

Refining rules on data release can prevent harm to patients

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When it was signed into law in 2016, the 21st Century Cures Act promised more efficient data exchange and much-needed privacy protections for patients in an increasingly technology-driven health care system. Physicians were especially supportive of provisions that promised to bring about long-overdue interoperability of electronic health records. But certain regulations issued to implement that law are undermining quality care and needlessly putting patients at risk.

At issue are rules issued by the Office of the National Coordinator for Health Information Technology (ONC) that effectively require the immediate electronic release of all test results to patients before those patients have had an opportunity to talk with their physician. Most of the time, an immediate release is exactly what the patient or caregiver wants. Physicians have similarly seen the benefits of informed, engaged patients who are able to review and document their own health data.

But in the rare cases when a radiologic test, biopsy or other procedure reveals unexpected and life-altering bad news, some patients have complained that being notified by an impersonal electronic communication has been distressing and harmful. We've seen countless examples, such as a parent learning of their child's leukemia recurrence before their physician has been notified and had the chance to share the news more personally, and answer questions about prognosis and treatment options.

Supporting patient rights

Unfortunately, new federal policies are indifferent to the harms that come to patients receiving bad news when least expected. And we know that many patients don't want to receive bad news through an impersonal email or text message. In a first-of-its-kind survey of 1,000 patients, the AMA, in a partnership with the patient-owned Savvy Cooperative, asked how patients would prefer to be contacted by their physician. Less than half of patients want their information immediately—with or without physician review.

Of those who want immediate access, more than 50% said debilitating, life-limiting or terminal illness results would change their preference on getting bad news. Taken together, 65% of patients want to speak with their physician first before getting life-changing test results.

Patients have also expressed their concerns to legislators and sought a more balanced approach. California, for example, passed laws preempting aspects of the Cures Act to prohibit electronic release of radiology and pathology results that reveal a malignancy until a physician has conveyed the information to the patient.

Physicians know that informed and shared decision-making is an essential element of the relationship we forge with our patients, a relationship centered upon an open and honest conversation. Patients need their information when and where they want it. Patients want to be in charge and use technology that meets their level of engagement. The care team, health system administrators, technology vendors, and others must all work in unison to support this relationship. But when federal policy gets in the way, patient needs can get trampled by inflexible requirements.

Most EHRs don't yet give patients control over how they get alerts about life-changing results. Physicians similarly aren't provided with options in EHRs to select which patients prefer that even devastating results be pushed out immediately without physician review. As a result, complex medical information pops up as an alert on a smartphone late on a Friday night, and some patients are frustrated when physicians didn't have the chance to provide interpretation or context.

That's why the AMA is asking ONC and the Department of Health and Human Services (HHS) to update and clarify federal guidelines. There are too many unanswered questions, and as a result, regulation has gotten out ahead of technology. Physicians should be free to draw upon their training and professional judgment to make rare exceptions to immediate data release, and should be given tools that support conversations with patients. For example, ONC should make federally certified EHRs honor a patient's alert preference and be able to accommodate physician review and brief delays for a small percentage of results.

Access vs. emotional harm

This is an important distinction. Patients have a fundamental right to access their own health information. Physicians are not seeking to be paternalistic guardians of patient-owned data—we know that different patients bring different preferences to the equation, and thus we are only seeking the option for rare, brief pauses to respect those preferences and reach out to patients with bad news. But the current implementation of the HHS rule doesn't recognize the complexities and consequences of certain test results, medical reports and clinical notes that benefit from physician review. All patients want access, but not all patients want access at the same time.

The current information-blocking exceptions established by HHS are entirely too narrow and don't do justice to the patient-physician relationship. The survey cited above demonstrates that the majority of patients support a brief and temporary hold on a limited amount of data to allow their physicians to bring their expertise to bear in sharing the results. But overwhelming fear of being considered an "information blocker" and facing large fines has prevented thoughtful implementation of HHS regulations—implementation that would prevent harm.

Patients benefit from immediate access to the majority of test results and other health information. But due to widespread confusion on how to comply with HHS' regulations, an elevated HbA1c level or a slight dip in your platelet count comes across the same as a tumor detected in a CT scan. Without talking to their physician, few patients would know that at least 95% of all lung nodules are benign. Imagine how you would feel getting your child's results late at night without explanation or context.

Patient privacy

Other aspects of ONC's data blocking regulations force physicians to also place patient privacy at risk. Patients trust their physicians to be guardians of their most sensitive medical information, and we take that responsibility seriously.

In most cases, ensuring that patients and their designated caregivers have access to physician visit notes and test results is important and appropriate. But in rare instances, patients may not want proxies who can access their medical records in EHR portals to view every progress note. We encounter these examples all the time in medicine, from the elderly patient who doesn't want their children to know they are asking for dementia screening, to the spouse who's worried their partner would read about intimate partner abuse

The rigid data-blocking rules have spread fear that respecting patient wishes in these instances and making these notes private could be labelled as violations. Strengthening federal EHR requirements and clearer communication from ONC is desperately needed.

Physicians strongly support interoperability and patient access to their medical records and test results. But in the rare exceptions when patients and physicians agree that a record should remain private or a devastating test result should first be delivered by a physician, we need electronic tools as well as regulatory flexibility to honor our patients' wishes and our own judgement.

HHS must realize the harm its current guidance on information blocking poses to the emotional and mental well-being of patients and refine its policies to limit these risks.