

Deliberate self harm in Sri Lanka: an overlooked tragedy in the developing world

Michael Eddleston, M H Rezvi Sheriff, Keith Hawton

The World Health Organisation's definition of health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity" clearly relates social and mental wellbeing to physical health.¹ For many years, however, attempts to improve health in the developing world concentrated on physical illness—mental health was relegated to the bottom of the list of priorities.² Only recently has it begun to appear at the forefront of international public health.³

Self poisoning in Sri Lanka

Sri Lanka has a high incidence of suicide—at least 40 suicides per 100 000 population each year compared with 8 per 100 000 in the United Kingdom.^{4 5} As part of a collaboration between the universities of Colombo and Oxford, we have been studying new treatments for self poisoning in Anuradhapura General Hospital, a secondary referral centre for 900 000 people living in the North Central Province of Sri Lanka. Our work there has allowed us to observe at first hand the tragic consequences of these deaths for the families and the community.

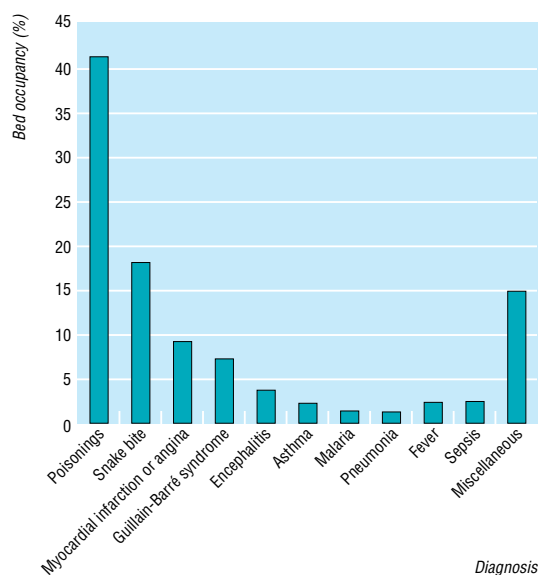


Fig 1 Bed occupancy in relation to diagnosis in the medical intensive care unit of Anuradhapura General Hospital, Sri Lanka, 1995-6

Summary points

Deliberate self harm is common in the developing world

Self poisoning with agricultural pesticides or natural poisons such as oleander seeds is an important cause of mortality in many rural areas

Case fatality rates of pesticides such as paraquat and organophosphates may exceed 60%

Medical management of acute self poisoning is currently poor—better management protocols would reduce mortality

Research to improve management and find ways of reducing deliberate self harm is urgently required

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During 1995 and 1996, 2559 adults (age range 12-73 years; 1443 men and 1116 women) were admitted to the hospital with acute poisoning, almost all as a result of deliberate self harm. Altogether 325 (12.7%) died in the hospital—246 men and 79 women (17.0% and 7.1% of admissions, respectively). The poisons used were pesticides, yellow oleander (*Thevetia peruviana*) seeds, and medicinal or domestic agents. Organophosphate and carbamate pesticides caused 914 admissions to hospital and 199 (21.8%) deaths, and oleander poisoning accounted for 798 admissions to hospital and 33 (4.1%) deaths over a 21 month period.

The number of patients admitted to hospital with acute poisoning in this region of Sri Lanka has increased enormously over the past five years, causing great stress to the already overstretched medical services. For example, in 1995 and 1996, patients with organophosphate poisoning occupied 41% of the hospital's medical intensive care beds (fig 1), preventing other ill patients from being admitted to the unit.

Deliberate self harm or attempted suicide?

Many people admitted for deliberate self poisoning were young: about two thirds were aged under 30. Few expressed a desire to die but, unfortunately, deaths are relatively common among the young. Sixty per cent of

deaths in female patients occurred in those aged less than 25 years. For most of the youngsters, self poisoning seems to be the preferred method of dealing with difficult situations. Examples include a 16 year old girl who died after eating oleander seeds because her mother said she could not watch television; a 13 year old boy who drank organophosphates after his mother scolded him, and who spent three weeks in intensive care being ventilated; and a 14 year old boy who presented in complete heart block after eating oleander seeds because his pet mynah bird had died.

The children are learning from people around them—they are surrounded by people who have previously attempted suicide. In interviews with 85 patients on the general medical wards, more than 90% stated that they knew someone who had harmed themselves, and 90% knew someone who had killed themselves. If knowing someone who has committed suicide is a risk factor for deliberate self harm, whole communities in Sri Lanka are at very high risk.⁶

The reasons for the epidemic are unclear. Sociologists have suggested that the young have few support systems and are unable to cope with societal and cultural demands.^{7,8} Frustrations felt by Sri Lanka's highly educated youth in the face of war, poverty, and the lack of opportunity at home and abroad are also likely to be exacerbating factors.⁹

High death rates

The case fatality rate in Sri Lanka is extremely high. Altogether 12.7% of patients admitted to Anuradhapura Hospital after self poisoning die, compared with 1-2% in the United Kingdom. The rate in men who have drunk organophosphate poisons reaches 60% during some months. The reasons for this high mortality probably include the toxic nature of the substances involved, the lack of antidotes, the long distances between hospitals, and overstretched medical staff. Acute pesticide poisoning does not occur just in Sri Lanka—it is a major problem throughout the developing world, with a worldwide incidence of 3 million cases and 220 000 deaths each year.¹⁰

We believe that reducing the number of suicides in the developing world should become an international public health priority. Our experience in Sri Lanka suggests that research to improve medical management of acute poisoning and to reduce the incidence of deliberate self harm will be important ways of achieving this.

Improving management

Research is urgently required. Organophosphates produce respiratory failure and peripheral neuropathies; paraquat results in multiorgan failure or a drawn out death from lung fibrosis. Cardiotoxicity induced by yellow oleander can progress to ventricular fibrillation that resists shock from a direct current, and the status epilepticus induced by organochlorine can be managed only in major hospitals with facilities for mechanical ventilation.¹¹

Protocols need to be developed for better management of these poisonings, particularly for use in rural units where patients first come into contact with the health services.¹² At present, many patients die before



Fig 2 "Lock up your pesticides." A Sinhalese poster suggesting four reasons why someone might decide to take pesticides and telling people to lock their pesticides away safely

they can be transferred to specialised hospitals. The available treatments also need to be subjected to rigorous trials. We still do not know, for example, whether pralidoxime is effective in organophosphate poisoning or whether activated charcoal improves the outcome.^{13,14}

Preventing self harm

One way of reducing deliberate self harm would be to limit access to poisons.¹⁵ However, in Sri Lanka, most cases involve pesticides or yellow oleander seeds, and reducing access to these agents will be difficult. Since pesticides are the most lethal, it will be important to limit their availability (fig 2). Unfortunately, the rural farmer will continue to need ready access to pesticides since they are an important part of the developing world's strategy for increasing its food production.¹⁶ Locking pesticides away safely (fig 2) is difficult in rural areas where farmers live in huts without bed, furniture, or cupboards. While it may be possible to ban the more toxic pesticides and replace them with safer ones, safer pesticides are expensive and therefore unaffordable in the developing world. Furthermore, banning particular pesticides has often led to the adoption of other, equally dangerous ones.

It seems much more important to strike at the core of the problem—the practice of deliberate self harm. It will be a major challenge to set up programmes that reduce its incidence. However, it is here that the greatest potential exists. Although untested, widespread education in schools to help children deal with life's

stresses and to get help, plus increased availability of counselling, may be the way forward.¹⁷

Conclusions

Deliberate self poisoning is a major problem in the developing world, where it is the cause of many deaths, particularly among young people. In suggesting ways of preventing deliberate self harm in the developing world we must be realistic, particularly since its incidence is still increasing in the West—2700 people are referred to hospital for self poisoning each week in the United Kingdom alone.¹⁸ It is likely to be even more difficult for the developing world, with its limited resources, to address this problem effectively. However, we think that the time has come to acknowledge the seriousness of the situation as a first step towards preventing this massive unnecessary loss of life.

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Managing demand

Managing demand for secondary care services: the changing context

Nigel Edwards, Martin Hensher

Little strong evidence exists to explain the sustained growth in demand for hospital services shown in the table, but changes in population structure, numbers of people living alone, pressures on primary care, risk management, patient expectations, and an increased ability to treat are frequently cited as possible reasons for this seemingly inexorable rise.¹

The desire to reduce, or at least contain, demand in the hospital sector is undoubtedly related to this growth and to the need to control costs. There is also a concern about the appropriateness of hospital care for many conditions, and there are growing opportunities to provide modes of care which may better meet patients' needs and may, in some circumstances, be cheaper.

The previous paper in this series discussed demand management at the interface between primary care and secondary care. Attempts to segment primary and secondary care are inevitably somewhat artificial. Figure 1, however, shows a highly simplified representation of the relation over time between the natural progression of a chronic illness and the thresholds between different healthcare sectors.

Summary points

There has been a sustained growth in demand for hospital services, which has been accommodated despite a decline in bed numbers

Further ways of managing demand for secondary care include condition-specific waiting lists, medical assessment units, use of protocols, and a single point of access to non-hospital alternatives

Once patients are in hospital protocols can help limit their stay, but the biggest impact will come from discharging patients to other forms of care

We need a new currency for secondary care, couched in terms of what needs to be done, rather than where it is done

This is the last of five articles on ways of managing demand for health care

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Hospital activity (thousands) in England 1991-2 to 1996-7

	1991-2	1992-3	1993-4	1994-5	1995-6	1996-7
Ordinary admissions (total acute)	5 404	5 460	5 573	5 662	5 844	5 864
Accident and emergency attendances (total)	13 305	13 070	13 289	13 812	14 234	14 080
Outpatient attendances (total acute)	31 825	32 595	33 362	34 452	35 398	36 057
Day case admissions (total acute)	1 530	1 781	2 076	2 433	2 806	2 910

Source: Department of Health. *Statistical Bulletin* 1997/20.

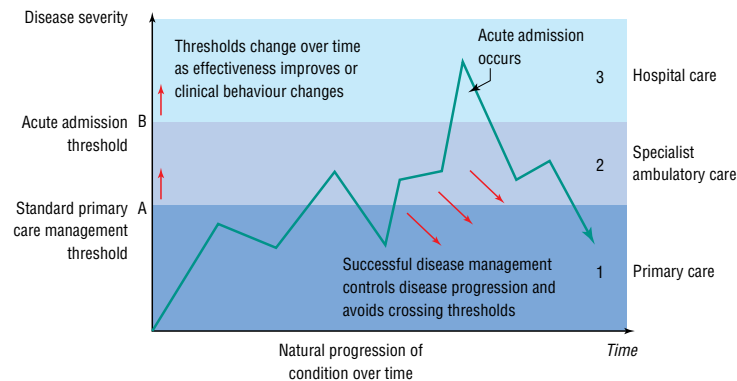


Fig 1 Schematic model of relation between disease severity and management thresholds over time

Below a certain degree of severity (threshold A) a patient's condition can be managed within primary care alone; beyond it, some specialist ambulatory care input is required—for example, outpatient referral or specialist home nursing. As a condition becomes more severe, hospitalisation may become necessary (threshold B). The focus of this paper is on demand management within and beyond secondary care. This includes patients' arrival at the admission threshold (B), their subsequent inpatient episode, and the management of their demand for resources after discharge.

Supply and demand for hospital care

Although the presumption often exists that many of the options for managing demand may have been exhausted once the patient has reached hospital, opportunities for managing demand for hospital services do exist at this stage. Three types of intervention are available (see box). The least sophisticated is to restrict the supply of beds. Roemer's law, which states that "a bed built is a bed filled," suggests that increasing supply will increase admissions or length of stay.² This seems to be confirmed by the work of Carr-Hill et al, who found that supply had a positive impact on hospital use.³ The demand for and supply of hospital services and beds therefore seem to be intimately linked, and it seems that the level of supply may act directly on the demand for admission to hospital.

Reductions in supply might therefore be expected to reduce demand and length of stay. In 1995-6 there were 21% fewer beds in England than in 1985 but 18% more inpatients were treated.⁴ Effective demand had apparently increased, while supply had reduced. In fact productivity had increased faster than reductions in supply—acute length of stay fell by 3.7% per year on average while the bed stock shrank by only 2.3% per

year.⁴ Thus closing beds had not actually reduced supply capacity.

Policies at the admission threshold

Waiting lists have long been held to be a key method of rationing and demand management in NHS. Waiting lists are not, however, as direct a method of demand management as is often supposed, as most patients placed on a waiting list do generally go on to receive treatment. Nevertheless, some studies have found that, after a period of waiting, some patients no longer require surgery. Sometimes, conditions may indeed be self limiting, but in others this amounts to a crude method of triage at the expense of those who require treatment.⁵ In the case of cardiac surgery, for instance, the reason for not requiring surgery is higher mortality among waiting patients.⁶

If waiting lists do reduce demand, it is probably because of their effect on the expectations and referral practices of general practitioners. This effect is unpredictable, particularly if Frankel and West are correct in suggesting that waiting lists may sometimes protect "patients and practitioners from being forced to acknowledge . . . the triviality or the intractability of particular conditions."⁷ Using waiting lists without explicit criteria for referral and inclusion can be inequitable, while delaying treatment may result in an emergency presentation, with increased risk to the patient and a higher cost of treatment.

An implicit assumption often exists that elective cases are less important than medical emergencies because we tend to equate abruptness of presentation with urgency of need. In fact many elective cases are urgent, while a significant proportion of emergency cases do not need to be admitted to hospital. An important innovation in emergency care in recent years has been the introduction of short stay observation or medical assessment units within or alongside accident and emergency departments, which aim safely to identify "borderline" patients who will not actually require admission—for example, by ruling out acute myocardial infarction.⁸ Meanwhile, admissions units are increasingly used to provide more intensive investigation and active treatment for up to 48 hours to allow early discharge or transfer to less acute wards.⁹

Approaches to managing demand for hospital care

Supply side measures

(Raising admission threshold B by constricting supply)
Closing beds or departments, reducing staffing, etc

Preadmission policies

(Preventing or deferring a patient from crossing threshold B)
Waiting lists (including condition-specific waiting lists)
Protocols for referral
User charges
Measures to prevent or divert admissions on presentation

Policies within the hospital

(Reducing resource use once a patient has crossed threshold B)
Reducing the length of time patients spend in hospital
Controlling consumption of resources in hospital

Changing the currency of demand: substitutes for hospital care

Despite their increasing popularity and clinical viability, evidence on the demand management potential of most of the established or proposed models of intermediate care remains unclear. As such substitutes for hospital care become more widespread, their very success may undermine the usefulness of existing currencies of demand for hospital care—that is, admissions and bed days. In future, effective demand management will require a currency that encompasses both hospital care and substitutes for hospital—for example, a “secondary care therapeutic episode”—without specifying demand for care in terms of institutions or buildings. Failure to do so might open the possibility of inadvertently expanding supply and demand through uncontrolled opening of intermediate care alternatives. Key challenges for future demand management in intermediate care include the following.

Substitutes for hospital admission

- The specificity of admission avoidance substitutes must be closely monitored, as their key risk is that they may accept patients who otherwise would not have been admitted to hospital
- If the aim of such substitutes is to treat a constant level of demand at a reduced cost, then their introduction must be accompanied by closure of acute capacity. Failure to close capacity will lead to increased supply, cost, and effective demand. They may, however, represent the most cost effective means of meeting an expanding demand

Substitutes for hospital stay (early discharge models)

- To tackle effectively the key source of demand for bed days, intermediate care must target the long stay bed blockers—that is, the hardest target group to move out of hospital
- Considerable care must be taken to compare fully the incremental costs of intermediate care and the acute care it seeks to replace
- The provision of intermediate care that is not accompanied by reductions in acute capacity will, again, increase supply, costs, and effective demand

Typically, such units will have a higher ratio of senior doctors than conventional accident and emergency departments, working more systematically to protocols of care for key conditions. Perhaps not surprisingly, more experienced staff, working at a more deliberate pace than their junior colleagues in the chaotic environment of accident and emergency, will display substantially higher admission thresholds. Another important feature of such models is their ability to provide a single point of timely access to non-hospital alternatives. A range of services which aim explicitly to prevent admission through provision of nursing and treatment in the home or in intermediate care facilities has been implemented in Britain, often with some success (but see box for discussion).

A final set of demand management tools operating on the admission threshold involves the use of financial incentives. Such incentives can apply to healthcare purchasers, providers, or users. A few studies from the United States have considered the impact of charging direct user fees to inpatients. Siu et al found that increasing levels of cost sharing by patients did indeed reduce admissions—but did so by reducing

both inappropriate and clinically appropriate admissions alike, suggesting that this approach is something of a blunt instrument.¹⁰

Changing the incentives of purchasers and providers will change organisational behaviour. Crucially, transferring financial risk to health care providers will tend to lead them to manage demand for their own services more robustly. The abandonment of contracting and a move to longer term fixed funding agreements¹¹ will represent a return to providers bearing greater financial risk, and this may reduce incentives to increase activity levels.

Post-admission policies

Once patients have been admitted to hospital two sets of strategies can be used to improve the appropriateness with which they use resources: improving efficiency, and earlier discharge of patients who have ceased to benefit from hospital care.

Successfully managing the demand for resources generated by patients once in a hospital bed relies critically on the use of protocols and guidelines. Their use improves the speed of decision making and organisation of care, reducing the number of interactions with professionals and minimising variations in patterns of care. As well as reducing length of stay, protocols have also been credited with having an impact on the use of drugs and other inputs such as nursing or therapy time¹² and achieve important benefits by reducing duplication or unnecessary use of investigations.

The biggest gains in managing demand for bed days are probably to be made from changing the model of care for the many inpatients who have ceased to benefit from the services of the acute hospital. In several specialties a relatively small number of patients account for a very high proportion of total bed days. Figure 2 shows the cumulative distribution of length of stay for general medicine and care of the elderly for a general hospital. After 14 days all but 20% of patients have been discharged—but these patients account for almost 70% of the bed days generated. Many of these patients will have ceased to benefit from acute hospital

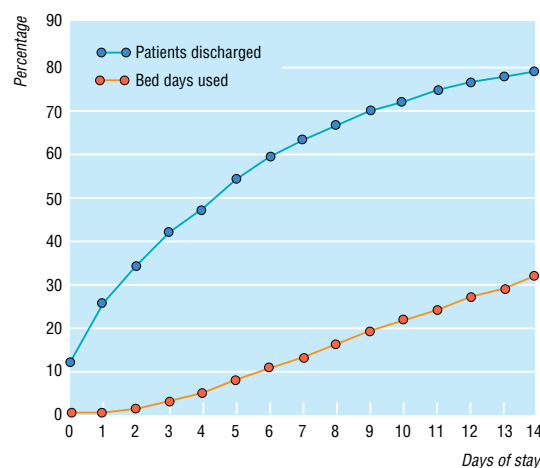


Fig 2 Cumulative use of beds and discharges by day of discharge in general medicine and care of the elderly, Burton General Hospital 1996-7 (source: South Staffordshire Health Authority)

care, and their reasons for being in hospital will often only tangentially relate to their reason for admission.

Published data suggest that 4.4-62% of bed days in acute care are inappropriate,¹³ depending on the specialties studied, the country in which the study was conducted, and the instrument used. The greatest opportunities for change are in the medical specialties, particularly care of the elderly, and orthopaedics. Clarke reviewed studies of the effect of length of stay on outcome, and, although noting methodological problems in almost every study, she confirms that "all studies reported find no important effect of shorter stay on health outcome."¹⁴

Nursing homes, residential care, and home care services generally are necessary to allow these "ceased to benefit" patients to be discharged. Overall, there is increasing consensus among clinicians, managers, and policymakers that intermediate care through models such as community hospitals, "step down" beds, nursing homes, and "hospital at home" is clinically effective and acceptable to patients. However, policy questions remain over the extent to which such alternatives can help with the management of overall demand for health care (see box).

Tertiary referral

Purchasers of health care have long been interested in tertiary referrals because of their high cost. There is also a suspicion that some of this work could be done more cost effectively locally. Any analysis of demand management in tertiary care is hampered by the absence of a meaningful definition. "Tertiary" referrals are no longer simply consultant to consultant referrals and, except in undisputed tertiary specialties such as cardiac surgery or neurosurgery, tertiary services often treat diseases with identical diagnostic codes to those seen in secondary care. Distance and the supply of health services seem to have an impact on demand, but attempts by policymakers to control demand do not seem to have succeeded.

Conclusions

Successfully managing demand for secondary care in a changing health care system requires attention to several lessons. The use of effective access filters at key thresholds will remain crucial. It will be important to ensure that, as the range of alternatives to admission grows, new access filters are inserted for these hospital substitutes. It is not hard to imagine a situation in which direct access by general practitioners to community hospital beds leads to substantial increases in overall hospitalisation—quite the reverse of what was intended. To ensure that the incentives to manage demand remain properly aligned with changing models of service delivery, thought will need to be given to a new currency for secondary care which captures its diagnostic and therapeutic qualities, rather than its institutional qualities.

Within secondary care, the important role of protocols in managing demand for healthcare resources will continue to grow. Initiatives such as the establishment of the National Institute for Clinical Excellence¹¹ could have a profound influence on improving the quality, appropriateness, equity, and

efficiency of care. The challenge here, however, is to guard against the ossification of practice: adherence to obsolete protocols remains a key driver of the substantial excess demand for hospital care in the former Soviet Union and Eastern Europe.

For these tools to be effective, they must be acceptable to individuals—both as patients and as citizens. Most crucially, patients and their families will increasingly be expected to accept home or intermediate care in place of admission, and to accept ever earlier discharge. In fact, the day surgery revolution of the late 1980s and early 1990s and long term changes in maternity care provide clear success stories. Nevertheless, more is required to change expectations than slick marketing and worthy exhortations to the public to accept the tenets of evidence based medicine. Crucially, expectations will adapt and changing patterns of care will be most readily accepted if patients' trust is won through positive experiences. If alternatives to hospital care are not properly resourced and well managed, patients will see only "cuts," shifting the burden of care on to them and their carers.

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Endpiece

Golden age of surgery

Perhaps there never was a Period of Time in which any Art was more cultivated than Surgery has been for the last thirty years.

Samuel Sharp, Preface to *A Critical Enquiry into the Present State of Surgery* (1750)

Submitted by Ann Dally, Wellcome Institute for the History of Medicine

Getting research findings into practice

When to act on the evidence

Trevor A Sheldon, Gordon H Guyatt, Andrew Haines

There is increasing interest in providing evidence based health care—that is, care in which healthcare professionals, provider managers, those who commission health care, the public, and policymakers consistently consider research evidence when making decisions.^{1,2} Purchasers, for example, should be able to influence the organisation and delivery of care (such as for cancer³ and stroke services⁴) and the type and content of services (such as using chiropractic for back pain or dilatation and curettage and drug treatment for menorrhagia⁵). Policymakers should ensure that policies on treatment reflect and are consistent with research evidence, and that the incentive structure within the health system promotes cost effective practice. They must also ensure that there is an adequate infrastructure for monitoring changes in practice and for producing, gathering, summarising, and disseminating evidence. Clinicians determine the day to day care patients receive in healthcare systems, and user groups (for example, patients, their families, and their representatives) are also beginning to play an important role in influencing healthcare decisions.⁶

The factors described below should be considered when deciding whether to act on or promote the implementation of research findings.

Convincing evidence of net benefit

Evaluating the methods of primary studies

Individual research studies vary in their degree of bias—that is, how much they are likely to underestimate or overestimate the effectiveness of an intervention. Observational studies, in which investigators compare the results of groups of patients who are receiving different treatments based on the patient's own or the clinician's preference, are susceptible to bias because the prognosis of the groups is likely to differ in unpredictable ways, leading to spuriously reduced or, more commonly, inflated treatment effects.

Rigorous randomised control trials greatly reduce bias by ensuring that the groups being compared are similar.⁷ As long as patients are analysed in the groups to which they were randomised, this type of trial permits a more confident inference that the treatments offered are responsible for differences in outcome. Randomised controlled trials are useful not only for testing the effectiveness of interventions in tightly controlled clinical settings but also across a wide spectrum of health research.^{8,9} Inferences are further strengthened if patients, care givers, and those assessing outcomes are blind to the allocation of patients to treatment or control groups and if follow up is complete.¹⁰

While randomised controlled trials are often regarded as the gold standard for comparing the efficacy of treatments, other study designs are appropriate for evaluating other types of healthcare technologies, such as diagnostic tests, or for assessing

Summary points

There is increasing interest in making clinical and policy decisions based on research findings

Not all research findings should or can be implemented; prioritisation is necessary

The decision whether to implement research evidence depends on the quality of the research, the degree of uncertainty of the findings, relevance to the clinical setting, whether the benefits to the patient outweigh any adverse effects, and whether the overall benefits justify the costs when competing priorities and available resources are taken into account

Systematic reviews that show consistent results are likely to provide more reliable research evidence than non-systematic reviews or single studies

Researchers should design studies that take into account how and by whom the results will be used and the need to convince decision makers to use the intervention studied

the potentially harmful effects of interventions.¹¹ Qualitative methods are increasingly being used, for example, to provide an understanding of patients' and professionals' attitudes and behaviours, the effects of culture, the context of healthcare, and their interactions.¹²

Whatever the appropriate design, practitioners will often discover that research evidence is biased or otherwise limited; for example, the investigators may have focused on inappropriate physiological end points rather than outcomes relevant to patients.¹³ In evaluations of the organisation of health care, providers must consider whether treatment effects were really due to the putative intervention; for example, in randomised controlled trials that found a positive effect of stroke units, was the impact really due to the organisational structure or to the greater skill or enthusiasm of those who established the units?¹⁴ Though practitioners will still need to use imperfect research information, new clinical policies should not be implemented unless clinicians find that there is strong evidence of benefit.

Evaluating the methods and results of systematic reviews

Systematic reviews can provide reliable summaries of data that address targeted clinical questions; they can also provide less biased estimates of treatment effects if they adhere to the criteria shown in the box.¹⁴

This is the second in a series of eight articles analysing the gap between research and practice

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Criteria that increase the reliability of a systematic review

- Use of explicit criteria for inclusion and exclusion; these should specify the population, the intervention, the outcome, and the methodological criteria for the studies included in the review
- Use of comprehensive search methods to locate relevant studies, including searching a wide range of computerised databases using a mixture of appropriate key words and free text
- Assessment of the validity of the primary studies; this should be reproducible and attempt to avoid bias
- Exploration of variation between the findings of the studies
- Appropriate synthesis and, when suitable, pooling of primary studies

A rigorous systematic review may sometimes leave the decision maker who is reading it uncertain. Classification of the strength of research evidence should consider each of the following four points. Firstly, the methodology of the primary studies may be weak. Secondly, unexplained variability between study results may lead to doubt about the results of studies that show larger treatment effects or those that show no benefit. Thirdly, small sample sizes may lead to wide confidence intervals even after results have been pooled across studies. Thus, the research evidence may be consistent with a large or a negligible treatment effect. Fourthly, because of the side effects associated with a treatment, or their cost, the balance between treating and not treating with an effective intervention may be precarious.

Grades of the strength of the evidence of the effectiveness of a treatment have been developed that account for the type and quality of the study design and the variability of study results.¹⁵ Thus, a systematic review of randomised controlled trials that show consistent results (such as trials of streptokinase for treatment of acute myocardial infarction²) would be graded as providing higher quality evidence than a review of randomised controlled trials that show variable results without a good explanation of the variability (heterogeneity).

The precision of the estimated treatment effect, and the trade off between the benefits and risks could also

be considered. When assessing risks it is important to note that many studies of efficacy, and reviews of these studies, do not provide sufficient information about the possible harm of treatments. Sample sizes in most randomised trials are usually not large enough and the study period not long enough to detect rare or long term harmful effects.¹⁶ Large observational studies may be useful in determining the probability of harm.¹⁷

Putting evidence of benefit into perspective

Evidence of effectiveness alone does not imply that an intervention should be adopted; adoption of an intervention depends on whether the benefit is sufficiently large relative to the risks and costs. For example, the small positive effect of interferon beta in the treatment of multiple sclerosis relative to its cost makes implementation of its use questionable.¹⁸

One approach to the decision about whether an intervention should be implemented is to determine a threshold above which treatment would routinely be offered and below which it would not. Decision makers might consider the threshold in terms of the number of patients one would need to treat to prevent a single adverse event (such as a death).¹⁹ The threshold number needed to treat defines the value above which the disadvantages of treatment outweigh the benefits (and treatment may therefore be withheld), and below which the benefits outweigh the disadvantages (and treatment may therefore be offered).²⁰ Because the cost of treatment and the benefit to the length and quality of life vary, each intervention needs a separate threshold; this threshold will also vary according to the values of the patient, or population, being offered the intervention.

When reliable data are available, a threshold might be expressed in terms of a cost effectiveness ratio that defines the cost of achieving a unit of benefit below which an intervention is seen as worth implementing routinely (for example, quality adjusted life years that take social values about the equity of health and resource allocation into account). Quantitative research evidence is inevitably probabilistic and subject to various forms of uncertainty; it is rarely the sole basis of decision making at the governmental or clinical level. Indeed, uncertainty is one obstacle to policymakers using research evidence.²¹ People differ in their willingness to take risks; these differences explain the variations in decisions made when the same evidence is evaluated by different people. However, research evidence should play an important, and greater, part in decision making and can provide a benchmark against which decisions can be audited.

Applying research to practice

Whether research evidence can or should be applied to a specific patient cannot always be deduced straightforwardly from the research. Results of evaluative studies are usually given as average effects. Patients may differ from the average in ways that influence the effectiveness of the treatment (relative risk reduction) or its impact (absolute risk reduction).^{22 23} Factors that clinicians and patients should consider before applying research evidence to a specific case are summarised in the box.



Factors to consider when applying evidence to individual patients

- Is the relative risk reduction that is attributed to the intervention likely to be different in this case because of the patient's physiological or clinical characteristics?
- What is the patient's absolute risk of an adverse event without the intervention?
- Is there significant comorbidity or a contraindication that might reduce the benefit?
- Are there social or cultural factors that might affect the suitability of treatment or its acceptability?
- What do the patient and the patient's family want?

Patients who participate in trials may not be typical of the types of the people for whom the treatment is potentially useful.²⁴ None the less, it is probably more appropriate to assume that research findings are generalisable across patients unless there is strong theoretical or empirical evidence to suggest that a particular group of patients will respond differently.²²

There may be a heterogeneity of effect across patients because of biological, social, or other differences that influence the effect of the intervention or the risk of an adverse outcome.^{24 25} For example, β blockers may be less effective than diuretics in lowering blood pressure in black people of African descent than in white populations.²⁶ Interventions are more likely to have a uniform impact when the effect of treatment is purely a biological process, and where there is less variation within the population than when many factors specific to the patient or specific to the context mediate the effect.²⁷ The issue of whether treatment effects are constant or are likely to be sensitive to patient and context is important when targeting effective treatments to economically disadvantaged groups of people with the aim of reducing inequalities in health. If, for example, smoking cessation interventions are less successful in poorer people, then such programmes might not have the anticipated effects on health equity.

Single patient randomised controlled trials (n of 1 trials) may help determine a particular patient's response to treatment in a number of chronic conditions, including chronic pain syndromes such as arthritis or chronic heart or lung disease, in which the benefit of treatment may vary widely between individual patients.²⁸

Clinicians must carefully consider treatments in patients for whom treatment may be contraindicated or where there is substantial comorbidity. In patients with comorbid conditions, a reduction in the risk of dying from one disease might not reduce the overall risk of dying because of the risk of a competing cause of death.

The effect of an intervention may also vary because patients do not share the same morbidity or risk.²⁹ For any given measurement of the effectiveness of treatment patients at higher risk will generally experience greater levels of absolute risk reduction or impact from treatment.^{25 29-31} For example, patients at high risk of dying from coronary heart disease who are treated with drugs to lower cholesterol will experience a greater reduction in the risk of dying than those at lower risk—that is, 30 patients at high risk might have

to be treated for five years to save one life, but 300 patients at low risk would have to be treated to save one life.^{32 33} Thus, a treatment that might be worth implementing in a patient at high risk may not be worth implementing in a patient at lower risk.^{32 33}

The decision whether to use a treatment also depends on factors that are specific to the patient. Clinicians will find that research studies that consider a range of important outcomes of treatment are more useful than those which have only measured a few narrow clinical end points. More qualitative research done within robustly designed quantitative studies will help practitioners and patients to better understand and apply the results of research.

Setting priorities

Implementation of research evidence occurs rarely unless there are concerted attempts to get the results into practice.³⁴ It is impossible to promote actively the implementation of the results of all systematic reviews because of the limited capacity of healthcare systems to absorb new research and the investment necessary to overcome the obstacles of getting research into practice. These costs must be considered in relation to the likely return in terms of improvements in health. The anticipated benefits of implementation vary according to factors such as the divergence between research evidence and current practice or the pressure of policies that influence the marginal benefit of further efforts at implementation.

When evaluating the same evidence different decision makers will use different criteria to prioritise treatments for implementation. Policymakers, for example, may look for societal gains in health and efficiency, while clinicians may consider the wellbeing of their patients to be most important.³⁵ Formal decision analysis may be helpful in setting priorities for implementation and in applying research evidence to the treatment of individual patients.^{36 37}

The degree to which clinicians see even good quality research as able to be implemented will depend on the extent to which the results conflict with professional experience and beliefs. This reflects an epistemological mismatch between the sort of evidence that researchers produce and believe in and the sort of evidence that practising clinicians value.³⁸ In many cases the implications of research evidence for policy and practice are not straightforward or obvious,³⁹ and this ambiguity may result in the same evidence giving rise to divergent conclusions and actions.⁴⁰ Depending on the perceived risks, the extent of change required, and the quality and certainty of the research results, many clinicians and policymakers will wait for confirmatory evidence. When designing studies investigators should consider how and by whom their results will be used. The design should be sufficiently robust, the setting sufficiently similar to that in which the results are likely to be implemented, the outcomes should be relevant, and the study size large enough for the results to convince decision makers of their importance.

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Doctors who changed a patient's life Today's dogma may be tomorrow's joke

She was a tall, distinguished looking, elderly woman who, despite having severe nephrotic syndrome, still carried herself erect. My inquiry about her medical history elicited a startling response.

Fifty years previously she had been an attractive, athletic young woman, engaged to be married, when she developed severe peripheral oedema. Her wealthy parents spared no expense in obtaining the best medical opinions available. All the distinguished doctors agreed that she had nephritis, that she should have strict bed rest in a darkened room, and that the prognosis was grave, telling her parents that she had, at most, six weeks to live.

After several weeks of full nursing care, it was apparent that not only was she not dead, but that she was also no longer oedematous. The experts again gathered and opined that she had indeed been fortunate, but that she would be delicate for the rest of her short life, and should avoid any physical exertion. They particularly emphasised that pregnancy would be extremely dangerous.

The marriage went ahead, but the plans were drastically altered. The couple bought a bungalow with a small garden rather than the rather grand property that they had planned, so that she need not exert herself. My patient and her husband realised that abstinence was the only effective contraception, so their long marriage was apparently never consummated.

Despite living the life of a semi-invalid, she did not have a further day's illness for 30 years, when she again developed severe oedema. She consulted a famous doctor, whose specialty was not

nephrology. Without much of an investigation, he prescribed steroids with dramatic effect. Twenty years later, for her third episode of the nephrotic syndrome, I performed a renal biopsy and countless other tests before prescribing steroids. The biopsy showed minimal change nephropathy, a condition characterised by relapses and remissions, either spontaneously or with the help of steroids.

As doctors, we sometimes forget that our utterances may be explicitly believed. The more dogmatic the statement and the more distinguished the doctor, the more likely it is that instructions may be slavishly obeyed. While the advice given to my patient may have been correct by the knowledge of the day, it was clearly nonsense, and it ruined her life. We should remember that today's dogma may be tomorrow's joke, and that its debunking may inadvertently leave some casualties in its wake.

John H Turney, consultant physician and nephrologist, Leeds

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake*, or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to.