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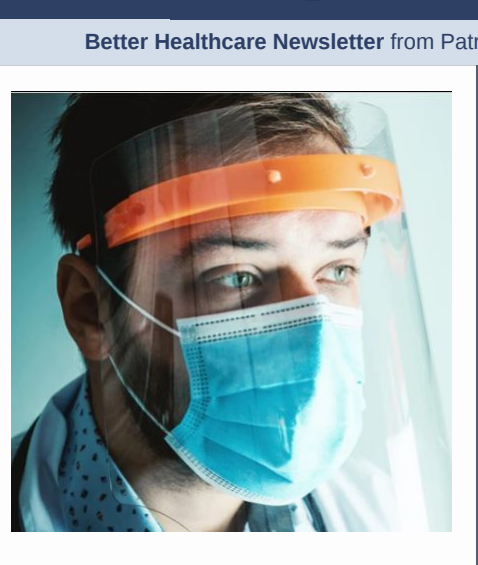
PATRICK MALONE & ASSOCIATES

Better Healthcare Newsletter from Patrick Malone



The worst public health crisis in a century has brought with it some swiftly changing coronavirus health measures, and many by now are reacting with weary exasperation, asking: "Why can't doctors get it straight? Why do they keep changing their minds and telling us to do so many different things?"

Yes, the public health messaging during the pandemic has left much to be desired, especially as too many parties have politicized or debased medical-scientific information and spread disinformation with ugly urgency.

But much of the disconnect between the public and the health experts comes from fundamental misconceptions about medicine, mainly in the extremes that doctors and scientists either walk on water or are all wet. Critics somehow want us to believe that patient care, especially in an emergency, should proceed in a neat and orderly way. Desiring a consistency in medical care has become a hobgoblin of pandemic thinking.

The advance of medicine follows its own, irregular path. It does not race straight ahead with going from one progress in science to the next, with absolutes in the field lining up in tidy fashion. Instead, medicine is rifer than ever with uncertainty, complexity, and for patients, high risks, costs, rewards, and losses.

These challenges have become glaring during the pandemic. But many patients and their loved ones also confront fast-shifting circumstances in daily fashion as they cope with late-stage illness and devastating injury.

Modern medicine has put huge strains on us all — to be as informed and thoughtful as possible and to ensure that doctors share with candor the best evidence they have for any given course of care. That may not make difficult medical journeys any easier. But it is crucial to improving treatments available to us all, especially in these pandemic times.

So in this issue of our newsletter, let's put some context into pandemic medical care, so we can all understand better how medicine really works in the 21st century.

Expect the unexpected in medicine

As any patient who has recent experience with serious illness or injury can attest, it is simply false to suggest that medicine magically has "set it and forget it" approaches to treatment, whether with a novel infection like the coronavirus or with well-known threats to health.

§ A friend may cajole his buddy to go to an emergency room because the pal — who is not drinking — suddenly feels dizzy, has trouble walking, slurs his speech, and may have weakness in an arm. It's a good bet that speedy ER response may rocket this patient, seemingly OK an hour or so before, into significant care for stroke, with many treatments launched.

§ Similarly, her family might take to the ER a woman who cut her hand in the kitchen a few days earlier when she develops signs of a serious infection, including chills, fever, disorientation, slow breathing, and plunging blood pressure. This patient may be headed to intensive care, undergoing dramatic treatment for sepsis.

§ An older man may resist seeing a doctor for what he thinks is a bad cold, muscle aches, high fever, coughing, labored breathing, and tiredness that has lasted for a few days. This patient also may quickly be admitted to an ICU for drastic measures to save his life from pneumonia.

While patients might accept how much medical response may change in emergencies like these, they still may be thrown for a loop as their treatments shift in less urgent conditions. They insist that doctors provide them with personalized, individual attention and care. But they may not see all that this means.

Individuals differ, and so too does their care

Because we are all alike and still all unique, we can respond to therapies and prescription medicines in very different ways. A drug that is considered standard and effective for most patients might not be for a sizable number of others, depending on factors such as gender, race, age, overall health, and the seriousness of the condition. Your doctor, based on considerations including your medical history and his or her experiences with you as a patient, may not prescribe drugs for you that your friends are taking for a similar disorder. You may react to them differently, including with risky side effects.

You also may start treatment for one condition that causes you to feel poorly and quickly find your doctor treating one, two, or several others. Federal researchers have found that more than a quarter of U.S. adults suffer from two or more "co-morbidities," serious conditions that include high blood pressure, coronary heart disease, stroke, diabetes, cancer, arthritis, hepatitis, weak or failing kidneys, asthma, or chronic obstructive pulmonary disease. Doctors can't get patients into more optimal shape by treating just one condition and ignoring others. It can be frustrating to patients, though, to learn that their care will be more difficult, complex, and sustained than they first thought.

Doctors' significant effects on patient treatment

They and their loved ones also should know that doctors and hospitals themselves may affect patients' treatment and outcomes — to the positive and negative.

Doctors may, for example, subject patients — sometimes almost routinely — to a cascade of exams, tests, and procedures that may be invasive, painful, costly, and sometimes unnecessary. Over-testing, over-diagnosis, misdiagnosis, and over-treatment plagued U.S. medicine in pre-pandemic times. It's a topic worthy of a whole newsletter, but know this: When it comes to medical screenings and tests, more isn't always better. Early detection may not be all that helpful with some conditions and diseases, contrary to popular belief. And it's, well, malarkey that doctors do something useful when they argue they practice defensive medicine against medical malpractice lawsuits by ordering excessive tests or procedures, just in case.

As health officials try to contain medical services' soaring costs, they have zeroed in on an important gateway: over-screening, over-diagnosing, misdiagnosing, and over-treating that add $200 billion in unnecessary expenses to our care, with over-treatment costing 30,000 lives a year of older (Medicare) patients alone.

It isn't taking patients' temperatures or checking their blood pressure or getting them one or two tests that reformers assail. It is the cascade of costly, invasive, painful, and unneeded tests and procedures that follow. Every medical intervention carries with it an element of risk — indeed, some experts estimated that medical errors ranked as the No. 3 killer of Americans, claiming 250,000 lives annually in pre-pandemic times.

An exasperating chunk of those preventable deaths occur each year due to health-care-acquired infections (HAIs). Due to overuse and abuse of antibiotics and poor infection-control practices, already sick or injured patients get worse when in medical care and exposed to an array of increasingly virulent bugs that teem in doctors' offices, clinics, hospitals, nursing homes, and other long-term care facilities.

Institutions insist they are doing their best to stamp out HAIs, including struggling with outbreaks of "superbug" (antibiotic resistant) infections. Patients and their loved ones must be on alert, for example, whether health workers do simple things like washing their hands and maintaining facilities that at least appear orderly and clean (though they still may not be hygienic) and are not malodorous. It also makes no sense to play the odds with your well-being by loading up with too casual or frequent exposure to the health care system.

Medicine's huge strides can't be ignored

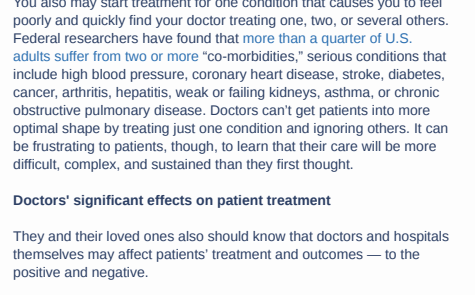
To be fair, heroic medical professionals also have made revolutionary improvements in our health — with rigorous scientific study (randomized clinical trials), breakthrough thinking, and better treatments, whether with prescription drugs or surgical procedures (see sidebars). Medical knowledge is exploding and this poses big challenges to experts in sorting out what it all means and how it best benefits patients.

Polio and smallpox, deadly infections that once mowed down huge swaths of humanity, have been largely eradicated, thanks to vaccines. HIV-AIDS is now a chronic and treatable condition, not a nearly automatic death sentence. The pandemic has upset positive trend lines. But death rates were on the decline for roughly half of common cancers. Deaths from heart disease have fallen dramatically over the past 50 years in the United States. Deaths from stroke also declined over the same period. Many of us, when we "go under the knife," even for major surgeries, have laparoscopic procedures involving only tiny incisions and maybe local rather than general anesthetic. It no longer is earth-shattering for patients to undergo life-changing and -saving transplants of an array of major organs and tissues, including hearts, lungs, kidneys, and livers.

Even the most cursory glance through medical history textbooks or a trip through fading recollections of people of a certain age will reveal how fraught were the prospects of success for what are now considered medical marvels, whether transplantation's early period marked by death and failure or retrovirals' rocky and angry path to providing a working treatment for HIV. Many medical advances occur after perceived failure and often after researchers take circuitous paths to favorable outcomes.

The New York Times reported on the decades of toil by Katalin Karikoa, a Ph.D. and a leading researcher in the science that led to the current, innovative coronavirus vaccines. Her "overnight" success not only debunks the widely spread falsehood that the vaccines cannot be trusted because they seemed to appear so quickly. Her commitment to science and what she considered a vital aspect of research is inspiring, humbling, and confounding in the ups — and plenty of downs — that she had to endure

'Medical reverses' occur often, and that's good



The criticism of "flip-flopping" pandemic health responses comes at a curious time in medical research. That's because investigators are pursuing a rising area of study on widely accepted treatments and how and why they win acceptance — and, more importantly, whether they work.

Doctors have come up with a telling name for the meandering course of many purported therapeutic advances, dubbing them "medical reverses." But reverses can mean progress, as medicine sheds time-honored treatments once scientific study proves them to be inef

The expanding catalog of these unnecessary and unhelpful approaches might stun many patients. Researchers scrutinized 3,000 or so studies published in top medical journals, finding that 396 involved 180-degree shifts in existing thought or with "practices that have been found, through randomized controlled trials, to be no better than a prior or lesser standard of care."

Doctors once blamed high stress and excess stomach acid, for example, for causing patients' ulcers. This erroneous belief led surgeons to perform serious operations in which they severed a key nerve to the stomach or to surgically remove part of that organ. In 1982, two researchers won a Nobel Prize for showing definitively that a bug named *Helicobacter pylori* causes peptic ulcers. Their study upended doctors' long belief that bacteria just could not possibly survive in an acidic environment like the stomach.

Drs. Vinay Prasad (University of California, San Francisco) and Adam Cifu (University of Chicago) have written extensively about medical reversals, reporting in one of their published studies:

"In the late 20th century, sudden cardiac death, particularly during the vulnerable period after [a heart attack], was deemed a 'worldwide public health problem.' A type of heart rhythm, premature ventricular contractions (PVCs), was thought to contribute to such deaths. A new generation of anti-arrhythmic therapy was developed with the ability to suppress PVCs up to 85% of the time. Cardiologists began using these medications in widespread fashion.

"In the late 1980s, the Cardiac Antiarrhythmic Suppression Trial (CAST) was conducted to assess the safety of what was then commonplace. Interestingly, recruitment for the trial was hindered by physicians who refused to let patients undergo randomization with a 50% chance of not receiving these medications. Fortunately, the trial was completed and showed that these drugs (encainide, flecainide, and later, moricizine) conferred greater mortality than placebo, and their use was curtailed for this indication.

"Vertebroplasty, the injection of medical cement into fractured bone, achieved widespread use without good evidence that it worked. First described in the late 1990s, vertebroplasty quickly gained popularity. In 2005, it was performed more than 27,000 times in the United States. A pair of articles published in the *New England Journal of Medicine* in 2009 conclusively showed that the procedure was no better than [a] placebo …"

A catalog of treatments turning180 degrees

Prasad, Cifu, and other experts point to other major medical reversals, including:

§ The 1990s scandal involving the purported weight-loss drug combination nicknamed Fen Phen. It became a diet fad, boosted by expensive Big Pharma advertising and marketing campaigns about a supposedly easy, convenient way to just pop pills to deal with obesity. But cardiologists reported increasing numbers of cases in which patients, many of them women, suffered serious heart damage after even limited exposure to the drug combination. Thousands of lawsuits against a drug maker ended the Fen Phen phenomenon, but not before significant numbers of patients suffered greatly.

§ For more than 50 years, hormone replacement therapy (HRT) was thought to prevent chronic disease, such as cardiovascular disease, in menopausal women. Several more recent (and more powerful) studies showed HRT provides no such benefits, and that some combinations of it may increase the risk of certain cancers, stroke, and blood clots. HRT may still be recommended for women with significant menopausal symptoms, such as hot flashes, but it is no longer prescribed to prevent chronic disease.

§ Surgery once was a common approach for a meniscal (cartilage) tear with osteoarthritis of the knee for adults ages 45 and older. This combination of problems is common among older adults and is detected often by MRI scans for knee pain. A 2013 study found that treatment first with physical therapy was just as effective as immediate surgery. Guidelines soon changed to advise nonsurgical treatment as the initial approach for knee problems in most middle-aged or older patients.

Distressing as the list of medical reversals may be — and Cifu and Prasad have included a whole chapter of them in their book *Ending Medical Reversal: Improving Outcomes, Saving Lives* — the increasing awareness of them also represents important progress, the doctors contend.

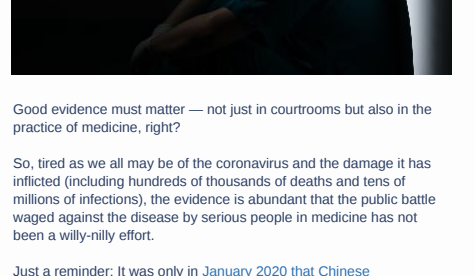
That's because they argue that too much of health care, even now in the 21st century, is taken for granted or relies on the idea of medicine as art rather than science. Medicine is conservative. It can take two decades or so for innovations on average to go from publication in respected journals to routine practice. But many routine practices also go unexamined and unquestioned for even longer, experts say.

The flood of money into medicine already has doctors under extreme time pressure — to see more patients, and to order more tests, procedures, and prescription medications. It is, at the same time, daunting toil — for patients and doctors — to stay current with the flood of information about medical practice.

Besides going along with long-standing medical practices, "just because," doctors may be too problem-focused and willing to offer what they think will be quick, "common sense" solutions, they have written:

"In current practice we continue to adopt new technologies not because they are supported by the strongest evidence base, but based on a common sense appeal that they should work. We can extend 'common sense' to signify any set of surrogate data trials, basic science rationale, or observational results … [This] prevailing attitude must be reconsidered. A common sense standard that a treatment will work can no longer justify its adoption. Twenty years into the era of evidence-based medicine, we must recommit to practicing based on good evidence."

Pandemic may be proving why evidence-based medicine matters more than ever



Good evidence must matter — not just in courtrooms but also in the practice of medicine, right?

So, tired as we all may be of the coronavirus and the damage it has inflicted (including hundreds of thousands of deaths and tens of millions of infections), the evidence is abundant that the public battle waged against the disease by serious people in medicine has not been a willy-nilly effort.

Just a reminder: It was only in January 2020 that Chinese researchers, at great risk to themselves, published the detailed gene sequence of a highly contagious virus that apparently had mutated recently and made the leap from animals to humans. Despite shambolic political reactions to the pandemic, medical scientists in short order dug into a substantial body of research on coronaviruses and vaccines, producing three shots that have proven safe and effective when given to hundreds of millions of people — and with rare side effects. Frontline health workers successfully have treated millions of patients for a deadly disease that was unknown mere months ago. Their work also has more than held up as the virus has mutated, throwing up multiple variants, including the highly contagious Delta strain.

Despite furious resistance from people proceeding without facts or science, public health officials, as retrospective studies already are starting to show, put in place measures that protected most Americans from calamitous illness and death.

It has been a rocky go. But along the way, officials have delivered the data, studies, and clinical observations so reasonable people could consider them — and by large, they have — and followed public health measures.

Frustration turning, wrongly, to abuse

Still, for exhausted health professionals, the unrelenting resistance they have encountered has been damaging, as a physician wrote on KevinMD.com, a site that gives doctors a public voice on issues that concern them. This practitioner was distressed at the negative reaction she received after signing a published letter urging people to carefully consider and to follow medical-scientific recommendations to quell the pandemic:

"As a relative political outsider, and someone who reads Nature and JAMA [the Journal of the American Medical Association] instead of the New York Times and the Washington Post, was it foolish of me to believe that evidence-based medicine was a stance unto itself? … Why is following medical recommendations now described as a political leaning? This is the era of guidelines and recommendations for all medicine. The only difference: Now the news covers us like we're the Olympics. The protocols for treating Covid aren't much older or better tested than the vaccine. Even beyond widely accepted (but new) Covid treatment protocols: how many patients and families have called out for anything at all, any drug or treatment — no matter how experimental — once they're sick? Were the people who aimed to 'cancel' me online suggesting they won't take any evidence-based treatment from a doctor?"

Prasad and Cifu have called on — and called out — doctors for failing to step up their practice, subjecting many of their treatments to randomized clinical trials with rigorous standards for the evidence they obtain. They concede that such trials are not always easy, nor cheap to run. They may not be feasible, depending on the risks they might subject patients to, or the complications that cannot be ruled out and might cloud their results.

Still, the profession harms its crucial credibility when it does not just replace one treatment with another but reverses itself on a procedure or drug. This is an avoidable blunder, the doctors say.

They and others underscore the importance of communicating constantly and with candor with patients about risks and rewards in their care. Doctors bear a huge responsibility, of course, to ensure their patients receive their fundamental right to informed consent. This means they are told clearly and fully all the important facts they need to make an intelligent decision about what treatments to have, where to get them, and from whom.

Prasad, who has extended his study of medical reversal to examining how hype and big money can harm patients by gulling them into taking costly cancer drugs with limited effects, also has this important view about taking the extreme view of medicine as a failure. As he told a colleague-interviewer:

"It is very tough as a clinician to go in there and say, 'Look, I was wrong about something I was doing. I wasn't wrong because I was ill motivated. I was wrong because everyone was wrong about this.' But I think we have to be honest about it. We do get things wrong. [But] we should be careful not to use these examples as reasons to dismiss all of Western medicine or all of biomedicine. There are a lot of people out there right now who are willing to seize upon the imperfections of medicine as reason for why we're wrong about everything, why vaccines may cause autism, or all sorts of conspiracy theories. We have to be careful to say, 'Look, we have gotten this wrong, but yet, medicine is still the best way of moving forward about issues of health.'"

Prasad, by the way, has stressed the pragmatic aspects of the call for practice reforms that he and Cifu have made, notably in discussing therapies in which there is "tremendous effect size," which he has explained, thusly:

"The classic example is you don't need a randomized trial for wearing a parachute when you jump out of an airplane. That's an intervention that has a 99.9999% improvement in overall mortality in a very short period of time. No one has ever called for a randomized trial of the parachute, and similarly, no one has called for a randomized trial of if I got hit by a bus and my femur were exploded out of my leg, and I had a compound fracture, no one has said, 'You need a randomized trial of putting it back in my leg or just leaving it out and letting nature take its course.'"

Are we at similar tipping points with public health advisories on the pandemic? We now know that disinfecting groceries didn't affect coronavirus infections, so we stopped this. We know that the Delta variant is savaging the unvaccinated and increasing risks for those who have gotten shots, while the vaccines' side effects have been rare. So, we're pushing for more people to get the jab.

And, yes, while the data may not be as iron-clad about face covering and distancing, when these practices occur, infections, community spread, hospitalizations, and deaths from the coronavirus have declined in this pandemic and other major outbreaks of infectious diseases. More data and study are under way.

Skepticism, not nihilism

But as the pandemic rages, isn't it weak tea for extremists and the resistant to complain about inconvenience, discomfort, or their asserted claims of inconsistency while huge numbers of people get sick, overwhelm hospitals, clinics, and health workers, and die? Is it clear now that the unvaccinated pose big risks to us all, not only when their illnesses stagger the health system but how they may be fostering the rise of even more problematic coronavirus variants? While health officials share more and more information about the steps they want us to take and why (i.e., real evidence), do we give platforms and credence to nonexpert opining — from political columnists, broadcast commentators, and people lacking in experience or credentials?

When the mechanic wants to weigh in on statistical data on community spread, is it time to remind him how he couldn't find the rattle in the car that eventually caused it to go dead? When the expert on public polling methods offers his ideas about pulmonary diagnoses and the proper application of certain prescription medications, is it time to remind him that critics say he was misguided on results of recent elections (something closer to his actual expertise)? When the nervy aunt is rattling the kids as they are setting off to school by discussing her "fact-checking" of public health data with her excellent Excel skills, is it too curt to remind her she hasn't even won the office baseball betting pool in years?

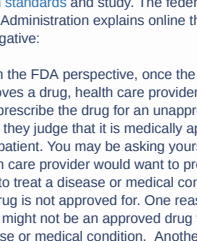
We can and should be skeptical — but not cynical or nihilistic — about medicine and medical information, which we can consume and apply with common sense and good judgment. We can help push our own harried doctors to stay current, too.

It is unacceptable, though, that the frustration with the inevitability of change in both the pandemic and medicine itself becomes a reason for a vocal extremists to berate and abuse medical personnel trying to provide reasonable care to the sick and injured and to save lives. Health workers, especially nurses, already are overwhelmed and upset that their lives are still upside-down with a fourth, Delta-variant surge.

Here's hoping we turn a lasting corner, and we quell the pandemic, so we don't need yet more public health recommendations. All medical interventions carry risks. But vaccines' benefits clearly outweigh their risks, so, if you haven't done so, please get your shots and help your loved ones get theirs. Face masks? Yes, please. They fall, really, into the category of seat belts, football helmets, prophylactics, telephone headsets, clean underwear, and more — they may not be optimal or always comfortable to don. But they protect both our own health and that of those around us. So we regret them more if we don't use them.

Of course, here's hoping that you and yours stay far from coronavirus illness and that you stay healthy throughout 2021 and far beyond!

'Off-label' prescribing gives doctors leeway, for good and bad



"You are not a horse. You are not a cow. Seriously, y'all. Stop it."

That message — a warning to consumers to refrain from ingesting an animal drug for intestinal worms that has been falsely touted as a way to prevent infection with the coronavirus — offers yet another unpredictable low in public beliefs about the fantasy of pills to make people healthy.

The pandemic has opened a Pandora's box of pharmaceutical what-ifs, launched by egregious why-nots from no less an authority than the nation's former president and his White House. President Trump and his men, in their evidence-lite and chaotic campaign against the coronavirus, erased decades of efforts to ensure prescription drugs are safe and effective.

This protection once occurred through a rigorous process of clinical testing and expert reviews. Instead, a presidential administration regularly and wildly hyped various unproven drugs.

Doctors, to be sure, long have been allowed to prescribe drugs "off label," that is, for purposes for which regulators did not originally subject them to tough standards and study. The federal Food and Drug Administration explains online this physician prerogative:

"From the FDA perspective, once the FDA approves a drug, health care providers generally may prescribe the drug for an unapproved use when they judge that it is medically appropriate for their patient. You may be asking yourself why your health care provider would want to prescribe a drug to treat a disease or medical condition that the drug is not approved for. One reason is that there might not be an approved drug to treat your disease or medical condition. Another is that you may have tried all approved treatments without seeing any benefits. In situations like these, you and your health care provider may talk about using an approved drug for an unapproved use to treat your disease or medical condition."

Off-label prescribing has become common enough that the American Cancer Society discusses it on its site. The organization reports, for example, that oncologists may use medications approved for only one type of cancer to treat another because doctors know two types of tumors may be similar enough that the drug may be helpful, especially in desperate circumstances.

In psychiatry, too, experts have found that off-label use of certain drugs may be beneficial. Researchers have theorized that the debilitating condition of depression may not be solely related to imbalances of just one kind of brain hormone, notably the now-familiar serotonin. In searching for other brain-chemistry pathways, they have reported positive responses by giving patients ketamine. It may be more familiar to consumers as an anesthetic, an animal tranquilizer, or a much-abused party drug.

For patient advocates, the instances of off-label prescribing that have proved harmful may outweigh the beneficial examples.

Specialists have come under heavy fire for their off-label prescribing of powerful psychiatric drugs to the young and old. Critics have assailed doctors for ordering anti-psychotic medications for pediatric patients, some as young as age two. Regulators cracked down on off-label prescribing of anti-depressants to those younger than 25, warning the drugs could increase the risk of suicidal thinking and behavior. And officials have campaigned against nursing homes and other long-term care facilities giving senior residents powerful meds like Risperdal, Seroquel, and Zyprexa to make them more docile and compliant. This practice, critics say, is tantamount to putting pharmaceutical restraints on the elderly.

During the pandemic, Trump and his men — with little or no facts to support doing so — pushed doctors, hospitals, and government agencies to give powerful drugs off-label to patients, purportedly to battle the coronavirus. Many medical authorities balked at the presidential pressure. They declined to prescribe White House-promoted remedies freely until they underwent some testing for their safety and effectiveness against the coronavirus.

The list of drugs, tub-thumped by Trump and others, grew long: chloroquine, hydroxychloroquine, azithromycin, remdesivir, ritonavir, lopinavir, Actemra, Oseltamivir, Ribavirin, Umifenovir, interferon, baricitinib, imatinib, dasatinib, nitazoxanide, camostat mesylate, tocilizumab, sarilumab, bevacizumab, fingolimod, and eculizumab.

Doctors quickly found no reason to prescribe many of these prescription medications. Repeated, rigorous research on one of the most hyped therapies — the anti-malarial drug hydroxychloroquine — have failed to show it has usefulness in coronavirus care.

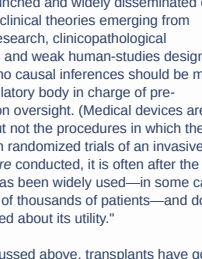
The New England Journal of Medicine reported researchers' findings on remdesivir, an existing anti-viral drug that was pushed by the White House and approved for coronavirus treatment: "Our data show that remdesivir was superior to placebo in shortening the time to recovery in adults who were hospitalized with Covid-19 and had evidence of lower respiratory tract infection."

The influential review by the Cochrane group reported this about their researchers' findings on the much-promoted treatment using antibodies and convalescent blood plasma replacement: "We are very confident that convalescent plasma has no benefits for the treatment of people with moderate to severe Covid-19. We are uncertain about the effects of convalescent plasma for treating people with mild Covid-19 or who have no symptoms. We found about 130 ongoing, unpublished, and recently published studies. We will update our review with evidence from these studies as soon as possible."

Trump and others infected with the coronavirus have shown good outcomes after receiving a treatment using cloned antibodies, and, in the twists-and-turns of pandemic pharmaceuticals, the monoclonal antibodies are rising in use and effectiveness, especially against early cases, experts say.

As for Ivermectin, it supposedly was shown in Latin America to suppress the coronavirus in high doses in lab tests, and doctors have given it to patients overseas. As the Delta variant has caused the fourth pandemic surge in this country, especially in the South and Midwest, conservative media and social media have resurrected the unsupported views about Ivermectin and the coronavirus. But poison-control officials in Louisiana and Mississippi have reported increases in illnesses in people taking the livestock de-worming drug.

Surgeons can be lionized for pushing bounds. But not always.



While patients might express great unhappiness with most doctors if their treatment takes a sudden and uncertain turn, the public and popular media long have lionized surgeons for their dramatic responses to operating room crises.

Indeed, surgeons have built lucrative practices based on their reputation in handling specialized and difficult cases. They have pushed traditional bounds of practice, often to patients' benefits. At the same, though, their trial-and-error methods to improve their field is subject to far less oversight, say, as compared with prescription medications, as researchers have noted in published studies:

"Before their release for use in the public, new prescription drugs must be of proven efficacy and safety, demonstrated in randomized controlled trials, under regulations enforced by entities such as the U.S. Food and Drug Administration or the EU European Medicines Agency or directives issued by bodies such as the International Conference on Harmonisation.

"Conversely, new invasive therapeutic procedures are often launched and widely disseminated on the basis of clinical theories emerging from laboratory research, clinicopathological correlations, and weak human-studies designs from which no causal inferences should be made, with no regulatory body in charge of pre-dissemination oversight. (Medical devices are regulated but not the procedures in which they are used.) When randomized trials of an invasive procedure are conducted, it is often after the procedure has been widely used—in some cases in hundreds of thousands of patients—and doubts have emerged about its utility."

Still, as discussed above, transplants have gone from rare, headline-capturing surgeries by pioneering specialists to frequent operations.

Surgeons also have pioneered less painful and invasive techniques, notably laparoscopic surgery that features "keyhole" cuts and possibly local pain relief, sparing patients from sizable incisions, scarring, and extensive anesthesia.

Heart surgeons have advanced their field, so that they can still the beating heart and operate directly on this crucial organ, deploying sophisticated machinery that pumps the blood and sustains patients' lives. They also can thread tiny cameras, robotic surgical tools, and even intricately folding valves through distant blood vessels in the wrist or groin as they make extensive repairs to the heart.

Surgeons now tap an array of technologies to treat tumors and highly specific areas of the brain, giving patients new options in dealing with neurologic disorders and deadly and debilitating diseases. Neurosurgeons have made major headway in treating once-fearsome conditions that can damage the brain such as strokes and cancer.

Orthopedic surgeons and neurosurgeons at the same time also have drawn increasing regulatory and media scrutiny for building financial empires based less on their operating skill and more on their acumen in designing, promoting, and selling an array of surgical hardware used to repair and replace knees, shoulders, necks, and spines.

Questions also increase by the day as surgeons press hospitals to spend $1 million or more annually on robotic devices that specialists say make them more comfortable during long procedures. Critics say robotic surgical machines make operations longer and more costly — and a growing body of research says the devices show little benefit to patients. News media have reported patient harms blamed on robots.

The rise of laparoscopic surgery for women, meantime, has become an increasing concern. Regulators, for example, stepped in — in tardy fashion, critics say — as news organizations reported increasing numbers of women suffering surprising cancers after "key-hole" gynecological procedures.

Studies have zeroed in on a key aspect of the surgeries that may be to blame — the use of a morcellator or grinder to quickly deal with unwanted tissues resulting from laparoscopic procedures such as hysterectomies. The devices are supposed to not only macerate but remove the material. They may, instead, spread them throughout the abdominal cavity and into the bloodstream, pushing cancer cells as a consequence and causing fatal metastatic cancer.

The FDA since has warned surgeons about laparoscopic gynecological procedures altogether, as well as specialists' attempts to expand robot-assisted breast operations.

When surgeons promoted and sought to expand what many believed was an important procedure for those with serious weight problems, state regulators were forced to step in, cracking down on pop-up clinics performing the lap-band operation. Five patients died after undergoing the procedure, in which surgeons band off part of the stomach to restrict patients' food intake and cause them to drop weight.

While this operation was heavily advertised — and in the case of problematic clinics in California not optimally performed or monitored — surgeons eventually let this approach fall by the wayside. Its advantage was that it could be reversed. But its results over the longer term turned out to be disappointing. Instead, surgeons now tend to perform either a gastric bypass or sleeve procedure, operations that both reduce the size of the stomach permanently and can be done laparoscopically. These are serious operations for those with significant obesity and require patients' long-term commitment to diet and lifestyle changes.

Recent Health Care Blog Posts

Here are some recent posts on our patient safety blog that might interest you:

- Patients, regulators, hospitals, and doctors themselves need to open their eyes and ask tougher questions about the eyebrow-raising trend occurring among a specialized set of "sawboneses" — orthopedists and neurosurgeons. Hundreds of them are profiting handsomely, not on their medical skills but rather their investments in and relationships with surgical hardware. The specialists also are increasingly reliant, in dubious fashion, on medical device salespeople.
- Senate Democrats, including chairs of two powerful committees, have started to tackle the nightmarish problems that experts blame for allowing the coronavirus pandemic to take a terrible toll on vulnerable residents of nursing homes and other long-term care facilities. Under a bill introduced by Ron Wyden, an Oregon senator and chair of the Senate Finance Committee, and Bob Casey Jr., a Pennsylvanian and chair of the Aging Committee, federal officials would both push and assist the facilities to improve health worker staffing, infection control, and regulatory oversight, notably through better inspections, the Associated Press and other news organizations reported.
- Millions of patients with serious, diagnosed sleep disorders now are wrestling with a daytime nightmare: Medical devices designed to help them avoid damage from their conditions have been recalled for major and concerning defects. But consumers complain that they're getting poor and too little information about their health options until the device maker more fully addresses the products' problems.
- More than 100,000 people in this country died last year due to diabetes. That's 17% more than the year before. And in younger age groups, it's even worse: deaths from diabetes climbed 29% last year among those ages 25-44, federal data show. The figures should raise huge alarms that diabetes, as exposed by the coronavirus pandemic, is "out of control," reported Chad Terhune, Robin Respaut, and Deborah J. Nelson for Reuters news service. Their investigation, including an analysis of federal data to draw a depressing depiction of diabetes' significant damages to the health of millions of Americans, found that the pandemic only begins to show huge failures in the care of what should be a manageable illness
- The U.S. health care system, again, ranks last among 11 high-income countries — the seventh such time it trailed its peers since a leading, independent nonprofit conducted its first study in 2004. The Commonwealth Fund, in its latest published research, says it examined 71 different measures to study health systems in Australia, Canada, France, Germany, the Netherlands, New Zealand, Norway, Sweden, Switzerland, the United Kingdom, and the United States. The U.S. performed worst among these countries.

HERE'S TO A HEALTHY REST OF 2021!

Sincerely,

Patrick Malone

Patrick Malone & Associates

IN THIS ISSUE

Expect the unexpected in medicine

'Medical reverses' occur often, and that's good

Pandemic may be proving why evidence-based medicine matters more than ever

'Off-label' prescribing gives doctors leeway, for good and bad

Surgeons can be lionized for pushing bounds. But not always.

BY THE NUMBERS

87,000
Number of published studies and papers on the coronavirus between the start of the pandemic and October, 2020. Compare that to onetime "hot topic" of nanoscale science, which took 18 years to see 90,000 studies.

$470 million
Estimated sum paid by Medicare for lap-band procedures between 2007 and 2013. As research has shown the surgery has poorer outcomes and requires more procedural fixes, it has plummeted from 35.4% of 158,000 bariatric weight loss operations in 2011 to 0.9% of 256,000 such surgeries in 2019.

73 days
Estimated time in 2020 in which medical knowledge doubles. In 1950, this would have taken a half century, 7 years in 1980, and by 2010, 3.5 years.

250,000
Estimated number of patient lives lost annually in pre-pandemic times due to medical errors — more people than die of respiratory disease, accidents, stroke and Alzheimer's, according to researchers, led by a professor of surgery at Johns Hopkins. This means that medical errors ranked as the third leading cause of death in the U.S.

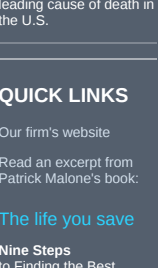
QUICK LINKS

Our firm's website

Read an excerpt from Patrick Malone's book

The life you save

Nine Steps to Finding the Best Medical Care — and Avoiding the Worst



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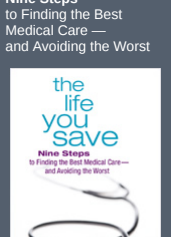

Read our Patient Safety Blog, which has news and practical advice from the frontlines of medicine for how to become a smarter, healthier patient.

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Proven and practical ways to slow or prevent cognitive decline

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Getting ready for a return to more normal health care

You Can Eat This… But Why Would You?

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Secure Health Records: A Matter of Privacy and Safety

Standing Tall Against a Fall

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