Value-Based Healthcare Administration and the Rise of Medical Devices

INFINITI RESEARCH

INTRODUCTION

Heart disease, cancer, unintentional injuries, lower respiratory diseases, strokes, Alzheimer's, diabetes, influenza/pneumonia, kidney infections, suicide, septicemia, as well as chronic liver/cirrhosis, in that order, represent the leading causes of death in the US every year. Together these conditions were responsible for nearly 77% of all yearly fatalities. Annually, heart disease and cancer claim the most share (46%) of deaths. National health spending touched $4.3 trillion in 2021 and is projected to hit $6.8 trillion in 2030, and this accounts for nearly a fifth of the US economy. On a per-person basis, health spend jumped from $1,875 (in constant 2020 dollars) in 1970 to $11,461 and $12,531 in 2019 and 2020 respectively. Per capital health spend is on an upswing since 2019 in the wake of the COVID-19 pandemic.

Outrageous healthcare costs

Out-of-pocket expenses, i.e., medical expenses not reimbursed by insurance, is expected to balloon to a little less than $800 billion by 2026. At the same time, by 2024, public spending will likely be cut back to 46%, down from a high of 51% in 2020. As it is, many American adults are challenged with medical costs, and this is often preventing them from getting the care they need. Rising out-of-pocket expenses had consequences for even insured adults, 46% of whom had difficulties paying their medical bills. Durable and non-durable medical goods equipment comprised 0.7% of the national health spend in 2019-2020.

Enter: Value-based care

In real terms, the value-based care model includes management of scarce hospital bed days, admission rates (admissions/1000 patients), using outpatient clinics whose costs are lower than those of hospitals. It also makes abundant use of skilled nursing facilities as well as primary and urgent ambulatory care. The focus is on lower hospitalization rates, shortened hospitalizations, and palliative care and hospices for terminally ill patients. Besides, specialist care, often bordering on extortionate rates, is discouraged in favor of generalist primary care medical doctors.

Mega Drivers of the Medical Devices Market

In a nutshell, value-based care, unlike anything that has gone before it, is serious about delivering on the promise of keeping healthcare costs to a minimum by using smart machines and the like. The idea of taking healthcare to where the patient is (e.g., home), enhancing patient experience (e.g., personalized healthcare, pain reduction, faster recovery), and cranking up overall efficiency is at the heart of the new approach. Seamless integration of existing medical data, systems, and people, as well as faster medical device connectivity, is going to be crucial to the continued success of this model. The tidal wave of structured and unstructured patient data must be analyzed and interpreted to improve outcomes and tailor personalized healthcare experiences. This is a needle-in-a-haystack search beyond the pale of human intelligence, so, without a doubt, AI and machine learning technologies need to be pressed into service. Outcome-based care is a dynamically evolving world, where events overtake conventional medical wisdom, and it is important that surgeons, physicians, healthcare workers, and medical students are up to date on the latest issues. Virtual reality applications can significantly aid medical and nursing pedagogy by realistically replicating patient-interaction scenarios on a budget.

With Increased investments on healthcare administration and rising emergence of medical devices, it is essential for a major player to build robust strategy

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Best Approach to the Market Scenario

In order to be able to walk the talk on outcome-based care, healthcare systems need a fail-safe enabling infrastructure comprising the following medical device technologies:

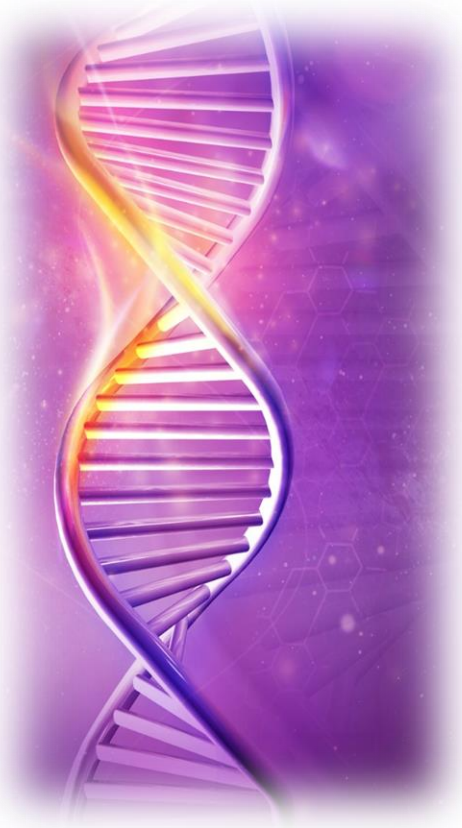
1. Wearables, Apps: Supporting health and wellness

Wearables are etched in the popular imagination as a wristband, watch, or earwear for tracking steps, calories burnt, and metering exercise intensity. These electronic devices have rapidly outgrown that early stage to monitor a patient's blood pressure, heart rate and glucose levels. Take UrgoNight released in 2019 by French company UrgoTech and retailing at $800. This brain-wave-reading headband/app uses electroencephalogram (EEG) measures and app-based mental activities to retrain the user's brain to help her/him sleep better. For best results, the makers of the app recommend wearing the headband for 20 minutes a day, three times a week, for a three-month period. Insomnia is a common-enough disorder, with up to 10% of all US adults experiencing sleeping difficulties and associated fatigue and attention difficulties by day at least thrice a week for more than three months.

More and more products are making their presence felt in the proactive/preventative care segment. Bose Sleepbuds II, costing around $400 is from Bose Corporation, known for its audio speakers for over three decades. Sleepbuds are specially designed to enable sound sleep. Consider a few more examples. Livongo, part of telehealth provider Teladoc since 2020, provides remote care to patients struggling with diabetes, hypertension, depression, and anxiety. Meanwhile, Ping An Good Doctor connects patients with over 48,000 in-house and external physicians, health management experts, nutritionists, and counsellors via its app. The startup funded by Shanghai's Ping An Insurance Group also runs unstaffed AI-powered clinics for the initial round of patient screening. As in March 2022, the company had 420 million registered users and cumulative consultations totaling 1.27 billion.

2. Genomic medicine, support platforms: Promoting personalized care

Increasingly, outcome-based care focuses on preventing, diagnosing, and treating diseases in a way that really matters to individual patients. Most importantly, it is based on providing the patient with the most optimum dosage or health regimen based on her/his personal/genetic/lifestyle data, and risk factors. The age-old practice of generic treatment has had its day and served its purpose, but it fails to satisfactorily answer the challenges in present-day healthcare since it is still based on population averages and trial and error approaches for drug prescription. In the old school, deciding what drug to administer and the amount in which it is to be taken and how often (dosage) doesn't typically consider individual differences in absorption, distribution, metabolism, and excretion. It also doesn't give due consideration to the concentration of a drug at the cell receptor site and its resulting effect. Suffice to say that generic treatment fails to satisfactorily address the aspirations of patients, especially in these times of hyper-personalization. Personalized care or precision medicine is the inadequately met need businesses from Exact Sciences, Baze, and Cariloop to GE's Pristina Mammography System are seeking to address at different levels.



Cologuard from Exact Sciences, a self-described company of "cancer fighters," is a non-invasive technique for screening colon cancer. The test involves shipping a stool sample to a lab, where it is perused for microscopic blood and altered DNA, which might be indicative of precancerous growths in the colon lining. While Cologuard is not a substitute for prevailing colonoscopy, it has received the FDA's stamp of approval in August 2014 and its popularity has soared amid the Covid-19 pandemic. Baze, founded in 2014, offers personalized nutrient and supplement recommendations based on the customer's lifestyle data (e.g., habits), anthropometric detailing (height, weight, body mass index, body circumference, waist-to-hip ratio), and blood nutrient levels captured via an at-home blood test.

3. Artificial Intelligence: Helping make sense of the tsunami of data

This ought to be mentioned in the same breath as the personalized care previously discussed. Personalized care is well thought of in terms of its curative and preventive effects and high precision, all of which are predicated on insights derived by decoding vast volumes of data. Healthcare providers struggle to derive deep and accurate information from the tsunami of data coursing through their system from multiple sources. Such data points certainly include hospital records, medical records of patients, and medical test results. That's not all. Providers have to also deal with the mushrooming amounts of data coming in from the "Internet of Medical Things" (e.g., remote patient monitoring devices, wearable medical devices, hospital beds fitted out with sensors).

Time is of the essence in healthcare, so adoption of AI algorithms is essential to quickly interpret large amount of data while machine learning (ML) solutions can help by way of automated decisions in a range of contexts. Some businesses have already seized the opportunity for AI and ML in therapies ranging from rapid diagnosis to robot-assisted surgeries. Intuitive Surgical's FDA-approved robotic surgery assistant Da Vinci lightens the surgeon's load by letting her/him work on a console. At the same time, the AI-powered system "translates" her/his hand movements in real time to perform minimally invasive operations such as for hernia.

Leveraging ML-powered technology, blood testing company Freenome studies RNA transcripts, DNA chromosomal patterns, and proteins in the system to find early signs of cancer in a standard blood draw before the disease can start to ravage the body. By January 2022, Freenome sailed past the $1 billion mark in total funding. In March 2022, VirtuSense was recognized as one of Fast Company's most innovative companies in the medical devices space. The company earned a spot in the big league with its proactive medical care devices like VST Balance.

4. SaMD: Empowering software to perform more medical functions

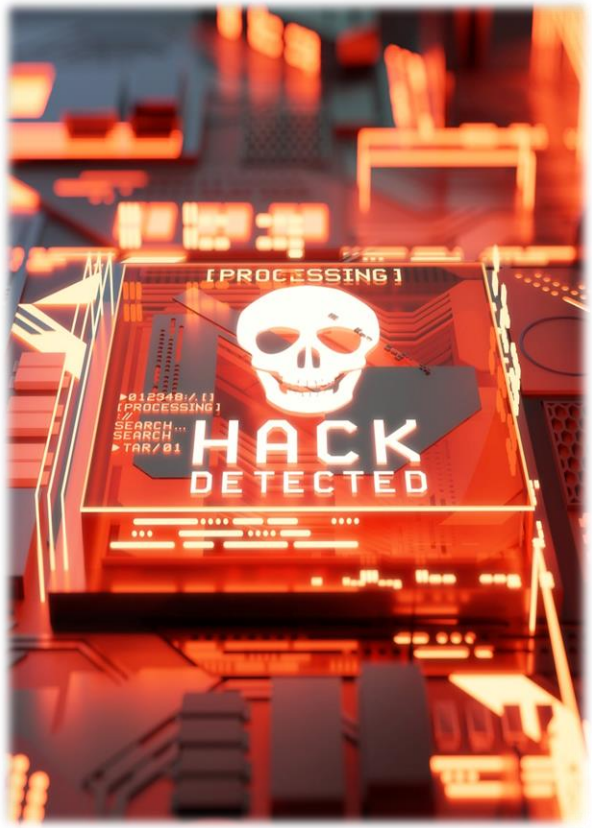
The new normal of personalized care is powered by massive aggregation of data from umpteen sources and use of advanced statistical tools to discover hidden patterns and evidence. It is based on this that critical treatment decisions are made for individual patients. Seamless sharing of information across medical devices, without irritable interruptions, buffering issues, and other discernible errors, is key to making timely and informed decisions that benefit patients. Siloed data islands are conspicuously old-fashioned and needlessly self-limiting. Therefore, it is important that medical devices are capable of seamlessly “talking” and sharing relevant information with other medical devices. Improving medical device connectivity is at the core of the software as a medical device (SaMD) model.

SaMD is, essentially, any standalone software application or mobile app created to carry out a medical task, independent of any hardware medical device. That said, SaMDs are designed to be hooked up with other SaMDs, hardware medical devices, and general-purpose software. The SaMD market is seeing scorching growth at a CAGR of 21.9% and is expected to be just shy of $90 billion by 2027.

Early entrants have made some headways already. Pear Therapeutics’ packages provide a way out of psychological reliance on psychotropic substances, including illegal drugs by applying a regimen that includes cognitive therapy lessons and fluency training. The app also keeps doctors up to date regarding patients’ progress and challenges they face in their recovery journey. In a single year, 2021, Pear was awarded the State Opioid Response 2.0 grants by three US states. Tidepool is another player that continues to grab eyeballs with its Loop, an automated insulin dosing app for iOS designed to help manage type 1 diabetes. Loop interfaces with several insulin pumps and continuous glucose monitoring systems (that track blood glucose levels) to automatically dose insulin. The app ensures the user’s glucose stays within a desired level.

5. Cybersecurity: Making sure medical devices and patient information are secure

Even as the SaMD is seeing a boom, there are looming concerns about unlawful access and damage to their data and disruption of operations by malicious hackers. Attackers very often seek to secure a toehold in healthcare networks, before gaining deeper access, via unprotected medical devices. Legacy devices, nearing end of life, are particularly vulnerable to cyberattacks. In May 2017, ransomware attack, orchestrated using the WannaCry worm, encrypted files on systems in more than eighty hospitals in the UK and cost the country's National Health Service £92m in service disruptions. Hospitals are today crammed with devices, so much so that it is very easy to lose sight of their security though it is a critical element. A single personal health information (PHI) record is, on average, more than 300x pricier in the cyber market than, say, a piece of credit card information! The lure of PHI is too tempting for hackers, and the result is that medical databases are particularly targeted.



The FDA works closely with device manufacturers, besides hospitals, healthcare providers, threat researchers, and various federal agencies to bolster medical device cybersecurity and reduce risks. From time to time, the FDA comes out with guidance and safety communications for medical device manufacturers. Device makers are mandatorily required to report to the FDA instances where their devices have caused or contributed to a death or serious injury. Where their device has malfunctioned and this is likely to cause or contribute to a death or serious injury, manufacturers are again required to report the same to the FDA. Regulatory mandates for device makers are tightening by the day.

Key Recommendations

In the premarket stage, device manufacturers must focus renewed attention on designing security features into the product, performing security testing, and providing useful information to the users to operate the device securely. The devices must be configured to limit data transfer with less secure devices and environments to curb unauthorized access. The use of strong encryption around critical data that is stored or transferred to/from a device and cryptographically strong passwords can never be overemphasized. The manufacturer should consider risks such as unauthorized modifications/updates to the device software, including to third-party and open-source operating system software. End users/user groups should only be granted fine-grained access to the device, only based on the actions they need to perform in the organization.

Controls such as access authorization (e.g., passwords, hardware keys, biometrics) and anti-malware have now become bare necessities for medical devices. In the post market scenario, device manufacturers would be expected to shoulder the responsibility for device cybersecurity with other ecosystem partners such as healthcare providers, distributors, and consumers and specialty providers of medical device cybersecurity. These include the likes of Bitglass, CyberAngel, CyberMDX, Cynerio Imprivata Irdeto Medigate Protenus Sternum, VDOO, and Virta Labs. More recently, a bill referred to the US House Committee on Energy and Commerce, in May 2022, requires medical device makers to track, spot, and remedy post-market cybersecurity vulnerabilities and make software updates available to the device throughout its lifecycle. So far as device manufacturers are concerned, there are many unique opportunities lying ahead and, almost certainly, a few challenges, and the time to act is now.

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