Precision Medicine Sparks New Conversations about Patient Data

Patient data is at the heart of precision medicine, but privacy concerns and unanticipated use cases could cause problems for large-scale research efforts.

By Jennifer Bresnick

April 19, 2016 - The Precision Medicine Initiative (PMI) is generating a great deal of excitement among researchers, clinicians, developers, and patients with an eye on curing cancer, managing diabetes, or eliminating Alzheimer's disease.

With unfeigned enthusiasm from the current administration and wholehearted commitment from top federal agencies reveling in the promise of steady funding for research and development, **the Precision Medicine Initiative** holds the promise of unlocking a new world of tailored, personalized care.

But with opportunity comes responsibility, says Gerard Nussbaum, Director of Technology Services at management consulting firm Kurt Salmon, especially when patients are entrusting their most personal data to research organizations and potentially breachable data banks.

Understanding the nation's changing attitudes towards consent and data sharing – and developing regulations that are both firm and flexible to meet future challenges – will be essential if the healthcare industry is to continue building the foundations of a system that can truly harness what precision medicine has to offer.

Just getting to the point of turning the PMI into a national effort has taken years of difficult, anonymous, and often under-funded work, Nussbaum told *HealthITAnalytics.com*.

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"The concerted focus on establishing funding at the federal level and organizing large cohorts of participants certainly gets people's attention," he said. "A lot of people might think that these breakthroughs are like Athena leaping from the head of Zeus fully formed, but all of this progress is really just a continuation of things that have been happening in medicine and clinical research for a long time."

While many these efforts have resulted in important new discoveries that have saved countless lives, the fragmented nature of the research community has also produced problems that may be familiar to any EHR user: the slow build-up of sub-optimal practices that collect into insurmountable roadblocks.

One of these problems is the growing disconnect between current patient privacy regulations like HIPAA and the **quickly evolving opinions of the public**, which is now used to splashing their secrets across the internet.

As smartphones, wearables, and mHealth apps change consumer attitudes towards when and where it is appropriate to share personal information, existing legislation may soon appear to be an antiquated relic of a pre-internet society, where social media didn't exist and the genetic testing was too time-consuming and expensive for the average patient to think about.

But thanks to **next-generation genomic sequencing techniques** that have started to bring DNA testing into mainstream clinical care, the conversation over the data typically collected for precision medicine efforts has to become significantly more nuanced.

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"When we talk about **HIPAA and protected health information** in terms of research, we're talking about deidentification," said Nussbaum. "If you obscure these pieces of information or take the elements out of the data set, it no longer qualifies as protected health information, and some of the restrictions under HIPAA don't apply, right?"

For traditional research or population health management, that may be true, he said. But introducing genomics into the equation fundamentally changes the nature of the game.

"A person's genetic profile is unique, and ultimately, you can match it back to one person whether or not their name and address are included in the file. So can we really deidentify this data?"

The questions about patient privacy and consent don't end there. Innovation happens much faster than regulation, and even the most well-intentioned lawmakers cannot predict the future.

Rules that attempt to govern the usage and distribution of patient information for precision medicine must be stringent enough to prevent violations of current standards, but open-ended enough to cover situations that may not even enter the imaginations of this generation of stakeholders.

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"What we can do today in terms of using genetic information is a small subset of what we're going to be able to do in five or ten years," explained Nussbaum.

"GINA, the Genetic Information Non-Disclosure Act, has all sorts of prohibitions that say you can't use genetic data in insurance situations or in employment decisions. When they passed the law, those uses were more of a theoretical possibility than a reality. But look how quickly that has changed."

Precision medicine researchers also run into problems when it comes to reusing patient data for additional projects. Patients may not always be aware of how their information will be used in the future - nor do they always have control over where their data might end up.

Patients volunteering for the Kaiser Permanente Research Bank, for example, are warned in the fine print of the consent documents that their deidentified information could land in the hands of the National Institutes of Health, and may be used again and again by the wider community of medical researchers in ways that did not explicitly receive their consent.

"Studies that use samples from the KP Research Bank may receive grants from the government through the National Institutes of Health (NIH) and other agencies," the consent document explains.

"The federal government requires that research information including genetic information that was paid for by American tax payers to be shared with other scientists. Scientists can use this information to learn even more about health and disease."

Patients may not ever know where their contributed information will travel during secondary or tertiary uses of their data. That may not bother some volunteers, but could be a disturbing concept for others.

"The Precision Medicine Initiative provides a focal point for having discussions about patient privacy, data collection, and data usage in more concrete manner, because the PMI has backing at the federal level," Nussbaum said. "It is vitally important to talk about what is permitted – not just legally, but in terms of societal acceptance."

While the instant gratification of securing a friend's "likes" on a health-related update may be encouraging consumers to share their personal information through every available medium, data collection for the PMI will still be **a formalized affair**.

The NIH and other entities overseeing data aggregation projects are hoping that provider organizations will become major partners for patient recruitment.

Clinicians might be in the perfect position to collect a little extra blood during a routine physical or add a quick cheek swab to a wellness visit, but physicians may not

feel as if they have the time, expertise, or interest required to educate patients about the PMI Cohort or address the serious consent issues involved in participating.

"We can't seek to turn our physicians – especially in primary care – into the experts on this," Nussbaum said, because they have far too much on their plates already. Physicians will likely balk at the idea of add extra steps to the workflow for the benefit of third-party researchers, especially since there is currently no reimbursement mechanism for completing those processes.

"In healthcare, one of the key issues we look at is helping people to work to the maximum scope of their license," said Nussbaum. "We want start taking some of these tasks away from physicians so they can focus on what each provider to trained best to do."

Instead of having the physician add five or ten minutes to their appointments by explaining what the PMI is and why their patient may want to participate, "maybe what we should have is a patient educator to talk about these issues," he suggested.

"The bulk of the information delivery could be conducted by a very knowledgeable clinical educator, not the physician. That doesn't mean the physician is not responsible for understanding it. It just means she is not the one taking the extra time to introduce these concepts."

Professional societies, specialists, and patient advocacy groups are also likely to take a starring role in patient education and encouragement, he added. When data collection efforts are focused around a particular condition or disease, they can be highly successful.

"We have gathered some of our best research data from patients and families who have a vested interest in a disease," said Nussbaum. "They are willing to cooperate because there's a sense of participation and bettering the lives of someone they care about."

"We shouldn't forget that these organizations have done a lot of the work when it comes to figuring out how to recruit patients and keep them in the loop by giving them the updates they want at a consumer-friendly level."

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