How are qualitative methods being used alongside complex health service RCTs?
A systematic review

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Background

- Qualitative methods are important in evaluating the effects of complex interventions

- Little research has examined:
  - How qualitative methods are currently used in RCTs
  - How they could be used to improve the usefulness and policy relevance of trial findings.

Study objective

To review systematically the use of qualitative approaches in RCTs of complex health service interventions

Outline of presentation

- Methods of the review

- Key findings, focusing on the qualitative studies linked to the RCTs included in the review

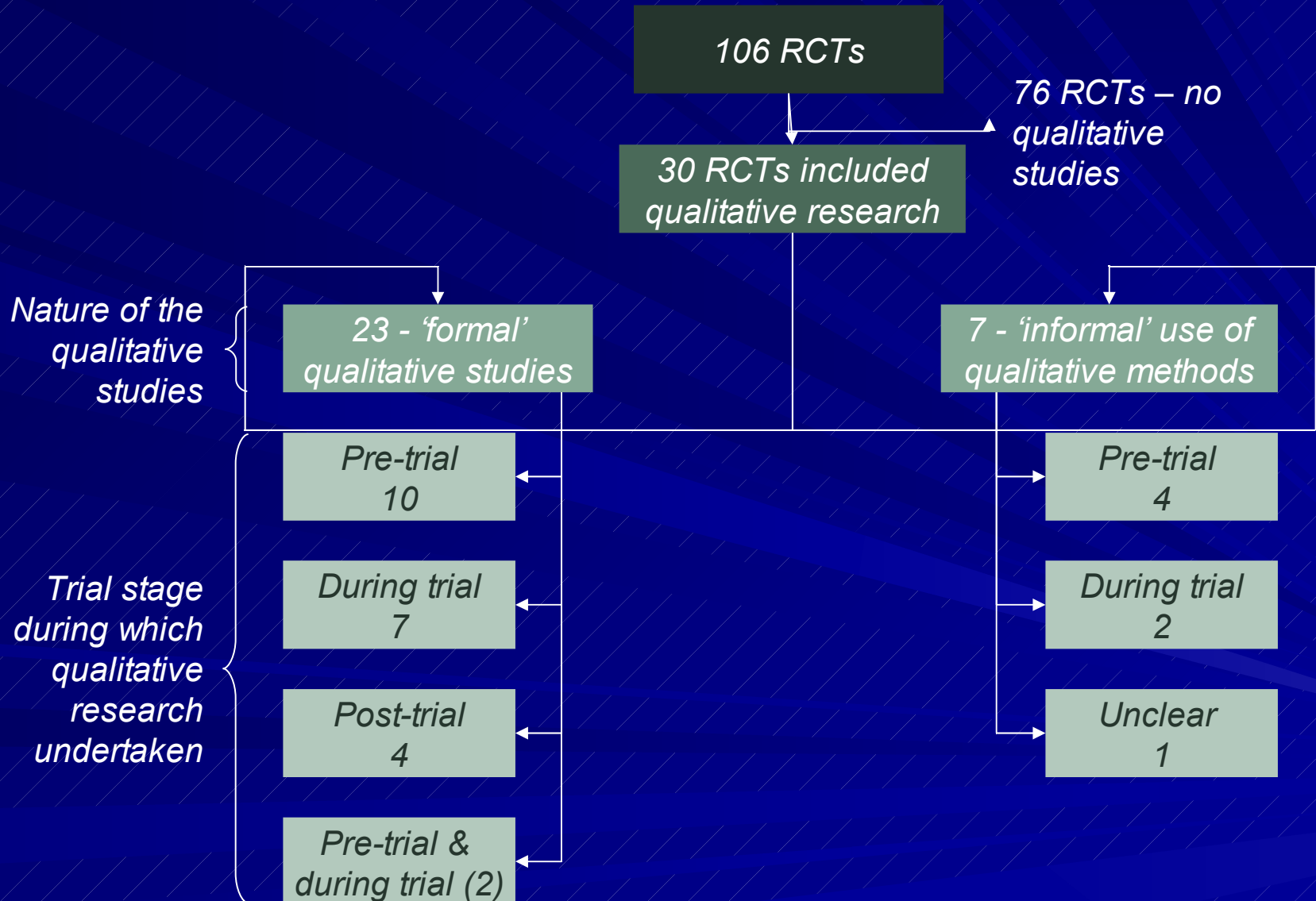- Implications of the review findings

- Future work

Methods

- Random sample of 106 RCTs from the Cochrane EPOC (Effective Practice and Organisation of Care) Review Group register, published in English in 2001, 2002 and 2003

- All published and unpublished qualitative studies linked to these RCTs identified through database searches and contact with RCT authors

- Data extracted from each study set by two reviewers using a standard form. This included:
  - Descriptions of the RCTs and qualitative studies
  - The quality of the RCTs and the qualitative studies
  - An assessment of the complexity of the intervention evaluated in each RCT
  - The approaches (if any) used by the authors to combine the RCT and qualitative study findings.

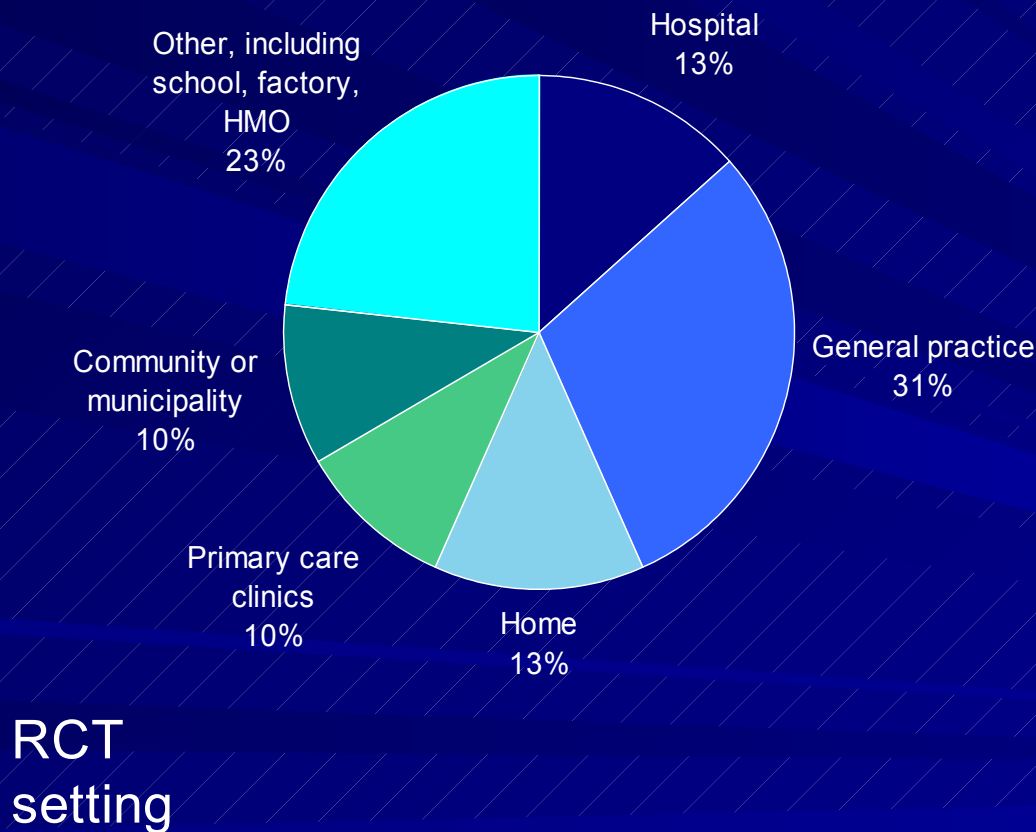- A narrative synthesis of the review findings was performed

Identifying qualitative studies

- Checked primary RCT paper for citations of qualitative studies

- Located primary RCT on Pubmed and then searched for:
  - related studies
  - studies published by the first and second authors of the RCT (and others, if necessary)

- Located primary RCT in Science and Social Science citation index and checked list of studies citing primary RCT

- Sent standard email and reminders to corresponding author (if email address available), or whichever author had a locatable email address, requesting information on qualitative studies linked to their RCT
  → responses for 72% of papers (76/106)

→ Correspondence with authors identified the largest number of studies

Findings: overview of studies

Description of RCTs that included qualitative research

Hospital
13%

Other, including school, factory, HMO
23%

General practice
31%

Community or municipality
10%

Primary care clinics
10%

Home
13%

RCT setting

- Level of care:
  - 80% (n=24) primary
  - 7% (n=2) secondary
  - 13% (n=4) mix of levels
- All conducted in high income countries
- Main health service issues addressed:
  - Mental health
  - Appropriate use of medicines
  - Sexual health

Description of qualitative studies – stated objective/s

- Pre-trial studies (n = 14): [1]
  - To explore the knowledge, attitudes or practices of the target groups (n = 7)
  - Intervention development (n = 8)
  - To explore the illness experience of consumers (n = 2)
  - Instrument development (n = 2)

- During trial studies (n = 9): [2]
  - To describe the intervention as delivered (n = 2)
  - To explore issues influencing the effects of the intervention (n = 2)
  - Other (all n = 5)

- Post-trial studies (n = 4):
  - To explore participant experiences of the intervention (n = 2)
  - To explore issues influencing the effects of the intervention (n = 1)
  - To analyse intervention development (n = 1)

[1,2] Includes studies done both pre- and during trial

Description of qualitative studies - methods

- **Methodological approach:**
  - Grounded theory (n=3)
  - Ethnography (n=2)
  - Action research (n=1)
  - Narrative approach (n=1)
  - Other (n=4)
  - Not specified (n=19)

- **Sampling:**
  - 43% (n=13) of studies did not describe their sampling approach
  - Remaining studies used a mix of purposive, convenience and random sampling

- **Data collection methods:**
  - Many studies used several methods (n=10), with interviews and group discussions most frequently used
  - Interviews (n=10) and focus groups (n=5) also most commonly used single method

- **Data analysis:**
  - 46% of studies (n=14): no information provided
  - Thematic / content analysis was the most commonly reported approach (n=9). Also some use of grounded theory (n=2) and Framework (n=1)

Linking the qualitative and RCT studies

- **Links between the qualitative and RCT research teams:**
  - 53% (n=16): papers share authors, but links between the studies not explicitly made
  - 30% (n=9): explicitly described some level of linkage between the study teams
  - 17% (n=6): unclear

- **Integration of qualitative and RCT analysis and interpretation:**
  - 30% (n=9): analyses conducted separately, some integration in interpretation
  - 67% (n=20): no integration found / not reported / unclear
  - No studies reported integration of both analysis and interpretation and only 2 studies stated explicitly that they had used a 'mixed method' approach

Quality of the qualitative studies

- Sufficient data available to allow quality assessment in 20 studies
- Study quality highly variable

- Key weaknesses in reporting:
  - Only 20% provided a clear justification for the qualitative approach used
  - Inadequate descriptions of context, sampling, data collection and analysis methods common
  - Reflexivity: poor description of the role of the researchers in 85% (n=17) studies
  - How ethical issues taken into consideration: unclear in 75% of studies

- Key strengths in reporting: ☺
  - 90% had a clearly stated research question
  - Claims made supported by sufficient evidence in 55% (n=11) of studies

Conclusions

- Qualitative studies alongside RCTs in this field remain uncommon

- More attention needs to be paid to the use of qualitative approaches for:
  - Intervention development
  - Process evaluation

- Qualitative study quality is a key concern

- Little explicit integration of qualitative and RCT data

Future work

- Application of same approach to +-100 RCTs included in the Cochrane review of audit and feedback interventions

- Ethnographic case studies of RCT teams that have utilised qualitative approach alongside their trials

- Develop guidance for trial teams who plan to utilise qualitative methods

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