Designing and reporting studies for improved value and reduce waste:

Mixed methods as a means to improve value

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Mixed Methods - Health Care Intervention Studies

• Pragmatic toolbox of scientific methods\textsuperscript{1,2} combined with Public and Patient Involvement and Engagement (PPIE)
• Data is triangulated to answer a priori and emergent research questions
• Complex health and social care intervention research\textsuperscript{3}
  – Process evaluations – recruitment, fidelity, engagement, reach, context\textsuperscript{4}
  – Used particularly in early-stage research
    \textit{Intervention development}\textsuperscript{5} and feasability studies\textsuperscript{6}
  – Or late-stage research when effectiveness established
    \textit{How will implementation vary nationally? Internationally?}
    \textit{Does the intervention work better in some places than others?}\textsuperscript{7}
    \textit{Does the intervention require adapting to local context?}\textsuperscript{8}
  – Understanding outcomes in full trials and data linkage studies
    (less common)
Mixed Methods in Trials and Big Data Studies

FLAMINGO
Flow of hospital admissions in children and young people to inform interventions
Data linkage, SRs, qualitative interviews and PPI

Effect of financial voucher incentives provided with UK stop smoking services on the cessation of smoking in pregnant women\textsuperscript{12,13}

Game of Stones
Effectiveness and cost-effectiveness of text message and endowment incentives for weight management in men with obesity\textsuperscript{14}

Funding: Cancer Research UK (C48006_A20863); Chief Scientist Office, Scottish Government (HIPS_16_1); HSC Public Health Agency Northern Ireland (NI; SM/R/22); Health and Social Care R&D Division NI Opportunity-Led Research Award (COM/5352/17); Chest Heart and Stroke Northern Ireland 2017_09; Scottish Cot Death Trust; Lullaby Trust 272.

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Refining logic models

Purpose and population
Intervention development in the pathway for unscheduled acute illness in children, access to care and admissions to hospital

Whole Systems and Multi-Stakeholder Approach to Intervention Development

Systematic Review Evidence

Programme Theory

Context - macro
- Rising admissions
- Covid pandemic
- NHS staff shortages and workload
- Health Inequalities

Right method, time, place, person, process,

Family, Staff and Society Values

Intervention Components, Processes and Mechanisms: TIDieR

Outcomes - Short, Intermediate and Long Term that matter to children, families, staff, society
Atlas of variation for hospital admissions in children

Short stay admissions increasing year on year

5 of the 11 Health Board regions purposively identified for mixed method case studies:
(i) high or low SSA rates
(ii) very high or very low population density
(iii) with a paediatric-specific Emergency Department (ED) or ED for all ages.

Some themes and variables:
Structure and process pathways from home to hospital via GP, Out of Hours Services, ED, Observation wards and Admission wards
Geography, socio-economic factors, different medical conditions……..
Families were unsure at what time point in their hospital visit their child was officially classified as “admitted”

it gets terribly confusing – how do you actually count referrals, admissions, turnarounds, whatever? The way our unit is set up, the assessment unit has [number] beds in it and it is physically, geographically next door to the ward and I think if, for whatever reason, the child is transferred through to the ward, then that becomes an admission. Otherwise, it is not counted as an admission. (Consultant, HB6)

CONFLICT: quant and qual data. Hospital proximity. Heuristic or availability bias

So when you're in [City] you wouldn't have a qualm about saying to someone 'can you nip up to the kids ED and they'll check you over and might do an x-ray and send you home' but you're not going to do that for someone who's, you're talking about a six or seven hour round trip. (GP HB4)
Qualitative data: What are the outcomes that matter to parents and professionals? \(^{10}\)

- **Parents**
  - Easy access to urgent care
  - Input from staff trained in paediatrics

- **Paediatricians**
  - Reduce number of short stay admissions

- **Shared Safety**
  - Reduce anxiety and uncertainty about illness trajectory
  - Time for skilled observation and reassurance
Refining logic models for Intervention development

**INPUTS/DRIVERS – see DAGIT**

- Parent and child factors: e.g. socio-demographic characteristics; health; wellbeing; knowledge; support; social media; past experiences
- Other factors: e.g. geography, time, transport

**WHO; WHEN; HOW; TRIAGE COMMUNICATION**

- **CONTACT WITH NHS**
  - Assessment/Triage: Infection (8/10 top diagnoses) ▲
  - non-infectious (2/10 – non-febrile seizure; constipation) ▲
  - Meso – local service organisation, care pathways and structure; Staffing; resources. ▲ ▲

**CONTEXT POST CONTACT WITH NHS**

- Mcleroy Ecological Model of Health
  - Macro – e.g. Covid; NICE Guidelines; National Targets; staffing resource; economic and climate

**NHS PROXIMAL OUTCOME < 30 DAYS**

- Observation in community setting
- ZERO DAY ADMISSION
- NON-ZERO DAY ADMISSION
- SEEN= NO ADMISSION
- READMISSION <30 DAYS

**DISTAL OUTCOMES**

- SAFE WELL CHILD
  - FAMILY reassured, Satisfied with care, informed. Safety net/plan in place

For peer review only - http://www.open.bmj.com/site/about/guidelines.shtml
CPIT III RCT – Incentives for smoking cessation in pregnancy

Adjusted odds ratio 2.78 (1.94 to 3.97) P<0.001

7 Centres: 5 selected for in-depth case studies

944 Pregnant women who are smoking

2 Groups:
- Incentives for smoking cessation <36 weeks and SSS
- Standard Stop Smoking Services (SSS) Control group
CPIT III Trial – Realist evaluation to understand variation in usual care and SSS by site\textsuperscript{13}

**5 Longitudinal Case Study Sites**
- Site observations and fieldnotes (n=85)
- Interviews Participants (n=22)
- Maternity staff (n=12)
- SSS staff (n=17)

**Context, Mechanism, Outcome (CMO = 9) for barriers and facilitators encountered for providing SSS within usual care in CPIT III e.g.**

- Problems with capacity in SSS (C) reduced the time and attention staff could provide (M) increasing the likelihood of sub-optimal cessation support for pregnant (O).

- Co-location and good working relationships between maternity and smoking cessation professionals (C) prioritises and reinforces smoking cessation (M) optimising the importance of quitting for women (O).
Does usual care matter when implementing incentives for smoking cessation in pregnancy?

**Paper 2**
Understanding variations in:
- Recruitment rates
- Staff attitudes to incentives and the CPIT III trial

Additional end of trial staff survey to complement case study data and search for disconfirming or seldom heard perspectives (Covid)

**Paper 3**
Exploratory Integration of all quantitative, health economic and qualitative data by site

Site tables: trial outcomes; health economic costs and the usual care CMO barriers and facilitators for maternity care and smoking support services (Paper 1) and recruitment (Paper 2)
A priori decisions in RCTs

…… mixed methods to maximise value

Evidence gaps? Under-represented populations?

A priori hypotheses?
- Explanatory?
- Exploratory?

Who will be blind to group allocation? Independence?

How certain is the causal pathway? Are any mediators and moderators of effectiveness known?

PROSPECTIVE Trial protocol Statistical Analysis Plan Process Evaluation Analysis Plan

Under what circumstances will data collection and analysis be iterative? Emergent RQs? Disconfirming data sought?

How important are setting and context likely to be?
Data collection to understand outcomes

Baseline Data

Primary Qualitative Data

Avoid interactions between process evaluations and the interventions you are testing

Participants can text real time feedback to research team?
Audio-recordings? Fly on the wall observations?

Are control group interviews necessary?
Prepare your protocol for unusual findings (Pre-mortem)

Fictional participant level data scenarios from a weight loss trial

Explore outliers and divergent cases

- Systematic Reviews
- Similar Trials
- Sub-group analyses
  - Confirmatory
  - Exploratory

Qualitative data
PPIE
Questions?

Thank you

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