Title:

Evaluating the Liverpool Care Pathway for Care of the Terminally Ill in Rural Australia

Running title:
The Liverpool Care Pathway in Rural Australia

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ABSTRACT

Purpose. This study evaluates a pilot implementation of the Liverpool Care Pathway (LCP), a clinical tool used to guide the care of dying patients in the last days of life, on the end of life care for dying patients in three regions in rural Australia.

Methods. The LCP was implemented at thirteen participating sites: nine hospitals (general wards), one community-based palliative care service, and three in-hospital palliative care units. To evaluate the implementation of the LCP, 415 eligible patient records were examined: 223 Pre-implementation and 192 Post-implementation (116 on the LCP and 76 receiving usual care). The primary analysis compared all patients Pre-implementation of the LCP versus all patients Post-implementation.

Results. *Increases* were found Post-implementation for communication with other health professionals and with patients or family (Pre-69%, Post-87%; p=<0.000), use of palliative medications (Pre-87%, Post-98%; p=<0.000) and frequency of symptom assessments (Pre-66%, Post-82%; p=<0.000). *Fewer* blood and radiological investigations were conducted and venous access devices used in the Post-implementation groups than in the Pre-implementation period.

Conclusions. This study suggests that when rigorously implemented, the LCP improves important components of end-of-life care for dying patients and their families.

INTRODUCTION

In Australia in 2010 and 2011, 52% of deaths occurred in a hospital (including hospices affiliated with hospitals).[1] Estimates suggest that almost three quarters of deaths could be anticipated.[2] However, one study found that that only 30 to 40 percent of these patients had *any* contact with a specialist palliative care service.[3] Consequently, the majority of terminally ill patients are managed by non-specialist palliative care clinicians.[4, 5] The literature suggests that many non-palliative care clinicians lack experience in managing end-of-life symptoms. In addition, recognition of the dying phase often occurs very close to death (commonly only 24 to 48 hours before death) and specialist palliative care input, particularly out of hours, is not always readily available.[6, 7]

Integrated care pathways (ICPs) are a popular strategy for fostering the use of evidence-based clinical practice guidelines and reducing medical errors.[8, 9] The Liverpool Care Pathway (LCP) is an end-of-life ICP based on the hospice model of care for use in the acute care setting. It was designed to improve the organisation and quality of palliative care in the last days of life through best practice comfort measures, symptom control, psychological and spiritual support, communication with family and the primary healthcare team, and documentation of the care provided.[10, 11] Previous studies have shown that end-of-life ICPs, particularly the LCP, are generally well regarded by health care professionals and are perceived to improve the care of dying patients, particularly with regard to symptom control, communication and documentation of care.[12-26] The LCP is now used in over 20 countries worldwide.[27]

Nevertheless, the evidence supporting the LCP's effectiveness in obtaining a good death remains equivocal.[28-31] For example, in the only cluster randomised trial of the LCP, Constantini et al.[32] found improvements in dignity, respect, kindness and the control of breathlessness, and an increased use of opioids and medications for pulmonary secretions.

However, they found no significant difference in overall quality of care toolkit scores between cancer patients who died in wards in which LCP had been implemented and those in which it had not.

Recent well-publicised instances where end-of-life ICPs appear to have been misused have created controversy around the LCP in the UK.[33-35] An independent review of the public's concerns about the LCP concluded that, when applied correctly, the Liverpool Care Pathway helps generalist clinicians provide a dignified and pain-free death to their patients, supporting the principles underpinning the guidelines. Nevertheless, the questions raised by the inquiry resulted in the Panel recommending that the LCP be replaced by an individualized end-of-life care plan for each patient.[36] This study aimed to evaluate changes in the use of diagnostic and therapeutic interventions, clinical assessments and communication by health professionals with other clinicians, patients and families in a heterogeneous sample of patients in rural Western Australia (WA).

METHODS

A team of senior general and palliative care nurses, doctors and managers collaborated to modify the LCP Version 11 for the WA context. With the permission of its originators, the hospital, hospice, community and care home versions of the LCP were standardised, and minor amendments were made to the terminology to address the cultural differences. For example, goal 6 was modified from discussing *chaplain/religious advisors* (original version 11) to *spiritual/religious advisors* in the WA version. The modified LCP was then piloted in four palliative care services in urban WA to determine its suitability to WA and to inform the future state-wide implementation. Initial feasibility work conducted prior to the evaluation highlighted the need for a systematic approach to implementation, with training support for service providers throughout the intervention period. The results reported here are derived from a second phase implementation of the LCP in 13 health care sites in rural WA. Specific

comparisons were performed between patients who died in hospitals in the eleven months prior to the implementation of the LCP (Pre-LCP) and patients who died while on the LCP in the first seven months after the implementation of the LCP; e.g., Post-LCP and a contemporaneous cohort of patients who died in the same seven months post-implementation, but were not formally cared for on the LCP (Not-LCP)

The intervention was managed by a centralised group of experts coordinated through the WA Department of Health's Palliative Care Network to ensure up to date, consistent and ongoing education of providers, support and guidance during implementation. Ethics approval was obtained from the WA Country Health Service (Ref. No. 2009:10), Edith Cowan University Human Subjects Review (Ref. No. 3992), and St. John of God Health Care ethics committees (Ref. No. 357). Due to the potential for causing distress for the patient prior to death, and bereaved family members after the death, the ethics committees granted approval to waive consent.

Setting. As a pragmatic capacity building project, all rural health services, including palliative care providers, which had not previously used the LCP, were invited to participate. Thirteen sites agreed to take part in the pilot: 9 community hospitals, 1 community palliative care service and 3 in-hospital palliative care units.

Eligibility criteria. Patients were eligible for inclusion in the data collection if they were 18 years or older and did not die within 24 hours of hospital/clinical site admission. Pre-intervention medical record data collection occurred between January 1, 2009 and November 30, 2009. Intervention data was collected between December 1, 2009 and June 30, 2010. All patients who were expected to die within 72 hours at participating sites were the target for the intervention. Eligible patients (i.e., those identified as dying by clinical staff), in collaboration with their families (where appropriate), were offered the opportunity to be cared for according to the LCP. Only one patient refused the LCP and was cared for using standard

practices. Patients in the Post Not-LCP group were cared for using 'standard care' and were included in the medical record data abstraction based on study eligibility. However, due to limitations of staff in these rural communities, patients in the LCP and Not-LCP groups were often cared for by the same clinical teams.

Determination of LCP and Not-LCP patients. As recommended by the developers of the LCP, introduction of the LCP was left to the discretion of the most senior clinician managing each patient.[11] As a result, some patients who died in the demonstration wards were not offered the LCP. While we were unable to collect observational data on team interaction regarding commencing the LCP, anecdotal information from the clinicians involved suggested that reasons for this included: 1) disagreement within the clinical team as to whether the patient was dying; 2) a last attempt at rescue before offering the LCP; or 3) clinical over-estimation of survival time left to the patient. This cohort of patients thus formed a 'natural' contemporaneous comparison group which served as our control (Not-LCP).

Implementation. The project used a participatory action research approach [37] and the Plan-Do-Study-Act quality improvement implementation methodology.[38] A multi-disciplinary "train the trainer" approach was adopted with a minimum of two senior nurses from each site to manage the implementation. Three methods of collaboration were used to train health professionals in quality improvement techniques and the LCP: 1) three structured training sessions (14 hours total) conducted over 12 months for both site champions and other participating health professionals; 2) monthly 'coaching' telephone, video conference calls or site visits by the implementation team to address concerns with the LCP implementation and to provide support; and, 3) monthly quality improvement data collection and feedback to teams on performance in implementing changes in practice based on the LCP goals of care. Training focused on clinical aspects of end-of-life care, communication skills development

between clinicians and patients and family members with clinicians, and education on the clinical use of the LCP. A palliative care resource kit was provided to the LCP champions at the first training session.[39]

Data collection. Information regarding all care provided during the last hospitalisation was extracted from the medical records of eligible patients. All treatment and procedure items were classified according to broad therapeutic categories and the expected direction of changes in outcomes as a result of the use of the LCP were identified by a panel of palliative care clinicians (two physicians, two nurses and one pharmacist) and the research team (Table 1).

Table 1: Classification and criteria for therapies and procedures

Classification	***Expected change direction***	***Criteria***
Communication with family, other clinicians	↑	Evidence of ≥ one medical or nursing contact and discussions with the patient's GP and family within last 72 hours of life
Ongoing symptom assessments	↑	4 hrly assessments of pain, agitation, respiratory tract secretions, dyspnoea, nausea & vomiting, psychological/spiritual issues conducted throughout the last 72 hours of life
Palliative medications prescribed/administered e.g., opioids, anticholinergics, etc.	↑	Prescription and ≥ one administration of a palliative medication for terminal comfort during last 72 hours of life e.g. of opioids, anticholinergics, antiemetics, anxiolytics
Use of venous access device	↓	Peripheral intravenous/central venous catheter access device inserted or in place in last 72 hours
Gastroenterology procedures	↓	Gastroenterological tube (e.g. nasogastric tube, percutaneous endoscopic gastrostomy tube, gastrojejunostomy feeding tube) inserted or in place in last 72 hours
Oxygen therapy	→	Use of oxygen therapy via nasal prongs, mask, CPAP, etc (excluding ventilated)
Allied Health Interventions e.g. Speech, OT, Physiotherapy, Dietician	↓or →	Access to speech therapist, occupational therapist, physiotherapist or dietician
Blood Investigations e.g., urea, electrolytes, full blood picture	↓	Any blood investigations undertaken in last 72 hours
Drainage e.g., pleural tap, ascites tap	↓or →	Any drainage tube e.g., pleural tap, ascites tap, urinary catheterisation inserted or in place in last 72 hours
Radiology Investigations e.g., x ray, ultra-sound	↓	Any radiology investigations undertaken in last 72 hours e.g., x ray, ultra-sound

↑ expected increase in use of this therapy or aspect of care
↓ expected decrease in use of this therapy or aspect of care
→ use of this therapy or aspect of care expected to remain constant

Sample Size. Sample size was constrained by the number of eligible deaths at the selected sites. A sensitivity power analysis showed that at the 5% significance level, the available data was sufficient to provide at least 80% power to detect a 10% difference for the comparison between Pre-implementation and Post-implementation samples.

Data analysis. The primary outcome measures were: utilisation of invasive medical investigations/interventions, symptom management and assessment, communication with patient/family and among health professionals. Outcome variables were dichotomous (i.e., yes/no) with patients deemed as having a procedure (yes) if there was documentation in the medical records of that procedure having been conducted within 72 hours of death. Chi-square analyses were used to assess between-group differences. The primary analysis was all patients Pre-implementation of the LCP versus all patients Post-implementation. Secondary analyses were undertaken to assess the effect of the formal use of the LCP compared to being cared for by staff who may have received the LCP training without using the LCP formally. These involved comparing Pre vs LCP; Pre vs Post-Not LCP and LCP vs Post-Not LCP. Differences in baseline characteristics were assessed by examining descriptive statistics such as frequencies, means and standard deviations, or medians and interquartile ranges, as appropriate. All analyses were performed using SPSS: Version 17 or higher.

RESULTS

There were 415 eligible deaths over the data collection period. Of these, 223 occurred in the Pre-LCP period and 192 in the Post-implementation period. Of the Post-implementation deaths, 116 (60%) were cared for using the LCP and 76 (40%) received 'usual' care (Not-LCP group).

Patient Characteristics. The mean age of patients was 77.1 years (*95% CI:* 76.0 to 78.3), the majority were male (54%) and had a non-cancer diagnoses (63%) (Table 2). On average, patients were hospitalised for 11.9 days prior to death (*95% CI:* 10.1 to 13.4), with

59% having a length of stay of less than one week. More patients died of non-cancer illnesses in the LCP and Not-LCP groups than in the Pre-LCP group (69% and 58% vs 54%; p=0.023). Deaths were not evenly distributed between the sites during the study period. The number of deaths per site ranged from 1 to 54 in the Pre-implementation period and 1 to 45 in the Post-implementation period, with substantial differences between the Pre and Post-implementation periods at some sites. For example, one of the larger sites contributed 29 cases to the Pre-LCP group, but only 16 to the Post-implementation cohorts: 2 in the LCP group and 14 in the Not-LCP group. Five sites contributed ≤5 cases to the LCP group, and nine sites contributed ≤5 cases each to the Not-LCP group.

Table 2: Patient Characteristics by Pre and Post: LCP and Not-LCP

	All patients	**Pre**	**Post LCP**	**Not-LCP**	***p***
Age					
Mean (years)	77.1	77.6	76.4	77.0	
(95%CI)	(76.0 to 78.3)	(76.1 to 79.1)	(74.0 to 78.8)	(74.0 to 79.9)	0.669[a]
Gender *n(%)*					
Male	176 (42)	96 (43)	48 (41)	32 (42)	
Female	226 (54)	121 (54)	64 (55)	41 (54)	
Unknown	13 (3)	6 (3)	4 (3)	3 (4)	0.982[b]
Diagnosis *n(%)*					
Cancer	155 (37)	70 (31)	53 (46)	32 (42)	
Non cancer	260 (63)	153 (69)	63 (54)	44 (58)	0.023[b]*
Length of Stay					
Mean (days)	11.9	12.1	10.6	13.3	
(95% CI)	(10.1 to 13.7)	(9.8 to 14.5)	(8.9 to 12.3)	(6.2 to 20.3)	

NB: Numbers may differ due to missing data.
*** Significance assessed at alpha=.05**
[a] analysis using ANOVA
[b] analysis using Chi-Square statistic

Length of Time on the LCP. For patients cared for on the LCP, the mean number of days on the LCP prior to death was 4.2 days (*95% CI*: 3.4 to 4.9; *median* 3 days, *IQ range* 4). Mean length of time on the LCP for cancer patients was 3.8 days (*95% CI*: 2.9 to 3.7) while for non-cancer patients, mean length of time on the LCP was 4.4 days (*95% CI*: 3.2 to 5.7). These differences were not significant.

Overall Comparison of Use of Interventions Pre and Post-implementation of LCP. Communication with family members and other clinicians (p=<0.001), routine symptom assessment (p=<0.001) and pre-emptive prescribing of end-of-life medications (p=<0.001) improved in all patients in the Post-implementation period (Table 3).

Table 3. Comparison of use of interventions for all patients in the last 72 hours life, Pre versus Post-implementation of LCP

	Pre		*Post*		Chi	
Medical Procedures	***n***	***%***	***n***	***%***	**square**	***p***
Communication with family, other clinicians	153	(69)	172	(87)	26.772	<0.001*
Ongoing symptom assessments e.g., pain other symptoms	147	(66)	158	(82)	14.197	<0.001*
Palliative medications prescribed/administered e.g., opioids, anticholinergics, etc.	193	(87)	188	(98)	17.731	<0.001*
Use of venous access device e.g., intravenous/central venous catheter	46	(21)	34	(18)	0.565	0.452
Blood Investigations e.g., urea, electrolytes, full blood picture	53	(24)	36	(19)	1.541	0.214
Radiology Investigations e.g., x ray, ultra-sound	50	(22)	30	(16)	3.036	0.080
Gastroenterology procedures	1	(0.4)	1	(.5)	0.011	0.915
Oxygen therapy	43	(19)	39	(20)	0.069	0.793
Allied Health Interventions e.g. Speech, OT, Physiotherapy, Dietician	31	(14)	34	(18)	1.132	0.287
Drainage e.g. pleural tap, ascites tap	33	(15)	29	(54)	0.008	0.931

*Significance assessed at alpha=.05

Comparison of Use of Interventions Pre and LCP. Use of venous access devices (p=0.017), blood investigations (p=0.018), and radiological investigations or treatments (p=0.012) were lower in the LCP group when compared to the Pre-LCP group. In addition, routine symptom assessment (p=0.006), pre-emptive prescribing of end-of-life medications (p=0.001) and communication with family and other clinicians (p=<0.001) were higher in the LCP group (Table 4).

Table 4: Patients receiving interventions in the last 72 hours life, Pre versus LCP

	Pre		*LCP*		Chi	
Medical Procedures	***n***	***%***	***n***	***%***	**square**	***p***
Communication with family, other clinicians	153	(69)	101	(87)	13.840	<0.001*
Ongoing symptom assessments e.g., pain other symptoms	147	(66)	93	(80)	7.498	0.006*
Palliative medications prescribed/administered e.g., opioids, anticholinergics, etc.	193	(87)	113	(97)	10.255	0.001*
Use of venous access device e.g., intravenous/central venous catheter	46	(21)	12	(10)	5.689	0.017*
Blood Investigations e.g., urea, electrolytes, full blood picture	53	(24)	15	(13)	5.587	0.018*
Radiology Investigations e.g., x ray, ultra-sound	50	(22)	13	(11)	6.343	0.012*
Gastroenterology procedures	1	(0.4)	0	(0)	0.522	0.470
Oxygen therapy	43	(19)	18	(16)	0.733	0.392
Allied Health Interventions e.g. Speech, OT, Physiotherapy, Dietician	31	(14)	19	(16)	0.373	0.542
Drainage e.g. pleural tap, ascites tap	33	(15)	16	(14)	0.062	0.803

*Significance assessed at alpha=.05

Comparison of Use of Interventions in Post Cohorts. The use of venous access devices (p=0.001), blood investigations (p=0.011) and radiology investigations (p=0.037) were lower in the LCP group than in the Not-LCP group (Table 5). Contrary to expectations, the use of oxygen appears higher in the Not-LCP group than in the LCP group. Conversely, communication, ongoing symptom assessments and the use of palliative medications were not significantly different between the LCP and Not-LCP groups.

Table 5: Comparison of use of interventions in the last 72 hours life, LCP versus Not-LCP

	LCP		*Not-LCP*		*Chi*	
Medical Procedures	***n***	***%***	***n***	***%***	***square***	***p***
Communication with family, other clinicians	101	(87)	71	(93)	1.985	0.159
Ongoing symptom assessments e.g., pain other symptoms	93	(80)	65	(86)	0.903	0.342
Palliative medications prescribed/administered e.g., opioids, anticholinergics, etc.	113	(97)	75	(99)	0.363	0.547
Use of venous access device e.g., intravenous/central venous catheter	12	(10)	22	(29)	10.904	0.001*
Blood Investigations e.g., urea, electrolytes, full blood picture	15	(13)	21	(28)	6.513	0.011*
Radiology Investigations e.g., x ray, ultra-sound	13	(11)	17	(22)	4.339	0.037*
Gastroenterology procedures	0	(0)	1	(1)	1.534	0.215
Oxygen therapy	18	(16)	21	(28)	4.163	0.041
Allied Health Interventions e.g. Speech, OT, Physiotherapy, Dietician	19	(16)	15	(20)	0.355	0.551
Drainage e.g. pleural tap, ascites tap	16	(14)	13	(17)	0.393	0.531

*Significance assessed at alpha=.05

Comparison of Use of Interventions Pre versus Not-LCP. The comparison between the Pre and the Not-LCP groups showed no substantive reduction in invasive medical procedures. In particular, there were no significant differences in the use of venous access devices, blood or radiology investigations (Table 6). However, communication with family and other clinicians (p=<0.001), ongoing symptom assessments (p=0.001), and use of palliative medications (p=0.003) were significantly higher in the Not-LCP group.

Table 6: Comparison of use of interventions in the last 72 hours of life, Pre versus Not-LCP

	Pre		*Not-LCP*			
Medical Procedures	***n***	***%***	***n***	***%***	***Chi square***	***p***
Communication with family, other clinicians	153	(69)	71	(93)	18.568	<0.001*
Ongoing symptom assessments e.g., pain other symptoms	147	(66)	65	(86)	10.562	0.001*
Palliative medications prescribed/administered e.g., opioids, anticholinergics, etc.	193	(87)	75	(99)	8.95	0.003*
Use of venous access device e.g., intravenous/central venous catheter	46	(21)	22	(29)	2.233	0.135
Blood Investigations e.g., urea, electrolytes, full blood picture	53	(24)	21	(28)	0.455	0.50
Radiology Investigations e.g., x ray, ultra-sound	50	(22)	17	(22)	0.000	0.992
Gastroenterology procedures	1	(0.4)	1	(1)	0.642	0.423
Oxygen therapy	43	(19)	21	(28)	2.349	0.125
Allied Health Interventions e.g. Speech, OT, Physiotherapy, Dietician	31	(14)	15	(20)	1.483	0.223
Drainage e.g. pleural tap, ascites tap	33	(15)	13	(17)	0.232	0.630

*Significance assessed at alpha=.05

DISCUSSION

We evaluated changes in the use of diagnostic and therapeutic interventions, clinical assessments and communication by health professionals with other clinicians, patients and families when the LCP was introduced into multiple health services in rural Western Australia. We found that the overall training program and implementation of the LCP resulted in an increase in communication with family members and other clinicians; routine symptom assessment; and, pre-emptive prescribing of end-of-life medications.

We also found that the formal implementation of the LCP and care of patients using the LCP document resulted in a decrease in the use of invasive medical procedures and an increase in the documentation of assessments, coupled with an increase in the use of palliative medications. The LCP is intended to reduce the number of inappropriate or unnecessary procedures and treatments while increasing appropriate end-of-life care. These

findings suggest that there was an overall improvement in end-of-life care, with a strong focus on symptom relief. From this perspective, the implementation in WA was successful in achieving the goals of the LCP.

Consistent with expectations, three important domains of potential active treatment (use of venous access devices, blood investigations, and radiology investigations) were significantly lower in the LCP group than in the Pre-LCP and Not-LCP groups. On the other hand, the Not-LCP group did not differ significantly from the Pre-LCP group on these domains. This suggests that the difference between the LCP and Not-LCP groups were not due to any secular or seasonal trends. Contrary to expectations, however, communication, ongoing assessments, and the use of palliative medications increased not only in the LCP group but also in the Not-LCP patients.

The use of oxygen therapy appeared to be substantially higher in the Not-LCP group than in the LCP group. This was also the case when the Not-LCP group was compared to the Pre-LCP group, although this difference did not meet the standard for statistical significance. On the other hand, the LCP group did not differ significantly from the Pre-LCP on this domain. This finding, therefore, may be an anomaly resulting from small numbers.

The current research literature shows some improvement in the care of the dying when using the LCP, particularly as a result of the structured prompts for the goals of care. In our study, 60% of Post-implementation deaths were cared for on the LCP. Previous studies report variable usage of the LCP ranging from 34% to 87%).[16, 17, 22-25] Patients on the LCP in this study were cared for using the LCP for an average of 4.2 days (median 3 days), with no difference in length of time using the LCP for cancer and non-cancer patients. This is longer than in much of the literature. For example, Veerbeek et.al., (2008) found a median duration of 63 hours on the LCP in home care, 35 hours in the nursing home, and 16 hours in the hospital.[24] Consistent with Constantini et al., we found that the administration of

potentially appropriate palliative medications, such as opioid and anticholinergics, increased in the Post-implementation groups. However, unlike Costantini, we found that documentation of communication with family members and between clinicians improved in the post-implementation groups.

Finally, participating sites in our study had no previous experience of the LCP and, apart from the three dedicated palliative care units, had no specialist palliative care support. Training in the use of the LCP and support for its implementation used a standardised approach provided centrally by palliative care clinical training experts with the support of the WA Country Health Service.

Strengths and Limitations of the Study. This study aimed to address some of the methodological issues encountered by previous research. First, our study evaluated the LCP as it was implemented in practice within the state health services, using a quality improvement training process that supported providers throughout the demonstration with continuous education, quality improvement problem-solving techniques, and monthly coaching calls to address problems in the field. Second, we used a Pre/Post intervention design with an added contemporaneous comparison group of patients who died within these organizations during the intervention period but did not receive the intervention. This design allowed for the evaluation of any secular trends in clinical care that could have influenced the implementation of the LCP. This comparison group provides added efficacy to the evaluation design. Third, while much of the LCP literature focuses on cancer deaths, this study included patients dying from both cancer and non-cancer diagnoses and was conducted over multiple types of service providers and care settings. Finally, our study focused on relevant clinical care processes directed at dying patients, looking for improvements in individual patient outcomes that would be clinically and personally meaningful to both patients and their families.

Nevertheless, our study also has limitations. First, participants were not randomised to intervention and/or control groups. This was due to the fact that the study was an evaluation of the LCP as implemented at specific sites, which were determined by the WA Department of Health. As a result, randomisation was not practical or feasible. Therefore, a Pre/Post intervention design, together with a contemporaneous control cohort and quality improvement implementation process, was used to address the clinical and service delivery questions identified in this study. Under the circumstances, we believe that this was the best design that was achievable.

Second, we relied upon patient records to ascertain the care provided to patients. Medical record review is highly dependent on the accuracy, completeness, and legibility of patient records. A particular focus of the LCP is the documentation of care. Thus, some outcomes, particularly communication, may have been under-reported in the Pre and Not-LCP groups. However, most outcomes of interest in this study, i.e., clinical care and procedures or investigations in the last days of life, require specific data documented in the patient's medical record. The alternative would have been to rely on carers' or bereaved family members' recall of care provided to the patients in the last days of life. Such recall is subject to response and recall bias and is likely to be less accurate than the written record in the patients' files.

Third, our study was set in sparsely populated rural areas, in which the availability of intensive invasive procedures may have been limited. Therefore, the findings may not be generalizable to all rural or to urban settings nor to improved health service delivery system-wide. Furthermore, the sparseness of the population meant that no single site had a sample size that was sufficient to assess the implementation of the LCP. Even after collecting all available data from 13 sites, the overall number of eligible deaths in the reference periods was lower than anticipated. These differences can be attributed to the fact that the number of

deaths at a given site in a given period cannot be accurately predicted. As a result, there was insufficient statistical power to control for differences in care practices across sites or for different diagnoses, in the naïve analysis presented here. The results should therefore be interpreted with caution, pending more sophisticated statistical modelling.

Finally, while extensive efforts were made throughout the implementation period to support and educate clinicians on the appropriate use of the LCP, we were unable to directly assess the manner in which the LCP was interpreted and then applied by the clinical teams in the implementation organizations. Based on the intensive quality improvement education sessions conducted over the course of the demonstration, the assumption was made that the LCP was implemented approximately the same way across all the sites.

New interventions need to be critically evaluated to assess benefits and risks; nevertheless, innovation is necessary to meet the challenges of providing optimal care for the dying in the future. [40] The WA Health Department addressed this dilemma by first pilot testing the LCP in four palliative care settings before testing the LCP in the larger project in the 13 rural settings reported here. However, this study does not address some of the major unanswered questions in the literature. These include: developing a firmer understanding of the content and process of the clinical team discussions initiating the LCP (e.g., clinical team discussions; communication with the family) as well as a better understanding whether it is the content of the LCP training itself or the quality improvement implementation process that contributes most to the successful implementation of the pathway.

CONCLUSION

This study supports the conclusion that a structured, centralised and directed implementation of the LCP can be successful in improving important aspects of clinical and supportive care during the last days and hours of life.

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