



Q&A: Kathy Hudson

Precision medicine goes megascale

The US Precision Medicine Initiative (PMI) aims to gather health data on at least one million volunteers. Kathy Hudson, deputy director for science, outreach and policy at the US National Institutes of Health (NIH), led its creation, and spoke to Nature about the challenges she faced.

What does the Precision Medicine Initiative need with one million volunteers?

The mission is to create the knowledge, policies, infrastructure and culture to enable more targeted therapies and prevention to keep people healthy. This is the biggest ever longitudinal cohort research programme in the United States. It will create an astonishingly rich array of data that can be used to address issues in health and disease that have dogged us forever, especially in the area of health disparities.

What have you learned from the huge cohort programmes in recent years, such as the Million Veteran Program and the UK Biobank?

You need to start with a small, coherent data set that is defined ahead of time. You don't want to collect everything that everybody might find valuable. Over time, the data set can expand as the infrastructure becomes available.

All the components of the programme must work together. The criteria for picking our partners are not just about how excellent they are, but about how well they will work with the rest of the team. That has not been the case in some previous efforts.

We've also ensured that data are rapidly and widely available. We are creating an awesome data set and need an infrastructure that incentivizes research uses of those data. That has to be in our minds as we build it. And data sharing isn't just between researchers, but also with participants. That makes the PMI unique.

Will participants play an active part in the PMI?

We are co-designing this programme with prospective participants. We have folk on the working group who are participant representatives, and we've included them in all of the levels of governance.

Participants will also decide who can access their information. If someone wants to share his or her data with their health-care provider, or wants us to do that, we will set it up. Access to information will not be mediated by health-care providers, as has been normal practice.

Recruiting volunteers for clinical studies is difficult. How do you plan to do it?

There are two ways that volunteers can come to the cohort programme. One is through health-care providers. These partners will

make information about the programme available to the people they serve, and they will be responsible for doing the initial health exam and collecting the biological specimens. That approach is familiar for the NIH.

When President Obama announced the PMI he said he wanted it to be widely available. That's why we created the direct volunteer concept, so anybody, anywhere can raise their hand to participate. We want to make sure we include everybody, not just the tech-savvy, fitness-conscious middle-aged or young folk.

What new issues does that raise for trials?

How do you engage people? How do you collect their information? How do you stay in contact with them? How do we make information about the programme available to people who don't have Internet access? And how do we get to people on the lower end of the socio-economic ladder, who are underrepresented in biomedical research and are generally in poorer health? We haven't ever undertaken citizen science at this scale before, so it is a challenge to design the system so it is open, inviting and rewarding for everybody.

Are you also grappling with questions raised by incorporating data gathered by patients?

Yes. The new PMI Participant Technologies Center will make sense of data from wearables, sensors and detectors. The device I'm wearing on my wrist tells me how many steps I take per day, but actually the raw data it generates could give us a lot more insight. Integrating these kinds of data and new technologies is an exciting part of the cohort programme.

How will you maintain trust between all players, especially the volunteers?

We need to make sure that our decisions about what data to collect, how to protect it, how to share it, and what we will learn from it are all informed by participant voices. We have to be super-transparent, so any participant, prospective participant or member of the public can know what we're doing. We also need to be sure that the science we do will enrich our relationship with participants and not erode it.

And we need to keep our promises. That means honouring our commitments to involve participants at all stages and to do everything we can to protect the privacy and security of the information we collect. There are no perfect systems, and we live in a dangerous world, but we'll do everything we can to protect the privacy of the people we are working with.

What do you worry about late at night?

Privacy and security issues! I also worry about the pace, as we are doing this at an unprecedented speed. We need to make sure we move fast, but that we do things right.

INTERVIEW BY ERIC BENDER

This interview has been edited for length and clarity.