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PATRICK MALONE & ASSOCIATES

Better Healthcare Newsletter from Patrick Malone

Dear Jessica,

Most 21st century Americans would condemn dated practices damaging to women like neck stretching, foot binding, and ritual genital mutilation. Does modern medicine, however, need its own reckoning now for what the profession and others politely term *disparities* in women's health care?

News reports describe problematic reproductive health treatments received by tens of thousands of women. Doctors, especially surgeons — with tradition-based privilege that should alarm all patients — too often experiment on women with techniques and gadgets, finding years later these may have inflicted a terrible toll.

Although women's health care has become a polarizing political

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BY THE NUMBERS

$1 billion

Sums paid out so far by device makers to settle tens of thousands of women's complaints about pelvic mesh procedures

issue, less heat and more light is needed. We must know more — and do more — to reduce the disfigurement, injury, and even deaths inflicted on half of Americans. Too many are receiving medical services that generations hence may see as rooted more in mumbo jumbo than evidence and science.*

*By the way, if you see colored text in this email, it's a hyperlink that you may click on to get more information online.

As doctors 'innovate,' women suffer injuries from medical mistreatment

A steady run of news reports has exposed the ways that doctors and hospitals put big numbers of women's health and lives at risk:

- Tens of thousands of women have complained that a surgery to implant mesh (as shown above) to bolster weak pelvic tissue, instead has inflicted on them incontinence, chronic pelvic pain, and pain in the groin, hip, and leg, and with intercourse. Others say they suffer complications as if they had the immune-system disease lupus, leaving them with runny noses, muscle pain, fogginess, and lethargy. As many as 4 million women globally have undergone mesh surgeries to treat urinary incontinence and weakening of walls in the abdomen that causes prolapses, the Washington Post reported, quoting a UCLA expert as estimating that 5 percent — or 150,000 to 200,000 — of those patients have experienced complications.

- The federal Food and Drug Administration (FDA) just warned surgeons about leaping ahead with minimally invasive, robot-assisted mastectomy and other cancer-related surgeries. The procedures have been tested and are growing in popularity in Europe. But U.S. regulators cautioned that rigorous research has failed to show the surgeries have significant benefits to patients in preventing or treating cancer. And it is too early to know if the treatments create major risks, as has occurred with

10%

Percentage of 600,000 hysterectomies performed annually in U.S. for cancer and considered potentially lifesaving. The rest are essentially elective, and some believe that many are unnecessary.

50,000

Number of U.S. women each year who suffer severe maternal morbidity, unexpected labor and delivery outcomes resulting in significant short- or long-term health consequences.

20%

Pay disparties on average between female and male specialists, with men vascular surgeons getting $89,000 annually more and male pediatric rheumatologists paid $45,000 more than women counterparts.

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

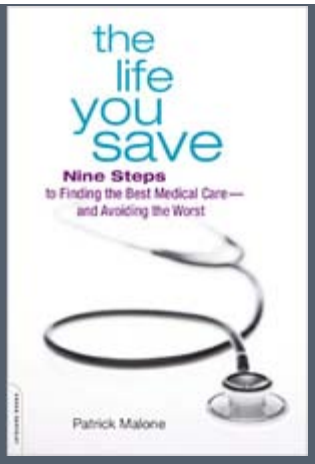
morcellation (see item below) and minimally invasive surgery for early-stage cervical cancer (next item). The FDA acted after news reports of experimental mastectomy surgeries occurring in a community hospital in New Jersey, a practice denounced by a patient advocate whose wife died after a morcellator procedure.

- New studies have raised troubling questions about a much-touted minimally invasive surgery for early-stage cervical cancer. The procedure removes the uterus, part of the vagina, and other surrounding tissues via small incisions and with special laparoscopic instruments, including robots. Surgeons have advocated for this surgery rather than make a large incision in an "open" procedure, arguing that the less invasive approach promotes less discomfort and faster healing for patients. But data have shown that "the minimally invasive approach was more likely to result in recurrence of the cancer and death," the New York Times reported, based on findings from two published studies.

- It took a Wall Street Journal investigation to get surgeons to reconsider use of a grinding tool, a so-called "morcellator," in hysterectomies. The device had become common in yet another minimally invasive procedure before investigators showed that it spread cancer cells and the disease throughout patients' bodies. The FDA only belatedly stepped in to warn against the device's use, a caution it recently retained even as the agency is pushing to speed up its approval processes for medical devices at the industry's behest. The agency has not banned the device outright. It's difficult to know how many women may have been operated on with morcellators, approved by the FDA in 1995. But by 2014 the number may have hit as many as 250,000, based on such laparoscopic surgeries conducted in that time, a percentage of them done with the tool before it received negative press.

- Weight-loss surgeons, meantime, quietly have given the heave to lap-band procedures — too often performed on women — only after seeing how often the 25,000 or so operations required follow-up work and failed to produce promised results. Uncle Sam threw a half-billion dollars at this operation for seven years before its effective abandonment.

- The FDA has issued fresh warnings about the perils of breast implants and a rare form of cancer: anaplastic large cell lymphoma (ALCL). The agency said it is focusing on textured implants and reported cancers in at least 660 cases, killing



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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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PAST ISSUES

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What you need to know right now about your health insurance

nine women. As the National Center for Health Research points out: These are just the latest concerns about implant surgeries performed on more than 400,000 women and teenagers annually, with 75 percent for augmentation of healthy breasts and 25 percent for reconstruction after mastectomy. The procedure's popularity has soared, tripling since 1997 but without necessarily meaning that many more women have implants. Many women are replacing old, broken or problem-causing implants, which they may need to do every 10-15 years or more often.

- Surgeons who perform reconstructive breast procedures learned only recently — to their surprise — how burdensome the procedures can be for patients: 1 in 3 women develop postoperative complications over the next two years, with 1 in 5 requiring more surgery, and in 1 in 20 cases, the reconstruction failing, the New York Times reported of the published findings of medical researchers. Experts quoted by the newspaper said the study was noteworthy for "filling in the blanks that aren't always explained to women, so they know the pros and the cons and can make good decisions."

Why in 2019 isn't the medical establishment giving women the information they're owed and the evidenced-based treatment they need and deserve? All patients have the fundamental right of informed consent, with medical caregivers required to explain therapies to them fully, so they know and understand their options and rights to choose what they want done to them, by whom, and how.

Historically, medicine has experimented — and blundered — with women's care. The American Association for Justice reviewed decades of health disasters for women, including doctors urging "emotional," moody, and even "hysterical" women to take everything from cocaine to morphine to barbiturates to tranquilizers to deal with their "female condition." Women also have been told by caregivers to maintain feminine hygiene with products including bleach and talc, a common substance that juries are deciding is linked to female cancers. The group also recounts global health calamities caused by what it sees as medical science's assault on women, including scandals involving:

- thalidomide, a drug that caused major birth defects;

- diethylstilbestrol (DES), a synthetic estrogen that has led to birth deformities and sterile children;

coverage

You Can Eat This... But Why Would You?

Looking Ahead: Preparing for Long-Term Care

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- the Dalkon Shield, an intrauterine contraceptive device linked to pelvic inflammatory disease and sterility.

Meantime, 85,000 women annually may be freed only now from aggressive, costly treatments that have become a dreaded part of breast cancer care. New research suggests that thousands of women with early-stage breast cancer who now are told to get chemotherapy don't need it, while a larger number of patients can benefit by halving the time they're told to take an expensive drug with harsh side effects, especially for the heart.

Medical and social advances occur slowly — and at significant cost

For both women and men, social progress and medical advances too often have occurred slowly and at high cost. Optimists may look at the bullet points listed above and see that, yes, bona fide research is yielding solid information that promises to change and save lives.

That sunny view, however, may ignore the persistence in medicine of sexism and stubborn resistance to change. Experts estimate that it takes 17 years before sound, useful medical research becomes a full part of doctors' actual practice. It will take the profession longer than that, it appears, to erase caveman attitudes about women (see sidebar). Women doctors, for example, get a bad deal on a matter as basic as pay: They earn, on average, 20 percent less than men do, even in various specialties, data from 36,000 self-reporting MDs has found. Male vascular surgeons earn $89,000 more annually than their female counterparts, while male pediatric rheumatologists get about $45,000 more than their female peers do.

To become doctors and to keep practicing well, women face a relentless gantlet of "bro culture," in which crude language is common, they are addressed as "girls," and other signs of sexism also are rampant. Women doctors say they are regularly subjected to inappropriate sexual advances and coercive or threatening language. In a survey of established women faculty members at academic medical centers, 52 percent reported harassment in their careers, compared with 5 percent of men.

The American Medical Association has reported that only 12 percent

of internal medicine, 1 percent of surgical, and 22 percent of obstetrics and gynecology department chairs at prestigious academic medical centers are women — figures tough to reconcile because 83 percent of ob-gyn residents are women.

Women's reproductive systems are more complex than men's, and they merit great focus. But for centuries, doctors and medical scientists concerned themselves about female health mostly with women in childbirth. (A crisis now in maternal health care shows they haven't done well here, either. See sidebar.) Men got the lion's share of medicine's attention when they fought wars, got sick in factories, and needed care as breadwinners in most households.

Now that the world has changed, especially in the United States, and women have achieved greater parity in society, medical science finds itself racing to catch up. But no less than the august National Institutes of Health, a crucial federal funder of research, has needed to browbeat institutions nationwide into taking women's health seriously. The agency has directed medical scientists to include adequate numbers of women in clinical trials, as well as to begin testing theories in female lab animals and in female tissues and cells. NIH Director Francis Collins just offered a full, formal apology to women and women scientists for the agency's failure to step up sooner and more robustly to halt sexism and sexual harassment in science and its harms. Collins' apology occurred on the same day that the nonprofit Time's Up movement announced it launched a health care affiliate to tackle gender discrimination, sexual harassment, and inequality.

As for women and surgery, a hidebound culture and macho traditions also may lead to less than optimal results: Let's talk about boundary-pushing clinical cowboys, particularly surgeons with swagger. It's more than stereotype that reputations get made — along with a lot of money, both for individuals and institutions — if specialists distinguish themselves with techniques and tools. When does it cross the line? And how?

"Novel" or "path-breaking" or aggressive surgeries can lead to valuable new ways to care for patients. They should, however, concern not only women but men, too, and raise issues as to whether surgeons have been too gung-ho to experiment.

It may be hard for hospitals to keep surgeons in check when so many are spending $1 million for one fancy new surgical robot — a device for which institutions nationwide expend a total exceeding $3 billion. Still, the institutions, other doctors, medical scientists, regulators, and lawmakers should poke hard at hallowed practices like minimal oversight of surgeon "innovations." As the New York Times reported: "Surgery is not regulated the way drugs are. Although the [FDA] must approve new surgical devices, it does not control the way they are used. A tool approved for one purpose can be used for another. Surgeons can try new approaches, and innovations can catch on and spread, as long as hospitals allow it."

Photo: Assn. of Black Women Physicians

A healthier outlook for women's care?

All surgeries carry risks, some more formidable and none ever to be taken lightly. As mentioned, doctors must explain not only treatments but also their perils and costs. This fundamental practice stands out even more with women's reproductive procedures — many of which may be elective and unnecessary.

Doctors cannot downplay patients' misery with pain, cramping, and excessive bleeding. But the No. 2 surgery for women — hysterectomy, or the removal of the uterus, and often the cervix and ovaries as well — is often not considered a medical necessity. More than 600,000 of the procedures are performed annually, and as many as 20 million women may have had hysterectomies. But just 10 percent of these procedures each year are related to cancer, and, therefore, considered lifesaving. A third of the operations seek to treat fibroids, growths that may or may not be serious (cancerous) and whose removal may or may not resolve women's bleeding, pain, and cramping.

Fibroid-related problems, detected in women in their 40s, often resolve at menopause. Doctors can treat pain, bleeding, and other symptoms with medications, exercise, and alternative procedures less drastic than hysterectomy, which ends women's childbearing.

Women should insist that their doctors set aside ample time with them for a robust discussion of a major procedure like hysterectomy. That must include candid talk about risks (including infection and adverse reaction to anesthesia) and side effects (incontinence, bowel and other tissue damage, and infertility). Patients also need to know that there's a possibility the procedure may not resolve their problems because it may not, for example, deal with endometriosis, an inflammation of tissues that can reach throughout the abdominal cavity.

Patients also must understand clearly how their operations will go.

Surgeons may promote laparoscopic procedures, minimally invasive or key-hole operations that are supposed to be more cosmetic and cause less blood loss, while carrying faster recovery times and less patient discomfort. These surgeries also may keep patients on the table longer, exposing them to greater risks, for example, with anesthesia. Medical scientists are finding that laparoscopic surgeries may spread cancerous tissues or may cause other kinds of injury when doctors — for example, to increase their field of vision — use inert gases to expand areas they're operating in.

Women may need to be skeptical and ask tough questions of surgeons who tout their planned use of surgical robots. These, as discussed, are costly for hospitals to buy — and patients foot the bill. Research hasn't supported doctors' claims that robotic surgeries produce better results for patients.

Prevention also may play a key role in reducing harm to women receiving medical services.

Medical science has shown how genital human papillomavirus (HPV) causes cancers of the cervix, vulva, vagina, penis, anus, and certain head and neck cancers. These can be reduced, if parents will get over unfounded, blue-nose concerns and ensure their boys and girls get HPV vaccinations. It will take time and greater commitment by grownups to get more kids inoculated, so that HPV and cervical cancer diminishes — as does the need for surgeries to treat them.

Women — and men — may reduce their cancer risks, researchers say, by eating well, exercising, getting enough sleep, not smoking, drinking alcohol in moderation, and keeping off excess weight. This need not be drudgery, and it's worth launching into healthful activities while the year's still young. Maintaining activity and other healthful regimens becomes even more key for many women during menopause, when they also may want to inform themselves fully about hormone replacement therapies that can cause other major issues affecting their health.

When we feel better, by the way, we look better. Still, few of us are destined to be movie stars, fashion models, or jocks so handsome as to adorn magazine covers. There are situations in which reconstructive or reparative surgery can be appropriate, helpful, and responsible. But does the world need to spend tens of billions of dollars for risky, unnecessary augmentation or cosmetic surgeries? Must women really cut up their bodies and stick in them different kinds of devices that may or may not make them more "beautiful" — and to whom? By the way, because many augmentation and cosmetic procedures aren't covered by insurance and women pay for them out of pocket, the costs of the implants themselves often are significantly higher. Doctors and hospitals don't miss any ways to gouge women patients.

Maybe if we don't objectify women and their bodies, if we love, respect, educate, hire, promote, and pay them as equals to men, maybe we all could relax the American obsession with youth and

looks? Maybe if we recognize that women's health, and their reproductive systems, are complex and need unique care, we could battle separately over the tough issue of abortion while still safeguarding the lives and wellbeing of half the nation's population? Maybe, too, if gender equity became a reality in medicine, women might be experimented on less and receive better medical care? Research data, mapped in charts, shows interesting trends: a rising slope of women entering — indeed, dominating — this field, with a dropping line for the number of major procedures like hysterectomies and other reproductive surgeries.

In my practice, I see the harms that patients suffer while seeking medical services, and experience has shown me that one of the best ways to avoid bad medical care is to stay well. May you and yours be healthy and happy throughout 2019!

Maternal health crisis: A shame of U.S. system

It's a terrible thing when a measure of U.S. health is mentioned in the same breath as Afghanistan, Lesotho and Swaziland. But America shares with those developing nations the shame of having a climbing maternal mortality rate.

National Public Radio and Pro Publica, a Pulitzer Prize-winning investigative website, reported disturbing findings when digging into this bad news:

"In the course of our reporting, another disturbing statistic [besides that of maternal mortality] emerged: For every American woman who dies from childbirth, 70 nearly die. That adds up to more than 50,000 women who suffer 'severe maternal morbidity' from childbirth each year, according to the Centers for Disease Control and Prevention. A patient safety group, the Alliance for Innovation on Maternal Health, came up with

A big sign of changes ahead

Women crossed an important threshold recently that may presage big changes in medicine as we know it: In 2017, more women than men enrolled in the nation's medical schools, the 21,338 female students representing 50.7 percent of all those matriculating in institutions belong to the Association of American Medical Colleges.

That trend also held in the area around the nation's capital, the Washington Post reported:

"In 2017, women represented 54 percent of entering students at the Howard University College of Medicine and 53 percent at Johns Hopkins University School of Medicine. At the Georgetown University School of Medicine, 48 percent of entering students last fall were women, but Stephen Ray Mitchell, dean for medical education, said women constituted a majority for the first time in 2002 and that classes since then 'generally run about 53 percent women.' Matriculants at the University of Maryland School of Medicine in Baltimore were 59 percent female in the fall, and women have been in the majority for 19 straight years."

an even higher figure … around 80,000."

The news organizations also talked with obstetrician Peter Bernstein, director of the Maternal-Fetal Medicine division at Montefiore Medical Center in New York, who told them American women may survive giving birth but do so at a cost: "Women can wind up losing their uterus and therefore becoming infertile. They can wind up with kidney problems. They can have heart attacks. They can have brain damage from all the blood that they've lost."

The journalists point out there's more: "Women develop pregnancy-induced high blood pressure known as pre-eclampsia, which can lead to a stroke and organ failure; parts of the placenta can be left behind, which can lead to infection; and a woman giving birth is more prone to blood clots that can be life-threatening ... The treatment for these complications can become an ongoing financial burden, and the trauma suffered from physical complications can lead to persistent emotional and psychological pain."

What's driving this? As the news organizations reported: "In the U.S., the rate of severe complications from childbirth has been rising faster than the rate of women who died. The rate of women nearly dying almost tripled between 1993 and 2014, according to the CDC. To help explain those dire statistics, experts point to risk factors that have increased in recent years: American women are giving birth at older ages and are more likely to have problematic conditions like obesity, high blood pressure and diabetes."

Black women have been hit hard, dying, as NPR reported, "at three to four times the rate of white mothers, one of the widest of all racial disparities in women's health." The affected mothers include pop superstar Beyoncé, tennis champion Serena Williams, and the late Shalon Irving, a respected epidemiologist with the federal Centers for Disease Control and Prevention.

Segregated hospitals bear some of the blame, with this concern hot in Washington, D.C., where maternal mortality rates are unacceptably high and problematic care and finances have shut a major facility that provided maternity services to a sizable and poor part of the nation's capital.

As the #MeToo movement has fought inequities, injustice, and violence against women, social media have been abuzz with women doctors, describing the difficulties of their day-to-day battles to be treated with dignity and respect. Patients and colleagues too often still dismiss and demean highly trained specialists. Sexism and sexual harassment are sadly real and persistent. The slams that women must confront daily in medical science were documented in a landmark 2018 study by the National Academies of Sciences, Engineering, and Medicine.

It's also tough to understand why women aren't thriving and rising more in medicine and medical science for doing outstanding work.

Yusuke Tsugawa and Ashish Jha analyzed data on more than 1 million patients and found that "female physicians had lower … mortality rates compared to male physicians" for hospitalized patients who were studied 30 days later. When they examined patient outcomes for women vs. men doctors in the eight most common conditions treated in hospitals, "female physicians had better outcomes." This was truest for patients in bad shape, they found, writing, "The sicker you are, the bigger the benefit of having a female physician."

Photo: Assn. of American Medical Colleges

More study may be needed to assist black women. But, frankly, the challenge of childbirth and solutions to safeguarding women are hardly new: California, unlike many other parts of the nation, has reduced risks for its mothers by committing public resources to provide prenatal care and assistance for moms, with follow-up after their children are born. Further, as the Washington Post reported, public health officials, doctors, and hospitals have zeroed in on "problems that arise during labor and delivery, using data collection to quickly identify deficiencies (such as failing to have the right supplies on hand or performing unnecessary Caesarean sections) and training nurses and doctors to overcome them."

But as political partisans take aim at programs across the country that provide any government support in health care — efforts like Medicaid and funding for women's reproductive health — will America put its mothers and babies at risk, even allowing them to die, by failing to help with maternal care?

Recent Health Care Blog Posts

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

- As tens of millions of Americans struggle with workplace medical insurance that provides them with little benefit when they most need it, consumers may wonder just how naïve their employers may be in overlooking industry SPIFFs, SPIVs, and other little-discussed payments that jack up costs and may reduce benefits. Before any confusion arises, don't think about health insurance in high-minded terms, and, instead, as just another business transaction — maybe what occurs at the cheesy used car dealership in the neighborhood. There, customers have gotten savvy about bonuses (Sales Promotion Incentive Funds or Sales Promotion Incentives) ladled on salesmen. Pro Publica, a Pulitzer Prize-winning investigative site, deserves credit for digging in to the medical insurance business to show how similar incentive programs proliferate in brokerages that purportedly help companies of all sizes figure how to cover their employees' health needs.
- Patients and reformers attacking skyrocketing health care costs may want to focus less on doctors and more on big, shiny hospitals, where in just five years prices soared by 42 percent for inpatient care versus the still sizable 18 percent price hikes that MDs scored.

Those findings are part of a new study that examined medical costs based on actual payments, focusing on common procedures like deliveries of babies (vaginal and cesarean), colonoscopies, and knee replacements.

- The federal Food and Drug Administration failed to protect the nation's young against Big Tobacco's harms with slow-poke responses to the rise of e-cigarettes, as well as tardy regulation of flavorings for combustible cigarettes and liquids used in "smokeless" vaping, health advocates say. The American Lung Association, in its annual "State of Tobacco Control" report, ripped FDA Commissioner Scott Gottlieb and his agency for postponing oversight of e-cigarettes and vaping — a hard-won crackdown approved in the Obama Administration — to further study the harms of the devices and practices.
- If anyone around doubts still the threat that the opioid crisis poses to the nation, a drug bust involving a vegetable truck in Arizona should provide powerful persuasion: Federal agents, suspicious about the vehicle's floor, loosed a drug-sniffing dog, resulting in the seizure of not just 395 pounds of methamphetamines but also 254 pounds of fentanyl. Fentanyl is a synthetic opioid, a lab-created super drug that packs a wallop for users in tiny grains or flecks. The record-setting seizure at the Arizona border stop amounted to 144 or so kilograms of fentanyl, with drug enforcement officials estimating that just 1 kilogram of fentanyl can produce 1 million fatal doses. That means just this one bust had the potential to cause 144 million deaths.

HERE'S TO A HEALTHY 2019!

Sincerely,

Patrick Malone
Patrick Malone & Associates


mailchimp