

## **Assessment of clinical practices, the design of clinical policies and the role of Health Technology Assessment - the perspective of a Canadian general internist.**

The way a physician practices medicine is affected by a large number of factors. These include: the clinician's education; clinical experience; the influence of peers; advertisements and promotion (mostly from the pharmaceutical industry, but also from other groups); continuing medical education; the results of original research; clinical practice guidelines and clinical decision rules; the local practice environment (cultural, physical, etc.); the availability of resources; and the regulations governing the practice of medicine and the availability of medical technologies.

The purpose of health technology assessment is to synthesize the best available information on the safety, effectiveness, costs and consequences of health care technology, and thus to assist decision making. Some have suggested that health technology assessment should be viewed as the bridge between science and policy<sup>1</sup>; a tool to appropriately incorporate new scientific knowledge into practice. Some components of health technology assessment can directly affect the interaction between patients and physicians. **Evidence based medicine** helps physicians to accurately read the medical literature and incorporate the results of clinical studies into their practices. **Clinical practice guidelines** attempt to synthesize the available literature on a particular topic in a way that is useful to clinicians, and it is hoped that this will optimize clinical practice. **Clinical decision rules** are aids to physician decision making that include three or more variables from the history, physical examination or simple diagnostic tests. **Care maps** are means of translating clinical practice guidelines into actual clinical practice (e.g. standardizing post operative care after hip joint replacement). Other components of health technology assessment affect physicians' practices more indirectly. Most clinicians are not actively involved in the allocation of health care resources, or the development of regulations affecting the availability of drugs and devices. Thus, the focus of this paper will be upon evidence based medicine, clinical practice guidelines, clinical decision rules, and care maps.

### **Evidence based medicine**

The evidence based medicine movement is best-known through a series of articles in JAMA<sup>2,3</sup> and the Centre for Evidence-based Medicine in Oxford. The goal of training all physicians to be able to efficiently identify the literature that is relevant to a particular clinical situation, critically appraised it, and then apply the results to that situation is an admirable one. Evidence based medicine is being actively taught at the undergraduate and postgraduate level in most, if not all, Canadian medical schools. Thus, it is likely that future physicians will be much more skillful at assessing the literature than many physicians currently in practice. This is an extremely positive development. However, the busy pace of most physicians' everyday practice, the huge amount of literature to read, problems with timely access to the literature, and clinicians' concerns about inadequate mastery of the skills of evidence based medicine leave room for other tools to optimize clinical practice.

### **Clinical practice guidelines**

Clinical practice guidelines have been defined as "systematically developed statements to assist practitioners and patient decisions about appropriate health care for specific clinical circumstances"<sup>4</sup> In Canada, there is considerable interest in clinical practice guidelines. The reasons for this are multifactorial:

1. The volume of new medical information: The medical literature is voluminous, and is increasing daily. It is very difficult for clinicians, even those well-trained in evidence based medicine, to identify and read all of the literature that is relevant to their practice. Well-developed clinical practice guidelines synthesize the literature on a particular topic into an understandable and clinically useful format, which clinicians can comprehend quickly.
2. The increasing complexity of care: Not only is there more medical literature, but there are more effective therapies available. Fifteen years ago, congestive heart failure was treated with salt restriction, diuretics, and digoxin. Since then, clinical trials have convincingly demonstrated that ACE inhibitors improve morbidity and mortality in patients with heart failure. More recently, a class of medications that was previously felt to be contraindicated in patients with heart failure (beta blockers) have been shown to be beneficial in some patients with heart failure. Many other new drugs are now being actively evaluated for the treatment of heart failure, and some are likely to be licensed in the next few years. The good news is that there is good evidence that the new therapies considerably improved patient outcomes. The bad news is that treating a very common disorder, heart failure, is increasingly complicated. Clinical practice guidelines help clinicians keep pace with this rapidly expanding literature in a more efficient fashion than reading the original studies.
3. Existence of a care gap: For many years it has been documented that clinicians sometimes use ineffective, and occasionally dangerous therapies<sup>5,6</sup>. Indeed, these observations were an important impetus for the development and expansion of clinical epidemiology, the randomized controlled trial, and evidence based medicine. More recently, there has been increasing evidence that clinicians also **under use** some efficacious therapies such as aspirin, beta-blockers, and statins for patients with coronary artery disease<sup>7</sup>. This "care gap" is of concern to patients, clinicians and policymakers alike, and it is hoped that clinical practice guidelines will decrease its magnitude.
4. Narrow "therapeutic window" for some therapies: Some efficacious therapies can be disastrous if given to the wrong patients. For example, tissue plasminogen activator, when given to stroke patients within three hours of the onset of symptoms can improve the likelihood of a good functional outcome after the stroke. However, when the same drug is given 3 to 6 hours after the stroke, it can lead to an unacceptable rate of intracranial hemorrhage. Clinical practice guidelines, by clearly indicating which patients should and should not be treated, have the potential of optimizing care.

**5. Concern about the increasing costs of health care:** Because of the financial constraints on most health care budgets, there is great interest in minimizing the waste of resources. Thus, if some therapies or diagnostic procedures are shown to be ineffective (e.g. repeat ultrasonography in uncomplicated pregnancies, routine chest x-rays in healthy individuals prior to surgery), and clinical practice guidelines discourage the use of those procedures, then health care should be more efficient. Clinical practice guidelines can also encourage the use of therapies in subgroups of patients likely to have the greatest benefit. Statins will, on average, provide a larger absolute benefit to hypercholesterolemic patients who have had a recent myocardial infarction, than to hypercholesterolemic patients who have never had a myocardial infarction. If there is a limited budget for statins, it would seem sensible to use them in the patients most likely to benefit.

**6. The rise in consumerism:** Health care consumers are becoming better educated, and have access to many sources of information, including the internet. In many instances, patients are aware of new therapies before their physicians. Clinical practice guidelines, provided they are up-to-date, can be used to explain the current "standard of care" to patients.

### **Issues in the design of clinical practice guidelines, from the point of view of physicians**

Much has been written about clinical practice guidelines, and I do not intend to review this voluminous literature. However, it is reasonable to consider some of the issues that are of most relevance to practicing physicians.

There is a tension between clinical practice guidelines that are developed locally, and those that are developed at a more provincial or national level. Locally developed guidelines have the advantage of "buy in" from local clinicians, and have been developed with the realities of the local practice milieu in mind. However, the local guidelines developers often do not have the resources or time needed to comprehensively reviewed the literature<sup>8</sup>, and therefore these guidelines may not have the same quality as guidelines developed by groups with more resources at their disposal.

In order to be relevant, clinical practice guidelines must be up-to-date. All guidelines should clearly indicate when they were developed, and when the next revision is planned<sup>4</sup> It is obviously impractical to update guidelines whenever a new piece of information becomes available. However, it is important that they are as current as possible.

Physicians are often concerned that guidelines may become standards. If the guidelines are too specific, they may limit the appropriate use of the "art of medicine" and encourage "cookbook medicine" On the other hand, if they are too general, they are not very useful in guiding clinical practice. The appropriate balance between specificity and generality is not always easy to achieve.

There is debate about whether or not it is appropriate to incorporate costs into clinical practice guidelines. Those who argue that costs should not be incorporated suggest that physicians are concerned about providing the best possible care to their patients, and will view guidelines that incorporate costs with suspicion. Others argue that one of the reasons that clinical practice guidelines are developed is to encourage the cost effective use of resources, and that to ignore costs is unrealistic. One possible way out of this impasse is to first develop "evidence based recommendations" using only information about effectiveness and side effects. These recommendations can then be modified into clinical practice guidelines that consider "modulating factors" such as the availability of resources, local practice patterns, the demographics of the population, etc.<sup>9</sup>.

Many clinical decisions are value laden. Two sensible people, when confronted with the same decision and provided with the same information, may make entirely different decisions, each of which is appropriate for that person. For example, some menopausal women, when fully informed of the risks and benefits of hormone replacement therapy, choose to take hormone replacement therapy, while others do not<sup>10</sup>. It is difficult, and perhaps inappropriate, to develop clinical practice guidelines for value laden decisions. In these circumstances, decision aids may be more appropriate than clinical practice guidelines. Decision aids present patients the options, benefits and risks appropriate to their clinical situation. Decision aids can markedly improved knowledge, and can also improve satisfaction with the decision-making process<sup>10</sup> More studies of decision aids in actual clinical practice are needed.

The development of high-quality clinical practice guidelines is time-consuming and expensive, and it is often impossible for local groups to obtain the necessary funding. The pharmaceutical industry is often willing to fund the development of guidelines, but there is an obvious concern about the potential introduction of bias into the guidelines. Similarly, it is perceived that those who fund health care have an agenda as well, which is to decrease overall costs. Canadian clinicians are most likely to trust guidelines developed by their own specialty societies (e.g. the Society of Obstetrics and Gynecology) rather than by other groups<sup>11</sup>.

In most cases, the simple publication of a guideline is unlikely to affect practice<sup>12</sup>. A number of strategies, tailored to the local environment, must be used. These include identification of local opinion leaders, academic detailing, presentation of the guidelines in an easy to read format, and making a guideline available at the time a physician sees a patient (e.g. with computerized reminders).

### **Clinical decision rules**

Clinical decision rules are tools to assist clinicians in diagnostic decision-making. They consist of three or more easy to measure variables, and either provide clinicians with a probability of disease ("the chance that this patient has an ankle fracture is one percent") or a course of action ("do not x-ray this patient")<sup>13</sup>. Clinical decision rules are developed to simplify clinical practice, optimize patient care, or save resources. The development and validation of clinical decision

rules can be time consuming and resource intensive. For example, over 10,000 patients with ankle injuries were studied when developing and validating the Ottawa Ankle Rules<sup>14-17</sup>.

There are relatively few examples of clinical decision rules that are frequently used in clinical practice. The Ottawa Ankle Rules have been used in a number of countries including Canada, the United States<sup>18,19</sup>, France<sup>20</sup>, and Spain. Possible factors contributing to their relatively wide use include the fact that they were developed and validated in a methodologically sound manner using large numbers of patients, the rules are simple to use, are clinically sensible, and provide clinicians with a course of action. It remains to be seen whether clinical decision rules will also be used for conditions in which the consequences of missing an abnormality are more serious (e.g. cervical radiography for patients with minor neck trauma). Our group is currently developing and validating such a clinical decision rule. The true impact of clinical decision rules upon clinical practice and policy has not yet been determined.

### Care maps

Care maps are tools that translate clinical practice guidelines into day-to-day practice. They have been most frequently used for in-hospital care. Examples include care maps for the postoperative care of patients having a total hip joint replacement (including instructions about ambulation, bowel habits, deep venous thrombosis prophylaxis, blood transfusion, etc.) and care maps for the management of uncomplicated myocardial infarctions (encouraging the use of beta-blockers, aspirin, and thrombolytics; and discouraging the use of calcium channel blockers). Care maps are most easily developed for conditions in which the patient population is relatively homogeneous. Many studies have documented decreases in the length of hospital stay associated with introduction of care maps, but there have been very few randomized trials evaluating their impact upon the quality of care. Nonetheless, it would seem reasonable to hypothesize that care maps that are based upon evidence based clinical practice guidelines may decrease the magnitude of the "care gap".

### Forget the theory... what happens in the real world?

There is often a considerable "rhetoric gap" between the theory that is provided in lectures such as this, and what actually happens in the real world. In my practice, and that of my closest colleagues, clinical practice guidelines are rarely used at the bedside. Our pockets are not bulging with plastic cards containing the latest and most up-to-date approaches to the management of heart failure, hypertension, etc. However, clinical practice guidelines do affect practice because they are part of our culture when discussing patients, talking with colleagues, presenting rounds, etc. The clinical practice guidelines that we use most often are those developed by the various Canadian medical professional societies, as well as some from the United States and Great Britain. However, there are a number of common conditions (e.g. pneumonia) for which clinical practice guidelines are not being followed in our institution, and the care provided varies considerably from clinician to clinician. The reason for this is lack of time available for clinicians to identify appropriate clinical practice guidelines, insufficient energy on the part of clinicians to persuade their colleagues to follow guidelines, and the fact that no one within the division of general medicine has been put in charge of optimizing our division's clinical practice.

Care maps are being used with increasing frequency for the management of the postoperative patient, but are not used frequently in general internal medicine. A care map has been developed for the management and investigation of patients with acute stroke. This has met with limited success because of disagreement among clinicians about the appropriateness of various investigations (e.g. does every stroke patient need an assessment by speech therapy?) and the heterogeneous nature of our stroke population (ranging from otherwise healthy forty year olds with minor strokes to demented ninety year olds with devastating strokes).

The Ottawa Ankle and Knee rules are used routinely in our emergency departments. This is not surprising, since this is the center in which the rules were developed. A recently developed clinical decision rule for the diagnosis and management of patients with suspected deep venous thrombosis has also been enthusiastically embraced<sup>21</sup>. Although this rule is more complicated than the Ottawa Knee or Ankle rules, it is being used because it simplifies the life of emergency physicians and internists. It allows patients presenting with suspected deep venous thrombosis during the nighttime hours to be safely and appropriately managed without either admitting them, or having to arrange for technicians to come into the hospital to perform radiographic tests. Thus, the slight complexity of the rule is acceptable to clinicians because it simplifies clinical practice.

### Other aspects of health technology assessment that affect everyday clinical practice in Ottawa Canada

I suspect that if I asked clinicians in Ottawa what their biggest concerns are regarding their day-to-day practice and patient care, they would volunteer the following issues: inadequate access to home care and social services in the community, lack of the appropriate number of chronic care beds, the length of surgical waiting lists and the waiting time required to see specialists, concern that some drugs that should be paid for by the Ministry of Health are not, and the decreasing number of in-hospital beds. These issues could be potentially addressed in a scientific and systematic fashion by health technology assessment. Indeed, Ontario does have a fairly well established method of incorporating the results of economic evaluations into decisions about which drugs to reimburse<sup>22</sup>. Similarly, there is a method for prioritizing patients on waiting lists for coronary artery bypass surgery, although waiting times for surgery still vary among hospitals<sup>23</sup>. However, there seems to be no evidence-based method of determining hospital budgets, the number of chronic care beds needed, or the intensity of home care needed. Instead, resources appear to be allocated on the basis of who screams the loudest (some of those screams are quite justified), theoretical management plans that often bear little resemblance to

reality, and the date of the next provincial election. It is not clear that anyone yet has the will or discipline to allow health technology assessment to affect these processes.

### References

- {1. } Battista RN. Health care technology assessment: linking science and policy-making. *Can Med Assoc J* 1992; 146:461-462.
- {2. } Guyatt GH, Sackett DL, Cook DJ, for the Evidence-Based Medicine Working Group. Users' guides to the medical literature. II. How to use an article about therapy or prevention. A. Are the results of the study valid? *JAMA* 1993; 270:2598-2601.
- {3. } Guyatt GH, Sackett DL, Cook DJ, for the Evidence-Based Medicine Working Group. Users' guides to the medical literature. II. How to use an article about therapy or prevention. B. What are the results and will they help me in caring for my patients? *JAMA* 1993; 271:59-63.
- {4. } Hayward RSA, Wilson MC, Tunis SR, Bass EB, Rubin HR, Haynes RB. More informative abstracts of articles describing clinical practice guidelines. *Ann Int Med* 1993; 118:731-737.
- {5. } The EC/IC Bypass Study Group. Failure of extracranial-intracranial arterial bypass to reduce the risk of ischemic stroke. *N.Engl.J.Med.* 1985; 313:1191-1200.
- {6. } Echt DS, Liebson PR, Mitchell LB, Peters RW, Obias-Manno D, Barker AH, et al. Mortality and morbidity in patients receiving encainide, flecainide, or placebo. The Cardiac Arrhythmia Suppression Trial. *N.Engl.J.Med.* 1991; 324:781-788.
- {7. } Soumerai SB, McLaughlin TJ, Spiegelman D, Hertzmark E et al. Adverse outcomes of under use of beta-blockers in elderly survivors of acute myocardial infarction. *JAMA* 1997;277:115-121
- {8. } Thomson R, McElroy H, Sudlow M. Guidelines on anticoagulant treatment in atrial fibrillation in Great Britain: variation in content and implications for treatment. *BMJ* 1998;316:509-513
- {9. } Browman GP, Mohide EA, Hayward RSA, Pritchard K, Gafni A, Laupacis A, et al. The practice guideline development cycle: A conceptual tool for practice guidelines development and implementation. *J Clin Oncol* 1995; 13:502-512.
- {10. } O'Connor AM, Tugwell P, Wells G, Elmslie T, Jolly E, Hollingworth G, et al. Randomized trial of a portable, self-administered decision aid for post-menopausal women considering long-term preventive hormone therapy. *Med Dec Making* 1998; 18:295-303.
- {11. } Hayward RS, Guyatt GH, Moore KA, McKibbon KA, Carter AO. Canadian physicians' attitudes about and preferences regarding clinical practice guidelines. *Can Med Assoc J* 1997; 156:1715-1723.
- {12. } Lomas J. Diffusion, dissemination, and implementation: Who should do what? *Annals of New York Academy of Science* 1993; 703:226-228.
- {13. } Laupacis A, Sekar N, Stiell IG. Clinical prediction rules: A review and suggested modifications of methodological standards. *JAMA* 1997; 277:488-494.
- {14. } Stiell IG, Wells GA, Laupacis A, Brison R, Verbeek R, Vandemheen K, et al. A multicenter trial to implement clinical decision rules for the use of radiography in acute ankle injuries. *BMJ* 1995;311:594-597.
- {15. } Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Worthington JR. A study to develop clinical decision rules for the use of radiography in acute ankle injuries. *Ann Emerg Med* 1992; 21:384-390.
- {16. } Stiell IG, Greenberg GH, McKnight RD, Nair RC, McDowell I, Reardon M, et al. Decision rules for the use of radiography in acute ankle injuries. Refinement and prospective validation. *JAMA* 1993; 269:1127-1132.
- {17. } Stiell IG, McKnight RD, Greenberg GH, McDowell I, Nair RC, Wells GA, et al. Implementation of the Ottawa Ankle Rules. *JAMA* 1994; 271:827-832.
- {18. } Solomito AL, Singal BM, Radack M. Ankle radiography in the emergency department: A prospective validation of Ottawa Ankle Rules. *Acad Emerg Med* 1994; 1:A64

{19. } Verma S, Hamilton K, Hawkins HH, Kothari R, Singal B, Buncher R, et al. Clinical Application of the Ottawa Ankle Rules for the use of radiography in acute ankle injuries: An independent site assessment. *AJR* 1997; 169:825-827.

{20. } Auleley G, Ravaud P, Giraudeau B, Kerboull L, Nizard R, Massin P, et al. Implementation of the Ottawa Ankle Rules in France. *JAMA* 1998; 277:1935-1939.

{21. } Wells PS, Anderson DR, Bormanis J, Guy F, Mitchell M, Gray L, et al. Value of assessment of pretest probability of deep-vein thrombosis in clinical management. *Lancet* 1998; 350:1795-1798.

{22. } Detsky AS. Guidelines for economic analysis of pharmaceutical products. A draft document for Ontario and Canada. *PharmacoEconomics* 1993; 3:354-361.

{23. } Naylor CD, Sykora K, Jaglal SB, Jefferson S. Waiting for coronary artery bypass surgery: population-based study of 8517 consecutive patients in Ontario, Canada. The Steering Committee of the Adult Cardiac Care Network of Ontario. *Lancet* 1995; 346:1605-1609.