

Involving people in developing interventions for trials

Pat Hoddinott

Chair in Primary Care



Improving health through research  CHIEF SCIENTIST OFFICE



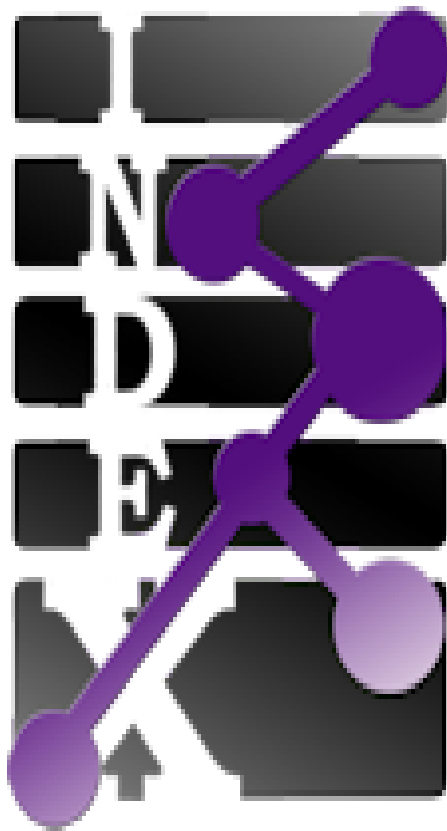
UNIVERSITY OF
STIRLING



Overview

- What approaches are there to intervention development?
- What methods do we use to involve others in the process?
- What are the strengths and limitations of these methods?
- How do research teams make decisions?

Background



MRC Funded

Identifying and critiquing different approaches to **Developing complex** interventions.

CI: Alicia O’Cathain, Sheffield; Team from Stirling, Bristol and Southampton

BMC: Pilot and Feasibility Studies – special series on Intervention Development

<http://www.pilotfeasibilitystudies.com/series/interventionDevelopment>

Hoddinott P. Pilot and Feasibility Studies (2015) 1:36 DOI 10.1186/s40814-015-0032-0

Complex Intervention Development

- Important because we need interventions that are:
 - effective/cost-effective
 - implemented in practice
 - sustainable
 - acceptable to taxpayers
- Yet
 - methods are poorly reported
 - there is considerable research waste
- **1/101 reported new medical discoveries are widely used.** Contopoulos-Ioannidis DG, et al. Science. 2008;321(5894):1298–9.



Rationale for involving other people

- Moral and ethical imperative where services are publicly funded
- To improve the research through 3 key functions:
 - Research decision making
 - Advancing understanding
 - Capturing knowledge - facts, experiences, tacit understanding, awareness.....opinion, beliefs.....



.....Data?

Some approaches to intervention development

- Evidence based – NICE or systematic reviews
- Theory-based – e.g. COM-B; Theoretical domains Framework
- Logic-based – inductive, deductive, models
- Person-based – e.g. e-health
- Paradigm-based – e.g. participatory research
- Methods-based – e.g. qualitative research, mixed methods

Participatory approaches to intervention development

- Language differs across disciplines and a common definition is hard to pin down

- Co-design, Co-production, Co-creation...
- Action Research
- Community Development Approaches

Participatory Approaches

They all share key tenets:

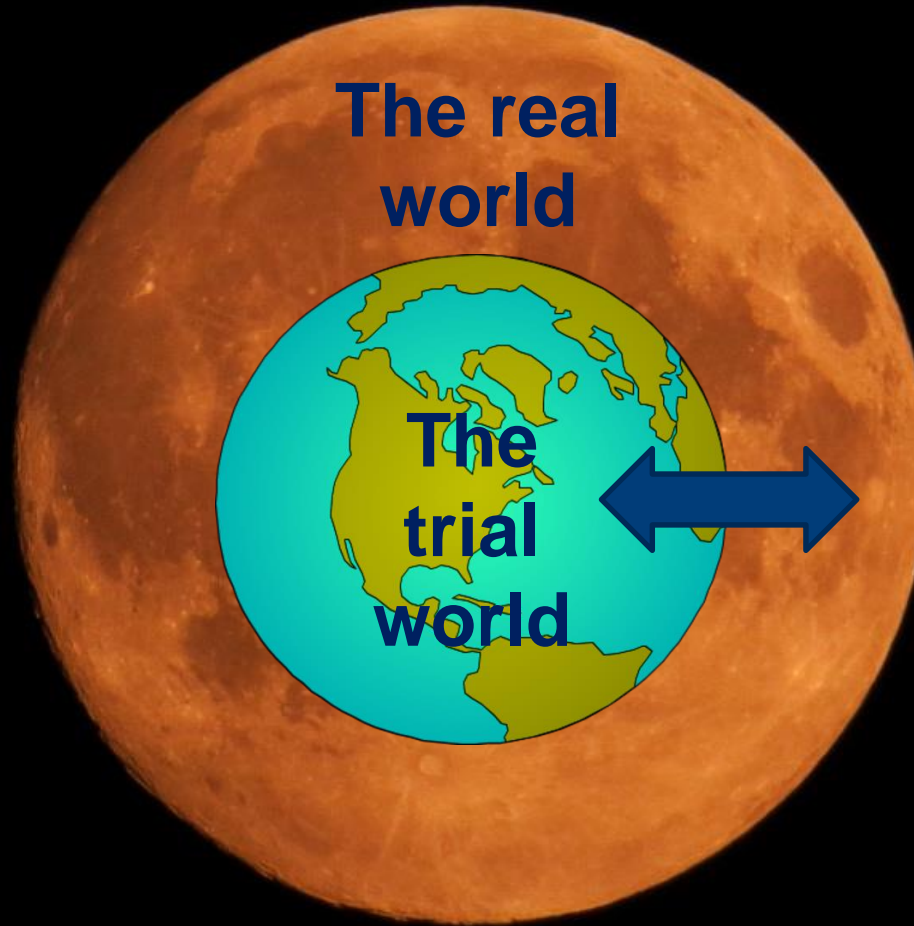
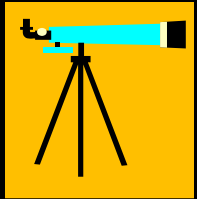
- *a democratic impulse*
- *iterative data collection and analysis*
- *simultaneous contributions to science, improvement and change*

Mertens DM. Transformative paradigm mixed methods and social justice. Journal of Mixed Methods Research. 2007 Jul 1;1(3):212-25.

Morrison B, Lilford R. How can action research apply to health services? Qual Health Res 2001;11(4):436-449.

Meyer J. Qualitative research in health care. Using qualitative methods in health related action research. [Review] [23 refs]. BMJ 2000 Jan 15;320(7228):178-181.

The integration problem



Recruitment

Fidelity

Retention

Implementation

QR and PPI - definitions

- *In qualitative health research people and situations **provide or are a source of data** for developing an enhanced understanding of perceptions, experiences and behaviour*
- *In PPI people including patients/carers **discuss and sometimes share decisions** in order to enhance research design and conduct*

PPI and qualitative research

- Both are increasingly used in trials
- They are different, although they are sometimes conflated in grant applications and reports
- They can be complementary and synergistic

SMALL GROUP DISCUSSION (1)

When designing an intervention - what are the strengths and limitations of:

1. Qualitative research
2. PPI
3. Participatory approaches?

How are people selected?

Qualitative research

Systematic sampling strategy

Single or serial interviews

Participants usually have no research experience

Purposive, theoretical, diversity, snowball for hard to reach, disconfirming data

How many?

Saturation for key themes

Rigour

PPI

Variable. Selection not always transparent

Continuity over years; “in the team”. Group think?

Single or multiple topics/projects

Trained? Professionalised?
How representative?

How many?

1-2, sometimes a group, outreach, charities, social media

How do people contribute?

Qualitative

Skilled staff collect data (interviews, focus groups, observations.....)

Ethics approval

Discipline/epistemology driven

COnsolidated criteria for REporting Qualitative research (COREQ) <http://www.equator-network.org/>

Power relations:

The researcher and the researched

PPI

Team meetings, email. Task orientated – leaflets, outcome measures, dissemination

No ethics approval required

Drivers not always transparent

GRIPP (Guidance for Reporting Involvement of Patients and Public). Staniszewska et al. (2011)

Power relations:

Patient and public involvement as equals?



Participatory
Approaches

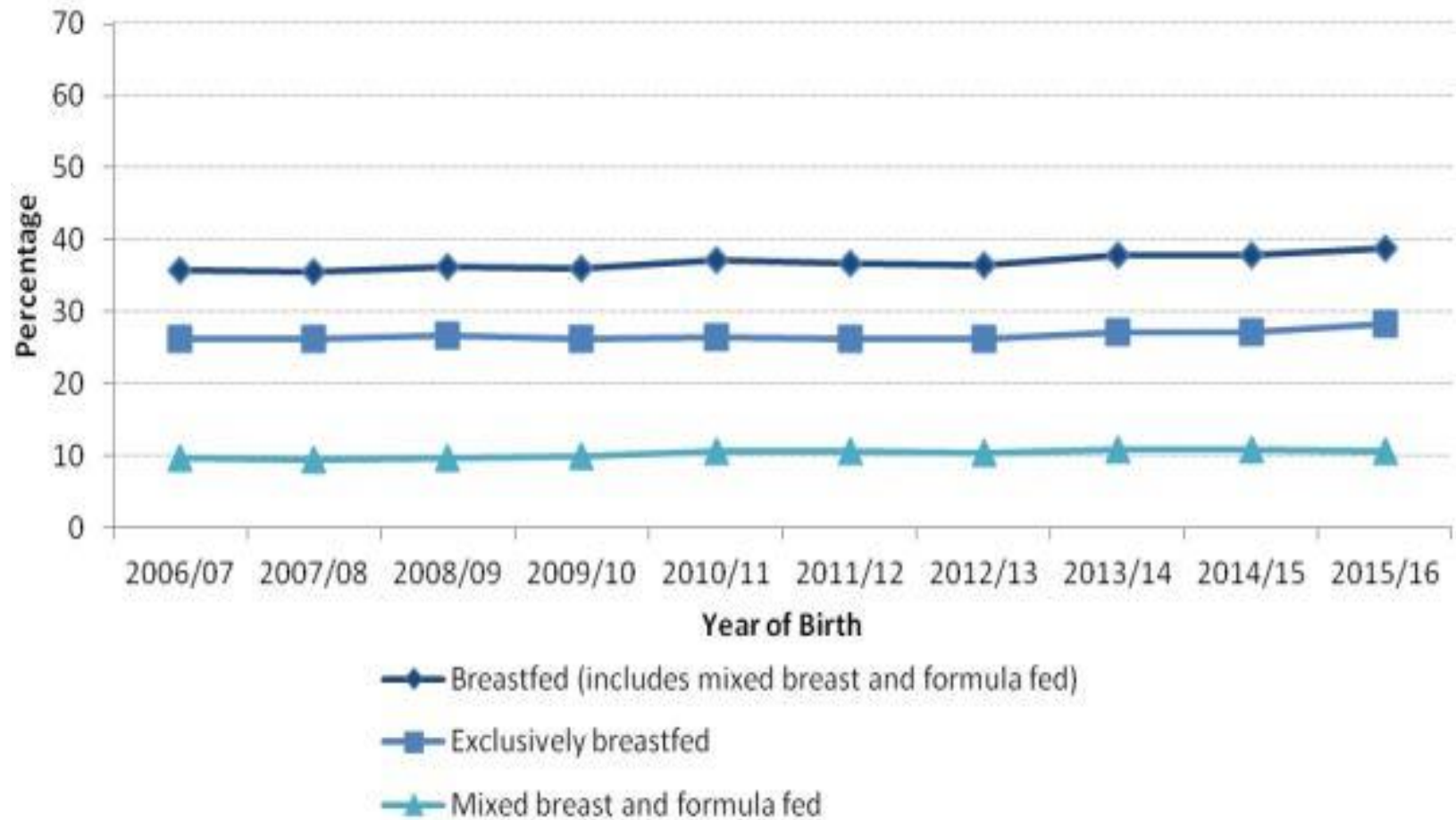


Breastfeeding



Breastfeeding in Scotland

6-8 weeks, Health Visitor “Baby Check”



Global evidence - UK idiosyncrasy

Cochrane Systematic Reviews:

Any additional support – professional or lay increases breastfeeding duration and exclusivity. (Renfrew et al 2012)

But not in the UK! (Hoddinott et al 2010, 2011; Jolly et al. 2012)

Some things...

....work in some places

....for some people

....at some times

....under some circumstances

How do we change “some” to “most” in an efficient and sustainable way?

A cautionary tale

- Qualitative research on infant feeding decision making
- An action research breastfeeding coaching intervention (Before and After Cohort Design).
Significant increase in breast feeding at 6 weeks
- The Breastfeeding in Groups Trial (BIG).
Cluster RCT embedded in qualitative research
 - **no effect**
 - **action research was probably the effective component**

References: (Hoddinott et al.: BMJ, 1999; Birth, 2006; Family Practice, 2007; BMJ, 2009; Social Science and Medicine, 2010)

SMALL GROUP DISCUSSION (2)

Consider how you could use PPI, qualitative research and/or participatory methods to strengthen the design of an intervention to meet the commissioning brief below.

Facilitating the return to work of NHS staff with common mental health disorders (Adapted from NIHR/HTA Commissioning Brief 2015)

THANK YOU

- Colleagues, patients and lay representatives who have contributed to this talk
- NMAHP-RU receives funding from the Chief Scientist Office of the Scottish Government Health and Social Care Directorates.

Contact: p.m.hoddinott@stir.ac.uk

Tweet:  *@PatHoddinott*