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Healthcare Providers Adjust to Anti-Information Blocking Regulation Impact on Patient Interactions

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NEW YORK – Doctors, particularly oncologists, are worried that the US government's anti-electronic health information blocking regulations that went into effect four months ago are disrupting their already overstretched schedules and interactions with patients.

The US Department of Health and Human Services' Office of the National Coordinator for Health Information Technology (ONC) last year finalized regulations implementing provisions of the 21st Century Cures Act, which sought to improve health IT interoperability and ease patients' ability to access their electronic health information without delay and at no cost. The Cures Act, the sprawling medical innovation bill that President Barack Obama signed into law in December 2016, specifically restricts certain "actors" — health technology developers, health information networks, and healthcare providers — from "information blocking," which the law defines broadly as any actions that "interfere with, prevent, or materially discourage" people's ability to access or exchange their electronic medical data.

In the final interoperability rule, the ONC said that health IT providers and doctors must provide certain types of electronic health information — clinic notes, lab results, imaging reports, and pathology reports — as soon as they are finalized to patients who request them. The ONC also outlined the exceptional circumstances in which healthcare systems could delay the release of medical data to patients, for example, to prevent harm. A doctor must decide based on a patient's specific circumstances that delaying release of electronic health information will mitigate harm. Moreover, healthcare organizations cannot implement blanket policies, for example, to delay the release of all abnormal pathology reports or all cancer genetic tests.

With these anti-information blocking provisions, drafters of the Cures Act aimed to remove barriers, such as excessive paperwork, long wait times, and high fees patients were encountering when trying to access their health data. Improving public visibility into the costs and outcomes of medical interventions would allow patients to comparison shop for care, they hoped.

"Consumers feel like there is no transparency in medicine," said Cori Feist, a genetic counselor at Oregon Health & Science University, who is involved in education and policymaking within the National Society of Genetic Counselors. The interoperability and information blocking provisions of the Cures Act are "all about transparency and ownership," she said. "It's not only about cutting down healthcare costs, but also about making patients more responsible for their own care."

Implementing legislators' vision, however, has proven more difficult. While most doctors and other healthcare professionals, hospital administrators, and labs agree that individuals should have easy access to their own medical data, deficiencies in the current health IT infrastructure, existing institutional policies around the release of medical data, longstanding expectations regarding the doctor-patient relationship, and a global pandemic has challenged stakeholders' compliance efforts.

Moreover, ONC's regulations, which went into effect in April, are new, complex, and yet untested. Due to relatively limited awareness of the latest regulations in the general population, ONC hasn't adjudicated a complaint against a healthcare provider for information blocking, and as such there are no real-world examples of when a provider could face "disincentives," which the agency has also not yet defined, for delaying or limiting a patient's access to their medical data.

Although compliance practices somewhat vary among healthcare institutions, in response to the new regulations, many medical centers are sharing lab results, including genetic test results, clinic notes, and pathology reports as soon as they are finalized with patients who have signed up to receive information in their electronic health record (EHR) through online portals. Previously, it wasn't uncommon for institutions to automatically delay all lab reports by a few days to give doctors time to discuss results with patients or release just normal reports to patients through online portals but delay release of abnormal findings.

But since ONC's final rule went into effect restricting such blanket policies to delay release of electronic health information, some doctors are already noticing that more patients are seeing abnormal lab and pathology reports, before they've had a chance to call and discuss the findings. When Justin Maykel, chief of colorectal surgery at UMass Memorial Health Care, recently called a patient to deliver a cancer diagnosis, the patient already knew, having seen it in the online portal.

"I understand the patient's perspective," he said. "These are their bodies. They have full rights to access the results. They own those results. I'm 100 percent on board with that." Still, the experience made Maykel worry that more of his patients would receive a life-changing diagnosis alone at home because of the new regulations.

"This is not about gatekeeping or God complexes," Maykel said. "It's about us [doctors] being allowed to perform our jobs and fulfill that doctor-patient relationship." In that relationship, which he described as a partnership, Maykel sees it as his responsibility to support patients through difficult diagnoses and help them understand the results of diagnostic workups, so together they can decide on a care plan.

Now, because of the data release policy changes at institutions due to the new regulations, doctors say they often don't have time to reach patients before they see it via electronic communication. To avoid patients learning of a cancer diagnosis or becoming anxious about test results, doctors say they are racing to reach patients.

Holly Pederson, director of medical breast services at Cleveland Clinic's breast center, is often so busy in the clinic that it's not uncommon for her to forgo meals and bathroom breaks. Despite seeing abnormal test results for patients in her in-box, she usually can't call them until the end of the day, even though she knows that these patients may see these results and become anxious. Pederson said she often gets messages from patients through the patient portal about abnormal results they've seen and she'll see that they are also reaching out to other providers wanting to discuss the results because they're scared.

Increasingly Pederson's interactions with patients are over questions they have about standard medical language in their medical record that is meant for other providers. For example, any time a lesion or mass is biopsied, the patient's record will note that it is "suspicious for malignancy," even if there is very little chance the mass is cancerous. For example, according to national mammographic

classifications, commonly patients can have anywhere between is a 2 percent to 95 percent chance of malignancy, but that wide variance is not clarified in the report. A conversation with their doctor may have made patients less anxious about that information, Pederson reflected.

"This is not resulting in patient autonomy and empowerment," if they don't understand the information they're seeing in their chart, she said. "It's resulting in anxiety ... and [creating] distance from their providers who, 98 percent of the time, really are trying to get back to patients quickly."

Over more than three decades of practicing medicine, it seems to Pederson that physician burnout is worse than ever. In her view, the latest information blocking rules aren't helping. She regularly works late into the night not only dealing with her usual duties, but also with an increasing volume of emails and calls from patients about information they've seen in their electronic record.

"If the aim [of the new regulations] is to improve transparency in healthcare, it doesn't achieve that," she said, expressing disappointment over the "negative language" in the Cures Act implying that physicians are deliberately blocking patients' access to their medical data in some way. "It damages the doctor-patient relationship by not giving doctors the ability to discuss abnormal results with patients first," she said.

Giving patients options

While doctors and healthcare systems are adjusting to the new regulations, Meagan Farmer, a genetic counselor at the University of Alabama at Birmingham (UAB), questioned whether these data access rules will really result in the kind of harm to patients that doctors fear. Since genetic counselors are often the ones conveying genetic test results to patients, sometimes Farmer is the bearer of bad news, and sometimes, she must deliver it to patients in the course of their busy lives.

"I call patients with bad news of a positive genetic test result, and they are standing in Wal-Mart," Farmer said. "I always ask, 'Is this a good time?' but they never say, 'No.' They want that information even if it's a terrible time. And then, I give them the bad news with them standing in Wal-Mart." Doctors, similarly, have to deliver all manner of sensitive medical information to patients, and these interactions don't always happen under ideal circumstances, she added.

Farmer is also genetic clinical operations director at My Gene Counsel, a health technology company that provides online education to prepare patients for genetic testing they're about to receive, and in the post-test setting provides reports to patients and to clinicians that explain and contextualize the results. On a recent visit to UAB's interdisciplinary breast cancer clinics, which have implemented My Gene Counsel's reports to support physician-initiated genetic testing, Farmer observed genetic counseling assistants as they informed patients that they could learn about their test results from My Gene Counsel reports online before they've had a chance to talk to their doctors or they could wait to access that online information if they'd rather hear about it from a healthcare provider first.

"Almost every patient said they prefer to learn about their results from patient portals before discussing it with a physician or nurse. They said reducing the wait time makes them less anxious and they feel more prepared to discuss when the call [from the doctor] comes," Farmer said. "We've been hearing this feedback on Twitter, but it was helpful to hear it firsthand."

Last month, when Maykel tweeted his reservations about the changes at UMass Memorial Health as a result of ONC's rule, some medical professionals shared similar concerns over patients learning of a cancer diagnosis or miscarriage via online portals without support. But many non-medical individuals pushed back, asserting their right to access their own data. Many bristled at the suggestion that they should have to wait to learn pertinent health information through a doctor, characterizing it as gatekeeping or medical paternalism.

While Maykel disagrees with the characterization of doctors as gatekeepers of their patients' medical information, he said he realized from this experience that the healthcare system needed to do a much better job of educating and preparing patients, before doing diagnostic workups, about the types of information they might see in their online records, that they might see this information before speaking to a doctor, and that the content may be upsetting. And if patients would rather receive this information through their doctors, they should also know not to look in their patient portals, he added. "We need to have each patient communicate to us how they want to receive results, and we need to honor that perspective and wish," Maykel said.

'Genetic exceptionalism'

Even though Beverly Hay, a clinical geneticist at UMass Memorial, does pre-test counseling with her patients to prepare them for the types of genetic test results they might receive, she worries particularly about patients who have variants of unknown significance (VUS) — a result indicating that it is unclear whether a detected genetic change increases the risk of a disease like cancer or is harmless — before she has had a chance to explain this to patients.

According to guidelines, doctors shouldn't make medical management decisions based on VUS, but such findings should be explained to patients in the context of their personal and family histories of cancer, which is difficult even for non-geneticist doctors, she said. Studies have shown, for example, that patients may agree to unnecessary preventive surgeries based on the recommendation of doctors lacking genetics expertise.

Such overtreatment may increase, some worry, if patients see test results in their records alone, misunderstand them, and get scared. "What's been hard is that there can often be a lag time of a couple days between when patients discover that [VUS] and when I can actually get back to them," Hay said. "And I feel so bad because I don't want them to be anxious or worried or misinterpret a VUS as [disease causing]." The field should consider different models for communicating this type of information to patients, she noted, so they're not worrying while waiting for their doctors to call.

While ONC was developing its regulations around information blocking, members of the lab community requested that the agency allow healthcare organizations to delay the release of lab results, in particular certain types of genetic test results, so doctors would have time to review the findings and answer questions "in a way that builds the clinician-patient relationship." Stakeholders pointed out that it was standard practice for many organizations to automatically delay the electronic release of certain lab results to patients to allow for this exchange.

But the ONC wasn't swayed and noted that under the law physicians would have to make a case-by-case decision to delay release of test results to prevent harm, or organizations could advance policies to delay patients' access to electronic health information when experts agreed or there was data demonstrating a risk that someone could physically hurt themselves or another person if they learned this information without appropriate support. For example, in the case of Huntington's disease, a degenerative brain condition caused by an inherited genetic mutation, there is a documented high rate of suicide among patients, and guidelines recommend that genetic testing should be provided with genetic counseling and psychological support.

Aside from such narrowly defined policy exceptions, the ONC said the healthcare community provided no evidence that routinely delaying the release of a broad category of lab tests to patients would necessarily reduce the risk of harm compared to if they had access to the reports as soon as they were finalized. The view held by some in the healthcare community that ONC should allow providers to delay the release of genetic test results to patients raises questions about genetic exceptionalism, said Farmer.

"Some feel we should treat all genetic information like it's special, but others question whether we should be treating it differently from other types of sensitive health information, for example, HIV test results," Farmer said. "Are we doing a disservice to people if we treat all genetic information like it's special and potentially block or delay access, rather than putting systems in place that responsibly support earlier access?" As institutions develop data access policies in line with the latest regulations and consider the benefits and risk of existing workflows, Farmer suggested they engage specialists in genetics.

In practice, when it comes to genetic tests, current health IT interoperability limitations are allowing doctors time to review results before releasing them to requesting patients. Allison Kurian, who, as the director of Stanford University's women's clinical cancer genetics program, manages women at high risk of developing breast and gynecological cancers, said that while she worries about her patients seeing pathology and radiology reports without the appropriate support because of the new regulations, she hasn't had the same concerns about cancer predisposition genetic testing that she orders from an outside commercial lab.

"Most electronic medical records have not done a very good job of seamlessly importing data from an outside laboratory in a way that is computable," Kurian said. "[The results] have to be scanned in as a PDF by a human being, but typically doesn't flow in a way that is seamless and computable."

Most providers in the US currently outsource genetic testing services. This is also the case at UMass Memorial, but when genetic test results are relayed to patients depends on whether a particular lab's reports are integrated directly into the hospital's EHR, or if the results are reported first into the lab's own portal and have to be manually put into the hospital's system.

When lab results are directly integrated into the EHR, they are released to the patient at the same time as the doctor, according to Hay. When the results are reported into the lab's portal and must be placed in the EHR, "we do have a little bit more time before the patient is notified," she said.

However, this deficiency in the way that most genetic test results currently live in the EHR doesn't comport with the vision of interoperability the drafters of the Cures Act had. Clearly, legislators hadn't anticipated this challenge, reflected Feist. "Right now, we have a little bit of time," she said. "But it's more of a logistical savior."

Genetic tests reports are among the types of lab results that providers must furnish electronically to patients upon request under ONC's final rule, and while labs are also subject to the law, they aren't required to create patient portals. As such, most commercial genetic testing labs are reporting results to doctors through their own lab portals and giving them the option to delay release of results to patients who haven't requested to see their electronic health information.

However, when patients request their test results from labs, they "should provide the result directly to the patient as soon as possible," according to Utah-based Myriad Genetics. Since ONC's final rule went into effect, Myriad, which provides tests for cancer risk assessment, prenatal tests, and companion diagnostics for personalizing cancer therapy, hasn't seen much of an increase in patients requesting their test results directly from the lab. According to Kim Linthicum, Myriad's senior VP of government affairs and public policy, patients mostly request their results from the lab when they haven't been able to get in touch with their doctors.

Outside of such requests, Myriad isn't changing its reporting practices as a result of ONC's rule and will continue to release test results to doctors first. Specifically, for prenatal genetic tests, the lab releases normal results to doctors and patients through a portal at the same time, but when there is a clinically significant finding, doctors have the option to delay results to patients by a few days or release them sooner if patients want.

Still, Myriad, which is undergoing a strategic restructuring and is planning to launch a polygenic risk score for breast cancer through a direct-to-consumer service next year, is considering online portals and other tools to better engage with patients and doctors. "We are going through this transformation and really thinking about how we better position ourselves as a personalized medicine company and harness and leverage the technology, data, and patient information we have in a timely, effective way," said Linthicum. "A lot of things are on the table."

Toward a consumer-centric future

Over the past decade, the genetic testing industry has increasingly been shifting toward the consumer market spurred by the popularity of ancestry and recreational genomic testing services. Labs undergoing this evolution, like Myriad, are carefully considering how to convey test results so both patients and physicians understand them.

"As we move toward a potentially different view in the future, our reports will have to look very different," said Susan Manley, senior VP of medical services at Myriad. "We're always talking and thinking about that and struggling to find the sweet spot for the information because it goes to both healthcare providers and patients."

OHSU's Feist expects that as more commercial labs engage directly with the consumer market, they will implement patient portals, as well as education and support services, to facilitate quicker access to genetic test results in line with the aims of the Cures Act. Then, if it's taking a while for their test results to be scanned into the EHR, "patients can just log into [the lab's] patient portal and can get their results that way," said Feist.

California-based Color pioneered a model where patients can initiate an online order for cancer predisposition genetic testing, which is then approved by a third-party physician network. While it may not be the patient's personal physician that is approving that order, and patients with actionable findings may not receive results through a physician at all, they're not learning they are at increased risk for cancer alone — they have to learn about it over the phone with a genetic counselor. "The idea that patients should get access to their results has always been built into the way we thought about our products," said Color CSO Alicia Zhou.

Cognizant of also keeping the doctor in the loop, the company offers to connect patients to medical providers in their area, share results with patients' own doctors, and Color's genetic counselors spend around 40 percent of their time talking to healthcare providers explaining patients' test results.

Although Color initially launched as a consumer-facing testing service, the majority of the company's genetic tests today are ordered by doctors and health systems. If doctors decide to interpret test results themselves, Color gives them the option to release test results to patients at the same time they receive it (if patients prefer) or delay release by a week or a month if physicians determine that a patient may be harmed by learning the results outside of a consultation.

Because of the healthcare community's initial trepidations about the potential for harm with Color's consumer-facing model when it launched in 2015, the company's founders put much thought into what types of test results to report and not report directly to patients and how to communicate findings responsibly. For example, the company doesn't report VUS results when tests are ordered by consumers, but it does report them if requested by physicians.

Moreover, because its test results were being delivered to consumers and could land on the desks of doctors without genetics expertise, the company also worked on the design of its test reports. Zhou recalled how 10 years ago, genetic test reports for cancer risk were just "alphabet soup" and strings of numbers describing a detected variant's position on the chromosome. But after putting its reports

through comprehension testing, the company reconsidered typical terminology used in the field, such as "genetic variant" or "mutation," that its non-expert customers had difficulty grasping.

The company decided to color-code reports red when there was an abnormal finding and green when there wasn't, recognizing what patients really needed was to understand that they have abnormal results but not necessarily the exact genetic variants, Zhou said. Color still includes the technical details for physicians later in the report, but she noted that doctors also appreciate a nicely designed report that flags the "take-home messages" in plain language up top.

"You can think of the report as an opportunity to really educate and inform the patient" about what the results mean in terms of treatment or further follow-up testing, she said. The recent anti-information blocking rules are "just going to cause genetic testing and diagnostic labs to have to put more thought into the report design process," Zhou added.

Reflecting on the concerns of oncologists who are worried about patients finding out sensitive medical information on their own, Farmer noted that at least in the genetic testing space, more healthcare providers are embracing automated, electronic education tools, such as the reports provided by My Gene Counsel, to better prepare patients for what they might see in the EHR. In situations where doctors aren't immediately available to discuss test results with patients, she suggested that tools like My Gene Counsel's reports can help provide preliminary education and context to ease patients' worries and be an educational resource, not just for doctors, but also nurses, who can support doctors by explaining results to patients.

Just as genetic counselors support doctors by explaining genetic test results to patients, Feist suggested that the healthcare system train nurses and medical assistants, and pay them fairly, to help doctors evolve their practice for a future where patients will have greater access to their medical data. "We've all learned through this pandemic that you can still provide good care through electronic means, virtual visits, telemedicine, online portals," Feist added. "Medicine is changing."

Outside of genetics it remains to be seen how the latest regulations will impact patient communications in other areas of medicine. Maykel maintained that pathology and radiology reports, which are generated within medical centers and written for other doctors, needed to keep using the language of medicine, and the best way to educate the patient was through conversation with the healthcare provider.

"If a patient chooses to access their medical records, then they're taking on the responsibility of understanding medical terminology, because that is the way that we communicate and document medical care among physicians," he said. "The opportunity for communicating in layman's terms … is through that relationship between a provider and a patient."

Remember the goal

It's still early days for the medical establishment in terms of figuring out the true impact of the information blocking regulations on patient care and best practices in terms of compliance. Healthcare providers and the government are "in a learning phase" right now, said Myriad's Linthicum.

Peter Yu, physician-in-chief at Hartford Healthcare Cancer Institute, reminded that although the term "information blocking" has a negative connotation, the Cures Act has been good for cancer care. The law provided funding for key cancer research programs, such as the Cancer Moonshot and the All of Us Research Program and enabled the US Food and Drug Administration to make more use of real-world evidence to approve drugs.

"Five years down the road [since the bill became law], we've come to the part about information blocking ... [which] has kind of a negative connotation, like someone's doing something wrong and we're punishing you," Yu said. "But the overarching goal of this act was to speed up cures in the 21st century through a variety of regulatory mechanisms, by focusing on precision medicine and interoperability .... [and by] unlocking data to make it more available not only for research but also for patients."

While the aims of the Cures Act may be laudable, Hay reflected that much work remains before access to healthcare information is truly equitable. Her patients come from a variety of socioeconomic backgrounds, and most non-native English speakers with whom she interacts with the help of interpreters are less likely to be signed up for electronic access to their medical records. Some of her patients don't have computer or internet access. This law "sets up some inequities where the people who are better off, both in education and financially, may benefit more from this than others," she said.

Ultimately, Feist and others expect the medical establishment will have to evolve in terms of how it communicates health information to patients. Particularly if personalized medicine is the goal, as many medical professionals have championed, then according to Color's Zhou, those doctors must support efforts to increase patients' ability to access and understand their medical data including genetic test results.

"If we really do believe that the future of medicine is precision [or] individualized medicine — all of these lofty terms that we use — that requires more individuals to have access to genomics," she said. "You have to embrace the idea that more folks are going to be able to see these results and understand these results, because there's no way you're going to scale through the population if it's always going to be gatekept by a specific small set of providers."

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