

AFTER THE STORM

The pandemic has revealed dire flaws in American medicine. Can we fix them?

BY SIDDHARTHA MUKHERJEE



At 4:18 A.M. on February 1, 1997, a fire broke out in the Aisin Seiki company's Factory No. 1, in Kariya, a hundred and sixty miles southwest of Tokyo. Soon, flames had engulfed the plant and incinerated the production line that made a part called a P-valve—a device used in vehicles to modulate brake pressure and prevent skidding. The valve was small and cheap—about the size of a fist, and roughly ten dollars apiece—but indispensable. The Aisin factory normally produced almost thirty-three thousand valves a day, and was, at the time, the exclusive supplier of the part for the Toyota Motor Corporation.

Within hours, the magnitude of the

loss was evident to Toyota. The company had adopted “just in time” (J.I.T.) production: parts, such as P-valves, were produced according to immediate needs—to precisely match the number of vehicles ready for assembly—rather than sitting around in stockpiles. But the fire had now put the whole enterprise at risk: with no inventory in the warehouse, there were only enough valves to last a single day. The production of all Toyota vehicles was about to grind to a halt. “Such is the fragility of JIT: a surprise event can paralyze entire networks and even industries,” the management scholars Toshihiro Nishiguchi and Alexandre Beaudet observed the follow-

ing year, in a case study of the episode.

Toyota's response was extraordinary: by six-thirty that morning, while the factory was still smoldering, executives huddled to organize the production of P-valves at other factories. It was a “war room,” one official recalled. The next day, a Sunday, small and large factories, some with no direct connection to Toyota, or even to the automotive industry, received detailed instructions for manufacturing the P-valves. By February 4th, three days after the fire, many of these factories had repurposed their machines to make the valves. Brother Industries, a Japanese company best known for its sewing machines and typewriters, adapted a computerized milling device that made typewriter parts to start making P-valves. The ad-hoc work-around was inefficient—it took fifteen minutes to complete each valve, its general manager admitted—but the country's largest company was in trouble, and so the crisis had become a test of national solidarity. All in all, Toyota lost some seventy thousand vehicles—an astonishingly small number, given the millions of orders it fulfilled that year. By the end of the week, it had increased shifts and lengthened hours. Within the month, the company had rebounded.

Every enterprise learns its strengths and weaknesses from an Aisin-fire moment—from a disaster that spirals out of control. What those of us in the medical profession have learned from the COVID-19 crisis has been dismaying, and on several fronts. Medicine isn't a doctor with a black bag, after all; it's a complex web of systems and processes. It is a health-care delivery system—providing antibiotics to a child with strep throat or a new kidney to a patient with renal failure. It is a research program, guiding discoveries from the lab bench to the bedside. It is a set of protocols for quality control—from clinical-practice guidelines to drug and device approvals. And it is a forum for exchanging information, allowing for continuous improvement in patient care. In each arena, the pandemic has revealed some strengths—including frank heroism and ingenuity—but it has also exposed hidden fractures, silent aneurysms, points of fragility. Systems that we thought were homeostatic—self-regulating, self-correcting, like a human body in

Efficiency at the cost of resilience is like a silent aneurysm waiting to rupture.

good health—turned out to be exquisitely sensitive to turbulence, like the body during critical illness. Everyone now asks: When will things get back to normal? But, as a physician and researcher, I fear that the resumption of normality would signal a failure to learn. We need to think not about resumption but about revision.

Start with health care as a delivery system. In this state of emergency, delivering care has required both personal protective equipment (masks, gowns, gloves) for medical personnel and devices (including supplemental oxygen and ventilators) for patients. In the absence of effective drugs, care is mainly supportive. As the pandemic advanced, the delivery of these goods to hospitals and clinics should have been akin to a soldierly deployment, a meticulous, coordinated response—Toyota reassembling a supply chain within a matter of days. Instead, the medical infrastructure of one of the world's wealthiest nations fell apart, like a slapdash house built by one of the three little pigs.

N95 respirators, those heavy-duty face masks with two straps and a metal nose bridge, are a case in point. Before the pandemic, each cost between fifty cents and a dollar or so. They come in various sizes and styles, and every year health-care workers have their size “fit tested,” to make sure that air can't get in around the edges. (A puff of aerosolized saccharin might be sprayed near your face; if you can detect the sweetness, the mask isn't fitting properly.) The N95, meant for a single use, is designed to filter particulates as small as 0.3 microns in diameter. In the pre-pandemic world, when I encountered a patient suspected of having influenza or TB, say, I would put one on, and discard it in the biohazard trash after each use.

But mid-crisis, when the need for these masks in hospitals and clinics was most acute, doctors and nurses ran short. An anesthesiologist from New Jersey told me that he was forced to reuse his mask for the whole day: “We get one, per shift, per day.” His nursing staff, he said, initially got none. A resident in Boston who worked in an E.R. told me that he had no N95 mask until the end of March; the few that were available were reserved for medical staff performing in-

tubations and bronchoscopies—procedures that can send viral particles airborne, and pose the highest risk of infection. He recalled seeing a patient with symptoms that could have signalled COVID-19: “When I went to examine him, I had a surgical mask”—a simple clothlike cover, leaky at the sides—“and a face shield I had been cleaning and reusing for a month.”

We've all heard stories about the absence of masks in hospitals; we know that their production was typically outsourced to suppliers in China, which were buffeted by the very contagion that made these devices so necessary. Meanwhile, the shortage of these mass-manufactured fifty-cent items has imperilled the safety of our medical personnel. The question is: Why? Days after the Aisin fire, a typewriter factory was putting out brake-system components. Why weren't our suppliers responding with the same urgency and resilience?

The story of Mike Bowen, a manufacturer in North Richland Hills, Texas, offers some clues. His company, Prestige Ameritech, which he and his partners started fifteen years ago, is among the country's largest domestic manufacturers of surgical and N95 masks. Because companies that moved manufacturing abroad—including Bowen's old employer, Kimberly-Clark—would undercut him on price, he often had a hard time landing orders. “Hospitals typically don't order masks as individual buyers,” he told me. He spoke deliberately, with the slightest Texan drawl. Instead, they negotiate contracts as members of a Group Purchasing Organization—representing hundreds or thousands of hospitals—and, as Bowen explained, the G.P.O. always “chooses the cheapest bid.” His business struggled. In 2009, though, preparations were made for the H1N1 influenza pandemic, and Bowen was asked to ramp up his production of face masks to meet the anticipated demand. “We bought the old Kimberly-Clark factory,” he recalled. “We outfitted it with new machines. We hired an extra hundred and fifty people. And then, when it ended, the whole thing fell apart. The people that we helped went back to the foreign-made masks. So we had to lay off all of those people.” Bowen almost went bankrupt. “Hospitals promised to retain us as suppliers after the

flu.” But promises are not contracts. “We were just naïve,” he said.

Bowen kept thinking about the next pandemic, when the supply of masks from China might plummet and the demand for domestic masks might surge again. He sent letters warning about a potential supply-chain problem to President Obama in 2010, and to President Trump in 2017; he wrote to the Defense Secretary; to hospital-safety associations; to officials at the Centers for Disease Control—hundreds of letters in all. He must have seemed, at times, like an obsessive crank. “I got a form letter from the White House, thanking me for my concerns,” he said. “Everybody ignored it.”

When COVID-19 hit, China shut down many of its factories, and retained most of its diminished production of masks for its own use. For a while, exports declined to a trickle. Today, Bowen's company has increased its manufacturing almost fourfold, producing at least a million masks a day. But that's only a fraction of the demand; he has had to turn away orders for hundreds of millions a day.

There's another place that hospitals and clinics could have looked to for masks, gloves, and gowns: the Strategic National Stockpile—a repository of emergency equipment that can be deployed on short notice during a crisis. On March 4th, six weeks after the first case of COVID-19 had been reported in America, the S.N.S. announced its intention to buy six hundred million N95 respirators in the next eighteen months. Even if private-sector orders were cancelled when the pandemic subsided, the contracted companies—Honeywell, Dräger, 3M, Moldex, and O&M Halyard—would thus have a guaranteed buyer. But pandemics don't go on hiatus for eighteen months, patiently waiting for medical supplies to accumulate. The day after the S.N.S. announcement, the state of Massachusetts requested seven hundred and fifty thousand N95 masks (and a similar number of surgical gowns and gloves) to protect its doctors and nurses. Two weeks passed—each bringing grim news of viral spread—before the state received a tenth of that number.

When I e-mailed the Strategic National Stockpile, a spokesperson emphasized that the role of the S.N.S. was “to supplement”—her emphasis—“state and

local supplies during public-health emergencies,” not to fulfill everyone’s needs. But how many N95s were there in the stockpile to start with? The answer was thirteen million. New York and California, between them, have about three million health-care workers. If a fifth of that workforce were involved in some contact with virus-infected patients, and if no more than two N95 masks were used per worker each day, the entire S.N.S. supply would last eleven days.

Our delivery mechanisms have also broken down for the people trying to measure and manage the crisis. In this effort, the most important tool is the detection kit. At a population level, detection enables mapmaking: quantifying the size and the sources of an infection and tracking its movements. For an individual patient, it enables plan-making: assessing whether you’ve been infected and should be isolated, and tracing whom you’ve put at risk. In the later stages of a pandemic, the ability to test on a wide scale allows agencies to concentrate on hot spots and contain them with limited, local lockdowns.

The C.D.C., which had known about the Wuhan outbreak since December, started making detection kits in January. According to reporting from the *Washington Post*, on February 8th, one of the first C.D.C.-made detection kits for the new coronavirus, freshly approved by the Food and Drug Administration, arrived at a public-health lab in Manhattan; it contained a set of chemicals, or reagents, meant to isolate the virus’s genetic material, and a set of three “probes” to amplify the material and then determine whether it was from the coronavirus. Time and again, technicians in New York found, one of the probes—probe N₃—registered false positives: even distilled water triggered a positive result.

As the days dragged by, researchers at the C.D.C. tried to rejigger the test and make sure that its results were reliable. (The F.D.A. says that the original design it approved had performed well; the trouble arose when additional lots of the kit were manufactured.) Although the World Health Organization had distributed a quarter of a million tests, manufactured by a German lab and widely used elsewhere, the F.D.A. had authorized only the C.D.C.

kit. When labs at American hospitals and elsewhere devised detection assays of their own, the agency prohibited their use until an “Emergency Use Authorization” had been applied for and granted.

The “Emergency Use Authorization” protocol, less demanding than the ordinary approval process, was designed to make the agency nimbler, while preventing people from peddling useless tests, drugs, or devices during an emergency. Yet, for some researchers, it would prove to be a roadblock in itself.

I spoke to Alex Greninger, the assistant director of the virology lab at the University of Washington. It’s one of the largest virology labs in the country, and researchers there began developing a test just days after the first case of COVID-19 was detected on American soil—a thirty-five-year-old man who appeared at a clinic in Snohomish County, Washington, on January 19th, coughing and feverish.

Greninger, a square-jawed athletic figure who favors hoodies over suits, didn’t blame anyone at the C.D.C. or the F.D.A.; in fact, he told me that he found the officials “extremely responsive and easy to work with.” As he described the situation, it was the *process* that failed. For Greninger’s team, devising a lab test for the new coronavirus, SARS-CoV-2, wasn’t particularly difficult: its genomic sequence was already available, which made it possible to design the right probe for detecting the viral material. Securing samples of that material to validate the test wasn’t easy, but Greninger found a way. The next step was getting the F.D.A. to permit its use. He and his colleagues spent almost a hundred hours filling out a baroque, thirty-page form, filing the authorization request on February 19th. Still no dice: he had e-mailed the material, and the F.D.A. insisted that he print it out and mail a hard copy, along with the digital file in physical form, such as a thumb drive or a CD, to a separate “documentation” office. (This requirement was later withdrawn.)

“They worked as efficiently as they could,” Greninger said, “but the hard copies probably increased the turnaround by several additional days.” (The F.D.A. says that, on the contrary, it reviewed the electronic application immediately.) What gave the matter particular urgency is that the bulk of patient testing is done

by commercial clinical labs or academic labs, and the C.D.C. initially distributed its kits only to “C.D.C.-authorized” military and state and county public-health labs, which do a fraction of over-all testing. Meanwhile, the infection spread on flights and in movie theatres and during visits to grandparents, seeding itself in other cities and states: New York, New Jersey, Louisiana, Connecticut. Yet, by the last week of February, only a few hundred tests per day were being performed. On February 28th, Greninger and colleagues sent a letter to Congress, noting, “No test manufacturer or clinical laboratory has successfully navigated the E.U.A. process for SARS-CoV-2 to date.”

The next day, the F.D.A. relaxed its position, allowing “high complexity” clinical labs to test for virus infection in advance of agency review and approval. A simplified E.U.A. form was soon made available. Greninger e-mailed me two versions of the E.U.A. application. The original one, from January 19th, was thirty pages and filled with dense boilerplate. “In the first version,” Greninger told me, “they suggested the lab test twenty-five positive cases. But when we were looking at this, in mid-February, there were only fourteen confirmed cases in the U.S.” This posed a metaphysical question: How can one validate an emergency test before an emergency occurs? The F.D.A. duly worked with the C.D.C. and the N.I.H. to make more viral samples available, lowering the hurdles for test validation without compromising the quality of the test. A later version of the E.U.A. form, from March 7th, was just seven pages. Between February 28th and March 1st, Greninger’s team worked around the clock to prepare the virology lab for testing hundreds of patient samples. By Monday, March 2nd, the lab had begun its first tests. A full forty-three days had passed since that COVID-19 patient turned up in Snohomish County.

This is hardly the first time that the F.D.A. has faced the challenge of finding the right balance between safety and speed. In October of 1988, fifteen hundred AIDS protesters from the direct-action group ACT UP arrived at the agency to stage a “takeover.” While agency scientists, horrified and confused, peered out of their windows, activists draped banners and put out tombstone-shaped signs. (“RIP: KILLED BY THE F.D.A.”) As the

H.I.V./AIDS researcher and activist Mark Harrington recounted, it was part of ACT UP's "Drugs Into Bodies" agenda, propelled by an urgent logic: AIDS was nearly always fatal, and time-consuming precautions seemed the opposite of cautious—patients were being protected to death. The logic sank in. One way that the F.D.A. eventually responded was by developing an "accelerated approval" process. It would permit the use of "surrogate" metrics to judge the success of a medicine; that is, rather than waiting to measure patient survival rate over some period of time, researchers could establish effectiveness simply by documenting a decrease in viral loads, or the recovery of the immune system. Trials became leaner and swifter, expediting the development and approval of the antiviral "cocktail" therapies that are now used to treat patients with H.I.V.

For COVID-19, in turn, the F.D.A. has sought to fast-forward trials by means of its Coronavirus Treatment Acceleration Program, working with developers of treatments and vaccines. Still, the speedier approach has its own pitfalls: it makes it easier for products that are marginally effective—or outright ineffective—to slip into the system. "Drugs Into Bodies" too easily devolves into bad drugs delivered into vulnerable bodies. The same applies to devices and detection assays. A recent fiasco in the U.K. illustrates the point: the government spent twenty million dollars on COVID-19 tests, peddled by two Chinese companies, that proved unreliable.

As Greninger was quick to point out, without some F.D.A. approval process, testing could become a free-for-all. And in the aftermath of the testing debacle we're seeing a pendulum shift toward underregulation. The F.D.A. has allowed more than ninety companies to offer antibody tests meant to determine whether someone has already been infected and possibly acquired immunity. But it has reviewed and authorized only four. In short, the F.D.A. has essentially recused itself from evaluating these tests before they come on the market. Poorly regulated and unreliable tests, could, unfortunately, complicate recovery. Some nations, such as Italy and the U.K., are considering giving return-to-work "immunity passports" to those who have antibodies against the virus. This is a



divisive, ethically fraught approach to begin with. Add in diagnostic errors, and it could be a lethal one.

Tests, drugs, devices, procedures: all these draw on medicine as a research program. Major innovations in clinical care are often driven by scientists working with cell cultures, animal models, and even computational models—work done in vitro, in vivo, in silico. Lifesaving treatments found in I.V. bags and pill bottles generally had their origins in petri dishes and microarrays. Scant the lab research, and a patient will pay the price.

"I am busier than I have ever been," Susan Weiss, a professor of microbiology at the University of Pennsylvania, told me. Instantly recognizable in the long passageways of the lab by her nimbus of curly brown hair, she has spent her career working on coronaviruses. While other labs at the university are under lockdown, hers is now in hyperdrive: she is studying coronavirus proteins and their interaction with the human immune system—a topic she has pursued for forty years. Her work has helped that of other Penn scientists, including the virologist Sara Cherry, who are searching for drugs that might block coronaviruses from entering cells and replicating.

But this flurry of attention was preceded by a long period of neglect. "Just a few decades ago, we were on the periphery, even among virologists," Weiss told me. The first coronavirus conference was organized in 1980, in Würzburg, Germany. There were sixty people at the conference—"virtually the entire coronavirus group at that time." Federal grants were scarce, and her lab, along with the small band of researchers, struggled for decades with minimal funding. Then, in 2003, SARS hit. "And, of course, suddenly everyone was interested," Weiss recalled.

That September, the National Institutes of Health put out a "Request for Applications" to study SARS. The N.I.H. organized workshops featuring "international experts in the fields of coronavirus biology," and blue-ribbon panels on topics like "priority pathogens," bio-defense, and vaccines.

"We were suddenly in the middle of all attention," Weiss said. Then SARS stopped spreading, and the interest evaporated.

But surely, I asked Weiss, someone should have anticipated that another similar pandemic might arise?

"You would think so, wouldn't you?" Weiss said, her voice tightening in indignation. "You would *think* so." If the research on coronaviruses had kept

pace, we might have had an array of treatment options, even a vaccine platform that could be adapted for the coronavirus now circulating, a cousin of the one that causes SARS.

I searched a database called Grantome to confirm Weiss's observations. The plot of federal grants awarded for coronavirus research in the past few decades looks like a bell-shaped curve. In the nineteen-nineties and early two-thousands, there were typically between twenty and thirty such grants a year; these were the lean decades that Weiss had referred to. Predictably, the number surged after 2003, when SARS arrived, reaching its peak of a hundred and three in 2008. And then came the decline. This year, no doubt, the line will rise again.

"The investigators came and then they left," Stanley Perlman, a microbiologist at the University of Iowa, told me. He's another veteran coronavirus researcher who has watched labs drift away from his field of concern.

To be fair, the N.I.H. awards most of its grants based on unsolicited applications it receives from scientists, and it must balance national priorities. "Look, we live in uncertain times," Michael Lauer, a senior administrator at the N.I.H., said. "The N.I.H. cannot predict pandemics any more than anyone else can." And, he stressed, "there's already an internal effort to maintain a diverse portfolio within the Institutes. The whole of the N.I.H. evaluates its entire portfolio every five years. And some of the grants build the infrastructure to pay for clinical trials that can be rapidly deployed during a pandemic"—a network of clinicians who can move as a body when needed.

Still, the bell-shaped curve of coronavirus funding nagged at me. Boom-and-bust cycles in research have consequences: lab technicians are skilled workers who are laid off or retrained as priorities shift. When I worked in a viral immunology lab as a grad student at Oxford, our research infrastructure was supported by dozens of technicians, each trained one-on-one by yet another layer of skilled technicians. It was a product of time and the accretion of expertise. A well-run, focussed lab is like a village, not a Quonset hut you can put up overnight.

What's more, it was known that SARS and MERS were deadly coronaviruses with animal reservoirs that could hop

EVICION

Back from Dublin, my grandmother
finds an eviction notice on her door.
Now she is in court for rent arrears.
The lawyers are amused.
These are the Petty Sessions,
this is Drogheda, this is the Bank Holiday.
Their comments fill a column in the newspaper.
Was the notice well served?
Was it served at all?
Is she a weekly or a monthly tenant?
In which one of the plaintiffs' rent books
is she registered?
The case comes to an end, is dismissed.
Leaving behind the autumn evening.
Leaving behind the room she entered.
Leaving behind the reason I have always
resisted history.
A woman leaves a courtroom in tears.
A nation is rising to the light.
History notes the second, not the first.
Nor does it know the answer as to why
on a winter evening
in a modern Ireland
I linger over the page of the *Drogheda
Argus and Leinster Journal*, 1904,
knowing as I do that my attention has
no agency, none at all. Nor my rage.

—Eavan Boland

to humans. Disease modellers had determined that a respiratory virus with modes of transmission similar to SARS-CoV-2 was a likely culprit in a future pandemic. Why wasn't our research investment remotely commensurate with our threat assessments?

On Sunday, April 4th, Tatiana Prowell, a doctor at Johns Hopkins, messaged me on Twitter. She forwarded an e-mail from a radiologist in Los Angeles, along with a CT scan of a young patient's lung, with a golf-ball-size clot. An unusual finding was cropping up in patients with severe SARS-CoV-2 infections: blood clots in the lung, called pulmonary emboli (P.E.s), and strokes caused by clots in the brain. Some were tiny, nearly undetectable, and some were huge. "I think this is a major unrecognized cause of mortality," Prowell wrote. "My phone is full of msgs from physicians from every specialty asking if oth-

ers are also seeing unexpected thromboembolic events in young, healthy patients with COVID-19. Neurologists getting consulted for stroke, cardiologists finding large clots on echocardiograms, nephrologists noticing dialysis catheters clotting, radiologists finding PEs on scans. I think there is a slow collective awakening to the fact that this is not an isolated phenomenon."

In fact, the "slow collective" awakening was already well under way—elsewhere. Chinese doctors had apparently seen such blood clots, and started giving patients blood thinners to prevent them. ("Why are American doctors so resistant to learning from excellent Chinese doctors who . . . have been on the front line longer," someone admonished me on Twitter.) One patient—a man in his twenties—texted me a picture of bluish spots on his thighs, evidently a scattering of minuscule clots in the skin. I e-mailed a doctor in London; in autopsies, he told

me, “we are finding micro-emboli, small clots, in the lungs.” During the next few days, my in-box and my Twitter feed brimmed with notes from doctors and researchers remarking on these findings, and wondering about trials for virus-infected patients and blood thinners.

Is this loose, informal transmission of anecdotal findings—call it chatter, call it rumor—part of medicine? It isn’t what anyone is taught in medical school; it doesn’t fit in with the professional’s image as a purveyor of rigorously tested interventions. But continuous, iterative clinical knowledge—the kind that can be updated minute by minute—is invaluable during this tumult, when time is of the essence and there’s scant research to fall back on. Such updates are like weather reports in the middle of a storm. They matter in the moment; once the storm passes, they’re yesterday’s news. COVID-19 has similarities to familiar conditions, but it is a new condition and, like all new conditions, it has its peculiarities. When doctors exchange notes on their experiences—about an odd incidence of blood clots, about a ventilator setting that seems easier on the lungs, about the results of putting patients in a prone position in order to ease breathing—they can adjust treatments and improve patient outcomes. Not every provisional finding will pan out. Medical chatter can prove misguided, just as there’s plenty of bunk in open research archives. Still, anecdotal patterns can lay the groundwork for a case series, and then a case-control study, and, ultimately, a randomized, controlled trial of a clinical approach. Already, observations that began as scattered tweets about emboli in COVID-19 cases have migrated into preprint journal articles, Webinars, and official recommendations from professional bodies.

The way clinicians have made use of Twitter and Facebook during this crisis has been a heartening development. We’ve cobbled together an informal medical bulletin board for the pandemic; even as we wade through the muddy slop of fake news, we have a forum of exchange that is flexible, versatile, and timely. This is a story of something that’s gone right—and of something that’s gone very wrong.

That’s because clinical medicine is, among other things, an information system, and a central part of that system is

broken. Patient records that once were scribbled on clipboards now sit in electronic medical-record (E.M.R.) systems, many of them provided by the Wisconsin-based software company Epic. A standardized digital database of patient-care records, searchable across hospital and medical-care systems, could be an invaluable way of identifying effective approaches to a novel disease—like moving from a patchwork meteorological system where towns keep their own records of wind and rainfall to a national weather-tracking grid. A putative advantage of digital hospital records is to enable on-the-fly searches—not the kind of data project that the N.I.H. might fund (its grants take weeks to process even on an accelerated schedule) but the kind that might be completed in an hour. Perhaps, I thought, we should be advising COVID-19 patients to call us if they suspected clots—if their breathing rate and heart rate increased suddenly, for instance. Perhaps our hospital system’s emergency department should be alerted.

Because clotting is a frequent issue among patients with cancers, I called my colleague Azra Raza, the director of Columbia’s Myelodysplastic Syndrome Center, to ask if we could search through the database of her patients for any who had reported being infected, and, if so, had experienced blood clots. She sighed. “I can’t think of a simple way to do this,” she told me. “And in any case, because of all the concerns around privacy, if you wanted to report the findings you would have to file with the institutional review board.”

“But that would take a month, at least,” I protested. (In recent weeks, many hospitals have accelerated their review process to deal with the pace of the pandemic.)

“It’s the way the system is,” she said. “If you want to report the number of times a patient has cut her nails in the last week, you would need approval. And it’s not easy at all to search the E.M.R. for any of this information. You’d have to hire someone specifically to look through it.”

A cardiologist at Massachusetts General Hospital, in Boston, echoed this frustration on Twitter: “Why are nearly all notes in Epic . . . basically *useless* to un-

derstand what’s happening to patient during hospital course?” Another doctor’s reply: “Because notes are used to bill, determine level of service, and document it rather than their intended purpose, which was to convey our observations, assessment, and plan. Our important work has been co-opted by billing.”

The promise of bringing medical recordkeeping into the digital age was to maintain a live record of a live patient, enabling clinicians to track patient care across hospital systems and over time. Instead, we’ve been saddled with systems that cut into patient care (clinicians typically spend an hour feeding documentation into a computer for every hour they spend with patients) and, often, are too fragmented to allow a patient’s file to follow her from one medical center to another. The E.M.R., as a colleague of mine put it, is “electronic in the same sense that your grandfather’s radio is electronic.” The energized, improvisatory role of medical Twitter inevitably draws attention to what our balky, billion-dollar systems should have been providing—to the cost, in dollars and lives, of the rapid clinical learning that we’ve forgone.

It’s hardly news that our E.M.R. systems have failed medicine, and yet an executive order from New York State, issued at the end of March by Governor Andrew Cuomo, amounted to a grim epitaph: “Health care providers are

relieved of recordkeeping requirements to the extent necessary for health care providers to perform tasks as may be necessary to respond to the COVID-19 outbreak. . . . Any person acting reasonably and in good faith under this provision shall be afforded absolute immunity from liability.”

A system designed to expedite and improve the delivery of health care was officially recognized as an obstacle.

“When the tide goes out,” Warren Buffett once said, “you discover who has been swimming naked.” The pandemic has been merciless in what it has exposed. In many cases, the weaknesses in our medical system were ones that had already been the subject of



widespread attention, such as the national scandal of health-care coverage that leaves millions of Americans uninsured. In others, they *should* have been the subject of widespread attention, because we had plenty of warning. Again and again, in the past several weeks, we've heard of shortages—shortages of protective gear, of ventilators, of pharmaceuticals. Yet, even before the crisis, medicine was dealing with troubling scarcities of needed drugs and support systems. Last summer, long before the pandemic, pulmonologists were raising concerns about a lack of oxygen supplies—the result of cost-cutting measures by suppliers of durable medical equipment. Competitive-bidding programs drove margins down so low that more than forty per cent of such companies—responsible for the supply of portable oxygen tanks and concentrators—went out of business. Inventory diminished; delivery times increased. Patients suffered. Neeta Thakur, a pulmonologist and researcher at the University of California in San Francisco, told me about the byzantine process (involving “ten to fifteen disconnected steps”) that was required in order for a patient to receive oxygen at home—a patient who is then at the mercy of the intermittent delivery schedules of understocked vendors. The problem builds into a failure cascade: if patients cannot be discharged from the hospital because they cannot have oxy-

gen at home, the resultant logjam delays the treatment of other patients who need those beds for acute care.

The pharmaceutical system was clearly fraying as well. Vincristine, which I use to treat blood cancers, was among a hundred important drugs that have been in critically short supply in recent years. Even bags of sterile saline solution—the most basic I.V. fluid, nothing more than salt and water—were hard to source. (Many American hospitals used bags made by a single manufacturer, in Puerto Rico, which was devastated by Hurricane Maria.) An F.D.A. report published in October noted that manufacturers had little incentive to produce less profitable drugs; that the market failed to reward “‘mature quality systems’ that focus on continuous improvement and early detection of supply chain issues”; and that “logistical and regulatory challenges make it difficult for the market to recover from a disruption.” If one factory went offline, the entire nation's supply of a critical drug could be imperilled.

As such pre-pandemic stories proliferate, they point toward more fundamental reckonings. Leave aside the tragedies of those who died alone in isolation rooms in hospitals, or of the disproportionate disease burden borne by African-Americans and working-class immigrants. Leave aside the windblown avenues of an empty, joyless city, the

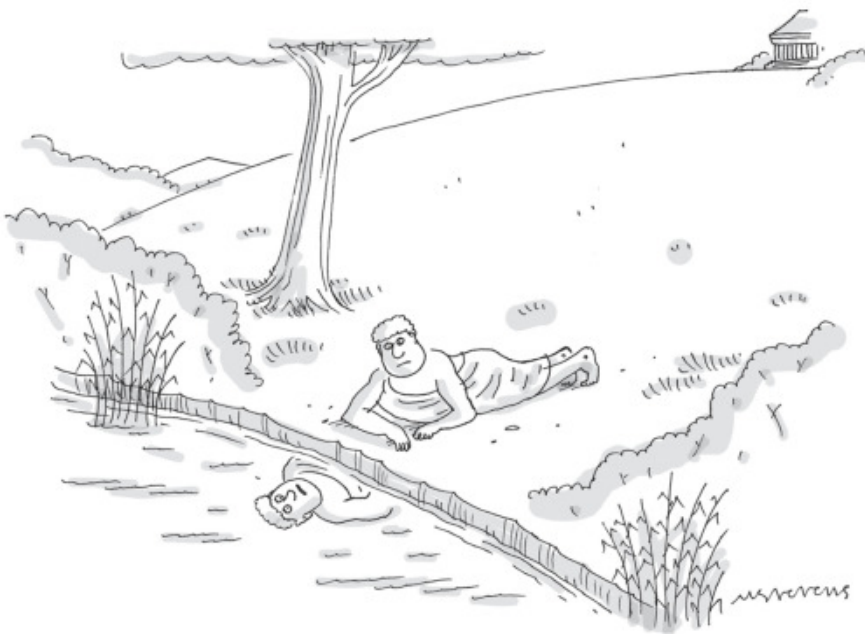
generation-defining joblessness that has shifted so many from precarity to outright peril. To what extent did the market-driven, efficiency-obsessed culture of hospital administration contribute to the crisis? Questions about “best practices” in management have become questions about best practices in public health. The numbers in the bean counter's ledger are now body counts in a morgue.

For decades, consultants had taught the virtues of taut business practices. “Slack”—underutilized resources, inventory waiting to be put to use—was shunned. I spoke to David Simchi-Levi, an M.I.T. professor who studies supply-chain economics and how enterprises respond to disasters. “Cost is easy to measure,” he told me. “But resilience is much harder.” So we reward managers for efficiencies—and overlook any attendant fragilities. His view can be summarized simply: we've been overtaught to be overtaut.

“We've been teaching these finance guys how to *squeeze*,” Willy Shih, an operations expert at Harvard Business School, told me, emphasizing the word. “Squeeze more efficiency, squeeze cost, squeeze more products out at the same cost, squeeze out storage costs, squeeze out inventory. We really need to educate them about the value of slack.”

Simchi-Levi is particularly interested in two variables that could serve as metrics for resilience. The first is the “time to survive”; that is, how long can an enterprise endure when there's a sudden shortage of some critical good? The second is the “time to recover”: how much time will it take to restore adequate supplies of some critical good? By quantifying each variable under different scenarios, a business can model its ability to recover from a disaster. He told me about floods in Thailand that shut down factories responsible for critical computer and automotive parts. Afterward, some companies expanded their supply lines to other parts of Asia. Having seen the fragility of a tight chain, those companies had now established a network with some spring in it. In the future, their “time to survive” would exceed the suppliers' “time to recover.”

Toyota's recovery from the Aisin factory fire in 1997 can sound like a story of triumph, as, in many respects, it was. But the company's executives realized



“Could we cut it short today? I need a little me time.”

that it was also a story of failure. The company shouldn't have been so vulnerable to such an event. The fire, along with a later disaster—the 2011 earthquake, which cut off its supply of a crucial microchip—taught Toyota the value of redundancy and risk assessment. It modified its just-in-time system to allow for at least a month's worth of specialized components, building strategic slack into its operation. It created a database, called RESCUE, with dozens of companies organized into tiers, their risks regularly evaluated under conditions of adversity, and information on sixty-eight hundred parts continually updated. The company maintains constant communication with its suppliers under "ordinary operating conditions." But it also trains employees to operate during disasters, and evaluates the risk to the entire company if nodes in the network should falter. No enterprise is truly disaster-proof, but in cultivating networks of mutual loyalties the company has engineered resilience.

Yet resilience isn't simply a matter of having supplies at hand. In Shih's view, the most critical kind of slack doesn't take the form of a stockpile. Rather, he told me, "I think of slack as *capacity and capabilities*." What you really want to measure, model, and establish is the capacity to build something when a crisis arises. And this involves human as well as physical capital. We need to measure talent, versatility, and flexibility. Overtaut strings inevitably break.

Resilience in our medical system will involve more than considerations of physical supplies. Take the debacle of the C.D.C. detection kit. Here's where attention to "mature quality systems" matters. South Korea has so many test kits that it's now exporting them for use in the United States. What was its approach? The government identified more than twenty reputable vendors, certified their products through a sound evaluation process, and set their factories loose to meet the demand. That's what the C.D.C. should have done, long before the pandemic arrived on these shores. In preparation for a future pandemic, the C.D.C. could run the equivalent of fire drills, identifying the capacity, almost on the model of Toyota's RESCUE database, to create and mass-manufacture such kits during a time of crisis. The organi-

zation, rather than closing itself off, working chiefly with state and military labs, could fortify lines of communication with the commercial and clinical labs that actually serve the vast majority of patients. The F.D.A. could have had a streamlined E.U.A. form already in hand—preferably without a requirement that it be sent by pigeon post—rather than having labs waste critical time placating its bureaucracy. Before the next public-health crisis emerges, the F.D.A. must think hard about how to balance speed and oversight, adjusting the ratio to meet the moment but abandoning neither.

Slack can be costly. As Greninger put it, "Right now, I have machines and reagents to test tens of thousands of patients for SARS-CoV-2. That's basically all the clinical virology lab is doing. What will happen when the epidemic is over?" Once the incidence of COVID-19 subsides, so will the sense of urgency when it comes to building infrastructure, or stockpiling equipment—masks, ventilators, reagents—that might sit unused in warehouses for a decade or more. We need purchasing procedures that control costs without creating conditions in which critical supplies vanish during a crisis. We need a Strategic National Stockpile that has sufficient inventory to ease temporary shortages. But, most of all, we need an identified capacity—a network that can be activated on demand, repurposing manufacturing lines, recalibrating agency protocols.

In research, too, we need strategic reserves and cultivated capacities: a scientific infrastructure directed at our existential threats—categories of pathogens with the potential to disrupt human communities en masse. This may require regular "Requests for Applications," determined by an advisory panel, that will encourage researchers both to advance our microbiological understanding of such agents and to develop interventions and therapeutic platforms. The N.I.H. has many funding priorities; this agenda must take its place among others. Yet it cannot be allowed to slip to the margins as ambitious researchers move toward new areas of excitement. Research does not benefit from a feast-or-famine ecology.

Finally, we need to acknowledge that

our E.M.R. systems are worse than an infuriating time sink; in times of crisis, they actively obstruct patient care. We should reimagine the continuous medical record as its founders first envisaged it: as an open, searchable library of a patient's medical life. Think of it as a kind of intranet: flexible, programmable, easy to use. Right now, its potential as a resource is blocked, not least by the owners

of the proprietary software, who maintain it as a closed system, and by complex rules and regulations designed to protect patient privacy. It should be a simple task to encrypt or remove a patient's identifying details while enlisting his or her medical information for the common good. A storm-forecasting system that warns us *after*

the storm has passed is useless. What we want is an E.M.R. system that's versatile enough to serve as a tool for everyday use but also as a research application during a crisis, identifying techniques that improve medical outcomes, and disseminating that information to physicians across the country in real time.

No set of reforms will deal with every problem, such as a President who, bickering with scientists, equivocated and delayed what could have been a lifesaving, economy-protecting, coordinated response. Given the resolve and the resources, however, much is within our grasp: a supply chain with adequate, accordioning capacity; a C.D.C. that can launch pandemic surveillance within days, not months; research priorities that don't erase recent history; an F.D.A. that serves as a checkpoint but not as a roadblock; a digital system of medical records that provides an aperture to real-time, practice-guiding information.

"Recovery" is the word of the moment; it connotes a return to a previous state of well-being. For many patients with chronic conditions, though, treatment aims not to restore a baseline of precarious health but to reach a higher baseline. Some of medicine's frailties are new; some are of long standing. But what the pandemic has exposed—call the experience a stress test, a biopsy, or a full-body CT scan—is painfully clear. Medicine needs to do more than recover; it needs to get better. ♦

