DO GUIDELINES INFLUENCE PRACTICE?

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Clinical practice guidelines are consensus statements systematically developed to help physicians, and ultimately patients, make decisions about appropriate health care for specific clinical circumstances. Over 20 years ago the American College of Cardiology (ACC) and the American Heart Association (AHA) established a joint task force to define the role of specific, non-invasive and invasive procedures in the diagnosis and management of cardiovascular disease.[1] More specifically, this was initially aimed at establishing the appropriate utilisation of technology in the diagnosis and treatment of cardiovascular patients and was initially directed towards the development of guidelines for permanent cardiac pacemaker implantation. Subsequently, task forces have played an important role in developing other guidelines for a host of cardiovascular, medical, and surgical conditions as well as diagnostic procedures. Using rules of evidence and clinical recommendations originally developed by Sackett for the use of antithrombotic agents, a relatively systematic approach (see box) towards the generation of guidelines has emerged.[2] Framed by three levels of evidence, recommendations are categorised as: (1) data derived from multiple randomised clinical trials; (2) data derived from a single randomised trial or non-randomised studies; and (3) where data does not exist but a consensus opinion is developed from a variety of experts.

CONSENSUS OPINION

When recommendations emerge from consensus opinion, these often emanate from strongly held and sometimes diverse views giving some substance to the perspective of Abba Eban, former Israeli Ambassador to the United Nations, who suggested that "consensus means that lots of people say collectively what no one believes individually". Approximately 25 such guidelines have emerged since the ACC/AHA commenced joint production of these in 1980 making it difficult to stay abreast of the volume of recommendations. Indeed, as recently reported by Ohman and Peterson, even within the three guidelines for ischaemic heart disease encompassing chronic stable angina, unstable angina, and acute myocardial infarction (which are frequently updated), there are a total of 462 recommendations.[3] Such a litany of options underscores the need for the emergence of critical pathways and care maps that translate such guidelines into practical tools and protocols detailing specifically how the process of care should unfold as tailored to individual institutions.[4] These are especially useful in high volume, procedure related activities and medical conditions that consume substantial resources. Commonly, in cardiovascular disease, they have been applied to patients with acute ST segment elevation myocardial infarction as it relates to the use of fibrinolysis and percutaneous coronary intervention, and the early management of patients with chest pain in chest pain units and/or observation areas.

The European Society of Cardiology and Canadian Cardiovascular Society have been similarly active in the development of guidelines and there is strong impetus for international collaboration. To the extent it is feasible, harmonisation of such guidelines in order to make the best use of evolving data and opinion is most desirable. Agreement across countries and even continents may well be achieved by a community of experts and professional societies, but the challenges around implementation may well impede their effectiveness. Hence, the number of available expert providers, their system of remuneration, the health care system(s) in which they work, and the distribution of technologically advanced facilities across diverse geographical terrains poses substantial challenges.

In 1989 the Agency for Health Care Policy and Research (AHCPR) was created to "enhance the quality, appropriateness and effectiveness of health care services through the establishment of a broad base of scientific research and through the promotion of improvements in clinical practice in any organization financing and delivering health care services".[5] Part of their charge was to develop guidelines. In order for this agency to fulfil its mandate the Institute of Medicine convened an advisory committee which issued a report in 1990 within which practice guidelines were defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances".[6] In a 1994 document developed by the

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Guideline recommendations: classification

- Class I: general agreement that a procedure or treatment is useful and effective
- Class II: conflicting evidence or divergence of opinion exists
- Class IIa: weight of evidence or opinion favours utility or efficacy of procedure or treatment
- Class IIb: weight of evidence or opinion is less well established
- Class III: evidence or general agreement that the procedure or treatment is either not useful or effective or in some cases may be harmful

Canadian Medical Association derived from a workshop of 40 health care organisations who formulated six background research papers, a statement of guidelines for Canadian clinical practice guidelines was developed according to three categories: philosophy and ethics, methods and implementation, and evaluation.[7] From the philosophical and ethical perspective it was perceived that the goal of guidelines should be to improve the quality of care enabling informed decision making between patients and well prepared physicians who discharge their primary responsibility to their patients in an ethical framework. A methodology was articulated concerning the need for a clear statement of goals by physicians in collaboration with other health care providers and patients as appropriate. The nature, strength, and timeliness of the evidence supporting the guidelines were to be cited and external review by appropriate experts and user groups undertaken before implementation. A standard format for on-line abstract publication with the National Library of Medicine in the USA was developed and the effectiveness after implementation, user feedback and a strategy for review and revision was suggested as an important component to incorporate.[8]

Some have argued—for example, the American College of Emergency Physicians (ACEP)—that guidelines consist of detailed or expanded lists that are meant to prompt physicians to consider actions that should be modulated by individual patients, their circumstances, and other factors.[9] Their premise is that guidelines are not always followed and that there is no implication that failure to follow them is improper. Although this approach would be too lenient for many, the ACEP goes on to distinguish guidelines from rules which are defined as actions "reflecting principles of good practice in most situations. There may be circumstances when a rule need not or cannot be followed; in these situations it is advisable that deviation from the rule be justified in writing. Inability to comply with rules should be incorporated in institutional policies".

IMPETUS FOR DEVELOPING GUIDELINES

The impetus for the development of clinical guidelines arises from at least three diverse forces triangulated in fig 1. Whether or not these forces are aligned towards the enhancement of patient care displayed at the apex of the triangle is moot. Unquestionably, spiralling health care costs and unfettered use and access to an expanding array of diagnostic and therapeutic options has positioned those individuals and groups charged with the responsibility of resourcing health care to embrace a more systematic approach to their implementation. Heterogony between individual practitioners, generalists and specialists, and within and across geographic regions have been another incentive for guideline development. An additional principal stimulus has been the extraordinary evolution of high cost, high technology based diagnostic and

Figure 1 The need for guidelines.

treatment modalities—especially in the care of patients with acute coronary syndromes—that has led to increased complexity in care. This has been especially challenging to non-specialty providers who in many countries form the majority of first line contacts for this growing segment of the population. Especially vexing is an understanding of what incremental advance each new treatment provides, despite the accompanying—often robust—statistical evidence of a modest gain achieved on a platform of prior established treatment.

Notwithstanding clinical trial evidence of the efficacy of a variety of novel treatments, the extent to which these treatments are applied—that is, their effectiveness—has emerged as a central issue in contemporary medicine. This is perhaps best demonstrated by the extraordinary variability in the extent to which treatments are applied within individual groups of practitioners and institutions across national and international boundaries. Failure to apply the evidence based treatment derived from clinical trials to clinical practice has popularly become known as the "care gap" and a variety of surveys, registries, and clinical trial information has emerged to highlight this important issue and devise resourceful strategies to address it.

Recent examples of the variability in the application of evidence based treatment have indicated that one basis for differences relates to whether or not the institution involved is a major teaching hospital. Hence, Alison and colleagues studied 237 754 myocardial infarction patients from the Medicare database who were perceived to be "ideal candidates" for the receipt of aspirin, angiotensin converting enzyme (ACE) inhibitors or β blockers.[10] A gradient of diminishing use of these treatments was evident between three groups of hospitals characterised as major teaching (best) versus those perceived to be minor teaching or non-teaching institutions.

Across international boundaries we have similarly observed substantial variation in the use of aspirin, β blockers, ACE inhibitors, and lipid lowering agents in patients convalescing from acute coronary syndromes and entered into a large clinical trial.[11] Other instances where pronounced variability among post-myocardial infarction patients is evident include the use of in-hospital revascularisation: here patients with similar inclusion and exclusion criteria convalescing from fibrinolysis are managed very differently.[12] These differences appear likely to impact on longer term mortality.

QUALITY OF MEDICAL CARE

The Institute of Medicine, which has played a major role in highlighting issues around the quality of medical care, has recently focused on the problem of medical errors and the gap that exists in the delivery of quality care. Quality of care is defined by the Institute of Medicine as "the degree to which

Barriers to implementation of guidelines

- General resistance to change
- Loss of professional autonomy
- Economic disincentives
- Perceived threat of litigation
- Inadequate skill set
- Lack of decision to support technology
- "Does not apply to my patient"
- Out of date/ moving target

The 8 high Cs for guidelines

- Clear
- Concise
- Comprehensive
- Consensual
- Cost sensitive
- Credible
- Contemporary
- Centred on patients

health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge".[13] In his address to the annual convocation to the American College of Cardiology, the president of the Institute of Medicine, Kenneth Shine, challenged the college to take a leadership role in closing the gap in quality care by:

- enhancing standardised data systems for collecting data on outcomes and process of care
- closing the gap between average and "best" care with particular emphasis on the disadvantaged and underserved
- introducing the principles of quality improvement into the education of all those in training
- identifying best practices such as the development of computerised patient records essential to the provision of timely, appropriate and non-redundant care
- defining the range of high quality performance for common conditions and procedures with appropriate accounting for patient risk
- publicising surgical morbidity and mortality results to permit patients and physicians to make informed choices
- developing acceptable performance standards so that patients, advocate groups, and corporations or governments can collaborate optimally in enhancement of quality.[14]

Given the substantial impetus to the development of guidelines, what are the obstacles to their implementation? Among established practitioners the general resistance to change in patterns of practice is a traditional one (see box). Loss of professional autonomy, concern about litigation, and potential economic disincentives are other issues that individual physicians may perceive. Recognition that the skill set required is lacking or that the requisite information technology and support required does not exist are other barriers. Finally, the recognition that certain disease entities are subject to extraordinary change, thereby forcing the guidelines to hit a moving target, leads many seasoned practitioners to question their relevance and the notion that externally developed guidelines do not apply to their patient at a specific point in time. It has also been stated that guidelines will stifle innovation and creative thinking by creating a culture of so-called "cookbook medicine" that will ultimately support mediocre rather than outstanding patient care.[15 16]

At least three examples in the cardiovascular arena provide some support for enhancement of patient care based on the implementation of guidelines/critical pathways. The first of these relates to the reduction of door-to-needle thrombolysis administration time in acute ST segment elevation myocardial infarction. The introduction of a critical pathway in the emergency department at the Brigham's Women's Hospital in Boston was associated with a reduction in median door-to-drug time from 73 to 37 minutes based on a comparison with historical controls acquired during the six months before a critical pathway implementation. Interestingly, whereas the pathway introduction reduced door-to-needle time in both males and females, it also narrowed the longer time-to-treatment for women versus men from 35 to 10 minutes.[17]

A second example from Rush Presbyterian/St Luke's Medical Centre in Chicago demonstrates the impact of dissemination of AHCPR unstable angina clinical practice guidelines. This consecutive study of two groups of medium and high risk patients with unstable angina revealed that after the introduction of guidelines there was more frequent use of aspirin, β blockers, and earlier application of coronary angiography with resulting less frequent recurrent angina, myocardial infarction, and death.[18]

Finally, using specific guidelines for the management of hospitalised patients with heart failure including treatment with ACE inhibitors, application of diagnostic echocardiography, and implementation of daily weights, a guideline based care management team was able to achieve higher rates of ACE inhibitor use and better adherence to guidelines for the assessment of left ventricular function than daily weight monitoring with resultant reduction in the length of stay and cost of hospitalisation.[19]

Development Strategy	Dissemination	Implementation	Evaluation
Internal	Specific	Patient reminder at a point care	Personal
Intermediate	CME	Patient specific feedback	Group
External – local	Targeted mail	General feedback	Institutional
External – general	Journal publication	General reminder	Profession

Figure 2 Practice guidelines effectiveness. CME, continuing medical education. Adapted from Grimshaw and Russell.[20]

My own personal algorithm and checklist comprises the eight high Cs characterising the key features for successful development and implementation of guidelines (see box). The implementation of evidence based medicine finds its most receptive ground when there are local champions and opinion leaders who are supportive, there is accessibility to the best evidence through user friendly information technology, and the qualifications and knowledge of the providers are optimal. If these individual components are present and the health care system provides wide accessibility and third party coverage, then success is more likely. This is also true if a quality assurance audit and feedback system is in place at participating institutions and they have participated in gathering the evidence supporting the guidelines.

EVIDENCE OF IMPACT OF GUIDELINES ON PRACTICE

What is the evidence that guidelines can provide a meaningful impact on medical practice? Grimshaw and Russell identified 59 published evaluations of clinical guidelines that met defined criteria for scientific rigour and concluded that explicit guidelines could improve clinical practice.[20] In fig 2, adapted from their work, it is evident that the development strategy, method of dissemination of the guidelines, how they are implemented and what process of evaluation exists are key to the likelihood of them being effective. Since their review the number of guidelines have continued to proliferate such that their sheer number and the emergence of different guidelines for the same or similar conditions may be overwhelming for the average practitioner. An electronic compendium of guidelines is maintained by the National Guideline Clearing House (www.guidelines.gov) which allows searching by topic and access to both summaries and full compendiums of particular guidelines, usually available on the website of the responsible professional organisation.[5]

Cardiovascular medicine has led the way in the emergence of large scale clinical trials to assess robustly the usefulness of novel diagnostic and therapeutic advances. We have been less successful in subtraction than we have in addition as it relates to the emergence and application of high risk, high cost treatments and technology. Recent developments suggest our profession is awakening to the need to assume a more visible leadership role in the understandably important and emerging emphasis on outcomes and the application of evidence based practice. In so doing, we must strike the right balance between preserving the fundamental elements of the doctor/patient relationship, the recognition that uncertainty as to which option is best for an individual patient will always exist, and that clinical judgement based on knowledge and experience must retain the ability to trump the application of general guidelines in specific circumstances.

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