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IDASH Projects: Protecting Privacy and Patient Rights in the Name of Scientific Progress

In the years since the best-selling book “The Immortal Life of Henrietta Lacks” made the issue of informed consent and patient privacy a national topic of conversation, scientists and clinicians have continued to struggle to develop a comprehensive methodology for collecting and sharing data from patients and research subjects without jeopardizing their rights.

The University of California, San Diego’s iDASH project aims to address some of these fundamental challenges to research progress with its most recent series of “Driving Biological Projects” (DBPs). iDASH, or Integrating Data for Analysis, Anonymization and Sharing, is affiliated with the Qualcomm Institute and provides tools and infrastructure for bioinformatics researchers to launch and implement studies that are often global in scale.

The three DBPs announced for 2013-2015 include an effort to preserve research subject privacy for African-Americans suffering from Kawasaki Disease, a project to improve research literacy among Hispanic/Latino populations and a study to determine which methods are most effective for securing informed consent for biospecimen collection and data sharing among low-income, uninsured and underinsured women.



Director Lucila Ohno-Machado

iDASH Director Lucila Ohno-Machado says that ensuring patients and research subjects trust and understand how data for research are acquired, stored and distributed is crucial, especially as trials and studies increasingly involve minority populations and international collaborations.

“We believe, by giving patients choices and allowing them to know what’s happening to their data and what they are consenting for, we would have a much greater uptake in participation in research,” she adds. “The

concerns patients and research subjects have about privacy are not yet countered by a large demonstration that the use of that data can benefit health and healthcare. These DBPs are one step toward demonstrating that.”

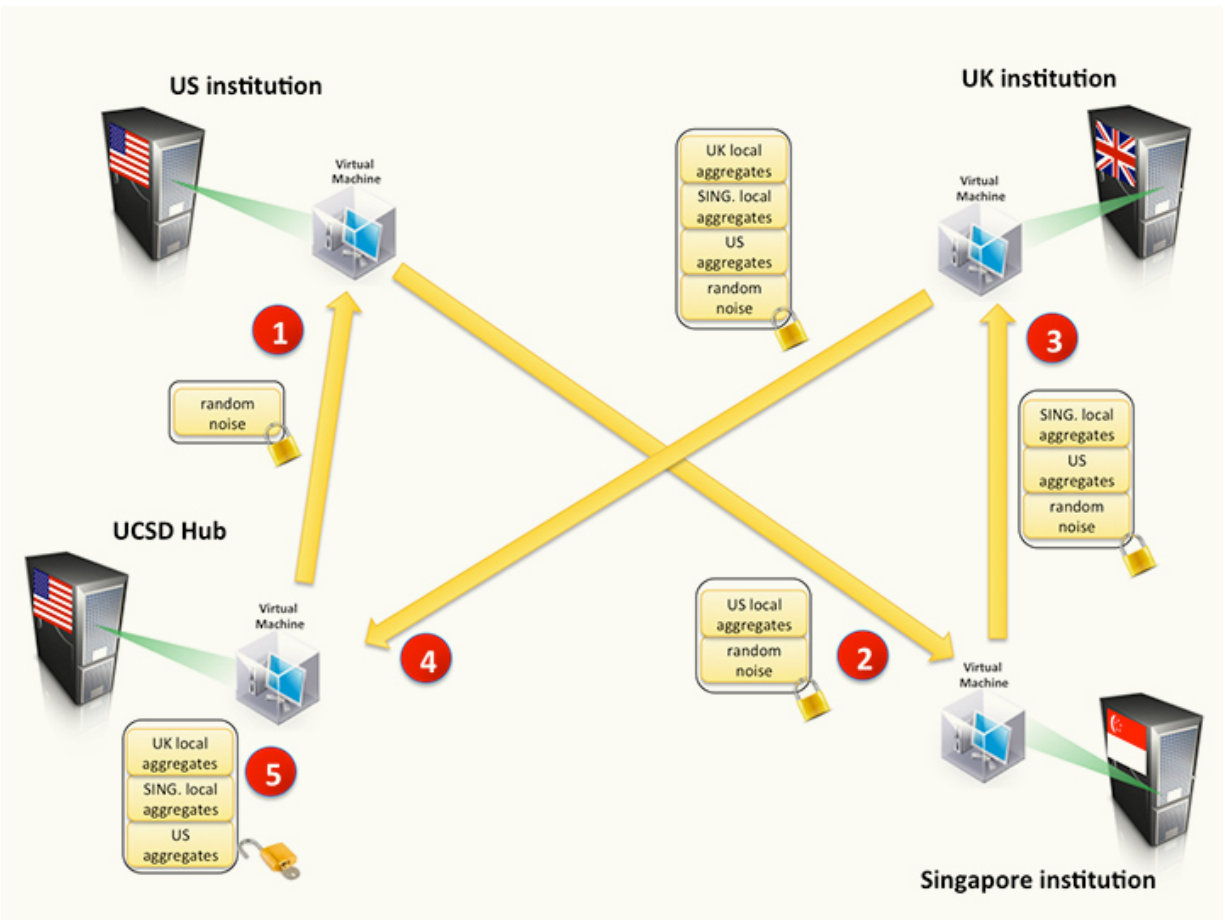
The current DBPs were selected based on their alignment with both the goals of iDASH and the mission of the National Institutes for Health, which established iDASH in 2010 as a National Center for Biomedical Computing.

In addition to the pro-social goals of providing greater access to and understanding of healthcare and health research, the three DBPs will also drive advances in computing. In the case of the researchers studying Kawasaki Disease in African Americans, the team will develop a set of open-source, privacy-preserving computer algorithms that will make it possible to compare genotype data from U.S. children of African-American descent without revealing the identity of those patients.

“At first, nobody thought you could identify someone by knowing a lot about their genome because it was so complicated,” explains Dr. Jane Burns, a professor of Pediatrics in the UC San Diego School of Medicine, director of the UCSD Kawasaki Disease Research Center and the principal investigator on the project. “Now we can I.D. people just through their SNP data” or single nucleotide polymorphisms. “Genetic data is now coming under all the privacy scrutiny being applied to someone’s name or birthdate or street address.”

Compounding that problem are the disparate policies around the world for regulating data privacy. Kawasaki Disease is so rare that obtaining any significant genetic sample size requires international collaboration, but the data-sharing standards in Western Europe and parts of Asia are more stringent than those in the United States. This means that U.S. researchers are often restricted from accessing or sharing the control data they need to analyze, for example, why certain African-American children are more susceptible to Kawasaki Disease.

To bypass this problem, Jihoon Kim, a senior statistician for the UCSD Division of Biomedical Informatics, is leading a team of computer scientists at UCSD to develop a set of algorithms that ensure researchers can query and derive information from genetic data without compromising the privacy of the patients. These algorithms will allow Burns’ team at UCSD to gain access to data samples from French Afro-Caribbeans and Africans (which are currently stored at research facilities in Singapore and London). They will then compare those samples to samples from African-Americans.



“Not only will the tool allows us to aggregate the data without looking at individual-level sequences, it will also be made available to researchers working on other rare diseases for the NIH,” Burns added. “With this tool, we’re addressing privacy, but we’re also addressing an unmet need in an often ignored and overlooked population that has an important risk factor for a disease that needs to be better understood.”

Another frequently overlooked population — Hispanics and Latinos — are often erroneously perceived by researchers as being reluctant to share data and biospecimens. This is significant because Hispanics/Latinos now make up the largest racial/ethnic population in the United States. Furthermore, a number of health conditions — from diabetes to heart disease — are becoming increasingly prevalent in these communities, and it is important that the Hispanic/Latino population be included in large studies involving genetic data.

Greg Talavera, professor of Health Promotion and Behavioral Sciences in the Graduate School of Public Health at San Diego State University, leads a second DBP. Talavera and his team will use a variety of methods to explore cultural and language factors that influence the informed consent process. The end goal is to develop a suite of strategies for increasing patient understanding of the consent forms and increasing Hispanic/Latino engagement in research.

The project will also develop tools for secure data storage, ensuring privacy and analyzing datasets via collaboration between iDASH, the Clinical and Translational Research Institute, and the School of Medicine.

“It’s important to confirm that patients fully understand what they are signing up to, and to identify gaps in their knowledge so we can design better consent instruments,” said Ohno-Machado.

The third iDASH project, which is being led by Elena Martinez, a professor of Family and Preventive Medicine at UC San Diego, is a pilot study to compare two methods for obtaining informed consent for biospecimen collection at an oncology clinic in Phoenix, Arizona that typically serves patients from underserved communities. The researchers will examine whether there is a measurable difference in obtaining consent from patients when the consent process is explained by a research assistant vs. a physician. They will also determine whether consent is affected by age, race/ethnicity, health literacy, cancer risk perception, language use, insurance coverage, and breast cancer vs. non-cancer diagnosis.

“The larger research goal is to ensure that the biospecimens that we have available are representative of the entire population of the United States,” says Martinez. She adds that many minority populations have been historically reluctant to share their data with researchers because of privacy abuses and other infractions suffered by individuals such as Henrietta Lacks, those affected by the Tuskegee Syphilis Experiments and some Native American communities.

“There are very valid reasons why some individuals might be reluctant to give consent to share their specimens, but we also believe it’s a myth to assume that all minority populations feel the same way,” says Martinez. “What we’ve seen in the literature is that there is no similar example of reluctance in Hispanic/Latino populations, for example.”

But even when individuals are willing to share biospecimens (in the case of the iDASH project, saliva and breast tumor tissue samples) researchers lack a ‘best practice’ for obtaining consent, from recruiting patients from heterogeneous populations to overcoming language barriers and clarifying medical jargon.

“Health literacy affects a lot of people, not just undereducated people,” notes Martinez. “A patient who is new to the clinical process is like me as a research professor trying to understand legal jargon. And the language barrier is significant. There are medical institutions

in San Diego, some very prominent, where a health care provider has to call a number and wait for that person to get a translator on the phone in order to go through the consent process. You can imagine how complicated that is. The physicians aren't comfortable with that.

“We have to figure out a way to make individuals aware of what they are consenting to in a language and culturally appropriate process, either in writing or by using technology.”

One of the technologies the iDASH team plans to experiment with is a video for the iPad that will be shown to the participants prior to obtaining informed consent from a research assistant or the physician. If the video is effective as a means for informing subjects about consent, then it can be adapted for use in other NIH research studies, as well as further studies in cancer prevention.

Says Martinez: “It's important that whatever successes we have in the future in cancer prevention and cancer treatment, that these benefit all members of the population, not just those in higher socioeconomic classes. But in order to do that, it's important that we have research participation from all segments of society.”

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