

Clinical Guidelines as a Tool for Ensuring Good Clinical Practice

Eyal Zimlichman MD¹ and Ahuva Meilik-Weiss RN^{2*}

¹Department of Medicine B and ²Clinical and Economic Performance Assessment Unit, Sheba Medical Center, Tel Hashomer, Israel

Key words: clinical guidelines, quality, adherence, organizational culture and behavior

IMAJ 2004;6:626–627

The role of clinical guidelines as a tool for ensuring good clinical practice and generating health gain is gaining interest around the world. Adherence to clinical guidelines presumably leads to improved health outcome, reduces health expenditure, and prevents unnecessary interventions that might cause complications. However, with the growing interest and obvious potential, certain concerns have arisen – stemming mainly from uncertainty about guideline validity, development and effectiveness.

Although many definitions and several terms have been used to describe clinical guidelines, a widely accepted definition is that of the Institute of Medicine: namely, “systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances” [1]. Regardless of different definitions, guidelines are developed with the aim of: a) describing appropriate care based on scientific evidence; b) controlling organizational healthcare expenditures; c) reducing variability in health practice among practitioners; and d) allowing for quality assessment and quality improvement activity, including clinical audit. All this while taking into account organizational factors, community characteristics, economic constraints, and, at the same time, leaving room for justifiable variations in practice.

In this issue of *IMAJ*, Kahan et al. [2] evaluate the pharmacoeconomic effect of introducing a new guideline for the empiric treatment of uncomplicated urinary tract infection by the Leumit Health Fund. Indeed, UTI has been the target of numerous clinical guidelines and protocols arising from its frequency in outpatient and inpatient settings [3], antimicrobial resistance issues, economic implications, and wide variability of care [4]. The authors conclude that issuing a new pharmacopolicy for the treatment of UTI (designating nitrofurantoin as the new drug of choice) did not lead to the clinical or economic effect expected, and suggested that new methods be designed and implemented by the fund to insure adherence to guidelines.

Their findings are not surprising. In fact, analyzing the relevant literature reveals the ambivalence towards guideline effectiveness. In a randomized controlled trial conducted in a primary care setting in Norway, Flottorp and co-researchers [5] assessed the effect of tailored interventions aimed at implementing guidelines for the management of UTI and sore throat. Although rigorous implementation techniques were used (including public publication, patient educational material, computer-based reminders during consultation, and interactive courses for general practitioners), the authors concluded that these interventions had minimal effect in changing

clinical practice. In another randomized controlled trial, Doyne et al. [6] attempted to measure the effect of an academic intervention program on community pediatricians’ antibiotic-prescribing patterns. Whereas the study group of pediatricians participated in an educational program, the control group received only the printed guidelines. Similar patterns for antibiotic prescription rates were seen before and after intervention, and wide variations in prescription practices were observed.

In France, in an effort to control ambulatory care costs, regulatory practice guidelines were introduced by law in 1993. Physicians who do not comply with these guidelines can be fined. In an observational study, Durieux and associates [7] evaluated the level of awareness and knowledge of these regulatory practice guidelines among 321 family physicians. Again, despite implementation of a national health policy, the awareness and knowledge of these guidelines among French family physicians was weak. The authors conclude that, despite financial penalties, it is doubtful whether clinical policy will have a long-term effect on physicians’ behavior.

Contrary to the conclusions of the above-mentioned studies, the pioneer work of Grimshaw and Russell in 1993 drew somewhat different conclusions [8]. In a rigorous overview of published evaluations of clinical guidelines, they found that 55 of 59 studies detected improvement in the process of care after the introduction of guidelines. They concluded that when introduced in the context of thorough evaluations, explicit guidelines improve clinical practice. However, the extent of the improvements in performance varied considerably. Following their findings, Grimshaw and Russell [8] went on to explore the subject and summarized their interpretation in two articles published in the *Quality in Health Care* journal [9,10]. They concluded that the introduction of clinical guidelines is a complex process with three crucial stages: development, assimilation of the guidelines by clinicians (dissemination), and ensuring that clinicians act on the guideline (implementation). Indeed, by analyzing the literature, they provide a basic framework for those who use guidelines [Table 1], while stating that the evidence available is still sparse.

The subsequent years brought a proliferation of published guidelines, which prompted questions about the validity of these guidelines. Indeed, the multiplicity of clinical guidelines has probably contributed to non-adherence. This was shown, for instance, in the case of community-acquired pneumonia as described by Flanders and Halm [11]. When comparing eight international practice guidelines for the treatment of community-acquired pneumonia, the authors found several conflicting recommendations, specifically for the management of inpatients with this

* Soon to receive a PhD degree

UTI = urinary tract infection

Table 1. Factors that affect the successful introduction of guidelines*

Probability of being effective	Development strategy	Dissemination strategy	Implementation strategy
High	Internal development group	Specific educational intervention	Reminder at time of consultation
Above average	Intermediate development group	Continuing medical education	Patient specific Feedback following consultation, financial incentives
Below average	External local development group	Posting targeted groups	General feedback
Low	External national development group	Publication in professional journal	General reminder of guidelines

* Adopted from Grimshaw and Russell [10]

entity. They conclude that assuring consistency among the clinical guidelines published is crucial if professional society practice guidelines are to fulfill their promise as tools for improving the quality and outcomes of care. As the result of renewed calls for validated criteria to assess the quality of guidelines, an attempt was launched by an international group of researchers from 13 countries – AGREE (the Appraisal of Guidelines, REsearch and Evaluation) Collaboration – aimed at developing an appraisal instrument [12]. The instrument was shown to be sensitive to differences in important aspects of clinical practice guidelines, by adoption of common standards. The developers recommend that guideline producers use this instrument when planning their programs, and that potential guideline users use it to evaluate the quality of guidelines before adopting them.

Another aspect we have to take into consideration when implementing guidelines is the organizational culture and behavior and its patterns in dealing with changes and regulations. As best practices are often frustratingly slow to spread in health systems, current thinking attributes this also to the phenomenon of "resistance to change." If the organization were running like a well-oiled machine, then we should be able to install a best practice in the organization, just as we might install a higher performance carburetor on a car: if the new part fails to fit smoothly, we simply give it a good whack to get it in. In this view of organizations, strong leaders are needed to overcome resistance and install best practices from elsewhere.

The metaphor of complex adaptive systems acknowledges the behavior that we label resistance to change, but suggests that, rather than resisting, organizational leaders might find more positive ways to encourage change. The current approach suggests encouraging creativity and innovation, especially in complex systems [13].

Furthermore, creativity is not synonymous with innovation. Rather, "Innovation is the successful implementation of creative ideas by an organization" [14]. This definition distinguishes between the generation of new ideas and their implementation. While creativity is the dominant factor, one also has to demonstrate a high level of initiative to bring ideas to the implementation stage [15]. This relatively new terminology places the responsibility of implementing not only organizational change but also clinical changes in health organization leaders.

Finally, as we have shown, the process that leads from developing a clinical statement to having an impact on patient care is complex and has many potential pitfalls. As with the principles of change management, whatever the strategy chosen, an investigation into possible barriers should be an essential part of

any program. We believe that although demanding effort and resources, the potential for guidelines to influence the quality of patient care is considerable, and should not be overlooked by health officials.

References

1. Field MJ, Lohr KN. Guidelines for clinical practice: from development to use. Washington, DC: National Academy Press, 1992.
2. Kahan NR, Kahan E, Waitman D-A, Chinitz DP. Economic evaluation of an updated guideline for the empiric treatment of uncomplicated urinary tract infection in women. *JAMA* 2004;6:588–91.
3. Foxman B, Barlow R, D'Arcy H, Gillespie B, Sobel JD. Urinary tract infection: self-reported incidence and associated costs. *Ann Epidemiol* 2000;10:509–15.
4. Stamm WE. Scientific and clinical challenges in the management of urinary tract infections. *Am J Med* 2002;113(1A):1–4S.
5. Flottorp S, Oxman AD, Havelrud K, Treweek S, Herrin J. Cluster randomised controlled trial of tailored interventions to improve the management of urinary tract infections in women and sore throat. *Br Med J* 2002;325(7360):367.
6. Doyne EO, Alfaro MP, Siegel RM, et al. A randomized controlled trial to change antibiotic prescribing patterns in a community. *Arch Pediatr Adolesc Med* 2004;158(6):577–83.
7. Durieux P, Gaillac B, Giraudeau B, Doumenc M, Ravaud P. Despite financial penalties, French physicians' knowledge of regulatory practice guidelines is poor. *Arch Fam Med* 2000;9(5):414–18.
8. Grimshaw JM, Russell IT. Effect of clinical guidelines on medical practice: a systematic review of rigorous evaluations. *Lancet* 1993;342(8883):1317–22.
9. Grimshaw JM, Russell IT. Achieving health gain through clinical guidelines. I: Developing scientifically valid guidelines. *Qual Health Care* 1993;2(4):243–8.
10. Grimshaw JM, Russell IT. Achieving health gain through clinical guidelines. II: Ensuring guidelines change medical practice. *Qual Health Care* 1994;3(1):45–52.
11. Flanders SA, Halm EA. Guidelines for community-acquired pneumonia: are they reflected in practice? *Treat Respir Med* 2004;3(2):67–77.
12. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *Qual Saf Health Care* 2003;12(1):18–23.
13. Plsek PE, Greenhalgh T. The challenge of complexity in health care. *Br Med J* 2001;323:625–8.
14. Amabile TM. Stimulate creativity by fueling passion. *EHandbook of Principle of Organizational Behavior*. Malden, MA: Blackwell, 2000:331–41.
15. Zimmerman BJ, Lindberg C, Plsek PE. *Edgeware: Complexity Resources for Healthcare Leaders*. Irving, TX: VHA Publishing, 1998.

Correspondence: Dr. E. Zimlichman, Dept. of Medicine B, Sheba Medical Center, Tel Hashomer 52621, Israel.

Phone: (972-3) 530-2661

Fax: (972-3) 535-2855

email: zimlich1@zahav.net.il