Evidence based implementation of complex interventions

Multi-method evaluation and high quality reporting are essential

The Ottawa ankle rules can reduce unnecessary radiographs in patients with ankle injury; two controlled before and after trials showed benefit—they reduced radiographs by 26% and 28%, with no adverse consequences. The rules have been described as “a safe, cost effective, and reliable approach to assessing injured ankles with impressive consistency.” Given this, surely all staff in all emergency departments should be using these rules. This is not the case, however—surveys have shown variable uptake. Furthermore, even when the rules are promoted within a service with a carefully developed implementation plan, as described by Bessen and colleagues in the linked quality improvement report, the effect seems modest. Why should this be?

Recognition of the problems of implementation is not new—it is hard enough for drugs with proved efficacy, yet alone complex interventions such as the Ottawa ankle rules. Although we need evidence to tell us which interventions work and should be widely implemented, we also need evidence on what can effectively enable wide implementation. This is the focus of the Cochrane Effective Practice and Organisation of Care Group, which undertakes systematic reviews of educational, behavioural, financial, regulatory, and organisational interventions designed to improve health professional practice and the organisation of healthcare services. Broadly speaking, their findings show that no single strategy is sufficient, and that combined approaches are probably needed, although even these have only modest effect sizes.

Bessen and colleagues describe significant 8.6% and 12.5% reductions in ankle radiographs in two centres after a multifaceted strategy. These reductions are less than has been seen in previous studies, however, despite a high baseline. Was this an important reduction? Yes—if applied across accident and emergency departments this would lead to considerable savings and release resources for other priorities. Could it be better? Probably, not least because triage nurses continued to send all patients for radiography.

What might explain this apparently modest effect? The authors undertook a barrier analysis, mapped treatment processes, carried out key informant interviews, and implemented a strategy designed to tackle the identified barriers, engaging the target group in design and implementation. They identified change champions and opinion leaders, and they introduced a radiography request form that incorporated the ankle rules. Although there were no negative consequences for staff who ordered unnecessary radiographs in this study, the authors otherwise describe a robust approach to the development and implementation of interventions.

Attribution is a big problem. Some people would argue that a study such as this cannot demonstrate causation and that its findings are not generalisable. Others argue differently, while encouraging more robust quality improvement science. Although they are not randomised controlled trials, such quality improvement studies have value—this is the basis of the recent standards for quality improvement reporting excellence (SQUIRE) publication guidelines that emphasise key elements to help authors report such studies and help readers interpret them.

A key element is the analysis and interpretation of any apparent effects. The authors discuss the changes measured and the factors that might have contributed to them. However, although much of their discussion is intelligent, some is unsupported by robust data. For example, they state that staff reported increased confidence in explaining to patients why radiography wasn’t needed, but this seems to be anecdotal. They suggest that the new radiography request form is important, but the reduction in radiographs was greater in the site that used it less. Here is a case for more robust multi-method approaches to such quality improvement studies. In depth qualitative research alongside the project could have allowed a clearer understanding of the features of the intervention that were more or less effective, and how the approach might be improved.

Another reason that the effects were limited might be the absence of strong reference to theoretical underpinnings of individual and organisational behavioural change. Although they developed and implemented their intervention with reference to Grol’s framework, the use of robust theories of behavioural change applied to such work remains rare. Yet relevant theories of clinical and organisational behavioural change are available to enhance the potential effect of interventions.

Finally, perhaps we expect too much of such approaches to implementation. We accept drugs that have a relatively small effect at an individual level (if not at a population level). For example, the Medical Research Council trial of treatment for mild hypertension suggests that we need to treat 833 patients for one year (all exposed to drug treatment and its...
consequences) to prevent one stroke. This might be characterised as strong evidence of a weak effect. In contrast, organisational interventions that have arguably a much greater marginal effect are described as having a modest impact.

In conclusion, major challenges to the implementation of interventions into practice remain, especially in the case of complex interventions. We need reliable design and reporting of quality improvement studies, supported by SQUIRE guidelines; good multi-method development and evaluation of complex quality improvement interventions, supported by guidance such as the MRC framework, and further robust research in implementation science as suggested by a recent UK review. This last requirement would need enhanced funding within the National Institute for Health Research programme in the United Kingdom.

Do not-for-profit nursing homes provide better quality? Possibly, but current evidence is too weak to prove a causal association

In the linked systematic review, Comondore and colleagues assess the relation between profit status and the quality of care in nursing homes and conduct a meta-analysis of four quality measures. The association between profit status and the quality of health care has been controversial for decades. The controversy stems partly from theoretical ambiguity and partly from lack of definitive empirical evidence. In theory, not-for-profit healthcare providers may provide a higher quality of care because their mission might include quality and because they do not need to divert resources to shareholders and taxes. On the other hand, for-profit providers may feel greater pressure to compete on price and quality, and this may result in higher quality care that is also more efficient. Unfortunately, rigorous testing of these competing theories is limited because it is impractical to conduct randomised controlled trials of profit status. Methods to mimic randomisation in observational studies (for example, instrumental variables) are not always viable. Thus, empirical evidence cannot determine with certainty which theory is closer to the truth.

The nursing home sector is no exception to this controversy. Comondore and colleagues report that existing studies predominantly favour not-for-profit nursing homes, in that 40 of 82 studies showed significantly better quality in not-for-profit homes. The inconsistency of the findings probably reflects the challenges of using observational data. No review or meta-analysis can overcome the empirical limitations common to all the studies reviewed—we still do not know whether not-for-profit status is the reason for higher quality of care. In other words, if a for-profit nursing home became not-for-profit, would its quality improve? The authors note this caveat, but it is worthy of greater consideration in terms of practical implications.

The lack of causal evidence is particularly problematic in that most of the studies were conducted in the United States, where the relation between nursing home profit status and payer mix is unique among healthcare sectors. Whereas not-for-profit status is normally associated with a community oriented mission, including care for the indigent, which would justify the tax exemption status, not-for-profit nursing homes in the US tend to focus on the clinically more severe and financially more lucrative end of the payer spectrum. For-profit facilities usually have a less lucrative payer mix and take on a larger proportion of (indigent) Medicaid beneficiaries. Thus, it could be argued that differences in quality stem from differential revenues rather than mission or diversion of resources to shareholders. Indeed, not-for-profit nursing homes with large Medicaid populations often provide a similar level of quality to that of for-profit homes.
be that inadequate risk adjustment confounds the association, because for-profit and not-for-profit nursing homes tend to have different populations in terms of clinical needs.

The degree to which this uncertainty over causality matters depends largely on perspective. To prospective nursing home residents, their families, and care providers concerned about placement in a high quality nursing home, not-for-profit status may act as an indicator of high quality care. The reasons for higher quality in not-for-profit homes are largely irrelevant. Consumers already seem to be guided by this indicator, although it should be supplemented with personal experience in visiting the home and monitoring care.

From a policy perspective, the uncertainty over causality matters a great deal. It is not at all clear, for example, that banning for-profit providers from the nursing home sector would raise quality. It might, but many factors other than profit status have been strongly linked to the quality of nursing home care, such as the proportion of residents on Medicaid and the extent of poverty in the surrounding neighbourhood. Facilities that change profit status will probably maintain these other characteristics. Thus, if differences in quality between for-profit and not-for-profit nursing homes stem at least in part from differences in revenues rather than mission, eliminating for-profit homes may do little to eliminate the quality of nursing home care, such as the proportion of residents on Medicaid and the extent of poverty in the surrounding neighbourhood. Facilities that change profit status will probably maintain these other characteristics. Thus, if differences in quality between for-profit and not-for-profit nursing homes stem at least in part from differences in revenues rather than mission, eliminating for-profit homes may do little to eliminate differences in quality.

Experimental data—data from a situation in which nursing homes are forced to change profit status—are needed to increase our understanding of the causal association between profit status and the quality of nursing homes. Comonord and colleagues note that many European countries with historically public, not-for-profit, healthcare systems are now considering privatisation. Although current evidence is too limited to inform the potential effect of such a policy change on quality of care, the policy change itself could provide useful experimental data.

7 Mor V, Zinn J, Angelelli J, Teno JM, Miller SC. Driven to tiers: socioeconomic and racial disparities in the quality of nursing home care. Milbank Q 2004;82:327-56.

End of life decisions and quality of care before death

Let the data speak for themselves

In the linked study, Van den Block and colleagues report a national mortality follow-back study of end of life care in Belgium conducted during 2005 and 2006. Information was obtained from a prospective weekly surveillance survey of general practitioners regarding non-sudden deaths. It included information about the goals of care, medical decisions, and interventions used during the last three months of life.

The findings are a valuable contribution to understanding the context of dying in Belgium. They detail the frequency of team based palliative care; involvement of generalists; use of intensive alleviation of symptoms, which can extend to palliative sedation (termed continuous deep sedation); and the incidence of euthanasia and physician assisted suicide. However, the authors’ interpretation of the data and the conclusions they reach raise questions. Their conclusion that life shortening decisions, including euthanasia and physician assisted suicide, are not related to a lower use of palliative care in Belgium and often occur within the context of multidisciplinary care, misrepresents the frequencies they report and is tangential to the main findings.

More importantly, the results show that intensive management of symptoms during the last three months of life was highly correlated with more frequent involvement of patients’ general practitioners and with referral to multidisciplinary palliative care. Both findings have relevance to healthcare policy and point to fruitful areas for quality improvement.

They found that, in a country where euthanasia and physician assisted suicide are legal, these acts occur relatively infrequently. Only 22 instances of euthanasia or physician assisted suicide were recorded—1.3% of all 1690 non-sudden deaths. Despite this low proportion the authors spend much time interpreting the association of life ending actions and palliative care, although the incidence was only 2% (13/661) in patients receiving palliative care. They assert that the higher prevalence of euthanasia in inpatient palliative care units and private homes than in hospitals—an effect that was not significant in multivariate analyses—shows that “such decisions are often being performed within settings delivering multidisciplinary palliative care.” The data actually show that they are rarely performed at all.

We can take some comfort in that. We can fairly conclude that in Belgium—where universal access to health care exists, including broad access to team based palliative care, and where primary care doctors often remain involved in their patients’ care through to the end of life—legalising euthanasia has not led to a high
frequency of hastened deaths. Furthermore, the significant association between spiritual care and intentional deaths suggests that these acts were not impulsive, but occurred after thoughtful consideration. However, it would be a mistake to suggest that these findings dispel concerns about euthanasia or that they support including euthanasia within palliative care.

In addition to scientific equipoise, controversial subjects require careful and consistent use of language and clear definitions. Several categories used in this survey confound importantly distinct actions and intentions, obscuring meaningful interpretation of the data. Footnotes to the categories of intensified symptom alleviation and decisions to avoid life prolonging treatments do not distinguish between acknowledging that an earlier death might occur and explicitly ending a patient’s life. A person’s decision to accept a natural death by saying no to intubation or renal dialysis is categorically different to a person requesting a lethal injection. And to be clear, even towards the end of life, intensive management of symptoms and suffering need not hasten death.4,5

A stated purpose of this study was to respond to a lack of empirical data to support or refute viewpoints, which specifically include formal statements by the World Health Organization and palliative care associations that palliative care does not hasten death.6,7 This intention misconstrues the roles of a profession’s principles, evidence base, and practice. Formal principles articulate the mission, fundamental values, and goals of a profession and frame the direction and scope of the discipline’s activities.7 Principles do not depend on empirical data; instead a discipline’s research agenda and resulting evidence base are developed to advance practice and further goals determined by its principles.

It is also true that professional principles can evolve over time. However, good reasons exist for the relatively new specialty of palliative medicine to reaffirm the principle of neither hastening nor prolonging death. This stance asserts neutrality in matters about which people have deeply personal and widely divergent feelings. On the one hand, some patients and public proponents of legalising euthanasia and physician-assisted suicide argue passionately for inclusion of intentionally ending life within the continuum of palliative treatments. On the other, as dramatically revealed by the cases of Terri Schiavo in the United States and Eluana Englaro in Italy, equally passionate “right to life” advocates assert that vulnerable people must be protected from a “culture of death” promoted by bioethicists and by hospices and palliative care practitioners.8-10 These opposite poles of concern have one thing in common: a deep distrust of doctors and the institutions in which they practise. In stating that palliative care neither hastens nor prolongs death, the specialty affirms its primary goal of alleviating suffering and improving quality of life for the patients and families served.

The authors are correct in their conclusion that palliative care and legalised euthanasia can coexist. Was this really in question? People from both ends of the political spectrum agree on the need for unhindered access to high quality palliative care, even in jurisdictions where euthanasia or physician assisted suicide is legal.

To move forward it is important to state clearly what we know and do not know. We do not know that legalising physician assisted suicide in Oregon “resulted in more hospice referrals and training of physicians in palliative care.”11 Descriptive data from the US contain no evidence for a cause and effect association. The improvements in Oregon began well before the law took effect. Similar improvements have occurred in other states in which physician assisted suicide is illegal, some of which meet or exceed Oregon in these parameters.12 Further descriptive and comparative research is needed in jurisdictions where life ending procedures are legal and those where they are proscribed to elucidate patterns of decision making and clinical practice, and associated outcomes of quality of life and end of life experience, in patients with advanced incurable conditions. Such research must be crafted, conducted, and reported with care.