provided no rationale for doing so. Without information, those who want NIH to give more attention to women's health, like Schroeder and Representative Olympia J. Snowe (R–ME), have made their case by citing glaring examples. Snowe pointed out that although heart disease is the leading cause of death in women over 60, it's uncertain whether taking aspirin will be beneficial to women because they weren't studied.

But the aspirin study also shows why it is sometimes difficult to include women in study populations. Charles H. Hennekens, professor of medicine and preventive medicine at Brigham and Women's Hospital in Boston and director of the study, says that, in the early 1980s when the protocols were being designed, he intended to look at women as well as men. But he was stumped by the numbers. The study used physicians as subjects, and at the time, only 10% of those over 40 were women. And while 1 in 5 men could be expected to have a significant coronary event by the time they were 60, the corresponding number was 1 in 17 for women. So to get adequate statistical power to make conclusions about both sexes, he would have needed a far larger subject pool. "We would have needed a huge sample size," he says. "We could not have included just a few thousand women into the study and claimed that we could have gotten an answer in women. And also it would have compromised our ability to get an answer in men."

Hennekens believes the time is now right to do a study on women based on the findings in males. "I support the idea completely of doing studies in women and in minorities." But he worries that shoehorning women into studies for political rather than scientific reasons would be disastrous.

For now, the emphasis seems to be on collecting data and looking at the issue of including women in trials rather than mandating that it be done. Schroeder will introduce an omnibus women's health package next month that would create a Center for Women's Health Research and Development at NIH to coordinate research. The Institute of Medicine is considering a broad study on the inclusion of women and minorities in clinical trials. There is also a new political lobby, the Society for the Advancement of Women's Health Research, that is planning to bang the drum for more attention to women in federal health care.

For his part, Raub is willing to do more. "The emergence of stronger advocacy for women's health is good for the country," he says. "I don't believe it's a system badly out of focus," he said. "It needs some fine-tuning, and we're getting on with it."

■ JOSEPH PALCA

Breast Cancer Therapies Weighed

Even as the National Institutes of Health came under fire last week for giving short shrift to women in the institute's basic and clinical research programs (also see p. 1601), the report of a recent NIH consensus conference points up the need for more research on one major women's health issue—how to treat early breast cancer. Although the experts convened by the NIH were able to agree on the best surgical treatment for women with early breast cancer, they couldn't resolve the more controversial issue of whether the patients should subsequently receive systemic treatment—chemotherapy or hormone therapy—to prevent recurrence of their disease.

And that will still leave many of the 150,000 or so women a year diagnosed with breast cancer—and the physicians who must advise and treat them—uncertain about the best therapeutic course to take. These are the women, about 75% to 80% of the total, whose cancers have been detected early.

At least on the point of primary therapy for early breast cancer, there appears to be a consensus among researchers. The panel reaffirmed what experts have been saying for several years: removal of the lump and nearby lymph nodes, followed by irradiation, is just as effective as a mastectomy. This treatment "is preferable because it provides survival equivalent to total mastectomy and also preserves the breast," concluded the panel, which was chaired by William C. Wood, chief of surgical oncology at Massachusetts General Hospital in Boston.

Risk estimates for breast cancer recurrence still need sharpening.

But then came the contentious question: should women with early breast cancer, especially those without detectable lymph node metastases, receive drug therapy to prevent recurrence of the disease? Currently, 70% of such cancers are successfully treated with surgery and radiation alone. Thirty percent can be expected to recur, however, and predicting which patients will fall in that 30% is still very uncertain.

For this reason, about 2 years ago, the National Cancer Institute issued a clinical alert saying that additional treatment with drugs or hormones is a "credible therapeutic option worthy of careful attention" for all early stage patients. This pronouncement engendered a storm of criticism. Some cancer experts objected on the grounds that the benefits would not outweigh the risks and discomfort posed by the drugs for the majority of women who would not have recurrences anyway. Michael Friedman of NCI's cancer treatment evaluation program says that many clinicians misinterpreted the alert: the NCI never meant to say that all node-negative patients *should* get the adjuvant therapy, he says, but just that they should consider it.

Which is why the NIH convened the consensus panel: to help clear up the confusion and see if available data could provide further guidance for node-negative patients and their physicians. For one set of patients the panel did. It concluded that in cases where tumors are 1 centimeter or less in diameter and no lymph nodes are affected, the likelihood of recurrence is so small (10%) that the benefits of adjuvant therapy would be insignificant.

But for the patients with larger tumors, the panel concluded that the decision is an individual one that depends on personal preferences and a variety of prognostic factors that can help to indicate whether a woman is at high risk of having a recurrence and should therefore have adjuvant therapy. The panel cited tumor size, estrogen receptor status (the presence of such receptors in a tumor improves prognosis), the degree of tumor cell abnormality, and the tumor cell proliferation rate as among the most reliable of these predictive factors.

But even taken together these factors cannot provide 100% certainty about a patient's fate, and the panel did not come up with specific criteria to guide individual decision-making about follow-up therapy. Indeed, panel member James Ingle of the Mayo Clinic said a "major future goal" should be the development of "risk profile systems" that will make it possible to be more specific on individual risk estimates. But at this point, there are too many gaps in data to achieve that goal. And the only way to plug such gaps is through research dollars. "The many unanswered questions," said the panel, "make it imperative that all patients who are candidates for clinical trials be offered the opportunity to participate."

■ CONSTANCE HOLDEN