
Update / Le point

A flow diagram to facilitate selection of interventions and research for health care

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Decisions about health care should be informed by systematic review of valid research evidence on the effects of interventions on health outcomes that matter. If systematic review suggests it is likely that a health care intervention does more good than harm in some settings, questions must be addressed about the local applicability of the intervention, its cost-effectiveness, and feasibility of implementation. If systematic review suggests that it is unlikely that an intervention does more good than harm in any setting, its use should be discouraged, while existing interventions are improved or alternative interventions developed. If it is uncertain whether an intervention does more good than harm, further analysis of existing data or new controlled trials are required. The article contains a flow diagram, which provides a structure for making such decisions.

Introduction

In poor and rich countries alike, planners and providers of health services and health research face the challenge of deciding how to make effective use of limited or contracting resources. Promoting equitable access to health services is an important health policy objective; however, better access will not improve health unless the care provided does more good than harm. By “good” we mean all positive benefits of health care: an improvement in the quality of life or a prolongation of life. By “harm” we mean the unintended negative consequences to individuals affected by the form of health care in question, whether or not they were the principal focus of the intervention.

This criterion of effectiveness — doing more good than harm — can be applied to health care interventions across the board. Examples include the

following: curative medical and surgical treatments; the care offered by nursing and other professionals in health facilities or domiciliary settings; preventive immunizations; nutrient supplements; care offered by volunteers in the community; health education in schools; and regulatory or fiscal interventions to encourage health-promoting behaviour.

Policy-making in the health sector is complex and takes place within a given social, economic, and political context. Decision-makers may take different views as to whether a particular service should be provided by the public or private sector and whether it should be financed using public or private resources (1). However, it is becoming increasingly accepted that decisions about health service provision should be informed by valid evidence of the effects of health care interventions, along with an appreciation of the costs of providing such interventions, the competing priorities, and the population's values and preferences. Rationally, this process of decision-making in health care begins with efforts to identify health problems of high priority; i.e. problems that are common, serious, resource-consuming, of community concern, and potentially amenable to interventions (2–4). Decision-makers need reliable evidence to assess the relative merits of alternative strategies for preventing, treating, and researching the priority problems identified.

In recent years, the importance has increasingly been recognized of improving the evidence base for guiding such decision-making by conducting systematic reviews of research evidence (5). This is appar-

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ent among those using health care (6) as well as those providing it (7), health research funding bodies (8), those assessing the academic performance of health research institutions (9), government advisory bodies (10), those promoting policy changes (11), and organizations responsible for funding and purchasing health services (12).

The best evidence for the effects of an intervention comes from randomized comparisons of individuals or groups since these avoid the selection biases inherent in observational studies (13). Randomized controlled trials have shown, for example, that aspirin reduces mortality after myocardial infarction by about 23% (14) and that improved treatment of sexually transmitted diseases in rural Africa reduces spread of human immunodeficiency virus (HIV) by up to 40% (15). Analysis of the results of all well-controlled trials in systematic reviews provides powerful evidence for the effects of interventions (16–18). Access to the results of systematic reviews, and to information about reviews being prepared, has now been facilitated through publication of sources such as *The Cochrane Database of Systematic Reviews*, *The York Database of Abstracts of Reviews of Effectiveness* and the journal, *Evidence-based medicine* (19–21).

Against this evolving background, we present in this article a flow diagram as an aid to selecting health care interventions and identifying research needs. The diagram should be helpful as an aid in system-wide planning, in assessing interventions for a single group of health problems, in evaluating a single intervention, and in prioritizing research on health care interventions. In the flow diagram (Fig. 1), the crucial step, shown in double-edged boxes, is determining whether a systematic review shows the following:

- it is likely that an intervention does more good than harm in some settings;
- it is unlikely that an intervention does more good than harm in any setting; or
- it is uncertain whether an intervention does more good than harm.

When it is likely that an intervention does more good than harm in some settings

An intervention does more good than harm when — compared with doing nothing or with an alternative intervention (and after taking into account the confidence intervals around the estimates of effect) — the

beneficial effects of the intervention outweigh the harmful effects in some settings, populations, or patient groups (22). Examples of such interventions include use of low-dose aspirin for reducing the burden of nonfatal myocardial infarction and stroke (23); vitamin A supplementation for reducing childhood mortality in developing countries (24); and home visiting to prevent childhood injuries in Europe and North America (25).

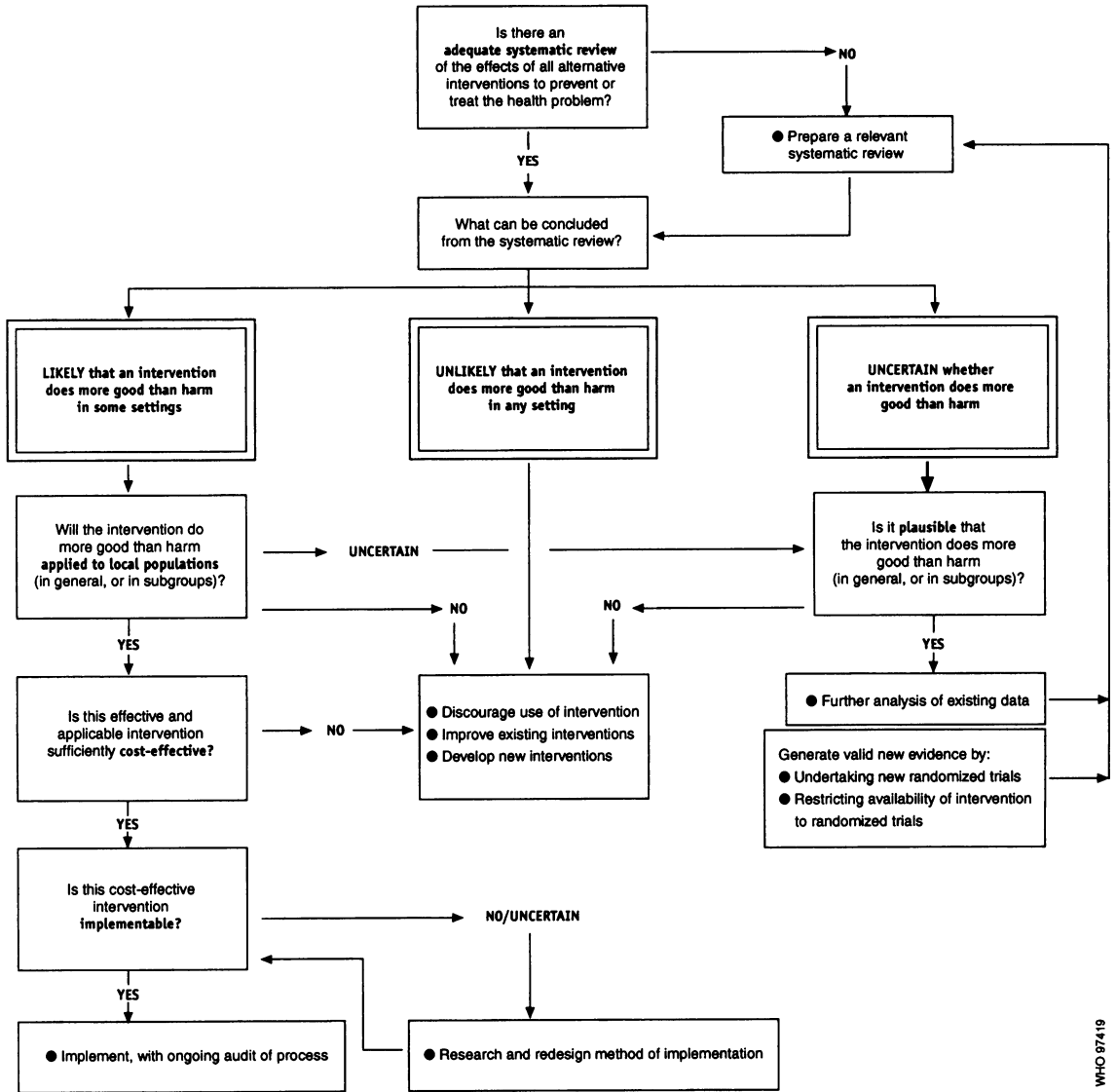
Applicability

If a systematic review shows that an intervention is likely to do more good than harm in some settings, populations or patient groups, its applicability to the particular setting of interest needs to be examined. There is sometimes reluctance to accept that the results of research carried out in other places and at other times are applicable to local circumstances. However, the systematic review may include studies of the intervention that have been conducted in a range of settings, suggesting wide applicability. The use of antenatal corticosteroids in women expected to deliver preterm provides such an example (26). Reluctance to accept strong evidence of effectiveness from research performed elsewhere is difficult to justify unless it can be proved that the effect in local populations is likely to be different from that in the trials included in the review (27). For most drug interventions, this is unlikely to be the case. For social interventions, however, the effectiveness may vary substantially from one group or area to another, depending on factors such as literacy, income, cultural values and access to media and health services. For example, home visiting to prevent childhood injuries, which has been shown to be effective in a systematic review of controlled trials conducted in the USA, Canada, the United Kingdom and Ireland (25), may not be applicable in low- and middle-income countries.

Local populations or subgroups may differ in the extent to which the benefit of the intervention outweighs harm (28–30). For example, a reduction in embolic stroke through use of anticoagulants in individuals with atrial fibrillation carries a large benefit for those at high risk of stroke; however, the small benefit to those at low risk is outweighed by the harmful effects of anticoagulation, such as intracranial haemorrhage (28). Also, cholesterol-lowering drugs may be beneficial to those at particularly high risk of coronary heart disease, but for those at low risk the harm may outweigh the benefit (31).

On occasions, there will be insufficient evidence to decide whether the intervention will do more good than harm in local populations, and extra infor-

Fig. 1. Flow diagram for selecting health care interventions and identifying research needs.



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mation will be required about the frequency and severity of side-effects, level of risk of the outcome the intervention is intended to prevent, and population preferences or values (28). Further analysis of pooled data from all the valid studies may also be needed to assess effects in relevant subgroups (23).

Cost-effectiveness

If interventions have been shown to be effective, either overall or in subgroups of a population, their cost-effectiveness must be considered. Different methods of organizing interventions vary in their

labour and time costs; also, factors such as the scale of provision, and whether or not they are provided alongside other interventions and health service activities, may influence the cost-effectiveness (32). Some interventions remain cost-effective across a wide cost range, e.g. antenatal corticosteroids (33), and this evidence needs to be translated into action. Others may be considered sufficiently cost-effective in some circumstances, but not in others. For example, mammographic screening of women over 50 years of age is considered sufficiently cost-effective in many wealthy countries but not in poorer countries where breast cancer incidence is lower, and there are more pressing demands on scarce resources (34).

Implementation and ongoing audit

If it has been shown that an intervention is likely to do more good than harm and that it is likely to be cost-effective if implemented, policies or guidelines based on the evidence should be formulated (35) and intervention plans developed and piloted, taking account of local circumstances and views. If pilot implementation establishes that the proposed intervention is logistically and politically feasible in the local setting and is acceptable to users, it should be introduced more widely, together with an ongoing audit to ensure that those who can benefit from the intervention receive it and that its quality is adequate (36–39). On the other hand, if the pilot implementation programmes fail, further research may be needed to assess how to improve methods of implementation.

When it is unlikely that an intervention does more good than harm in any setting

Systematic review may show that it is unlikely that an intervention does more good than harm in any setting, or that it is unlikely to be superior to existing alternative interventions. Also, although an intervention has been shown to have the potential to do more good than harm, it may be either inapplicable or not cost-effective in the population under consideration. In any of these circumstances, use of the intervention is an undesirable drain on limited resources and such use should be discouraged.

If an intervention with any of these characteristics is not yet in widespread use, it may be possible to prevent its further dissemination; however, the intervention may already be in wide use, for example electronic fetal heart rate monitoring as a screening

test in the absence of facilities to confirm a diagnosis of suspected fetal hypoxia (40). Persuading people to abandon an intervention is often not easy, particularly if no acceptable alternative is readily available. Levers to discourage use of ineffective interventions have been developed most effectively in pharmaceutical prescribing, using reimbursement schedules such as those in Australia (41). In the United Kingdom, purchasing authorities are often in a position to specify the types of services they are willing to fund, although this may at times conflict with advice offered by local health professionals (42). A variety of other techniques have also been shown to change practices, such as clearly stated and widely disseminated clinical guidelines, systems of audit, and continuing professional development activities (37, 43–46). Formal demonstration of the inadequacies of an intervention should also prompt further research to improve existing interventions or basic research to develop new alternatives.

When it is uncertain whether an intervention does more good than harm

Systematic reviews of research findings often reveal uncertainty about the effects of health care interventions. Even if there are high quality trials of interventions in which biases have been well controlled, the confidence intervals around the estimates of the effects may be wide, making it impossible to decide whether the benefits outweigh the harm. Also, there may be doubts about the applicability of the available evidence to local populations or subgroups.

Often, there may be no randomized trials of adequate quality or they may not have addressed important outcomes. In the first of these instances, a decision needs to be reached about whether such trials are or are not feasible (47). If they are not feasible, decisions have to be based on the most valid available evidence identified by systematic review of observational studies (47, 48). If no trials have addressed important outcomes, causal pathways can be constructed, mapping out the necessary sequence of events between the intervention and final outcome (49, 50); the evidence can then be assessed for each step along the pathway. There may be randomized trial evidence for the effect of the intervention on an intermediate measure, and decisions can then sometimes be made on the grounds that the evidence on the effect of the intermediate measure (e.g. stopping smoking) on final outcome (e.g. mortality) is well established.

Wide, uncontrolled application of new interventions of uncertain benefit is rarely justified, even though policy-makers, planners, and providers may feel under pressure to make the intervention available. In the past, implementation without strong evidence has led to loss of life; for example, the widespread use of anti-arrhythmic drugs following myocardial infarction before the adverse effects on mortality outcomes had been demonstrated in randomized trials (51).

The general implementation of interventions of unproven value consumes resources that could potentially be deployed more effectively elsewhere. This does not mean that such new interventions are not desirable, but it does call for their careful assessment. For example, systematic reviews of controlled trials of routine iron supplementation in pregnancy (52) and of routine antimalarial chemoprophylaxis during pregnancy (53) have so far been unable to detect important beneficial effects for either intervention. However, estimates for the effects of these policies on substantive outcomes are very imprecise — and certainly compatible with important beneficial effects. Furthermore, most of the trials of routine iron supplementation have been carried out in high-income countries but the benefits may be larger in low- and middle-income countries, where iron deficiency is more common and severe.

If it is plausible that the intervention being considered could do more good than harm, uncertainties such as those illustrated above might be addressed using data available from systematic reviews to explore effects on subgroups. For routine iron supplementation during pregnancy, for example, it might be possible to obtain data for individual persons from all the relevant trials and conduct further analyses, stratified by the level of haemoglobin at the time of randomization. If this approach is not helpful, questions about the value of the intervention are best answered by conducting more randomized trials.

Where an intervention is not already in wide use, its availability should be restricted to controlled trials to assess its effects, particularly if it is very costly (54). For example, until a randomized trial had yielded strong evidence that mortality could be reduced without a reciprocal increase in devastating morbidity among survivors, use of extra-corporeal membrane oxygenation for severely asphyxiated neonates was initially available in the United Kingdom only as part of a multicentre randomized trial (55).

The evidence generated by new trials should be used to update existing systematic reviews or to initiate new ones. The systematic review–research cycle then continues until there is sufficient evidence upon

which to base decisions for health care. For example, a systematic review, recently updated in the light of evidence generated by a new trial, has made it clear that magnesium sulfate should now be regarded as the drug of choice for treating eclampsia (56).

Conclusions

Decisions on health care are complex and subject to many influences. Recognizing their complexity, however, should not deter efforts to encourage a more rational basis for decision-making, supported by evidence for the effectiveness, applicability to specific population groups, and cost-effectiveness of the proposed interventions.

Clinicians, planners, managers, politicians and communities should be aware of the findings of systematic reviews so that these are taken into account in the debates and negotiations surrounding the introduction, expansion, or reduction of health care interventions. Systematic reviews are becoming available in electronic format, enabling those concerned with health to identify regularly updated evidence that is relevant to their decision-making.

The results of the few hundred systematic reviews that have already been carried out pose a substantial challenge to those responsible for commissioning, managing, and providing health services: health authorities and decision-makers are failing to provide forms of care that are known to be effective, while acquiescing in the provision of other interventions that are very unlikely to improve health or are inferior to alternatives. Nevertheless, it is important to note that there are still large numbers of health care interventions whose benefit appears uncertain, even though they have been the subject of randomized trials. This information gap offers a substantial agenda for systematic reviews. With support from health planning and research funding bodies, this challenge is now being tackled in a number of countries (19), but much more could be done.

We hope that the approach outlined in the flow diagram we have presented will encourage the more rapid introduction of effective interventions, discourage the introduction or promote the withdrawal of ineffective interventions, and provide a framework for identifying interventions that should be investigated using randomized trials so that their effects can be assessed.

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Résumé

Un ordigramme pour faciliter le choix des interventions et des recherches à entreprendre en matière de prestations de santé

Il importe que les décisions à prendre dans le domaine des prestations de santé reposent sur un examen systématique des conclusions des recherches sur les effets de différentes interventions dans des secteurs importants. Si cet examen systématique donne à penser qu'une intervention a des chances de faire davantage de bien que de mal dans certains contextes, il faut chercher à déterminer si cette intervention peut être appliquée au niveau local, si elle offre un bon rapport coût/efficacité et comment elle peut être mise en oeuvre. S'il ressort de l'examen systématique qu'une intervention risque de faire davantage de mal que de bien dans quelque contexte que ce soit, il faut en décourager l'utilisation et améliorer les interventions existantes ou mettre au point d'autres interventions. S'il est difficile enfin de savoir si une intervention fera davantage de bien que de mal, il conviendra de procéder à une analyse plus détaillée des données existantes ou à de nouveaux essais contrôlés. L'ordigramme (voir p. 24) fournit un schéma pour la prise de ces décisions.

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