

## Marie Curie Research Grants Scheme

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Research Assessment Outcome Measures for Malignant Bowel Obstruction (RAMBO)

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### Research abstract

#### Background

Malignant bowel obstruction (MBO) affects between 10-50% of ovarian and 15% of gastrointestinal cancers. It is one of the most distressing complications of cancer; causing symptoms which include nausea, vomiting, abdominal distension, colic, pain and constipation. It often requires hospitalisation for persistent unresolved symptoms. MBO reduces quality of life. Non-surgical palliative approaches to symptom control usually involve a combination of antiemetics, acid suppression and/or parenteral antisecretory agents (anticholinergics or somatostatin analogues), with gut decompression (nasogastric or gastrostomy tube). Current evidence is inadequate; clinical guidelines favour somatostatin analogues but recommendations are based largely on case series and inadequately-powered clinical trials. Recently two adequately powered, well-conducted clinical trials demonstrated no objective benefit and one suggested evidence of harm. Importantly, these trials included a placebo arm to account for the natural history of MBO, which is largely unknown except that spontaneous resolution with recurrence is common. However, these trials do not appear to have impacted on subsequent guidelines or clinical recommendations. A recent systematic review of somatostatin analogues, using objective tools to evaluate data quality, concluded that there was moderate evidence of *no* benefit, and only poor evidence for their use. The authors acknowledged the challenges of evaluating current data given the varied clinical outcomes used and the lack of an agreed core outcome set for consistent clinical and research evaluation of MBO. Most importantly, there are no data to indicate that the current commonly used outcome measures reflect what is important to patients and carers, and the benefit they consider to be clinically meaningful. This issue was first highlighted in 2007 but has not been addressed; attention is long overdue.

#### Aim

1. To review the current scope of outcome measures used to evaluate MBO through answering the following questions:

- What outcome measures are currently used to evaluate MBO within the context of clinical studies and practice?

- What symptoms and effects do patients with MBO, their carers and clinicians consider most important, and what improvement would be considered clinically meaningful?
- How do currently used outcomes map to those important to patients, carers and clinicians, and, in consequence, what are the gaps and limitations in current practice?

2. To develop a set of core outcomes that is specific to MBO

### Methods

1. **Systematic review:** Databases and the grey literature will be searched using MeSH terms and key words. Results will be screened for inclusion against predefined criteria. Included studies will be appraised for quality and bias, by two independent reviewers, with access to a third for arbitration. A range of evaluation methodologies (e.g. RCTs, case series/reports, qualitative studies) are anticipated for inclusion. Evidence will be synthesised following a thematic approach and where possible combined and compared using meta-analytic techniques.
2. **Qualitative interviews** will be undertaken with patients who have experienced MBO and their carers and clinicians (palliative care, oncology, primary care, surgery). They will explore their experiences of MBO with a focus on the aspects of the symptoms and changes in them that are most important to them. Thematic analysis will be used to identify the most important components of their experience.
3. **Core Outcomes** common to both review and interview findings, and all identified from the interviews will go forward to the expert panel.
4. **Expert panel/Delphi survey:** The data extracted on outcomes will be discussed by an expert panel and fed into a Delphi survey to reach consensus on a set of core outcomes to propose to the Delphi panel to refine and rank in order to achieve consensus. The expert panel and survey will include people with experience of MBO academics, clinicians (palliative care, oncology, primary care, surgeons).

### Outcomes

- This review will identify what outcomes are currently used to evaluate MBO.
- The qualitative study will identify what matters most to patients with MBO and their carers in terms of the target symptoms and degree of change, which is clinically important in response to an intervention.
- The development of a core outcome set for MBO in palliative care has been registered with COMET and will facilitate consistency and comparison between future studies.
- This resource would also facilitate assessments of, and responses to, the management of MBO in clinical practice