Are guidelines ethical? Some considerations for general practice

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SUMMARY
Guidelines have been promoted in various roles in general practice, e.g. to improve quality of care, to assist patient decision making, and to improve resource allocation. This paper examines these claims using ethical analysis. Guidelines may help general practitioners to act for the good of their patients and avoid harm; but, on their own, guidelines cannot ensure quality of care or the protection of patients' interests. Patient choice may be limited rather than enhanced by following guideline recommendations. Guidelines contribute to rationing of resources but do not use explicit criteria for this. The ethical implications for guideline use are complex and far-reaching.

Keywords: evidence-based medicine; guidelines; ethics.

Introduction
GUIDELINES form a potentially valuable bridge between evidence-based medicine and clinical practice. Adherence to guidelines can improve quality of care, reduce inappropriate variations in practice, and improve cost-effectiveness of care.1-3 Guidelines may improve resource allocation decisions and assist patient participation in decision making.4,5 These are significant claims which, if realised, have the potential to make major contributions to health care. One of the tasks of medical ethics is to analyse, clarify, and evaluate these kinds of claims from a moral perspective. This paper offers an analysis of ethical issues raised by the use of evidence-based guidelines in general practice.

Guidelines and ethics
Before examining specific issues in detail, it may be helpful to outline the relationship between guidelines and ethical principles (Box 1). Many guidelines specifically recommend treatments that have been shown to be effective, providing an evidence base for the fundamental ethical requirement of acting for the good of the patient. Secondary prevention of coronary heart disease is an uncontroversial example of this: taking daily aspirin to avoid a heart attack is very much in the patient’s best interests.6 Cessation of practices which have been shown to be harmful meets the ethical requirement of non-maleficence. The recent Scottish Intercollegiate Guidelines Network guidance on unerupted third molar teeth recommends not removing asymptomatic teeth on the grounds that removal causes significant morbidity, making an explicit link with non-maleficence.7 Guidelines may support respect for patient autonomy by providing evidence about the risks and benefits of interventions. The New Zealand Guidelines Group publication on hormone replacement therapy includes a summary of evidence in tabular form that provides important information for women making decisions about hormone replacement therapy. Using this table to identify relevant issues for individual women is a way of respecting autonomy.8 Finally, the use of guidelines to end inequitable access to treatment can meet some of the requirements of justice. The National Institute for Clinical Excellence guidance on taxanes for the treatment of breast cancer is an example of a guideline aimed at ensuring that all women have equal access to this treatment, irrespective of where they live.

At first glance, we might think that the use of guidelines must be ethically required, if using them will support ethical practice. However, the situation is more complex than outlined so far. The following sections give a more detailed analysis of the relationship between guidelines and these ethical principles.
Evidence-based guidelines may be used to improve quality of care in a number of ways but it is their role as an audit tool which has been most widely promoted. As ethical aims, these are irreproachable. In practice, beneficence and non-maleficence are associated with three specific aspects of guideline use:

- improved quality of care;
- reduction in inappropriate variations in practice; and,
- improved effectiveness.

**Improved quality of care**

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**Ethical principle**

- Beneficence (act for the good of the patient)
- Non-maleficence (do no harm)
- Respect for patient autonomy (patients’ right to make decisions about their care)
- Justice (fairness in health care)

**Potential contribution of evidence-based guideline**

- Use of guideline to recommend treatments of proven efficacy
- Use of guideline to recommend cessation of practices shown to be harmful or useless
- Use of guideline to give patients information and to aid in decision making
- Use of guidelines to guide allocation and rationing decisions

**Box 1. Relationship between ethical principles and guidelines.**

**Beneficence and non-maleficence**

Acting for the good of the patient and avoiding harm have been identified as important benefits of guidelines. As ethical aims, these are irreproachable. In practice, beneficence and non-maleficence are associated with three specific aspects of guideline use:

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Rationing is unavoidable in health care, owing to finite resources. Guidelines may contribute to rationing by offering definitive statements about effectiveness and/or efficiency. However, we need to ask how decisions about rationing should be made, and whether it is right for guidelines to contain covert economic decisions for implementation by GPs.

There are major inequalities in the distribution and treatment of ill health in the UK, and the reasons for these inequalities are complex, and many of them lie beyond the health arena. However, the way that health services are organised, and the distribution of health care goods within these services, have the potential to make significant reductions in the inequalities. This creates a moral imperative for guidelines to include a specific equity assessment in their recommendations, indicating the expected effects of following the guideline recommendations upon the least well off.

Economic assessments used in health care aim at achieving the greatest good for the greatest number, and this population approach may lead to inequitable results. For example, there are excess mortality rates for coronary heart disease (CHD) in some ethnic groups and in manual workers compared with skilled workers. However, risk factors identified in a national, evidence-based guideline for the primary prevention of CHD do not include ethnicity or socio-economic status. This means that an apparently equitable application of the guideline across the UK would do nothing to alter the excess mortality rates in these groups. Without explicit principles we run the risk of ad hoc resource allocation depending upon the adherence of GPs to guidelines; a process which may well conform to the law of inverse care and favour the well resourced at the cost of the least well off.

Guidelines already contribute to rationing processes. To be morally acceptable, rationing criteria should be explicit and should address equity issues. The level at which rationing occurs requires thought; leaving decisions about access to resources with GPs protects clinical freedom but may exacerbate inequities.

**Justice: guidelines as tools for rationing**

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**Respect for patient autonomy and patient participation in decision making**

Respect for patient autonomy is a fundamental principle of medical ethics, demonstrated in practice by facilitating patient choice. However, there is a tension between the use of guidelines and respect for patient choice. Guidelines rarely offer sufficient information or options to facilitate genuine choice. If a GP follows a guideline, the patient remains free to refuse the recommended intervention, but the capacity for choice among a range of acceptable alternatives is severely curtailed in several ways.

The range of treatment options is predetermined.
Guidelines recommend interventions for which there is evidence of effectiveness; in practice, options are often restricted to pharmaceutical interventions. Two factors bias research towards producing evidence for pharmaceutical interventions. First, the currently accepted hierarchy of evidence privileges randomised controlled trials. Pharmaceutical interventions are ideally suited to production of placebos for use in trials, in contrast with other interventions, such as counselling, physical therapies and lifestyle interventions. Secondly, pharmaceutical companies are major funders of research. This makes it easier for researchers to secure funds for investigating pharmaceutical interventions, rather than for less profitable interventions, such as exercise.

Next, the availability of evidence for interventions depends upon results from research programmes, which are directed by the scientific community. The conditions, interventions, and outcomes of interest to consumers, may not be represented. In addition, the review process during guideline development involves choices about those outcomes to be counted as benefits or burdens. This is a crucial part of the process, and one that has relied upon biomedical outcomes, rather than those identified by consumers.

Finally, successful implementation is described as adherence to guidelines. The presence of a guideline, together with audit requirements, may consciously or unconsciously bias GPs’ presentation of information and choices in favour of the guideline recommendations.

These limits on patient choice are difficult to reconcile with current conceptions of respect for patient autonomy or evidence-based patient choice. If health care is about improving health in ways that people value, this process should be informed by the views of those affected. We need to acknowledge consumer expertise and the therapeutic benefits of incorporating patient concerns.

At the level of the consultation, there may be morally robust reasons for considering limits on patient choice. Unfettered patient choice may lead to greater inequities in health care, through the diversion of scarce resources towards those who voice the loudest preferences, rather than those with the greatest health care needs.

Ethical issues in guideline development

The development of guidelines raises several process issues with ethical dimensions. These include choice of topics, group composition, definition of benefits and harms to include as outcomes, evaluating evidence, and forming recommendations.

Selecting a topic for guideline development involves some prioritising, as guideline development is time consuming and costly. Several criteria have been suggested to assist this process.

These criteria are not ranked, and there is little information in the public domain as to how topics are selected, although it is reasonable to suspect that the existence of evidence is a prerequisite. In particular, there is no explicit moral focus, such as equity, as has been advocated above. An equity focus would require topics to address conditions that are documented to be major health problems for disadvantaged groups. Ideally, epidemiological data would be supplemented, through consultation with relevant groups, to frame appropriate topic questions. This would ensure the production of guidelines that address conditions in practical ways. There is a problem in that the evidence may not exist for priorities chosen in this way, in particular for addressing disease management in certain socioeconomic groups. If this is the case, it is important to document this and feed the results into the priority-setting processes for research funding.

The priority-setting process is open to nominations by interested people or groups. Given the amount of work involved in submitting an application to develop a guideline, enthusiasm is a highly desirable, if not necessary, ingredient. However, enthusiasm may be misdirected or fuelled by morally irrelevant considerations. We need a way of setting priorities in an explicit and overt process with clearly defined criteria, and then seeking applications on the topics selected by this process.

The effects of group composition upon final recommendations is well documented. Group members represent their professional interests, making it possible for groups to reach covertly biased conclusions. Use of multi-disciplinary groups will decrease the potential for this, although it is possible that internal dynamics may allow overruling of some interests by more vocal or powerful others.

Defining which benefits and harms should count as significant outcomes, and evaluating research against these criteria, are processes requiring interpretation and judgement. Again, use of multi-disciplinary teams, attention to equity, and positive inclusion of consumer perspectives, will all contribute to the development of ethically robust guidelines.

Forming recommendations is the final part of the process. The nature of the recommendations must surely reflect the purpose of the guideline, with clear identification of the full range of considerations, including economic considerations, which have influenced the group.

Ways forward

There are a number of ways to address these issues. The first and perhaps the most important task is to debate and clarify the moral basis upon which priority setting and resource allocation decisions should occur. No single approach is perfect, and it is most likely that an imperfect mixture of equity and rescue will be the best we can manage. But this is very much a matter of public and professional concern; if certain services are curtailed to some patients, we must be able to understand why this is so. Questions of effectiveness and efficiency may then be addressed once the moral direction has been set.

There are a number of ways in which the development process for guidelines could be ethically strengthened.

**Box 3. Possible principles for distributing health care goods.**

- To achieve the greatest good for the greatest number
- To meet medical need
- To redress existing inequalities
- To give everyone a fair share of resources
- To express solidarity with and support for the suffering
- To ensure equal access to health care resources
Assessment of the major causes of morbidity and mortality for a given population
• Uncertainty about the appropriateness of a current health care practice/process
• Uncertainty about the evidence of effectiveness of a current health care practice/process
• Financial considerations
• Robust evidence of effectiveness
• Realistic expectation that change is possible and desirable and that following the guidelines will lead to improved quality of care and/or patient outcomes.

Box 4. Current criteria for selection of guideline topics.

These include identifying how guideline development groups are chosen, how interventions and outcomes are chosen, what kind of group processes are used, and how the evidence is synthesised and evaluated. More specific suggestions have been published elsewhere.43,44

Information about the development of specific guidelines should include explicit documentation about the methods used to assign values to alternative options where this has occurred.45

Finally, we need to work out how guidelines should be used and question whether current ideas concerning implementation and compliance are useful.12 This will require greater discrimination about the purpose of guidelines. A guideline that documents new evidence about the harmful effects of a widespread practice is morally compelling and warrants concerted efforts to change practice. Conversely, a guideline that informs practitioners and patients about a range of options for the management of a problem should be seen as an educational tool for improving informed choice for patients. Measuring adherence to the guideline in such a case will not yield information about the success or otherwise of its implementation. Different purposes require different implementation strategies, depending upon the nature of the problem.

If guidelines are to address variability, we need to understand how and why variation occurs in general practice and to develop reliable ways of identifying and acceptable variations. When variation is owing to external barriers, implementation and compliance are useful.12 This will require greater discrimination about the purpose of guidelines. A guideline that documents new evidence about the harmful effects of a widespread practice is morally compelling and warrants concerted efforts to change practice. Conversely, a guideline that informs practitioners and patients about a range of options for the management of a problem should be seen as an educational tool for improving informed choice for patients. Measuring adherence to the guideline in such a case will not yield information about the success or otherwise of its implementation. Different purposes require different implementation strategies, depending upon the nature of the problem.

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