

Editorial for Palliative Medicine Special Edition

The need for new perspectives on evaluation of palliative care

Background

This special issue of Palliative Medicine considers different approaches to palliative care evaluation. It has its origin in a meeting organised in 2010 by the Capacity Building and Methodology Themes of the Cancer Experiences Collaborative (see next editorial), in light of an increasing recognition that the traditional randomised controlled trial (RCT) design does not always provide the best approach to much needed evaluation in palliative care.

There is a clear need to subject palliative care to comprehensive and robust evaluation to improve the evidence base for palliative care provision¹. The RCT remains the gold standard for establishing the efficacy and effectiveness of interventions. However, there is a considerable lack of RCTs in palliative care, in particular traditional RCT designs, i.e. where individual patients are randomised to treatment or control conditions. Where such trials are reported, they may often provide inconclusive evidence due to challenges associated with conducting trials in palliative care². At worst, adopting a research design that cannot be successfully implemented may appear to undermine palliative care by failing to show any significant benefits of such care, at best it represents a considerable use of time and resources in return for limited results.

We therefore need to take stock to ensure we use the best possible but feasible methods in our repertoire for evaluation. In doing so we must not forget why the principles of the original RCT design are important in obtaining robust evidence for effectiveness, and retain these where possible.

Part of the problem in evaluating palliative care is that we are almost always dealing with a complex intervention. Complex interventions are interventions containing several interacting components, and their complexity may e.g. relate to the complexity, number, and flexibility of the components of the intervention itself and/or the groups, organisational levels and outcomes targeted³.

There is increasing recognition, not just within palliative care, that the evaluation of complex interventions requires a departure from the approach adopted in drugs trials from which RCTs

originated. The MRC Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health⁴ recognised the need for a better understanding of the intervention and its components, the barriers to its implementation, the process of evaluation itself, the potential range of outcomes and the role for qualitative research alongside quantitative methods. Nevertheless, it was still based on the linear model of drugs trials and firmly focused on RCTs.

The MRC New Guidance³ on evaluation of complex interventions (having dropped reference to RCTs in its title) has evolved to give greater coverage of non-experimental methods, and distances itself more from the drug trials model and the assumption that clinical trials provide the template for all approaches to evaluation. It also to a greater extent recognises the constraints on researchers' choice of intervention and evaluation methods; that often researchers will have no influence over the development of the intervention or its implementation; and that ethics or political context may prevent randomisation or withholding of the intervention. It notes that "given the cost of such interventions, evaluation should still be considered: 'best available' methods, even if they are not theoretically optimum, may yield useful results"³ (p 8).

Palliative care research shares all the challenges associated with evaluation of complex interventions. It has further challenges associated with research on palliative care patients that may make evaluation harder, including ethical and emotional concerns over manipulating interventions (or even 'questioning' their value), as well as pragmatic problems of recruitment, attrition, data collection and missing data. An MRC Methods Research Programme project led by Irene Higginson, Kings College London, is underway to establish specific guidelines for research within palliative care building on the MRC Guidance, although it should be recognised that the difference in challenges faced by palliative care researchers is a matter of degree rather than being a class apart.

Topics of papers included in this Special Issue

Despite the challenges, we should obtain the best evidence we can and aim for well designed RCTs where possible. Traditional RCT design with individually randomised patients can be made to work in palliative care in some circumstances⁵. However, ethical concerns over withholding potentially beneficial interventions from dying patients or delaying interventions for those with limited life span, as in waiting list RCT designs, may present a barrier to such trials. An acceptable alternative may be Fast Track RCTs, where randomisation can lead to faster access to the intervention, as explained in the paper by Higginson in this issue.

Randomisation of individuals, even if it leads to faster intervention, may still raise considerable ethical and pragmatic concerns. Cluster RCT designs, where 'clusters' rather than patients are randomised and all patients within a 'cluster' (e.g. a GP practice, hospice home care team) receive the same care, may prove more feasible and acceptable, in part because this situation is similar to the local variations in care often experienced due to differential service implementation in different areas. Nevertheless, cluster RCTs present their own challenges, and Ian Russell considers the pros and cons of such designs in a second paper in this issue.

Regardless of trial design the challenges of palliative care research mean that we may need to work even harder than other disciplines to make our research protocols viable. The paper by Audrey considers the essential role of qualitative research in aiding the development and conduct of trials, also reflected in the emphasis MRC guidance places on such work in the preparation and process of trials^{3,4}.

Nevertheless, in many cases RCTs are not feasible, particularly where researchers have no control over the intervention. The End of Life Care Strategy¹ for England recognises the need to develop methods that can evaluate the natural experiments that arise from service re-design. Here we need to evaluate through the best methods possible for the situation. While not optimum, non-experimental methods such as well-conducted before-after studies can yield useful results, although the possible biases inherent in such methods must be considered³. Costantini considers how such designs may represent an evaluation in their own right or form the preparatory work for future trials.

It is of limited use to establish whether an intervention appears to work or not, however robust our method, if we do not know why it works, what aspects of the intervention or its context make it work, and how it may be translated to other contexts^{3,4}. Addington-Hall's paper highlights the value of mixed-methods approaches where insights gained from qualitative and quantitative approaches complement each other to provide a more in-depth understanding of the intervention evaluated.

The MRC New Guidance³ also highlights the need to understand the context in which an intervention works, the interlinking processes taking place and the intervention's impact at different levels, i.e. the broader system. Furthermore, in some cases the intervention itself may be considered a complex system or be aimed at changing complex systems⁶. In such circumstances case study

approaches may offer useful avenues for evaluation, and Walshe's paper discusses when and where such methods may be fruitfully applied.

Taking this a step further, we need to recognise that complex interventions are not immutable, they will often themselves be influenced by their broader political, cultural and organisational context. The relevant actors and their interaction with an intervention will affect and shape both the intervention itself and its outcomes. An understanding of such processes and their relation to successful implementation is likely to make important contributions to palliative care evaluation. The paper by Froggatt and Hockey considers how participatory action research may offer valuable insights in this context.

Clearly there are other approaches to evaluation that we have been unable to include in this issue, ranging from variants on the RCT design to systems approaches that involve broader sociological or economic perspectives and larger datasets. However, in general we need to be aware of the broader repertoire of methods at our disposal and select the best method or methods available for each situation and question. Furthermore, we are unlikely to have all the relevant questions answered by one method or any one study. It is therefore important to be conscious of how each study will contribute to a larger process of evaluation, whether we use the framework laid out by the MRC to guide this or some other framework. We must stop conducting isolated pieces of palliative care research.

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¹ Department of Health (2008). End of Life Care Strategy: promoting high quality care for all adults at the end of life.

http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_086277

² Hanks GW, Robbins M, Sharp D, Forbes K, Done K, Peters TJ, Morgan H, Sykes J, Baxter K, Corfe F, Bidgood C. The imPaCT study: a randomised controlled trial to evaluate a hospital palliative care team. *British Journal of Cancer*; 87: 733-739.

³ Craig P, Dieppe P, Macintyre S, Mitchie S, Nazareth I, Petticrew M (2008) Developing and evaluating complex interventions: new guidance. Prepared on behalf of the Medical Research Council.
www.mrc.ac.uk/complexinterventionsguidance

⁴ Medical Research Council. A framework for the development and evaluation of RCTs for complex interventions to improve health. London: MRC, 2000.

⁵ Temel JS, Greer JA, Muzikansky A, Gallagher ER, Admane S, Jackson VA, Dahlin CM, Blinderman CD, Jacobsen J, Pirl WF, Billings JA, Lynch TJ. Early palliative care for patients with metastatic non-small-cell lung cancer. *N Engl J Med* 2010;363:733-42.

⁶ Shiell A, Hawe P, Gold L. Complex interventions or complex systems? Implications for health economic evaluations. *BMJ* 2008; 336: 1281-1283.