

## Science, Public Health, and Public Awareness: Lessons from the Women's Health Initiative

In science, as in life generally, no good deed goes unpunished. One very good deed was the decision to conduct the Women's Health Initiative (WHI) study on hormone therapy. Another was ending the combination estrogen and progestin arm of the trial once it became clear that many of the supposed preventive benefits of the hormone drug therapy were illusory and that for many women, the drugs were actually harmful. So it was perhaps inevitable that the July 2002 announcement of the study's end would provoke a punishing backlash.

Countless women stopped taking hormones cold turkey and voiced a bitter sense of betrayal that the medical establishment had assured them for so long of the drugs' benefits. Across the country, many stunned physicians lapsed into a sort of post-WHI shock syndrome; in denial or disbelief at the trial's results, some doctors simply told their patients to ignore them. Meanwhile, professional groups such as the American College of Obstetricians and Gynecologists (ACOG) went into overdrive. An ACOG task force hastily drew up recommendations for what physicians should tell their worried patients. Along with other clinical and professional groups, ACOG complained that the National Institutes of Health (NIH) hadn't given it any warning of the study's results or a chance to review the data.

In reaction to this firestorm, the NIH scheduled the October 2002 scientific workshop described in this issue by Kirschstein (1). The conference was partly an exercise in damage control and partly an effort to paint the broadest possible picture of our current understanding of the benefits and harms of hormone therapy. Staging the workshop, too, was a good deed that should not be punished—and will not be by this writer, who served as a presenter at the conference. But an examination of the entire episode does suggest that communicating major study results should be handled differently in the future, to better enable the NIH to carry out its mission to protect and improve human health.

### COMMUNICATING THROUGH THE NEWS MEDIA

Concerned that the study results would leak before participants in the trial could be notified, NIH officials decided against holding extensive advance briefings for the clinical community. Instead, they halted the trial, mailed notification letters to participants, unveiled an article on the findings through the *Journal of the American Medical Association* (2), and held a major briefing for the news media—all within a time span of several days. The effect was to place the news media in the role of primary communicator of the study findings to both the clinical com-

munity and the public. And we in the news media were not entirely up to that task.

First, the news media generally did a poor job of communicating a basic point about the data from the trial: that there was a considerable difference between the relative and absolute risks of combination hormone therapy. Although taking the estrogen plus progestin combination drug (Prempro, Wyeth Pharmaceuticals, Radnor, Pennsylvania) increased the relative risk for breast cancer by 26% over the 5 study years, an individual woman's absolute risk for developing breast cancer, at approximately 0.3% per year, was increased by only 0.1% per year (2). Yet most articles and broadcast segments tended to focus exclusively on either the small absolute risks or the larger relative risks, neglecting the more even-handed picture that presented both. Since the sharply increased relative risks got the most play, news coverage about the trial's findings had an alarming cast. This fact may have contributed to the perhaps ill-advised decision of many women to suddenly quit taking the drugs, rather than weaning from them gradually or closely evaluating their own disease risk profiles before discontinuing hormone therapy.

Second, the news media did not adequately convey that WHI was a prevention trial and that its results mostly shed light on use of hormone therapy for disease prevention. Thus, the trial's overwhelming conclusion was that Prempro should definitely not be used to prevent heart disease, since if anything it appears to cause or aggravate this disease in many women. Nor should Prempro be used to prevent colon cancer or osteoporosis, since the risks for developing diseases such as breast cancer and heart disease clearly outweigh the small preventive benefits. By contrast, WHI was not designed to answer what became the central question for many women after the trial results were released: Do the symptom-relieving benefits of hormone therapy outweigh the higher risks for breast cancer, heart disease, heart attack, and stroke? Few news reports reflected fully on the notion that, as important as the WHI results were, they inevitably left this critical question about hormone use unanswered. Women were left to ponder the question alone or to raise it with their physicians, most of whom didn't really know the answer, either.

### IMPORTANCE OF A PUBLIC HEALTH APPROACH

This history suggests two main lessons. As crucial as the news media are in disseminating health information, and as much as we need to raise our own standards of performance, we should not necessarily be relied on as the primary means of communicating a complicated health story to the public. In the future, the NIH will have to take a more comprehensive public health approach in commu-

nicating study results of this magnitude. Notwithstanding the risks for leaks, the clinical community will have to be brought in sooner to evaluate the data and assess the implications for patient care. In cooperation with clinical and professional groups, the NIH and other government agencies should prepare an action plan for communicating with patients on how to apply study findings to their personal situations. Comprehensive information tools for patients should be prepared and at the ready, such as CDs or Web-based materials that patients and doctors could access immediately.

A second lesson is that the NIH has a crucial role to play in supplying an “instant context” for any given study by pulling together the extensive knowledge that already exists across the institutes. As the scientific workshop made abundantly clear, the WHI results shouldn’t have been news to specialists who had closely followed all trials of hormone therapy. The earlier Heart and Estrogen/progestin Replacement Study (HERS) had shown increased risks for heart disease from hormone therapy use, and participants in both groups of the WHI study had been notified in 2000 and 2001 that increased risks for heart attacks, stroke, and blood clots were already showing up (3). But the public and even much of the clinical community often have trouble keeping the developing larger picture in sight as these study results dribble out over time. Moreover, much additional information is already known about hormone therapy’s other effects on areas such as cognitive function. At major junctures such as the end of the WHI trial, it should fall to the NIH to pull all these threads together for people. The NIH also should make the information available in user-friendly ways in tandem with the release of a key study’s findings, rather than weeks afterward. This would not only better serve the public health but also demonstrate the important truth that clinical science is almost always about discovering how new pieces fit into a puzzle already under assembly.

It is none too soon for the NIH to start down this more comprehensive communications path. Results of the

estrogen-only arm of the WHI trial are expected in 2005 and could provide a trial run for a new approach. What’s more, the job of explaining and interpreting for the public the results of the combination therapy trial is clearly not yet finished. A recent poll sponsored by the Partnership for Prevention, a membership association of corporations, nonprofit organizations, and state health departments, shows that nearly one third of older women still believe that hormone therapy can help protect them from heart disease, breast cancer, and stroke (4). That’s a useful reminder that, for science, an outcome even worse than punishing good deeds is ignoring them—especially when those deeds yield knowledge that could help to save lives.

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