Biobank managers bemoan underuse of collected samples

Hundreds of thousands of individuals have freely donated bits of their bodies to biological repositories, proffering a vial of blood or a slice of skin in exchange for the promise of advancing medical research. But contrary to donor intentions, many of those specimens are sitting unused in lab freezers, suggesting that the biobanking system is not as efficient or effective as it could be.

According to a first-of-its-kind survey of 456 biobank managers in the US, nearly 70% of those questioned expressed concern that the samples in their repositories are underused. "Biobankers really worry," says Gail Henderson, a medical sociologist at the University of North Carolina–Chapel Hill who led the study published in late January (*Genome Med.* **5**, 3, 2013). "They have an imperative to collect, but they really want to make sure the specimens are used, and they worry about how to make that happen."

It's not just a problem unique to US institutions either. "There are so many samples and data connected to these samples, but nobody is using them," says Loreana Norlin, a project manager at the BioBanking and Molecular Resource Infrastructure of Sweden, a national biobanking facility and network based at the Karolinska Institute in Stockholm. "They're lying around in a freezer."

Numerous causes for this underuse have been proposed, including the supply of samples outstripping demand, restrictive policies that allow only researchers affiliated with particular institutions or projects to access certain biobanks, and poor marketing. To encourage more researchers to use biobank wares, Liz Horn, former director of the Genetic Alliance BioBank, a Washington, DC–based repository operated by five patient advocacy organizations, recommends that biobanks advertise their collections at institutional events and external conferences. "You can't just collect," she says.

Without fail

The Mayo Clinic Biobank, for example, regularly publicizes its collection during grand rounds at the Rochester, Minnesota–based hospital, enticing researchers with results gleaned from past studies done with the biobank's samples. "Our feeling is if people don't use the samples, then it's a failure," says James Cerhan, principal investigator of the Mayo biobank.

In addition to homegrown advertising, biobanks may need to work together to fulfill their mission, notes Horn. "Standardization is going to be important for researchers to get samples from different collections," she says, "and we need catalogs that say where these samples exist."

A national registry, like that currently being built in Sweden, could show researchers comparable types and quantities of samples within biobanks around a country. Meanwhile, accreditation could provide further incentives for biobanks to harmonize collections and encourage use. Two years ago, the College of American Pathologists introduced a Biorepository Accreditation Program, and already 18 banks have been certified and an additional 15 are in the process.

"It's expensive," says Henderson, "but it might be a first step toward making biobanks into a harmonized system."

Megan Scudellari

Bioethicists propose routine randomization of therapy in clinics

People visiting the doctor don't necessarily expect to be partaking in a research project. But a new report from US ethicists proposes that blurring the line between clinical care and clinical trials would ultimately improve medicine.

For many medical conditions, doctors and patients must choose from several treatment options approved by the US Food and Drug Administration (FDA). Often, though, there's little data showing which therapy is most successful. The new report suggests that, when the various treatment options have similar risk profiles, healthcare providers should be allowed to randomize the type of therapy given and collect data, either with or without special patient consent (*Hastings Cent. Rep.* **43**, S4–S15, 2013). The authors argue that the care that individuals receive is already somewhat random and can depend largely on the doctor they choose or the hospital closest to their home.

There is a need for more data to help people pick amongst the multitude of treatment choices available today. For example, the fact that a man diagnosed with prostate cancer is made to select somewhat arbitrarily from either surgery, chemotherapy or monitoring, when millions of patients before him have already decided on one of these treatment options, is "remarkable," says report coauthor Nancy Kass, deputy director for public health at the Johns Hopkins Berman Institute of Bioethics in Baltimore. If healthcare institutions had collected outcome data for each patient, doctors might have learned that one approach was most successful.

Several European countries and Canada make use of clinical data, even without asking for consent from patients, according to Sean Tunis, president of the Center for Medical Technology Policy in Baltimore and a study coauthor. More countries have been starting to do randomized trials in a clinical setting, he says, citing a study conducted primarily in Argentina that examined how a second opinion might reduce rates of Caesarean sections (*Lancet* **363,** 1934–1940, 2004).

In the US, the Office for Human Research Protections (OHRP), a division of the Department of Health and Human Services based in Rockville, Maryland, is ultimately responsible for dictating the terms of trials that ensure that they do not pose undue risk for participants. The OHRP already plans to revise its regulations on research, known as the Common Rule, having released a preliminary report in July 2011. The revisions attempt to make research less burdensome by shortening the consent process or requiring only one institutional review board (IRB) appraisal for domestic, multisite studies.

Making better use of the data created by current patients is a goal of the Common Rule revisions, according to OHRP Director Jerry Menikoff. But he doesn't see a need for the randomization the authors suggest, adding that many researchers think access to the data itself—without randomization—will be enough. "A lot of researchers think we could do wonderful things with just the information," he says.

The study authors are correct in saying that sometimes the treatment selected is the result of a gamble, says Collin O'Neil, a bioethicist at New York University. But if patients are randomized in a clinical setting, their doctors will no longer be guided by what they think is best for each patient's health, but instead by the randomization.

There are often subtle reasons doctors prefer one of two similar drugs, and patients may have a personal preference between side effects that are described as similarly severe, Menikoff says. For these reasons, he believes Faden and Kass are overestimating the number of scenarios appropriate for their proposed trials, as well as doctors' willingness to come on board.

Susan Matthews