

### INVOLVING PATIENTS IN RESEARCH

How has this involvement of patients in research come about? In Chapter 3 we showed, for example, how the treatment excesses formerly imposed on women with breast cancer led to challenges and changes, both from a new breed of clinician-researchers and then from patients. Clinicians and patients collaborated to secure the research evidence that met both rigorous scientific standards and the needs of women. When women challenged the practice of radical mastectomy they signalled that they were concerned about more than eradication of cancer: they demanded a say in the tactics employed to identify effective ways of dealing with the disease.

For those patients and members of the public who want to become fully involved as co-researchers, there are several possible avenues. For example, they can be involved individually or as a member of a health/disease support group, or they may participate in a facilitated group activity such as a focus group. Irrespective of the mechanism of their involvement, it will certainly help if they become familiar with the nuts and bolts of research methodologies so that they can contribute confidently and effectively in partnership with health professionals. And for this they will require good-quality information and training relevant to their role. We go on to explain in Chapter 12 why the way in which this information is presented, especially in terms of statistics, is critically important to proper understanding. There are also many less prominent ways in which patients and the public can contribute to research efforts, particularly if we can develop a culture of collaboration which accepts insights and observations from a patient's viewpoint.

Today's active patient-researchers can look back thankfully to the pioneering activity of early 'patient pioneers' who realized that they should speak up and challenge the status quo – and that to do so they needed accurate information. For example, in the USA in the early 1970s, a small group of breast cancer patients, led by Rose Kushner, set about educating themselves so that they could become effective. Then they started to educate others. Kushner was a breast cancer patient and freelance writer who, in the

## LAY PEOPLE HELP TO RETHINK AIDS

'Credibility struggles in the AIDS arena have been multilateral: they have involved an unusually wide range of players. And the interventions of lay people in the proclamation and evaluation of scientific claims have helped shape what is believed to be known about AIDS – just as they have made problematic our understanding of who is a “layperson” and who is an “expert”. At stake at every moment has been whether specific knowledge claims or spokespersons are credible. But at a deeper level, the stakes have involved the very mechanisms for the assessment of credibility: how are scientific claims adjudicated, and who gets to decide? [As this study shows,] debates *within* science are simultaneously debates *about* science and how it should be done – or who should be doing it.'

Epstein S. *Impure science: AIDS, activism and the politics of knowledge*. London: University of California Press, 1996.

early 1970s, challenged the traditional authoritarian physician-patient relationship and the need for radical surgery.<sup>12</sup> She wrote a book based on her thorough review of evidence of the effects of radical mastectomy. By the end of the decade, her influence and acceptability were such that she worked with the US National Cancer Institute reviewing proposals for new research.<sup>13</sup> Similarly, in the UK, lack of information prompted women to take action. For example, Betty Westgate set up the Mastectomy Association in the 1970s, and in the 1980s Vicky Clement-Jones founded the charity CancerBACUP (now part of Macmillan Cancer Support).

People with HIV/AIDS in the USA in the late 1980s were exceptionally knowledgeable about their disease. They were politically geared to defend their interests against the establishment, paving the way for patients to participate in the design of studies. This involvement ultimately led to a choice of treatment options being offered to patients in the studies and flexible designs to encourage participation. This example was

followed in the early 1990s in the UK when an AIDS patient group was involved in studies at the Chelsea and Westminster Hospital, London: the patients helped to design studies.<sup>14</sup>

These AIDS activists made researchers sit up: what some researchers had viewed as havoc caused by organized patient groups was in fact a legitimate challenge to the researchers' interpretation of uncertainty. Until then, the researchers' approach had overlooked the patients' preferred outcomes. On the other hand, patients came to appreciate the dangers of making hasty judgements about the effects of new drugs and of demanding release of a 'promising' new AIDS drug before it had been evaluated rigorously. The researchers may have remonstrated that 'compassionate release' of new drugs in this way had merely prolonged the agony of uncertainty for current and future patients. However, the patients countered that it ultimately hastened the understanding of both patients and researchers about the need for unhurried, controlled evaluations of treatments, designed jointly, and taking account of the needs of both parties.<sup>15</sup>

In the 1990s, one AIDS trial provided a particularly clear illustration of the importance of patient involvement in research. This was at a time when the drug zidovudine had recently been introduced for the treatment of AIDS. In patients with advanced disease there was good evidence of a beneficial effect. The obvious next question was whether use of zidovudine earlier in the course of infection might delay disease progression and further improve survival. So, trials were begun in both the USA and Europe to test this possibility. The US trial was stopped early when a possible but still uncertain beneficial effect was found. With active participation and the agreement of patient representatives, and despite the US results, the European trial continued to a clear endpoint. The conclusions were very different: zidovudine used early in the course of infection did not appear to confer any benefit. The only clear effects of the drug in these circumstances were its unwanted side-effects.<sup>16</sup>