United Kingdom Becomes the Cancer Clinical Trials Recruitment Capital of the World

By Gunjan Sinha

The more cancer patients that doctors recruit into clinical trials, the faster they can test new therapies. Yet recruitment remains abysmally low—except within the United Kingdom. Last year 32,000 patients—the equivalent of 14% of Britain’s annual cancer incidence—participated in cancer clinical trials.

“That’s the highest rate of cancer clinical trial participation of any country in the world,” said Richard Kaplan, M.D., associate director of Britain’s National Cancer Research Network (NCRN). By contrast, less than 3% of all U.S. cancer patients participate in clinical trials, according to the National Cancer Institute.

Beginning in the early 1990s, the United Kingdom’s Department of Health set out to overhaul cancer care. The National Health Service (NHS) not only established regional networks to ensure better access to care but also in 2000 set up NCRN to boost clinical research—and clinical trial participation jumped.

Can the United States boost its own clinical trial participation by following Britain’s lead? Not quite, experts said, but the United States is working toward improving clinical research in other ways.

The Backdrop

Britain’s cancer network was borne from research suggesting that U.K. patients received inferior cancer care. According to the Eurocare-3 study published in 2003, British patients were up to 30% less likely than their European counterparts to survive cancer. The study pooled data from 19 countries between 1990 and 1999.

The study only confirmed widespread fears. For decades, patients had complained that doctors were catching cancers too late to treat them effectively, partly because of the time between diagnoses and treatment at a specialized care facility was often longer than 1 month. To address the disparity, the NHS created a cancer care network during the late 1990s by dividing the country into regions and making hospitals and specialists responsible for cancer care within their designated region. Scotland and Wales followed suit. Each region set up a structured referral system, streamlining access to specialized cancer care, Kaplan explained.

But these regional cancer care clusters did not coordinate clinical research. That task was added in 2000 when a consortium of health care groups and funding agencies created the NCRN. As part of its overall cancer plan, the U.K. health department joined with other government agencies and large charities to pledge substantial funds to set up the research network’s infrastructure. By 2004, the NHS had allocated an additional £570 million ($1.1 billion) each year to improve patient access to specialized cancer care and boost clinical research.

Recruitment in Practice

About £5 million ($10 million) of that goes to the NCRN, which in turn distributes the additional funds to regional networks on the basis of population size and, increasingly, on performance. There are now 41 networks across the United Kingdom. Although these regional networks allocate funds to suit the network’s needs, most have hired more staff such as dedicated research nurses and data managers to satisfy goals laid out in the department of health’s cancer plan to increase clinical trial recruitment.

For time-strapped doctors, support staff have smoothed the traditionally kinked path from patient to clinical trials. Dedicated nurses interact with patients and clinicians to determine whether a patient is eligible for a particular trial. They also explain trial details to patients, handle informed consent, and ultimately register patients in any given trial. Data managers collect follow-up data and log information in databases.

NCRN’s initial mandate was to double clinical trial participation from 3.5% in 3 years. The agency rocketed past it—14% of cancer patients now participate in clinical trials. Preliminary studies also show that care has improved. The rate of rectal surgery to remove diseased parts of the large bowel or rectum, for example, has fallen from 24.5% to 18% from 2001 to 2005—suggesting that physicians are detecting and or treating bowel cancer earlier.

Patient advocacy groups, such as CancerBaCUP, have also largely applauded the improvements but are calling for a second plan to address remaining shortfalls. “Whilst we are pleased at the progress, there are still unacceptable delays in waiting times for some diagnostic procedures, a shortage of suitable information for patients, and a lack of coordination of services,” said Joanne Rule, chief executive of the U.K. cancer patient advocacy group. For example, patients in some regions still experience unacceptable delays in treatment, Rule said, because of an acute shortage of radiographers.

“There is also the ongoing issue of access to drugs and spending on cancer treatments still lagging behind [those of] other European countries.”
In November 2006, the U.K. government announced a cancer reform strategy for the coming years that will focus on helping networks improve cancer prevention, early diagnosis, and universal access to standard care.

As for patients gaining access to experimental therapies, however, experts agree that progress has been stellar. “The United Kingdom has done a tremendous job,” remarked Ted Trimble, M.D., head of surgery at NCI’s Cancer Therapy Evaluation Program. The NHS set up their network with help from NCI. “But we don’t have National Health Service in the United States, and so we can’t set up such a system.”

Barriers in the United States

Instead, the United States’ cooperative group system handles most clinical trial recruitment and research. The system has had some success, Trimble and Kaplan both emphasized. In the late 1990s, NCI created a new agency, the Clinical Trials Support Unit, so that clinicians can enroll patients into trials sponsored by cooperative groups even if the doctors are not members.

But geography and the U.S. health care system present barriers to patient recruitment. Many cancer patients live far from treatment centers, and many health insurers do not pay for experimental therapies—barriers that don’t exist in the United Kingdom. Moreover, all U.K. oncologists belong to the cancer network. By contrast, collaborative groups in the United States require membership, and not all oncologists are members. Doctors or patients may find the search for trials or the referral process cumbersome and not worth their time.

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The difference in health care systems affects clinical trial participation in other ways, too. In the United Kingdom, the newest cancer treatments aren’t available until the NHS decides that there is enough clinical evidence that a treatment is effective, said Kaplan, who directed the cooperative group program for the NCI before taking a job at NCRN 3 years ago. So clinical trials often are the only way patients can get access to the latest drugs. In the United States, oncologists can prescribe drugs as soon as the drugs hit the market.

Despite the relatively low numbers of U.S. clinical trial participants, NCI is hoping to improve clinical research in other ways. Through the Clinical Trials Support Unit, NCI is reducing duplicative studies. The agency has also created a review mechanism to decide which trials are most worthwhile to pursue.

NCI also counsels health care agencies abroad and is advising them to follow Britain’s lead. Irish, French, and Italian health care officials do consult with NCI and have pledged to tighten their cancer research networks to boost clinical trial recruitment in their own countries; developing countries are in the loop too, Trimble said.

“Coordinating clinical trials globally is critically important,” Kaplan said. Harmonizing design criteria, such as eligibility, endpoint definitions, and control arms, will make validating and interpreting results easier. It will also further cut the number of duplicate trials and encourage complementary ones—all of which will speed up testing of new cancer therapies even though U.S. recruitment remains relatively low, he added.

That won’t, however, help recruit more U.S. cancer patients into potentially life-extending clinical trials, which is unfortunate, Kaplan said.

“U.S. cancer patients ought to have at least as much access to potentially life-extending experimental therapies as U.K. patients.”

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