



21st Century Cures Act: Implementation Without Understanding Implication?

David E. Gerber, MD¹

I still remember the first time we lost the race. It was a few weeks after the hospital system had launched the patient portal, the secure web-based platform allowing patients to communicate directly with medical providers and view their test results. As a medical oncologist, I order many tests, including laboratory evaluations to assess treatment toxicity and radiology studies to assess treatment efficacy. To limit patient confusion and anxiety, my staff and I had started scheduling follow-up visits soon after these tests were performed, as results were released electronically to patients 72 hours after they were reported in the medical record. As long as we could see patients in clinic before reports were sent, I could review the report itself, images from radiology studies, and convey my clinical impression. Patients would thus be forewarned about clinically meaningful changes, or advised not to worry over normal variants.

But this day, our coordination efforts fell short. Because of a personal conflict, the patient rescheduled his clinic appointment to the following week. As a result, on a Friday afternoon, his e-mail inbox pinged to notify him of a new test result, the first time he would see it. In this case, it was a follow-up chest computed tomography scan. Like most imaging studies, this scan had a detailed narrative of technique, findings, and impressions. Description of the lungs alone took up 24 lines of text. Despite all of the complex and potentially frightening terminology (*tortuous thoracic aorta* and *abrupt cutoff of central bronchi*), nothing had changed. The mass had remained stable for years, and it would remain unchanged for years to come. However, that is not what the patient's wife gleaned from the report.

She later shared her reaction with me: "I read the report shortly after walking in the door from our vacation. I couldn't tell my husband what it said, as it was too scary to talk about, and I didn't want to break down in front of him. I didn't know what the terms meant or how serious they were. My legs felt wobbly like they were when he was originally diagnosed. I was afraid he could die suddenly of pulmonary or heart problems. I was scared that his only good lung was being invaded with cancer and he would have to come off the clinical trial—and we didn't have a good backup plan in place for another trial. I literally spent the next 1 1/2 days researching clinical trials that he might qualify for,

without any success. After reading the report, I had to leave to go get my allergy shot. While waiting the required 30 minutes after my shot, I had time to think. I burst into tears, and the staff let me wait in an examination room to give me some privacy."

Designed to promote patient access to electronic health information, advance innovation, and address information blocking practices, the 21st Century Cures Act went into effect on April 5, 2021. This bipartisan legislation mandates that all medical test results now be released immediately to patients. Since that time, scenarios like the one above occur all too regularly in my practice. In the first month alone, two different patient families devoted hours to researching the term *white matter changes* in the reports of brain magnetic resonance imaging scans of their elderly relatives. In both cases, this relatively common and medically insignificant finding obscured the positive news the scans conveyed: no evidence of brain metastases.

Entirely normal results are exceedingly rare in clinical medicine. As a medical oncologist, I order comprehensive metabolic panels and complete blood counts with differential every few weeks to assess adverse effects and plan future treatment. The former test typically has about 15 different components; the latter, almost 25. A laboratory test reference range covers values expected in 95% of the population. With a 5% likelihood of an abnormality for each individual result, by chance alone there is almost a 90% chance that either the metabolic panel or blood count will have an abnormal result somewhere in it.

Clinicians are continually asked to see more patients in less time. When we devote time to reassuring worried patients and caregivers that an abnormal serum chloride or mean corpuscular hemoglobin concentration is not clinically meaningful, there may be less time to discuss truly important matters, such as reviewing prognosis, providing education on treatment adverse effects, or managing symptoms.

Conversely, some abnormal results are truly impactful. Radiology studies may demonstrate cancer progression. That may mean changing treatment, or in some cases stopping treatment altogether. If patients may first learn of this information while scrolling through lengthy reports on their smartphones or home computers, the experience may be terrifying. In this

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isolated context, there is no one to summarize in understandable language, to explain next steps, to reassure them. With the Cures Act specifically prohibiting information blocking, it is clear that potentially anxiety-provoking results are insufficient to invoke the preventing harm exception to immediate results release.

Multiple studies show that physicians and patients have different preferences about mode of communication. For medical questions, test results, or treatment instructions, patients are more likely to prefer online communication, while physicians generally prefer in-person discussions.¹ However, patient preferences depend on the scenario, with online result delivery desired far less often for sensitive tests such as biopsy results.² For cancer-related imaging results, it appears that patients generally want initial information from their physicians and only prefer immediate electronic delivery if it means receiving the results more than six days faster.³

In a survey of medical oncologists, 87% stated that patients receiving abnormal or confusing pathology or radiology results before talking about them with a physician had a harmful effect; 49% reported that the release of radiology and pathology results had a negative effect on communication with their patients, compared to 7% reporting a positive effect.⁴ These concerns are not limited to cancer specialists. A study of primary care and multispecialty physicians found that only 21% were comfortable with direct release of abnormal test results.⁵

It is difficult to find a scenario comparable to our current delivery of medical information. On an airline flight, I do not request readouts from dozens of flight deck monitors, but rely on the crew's summary of weather conditions and expected arrival times. Nor do I comb through an automotive diagnostic test of engine, transmission, exhaust system, brakes, and other components before hearing a mechanic's overall assessment and recommendations.

It is well documented that information empowers and engages patients and caregivers.^{6,7} Stipulated by the Federal Health Insurance Portability and Accountability Act of 1996 (HIPAA) and made feasible by electronic systems, patient-accessible medical records may improve certain areas of medical care, including doctor-patient communication.⁸ The Institute of Medicine report Crossing the Quality Chasm suggests that enhanced information flow between patients and providers might reduce errors and improve quality.⁹ In a recent extension of this trend, the 21st Century Cures Act also mandates provision of straightforward and open access to clinician notes.¹⁰ Early studies have suggested that oncology patients have interest in and may benefit from this practice.¹¹

While considering the potential benefits of data exchange, however, we must remember that the order of information delivery clearly matters. Before the current era of instantaneous electronic delivery of test results, I routinely printed out reports during a clinic visit, annotated them with comments and underlining, and provided them to the patient. When we invert this sequence, we face unintended consequences. Radiology and pathology reports are not written with a patient audience in mind. They may contain bewildering and misleading language, or transcription errors. Confusion and unnecessary distress result. Timing result release according to content (good v bad news) is not practical, and patients would soon associate any delay with worrisome findings.

As medical providers, we cannot remove ourselves from operational discussions and decisions. Nor can we afford a position of learned helplessness. Where are the data showing that conveyance of potentially complex and sensitive clinical information *immediately*, before clinician discussion, improves outcomes or satisfaction? In medical practice, we strive to base our decisions on the best available evidence. Laws and guidelines affecting the profession should be held to the same standard.

AFFILIATION

¹Departments of Internal Medicine (Hematology-Oncology) and Population & Data Sciences, Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, Dallas, TX

CORRESPONDING AUTHOR

David E. Gerber, MD, Division of Hematology-Oncology, Harold C. Simmons Comprehensive Cancer Center, University of Texas Southwestern Medical Center, 5323 Harry Hines Blvd, Mail Code 8852, Dallas, TX 75390-8852; e-mail: david.gerber@utsouthwestern.edu.

AUTHOR'S DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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David E. Gerber

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