

The AMBER care bundle for hospital inpatients with uncertain recovery nearing the end of life: the ImproveCare feasibility cluster RCT

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Declared competing interests of authors: Irene Higginson reports involvement in the following National Institute for Health Research (NIHR) funding boards: Health Services and Delivery Research Commissioning Board (2009–15), Health Technology Assessment (HTA) Efficient Study Designs (2015–16), HTA End of Life Care and Add on Studies (2015–16) and Service Delivery and Organisation Studies Panel (2009–12). Wei Gao reports involvement in the NIHR HTA End of Life Care and Add on Studies Board (2015–16).

Disclaimer: This report contains transcripts of interviews conducted in the course of the research and contains language that may offend some readers.

Published October 2019

DOI: 10.3310/hta23550

Scientific summary

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Health Technology Assessment 2019; Vol. 23: No. 55

DOI: 10.3310/hta23550

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Background

Each year, of 500,000 people who die in the UK, more than half of their deaths occur in hospital, despite an indication that most patients and their families prefer to die at home. Major reasons for dying in hospital is poor communication about declining health between patients and health-care professionals, and poor identification and management of patients whose situations are 'clinically uncertain'.

Clinical uncertainty is a complex concept. Situations of clinical uncertainty usually result from several inter-related factors. If uncertainty is not explicitly addressed, patient outcomes are worse. Their outcomes are influenced by the lack of discussions about their situation and preferences for care and death. Clinical uncertainty also has an impact on clinicians' confidence and their practice. Clinicians frequently struggle with uncertainty and feel inadequately trained to deal with these situations, which can result in overtreatment or overinvestigation.

Increased attention has been given to poor hospital care and inadequate communication, particularly among the elderly and dying. The Liverpool Care Pathway for the Dying Patient, which was designed to provide those at the end of life with the best possible quality of care, sparked criticism after an independent review identified that it often was not implemented appropriately, leading to poor patient outcomes. Such reports highlight the devastating effect that poor communication and lack of honesty can have on patients and their families towards the end of life. However, when clinical uncertainty is acknowledged and managed alongside high-quality care, collaborative decision-making is possible. This empowers patients and carers, and in turn leads to improved outcomes and increased satisfaction with care. The AMBER (Assessment; Management; Best practice; Engagement; Recovery uncertain) care bundle has been developed as a potential solution to caring and supporting patients and their relatives in this situation.

The AMBER care bundle aims to make clinical decision-making explicit in situations of uncertainty by encouraging the clinical team (1) to develop and document, within 12 hours, a clear medical plan in conjunction with the patient and relatives, (2) to consider anticipated outcomes and (3) to consider resuscitation and escalation status.

Aims and objectives

Aim

To determine the feasibility of a pragmatic, multicentre, cluster randomised controlled trial to optimise the design of the intervention, and to define the outcomes, for a definitive trial of the AMBER care bundle versus usual care.

Objectives

1. To examine recruitment, retention and follow-up rates at both patient and cluster levels.
2. To test trial data collection measures and determine their optimum timing in a larger trial.
3. To assess the degree of contamination at a ward level due to 'between-ward' staff and patient movements.
4. To provide a preliminary estimate of the effectiveness of the AMBER care bundle compared with standard care to inform sample size calculation for the full trial.
5. To estimate the intracluster correlation coefficient and likely cluster size.

6. To examine differences in the use of financial resources between the AMBER care bundle and standard care.
7. To examine the extent to which the AMBER care bundle requires further refinement or adaptation (e.g. referral criteria to identify which patients would benefit most) to suit local conditions.
8. To assess the acceptability of the AMBER care bundle to patients, their families and health-care professionals.
9. To determine the 'active ingredients' of the AMBER care bundle that need to be maintained to ensure fidelity of the intervention for a full trial.
10. To assess compliance with and barriers to the delivery of the AMBER care bundle.

Research design

This was a mixed-methods feasibility cluster randomised controlled trial across four district general hospitals in England.

Trial setting and participants

The trial took place in one or two medical wards at each of the four district general hospitals. Trial wards were chosen based on those with the highest numbers of deaths per year, which were derived from heat maps.

The participants included patients or their relatives, when patients met the following criteria: they were located on one of the intervention or control wards, were aged ≥ 18 years, were deteriorating, were in a clinically uncertain situation with limited reversibility, were at risk of dying during their current episode of care despite treatment and were able to provide written informed consent or assent through a personal consultee. Potential participants were identified by research nurses, in conjunction with health-care professionals.

Outcome measures and data collection

Two candidate primary outcome measures were tested during the trial: (1) the Integrated Palliative care Outcome Scale 'Patient/family anxiety and communication subscale', which includes items about receipt of information, practical matters, sharing feelings with family, being at peace, and patients' and families' levels of anxiety and depression, and (2) the 'howRwe', a patient self-reported experience measure, which captures changes in patients' perceptions of their experience of care.

Research nurses conducted face-to-face interviews on each ward with patients, or their relatives, to collect baseline data including demographic and clinical circumstances. At this time point, the Patient/family anxiety and communication subscale of the Integrated Palliative care Outcome Scale and the *howRwe* were measured. These two measures were reassessed at time point 1 (days 3–5) and time point 2 (days 10–15). In addition, the Client Service Receipt Inventory was used to collect information on resource utilisation, measuring the use of health, social and informal care 3 months prior to the hospital admission at baseline and during the inpatient stay in hospital at 10–15 days. The EuroQol-5 Dimensions, five-level version, was used to measure health-related quality of life at all time points.

Furthermore, we made use of a modified QUALYCARE postal survey to collect data on the experience and satisfaction of care, and the quality of information/communication from the perspective of family or close friends of deceased patients who were cared for on the trial wards at a minimum of 10–12 weeks after their death.

We also developed a tool to characterise best standard care across all of the trial sites. This was measured at baseline, mid patient recruitment and at the end of patient recruitment. Data were collected from different health-care professionals to obtain a broader understanding of this type of care. Survey questions addressed care planning, recognising dying, referrals and discharge procedures.

Case note reviews were conducted based on a purposive selection of 20 participants on each ward. These reviews provided information on the care provided to this participant group prior to implementation of the AMBER care bundle.

Qualitative components and data collection

The qualitative components included interviews with patients and relatives, non-participant observations of multidisciplinary team meetings and focus groups with health-care professionals.

Interviews with patients and relatives

Before approaching the patient, research nurses discussed potential participants with the clinical team to determine if they were appropriate to interview. If suitable, the research nurse then asked if they would be willing to be interviewed by the trained researcher. Relatives were approached while they were visiting the patients. The interview topic guides aimed to explore patients' and relatives' insights into care, the quality of communication and information provided and their perception of involvement in critical decisions regarding care and treatment while in the hospital.

Non-participant observation of the multidisciplinary team meetings

The researcher obtained written informed consent from health-care professionals who had their views and behaviours observed and recorded in field notes during meetings. For all wards, we recorded who was present at the meetings, the frequency of the meetings, the length of meetings and the type of conversations relating to patients identified as fulfilling the inclusion criteria (or identified as AMBER). We also took note of which professions contributed to conversations, what specific actions were discussed that related to their care and how decision-making processes developed, including the management of end-of-life issues.

Focus groups with health-care professionals

A focus group was conducted at each of the trial sites. A range of health-care professionals were involved and provided written consent prior to the focus group. During the focus groups, health-care professionals shared their experiences of caring for patients with clinically uncertain recovery, and their families, teamwork, emotional support, communication, trial procedures and outcomes. At the intervention sites, health-care professionals also shared their views on the AMBER care bundle and made suggestions for its improvement.

Results

Feasibility of trial procedures

We recruited 65 participants, many of whom were elderly, with multiple morbidities. Out of 220 eligible participants, only 19 (8.6%) declined to participate in the trial, supporting the feasibility of trial recruitment. We had planned for recruitment to take 3 months at each trial site, but the screening to recruitment rate and time needed to inform and consent potential participants highlighted that this time frame was not adequate. We also identified that the majority of participants lacked adequate mental capacity to provide informed consent, necessitating a proxy to participate.

In addition, the recruitment of potential patients in the control arm proved to be highly challenging. Health-care professionals had particular difficulty interpreting the 'patients who are at risk of dying during their episode of care despite treatment' eligibility criterion. Simplification of the eligibility criteria and an objective pre-screening criterion may aid the screening and recruitment of potential participants.

The trial had a high attrition rate, largely due to discharge from hospital, which made collecting data at 10–15 days after baseline unfeasible. The number of patients discharged made data collection at time point 2 unfeasible. Based on our findings, capturing potential participants at an earlier stage of their hospital admission is recommended for a future trial.

Refinements and adaptations of the AMBER care bundle

Our qualitative findings highlighted important refinements needed to the AMBER care bundle before being tested in a definitive trial. First, the AMBER care bundle inclusion criteria, particularly the criterion 'risk of dying during patients' episode of care despite treatment' is challenging to interpret, leading to issues when identifying eligible patients. This criterion relies on prognostic skills that many health-care professionals believed they did not possess. Health-care professionals noted that more emphasis should therefore be placed on other criteria when identifying patients. Based on these findings, the eligibility criteria should be simplified, with the focus on the 'clinical uncertainty' of the patient, rather than prognostication. Second, issues around communication were identified from patients', relatives' and health-care professionals' perspectives. The health-care professional focus groups highlighted discrepancies in the communication skills and confidence among different professional groups. Patients and relatives also often mentioned in the interviews that the main sources of information regarding patients' conditions and progress were doctors, rather than nurses who were more accessible. Based on these findings, it is suggested that the communication skills training that complements that of the AMBER care bundle could be provided to serve different proficiency levels and improve confidence across all health-care professionals. Moreover, training must be replenished at regular intervals.

The acceptability and fidelity of the AMBER care bundle

The acceptability of the AMBER care bundle was explored by analysing data from the qualitative components with health-care professionals and, in some instances, patients and relatives. Broadly, the AMBER care bundle was accepted by those involved. All stakeholders welcomed the early discussions that emphasised decision-making around patient and family preferences. At the intervention sites, observations of multidisciplinary team working and collaborative decision-making regarding the AMBER care bundle suggested further acceptance of the intervention from health-care professionals. Documenting conversations and decisions in medical charts, required as part of the AMBER care bundle, was not seen as a burden by health-care professionals. Health-care professionals also commented on the simplicity of documentation, which provided a systematic process aligning all those involved in the care of the patient. Although the intervention was acceptable while they received support from the nurse facilitator, health-care professionals questioned the acceptability of the AMBER care bundle without dedicated continued support. Critical decisions would need to be made by health-care professionals to ensure that a dedicated 'AMBER care bundle champion' was available, thus ensuring sustainability of the intervention.

Fidelity of the intervention delivery was assessed via a review of participants' clinical notes. Compliance with the AMBER care bundle components was high; however, there were instances when the AMBER care bundle components were not recorded within the required 12-hour time frame.

Active ingredients

Despite not being able to test the clinical effectiveness of the AMBER care bundle statistically, through qualitative components, we identified a number of 'active ingredients' that should remain in place when the AMBER care bundle is evaluated in a definitive trial. First, the inclusion criterion 'recovery is clinically uncertain' prompted health-care professionals' awareness of a patient population, which previously received less attention, in both trial arms. In addition, the daily review of patients' 'AMBER care bundle status' became routinised into the clinical practice on intervention wards. Second, the concise documentation associated with the AMBER care bundle provided a system of conveying important information to ward staff, particularly those working out of hours. Finally, the role of the nurse facilitator was key to the successful intervention delivery.

Candidate primary outcome measures

The trial was not powered to detect the clinical effectiveness of the AMBER care bundle. Based on data available from our candidate outcome measures, we cannot draw conclusions about differences between the two arms of the trial.

We selected two candidate primary outcomes to be evaluated for a definitive trial. The Integrated Palliative care Outcome Scale subscale, although not powered to detect differences, showed variance and change over time, which implied that it would be able to capture a range of scores in a definitive trial. Trends in this measure indicated that patients experienced moderate levels of anxiety and worry, as expected with this population. Perceived levels of anxiety and worry for family members were consistently higher during the hospital stay for both trial arms. The completeness of the data and the acceptability of the *howRwe* measure were also good. However, this measure was reported only by patients, which reduces the utility of the tool. Further exploration is needed to determine whether or not proxy data collection is feasible for this measure. Notably, for both measures the levels of missing data were relatively small, indicating that outcomes can be successfully collected from this population.

Health economics and cost-effectiveness

It was feasible to collect the data on health and social care service use, informal care provision and quality of life at baseline and at 10–15 days. Missing data were not problematic (< 9.0% of data were missing). Implementation costs are only part of the real intervention costs because changes in time and efforts from health-care professionals could not be accurately captured. A diary recorded by the nurse facilitator successfully tracked the resource use in intervention sites. A predetermined format of the diary could be developed with the prior information on the participating sites in a future trial.

Conclusion

This feasibility trial has demonstrated that an evaluation of the AMBER care bundle, among an acutely unwell patient population, although technically possible, is not practical. Considerable changes would be required to evaluate this complex intervention in a pragmatic trial. Specifically, the manner in which the trial is explained to potential participants, the consent process, the eligibility criteria for the AMBER care bundle (which, for the purposes of this feasibility trial, informed the inclusion criteria) and the timing of data collection should be reconsidered. Alternative strategies to undertake a robust evaluation of the AMBER care bundle are therefore required, including incorporation of a patient-centred outcome measure (e.g. the Integrated Palliative care Outcome Scale) into routine clinical practice or making use of other routinely collected hospital data that could identify the potential benefits of the intervention. However, they too would require feasibility testing to ensure the 'de-risking' of a definitive trial. We were unable to provide a preliminary estimate of the clinical effectiveness or cost-effectiveness of the AMBER care bundle or to determine the optimum cluster sizes. However, we identified active ingredients crucial to the success of the AMBER care bundle. We also suggest amendments to the intervention based on these findings.

Trial registration

This trial is registered as ISRCTN36040085. National Institute for Health Research (NIHR) Portfolio registration number 32682.

Funding

Funding for this study was provided by the Health Technology Assessment programme of NIHR.

ISSN 1366-5278 (Print)

ISSN 2046-4924 (Online)

Impact factor: 3.819

Health Technology Assessment is indexed in MEDLINE, CINAHL, EMBASE, The Cochrane Library and the Clarivate Analytics Science Citation Index.

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This report

The research reported in this issue of the journal was funded by the HTA programme as project number 15/10/17. The contractual start date was in January 2017. The draft report began editorial review in October 2018 and was accepted for publication in March 2019. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the reviewers for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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