

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.

Co-Authors



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<http://www.csi.kcl.ac.uk/morecare.html>



International Observatory
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MORECare Project Description

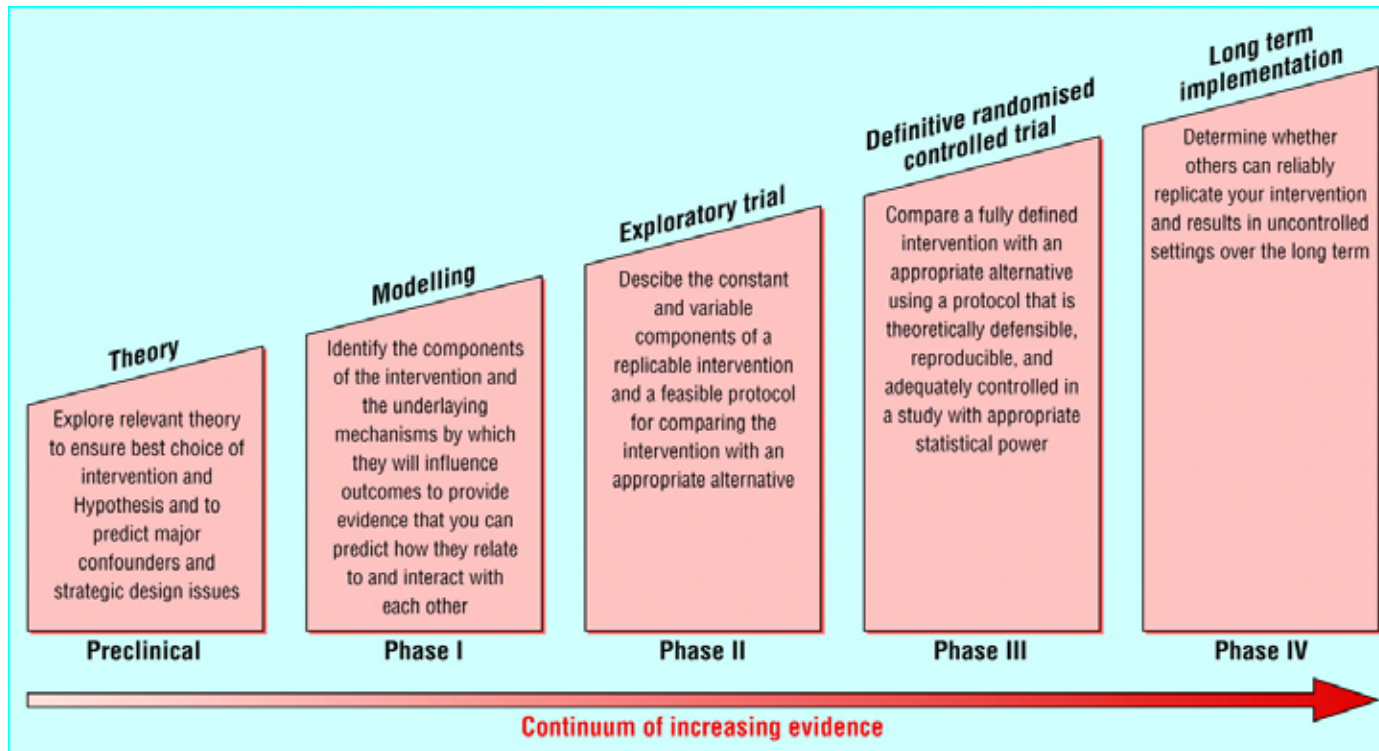


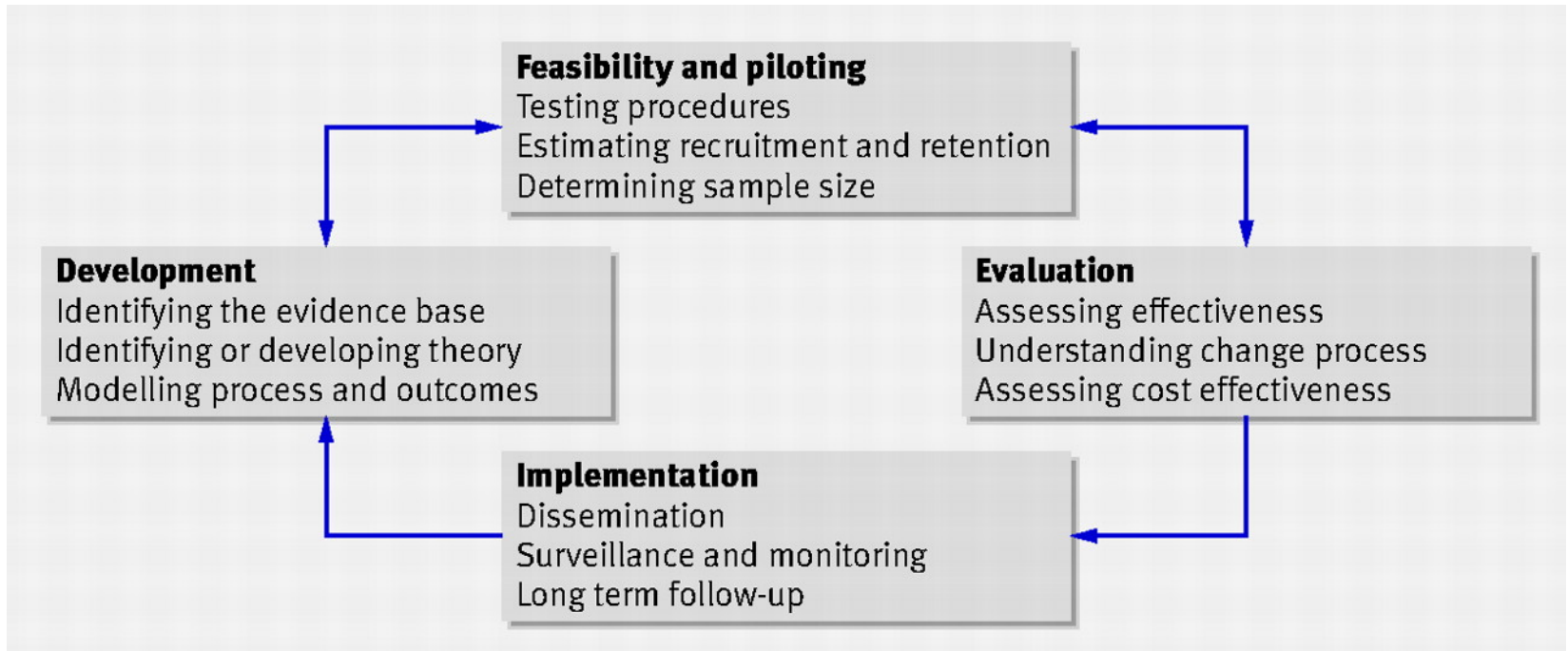
Aims:
The aim of MORECare is to identify, appraise and synthesise 'best practice' methods for the evaluation of EoLC, particularly focussing on complex service-delivery interventions and reconfigurations

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MRC Framework/Guidance







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



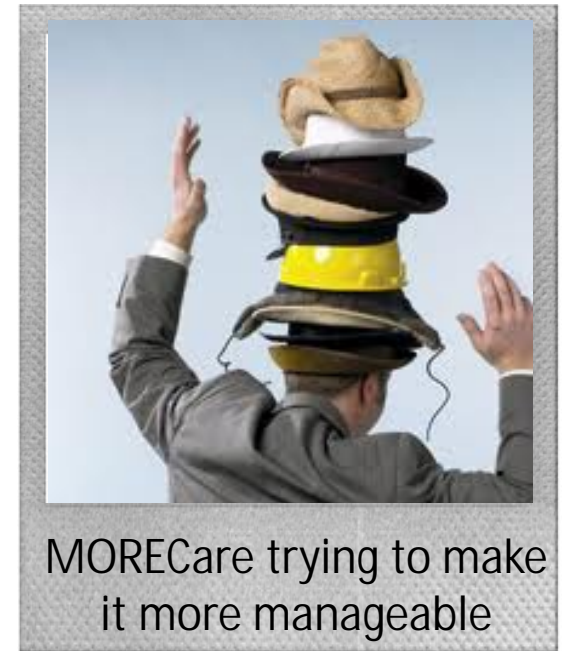
Ethics



Mixed Methods
Research

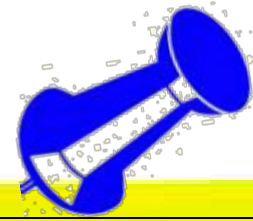


Outcome
Measurement



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

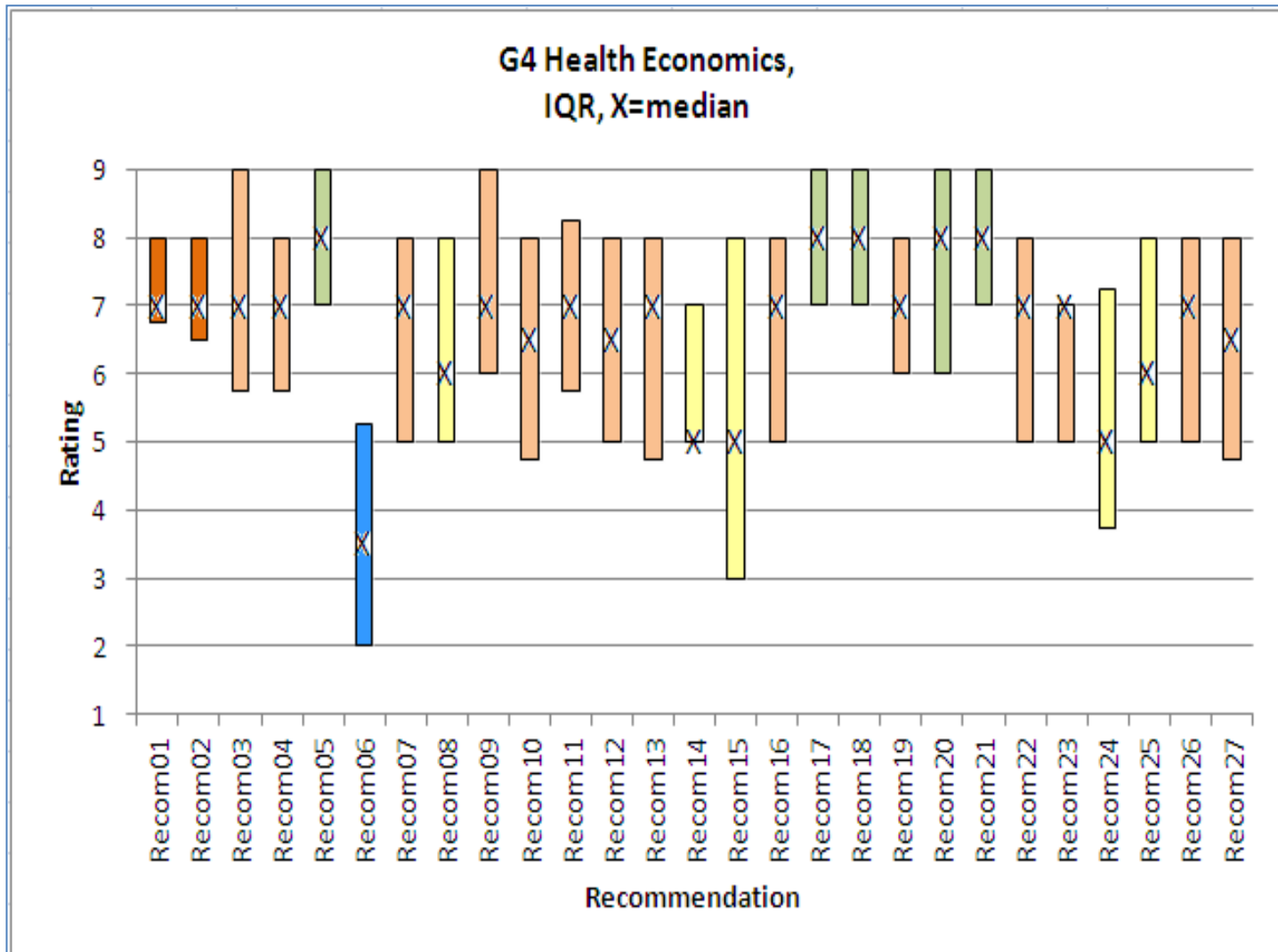
- Selected researchers and subject experts to attend
- 3 presentations given about selected topics with time for discussion
- Broke into nominal groups who made recommendations individually
- Each member of the group then shared them
- Ended up with about 100 recommendations per think tank

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

Rating	Median	Range	Code
Strong agreement/high consensus	≥ 8	< 2	1
Strong agreement/low consensus	≥ 8	≥ 2	2
Moderate agreement/high consensus	$< 8 - > 6$	< 2	3
Moderate agreement/low consensus	$< 8 - > 6$	≥ 2	4
No agreement/high consensus	$\geq 4 - \leq 6$	< 2	5
No agreement/low consensus	$\geq 4 - \leq 6$	≥ 2	6
Moderate disagreement/high consensus	$< 4 - > 2$	< 2	7
Moderate disagreement/low consensus	$< 4 - > 2$	≥ 2	8
Strong disagreement/high consensus	≤ 2	< 2	9
Strong disagreement/low consensus	≤ 2	≥ 2	10

Health Economics



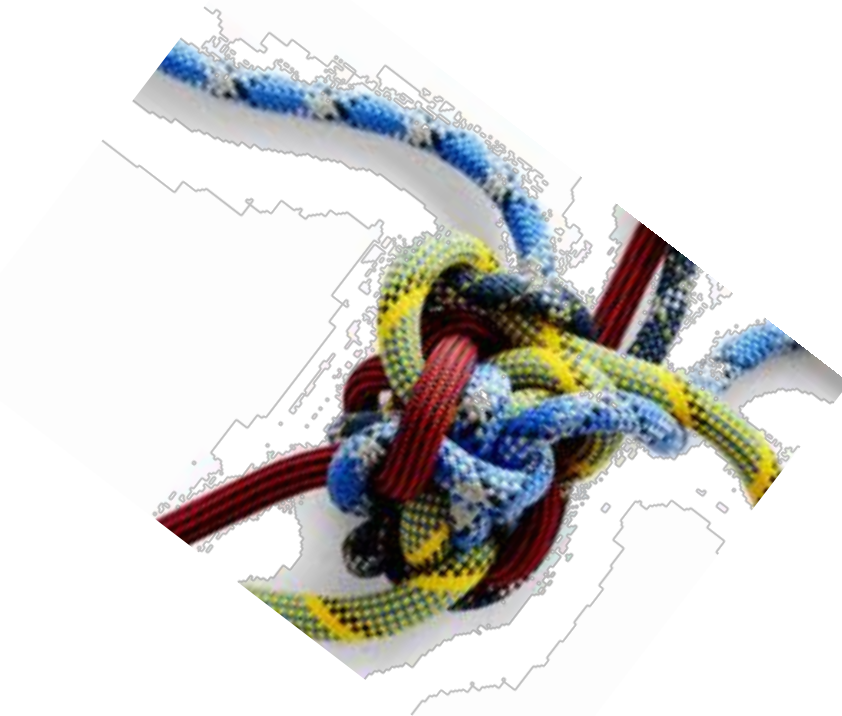
N=34

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

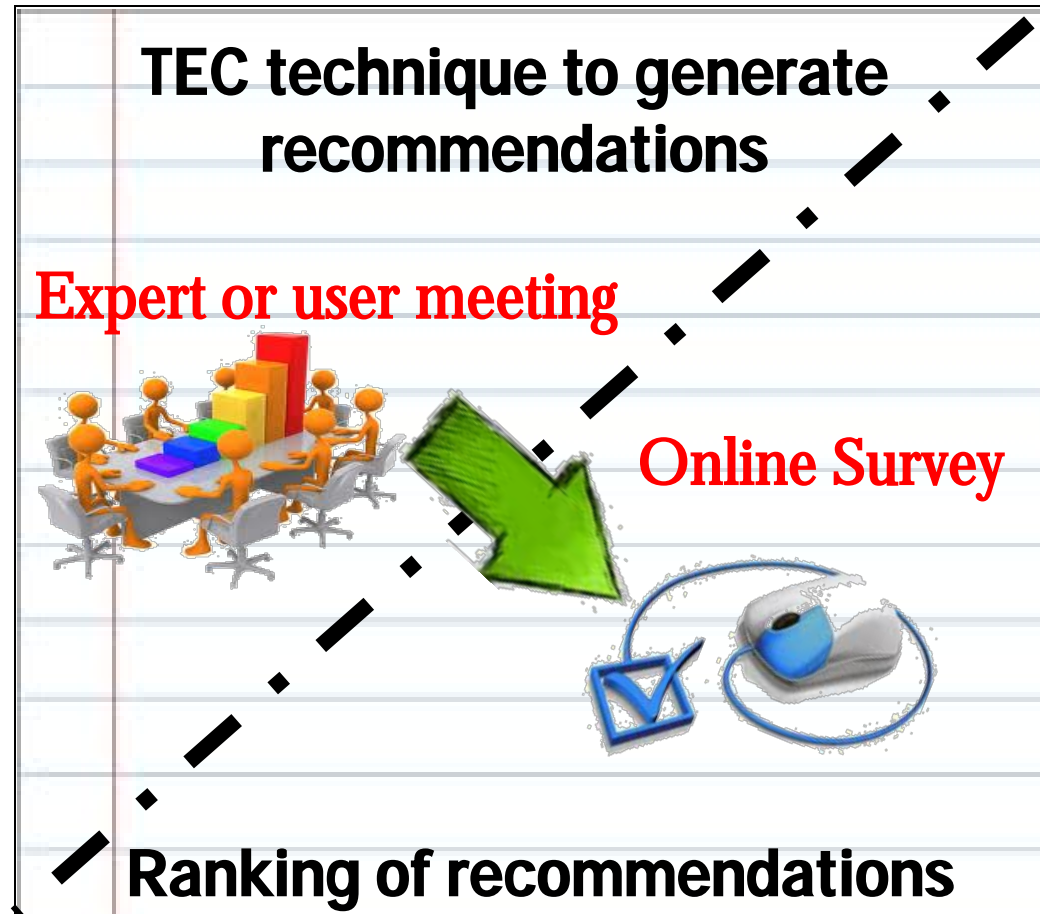
Agree focus, scope literature and identify topic experts

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

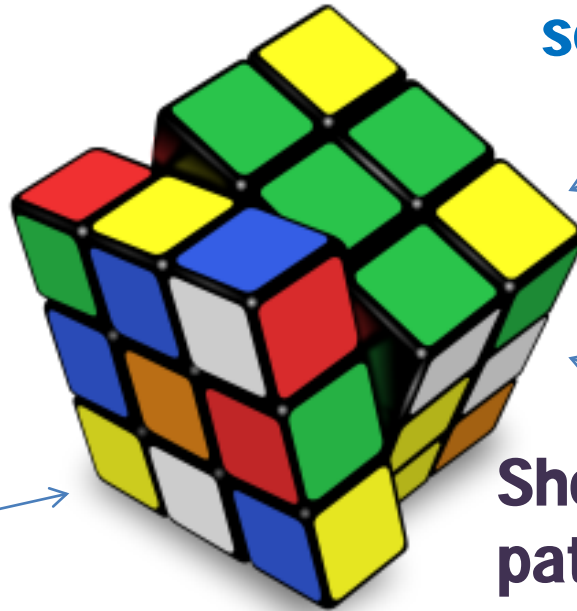
- Outcomes
- Mixed methods
- Ethics
- Health Economics
- Statistics



Outcome measurements

Some challenges

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

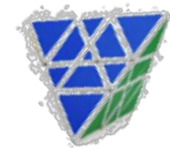


Choose an outcome measure that is validated in one setting or several?

Should I use staff, patient, observer, or proxy/caregiver reported measures

Top 3 recommendations ranked by area

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



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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

Piloting

Development

Evaluation

Implementation components

Integration

Costs

Mixing paradigms

Space to publish all data

Evaluations of Complex Interventions





**Participant
information sheet for
research on fatigue**

- 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?



Hot Topics

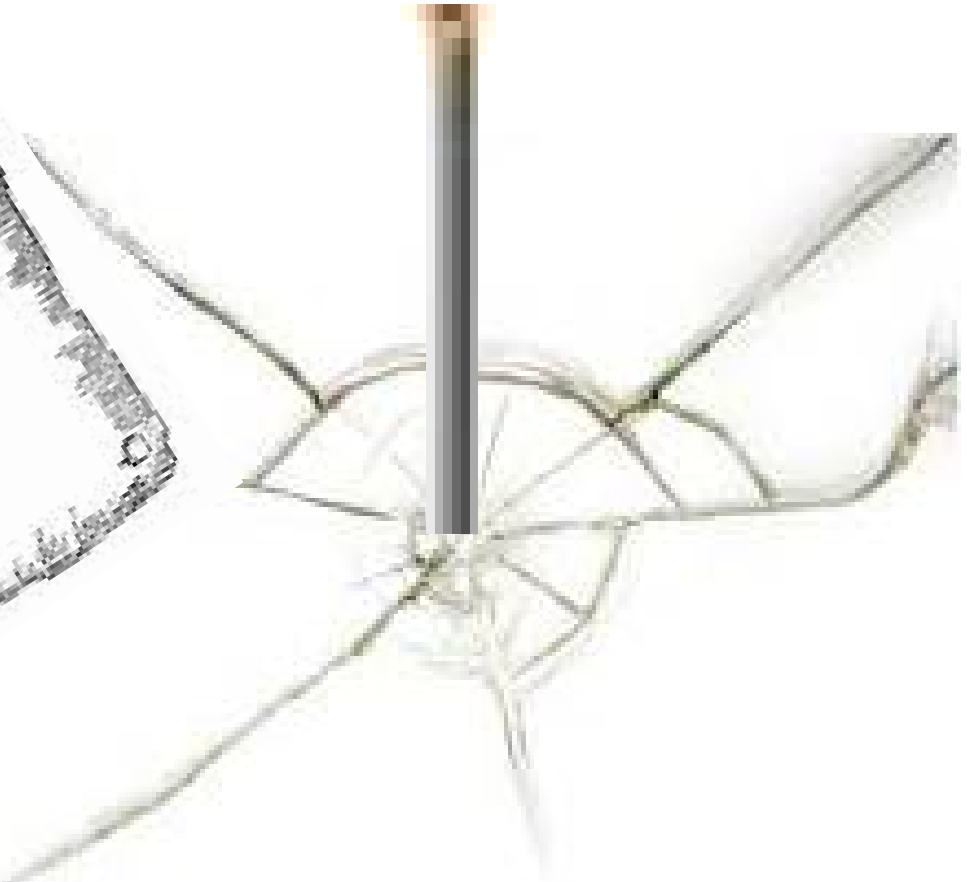
Much disagreement –
low consensus fierce
debate about QALYs
BUT

- Assess costs from a
SOCIAL 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



WARNING

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,

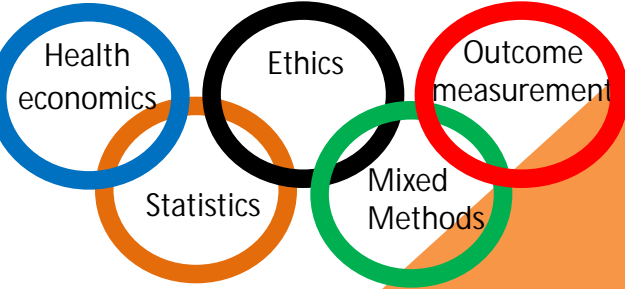
Missed data item in questionnaire

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.



4

Study designs need to build from phase II to III, which often does not happen in pall and end of life care research, this is perhaps a major block and may be related to research funding challenges. Also need to consider alternatives to randomised controlled trial, to give policy makers pragmatic answers

3

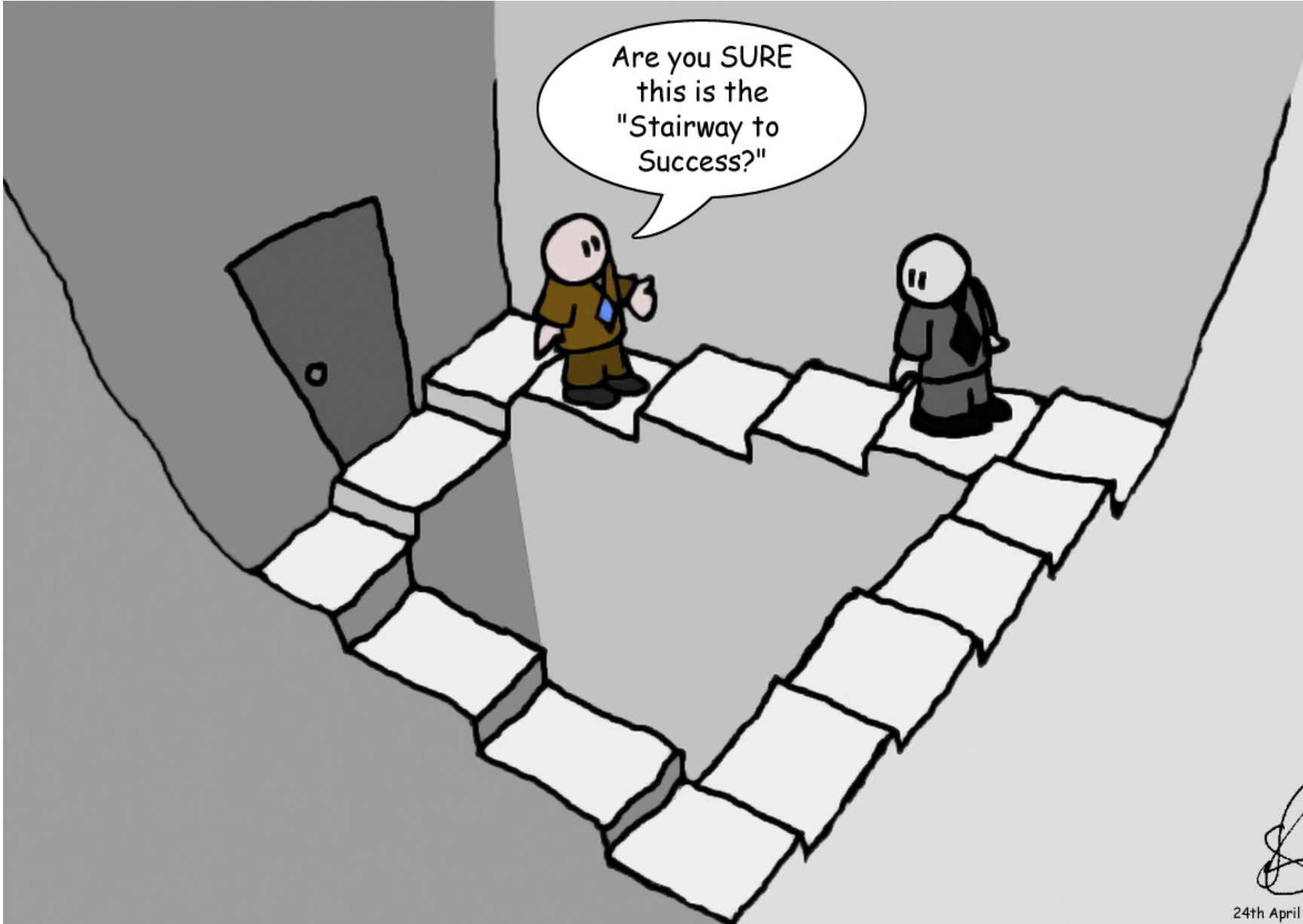
Two of the pre-requisites for research – ethics and patient wish for participation are easily met. Other pre-requisites for research – funding and health professional involvement are more problematic.

2

There is a need to train research ethics committee members, funding body members and academics/practitioners in palliative care.

1

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 affects 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 individual's 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.