

personal, individual physician-related factors discussed above, plus the shift in the patient population from the 1930's onward (especially beginning in the 1960's) to those with less advanced disease, helped precipitate trials of less extensive surgery.

There are several other possible reasons for the reluctance of the medical profession to accept less extensive surgery for breast cancer. One is that the "burden of proof" has been viewed as resting with the innovators as opposed to those surgeons performing the traditional forms of mastectomy. That the radical mastectomy clearly was regarded as the treatment of choice for about 90 years is evidence enough that the burden was on the proponents of lesser surgery. The impact of burden of proof is as powerful in medicine as it is in law. It was clearly up to the proponents of change to make a strong case for that change. Radical mastectomy is "innocent until proven guilty."

The structure of medical specialization has also contributed to the situation. Chemotherapy, radiotherapy, and surgery are the domains of three separate medical specialties—internal medicine, radiology, and surgery (or obstetrics-gynecology in certain parts of the United States). It is human nature to believe in what one does. Thus, to design and carry out a clinical trial of surgery v. radiation therapy is not as easy or feasible as it would be if these treatment modalities were under the domain of the same specialty. And because several of the less extensive forms of surgery are used in conjunction with radiotherapy or chemotherapy (to a greater extent than is radical mastectomy in most cases), comparative trials among the forms

of surgery are also difficult to set up. Similarly, surgeons who become identified with specific forms of surgery for breast cancer form what are very much like special ties-within-a-specialty. Here, too, trials are difficult to conduct, and their persuasive value is diminished.

One other point regarding medical specialization and its influence on the acceptance or rejection of innovation is applicable to the present case. Surgeons (to make a broad but generally accurate observation) tend to be more concerned with prolongation of life than do other specialists, such as psychiatrists. The innovators in surgery for breast cancer observed here (e.g., Cope and Wise) have had significant associations with or interest in psychiatry and have been more concerned with quality of life issues such as the psychological impact of radical procedures.

There is also an international aspect to the change process we have been examining. Much of the early testing of less extensive surgery was conducted abroad, especially in England, and the acceptance of such surgery occurred earlier in other countries than it did in the United States. Several possible factors explain this situation. Surgical intervention is less frequent and less aggressive in England than it is in the United States (8). Also, Halsted's reputation was much greater in the United States than abroad; in the United States, he has often been called the country's greatest surgeon. A possible economic motive may also play a role in the international difference: In England, most physicians are salaried members of the National Health Service, while in the United States, fee-for-service medicine predominates.

CONCLUSIONS: REFLECTIONS ON THE CHANGE PROCESS

This is a case study on change in medical practice. It has examined the personal and social or professional elements that may have contributed to or worked against the reduction in use of radical mastectomy in favor of the use of less extensive forms of surgery. All of the material presented so far has been descriptive.

In this concluding discussion, we offer some observations concerning the change process and possible areas where it might be made *more rational*.

First, physicians should write and speak directly to the public on controversial issues and not be criticized by their peers for doing so (34).

Breast cancer is a topic to which the public media are willing to devote substantial space, and most women are willing and able to follow and enhance this sort of technical and social debate.

Second, medical conservatism has strengths and weaknesses. Rushing to the latest fad is by no means desirable. Conservatism, however, often implies that a specialty group has developed a consensus, and that an outsider, fresh to the debate, may not be in agreement with it. Specialty groups should be willing to test their consensus by having outsiders inquire into the state of knowledge.

Third, an intelligent, informed patient could reasonably choose between clearly explained alternatives and ought to be allowed to do so. The surgeon who is willing to provide only one procedure and gives the patient no option does harm. This practice is common and has led State legislatures to propose bills requiring that options be explained and presented to all breast cancer patients. Such laws should be unnecessary.

Fourth, although economic incentives can explain the present situation in part, this does not justify overhauling fee-for-service surgery. There is no neutral economic system. Perhaps this case study makes the point that fee-for-service surgery and institutions with surgeons on salary should compete in an environment where patients can choose the economic system they prefer. Choice and competition certainly may be beneficial, but, in order to be so, will require active cultivation.

Fifth, the research community and the governments that support research have failed in several respects. Randomized clinical trials are expensive and often difficult to perform. Why did it take seven separate trials, performed over 15 years, to change expert consensus? A trial ignored is almost as bad as a trial not performed and is also a waste of scarce research resources. Much more attention should be given to considering what types of research methods and administrative procedures are needed to appropriately change expert consensus. Such consideration requires thought about strength of prior opinion, participation by opinion leaders, and careful marketing of the results to the practicing surgical community. This suggests study of the personal and social context of change, which we have attempted to begin in this case study.

Sixth, the ground rules for consensus formation need clarification. Where does the burden of proof lie? If the burden of proof had been shifted, the history of the breast cancer surgery debate would have been very different. Imagine that in 1966 the Kaae and Johansen (37) and the Brinkley and Haybittle (s) studies had been declared the best available evidence at that time. The burden of proof for demonstrating the desirability of radical mastectomy would then have fallen on those who believed in it. Since quality of life is lower with radical surgery, any surgeon wishing to perform radical mastectomies would have had to have conducted a trial whose results showed enough gain in prolongation of life to offset the loss in quality. If this situation had existed in 1966, it is likely that almost no radical mastectomies would have been performed in the last 15 years.