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How consumers can and should improve clinical trials

HIV-AIDS changed forever the expectations of consumers in clinical research. Instead of participating in clinical trials as “subjects”, consumers became equal partners with their physicians. For many doctors this sea change was hard to accept. There was early resistance. The power of paternalism was difficult to shrug off. And, in HIV-AIDS, although activists succeeded in winning the right to shape the agenda of AIDS research, their victory did not come without a cost. As Kevin Frost of the American Foundation for AIDS Research declared at last week’s Society for Clinical Trials meeting in Denver, the process of clinical research was strengthened by consumer participation. But some of the negotiated trials were dirty and ill-disciplined as a result.

Breast cancer has been another example of strong consumer activism. Perhaps the world’s most influential medical consumer lobby group is the US National Breast Cancer Coalition. The goal of the Coalition is nothing less than to eradicate breast cancer. For the NBCC, breast cancer is more than a health issue—it is also a political matter. The Coalition’s impact has been substantial. For example, according to NBCC’s president, Fran Visco, their collaboration with Genentech brought trastuzumab (Herceptin) to women 2 years earlier than would have been the case without their advocacy. So is the subject of consumer participation in clinical research now resolved? Not according to Visco—“it is still an issue”, she said.

The contributions of US consumers come at all levels in the clinical trial process—study design, steering committees, institutional review boards, and data and safety monitoring committees. At the National Cancer Institute, for example, consumer advocates have become a routine part of its decision-making procedures. In Denver, Michaele Christian argued that consumers make NCI scientists think more broadly about the impact of their research on patients. And their lack of professional relationships with investigators enables them to raise awkward issues. Yet difficult problems remain.

Although the purpose of the NBCC is clear—to improve the effectiveness of research, to widen access to care and clinical trials, and to influence public-policy making—one question persists: who is a

legitimate advocate? Visco, together with Irene Rich (US Department of Defense Breast Cancer Research Program), leaned towards the view that advocates ought to be breast cancer survivors who represent a constituency. Ideally, they should be elected or nominated by a group. Only through such close identification with the disease in question could one be assured that the advocate was fully apprised of the issues, they argued.

But Frost poured scorn on such a narrow perspective. At AMFAR he represented no-one but himself, a gay man who neither has AIDS nor is HIV positive. Should his lack of infection exclude him from debates about AIDS? He argued for caution in trying to define who can be an advocate. A positive definition of inclusion inevitably requires exclusion. This was “treacherous ground”.

The balance of argument suggests that there is no single right answer to the question of who is a legitimate consumer advocate. Rather than debate the semantics of advocacy and activism, greater effort should be expended in encouraging maximum participation by all concerned individuals. Inclusiveness must extend beyond the signature issues of HIV-AIDS and breast cancer. Where are the consumer advocates for heart disease or paediatric illness? Or, going beyond the interests of western medicine, malaria or tuberculosis? Those who have already established successful advocacy organisations could help colleagues in other fields get started.

Another step forward would be for physician leaders to invite consumers to conferences that have hitherto largely been the province of health-care professionals. Why not develop a large consumer caucus at the American Heart Association, for example? One that works equally with cardiologists to influence the agenda of research. And how could these partnerships be nurtured elsewhere? Europe, for instance, has a far less mature activist culture than the USA. Among the many benefits, such alliances would provide a conduit for the results of clinical trials to be effectively implemented and they would likely help recruitment to research. These goals are surely shared by specialists and consumers alike. In Frost’s words, “It’s not rocket science”.

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