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HEALTH CARE MANAGEMENT
ALUMNI ASSOCIATION

THE WHARTON HEALTHCARE QUARTERLY

AUTUMN 2020, VOLUME 9, NUMBER 4

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EDITOR'S LETTER

Z. Colette Edwards, WG'84, MD'85
Managing Editor

To learn more about Colette, click here.

It has been almost a year since the entry of the novel coronavirus into our collective global lives. It first appeared on the scene in China in November 2019. The degree of disruption it has caused has been at an expansive scale and makes it unlikely things will ever return to the way they used to be. That reality presents the opportunity to build on the transformational changes which have already been manifest and to make the investments necessary to create a sustainable future.

COVID-19 has laid bare a broad and extensive array of inequities which have existed for a very long time. Between the disproportionate burden borne by people of color relative to the complications and lethality of the coronavirus, the global response to the murder of George Floyd, the tens of millions who are unemployed (many of whom who have also lost their job-based healthcare coverage as a result), the number of small businesses which have been shuttered permanently, and the massive food insecurity which has resulted in miles-long lines for food pantry boxes, all while the stock market remains strong and massive tax cuts are enjoyed by the top 1%, the rapidly increasing wealth and opportunity gap has been exposed in a way that has been experienced viscerally by much of the populace.

Caregivers, (with care recipients from infants to the elderly) have been challenged like never before to be stewards of the health, well-being, growth and development of their loved ones and clients in an environment of uncertainty, new routines and precautions, and needs for which they were not prepared nor trained. There has been greater recognition and appreciation for front-line workers who put their lives at risk every day to keep some semblance of the old world on track for those of us who have the ability and luxury of being able to work from home.

The healthcare sector has proven it can move nimbly and creatively. Medical professionals have adjusted quickly as the virus continues to morph over time. They have learned to be much more attuned to the possibility of both zebras as well as horses. Care delivery modalities and reimbursement methodologies have flexed, resulting in the accelerated growth of telemedicine and remote monitoring. And the benefits of living as healthy a lifestyle as possible, managing chronic conditions, and being proactive about preventive care have been even further clarified.

The future is uncertain, especially in an election year. However, COVID-19 has taught us we are much more dependent on each other than we may have realized. It has left no doubt that life is better for a greater number of people when we work together. We are facing lost dreams, grief and mourning, the exacerbation of mental health and substance use disorders, rising rates of stress/anxiety/PTSD/depresssion/suicide, lost savings and financial insecurity, educational experiences which fall short of expectations and which may threaten the quality of both teaching and learning, and so much more.

We must each value the lives of others as much as our own if we are to survive, much less thrive. Otherwise, the long-term and collective trauma of the virus, about which we still have much to learn, will be even more damaging, and people will literally die and lives will be lost that could have been saved.

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Managing Editor

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THE PRESIDENT'S DESK

Maria Whitman, WG'05

To learn more about Maria, click here.

Dear Alumni and Friends,

Let me begin by sending my hope that you and your families continue to be well in this year of uncertainty and challenge.

Last year at this time, I wrote about the experience of healthcare. It always amazed me that somehow the expectations of availability, experience, and value we demand in every other transaction in our lives do not translate consistently to how we experience and consume healthcare – one of our most fundamental needs. And as this year goes on, we become increasingly aware of the gap and how it is widening.

Recent estimates of individuals losing their health coverage this year range up to 20 million people. In the U.S., about half of individuals have health insurance tied to their employment and as we know, there are many who have lost jobs or are furloughed, etc. In my own research with patients, individuals are making more conscious choices to delay or reprioritize elements of health because they are deciding the risk is greater than the benefit in this moment, they cannot afford it, they do not see the importance, are making trade-offs on the definitions of urgent (this varies of course with diagnosed diseases), or they do not have access to it. In addition, this year has called to light the increasing socioeconomic and racial disparities in healthcare.

Lewis Dartell in a BBC article in June said, "while being enormously disruptive and painful, crises also invariably nurture the emergence of a great common purpose, solidarity, creativity, and improvisation." I was speaking to an HCP last week who said his institution moved to telehealth as did many amidst the pandemic, but he has many patients who live without access to strong WIFI to do a proper telehealth visit. So, they invested in WIFI in their parking lot, giving those who need it a place to go to complete a visit.

There are many stories that have emerged in 2020 – from small, local, focused efforts for a community like this example to corporations shifting their core capabilities to support gaps in services and equipment. Improvisation has abounded, but, as we look forward, an important question is how we will we make meaningful and lasting change on these dimensions. The new class of HCM students is already thinking about this critical question, and I was energized by their focus on understanding the challenges of the moment when I was with them in August for orientation. I sincerely hope this is a place we as a community of healthcare leaders will put our energies, passion, and expertise behind solving through action. And we are committed to enabling that progress.

In a normal year, we would leverage our annual Alumni Conference to create a forum for information exchange and connection on the most important topics of the moment. We are sad an in-person conference is not a possibility this year, but we also see the incredible opportunity the virtual forum creates to reach a wider breadth of Alumni, in increments of time that work for our lives and this moment.

To that end we are bringing to life a series of mini-summits over the course of the coming months. Each mini-summit will begin with a

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continued

THE PRESIDENT'S DESK

fireside chat or TED-style talk from a keynote, followed by a moderated audience Q&A, and then end with small virtual break-outs to debate, discuss, and network. Matt Ridley, the author of *How Innovation Works - And Why It Flourishes in Freedom* asserts that innovation is an incremental, bottom-up, fortuitous process that happens as a direct result of the human habit of exchange. Our hope and intentions are to foster innovation and create opportunities for natural collisions of ideas with more of us virtually building awareness, challenging the thinking, and sparking change.

Our first WHCMAA Mini-Summit will feature a fireside chat with Conrod Kelly, an expert on social determinants of health (SDOH), about the intersection of racial disparities in healthcare and the SARS-CoV-2 pandemic. For more, visit the Upcoming Events page of our website. We hope you will join us there.

As always, we encourage you to keep the dialogue going. Bring your thought leadership, research, experiences, and ideas to our community:

LinkedIn: Wharton Health Care Management Alumni Association
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Wharton Knowledge Network: whartonhealthcareopen@googlegroups.com
LinkedIn public channel: https://www.linkedin.com/company/whcmaa/

Stay safe, healthy, and happy. We hope to see you soon.

Kind regards,

Maria Whitman, WG'05
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ALUMNI NEWS

Constance (Connie) Kraftson McDowell, WG'75
Retired in June 2020 from a 45 year career in healthcare IT – 2.5 years in administration and IT at Hospital of the University of Pennsylvania (1975-77), 3 years of IT consulting at Arthur Andersen & Co. (now Accenture) (1978-80), and over 39 years mostly in product manager/ application architect roles at Shared Medical Systems/ Siemens Healthcare Solutions/Cerner in Malvern, PA.

Approaching my 45th wedding anniversary with my husband, Glenn McDowell (BA from University of Pennsylvania '74). We are parents of 4 adult children, all adopted – Alastair and Shelby domestically and Anya and Andrei from Russia in 2001, when they were 11 and 10 years old. Glenn is a pastor and director of Philadelphia Gospel Movement with a vision to see Greater Philadelphia flourish spiritually, economically, and culturally through the grace of Jesus Christ.

Contact Connie at: mcdowell.fam@verizon.net

Theo Brandt-Sarif, MD, WG'86
I continue consulting to pharmaceutical and biotech sponsors, serving as physician medical monitor on phase 1-3 clinical trials.

In addition, over the past decade I have helped over 10 clinical trials meet or exceed their patient enrollment targets by significantly speeding up recruitment. Either in "rescue mode," or proactively as the trial is getting started.

COVID-19 has, of course, placed significant challenges in the way we conduct clinical trials. The consequences will be profound. I am working tirelessly to help my clients get their trials back on track.

On the home front, we, like most of you, have been in lockdown with our 17 year old daughter/high school graduate since March. Exciting news is that our first grandchild is due to be born to our younger son and daughter-in-law in London this November. So much to look forward to.

Contact Theo at: Theo@PatientRecruitmentSpecialist.com

Learn more.

Amanda Hopkins Tirrell, MBA, FACHE '86
A COVID Spring has turned into a COVID Summer with my interim executive management consulting business pretty much grounded. It is more than a challenge to move about the country with pandemic travel restrictions between and among the various hot-spot regions of our country! As a result, I have been focusing on work that I can do remotely from my home-office based in North Augusta South Carolina and limit my onsite engagements for now to a reasonable and safe day trip driving radius which ranges from Atlanta to Greenville to Charleston.

For the last several months, I have been advising a couple of Software as a Service (SaaS) start-ups, which has been very interesting. One company is developing a Primary Care Access Analytics product that unlocks capacity and gives physicians and their teams insights into transforming their model of care to meet the pent-up demand for primary care made even worse by the pandemic. My other client offers a cloud-based behavior diagnostic tool that helps care managers working with providers, employers, and payers to help patients with Type II diabetes overcome SDOH and other barriers to achieve better health outcomes and reduce costs.

My MOST fun project during this COVID time was hosting a WHCM Class of '86 Zoom Mini-Reunion and Happy Hour. June Kinney and Skip Rosoff joined us, and a great time was had by all! I am proud to say that we have really come a long way since LOTUS 123!

Seriously, thank goodness for this technology that has allowed us to reconnect and stay close and, more importantly, to reach our patients and their families during this unprecedented time. Wishing all my fellow Wharton Healthcare Alumni wherever you are a healthy and safe passage through these COVID times!

Contact Amanda at: Amanda@hopkinstirrell.com

Learn more.

Josephine N. Harada, WG'08
Josephine Harada was recently appointed Vice President of Business Development at Thrive Earlier Detection, following its $100M Series A. Thrive is a healthcare company focused on incorporating earlier cancer detection into routine medical

ALUMNI NEWS

care to extend and save lives. Thrive is developing CancerSEEK, a liquid biopsy test that is designed to detect many cancers at earlier stages of disease. CancerSEEK will serve as the core of Thrive's integrated cancer information offering. Thrive closed a $257M Series B in July 2020 to support its registration studies and commercialization efforts.

Prior to Thrive, Josephine served as the Head of Business Development at 10x Genomics, where she oversaw all business development activities and implemented and managed strategic partnerships to accelerate and strengthen 10x Genomics' platform and application pipeline. Previously, she additionally executed strategic partnerships with biopharmaceutical companies as part of the business development team at Foundation Medicine, a company dedicated to transforming cancer care by delivering molecular insights on each patient's unique cancer to inform the selection of targeted and immunotherapies.

Josephine started her scientific career at the Genomics Institute of the Novartis Research Foundation and the Scripps Research Institute developing advanced genomic technologies. Dr. Harada completed her PhD in Molecular Biology at UCLA, received her MBA with a focus on Healthcare Management and Finance from the Wharton School, and holds a BS from MIT in Biology. A passionate advocate of genomic medicine, Josephine remains committed to the development of genomic innovator products and molecular therapies and to accelerating the adoption of personalized medicine interventions into mainstream care.

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Learn more.

Smita Mukherjee, WG'09

A few years ago, I read a book by Richard Shell that said career "success is not a single, once-and-for-all destination. It is a journey with way stations and stopovers. You can get to one place, enjoy it, and then move on." This is exactly how I feel as I bid adieu to Novartis Oncology to join Bristol-Myers Squibb (BMS) in the market-leading Multiple Myeloma Franchise as an Associate Director in Marketing. I will be part of the Revlimid - Multiple Myeloma team. I am eagerly looking forward to learning about this disease state and understanding the patient journey to see how our portfolio of current and pipeline products can serve the needs of people with multiple myeloma. I am excited for this new chapter in my career!

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Learn more.

Anne Marie Aponte, WG'12

Anne Marie has taken on a new role as Co-Founder and Chief Operating Officer of a Stealth Company currently being launched by the New York-based venture studio, Redesign Health. This new venture will focus on senior care, an area of growing importance and opportunity as our population continues to age. Anne Marie most recently led Partner Strategy at DispatchHealth, the leading provider of in-home medical care. Prior to that, Anne Marie led Operations at Accolade, the healthcare advocacy company which recently celebrated its IPO.

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Learn more.

Tommy Meyerson, WG'20

In August 2020 Tommy moved to Franklin, Tennessee, to start work at DaVita Kidney Care's healthcare management program for recent MBA graduates. He and his wife are looking for friends and mentors in Tennessee and can be contacted at thomas.meyerson@gmail.com.

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THIS MONTH'S PHILOSPHER:
EDWARD CHAN, WG'11

To learn more about Edward, click here.

THE PHILOSOPHER'S CORNER

LIFE LESSONS

If I knew then what I know now, ***I would have...***

- prioritized in-person quality time with friends and family around the world given the new COVID-19 norm.

If I knew then what I know now,
I would NOT have...

- been as naive as I was about the endless possibilities of career paths that exist in the world. I grew up with tunnel vision that prioritized academic achievements rather than curiosity and life experiences.

FAVORITE QUOTES

1. "Good is the enemy of great. And that is one of the key reasons why we have so little that becomes great... Few people attain great lives, in large part because it is just so easy to settle for a good life." ~Jim Collins
2. "Don't let the noise of others' opinions drown out your own inner voice." ~ Steve Jobs
3. "Money never sleeps." ~Various
4. "You can quit if you want, and no one will care. But you will know the rest of your life." ~ John Collins (This was the quote that kept me going through training for my Ironman triathlons.)

RECOMMENDED READING

Fascinating reads on infamous personalities:

1. *Billion Dollar Whale: The Man Who Fooled Wall Street, Hollywood, and the World* by Tom Wright and Bradley Hope
2. *Bad Blood: Secrets and Lies in a Silicon Valley Startup* by John Carreyrou
3. *Black Edge: Inside Information, Dirty Money, and the Quest to Bring Down the Most Wanted Man on Wall Street* by Sheelah Kolhatkar

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THIS MONTH'S PHILOSPHER:
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AFFIDAVIT: HEALTHCARE AND THE LAW - COULD COVID-19 DATA HELP MEDICAL DEVICE MANUFACTURERS ACCELERATE THE FDA APPROVAL PROCESS?

Medical device shortages and shortcomings during the COVID-19 pandemic have led the Food and Drug Administration (FDA) to grant Emergency Use Authorization (EUA) to many medical devices manufacturers. Were it not for these EUAs, these manufacturers would be unable to market their devices, as their FDA applications would still be pending. Once the present "emergency" ends, these EUAs will expire, and manufacturers will again be unable to market their devices for the indications cleared under the EUA.

Still, the real-world evidence (RWE) gained about these devices while marketed under the EUA need not be lost with the passing of the pandemic. Once the pandemic ends, manufacturers should be able to use the data collected to support their pending applications for market clearance and for new indications for already-cleared devices.

When a manufacturer wishes to market a new medical device or market an already-cleared device with modifications or for new uses, it must obtain pre-market clearance, either through a Premarket Approval Application (PMA), a De Novo Classification Request, or a 510(k) submission. In each case the applicant must show the device is safe and effective for the proposed indications for use. For example, a 510(k) must demonstrate a device is safe and effective by showing it is substantially equivalent to an already-cleared device. *See id.* §§ 807.92(a), 807.100(b). "[S]ubstantial equivalence" means the new device (1) has the same intended use as the predicate device and (2) either has the same technological characteristics as the predicate device or has enough data showing it is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness than the predicate device. See id. § 807.100(b).

For devices found not to be substantially equivalent, or found to be substantially equivalent to a Class III (i.e., high-risk) device, manufacturers must seek a De Novo Classification or file a PMA. Both the De Novo and PMA process have more stringent requirements than the 510(k) process.

EUA creates a fourth pathway. During certain emergencies, as declared by the Secretary of Defense, Health and Human Services, or Homeland Security, the FDA may authorize the use of an unapproved medical device if that device is intended for use during such an emergency. *See* 21 U.S.C. §§ 360bbb-3(a)(1), (b)(1) (2017). The FDA may do so only if the following factors are satisfied: (1) the agent causing the emergency can cause a serious disease or condition, (2) the available scientific evidence shows the device may be effective in treating the disease or condition, (3) the known and potential benefits of the device outweigh its known and potential risks, and (4) no adequate, approved alternatives are available. *See id.* § 360bbb-3(c).

The data requirements for factors 2 and 3 are not particularly difficult to satisfy; whereas the 510(k), De Novo, and PMA processes require evidence of "effectiveness," EUA designation only requires evidence that a device "may be effective." FDA, *Emergency Use Authorization of Medical Products and Related Authorities: Guidance for Industry and Other Stakeholders*, 8 (2017). Given the lower bar, the FDA will consider most forms of scientific evidence when making an EUA determination, from device performance data to patient experiences. See id. at 8, 14-15. EUA applications should describe the device, its intended uses, its safety and effectiveness and its risks and benefits. See id. at 11-15. As mentioned above, EUAs usually expire

upon termination of the relevant emergency declaration. *See* 21 U.S.C. § 360bbb-3(f) (2019).

Because EUA devices typically lack extensive clinical trial data, EUAs often rely on RWE — evidence of a medical device's risks and benefits obtained from a source other than traditional clinical trials. *See* 21 U.S.C. § 355g(b) (2017). While traditional clinical trials typically occur in specialized, controlled research settings with specific populations and intensive data monitoring and auditing, RWE instead comes from analyzing real-world data (RWD). *See* FDA, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices: Guidance for Industry and Food and Drug Administration Staff*, 24 (2017). RWD are data that concern patient health status or healthcare delivery and are collected routinely during the provision of healthcare; sources include electronic health records, claims and billing data, and disease registries. *See id*. at 4. Since RWE come from RWD, RWE sources can span the spectrum from observational studies within an existing dataset to large simple trials. *See id*. at 4, 8.

RWD must be *relevant* and *reliable* for FDA to consider the resulting RWE in deciding whether to grant EUA. *See id*. at 9, 12. RWD are relevant if they contain sufficient detail to capture the device's uses, the outcomes of interest and the questions of interest, and are interpretable using informed scientific judgment. *See id*. at 13. Whether RWD are reliable depends on how they were collected and whether adequate processes were in place to assure data quality. *See id*. at 15.

The FDA expects to use RWE in EUA determinations, and has done so recently, given that traditional clinical trial data are often unavailable for such devices. *See* FDA, *Emergency Use Authorization*, 13 (2017). Examples of RWE considered in granting EUAs in the COVID-19 emergency include: bench performance tests used to approve the Airway Dome for HCPs; data extrapolated from the "reported clinical experience" used to approve the Impella RP system manufactured by ABIOMED; and ECG and echocardiogram datasets from electronic health records used to approve the ECG Low Ejection Fraction Tool (ELEFT), a software intended to be used by healthcare professionals to provide an assessment of Left Ventricular Ejection Fraction (LVEF) for use as a diagnostic aid to screen for potential cardiac complications associated with coronavirus disease 2019 (COVID-19) or underlying cardiac conditions that may affect clinical management of COVID-19. See IkonX, Inc., FDA Emergency Use Authorization Letter, 2 (July 24, 2020); Abdiomed, Inc., FDA Emergency Use Authorization Letter, 2 (May 29, 2020); Eko Devices, Inc., FDA Emergency Use Authorization Letter, 2 (May 11, 2020).

When the COVID-19 EUAs expire, device manufacturers should be able to use the RWE in their EUA applications and the RWE generated by their EUA use to support their pending applications for both marketing clearance and additional indications for already-cleared products.

Manufacturers could simply utilize FDA's existing supplementation processes to provide newly acquired RWE. For example, PMA applicants may amend pending applications and *must* periodically update them with new data "that may reasonably affect an evaluation of the safety or effectiveness of the device." 21 C.F.R. §§ 814.20, 814.37 (2019). With pending *De Novo* Requests or 510(k)s, we suggest that applicants approach the FDA with a proposal of how best to incorporate RWD and RWE generated during EUA use.

To be sure, supplementing an application with additional data requiring review may not accelerate the process. Still, more data indicating a device is safe and effective should make it more likely for the FDA to conclude the device is safe and effective (or not, as the RWE may suggest) and enable the FDA to draw its conclusion faster. Therefore, manufacturers should be able, and encouraged, to support their device applications using all of the available RWE once the devices' EUAs expire.

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DOWNLOADING SUCCESS: LEADERSHIP OF TELEHEALTH INNOVATION FOR HEALTHCARE PROVIDERS

While COVID-19 takes its toll on so many areas of our lives, within the world of health information technology it has rocketed healthcare providers into the future. Around telehealth – which includes videoconferencing as well as remote patient monitoring and mobile health applications – organizations have resourced and ramped up initiatives that otherwise were moving along gradually. It is safe to say the era of telehealth is here. However, its continued rapid expansion and success depend on:

Continued support from policymakers and insurers to expand coverage of telehealth services and extend regulatory flexibilities even once the pandemic has subsided. In a positive sign, the Trump administration signed an executive order in August to promote telehealth even once the pandemic passes.

- Advances in the telemedicine technology infrastructure
- Ensuring programs are effective and equitable for all
- Determining who best to lead telehealth initiatives within healthcare providers

WHICH EXECUTIVE LEADS?

This expedited approach has meant there is no consensus on who should lead telehealth initiatives at provider organizations. A key question — clinician or non-clinician? It can be either, but in situations in which physician buy-in and change is needed, a physician is desirable.

Depending on the organization, telehealth services are being overseen by:

CIO: This often makes the most practical sense, as the CIO in many organizations oversees traditional IT functions (information systems, technology infrastructure, data warehouse, etc.) as well as digital strategy. At rural facilities – where the need is greatest – expect the CIO to have broad responsibilities and therefore to drive telehealth adoption. In larger organizations, there may be a dedicated "Director of Telehealth" or similar title beneath the CIO who can focus on it exclusively.

Chief Digital Officer: Most larger healthcare organizations are realizing they need a CDO to create and oversee digital strategy on a par with the CIO role. Digitalization encompasses telehealth and requires full-time attention, and the CDO is well-positioned to take on this responsibility and significantly improve the consumer experience.

CMIO: As a clinician and technologist, the Chief Medical Informatics Officer has a strong background to lead telehealth efforts. The question is, does this role have the support and executive leadership of a CMO or CIO?

COO, CMO (or other business or clinical operations leader): Many organizations are folding telehealth under an operational position. This may be practical but runs the risk of telehealth not having a clear champion.

VP, Telehealth or Chief Telehealth Officer: We're just beginning to see this dedicated role created, though with little consistency as to how it is defined. Should it be a physician or not? The jury is still out.

We are also seeing other titles – from VP of Virtual Medicine to Chief Medical Technology Officer to Chief Clinical Transformation Officer – crop up to oversee telehealth expansion. And in some organizations a dyad model with, say, a non-clinician director of telehealth partnering with a medical director of telehealth is being tested.

Whoever oversees the telehealth function, success requires information technology leadership to align with business and clinical operations teams. While one person may drive telehealth adoption, it will take a team approach to make it work in a seamless and secure manner to achieve success.

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CYBERVITALS: CONNECTIVITY IN HEALTHCARE ENTREPRENEURSHIP

Healthcare is accused of a lot of things: being inefficient, slow to change, and ineffective in adopting technology. It seems like the perfect breeding ground for disruption and new ideas - but are we sufficiently considering cybersecurity as we innovate?

STATE OF AFFAIRS

A look at research and development (R&D) investment in healthcare in 2018 shows that healthcare was the second most well invested industry, with a prediction that by 2020 healthcare would surpass computing/electronics R&D. While acknowledging the pandemic has indelibly changed how healthcare is valued in the foreseeable future, it should not be surprising that we see healthcare data from 2019 reached unprecedented value for exits.

With so many of the innovations focused on connectivity, cloud-based assessment, or even bluetooth-enabled functionality, why is it that healthcare cybersecurity is often only discussed as related to HIPAA? Is it the fear of showing up on the U.S. Department of Human and Health Services (HHS) wall of shame, or the headlines regularly outlining another leak of personal health records that contribute to this myth?

The truth is, healthcare cybersecurity is so much more than that, as every system that enables the delivery of care relies on secure connectivity. Think about all the medical devices that operate in healthcare delivery organizations (HDOs), or the electronic health record (EHR) system and the equipment required to monitor a patient's home in a rural corner of the world, for example. With every assumption care providers make about how a system is designed or what users will try to do with it, we see a crack where cybercriminals can and will try to break in.

Even in the midst of a pandemic, cybercriminals have exploited that connectivity by shutting down a testing facility in the Czech Republic, attacking vaccine testing facilities, and sending more than 18 million COVID-19 related scam emails on a daily basis. leave to recuperate.

TREND OF CONNECTIVITY

We often dream of healthcare innovation as changing a clinical intervention or enhancing a patient experience. Yet increasingly, this includes connecting devices with a desire to 'do something' with the data gathered. Increased connectivity ushers in new possibilities for clinical care, while also introducing a mandate for transparency throughout the value chain.

The convenience developed by the tech industry has seemingly filled in the need for COVID-19 socially distanced groceries, food delivery, and video chats. But the reality is, many of these services employed a common working practice in the startup world: fail early, fail fast, and fail often.

While this iterative process helped these platforms, it unfortunately does not translate to healthcare startups. When the care of a person is on the other end of a piece of technology, failing has real consequences.

While tech has made a big difference in supporting COVID-19 responses, these are all reactionary behaviors. In general, healthcare cybersecurity is not embedded into existing processes elegantly, is difficult to maximize for scalability, and, all-too-often, is not efficient.

When combined with the idea that the budget for healthcare IT as a percentage of revenue is almost twice as much as it is in other industries, yet healthcare is targeted for cybercrime 2-3 times more frequently than any other industry, it seems healthcare connectivity and cybersecurity are in need of disruption. Thankfully, and accelerated by the pandemic, these systems will be rebuilt in our lifetime. In a way, this will allow for normal functions through future "black swan" events.

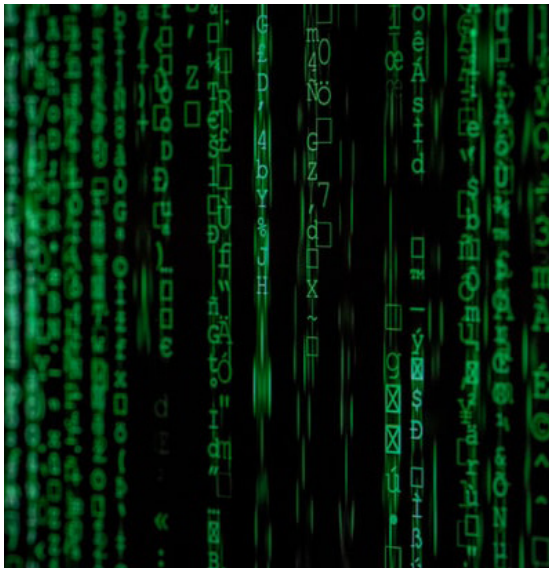
CONSIDER CYBERSECURITY WHEN INNOVATING

Healthcare must somehow find its own standard for secure connectivity. Many of the startup idioms, such as pushing out a minimum viable product (MVP), catching a hot trend, or moving fast and breaking things, do not work in healthcare.

Last year, researchers showed that hackers can manipulate real lung CT scans and trick both practitioners and algorithms into misdiagnoses. In recent months, the mass pooling of genetic and personal health information has shown great results in care, but also introduced new privacy concerns.

Earning and maintaining trust, just like in patient care, is the only way to ensure a product will be relied upon by patients and providers.

As the pandemic has shown us, well-designed systems can enable telemedicine to be an effective and efficient alternative to treat those who do not require physical care. For this to continue once patients "have a choice" to return to in-person care, innovation in this platform will need to occur to meet patients' needs. And steps will need to be taken to ensure health disparities



are not further exacerbated by the shift to virtual care due to inequality in access to the technology necessary to support telehealth appointments.

The software that will enable real-time, continuous monitoring will need to be developed in order to provide confidence the data is reliable. Vulnerable populations will directly benefit from technology that can address and understand the complex health needs of patients without introducing new risks. And in the zealous pursuit of leveraging algorithms to assist in diagnostics, focus is required to avoid or correct for the bias which can lead to incorrect conclusions and/or result in a negative impact on the equitable allocation of resources.

A recent report found unskilled hackers can breach about three out of four companies. And those who watched the Twitter hack unfold can anecdotally see that even large technology companies can be victims of cybercrime.

Developing a more secure health system isn't just good for the short term; it will support the technology community for the next decade. To earn the title of responsible innovators, a concerted effort to address security must be made.

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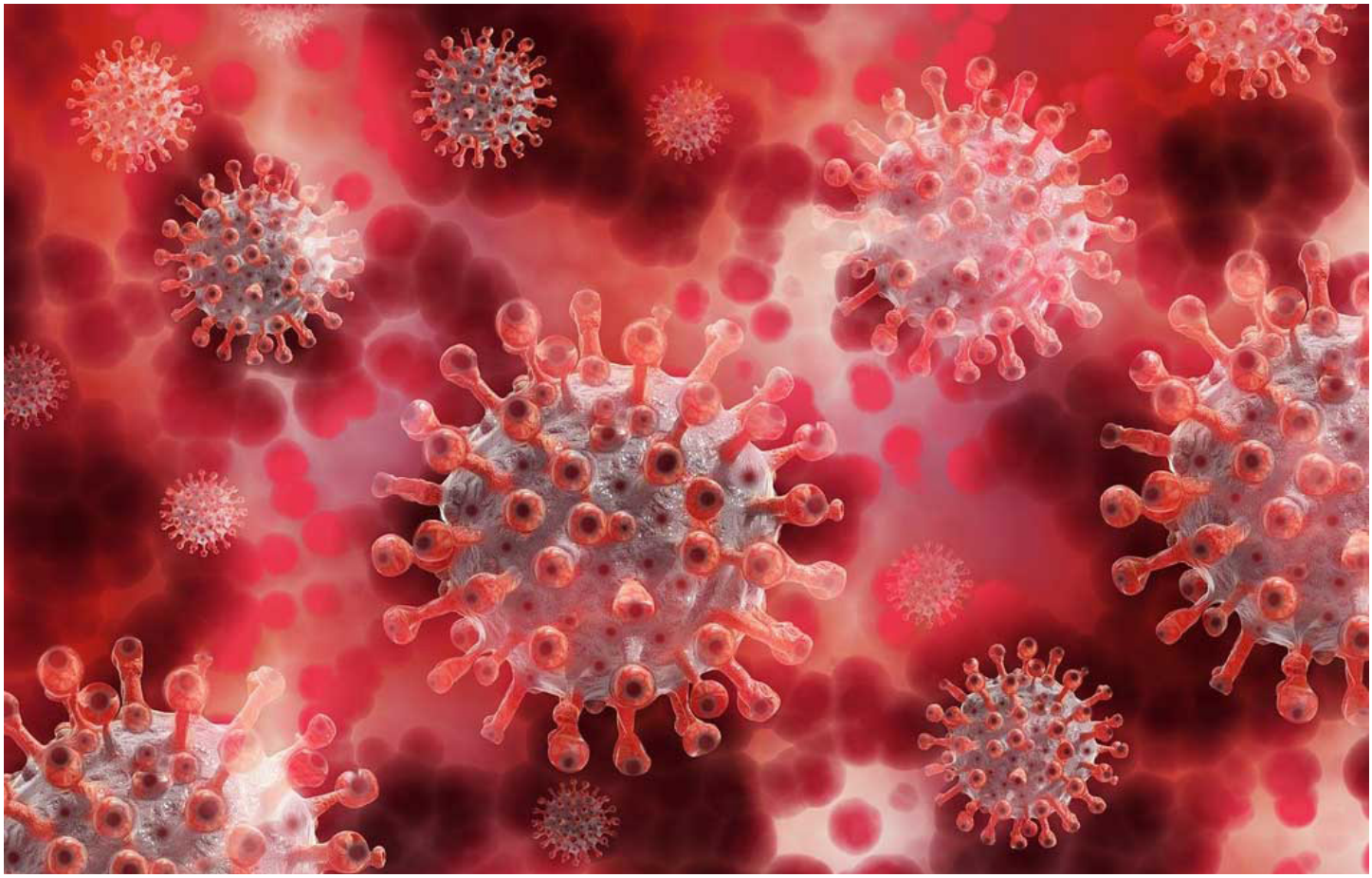
THE HIDDEN "BLESSINGS" OF COVID-19 : LET'S NOT BLOW IT, PEOPLE!



COVID-19 is a devastating virus. It affects every corner of the globe with more than 47 million confirmed cases and well over 1.4 million deaths globally. The U.S. leads the world with 25 percent of each of these numbers. The future is uncertain, and it is unlikely things will ever go back to "normal" again. And therein lie the hidden "blessings" of COVID-19.

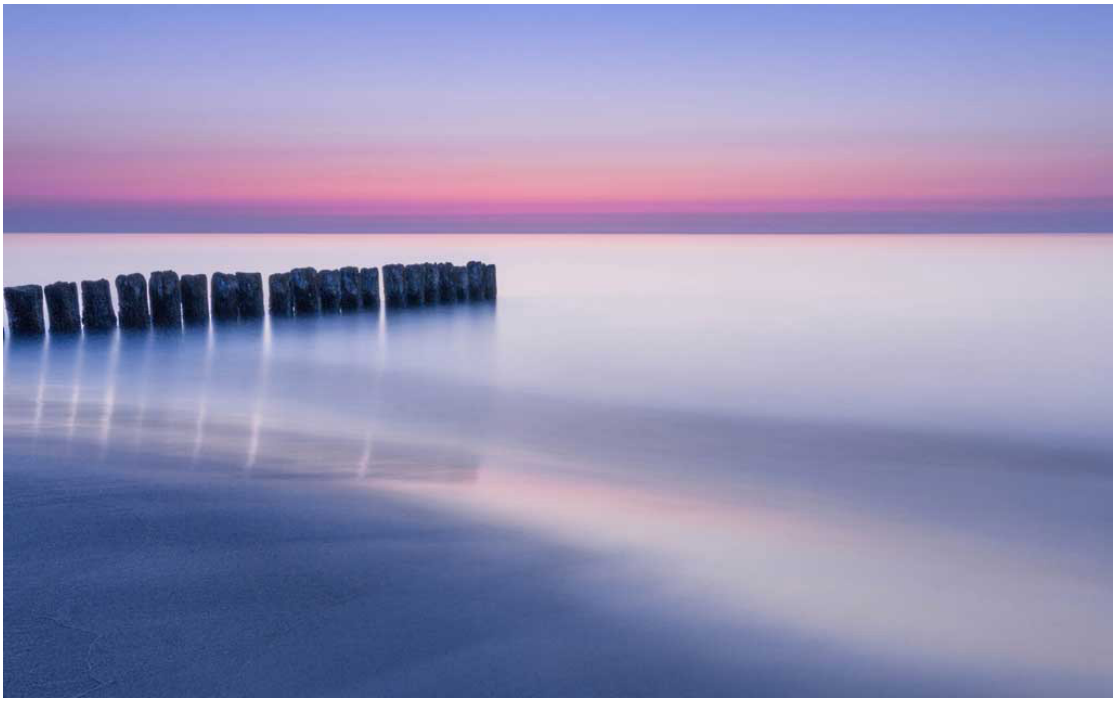
The novel coronavirus is transformational, forcing us to change whether we want to do so or not. It's moving at lightning speed, not caring one whit if we are ready.

In the U.S., the virus is surging well past its prior peaks, and ICUs are filling to 100% capacity again. And we are now in our third major surge since February.

To add to an already complicated picture, there was a report several months ago of an emerging flu virus, G4, discovered in pigs in China. G4 is similar to H1N1, can spread from pigs to people, and current seasonal flu vaccines are reported to not be protective. This virus has the potential to become a pandemic.

"As the current crisis ultimately abates, we need to remember the lesson that the system can be reset."

~ Pamela Hartzband, MD



For several years it has been difficult for me to imagine how the world and the human race would be able to dig out of the hole we created. I believed it would take an unprecedented and global event to save us from ourselves. Mother Nature seems to have given us a second chance and the opportunity to create a "new normal." **Let's not blow it, people!**

PERSONAL BLESSING #1: COMFORT AMIDST GRIEF

My father died in December 2019, two days before his 93rd birthday, after a long and difficult journey through cerebrovascular dementia.

He was a brilliant, compassionate, dedicated, and beloved physician and was a man frequently ahead of the times. He was a devoted, gentle, and loving father of two children, who believed his daughters should never be limited in their dreams and aspirations because of their female gender or race.

I miss him every day. Most of the time his death still does not seem quite real because I feel his spirit so strongly.

So how was his death a blessing? He passed from the earth pre-COVID.

He was hospitalized 8 times the year of his death and would have been at high risk for severe complications and death from the novel coronavirus. Just imagining the anguish if he had died in the hospital all alone and, due to his dementia, likely thinking he had been abandoned when he took his last breath is haunting.

And then not being able to have the opportunity to celebrate his life in person with family and friends would have made things even more heartbreaking.

Timing is sometimes everything, and I feel immense gratitude for his having been spared a COVID death. And, in that way, the coronavirus has helped bring comfort on days when grief is strongly making its presence known.

PERSONAL BLESSING #2: EVEN MORE SPECIAL FAMILY TIME

Except for two and a half weeks thus far, I have spent the year with my mother. She had knee replacement surgery, thankfully at the hands of a skilled surgeon and without complications. Her recovery was uneventful and proceeded more quickly than anticipated.

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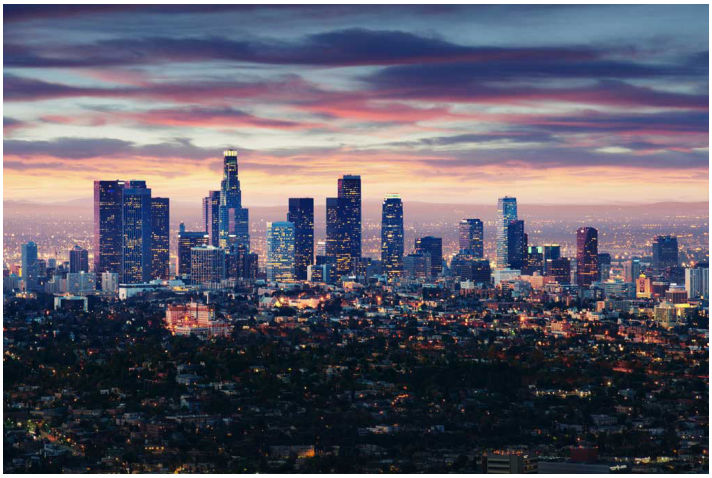
And then COVID-19 arrived on the shores of the U.S. So we've been sheltering in place together since February, taking as many precautions as possible to reduce the risk of exposure and infection. The blessing? I treasure this opportunity to spend so much concentrated time with her, especially so soon after my father's death.

CLIMATE CHANGE

"We are the first generation to feel the impact of climate change and the last generation that can do something about it."

~ Jay Inslee

By 2019 we seemed to have reached the point where even taking all the actions recommended by the scientific community would still have been way too little way too late. However, it's mind-blowing to see how quickly (less than a month!) the air became crystal clear in places like Los Angeles, China, and India with cars off the road due to a global quarantine.



The Blessing: Vanishing pollution and air quality that is better than it has been in decades has shown in a very visible way that IF we become conscious and consistently committed stewards of the environment NOW, we have the power to reverse course and save a future in which the earth is not only habitable but life-sustaining.

Research by social scientists has found that when one person makes a sustainability-oriented decision, other people do too. You have the power to inspire others to take action.

A "TRIFECTA OF SUFFERING"

"The only thing necessary for the triumph of evil is for good men to do nothing."

~ Andrew Marshall

A second pandemic, the ongoing emotional fallout from COVID-19, followed the novel coronavirus pandemic.

And with the now widely acknowledged and long-standing epidemic of racial injustice, police brutality, and the frequent killings of African Americans at the hands of law enforcement, a "trifecta of suffering" has emerged.

8 minutes 46 seconds….the time it took for the life of George Floyd, an unarmed African American man in Minneapolis, to drain from his body under the knee of a white police officer on his neck, in full and brazen view for the entire world to see and clearly without fear of retribution.

The world is feeling turmoil and a wide range of emotions – fear, horror, disbelief, grief, heartbreak, anger, resentment, rage, an ignited sense of purpose and a reactivated commitment to action. For some, overwhelming physical and emotional exhaustion has set in. After all, we have seen some version of this movie for 400 years.

But much of the world had its eyes opened wide in less than 10 minutes to the deep-seated racism which stalks its victims each and every day. Sometimes in ways that are "small," but spirit-crushing (like the daily microaggressions so common in the workplace, which contribute to the emotional tax paid by Black people and negatively impact physical health and well-being), and sometimes ending in a horrific demise. And when an opportunity seems to present itself, it not infrequently may turn out to be a "glass cliff" Trojan horse.

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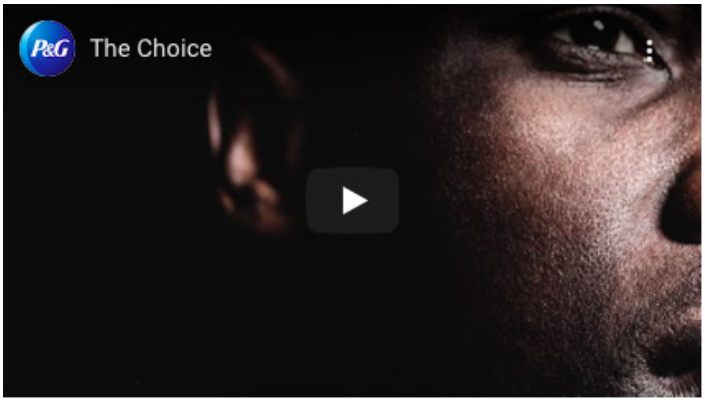
One way to begin to understand and walk in another's shoes is to get a glimpse of someone else's life…..in this case by way of Proctor and Gamble:

The tragedy of George Floyd's senseless death (and the many deaths that preceded it, including Elijah McClain, Ahmaud Arbery, Breonna Taylor as well as the death of Rayshard Brooks which followed 3 weeks later) has triggered global protests numbering in the millions.

For the first time in decades, there is renewed hope for substantive and concrete change powered by righteous rage, clear-cut demands, strategic actions, and a multicultural demand for the elimination of the myriad disparities created by design in the many internecine systems which have rigged the outcomes long before its victims are even born.

If you are not black, Proctor and Gamble inspires action and a choice of civic engagement. They point out racial inequality "didn't begin with us, but it can end with us. If we choose to act."

The Choice tells the story through the lens of the white community and focuses on its role in making equality a reality rather than a dream.



The Blessing: A "woke" global populace who hopefully will no longer ignore and cannot "unsee" the reality of racial injustice; those who have the passion and make the time to join the many generations who have been at the fight from the time the first slaves were ripped from their motherland, put on plantations, separated from their families, and physically violated …….but had the courage to consciously decide to live against all odds and build the resilience that has sustained the generations who have followed long after they died.

It feels like a multi-decade movement has evolved and been turbocharged to achieve material and sustainable change. One can only hope mightily that we don't fall back into incremental symbolism and an amnestic fog once the cameras have moved on to another story.

JUSTICE FOR ALL

Unemployment in the U.S. as a result of the coronavirus is front and center for millions of Americans and has laid bare the income inequality which has long existed.

Miles-long lines of cars for food pantry distributions, low-income workers deemed essential whose lives are endangered because they do not have the luxury of working at home, and the anticipated rental evictions and mortgage defaults forecasted to result in previously unseen levels of homelessness……. These are all signs of the fragility of the current economy and even tougher times ahead.

- 81.1%…..the amount paid to women as a whole compared to their white male colleagues who also work full-time, year-round. (The story is even worse for Native American and Alaska Native women, African American women, and Hispanic women. They earn only 75% of a white male counterpart.)
- 1 in 6 ……. the number of Americans who live below the poverty line
- 60 million ……. the number of Americans who do not make a living wage
- $32,731 ……. the average student loan debt in the U.S. in 2019
- 50-55 million……. the number of unemployed (if you also count those who are unemployed but don't qualify for an unemployment check, e.g., certain solopreneurs and small business owners, and those whose unemployment benefits have run out and have yet to still find jobs).
- 40% …… the percent of Americans who would not be able to afford a $400 unexpected expense
- 367 ……. the number of people in the United States exonerated by DNA testing (includes 21 who served time on death row)
- 14 …… the average number of years they served in prison before exoneration and release. These individuals have paid a dear price for a debt they never even owed.

Financial insecurity, fading American dreams, and the first several generations expected to be worse off than their parents all reflect a system that has increasingly favored those who have and has favored them to a greater extent than ever before.

The Blessing: A much more diverse portion of the populace is experiencing the breadth and depth of financial instability. It extends well beyond those often caught in a generational legacy of poverty due to a lack of access to opportunity.

With more people living paycheck to paycheck and soon to have no paycheck on its way at all, Americans of all stripes have been pushed like no other time, including the Great Depression.

Now that more people are in the same boat (where others have been at sea for far too long), a greater opportunity exists to step into the collective power that has always been present but often underestimated both by citizens and the system.

The power which won't take no for an answer and demands – with confidence, unerring determination, informed boycotts, and voting – changes like gender pay equity, a real living wage without the need for 3 jobs just to make ends meet, access to both affordable college education and housing, and race-blind criminal justice.

"Never doubt that a small group of thoughtful, committed, citizens can change the world. Indeed, it is the only thing that ever has."

~ Margaret Mead

Gen Y, Millennials, and Gen Xers are actively engaged and have higher expectations which

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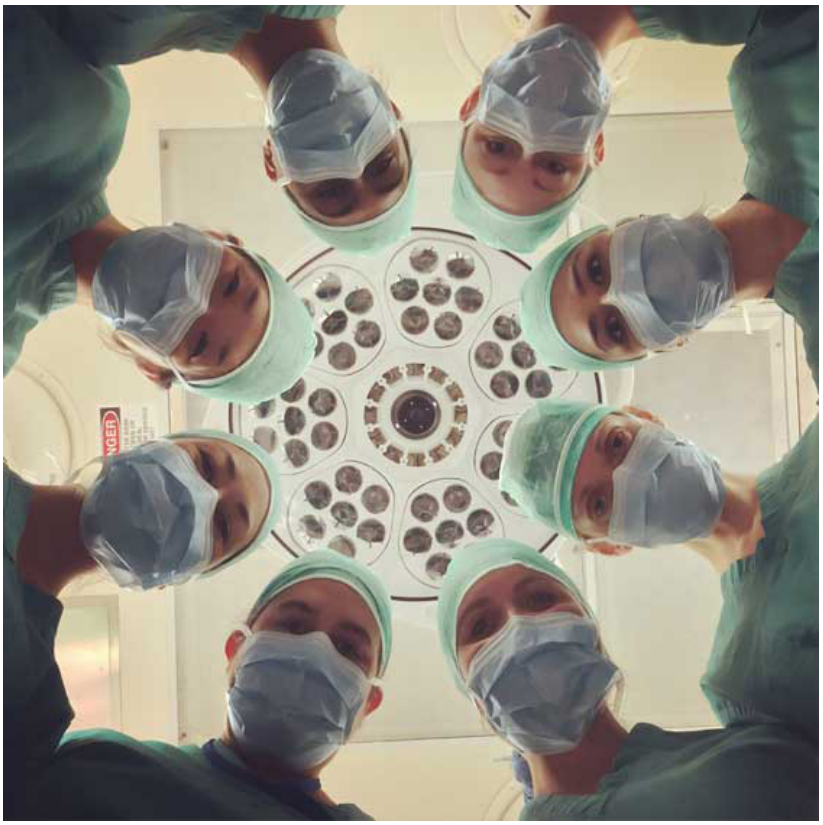
assume a more truly inclusive and just world than many of those in the generations preceding them.

With the multicultural, multi-generational movement sparked by George Floyd's death, there is opportunity to address many inequities simultaneously, particularly given that in many cases they are inextricably intertwined.



HEALTHCARE

- 3 – 4 times higher …… the maternal death rate of black women in the U.S. when compared to their white counterparts (regardless of socioeconomic status and educational level)
- 70% higher than the rest of the U.S. …. the mortality rate from opioid overdose for those age 25-44 living in Appalachia
- 12% …… the percentage of the U.S. population that is Black
- 30 – 90% …… depending on the locale, the percentage of the total deaths due to COVID-19 that are the fate of African Americans in the U.S.
- 1 in 4 …. the number of rural hospitals at risk of closure in 2020
- 1 in 5 …. the number of Americans impacted by a mental health condition
- 66.5% … the percentage of personal bankruptcies related to medical issues and the repercussions thereof, including income loss and job loss, reduced hours, and a preexisting debt load tipped over by medical bills into insolvency

"In times of crisis, things that people wouldn't normally think about or things they would think about sort of on a slow-burn basis start to get some traction. Crises have a way of making things happen."

~ Dr. Bruce Leff

The landscape for those in healthcare is changing dramatically. It is also unlikely to return to "business as usual."

Telehealth services are skyrocketing. As initial forays are made to provide services which were deferred in order to reduce the risk of exposure, infection, and spread of COVID-19, providers and health systems must develop processes and make adjustments to their workflows and physical plant in order to offer the physical and psychological safety needed for patients to return for in-person services.

Even those with symptoms of heart attack and stroke have avoided going to the hospital due to fear of catching COVID-19 in that setting, often either arriving too late for optimal intervention or dying a potentially avoidable death at home.

Unfortunately, the current surge will only exacerbate that reality.

Survival in the future will necessitate:

- innovation and an openness to new ways of thinking
- continuous identification and implementation of best practices
- data-driven agility in decision-making and execution
- collaboration that knows no borders
- human-centered design
- physician leadership
- a holistic view of health and well-being and a whole-person view of patients
- the eradication of health inequities
- strategic thinking with a view which incorporates a longer time horizon and a greater focus on proactive preparedness
- clinically, looking at the puzzle pieces of symptoms and signs and considering (1) both a zebra and as well as a horse and (2) the possibility that something counterintuitive may be required to treat and potentially save a life
- changes to medical education, training, and healthcare systems to support the emotional health and well-being of clinicians and to reduce the upward trends in burnout, PTSD, and suicide

The Blessing: The novel coronavirus has pushed all stakeholders in the healthcare system to change and change quickly. There is neither the time nor the option not to focus on the patient and not to accommodate and embrace both different modes of care delivery as well as amended reimbursement methodologies.

With all hands on deck, team-based care is now a survival technique for saving lives and sustaining clinicians as they are immersed in the overwhelm and emotional toll of supporting patients infected with a virus about which we still have much to learn. In the process, many have found a renewed sense of purpose and a return to the reason they chose to enter the field of medicine in the first place.

Providers and payers have been reminded of their inextricable interdependencies. Scientists and big Pharma across the globe have collaborated and are running parallel or serial stage pathways of development in the race to find an effective and safe vaccine.

Innovative and disciplined start-up technology and service companies have had the luxury of laser focus, with both well-defined needs and a market ready for their offerings.

And the often underestimated benefit and positive impact of simplicity, common sense, logic, reason, and pragmatism have been rediscovered and have resumed their rightful place on stage.

I will say it again. Mother Nature, by way of COVID-19, seems to have given us a second chance and the opportunity to create a "new normal." And that new normal has the mega-potential for designing a humane and caring world guided by the lessons the coronavirus has taught us – I value your life and protect you, and you value my life and protect me in order for each of us to survive. **Let's not blow it, people!**

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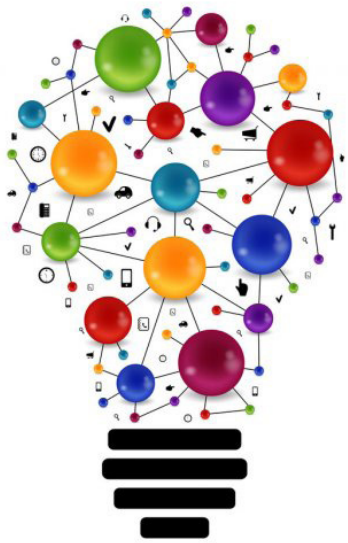
LEARNING FROM THE CRISIS

The COVID-19 crisis has created more turbulence and disruption for our healthcare system than any event in recent memory. And as many have noted (see for instance the thoughtful piece on innovation at Penn Medicine[1]), years of innovation and change have been packed into months of response by a system stretched to capacity but ultimately able to bravely hold itself together and respond to the crisis. While organizations intensely focus on their response to the urgency of the moment, there has been little time to look beyond what *Forbes* called "the innovation bubble"[2] to the middle and longer-term horizons—to reflect on these urgent innovations and consider how they might help us prepare for the future.



As we ready ourselves for whatever comes next, most likely a new normal with ongoing waves of disruption, organizations can ask themselves a series of questions that will help them learn from the crisis:

- What forces of change have emerged that will have a positive impact on health and healthcare going forward, and how will they impact your work and the patients you serve?
- What innovations from COVID-19 are valuable to carry forward, and which would best be left behind?
- What can you learn about the culture of your organization through this stress test? In what ways has culture helped you weather the crisis thus far? And where has your culture been stretched, perhaps to a near breaking point?

Working with clients across the healthcare ecology, we have observed a lot from which to learn and upon which to reflect.

On the positive side, there have been a whole series of rapid innovations that organizations can take forward. Our colleague Elizabeth Armstrong from the Harvard Macy Institute sees these as "silver linings"— good news we can glean from these stormy times.[3] These silver linings have made differences both small and large, including:

- The discovery that proning COVID patients facedown helps their breathing and makes them less likely to need intubation and require going onto a ventilator.
- The rapid shift to telehealth for many formerly face-to-face visits, including behavioral health, that can keep patients out of the hospital and have a huge positive impact for both providers and the public. Payors' willingness to reimburse these telehealth visits made a significant difference in enabling the spread of these virtual modalities. Whether we see a continuation of digital healthcare or a significant return to face-to-face encounters that work well virtually remains to be seen.
- The remarkable ability for pharmaceutical companies to rapidly innovate and develop medicines, including vaccines moving through clinical trials. The ability to dial up the timeline and marshal capital and federal dollars here has been critical. We all eagerly await the results of these trials and are already seeing benefits from COVID-19 related treatments.

LEARNING IN THE THICK OF IT

We encourage organizations to take stock now of the rapid innovations they have experienced and consider which to sustain and how (and which to leave behind). We look at these as "found pilots,"[4] home-grown innovations from which organizations can learn and build on for their desired future. An after-action review would be an ideal tool to use to do this work. We also encourage organizations to consider what they can learn about their culture through this crisis. Some relevant cultural questions include:

- Were providers easily able to work together across professional roles and hospital units or not? And what enabled this collaboration when and where it worked?
- Did decisions get made in ways that were experienced as agile and supportive? Or too top-down and rushed?
- Did staff feel appreciated as much inside the organization as they were celebrated outside of it?

A timely conversation about your organizational culture, how it has supported innovation (or resisted it), and the cultural assets you can build on into the future can provide a helpful focus for learning from this moment.

On a more challenging note, it is clear the crisis has opened up fissures at the system level that will need to be addressed:

- The vast disparities in resources and resilience among healthcare institutions. There are clearly hospitals and systems that have the cash flow and capital to more sustainably navigate the crisis and those that are struggling through. From a systems perspective, these disparities hurt our communities overall.
- The lack of leadership nationally which led to a lack of preparation to anticipate and respond to emerging infectious diseases in ways that learn from the COVID-19 response.
- The limits of our employee-based insurance system, as many workers have lost their jobs and subsequently their access to health insurance.
- The ability of providers to move beyond the limitations of role and scope of practice and step in during a clinical crisis.

On the broadest level, it is clear we need to build a stronger, more resilient healthcare system that truly operates as a system. As the McKinsey Global Institute noted,[5] "the crisis is a reminder of just how much health matters for individuals, society, and the global

economy." The opportunity we have to learn from this crisis and advance global health is both the greatest challenge and opportunity.

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OPEN WIDE: TOOTH DECAY - FROM CONDITION OF HUMANITY TO CONSIGNMENT TO MEDICAL HISTORY? PART 3

A RECAP FROM PART 2…..

Dentistry didn't really shed its folklore-ish conjectures on the causes and treatment of tooth decay (more formally known as "caries") until the early 20th century, when it took a step into the modern scientific era with the discovery that demineralization of tooth enamel – decay - was brought about by bacteria on tooth surfaces producing acids through the fermentation of carbohydrates. An understanding of the bacterial nature of the disease then led to the quest for suitable agents to treat it, one very effective one being a solution of silver nitrate, simply applied to the decayed area of the tooth. It involved little if any removal of tooth structure, no needles, and no drills.

For reasons that are unclear and not fully understood, dentistry for the most part did not continue this scientific inquiry, and instead continued along its historic trajectory of removal of tooth structure to get at decay, and then rebuilding that lost structure. All of this was furthered by the development of new materials, techniques, equipment, and notably local anesthetics, to the point where "cosmetic dentistry" entered the lexicon.[1] The opportunity to build upon over a century's worth of research, understanding, knowledge, and clinical application, and thus to refashion dental care, became lost as dentistry defined and confined itself to evermore intricate, involved, and costly mechanical procedures centered upon creating "that perfect smile."

The scientific inquiry did not entirely cease, however. In more recent years the oral biome has received attention, giving a more encompassing and nuanced view of the oral environment and its contribution to, or protection from, tooth decay. An updated version of silver nitrate has been developed, now incorporating the known antibacterial properties of fluoride along with silver in a new compound silver diamine fluoride, or SDF. And fluoride is also incorporated into a material called glass ionomer cement, or GIC, a material that can be used where, separate from or in conjunction with SDF, restoration of tooth structure is indicated, or for use as a sealant. In both instances, slow release of fluoride over time acts as a preventive on the immediate and surrounding teeth.[2]

A more refined generation of the science of tooth decay has emerged, vastly different from the arrested science of "drill and fill" from over a century ago.

PART 3 - WHAT HAPPENS NEXT?

The ground is shifting under the foundations of conventional dentistry. Its "surgical" approach of drilling a cavity is an expensive proposition in both money and time (and for certain, anxiety for the patient) involving all manner of specialized equipment, materials, and techniques, available only in the specialized setting of the dentist's office. Unnecessarily destructive of tooth structure, its treatments are prone to failure and the need to be redone, at even greater cost. Most particularly, the very notion of a surgical versus a medical approach as front-line treatment of a bacterial infection is unique to dentistry, propelled more by historical momentum than by science. (Even the routine surgical treatment of ulcers and appendicitis has given way to antibiotic treatment as highly effective first-line measures.)

In contrast, treating tooth decay medically, in accord with the microbiological science, involves no specialized equipment, technique, or practice settings, and the materials, SDF and GIC, are inexpensive and easy to use. Application can be done in minutes, with a microbrush in the former case, and with a gloved finger in the latter, by non-dentist personnel who can be readily trained in the simple techniques. But this also illustrates a fundamental, definitional change in dental treatment. No longer is dental care defined as putting the drill to the tooth. Instead, it is applying silver and fluoride to the disease-causing bacteria to arrest the decay.

It's a wholly different paradigm. Issues of cost and access as barriers to care virtually disappear. A therapeutic drop of SDF costs $0.79 versus $86-$606 for a filling. Cadres of non-dentist personnel, working in venues

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OPEN WIDE: TOOTH DECAY - FROM CONDITION OF HUMANITY TO CONSIGNMENT TO MEDICAL HISTORY? PART 3

far outside the dental office, including 200,000 dental hygienists, 290,000 nurse practitioners, and 119,000 physician assistants, not to mention registered nurses, school nurses, pharmacists, even physicians and others, can be easily trained in applying SDF and GIC, making access issues essentially moot. And not to be overlooked, the patient spends but minutes in the chair, experiencing no pain.

Putting these elements together – low cost, easy access, speedy and effective treatment and combined with a better patient experience – means the market for dental care stands to be completely upended. The private, solo, fee-for-service practice, the paradigm of "drill and fill" dentistry and the most prevalent dental business model, will be hard pressed to compete with new, more flexible, more welcoming organizational models responding to consumer demand for affordable, accessible, quality dental care. These models could include:

- Retail clinics offering dental care either through nurse practitioners, physician assistants, or dental hygienists, linked via teledentistry to dentists should consultation or referral be needed.
- Physicians' offices, particularly pediatricians, also offering dental care, and again linked via teledentistry if needed.
- School-based clinics.
- Mobile dental hygienists, rendering care to the homebound and facility-bound patient, and again data linked.
- At its most sophisticated, a dACO (dental Accountable Care Organization), integrated into an ACO for comprehensiveness of care, alternative payment mechanisms, quality assurance and evaluation of care programs, outcome measures, population health management, and more.

A subtlety needs to be noted. The science extending back over a century that led to the initial understanding of the bacterial nature of tooth decay, and then to its treatment with inexpensive, highly effective substances, since updated, has now laid the groundwork for new organizational models of care. These new models lower cost and geographic, socioeconomic, cultural, and other barriers to care, so that can be seen in a wide variety of venues, or have care taken to patients. Instead of treating teeth after the damage has been done, well organized, responsive, and anticipatory dental care resources will be addressing the disease as it exists in society for whatever reason, and intercept it early. No longer will tooth decay, at least in its most severe forms, be considered inevitable.

HOW TO GET THERE

The private, solo, fee-for-service dental practice is the predominant model of dental care for a reason: it has been protected economically, organizationally, and even scientifically by state dental practice laws. (The exclusion from Medicare also means dentistry had been outside policy developments shaping the rest of healthcare.) Society has paid the price in terms of high costs, restricted access, and dubious appropriateness and quality of care as a result. In addition to the incomplete and arrested science upon which traditional dentistry has been built, it is these political barriers that stand as impediments to better oral health for the population.

Needless to say, removal of restrictive state dental practice laws can be well nigh impossible given entrenched financial interests. Nonetheless, some entrepreneurial thinking could tip the balance in favor of the public interest:

- Retail clinics could offer dental care through NPs, PAs, or hygienists practicing under their clinic license. Where needed, the clinics could establish affiliations with like-minded dentists for consultative or referral situations.
- WalMart is one example of a major retailer getting into the primary and urgent care markets and offering a number of services in one facility. Customer focus, particularly with regard to affordability and attention to patient needs, is its stated business priority. If it properly responds to dental needs by incorporating the medical management of tooth decay in its offerings, its prominence in the market stands to

reshape dental care delivery.

- Executives of healthcare systems should think of developing or affiliating with a "medical management of caries" unit as part of primary care offerings in order to gain competitive advantage in the marketplace. Historically, dental care has been excluded from the rest of medical care, and patients are often at a loss as to where to seek regular dental care. A health system offering dental care could benefit not only by serving as a portal of entry for new patients, but also for integrated care that such patients may also be seeking.
- A group of entrepreneurial dentists, subscribing to the principles of medically managed dental care, could form their own corporation, with satellite facilities staffed by hygienists and set up in store fronts; or hygienists staffing other physician offices; or serving as a training center in the use of SDF and GIC for other non-dentist personnel. Also, such a corporation could affiliate with retail clinics or large healthcare systems for the provision of dental care.

Other arrangements are conceivable, and each would likely encounter some obstruction from state dental boards, but the thought is these obstructions could be legally circumvented by including dental services under a broad medical licensure to practice. The better dental health offerings would then be recognized by the consumer, thus transforming the dental care market.

IN CLOSING

Much more can be said, perhaps at another time. The takeaway point here is that society has been saddled with narrow and outmoded doctrines, assumptions, and means for obtaining dental care, needlessly enduring the financial and morbidity costs of tooth decay. It can be better served by replacing the existing edifice with a responsive system of dental care delivery, scientifically grounded in modern understanding and treatment of the disease.

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2. For more information on the science behind tooth decay and the medical management of caries, an abundance of information can be found at Mmclibrary.com.

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WHARTON AROUND THE GLOBE: REIMAGINING HEALTHCARE IN NICARAGUA

This past winter break, six members of the Wharton Global Health Volunteers (WGHV) traveled to Nicaragua to work with Pro Mujer on a comprehensive healthcare strategy focused on women. Founded in 1990, Pro Mujer has become one of Latin America's leading organizations committed to the empowerment of women through finance, health, and educational services. With a long history of providing financial assistance through microloans to women, Pro Mujer sought out the assistance of WGHV to assess opportunities to expand their services to cover a critical healthcare gap in Latin America.

Pro Mujer currently operates one pharmacy out of its Leon clinic, the first retail operation for the organization. Furthermore, Pro Mujer hypothesized that women, the main target audience, are less likely to seek out medical help for themselves, but much more motivated to find care when it's for their family. The team focused on three overarching objectives to craft the final healthcare strategy:

1. Accessibility
2. Profitability
3. Efficiency

ACCESSIBILITY

Over the course of the week, the WGHV team visited multiple Pro Mujer clinics in Managua, Leon, and Masaya to understand the current healthcare experience. Our visits included rural meetings in communities without electricity to busy urban clinics in the capital of Nicaragua. Observing the full spectrum of daily life, commute, and surroundings helped ensure the team started from a place of empathy.

The majority of Pro Mujer's healthcare clients started as microfinance loan clients, and, as a result, the current customer journey was not suited for a healthcare-first strategy. The WGHV team crafted a three-phase roadmap to focus on serving clients beyond microfinance by enticing new clients, engaging deeper, and extending relationships beyond the first clinic visit. Some of the recommendations included free educational materials, a Pro Mujer network of external specialists, and a word of mouth referral bonus program.

PROFITABILITY

Many non-profit organizations struggle with their dependence on fundraising to finance operations. For this reason, Pro Mujer emphasized the need to provide healthcare services in a fiscally sustainable way. The WGHV team identified restructuring the current pricing scheme as one quick and effective strategy for top-line growth. Currently, Pro Mujer offers two health packages: a low cost 'basic' tier that includes a simple exam and consultation, and a high cost 'premium' tier that includes an additional predefined set of tests and services.

In order to provide a comprehensive health journey that proactively caters to the needs of women at each life stage, the WGHV team recommended health packages that aligned to the life stage of the users: Basic, Family, and Comprehensive. Each package caters to a specific age group and contains services and exams that align with the health needs of a typical woman in that life stage. For example, the redesigned Family plan targets women who are looking to start a family or already have children. On top of basic care, this plan would also include sexual health consultation and exams and pediatric services for children of the plan holder. Over 95% of Nicaraguans live in a family unit, and, for most women, providing medical care for their dependents is a higher priority than receiving medical care for themselves. Designing a plan for this specific type of user meant Pro Mujer would be better able to reach and serve this major customer base.

EFFICIENCY

Lastly, the team identified efficiencies to improve the patient experience, reduce the cost of operations, and create more sustainable practices. To start, we captured a comprehensive list of pain points through stakeholder interviews, observations, and an analysis of existing data. Through this assessment, the team identified inefficiencies in the customer experience, such as long wait times and confusing intake processes, and the backend processes around record-keeping.

In response to these pain points, the team created a two-phased strategy focused on both immediate short-term tweaks and larger structural changes. One immediate low-cost improvement was adjusting the physical flow of the Pro Mujer centers to embed healthcare enrollment tasks with other workflows. Instead of redundant registration and verification processes, creating one patient-centric streamlined flow meant avoiding long wait times and complicated intake steps. The team also identified some long-term enhancements, including investing in digital solutions, such as self-serve patient portals and CRM systems to improve existing manual processes and reduce redundancy.

Back row from left to right: Abelardo Vidaurreta (Pro Mujer), Will Davenport (WG '20), Andrew Lay (WG '20), Marcos Lavandera (Pro Mujer)

Front row from left to right: Jenny Fernandez (WG '20), Kira Mengistu (WG '21), Karla Celis (Pro Mujer), Minji Kim-Hoffman (WG '21), Rita Costiv (WG '20), Hialmar Bermudez (Pro Mujer), Gloria Ruiz (Pro Mujer)

Pro Mujer believes women can become powerful agents of change for themselves and their communities if given access to the right opportunities. The WGHV team feels incredibly fortunate to have worked with Pro Mujer on furthering this mission, specifically focusing on the critical task of reimagining a better healthcare system to support women in Nicaragua.

The lessons we learned will stay with us long past this engagement, and we would like to thank the Pro Mujer team and the alumni for enabling us to play a small part in this important mission of empowering women across Latin America.

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