Lessons from the Liverpool Care Pathway—evidence is key

Across health care there is a need to improve care for people who are dying, which has led to widespread uptake of the Liverpool Care Pathway (LCP) before adequate assessment. The effect of poor assessment was worsened when LCP was taken up by bureaucrats who did not understand the implications of widespread implementation of an initiative for which the net effects were poorly defined.1,2

LCP was taken up in emergency rooms,3 nursing homes,4 and inpatient units, including intensive care.5 Not every patient whose care was guided by LCP had necessarily been reviewed by a senior clinician to establish whether their illness was terminal. Implementation of LCP became a matter of pattern recognition, and could be applied in clinical scenarios where such patterns had differential diagnoses ranging from reversible to irreversible causes; at times, junior staff were asked to make these assessments.2

In The Lancet, Massimo Costantini and colleagues describe a rigorous assessment of the effects of LCP on patients and are to be commended for doing such an important study.6 In a multicentre cluster randomised trial comprising 308 patients with cancer and their families, carried out in Italian hospitals, there was no significant difference noted between patients who died in wards in which LCP had been implemented as compared with those in which it had not, as judged by the trial’s primary endpoint, the overall quality of care toolkit scores (70·5 vs 63·0 on a scale of 100, cluster-adjusted mean difference 7·6, 95% CI –3·6 to 18·7). Such studies are feasible, ethically necessary, and a crucial step in bridging clinical guidelines and widely implemented health-care policy. Guidance from the UK’s Medical Research Council for the assessment of complex interventions provides a clear framework for such research.7 This work is hard to do and data are often missing, but that does not reduce its importance or the necessity to deal with such limitations.

The results of Costantini and colleagues’ study did not show the benefits anticipated based on the results of less rigorous reports.8 There are a myriad potential explanations, including poorly chosen endpoints, and substantial differences between the Italian health system and that in the UK, where LCP was developed; it might be that the quality of care for people who are dying in Italy is much better than in other countries, reducing the opportunity to show benefit. A more likely conclusion is that the benefits generated by the systematic implementation of the pathway are, at best, slight. In view of the little or no clinical benefit compared with standard care, any harms to individuals exposed to LCP, including premature death, are unacceptable.

The study by Costantini and colleagues was done properly, with careful training of participating clinicians. It was not done in the emergency department but rather in hospital wards, where people had been adequately assessed both in the emergency department and during their subsequent clinical care. These features might also explain why the perceived harms reported in other places where LCP has been implemented2 were not reported in this study.

Every new intervention needs to be critically assessed for its benefits and harms. Often, as clinicians and policy makers, we focus on the perceived benefits without remembering to measure the harms to define the net effect. There is a special need to focus on any perverse incentives that might result from policy change, as has been suggested in the popular press and peer-reviewed literature.9,10 In much of the literature in which the evidence is addressed for the purpose of informing policy, the assumption is that good evidence is not being translated into policy.11 By contrast, when there is an absolute lack of evidence, policy makers have widely introduced a new method without adequate assessment.

There are important lessons to be learned from this process. Increasingly, clinicians are asked to justify their

www.thelancet.com  Published online October 16, 2013  http://dx.doi.org/10.1016/S0140-6736(13)62039-5

Published Online
October 16, 2013
http://dx.doi.org/10.1016/S0140-6736(13)62039-5
See Online/Articles
http://dx.doi.org/10.1016/S0140-6736(13)62039-5
practice against the best available evidence. By contrast, generally, policy makers are not. Any intervention is going to have drawbacks—not if, but when, how many, and of what magnitude, no matter how appealing the intervention. In health policy, a particular risk is that a perverse incentive for a suboptimum outcome is introduced through regulations and reimbursement.

As demonstrated by the results of Costantini and colleagues’ study, a government, when introducing such initiatives, should properly assess them in rigorous trials of health services, preferably randomised; if this cannot be achieved then a formal prospective assessment of new interventions as they are implemented must be the minimum standard. Either assessment should be done in a health-care environment where new interventions are thoughtfully introduced, corresponding data are routinely gathered for the interventions, and analyses inform understanding of the net benefit and opportunities for iterative enhancement—namely, a learning health system framework, as described by the US Institute of Medicine.12,13 Such a process could have avoided some of the pitfalls attributed to LCP. Not to put prospective assessment in place has long-term consequences that otherwise could be avoided. Such studies are not only feasible, as shown by Costantini and colleagues, but can be designed, undertaken, and analysed to change practice and policy.

The goal of any national policy initiative is to improve health outcomes. A decade after widespread uptake, which part of government should take responsibility for the widespread policy imperatives informed by the results from studies of LCP: politicians, bureaucrats, clinician advisers, or all three groups? The results of the only adequately powered study of LCP so far have not shown clinically meaningful differences for patients—the ultimate measure of useful health policy. Looking to the future, there is a need for government and other funders to be far more willing to fund research into health services that can inform policy and for many more senior clinicians to contribute to shaping national clinical policies.

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APA has research funding from Daiichi Sankyo, Celgene, Helsinn, Dendreon, and Pfizer distributed to Duke University Medical Center, with pending funding from GlaxoSmithKline, Genentech, Bristol-Myers Squibb, Insys, and Kanglaite; has consulted with or received honoraria from Novartis, Bristol-Myers Squibb, and Pfizer; and has corporate leadership roles in Advoset and Orange Leaf Associates. DCC declares that he has no conflicts of interest.