consolidate and optimise both the constant and variable elements of the pharmacy alcohol identification/brief advice (IBA) service in NHS Northwest, and

2. To inform planning for current and future pharmacy based services promoting safe consumption of alcohol.



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MRC Framework for Complex Interventions

PDF (Briefing paper: Commissioners) - Supplemental Material
1MB

PDF (Briefing paper: Pharmacy Leaders) - Supplemental Material
1MB

PDF (Briefing paper: Pharmacy Providers) - Supplemental Material
1MB

PDF (Briefing paper: Service users and advocacy groups) - Supplemental Material
1MB

PDF (Appendices) - Supplemental Material
2MB

Gray et al 2015 https://clok.uclan.ac.uk/5972/?template=default_internal

Part 2 – The three ‘E’s

1. Evidence
2. Ethics
3. **Epistemological markers**

Dimensions and Markers

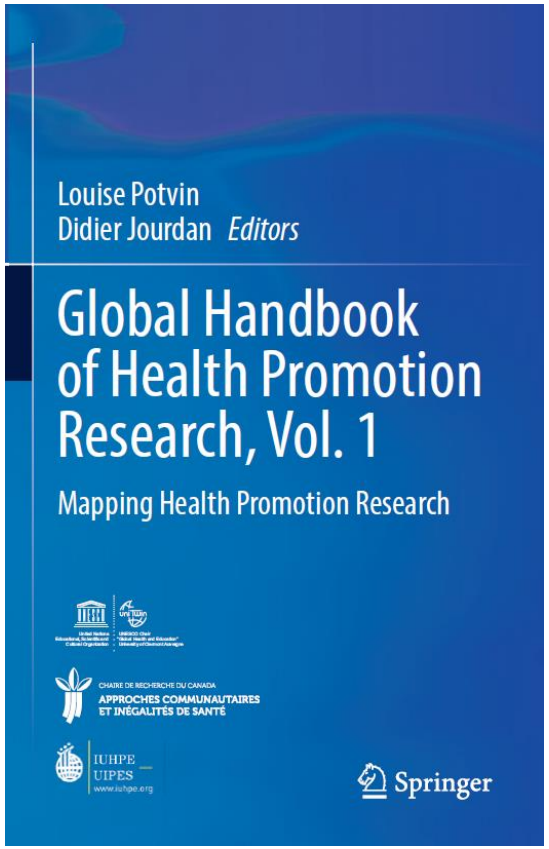
Dimensions and markers to navigate the field of health promotion research

Three dimensions

Ethical references	Research objects	Epistemological framework

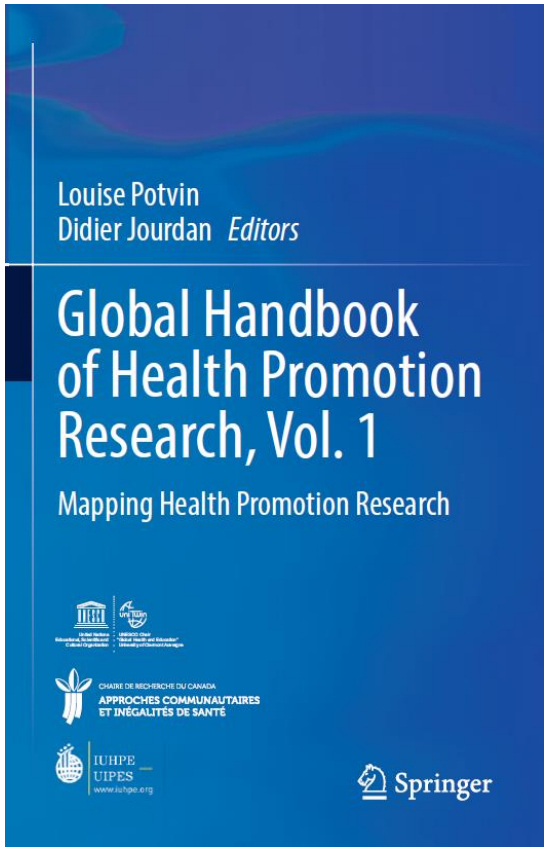
Eleven markers

Ethical references	Research objects	Epistemological framework
• The ethical horizon of the research • The source of legitimacy of the research • The status of the people involved in the research • The ethical foundations of research approaches	• The categories of actors practices relate to • The relationship to social change • The types of interventions studied	• The recognition of diverse forms of knowledge • The embeddedness of research practices in context • The relationship between researchers and stakeholders • The articulation of knowledge production and sharing



https://link.springer.com/book/10.1007/978-3-030-97212-7

Ethical Horizon and Legitimacy



1 - Ethical horizon

Table 50.1 Descriptors of the ethical horizon of health promotion research

Marker	Descriptors
The ethical horizon of the research	Values and principles derived from the Ottawa charter
	Salutogenesis ethical framework
	Critical pedagogy of Paulo Freire
	Contemporary social struggles

2 - Legitimacy

Table 50.2 Descriptors of the source of legitimacy of the research

Marker	Descriptors
The source of legitimacy of the research	Facilitating social transformations in favour of more justice
	Transforming settings or services in order to make them healthpromoting
	Empowering people and groups living in vulnerable conditions
	Considering the social and environmental determinants

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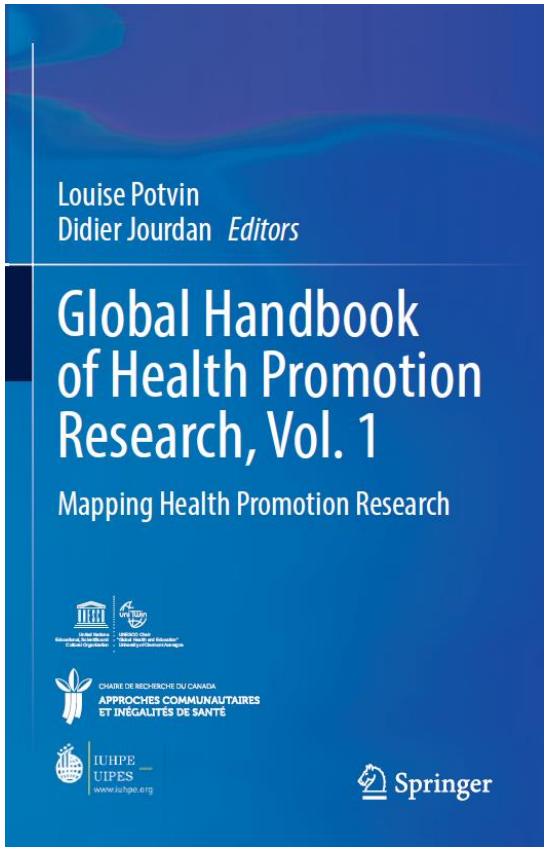
People and Ethical Foundations



3 - Status of the people involved

Table 50.3 Descriptors of the status of the people involved in health promotion research

Marker	Descriptors
The status of the people involved in the research	People are able to take control of their health
	People's experience is valued in the research
	People's participation is a prerequisite
	People's knowledge is valued in the research

4 – Ethical foundations of approaches and methods

Table 50.4 Descriptors of the ethical foundations of research approaches

Marker	Descriptors
The ethical foundations of research approaches	Research protocols meet guidelines and standards of research ethics
	An explicit normative framework informs research approaches

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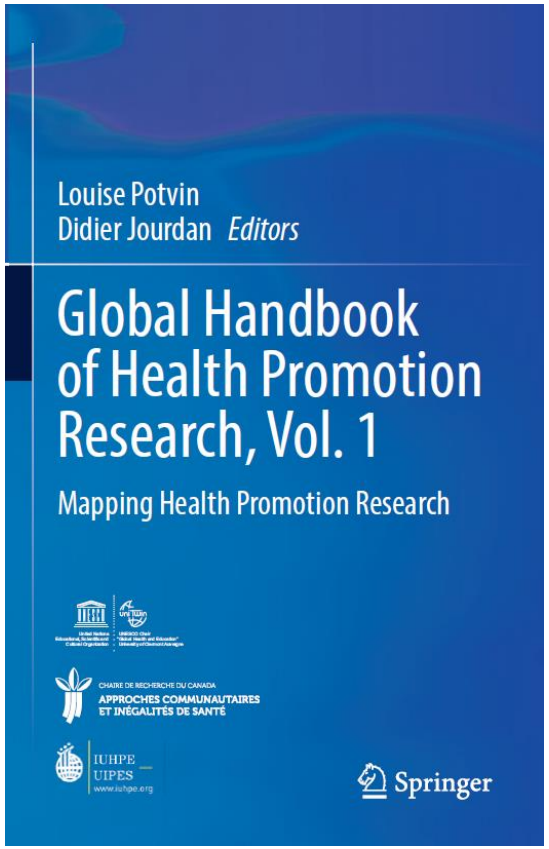
Epistemological Markers Pt1

1. The recognition of the various forms of knowledge that need to be combined in a regulated dialogue to explain and illuminate health-promoting and health promotion practices.

2. The embeddedness of research practice in context, embracing complexity and using a systems perspective to produce explanations that answer the questions below:

How does this health promotion/-promoting practice come about?

What kinds of outcomes can be expected for whom, and under which circumstances?



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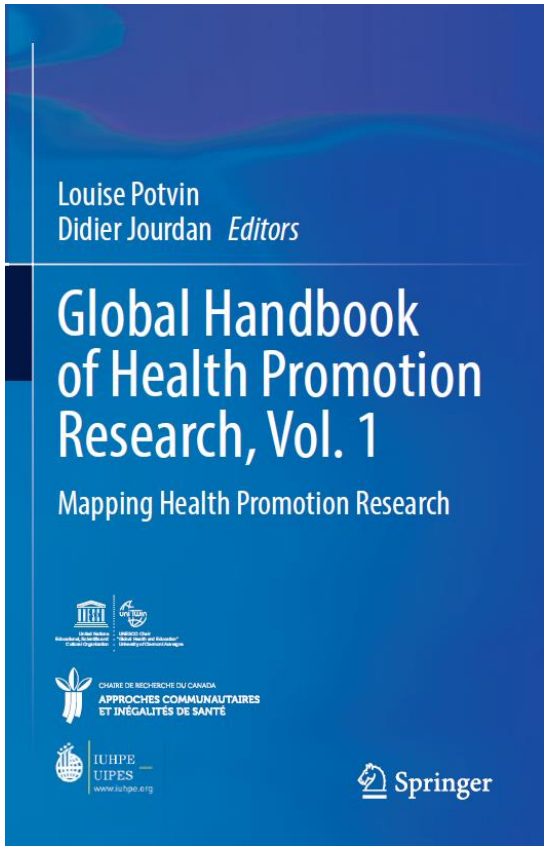
Epistemological Markers Pt2

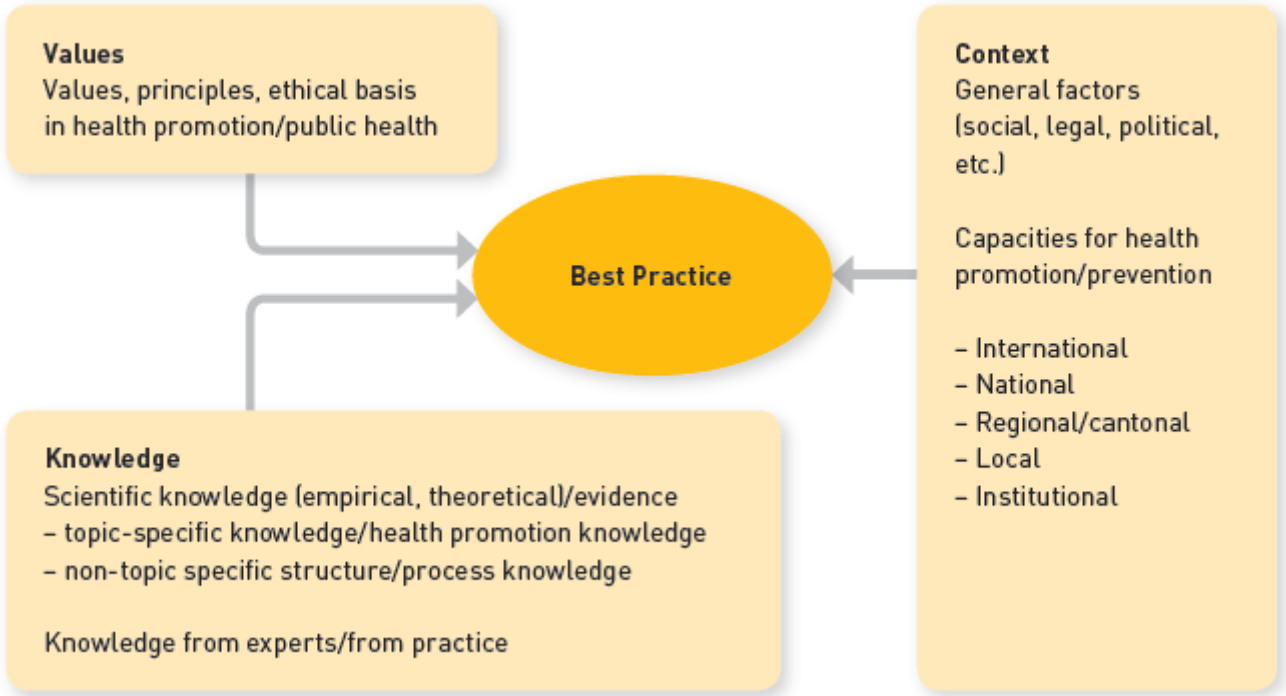
3. The relationship between researchers and other stakeholders involved in the research and in the practice under study. Although this relationship takes various forms, there is a critical examination of how it shapes the knowledge produced.

4. The articulation of knowledge production and sharing, recognizing that closing the science-practice gap requires different work from the various stakeholders, including the researchers, involved in the research.



Over to you...

Best Practice Dimensions (Health Promotion Switzerland)



The Tuskegee Syphilis Study

- Conducted between 1932 and 1972 by the USA Public Health Service and CDC
- 600 African American men – 399 with latent syphilis and 201 who were not infected
- Told that it would last only 6 months
- Incentivised with ‘free healthcare’ – but used disguised placebos
- None of the infected men received penicillin despite wide availability & evidence by 1947

Tuskegee Syphilis Study

A doctor draws blood from one of the Tuskegee test subjects

Dates	1932–1972
Locations	Tuskegee, Alabama
Funding	U.S. Public Health Service (PHS)

https://en.wikipedia.org/wiki/Tuskegee_Syphilis_Study