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A review of clinical practice guidelines found that they were often based on evidence of uncertain relevance to primary care patients

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Abstract

Objectives: Primary care patients typically have less severe illness than those in hospital and may be overtreated if clinical guideline evidence is inappropriately generalized. We aimed to assess whether guideline recommendations for primary care were based on relevant research.

Study Design and Setting: Literature review of all publications cited in support of National Institute for Health and Care Excellence (NICE) recommendations for primary care. The relevance to primary care of all 45 NICE clinical guidelines published in 2010 and 2011, and their recommendations, was assessed by an expert panel.

Results: Twenty-two of 45 NICE clinical guidelines published in 2010 and 2011 were relevant to primary care. These 22 guidelines contained 1,185 recommendations, of which 495 were relevant to primary care, and cited evidence from 1,573 research publications. Of these cited publications, 590 (38%, range by guideline 6–74%) were based on patients typical of primary care.

Conclusion: Nearly two-third (62%) of publications cited to support primary care recommendations were of uncertain relevance to patients in primary care. Guideline development groups should more clearly identify which recommendations are intended for primary care and uncertainties about the relevance of the supporting evidence to primary care patients, to avoid potential overtreatment.

Keywords: Clinical practice guidelines; Primary care; Quality of evidence; Review; Health technology assessment; Strength of recommendations

1. Introduction

Clinical practice guidelines are an increasingly important driver of decisions about patient care. They have been defined as ‘‘recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options’’ [1]. Guidelines have traditionally been developed to simply provide guidance for clinical decision making, but they are becoming embedded in the structure of UK primary care through their translation into indicators of quality of care in a national ‘‘pay for performance’’ financial incentive scheme (the Quality and Outcomes Framework) and through the development of quality standards to inform decisions on health care planning and commissioning [2]. This increasing use of guidelines to develop incentives and standards for primary care may lead to more patients at lower risk of adverse outcomes receiving treatment and exposure to potential adverse effects.

Groups developing guidelines about the care of primary care patients will use the current best evidence from primary care or lower risk populations where it exists. If high-quality primary care evidence is not found, the best evidence available may be from a secondary care or higher

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What is new?

- The applicability of clinical practice guidelines to primary care has been questioned for individual conditions such as hypertension and depression, and concerns have been raised about guidelines promoting overtreatment of low-risk populations.
- Until now, evidence from a systematic appraisal of the relevance to primary care of published guidelines has been lacking.
- Nearly two-third of the research cited in support of National Institute for Health and Care Excellence guideline recommendations for primary care was of uncertain relevance to primary care patients, with little or no acknowledgment of this uncertainty.
- Guideline development groups should more clearly identify which recommendations are intended for primary care and uncertainties about the relevance of the supporting evidence to primary care patients, to avoid potential overtreatment and adverse effects.

risk population. This entirely appropriate approach leads to problems when a guideline development group (GDG) assumes that the evidence from research conducted on a higher risk population can automatically be applied to a lower risk primary care population. If uncertainty about the evidence is not explicitly acknowledged, the integrity of the guideline is compromised and patient harm may result [3,4]. The benefits of treatment are usually lower in populations at lower risk of adverse outcomes, whereas the risk of harm from adverse treatment effects remains constant. Patients seen in primary care typically have less severe illness than those in hospital, and so evidence from trials conducted in secondary care may have limited relevance and result in harms outweighing benefits [5].

An example of taking evidence from a higher risk population and applying it to a lower risk population is the Quality and Outcomes Framework indicator and National Institute for Health and Care Excellence (NICE) heart failure guideline recommendation that all primary care patients with chronic heart failure (including low grade) should be offered β-blockers and ACE inhibitors. This indicator is supported by evidence generalized from higher risk populations (New York Heart Association grades III−IV), in which there is clear evidence of benefit, to lower risk populations, in which the evidence of benefit is more equivocal. The potential harm is the adverse effects of β-blockers experienced by some patients, and the substantial risk of acute kidney injury from ACE inhibitors, which may account for a tenth of the increase in hospital admissions because of an acute kidney injury [6]. It is therefore uncertain what the balance of harms and benefits might be in a typical primary care patient [7,8], and a general practitioner needs to know about this uncertainty when, for example, considering prescribing a β-blocker to a patient with a relative contraindication to a β-blocker therapy from a comorbid condition. This vital information about uncertainty and the balance of benefits and harms is hard to find in the Quality and Outcomes Framework guidance or NICE guideline, which presents a single approach rather than acknowledging that there are several acceptable alternatives for low-risk patients.

Another example where it is hard for the user of a clinical guideline to know about the balance of benefits and harms for a typical primary care patient is the Quality and Outcomes Framework incentive to prescribe aspirin or an alternative antiplatelet to all patients with peripheral arterial disease, most of whom do not have symptoms and are managed in primary care [9]. The evidence that antiplatelet therapy can reduce serious vascular events comes primarily from a large subgroup analysis of the Antithrombotic Trialists' Collaboration meta-analysis in high-risk patients and a similar review conducted by NICE [10,11]. However, the authors caution that their results may not be applicable to low-risk patients, and others have calculated that the number of potential reductions in coronary heart disease events exceeded the number of potential precipitated adverse bleeding events only for patients with a 1% or greater annual risk of coronary heart disease events [12]. A third example is chronic kidney disease (CKD), where there is evidence of benefit to high-risk populations but no evidence of benefit in people with early-stage CKD at a low risk of future disease [13]. Both primary care physicians and specialists have expressed concerns about potential harms from overtreatment resulting from expanding definitions of CKD in guidelines.

A small pilot study suggested that the evidence base for primary care guidelines might not be relevant to most primary care patients, with important implications for patient safety [14], and we wanted to systematically examine the evidence base for clinical guidelines used in primary care. We used guidelines from the NICE as it has been a leading provider of evidence-based clinical guidelines in the United Kingdom since 2002 [15]. NICE's highly respected methods compare well with the U.S. Institute of Medicine's standards for trustworthy guidelines [1,16−18] and with the international consensus that guidelines should be developed using an explicit and transparent process that minimizes distortions, biases, and conflicts of interest; should base recommendations on a systematic review of the existing evidence; should include experts and patient representatives on a multidisciplinary GDG; and should consider important patient subgroups and patient preferences [1,19,20]. The development of NICE clinical guidelines follows a well-established process [16]. When a topic has been chosen, a National Collaborating Centre (NCC) is commissioned to develop the guideline. The NCC prepares the scope which sets out what the guideline will and will not cover and recruits the GDG. Review questions are