MORECare: A framework for conducting research in palliative care

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International Observatory on End of Life Care
Methods for evaluating service delivery models in End of Life Care

• End of Life Care research presents its own unique problems.
• MRC made a call through the Methodological Research Programme to evaluate this.
• Collaboration between King’s College, London, University of Manchester, University of Edinburgh and University of Aberdeen.
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http://www.csi.kcl.ac.uk/morecare.html
MORECare Project Description

Aims:
The aim of MORECare is to identify, appraise and synthesise ‘best practice’ methods for the evaluation of EoLC, particularly focusing on complex service-delivery interventions and reconfigurations.
MRC Framework/Guidance

A FRAMEWORK FOR DEVELOPMENT AND EVALUATION OF RCTs FOR COMPLEX INTERVENTIONS TO IMPROVE HEALTH

This document is a discussion document drafted by members of the MRC Health Services and Public Health Research Board. It is intended to provide a framework for individuals considering the evaluation of a complex intervention. It does not set out a set of required steps in carrying out trials in this area.

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Developing and evaluating complex interventions: new guidance

Prepared on behalf of the Medical Research Council by:
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www.mrc.ac.uk/complexinterventionsguidance
MRC framework for complex interventions (2000)

- **Theory**
  - Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues

- **Modelling**
  - Identify the components of the intervention and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other

- **Exploratory trial**
  - Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention with an appropriate alternative

- **Definitive randomised controlled trial**
  - Compare a fully defined intervention with an appropriate alternative using a protocol that is theoretically defensible, reproducible, and adequately controlled in a study with appropriate statistical power

- **Long term implementation**
  - Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term

*Continuum of increasing evidence*
Evaluating Complex Interventions

Question:
How many hats does it take to evaluate complex interventions in EoL&PC?

Answer: Many ... here are the ones we looked at in more detail for the MORECare project.

- Statistical Analysis
- Health Economic Assessment
- Ethics
- Mixed Methods Research
- Outcome Measurement
- I ❤ MRC Guidance

MORECare trying to make it more manageable.
MORECare Methods

Initial literature scoping, formation of expert group, initial identification of issues

- Literature appraisals of methodological, ethical, legal and other issues and identify solutions and best practice
- Stakeholder consultation on needs and views, web-based followed by nominal group techniques

Preliminary synthesis of issues, best practice and potential solutions

- Transparent expert consultations: users, outcome measures, health economics, ethics, mixed methods, statistics

Final synthesis resulting in guidance, case studies, dissemination
Systematic reviews

Methods used and challenges encountered in developing and evaluating palliative and EoLC services

Experiences and views of participation in palliative and EoLC research

Strategies for recruitment of participants to palliative and end of life care research via health professionals
Consensus activities:
Transparent Expert Consultations

– When there is a lack of clarity or when there is no evidence.
– Using Nominal Group techniques.
– Using online consultation to clarify guidance.
Stakeholder consultations - methods

- How would you want results from palliative care studies presented to you?
- 45 minute facilitated discussion
- Then spent 15 minutes writing their recommendations individually
- Shared with the group
- Went through to check for duplicates & clarity
- Each ranked the recommendations
Expert think tanks

• Selected researchers and subject experts to attend
• 3 presentations given about selected topics with time for discussion
• Broke into nominal groups who made recommendations individually
• Each member of the group then shared them
• Ended up with about 100 recommendations per think tank
Analysis

• Created rules to account for:
  – Median score i.e. level of agreement with the recommendation
  – Level of consensus around the agreement

• Interested in the which ones with strong agreement and which with disagreement
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<th>Range</th>
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<td>≤2</td>
<td>≥2</td>
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</table>
Health Economics

G4 Health Economics,
IQR, X=median

N=34
Online consultation

• Reduced the recommendations by removing:
  – Duplicates
  – Too generic recommendations

• Final recommendations put in an online survey where participants asked to rank how much they agreed with it
  – (1 strongly disagree - 9 strongly agree)
  – Sent to all members of the workshop plus PAG
Meetings

• 3 Stakeholder consultations
  – 2 with service users
  – 1 with commissioners and managers

• 5 Expert think tanks
  – Health economics
  – Mixed methods
  – Ethical considerations
  – Statistical considerations
  – Outcome measurements
MORECare Expert meetings

Who were the experts?
Expert panel and other experts identified in literature

Agree focus, scope literature and identify topic experts

Generic research, not only palliative care

Aimed always to include experts in the methods external to palliative and end of life care

Researchers, clinicians and service commissioners

Patients, users and policy makers
Stakeholder consultations – main recommendations

• Clear presentation of results using common terminology.
• Don’t just report the primary outcome of the trial – include quality of life data too.
• Give a description of what it was like to be on a trial including participant comments.
• Develop a system to rate the quality of the research.
• Develop clearer definitions of terms for palliative/end of life care research.
Stakeholder consultations – main dilemma

• One group strongly supported the idea that researchers should not be mealy mouthed in identifying End of Life

• The other was clear this should not be clearly identified for fear of upsetting participants.
Expert Recommendations

• Outcomes
• Mixed methods
• Ethics
• Health Economics
• Statistics
Outcome measurements

When should the primary outcome or end point be measured? A trade off between attrition and time for the intervention to have an effect.

Some challenges

Choose an outcome measure that is validated in one setting or several?

Should I use staff, patient, observer, or proxy/caregiver reported measures?
### Top 3 recommendations ranked by area

<table>
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<tr>
<th>Recommendations</th>
<th>Median (1&lt;sup&gt;st&lt;/sup&gt; - 3&lt;sup&gt;rd&lt;/sup&gt; quartile)</th>
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<tr>
<td><strong>Measurement properties</strong></td>
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<tr>
<td>... easy to administer and interpret (e.g. short and low level of complexity)</td>
<td>8 (7-9)</td>
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<tr>
<td>... applicable across care settings to capture change in outcomes by location</td>
<td>8 (7-9)</td>
</tr>
<tr>
<td>... responsive to change over time and capture clinically important data</td>
<td>8 (7.8-8)</td>
</tr>
<tr>
<td><strong>Timing</strong></td>
<td></td>
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<tr>
<td>Time points require clear identification to establish a baseline</td>
<td>7 (6-9)</td>
</tr>
<tr>
<td>Time points need to be established before conducting the evaluation.</td>
<td>7 (5-8)</td>
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<tr>
<td>When prospective measurement is used, end points should correspond to when the effect of the intervention is expected to take place.</td>
<td>7 (6-8)</td>
</tr>
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Mixed Methods

- ensure appropriate multi-disciplinary skills mix or training of team define the theoretical paradigm, method of integrating results and safeguards to ensure rigor at the outset

- plan investigation carefully to avoid undue burden of qualitative and quantitative questionnaires – perhaps dividing data collection or selecting questions and/or samples appropriately

- take into account any potential therapeutic effect of qualitative interviews where participants can express their feelings, if these are similar to components of the intervention

- ensure research nurses or those collecting data are appropriately trained in qualitative data collection

- Evaluations of Complex Interventions

- Integration

- Mixing paradigms

- Space to publish all data

- Costs

- Implementation components

- Evaluation

- Development

- Piloting
• Create **Research Ethics Network** for Palliative and End of Life care

• **Train those working in on ethics and governance committees** in the specific issues.

• **Collaborate with patient and caregivers** in the design of the study

• **Attend** the ethics committee meeting with a caregiver or patient

• **Ensure proportionality in information sheets**, as excessive information can be tiring/distressing for very ill individuals.

• **Review and amend the law** regarding consent so that **advance consent** for studies other than clinical trials of medicinal products applies.

• Allow for **reflection and comment in questionnaires?**
Much disagreement – low consensus fierce debate about QALYs

BUT

- Assess costs from a SOCIETAL perspective
- Attention to response shift at EoL
- Need to understand more about societal and personal preferences
- Develop robust methods which take account of changes in preferences
At outset the analysis plan must include handling of missing data and should be tested with the feasibility of the intervention.
Handling attrition & missing data

Attrition due to death and illness is to be expected in palliative and EoLC studies. It is an inevitable finding, and indicates that a relevant population of patients and families have been included in the study.

Levels of and reasons for attrition should be planned for, recorded, and routinely reported and explored.

Attrition should not be seen as a fault of the design, unless markedly different to that planned for. BUT

Missing data should be assumed NOT to be “at random” unless proven otherwise.

Results from different methods of imputation should be tested – noting that ‘using only complete cases’ is a form a imputation.
Handling attrition & missing data

All reporting should include information on levels and reason.

We propose a new taxonomy of attrition:

• ADD  Attrition Due to Death
• ADI  Attrition Due to Illness
• AaR  Attrition at Random

Missing data: reasons which are not due to attrition. For example, Missed questionnaire, Missed data item in questionnaire
These have implications for analysis and may allow different imputations

Explore different imputation models
MRC guidance is endorsed, and is appropriate for palliative and end of life care.

Study designs need to build from phase II to III, which often does not happen in palliative care research due to its related to end of life care. MRC guidance is endorsed, and is appropriate for palliative and end of life care.

Two of the pre-requisites for participation are easily met. Other pre-requisites wish for participation are more problematic. There is a need to train research ethics committee members, funding body members and academics/practitioners in palliative care.

Think implementation at all stages.
Are you SURE this is the "Stairway to Success?"
**Statistics**

It is important to define and report different types of attrition and consider how timing of data collection effects attrition. A taxonomy could include ADD – attrition due to death; ADI – attrition due to illness; AaR – attrition at random.

Investigate the pattern of missing data and/or the conduct of the study to identify the cause of missing data, in order to inform the choice of imputation method.

A clear statistical analysis plan (SAP) is required that identifies how to deal with missing data.

There should be clear reporting of the types and amount of missing data and attrition in Palliative and EoLC studies and the imputation methods employed.

**Ethics**

To enhance participation in research on palliative and EoL (End of Life) care requires closer working and open communication between practitioners, researchers and users to increase awareness and understanding of palliative and EoL care research.

Practitioners, members of research ethics committees and researchers need adequate training in order to address the practical and ethical challenges associated with assessing and conducting research at the EoL.

Respect is required for autonomous decisions of patients and carers regarding their participation in research to avoid limiting their participation through inappropriate gatekeeping and paternalistic attitudes.

Incorporate wide inclusion criteria in studies on palliative and EoL care a sensitive approach to recruitment is required that demonstrates empathy, is responsive to an individuals level of understanding and emphasises the voluntary nature of participation.

Require clear codes of conduct, standards and competencies for assessing research in palliative and EoL care.

**Health Economics**

Costing should be from the societal perspective and as well as statutory services include costs of other formal care.

Attention must be paid to the response shift that occurs at the end of life as priorities and valuation change.

Researchers should give consideration to the implications of decisions on the equitable distribution of care.

More research is needed to examine societal preferences about end of life care and to clarify what counts as a legitimate and valid equity judgement.

We need to develop robust methods for assessing outcomes which take into account preferences and the way these change over time.

**Mixed methods**

integrating quantitative and qualitative methods) research is a particularly useful approach for palliative and end of life care research.

The degree of respondent burden needs careful consideration in palliative and end of life care research, including in prioritisation of key outcome measures, qualitative questions, or splitting data collection may be necessary.

**Outcome measures for evaluations of palliative and EoL care services should be responsive to change over time and capture clinically important data.**