Choosing a Path That Puts Patients at the Center

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Mobile health technology can choose from two paths: one that treats participants as customers, and the other that enables a patient-centered health approach.

As more and more medical devices integrate sensors and networking, it will be possible to develop very powerful models of illness and disease, sweeping away old taxonomies of disease based on centuries-old narrative descriptions of symptoms. New taxonomies will emerge based on objective features (i.e., genotype, voice, gait, balance) that will be collected in machine-readable formats from the integration of molecular/omics data with the extensive data flowing in from smartphones and sensors.

This isn't hypothetical. At Sage Bionetworks, we've developed a novel smartphone-based clinical study focused on symptoms of Parkinson's disease (PD) called "mPower." After its first six months, the mPower study includes more than 1,500 participants with PD and nearly 9,000 participants without PD, drawn from all 50 states without any traditional advertising or recruitment.

The study consists of survey questions (taken from instruments commonly used in PD studies and clinical management), novel daily and weekly activities that leverage the sensors on the smartphone to measure the performance of the participant on structured tasks, and finally the ability to collect "passive" information like the number of steps taken with the phone, or how far the person moves within a given day.

Based on the first six months, our frequent and dense sensor-based approach allows for remarkable new analyses of the impact that

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interventions and lifestyle have on symptoms as measured by the sensors on the phone in a personalized approach. For example, where most patients with PD may have data gathered once or twice by their neurologist during the trial period, we gathered an average of nearly 500,000 observations per individual in that same period.

For those patients who have provided the most data (usually performing tasks multiple times a day, before and after symptom-modulating drugs), we have developed preliminary "personalized classifiers" of the impact

medications have that are based on the performance on a set of simple tasks. Whereas a neurologist may only be able to observe the number of times a patient can tap on a table in 20 seconds (speeded tapping), the sensors in the smartphone measure the same performance at orders of magnitude with more detail and resolution. A simple example: sensors capture both what the clinician knows (that L-dopa can increase tapping speed in some individuals) and what the clinician cannot know (that L-dopa can increase tapping accuracy in some individuals).

Recognizing that PD is a complex disease with each individual having a different constellation of symptoms, the sum of these features over time may provide a finer description of the manifestation of disease for an individual, both in the dimensions of an activity as well as in the fluctuations over time, than has ever been possible. Think of the impact of engaging patients in their own diseases and tracking not just symptoms but also modulators.

But this vision for participants and medical research has two potential paths.

On one, we simply allow this new system of taxonomy and intervention to emerge without intervention. Private pharmaceutical and technology companies that are driven by profit will stay focused on major diseases, silo the data, and monetize it as therapeutic guidance or by selling restricted data access. Health payers are driven by reimbursement: they need phenotypic data to help them determine who should/should not be reimbursed. This do-nothing path virtually guarantees that digital clinical studies will resemble our consumer culture—one where privacy and individual autonomy are lost, and almost impossible to engineer back into a roaring economic engine. It is a world where we are customers first and citizens second.

On the other path to reach this new solution we adopt the same technologies, but re-orient the roles of the stakeholders to place individuals in the center, as citizens. This role change, combined with data gathering and analysis platforms, could enable a participant-centered health approach rather than a customer-centric one. In our vision, the mobile health clinical studies leverage smartphones as well, but they are both open and participant-centered. On this path, people get back the data they need in real time to make informed decisions for themselves, and they reclaim their voices and sense of empowerment about managing their own health rather than continuing to assume that their health depends exclusively upon some medication or therapy. On this path, data analysis isn't restricted to the study investigator or who buys access, but can be mediated through collaborations, challenges, and open access to allow for unexpected lead-user innovation and, even more importantly, the transparency that will allow scientific scrutiny and reproducibility. And our vision of openness is one that encourages innovation, profit, and growth for the private sector.