

Medical Error

A 60-Year-Old Man With Delayed Care for a Renal Mass

Gordon D. Schiff, MD, Discussant

DR DELBANCO: Mr B is a 60-year-old man with a renal mass discovered by magnetic resonance imaging (MRI) that was not addressed clinically for several months. A self-employed businessman, he is married and has children. He has commercial health insurance.

For many years, Mr B received primary care from Dr X, who works in a practice at hospital A. Troubled by intermittent hip and back pain, Mr B sought care at hospital B from various subspecialists. Approximately 8 months before the conference, an MRI was performed at hospital B to further evaluate his back symptoms, which were previously diagnosed as spinal stenosis and for which he and his orthopedic physician were considering surgical intervention. The interpretation included description of “a cystic mass present along the inferior pole of the left kidney measuring approximately 3.5 cm in diameter. This does not have purely cystic characteristics. Because of this, further evaluation is recommended with the means of CT [computed tomography] both with and without contrast.”

The report indicated that a “copy” was sent to the referring specialist at hospital B and to the “PCP.” However, neither the specialist at hospital B nor Mr B or his primary care physician, Dr X, recalls being made aware of the renal findings at this time. Moreover, Dr X found no record of ever receiving a copy of this MRI report.

The specialist at hospital B recalls trying to notify Dr X after becoming aware of findings but believes there was no response and instead mailed a copy. This specialist also recalls mentioning the finding to Mr B and asking him to contact Dr X to arrange follow-up, but Mr B does not remember this happening.

Mr B does vividly remember being told of the renal mass 4 months later when he was seen for another orthopedic follow-up visit at hospital B. He immediately called Dr X about the findings; Dr X recommended CT evaluation, which was expeditiously arranged. The CT report noted an “enhancing exophytic mass lesion at the lower pole of the left kidney; findings are concerning for renal cell carcinoma.” Mr B sought consultation from 2 urologists and decided to have

Mr B, a 60-year-old man with back pain, was not informed of an incidental finding of a renal mass suggestive of cancer on a magnetic resonance imaging scan. Failure and delays in test follow-up are a frequent problem in medicine, occurring in more than 5% of significantly abnormal ambulatory test results. Rather than simply blaming involved clinicians, systems for managing tests need to be reengineered using methods from reliability sciences. These begin with investigations into the systemic causes of the failures, then application of approaches such as heightened situational awareness, closed-loop systems, improved handoffs, just-in-time work, culture and practices of stopping to fix problems, forcing functions and simplification, enhanced visual cues, and cautious use of information technology and redundancy, all while avoiding suboptimization. Emerging test management systems and critical test follow-up recommendations illustrate how applying these principles can enhance this important aspect of patient safety.

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surgery at hospital C, where a benign oncocytoma was removed from the kidney.

Mr B recovered after a somewhat complicated hospital course. He decided to transfer his care from Dr X to a new primary care physician in a “concierge care” retainer practice charging several thousand dollars annually. Mr B continues to have symptomatic spinal stenosis treated with nerve

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Author Affiliation: Dr Schiff is Associate Director of the Center for Patient Safety Research and Practice, Brigham and Women's Hospital, and Associate Professor of Medicine, Harvard Medical School, Boston, Massachusetts.

Corresponding Author: Gordon D. Schiff, MD, Division of General Internal Medicine, Brigham and Women's Hospital, 1620 Tremont St, Third Floor, Boston, MA 02120 (gschiff@partners.org).

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blocks and physical therapy and may have surgery in the months after the conference.

MR B: HIS VIEW

I really felt that the whole condition was missed, because back in June, when I had the MRI, it showed that there was a mass in my kidney that clearly, as the report said, had to be taken care of. So, at the original hospital that did the MRI, nothing was done. And nothing was done by my primary care physician, who supposedly had received a letter. The only reason the condition was discovered was because my spine doctor, after I had had shots to alleviate pain in my spine, called me and asked me if I had done anything about my kidney, and, if not, I really should take care of it . . .

When the spine doctor called me, I had no knowledge of the condition. I felt alone and uncared for. I knew that something was missed along the way and that there was a definite lack of coordination between the hospitals and the doctors. Had the first hospital called me and told me of the condition, I would have called the primary care physician. But, I think the gravity of a situation may not be fully understood by a patient so that he will act proactively. I think the best course of events is that the hospital—whoever discovers it—takes responsibility to make sure that the primary care physician is aware of the condition.

I think it's a system problem, in the sense that the system didn't require the radiologist or whoever sees an abnormal result outside of his medical area to follow up on the situation by calling the primary care physician. I think there has to be something in place that puts responsibility squarely on the shoulders of the person who discovers the abnormality, especially if it's not in his field. I have heard that the original hospital has changed the total procedure, and now it's the responsibility of the radiologist to call the primary care physicians, to make them aware of a serious situation, even though they're at 2 different hospitals.

As a 60-year-old man with some medical problems, I changed my primary care physician to a concierge practice because based on my experience, I felt it was better. I believe I will receive more personal care by going to a doctor who had, on his patient list, 200 patients, as opposed to someone who was seeing 1500 patients. I felt that the care would be superior, more personal, and it was something that I think I need as a 60-year-old person facing medical problems in the future.

DR X: HIS VIEW

This patient of mine had this musculoskeletal problem, saw a specialist, and had a test done to evaluate his particular problem. And, in the process of doing that, the imaging study revealed an incidental finding that was significant. It appears that the patient was not made aware of how important that was, if he was made aware at all. In this particular instance, I never spoke to the ordering doctor and have never had any relationship with that doctor. And, to this day, even

after the finding, I never had any kind of contact with that person. It's just between me and the patient.

In many instances, a patient has been seen by one specialist, referred to another subspecialist, and even onto a third. And each one of them thinks the other doctor is a referring doctor. So, you have no input. And sometimes I've had people come back and say, "I had my knee done, a new knee done a month ago." And I'm saying, "Well, when did you—you know, who did that?" "Well, some doctor at some outside place. . . ." I had no input.

I think that there's always going to be a Cadillac or Mercedes kind of care. And there's always going to be the good old-fashioned quality transportation of the Ford and Chevy. I think some people want more, and they can afford more. But, in the end, with a good-quality vehicle, you get to the same place at pretty much the same time. With high-quality/good-quality care, the person who sees a doctor who's not concierge will end up with the same kind of end result as a person who [sees a doctor who is concierge]. The only difference is how you get there.

AT THE CROSSROADS: QUESTIONS FOR DR SCHIFF

How common is this sort of problem? How do you sort out what went wrong? What can we learn from experiences outside of medicine? What approaches to improving communication and reliability hold promise? What is the responsibility of the individual physician? What is the role of the patient in preventing error? What does the future hold?

DR SCHIFF: Mr B is justifiably upset because a spinal MRI showed a suspicious-for-cancer renal mass that he did not learn about for more than 4 months, despite 5 visits to his back specialists and primary care physician. He wants to know how and why this happened, who was responsible, and how can it be prevented in the future—both for him and for other patients.

Happily, rather than a malignant tumor growing and metastasizing during these months, the mass proved to be a benign oncocytoma, to the surprise of both the radiologist and renal surgeon. It is also fortunate for this discussion, because if it had been a cancer, Mr B notes that "I would be down filing a malpractice suit rather than sharing this case with you today."

Unfortunately, the problem of failed and delayed communication and action on radiograph and other test results is widespread.¹ I became interested in this problem after seeing several deaths due to theophylline toxicity. To understand how such deaths might have been prevented, I and coauthors reviewed charts of patients with toxic levels and found recurring failure of timely test follow-up.² One elderly woman admitted for an acute myocardial infarction was given theophylline and developed nausea, vomiting, and abdominal pain. Based on a history of an asymptomatic gallstone, she was rushed to surgery. Undergoing laparotomy 1 day after myocardial infarction, she developed multiple

complications and nearly died during the ensuing 3-month hospitalization. Only when I reviewed her chart a year later was her toxic theophylline level—the likely cause of the vomiting—uncovered.

Poon et al³ surveyed 262 Harvard physicians in 15 internal medicine practices, and 83% reported regret over a test result that had not been communicated to them or their patients in a timely fashion. The respondents stated that this had occurred an average of 2.3 times in the previous 2 months. Thus, for the 10 000 physicians insured by Harvard's malpractice insurer alone, this extrapolates to more than 150 000 instances of delayed or failed test follow-up annually, each representing the possibility of a malpractice case, depending on the consequences of the delay.

The frequency of failed test follow-up varies between 1% and 60%, depending on the test, setting, and measurement methods. These varying vantage points for examining failure rates include patient and clinician surveys, chart reviews, and malpractice litigation claims (TABLE 1). Methodological challenges abound in each of these settings and include varying criteria as thresholds for cutoff values to define actionable abnormal values, varying criteria for time frame (How long is a delay?), heterogeneous types of tests (laboratory tests, radiographs, specialty procedures, inpatient/outpatient), and difficulty in determining clinician awareness, patient awareness, and actions taken. Because of these methodological limitations, it is difficult to compare published studies to derive exact rates that might apply to Mr B. However, 3 recent studies illustrate the frequency of the problem, with 2 studies examining failures to follow up on radiology results. Casalino et al¹¹ reviewed 5434 randomly selected primary care patients and found that the overall rate of failure to inform or to document informing was 7.1% of 1889 abnormal test results. In 2 Veterans Administration (VA) hospitals, Gordon et al⁹ found that 60% of CT scans reporting an incidental aortic aneurysm lacked evidence of recognition within 3 months; 18% were never noted in the medical record. Singh et al,⁸ studying VA radiology abnormalities, found that 92 of 1196 (7.7%) lacked timely follow-up, including lack of timely follow-up in 11 of 154 (7.1%) renal, kidney, or ovarian masses. It is noteworthy that for most of these abnormalities that failed to be documented or followed up, an electronic alert had been sent and subsequently acknowledged by the ordering physician, suggesting that such simple “fixes” may be insufficient to ensure reliable documentation and follow-up.

Sorting Out What Went Wrong: The “Second Story”

Whenever an adverse event occurs, there is usually a “first story” that is straightforward, obvious (in terms of who or what is to blame)—and often wrong. The concept of digging deeper to uncover and understand the “second story” is embodied in modern approaches to investigating errors and accidents, such as the “5 whys,” and in various techniques for “root cause investigation.”¹⁸⁻²⁰ Peeling away lay-

ers of blame and responsibility and moving from proximate causes to underlying systematic or latent factors is a critical first step for uncovering deeper truths, as well as setting the stage for productive, rather than defensive, responses needed to understand problems and prevent their recurrence.

For Mr B, the initial story was that the radiologist and/or ordering physician at the outside hospital forwarded the abnormal MRI report to the primary care physician, but it somehow got lost in the mail. The first question is why the US mail was used to send potentially time-sensitive critical information. First-class mail actually is delivered on time 96.3% of the time, and only 1 in 200 pieces of mail is lost.²¹ While this 99.5% reliability falls short of 100% guaranteed transmission of the result, given the other vulnerabilities uncovered in Mr B's case, it is unlikely to be the weakest link in the faulty communication chain. Indeed, while the error was ostensibly failure to follow up an “incidental” finding of a kidney tumor on the June 2009 MRI performed for a spine problem, that radiology report remarkably also mentions that “this [mass] was present on a prior 2008 examination.” Why wasn't this earlier abnormal result followed up? I found that Mr B actually had a number of prior abnormal kidney imaging studies, plus ongoing hematuria during the preceding years. While there is controversy about their interpretation and best follow-up actions for these abnormalities, each should have been noted with an assessment and follow-up plan.

Two months *after* the critical abnormal 2009 MRI, Mr B was seen at the primary care physician's office for hematuria and fever. The covering physician who saw the patient as well as Dr X, who saw the patient a week later, were unaware of the 2009 MRI, since it was performed at the outside hospital. Ironically, although this case perfectly illustrates the need for better electronic test result “interoperability”—permitting test results from one hospital to be viewed by caregivers at another—these 2 hospitals were actually part of an experimental linkage that permitted looking up results from each other's hospitals. The patient might be “blamed” for not mentioning the study, for irregular follow-up with his primary care physician, and for seeking out and making referrals on his own, but Mr B was also in the dark about the MRI findings. The spine physician's note from 1 week after the sentinel MRI describes in detail the MRI findings of “severe spinal stenosis and degenerative spondylolisthesis,” omitting any mention of the renal mass described in the lead paragraph on the radiology report. Displaying what has been called “inattention blindness” (the phenomenon of not being able to perceive things that are in plain sight)^{22,23} to the renal finding, the surgeon proceeded to plan spine surgery for Mr B.

While systems for flagging, communicating, and tracking significant abnormal results differ widely among departments of radiology, emerging recommendations and

Table 1. Failures and Delays in Follow-up of Clinically Significant Outpatient Test Results

Source	Method/Participants	Test/Result	Sample Size	Findings
Clinician survey				
Poon et al, ³ 2004	Harvard general medicine physicians	Various tests	262	83% reported at least 1 delay in reviewing test results in previous 2 mo; 49% dissatisfied with their own system for managing test results.
Wahls and Cram, ⁴ 2007	Veterans Administration clinician survey	Various tests	441	37% had seen patients with diagnosis or treatment delays in past 2 weeks attributed to a missed result; 15% reported ≥ 2 such encounters.
Patient survey				
Schoen et al, ⁵ 2005	International patient survey	Various tests	1527	16% in United States reported experiencing delays in being notified about abnormal test results—highest among 6 surveyed nations.
Tracking abnormal results identified by laboratory/radiology				
Edelman, ⁶ 2002	Laboratory identification followed by chart review	Elevated glucose, hemoglobin A _{1c}	1426	Retrospective review of 1426 patients with glucose >200 mg/dL or hemoglobin A _{1c} >7%; no mention of laboratory tests or diabetes in the medical record in 18%
Nazareno et al, ⁷ 2007	Pathology identification followed by chart review	Positive <i>Helicobacter pylori</i> biopsy	143	8% of 143 outpatients were not followed up and treated because of various factors.
Singh et al, ⁸ 2009	EMR review of patients with electronic alert generated for abnormal tests	Abnormal imaging tests	1196	8.1% of electronic alerts/abnormalities were not acknowledged; 7.7% of results overall lacked timely follow-up but no correlation with which alerts were electronically unacknowledged.
Gordon et al, ⁹ 2009	Electronic search of free text radiology reports followed by EMR chart review	Dilated aorta on computed tomography scan	440	91 were new findings. Of these, no documentation of recognition in 58% within 3 mo, 9% of which were ≥ 5.5 cm.
Singh et al, ¹⁰ 2009	EMR review, clinician interviews	Positive fecal occult blood test	490	Lack of timely follow-up in 29.9% (decreased to 5.4% after software reconfiguration)
Chart review				
Casalino et al, ¹¹ 2009	Medical record review	Multiple tests	5434 charts in 19 community-based and 4 academic practices	1889 abnormal results with overall rate of apparent failures to inform or document informing patient in 7.1% (range, 0%-26.2%)
Kern et al, ¹² 2006	EMR chart review	Elevated glucose	301	3%-14% of charts (depending on cutoff chosen) had elevated glucose values, of which 50% lacked any documentation of recognition or plans for subsequent workup.
Nepple et al, ¹³ 2008	Retrospective review of PSA in prostate cancer patients followed by EMR chart review	Elevated PSA	327	15.6% had delay (>180 d) in clinician response or action.
Linking laboratory and pharmacy data to uncover failures				
Schiff et al, ¹⁴ 2000	Linking laboratory and pharmacy data followed by chart review	Elevated serum potassium	701	2.4% of patients taking oral potassium supplementation with potassium >5.3 mEq/L showed no documentation of awareness or change in therapy.
Cram et al, ¹⁵ 2005	Linking abnormal scan with pharmacy data, chart review, and physician interview	Abnormal DXA scans	48	23% of all abnormal scans lacked evidence that clinician had reviewed them.
Schiff et al, ¹⁶ 2005	Linking laboratory and pharmacy data followed by patient phone calls	Elevated TSH	982	2.3% with TSH >20 mIU/L were not given therapy or were unaware of their results (with additional 5.5% lost to follow-up, thus also potentially unaware).
Mixed methods				
Elder et al, ¹⁷ 2009	Observations, interviews, surveys of family practitioners and their patients	Various test results	4 offices; 37 clinicians; 25 charts from each office; 53 patients	Although most patients (87%-100%) acknowledged receiving their test results, a smaller percentage of patient charts documented patient notification (58%-85%), clinician response to the result (47%-84%), and follow-up for abnormal results (28%-55%).

Abbreviations: EMR, electronic medical record; PSA, prostate-specific antigen; TSH, thyroid-stimulating hormone.

practices, discussed below, appear to be neglected or missing in Mr B's management.^{1,24-27} Finally, although controversies in the interpretation and management of renal masses are peripheral to this discussion, radiologic interpretation and decision making are hardly straightforward. Autopsy examination of patients older than 50 years shows that half have at least 1 cystic mass, and nearly one-third of CT scans performed in patients older than 50 years reveal a renal cyst or mass.²⁸⁻³⁰ The Bosniak classification system attempts to distinguish benign cysts from more worrisome masses based on size, calcifications, density, septations, contrast enhancement, and wall thickness. Mr B's mass was probably category III, an indeterminate group usually recommended for invasive diagnostic interventions to rule out cancer.^{31,32} However, these criteria are neither well validated nor perfectly sensitive and specific, particularly in their ability to ensure timely excision of a renal cell carcinoma, the most common cause of a solid renal mass. As illustrated by the preoperative assessment of cancer by Mr B's radiologists and urologists, they also offer imperfect guidance for avoiding invasive procedures for benign lesions such as he turned out to have.

As I walked into the office of Dr X, thinking about these "Swiss cheese" holes³³ and complexities in the management of this case, I was struck by finding papers stacked on every surface of the desk and floor. It reminded me of . . . my own office. Could the paper MRI report be lost there somewhere? Dr X was certain it was not. What I do know is that I recently found a 3-month overdue, unmailed property tax bill payment letter beneath a stack in my office!

The Emerging Science of Reliability: Picking Up Where Vigilance Leaves Off

The lens of reliability science can help clinicians view such glitches differently. Instead of seeing dysfunctional post offices, careless rushing physicians, narrowly focused specialists, "overly empowered" patients, messy desks, and conflicting versions of the "truth," reliability science brings a different picture into focus. Viewed through what needs to become a new basic science for health care delivery, this blur of seemingly blameworthy factors and persons is clearly seen as processes begging for improvement.³³⁻³⁷ Efforts to pinpoint who is telling the "truth" and who to blame, often involving acrimony, accusations, and lawyers, are replaced by approaches that emphasize learning from mishaps and system redesign to minimize their recurrence.

Drawing on various terms and approaches from reliability science—continuous quality improvement, lean production, mistake proofing, and resilience thinking about complex systems—permits a different view of Mr B's case.^{35,36,38-44} To illustrate their relevance for managing test results, I summarize selected concepts applicable to this case, trying to avoid the jargon that may lead physicians to dismiss "industrial approaches to quality" as failing to respect the needs and nuances of clinical care.

Situational Awareness and Anticipation of Problems. Studies of high-reliability organizations, such as accident-free nuclear reactors and exceptionally safe aviation organizations, demonstrate that they are characterized by a culture of nervousness, where employees are constantly worrying about what can go wrong while anticipating and preparing for errors and rare disasters.^{41,45,46} Tamuz and Harrison⁴¹ illustrate translation of this approach to anticipating errors from computerized physician order entry. The recognition that incidental imaging abnormalities are among the highest-risk situations for failed follow-up and malpractice suits, especially in the absence of clear delineation of who is responsible, suggests the need to have a similar heightened worry level and design of offsetting safeguards.⁴⁷⁻⁵⁰

Need for Closed-Loop Systems. "Closing the loop" so that actions feed information back to signal that expected actions have occurred is a fundamental principle of engineering.⁵¹ Feedback from the "downstream" clinical areas to the "upstream" report-generating area, such as the radiology department, is essential. Only then can a radiology department or overall organization confirm which abnormal results have been received, acknowledged, and acted on and, more importantly, identify which have not.

Attention to Handoffs and Teamwork. Most failures in quality result from inadequate communication, particularly in handoffs between individuals and departments, rather than from particular individuals or departments failing to do their jobs properly.⁵²⁻⁵⁶ The laboratory may do a good job processing specimens, the radiologist reading radiographs, but it is in the handoff to the clinician where quality more often fumbles. Effective handoffs entail skillful teamwork, not simply dumping a hot potato so those in the laboratory can document in their computers that they put the result on someone else's plate. Rather, handoffs must be designed to make it easier for the clinical team to receive and act on the result, such as a system that immediately proposes an order for a follow-up radiograph that can then be completed with a single keystroke for the clinician to approve the order.

Do Everything "Just in Time." As much as humanly and organizationally possible, work processes should occur immediately, rather than "batching" work by setting it aside to do later.^{57,58} Doing today's work today ensures that the future is protected for tomorrow's work. There is no need to remember to document yesterday's test result actions if they are acted on when they are received.⁵⁷ The wasted time and attention in looking for a test result that has been set aside, or from "phone tag," is incalculable. Touching each piece of paper just once reduces errors and saves time. This holds true for those generating the test result as well as those receiving it. If specimens or radiographs are processed quickly, it is less likely that the ordering physician will be off duty when a critical result is reported.

Build a Culture and Practices of Stopping to Fix Problems. While appearing to contradict continuous-flow

“just-in-time” techniques, “stop-the-line” approaches to fix problems in real time, introduced in assembly production, are now finding their way into health care.⁵⁹ Without such a culture and practices, the corrosive signals and effects of chronically ignored or tolerated quality problems and/or worker frustrations have an immeasurable and widespread effect on morale and other work attitudes and behaviors.

Virginia Mason Hospital has adopted this approach in the form of patient safety alerts that bring leaders to the front line to immediately investigate and fix safety issues.⁵⁹ In a study with a single gynecologist, using a combination of loop-closing feedback, improved teamwork between the laboratory and clinician, and fixing identified specimen problems (termed *discrepancy analysis*) in real time, Raab et al⁶⁰ decreased the number of inadequate-for-interpretation Papanicolaou test results from 9.9% to 4.7%. Buesa⁶¹ reduced the number of unprocessed histology specimen “blocks” from an average of 180 (and as high as 800) to fewer than 5 per day. The experiences of primary care physicians such as Dr X, who states that he is “drowning from overload from tests that I didn’t even order,” represent an opportunity to address the next near miss related to laboratory communication as a stop-the-line event to identify and fix potentially serious flaws in results management systems.

Use Forcing Functions, Simplification, and Standardization to Reengineer Work Processes. Redesigning systems to make it harder to do the wrong thing and easier to do the right thing is more effective in decreasing errors than memos, continuing medical education, incentives, and threats.^{34,62} Simplifying processes to decrease complexity and the number of steps involved is also powerful. A process with 30 or 35 steps, each performed with 98% accuracy, will fail half the time. Complex systems for ordering, performing, reporting, and acting on test results easily have that number of steps. When each physician, laboratory, imaging center, or specialty test (eg, echocardiogram, 24-hour Holter monitor, pulmonary function test, electroencephalogram, endoscopy) has its own approach to ordering and reporting, such complexity multiplies exponentially. Further illustrating this complexity that begs for standardization and simplification, a study showed that in the course of 1 year, a typical primary care physician needs to share and coordinate care with 229 physicians in 117 practices.⁶³ Obviously, minimizing the total number of tests and referrals by more critically weighing their appropriateness (Did Mr B need to be cared for at 3 different hospitals with so many different physicians and imaging tests?) can decrease unnecessary complexity and opportunity for errors.

Use Visual Cues to Facilitate Work and Ensure Problems Are Not Hidden. Visual systems convey information in the work environment so individuals “know by looking.”⁶⁴ A familiar simple example is the “flow sheet” that visually cues clinicians to trends in patients’ test results or vital signs.⁶⁵ But for such cues to be workable, they cannot be overloaded by distracting clutter, which is the reason Japa-

nese quality experts champion the “5-S system” (approximate English translation: sort, straighten, shine, standardize, sustain) to obsessively keep the work environment clean.⁶⁶ A laboratory slip needing action would be harder to overlook if it were the only piece of paper on my desk. Electronic solutions likewise will need to be attentive to this principle in visual design of flagging and tracking systems for results management.⁶⁷

See for Yourself to Thoroughly Understand the Situation. Engineers are learning to take advantage of the wisdom and experience of frontline staff.⁶⁸ I was shown the full interview videos with Mr B and Dr X, but only after I spoke directly with them, observed workflow, and viewed the actual reports did I begin to appreciate many of the things that went wrong, as well as the constraints the staff faced. This principle of *genchi genbutsu* (“go and see”) links closely to another attribute of high-reliability organizations: reluctance to simplify analysis when trying to understand events or processes.^{35,46,69,70}

Use Only Reliable, Thoroughly Tested Technology. Process redesign and information technology have been described as natural partners.^{71,72} Information technology can be a powerful tool for improvement but it can also cause new problems. Done right, information technology can enable rapid communication, automate and standardize processes, enhance display, facilitate electronic decision support, filter and flag results, enable asynchronous communication with patients via e-mail and secure portals, and track the results.⁷² But it can also create new failure modes, especially when paper and electronic processes coexist. Casalino et al¹¹ found that partial electronic medical record systems (paper-based progress notes and electronic test results or vice versa) were associated with higher follow-up failure rates compared with not having an electronic medical record. With current national attention on “meaningful use” and greater software vendor accountability, it is a good time to identify ways to improve the design of such systems. In addition to interoperability issues forcing dual paper and electronic results systems, shortcomings include poorly designed cue functionality for results management and workflow integration that requires excessive keystrokes, duplicated efforts, and problems related to delegating routine functions to other staff.

Caution Use of Redundancy. To ensure this problem does not recur, Mr. B has committed himself to obtaining copies of all of his tests and records, which he will carry to each of his visits. While this is definitely a “patient-centered” approach to data interoperability and may make errors like the ones he experienced less likely, it is embarrassing that health care information management systems have failed him to such an extent that he has to develop his own duplicate medical record. It also raises broader questions related to the role of redundant systems in patient safety, which have been advocated as a method for making many health care processes more fail-safe.⁷³

Test result management is frequently invoked as an example in which redundancy can play an important role: the patient can cross-check results that clinicians may have overlooked. However, giving patients a *role*, which I strongly advocate, should not be confused with making them *responsible*, which I do not favor, particularly if it means physicians abdicating their responsibility. Research from systems engineering demonstrates that one highly reliable system is superior to multiple less-reliable redundant systems.³⁵ To the extent that redundancy increases complexity, dilutes responsibility, and even encourages risk taking, it should be questioned as a safety strategy.⁷⁴ Redundant parallel systems can also be costly, since duplicate efforts use valuable clinician (and patient) time and resources that could otherwise be freed up if a single reliable system existed.

Applying these powerful constructs to improving test communication and management suggests a variety of approaches and practices that could have prevented the error Mr B experienced. TABLE 2 draws on these concepts, as well as on the work of a number of initiatives designed to advance the management of critical test results.

In conclusion, I thank Mr B, who shared his story and provided the opportunity to candidly examine the case without the fear and defensiveness engendered by a malpractice suit. Mr B is enabling less-defensive learning. He and other

concerned patients can help provide the information and feedback necessary to build a better system.^{75,76} Finally, clinicians must never forget that test results, such as laboratory or radiology reports, are not widgets. Rather, they can represent life-and-death information, including a new diagnosis of cancer or human immunodeficiency virus infection. Even normal results can painfully intersect with the anxieties of patients whose bothersome symptoms disappointingly find no explanation. As this discussion illustrates, Mr B is not alone in his anxieties about having his results delayed or lost, but there are many ways, with patients' help, that the health care system can and must do better.

QUESTIONS AND DISCUSSION

QUESTION: I would like to follow up on the concept of the concierge practice. From the patient's point of view, it seems almost intuitive that part of the solution to his problem would be going from a provider who cares for 2000 patients to a practice caring for 200, but this does not seem to be a solution for all patients.

MR B: I wish to comment on my experience with my new physician. My wife and I were with our primary care physician [Dr X] for over 20 years. We had a personal relationship and have nothing but good things to say about him. But with the concierge office, where I've been for the past 2

Table 2. Building a System for More Reliable Test Follow-up^a

Redesign Recommendation	Logic	Specifications
Tests need to be tracked from order to completion, receipt, and action.	Failures need to be visible, rather than invisibly falling through cracks.	Each step needs to be acknowledged and documented. Critical tests ordered but not performed and results lacking acknowledgment or expected action need to be tracked.
Develop standardized approach for every test and test-generating area to define and flag clinically significant abnormal results.	"Panic values" were a major advance in the 1970s, but nonurgent, action-requiring abnormal results are now the biggest problem. Lack of standardized, coded system is difficult for clinicians and for systematic tracking.	Each testing area should delineate criteria for abnormal results using 3 levels of urgency—immediate/life-threatening, urgent, and nonurgent but critical to follow up, defining time frames for receipt and action for each level of urgency and tagging results meeting criteria.
Eliminate ambiguities regarding whom to contact for critical abnormal results, and delineate their responsibilities.	Confusion leads to errors, particularly related to responsibilities of ordering specialists and cross-covering physicians vs primary caregivers. Redesign is needed to overcome fragmented outpatient services and increasing inpatient "shift work."	Emerging consensus that initial responsibility belongs to the <i>ordering</i> clinician to receive, act on, and/or relay critical results, backed up by the <i>covering</i> clinician when unavailable for more urgent results.
Outpatients should be informed about all test results, even normal results.	Creating expectation that he/she will hear about all results allows patient to serve as reliability backstop for unreported results.	Multiple ways to communicate with patients depending on the result, the patient, and available technology. Web-based secure patient "portals" are increasingly useful as ways to post results.
Tracking and system oversight monitoring	Just as someone needs to "own" each critical result, someone needs to be responsible for tracking outstanding results and identifying problems and system improvement opportunities.	Create test result quality office/person to track abnormal results unaddressed after predefined intervals, troubleshoot/investigate when clinicians are not reachable or results are sent to wrong physician, monitor and improve performance based on incidents and aggregated data.
Advanced systems to support clinicians in test result management	Further overloading busy clinicians with more tests to follow up without supporting ability to do so is not effective system redesign. Need automation, delegation, and cognitive support tools.	Results management system redesign and tools featuring interoperability with all testing areas (eg, cardiology, endoscopy), linking to contextual information (past results, problems, drugs), and electronic decision support to identify and streamline carrying out next actions.

^aAdapted from multiple consensus guidelines and recommendations, including the Massachusetts Coalition for the Prevention of Medical Errors Communicating Critical Test Results collaborative; the Partners Communicating Clinically Significant Test Results Task Force; the Alert Notification of Critical Radiology Results collaboration project of the Brigham and Women's Hospital, Beth Israel Deaconess Medical Center, and the University of Chicago; and the CRICO Risk Management Foundation's Office Practice: What Works.

or 3 months, if I have a test, I get a call the next day or the day after with the results. I think it's a function of him having 200 patients, whereas it's impossible for primary care physicians with a large practice to have the same flexibility.

DR SCHIFF: Mr B's comment raises a number of important issues. First, all patients should receive results of their tests in a timely fashion and should not have to switch to a "concierge" physician to have this reasonable expectation met. But we currently have a situation where many physicians and patients need help. If a plane is crashing, moving to first class generally does not improve your chances of survival. My patients receive timely results, largely because my hospital has an advanced electronic results management system⁷⁷ linked to our electronic medical record and to a "patient portal," which is increasingly being used as an efficient approach for communicating results to patients.^{78,79} I wonder whether Mr B's new concierge physician will have good access to his prior radiology and other results, which, as we have seen today, are often important for decision making about any subsequent findings.

Second, there is a larger quality concept that is germane here—the concept of suboptimization that Deming⁸⁰ and others warn against. Suboptimization refers to the process of optimizing one element of the system at the expense of other parts of the system and the larger whole. Test result ordering and reporting perfectly illustrate this principle, as we find with each laboratory and testing area optimizing its own systems for ordering and reporting. Such customization and fragmentation can create a more complex and dysfunctional system overall. Likewise, each physician's office (and often each individual practitioner in that office) has its own personalized system for reviewing results. While flexibility and experimentation are good, potential gains from a more optimized overall system should not be forsaken. I see similar shortcomings embodied in "concierge" approaches, which are a suboptimized solution to larger health system problems, such as primary care physician shortages, inadequate practitioner time, and the imperative for more reliable and patient-centered care. To the extent that such care reduces the availability of already scarce primary care physicians and diverts resources away from allocation based on need rather than ability to pay, it may actually make the problems worse.^{81,82}

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REFERENCES

- Schiff GD. *Getting Results: Reliably Communicating and Acting on Critical Test Results*. Oakbrook Terrace, IL: Joint Commission Resources; 2006.
- Schiff GD, Hegde HK, LaCloche L, Hryhorczuk DO. Inpatient theophylline toxicity: preventable factors. *Ann Intern Med*. 1991;114(9):748-753.
- Poon EG, Gandhi TK, Sequist TD, Murff HJ, Karson AS, Bates DW. "I wish I had seen this test result earlier!": dissatisfaction with test result management systems in primary care. *Arch Intern Med*. 2004;164(20):2223-2228.
- Wahls TL, Cram PM. The frequency of missed test results and associated treatment delays in a highly computerized health system. *BMC Fam Pract*. 2007; 8:32.
- Schoen C, Osborn R, Huynh PT, Doty M, Zapert K, Peugh J, et al. Taking the pulse of health care systems: experiences of patients with health problems in 6 countries. *Health Aff (Millwood)*. 2005(suppl Web exclusives):W5-509-W5-525.
- Edelman D. Outpatient diagnostic errors: unrecognized hyperglycemia. *Eff Clin Pract*. 2002;5(1):11-16.
- Nazareno J, Driman DK, Adams P. Is *Helicobacter pylori* being treated appropriately? a study of inpatients and outpatients in a tertiary care centre. *Can J Gastroenterol*. 2007;21(5):285-288.
- Singh H, Thomas EJ, Mani S, et al. Timely follow-up of abnormal diagnostic imaging test results in an outpatient setting: are electronic medical records achieving their potential? *Arch Intern Med*. 2009;169(17):1578-1586.
- Gordon JR, Wahls T, Carlos RC, Pipinos II, Rosenthal GE, Cram P. Failure to recognize newly identified aortic dilations in a health care system with an advanced electronic medical record. *Ann Intern Med*. 2009;151(1):21-27.
- Singh H, Kadiyala H, Bhagwath G, et al. Using a multifaceted approach to improve the follow-up of positive fecal occult blood test results. *Am J Gastroenterol*. 2009;104(4):942-952.
- Casalino LP, Dunham D, Chin MH, et al. Frequency of failure to inform patients of clinically significant outpatient test results. *Arch Intern Med*. 2009; 169(12):1123-1129.
- Kern LM, Callahan MA, Brillon DJ, Vargas M, Mushlin AI. Glucose testing and insufficient follow-up of abnormal results: a cohort study. *BMC Health Serv Res*. 2006;6:87.
- Nepple KG, Joudi FN, Hillis SL, Wahls TL. Prevalence of delayed clinician response to elevated prostate-specific antigen values. *Mayo Clin Proc*. 2008; 83(4):439-445.
- Schiff GD, Aggarwal HC, Kumar S, McNutt RA. Prescribing potassium despite hyperkalemia: medication errors uncovered by linking laboratory and pharmacy information systems. *Am J Med*. 2000;109(6):494-497.
- Cram P, Rosenthal GE, Ohsfeldt R, Wallace RB, Schlechte J, Schiff GD. Failure to recognize and act on abnormal test results: the case of screening bone densitometry. *Jt Comm J Qual Patient Saf*. 2005;31(2):90-97.
- Schiff GD, Kim S, Krosnjak N, et al. Missed hypothyroidism diagnosis uncovered by linking laboratory and pharmacy data. *Arch Intern Med*. 2005;165 (5):574-577.
- Elder NC, McEwen TR, Flach JM, Gallimore JJ. Management of test results in family medicine offices. *Ann Fam Med*. 2009;7(4):343-351.
- Bagian JP, Gosbee J, Lee CZ, Williams L, McKnight SD, Mannos DM. The Veterans Affairs root cause analysis system in action. *Jt Comm J Qual Improv*. 2002; 28(10):531-545.
- Sweitzer SC, Silver MP. Learning from unexpected events: a root cause analysis training program. *J Healthc Qual*. 2005;27(5):11-19.
- Browne AM, Mullen R, Teets J, Bolling A, Steven J. *Common Cause Analysis: Focus on Institutional Change*. Rockville, MD: Agency for Healthcare Research and Quality; 2004.
- US Postal Service. Quarterly performance for single-piece first-class mail: mailpieces delivered between 10/01/2010 and 12/31/2010. http://www.usps.com/serviceperformance/_htm/FY2011_Q1_Single_Piece_First_Class_Mail_Quarterly_Performance.html. Accessed April 8, 2011.
- Mack A. Inattentive blindness: looking without seeing. *Curr Dir Psychol Sci*. 2003;12(5):180-184.
- Simons DJ. Attentional capture and inattentive blindness. *Trends Cogn Sci*. 2000;4(4):147-155.
- Hanna D, Griswold P, Leape LL, Bates DW. Communicating critical test results: safe practice recommendations. *Jt Comm J Qual Patient Saf*. 2005;31 (2):68-80.
- Singh H, Vij MS. Eight recommendations for policies for communicating abnormal test results. *Jt Comm J Qual Patient Saf*. 2010;36(5):226-232.
- Jackson C, Macdonald M, Anderson M, Stevens P, Gordon P, Laxer R. Improving communication of critical test results in a pediatric academic setting: key lessons in achieving and sustaining positive outcomes. *Healthc Q*. 2009;12: 116-122.
- Garvey CJ, Connolly S. Radiology reporting—where does the radiologist's duty end? *Lancet*. 2006;367(9508):443-445.
- Kissane JM. The morphology of renal cystic disease. In: Gardner KD, ed. *Cystic Disease of the Kidney*. New York, NY: John Wiley; 1976.
- Laucks SP Jr, McLachlan MS. Aging and simple cysts of the kidney. *Br J Radiol*. 1981;54(637):12-14.
- Carrim ZI, Murchison JT. The prevalence of simple renal and hepatic cysts detected by spiral computed tomography. *Clin Radiol*. 2003;58(8):626-629.
- Leder RA. Radiological approach to renal cysts and the Bosniak classification system. *Curr Opin Urol*. 1999;9(2):129-133.
- Israel GM, Bosniak MA. An update of the Bosniak renal cyst classification system. *Urology*. 2005;66(3):484-488.

33. Reason J. Human error: models and management. *BMJ*. 2000;320(7237):768-770.
34. Berwick DM. Continuous improvement as an ideal in health care. *N Engl J Med*. 1989;320(1):53-56.
35. Luria JW, Muething SE, Schoettker PJ, Kotagal UR. Reliability science and patient safety. *Pediatr Clin North Am*. 2006;53(6):1121-1133.
36. Pronovost PJ, Berenholtz SM, Goeschel CA, et al. Creating high reliability in health care organizations. *Health Serv Res*. 2006;41(4 pt 2):1599-1617.
37. National Academy of Engineering and Institute of Medicine. *Building a Better Delivery System: A New Engineering/Health Care Partnership*. Washington, DC: National Academy Press; 2005.
38. Boston-Fleischhauer C. Enhancing healthcare process design with human factors engineering and reliability science, part 2: applying the knowledge to clinical documentation systems. *J Nurs Adm*. 2008;38(2):84-89.
39. Dixon NM, Shofer M. Struggling to invent high-reliability organizations in health care settings: insights from the field. *Health Serv Res*. 2006;41(4 pt 2):1618-1632.
40. Fei K, Vlasses FR. Creating a safety culture through the application of reliability science. *J Healthc Qual*. 2008;30(6):37-43.
41. Tamuz M, Harrison MI. Improving patient safety in hospitals: contributions of high-reliability theory and normal accident theory. *Health Serv Res*. 2006;41(4 pt 2):1654-1676.
42. Clancy CM. Mistake-proofing in health care: lessons for ongoing patient safety improvements. *Am J Med Qual*. 2007;22(6):463-465.
43. Shapiro MJ, Jay GD. High reliability organizational change for hospitals: translating tenets for medical professionals. *Qual Saf Health Care*. 2003;12(4):238-239.
44. Vest JR, Gamm LD. A critical review of the research literature on Six Sigma, Lean and StuderGroup's Hardwiring Excellence in the United States: the need to demonstrate and communicate the effectiveness of transformation strategies in healthcare. *Implement Sci*. 2009;4:35.
45. Battles JB, Dixon NM, Borotkanics RJ, Rabin-Fastmen B, Kaplan HS. Sense-making of patient safety risks and hazards. *Health Serv Res*. 2006;41(4 pt 2):1555-1575.
46. Hines S, Luna K, Lofthus J, et al. *Becoming a High Reliability Organization: Operational Advice for Hospital Leaders*. Rockville, MD: Agency for Healthcare Research and Quality; 2008.
47. Berlin L. Communicating radiology results. *Lancet*. 2006;367(9508):373-375.
48. Gandhi TK, Kachalia A, Thomas EJ, et al. Missed and delayed diagnoses in the ambulatory setting: a study of closed malpractice claims. *Ann Intern Med*. 2006;145(7):488-496.
49. Spear SJ, Schmidhofer M. Ambiguity and workarounds as contributors to medical error. *Ann Intern Med*. 2005;142(8):627-630.
50. Raab SS. Improving patient safety by examining pathology errors. *Clin Lab Med*. 2004;24(4):849-863.
51. Schiff GD. Minimizing diagnostic error: the importance of follow-up and feedback. *Am J Med*. 2008;121(5)(suppl):S38-S42.
52. Cohen MD, Hilligoss PB. The published literature on handoffs in hospitals: deficiencies identified in an extensive review. *Qual Saf Health Care*. 2010;19(6):493-497.
53. Patterson ES, Wears RL. Patient handoffs: standardized and reliable measurement tools remain elusive. *Jt Comm J Qual Patient Saf*. 2010;36(2):52-61.
54. Gandhi TK. Fumbled handoffs: one dropped ball after another. *Ann Intern Med*. 2005;142(5):352-358.
55. Arora VM, Manjarrez E, Dressler DD, Basaviah P, Halasyamani L, Kripalani S. Hospitalist handoffs: a systematic review and task force recommendations. *J Hosp Med*. 2009;4(7):433-440.
56. Solet DJ, Norvell JM, Rutan GH, Frankel RM. Lost in translation: challenges and opportunities in physician-to-physician communication during patient handoffs. *Acad Med*. 2005;80(12):1094-1099.
57. Institute for Healthcare Improvement. Improve work flow and remove waste: use just-in-time processing. <http://www.ihl.org/IHI/Topics/OfficePractices/Access/Changes/IndividualChanges/UseJustInTimeProcessing.htm>. Accessed January 15, 2011.
58. Spear S. *The High Velocity Edge: How Market Leaders Leverage Operational Excellence to Beat the Competition*. New York, NY: McGraw-Hill; 2009.
59. Furman C, Caplan R. Applying the Toyota Production System: using a patient safety alert system to reduce error. *Jt Comm J Qual Patient Saf*. 2007;33(7):376-386.
60. Raab SS, Andrew-Jaja C, Condel JL, Dabbs DJ. Improving Papanicolaou test quality and reducing medical errors by using Toyota Production System methods. *Am J Obstet Gynecol*. 2006;194(1):57-64.
61. Buesa RJ. Adapting lean to histology laboratories. *Ann Diagn Pathol*. 2009;13(5):322-333.
62. Grimshaw JM, Shirran L, Thomas R, et al. Changing provider behavior: an overview of systematic reviews of interventions. *Med Care*. 2001;39(8)(suppl 2):II2-II45.
63. Pham HH, O'Malley AS, Bach PB, Saiontz-Martinez C, Schrag D. Primary care physicians' links to other physicians through Medicare patients: the scope of care coordination. *Ann Intern Med*. 2009;150(4):236-242.
64. Grout JR. Mistake proofing: changing designs to reduce error. *Qual Saf Health Care*. 2006;15(suppl 1):i44-i49.
65. Ruoff G, Gray LS. Using a flow sheet to improve performance in treatment of elderly patients with type 2 diabetes. *Fam Med*. 1999;31(5):331-336.
66. Liker JK. *The Toyota Way: 14 Management Principles From the World's Greatest Manufacturer*. New York, NY: McGraw-Hill; 2004.
67. Powsner SM, Tuft ER. Graphical summary of patient status. *Lancet*. 1994;344(8919):386-389.
68. Tucker AL, Singer SJ, Hayes JE, Falwell A. Front-line staff perspectives on opportunities for improving the safety and efficiency of hospital work systems. *Health Serv Res*. 2008;43(5 pt 2):1807-1829.
69. Hines S, Luna K, Lofthus J. Becoming a high reliability organization: operational advice for hospital leaders. <http://www.innovations.ahrq.gov/content.aspx?id=1698>. Accessed January 15, 2011.
70. Spear SJ, Bowen HK. Decoding the DNA of the Toyota Production System. *Harvard Business Review*. 1999;77:96-106.
71. Davenport TH, Short JE. The new industrial engineering: information technology and business process redesign. *Sloan Manage Rev*. Summer 1990:11-27.
72. Bates DW, Gawande AA. Improving safety with information technology. *N Engl J Med*. 2003;348(25):2526-2534.
73. Pronovost PJ, Holzmueller CG. Partnering for quality. *J Crit Care*. 2004;19(3):121-129.
74. Vaughan D. The dark side of organizations: mistake, misconduct, and disaster. *Annu Rev Sociol*. 1999;25:271-305.
75. Hibbard JH, Peters E, Slovic P, Tusler M. Can patients be part of the solution? views on their role in preventing medical errors. *Med Care Res Rev*. 2005;62(5):601-616.
76. Schiff GD. Respecting and reflecting on diagnostic errors. September 16, 2006. <http://healthaffairs.org/blog/2010/09/16/respecting-and-reflecting-on-diagnostic-errors/>. Accessed January 15, 2011.
77. Poon EG, Wang SJ, Gandhi TK, Bates DW, Kuperman GJ. Design and implementation of a comprehensive outpatient Results Manager. *J Biomed Inform*. 2003;36(1-2):80-91.
78. Silvestre AL, Sue VM, Allen JY. If you build it, will they come? the Kaiser Permanente model of online health care. *Health Aff (Millwood)*. 2009;28(2):334-344.
79. Weingart SN, Rind D, Tofias Z, Sands DZ. Who uses the patient Internet portal? the PatientSite experience. *J Am Med Inform Assoc*. 2006;13(1):91-95.
80. Deming WE. *Out of the Crisis*. Boston, MA: MIT Press; 2000.
81. Pasquale F. Access to medicine in an era of fractal inequality. *Ann Health Law*. 2010;19(2):269-310.
82. Carnahan SJ. Concierge medicine: legal and ethical issues. *J Law Med Ethics*. 2007;35(1):211-215.