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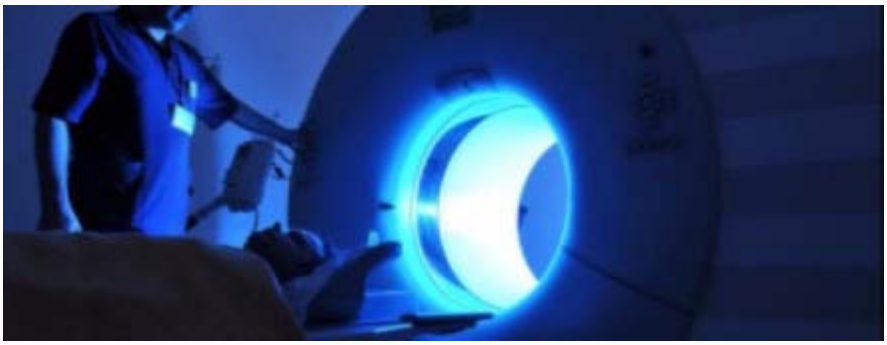
PATRICK MALONE & ASSOCIATES

Better Healthcare Newsletter from Patrick Malone

This mix of medical misconceptions can be harmful to your health



Dear Jessica,

A mix of medical misconceptions may be hurting your pocketbook and harming your health. But there's a ready cure at hand. Take these two evidence-based findings that challenge conventional wisdom:

- 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.

Think twice before you leap into more medical testing or to letting your doctor order more screenings for you. You may not want to just say no. But you need to ask this smart, important question: Why?

IN THIS ISSUE

BY THE NUMBERS

$200 billion

Estimated annual cost of over-screening, overtesting, and over-diagnosis in U.S. medical system

In this month's issue, we talk about the why, and the why not.

Excess medical screens: big risks, big costs

We Americans spend $3 trillion a year on health care, nearly one in six dollars of our entire economy. But our system, some experts say, suffers from a "sickness" of greed and excess. According to them, we're in the throes of an "epidemic of unnecessary care." As health officials try to curb medical services' soaring costs, they're increasingly focused on an important gateway: Over-screening, over-testing, and over-diagnoses that add $200 billion in unnecessary expenses to our care, with over-treatment costing 30,000 lives a year of older (Medicare) patients alone.

Look at your own bills and see how a routine, relatively inexpensive doctor visit can blow up with added testing costs. These might include tests for cholesterol (costing as much as $1,000), Vitamin D deficiency ($50 or so), diabetes (blood sugar $20), breast (mammograms, often covered by insurance but $20 to $60), or prostate cancer (PSA test $40).

To be sure, appropriate, timely medical tests and screens can be life-changing, even life-saving. But experts—including Uncle Sam, the nonpartisan and independent Consumers Union, and more than two dozen leading groups representing an array of medical specialists—warn that American doctors and hospitals reflexively order too many tests whose potential harms outweigh their benefits.

Independent, expert advisors

You may have read about the Choosing Wisely campaign by Consumers Union, the health-focused ABIM Foundation, and the many medical groups, or the excellent recommendations of the U.S. Preventive Services Task Force (USPSTF). These and other medical science groups, made up of top independent experts, scour the best

30,000

Estimated number of deaths among Medicare patients alone due to overly aggressive care often tied to over-screening and over-testing

36-fold

Estimated surge from 1950s to 2010s in medical journal articles, mostly favorable, on early detection

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The Life You Save

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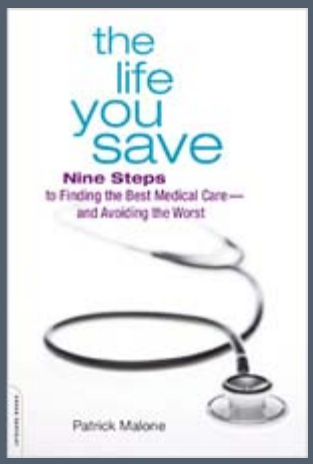

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available evidence, talk with leading practitioners, and try to cut through the mumbo jumbo to help inform the public.

They've scrutinized whether so many of us should undergo regular thyroid screenings (no), tests for Vitamin D deficiency (no), tuberculosis (maybe), carotid artery blockages (no), blood sugar (yes), and cervical cancer (yes but depending on age). They've weighed in on if, except in specific conditions, we should have CT (computed tomography), CCTA (CT scans with dyes), PET (positron emission tomography) and ultra sound scans for heart and cancer check-ups. (Answer: mostly no).

You're likely familiar with their advisories that doctors, for example, stop routine screenings for many older Americans for colon, breast, and prostate cancer. The experts' careful explanations have attracted major attention in news stories. But the opposition may be going too far. Medical specialty groups can and do disagree with such recommendations. But some political partisans now want to pass laws to rein in the voluntary, evidence-based work of the USPSTF. That's not smart, nor good for patients.

In my practice, I see the major harms that patients can suffer from medical services. My experience, as well as mounting evidence, tells me that reducing rather than increasing patients' exposure to shot-in-the-dark medical testing can be beneficial. Some experts estimate that medical errors claim 685 American lives daily and now may be the third leading cause of death in the United States, trailing only heart disease and cancer. Less can be more.

As Choosing Wisely and the USPSTF point out in their recommendations, it isn't just the tests that can increase patient risks of harm, such as what can occur if a colonoscopy causes bleeding or punctures in the colon. Screenings can cause a cascade of follow-on procedures, many costly, painful, and invasive. Their "false positives" can prompt doctors to order biopsies, more tests, and exploratory surgeries. With breast and prostate tests, scans for two of the most common cancers for women and men, medical science hasn't advanced sufficiently so tests show more than the presence of suspicious tissue or a worrisome body response (buildup of antigens in the blood, for instance). Screens can't tell us which cancers are aggressive, potential killers that need urgent attention, and which are slow growing, might never become harmful, and might be treated with "watchful waiting." Patients' quality of life can be hugely affected by how their doctors look at test results and then decide their care.

Popularizing early detection

Since the 1950s, medical practice has enshrined the idea that early detection can be decisive. A recent study found a 36-fold, storm-like "surge" in medical journal studies from the 1950s to the 2010s about early detection and prevention of disease and their advantages. Has medical science fed a public misconception about the role of testing

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

PAST ISSUES

Spring clean your meds to save costs and health
Our vehicles are killing us - and we can do a lot to stop it
Diabetes: The new and the tried-and-true for coping
Why caregivers deserve a special Valentine
Realistic resolutions for a healthier 2017

More...

and screening in the battle to better our well-being?

Consider our experience with tuberculosis, once feared, debilitating, and epidemic. Health officials used to screen for TB robustly, requiring restaurant workers, for example, to undergo regular skin tests and X-rays. Detection played a role in reducing TB's harms. But medical historians see greater impact from the development of more effective antibiotics to treat the infection. Cancer experts similarly are in the midst of reconsidering if they need to scale back their big public emphases on early detection, screening, and disease outcomes: The frequent, emotional claims that tests "save lives," isn't well supported by hard evidence.

Financial considerations

As with all matters medical, economics—cold, hard cash—can't be ignored in discussions of over-screening and over-testing. Call it medicine's version of car dealers up-selling things like new vehicle undercoating. Doctors can make more money, directly or indirectly, by ordering more tests that lead to more procedures and referrals. Many are on staffs of hospitals or specialized centers that have built big, pricey pathology labs, imaging centers, or procedure suites. They have specialist colleagues who need to be kept busy, not the least of whom are pathologists. Their lives have gotten hectic in many big hospitals, where they have become all too fallible arbiters of a vast and burgeoning array of tests in fast-changing medicine.

Even ophthalmologists may be over-testing. Peter Provonost, a doctor, Johns Hopkins Medicine senior vice president, and director of the Armstrong Institute for Patient Safety and Quality, has written that we could save $500 million by eliminating unnecessary tests for seniors having cataract surgery. Citing a Johns Hopkins ophthalmologist's study, he says doctors and hospitals needlessly subject these patients to extensive pre-surgical screenings as if they were undergoing a major operation. This regimen is required, even though cataract patients mostly will sit in a chair, with anesthetic eye drops and mild sedation for a procedure that affects only their eyes. Research shows complications from cataract surgery are rare, and rarer still are patients who benefit from the extensive screening. Half of the 20,000 patients who elect the procedure are forced into this big expense. Many have the surgery covered by Medicaid and Medicare, meaning we taxpayers fund this over-screening.

To hear some doctors tell it, blame for over-testing should fall on lawyers like me. GOP leaders, including Tom Price, an orthopedist and the Health and Human Services secretary, say fear of malpractice lawsuits forces too many doctors to practice defensive medicine, ordering screenings and tests, just in case, and to protect themselves. Their arguments have been refuted by independent, nonpartisan, and authoritative sources. That still may not stop them from using their unsupported ideas to strip harmed patients of their right to pursue appropriate legal redress.

But, to be fair, if we're pointing fingers about over-screening and

over-testing, maybe we all should look in the mirror and ask whether we share some blame. Why?

Will 'DTC' tests really make us healthier?

Although most of us hate getting poked and prodded and loathe surrendering bodily materials and intimate information, medical tests must appeal to a growing number of Americans who are targets of businesses' direct to consumer (DTC) marketing. Some of these practices have been around awhile. But, go figure: Patients are jumping in, often without their doctors, and getting medical tests in a burgeoning trade that was valued at $15 million in 2010 but will be worth an estimated $350 million by 2020.

They're taking what experts deem to be "low value" tests of blood, urine, and saliva for a host of conditions, including heart disease and cancer. Some companies offer elaborate, expensive high-tech imaging screens. One study, which already is showing its age, identified at least 20 vendors offering more than 125 tests for everything from non-contrast CT imaging to vitamin deficiency, heavy metal poisoning, hormonal imbalance, sexual diseases, and substance abuse.

Companies can sell screenings to patients directly without M.D. involvement, because they're not practicing medicine. They're racing through legal loopholes in which they must show their tests are accurate and valid but not much more. The companies involved include start-ups and big, long-established concerns.

Gene testing's trendy

Genetic tests are a new hot frontier. The federal Food and Drug Administration raised eyebrows when it reversed itself and allowed the 23andMe company to sell straight to patients its saliva tests, which it says provides consumers both genealogic data as well as

information on their genetic risk for diseases like Alzheimer's and Parkinson's. The FDA approval came with conditions—the company, for example, pulled back from its earlier, more extravagant claims. And it now must provide much more extensive explanations of scan results, including that its tests show disease risks and do not diagnose illness. But for now, 23andMe has a valuable lead in a growing market, and it is only adding to what experts say is its larger aim: to create a huge database of patient information. Its sources are anonymous but volunteer subjects are providing data that 23andMe can profit from by selling it to other medical services' companies, such as those in Big Pharma.

Theranos, a scandal-ridden blood testing start-up, also sought to benefit from consumers' eagerness for screenings. The company, a Wall Street darling once valued at more than $9 billion, claimed its proprietary approach would allow it to collect just a drop of blood from patients at pharmacies, then to run hundreds of tests at a far lower cost than any existing lab could. Journalists—notably from the Wall Street Journal—and regulators shredded the secretive company's hype. But why did it hold such appeal? Why are companies like 23andMe flourishing, beyond the popularity of genealogy as a hobby?

What the rich do

Part of the boom in medical testing, despite its costs and risks, may rest in a troubling reality of contemporary American society: We've created new and extreme wealth. While many of us struggle with the costs of health insurance and medical services, some of the royally rich want their high life to extend as long as possible—including by undergoing at any cost any screen or test that might offer any health advantage. Billionaire Mark Cuban caused a social media kerfuffle by arguing that we're on the brink of big-data and tech-driven breakthroughs in medical care, and, only by big numbers of people establishing a "baseline" of information on themselves can they reap future benefits and contribute to advances. He urged his millions of Twitter followers to undergo quarterly blood tests, then battled with health journalists and experts who questioned his ideas.

Besides the moguls of Silicon Valley, it's also true that doctors, hospitals, and too-docile media have promoted expansive use of medical screens. Healthnewsreview.org, a nonprofit, independent, health information watchdog site, has ripped doctors and hospitals for staging health fairs and promoting (with press help) unnecessary medical tests. Other public interest groups have not only joined in criticizing the fairs but also in assailing hospitals for equipping mobile testing units and sending these out into communities. The hospitals aren't providing underserved areas with desperately needed medical services—they're mostly just promoting themselves and building business.

Those mobile operations, by the way, long have been under fire for providing screenings of little value. Their fees—$100 to $150— for a menu of tests may seem nominal. But look at the long lines of test subjects and do the math. The companies take in a lot of money and

don’t do much for it. A healthy West Coast colleague with excess health-savings account funds ticked his doctor off by playing guinea pig. He went to a mobile site, answered questions about his health and life, got his pulse and temperature taken, blood pressure measured in his legs and arms, and a 30-second wave of his neck (carotid artery) with an ultrasound wand. Cost: $150 for 10 minutes. That was 15 years ago. He’s still on the company’s mailing list and gets re-screening invitations quarterly. Plus, he now gets junk mail for myriad medical products and services.

Caveat emptor, friend. But how about you? Are you bugging your doctors for screens you don’t need?

Skeptical patient-consumers will be key to reversing over-screening

It won’t be easy to eliminate over-screening, over-testing, over-diagnoses, and over-treatment. But patients, doctors, and hospitals are trying.

In California, hospitals are reporting progress by halting doctors’ reflexive ordering of batteries of tests that can add to the institution’s and patient’s costs, and, under existing health care reforms, can result in penalties. They’re doing so by eliminating check-boxes or buttons in electronic health records that let doctors too quickly and conveniently tick off laundry lists of screens. Some flag doctors when they try to enter into the hospitals’ computer systems any treatment plans that contravene recommendations in Choosing Wisely or by USPSTF and other evidence-based standards of care. Many hospitals meet regularly with medical staff members to show them detailed records of how they care for their patients, what it costs, and how it compares with national standards and their peers internally and across the country.

These measures can be beneficial not only in curbing over-screening and over-testing but also in bettering care—some research shows that treatment outcomes improve when doctors reduce testing and follow hospital standards. These measures also can play crucial roles

in getting doctors and patients engaged in the tough and too-often-skipped conversation about the overall and soaring costs of medical services.

Being informed

One of your fundamental and most important rights in medicine concerns your informed consent for any medical procedure. Informed consent expresses a concept at the core of any free society: Each person has a right to decide what to do with his or her own body, as long as he or she doesn't hurt someone else. Your doctor, knowledgeable in her field, must provide you with full information so you can make sound decisions about your care. You may find, as research has shown, that once screens and tests are explained, you may skip them.

You and your loved ones should feel free to ask your doctor about medical tests or screens: Are they diagnostic or opportunistic? Do you already have symptoms or display evidence of a possible disease or condition that your doctor wants to diagnose and confirm to set a course of treatment? Or, as long as you're in the office or hospital, is your doctor measuring or checking you or the way your body is functioning? You should ask your doctor how she's accounting for your age, gender, overall health, and family history when ordering tests or screens. What are your risk factors for specific diseases or disorders, and what are your preferences about your care? The World Health Organization says that, when it comes to screenings and tests, they should be done only: for diseases with serious consequences; if they have potentially clear health benefits; and if they are reliable and not harmful in themselves. WHO cautions that, with testing, there must be an effective treatment for a disease when detected at an early stage–and scientific proof that treatment is more effective when started before symptoms arise.

You need, of course, to get your doctor to discuss with you the cost, value, and outcomes of screens or tests. The priciest screen isn't always best for you, meaning it might not reveal much, might not be needed, or might come with risks that outweigh its benefits. If you tweak your back, you may not need imaging tests with their radiation exposure risks and costs of up to $6,000, when rest and a few days of discomfort will deal with your issue. A top specialist beat a friend of mine to the punch, telling him he was ordering a $150 exam rather than a recommended $7,000 test. He said the costly screen informed him less—and he had demonstrated with a volume of patients, treated successfully, the value of the cheaper test. It isn't easy for patients to determine such issues. No one expects you to read a pile of medical journals. But your doctor can help you, for example, by sharing the easy-to-understand Number Needed to Treat (NNT) of a screen, drug, or procedure. (See sidebar)

When all's said and done, what did a given screen or test show? Your doctor should spend appropriate time with you to discuss results and next steps. Understanding and interpreting tests isn't always easy and clear. Medicine can be subjective, as much healing art as

science. Your results may be skewed: Did you take that cholesterol test after returning from a learn-to-cook vacation in Paris? Did you slip up and eat jelly doughnuts before having a fasting blood sugar test? Doctors are finding great value in screening select patients for the BRCA gene, an indicator of increased cancer risks. But what happens if it is found is complex and can be a freighted matter requiring careful explanation and consideration before deciding next steps. Frankly, my involvement in a BRCA testing-and-misdiagnosis lawsuit leaves me scratching my head about do-it-yourselfers eager and quick to undergo genetic tests and other medical screens. Most of us grow out of playing doctor early on, right?

But my best wish to all is that we just stay so healthy that we can avoid needing any tests, screens, or other medical services at all!

An annual exam? Maybe not.

The annual physical exam is Exhibit One of an unneeded medical service and deserves to go the way of the rotary telephone.

It's important for patients to establish and maintain solid relationships with their doctors. It should be built when they're healthy and well, not just in the duress of major illness. It shouldn't be a matter of luck, so some regular contact with your doctor is key. But researchers found the annual physical becones a poorly defined ritual, during which some doctors do too much, way too much.

There are worthwhile preventive measures that can be part of a periodic visit with your doctor. You'll find that many of these, as well as your caregiver's time, may be covered by existing health insurance plans, making them affordable, too.

A helpful number to assess medical tests & treatments

Evaluating drugs and medical therapies can be confusing for lay people. The Number Needed to Treat (NNT) offers a quick, single figure that can be helpful.

The NNT gives a short-hand summary of how many people would need to be treated (with a drug or therapy or screening test) so that one individual benefits. The number comes from scrutiny of the best available medical-scientific evidence,

Smaller NNT numbers are generally better. Look at some NNT's for:

- a mammogram for a 50-year-old average-risk woman is 2,970. That means almost 3,000 women must undergo this preventive scan before one woman's life would be saved.

If you're a superstar at work, maybe a CEO or other C-suite executive, your company may offer you a popular perk—the executive health screen or comprehensive physical. These often are performed at big-name medical centers (Johns Hopkins, the Mayo or Cleveland Clinics, etc.) and cost corporations from $2,500 to $10,000. You'll undergo a broad range of screens and tests, potentially including some with higher risks (full body imaging scans). You'll spend quality time talking with medical specialists, and you'll stay in luxe quarters. It may feel like you're visiting a spa.

Just so you and your company know, the value and effectiveness of these executive health programs hasn't been shown.

- age 50-plus average-risk individuals and colonoscopy—the number of patients doctors would need to invite to save one life—is 871.

- average risk 50-plus men and the prostate specific antigen (PSA) test—the number needed to treat to avert one death—was 48 in one European study. But others have found the PSA does not help prevent death from any cause or from prostate cancer, whereas 1 in 5 men who undergo it suffer harm because they then are subjected to a biopsy due to a false positive reading.

- high-risk smokers and CT scans—the number needed to treat to prevent one death—is 271. But 1 in 4 patients also is harmed by a false positive, while 1 in 30 is harmed by related, unnecessary surgery, and 1 in 161 patients is harmed by related surgical complications.

  You can check out many more NNT numbers at this website sponsored by a group of doctors who are expert in number-crunching.

Recent Health Care Blog Posts

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

- Hip and knee replacements, especially among seniors, have become so prevalent that almost 7 million Americans by 2010 had undergone the surgeries. With the cost to Medicare of knee replacements running between $16,500 and $33,000, and with roughly half of the procedures' expense occurring post-operatively, there's some good news for patients on saving money—and staying safer too. Patients may want to get themselves out of the hospital and stay out of in-patient rehab centers in favor of well-planned, careful recuperation at home, studies show. The research focused on single adults living alone, and whether they fared better over the short- and long-term by rehabbing from total knee and hip replacements at skilled nursing facilities or at home, particularly if their home care was

well considered and followed through. They did at least as well and were happier recuperating at home, researchers found, adding that they also may have been safer: That's because a third of patients in rehab facilities suffered adverse events in their care, a rate comparable to unacceptably high hospital harms and those in skilled nursing facilities. Even if knee- and hip-replacement patients spend an extra day in the hospital, then headed home, they saved $10,000 or so on their surgeries, the New York Times has reported.

- Patients' pocketbooks benefit when hospitals take simple steps to prevent Big Pharma from swaying what gets scribbled on doctors' prescription pads: Just by curbing drug sales people's free access to hawk their wares, teaching hospitals have found that their doctors tended to order fewer promoted brand-name drugs and instead prescribed less costly, more generic versions, research shows. The study, published in the Journal of the American Medical Association, was based on an analysis of more than 1 million scripts by more than 2,000 MDs at 19 academic medical centers, comparing their prescribing to almost 25,000 control physicians elsewhere. Researchers looked at records on 262 drugs in eight classes in a period from 2006 and 2012. Where teaching hospitals—under pressure from patient-consumers and pricing lawsuits—had put in place policies to rein in Big Pharma's high pressure selling, including with meals and gifts, doctors reduced their prescribing of pricey brand-name drugs, the researchers found.

- A new investigation of one of the great shames of American medical care raises big questions about why labor and delivery is more dangerous to new mothers in the U.S. than just about anywhere else in the civilized world.To their considerable credit, National Public Radio and Pro Publica, a Pulitzer Prize-winning investigative news site, have joined forces to examine why 700 to 900 American women die each year from pregnancy related causes, and 65,000 nearly die. The news organizations say Americans are "three times more likely to die in childbirth than women in Canada, and six times more likely than Scandinavian women." And while U.S. maternal deaths are rising, their numbers were plunging in developed countries from England to South Korea. After six months of researching hospitals, including those with newborn intensive care units or NICUs, the reporters found that institutions, doctors, and nurses can be "woefully unprepared for a maternal emergency." Although many hospitals are focused on a barrage of policies and compliance measures to safeguard patients, too many have a hodge-podge of protocols for dealing with "potentially fatal delivery complications, which in some cases allowed treatable complications to proceed to a lethal level."

- Although critics—including the agency's incoming chief—want the federal Food and Drug Administration to speed its approval processes for prescription medications, new research shows there can be significant risks in a go-go-go approach to Big Pharma oversight. Experts at Yale Medical

School have found that a third of the drugs that hit the market with FDA approval between 2001 and 2010 suffered major safety issues that were only found after the medications became publicly available. Of 222 drugs scrutinized by researchers, 71 were withdrawn or required public announcements about their previously undiscovered risks, including some that were slapped with “black box” warnings—one of the FDA’s most stern indicators a medication carries significant side effects. The authors of the study, published in the Journal of the American Medical Association, said the drug approval process is imperfect, and it can frustrate many because it can be time-consuming, taking years for a medication to go from lab bench to bedside. But even with the current, multi-step process, in which many drugs must undergo animal and human clinical trials, it can take roughly four or so years more before further safety issues arise with approved products, the researchers said. They noted that safety concerns developed more often with drugs that get the green-light near deadlines for them to do so, and those that received expedited consideration.

HERE’S TO A HEALTHY 2017!

Sincerely,

Patrick Malone
Patrick Malone & Associates