Study Finds Docs Could Face Greater Malpractice Risk in Personalized Rx Era

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Increasing public awareness of personalized medicine, coupled with shifting trends in medical malpractice case law, has made healthcare providers increasingly vulnerable to liability related to genetic testing, research by Arizona State University has found.

Gary Marchant, director of ASU's Center for Law, Science & Innovation, and Rachel Lindor, a scholar at the center, recently identified more than 50 cases in the Westlaw database in which patients sued their doctors or other health professionals for negligence in recommending, conducting, or reporting results from genetic tests. In these cases, physicians were held liable for a range of claims, such as not taking an adequate family history; failing to recommend the right kind of testing; not referring the patient for genetic counseling; interpreting a test result incorrectly or in an untimely fashion; not recommending the right risk-mitigation strategies; and failing to disclose test results to family members who may be at risk for a hereditary illness.

"Though drug manufacturers, hospitals, and pharmacists have all been the subject of lawsuits related to genetic technologies, physicians appear to be the most vulnerable group. Courts are willing to require the use and understanding of genetic information even before the medical community itself is ready and able to do so," Marchant and Lindor wrote in an abstract presented during a poster session at the American Society of Clinical Oncology's annual meeting this month.

The study's results will be published in more detail in the July issue of Personalized Medicine.

As more genomically guided medicines come to market, "we have two of the triggers of liability: rapid technology change and huge uncertainty," Marchant told PGx Reporter.

Although there have been relatively few lawsuits so far decided against physicians related to personalized medicine, Marchant believes that the combination of rapid advancements in the genomics field, consumers' growing expectations about the positive impact of genetic testing, and changes in the litigation landscape could bring an onslaught of expensive malpractice lawsuits against physicians in coming years.

Changing Legal Landscape

While most doctors still lack adequate training to make healthcare decisions based on genetic tests, an increasing number of their patients are likely to inquire about genetic testing or ask them to interpret results from genome scans purchased online. This gap between advancing science and physicians' knowledge can be legally troublesome for

healthcare providers, particularly since the liability landscape is also shifting in terms of what evidence juries will consider in medical malpractice cases.

A plaintiff suing a doctor for malpractice must show that the physician failed to provide care, which resulted in injury. Generally in such cases, the plaintiff's lawyers must prove that the doctor took action that was not in line with the customary practices of other healthcare providers in the local region.

According to Marchant, however, this locality standard is changing. As a result, in several malpractice cases doctors have been judged against what physicians are doing around the country. Similarly, juries appear to be increasingly deciding cases by the so-called "reasonable person" standard, where instead of considering customary physician practices, members of the jury evaluate whether a doctor's actions were in line with what a reasonable person under the same circumstances would have done.

These trends are particularly significant when it comes to personalized healthcare, since some major hospitals, universities, and research centers around the country — MD Anderson Cancer Center, Massachusetts General Hospital, Mayo Clinic, Scripps Green Hospital, to name a few —have already incorporated genomics into patient care. However, general practitioners outside of these centers are unlikely to have the resources or the expertise to appropriately incorporate genomic information into their practices.

Given the increasing application of the "reasonableness person"

criteria and judgments based on a national standard, the onus is increasingly falling on healthcare providers to demonstrate some level of familiarity with genetic testing options when they are available.

As an example, a doctor would no longer be able to take the defense that he didn't conduct genetic testing to discern a patient's sensitivity to warfarin because he has been using the international normalized ratio for many years.

The FDA has updated the label for warfarin to recommend that doctors use genetic testing to guide dosing decisions. However, the FDA-cleared label does not require doctors to conduct such testing, which compounds uncertainty in an area of medical practice where scientific evidence isn't yet conclusive as to when warfarin sensitivity testing is clinically useful (PGx Reporter 02/03/2010).

"The key thing for the doctor is to be aware of what the status is for these things. The worst thing would be to be deposed and say, 'No, I was not aware that the FDA changed the label for warfarin," Marchant said. "They need to be aware of it and talk with the patient about it.

They also need to document why they didn't recommend a genetic test. For instance, maybe they needed to start the patient [on the drug] immediately and couldn't have gotten the test results in time."

Also working against doctors is the fact that expert guidelines aren't binding in court. As such, a doctor wouldn't necessarily win a malpractice suit by arguing that he didn't offer

genetic testing to a patient because he or she didn't fit the profile of someone who should receive such testing according to professional guidelines.

In the case of BRCA 1 and BRCA 2 testing for gauging the hereditary risk of breast and ovarian cancer, patient groups, professional societies, and government bodies have issued guidelines recommending against using Myriad's BRACAnalysis test as a screening tool, and only testing those patients whose medical and family history suggest they are at heightened risk for these diseases.

Furthermore, unnecessary genetic testing can increase healthcare costs, and as such many insurers are developing mandatory genetic counseling and preauthorization schemes to ensure that only those patients who meet treatment guidelines are being tested. However, the fact that an insurer won't cover testing is not a viable defense for a doctor, Marchant noted.

In 2008, Sandra Downey sued her surgeon, Gary Dunnington, in an Illinois appellate court, alleging that he failed to recommend genetic testing for BRCA 1/2 mutations, and she underwent prophylactic surgery without the aid of this information. In this case, the jury ruled in favor of the defendant, finding that the doctor had recommended testing, but the patient had chosen not to get tested or counseled because she could not afford it. BRCA testing with Myriad's BRACAnalysis test can cost upwards of \$3,000.

Although the jury ruled on the side of the doctor, Downey v.

Dunnington established that cost concerns barring genetic testing cannot be a physician's defense for recommending against such an intervention if it is medically warranted. The best defense for a doctor in such cases, according to Marchant, is to offer the test as an option to the patient with the caveat that the test is expensive and may not be covered by insurance.

Rising Patient Expectations

The ASU study found that plaintiffs are also bringing new types of charges that fall outside of doctors' established defenses. For example, a patient could sue a doctor claiming violation of informed consent requirements because the physician failed to disclose relevant genetic information that could have influenced his or her treatment choices. According to Marchant, courts are taking a "patient-centric" approach in this regard by giving more weight to what a "reasonable patient" might consider important information in making healthcare decisions, over what a reasonable physician might consider in making a medical diagnosis.

However, the information that patients may consider to be important in making decisions about their healthcare can certainly be influenced by industry marketing. In line with the "take charge of your own health"

movement in healthcare, DTC genomics firms are marketing gene scans online that gauge predisposition to hundreds of diseases and response to prescription drugs, such as warfarin and the anti-platelet drug Plavix.

No malpractice suits have resulted yet from a doctor failing to act on test results that a patient bought from a consumer genomics firm.

However, direct-to-consumer marketing of genetic tests can increase patients' expectations that such interventions will have a positive impact on their health, even though consumer genetics firms themselves acknowledge that the reports sold to customers contain data based on preliminary research.

Marchant believes that the growing prevalence of consumer genomics companies, such as 23andMe and Decode Genetics' DecodeMe service, can be a liability risk for the companies as well as physicians. He described a hypothetical situation in which a woman receives her 23andMe results and finds out that she doesn't have the BRCA mutations linked to breast and ovarian cancer risk for which the company tests. Based on these results, she chooses to not keep up with mammograms and regular checkups, but down the line it turns out that she did have rarer BRCA mutations that are not included in the test and she does get breast cancer.

"There have been no cases like this, but if it happens then it will be interesting to see where the blame lands" — with the doctor or with the consumer genetics firm, Marchant reflected. Although consumer genetics firms require customers to agree to terms that state that the genetic information provided through their services is for research use and not for medical decision making, it remains to be seen if those waivers will hold up in court.

Meanwhile, Marchant noted, the doctor can also get into trouble if, for example, a patient brings in a 23andMe result showing that he isn't likely to respond to a drug, such as Plavix, but the doctor doesn't follow that information and then gives the patient the drug, which results in adverse reactions. When judged by the "reasonable person" standard, the doctor may be hard pressed to find a defense in such a case.

"These cases are litigated after a patient has had a bad result and things look a lot different ... at that point than when the doctor made his decision," Marchant said. "A judgment of reasonableness [being determined] by the jury after the fact could potentially include a lot of inherent biases ... that are really subjective inputs. It does raise real risk in this area where we already have so much uncertainty."

Increasing Duties

The incorporation of genetic information into medical practice also stands to add new ethical duties to the physician's already long list of responsibilities by keeping not only patients informed, but also their families.

Decisions in recent cases have challenged the notion that a physician's duty to care is limited to his or her patient. In Safer v.

Pack, for example, plaintiff Donna Safer sued the estate of her father's physician, George Pack, with whom she had no physician-patient relationship. Decades earlier, Pack had treated Safer's father, Robert Batkin, for a hereditary form of colon cancer, but had kept

the cause of Batkin's illness from the family at the patient's request. When Safer was diagnosed with colon cancer decades later at the age of 36, she obtained her father's medical records, which showed that she had the same type of hereditary colon cancer.

In the late 1990s, Safer filed suit against the estate of Pack, who had passed away in 1969, alleging that Pack had a duty to warn her family that Batkin had a hereditary form of colon cancer and that this could heighten her risk for the disease. A trial court in New Jersey found in favor of Pack, holding that a physician-patient relationship must be present for a doctor to have a duty to warn. However, Safer appealed, and the appellate division of the New Jersey Superior Court reversed the lower court's decision, holding that a physician still had a duty to warn relatives with whom there was no physician-patient relationship.

This case could set a critical precedent for physicians as the rapidly dropping cost of whole-genome sequencing makes it a much more accessible tool for use in research and in patient care. While whole-genome sequencing promises to yield critical insights into a person's health, it will also return incidental findings that the patient doesn't wish to know or that might have healthcare implications for the patient's family.

Several research groups are examining this issue. For example, as part of a study using whole-genome sequencing to investigate the genomic underpinnings of pediatric brain cancers, Canadian researchers are considering the methodology by which they can report medically significant genomic data to patients and their families.

Conrad Fernandez of Dalhousie University, who is in charge of handling the ethical aspects of the study, told PGx Reporter that the project will surely uncover gene associations that are associated with other diseases, and researchers are in the process of figuring out how this information will be reported to patients and families.

"The plan is to provide all significant results through a genetic counselor or clinician," Fernandez said, adding that the researchers will defer to the advice of their scientific advisory board when the decision to report is not clear, as recommended by the National Heart, Lung and Blood Institute's guidelines for reporting genetic research data to study subjects. Published last December, the guidelines recommend that researchers create an advisory body to guide data reporting decisions and engage community members about how to share significant genetic risk information that could impact a large group of people.

Similarly, the American College of Medical Genetics' Social, Ethical, and Legal Issues Committee is developing guidance on how researchers and doctors should categorize data emerging from whole-genome sequencing. "We begin with the presumption that only clinically valid information is to be returned, and then focus on the types of information that will become available," ACMG told PGx Reporter in a statement.

ACMG acknowledged that there is agreement among experts that for pediatric patients, physicians have a duty to report actionable genetic information. But it is still unclear

when and how to report information that may not be actionable, as well as medically actionable genomic data that individuals may not need to know until they are adults.

In an effort to protect themselves against liability from patients' family members while protecting patient confidentiality agreements, some doctors are providing patients with a letter for their family members with information about potential genetic risks and how to get medical assistance. "This takes the provider out of the position of having to violate patient privacy by going directly to family members," ACMG said in the statement. "However, providers will still face the dilemma of having to override a request from a patient to keep their genetic information private from their family members when the information may suggest significant risks to them."

Doctors' Defense?

In an environment of rapid medical advancements and legal uncertainties, there are few surefire defenses for practicing physicians.

Drug and diagnostics developers are partially protected against litigation from patients who experience adverse reactions from their products if the label lists the risks associated with the interventions, but doctors don't have similar defenses. FDA labeling for personalized medicine products is often limited to a recommendation for genetic testing, leaving it largely up to the doctor's discretion as to which patients should be tested.

Although expert guidelines currently aren't binding in medical malpractice suits, President Barack Obama has indicated he would support proposals that would limit liability for physicians who follow clinical practice guidelines.

"While I'm not advocating caps on malpractice awards which I believe can be unfair to people who've been wrongfully harmed, I do think we need to explore a range of ideas about how to put patient safety first, let doctors focus on practicing medicine, and encourage broader use of evidence-based guidelines," Obama said in a speech before the American Medical Association in 2009, addressing how malpractice reform can help abate the rising healthcare costs resulting from litigation-averse doctors ordering tests and treatments defensively.

"That's how we can scale back the excessive defensive medicine reinforcing our current system of more treatment rather than better care."

This proposal, if it finds its way into legislation that is enacted into law, would "give the [application of] guidelines more legal clout, not only in a personalized medicine context, but more broadly,"

Marchant said. "But then the problem becomes, which guidelines do you follow?"

Predicting an explosion in medical malpractice lawsuits in coming years, Marchant recommends improving healthcare providers' genomics expertise. This knowledge gap has been recognized by the AMA, and several medical schools across the country have

announced courses that will allow doctors, nurses, and pharmacists to specialize in genomics and pharmacogenomics (PGx Reporter 02/09/2011).

For the time being, however, it seems the best defense for a doctor may be to keep up with genomics advances as best as possible and leave the ultimate decision on genetic testing up to the patient. "By explaining the facts to the patient the doctor can protect himself,"

Marchant said. "As long as the patient makes the decision, the doctor is going to be okay."