# COVID-19: A CATALYST FOR IMPLEMENTING CONNECTED HEALTHCARE PRODUCTS?

**Napoleon Monroe, Managing Director, New Directions Technology Consulting, analyses how COVID-19 is catalysing a wide range of reactions in healthcare. He says drug and device connectivity are essential to improving patient access to treatment – and patient outcomes – as well as reducing overall cost. Factors such as personal and population health – along with societal, technological, commercial, regulatory and legislative reactions – are interwoven in the changes. Mr Monroe argues that considering the possibilities for patient outcome improvement is critically important – and our outcomes, our lives and our companies depend on reactions to the catalyst.**

Almost every assumption about healthcare made before COVID-19 is being reconsidered or upended. The speed of change in healthcare – including accelerated patient outcome assistance and product connectivity – is suddenly in the spotlight.

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Social distancing, restrictions on personal interaction and provider access limitations have forced immediate wide adoption of telemedicine – for limiting the spread of the disease, improving access to informed care, understanding individuals' health and contacts across a broad population, and promoting individual responsibility for self and family. The US Federal Communications Commission (FCC) granted US$68 million (£55 million) for COVID-19 telehealth programme applications as part of the $2 trillion Coronavirus Aid, Relief, and Economic Security (CARES) Act.

Once tried – and especially once services are expanded and improved – the adoption and growth of telemedicine is likely to be permanent. A report in May 2020 from McKinsey & Company, *Telehealth: a quarter-trillion-dollar post-COVID-19 reality?*, documents what it calls "the massive acceleration in the use of telehealth since the COVID-19 pandemic". Patient and caregiver adoption has moved from 11% to 46% and providers are now seeing 50–175 times the number of patients via telehealth compared with before the pandemic. Pre-COVID-19, total annual revenues in telehealth were approximately $3 billion. With further provider adoption, up to $250 billion of US healthcare spending could be virtualised.

McKinsey discusses five models (some elements of the models are already practised). Within the scope of the models, one can envision:

- Remote medication outcome assistance for diagnosis and adherence, compliance and administration
- Urgent care triage and treatment
- Virtual office visits enabled by remote patient monitoring, and digital diagnostics and therapeutics
- Near-virtual office visits, combining virtual access to physician consults with other entities for testing and specialty services
- Remotely delivered home health services for the elderly and disabled including personal, physical, behavioural and occupational assistance.

Healthcare systems around the world were – and still are – paying, directly and indirectly, for medications and devices which are often not used or are used improperly. Medication and device outcome

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assistance can benefit from these sunk costs when outcome assistance barriers are removed. Telemedicine is a catalyst for breaking the legacy barriers.

Effective COVID-19 prophylaxis and treatments will rely on medication adherence and compliance. Even a vaccine may require multiple doses or boosters. Therefore, medication adherence and compliance have received greater recognition in outcomes research. Connected products are being used to gather population data and improve individual electronic medical records and to reduce interpersonal and system communications failures.

Lockdowns have affected clinical trials of medications, which have been moved away from dedicated clinical trial sites. Connectivity enables more meaningfully distributed clinical trials – and the immediacy of connected products has sped up the process.

Psychiatry is another area now receiving far more attention as the effects on mental health related to COVID-19 become widespread. Psychiatric outcomes are extremely sensitive to medication adherence and compliance.

Many of these changes are predicted to outlast COVID-19. The traditional wisdom that patients and practitioners would reject telemedicine was disproved when there was no choice but to accept it. While face-to-face is rightly preferred, telemedicine is less costly for patients and many other stakeholders; and can suffice for many visits. Once telemedicine is adopted, regression to old systems will be difficult.

The following are just some examples of changes brought about by the pandemic:

- Practitioner shortages, acknowledged before COVID-19, became extreme and were eased by telemedicine.
- Temporary payment parity was granted for telemedicine consults related to COVID-19. While universal parity is not likely, a Bloomberg editorial predicts two-tiered reimbursement for medical office visit (OV) and telemedicine after the pandemic – full for OV and reasonable, but less, reimbursement for telemedicine.
- US Health Insurance Portability and Accountability Act (HIPAA) regulations were relaxed for providers with existing patient relationships acting in good faith. The need for rapid responses to the pandemic also sped up turnaround times and innovation.
- Nationalistic considerations grew.
- Many barriers to telemedicine were temporarily removed. Going back to prior restrictions will be difficult.
- In the US, Governors have issued waivers for practice across state lines for COVID-19, extending prior agreements.
- Automated product identity is now recognised as having greater importance in post-market surveillance due to accelerated trials; and adulterated, misbranded ineffective, recalled, stolen, counterfeit and diverted products, which are currently of great concern.
- Medication compliance is recognised as important in combating COVID-19 and ensuring readiness for any future pandemics.
- Building on opioid and fintech controls, payers have proposed means to limit fraud and abuse of telemedicine.

## FUTURE SCENARIOS FOR US HEALTHCARE

Three model scenarios for US healthcare will predict how outcome assistance and connected combination products will be viewed in the future. In all scenarios, the US and state governments will remain the largest payer for Medicare, Medicaid, government employees and retirees. Deficits will demand that governments control costs. US healthcare stakeholders will have to rely more heavily on new applications of newer technology than in the past. Telemedicine and connected products will be more important to all stakeholders than before.

### Scenario One

Some predict that there will be little substantive change to the fee-for-product service models. Haven (the two-year-old Amazon, Berkshire Hathaway and JPMorgan coalition) has tried to bringabout change but so far it appears that the fragmented stakeholder systems have shown little interest. There have been few announcements of progress from Haven – and Haven Chief Executive Officer Dr Atul Gawande announced his resignation in May 2020. The earlier 54-company Health Transformation Alliance as well as Walmart succeeded in chipping away at some costs. Nevertheless, stakeholder resistance and US post-COVID-19 unemployment – which has taken many more people out of the employment healthcare insurance pool – make it apparent that, ultimately, dramatic change will come no matter which political party is in power.

### Scenario Two

Others predict mandatory price controls and allowing negotiation and importation. However, price controls are not enough, and are likely to be badly administered and will kill much valuable US innovation. Importation is not adequate and will be blocked based on national needs and large US volume requirements. Pharma will have fewer tools to differentiate and justify costs, meaning telemedicine and connected products will be more important to all stakeholders than in the past.

### Scenario Three

Lastly, others predict a "healthcare for all" model. However, none of the proponents or opponents are yet willing to define the rationing which will go along with this effective state takeover of basic healthcare. Opponents are unwilling to consider the possibilities, acknowledge that disparities in health lead to further socio-economic disparities or discuss the current rationing. It is likely that the US will evolve into a German, Dutch or French style system for basic needs and a parallel private free market for anything beyond basic care.

In all three scenarios, telemedicine and connected drug delivery products will be used more to help improve patient outcomes and control total healthcare costs. As pharma and device manufacturers have the most knowledge about the drugs and devices they manufacture, a prescription for

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a drug or device should qualify as an existing patient relationship to allow information exchange. Among the various stakeholders, connected product manufacturers, or their contractors, are the best positioned to assist with adherence and compliance.

Before COVID-19, there was great resistance to – and limited perceived need for – major change in US healthcare fee-for-service, in-person healthcare delivery. The fragmented nature of US healthcare presented significant barriers to change. Some issues in two categories were:

### Great Resistance

Different stakeholders have put up great resistance because they thought:

- Changes to established fee-for-product and service models are threatening
- We might lose our advantages with changes through legislation or otherwise in our various legacy stakeholder models
- Reimbursing telemedicine would bankrupt payers
- There is limited or no payback for connected diagnostic devices or drug/device combination products

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- Changes to improve outcomes would add cost for some stakeholders
- Connected products are not interoperable and are difficult for patients to use
- Adding patient outcome assistance would delay marketing and may add legal liabilities
- Any change from centralised, randomised clinical trial approval could jeopardise the entrenched approval and payment systems
- Patient privacy might be put at risk. We must abide by existing HIPAA regulations.

### Limited Perceived Need

There was a perception of limited need among stakeholders, who believed, for example, that:

- Inertia in systems already in place is comfortable
- We can continue to merge, acquire, lobby, advertise, automate, add lower paid staff, and make others (and even ourselves) more efficient and keep on going
- Patients' opinions are uninformed and difficult to evaluate
- Payment for outcomes and closer post-market surveillance won't become broad-based realities
- We can continue to rely on the randomised control trial approval process to be paid.

## POST-COVID-19 CATALYSTS

However, over the past few years even prior to COVID-19, many catalytic factors have emerged, encouraging healthcare stakeholders to take actions to promote better patient outcomes:

### Health

As the population ages, we have experienced growth of known chronic diseases which still go undiagnosed, undertreated or untreated and, therefore, worsen. Some of these conditions even seemed to be moving towards better control – but new diseases and new treatments have been overlaid on those previously identified. The complexities of patients' comorbidities and treatment possibilities have made focus difficult. There is greater recognition of overall treatment costs and the costs of poor outcomes related to non-adherence and non-compliance. There is also recognition that medication use – and non-use – are valuable diagnostic tools.

### Societal

Provider access has become increasingly difficult because of factors including provider consolidations, fragmented and overlapping healthcare bureaucracies, provider specialisation with limited numbers of generalists who must often function as gatekeepers, less generous employee insurance, contract workers not covered by employer insurance, and healthcare inflation outpacing wage growth for many years. In addition, the media has, for many years, highlighted the role of health disparities on outcomes. Pharma has also gained a far greater understanding of human and economic factor issues, and attempts to limit provider costs have made specialty products available for home administration.

### Technological

Biologics, other specialty medications and remote diagnoses have become extremely important. Smartphones with sophisticated communications capabilities are ubiquitous and health apps are available and used by many patients. And healthcare product automated identity and data capture (AIDC) systems – including product serialisation barcoding systems – have been around since 2013, although adoption has proceeded slowly.

Predictions have been made that technology will open many more lasting possibilities for telemedicine – and investments in this area have been substantial. Stakeholders such as pharma companies and their suppliers, technology companies, providers, payers, medical device and consumer device companies, healthcare distributors and information companies have invested in smarter, simpler-to-use drug delivery and diagnostic devices, remote professional and personal software and hardware products, communications, security, analytics information gathering, analytics and processing.

Entities experimenting with advancing healthcare improvements have uncovered and addressed interpersonal and system communications failures. Blockchain and other security systems have also been developed outside healthcare to address security and privacy concerns. Nevertheless, as of early 2020, the digitisation and integration of healthcare information lagged other sectors of the economy.

### Commercial

The last decades have witnessed huge growth of medication and device spending. Consolidations within and beyond healthcare stakeholder categories have gathered speed. Outsourcing to more specialised companies, often abroad, lengthened supply chains and created interdependencies. These actions provided economies of scale and growing market influence for larger companies.

In the last few years, new stakeholder combinations beyond legacy pharma stakeholders explored how to change existing modes of delivery – CVS Health/Aetna being one of the most striking.

Large pharma companies have focused on expensive biotech and other specialty products – leaving lower cost generics to others.

Cost savings related to "televisits" were recognised and published in some quarters. Tiered pricing proposals were floated to rationalise telemedicine and office visit encounters.

The period 2017–2019 saw prescription drug and device recalls, regulatory letters and back orders based on human factors, tightened regulatory restrictions and other causes. In 2019, a device tracker database for connected drug products became newly available. In 2019–2020, new stakeholder developer combinations realised the need to simplify and make products interoperable.

Coalitions actively promoted change and innovation. But change was slow in coming.

### Regulatory and Legislative

Over the years 2016–2020, there has been slight relaxation of some US FDA regulatory requirements. The 21st Century Cures Act in 2016 encouraged patient data interoperability and accessibility, and many innovations. Limited compacts for licensure portability allowed some practice across state lines. In addition, complicated, antiquated HIPAA rules, which limited adoption of telemedicine, protected major suppliers and priced out smaller practices from buying telemedicine software, have been under fire.

Pharma has also developed more effective regulatory strategies for smart drug delivery products. Controls on billings were implemented to prevent overprescribing and professional abuse of controlled substance licences. Indictments were handed down and sentences imposed to limit fraud and abuse in billing. A 2019 Executive Order encouraged artificial intelligence, but by early 2020, medical data sharing was still opposed by some stakeholders.

The past is an invitation to future healthcare change and improvements. Ask how each of the aspects above are likely to change in the post-COVID-19 world, and it becomes self-evident that COVID-19 will prove to be a powerful catalyst for a connected future for healthcare.

## ABOUT THE COMPANY

In the area of drug delivery, New Directions Technology Consulting is the exclusive market developer for the mMed patent portfolio. Medication telemanagement systems based on the portfolio can be used to develop innovative health and wellness programmes.

## ABOUT THE AUTHOR

**Napoleon Monroe**, the sole inventor of the mMed medication-telemanagement patents, has been involved in the successful commercialisation of patents for decades. He spent more than 20 years at Survival Technology (now part of Pfizer), where he built up and managed its IP portfolio. There, he invented three medical devices that were patented and commercialised – two for autoinjectors and one for a transtelephonic peak-flow monitoring device. Mr Monroe also led teams that invented, prototyped, tested, commercialised and scaled up emergency pharmaceutical delivery systems, such as the original EpiPen, for treatment of anaphylactic shock, and the Antidote Treatment Nerve Agent AutoInjector delivery system, which still protects US and allied military and civilian personnel.