
Editorial

Clinical Preventive Services: How Should We Define the Indications?

In fact, prevention and prophylaxis more and more will become medicine's primary approach to challenging diseases.... Victory can come only when preventative measures eliminate the need for aggressive action.¹

The case for promoting many clinical preventive services is compelling. For example, randomized controlled trials have shown that screening mammography for women older than 50 years of age increases life expectancy.² Substantial evidence is also available that treatment of moderate and severe hypertension prevents death from stroke and congestive heart failure.^{3,4} Case-control trials have provided convincing evidence that screening for cervical cancer can prevent deaths from this condition.⁵ Some investigators have estimated that up to 70% of all premature deaths might be prevented if interventions could control just seven classes of risk factors—cigarette smoking, air pollution, dietary excesses and deficits, hazardous work sites, alcohol abuse, nonmedical drug use, and hypertension.⁶

Nonetheless, evidence of efficacy is "seriously incomplete" for most of the preventive services that have been advocated at one time or another.⁷ This situation would not be a problem if preventive services were without risk, but some interventions to prevent death are invasive (such as mastectomy and prostatectomy to prevent death from cancer), the cost of most will not be offset by a reduction in health-care costs,⁸ and many have the potential to produce undesirable side effects.⁹ This forces us to ask, "How do we

define the indications for a preventive service when our knowledge is incomplete?"

Strategies for Dealing With Incomplete Knowledge.—Although a widely accepted framework exists for inferring causality from epidemiologic observations,¹⁰ no such guidelines are available to help us decide which preventive services should be implemented. When the Canadian Task Force on the Periodic Health Examination began its deliberations, it recognized that recommending services on the basis of logic or medical authority alone created the risk of advocating interventions that are expensive and either harmful or ineffective. They responded to this problem by reporting both their recommendations for intervention and the quality of the data on which their recommendations were based.¹¹ This convention was recently adopted by the US Preventive Services Task Force¹² (Table 1).

In order to make a "must intervene" recommendation, both groups generally required evidence from at least one randomized clinical trial that the intervention was effective in detecting, treating, or preventing the condition it was designed to address. The recommendations, however, were also based on two other factors—the burden of suffering caused by the condition and the characteristics of the intervention.

It can be argued that this emphasis on trial evidence of effectiveness tends to cause bias against recommendations for preventive services because it does not fully consider the knowledge derived from other sources: studies of the natural history of diseases, cross-cultural observations, generally accepted models of disease causality, and expert opinion. This practice also excludes interventions that are difficult and expensive to test with randomized trials—among others, community-based initiatives and screening for rare cancers.

As an alternative, the process of consensus development has been advocated as a method of fully applying all aspects of our knowledge. The consensus process can be used to summarize and

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Table 1.—Quality of Evidence Grades and Classification of Recommendations of the US Preventive Services Task Force

Grade or classification	Description
<i>Quality of evidence grades</i>	
I	Evidence obtained from at least one properly randomized, controlled trial
II-1	Evidence obtained from well-designed controlled trials without randomization
II-2	Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group
II-3	Evidence obtained from multiple time series studies with or without the intervention. Dramatic results in uncontrolled experiments (such as the results of introduction of penicillin in the 1940s) could also be regarded as this type of evidence
III	Opinions of respected authorities based on clinical experience, descriptive studies, or reports of expert committees
<i>Classification of recommendations</i>	
A	There is good evidence to support the recommendation that the condition be specifically considered in a periodic health examination
B	There is fair evidence to support the recommendation that the condition be specifically considered in a periodic health examination
C	There is poor evidence regarding the inclusion of the condition in a periodic health examination, but recommendations may be made on other grounds
D	There is fair evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination
E	There is good evidence to support the recommendation that the condition be excluded from consideration in a periodic health examination

Modified from Lawrence RS, Mickalide AD: Preventive services in clinical practice: designing the periodic health examination. JAMA 257:2205-2207, 1987. By permission of the American Medical Association.

simplify knowledge that nonexperts find difficult to interpret. It can also be used to encourage action by minimizing the appearance of tentativeness and minimizing the likelihood that various individuals or organizations will issue apparently contradictory messages.

When we use consensus, however, we must exercise caution because of the following three reasons in particular:

1. Although knowledge promotes the ability to reach consensus, the ability to reach consensus cannot be equated with knowledge.

2. Research is needed if new medical knowledge is to emerge; efforts to achieve and maintain consensus inhibit the acquisition of new knowledge by discouraging novel thinking and giving the appearance that further research is not needed.

3. The paradigm of modern clinical medicine is shared decision making by the clinician and the patient—that is, informed consent. To the extent that using consensus to fill the gaps in our knowledge conceals these gaps from the

patient, consensus violates the spirit of informed consent.

Remembering That Consensus Is Not Equivalent to Knowledge.—It has been demonstrated that knowledge increases the probability that consensus will be achieved.¹³ Nevertheless, we must be cautious in concluding that the ability to achieve a consensus indicates that we possess knowledge. At one time, there was consensus that Atlas held up the earth; later, there was consensus that the sun rotated around the earth. There was once consensus that hand washing was irrelevant to puerperal and surgical wound sepsis.¹⁴ In 1898, a US government official report stated the consensus that yellow fever was spread by fomites.¹⁵

It is true that we have more available knowledge than the persons who achieved errant consensus in the past. It is also true that we possess superior analytic tools and that the issues are different. These facts notwithstanding, is it wise to consider ourselves fundamentally different by assuming that we today are not

susceptible to the same sources of error that misled people in the past?

Consensus and the Search for New Knowledge.—Because of our lack of knowledge,⁷ we must conduct research if we are to learn precisely which preventive services are appropriate. Nonetheless, research threatens consensus because it expresses alternative hypotheses about what we believe to be true. Likewise, as the critical thinking that leads to new knowledge threatens consensus, so enforcing consensus threatens the ability to achieve new knowledge through critical thinking and research.

Studies have shown that setting the achievement of consensus as a goal tends to suppress the expression of new ideas.¹⁶ Although extreme in the case of Galileo and Copernicus, consensus can be used to intimidate; Galileo spent many years under house arrest because he published a treatise that supported the observation by Copernicus that the earth rotated around the sun. Can we justify the benefit of the singleness of thought that we gain from enforced consensus when we consider the potential cost in lost opportunity to learn?

Consensus and Informed Consent.—The current paradigm of clinical medicine is shared decision making. The patient presents a complaint to a physician, and the physician attempts to remedy the problem by applying medical science and art. The patient contributes expert knowledge of his or her own utilities; the physician contributes expert knowledge of medical science.

The legal obligation of informed consent indicates that the physician is expected to respect the patient's expertise about his or her own affairs and to share the decision-making process. In only three cases is the physician permitted to carry out action without the consent of the patient: (1) incarceration when the patient is dangerous to himself or others because of mental incompetence, (2) notifying public health officials when the patient poses an infective threat to the community, and (3) immunizing children. The fact that the medical practice act of Minnesota specifically prohibits the physician from

promising the patient that a treatment will result in cure¹⁷ is also an indication that society wants the physician to speak truthfully.

Consensus can be used in the absence of clear evidence that an intervention is efficacious. Consensus can also be used to imply that evidence of efficacy is present when that evidence is lacking. When we miscommunicate what we know about the efficacy of preventive services, however, do we not violate the principle of informed consent?

Conclusion.—The words of Hippocrates, "*primum non nocere*," remind us that we must not harm our patients in our zeal to prevent disease. A quote from Sherlock Holmes¹⁸ suggests that our own minds can fabricate the evidence for efficacy of interventions to prevent disease: "It is a capital mistake to theorize before one has data. Insensibly one begins to twist facts to suit theories, instead of theories to suit facts." Even so, we must be equally cautious that we do not interpret these admonitions as license to do nothing. In clinical medicine, to decide to do nothing is to do something.

If we choose to do nothing, we may be ignoring the fact that preventive services potentially can have an important influence on the mortality experience of Americans. The burden of potentially preventable disease is enormous,^{19,20} and evidence has shown that intervention to prevent conditions such as coronary heart disease can reduce both the mortality rates²¹ and the financial²² and psychosocial²³ aspects of this burden without causing anxiety or ill-feeling.²⁴

Medicine is charged with the advancement and dissemination of knowledge about how to prevent death. The consensus process can and should be used to interpret and disseminate our knowledge and to identify where continued research is needed. Consensus, however, should not be used as a means to refute knowledge based on experiment and observation or to imply that we have knowledge that we actually lack; the potential for impeding our learning process is far too high.

The lack of evidence from randomized controlled trials that an intervention is efficacious should not prevent us from recommending it if

other evidence is compelling; however, we should not assign equal weight to all classes of evidence. We should not be embarrassed to admit that a recommendation must be based on a "best guess" because of inadequate information. Rarely are we certain in other areas of clinical medicine.

Most patients wish to be fully informed about the basis of decisions for therapeutic services; no evidence has indicated that they feel differently for preventive services. We do not need to overstate the burden of potentially preventable disease and the potential benefit of efficacious preventive services—the truth is compelling enough. When we define the indications for a preventive service, it is in the best interests of our current patients, our future patients, and ourselves not only to state what we recommend but also to state explicitly and truthfully the evidence for our recommendations.

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