Liverpool Care Pathway for patients with cancer in hospital: a cluster randomised trial

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Summary

Background The quality of care provided to patients with cancer who are dying in hospital and their families is suboptimum. The UK Liverpool Care Pathway (LCP) for patients who are dying was developed with the aim of transferring the best practice of hospices to hospitals. We therefore assessed the effectiveness of LCP in the Italian context (LCP-I) in improving the quality of end-of-life care for patients with cancer in hospitals and for their family.

Methods In this pragmatic cluster randomised trial, 16 Italian general medicine hospital wards were randomly assigned to implement the LCP-I programme or standard health-care practice. For each ward, we identified all patients who died from cancer in the 3 months before randomisation (preintervention) and in the 6 months after the completion of the LCP-I training programme. The primary endpoint was the overall quality of care toolkit scale. Analysis was by intention to treat. This study is registered with ClinicalTrials.gov, number NCT01081899.

Findings During the postintervention assessment, data were gathered for 308 patients who died from cancer (147 in LCP-I programme wards and 161 in control wards). 232 (75%) of 308 family members were interviewed, 119 (81%) of 147 with relatives cared for in the LCP-I wards (mean cluster size 14·9 [range eight to 22]) and 113 (70%) of 161 in the control wards (14·1 [eight to 22]). After implementation of the LCP-I programme, no significant difference was noted in the distribution of the overall quality of care toolkit scores between the wards in which the LCP-I programme was implemented and the control wards (score 70·5 of 100 *vs* 63·0 of 100; cluster-adjusted mean difference 7·6 [95% CI –3·6 to 18·7]; p=0·186).

Interpretation The effect of the LCP-I programme in our study is less than the effects noted in earlier phase 2 trials. However, if the programme is implemented well it has the potential to reduce the gap in quality of care between hospices and hospitals. Further research is needed to ascertain what components of the LCP-I programme might be effective and to develop and assess a wider range of approaches to quality improvement in hospital care for people at the end of their lives and for their families.

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Introduction

In most high-income countries, between a third and two-thirds of patients with cancer die in hospitals.[1–3] Deaths in institutions are estimated to increase substantially in the next decades.[4,5] Best palliative care for dying patients with cancer and their families should be provided in all care settings.[6] However, in hospitals, patients with cancer often have unrelieved and poorly treated physical, emotional, and spiritual distress.[7] Family members often do not receive the desired support and effective communication before and after the patient's death.[8] Appropriate training in end-of-life care is often lacking for health-care professionals,[9,10] although this care is crucial in medicine.[11]

Globally, an increasing concern is to improve the quality of end of life for patients.[12] Several major initiatives and national strategies have been developed and implemented worldwide.[13,14] These include complex educational interventions,[15] and the introduction of advance planning[16] and end-of-life care pathways.[17–20]

The Liverpool Care Pathway (LCP) programme for dying patients[17] was developed during the late 1990s at the Royal Liverpool University Hospital with the Marie Curie Hospice Liverpool, Liverpool, UK. It aimed to transfer hospice practices of end-of-life care to hospitals. Results of qualitative studies[21,22] and before-and-after non-controlled trials[23,24] suggest that the LCP programme could improve the quality of end-of-life care for patients in hospitals. However, the conclusions drawn from the results of two systematic reviews[25,26] were that without further evidence recommendations cannot be made for the use of end-of-life pathways for the care of dying patients.

In Italy, about a third of patients with cancer die in hospital.[1] According to a national survey, patients dying with cancer had poorly treated or untreated symptoms. A third of family members expressed dissatisfaction with the quality of end-of-life care, and few received basic information about treatments and the process of care.[27] This poor quality of care in Italian hospitals draws attention to the need for interventions to improve care. We translated and adapted the LCP programme to the Italian context (LCP-I), and piloted and assessed it in a phase 1/2 study.[22,28,29] We designed a cluster randomised controlled

trial to assess the effectiveness of the LCP-I programme in improving the quality of end-of-life care provided to patients with cancer dying in hospital wards.[30] We tested the hypothesis that outcomes for patients and families could be improved through procedural changes by the introduction of the LCP-I programme.

Methods

Trial design and patients

In this cluster randomised trial, pairs of general medicine hospital wards were stratified by region, matched for assessment period, and randomly assigned to implement the LCP-I programme or to follow standard health-care practice.

The objective of the LCP-I programme was to improve the quality of care for patients dying with cancer, but the targets of the intervention were the ward professionals. The effect of the LCP-I programme was measured on clusters of patients and their families in hospital wards.

The study protocol, published and registered on ClinicalTrials.gov,[30] was approved by the ethics committees of the National Cancer Institute of Genoa, Genoa, Italy (Sept 14, 2009), and all participating hospitals.

The ethical issues of this research have been discussed in detail in the protocol.[30] A bioethicist, and clinicians, among others provided advice about the ethical issues, which were monitored throughout the study. LCP is a quality improvement programme, which has been introduced in many hospitals internationally, with clinical and hospital management approval but not ethical approval—a standard practice for such programmes. However, ethical approval was sought because LCP-I was introduced with research and used to assess the effects of the research. Another important consideration is the assessment of the vulnerable and bereaved family members.[31] Our research interviewers were professionals with experience in supporting bereaved family members, and were trained to listen to their concerns and views in a supportive manner. We established procedures for support provided by the interviewers of bereaved family members, including checking whether the family members wished to stop the interview, and provision of information about local services. These procedures are in accordance with the MORECare guidance.[32]

Inclusion criteria for the wards were at least 25 cancer deaths per year, consent from the hospital management and the head of the ward, and a specialist palliative care team (PCT; from inside or outside the hospital) to implement the LCP-I programme in the ward. To prevent contamination, only one ward per hospital was identified for inclusion in the study.

For each ward, all patients who died in the 3 months before randomisation (preintervention assessment) and in the 6 months after the conclusion of the LCP-I programme were identified. Patients who died from cancer (International Classification of Diseases, Ninth Revision: 140·0 to 239·9) were eligible for inclusion in the assessment. Those who were relatives of a doctor or a nurse working in the hospital were excluded.

Information about the patient, closest family member during the last week of the patient's life in hospital, and the general practitioner was obtained for all cancer deaths. 2 months after the patient's death, the regional coordinator sent a letter to the identified family member to introduce the study. A subsequent telephone contact was made to ascertain agreement for participation.

15 general hospitals and one university hospital were identified. All PCTs were part of the inpatient units, with the remit of consultation in hospital wards (not necessarily the hospital they were matched to for the study).

PCT physicians and nurses were formally trained in and dedicated to full-time palliative care. All the teams were trained to use LCP-I in the 6 months before the start of the trial although they had already introduced the pathway in their inpatient units.

Randomisation and masking

Between Nov 23, 2009, and Dec 28, 2010, eight pairs of general medicine hospital wards from five Italian regions were identified as being eligible and having a specialist PCT that agreed to participate in the study. Randomisation was centralised at the trial centre of the National Cancer Research Institute of Genoa, which verified the eligibility and recorded details of each pair of wards and matched PCTs, assigned a numerical code for identification, and recorded the allocation.

Due to the nature of the intervention, the hospital staff, PCTs, and interviewers could not be masked to the allocation status. Family members were informed about the general aim of the study but not of the group assignment.

Panel 1 shows the details of the LCP-I programme. The LCP clinical documentation (version 11 for hospitals) was translated into Italian in compliance with the original format. A manual for support of the procedures of implementation by a PCT was developed for the study. Two leaflets, addressed to relatives or family members, were provided after the patient's death. One provided practical information about local services and the other provided information about common emotional reactions after bereavement and local contacts for support.

The LCP-I programme is articulated in ten steps, each with specific goals (panel 1). The implementation commenced with the PCTs providing an intensive 12 h training phase for all ward physicians and nurses, with focus on care of the dying individual and on the procedures for the LCP-I documentation (step 4). Afterwards, the ward staff, closely supported by the PCT, started using the LCP-I clinical documentation for all identified patients who were dying (steps 5–8). The PCT supported and supervised the implementation process through repeated coaching, telephone and direct guidance, and clinical audits with discussion of clinical cases.

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