Conceptual and Practical Aspects of Clinical Practice Guidelines in Family Medicine

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This paper explores the conceptual and practical aspects of clinical practice guidelines in family medicine. It focuses on four questions: a) What are the guidelines and which issues do practice guidelines aim to resolve? b) Which criteria or principles should be used to set good practice guidelines? c) What are the problems or pitfalls inherent in the development and dissemination of guidelines? d) Which factors impede on guideline implementation within the context of family medicine? These questions are discussed in terms of recent relevant literature from the point of view of the end-user – the practitioner. The major conclusion drawn from debating these four questions is that clinical guidelines are increasingly becoming part of current practice and will become more prevalent over the next decade. However, guidelines will not address all the uncertainties of current clinical practice and should only be considered as one strategy capable of enhancing the quality of patient care [1]. Unfortunately, the need for evidence to support common advice used in family practice is more complex than many recognize. Only the integration and application of disease-specific and sociocultural knowledge, along with an understanding of the unique values and needs of individuals, families and communities, can generate fully beneficial clinical guidelines.

What are the guidelines and which issues do practice guidelines aim to resolve?

Over the past decade, clinical guidelines have increasingly become an integral part of clinical practice. Guidelines continuously impact on clinical decision-making and on both governmental and insurance health expenditure [1]. Clinical guidelines can be thought of as "generic decisions or recommendations intended for a collection of patients rather than for a single patient" [2]. Sackett et al. [3] define clinical practice guidelines as "user-friendly statements" for a collection of patients, based on the best external evidence. The American Academy of Family Physicians defines a clinical policy as "a recommendation issued for the purpose of influencing decisions about health interventions" [4]. The Agency for Health Care Policy and Research defines practice guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances" [5]. Different definitions represent different attitudes to guidelines. Family physicians in Israel should lead a public discussion on the suitable definition for guidelines in the context of family medicine in Israel.

The broad interest in clinical guidelines can be attributed to issues facing most healthcare systems, namely rising healthcare costs, more expensive technologies, and an aging population. These issues also involve variations in service delivery, which are sometimes a result of inappropriate care, overuse or underuse of services, and the intrinsic desire of healthcare professionals to offer – and of patients to receive – the best possible care [6].

The distinct goals of professional societies, government agencies and insurance companies influence guideline development and lead to conflicting recommendations. While guidelines can be used as educational tools, they are also becoming the standard for assessing quality in clinical practice [1,7]. Most guidelines developed at the federal level address clinical dilemmas in daily practice that generate high healthcare costs. At the AHCPR, for example, guideline topics are selected if they are condition-specific, highly prevalent and very costly. Moreover, these topics are chosen if they carry a significant burden of suffering for which health outcomes are identifiable and modifiable, and if there is sufficient scientific information of reasonable quality and quantity to support guideline recommendations [8]. The AHCPR approach is a government-sponsored initiative aimed at eliminating inefficient, unnecessary care. Emphasis is on developing evidence-based guidelines for multidisciplinary use and on including patients' preferences. Each guideline involves substantial investments in order to support the work of expert panels and independent scientific institutions involved in the process [9]. The approach in The Netherlands derives from an initiative undertaken by family physician organizations to support family physicians in their daily work and enhance the position of family medicine in healthcare. This approach balances both the scientific evidence

AHCPR = Agency for Health Care Policy and Research

and feasibility of the guidelines in practice and their acceptance by family physicians [9].

Which criteria or principles should be used to set good practice guidelines?

"Good" clinical practice guidelines should be valid, reliable, clinically applicable, flexible, clear, multidisciplinary, periodically reviewed and well documented [4]. David Eddy [2], who proposed criteria to compare and contrast different approaches to guideline development, suggested that guidelines be accurate, accountable, predictable, defensible and usable. 'Accurate' implies that the guidelines, if implemented, should produce the health outcomes its developers intended. 'Accountable' implies that the rationale for the recommendations and the evidence on which they are based should be clear. A guideline is predictable if clinicians and policy makers can anticipate the health and economic consequences arising once the guideline is implemented. In order to be defensible, a guideline should provide the information necessary to resolve conflicts that may arise from other guidelines. Finally, in order for a guideline to be usable, clinicians should be able to tailor the guideline to individual patients and practice settings [10].

In other words, "good" clinical practice guidelines are intended to influence medical decision-making by: a) summarizing scientific data on a clinical problem; b) combining this information with the costs, outcomes, and patient preferences for varying management strategies; and c) recommending management of the clinical problem supported by this information. The likely impact on the primary care practitioner's daily work should be taken into consideration as the guideline is being developed [11].

What are the problems or pitfalls inherent in the development and dissemination of guidelines?

Although a great deal of emphasis is placed on guideline validity and reliability, they are not always developed accordingly. A recent review in the *Journal of the Royal Society of Medicine* defines a well-constructed guideline as one that: a) specifies the types of professionals involved in the guideline's development, b) defines the strategy used to identify primary evidence, and c) provides a clear grading of the recommendations [11]. A review of 431 sub-specialty society guidelines, however, showed that 54% did not include any of these elements and only 5% included all three of them [12].

Making printed information available to clinicians seems to have little impact on either process of care or patient outcomes [13]. The scientific validity and reliability of the guidelines attract most of the attention, while less attention is paid to the guideline features likely to determine their use within the scope of decision-making in clinical practice [14–16].

In an observational study, Grol et al. [14] found that, in order to be used, guidelines should be compatible with existing values and routines among the target group. They should be defined precisely, including specific advice on actions and decisions in different cases. The scientific basis for the recommendations entailed in the guidelines is also important. Recommendations were better adhered to when an explicit description of the scientific evidence was available, straightforward and unambiguous. A recommendation was used less when compliance affected the organization and/or staff in practices, when it demanded extra resources or the acquisition of new knowledge and skills, or when it provoked negative reactions in patients [14].

However, even the development of efficient guidelines does not ensure their practical use. Systematic reviews of strategies designed to change professional behavior show that the relatively passive methods of disseminating and implementing guidelines through publication in professional journals or mailings to targeted healthcare professionals rarely lead to behavioral changes [17–19]. Lomas [20] observed that the failure of passive dissemination strategies is hardly surprising given the many factors influencing healthcare professionals' behavior.

Grol [21] proposes a model that can be used to modify physicians' behavior. The model consists of five main steps of what he calls the "Quality Cycle":

- developing a proposal for change and identifying obstacles to change
- linking interventions to obstacles
- designing a plan
- implementing the plan
- assessing the progress.

An alternative model for changing provider behavior is the "practice ecology" metaphor. This metaphor highlights the different levels at which the family practitioner operates and the dynamic interactions between them [22]. In his study of decision-making in general practice, Essex [23] identified 10 categories of factors affecting decisions: the nature of the health problem, patients' expectations, compliance, the impact of requests made by the patient's family, the doctor's mental state, workload, availability, time and resource constraints, ethical considerations, and management factors. All these should be taken into consideration when planning interventions for guideline implementation [22]. There is a very large body of literature on changing physicians' behavior, but this is beyond the scope of this paper.

Physician adherence is critical to translating recommendations into enhanced outcomes. Physician adherence to guidelines may be hindered by a variety of potential barriers such as a lack of awareness and/or familiarity affecting the physician's knowledge of a guideline or attitude (such as lack of agreement, self-efficacy, outcome expectancy), as well as the inertia stemming from previous practice [24]. External barriers can also affect a physician's ability to adhere to recommendations [25].

The effect of the type of problem on physicians' behavioral change is rarely considered. Some problems are more apt to inspire changes in provider behavior than others. Because such problems are a detectable and common – though not routine – part of the biomedical domain, providers can "do something"

about the problem and ensure quality of treatment accordingly [22].

Different professional and organizational strategies can be used to overcome various barriers. For example, educational approaches (seminars and workshops) may be useful for barriers pertaining to family physicians' knowledge. Audit and feedback may be useful when family physicians are unaware of sub-optimal practice. Social impact approaches (local consensus processes, educational outreach, opinion leaders, marketing) may be useful for barriers pertaining to the existing culture, routines and practices of family physicians. Reminders and patient-mediated interventions may be useful when family physicians experience difficulties processing consultation-related information [20].

Education is the most commonly used change facilitator and one of the least successful [26]. Educational strategies include formal continuing medical education programs, outreach visits, consulting local opinion leaders, patient education materials, feedback, audits and reminders. Rarely do these have a lasting effect on patient outcomes [17]. Education and protocol-type strategies assume that rational know-how or enhanced tools will generate change. This reflects the high value our culture places on scientific rationale and technology and the associated belief that physicians will respond to good evidence [27]. In order to be effective, education must be specifically tailored to: a) the knowledge, attitudes and skills required to implement the guideline; b) the intensity of treatment expected of the provider; c) the special needs of particular patient populations; and d) the context and setting in which the intervention will be delivered. These change strategies also assume linearity, namely that a change or intervention in A will directly and predictably lead to a change in B. This has not consistently been the case. In non-linear relationships the surprise element is often the norm. Small actions can have dramatic effects while large changes may only yield minor results, such as in practice guidelines [27].

We require new understanding grounded in the knowledge of the unique configurations of individual practices, which have the potential to lead us toward change interventions [15].

Which factors impede guideline implementation within the context of family medicine?

Due to the nature of primary care, clinical guidelines do not comply with the family physicians' need to integrate and prioritize a broad range of healthcare services. As a result, they are often blamed for not translating knowledge into practice [28].

Evidence-based clinical practice guidelines can be viewed as a way of extending the approach of evidence-based medicine from the single patient to improving clinical practice for a group of patients [29]. Evidence-based clinical practice guidelines are based on randomized controlled trials. Several characteristics of family practice mar the ability to answer important questions on randomized controlled trials, since they are primarily based on the traditional biomedical paradigm and associated reductionist assumptions of materialist inquiry [29]. Family physicians address at least 100 problems in 30 or more patients each day, and the outcome of most of these encounters is merely straightforward advice [30]. About 40% of all new disorders in family practice do not evolve into conditions that meet accepted diagnostic criteria [30]. In its modern sense, diagnosis means assigning the patient's illness to a category that links the symptoms to a pathological process and, in some cases, to a specific cause [29]. Both problem-solving and decision-making in family medicine have a wider scope than making a diagnosis [30,31]. The solution to a patient's problem may have very little to do with the diagnosis. James Mackenzie [32] very aptly described it many years ago: "I had not long been in the practice when I discovered how defective was my knowledge. I left college under the impression that every patient's condition could be diagnosed. For a long time I strove to make a diagnosis and assiduously studied my lectures and textbooks, without avail. For some years I thought that this inability to diagnose my patients' complaints was due to personal defects, but gradually, through consultations and other ways, I came to recognise that the kind of information I wanted did not exist."

Decisions have to be made at all stages of the clinical process. This decision-making process itself consists of a set of decisions. Management decisions have to be made prior to, and often in the absence of, a diagnosis [30]. The preferred management of undifferentiated disorders is "watchful waiting," a step that requires a trusting relationship between the physician and the patient.

In addition, the language used for discussing problems in the family practice setting reflects experience that may not fit into a given category. This makes differentiating syndromes as well as collecting information regarding practice patterns problematic [22]. Moreover, the absence of clear definitions for undifferentiated disorders makes exploring their management methodologically difficult in the purist world of randomized controlled trials [29].

Other common disorders managed in family practice include the monitoring of chronic disease that tends to occur in individuals with co-morbidity. Usual randomized controlled trial methods require individuals with a single diagnosis. Patients do not usually present with exclusively physical or psychological problems; rather, the latter are often a complex mixture of physical, psychological and social elements [30].

The context in which a patient is cared for includes factors specific to that individual and the society in which he or she lives. A specific situation can affect decisions about treatment, even though good quality evidence may be available to support a specific course of action. The issue of health resources is vital to applying evidence. Although there is good evidence for some preventive measures, applying such evidence may be inappropriate in less developed countries where inadequate nutrition and housing are major issues and life expectancy is less than 60 years [29]. Economic factors also have a major effect on the application of evidence in the context of the individual patient. For example, according to the evidence, a

patient with an elevated cholesterol level requires medication. But should we offer it to him even if he cannot afford it?

Medical decisions in primary care are affected by patient preferences, which are distinct from the biomedical aspects of disease. A patient whose father died of prostate cancer may insist on routine prostate-specific antigen screening even if he understands the evidence that the high false-positive rate for PSA leads to unnecessary biopsies. His concern will override the fact that 85% of prostatectomies provide no benefit and have the added potential for catastrophic side effects [29].

If family practice is to be patient-centered, the context of the individual should be integrated within the available evidence in order to determine the optimum course of action for each patient [30,33]. Applying value judgments to individuals should always allow for common ground between the family physician and the individual [34]. Once individuals understand the evidence on the benefits and risks of a particular therapy, they must take into account their own context and values when reaching a decision. The family physician must provide guidance on the quality of the evidence available and its relevance to the individual's personal context [34].

The idea of setting targets for various procedures in family practice creates tension between population-based data and individual patient-physician encounters. Providing the physician with economic incentives to achieve targets of up to 100% population coverage of preventive procedures clearly reflects the supreme value granted to population-derived evidence and disregards the patient's personal context and values. This creates a conflict of interest for the family physician, who is encouraged to override the patient's perspective.

Stewart [35] reviewed the literature on the benefits of patient-centered healthcare provision by general practitioners and found that patients' satisfaction with their relationship was highest when they took part fully in the decision-making. Moreover, patient compliance with the agreed upon strategy was better when the decision was a joint one. Working out and accommodating each patient's specific context and values can provide better health outcomes. In the past, there were few intrusions on the privacy of the patient-physician relationship. Physicians have expressed concern that guidelines would devalue the "art of medicine" and threaten clinical autonomy [36].

The clinical validity and efficacy of utilizing evidence-based guidelines as quality evaluation tools are threatened if patients' goals are not adequately assessed; without these assessments, we are liable to confuse uniformity with quality. Physicians confronted with these personal patient factors were less likely to adhere to the clinical guidelines' specific recommendations, and their responses may well be consistent with broader definitions of quality patient care [28]. Grol and Jones' [37] review of guidelines over the last 20 years emphasizes that we have come a long way but probably still have a considerable distance to travel: "Looking into the crystal ball, we will have to consider how best to incorporate the views of patients in the development and implementation of guidelines, taking place in an increasingly patient-centered climate."

Physicians who did not adhere to the guidelines because of patient preferences should not be judged as practicing lower quality medicine, as measured by performance profiles. Disease-specific quality measures only reflect one aspect of care. The context in which illness presents, the patient seeking medical care, and the concerns or preferences the patient has about his or her overall situation are important variables to be considered by primary care physicians. Family physicians should record the rationale for decisions contrary to guideline recommendations, especially when decisions are made in response to personal non-disease factors [27].

PSA = prostate-specific antigen

Conclusion

Clinical guidelines are increasingly part of current practice and will become more prevalent over the next decade. However, guidelines will not address all the uncertainties of current clinical practice and should only be considered as one strategy capable of enhancing the quality of patient care [1]. Unfortunately, the need for evidence to support common advice used in family practice is more complex than many recognize. Only the integration and application of disease-specific and sociocultural knowledge, along with an understanding of the unique values and needs of individuals, families and communities, can generate fully beneficial clinical guidelines.

As Eddy stated [10], "It is not stretching things too far to say that whoever controls practice policies controls medicine." The real question for family physicians is who will have such control. In order to achieve control, our challenge for the future is to develop the science of family medicine and thereby provide family physicians with evidence for their daily work. We need to generate fresh knowledge based on the needs of patients, families and communities in order to achieve integrated healthcare.

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