Prevention. How much harm? How much benefit? 4. The ethics of informed consent for preventive screening programs

Kenneth G. Marshall, MD, CCFP, FRCPC

Abstract • Résumé

Preventive interventions may have few or unproven benefits, or they may even be harmful. Since three of the fundamental precepts of Western biomedical ethics are beneficence, nonmaleficence and respect for individual autonomy, failure to obtain truly informed consent for many current preventive interventions may be unethical. However, there are many impediments to obtaining such consent. Physicians need to be aware of an immense amount of up-to-date, complex information. It may be difficult for patients to assimilate this information, and there is rarely time for physicians to become informed and to inform their patients. Clinical practice guidelines may be helpful, but not all are based on evidence, and recommendations are often conflicting. Medical institutions, as well as individual clinicians, can help solve these dilemmas. Authors and journal editors can make a commitment to report and publish well-referenced evidence-based guidelines. Organizations such as the Canadian Task Force on the Periodic Health Examination and the US Preventive Services Task Force can develop balanced, evidence-based patient-information material. Faculty at all levels of medical education can increase their emphasis on the ethics of prevention. Individual clinicians should avoid making clinical decisions on the basis of relative reductions of morbidity or mortality, should use evidence-based clinical practice guidelines rather than those based on authority whenever possible, should make use of patient-information material and, most important, should have a consistent policy of obtaining informed consent from patients before they participate in potentially harmful preventive programs.

Les interventions de prévention peuvent avoir des avantages peu nombreux ou non démontrés, ou même être nuisibles. Comme trois des préceptes fondamentaux de l'éthique biomédicale occidentale sont la bienfaisance, la non-malignité et le respect de l'autonomie de la personne, le défaut d'obtenir un consentement vraiment éclairé à l'égard d'un grand nombre d'interventions de prévention courantes peut être contraire à l'éthique. Il y a toutefois de nombreux obstacles à l'obtention d'un tel consentement. Les médecins doivent connaître un volume énorme de renseignements complexes à jour. Il se peut que les patients aient de la difficulté à comprendre ces renseignements, et les médecins ont rarement le temps de s'informer et d'informer leurs patients. Les guides de pratique clinique peuvent être utiles, mais ils ne sont pas tous fondés sur des données probantes et les recommandations sont souvent contradictoires. Les établissements médicaux et les cliniciens en particulier peuvent aider à résoudre ces dilemmes. Les auteurs et les rédacteurs de journaux peuvent s'engager à diffuser des guides fondés sur des données probantes et bien étayés. Des organismes comme le Groupe d'étude canadien sur l'examen médical périodique et le Preventive Services Task Force des États-Unis peuvent produire, à l'intention des patients, des documents équilibrés fondés sur des données probantes. Les enseignants à tous les niveaux de la formation en médecine peuvent insister davantage sur l'éthique de la prévention. Les cliniciens individuels devraient éviter de prendre des décisions cliniques fondées sur des réductions relatives de la morbidité ou de la mortalité, devraient utiliser, dans la mesure du possible, des guides de pratique clinique fondés sur des données probantes plutôt que sur l'autorité et des documents d'information des patients et, le plus important, devraient avoir une politique uniforme qui consiste à obtenir le consentement éclairé des patients avant qu'ils participent à des programmes de prévention qui pourraient être préjudiciables.

Dr. Marshall is associate professor of family medicine, McGill University, Montreal, Que.

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Reprint requests to: *Dr. Kenneth G. Marshall, Department of Family Medicine, McGill University, 517 Pine Ave. W, Montreal QC H3Y 1Y8; fax 514 398-4202*

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For physicians or patients to decide whether the benefits of a preventive program outweigh the harm, they must be able to answer the four questions posed in the first article in this series.

- Is there any proven benefit from the intervention?
- If there is, how great is it?
- Are there any adverse effects of the intervention?
- If there are, what are they, how serious are they, and how frequently do they occur?

Because the benefits of many preventive screening programs may be few or uncertain, and because such programs may lead to significant harm, patients must be able to make informed decisions about whether to participate and give their informed consent to do so. How is this to be done? How can the physician acquire the requisite data to disclose to the patient, how can the patient assimilate the information, and when will the time be found to do all of this? This article discusses the nature of informed consent for preventive programs, the need for obtaining such consent, the inherent difficulties in doing so and some proposed methods for overcoming these difficulties.

The nature of informed consent and informed decision making

Three of the basic principles of biomedical ethics that are particularly applicable to decision making concerning preventive programs are nonmaleficence, beneficence and respect for individual autonomy.[1] In simple terms, these principles mean that physicians should do good, do no harm and respect patients' wishes. In terms of preventive programs, these principles require physicians to inform patients of both the benefits and the harm of the programs and to respect their decisions; failure to obtain informed consent for preventive screening programs that have few or uncertain benefits and the potential for harm is unethical.[2,11] Many screening programs are experimental procedures and, therefore, are subject to the ethical standards required for clinical research protocols.[4,6]

The term "informed consent" is ambiguous. In its narrow sense, it refers to legal and institutional rules, exemplified by the forms that patients fill out before surgical or other procedures. Beauchamp[12] calls this type of assent given to a procedure or treatment recommended by a physician "institutional consent." In a broad sense, "informed consent" implies that patients assert their autonomy by playing an active role in decision making, not merely agree to someone else's recommendations. Beauchamp[12] calls this "autonomous choice," and this is the kind of consent that is ethically, if not legally, required for preventive programs that may have adverse effects. Deber[13,14] elaborates on this theme, making the case that what is really needed is "patient participation." In this type of participation, patients require an environment in which they are comfortable asking questions, expressing their own value systems and making their own decisions.

Reasons for obtaining informed consent

Although respect for patient autonomy is the overriding reason for obtaining informed consent for preventive interventions, there are several specific reasons for obtaining such consent in the case of screening programs.

Correction of patients' misconceptions about risks or benefits

One study found that young women overestimated their risk of dying of breast cancer twentyfold and the benefit of screening sixfold.[15] Other studies have shown that some women believe that mammography can prevent breast cancer or that a negative result of a mammogram means that nothing is wrong.[16,17]

A balance to physicians' power and influence over patients' decisions

Patients are more likely to participate in a preventive program if their physician recommends it than if he or she does not.[18,19] This influence over patients is acceptable, provided that optimistically enthusiastic or pessimistically nihilistic physicians do not intentionally or inadvertently use their authority to coerce patients into decisions that they do not really think are in their best interests.[8] Bias of this nature can be mitigated by an open discussion of the pros and cons of the program in question.

An obligation in physician-initiated interventions

In a typical patient–physician contact, the patient seeks out the physician for aid; in contrast, it is usually the physician who approaches the patient about preventive screening programs.[10,20–24] Physicians who broach the subject by recommending participation are suggesting to healthy people that, by taking part in a preventive program, they can be even healthier or maintain their health longer. Making such suggestions is a grave responsibility, which, many believe, puts a special onus on physicians to ensure that benefits clearly outweigh harm.[20–24] This view is articulated clearly by Cochrane and Holland.[20]

We believe there is an ethical difference between everyday med-

ical practice and screening. If a patient asks a medical practitioner for help, the doctor does the best he can. He is not responsible for defects in medical knowledge. If, however, the practitioner initiates screening procedures he is in a very different situation. He should, in our view, have conclusive evidence that screening can alter the natural history of disease in a significant proportion of those screened.

Proven or uncertain benefits for few, potential harm for all

The benefits of screening programs and subsequent therapeutic interventions may be uncertain,[5,6,17,22,25–28] but, even when benefits are proven, they are enjoyed by only a few,[23,29] usually many years in the future. Examples include a decreased rate of coronary artery events as a result of taking cholesterol-lowering drugs or a decreased rate of hip fractures as a result of taking hormone-replacement therapy. Yet everyone participating in the program is at risk of harm, a harm that often manifests itself immediately (e.g., anxiety resulting from an abnormal mammogram or impotence from a radical prostatectomy).[23,17] Although harm, like benefits, affects only a few, most of those affected receive no compensatory gain.

Recognition of the harm of preventive programs by patients and physicians

In much of medical practice patients already know that the therapeutic interventions, such as surgical procedures or antibiotic therapy, can have adverse effects. This is not the case with many preventive measures. Patients may think, "Aside from a little discomfort, how can a mammogram harm me?" or "A prostate-specific-antigen (PSA) test is just a blood test — how can that hurt?"[3]

Not only patients think like this. At a recent CMA presentation on prevention to more than 200 family physicians, I opened the session by asking for a show of hands from anyone who believed that screening procedures such as mammography, cholesterol-level assessment or stool testing for occult blood could harm their patients. Only about a dozen hands went up. This lack of awareness of the potential harm of preventive interventions undoubtedly accounts in part for the widespread failure to obtain adequate informed consent for such procedures.[2–6]

More specifically, the knowledge deficit often reflects physicians' lack of understanding of the detrimental effects possible at the various stages of the "screening cascade" (discussed in the previous article in this series) and of the very low positive predictive values achieved in programs to screen the general population.

Future generations of physicians may be no better informed. Two standard undergraduate textbooks on biomedical ethics make no mention of preventive programs in their sections on informed consent and deal with the potential harm of screening only in the most cursory fashion in the sections on prenatal screening and genetic testing.[30,31]

Antidote to the "evangelical fervour" with which some preventive programs are marketed

Medical organizations and the press often take a marketing approach to prevention. Advertisements aimed at the public may state that mammography will reduce the risk of dying of breast cancer, may encourage people to have their cholesterol level checked or may recommend PSA testing.[7,23] Physicians may be subject to a targeted form of advertising to encourage them to comply with certain clinical practice guidelines,[32–34] a technique called "academic detailing."[33,34] Another technique is to encourage respected physicians, called "local opinon leaders," to influence their colleagues.[33,34] There is nothing wrong with such approaches if the evidence of the benefit is firm and if there is objective discussion of the benefits and harm. In theory, academic detailing fulfils these requirements, since one of the ground rules is "providing authoritative and unbiased sources of information and presenting both sides of controversial issues."[33] Whether this is always done is another matter; one reason for scepticism is that, according to Haynes,[35] 22 out of 25 consensus conferences of the National Institutes of Health, culled from a MEDLINE search of articles published from 1990 to 1993, had no references to support their recommendations.

How much information must be given to patients?

To share in decision making or to give truly informed consent, patients need information — but how much? There is a spectrum of views on this question. The argument for giving patients relatively little information is based on benevolent paternalism or beneficence;[1,13,14] that is, physicians know what is best for their patients and giving them too much information may cause them to reject a preventive program that is good for them.[3,6,36] However, a paternalistic approach is ethically unacceptable in most Western cultures;[1,13] instead, it is generally accepted that patients should receive enough information to allow informed decisions,[7,10] or as much information as the patient freely chooses to have.[23] The data should be provided in language that the patient can understand[1,37] and in an atmosphere that is not intimidating and that fosters independent thought, questions and decisions.[13] In other words, comprehension is as essential as disclosure.[12]

The fact that patients need to be informed about the

benefits and harm of preventive programs does not mean that they are expected to function as members of a consensus conference and evaluate the merits of a wide variety of studies. It is the physician's job to present as objective a distillation of the data as possible, including clear statements concerning areas of uncertainty.[7,13,38] For screening programs, physicians should supply information on the nature of the screening program, the degree of benefits and the frequency and nature of adverse effects, including the implications of true-positive, false-positive and false-negative results.[7,10] Benefits should be expressed in terms of absolute reductions of morbidity or mortality, or the number of patients that need to be treated to prevent one adverse event. Hux and Naylor[39] have shown that patients are just as misled as physicians by relative reduction of morbidity or mortality rates.

Much of the harm of preventive screening programs occurs when a test has a positive result that needs to be investigated or a disorder is diagnosed and needs to be treated. One could argue that a full discussion of the degree of the benefits and harm and the significance of test outcomes could be reserved for patients who have a positive test result. However, this argument is unacceptable because, from a psychological point of view, it is too late to turn back once a positive test result is obtained. For example, a patient is only in a position to decide whether to have a PSA test to screen for prostate cancer if he fully understands its implications, including not only the possibility that the test may save his life but also the high rates of false-positive and false-negative results, the nature of further investigations if the test result is positive, the considerable morbidity that may result from a radical prostatectomy, the risk of dying from the surgery and the lack of conclusive evidence that treatment decreases mortality rates.[3,7,8,40] By contrast, if he does not understand or face these issues until after he has received a positive result of a PSA test or a biopsy, he is in a no-win situation; he either goes ahead with further tests and treatment, and subjects himself to the morbidity that this involves, or he does not and is left with the psychic trauma of knowing he has, or is likely to have, cancer.

Informed consent in non-Western cultures

The principle of disclosure is a fundamental aspect of Western biomedical ethics, but it does not necessarily apply in other cultures. In some communities the norm is to avoid all mention of harmful possibilities[41] or to have family members receive the requisite information and make the decision.[42] These contrasting values make it difficult to obtain informed consent, and physicians faced with a dilemma involving a patient from a non-Western culture may wish to seek an independant ethical review to help them deal with it.[43]

Should physicians give patients their personal recommendations about screening programs?

Conscientious physicians who take the time to explain to their patients the pros and cons of various medical interventions often hear the response, "Doc, I can't decide. What do you suggest?" Answering that question does not interfere with patient autonomy, provided physicians ensure that all patients are given the pros and cons of the intervention as well as the physician's personal opinion.[3,7,40] In the context of "well-person care," respect for patient autonomy also requires physicians to bring up and discuss established preventive programs with patients, even if the physicians are personally opposed to them.[40]

How can physicians acquire detailed knowledge about the many preventive programs that are extant?

Acquiring the knowledge needed to inform patients about all the pros and cons of even a few preventive programs, such as Papanicolaou smears to screen for cervical cancer, mammography to screen for breast cancer, breast self-examination to detect breast cancer, cholesterol-level testing to prevent coronary artery disease, stool testing for occult blood to detect colon cancer or PSA testing to detect prostate cancer, seems a daunting if not impossible task.[35] What is a busy clinician to do? The pat answer is to read the literature and faithfully attend continuing medical education courses. However, even if clinicians do this, they face numerous obstacles. Some articles and presentations are mere opinion, based on authority rather than evidence.[35] Others present the benefits only in terms of relative reduction rates, which should not be used for making clinical decisions, and still others that are clearly based on evidence carry such a ballast of complex statistics that they are incomprehensible to ordinary medical mortals.[44] Perhaps the most confusing aspect of the literature on prevention is the frequent contradictions among clinical practice guidelines by various reputable organizations.[35,40,45,46] For example, the recommendations of the American Cancer Society and the National Cancer Institute are more interventionist than those of the Canadian Task Force on the Periodic Health Examination and the US Preventive Services Task Force. The first two recommend mammographic screening for women between the ages of 40 and 49, whereas the other two do not.[47,48] In most instances, the guidelines of the American College of Surgeons and the American College of Gynecologists

follow the recommendations of the American Cancer Society.[49] A survey of physicians revealed that surgeons and gynecologists favoured more aggressive screening than did family physicians and internists.[49] Broad cultural differences may also affect the nature of guidelines.[50] It has been postulated that the muted enthusiasm for cholesterol-level screening in Canada, compared with the reaction in the United States, is related to a Canadian tendency to be cautious.[46]

A notable difference between the conservative and the interventionist groups is that, whenever possible, the conservative groups base their recommendations on evidence, whereas the interventionist groups more often accept "authoritative opinion."[51] One explanation for this phenomenon is a disparity in the attitudes of the members of the various organizations creating guidelines. Stephenson[52] has categorized physicians' attitudes toward case-finding and screening procedures as maximalist ("if in doubt, screen") or minimalist ("if in doubt, don't screen"). Jeyapragasan and Morris[53] have added a third category: ritualist ("I was taught it, so I do it"). According to Stephenson, the maximalist school is based on three concepts: physicians must prevent the worst possible eventuality; interventions are beneficial and do not have serious side effects; and physicians' anxiety over uncertainty can be relieved by accepting protocols or courses of action that, by implication, guarantee successful outcomes.

In contrast, the minimalist school is based on three different tenets: patient care must be based on evidence; above all, do no harm, or, in other words, consider the detrimental effects of any intervention; and management should be individualized, and this takes precedence over following protocols.

A practical approach for a physician who is trying to understand the benefits and harm of preventive programs is to read widely and critically, trust clinical practice guidelines that are based on evidence, such as those of the Canadian Task Force on the Periodic Health Examination[54] and the US Preventive Services Task Force,[48] be sceptical of those that are not based on evidence, and never make clinical decisions on the basis of relative reductions of morbidity or mortality.

How can time be found to make informed decisions?

Even if physicians have at their fingertips the data required to inform their patients adequately of the benefits and harms of preventive programs, there is rarely time to explain this information to patients one-to-one,[2,3,13] to allow patients to assimilate it[2,3,13] or to allow patients to become comfortable enough to ask pertinent questions and discuss the issues openly.[13,55] One solution is to use teaching aids as an adjunct to, although not a replacement for, patient–physician discussion. These aids include information sheets,[7–9,13] pamphlets, articles, books, videotapes[13,56] and interactive videodisks.[13,57] Although aids on many specific diseases are available, there is no widely accessible source of balanced, up-to-date patient information on preventive interventions. It would be a big advance in this direction if organizations such as the Canadian Task Force on the Periodic Health Examination and the US Preventive Services Task Force published such aids to accompany each of their recommendations. In the meantime, the best clinicians can do is collect what patient-information material is available, update it regularly[13,35] and, in some cases, add to it by writing information sheets of their own.[8]

Solutions

I have already mentioned a few possible solutions to the ethical dilemmas posed by preventive programs. These and other solutions may be implemented at the institutional level or at the level of the individual physician.

Institutional level

The following are some institutional policies that facilitate obtaining informed consent for preventive interventions.

- Authors and speakers should present the results of clinical trials in terms of absolute reductions of morbidity or mortality and the numbers of patients that need to be treated to prevent one adverse event, rather than as relative reductions of morbidity or mortality.
- Journal editors should reject proposed articles that fail to present results in these terms.
- Clinical practice guidelines should, whenever possible, be based on evidence and well referenced.
- Organizations such as the Canadian Task Force on the Periodic Health Examination and the US Preventive Services Task Force should consider publishing patient-information material to accompany each of their recommendations.
- Balanced, evidence-based patient information should be distributed not only through clinics and physicians' offices but also through the mass media.
- Formal courses in biomedical ethics at medical schools should include or increase the coverage of the ethical aspects of preventive programs.
- For medical trainees, the need for truly informed consent for preventive screening programs should be reinforced daily by their clinical teachers.
- The degree of the benefits of preventive screening programs, the potential harm from such interven-

tions and the need for informed consent should be covered more often in continuing medical education programs.

Individual level

The following is a practical approach for individual clinicians.

- Be aware that the benefits of prevention are often exaggerated and the harm minimized or ignored; with this in mind, read the literature on prevention critically.
- Never base clinical decisions on relative reductions of morbidity and mortality rates.
- Use clinical practice guidelines, but remember that they are not infallible and that, even when guidelines are based on evidence, they may not apply to individual patients; guidelines are meant to enhance clinical judgement, not inhibit it.[50]
- When guidelines are contradictory, as is often the case, favour those that are based on evidence. In many cases, this means giving more weight to guidelines from the Canadian Task Force on the Periodic Health Examination or the US Preventive Services Task Force than to those proposed by specialty organizations or advocacy groups concerned with specific diseases or conditions affecting specific organs.
- For any preventive program with rare or uncertain benefits, or with potential harm, be sure that patients are actively involved in deciding whether to participate.
- Make sure that, by expressing your own views, you do not intentionally or inadvertently coerce patients into a course of action that they do not consider to be in their best interests (benevolent paternalism). An open discussion of the benefits and harm of preventive programs helps to ensure a balanced perspective.
- Acquire and use balanced, evidence-based patient-information material about preventive interventions. If none is available, physicians and their colleagues may wish to write their own.

Conclusion

Preventive screening programs are a double-edged sword. Many have few or uncertain benefits, and all have the potential for harm. Programs of this nature are experimental, and the appropriate ethical norms for obtaining informed consent should therefore apply. As a profession, physicians should ensure that they promote only those interventions for which there is reasonable evidence that the benefits outweigh the harm. They should, in all cases, respect their patients' autonomy by ensuring that patients participate actively in decision making.

References

1. Vevaina JR, Nora LM, Bone RC. Issues in biomedical ethics. *Dis Mon* 1993;39:869-928.
2. Lee JM. Screening and informed consent. *N Engl J Med* 1993;328:438-40.
3. Marshall KG. Screening for prostate cancer. How can patients give informed consent? *Can Fam Physician* 1993;39: 2385-90.
4. Skrabanek P. The physician's responsibility to the patient. *Lancet* 1988;1:1155-7.
5. Skrabanek P. *The Death of Humane Medicine*. Bury Saint Edmunds, England: Saint Edmundsbury Press, 1994:31-7.
6. Skrabanek P. Why is preventive medicine exempted from ethical constraints? *J Med Ethics* 1990;16:187-90.
7. Hahn DL, Roberts RG. PSA screening for asymptomatic prostate cancer: truth in advertising [editorial]. *J Fam Pract* 1993;37:432-4.
8. Glode LM. Prostate cancer screening: a place for informed consent? [editorial]. *Hosp Pract* 1994;29:10-2.
9. Cassel CK. Breast cancer screening in older women: ethical issues. *J Gerontol* 1992;47(spec iss):126-30.
10. Edwards PJ, Hall DM. Screening, ethics, and the law. *BMJ* 1992;305:267-8.
11. Waldron G. Serum screening for Down syndrome. Informed consent is vital [letter]. *BMJ* 1993;307:500-1.
12. Beauchamp TL. Informed consent. In: Veatch RM, editor. *Medical ethics*. Boston: Jones and Bartlett Publishers, 1989:173-200.
13. Deber RB. Physicians in health care management: 7. The patient–physician partnership: changing roles and the desire for information. *Can Med Assoc J* 1994;151:171-6.
14. Deber RB. Physicians in health care management: 8. The patient–physician partnership: decision making, problem solving and the desire to participate. *Can Med Assoc J* 1994;151: 423-7.
15. Black WC, Nease RF, Tosteson A. Perceptions of breast cancer risk and screening effectiveness in women under 50. *J Natl Cancer Inst* 1995;87:720-31.
16. French K, Porter AMD, Robinson SE, McCallum FM, Howie JGR, Roberts MM. Attendance at a breast screening clinic: a problem of administration or attitudes. *BMJ* 1982;285:617-20.
17. Roberts M. Breast screening: Time for a rethink? *BMJ* 1989;299:1153-5.
18. Schapira DV, Pamies RJ, Kumar NB, Herold AH, Van Durme DJ, Woodward LJ, et al. Cancer screening. Knowledge, recommendations, and practices of physicians. *Cancer* 1993;71:839-43.
19. Baines CJ. Women and breast cancer: Is it really possible for the public to be well informed? [editorial]. *Can Med Assoc J* 1992;146:2147-8.
20. Cochrane AL, Holland WW. Validation of screening procedures. *Br Med Bull* 1971;27:3-8.

21. Holland WW. Screening: reasons to be cautious. Stringent criteria must be met before implementation. *BMJ* 1993;306: 1222-3.

22. McCormick J. Health promotion: the ethical dimension. *Lancet* 1994;344:390-1.

23. O'Hagan J. The ethics of informed consent in relation to prevention screening programmes. *N Z Med J* 1991;104:122-5.

24. Butler JA. Prevention may be more expensive than cure. *J R Soc Med* 1993;86:341-4.

25. McCormick J, Skrabanek P. Coronary heart disease is not preventable by population interventions. *Lancet* 1988;2:839-41.

26. Family Heart Study Group. Randomised controlled trial evaluating cardiovascular screening and intervention in general practice: principal results of British family heart study. *BMJ* 1994;308:313-20.

27. Imperial Cancer Research Fund OXCHECK Study Group. Effectiveness of health checks conducted by nurses in primary care: results of the OXCHECK study after one year. *BMJ* 1994;308:308-12.

28. Strandberg TE, Salomaa VV, Naukkarinen VA, Vanhanen HT, Sarna SJ, Miettinen TA. Long-term mortality after 5-year multifactorial primary prevention of cardiovascular diseases in middle-aged men. *JAMA* 1991;266:1225-9.

29. Rose G. Sick individuals and sick populations. *Int J Epidemiol* 1985;14:32-8.

30. Veatch RM, editor. *Medical Ethics*. Boston: Jones and Bartlett Publishers, 1989.

31. Mappes TA, Zembaty JS. *Biomedical Ethics*. 3rd ed. New York: McGraw-Hill, 1991.

32. Woolf SH. Practice guidelines: a new reality in medicine: III. Impact on patient care. *Arch Intern Med* 1993;153:2646-55.

33. Conroy M, Shannon W. Clinical guidelines: their implementation in general practice. *Br J Gen Pract* 1995;45:371-5.

34. Oxman AD, Thomson MA, Davis DA, Haynes B. No magic bullets: a systematic review of 102 trials of interventions to improve professional practice. *Can Med Assoc J* 1995;153: 1423-31.

35. Haynes RB. Some problems in applying evidence in clinical practice. *Ann N Y Acad Sci* 1993;703:210-24. (discussion 224-5).

36. Baum M. Informed consent may increase non-attendance rate [letter]. *BMJ* 1995;310:1003.

37. Annas GJ. Breast cancer screening in older women: law and patient rights. *J Gerontol* 1992;47(spec iss):121-5.

38. Walsworth-Bell JP. Doctors should admit uncertainty [letter]. *BMJ* 1993;307:1495.

39. Hux JE, Naylor CD. Communicating the benefits of chronic preventive therapy: Does the format of efficacy data determine patients' acceptance of treatment? *Med Decis Making* 1995;15:152-7.

40. Woolf SH. Screening for prostate cancer with prostate-specific antigen. An examination of the evidence. *N Engl J Med* 1995;333:1401-5.

41. Carrese JA, Rhodes LA. Western bioethics on the Navajo Reservation. *JAMA* 1995;274:826-9.

42. Blackhall LJ, Murphy ST, Frank G, Michel V, Azen S. Ethnicity and attitudes toward patient autonomy. *JAMA* 1995;274:820-5.

43. Gostin LO. Informed consent, cultural sensitivity, and respect for persons [editorial]. *JAMA* 1995;274:844-5.

44. Collins JA. Hormone replacement therapy and breast cancer: What is happening? *J Soc Obstet Gynaecol Can* 1995;17:1-10.

45. Angell M, Kassirer JP. Clinical research — What should the public believe? [editorial]. *N Engl J Med* 1994;331:189-90.

46. Krahn M, Naylor CD, Basinski AS, Detsky AS. Comparison of an aggressive (US) and a less aggressive (Canadian) policy for cholesterol screening and treatment. *Ann Intern Med* 1991;115:248-55.

47. Canadian Task Force on the Periodic Health Examination. *Canadian Guide to Clinical Preventive Health Care*. Ottawa: Health Canada, 1994:791.

48. US Preventive Services Task Force. *An Assessment of the Effectiveness of 169 Interventions*. Baltimore: Williams and Wilkins, 1989.

49. Csaja R, McFall SL, Warnecke RB, Ford L, Kaluzny AD. Preferences of community physicians for cancer screening guidelines. *Ann Intern Med* 1994;120:602-8.

50. Battista RN, Hodge MJ, Vineis P. Medicine, practice and guidelines: the uneasy juncture of science and art. *J Clin Epidemiol* 1995;48:875-80.

51. Sox HC. Preventive health services in adults. *N Engl J Med* 1994;330:1589-95.

52. Stephenson MJ. Gestational diabetes mellitus [editorial]. *Can Fam Physician* 1993;39:745-8.

53. Jeyapragasan M, Morris B. Are you a maximalist, a minimalist, or a ritualist? [letter]. *Can Fam Physician* 1993;39: 1878,1881.

54. Canadian Task Force on the Periodic Health Examination. *Canadian Guide to Clinical Preventive Health Care*. Ottawa: Health Canada, 1994.

55. Beisecker AE, Beisecker TD. Patient information-seeking behaviors when communicating with doctors. *Med Care* 1990;28:19-28.

56. Foundation for Informed Medical Decision Making. *The PSA Decision: What You Need to Know* [videotape]. Hanover, NH: The Foundation, 1994.

57. Lyon HC, Henderson JV, Beck JR, Mulley AG, Barry MJ, Fowler FJ Jr, et al. A multipurpose interactive videodisc with ethical, legal, medical, educational and research implications: the informed patient decision-making procedure. In: Kingsland LC, editor. *Proceedings. The 13th Annual Symposium on Computer Applications in Medical Care*; 1989 Nov 5–8; Washington. New York: Institute of Electrical and Electronics Engineers, 1989:1043-5.