

Whither preventive medicine?

David L. Sackett's commentary on preventive medicine¹ is a breath of fresh air which should become a hurricane in this world where life is becoming increasingly "medicalized." His last paragraph is particularly apt: "Experts refuse to learn from history until they make it themselves, and the price for their arrogance is paid by the innocent. Preventive medicine is too important to be led by them."

One might add a remark from an essay by Lancelot Hogben, a British scientist and economist, born in Portsmouth in 1895: "No society is safe in the hands of its clever people."²

Gabe Slowey
Rural Physician
Chesterville, Ont.

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It is ironic that just as HRT for menopausal women seems to be coming to an end (because of the recent announcement of significant health risks associated with these medications¹), some drug companies and some physicians are pushing the use of testosterone products for "male menopause."

Disappointed, frightened and perturbed women are dumping their pills and patches, and many of them are also dumping on the medical profession. In my own practice, most of the women who have been taking HRT have just one question for me: "Should I quit cold turkey, or should I stop gradually?" Fortunately, I feel no need for any mea culpas — I have largely resisted the siren songs describing the putative benefits of female HRT. But now I am hearing the same story for male HRT.

We physicians must now be wary of claims that testosterone products can improve libido, energy, mood, stamina, strength, lipid ratios and heart disease² — the same benefits that have been claimed for estrogen replacement in women. We are told that approximately a million Canadian men over age 60 are at risk of problems in these domains,² but the "cure" may be worse than the "disease" — a number of rather scary adverse drug reactions for one such testosterone product are to be found in tiny print in the prescribing information.³

It's bad enough when ads on television and in the print media bombard men with examples of lethargic middle-aged men made youthful and potent again. When we physicians get on the bandwagon, our unwary patients are put at additional risk of being given these testosterone products. As suggested by David Sackett,¹ physicians are strongly influenced by favours from drug companies. We still get much of our information at luxuriously catered meetings where we listen respectfully to prominent endocrinologists and urologists, who are often spokespersons for these same drug companies.

Luckily, 85% of eligible women rejected HRT for all these years. Will as many men resist such temptation?

David Rapoport
Family Physician
Downsview, Ont.

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David Sackett's wholesale condemnation of preventive medicine is neither original nor tenable.¹ For example, anti-vaccinationists have been with us for more than a century,² but vaccination and immunization have prevailed.

The major thrust of Sackett's com-

mentary is to rebuke the practice of "pursuing symptomless individuals and telling them what they must do to remain healthy." Have we all been wrong in diagnosing and treating symptomless hypertension, diabetes, HIV infection, silent coronary artery disease, dyslipidemia, and incidentally discovered breast cancer and melanoma? Is Sackett implying that the various associations and institutions issuing practice guidelines and standards of practice, with the advice and consent of clinical epidemiologists and biostatisticians, are all and always wrong? The conclusions of the WHI study³ are not disputed. To generalize from it to unrelated fields is scientifically invalid and ethically wrong because it deprives patients of the potential benefit of treatment.

Nicholas Forbath
Specialist, Internal Medicine
Associate Professor (Retired)
University of Toronto
Toronto, Ont.

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In the first paragraph of his commentary, David Sackett noted that the force of law has been used to mandate seat belt use.¹ In the third paragraph, he asserted that no personal health intervention should be undertaken in the absence of positive randomized trials.

With these 2 statements, he apparently advocates that seat belt laws be repealed until a trial is conducted in which those who are about to be involved in motor vehicle accidents are randomly assigned to either seat belt use or no seat belt use, with the group using seat belts experiencing a lower mortality rate. Similarly, I can only assume that Sackett is also opposed to

discouraging children from smoking until randomized trials in which large numbers of teenagers are assigned to smoking or nonsmoking groups showing that those who smoke experience greater long-term mortality rates. To extend this train of thought even further, we should presumably not ban drunk driving until randomized trials have demonstrated that it is dangerous.

Many of the preventive medical manoeuvres currently in use will never be supported by data from randomized trials. In the 3 examples outlined above, randomized trials would be unethical even if they were possible. The accumulated evidence from nonrandomized studies for the benefits of seat belts, the harmful effects of smoking and the dangers of drunk driving is so vast that further study would be in no one's best interest (except perhaps the tobacco industry).

The wearing of seat belts and the avoidance of smoking and drunk driving are measures that cannot conceivably be harmful. The nature of the evidence we require before advocating a preventive medical intervention depends on the nature of the intervention. A pharmacological intervention is vastly different from a lifestyle intervention, and the quality of the evidence we require may also be vastly different.

Mark C. Taylor

Department of Surgery
University of Manitoba
Winnipeg, Man.

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[The author responds:]

To the extent that Gabe Slowey and David Rapoport hold globally negative views on personal preventive measures and because Nicholas Forbath assigns me a nihilistic view of them, I disagree with all 3 of these correspondents.

During my clinical and health policy years I advocated and applied a wide array of personal preventive manoeuvres

because I was dedicated, not to global conclusions about the value of preventive medicine, but to methods for generating level 1 evidence¹ as to whether its individual elements did more good than harm (by level 1 evidence I mean either systematic reviews of randomized trials or "all-or-none" evidence by which, for a universally fatal condition, an intervention was followed by survival or a less frequent adverse outcome was completely eliminated by the intervention). On that basis I advocated and practised the vigorous detection and treatment of certain levels of symptomless elevated blood pressure,² never ordered testing of prostate-specific antigen in a symptomless man, and changed my practice and teaching about treating hypercholesterolemia from a negative to a positive stance when the accumulating evidence from randomized trials of statin drugs showed that they did more good than harm.

In response to Mark Taylor, because the absence of proof is not the proof of absence, folks like me don't advocate abandoning established practices just because they haven't been tested in randomized controlled trials. Moreover, seat belt use satisfied the second criterion for level 1 evidence as soon as users began to survive auto crashes that were previously uniformly fatal. Importantly, however, when this same criterion is applied to another auto safety tradition, school-based drivers' education, the level 1 evidence shows that this intervention doesn't create better drivers, only younger ones, and its net effect appears to be harmful.³

David L. Sackett

Trout Research and Education Centre
at Irish Lake
Markdale, Ont.

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Weighing the risks and benefits of tamoxifen

I read with interest Eric Wooltorton's article on tamoxifen for breast cancer prevention,¹ which directly followed a summary of the Women's Health Initiative (WHI) study on hormone replacement therapy (HRT).² The latter study was stopped early because the prespecified upper boundary for risk of breast cancer in the HRT group had been exceeded. To paraphrase Table 1 in Wooltorton's article,¹ it appears that, per 10 000 woman-years, tamoxifen was associated with 15 more cases of endometrial adenocarcinoma, 2 more cases of uterine sarcoma, 4 more cases of stroke and 5 more cases of pulmonary embolism (relative to placebo), for a total of 26 additional events or a 1.3% absolute risk increase over the 5-year period of the National Surgical Adjuvant Breast and Bowel Project (NSABBP). Tamoxifen was associated with fewer cardiovascular problems than reported for HRT in the WHI study,² but HRT did not cause any increase in endometrial cancer.

In the NSABP, the relative risk reduction for breast cancer among high-risk women who received tamoxifen was 49%.³ Perhaps the Gail model for identifying women at high risk of breast cancer⁴ could be modified to incorporate the known risks associated with tamoxifen, adjusted according to the patient's clinical characteristics, such as age, ethnic background and smoking status, to arrive at a net risk-to-benefit ratio. Without such a tool, it is difficult to get an accurate estimate of risk in clinical practice. A workshop has been held to quantify those risks,⁴ and the next step would be to incorporate the findings into a tool for hand-held or personal computers. A woman's decision to take tamoxifen would still depend on the values she places on different outcomes, such as stroke or breast