Diagnosis Overkill

Consumerism, bots, genomics, and the overtreatment epidemic

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1 Consumerism, bots, genomics, and the overtreatment epidemic

Business and technology trends are disrupting the medical diagnosis as we know it.

> **"Virtually every family in the country, the research indicates, has been subject to overtesting and in one form or another. The costs appear to take thousands of dollars out of the paychecks of every household each year. Researchers have come to refer to financial as well as physical "toxicities" of inappropriate care—including reduced spending on food, clothing, education, and shelter. Millions of people are receiving drugs that aren't helping them, operations that aren't going to make them better, and scans and tests that do nothing beneficial for them, and often cause harm."**
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> *– Dr. Atul Gawande, Overkill, 2009*

In the summer of 2015, Dr. Atul Gawande wrote about the epidemic of unnecessary care in the US. Due to a combination of defensive medicine, entrenched business practices, shifting medical guidelines, and a host of other factors, he wrote, Americans are getting overscreened, overdiagnosed, and ultimately, overtreated.

Dr. Gawande's prognosis bears reflection. You may be familiar with parts of his ongoing thesis on value in healthcare industry; his 2009 essay on hotspotting famously became required reading in Obama's White House. As a surgeon, caregiver, and academic journalist, he wove a story driven by statistics and patterns in utilization and outcomes data, which served as a catalyst for the national conversation about the unnecessary volume of care in American healthcare. Some of those numbers bear consideration:

- On average, every American receives one misdiagnosis in their lifetime, according to the Institute of Medicine (IOM)
- Medical care is the third-leading cause of death in the US, taking into account drug interactions, hospital acquired infections, and other inappropriate treatment

- 10 percent of patient deaths and 17 percent of adverse events in hospitals are thought to be attributable to such errors
- 5 percent of US outpatient visits, or about 12 million visits per year, involve a diagnostic error according to conservative estimates
- "About half" of those 12 million errors "have the potential to lead to severe harm," according to the British Journal of Medicine (BMJ)

That's roughly six million potential cases of harm attributable to unneeded care. Even if we set aside the whole "do no harm" thing for a moment, health economists have been teasing apart the business case for doing better by doing less for years. Medical costs are still the number one reason Americans declare bankruptcy. Wonks estimate that overtreatment leads to $750 billion in unnecessary costs each year, which adds up to about a third of our nation's overall healthcare spending.

Are we there yet?

The volume-to-value shift became one of the central themes of the Affordable Care Act. It directly and indirectly launched hundreds of Accountable Care Organizations (ACOs), which penalize hospital systems for inefficiency and error and reward them for hitting quality and cost benchmarks. ACOs were built on evidence generated by smaller, practice-level models called patient-centered medical homes (PCMH), which had been successful in managing costs and quality at some of the nation's leading delivery systems. From Dr. Gawande's perch in 2015, the overtreatment problem had a far rosier short-term prognosis; ACO's were growing in number and maturity, and the industry had started sending the right signals about adopting new models behind leadership from Washington.

But, where in 2015 value based care seemed like a silver bullet, in 2017 it's turned into a grey cloud. Today the ACA faces, at best, an uncertain future; with all of the uncertainty in Washington DC, health systems and payers alike have shifted into wait-and-see mode. Yet, even if the ACA makes it through all of the ongoing federal drama, the US healthcare system will remain woefully inefficient due to forces more powerful than political legislature.

While federal policy isn't the only path to improving healthcare costs and outcomes, it isn't the only obstacle, either. Business, technology, and science are ratcheting up the rates of diagnosis and treatment in ways completely unrelated to traditional healthcare delivery.

The business side of the patient-doctor relationship has become far more multifaceted than the traditional gatekeeper model was built for. Technologies throughout healthcare, from medical devices to chatbots, are making it far easier than ever before to generate diagnoses. And while business practices and emerging tech promises to perpetuate the trend of overtreatment, the genomics revolution will disrupt the entire concept of a medical diagnosis as we've known it.

2 Understanding overdiagnosis

Why are so many Americans getting diagnosed and treated inappropriately in the first place? Dr. Hardeep Singh, a leading researcher in this space, breaks down how the process of diagnosing a patient can be broken down into five components.

These structural descriptions reveal a set of deep-rooted challenges that should be familiar to any health reformer: Behavior change, cultural shifts, and incentive realignment among doctors and clinical caregivers at every level. At a system level, the aggregation of enough communication errors, missed passes, misinformation and the like add up to a rash of inefficient treatment patterns, which Dr. Gawande pinned on the map in places like McAllen, TX and Camden, NJ.

Some of these errors go deeper than a surface level fix. Journalist David Epstein explores the pervasive culture of overtreatment in a jarring critique of medical science, training, culture, and behavior. Even when they know better, when they're in the trenches of an episode of care, patients and doctors alike gravitate towards "doing something" as a rule of thumb.

As one doctor said to another in Epstein's piece: "Look, save yourself the headache, just do the surgery. None of us are going to be upset with you for doing the surgery. Your bank account's not going to be upset with you for doing the surgery. Just do the surgery."

That's a surgeon, talking about surgeons encouraging surgeons to err towards surgery when a patient comes in looking for a medically unnecessary surgery.

This isn't about pointing fingers at a few bad actors. It's about a culture of business medicine in which everyone, patients included, is hardwired to certain assumptions about the value of services, treatments, transactions. This is the reality that ACOs are nibbling around the edges of; it's why "reform" and "fix" are two different words in the world of healthcare.

When a culture of volume is hardwired into the very organizations and people, bandaid policies won't suffice. Health system consolidation aims to improve regional market share among patients through ratcheting up the volume of services they offer, continually adding to the number of facilities on the map, and winning patients' mindshare through marketing and network dominance. Despite the growth of value-based contracts, clinicians are always encouraged to operate in a selfish incentive paradigm wherein surgical centers of excellence and expensive diagnostic tests still drive revenues. It's no different from corporate consul-

tants, car mechanics, or your neighborhood pizza joint. In business, doing more is always better.

On the flip side of the coin, health insurance has been shifting away from the tight gatekeeping practices of the HMO model for over two decades now. PPO plans, popular among employers, encourage the commercially insured to seek out the care they want rather than a for a primary care doctor to make a diagnosis and referral. While plans with higher deductibles and out of pocket payments have been touted as a way to reduce utilization, ample studies show that these plans can discourage high-value preventative care, e.g. screenings for common cancers.

In part this dysfunction arises from needlessly complicated benefit designs, a pervasive lack of consumer-friendly access, low rates of health literacy and education. But more simply, as Dan Munro is fond of pointing out, "The System was never broken. It was built this way." All of this is to say that while better clinical workflows will help curb some of the diagnostic error that Dr. Singh points out, such peripheral reforms are akin to using a scalpel where we might need a bone saw.

Unfortunately as it turns out, more precise tools might not be the answer, either.

Old Doc, new tricks

A new wave of hardware gizmos is making it easier, quicker, and more cost-effective for physicians to make diagnoses. These medical devices aim to generate clinical grade, reliable diagnostic data at smaller sizes and prices:

"Other devices, such as mobile ultrasound scanner Lumify, made by Philips, delve even deeper into the human body. Last January, [Dr. Eric] Topol tweeted images of a head-to-toe smartphone ultrasound he performed on himself using the device — every organ from his thyroid, gall bladder and aorta, to his kidney, spleen and liver was imaged exquisitely via his phone. "It's $199 per month for unlimited use, compared to a $350,000 ultrasound machine in a hospital," he says. "To me that's revolutionary. I'd use it for every patient in my clinic."

Dr. Topol's enthusiasm for digital health tools is well known. But hospital systems aren't going to fall out of love with the big, expensive imaging toys that still drive billing and revenue. Industry forecasts predict year over year growth of imaging machinery through the end of this decade, driven by increased screening rates, higher specialization, global growth, and other factors. Recent GOP efforts to include a repeal of the medical device tax in the ACA replacement bill highlight how influential the medical device lobby is at a federal level. Suffice to say we're not likely to see fewer MRI machines anytime soon, even as more advanced equipment begins flooding the market, one trade show at a time.

That's the rub: Making diagnostics easier and cheaper just means we'll simply wind up doing a lot more testing with all of the new medical devices that the industry cranks out over years to come. It doesn't guarantee that the overall rate of testing becomes more accurate, more holistic, or more effective. Ironically, it was a younger Dr. Topol himself who pointed out an emerging trend of overtreatment by cardiologists in the 1980's:

"Topol coined the term, "oculostenotic reflex." Oculo, from the Latin for "eye," and stenotic, from the Greek for "narrow," as in a narrowed artery. The meaning: If you see a blockage, you'll reflexively fix a blockage."

3 Chatbots and the diagnosis democracy

Dr. Jay Parkinson of Sherpaa recently weighed in on the medical chatbot and the slow but steady automation of primary care. He notes the value proposition in deploying bot technology to do things like collect baseline risk assessments, deploy standard patient questions, and so on. This software is a far cry from legacy EMR of yore: A chatbot layer ostensibly offers system-wide, quickly scalable user interfaces (UI) that can talk to clinicians, solicit data from software systems and individuals, and serve as a much more dynamic form of clinical decision support for clinicians.

Today, clinical decision support (CDS) modules serve as a primitive level of artificial intelligence. Companies are already working on souping up CDS with better User Interfaces (UI). This may prove to pave the way for full diagnostic automation tomorrow – though we're not quite there yet in medical practice today. "I'm a little hesitant to have a bot identify what's going on and go down a rabbit hole," notes Dr. Parkinson. "Augmenting the human brain with AI is the way to go – working in partnership."

As might be expected, chatbot vendors are more bullish on the role that smart UIs can play in disrupting medicine. Ali Parsa, founder of a UK-based chatbots startup called Babylon, has been busy drumming up expectations to pave the way for his company's success: "An average human doctor does about 7,000 consultations a year. I don't think [Babylon] is going to be as good as a doctor. I think it is going to be 10 times more precise than a doctor. No human brain is ever going to be capable of doing anything of the sort."

The clinical market opportunity for a completely closed-loop medical AI will take time, regulation, and piloting to mature – but the consumer apps are already off to the races. For patients, these tools make it easier than ever to self-diagnose, order tests, schedule appointments, and more. Babylon is one of the leaders so far, having signed on clients ranging from large corporates like Cisco to the UK's National Health Service (NHS). Baidu, HealthTap, WebMD, Buoy, are on a rapidly growing list of vendors are building chatbots to serve as the next incarnation of Dr. Google.

This empowerment represents a huge step forward for the consumer movement in healthcare, which is a good thing for access and patient-centeredness. Yet, it conveniently ignores the central question raise by the self-diagnosis trend: Are we conflating what patients want with what patients need?

Of course, bots aren't the only instrument in this orchestra. Companies like Lemonaid and Nurx use virtual "doctor review" to approve patient requests for various prescriptions. A recent study suggested that the convenience of telehealth inflates utilization of services. The rise of concierge medicine and direct primary care offers both doctors and patients a hassle-free way to get what they want. CVS' Minute Clinics are incorporating point-of-care testing to make routine blood draws and some laboratory testing available to consumers under supervision of physician assistants and nurse practitioners. Ample evidence suggests that pharmaceutical companies' consumer advertising drives up rates of prescriptions, testing, and referrals.

These disruptions all highlight how traditional medicine is falling behind the relentless challenges posed by emerging business and technology trends. We don't know just yet how consumers will interact with a digital healthcare system that has none of the boundaries (geographical, temporal, administrative), that we've grown so used to bumping into.

We do know that healthcare systems will have to adapt significantly to handle a new wave of patients who can self-diagnose on their phone, get tested at home or in a pharmacy, self-refer through their health plan's provider network, and initiate a consultation about the surgery, medication, or treatment they want. But to paraphrase Bill Gibson, we're already here, just not all of us. The cultural factors underlying these disruptions – we want what we want, and it's good business to get it to us when we want it – are part of why we've gotten to the point where six million people get hurt due to mistreatment every year.

4 Diagnosis genomics will break the medical diagnosis

Genomic sequencing is playing a growing role in genetic sequencing for research and drug development. Today, patient testing is generally reserved for those who have already had a preliminary diagnosis, such as a rare disease or cancer. But Silicon Valley startups are not aiming to play a small, complementary role in helping doctors make decisions. They're aiming to disrupt the medical diagnosis altogether by going straight to the healthcare consumer. These genetic tests don't arm consumers with actual medical diagnoses, rather they report the risk of carrying the genetic traits for various diseases like Alzheimer's, Parkinson's, Celiac disease, hemochromatosis, and others.

Certainly consumers deserve the right to know their own genetic material so they can plan their lives accordingly, particularly when they face so much variation in treatment options, costs, and outcomes. One obvious challenge is that these tests are not definitive – they provide people with probability, and the vast majority of people are really bad at understanding probability. Administering tests on their own does not guarantee a value-add for patients. Math and science are not the same as health care.

But, showing people a numerical percentage next to an ominous disease makes for a great business model if you're a company aiming to sell tests and procure patient data. And thus, the hype cycle is in full swing in Silicon Valley. At the NewCo Shift conference, several genomics startups cited the same chart showing how sequencing costs have dropped dramatically over the last 15 years. One vendor shared that their price has come down to $249 per test. PatientsLikeMe has agreed to bring genomic testing services to its hundreds of thousands of users from a Chinese firm who also invested $100M in the company. The list of direct-to consumer testing companies goes on and on. The prevailing thinking regarding testing for testing's sake is captured in the ongoing debate between Mark Cuban and medical experts around routine blood draws.

Health insurance companies have quietly been encouraging these tests to help find high-risk patients sooner. Vendors like Interpreta and BaseHealth are packaging gene testing into standard analytics and quality improvement tools. Aetna has claimed a basic genetic test (not full genome sequencing) by Newtopia helped their members lose weight through personalized diet and exercise plans, an approach that one industry leader immediately called out as "stone soup." Even without delving into the efficacy and impact of these tests, it's clear that industry is conditioning consumers to embrace genetic screenings as part of routine care.

Targeting screenings at newborns and even pregnant mothers seems to be a popular goal. One of the speakers at the conference, talking about a rare heart condition, proclaimed that mass genomic screenings should help to "put some of these patients on statins by age eight." This bullish outlook is what we've come to expect from Silicon Valley – along with the lack of prac-

tical thinking, pragmatism, and patience required to bring these new tools into standard medical practice holistically and sustainably.

For starters, genomic data themselves are not optimized for the clinical trenches because they're being developed in entrepreneurial research silos. A clinician at the Children's Hospital of Pennsylvania (CHOP) said for test results, "[t]he current state of art is a seven- or eight-page PDF." CHOP is finding that primary care doctors are undertrained in genomics, and that the lack of up-to-date CDS tools are a substantial barrier to integrating genomic testing into clinical practice.

Besides recreating the same interoperability challenges healthcare has yet to overcome, this approach evokes Dr. Singh's research on the process breakdowns that lead to misdiagnosis and overtreatment. Until doctors are consistently able to digest test results, verify their accuracy, discuss them with specialists, compare them against the latest research, it's inevitable that patients will get misdiagnosed and mistreated.

It's already happening. As one Mayo Clinic researcher put it, "we're starting to see a lot of fumbles," such as the case of a man who had a defibrillator implanted based on a misinterpreted genetic test results. Healthcare also faces a shortage of genetic counselors, whose role is to help consumers understand, interpret, and act on their test results.

It's not inconceivable to imagine a consumer-driven future where people buy screening kits, find something, and contact a cancer center or drug company directly before they've interacted with a clinical team. The FDA has historically shown a willingness (if not the actual ability) to step in and shut down fraudulent marketing claims or correct bad corporate behavior. However, they don't always catch them all – like Proove, who was found buying off physicians to pump up profits.

What will happen when genetic testing companies start pouring millions in advertising to consumers on television and the web?

Here's Dr. Eric Topol chiming in again: "I wish the FDA and Consumer Reports and other public citizen watchdog agencies could provide this honest, objective recording and advise the public, but unfortunately, it isn't being done."

Under our new, business-friendly administration, we're yet to see what healthcare regulation will look like, but it's safe to say we shouldn't expect much. We may have just gotten a hint of what's to come: The FDA just issued a one-of-a-kind press release in which they not only approve 10 genetic risk screenings from genomics pioneer 23andMe, but also provided them with an exemption to the normal pre-market requirements for subsequent tests. This means that 23andMe can skip the stringent approval process in releasing subsequent screening tests. It's early – the comment period in the Federal Register is still open, but we should expect this to trigger a veritable arms race among genomics vendors.

5 How to do more about doing less?

"It isn't enough to eliminate unnecessary care. It has to be replaced with necessary care."

—Dr. Atul Gawandet

Given the forces of business, technology, and science that are expanding medical diagnostics, more overtreatment is inevitable. But, as the saying goes, every problem is an opportunity. Here are several areas where digital health companies can introduce improvements that may help to chip away at the $750 billion "inefficiency tax" the US pays every year—the cost of doing too much.

Better interoperability

Stop me if you've heard this one. Patients' healthcare data needs to be available to every doctor they see so that treatment decisions can be made in the most appropriate context. The ACA-driven wave of care coordination programs is a good start, but those are focused on high-risk patients, not the general public. For the latter, care coordination simply means data needs to be easily available between a telehealth app, a primary care doctor, a pharmacy clinic, a specialist, and so on – the easiest way to do that is to let data live inside a patient-controlled app. Hospitals, almost universally, have the technology in place in the form of an integration engine, which has the capability to send data to any application. Beyond clinical data, a patient's claims data should also follow them from health plan to health plan as they switch jobs, move, and live their lives.

More patient context

Can a medical history taken for a few minutes in an exam room really capture a person's full healthcare journey? Arguably, it can't really come close. Medicine can benefit immensely from motivational interviewing, shared goal-setting, between-visit check-ins and data capture, and so on. Philosophically these tactics fall under the category of empathy. Practically they will depend on a host of factors, from better medical school training to more self-determined and activated patients. And realistically, they will require new business models that propagate quality in relationships, not just quality in measurement.

Patient decision support

As access to care expands into new frontiers both digital and physical, it will become more important to ensure patients are given the information they need, at the level they need, to make the best clinical decision for their short- and long-term outcomes. We should continue to empower people to diagnose themselves, but make sure to tie emerging tools into insurance programs, outpatient, and specialty care.

Virtual checkups can be better tethered to real-world clinical guidance and alternative treatment options, based on a patient's medical factors (prior history) and lifestyle factors (affordability). Companies hawking consumer chatbots can make sure their products have digested the latest

clinical guidelines for common ailments, or that they're able to consider portions of a patient's self-reported medical history, and so on. Finally, we can do a better job ensuring that patients have access to the right people (e.g., genetic counselors, pharmacists, clinicians) who can answer (or solicit) their questions in a way that is cost-effective and time-effective for patients.

Health system behavior

There is no silver bullet to fix the dysfunctional culture of healthcare systems. However, there are plenty of policies that can help minimize misdiagnosis and overtreatment. With regards to genomics, Children's Hospital of Philadelphia's examples can be duplicated and scaled nationally to prepare primary care for the impending wave of genomic testing.

Another example is simply how we treat lower back pain. Healthcare systems can do a much better job implementing the latest medical guidelines into the trenches of their provider networks. This means discouraging use of the unnecessary pain medication that has spilled over into an opioid epidemic – potentially through physician-facing bots. It could mean reducing imaging orders, and partnering with practitioners of dry needling, massage, physical therapy, and so on. Health plans can easily curate the best options for a given patient based on their benefit policies, location, and stated preferences, and match them with low-cost, high quality alternatives to the orthopedic surgeons lurking in PPO directories with a scalpel.

Ultimately, our obsession with new tools and techniques does not have to be at odds with a scientifically and technologically revamped medical system. But the learning curve of adopting these new technologies in a responsible way, combined with the existing dysfunctions that pervade our health care payment and delivery organizations, mean that overdiagnosis and subsequent overtreatment will get worse before they get better.

ABOUT THE AUTHOR

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ABOUT PATCHWISE LABS

Patchwise Labs is a digital health agency with one simple aim: to make healthcare better for patients. We work with a select list of early- to mid-stage companies who are focused directly on helping patients. We run a business intelligence practice and offer a suite of creative services to help organizations define and accomplish their business and marketing goals.

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