Healthcare Delivery in the Information Age

Nilmini Wickramasinghe
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Elliot Sloane *Editors*

Digital Disruption in Healthcare

Springer

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Series Editor

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The healthcare industry is uniquely structured so that the receiver of the services (the patient) often isn't the predominant payer for those services (the insurance company). Healthcare interventions are often complex and typically involve multiple players including providers, payers, patients and regulators. This leads to economic dilemmas such as moral hazard, information asymmetry, and tangential considerations of cost versus quality creating obstacles on the road to delivering efficient and effective healthcare. Relevant data, pertinent information, and germane knowledge play a vital role in relieving these problems and can be most effectively obtained via prudently structured and well designed healthcare technology. Some of the major challenges facing today's healthcare organizations include demographic (longer life expectancy and an aging population), technology (incorporating advances that keep people healthier), and financial (escalating costs technological innovation) problems. In order to realize technology's full potential it is imperative to understand the healthcare-technology paradigm, develop sustainability models for the effective use of technology in a specific context, then successfully design and implement patient-centric technology solutions. Many of the problems with technology are connected to the platform-centric nature of these systems which cannot support seamless transfer of data and information, leading to inferior healthcare delivery.This new series focuses on designing effective and efficient technologically enabled healthcare processes to support the delivery of superior healthcare and provide better access, quality and value. It's main goal will be to identify the barriers and facilitators in moving from idea generation to concept realization and will navigate the key challenges in the field: bringing readers solutions and recommendations while identifying key factors in developing technology-enabled healthcare solutions.

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This book is dedicated to Our Families
This Series is dedicated to Leo Cussen:
Learned scholar, colleague extraordinaire
and good friend

Foreword

We are on the cusp of a paradigm shift in healthcare catalysed by technology advances. This book brings to the fore the elements that are shaping this transformation with a broad-based coverage of relevant issues. Interestingly, COVID has raised our sensitivity to scientific cooperation and technological innovation that extends beyond the current pandemic to address a broad range of challenges. Data analytics enabled by technology advances encourages advances in understanding. Devices providing data through the Internet of Things vastly outnumber people. Technology innovation continues to accelerate as opportunities emerge.

Unfortunately, though, the best of technological advancements will not succeed in the absence of an appropriate support infrastructure of systems, processes and policy. The importance of attention to processes is often underappreciated in getting technology and associated systems used and useful. In this sense, implementation involves more than just technological functionality. Healthcare processes can become exceptionally complicated and require significant attention as pointed out in Part II of this book. Process modelling can provide insight that assists in successful implementation.

However, without attention to implementation in the presence of sound policy, sustained behavioural change will not occur. As pointed out in Part III of this book, policy provides the framework and guidance within which people can function in a coordinated fashion. Finally, Part IV is dedicated to specific COVID-19 initiatives. Ultimately, the combination of technological advances coupled with effective processes and policy can achieve a bright future for healthcare from which all of us can benefit. This book is important in raising attention to healthcare in a way seldom seen that can inform a broad range of stakeholders.

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Preface

Digital disruption represents a change, at times a revolution, that is created by the incorporation of emerging digital technologies and business models into industry, practice and day-to-day life [1]. These innovative digital solutions and models typically impact the value of existing products and services and day-to-day operations. Hence, why the term 'disruption' is used. Fuelled by advances in technology and more specifically the technologies that make up the Internet of Things (IoT) [2], like never before, we have the opportunity to create better processes, solutions and ways to support all areas of our life and work.

Healthcare delivery in today's twenty-first century continues to contend with the triple challenge of exponentially increasing costs, aging populations and the rise of chronic care [3]. This has resulted in most countries around the world investing in technology-enabled healthcare reform with a view to provide better quality, better access and better value care, in general, and leveraging the opportunities and benefits afforded by the technologies of the IoT for the healthcare domain [3]. In contrast, though, this adoption and diffusion of digital health solutions has not been as rapid or radical as similar diffusions of digital solutions in other industries, notably banking, manufacturing and retail. However, since March 2020, when the world was faced with the challenge of the COVID-19 pandemic, without our digital health capabilities, it would have been almost impossible to provide care to citizens during harsh lockdowns. Thus, since March 2020, there has never been a more pressing time or urgency to try to incorporate the best technology advances and embrace digital disruption in healthcare, thereby making a focus on digital health solutions and the digital disruption that typically ensues an area of keen interest and paramount importance.

Our book serves to present a miscellany of chapters that focus on notable examples of utilising, incorporating, designing and conceptualising roles for digital technology solutions to enable and support superior healthcare delivery and wellness management. The rapid pace of the advancements in technology is exciting and a hallmark of this decade and century. Never more than now has healthcare delivery

needed to draw upon these developments to provide high-fidelity, high-quality and high-value care to all. This is indeed a nascent domain, and many issues around health literacy, policy, privacy and security, not to mention the direct and subtle as well as far-reaching implications for the various stakeholders (patients, clinicians, healthcare organisations, regulators, payers and the community at large), have yet to be fully understood or identified.

Our goal is simple in compiling the chapters to make up this work. We wanted to share with you, the reader, some of the critical touch points and help to enrich discussions and discourse and inspire further research into this critical domain; a domain that touches all of us and thus all of us should form considered opinions about its future directions. It is our belief that by building awareness, sharing unique examples and critical issues, challenges, barriers and facilitators encountered, it will help engage and ignite the imagination of researchers to explore further opportunities for digital health solutions. In this way, it will be possible to enable and sustain an environment where digital technologies support better monitoring, better data and better communications so that we have better access, better quality and a high value of healthcare delivery and wellness management for all as, when and how they need it, as well as design solutions to ensure we are both prepared and ready for future and perhaps catastrophic challenges.

The chapters making up this book have been arranged into four main sections as follows: (1) Technological Disruptions, (2) Process Disruption and Process Modelling, (3) People and Policy Considerations and (4) COVID-19-Pandemic Focus. We note that these sections are by design unequal, because we believe that the most significant aspect of digital disruption in healthcare is on the people and policy considerations. In addition, to be as contemporaneous as possible, we also include a small section on COVID-19-specific issues.

Specifically, the chapters are as follows:

Part I. Technological Disruptions

Chapter 1 How Technology Is Changing the Delivery and Consumption of Healthcare (Mark Wehde)

Chapter 2 Brain–Computer Interfaces: Taking Thoughts Out of the Human Body (Melissa Gregg)

Chapter 3 Towards Network Medicine: Implementation of Panomics and Artificial Intelligence for Precision Medicine (Robert D. Barber and Keith Kroeger)

Chapter 4 Data Analytics for Accountable Care Organizations in a Shifting Landscape of Health and Medicine (Suresh Chalasani, Madhumita Banerjee, and Gitika S. Chalasani)

Chapter 5 The Case for Digital Twins in Healthcare (Nilmini Wickramasinghe)

Part II. Process Disruption and Process Modelling

Chapter 6 Using Coloured Petri Nets for Optimisation of Healthcare Processes (Vijay Gehlot, Nilmini Wickramasinghe, Elliott B. Sloane, Michael Kirk, and Eric R. Miller)

Chapter 7 Towards Concept Realisation of Digital Health Technologies (Ruwini Edirisinghe)

Chapter 8 Clinical Tele-assessment: The Missing Piece in Healthcare Pathways for Orthopaedics (Oren Tirosh, John Zelcer, and Nilmini Wickramasinghe)

Chapter 9 Telehealth Implementation: A Synopsis of Patients' Experience of Clinical Outcomes (Chinedu I. Ossai, Stephen Vaughan, John Zelcer, and Nilmini Wickramasinghe)

Part III. People and Policy Considerations

Chapter 10 Disrupting LATAM Digital Healthcare with Entrepreneurship and Intrapreneurship (Luis E. Fernández)

Chapter 11 Data for Social Good: A Tripartite Approach to Address Diabetes Self-care and Patient Empowerment (Nilmini Wickramasinghe and Steve Goldberg)

Chapter 12 Realising the Healthcare Value Proposition of Better Access, Quality and Value of Care by Incorporating the Social Determinants of Health with Digital Health (Nilmini Wickramasinghe and John Zelcer)

Chapter 13 Why Do You Want Me to Use This EMR? (Amir Eslami Andargoli, Helen Almond, Dominic King, Jonathan Schaffer, and Nilmini Wickramasinghe)

Chapter 14 Leveraging Information Technology in Pharmacovigilance: Benefits for Pharmacists and Pharmaceutical Companies (Joel Fossouo, Rachael Mcdonald, and Nilmini Wickramasinghe)

Chapter 15 Scoping Mobile Clinical Decision Support Systems to Enhance Design and Recording of Usage Data Effectively: A Suggested Approach (Nalika Ulapane and Nilmini Wickramasinghe)

Part IV. COVID-19-Pandemic Focus

Chapter 16 Better Pandemic Preparedness with the Intelligence Continuum (Nilmini Wickramasinghe)

Chapter 17 COVID-19 Response in Australia and the USA (March–August 2020) and the Key Role for Digital Health: A Tale of Two Countries (Foluke Ajiboye and Nilmini Wickramasinghe)

Chapter 18 Digital Tools as Optimising Enablers of Quantitative Medicine and Value-Based Healthcare in a SARS-CoV-2/COVID-19 Pandemic World (Duane F. Wisk)

Chapter 19 The Internet Hospital in the Time of COVID-19: An Example from China (Jianqiu Kou, Zhengzhong Yan, and Nilmini Wickramasinghe)

No book can ever present in one volume a comprehensive collection covering all areas pertaining to the digital disruption in healthcare; however, we hope this miscellany of chapters we present will challenge our readers and be thought-provoking. We also hope that you have as much fun reading our book as we have had in compiling and writing it. The global pandemic has indeed served to highlight how fragile, dynamic and challenging healthcare delivery is, but it also provides us an opportunity to build and establish new models of care powered by digital health solutions that were once only imagined. In summary, we trust that on the completion of this

book, researchers, scholars, practitioners, consultants and the general public will all have a better understanding of how digital health solutions can be best harnessed to provide superior healthcare delivery and wellness management and will rise to the challenge of starting to build a better health and wellness environment for tomorrow, today.

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May 2022

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Part I
Technological Disruptions

Chapter 1
How Technology Is Changing the Delivery and Consumption of Healthcare

Mark Wehde

1.1 Introduction

Two disruptive technologies in the late 1800s turned the hospital from an institution for the destitute into a place of hope and healing. Historically, middle- and upper-class patients would be cared for, and even operated on, in their homes. Hospitals were primarily associated with poverty, infection and death. It was the profound changes brought on by the advent of anaesthesia and aseptic surgery that forever changed how and where we care for patients. By the mid-1900s, antibiotics were making a huge impact on health and longevity. The invention of the transistor in the 1940s, the integrated circuit in the 1950s, the minicomputer in the 1960s and the introduction of the first commercial microcontroller in the 1970s all lead to incredible improvements in diagnostics and therapeutics. Also, in the last half of the century, imaging systems, including CT, MRI, fMRI and PET scanners, coupled with the development of high-performance computers allowed for the development of sophisticated imaging systems for diagnosis and enabled the use of radiation and proton beam therapy systems for treatment of previously untreatable cancers.

Healthcare is about to experience a transformation perhaps even more profound than the disruptive changes that occurred over the last 150 years. Those changes that started with the advent of anaesthesia and aseptic surgery have led to the industrialisation of hospitals. Today, more and more physicians and equipment are being aggregated into extremely large healthcare systems due to economies of scale. Hospitals and healthcare systems are burdened by tremendous capital assets that will effectively limit their ability to respond to the changes in technology and consumer preferences that are core to the Fourth Industrial Revolution.

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The hospital of the future will be much different than the hospital of today. The massive physical infrastructure that we most often associate with a healthcare system will be primarily for those critically ill who need highly specialised equipment and expertise. But for most of us, healthcare will happen either in our communities or in our homes.

Healthcare systems are likely to adopt new models of providing care. Advanced care centres often combined with teaching hospitals will provide the most complex care. These hospitals will support very capital-intensive care. These tertiary and quaternary care centres will treat very challenging problems requiring the most specialised care.

Utilising a spoke and hub model, community centres will provide most routine care that requires a patient visit. This will include emergency care, although it is very possible that localised emergency care facilities will develop as a stand-alone service.

Most of the healthcare system is going to be designed around keeping people—not patients—well by providing ongoing monitoring of health conditions as a means of preventive care. Much of this care will be provided remotely and it offers the greatest chance of disruption of existing healthcare models.

1.2 Disruption of Existing Business Models

In his book, The Innovator's Dilemma, Clayton Christensen [1] described the role of disruptive technologies in undermining existing businesses and business models. To understand how the healthcare industry is on the verge of being disrupted, we need to look at the conditions put forth by Christensen.

Disruption of a business is a process that evolves over time. But change by itself is not disruption. The advent and wide adoption of EMRs, the improvements in diagnostics enabled by incredibly powerful computers and data analytics, the delicate operations supported by robotic surgery, the advances in genomics and proteomics and the advancement of proton and heavy ion therapy for cancer are among the amazing changes that have dramatically changed how we provide care for patients. However, they have not disrupted the industry. These innovations have mostly benefited the existing healthcare industry.

There are small-scale experiments ongoing, however, that do have the potential to be disruptive. Healthcare services are starting to be seen as a commodity with the arrival of online visits and wearable technologies that allow new entrants into the diagnostic field. With more and more data available digitally, the potential of data analytics and artificial intelligence (AI) allows new entrants and new participants. Once trained, an artificial intelligence system can often augment the performance of a highly trained specialist, allowing a greater volume of work at a much lower cost. And currently, most of the expertise in data analytics and artificial intelligence lies outside the healthcare industry.

The digital revolution has also led to an explosion in the availability and acceptance of wearable devices. Consumers are comfortable with technologies that monitor a variety of conditions. Our iPhones have been tracking our movement and shopping habits for years. New devices such as the iWatch and Fitbit allow for ongoing monitoring of activity and general health. Digital platforms now collect and analyse the data continuously and present results back to the consumer as a summary of behaviours or recommendations. It is not a great leap of the imagination to expect these wearable devices to morph into medical devices' capability of monitoring an individual's health and providing diagnostics or referrals based on a review of the data by a physician or machine learning system.

Pressure by government and private payers is also constraining pricing, often making it difficult for existing providers to provide service at a profit. This could mean that existing healthcare providers won't fight to retain certain less profitable aspects of their business, allowing a new entrant to provide a leaner and more profitable solution. This could be a challenging competitor for an existing healthcare organisation because often these low margin procedures still bring in a substantial amount of revenue needed to offset base capital costs for a major hospital system.

At the same time, we see new companies building very different business models. Standardised treatment protocols allow patients to be treated very efficiently and effectively without the significant overhead of a specialist. The acceptance of wearables is only a small step away from accepting devices that would provide ongoing measures of health, perform diagnostics and provide recommendations to visit a healthcare provider when something appears amiss. All of this points to the consumerisation of healthcare, where small, efficient providers address many of the most common needs, leaving the large healthcare centres to address the more complex health conditions.

1.3 Changing Population Demographics

1.3.1 Move Away from Rural Communities

Technology and cost are two drivers of changes in our healthcare systems. Another driver of change is population demographics. Rural communities are already facing challenges with access to healthcare, in part due to the lack of retention of primary care providers and the threat of financial sustainability.

An ongoing worldwide trend is the movement of people from rural to urban centres. The United Nations reported in 2009 that 54% of the world now lives in cities, up from 30% in 1950 [2]. With the movement of people away from rural communities eventually the population base will be insufficient to support effective medical care, particularly critical care services and complex care.

Small hospitals and healthcare systems have been closing for years in rural markets, with the recent COVID-19 pandemic accelerating that trend. But a significant

market remains in these rural communities which will soon be motivated to make use of remote care offered by companies supported by the new digital platform technologies if for no other reason than they have no other options.

1.3.2 Aging Population

Besides the movement away from rural areas to cities, another major driver will be our aging population. By 2050, the world will be home to 10 billion people, and 2 billion of these people will be aged 60 or older, including 434 million older than 80 years. Japan has the world's highest share of the population aged 65 and older, but the United States and Europe are not far behind [3].

We know that this is going to change our social structures. It also has a huge implication on healthcare as it is a simple fact that as we age we require more healthcare.

If that was not enough, we are seeing a dramatic shortage in the number of healthcare providers. The physician shortage is expected to reach 85,000 in the United States by 2032 due to the complexity of training, the aging population and associated impending retirements [4]. We must rethink how we train physicians and caregivers and how we provide care. Because this is not sustainable.

1.4 Digital Transformation

1.4.1 Hospital of the Future

In the future, two fundamental shifts will reshape the healthcare industry. First, healthcare will be delivered as a seamless continuum of care, away from the clinic-centred point-of-care model and with a greater focus on prevention and early intervention. Second, health and healthcare delivery will focus on each person as an individual. This is often referred to as the consumerisation of healthcare.

Longitudinal patient data sets—that is, data across time—will allow us to integrate medical data, financial data and data from home and self-monitoring sources, and we will be able to do this over a patient's entire life.

Advanced analytics and AI engines will generate unexpected insights for patients and their caregivers. We know that quality improvements require measures and metrics. But that data can be hard to access. This is going to change. We will be able to look at the data in different ways to figure out what is happening.

There will be a continuum of care model where patients may start at a major healthcare centre for serious illnesses before being transferred back into their community care facilities and eventually receiving care at home. Evashwick [5] categorises this care into seven categories: extended care, acute hospital care, ambulatory care, home care, outreach, wellness and housing.

We will see real-time refinement of individualised care solutions. We are going to have the data from home monitoring to make changes on the fly. The explosion in consumer wearable devices is going to morph into wearable medical devices over the next decade.

There will be a seamless integration of monitoring and care from clinical caregivers, social and community structures and family members. This is not a new idea; in fact, it is the idealised vision of healthcare. However, it is our newly interconnected world that makes this possible.

The hospital of the future will be in your home and your community. It will travel with you wherever you go. Only serious conditions will require a hospital stay. For most, the hospital will be in your home or occasionally in your community hospital.

All of this points to a need for the major healthcare systems to rethink their plans. Expansion no longer means more hospital beds or more brick-and-mortar facilities. It means providing care wherever the patient is.

1.4.2 Connectedness

By 2030 most of humanity will be connected. Over 90% of people will have a digital presence [6]. This has a significant impact on our society and how we can provide healthcare.

Once we are connected, our devices can also be connected. This allows devices to be developed that can improve healthcare delivery and therapy outcomes. This includes both wearable and handheld devices that we might only access occasionally, for example, a handheld injection device that tracks the administration of a prescribed drug. The performance of other devices, such as implantable devices for cardiac rhythm, can be monitored remotely and new operating parameters downloaded to the device if indicated.

One of the most pressing issues will be associated with chronic disease management. Often patients have multiple co-morbidities that must be simultaneously monitored and addressed—sometimes across several healthcare providers. Regular, ongoing monitoring of these patients is the key to preventing worsening conditions.

With the advent of 5G communication technology, the bandwidth available to mobile devices and applications increases by an order of magnitude. Perhaps even more relevant for wearable devices is the dramatic decrease in latency, that is, the delay between when data is sent and when it is received. We can expect much more responsive systems to be developed as this new communication technology is deployed [7].

1.4.3 Artificial Intelligence

One of the first things people ask when discussing artificial intelligence is when will we replace the doctor. This is a challenging endeavour. The best diagnosticians are detectives, turning over seemingly unrelated clues until the puzzle pieces start to fit together. To the untrained observer, this can seem almost magically intuitive. And yet even the best, most knowledgeable diagnostician can only know a portion of the knowledge available for disease identification.

Each day the National Library of Medicine Medline database indexes more than 1500 new journal articles and 55 new clinical trials [8]. All these factors now contribute to the knowledge overload, which all practicing physicians face in providing optimal care for their patients.

It is easy to suggest that we let the computer do it. In fact, for the last 30 years, we have been working to develop systems that can mimic the diagnostic ability of a physician, with not very encouraging results. It is challenging to mimic the pathways of the human brain, but researchers are now realising that a partnership between humans and machines might lead to superior results. Vinod Khosla [9], cofounder of Sun Microsystems, suggested that "80 percent of what physicians currently do might be replaced." It is likely that physicians will always be involved in providing oversight and review. AI systems are much more likely to be adjuncts, helping make the physician and care providers' job easier.

Modern AI systems have become much more sophisticated in large part due to the dramatic increases in processing power available to modern computational servers. Also, a historical problem in AI has been the paucity of the dataset—a problem now rapidly being addressed by the overwhelming adoption of electronic health records.

We are now using AI for drug development, diagnostic radiology, pathology and many other fields. AI systems excel at pattern recognition and that is perhaps why many of the first successful applications are in radiology and imaging.

AI and machine learning systems rely on having a large and accurate dataset for training. And once trained, they are extremely good at identifying subtleties that are often missed by humans. However, when they are wrong, they are often ridiculously wrong. Their value is incalculable due to their ability to identify pathologies missed by humans because they never tire or get distracted. But they will not replace a human entirely. A trained radiologist likely always be required to review and confirm the diagnosis provided by the AI.

1.4.4 Edge AI

Having tremendous datasets and processing power on a Cloud-based server allows us to unleash the full power of our modern computational engines. We can discover novel and unique ways of analysing and understanding data from patients. However,

these algorithms in many cases must migrate from the Cloud where we have almost unlimited resources, to the patient bedside or to wearable devices, where our computational power and data storage are more limited. There are simply times when the bandwidth limitation and latency become relevant. A self-driving car that must wait for a delayed response from the Cloud could lead to catastrophic results. Because of this we often need to move the computational power down to the device to allow for real-time performance.

Edge refers to the edge of the Cloud. This is where the Internet of Things (IoT) resides. Google autonomous cars do not send all their data to the Cloud for processing. And medical devices will often need to analyse data in real-time, meaning algorithms developed on the cloud against large data sets with virtually unlimited processing power will have to be scaled to small microcontroller systems running on batteries in a watch or another device attached to the patient.

The ability to provide continuous monitoring of patients through wearable sensors is going to allow early diagnostics of conditions before they worsen. The early diagnosis and treatment of diseases often result in improved outcomes.

1.4.5 Computational Power

We now have a supercomputer in our pocket. If the iPad 2 had been released in 1988, it would have been the most powerful computer in the world. The Cray-2, developed by a company founded in Minneapolis, was the fastest computer in the world from 1985 to 1990. Today, its computing power is equivalent to an iPhone.

Computational power has been fundamental to the advances that have occurred over the last decade. Some of the most significant successes have been based on AI systems that train on immense data sets and this has only been possible because of advances in processing speed and in our ability to store and access huge amounts of information.

It is not just the speed of modern processors but their architecture that has made some of these breakthroughs possible. It was an unexpected convergence of machine learning and graphical processing units (GPUs) developed for the gaming industry that has allowed many of these advances to occur [10]. By leveraging the highly parallel architecture of the modern GPUs, machine learning researchers were able to make computational intense calculations in a fraction of the time previously required. And it is quite often useful to have a complex algorithm present its results in real-time to make use of the data.

Currently, the processing power requirements of machine learning are increasing faster than improvements in the processors themselves. However, there are breakthrough technologies being explored including massively parallel architectures and quantum computing [11].

1.4.6 EMR

The only thing growing faster than knowledge is data. According to IBM Watson team lead Eric Brown [12], "the literature of medicine...currently contains about 24 million records and expands at a rate of 2,100 articles per day."

When this is combined with the amount of data in a typical EMR, which can amount to thousands of pages of data per patient, there is an almost unimaginable complexity to analysing, diagnosing and treating each patient in the best way possible. Data analytics allows us to filter and present the most important data to the care provider.

The use of big data in healthcare has the potential to improve decision-making and address inefficiencies in the healthcare ecosystem. For example, we can provide continuity over the entire lifetime of care. A patient is born, and we create a record. We can provide care and track results. We can follow up on the progress until the eventual death of the patient. This gives us incredible information on an individual patient. And now, we can use that data gathered from our current patients to help determine the best course of care for future patients through data analytics.

1.4.7 Real-World Clinical Trials

Currently, over 90% of clinical trials on new pharmaceuticals are sponsored by the people who manufacture them [13]. Not surprisingly these tend to favour the manufacturer. Goldacre [13] reports that with sponsored trials, sites performing clinical trials are often contractually prevented from disclosing the results without company approval.

With more and more data being stored online, real-time clinical trials can become a possibility. Imagine that a patient's symptoms, co-morbidities, treatments and outcomes are all available in an online system. This would allow anyone to compare the effectiveness of drugs based on real-world use on patients instead of carefully controlled, and often unreported, clinical trials.

1.4.8 Blockchain

Blockchain is a technology that has the power to give ownership of the data back to the individual while allowing others access to important shared information. Blockchain is defined as a distributed, decentralised data ledger but can be simply thought of as a shared database. The technology enables the creation of digital records and allows them to be shared and managed securely on a network. It keeps an incorruptible, decentralised log of all patient data in a highly secure fashion. A key concern with healthcare is the privacy of data. Blockchain "can help to ensure

the security of EHR systems, enhance the integrity and privacy of data, encourage organizations and individuals to share data, and facilitate both audit and accountability" [14].

An easy way to think of block change is as a ledger or record book. Their ledger book doesn't have a physical location. There are copies everywhere, on my computer, on your computer, making it impossible to change a local copy—because you must change them all or none. Although everyone has a copy, accessing your own data requires your own personal key or password.

Blockchain is known best for its use in cryptocurrencies. Applying the technology to healthcare is compelling because it can create unique digital identities, where all your data can be safely stored and accessed anywhere in the world. It also supports data exchange while safeguarding security, integrity and control of the data by its owner.

The most likely healthcare applications of blockchain will be to securely store patient records. These can be encoded with a private key only accessible to individuals who possess the key. This allows the creation of a healthcare record that can be accessed by the patient wherever they need care.

1.4.9 Home Monitoring

Imagine this. You are a physician visiting with a patient about their current health. They describe an occasional racing heart rate, dizziness, shortness of breath, excess sweating and general lethargy. You suspect atrial fibrillation and prescribe a Holter Monitor. Forty-eight hours later, you review the data and find nothing. Now what?

Continuous, long-term monitoring of heart rhythms is the answer. One day, two days, ten days and forty-five days later, the monitor is still there, unobtrusively capturing your heart rate, analysing the data and presenting your physician with suspect cardiac rhythms.

Twenty years ago, this would have involved a lot of body burden, including a large backpack and a heavy deep cycle battery. It would also have required complicated technologies to transmit the data to a healthcare provider where it would be painstakingly subject to human review. Today, we all know this is much simpler. We now have many simple options for both wearable and implantable devices.

Remote monitoring of patients is nothing new. We were sending patients home with Holter monitors 30 years ago. We had people transmitting data from home over phone lines. The difference is really the ease of connecting and transmitting data today.

Telehealth technologies will enable patients to send personal information to providers who can remotely diagnose health problems. IoMT (Internet of Medical Things) and other technologies will enable continuous real-time monitoring; and technologies such as apps and wearables will help promote healthy behaviours and identify health conditions early when they can be more easily treated.

The Institute for Healthcare Improvement Triple Aim Initiative describes three measures of a health system's performance: improving individual patient care, improving the health of an entire community and reducing the cost of care [15]. Preventive care can have a huge net positive impact on the health of a society and as these technologies become cheaper and more available, they can help drive improvements in our overall health [12].

The rapidly expanding consumer market for wearables points to the possibilities for home health monitoring in the future. Data will be gathered from body-worn sensors and instruments located in your home, analysed with highly sophisticated algorithms and relevant information will be shared with your healthcare provider. Your health will be tracked and changes that could be important will be flagged by the system and shared with you in time to make changes in lifestyles or medications or to receive timely treatment.

1.5 New Technologies

1.5.1 Neuroprosthetics

Neuroprosthetics in their simplest form is an interface to the brain that controls artificial limbs. Conceptually this is quite simple. The prosthetic itself is essentially a robot. A robot is a mechanical system designed to perform a function. In this context, they are generally designed to mimic some portion of the human body, for example, an arm or an eye. While this is generally true, other mobility systems such as exoskeletons or wheelchairs can also be described as neuroprosthetic if they are interfaced with the brain.

It is the interface to the brain or the nervous system that differentiates a robot from a neuroprosthetic. These devices can reply on a chip implanted in the brain, they can be controlled via electrodes mounted on the surface of the skull or they can interface to muscles or nerves in the periphery of the body.

Systems based on scalp electroencephalogram (EEC) have been explored for many years and are relatively simple to create. However, due to their location on the surface of the skull, they are less exact than systems that interface directly with neurons in the brain. They also are generally quite obtrusive. However, in many cases, they are preferred because they are simpler and safer. Recently, a study at Carnegie Mellon demonstrated a much higher resolution system than has previously been described and this may become the first mainstream application of this technology [16].

True brain–computer interfaces are rare in humans but have been studied in animals for decades [17]. The most common and successful to date is the cochlear implant. The greatest advantage of implanting a brain–computer interface is the high accuracy. However, there is still great resistance to the use of this technology in commercial applications in part due to the perceived risks of implanting devices in the brain.

One of the more interesting types of neuroprosthetics is sensory substitution where one sensory system which had been damaged is substituted with another. For example, using either electrical or vibratory stimulation on the torso, images or sounds can be presented to a person with either a sight or a hearing deficit [18]. With enough training, the brain remodels and routes the signals from the torso into the auditory or visual processing centres of the brain and those signals are perceived as sight or sound.

A new study led by neuroscientists from the University of Chicago brings us one step closer to building prosthetic limbs for humans that re-create a sense of touch through a direct interface with the brain [19]. Experimenters have been able to recreate a sense of touch in primate studies.

1.5.2 Robotics

Robotic surgery, as it exists today, is primarily an assistive technology for the surgeon. Typically, they leverage video imaging and small-scale manipulators to allow surgeons to perform minimally invasive procedures with unprecedented accuracy. The use of surgery through an endoscope goes back to the nineteenth century [20]. And while instruments have become smaller and more precise, allowing access through very small incisions or through the vascular system, they remain primarily an assistive device to the basic operations or a surgeon—cutting or sewing. In the future, these systems will be much more autonomous.

We are likely to see centralised surgical centres with links to remote locations—a spoke and hub model—where robotic surgery is performed [21]. This could be a boon to rural areas where for years physicians and surgeons have abandoned rural communities and moved to larger cities [22]. Another application could be robotic surgeons used in military units to perform surgery at the front lines while the surgeons remain safely behind. Newer low latency 5G networks will allow surgeons to operate at a distance, although there will still be practical physical limitations at significant distances. However, the use of artificial intelligence to help guide robotics will also likely allow them to perform some operations with minimal oversight from the surgeon, and this may extend the range of some of these surgical robots around the world—or even beyond to the space station, the moon or even supporting a mission to Mars.

Pharmacy robots will reduce errors and allow technicians and pharmacists to spend less time filling prescriptions and more time with patients while associated clinical decision-making systems will help identify drug interactions to prevent prescribing medications that interfere with each other [23].

1.5.3 Additive Manufacturing

Point-of-care additive manufacturing (3D printing) has been growing as a training vehicle for 3D visualisation for physicians as well as manufacturing non-implanted medical devices, such as surgical models and cutting guides or instruments.

We can create sophisticated augmented reality systems leveraging 3D visualisation and printed parts from images of the patient's own anatomy. This allows the training of surgeons on complex procedures prior to performing the surgery on patients.

We can also now create novel surgical tools and print them at the point of care, along with other non-implanted medical devices, such as surgical models and cutting guides or instruments. Manufacturers use additive manufacturing to develop inexpensive medical devices, such as spine cages or cranial implants. Additive manufacturing can also be used to create patient-specific implants that based on CT or MRI scans for use in complicated surgical procedures.

Currently, the additive manufacturing of patient-specific implants is time-consuming, taking weeks or even months to develop. The resulting printed implants are relatively expensive. Putting an additive manufacturing facility at the point of care will save time and money and will drive innovation by immersing technologists, engineers and clinicians in a collaborative environment.

One of the interesting new applications of neuroprosthetics and additive manufacturing is the creation of prosthetic limbs. The Bristol Robotics Laboratory (BRL) is now 3D printing neuroprosthetic arms for amputees [24, 25]. In the past, prosthetics that incorporate both aesthetic design and function have been too expensive for many [26]. This has been especially problematic for children as their nominal growth rate requires new or modified limbs on a regular basis. BRL and other companies are now starting to address that challenge by leveraging additive manufacturing and providing much lower cost, aesthetic and functional prostheses.

1.6 Summary

Healthcare is facing significant challenges even without the dramatic changes being brought on by the digitalisation of our world. Costs are rising at an unsustainable rate. The digitisation of health and healthcare is creating some fundamental challenges to our conception of privacy and ownership of data. And the rapid evolution of science and medicine is driving prices up and making it more expensive to provide care.

The hospital of the future will be in your home and community. It will travel with you wherever you go. Only serious conditions will require a hospital stay. For most, the hospital will be in your home or occasionally in your community hospital if extra vigilance is warranted. Medical staff will once again make house calls to collect blood and samples and provide medications and other daily care. In some cases, personal care will even be provided by robot assistants.

All of this points to a need for the major healthcare systems to rethink their plans. Expansion no longer means more hospital beds or more brick-and-mortar facilities. A more distributed model that centralises knowledge and expertise while distributing care will be the healthcare model of the future.

A lot of the challenge in healthcare is complexity. Healthcare is also highly fragmented with many stakeholders beyond the traditional patients, providers and payers. The list of stakeholders includes patients, physicians, insurance companies, pharmaceutical firms, medical device manufacturers, laboratory system and electronic medical record system providers and governments. In addition to the traditional stakeholders of patients, providers and payers, there are a significant number of large companies providing such services.

Healthcare is also a highly regulated industry and that makes it hard to take advantage of some of the advances in technology. Patient privacy is very closely managed and that prevents us from accessing the data to look at broad trends in treatment, diagnosis and outcomes.

Despite all the challenges inherent in changing a large and established system, the advances in technology brought on by the Fourth Industrial Revolution are about to disrupt healthcare in almost unimaginable ways. The confluence in advances in artificial intelligence/machine learning, additive manufacturing, virtual and augmented reality, robotics, virtual care and continuous monitoring of health conditions guarantee that healthcare will not look the same a decade from now.

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Chapter 2
Brain–Computer Interfaces: Taking Thoughts Out of the Human Body

Melissa Gregg

2.1 What Is a Brain–Computer Interface?

A brain–computer interface (BCI), also called neural-control interface and brain–machine interface, measures brain activity and translates the brain activity into a command to be carried out by an external device, such as a robotic arm or a cursor on a screen. Brain–computer interfaces have a long tradition in science fiction. For example, exoskeletons controlled by the brain were used in the movie *Robocop* and by *Dr. Octopus* in Spiderman. A BCI is used to control an exoskeleton and to steal thoughts from other brains in the movie *Elysium*. And, the Netflix series *Black Mirror* has portrayed many creative ways to use BCIs, such as recording brain activity to recreate and project memories on a screen, modulating brain activity to make one feel as if they are in a video game, stealing thoughts from the brain of an individual in a coma and modifying the environment that soldiers perceive.

Although the media often characterises BCIs as a new and emerging technology, BCIs have been a topic of investigation in the scientific world since the 1970s. In a famous article, Vidal [1] was one of the first to describe how to use an electroencephalogram (EEG) to create a BCI. According to Vidal, the neural signals measured from EEG can be "carriers of information in man-computer communication". The EEG is a technique for measuring brain activity that has been around since the 1920s [2], and the EEG technique is one of the most popular and least invasive ways to record brain activity for a BCI. Since Vidal's [1] claim, there have been impressive advancements in the use of EEG-recorded brain activity to control an external device. For example, Farwell and Donchin [3] were able to use the EEG technique

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to train human research participants to spell words with their thoughts by directing their attention to specific letters on a screen.

The technology underlying BCIs is possible because of the brain's electrochemical communication system. The brain is an organ, and like all organs in your body, the brain is made up of cells, which include glial cells and neurons. Neurons are particularly special because neurons conduct nerve impulses, which convey environmental information from our sensory systems to the brain, carry out the operations involved in thinking, feeling and acting and transmit commands to the body's muscles and organs. Every thought we have, every word we say, every movement we make, every memory and every emotion we experience is possible because our neurons are communicating. Neurons communicate with each other via nerve impulses, which are small electric signals that can travel from neuron to neuron at speeds faster than 200 mph [4]. During a nerve impulse, the cell membrane of the neuron experiences a rapid depolarisation, which is a change in voltage to a more positive value. The depolarisation travels down the length of the neuron, stimulating the release of neurotransmitters, such as dopamine or serotonin, at the synapse. The result of the exchange of neurotransmitters is an increased or a decreased possibility of an electrical reaction in the next neuron. The electrical reaction in neural communication can be measured. There are many techniques for measuring neural activity that have been developed over more than 100 years of neuroscience research. The discussion in this chapter will be limited to some of the techniques used in a BCI.

The most common non-invasive technique for measuring brain activity in a BCI is the EEG technique. The research participant is fitted with a snug electrode cap. The electrodes (which typically number anywhere from 1 to 280 electrodes) sit on the surface of the head and provide a continuous measure of neural activity generated by large populations of neurons. The neural activity appears as oscillating voltages often referred to as "brain waves". The frequency and the amplitude of these waves can indicate normal and abnormal (e.g. epileptic) brain activity and the frequency and the amplitude of the waves characterise certain states of awareness. For example, low-frequency, high-amplitude theta waves are reflective of a deeply relaxed state [5]. To incorporate the neural activity recorded via EEG in a BCI, the neural activity is analysed by a signal processing program that uses the neural activity to identify the person's intended message or intended motor command. These programs are often called decoders because they identify meaningful neural patterns. The meaningful neural patterns are then sent to a separate program or interface that uses the information to carry out a command, such as moving a cursor on a computer screen [6]. It should be noted that the process is not as simple as the user thinking "move the cursor", and the cursor suddenly moves in the desired direction. BCI systems require extensive practice, training and continual feedback to be effective [7].

EEG signals are fairly easy to acquire and they impose no harmful side effects or risks to the research participant. However, EEG by nature is a messy data collection technique. EEG signals are measured from electrodes placed on the surface of the scalp. The neural signals picked up by the electrodes become significantly

attenuated and distorted as they pass through the dura, skull and scalp. In addition, EEG signals can be contaminated by signals generated from muscle movements of the face and body and from other electrical equipment in the recording room [5]. An additional limitation of the EEG technique is the poor spatial resolution. EEG can provide a measure of neural activity in near real-time; however, the source of that neural activity can only be estimated (see [8] for a review of source modelling techniques). The poor spatial resolution of EEG makes precise motor movements in a BCI extremely difficult. Although the EEG technique is not very useful for making precise motor movements with an external device, the use of EEG in a BCI has been quite successful at providing assistive communication, for example, by allowing paralysed individuals to use their thoughts to move cursors on a screen or to select letters on a virtual keyboard [9].

An alternative and higher resolution technique for recording brain activity in a BCI is an electrocorticogram (ECoG), which involves the surgical implantation of electrodes. Similar to the EEG technique, the electrodes provide a continuous measure of electrical activity generated by neurons, however, rather than sitting on the surface of the head, the electrodes of an ECoG sit on the surface of the brain. The introduction of this approach for long-term recording of neural activity was established in animal research paradigms [10]. In one of the first experiments utilising data from an ECoG in a BCI, rats learned to use neural activity from the motor cortex to move a robotic arm to obtain water [11]. Incorporating an ECoG in a BCI is similar to the EEG technique: Neural activity is analysed by a signal processing program that translates the neural activity to a command in an external device.

Because the electrodes sit on the surface of the brain, the neural activity recorded from an ECoG provides higher fidelity data to a BCI system. Data acquired from an ECoG has better spatial resolution and is less susceptible to contamination by artefacts. The excellent spatial and temporal resolution of an ECoG has allowed for some impressive feats. For example, a tetraplegic individual with an electrode array surgically implanted over his motor cortex was able to use his thoughts to open an email, turn on a television and perform actions with a robotic arm [12]. Although there are more possibilities with an ECoG, there are some disadvantages. One of the major issues with an ECoG is the brain's reaction to the surgically implanted electrodes. Recording quality can deteriorate over time because of the brain's reaction to the electrodes, which can include inflammation, glial scar formation around the electrodes and cell death near the electrode sites [13].

2.2 Development of BCIs: Medical Applications

One of the main sources of inspiration for the development of BCIs has been the possibility of restoring function to people who have become disabled. Cochlear implants, which have been around since the 1960s, are examples of BCIs that restore hearing. In individuals with normal hearing, sound waves enter the ear, are amplified by the bones of the middle ear, are transduced into neural signals in the inner

ear and then processed by the auditory nerves in the form of electric signals. In individuals with specific types of deafness, a cochlear implant can bypass the non-functioning part of the ear. An external sound processor receives sound from the environment and passes the information along to surgically implanted electrodes that stimulate the auditory nerves, resulting in the experience of hearing (see [14] for a history of the cochlear implant). Following a similar logic, retinal implants can restore vision. In individuals with normal vision, light enters the eye, is focused by the cornea and lens and is transduced into electrical signals by the cells in the retina, the neural layer in the back of the eye. A retinal implant involves the surgical implantation of an electrode array in the retina. A pair of glasses that contain small cameras is worn, and the information recorded from the camera is sent to the implanted electrode arrays, which convert the information into electrical signals (see [15] for a review). It is important to note that cochlear implants and retinal implants do not restore sound and sight to the same level as an individual with non-impaired hearing and sight (see [16] for some illustrations of how individuals with retinal implants see the world).

BCIs have also been developed to restore or replace motor function in individuals who have become paralysed. In individuals with non-impaired motor function, voluntary movements of the body's muscles are generated by neural activity in the primary motor cortex and supplementary areas of the brain (the movements are coordinated and refined by other brain structures, including the basal ganglia and the cerebellum). The neural signals from motor areas of the brain eventually reach the body's muscles via peripheral motor nerves. Paralysis can occur if the signal from the brain to the body's muscles is disrupted, which often occurs in spinal cord injury. BCIs can assist paralysed individuals by essentially rerouting the motor signal from the brain to an external device, such as a robotic arm. In one of the first experiments utilising this idea on human research participants [12], an electrode array was surgically implanted on the motor cortex of two tetraplegic patients. After the implantation, the patients were instructed to imagine moving their arm and hand. The neural activity measured from the surgically implanted electrodes was sent to a program that translated the neural activity into a motor command to a robotic arm. The training was time-intensive, but eventually, the patients were able to use their "thoughts" to control a robotic arm. One patient was able to control the robotic arm with enough precision that she was able to use it to give herself a drink for the first time in 15 years (a video of this research participant can be found at the following link: https://news.brown.edu/articles/2012/05/braingate2).

Another version of a BCI designed to assist disabled individuals involves a system that sends the motor signals from the brain to a prosthetic limb and sensory signals from the prosthetic limb to the brain. These bidirectional BCIs send electrical signals from the prosthetic limb to tactile and proprioception areas of the brain. Bidirectional BCIs allow for the integration of motor and sensory information, which is needed for more precise interaction between the prosthetic device and the environment and to create the perception that the prosthetic is a "real" body part [17]. Bidirectional BCIs allow for prosthetic limbs to be moved with a high degree of accuracy, and they allow for movements to be coordinated with the environment,

which allows for prosthetic fingers to accurately grasp objects, button a shirt or type on a keyboard. Bidirectional BCIs are not as advanced as unidirectional BCIs, but there are several recent notable advances in the development of bidirectional BCIs. One recent experiment reported that a research participant with a bidirectional BCI was able to use tactile and proprioception information to determine which finger on a prosthetic hand was moving with 84% accuracy [18].

A different type of BCI has been designed to restore motor function by allowing disabled individuals to move within robotic exoskeletons. One group of researchers found that research participants could use their self-generated EEG signals to control movements of a lower limb robotic exoskeleton [19]. In a more recent study, the neural activity measured from an ECoG when a tetraplegic patient imagined moving was transmitted to a program that translated the neural activity into motor control of a full-body exoskeleton [20]. The training was extensive, but over the course of 2 years, the patient was able to use neural activity generated from imagined motion to move a virtual avatar with 64% accuracy and to move a full-body exoskeleton with 71% accuracy (a video of the research participant operating the exoskeleton can be found at the following link: https://www.youtube.com/watch?v=1GyJBBB8O_M).

BCI research and development has accomplished some amazing feats, particularly in the last decade. But, to achieve parity between normal sensory/motor abilities and BCI-augmented sensory/motor experience, the technology still has quite a way to go. Bionic eyes offer very low-resolution vision, cochlear implants convey only limited speech information and the movements produced by BCIs are slower, simpler and less precise than the movements that non-disabled individuals make every day. Part of the problem is that specialised areas of the brain do not operate in isolation. The motor cortex, for example, is connected to many other structures (e.g. supplementary motor areas, basal ganglia, cerebellum), and the neural communication among them contributes to the fluid movement of the body through a specific environment. Current BCIs are still fairly limited in the size and location of the neural population that can be accessed and recorded. The decoders in BCIs are also still quite limited. Simple neural patterns, such as those involved with a movement of the arm from the left to the right, are easily extracted by current decoders and translated into motor movements to an external device. But, the neural pattern associated with the movement of an arm to pick up a pencil, write a paragraph, grab a moving object and move fluidly through the environment to avoid obstacles is more complex and a challenge for current decoders [21].

2.3 The Implications of Turning Humans into Cyborgs

The direct interaction of the brain and machine raises some ethical issues and concerns. And, as BCI technology becomes more advanced, the ethical issues are going to become more pressing and more serious. One commendable application of BCI technology is restoring sensory and motor abilities, but one could imagine other

possible uses of BCI technology, such as enhancing the lives of non-disabled individuals. For example, a realistic and currently feasible possibility is that BCIs could be used to augment human intelligence. There are many published reports of experiments that have successfully used neuroscience techniques to optimise human performance. For example, researchers applied transcranial direct current stimulation (tDCS) to the left dorsolateral prefrontal cortex in neurologically healthy research participants [22]. Transcranial direct current stimulation is a noninvasive technique that delivers a weak electric current via electrodes on the surface of the head, and the electric currents alter neural functioning. The tDCS to the left dorsolateral prefrontal cortex resulted in improved performance on a test of verbal association and general intelligence. Other studies have found that brain stimulation through tDCS can improve attention, learning and memory [23]. If such human enhancements are possible with non-invasive electrical stimulation, imagine the possibilities of a surgically implanted electrode array. The electrodes could potentially be used to make humans smarter, more or less moral, calmer, happier, more aggressive, less aggressive, stronger and so on. Some may argue that these possibilities are positive options, but regardless of whether they are viewed in a positive or negative light, such human enhancements would necessitate a reframing of humanity and authenticity. One of the most concerning implications of neural enhancements is their potential to perpetuate and exacerbate inequity in society, and the possibility that such modifications could be done without the person's knowledge or consent.

Several other ethical issues have been raised over the use of BCIs [24]. For example, patients may avoid BCI-assisted technology to avoid the stigma associated with a disability or with being a human cyborg. There are also concerns over autonomy. The user's brain is the source of the neural activity for imagined movement, but the external device performs the action. Within this integrated brain–machine system, who or what is responsible for the action, the user or the machine? Although a disabled individual has regained some function, the ambiguity surrounding the accountable party in a BCI could make the user feel less autonomous. A related issue of concern is that of morality and legal responsibility. Imagine a hypothetical scenario in which the machine part of a BCI commits an illegal act but the user claims no knowledge or intent of the action. Is anyone or anything legally responsible?

One of the most important implications of brain–machine interaction is the possibility that the user's privacy will be violated. The brain and a machine are connected in a BCI, and the data collection device, such as a surgically implanted electrode array, is constantly recording brain activity. Medical BCIs collect brain activity and translate it to restore sensory and motor abilities, but there is the possibility that this brain activity could be used for something beyond the user's knowledge and consent [25]. This privacy issue is an important point that is revisited at the end of the chapter. Before the issue is considered further, I will provide an overview of some of the nonmedical uses of brain–computer interfaces, as the privacy issue applies to both medical BCI users and commercial BCI users.

2.4 Nonmedical Brain–Computer Interfaces

On the consumer side of things, BCIs come in all sorts of varieties. There is the Brainwave Starter kit, for example (https://store.neurosky.com/). The kit comes with a headband that contains one electrode to measure the electrical activity generated by neurons (this is essentially the same as the EEG technique described above, but limited to the single electrode). The electrode communicates via Bluetooth with an app that lets you see your brainwaves in real time. The app teaches the user biofeedback to alter attention and to relax. There are BCI games, such as MindFlex and Force Trainer, both of which use an electrode to measure neural activity. With some practice, your neural activity powers a fan that causes a ball to levitate. BCI video games have been in development for years [26], including Brain Invaders, a BCI version of Space Invaders. Self-driving cars have been in development for decades, but a more recent, related effort is the development of brain-controlled cars [27].

Some companies, such as Facebook and Neuralink, have their own BCI research programs. Facebook has developed sophisticated speech decoders, which are devices that can use brain activity to reconstruct the speech that someone is imagining (https://ai.facebook.com/). Speech decoders have the potential to restore communication abilities to individuals with locked-in syndrome or other severe communication disabilities. However, Facebook also intends to use the speech decoder technology in their own BCI that will allow anyone to use their thoughts to communicate with their devices, such as phones and computers. The implications are quite lucrative for Facebook: BCIs would allow the company direct access to data from human minds. Neuralink is also involved in the research and development of BCIs. One goal of Neuralink's research is to assist paralysed individuals. But, Neuralink has additional interests in BCIs. One goal of the BCIs being developed by Neuralink is the development of a small electrode array that can be easily and non-surgically implanted into any user's brain (in a process no more painful than an ear-piercing). The electrode array will read the user's brain activity and translate it to an external device, allowing the user to do things with their thoughts alone, such as opening apps or typing an email. A quote from the Neuralink website says, "Neuralink's long-term vision is to create BMIs that are sufficiently safe and powerful that healthy individuals would want to have them" (https://neuralink.com/applications/).

2.5 Privacy Concerns

Privacy is a significant concern for medical and nonmedical BCI users [28]. BCIs have direct access to brain activity, which raises some serious issues regarding how brain activity data will be used, how it will be kept private and how it will be kept safe from third parties with nefarious interests. Social media platforms, such as Facebook, collect tons of data from users based on their internet activity. Imagine

the possibilities if these platforms, or other third parties, such as the government or an employer, had access to your brain activity. Brain activity has the potential to reveal vast amounts of personal information, ranging from morality, honesty, psychological traits, mental states, emotions and attitudes towards other people. Commercial BCIs, such as those being developed by Facebook and Neuralink, would also allow our brains to connect directly to the internet, which means that others on the internet could connect to our brain, against our knowledge or will. There is the related possibility of BCI "hacking" where third parties could take control of BCIs and use them to harm the user or to harm others [29].

As BCIs continue to advance and move beyond restoring motor and sensory functions to augmenting able-bodied individuals beyond their human capacity, we need to be aware of the issues related to consent, privacy, identity, agency and inequality. The concern over potential ethical, moral and social justice issues in the context of BCIs has gained quite a bit of attention in the peer-reviewed literature recently [24]. The development of BCIs will also require new laws and prosecution policies. Currently, criminal liability requires a bodily movement. The manner in which "bodily" movement is treated within the criminal justice system will need some revising as BCIs become more popular [30, 31].

In summary, the development of BCIs is exciting. The BCIs portrayed in science fiction are, and have been for some time, a real possibility. There have been monumental leaps in our understanding of the processes underlying the human brain and in making a direct connection between the human brain and a machine. BCI development is an innovative area of research, but it should be approached and received with caution and forethought. The coming years will require some new rules about how brain data are collected, stored and used.

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Chapter 3
Towards Network Medicine: Implementation of Panomics and Artificial Intelligence for Precision Medicine

Robert D. Barber and Keith Kroeger

3.1 Introduction

Societal integration of artificial intelligence (AI), machine learning (ML) and deep learning (DL) technologies is widespread as individuals are inundated with their use in daily activities ranging from advertising to smart assistants to social media. Given unmatched ability to recognise relationships and novel trends through data mining and decision-making, AI, ML and DL are keystone approaches to deciphering information within a data-rich world. The transformative properties of AI and ML as applied to information technology are apparent in many fields, but in particular, innovative applications are emerging that both deliver and hold promise for improved healthcare. Market reports indicate that AI technologies in healthcare will reach a $31.3 billion share by 2025 with ~42% annual growth between 2021 and 2025 [1]. This growth is fuelled substantially by innovations in diagnostic and prognostic approaches. Initial use of AI-related technologies in diagnostics focused on imaging analyses, but advancements in the rapidly developing field of molecular assays are accelerating AI, ML and DL implementation in healthcare. More than 140,000 molecular diagnostic products can be found on the market, with 10–15 added each day according to one market analysis [2]. Many of these products offer individual molecular measurements and tests that can contribute important insights into various disease states. However, the added diagnostic and prognostic values of combinatorial molecular analyses have recently been recognised and have led to a

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new healthcare discipline, network medicine. This chapter provides an overview of network medicine within the context of the molecular assay ecosystem, associated AI, ML and DL approaches that empower molecular diagnostics in healthcare, visualisation approaches for panomic information and potential future directions and challenges regarding implementation of network medicine.

3.2 The Molecular Assay Ecosystem and Network Medicine

The advent of genome sequencing in the 1990s offered, at the time, the best prospect for the implementation of precision medicine and personalised healthcare. However, the complexity of biological systems limited initial efforts towards these healthcare goals. Subsequent development of additional high-throughput technologies to further interrogate cells at a molecular level has renewed the promise of precision medicine. Techniques are available to quantify every facet of a biological sample at a molecular level allowing one to decipher relationships or networks evident among this array of measurements [3]. Briefly, such molecular measurement techniques include:

- Genomics—Next-generation DNA sequencing or probe technologies such as fluorescence in situ hybridisation (FISH) are used to catalogue nucleotide sequences and loci among chromosomes.
- Epigenomics—Assortment of assays to assess DNA modifications that have the potential to influence gene expression. Approaches include variations in Chromatin Immunoprecipitation (ChIP) assays and Bisulphite DNA sequencing to measure the methylation state of genomic DNA as well as assays for enzyme activity involved in histone modifications.
- Transcriptomics—Microarray and RNA-Seq are prevalent techniques to profile and quantify coding and noncoding RNA molecules.
- Proteomics—Mass spectrometry (possibly including chromatographic steps) serves as the primary approach to profile and quantitate protein levels as well as post-translational modifications. New techniques for these measurements are under development [4].
- Interactomics—Protein–protein interactions (PPI) or networks mediate cell physiology. Interactions can be defined at various levels ranging from co-expression determined by measuring transcript or protein levels to physical contact as detected using assorted techniques [5, 6].
- Metabolomics—Mass spectrometry and various chromatographic techniques are applied to profile and quantitate various molecules present within samples. Lipidomics and glycomics are subsets of this discipline. Although applicable to other omic fields, microfluidic chips or “lab on a chip” systems are prevalent platforms to measuring metabolites.
- Microbomics—Community-level microorganism (bacteria, archaea, fungi, protozoa and virus) identification related to various environments of the human

body, which is typically determined by DNA sequencing or FISH analyses performed on samples.

- Exposomics—Concept that relates exposure to external factors throughout a person's life to alterations in levels or timing of molecules measured by other omic technologies [7].

Signals derived from these molecular measurements and the relationships identified within these data can enhance the utility of traditional disease biomarkers. Initial attempts have focused on omic data from independent assessments such as genomics or transcriptomics and have been successful at identifying numerous biomarkers such as single-nucleotide polymorphisms (SNPs) or RNA expression profiles [8, 9]. While the use of isolated omic technologies continues to have value and contribute to biomarker discovery, the integration of multiple omic technologies for the identification of disease states is rapidly supplanting the individualised omic approach [10–12]. Integrative studies have shown a combination of omic approaches also known as multi-omics or panomics offer added value at several levels as both independent and complementary measures. For example, a recent combination of metabolomics with microbiomics augments the primarily demographic nature of microbiome measurements revealing greater insight [13]. Notably, the perspective derived from panomic approaches provides more than a platform for diagnostics and prognostics as this discipline is also being utilised to "close the loop" regarding precision medicine and develop personalised therapeutics, as well [14].

As key contributors to precision medicine advancements, resolution and establishment of relationships among molecular biomarkers using panomics coupled to a deep understanding of cellular and molecular network interactions for disease recognition and treatment also serve as founding principles of a new, related discipline, network medicine [15]. Network medicine recognises the hierarchical nature of interactions within and among biological systems and their environments. In essence, cells, tissues and organisms are systems of interdependent biochemical reactions that respond to internal and external cues. The complexity of these biochemical networks is exemplified well by protein–protein interactions, where an individual protein may have on the scale of 10–100 different partners under varying cellular conditions. Prediction or measurements of cellular protein levels and their interactions can be linked to disease models [16]. Extrapolation of these measurements across all molecule types using panomics underscores the amplification of signal complexity as well as the high resolution of biological and health status that can be inferred from such data. Currently, the implementation of panomic data analyses and network approaches across healthcare is varied, with oncology and cardiology serving as leading fields [17–19]. The development of network medicine models within these particular fields is practical given these represent leading causes of mortality and morbidity in several countries and offer a wealth of molecular signatures associated with disease states. However, the adoption of network medicine in these and other medical disciplines remains nascent in part due to meaningful analysis of panomic high-dimensional biological data being complicated at several levels.

Concerns regarding effective panomic data integration into network medicine include, but are not limited to, complexity of data, limited curation of targets, technical artefacts related to signal to noise ratios, differentiation between causality and correlation, cost and reimbursement, reproducibility and satisfying regulatory requirements [20–22]. However, such challenges are being actively addressed. For instance, many disease states require population-level comparisons for the appropriate context of an individual's panomic report, and data availability in electronic health records can be constrained to fiefdoms created by health systems and research model networks [23, 24]. New data-sharing models have been proposed and infrastructure needs for panomic data reconciliation and availability are currently being addressed. Government-led initiatives have been key in integrating molecular data into electronic health records and supporting the necessary infrastructure for data sharing [25]. Numerous software applications and biobanks have become available for these different, individual molecular measurements and innovation in software tools for use in exploring potential disease features is an area of active research [26–28]. For example, specific applications are under development and available to address complexity issues with panomic data [29]. As evident in several of these novel computational tools, much of the progress regarding challenges associated with panomic data analysis and utility in network medicine has been achieved using artificial intelligence, machine learning and deep learning applications.

3.3 Artificial Intelligence, Machine Learning and Deep Learning

Artificial intelligence (AI), machine learning (ML) and deep learning (DL) form a hierarchy of analytical approaches. At the top level, AI is basically using computers to simulate the human mind, such as experiential learning, item recognition and decision-making. ML is an AI subset that equates data with experiences and specialised algorithmic techniques with learning. Applying the algorithms to the data is the basis on which machines can improve task performance. Finally, DL is an ML subset in which the algorithms are based on artificial neural networks that mimic information processing in the human brain through multiple layers of connected neurons.

Two broad classes of ML techniques are supervised and unsupervised. Supervised algorithms use example pairs of feature inputs and target outputs to learn the function that maps input to output. The primary goal is to create a predictive model based on the relationships between features and targets that can be applied to new values of inputs to generate outputs. Unsupervised algorithms, on the other hand, attempt to discover structure in inputs without reference to any outputs. The primary goal of these techniques is to find hidden input patterns instead of predicting outputs. These two classes can be further divided to distinguish among potential applications. Supervised methods are identified as either classification or regression, based on characteristics of the target output being predicted. Classification approaches require

a target that can only take discrete values, such as detection of a particular allele associated with a specific Mendelian genetic disorder such as sickle cell anaemia, cystic fibrosis and so on. In contrast, regression techniques apply when the target is continuous, taking on numeric values from a theoretically infinite set.

Unsupervised approaches can be classified as cluster identification, dimensionality reduction or association rule mining. In cluster identification, data cases are grouped such that cases in each group have similar values across the input features while the groups themselves have different values. For dimensionality reduction, the goal is to reduce an extremely large number of input features to a more manageable set. This can be done by eliminating features or by deriving new composite features that replace feature sets. Finally, in association rule mining, sets of "if-then" rules are derived that identify how features are related. For instances in which target output values are not available for all data records, supervised and unsupervised techniques can be combined in a semi-supervised method. One possibility is to use an unsupervised algorithm to identify similar cases and assign target values accordingly. An alternative is to use the cases with known target values to derive a supervised model that can generate predicted target values for the remaining cases. In either case, with target values now available for all cases, a new supervised model can be derived.

The following list briefly describes common ML algorithms that can be applied to address a variety of problems.

- Linear regression—a supervised regression approach that finds the best linear relationship between the input features and the output target.
- Logistic regression—a supervised classification method that predicts the probabilities of discrete output categories based on the values of the input features.
- Decision trees—a supervised technique that can be used for either classification or regression that forms successive splits of the output target based on the input features to derive the most homogeneous target groups.
- Random forests—a supervised technique for classification or regression that uses an ensemble of decision trees built from input feature and data case subsets, with the results from the individual trees aggregated into a single output prediction.
- XGBoost—a supervised method for classification and regression that uses an ensemble of decision trees to derive an output prediction, where each subsequent tree attempts to address areas where previous trees performed poorly.
- Support vector machines—a supervised classification approach that identifies boundaries (or hyperplanes) in a space defined by the input features that optimally separate the output classes from each other.
- Naive Bayes—a supervised classification method that determines class probabilities assuming all input features are independent of each other.
- K-means clustering—an unsupervised approach in which cases are grouped such that their distances to their group centre are smaller than their distances to the other group centres.

- Principal components analysis—an unsupervised technique for dimensionality reduction in which features are transformed into orthogonal linear combinations, known as principal components, which capture variability in the features, ordered such that each successive component accounts for less feature variability than its predecessor.
- Apriori algorithm—an unsupervised method for mining association rules that uses the most frequent individual feature values and value combinations to identify commonly occurring sets.
- Convolutional neural networks (CNNs)—deep artificial neural networks that usually consist of several layers (convolutional, nonlinear, pooling and fully connected classification) that automatically learn feature hierarchies using spatial characteristics.
- Generative adversarial networks (GANs)—a combination of two neural networks, one of which generates example cases based on the input features while the other network attempts to identify each example case as authentic or artificial.

While the power and depth of machine learning techniques can make them appear as a panacea, there are several limitations and challenges that must be considered when attempting to use these methods in practice. First, training machine learning models to produce useful results can require massive amounts of data to counter dimensionality issues [30]. This is particularly true for complex deep neural networks. Without expansive datasets, the model may fail to capture important characteristics and conclusions will be less than optimal. Second, initial processing to make data suitable for machine learning can be quite intensive. Lack of uniformity regarding data formats is a recurring challenge in biological data, including medical records. Data combined from multiple sources, which is a clear property of panomics, must be standardised to ensure compatibility. In addition, missing values must be addressed in some way and some field values may need to be recoded. Individual fields or field combinations can be processed into potential new features. This is particularly true for wide data consisting of numerous features that need to be distilled into a manageable, yet meaningful, set. Next, the complexity of the required data engineering and the fine-tuning of the ML models may require a specialised analyst familiar with omic data to ensure derived features and models are sensible. Finally, the issue of AI interpretability must be considered. Some techniques, such as DL models, are basically "black boxes" that yield outputs in response to inputs. How those inputs translate into specific outputs is not easily explained. Yet, for network medicine, there needs to be some level of explanation for consumers, whether researchers, medical professionals or patients, to have trust in the results. Still, the width and depth of panomic data have been demonstrated to offer an exceptional opportunity for use of AI, ML and DL techniques to contribute to healthcare.

Artificial intelligence has been successfully integrated into clinical support decision networks for several years and is widely viewed as transformative in healthcare [31, 32]. A continuum ranging from proof-of-concept studies to US Food and Drug Administration (FDA) approved healthcare AI applications for molecular biomarkers are currently available [33–35]. Recent work has demonstrated strong performances of DL approaches, suggesting a current trend in diagnostic applications

using these techniques [36–38]. However, continuous efforts are being made to improve and refine diagnostic approaches, indicating a high level of flexibility in applications [39]. As expected, cardiology and oncology are the primary disciplines that serve as areas of active research in the development and implementation of AI, ML and DL applications in network medicine [40–42]. This focus is due to the target richness, depth and heterogeneity of biomarkers in these disciplines that necessitate AI-related interventions to facilitate clinical trials [43]. However, the use of AI, ML and DL is expanding quickly to diagnostics in other medical fields, as well, and moreover, recent reports indicate AI-related approaches are beginning to outperform humans in identifying disease states at least under some conditions [44–47]. Furthermore, innovative approaches are being developed using combinations of machine learning algorithms such as a novel approach described as explainable artificial intelligence (EAI) [48]. This approach tries the random forest, XGBoost and Light GBM techniques and selects the best-performing model. This model is analysed by an explainable AI algorithm known as SHapley Additive exPlantations (SHAP) to discern complex microbiome compositions under changing environmental conditions. SHAP attempts to derive the specific contribution of each input feature to the resulting predictions, allowing an examination of how inputs drive the output. AI, ML and DL are clearly indispensable for network medicine, but hurdles regarding the ability of clinicians and patients to interpret, use and communicate findings from these analyses persist.

3.4 Data Visualisation and Interpretation

The network medicine concept reflects an intersection of the information age and the age of personalisation that has generated specific expectations from consumers, both patients and healthcare providers. Visualisation techniques for effective interpretation of higher order, complex biological datasets are under development [49–52]. The preponderance of implemented visualisation platforms is designed for researchers to interrogate data derived from panomic studies in efforts to identify correlations associated with disease states. While often conceived for specific data types, other more flexible tools and platforms are available for data visualisation, as well. For example, PHATE, a tool that provides a method to discern structure in data by an information-geometry distance between data points offers a powerful alternative to commonly used methods such as principal component analysis and *t*-distributed stochastic neighbour embedding [53]. Clearly, such tools are essential for identifying data relationships within network structures; however, it is also a clear expectation to develop additional meaningful tools for analysis dissemination to clinicians and patients.

Translation and visualisation of data analyses for clinicians and network medicine implementation remains a challenge, but substantial progress is being made [54]. Infrastructure for data management and custody has been under development for the past decade, and new models for electronic health records (EHRs) are being

explored to address challenges in effectively integrating network medicine data [23–25, 55, 56]. Regarding these models, one important consideration for EHRs and clinical support decision tools used in network medicine is the integration of mechanisms for meaningful clinician input. Clinicians offer experience and perspective that are not necessarily available for initial data analyses and modelling derived from molecular assays. Integration of clinical knowledge including personal context of individual patients has been shown to inform ML models and enhance patient outcomes related to imaging results, and one would predict that similar input would be valuable for multi-omic data models, as well [57]. However, the implementation of such a workflow seems rather idealistic. Engagement of clinicians in model refinement consumes their most valuable resource, time and concerns regarding time are validated by the implementation of reporting systems in electronic health records [58]. As a result, it appears software tools alone will be insufficient to support network medicine implementation.

Translating data effectively for patient communication has challenges, as well. The growth of consumer-oriented healthcare in the early 2000s coupled with a patient's desire for ready access to data on their mobile devices results in an expectation for effective communication and understanding of results [59, 60]. As a result, tools for dissemination of molecular data to patients require resources for communication with patient care teams, as well as suitable depictions and explanations of tests and results. However, omic data display for clinical decision-making can be multifactorial and complex. Multiple data analysis pipelines converge for correlative analyses for presentation in a clinical decision support system. As the number of applications for these approaches, as well as the complexity of biomarkers escalates, it would seem to be pragmatic to consider implementing alternative strategies to address this challenge beyond a data visualisation application. For instance, it is reasonable to suggest creating positions for medical data scientists as translational intermediates to deliver coherent data analyses for clinician review and patient consumption. This suggestion aligns well with the surge of genetic counsellor positions that occurred in response to genome sequencing and concomitant increased genetic screenings that looked to take full advantage of this omic approach for precision medicine. It would seem current genetic counselling curricula could be augmented with tracks for training in network medicine within a particular discipline such as oncology or cardiology. Further, augmentation of patient care teams with genetic counsellors prepared in molecular diagnostics would seemingly help alleviate clinician time constraints.

3.5 Future Directions in Network Medicine

It is expected that the molecular assay ecosystem will only continue to grow as new molecular biomarkers are discovered and more assays are being implemented through increased use of non-invasive sample collection, such as liquid biopsies [61–63]. This growth in molecular assay use will continue to be a driving force for

network medicine realisation, but it is important to note that the diagnostic and prognostic values of molecular assays do not exist in a healthcare vacuum. Rather molecular assays complement biomarkers identified from physiological, histological and radiology analyses. Interestingly, an explosion of data from non-molecular analyses analogous to those observed from omic approaches is occurring as well. This observation is perhaps best exemplified by the digitisation of the US Department of Defense's massive pathology specimen library [64]. Integration of these diverse data sets using artificial intelligence, machine learning and deep learning approaches for novel biomarker discovery and disease state identification will continue for the foreseeable future.

Advances in AI, ML and DL approaches have been impressive. Core architectures are constantly evolving into advanced modelling techniques and this is anticipated to continue [65]. These advancements are expected only to increase as progress is made in understanding relationships between AI and neuroscience [66]. As a result, the toolbox for diagnostics and prognostics in network medicine will continue to expand and such growth is critical as it is clear that no single approach addresses the needs in biomarker discovery and disease recognition. Rather, deriving information from complex biological data whether molecular, histological, physiological, radiological or combinations of these disparate data will require varied machine learning techniques or combinations of these approaches. For example, an ensemble of models that each leverage a different algorithm can produce a single prediction by treating their results as votes. Alternatively, a separate ML model can be derived using the ensemble model results as input features, in a process known as "stacking". However, the future of artificial intelligence, machine learning and deep learning on healthcare is not limited to diagnostics. As evidenced by the COVID-19 pandemic, AI-related approaches using network principles are instrumental and transformative for drug discovery and clinical trial management [67, 68]. Moreover, AI, ML and DL approaches are being integrated into several routine aspects of healthcare delivery ranging from administrative tasks to patient engagement, including telemedicine [69].

Analogous to improved algorithms in AI, ML and DL, resolution is always increasing and becoming more refined through the development of new technologies in biology and analysis of biological systems. It has been argued that recent innovations in single-cell analyses may displace traditional omic studies in precision medicine [70–73]. These techniques and associated nanotechnologies, such as quantum dots, utilise imaging and multi-omic approaches with the potential to eventually image molecules within individual living cells [74]. Such resolution will offer snapshots or perhaps real-time images of active cellular and molecular networks that can be used to extrapolate to tissue or organismal levels. These measurements provide a mechanism to identify subpopulations of cells within tissues exhibiting differential physiological effects. However, discernment of signals within omic data regardless of single-cell or multicellular samples will continue to require AI, ML and DL approaches. Given these roles ranging from biomarker identification to diagnostics to therapeutics to patient engagement, artificial intelligence is currently and will continue to be the single greatest contributor to innovation in healthcare.

3.6 Taking a "Moonshot" at Network Medicine Now

Even with massive data generation potential, improving data availability and the development of innovative tools for data analysis, the realisation of network medicine still faces considerable obstacles. Implementation of precision medicine or network medicine will occur when the healthcare market and community develop both confidence in these approaches and the systems necessary for their integration. It is important to note that required systems do not refer to simply computational and software tools for analysis, visualisation and interpretation of information derived by network analyses. Instead, financial models for network medicine are of greater consequence. Cost is a primary driver of healthcare services, and implementation will be sporadic or slow until network medicine presents a financially viable alternative that improves patient outcomes. However, the future is promising. It is obvious that network medicine offers cost savings through the acceleration of biomarker identification and reducing clinical time regarding discovery. Moreover, predictive models produced by AI, ML and DL techniques will save time and decrease cost for patient care teams provided information flow from testing to the team to the patient is productive. Clearly, the potential for increased costs of molecular assays and other tests is a concern. However, it is possible that AI, ML and DL approaches could be applied to manage judicious testing regimes by recognising patterns resolved from growing case studies of success regarding various disease states. In these ways, network medicine and personalised biomarker profiles will realise cost benefits, as well as care benefits, in terms of efficiency and effectiveness for individual patients.

While this prediction is promising, it would seem moving forward that a focused approach to the implementation of network medicine may be more effective at developing a convincing cost-benefit argument than the current distributed approach. While convincing arguments can be made for use of network medicine in the treatment of any disease state, the advanced biomarker discovery and analyses in cardiology and oncology indicate these disciplines are prime for a 'moonshot' network medicine initiative. Oncology was identified as an initial target for precision medicine [25] and among the diverse disease states comprising cancer, treatment of multiple myeloma offers a clear platform for potential improvements in cost, patient care and patient outcomes using network medicine. Multiple myeloma is an incurable cancer of plasma cells generally occurring in individuals 45 years or older. Importantly, precursor asymptomatic stages of myeloma have been identified. Monoclonal gammopathy of underdetermined significance (MGUS) was recognised over 40 years ago as a benign condition deserving subsequent periodic monitoring for progression to multiple myeloma [75]. An intermediate, active disease state in the progression towards multiple myeloma known as "smoldering multiple myeloma" (SMM) was recognised in 2007 [76]. As a nascent diagnosis, SMM biomarker discoveries and their prognostic value for the progression of this disease to multiple myeloma are still being explored [77]. Current measures to monitor the precancerous SMM state include complete blood count, haemoglobin levels,

monoclonal protein levels, free immunoglobulin light chain ratio, calcium levels and bone imaging to detect lesions. Typically this data is collected every 3–4 months for 5 years after initial diagnosis. Recently molecular biomarkers have been integrated into SMM prognoses, but primarily at the level of genomic markers using next-generation DNA sequencing or fluorescence in situ hybridisation (FISH) techniques [78, 79].

New reports highlight preliminary efforts to apply network medicine principles to multiple myeloma. Myeloma-specific ontology has been generated and used with artificial intelligence to extract relevant information from medical records [80]. Differential cell counts in bone marrow derived from less invasive techniques have been analysed using machine learning [81–83]. Treatment plans for multiple myeloma, as well as the development of artificial intelligence models, are beginning to arise from case studies using molecular biomarkers [79, 84–86]. Taken together, the emerging application of disparate molecular, histological, physiological and imaging techniques coupled to the longitudinal nature of disease progression and periodic screening make multiple myeloma a unique and powerful opportunity for network medicine. A large-scale, comprehensive clinical trial should be conducted including healthy individuals, individuals identified with MGUS, SMM patients and patients that have progressed to multiple myeloma with deep data being collected at all levels including panomics. By profiling changes over time in each population, patterns can be discerned and linked to progression. Such datasets have the promise to transform diagnostics, prognostics and potential treatments regarding myeloma for generations by providing clarity on the spectrum of genetic lesions, their effects at molecular, cellular and tissue levels and their consequences for this disease that can be translated on an individual patient basis.

3.7 Summary

It is a critical and promising time for network medicine. The maturation of panomic, artificial intelligence, machine learning and deep learning approaches has demonstrated the accessibility and value of this new discipline. The current developmental environment guarantees continued innovation in these data collection and analysis areas to deliver enhanced biomarker discovery for disease state diagnostics and prognostics. In particular, an increased scale of data availability will foster the development and implementation of improved and novel combinations of learning algorithms. Given these advancements in network medicine, consideration of addressing translational obstacles for network medicine is timely. Among these, communication appears to be a recurring theme, whether among the patient and patient care team or translating evidence regarding the benefits of network medicine for cost and patient outcomes to healthcare systems. As such issues are resolved, network principles and applications will deliver precision medicine and transform healthcare.

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Chapter 4
Data Analytics for Accountable Care Organisations in a Shifting Landscape of Health and Medicine

Suresh Chalasani, Madhumita Banerjee and Gitika S. Chalasani

4.1 Introduction

In 2018, the US government spent about 1.1 trillion dollars on healthcare, out of which about $583 billion was spent on the Medicare program [1]. About 18% of the Gross Domestic Product (GDP) in the United States is spent on healthcare, much higher than the other high-income countries. While spending the most money on healthcare out of any other country in the world, the United States has astonishingly poor healthcare outcomes and has the lowest life expectancy rates compared to all other OECD (Organisation for Economic Co-Operation and Development) countries, as well as one of the highest suicide rates. In terms of OECD averages, the United States has two times the rate of chronic disease and obesity but still manages to utilise more expensive healthcare technologies than other OECD nations. A recent study by Papanicolas et al. [2] found that, despite a large amount of healthcare spending, the United States lags in a few key metrics compared to other countries: (a) Percentage of adults who are overweight/obese stands at 70% in the United States, much higher than the other comparable countries; (b) Life expectancy in the United States is 78.8, lower than the other comparable countries studied; and (c) United States has the highest infant mortality rate (5.8 deaths per 1000 live births in the US; 3.6 per 1000 for all 11 countries studied).

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Furthermore, although the United States prioritises preventative measures and screening visits, general health and well-being outcomes remain poor. Even with this focus on prevention, the United States has the highest rate of hospitalisations from causes that could have been prevented. To add to these disheartening facts, American citizens somehow visit the doctor less frequently than all other OECD nations and have fewer physicians available as a whole [3]. Although all these facts are astonishing, the US welfare state is fundamentally and foundationally not comparable to other OECD countries, both in terms of economics and in terms of public priority. As healthcare spending in the United States continues to grow, consumers, taxpayers and elected officials are asking whether the high amount of healthcare spending is translating into healthcare quality.

From a philosophical perspective, the healthcare system is a social institution that constitutes a range of processes and structures to address some social need [4]. It is a set of organisations and systems, physical or ideological, that are connected to a specific sector of society and that serve to shape and channel behaviour towards specific ends [5]. The system comprises individuals, groups, organisations, practices, structures and purposes and to that end, Budrys [4] contends that healthcare delivery shares attribute with other societal institutions in the sense that it was constructed to meet specific societal needs in a way that reflects our values, behavioural expectations and culture. Through the analogy of viewing the American Healthcare system as "a house erected over multiple generations with each set of inhabitants building upon, remodeling, or altering the bricks of those coming before them," Hinote and Wasserman [5] explain how in the process of constructing this institution, each participant drew upon their understandings of health and the body, their values and their goals as both individuals and a collective society thereby constantly reproducing or reworking the form of the institution. The aforementioned authors argue that what is commonly thought of as the failure of the institution is really the failure of the stakeholders to contemporise and modernise it that plays a critical role in sustaining, fortifying and reproducing the inefficiencies of the system.

Viewing the healthcare system from the lens of the building block metaphor, we discuss several initiatives that are currently in place in the United States to improve the quality of care. We then present infrastructure schematics that may be used to analyse large-scale healthcare data. Next, we present specific examples of healthcare decisions that can be made using data analytics and how healthcare technical infrastructure can be utilised for data analytics, with the end goal of providing insights into healthcare delivery that achieve the objectives it was designed to meet – attend to the needs of the sick and promote health and well-being.

One of the initiatives is based on providing care for patients through healthcare entities designated as Accountable Care Organizations (ACOs). The broad theme of ACOs is to promote quality of care rather than volume of care or quantity of care [6]. ACOs participate in Medicare Shared Savings Program and are eligible for additional financial benefits if they demonstrate that they meet certain quality measures. The Centers for Medicare & Medicaid Services (CMS) define ACOs as follows [7]: "Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other healthcare providers, who come together voluntarily to give coordinated

high-quality care to the Medicare patients they serve. Coordinated care helps ensure that patients, especially the chronically ill, get the right care at the right time, with the goal of avoiding unnecessary duplication of services and preventing medical errors. When an ACO succeeds in both delivering high-quality care and spending healthcare dollars more wisely, it will share in the savings it achieves for the Medicare program."

All healthcare entities including ACOs are grappling with the explosion of data as data analytics is transforming every industry, from banking and finance to retail and certainly in the realm of patient care. In healthcare, huge amounts of data from disparate data sources have the potential to improve patient outcomes through improved analysis and decision-making [8]. Several aspects of ACOs are changing the clinical communication and some of the processes to improve patient outcomes [9]. In essence, the demand for quality of care while reducing healthcare costs and the extensive amount of data coupled with advanced technologies is leading us to an unprecedented era of digital health.

Some of the sources of digital information related to health include mobile wearable devices, sensors, electronic portals, virtual reality, analytics and machine learning tools and applications. Wearable devices such as smartwatches, fitness bands, and health monitors interface with smartphones and personal computing software to collect a wide variety of data [10]. They are commercially available and becoming popular in healthcare with an increasing number of Americans owning a smartwatch or fitness tracker. Wearable devices collect data either automatically through the use of sensors or by the user manually entering data into the device [11] and include a treasure trove of data from location, activity, sleep patterns, body temperature, blood pressure, blood oxygen level, heart rates and brain activities to fertile reproductive periods [12].

Cillers [12] cites examples of data that may be available for collection and analysis [11, 13–16] including location (GPS), air quality (phone sensor), diet and nutrition (user logging), activity/movements and sleep patterns (personal device sensors, accelerometers, pedometers, altimeters), muscle function and coordination (pressure sensors), skin conductance as a proxy for arousal (sensor attached to phone), temperature and fertile periods (thermometer, electrodermographs), heart rate, blood pressure and blood oxygen (heart rate sensors, oximeters, electrocardiograms, digital camera/flash), psychological disorders and personality traits (social media use, involvements with friends, behavioural patterns and activities when using a smartphone) and measuring cognitive functions and brain activity (brain wearables, cognitive sensors). The collected data may then be transferred to a mobile application or database to be statistically analysed and presented with visualisation techniques that show changes over time [17]. Sharing this information with healthcare providers will facilitate informed healthcare-related decision-making [18].

Aziz [19] reports the application of virtual reality (VR) in healthcare allows for increased operationalisation of health information and data whereby VR is used both for the training of healthcare professionals such as anatomy instructions and surgery simulations as well as for diagnosis and treatment. The use of VR allows for a three-dimensional computer-generated world that can be explored interactively

through a variety of peripheral devices and be effectively used for medical therapy, preventive medicine, visualisation of databases, skill enhancement and rehabilitation and medical education and training. Technological advancement in diagnostic imaging has allowed the use of VR in CT, MRI, X-ray imaging NM, ultrasound and computed radiography. VR simulation is also being used in the autopsy, microscopic examination and digital pathology paving the way for maintaining sustainable and efficient services and quality of care.

In this era of data abundance, artificial intelligence (AI) has introduced the possibility of using aggregated healthcare data to produce powerful models that can automate diagnosis [20] and enable an increasingly precision approach to medicine by tailoring treatments and targeting resources with maximum effectiveness in a timely manner [21, 22]. The potential of AI is vast and machine learning, a technique of AI is being developed and used to manage, decide and predict the results of healthcare data more precisely [23]. Automated medical image diagnosis is one of the most popular applications of AI and is successfully being used in radiology, ophthalmology, dermatology and pathology [24]. The authors [24] report additional usage of AI in genome interpretation, biomarker discovery, clinical outcome prediction and patient monitoring, inferring health status through wearable devices and autonomous robotic surgery.

In this chapter, we focus on technologies for data analytics applications in healthcare. The rest of this chapter is organised as follows. We first discuss ACO quality measures and give specific examples of how to compute ACO quality measures based on patient data. Then we present a few examples of technologies that are used for data analytics in healthcare. Before concluding this chapter, we give specific examples of applications of data analytics in healthcare.

4.2 ACO Quality Measures

To qualify for federal incentives, ACOs need to demonstrate that they are meeting certain quality measures every calendar year. The number of quality measures differs from year to year; however, the concept and some of the core measures remain the same. For example, in 2018, ACOs needed to report data on 31 quality measures [25]. These 31 quality measures are grouped into the following four different domains.

- Patient/Caregiver Experience (8 measures)
- Care Coordination/Patient Safety (10 measures)
- Clinical Care for At-Risk Population
  - Diabetes (2 measures scored as 1 composite measure)
  - Hypertension (1 measure)
  - Ischemic Vascular Disease (1 measure)
  - Depression (1 measure)
- Preventive Health (8 measures)

4.2.1 Quality Measures for Patient/Caregiver Experience

A few examples of the ACO patient/caregiver experience quality measures are:

- ACO-1: Getting Timely care, Appointments and Information
- ACO-2: How Well Your Providers Communicate
- ACO-3: Patients' Rating of Provider
- ACO-4: Access to Specialists

The data to compute these measures comes from the patient survey and Consumer Assessment of Healthcare Providers and Systems (CAHPS), conducted by the Agency for Healthcare Research and Quality (AHRQ).

4.2.2 Quality Measures for Quality Care Coordination/ Patient Safety

A few examples of the ACO care coordination/patient safety quality measures are:

- ACO-36: All-Cause Unplanned Admissions for Patients with Diabetes
- ACO-37: All-Cause Unplanned Admissions for Patients with Heart Failure
- ACO-38: All-Cause Unplanned Admissions for Patients with Multiple Chronic Conditions

The data to compute some of these measures comes from healthcare claims data. For example, for ACO-36, we compute the rate of acute, unplanned hospital admissions in 65 years and older population with diabetes.

4.2.3 Quality Measures for Clinical Care for At-Risk Population

A few examples of the ACO clinical care for at-risk population quality measures are:

- ACO-27: DM-2: Diabetes: Haemoglobin A1c (HbA1c) Poor Control (>9%)
- ACO-41: DM-7: Diabetes: Eye Exam
- ACO-28: Hypertension (HTN): Controlling High Blood Pressure
- ACO-30: Ischemic Vascular Disease (IVD): Use of Aspirin or Another Antiplatelet

For example, ACO-27 quality measure computes the percentage of patients in the age range 18–75 years with diabetes (type 1 or type 2) whose Haemoglobin A1c (HbA1c) test result is above 9%. The formula for computing HbA1c is as follows:

$$\left(\#\,\text{Patients with HbA1c} > 9.0\%\right) / \left(\text{Total}\,\#\,\text{Diabetic Patients}\right)$$

For the numerator, we take the number of patients whose most recent HbA1c level (performed during the measurement period) is above 9.0%. If a patient's test result is missing or the test was not completed during the year, such patients are also included in the numerator. For the denominator, the following patients are included: patients with at least two face to face encounters with different dates of service in an outpatient setting or non-acute inpatient setting, or patients with at least one face-to-face encounter in an acute inpatient or emergency department setting during the measurement period or the year prior to the measurement period (services that occur over both years may be counted). Furthermore, patients should be in the age range 18–75 years and need to have a diagnosis of diabetes (type 1 or type 2) for the year are included. Diabetic patients with a diagnosis of polycystic ovaries, gestational diabetes and/or steroid-induced diabetes are not included in the denominator counts.

Similarly, ACO-41 (DM-7) quality metric measures the percentage of patients in the age range 18–75 years with diabetes (type 1 or type 2) who had an eye exam (retinal) performed. The formula below is used to compute this quality measure value.

$$\left(\#\,\text{Patients with Retinal Exam}\right) / \left(\text{Total}\,\#\,\text{Diabetic Patients}\right)$$

For the numerator, the total number of patients who received a retinal eye exam during the measurement period or had a negative retinal eye exam (normal result) during the year prior to the measurement period is used. The process for computing the denominator is very similar to the process described for ACO-27.

4.2.4 Quality Measures for Preventive Health

A few examples of the ACO preventive health quality measures are:

- ACO-14: Preventive Care and Screening: Influenza Immunisation
- ACO-15: Pneumonia Vaccination Status for Older Adults
- ACO-17: Preventive Care and Screening: Tobacco Use – Screening and Cessation Intervention

For example, ACO-14 measures the percentage of patients who received the flu vaccine. As can be seen, data at the enterprise level is needed to compute every ACO quality measure. The next section presents the data architectures and technologies used in healthcare for computing ACO quality measures and decision-making.

4.3 Data Architectures and Technologies for Healthcare Applications

Figure 4.1 presents a high-level schematic of the infrastructure used for healthcare data analytics. Healthcare data can arise from a variety of sources. For example, smart meters that track the blood glucose levels of patients can transmit the readings (Sensor Data in Fig. 4.1). Medical records of patients in the United States are typically stored in electronic health records (EHR Data). Data from patient satisfaction surveys are available in a separate database. Epidemiology and data on public health and genome data are separate data sources. These diverse data sources are combined to form a data warehouse. Smaller data marts that are applicable for different departments can be created from the larger data warehouse. For example, a research division that is studying the effectiveness of specific medications in patients will utilise a different data mart compared to the division that needs to report the ACO quality metrics.

Several platforms/programs can be used to conduct analysis on data and arrive at meaningful conclusions. Some of these programs are SAS, SPSS and R. One advantage of R is that it is open-source and freely available. Spreadsheet software packages such as Excel can also be used to analyse data to some extent, though some of the tasks can take a significantly longer time with Excel compared to software packages such as R. Tableau and other tools such as Power BI can help visualise data with ease. To extract data from databases, structured query language (SQL) is a common language that works across multiple database formats. For example, a database query to extract patient lab test result data can be constructed as shown in Fig. 4.2.

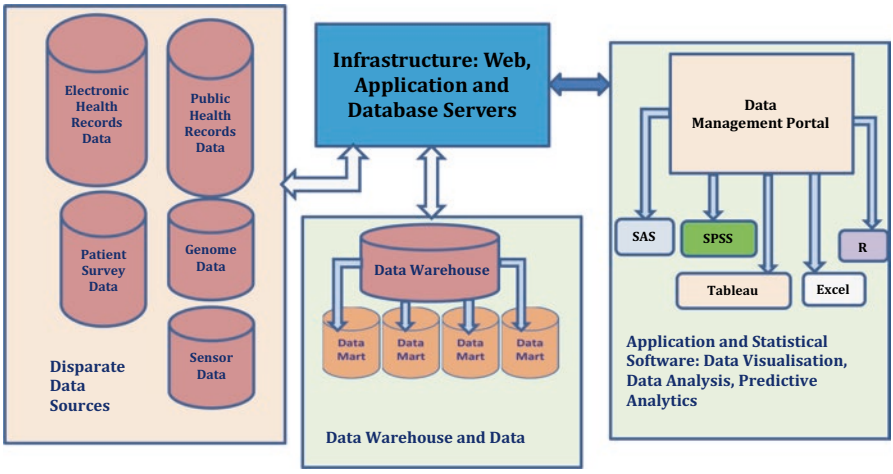

Fig. 4.1 An infrastructure diagram for healthcare data analytics

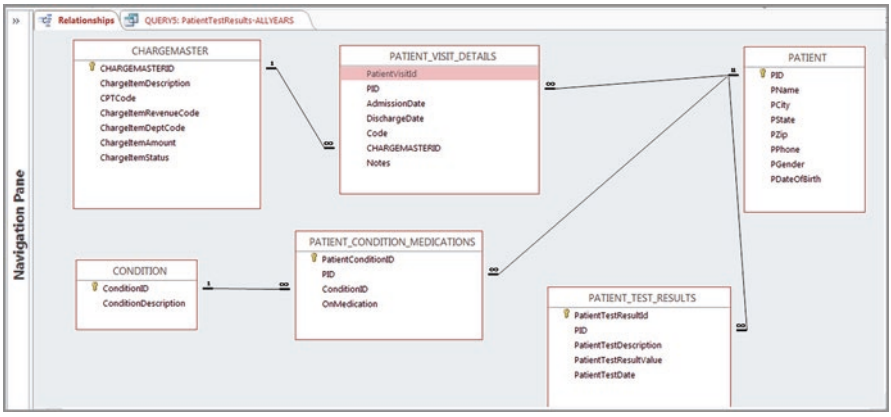

Fig. 4.2 A visual representation of a database query to extract patient test results data

4.3.1 Data Analytics: Example Application #1: Physician A Versus Physician B

You are working as an administrator for a large hospital system that is designated as an Accountable Care Organization. Your 65-year-old uncle John is diagnosed with diabetes and he wants to see a primary care physician (PCP) who demonstrates better results in controlling diabetes. Uncle John narrowed his choices to two physicians: Physician A versus Physician B. Knowing that both doctors work for the same hospital system where you work as an administrator, uncle John requested your help in deciding which physician he should select. You would like to help your uncle with the decision. How would you approach this decision-making scenario?

The approach you likely will follow consists of the steps outlined below:

1. Extract relevant data from the database. In this example, the sample data you will extract includes the HbA1c lab test results for diabetic patients for whom Physician A vs. Physician B are the primary care physicians.
2. Formulate the null hypothesis that the means of HbA1c values for patients of Physician A vs. Physician B are the same.
3. Utilise Microsoft Excel and/or R (or any other statistical testing tool) to conduct the t-Test to test the null hypothesis.
4. Interpret the statistical test results and draw conclusions on whether the mean blood sugar levels, as indicated by HbA1c, are similar for Physician A vs. Physician B.

The infrastructure components that are utilised in this example are indicated in Fig. 4.3.

As the quality movement in healthcare gains momentum, such statistical analysis can be expanded to compare the outcomes of different ACO measures across healthcare systems and regions. As patient data becomes available for easier access

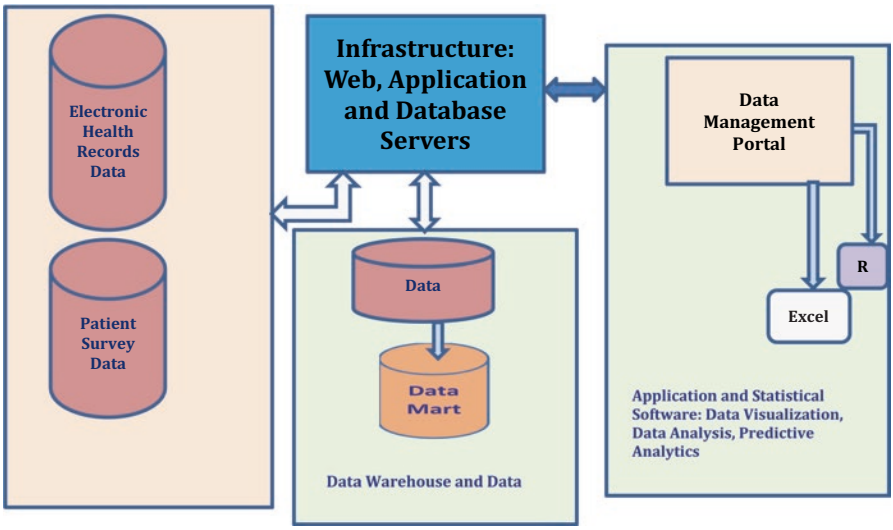

Fig. 4.3 Infrastructure components used in deciding between Physician A vs. Physician B as uncle John's physician

through initiatives such as Health Information Exchanges (HIEs), a large amount of treatment and outcomes data can be analysed. Based on this data, predictive analytics models can be used to find out the best possible treatment options based on patient data and treatment options.

4.3.2 Data Analytics: Example Application #2: Predicting the Future Sales of Medical Equipment

You are working as a sales manager for a large pharmaceutical company. Your company sells medicines and medical equipment such as defibrillators and coronary stents. You are planning to predict the total number of medical equipment such as the defibrillators that your company sells in the coming years. Likely, the growth is slow initially, then growth takes off as the product becomes more popular and then the growth tapers off. You can model the sales growth using a growth curve such as the S-curve or the Gompertz curve [26].

For the Pearl function, the formula is: $x(t) = L/(1 + a * e\text{^}(-b * t))$. Here, $x(t)$ is the sales at time t, and L is the maximum value that $x(t)$ can achieve. Constants a and b are used in the model to help determine the curve's shape. The inflection point for the curve occurs when $t = \ln(a)/b$, where $\ln(a)$ is the natural logarithm of a.

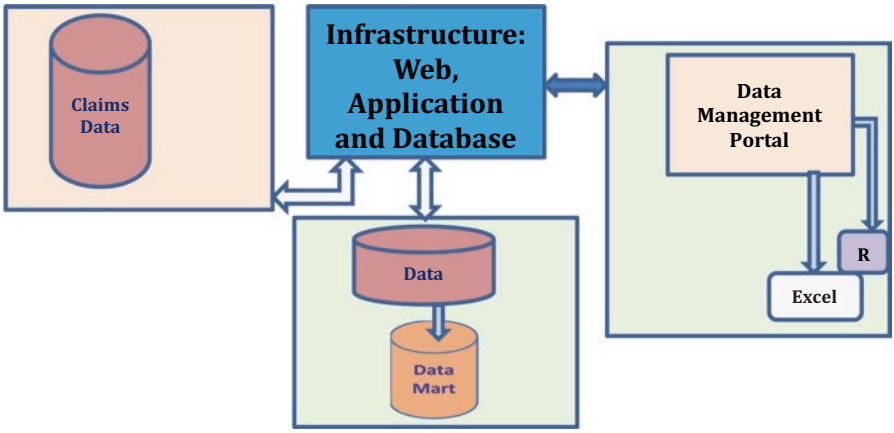

Fig. 4.4 Infrastructure components used in comparing reimbursements for different hospitals

Another growth curve model is defined by the Gompertz curve. For the Gompertz function, the formula is $x(t) = a * e^{(-c * e^{(-b * t)})}$. Here, $x(t)$ is the sales at time t. As t becomes large, $x(t)$ approaches a.

To fit these curves to predict sales, we can utilise the data from the sales data warehouse (or data mart). Though the sales data is not explicitly shown in Fig. 4.4, depending on the organisation (in this example, a pharmaceutical company), different data sources need to be brought in. In this example, you need to find the best fit values for L, a and b if we use the Pearl function; if we use the Gompertz function, you need to find the best fit values for a, b and c. The best fit values can be found either using Excel solver or using a programming package such as R.

4.3.3 Data Analytics: Example Application #3: Comparing the Reimbursement Amounts for Different Hospitals

You are working as an auditor at the Centers for Medicare and Medicaid Services (CMS). You are reviewing the claims submitted by four different hospitals in the same urban area of Milwaukee, WI for treating "Heart Failure and Shock without complication or comorbidity (CC) or major complication or comorbidity (MCC)." The MS-DRG code for this treatment is MS-DRG 293. You somehow suspect that there are significant differences among the reimbursements for this MS-DRG code for these four hospitals. You would like to investigate whether this is true or not. How would you approach this decision-making scenario?

The approach you likely will follow consists of the steps outlined below:

1. Extract relevant data from the database. In this example, the sample data you will extract includes the reimbursement data for all the claims submitted for the MS-DRG code 293 by the four hospitals.

2. Formulate the null hypothesis that the means of the reimbursements for MS-DRG 293 are the same for all four hospitals.
3. Utilise Microsoft Excel and/or R (or any other statistical testing tool) to conduct the ANOVA test to verify the null hypothesis.
4. Interpret the statistical test results and conclude whether the mean reimbursements are the same or not.

The infrastructure components are not the same as those shown in example 1. Since the CMS data sources are different, we need to obtain the relevant data on reimbursements from the claims data available in the CMS database systems. Except for the data sources, other infrastructure components may be the same as before in this example. Figure 4.4 shows the infrastructure components such as the claims data used in this example.

4.4 Concluding Remarks and Directions for Future Work

Healthcare is the largest service industry in the United States and constitutes the world's fifth-largest economy on its own [5]. Healthcare data arise from myriad sources such as electronic health records, sensors such as RFID tags and smart meters, public health agencies and patient surveys. The definition of big data for healthcare uses four V's: volume, velocity, variety and veracity [27]. As healthcare data grow, governmental agencies, hospitals, pharmaceutical organisations and insurance companies are trying to find meaning in the data [28]. Researchers need to utilise both technologies and statistical techniques to draw meaningful conclusions from healthcare data. Since 18% of the US GDP is in healthcare, there is a significant emphasis on data analytics in healthcare to improve quality of care as well as reduce healthcare costs.

Although a daunting task, the delivery system's effectiveness can be assessed by analysing the three domains of cost, quality and access. Today's complex healthcare institution has many players including new entrants such as the software developer, vendor and IT professional and each will play a critical role in gleaning insights from big data to initiate long-lasting and meaningful change. Harnessing the predictive technology and decision-making processes of big data, the healthcare industry can attempt to realise both quality outcomes and cost containment in patient care. Other challenges that need to be addressed include accessibility, privacy, security, usability, implementation costs, transportability, interoperability and standardisation [29].

For accurate diagnosis and prediction across different segments of the society, and to correct for bias, data need to be representative of race, class and gender. Due to cost, access and cultural issues, healthcare institutions often lack the data needed to fit algorithms for accurate analytics of specific populations [30]. Only then can such analytics be used to identify health needs, analyse problems and trends, conduct relevant research, plan and evaluate programs and justify budgetary costs and

administrative decisions. Furthermore, resolving issues related to data ownership and trust and investing in the development of efficient and streamlined analytics infrastructure with adequate attention to the representativeness of information will provide a step towards early intervention, quick and accurate diagnosis, appropriate treatment, reduced costs and improved healthcare quality. This new decade is poised to bring significant developments in terms of using analytics for improving quality and reducing expenses.

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Chapter 5
The Case for Digital Twins in Healthcare

Nilmini Wickramasinghe

5.1 Introduction

One of the defining features of the new millennium is the impact of digital technology that is revolutionising the world by improving everyday lives. In particular, the advances in the Internet of Things (IoT) are enabling what was only once imagined to become a possibility. Healthcare is no exemption, even if it has been slower to embrace digital solutions as rapidly as perhaps banking manufacturing and retail sectors. As healthcare is embracing digital solutions, we are not witnessing the dawn of health 4.0, a concept coined towards running healthcare services supported by data and technology, which enables the digital transformation of healthcare.

In fact, in healthcare delivery today we are not surprised to see the adoption of mobile solutions and apps, sensors, augmented, mixed or even virtual reality and 3D printing. Moreover, advances in genome sequencing have also meant that more sophisticated analytics, AI (artificial intelligence) and ML (machine learning) are also being incorporated to address various aspects around the provision of superior care. These advancements have been pivotal in offering quality healthcare services to all. However, technology development that has served to bring tremendous benefits to manufacturing and service sectors, in particular, has yet to be significantly embraced in healthcare, namely, digital twins.

Digital twin advancements are currently being used in service sectors to provide better analytical insights through simulations. This has been achieved by combining the already existing data with available simulation models to provide intangible replicas [1, 2]. This technology has empowered industry scientists with an opportunity to test ideas without engaging the real world thus limiting negative

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consequences that may have arrived in real-world testing. The trend has been driven by the technology efficiency and benefits that have significantly cut the costs of testing new ideas and concepts. This chapter contends that similar benefits can be realised in healthcare and, therefore, examines how we might conceptualise the digital twin technology application in the healthcare sector.

5.2 Digital Twin Concepts

It is generally accepted that one of the first instances of digital twins is found with NASA, which has been known to create mirrored systems, or simulated environments, to monitor unreachable physical spaces (e.g. spacecraft in mission) [3]. This is one of the first occurrences but since then, numerical models and computer simulations of varying complexity have gradually been introduced to diverse fields such as engineering, retail, service and manufacturing [5].

A typical digital twin has three key components [4]:

1. A component from the physical world (e.g. an object, a process, a person, etc.)
2. A virtual or a digital representation of the physical component and
3. A data stream that serves to connect the physical and virtual components.

This relatively new and nascent innovation is one of the fastest-growing technological solutions across all industries, and its concepts revolve around the convergence of physical and virtual worlds to produce a clear digital replica [5]. Through the use of different data sources, the advancement allows for learning and reasoning in an attempt to make optimal decisions (ibid). As the word "twin" suggests, the technology allows for virtual and physical object development. The creation is founded on extensive data collection from different points by using sensors and other information collecting devices. After collection, the information is interpreted and run through rigorous algorithms to come up with deep physical analytics. Analytic results summarise lessons learnt and opportunities that exist in the physical environment. The whole process is not only more cost-effective than testing real physical constructions but has also seen as useful in operations optimisation.

5.3 Digital Twins in Healthcare

Digital twins in healthcare have been described as the integration of data-rich sources with AI platforms to provide clinical solutions [6]. Such solutions then provide an ideal testing and monitoring environment and at the same time eliminate the need for physical objects and human subjects (ibid). In healthcare, while applications are still emerging, to date the technology has proved efficient in predicting procedure outcomes [7–10]. Furthermore, beyond outcome prediction, digital twins have empowered medical experts with the tools to customise therapies for individual patients (ibid).

Outcome prediction is one of the most important benefits of the application of digital twins in medicine [11, 12]. Cases exist where digital twin solutions have has been used in predicting different intervention results including to predict successful treatment scenarios in delicate procedures such as cardiac resynchronisation therapy (CRT) (ibid). By integrating digital twin technology, medical experts can easily predict patients that are more likely to respond to such therapies (ibid).

Smith, et al. described using AI to produce digital twins for Alzheimer's disease (AD) patients under treatment to reduce the number of failing clinical trials, although the trials were well-justified and well-funded [13]. Previously, using data from a randomised controlled trial was considered as a gold standard for Alzheimer's disease (AD), but with limited access to a small pool of Alzheimer's disease (AD) patients, it is becoming extremely hard to create randomised trials. The digital twin can create synthetic control subject records with matching baseline variable records with the patients under treatment which can enhance control groups in clinical trials [13]. This work also highlights that this new technology can improve the overall efficiency of trials by reducing the recruitment time and number of trials thereby improving product/therapeutic practices.

Recently another study which is in its initial stage has incorporated the digital twin (whole-body digital twin) concept for reversing diabetes based on precision medical treatment [14]. This study will use TPT (Twins Precision Treatment) to gather data related to blood and sensor along with remote coaching for nutrition and exercises (at a frequency of 90 days for duration 2–5 years) using mobile apps and this data will be analysed through AI. This will help in understanding and comparing how the digital twin for these patients under treatment matches in terms of treatment and recovery predicted by AI and data analytical techniques.

Successful healthcare outcomes are highly dependent on the accuracy and effectiveness of clinical decisions [11]. Technologies that both enhance and empower clinical decision-making processes have the potential to not only result in the better clinical outcome but higher quality care, high-value care and high patient satisfaction. Utilising digital twin solutions in this regard has the potential to lead to superior clinical decision-making. For instance, in oncology, prostate cancer specialists have multiple intervention options for their patients. However, choosing the right option is not a simple decision and can be dependent on different circumstances. Specifically, the choices include surgery, radiation and hormone therapy options [15]. By integrating relevant patient data and thereby constructing a digital twin of the patient, it can assist the clinician to choose the best option in relation to the risks involved and outcomes expected. The therapy process can be extended to more sophistication by combining digital twin resources with patient data imaging, lab and genetic data to come up with a more advanced therapy plan [15]. By following such a strategy, the aim is to maximise therapeutic benefits and minimise patient discomfort by making an optimal decision supported by mined and analysed data.

5.4 The Case for Digital Twins in Healthcare

There appears to be a strong case for focusing on trying to incorporate digital twins into healthcare today as this may be the way to address current concerns around limitations with precision medicine and lack of patient-centeredness of care. Much of medical research has been focused on treating patients in a generalised way and following prescribed, established practices, which include specified pathways for diagnosis, treatment and post-treatment recovery [16]. To help clinicians to navigate/decide their treatment pathways, atlases were produced which used scans of thousands of patients and created atlas for the future record [16]. Gradually, however, a growing realisation is occurring where there is an emphasis to look at each patient as an individual, unique person, with their own speed and pathway for treatment and recovery, which, in turn, has led to the focus on precision medicine (ibid). In essence, a precision medicine approach is an emerging approach for disease treatment and prevention that takes into account individual variability in genes, environment and lifestyle for each person [17, 18].

However, the precision medicine approach has not totally delivered as promised and, in particular, has not been able to include the current and real-time data generated by the patient, thereby making it misaligned with the concept of precision medicine [17, 18]. With the significant advancements in the myriad of data analytic techniques and artificial intelligence in healthcare, digital twins, which could be used to create digital representations of specific patients, and thereby enabling all critical and individual aspects to be captured and thus considered when formulating a treatment strategy, appears to fill this void.

5.5 Critical Considerations

As with all emerging innovations, the conceptualisation of digital twins for healthcare also brings with it multiple unsolved issues. First, the idea faces multiple challenges with respect to design and implementation in the healthcare industry. Unlike counterparts in manufacturing, constructing a digital twin of a person is more complex and complicated than creating a digital twin of a physical object of a car or plane. Moreover, challenges emanate from the core technology principle that requires successful and sustainable connections [19]. Given that the technology requires a conclusive connection between the real and virtual world for the real interaction, this process has proven difficult and technically challenging for most medical organisations with little resources (ibid). In addition, the technology also requires quality supportive resources such as sensors, databases and sophisticated algorithms for complete data mining and insights (ibid). These are clearly challenging for hospitals with inadequate financial and human resources to manage all these critical phases.

We also note that in general, the medical sector is likely to have difficulties utilising digital twin for outcome prediction [20]. This is related to likely technicalities

and risks involved in providing substantive evidence to support findings generated (ibid). Furthermore, inconsistencies between virtual models and physical objects have also become prevalent, making the whole process "untrustworthy" while possible technical errors in sensor data collection, simulation, or interpretation could lead to irreversible errors (ibid). Most of these errors can be traced back to the divergence between physical and virtual realms that have proven difficult to converge together (ibid). Beyond inconsistencies and errors witnessed, some healthcare facilities have abandoned using these systems due to lack of sufficient IT professionals or the cost to employ sufficient professionals; hence, most hospitals are short of capable personnel with the necessary system integration, monitoring and troubleshooting experience. Just like other technologies, it is challenging to account for the return on investments in using digital twins in healthcare contexts today.

5.6 Future of Digital Twins in Healthcare

The aforementioned considerations notwithstanding, we believe that digital twins have a critical role and future in healthcare. We expect as health 4.0 matures, healthcare organisations will continue using more and more digital health solutions, and thus the opportunities for incorporating digital twins will also increase. Moreover, medical engineers will still require simulating medical situations and digital twins will thus continue to avail the solution [21].

Contemporaneously, machine learning and AI field experts will expand, which will also result in field specialisation, with more healthcare technology-oriented workers expected. We suggest that this growth will be boosted by the need to bridge the gap between the demand and the supply of medical experts. In addition, the growth in subject personnel will also boost technological innovations within the healthcare domain. We also proffer that new digital twin-related inventions will be developed and patients will demand more personalisation in their care treatments.

As sophistication continues to evolve, digital twin technology will not only affect the patient care service delivery but will also improve other key areas. For example, through big data and other analytics, hospitals can draft personalised marketing messages for checkups and other consultative services. Although not fully implemented yet, it is anticipated that digital simulations will have a role in medical services marketing in the future.

5.7 Conclusions

In closing, we contend that digital twins are powerful technology innovations that are likely to revolutionise healthcare delivery as they have manufactured, albeit in a less dramatic, slower fashion. Moreover, we predict that within the next 5 years there will be a plethora of digital twin applications in healthcare. Such proxies of the

physical world will more than likely lead to new treatment protocols and faster recovery as well as better healthcare outcomes and higher patient satisfaction. In addition, we anticipate that such collaboration opportunities among physical world experts and data scientists will ultimately also lead to more expeditious solutions which, in turn, will provide higher value care.

The applications of digital twins, in general, are still in its infancy. However, its benefits have been felt across all industries. Its effects have been characterised by better efficiency and service delivery. This impact is yet to be fully realised in the healthcare sector; however, we believe this will happen in the next few years. Today, medical professionals can use real-time data to simulate medical situations and experiences. This has proved to be useful in providing high-quality medical intervention services. The digital disruption that digital twins will make in the healthcare sector is likely to be significant and bring with it new challenges but the benefits are also likely to be significant including better approaches for treating chronic conditions like diabetes, cancer and mental health issues like Alzheimer's and dementia. Our future research will focus on evaluating several instantiations of digital twins in healthcare contexts.

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Part II
Process Disruption and Process Modelling

Chapter 6
Using Colored Petri Nets for Optimization of Healthcare Processes

Vijay Gehlot, Nilmini Wickramasinghe, Elliot B. Sloane, Michael Kirk, and Eric R. Miller

6.1 Introduction

In recognition of the need to ensure significant incorporation of health information technology into healthcare delivery, the US Government passed the Health Information Technology for Economic and Clinical Health (HITECH) Act, which included incentives to accelerate the adoption of health information technology (HIT) by the healthcare industry. Given that healthcare information technology can dramatically improve healthcare services delivery, reduce cost, improve care efficiency, and patient safety, under a government mandate, hospitals and medical care providers were required to adopt/introduce electronic systems for the management and delivery of healthcare services.

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The adoption of electronic health records (EHRs) and electronic medical records (EMRs) has resulted in a large amount of healthcare data in electronic form that can be computationally processed. Several healthcare organizations are utilizing data mining, machine learning, and related approaches to analyze healthcare data and improve the quality of care. However, data analysis alone cannot give insights into the underlying process. For example, the efficacy of clinical interventions identified by data analysis cannot be evaluated unless the underlying cause and effects are modeled. A report by the US Institute of Medicine emphasizes that many serious errors result from systems and their interactions rather than individual failures [1]. Thus, to effect changes to improve healthcare and to design and deploy better systems for improving human health, we also need to adopt tools and techniques for process modeling, simulation, and analysis.

Although modeling and simulation are widely used in many sectors, their adoption in healthcare has been challenging. A study, reported in [2], investigates modeling and simulation in healthcare against a context of defense and manufacturing industries. The authors report limited evidence of modeling and simulation being used to drive change in the healthcare delivery system. In addition to the complexities of a healthcare system, both [3, 4] identify stakeholder issues as a barrier to the successful and widespread use of simulation in healthcare. Results of a relatively recent survey dealing with modeling and simulation in healthcare are reported in [5]. The key summary of the survey is that modeling in healthcare is perceived to be different and more difficult across a range of factors. Reference [6] highlight three challenges for health modeling: First, how good is good enough, that is, what level of details should be included in models; second, clearly understanding how modeling is linked to decision-making; and third, dealing with the cultural barriers to adoption of modeling and simulation in the health sector.

In 2017, Academic Emergency Medicine convened a consensus conference on *Catalyzing System Change Through Healthcare Simulation: Systems, Competency, and Outcomes* to assess the impact of simulation on various aspects of healthcare delivery. The work reported in [7] is the summary of a breakout session on *understanding complex interactions through systems modeling*. Specifically, it explores the role that computer modeling and simulation can and should play in the research and development of emergency care delivery systems. The authors note that "One underutilized approach to addressing problems in healthcare quality and value, particularly in emergency care, is through the use of computer simulation modeling."

Furthermore, they emphasize that "Not unlike high-fidelity patient simulation for training clinicians in clinical care through the use of mannequins, computer simulation provides a platform to inform decision making prior to implementation in the real world."

Ample data are confirming that the number of emergency visits in the United States is going up whereas the number of emergency departments providing such services is on the decline. Furthermore, COVID-19 forced many hospitals to reevaluate and reengineer their workflows. For example, recently a healthcare facility had to transform from a traditional model of care to a virtual model of care in orthopedic surgery. They followed an OODA (Observe Orient Decide Act) approach toward

this adaptation [8]. Although OODA is a powerful framework [9], it by itself does not provide a mechanism for validation to ensure, for example, patient safety is not compromised by the change. Access to a simulation-based tool, when used in conjunction with the OODA approach, can yield promising results. The authors of [7] note that "Computer simulation should be viewed as a necessary first step prior to implementation of a change in procedure or practice."

As noted earlier, stakeholder issues appear to be a barrier. However, in our own experience, part of the issue is the perceived learning curve associated with the simulation language (notation) and the lack of user-friendliness of associated tools. Even though stakeholders are not directly involved with actual model development, they need to be convinced that the adopted approach is user-friendly and, in particular, the adopted notation is understandable. This is where we see the strengths of a Colored Petri Nets (CPNs)-based approach and the underlying CPN Tools software [10–12]. The basic graphical/visual vocabulary of CPNs is small and intuitive, which renders them an attractive choice for modeling and simulation in healthcare.

The remainder of this chapter is organized as follows. Section 6.2 contains a hospital workflow example as described in [13]. We use this example to build our hierarchical CPN model, which we describe in Sect. 6.4. Before it, in Sect. 6.3, we give an overview of CPN and introduce the vocabulary of the CPN modeling language utilizing a simple example. Section 6.5 contains details of our simulation data collection and results. We present an approach to model verification and validation in Sect. 6.6. Finally, in Sect. 6.7, we present our conclusions.

6.2 Emergency Workflow Example

To illustrate our Colored Petri Nets-based approach, in this chapter we provide details of a CPN model of the emergency workflow described in [13]. The workflow, as described in the paper, is shown in Fig. 6.1. As depicted in this figure, there are two separate paths that a patient may take. The one on the left is taken by emergency patients whereas the one on the right is for elective surgeries where patients are initially hospitalized.

As part of the patient flow, the diagram explicitly depicts various resources that are needed at different stages of the flow. The aforementioned paper focuses on and distinguishes two types of resources: rooms (physical) and hospital staff (human). The various labels and their descriptions are given in [13] are as follows:

- Activity: reception (AA), transfer (AT), induction (AI), surgical operation (AO), and recovery (AR).
- Staff: nurse for reception (RI), anesthesiology staff for induction and operation (MSI), surgical staff for elective surgeries (MSH), surgical staff for emergency surgeries (MSU), nurse assistant (RAS), anesthesiology staff for recovery (MSR).
- Rooms: reception room (MA), induction room for elective surgery (MIH), induction room for emergency surgery (MIU), operating room for elective surgery (AOH), operating room for emergency surgery (AOU), recovery room (MR1).

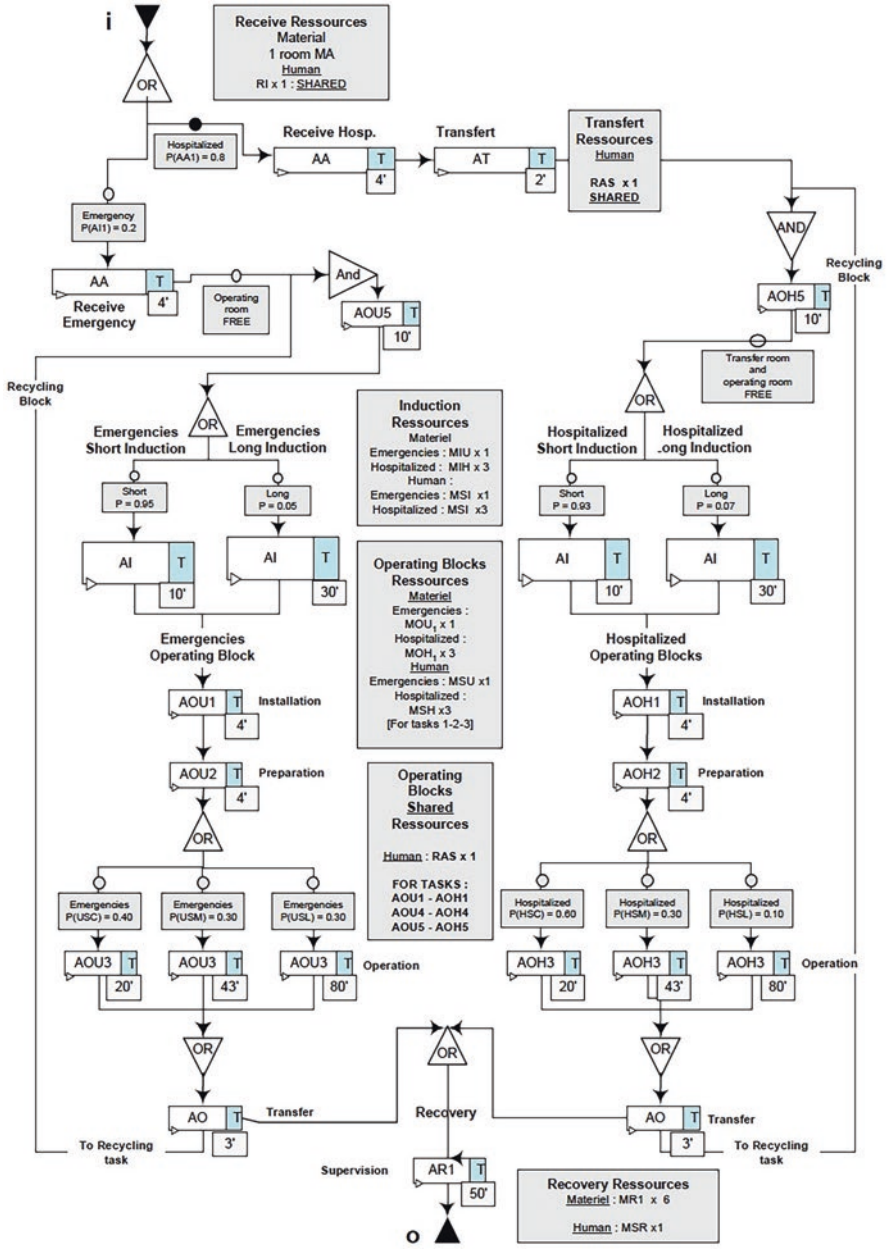

Fig. 6.1 The emergency workflow as described using a Workflow Management Systems (WFMS) notation in [13]. It describes the overall patient workflow in a healthcare system focusing on two different paths to OR, namely, Emergency workflow and Elective workflow

The shown diagram also gives delays in minutes for various activities as well as the probability of various choices. For example, the probability of a patient needing short induction on the emergency side is specified as 0.95, whereas the probability of short induction on the elective side is given as 0.93. In building our model, we use the same label and values where possible. For the benefit of the reader, before going into the details of our model, we give a brief introduction to the CPN vocabulary and modeling approach next.

6.3 Colored Petri Nets

Colored Petri Nets (CPNs) provide a graphical (visual) modeling notation well suited for concurrent and distributed systems in which communication, synchronization, and resource sharing play an important role. A key aspect of the CPN vocabulary is the ability to express a cause and its effect, which allows one to capture a workflow naturally. In terms of depiction, a CPN consists of *places* (depicted as circles or ovals), *transitions* (depicted as rectangles), and *arcs* (depicted as arrows) that connect a place to a transition or a transition to a place. Figure 6.2 shows a very basic CPN consisting of two places (P1 and P2) and one transition (T). We can interpret P1 as "Healthy," T as "Bug Bites," and P2 as "Sick," thereby expressing a cause and its effect.

Places are containers of *tokens*. Depending on the context, tokens may represent a state, a data value, a resource, or some other entity. Transitions represent (abstraction of) actions. The cause and effect dynamics of a CPN are defined using the *firing rule*, whereby tokens are removed from input places of a transition and deposited in the output places of a transition. Thereby, recording the fact that the associated action has occurred. The distribution of tokens across places in a net is called a *marking* and describes the global state of the system being modeled. As mentioned earlier, another crucial aspect of the CPN notation is its ability to express sharing of resources and associated constraints, which are also inherent to healthcare workflows. For example, the availability of an operating room or an infusion pump is a resource constraint that would be part of the flow of care in a hospital dealing with trauma patients.

The basic execution semantics of a CPN in terms of the firing rule above gives rise to several interesting net configurations and associated interpretations that are natural in modeling workflows. Figure 6.3 depicts some net configurations useful for expressing various communication and coordination activities that form part of typical healthcare workflows. For example, the *Sequential* configuration is useful in capturing the dependency that a patient must register at the front desk before being

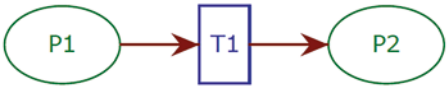

Fig. 6.2 A simple Colored Petri Net with two places and one transition

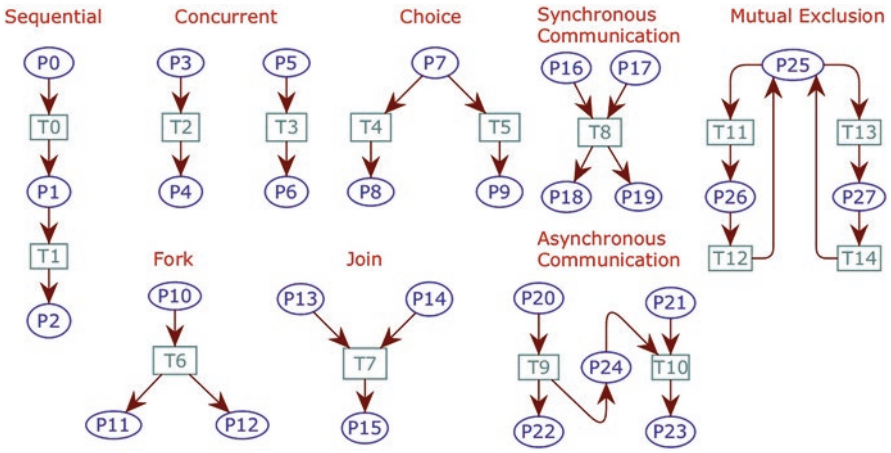

Fig. 6.3 Useful CPN configurations for modeling workflows and associated constraints [10]

examined by a nurse or a doctor. The *Concurrent* configuration captures the independence of events or flows. For example, a patient being checked for blood pressure is totally independent of another patient being checked into a trauma center. Therefore, these two actions can happen concurrently. The *Choice* configuration is useful in capturing the flow where two or more options are possible. For example, surgery or medication option for treating a tumor. The *Join* configuration provides a synchronization mechanism. For example, all test results must be in before proceeding further with the possible diagnosis or treatment. The *Synchronous Communication* is a generalization of the *Join* whereby it allows multiple outcomes. The *Asynchronous Communication* easily captures the flow where a test sample can be delivered to a lab by the clinical staff and then the lab can process it asynchronously without the staff waiting for it. Finally, the depicted *Mutual Exclusion* is useful in expressing resource-sharing constraints such as a single nurse cannot be attending to two different patients at the same time or a single monitor cannot be hooked to two different patients at the same time.

To explain the basic CPN notation further and its capability, we consider a concrete example of a very simple workflow where patients waiting for surgery can be taken in for surgery only if there is an operating room available. For this example, we are ignoring other resources, such as surgical staff, surgical instruments, and patient monitoring devices. The net in Fig. 6.4 captures this basic workflow. In this net, the active tokens are shown in small green circles. In this initial state, there are two *Available Operating Rooms*, as depicted by the associated token, and five *Patients Waiting for Surgery* as indicated by the associated token. The transition *In Surgery* can fire only if a patient is waiting (at least one token in the place named *Patients Waiting for Surgery*) and an operating room is available (at least one token in the place named *Available Operating Rooms*). The net in Fig. 6.5 is a snapshot of the next simulation step showing the state where one surgery is in progress (one token in the place named *Surgery in Progress*) and only one operating room is available, that is, the token count of *Available Operating Rooms* is now down to 1. At this

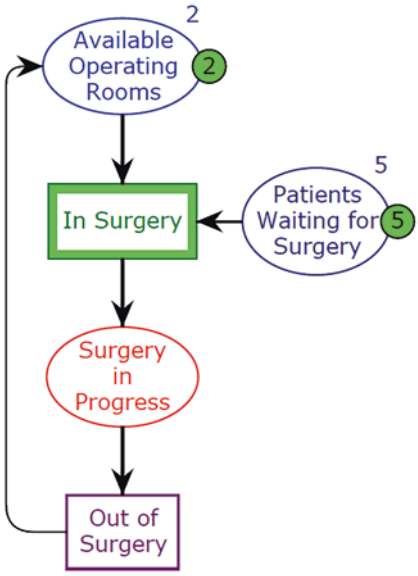

Fig. 6.4 A CPN model of a very simplified operating room workflow taking into account just the room availability. The net shows initially we have two operating rooms and five patients waiting

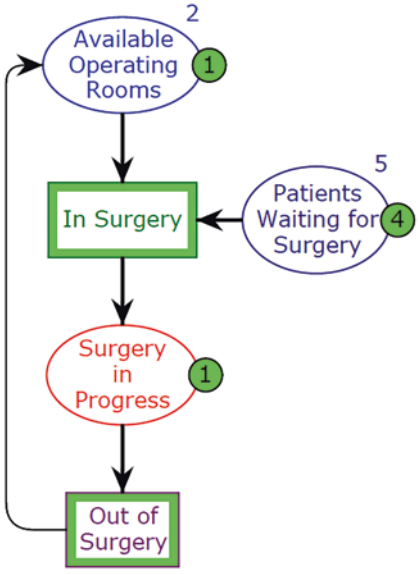

Fig. 6.5 The net showing a simulation state with 1 surgery in progress and 1 room available

stage, either another waiting patient can be taken in the surgery, or the current in surgery patient can be out of surgery or both since in the depicted net, both *In Surgery* and *Out of Surgery* transitions are simultaneously enabled (highlighted in green) and can fire. The net in Fig. 6.6 depicts the state where we have two patients in active surgery and we cannot take the next patient in since there is no token in *Available Operating Rooms* thereby disabling the *In Surgery* transition (not highlighted in green) although we have three more patients waiting. Once one of the

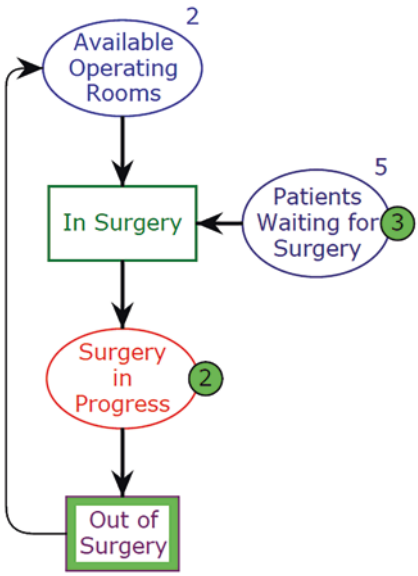

Fig. 6.6 The net showing the state where 2 active surgeries are in progress and we cannot take any more patients since the transition *In Surgery* is not enabled (highlighted in green)

currently active surgeries is done, a token representing room availability will be deposited in *Available Operating Rooms* via the arc connecting the transition *Out of Surgery* to *Available Operating Rooms*.

With this given background, we are now ready to describe the details of our CPN model. Readers interested in more details of CPN, including formal definitions and theoretical foundations, may refer to [14, 15].

6.4 CPN Model Details

We give details of our hierarchical CPN model that captures the details of the workflow shown in 1. The creation of hierarchical nets is based on the simple idea that any transition can be replaced or substituted by a (sub) net that details the activities underlying it. Such transitions are called *substitution transitions* (or *modules*) in the CPN parlance. Pictorially, a substitution transition is drawn with double rectangles.

The (hierarchical) net in Fig. 6.7 shows the overall patient workflow starting with the entry of a patient from reception to the exit from the recovery system. The shown patient workflow net consists of four modules, namely, *Patient Entry*, *Emergency Workflow*, *Elective Workflow*, and *Recovery*, and five places namely *To Emergency*, *To Elective*, *From Emergency*, *From Elective*, and *Discharge*. The diagram in Fig. 6.8 shows the module hierarchy, that is, the various sub-modules and their nesting structure that comprises our hierarchical model.

The tokens in the basic model in Fig. 6.4 do not carry any information. For a detailed analysis, we may want to carry additional information in tokens. For example, we may want to distinguish different types of operating rooms or patients with

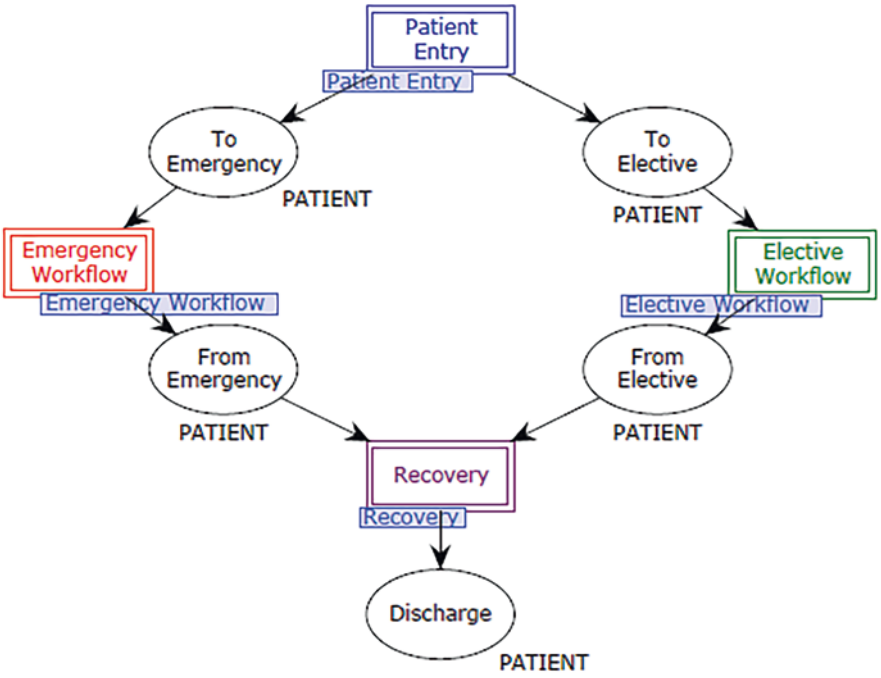

Fig. 6.7 The top-level net showing the overall workflow and associated modules

different conditions. CPNs provide an enhanced vocabulary to create tokens of different data types (or *colorsets* in CPN parlance) and utilize the full functionality of the underlying inscription language CPN ML, which is built on top of the functional programming language SML [16]. Before going into details of some of the submodules, we give a brief description of key colorsets used in this model below:

```
(* Model colset declarations *) colset PTYPE = with EM | EL; colset
PID = INT;
                colset PID_T = PID timed; colset AT = INT;

colset PATIENT = product PTYPE * PID * AT; colset PATIENTS = list
PATIENT;
               colset ROOM = with MA | MIU | MIH | AOU | AOH | MRI
| WR; colset ROOMS = list ROOM;
                colset HR = with RI | MSI | MSH | MSU | RAS | MSR;
colset STAFF = list HR;
                  colset PSTAT = product PATIENT * ROOMS * STAFF;
colset PSTAT_T = PSTAT timed;
                colset HRACT = product HR * ROOM timed;
```

Fig. 6.8 The module hierarchy of the CPN model. The module hierarchy depicts the various sub-modules and their nesting structure that comprises our hierarchical model

- OperatingRoomWorkflowNet
  - PatientWorkflow
    - Elective Workflow
      - Elective Reception
      - Transfer Activity
      - Elective Induction
        - Short Elective Induction
        - Long Elective Induction
      - Elective Operation
        - Elective Surgery
          - Short Elective Surgery
          - Average Elective Surgery
          - Long Elective Surgery
        - Clean Elective OR Block
        - Elective Preparation
    - Emergency Workflow
      - Emergency Reception
      - Emergency Induction
        - Short Emergency Induction
        - Long Emergency Induction
      - Emergency Operation
        - Emergency Surgery
          - Short Emergency Surgery
          - Average Emergency Surgery
          - Long Emergency Surgery
        - Clean Emergency OR Block
        - Emergency Preparation
    - Recovery
      - Enter Patient Waiting Area
      - Patient Recovery
    - Patient Entry

These types are used to carry the following information, which is used in the model description, creation, and simulation:

- `PTYPE` or patient type allows us to distinguish emergency `EM` from elective (`EL`). In general, a more complex type may be associated that will allow other patient or application-specific attributes.
- `PID` is patient ID and `PID_T` is the associated timed version. The latter allows the creation of the timed tokens to account for various delays and processing times.
- `PATIENT` is a compound type consisting of patient type, patient ID, and patient's arrival time. `PATIENTS` is a list of patients useful in describing a queue.
- `ROOM` is a room type based on the workflow described above and `ROOMS` is used to represent a set of rooms.
- `HR` is a human resource type per the workflow described above and `STAFF` is a list of those.
- `PSTAT` is a compound type that captures the status of a patient in terms of assigned rooms and assigned staff. `PSTAT_T` is its associated timed version for

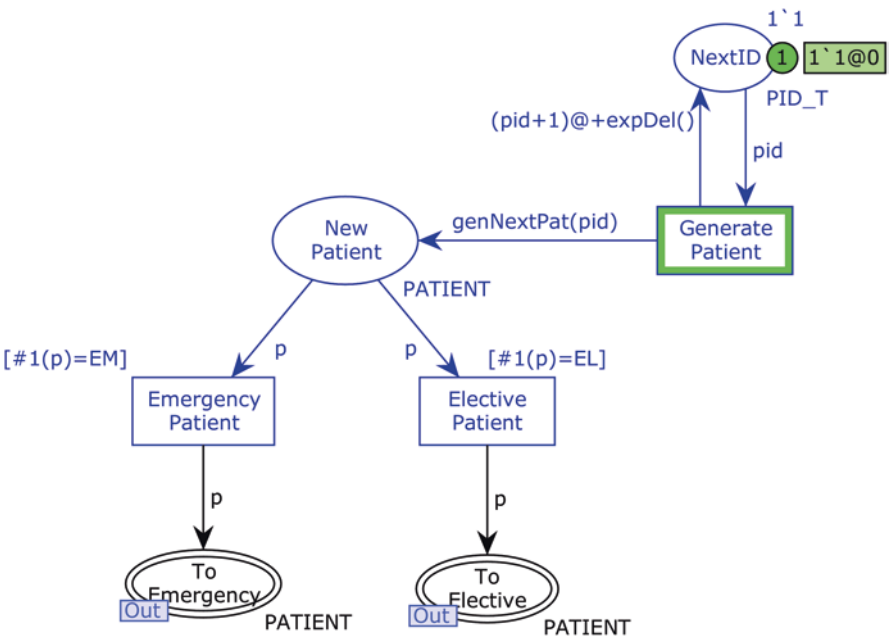

Fig. 6.9 The *Patient Entry* module responsible for the generation of patient traffic

performance metrics. `HRACT` is a compound type denoting which human resource is active (or assigned to) in which room. It is a timed colorset for performance metrics.

We start with the module *Patient Entry* module, which is shown in Fig. 6.9. This module is responsible for generating patients who either go for elective or emergency surgery. The original paper [13] specifies 80% to be elective surgeries and 20% to be emergency surgeries as shown in Fig. 6.1. However, it does not specify any arrival pattern or rate. Thus, in this chapter, we have assumed the interarrival time to be exponentially distributed. Using the file input/output and external process communication faculties of the CPN Tools, we can certainly drive a CPN simulation based on an actual log of patient arrivals if available. Internally, this module utilizes the type `PID_T` to generate a timed token with the next patient ID and arrival time. Based on this information, a token of type `PATIENT` is generated, which will move either to *To Emergency* or *To Elective* depending on the `PTYPE` value of the token.

NextID place represents the state of the number of patients with their waiting times. When *Generate Patient* transition occurs, it puts back a token in *NextID* with the next number and randomly generated a waiting time for the next patient. The CPN ML function `genNextPat(pid)` on the arc from *Generate Patient* is responsible for generating a patient token and depending on the patient type of this token, it will move either *To Emergency* or *To Elective*.

After this, the patient (or token) will follow the *Emergency Workflow* module or the *Elective Workflow* module of the net shown in Fig. 6.7. The two workflows

essentially differ in terms of the *Transfer Activity* module as given by the module hierarchy diagram in Fig. 6.8. We, therefore, focus mainly on the details of the *Emergency Workflow* module. Specifically, we present details of the following sub-modules: *Emergency Induction*, and its sub-module *Long Emergency Induction*; *Emergency Operation* and two of its sub-modules, namely, *Emergency Preparation* and *Long Emergency Surgery*; and finally the *Patient Recovery* module.

The next two modules, *Emergency Induction* and its sub-module *Long Emergency Induction* are shown in Figs. 6.10 and 6.11, respectively. Neither [13] nor Fig. 6.1 indicates an explicit queue, but in our model, we have put an explicit queue at the start of various activity stages for better accounting of delays. Otherwise, multiple tokens in a place are viewed as a multi-set with no specific order. As shown in the figure, when the transition *Add to Queue* fires, the incoming patient token will be added to the *Emergency Induction Queue*. The next patient in the queue enters the

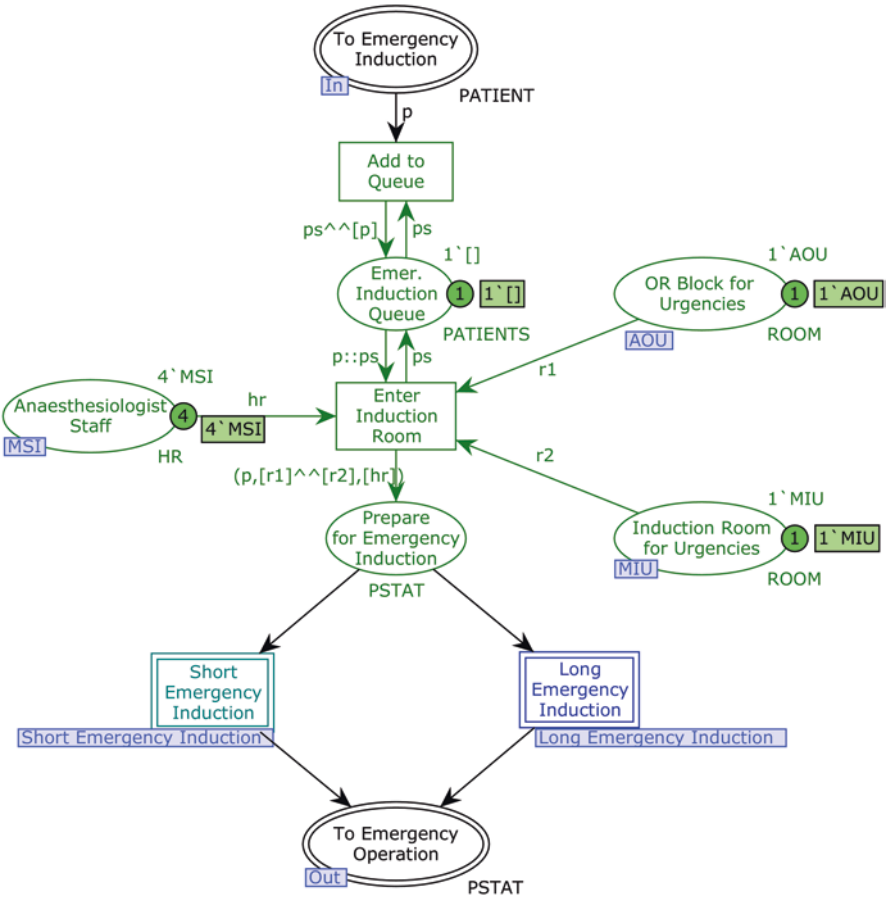

Fig. 6.10 The *Emergency Induction* module as shown in the module hierarchy of *Emergency Workflow* in Fig. 6.8

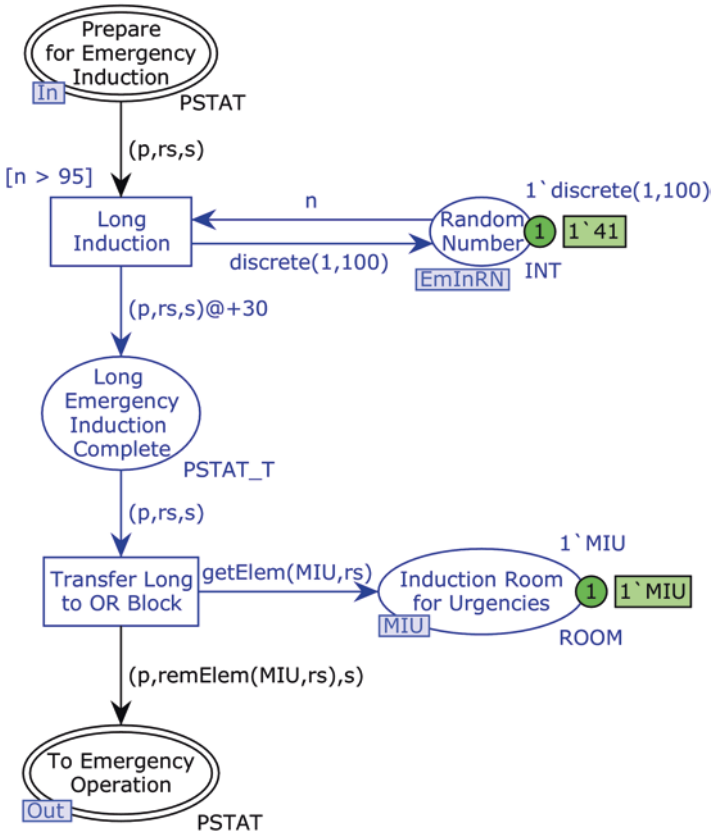

Fig. 6.11 The sub-module *Long Emergency Induction* of the *Emergency Induction* module as shown in the module hierarchy of *Emergency Workflow* in Fig. 6.8

induction room only if *OR Block for Urgencies* and *Induction Room for Urgencies* is available.[1] Additionally, it requires the availability of an *Anesthesiologist Staff*. All these resource constraints are captured in a very simple and visual manner by the incoming arcs of the *Enter Induction Room* transition in the figure.

The net in Fig. 6.11 shows the *Long Emergency Induction* module. The Boolean condition `[n > 95]` on the transition *Long Induction* and the random number in the connecting place *Random Number* guarantee the probability of long induction to be 0.05, as specified in Fig. 6.1. Note that the place *Random Number* is shared with the activities of the corresponding *Short Emergency Induction* (not shown) to ensure that both modules are using the same number in determining the firing of the associated transition. This sharing is achieved via the CPN notion of a *fusion set* whereby a set of places may be fused as one by associating a fusion tag with those

[1] We are using the term Urgency instead of Emergency per the original paper.

places. We have used the fusion tag *EmInRN* as shown in the figure above. An associated timed token in *Long Emergency Induction Complete* determines the time for long induction.

After induction, a patient moves to *Emergency Operation*, which itself consists of two sub-modules: *Emergency Preparation* and *Emergency Surgery*. As depicted in Fig. 6.1, emergency surgeries can be either of short duration or average duration or long duration. We only include the *Long Emergency Surgery* module here since the other two are similar. Figures 6.12 and 6.13 show the two sub-modules *Emergency Preparation* and *Long Emergency Surgery*, respectively. As shown in the associated net, *Patient Installation* requires the availability of *Medical Staff for Urgencies* and *Nurse Assistants*. Once *Patient Preparation* is finished, the *Nurse Assistant* becomes available for other patients as captured by the outgoing arc from *Patient Preparation* to *Nurse Assistant*. At this stage, the human resource *Medical Staff for Urgencies* is considered still in use, that is, busy. The prepared patient then enters *Emergency Surgery*. A patient requiring long surgery will follow the net depicted in Fig. 6.13. The Boolean condition `[n > 7]` on the transition *Long Emergency Surgery* and the random number in the connecting place *Random Number* guarantee the probability of long surgery to be 0.30, as specified in Fig. 6.1. An associated timed token in *Patient in Long Emergency Surgery* determines the time for surgery. When done, that is, the transition *Complete Long Surgery* fires,

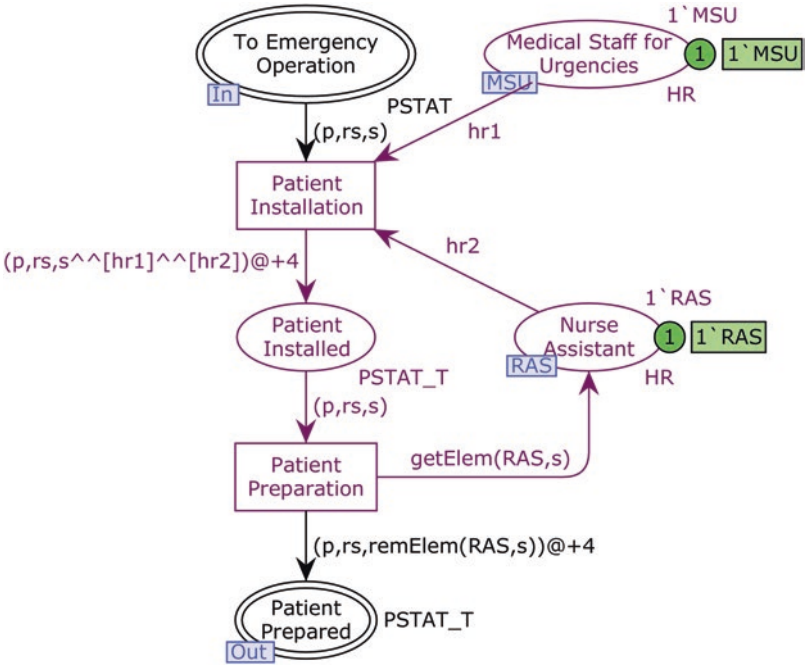

Fig. 6.12 The *Emergency Preparation* sub-module of *Emergency Operation* as shown in the module hierarchy of *Emergency Workflow* in Fig. 6.8

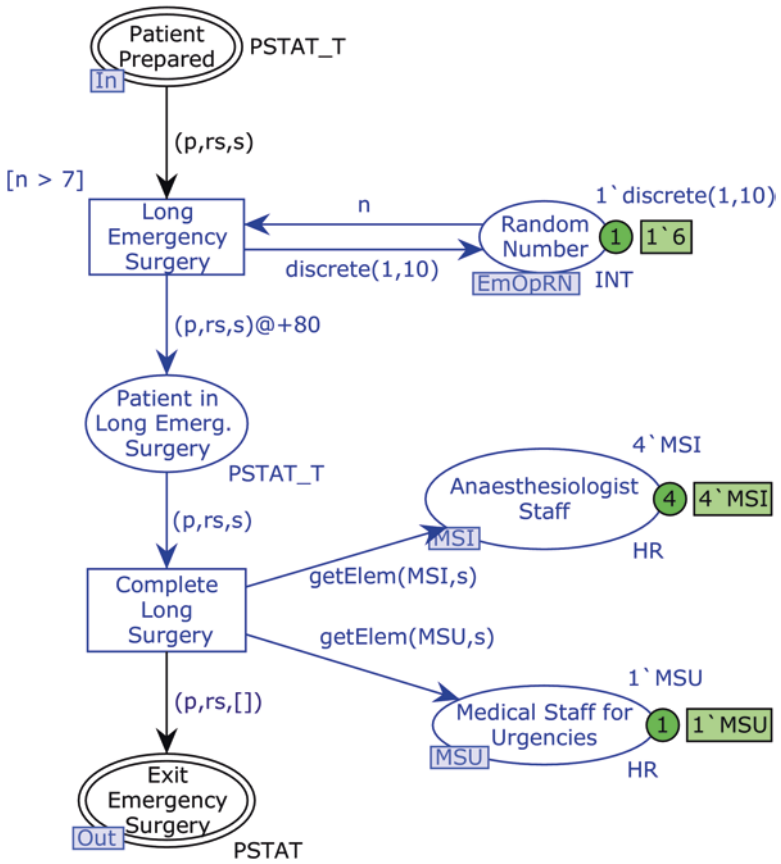

Fig. 6.13 The *Long Emergency Surgery* sub-module of *Emergency Operation* as shown in the module hierarchy of *Emergency Workflow* in Fig. 6.8

both human resources, namely, *Anesthesiologist Staff* from the induction stage and *Medical Staff for Urgencies* from the patient preparation stage are returned to their respective free pools.

The final stage is patient recovery. The associated *Patient Recovery* sub-module is shown in Fig. 6.14. As depicted in the associated net, Transfer to Recovery Room requires availability in the *Recovery Room* and an available *Anesthesiologist Staff for Recovery*. At this stage, the *Nurse Assistant* and the *Waiting Room* from the previous stage are returned to their respective free pools. An associated timed token in *Enter Recovery Room* determines the time for recovery. Once the recovery is complete, that is, the model time reaches the time stamp on the timed token, and the *Recovery* transition fires, the room and the staff are returned to their respective free pools, and the patient is moved to *Discharge*.

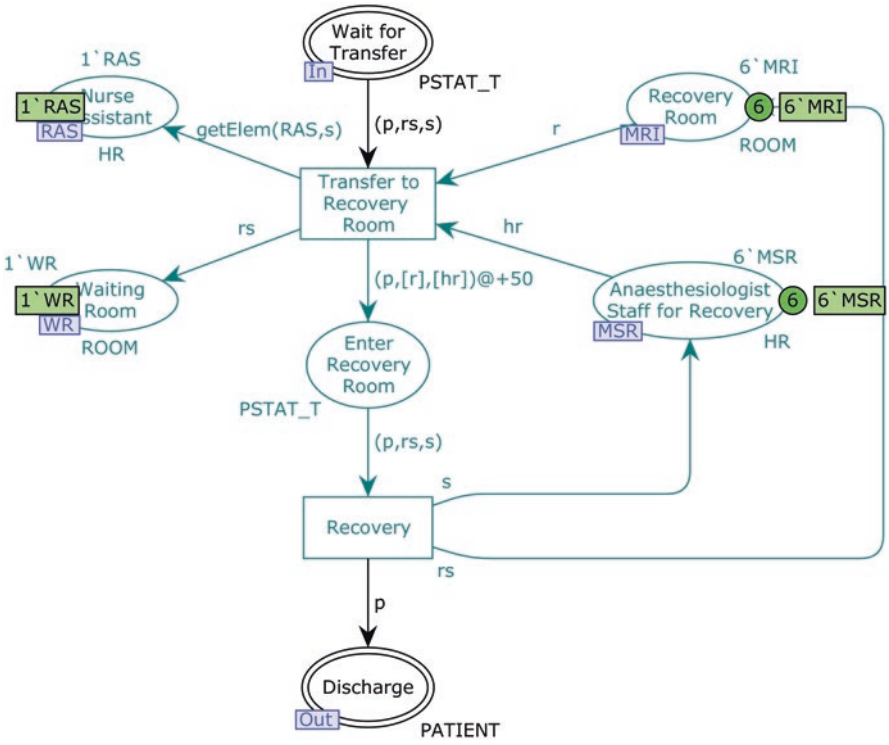

Fig. 6.14 The *Patient Recovery* sub-module as shown in the module hierarchy of *Emergency Workflow* in Fig. 6.8

This completes the discussion of our hierarchical CPN model. Next, we briefly describe the monitoring faculties of CPN Tools we utilized to collect data and generate performance reports.

6.5 Data Collection and Results

CPN Tools provide a monitoring facility to conduct performance analysis of a system [17]. Monitors are used to extracting relevant data during a simulation run. Monitors can be associated with any subnet of interest. Different types of monitors can be defined for a net. For example, a *simulation breakpoint monitor* can be used to stop a simulation run based on a specified condition. A *data collector monitor* is used to extract numerical data from a model during a simulation and to calculate statistics for the extracted data. The statistics that are calculated for a particular data collector are either untimed statistics or timed statistics (that is, time-dependent weighted statistics). The statistics that are computed and can be accessed from each data collector monitor are: count (number of data observations), minimum,

maximum, sum, average, confidence intervals for average, variance, standard deviation, the sum of squares, the sum of squares of deviation, first value observed, and last value observed. Once monitors have been created, the built-in function `CPN'Replications.nreplications` can be used to run any number of simulation replications, collect data, and calculate, among other values, 90%, 95%, and 99% confidence intervals for averages. It also auto-generates a *performance report* containing statistics, including confidence intervals, that are calculated for the *independent and identically distributed* (IID) data values in the replication output log files.

We set a breakpoint monitor for a 24-h period and ran simulation replications with a medium traffic flow with an average inter-arrival of 1 h and another with intense traffic flow with an average inter-arrival of 10 min. Table 6.1 contains some data from the first replication run. Our results show that the utilization rates of both the anesthesiologist staff and recovery rooms were low, highlighting a potential area to save resources. Furthermore, while the nurse assistant maintained a comfortably high utilization rate, the rate of the reception nurse was much lower, showing the potential of reclassifying them into a shared resource.

6.6 Model Verification and Validation

The starting point of building a simulation model should always be a conceptual model [18]. One may utilize an informal notation or a formalized notation in describing a conceptual model. Typically, the notation should be expressive enough to capture the key requirements. In general, a conceptual model is a blueprint for the computer (or simulation) model to be built. Once a model has been created, a key exercise is to carry out the verification and validation of the model. Towards this end, we recommend adopting the approach described in [19].

According to [19], *verification* is the process of determining that a model implementation accurately represents the conceptual description and specifications whereas model *validation* is the process of determining the degree to which a model is an accurate representation of the real world. In particular, "...operational validation is carried out to determine the simulation model's output behavior has the accuracy required for the model's intended purpose over the domain of the model's intended applicability."

Model building is a collaborative process and both verification and validation steps require input from the stakeholders and subject-matter experts [20]. Additionally, the validation step requires access to data from actual operations. Verification ensures that the key requirements have been captured by the model. Both verification and validation are iterative processes and should be carried out hand in hand with model building, preferably following an agile approach. In the past, quality data for healthcare applications may not have been readily available in all situations of interest, but with the advent and progress of digital health, a modeler may have easier access to data of interest. In the validation step, data generated

Table 6.1 Sample data from the auto-generated performance report after five simulation replications run of the model for a set of input parameters

Name	Avrg	90% half length	95% half length	99% half length	StD	Min	Max
AOH_Util_Rate							
count_iid	42.400000	6.052778	7.881103	13.070820	6.348228	32	49
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.558624	0.070717	0.092078	0.152711	0.074168	0.457873	0.658333
AOU_Util_Rate							
count_iid	7.800000	2.730292	3.555015	5.895997	2.863564	4	12
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.230602	0.134498	0.175125	0.290445	0.141063	0.080378	0.427827
Elective_MWT_Before_Induction							
count_iid	21.800000	3.529088	4.595098	7.620976	3.701351	16	26
max_iid	32.800000	25.112390	32.697934	54.229570	26.338185	9	70
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
sum_iid	88.200000	64.103394	83.466708	138.429656	67.232433	29	182
avrg_iid	3.916977	2.503606	3.259854	5.406473	2.625813	1.260870	7.000000
Emerg_MWT_Before_Induction							
count_iid	4.000000	1.348395	1.755697	2.911825	1.414214	2	6
max_iid	15.600000	15.382938	20.029566	33.219064	16.133815	0	41
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
sum_iid	16.200000	15.672738	20.406904	33.844881	16.437761	0	41
avrg_iid	3.366667	2.801055	3.647152	6.048806	2.937781	0.000000	6.833333
MR1_Util_Rate							
count_iid	48.000000	7.627675	9.931720	16.471771	8.000000	36	58
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1

min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.476619	0.028060	0.036535	0.060594	0.029429	0.432046	0.513455
MSI_Util_Rate							
count_iid	50.200000	8.591722	11.186970	18.553606	9.011104	36	61
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.491670	0.066555	0.086659	0.143724	0.069804	0.386145	0.581944
RAS_Util_Rate							
count_iid	191.600000	30.995497	40.358114	66.933990	32.508460	140	230
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.319927	0.051208	0.066676	0.110583	0.053708	0.234559	0.383495
RI_Util_Rate							
count_iid	52.600000	9.667157	12.587255	20.875980	10.139033	37	65
max_iid	1.000000	0.000000	0.000000	0.000000	0.000000	1	1
min_iid	0.000000	0.000000	0.000000	0.000000	0.000000	0	0
avrg_iid	0.071194	0.013382	0.017424	0.028898	0.014035	0.049827	0.088520
Total_Patient_Time							
count_iid	24.000000	3.813838	4.965860	8.235886	4.000000	18	29
max_iid	192.600000	24.267368	31.597661	52.404766	25.451915	167	220
min_iid	92.000000	6.105119	7.949254	13.183850	6.403124	85	97
sum_iid	2996.600000	627.867521	817.523564	1355.864008	658.515224	2061	3864
avrg_iid	123.928798	6.786832	8.836888	14.655991	7.118113	114.500000	133.241379

by a verified model is compared against real-life data and the model is fine-tuned by changing parameters, if necessary, to align with the real data.

As mentioned earlier, for data generation and validation purposes, CPN Tools software provides an extensive monitoring and simulation report generation facility [17]. A simulation report provides a complete execution trace of the model whereas a monitor is a mechanism in the CPN software that is used to observe, inspect, control, or even modify a simulation of a CPN. A variety of monitors can be defined for a given net. Monitors can inspect both the markings of places and enabling of transitions during a simulation, and they can take appropriate actions based on the observations as well as extract relevant data. It is only after the validation step that one should use a simulation model to evaluate "what-if?" scenarios for implementing changes in the underlying actual operations. The interactive simulation tool available in the CPN Tools software can be used for incremental model verification. It allows a modeler to step through various markings and even set desired markings in an interactive manner. Using this facility, a modeler can check whether the desired specifications have been captured in the model.

6.7 Conclusion

Adoption of modeling and simulation in healthcare continues to be a challenging issue. One key barrier is buy-in from the stakeholders. Certainly, as noted by [7], simulation-based approaches can help improve patient safety and help better manage resources in a costly and constrained system like healthcare. Of particular importance is emergency care since there is data confirming that the number of emergency visits in the US is going up whereas the number of emergency departments providing such services is on the decline. Furthermore, COVID-19 forced many hospitals to re-evaluate and re-engineer their workflows but in absence of any simulation-based tools, there is no simple way to evaluate the impact of such changes. In our own experience, we have found a Colored Petri Nets-based approach to be less of a barrier for the stakeholders owing to a simple and visual graphical representation of the net model and its associated intuitive semantics. Furthermore, the free CPN Tools software with its visual editing and simulation capabilities renders it a very user-friendly environment for model development and analysis. We illustrated our approach by employing an operating room workflow and taking into account a variety of resources and constraints (room and staff availability) in a natural manner using the hierarchical CPN notation. The modular approach offered by the hierarchical CPNs allows a model to be constructed incrementally and, therefore, supports a very agile approach. We presented details of data collection and summarized our results. We provided an approach for the verification and validation of CPN models.

As we now move into a post-COVID world, healthcare organizations also need to find the new normal. At this stage there are too many unknowns and uncertainties; however, we do know that more and more focus is now being placed on virtual care

models and possibilities. We contend that CPN modeling can be of great help and a strategic tool when trying to model and understand specific scenarios in healthcare contexts in which several divergent elements such as effectiveness, value, human input, and interactions must be tracked. In conclusion, given the advances in digital health and the availability of rich digital health data, we can make model-driven healthcare a reality to help improve patient safety and reduce cost.

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Chapter 7
Toward Concept Realization of Digital Health Technologies

Ruwini Edirisinghe

7.1 Introduction

With exponential technological growth, digital healthcare applications are emerging. In contrast with traditional technology- or platform-centric solutions, this new paradigm of patient-centric solutions aims to deliver better healthcare and to enhance wellness more effectively.

Home-cared elderly people, those who need monitoring-based assistive services, can benefit from such patient-centric solutions. As Norris, Stockdale, and Sharma [1], argue, these solutions enhance home-cared elderly people's quality of life by allowing them to live independently [2]. In addition, such technological solutions contribute to the economy positively due to the reduced hospitalization rates and cost of care.

According to Magnusson et al. [2], digital health systems provide services for three different stakeholder groups: for elderly patients living at home, for family caregivers, or for both groups. They go on to suggest that problems faced by eldered people include unavailability of ready access to a computer [3], or being unfamiliar with computers, which could discourage adoption, and can be ameliorated through targeted training to familiarize consumers with the relevant technology in their day-to-day activities.

As highlighted in Gov2020 [4], digital health will be a major motivation for future healthcare innovations. However, elderly consumers still show a slow adoption of digital health applications, despite smart mobile phones having been pervasive for almost two decades. Several studies on elderly people have found that older adults as a consumer group (aged over 50) remain reluctant to adopt smartphones [5–7]. As Edirisinghe [5] highlighted, more recent studies, too, show that such

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consumers are still reluctant to use smartphone services [8]. Among the major barriers to adoption are financial limitations due to retirement, age-related physiological challenges such as vision impairments, sociological, and psychological factors [8, 9] such as lack of technical skills and lack of interests [6, 10]. In addition, Berenguer et al. [8] state that seniors often do not take up digital health systems and services because they are not particularly designed for them. Supportively, Edirisinghe [5] argues that such technologies do not accommodate the lifestyle changes seniors experience and nor do they meet their needs. A study surveyed 90% of US elderly people found that they preferred to 'age in place' [11]. Edirisinghe [5] called for research by highlighting the significant responsibility such preferences place on healthcare researchers and technology providers to better support for independent living of this unique consumer group.

This chapter unpacks the innovation process for the development of patient-centric, innovative technology solutions for the coming digital health era. The example consumer group selected to demonstrate the concepts is elderly home-cared patients.

The next section presents monitoring technologies (which cover home monitoring systems, assistive technologies, and wearables) developed for elderly people since 2004.

Then a technology-based system for the digital era patient is proposed, along with an Internet of Things (IoT)-smart garment-based monitoring system. The idea generation stage for a prototype to assist elderly home-cared patients is also discussed.

Third, the chapter describes an innovation lifecycle based on technology readiness levels—vital to the effectiveness of the digital health technology development process.

7.2 Literature Review

7.2.1 Digital Health Solutions

An extensive review of the literature in digital health solutions [5] revealed that the existing evaluations and classifications were limited to a technology point of view. For example, a review conducted by Bozan and Berger [11] classified the technologies developed for ambient assisted living based on the advancement of the technology as first, second and third generation. Their classification was based on the detection, responsiveness, and prevention functionalities of each of the technology.

Edirisinghe, Stranieri, and Wickramasinghe [5] addressed this research gap by presenting a taxonomy for Mobile Health (mHealth). In addition to the technology aspect, this research investigated the often-ignored clinical, economic, and social aspects. The cohesive taxonomy presented by Edirisinghe, Stranieri, and Wickramasinghe [5] is based on technology, clinical, social, and economic dimensions. Each of the dimensions is composed of critical parameters where: (1)

technology dimension includes context parameters, communication aspect, scope of access, and technology evaluation; (2) clinical dimension includes clinical focus, clinical purpose, consumer group, and clinical evaluations; (3) economic dimension includes business case, change management, and disruptive technology; and (4) social dimension includes social context, end user, and usability. Edirisinghe, Stranieri, and Wickramasinghe [5] further highlighted the challenges pertaining to the slow adoption in mobile health and called for research in patient-centric solutions while supporting the needs of healthcare providers.

7.2.2 Digital Health Solutions for Elderly Consumer Group

A growing interest appeared in the literature around assistive digital health systems for elderly people living in their own homes. Literature also argued that the technology adoption of elderly people as a consumer group is slow [6, 7] and remained in its infancy [8, 10]. Their reluctance to adopt smartphones and associated services was mainly because of the ignorance of the practical aspects such as ease of use and user-friendliness more specific to this non-technology-savvy elderly consumer group [7, 8]. It is also vital to develop systems considering personal needs, capabilities, lifestyle, and aging process of home-cared elderly consumer group.

Body Area Network (BAN) [12] based home monitoring systems proposed for the elderly people monitor environmental variables such as light [13], audio signals [14], accelerometer data [15], active household appliances use [16], and image-processing to monitor occupants and falls [17] and to predict falls [18]. BANs also monitor wearer's physiological parameters [19–22] such as blood pressure [23] to generate smartphone-based alerts to the healthcare providers [24] and to provide various home assistive systems [25] ranging from robotic mobility assistance [26] to social robots functions [27], whereas some solutions were tailored for specific groups such as people with disabilities [28] and dementia [29, 30].

Despite the critiques [31] regarding the social robots' ability to fully satisfy the specific needs of elderly people and unverified reliability in detecting those needs, it is notable that researchers are attempting to provide personalized solutions [27] through personalized care modes.

More recently, Al-khafajiy et al. [32] propose a home-based monitoring system composed of a wearable connected to a smartphone app. In this study, heart rate was communicated via an email notification. Any abnormalities are communicated to the doctor. The practicality and ease of use in the system are yet to be evaluated because of the unrealistic expectation to wear the sensors all the time by the patients. In addition, it is expected that the elderly person used the smartphone to use this solution.

As technologies advance, the motivation of the researchers and developers to offer simple, easy-to-use systems for home-cared elderly people is attracting less attention. Wearable garments designed for elderly people are also of particular interest due to the style of interaction that the consumer group prefers. To address this

knowledge and practice gap, this chapter presents a smart garment-based system for home-cared elderly people with a particular emphasis on the innovation lifecycle.

7.3 The Patient of the Future Digital Health Era and Proposed Healthcare Monitoring System

The proposed system monitors patients in real-time. The system is robust enough to be installed in both indoor and outdoor settings and is composed of a cloud-based wireless sensor network to gather environmental parameters. The wearer's general health conditions and activities such as movement are monitored through a wearable garment. The data, transmitted to the smart handheld device, is fed to a web server through Wi-Fi or the cellular network. The proposed system is compatible with communicating to a personal smartphone or wall-mounted tablet. The proposed future IoT-based health monitoring system is an indoor setup. Outdoor environmental sensors such as local weather stations will be utilized in the case of outdoor monitoring.

The proposed system has two forms: (1) a simple smart garment-based system to warn anomalies for the patient's caregivers or the wearer; and; (2) a more cohesive system to assist a wide range of stakeholders, including emergency services, clinicians, caregivers, and hospital staff. Such caregiving consumer groups generally have extensive experience in adopting advanced features of smart devices and smart device-based services, unlike elderly consumers, who are reluctant to use them [6–8, 10].

The system is composed of the following sensors:

1. **Wearable sensors attached to the garment:** sensors that can measure various health variables, such as body temperature, heart rate, blood pressure, electrocardiogram (ECG), muscle activity and other biomedical conditions, and motion/activity are attached to the garment. The IoT-based smart garment can ultimately communicate with a smart device placed at home or a personal smartphone.
2. **Environmental sensors:** the conditions of the surroundings (indoor or outdoor) are monitored using sensors to collect various environmental parameters. These include sensors that can measure temperature, light, pressure applied on furniture such as bed (to detect falls), room proximity detection (to detect presences of the person in a particular room), humidity, and the presence of gas and smoke. Outdoors, local weather stations, or mini weather sensors can be used to capture relevant environmental parameters for the setup.

Considering an industry application for example, if the patient/person monitored is a construction worker, the environment where they work will be mostly outdoors. A future construction worker on a pervasive construction site [33] can use the proposed system to enhance health and safety in this workplace because heat stress is a significant risk in the industry [34].

The sensors in the smart garment form a BAN. They detect various parameters and then communicate with the mobile device via Bluetooth/Wi-Fi. The environmental sensors installed indoors or outdoors, communicate via Wi-Fi. This information flow enables the elderly patient's self-education. The mobile application visualizes the information and assists the patient in managing their own self-care. The data are ultimately communicated to the cloud-hosted web server. This cloud-enabled patient information will be sent to healthcare providers and relevant parties such as physicians, clinicians, emergency services, ambulances, and hospitals.

The patient-centric monitoring feature alerts the patient about abnormalities either through the sensors themselves or through the system. Other healthcare system stakeholders/end-users can access the relevant information through the cloud in real time. Server functionalities include abnormality detection and prediction. This enables visualization of patient's activities in real time. A prototype version of the proposed system is discussed in this chapter.

7.4 Smart Garment Prototype

Van Langenhove and Hertleer [35] (p. 63) define smart garments as: "Textiles that are able to sense stimuli from the environment, to react to them and adapt to them by integration of functionalities in the textile structure". According to Buechley and Eisenberg [36], cross-disciplinary creative and innovative experimentation in smart garments is possible through an integrated approach of disciplines: electrical engineering, computer science, and fashion and textile design. Also, Dunne [37] predicts that future smart garment applications will be available in various industries including medical, therapy, and rehabilitation.

This chapter proposes the first stage of a project Buechley and Eisenberg [36] envisioned. The project involved developing a smart garment-based system to support elderly people. A prototype of the concept was developed as discussed next.

7.4.1 Development of the Proof of Concept

The prototype was developed using LilyPad Arduino [38] embedded platform which can be programmed using the Arduino programming environment. The board of the LilyPad Arduino microcontroller was attached to the garment by stitching it. In the original prototype conductive threads were used in stitching. The board was powered with a 3.7 V LiPo (lithium polymer) battery. Figure 7.1 illustrates the sample of a smart garment.

Fig. 7.1 LilyPad Arduino-enabled smart garment

7.4.1.1 Sensors for Data Collection

The input variable of the smart garment is the body temperature of the wearer. It is measured using a LilyPad Arduino temperature sensor which was attached to the garment using conductive threads. LilyPad Arduino temperature sensor measurements were collected every second and it is programmable according to the needs of the wearer and healthcare system requirements.

7.4.1.2 Sensor Data Representation

The sensor data was represented in two ways: (1) visually through a change of color in a light-emitting diode (LED); and (2) in audio form using a speaker (buzzer). A LilyPad Arduino RGB (red, green, blue) LED was used as the visual data output sensor. LilyPad Arduino speaker was used as the audio-based data output sensor. Both LED sensor (indicating the color at the back of the garment) and speaker were attached to the garment using conductive threads and are shown in Figs. 7.2 and 7.3.

7.4.2 Alerting the Anomalies

The smart garment was developed with an inbuilt mechanism to alert any anomalies. The anomalies were indicated using the color changes of the LED and the sound emitted by the buzzer. In the current proof of concept, anomalies indicated by the LED lights in the smart garment will be extended to more sophisticated functions such as sending alerts to caregivers, clinicians, and medical professionals in the fully developed version.

General fluctuations of the temperate sensor readings were observed. An average of ten readings were obtained, to smooth out the fluctuations and to receive a stable temperature reading.

Fig. 7.2 Temperature sensor and speaker

Fig. 7.3 Tri-color LED

7.4.2.1 Normal Temperature and Anomalies

A reference temperature together with upper and lower predefined thresholds (offsets), were used to define the acceptable/normal temperature range. Anomalies were defined as the temperature variations beyond the predefined thresholds from the acceptable reference temperature.

Both normal temperature and anomalies were indicated visually using a tri-color LED light and audibly using the sound emitted in the speaker. When the body temperate reading is normal, the LED light indicates the green color and the speaker is silent (speaker is not activated). When the temperature reading is lower than the lower threshold temperature, LED color changes to blue, which represents a 'too cold' condition and the speaker emits a beeping sound (every 500 ms). If the temperature reading is higher than the upper threshold, the LED color changes to red, which represents a 'too hot' condition. During the 'too hot' condition, the speaker plays warning music to indicate the danger.

7.5 Technology Readiness of the Prototype

The objective of any innovation-based research project is ultimately to translate the findings of basic research into applied research. The solutions should be successfully adopted in the field as a result. Despite the challenges in the healthcare industry due to its unique structure and the varying and demanding needs of a wide range of end-user/stakeholder groups, it is vitally important that digital technological solutions follow the innovation lifecycle.

Hence, the focus of this section is on discussing the milestones of the innovation lifecycle to reach the concept realization stage from the idea generation stage. The technology readiness levels [39] model is commonly used as a guide for technology development. The levels of technology readiness [33] are:

- Level 1: Scientific research begins to be translated into applied research.
- Level 2: Once basic principles are observed, practical applications are formulated through analytic studies.
- Level 3: Active research and development is initiated to validate the research concept. The activities include analytical studies, and/or laboratory studies as part of knowledge production.
- Level 4: Applied investigation begins. Activities include validating the functions in a controlled environment, such as a testbed, laboratory, or through a scenario model.
- Level 5: Prototypes of basic technological components are integrated for testing in a simulated environment, either in a laboratory or (through data collected from a) case study.
- Level 6: Development captures the operational requirements. The prototype is qualified in an operational set-up representing a near-desired configuration. Activities include testing of the qualified prototype in a representative site set-up, and/or field tests.
- Level 7: Full, scaled-up system with all operational requirements met. The system, at the planned operational level, is demonstrated in multiple operational environments to verify generalizability.
- Level 8: Product commercialization begins. The technology is proven to function in its final form in any operational environment and is verified through developmental testing.
- Level 9: Industrial system is launched/deployed in an operational set-up, and is verified through operational evaluations and tests.

Table 7.1 illustrates the classification of the technology readiness levels to the research process, from pre-concept to industrial product.

The proposed system is expected to follow the innovation lifecycle and to achieve technology readiness levels. The proof of concept, demonstrated during prototype refinement in this chapter, is expected to be refined as the project progresses. For example, iterative cycles of prototype refinement and sophisticated thermal mannequin testing [40] have already been conducted.

Table 7.1 Technology readiness level classification of digital health technologies

Technology readiness level	
Preconcept refinement or knowledge production	1. Basic principles of concept/scientific research
	2. Formulation of technology concept and/or application
	3. Proof of concept
Applied investigation	4. Functional validation in a laboratory environment, test bed, or scenarios
	5. Prototype in a simulated environment/case study
Development and operations	6. Qualified prototype demonstrating critical functionality in a relevant operational environment
	7. Full, scaled-up system demonstration (pre-product with all requirements) in an appropriate generalization of real or operational environment
Industrial product	8. General product or technology completed and qualified through tests
	9. Industrial technology proven through successful deployment in an operational setting

Adapted from Edirisinghe, R. (2019). Digital skin of the construction site: Smart sensor technologies towards the future smart construction site. Engineering, Construction, and Architectural Management. 26(2):184–223, Table 1. Some modifications were made. https://doi.org/10.1108/ECAM-04-2017-0066, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/)

7.6 Conclusions

This chapter presents an IoT-based patient-centric technology solution for digital health monitoring for the future digital health era. With a specific focus on technology readiness levels of the innovation life cycle, this chapter also presented a prototype developed for elderly home-care patients as the consumer group.

This prototype system is offered to answer the viability of the research question: how the innovative technology-based solutions can be used to better support elderly patients living in their own homes? The prototype smart garment developed aimed at developing an IoT-based healthcare system for elderly people living independently to assist them to enjoy a more dignified life while saving the cost of care.

The full system development is currently ongoing, together with extensive laboratory testing for its robustness in various environmental conditions. The future work of the project will be to conduct real-world field trials.

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Chapter 8
Clinical Tele-Assessment: The Missing Piece in Healthcare Pathways for Orthopaedics

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8.1 Introduction

In Australia, the exponential growth of joint replacements, in particular total hip and total knee replacements (THR and TKR, respectively) is projected to reach an unsustainable burden by 2030 [1], which has many severe and far-reaching implications for healthcare delivery and for the demand on public and private hospitals. Given several key contributing factors, most notably an aging population and longer life expectancy [2], the most prudent way to address this is to leverage technology solutions that can support cost-effective, efficient and effective care delivery post-surgery. We proffer tele-assessment, a noted void in current telemedicine solutions for orthopaedic care, as such a solution.

A key bottleneck in the recovery from THR and TKR is the return to appropriate postural and functional control [3]. The current standard clinical pathway involves 12–60 face-to-face visits for 3 months [4]. This is not only costly and difficult to manage, especially for isolated and disadvantaged populations [4], but if not done successfully leads to poor clinical outcomes and low patient satisfaction [5]. Moreover, clinical best practice notes that this 3-month window post-surgery is imperative for optimal recovery and best results [6]. To address this critical aspect on the THR and TKR patient journey and support quality clinical outcomes and patient satisfaction as well as ease the burden for our healthcare system, we design, develop and test ARIADNE (Assist foR hIp AnD kNEe), a pervasive tele-assessment solution that can perform clinical tele-assessment to assess postural and functional

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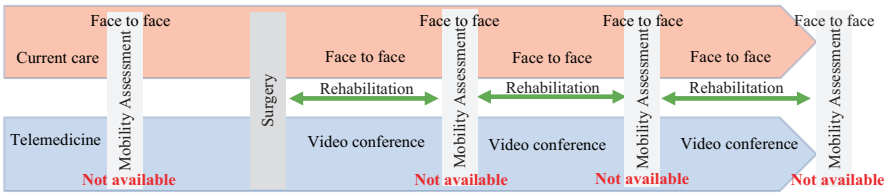

Fig. 8.1 Current standard care and telemedicine care pathway in orthopaedics

control to support post-surgery THR and TKR recovery. ARIADNE will enable objective, remote examination and monitoring of patient functional performance during their typically long rehabilitation journey, something that to date is missing from current telemedicine solutions especially in orthopaedic care (see Fig. 8.1). By implementing such a pervasive tele-assessment solution within the traditional practice, we have the potential to: (a) improve existing practice patterns, (b) shorten the recovery trajectory, (c) increase the likelihood for optimal clinical outcomes and (d) support a superior patient experience.

8.2 Background

Total hip or knee replacement is a common surgical intervention for treating advanced hip/knee osteoarthritis (OA). As a strategy to address the burden of disease of OA in Victoria and optimally align health services to consumers' needs and evidence, the Department of Health and Human Services commissioned the development of a Model of Care (MoC) for Osteoarthritis of the Hip and Knee. An MoC is an evidence and consultation-informed framework that describes what and how health services and other resources should be delivered locally to people who live with specific health conditions. In 2018 [7], the MoC recommended the "Innovation in service delivery model". The model was designed to establish: (1) telehealth services to improve consumers' access to specialist clinics for the purposes of clinical assessment, management planning and treatment and (2) web-based and smartphone app tools that deliver accurate health information and support behaviour change to consumers and care providers. The development of ARIADNE is designed to addresses the above acknowledgement of the importance of a telemedicine platform to improve healthcare services for rehabilitation following THR and TKR [7, 8].

Tele-rehabilitation via online video communication is an emerging area attracting increased attention as a potential alternative to conventional, face-to-face rehabilitation, suggested being an option for people located remotely to reduce the need for frequent travel [3]. A recent systematic review concluded that tele-rehabilitation can lead to better healthcare at lower costs [9]. An example is the tele-rehabilitation eHAB (NeoRehab, Brisbane, Australia) that enables real-time video conferencing to the patient's home and includes features such as recording instruction and exercises [10]. Similarly, MyRehab offers a tele rehabilitation communication system

via text or voice messages and video-conference, currently evaluated in an RCT with THR and TKR patients [11].

Indeed, tele-rehabilitation partially addresses some of the requirements of the MoC. However, a critical missing element in current solutions is tele-assessment which supports an objective remote postural and functional assessment integrated with web-based management and planning capabilities. ARIADNE addresses this key void by being able to transform standard care with a face-to-face assessment, mostly available only in major cities with experts, to provide remote assessment access and quality of care to a wider and remote community. Thus, ARIADNE will significantly enhance Australian healthcare services, ensuring objective postural and functional examination can be performed. It will provide the foundation for future telemedicine platforms for clinical trials and treatment monitoring.

To further improve upon the Australian telehealth system, the following objectives need to be addressed:

1. An *examination* into the measurement consistency and agreement of a newly established tele-assessment system with respect to a face-to-face clinical-based reference condition.
2. A *determination* of the feasibility and the extent to which the tele-assessment can be used by clinicians and patients to achieve effectiveness (accuracy and completeness), efficiency (resources needed for effectiveness) and satisfaction (comfort and acceptability).
3. An *assessment* of the cost-effectiveness associated with tele-assessment including those related to healthcare, purchase of equipment, mobile phone data usage and costs associated with establishing and delivering the service and analysing the results.

8.3 Overview of ARIADNE

In orthopaedics, performance measures following THR and TKR are required to identify patient functional competency and physical progress. In existing clinical practice, these postural and functional measures include: (1) range of motion, (2) postural balance, (3) chair rise, (4) 40-m fast-paced walk and (5) timed up and go (TUG) [7] and are executed face-to-face while the clinician manually records the duration and number of repetitions to complete the task. A more robust objective, but to date only used in research and not in clinical settings due to availability and accessibility, is quantifying performance using Inertial Measuring Units (IMU) motion sensors comprising accelerometers and gyroscopes [12–14] to measure linear acceleration and angular velocity, respectively. Once the raw data are captured, the level of performance is quantified by further well-defined signal processing methods [12, 13, 15–17].

ARIADNE has been developed and designed to support the above requirements and is built from previous work by one of the authors around web-based repository

applications Gaitabase and PROMsBase [18, 19] and leverages his research on the use of IMU motion sensor signals to capture, process and interpret postural and functional performance [16, 17, 20–23]. Gaitabase has been used by world-leading gait laboratories for clinical gait analysis, having 22 different centres in 8 different countries on four different continents. PROMsBase is routinely used at Western Health in Victoria to collect patients' satisfaction and wellbeing data pre- and post-joint replacement procedures with over 8000 questionnaires from over 10,000 surgery procedures now collected.

8.4 Development of ARIADNE

To be clinically useful as a tele-assessment platform, we extended the technology with unique integration methods of the web-based repository system coupled with the motion sensor IMU data captured from a mobile phone. During the assessment, the clinician remotely connects to the motion capture app installed on the patient's mobile phone that is strapped at the lower back (to measure postural control) or above the ankle (to measure joint angle) using an ankle strap (Fig. 8.2a). Once connected, the clinician remotely operates the app while the patient performs the specific functional task as instructed by the clinician (Fig. 8.2b). Once the task is

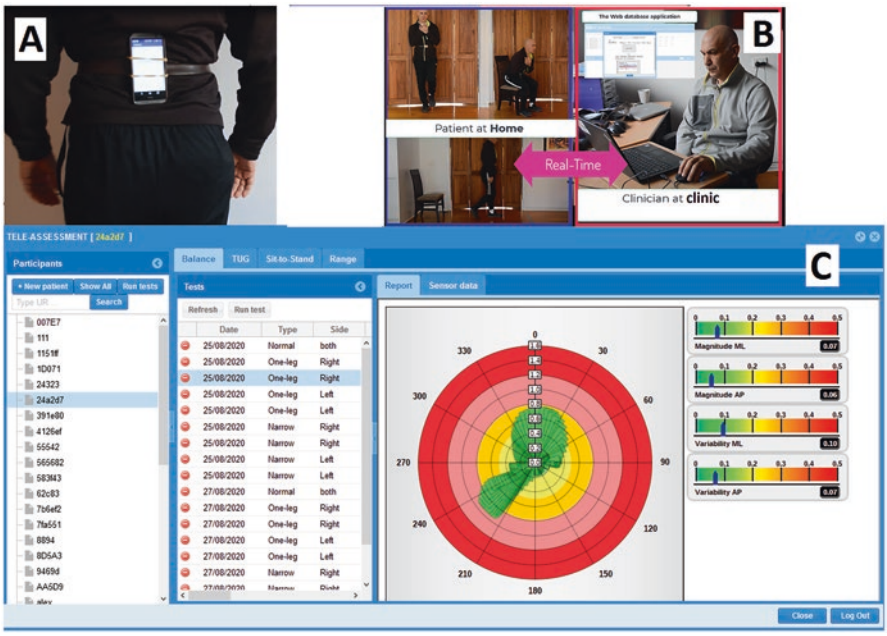

Fig. 8.2 Smartphone placement (**a**), remote tele-assessment of balance, sit-stand and TUG tests (**b**) and the web-based interface with balance report (**c**)

completed the clinician remotely saves the mobile sensors data that is automatically uploaded to the web-based application for further analysis to generate report on performance compared to healthy population (Fig. 8.2c). Both the clinician and the patient can login to the web application to evaluate performance and progress.

8.5 Preliminary Exploration

Validity and reliability: The validity and reliability of using IMU to measure the aforementioned five postural and functional assessments are well-documented in a range of population types including healthy older adults [24, 25], Parkinson disease [13], multiple sclerosis [14] and TKR [26], showing very good to excellent validity and reliability. These validity and reliability studies and the systematic review [25] used mobile phones motion sensors suggesting that mobile phones are non-inferior when compared to the other postural and functional measurement techniques. Furthermore, our pilot work validating our tele-assessment knee range with the golden standard video analysis also showed excellent correlation ($r = 0.98$) and very good agreement with a clinically acceptable bias of 5.4° with 17.3° and −6.4° for upper and lower 95% confidence bound, respectively (Bland-Altman Plot analysis, see Fig. 8.3).

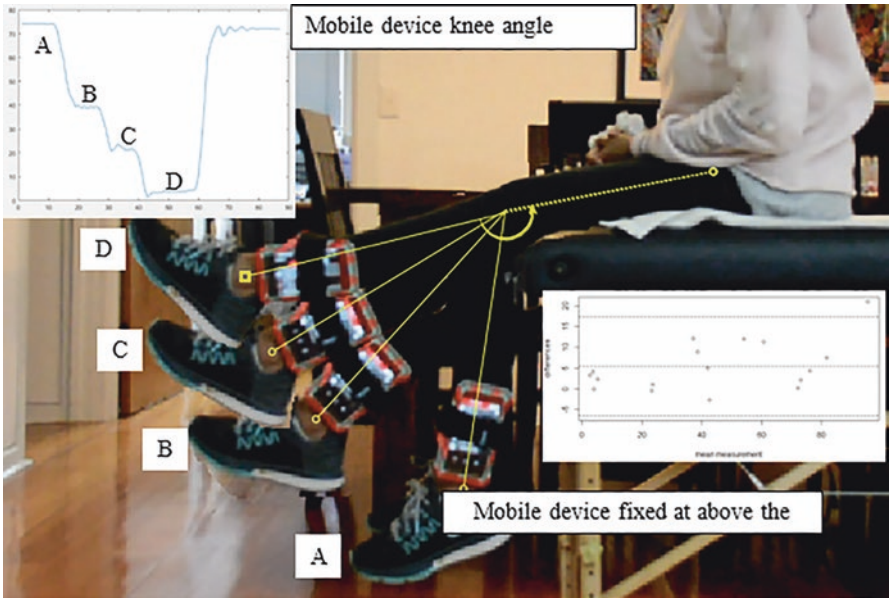

Fig. 8.3 Comparison in knee angle measurements between video analysis and ARIADNE. Mobile device is fixed to distal leg while the patient extends their leg to four knee extension positions (A, B, C, D). The top left is the mobile device outcomes. The bottom right is Bland Altman plot comparing measurement outcomes between the two methods

Table 8.1 Mean ± SD **Medio-lateral** and Anterior–posterior sway during 30 s double leg and single leg postural balance test (**lower values indicate less sway**)

Age group	Mediolateral sway (mean ± SD)	Anterior–posterior sway (mean ± SD)
	Double leg balance	
30–39	0.008 ± 0.002	0.011 ± 0.002
40–49	0.011 ± 0.014	0.009 ± 0.010
50–59	0.009 ± 0.010	0.012 ± 0.012
60–69	0.009 ± 0.002	0.015 ± 0.005
	Single right leg balance	
30–39	0.017 ± 0.013	0.015 ± 0.006
40–49	0.033 ± 0.042	0.024 ± 0.028
50–59	0.062 ± 0.096	0.065 ± 0.100
60–69	0.069 ± 0.035	0.046 ± 0.012
	Single left leg balance	
30–39	0.029 ± 0.016	0.022 ± 0.010
40–49	0.040 ± 0.052	0.027 ± 0.033
50–59	0.057 ± 0.069	0.053 ± 0.063
60–69	0.058 ± 0.013	0.046 ± 0.012

Figure 8.3 illustrates the assessment of knee joint range-of-motion test in sitting position. Supine position may also be used to evaluate knee range of motion. Our pilot work on the comparison in measuring knee angles using video analysis and ARIADNE showed a bias of 5.4° with 17.3° and −6.4° for upper and lower bound, respectively (Bland-Altman Plot analysis, see Fig. 8.3) and a significant 0.98 Pearson correlation coefficient.

Age-related deterioration in postural balance using ARIADNE: A pilot study investigates age-related changes in postural balance to determine the age at which balance deteriorates and falls risk increases. Twenty healthy adults (11 male, 16 female), divided into five age groups (30–39, 40–49, 50–59, 60–69) performed 30 s two-leg and one-leg stance postural balance test using ARIADNE. Similar anterior-posterior and medi-lateral sway magnitude were found between the age groups when standing on two legs. During unilateral stance postural sway was greater in the older (50–59, 60–69 years) groups compared to the younger (30–39, 40–49 years) groups (see Table 8.1). These results may suggest that postural sway may deteriorate from the age of 50 years and thus may increase fall risk.

8.6 Method

To test the proposed tele-assessment solution this section outlines the research plan. Tele-assessment is the missing piece in telemedicine care for orthopaedic rehabilitation. Unique aspects of ARIADNE include that it: (a) can provide remote, quantified, and postural and function control and (b) provide early detection of deviation,

problems and potential complications. Our pilot study will serve to incorporate key co-design principles to ensure clinician and patient input in the design and development of ARIADNE, and then test the definitive solution in terms of: (a) *desirability* (patients and clinicians), and clinician and patient *usability and acceptance*, (b) *reliability* (ability to deliver consistently on key clinical outcomes) and "*fit for purpose*" and (c) cost-effectiveness.

The tele-assessment platform: ARIADNE is very simple to use as it integrates a web-based database and interface platform and motion sensor data that is captured remotely from the patient's mobile phone while the patient performs their essential postural and functional measures, including [7]: (1) range of motion, (2) postural balance, (3) chair rise, (4) 40-m fast-paced walk and (5) timed up and go (TUG). The motion sensor data is processed to objectively quantify patients' performance level.

Primary Hypotheses: (a) ARIADNE will be *desirable* for, and *usable* by, both patients and clinicians and (b) ARIADNE will be clinically *reliable* and will meet the key needs for both clinicians and patients, "*fit for purpose*".

Primary Aims: to (a) assess desirability and usability of ARIADNE; and (b) assess clinical reliability including Minimum Detectable Change (MDC), and (c) evaluate if ARIADNE is fit for purpose.

Secondary Hypotheses: (a) ARIADNE will provide a *cost-effective* solution to support post-surgical recovery for THR and TKR patients; and (b) ARIADNE will support the healthcare value proposition of better access, quality and value of care for THR and TKR contexts.

Secondary Aims: to (a) determine the cost-effectiveness of ARIADNE; and (b) demonstrate that ARIADNE supports a healthcare value proposition of better access, quality and value for THR and TKR patients.

The study outcomes will create ARIADNE, a new tele-assessment solution to address a current gap in telemedicine delivery, that is desirable and useable for patients and clinicians, clinically reliable, fit for purpose and cost-effective with a high likelihood of addressing current issues around the sustainability of practice for THR and TKR patients. ARIADNE will be at the forefront in future telemedicine delivery models and will assist to advance Australia in telemedicine research, which, unfortunately, to date, is lagging, having only 6.3% of the telemedicine usability research published in the world [9].

8.6.1 Overview of Design

To ensure a robust solution it is essential to conduct a feasibility pilot study to measure the desirability, usability, reliability, MDC, fit for purpose, cost-effectiveness, and better access, quality and value of the tele-assessment platform for THR and TKR patients. The tele-assessment will be utilised during the conventional THR and TKR standard care pathways.

8.6.2 Participants

Patients: 76 patients (4 of whom will be solely involved in the solution co-design phase) from the Western Health outpatient clinic are to be recruited. On average 221 and 259 THR and TKR patients are treated each year at Western Health, respectively. Patients who are scheduled for THR and TKR as suggested by their consultant and meet the eligibility criteria will be invited to participate in the study by the researchers who will issue them with the information statement. Once the participant consents to participate, they will receive a written plan with booked dates for tele-assessment sessions with the responsible Community Based Rehabilitation (CBR) senior physiotherapists. Any participant considered to require surgery, such as revision, during the course of the study will be removed from the study. Inclusion criteria: (a) after THR or TKR, (b) have proficient English language skills (i.e. do not require an interpreter) and (c) have a mobile smartphone. Exclusion criteria: (a) THR or TKR with clinical complications and (b) do not possess and use a mobile smartphone.

Clinicians: the Senior Fellow physiotherapist and three physiotherapists from CBR will be recruited to deliver the tele-assessment sessions. The clinicians will have substantial experience in standard care for joint replacement patients.

8.6.3 Protocol

The project will begin with the ethics submission and a final ARIADNE *co-design* session with two clinicians and four patients (two TKR and two THR). Prior to tele-assessment at **T0**, clinicians and patients will participate in an educational focus group session. In this session, participants will be educated on the use of ARIADNE with preparation for their joint replacement journey.

Tele-assessments will be performed on ten occasions including; base-line pre-surgery-1 (**T1**), pre-surgery-2 (**T2**) and at 1 (**T3**), 2 (**T4**), 3 (**T5**), 4 (**T6**), 5 (**T7**), 6 (**T8**), 9 (**T9**) and 12 (**T10**) weeks post-surgery. The duration of each tele-assessment session is 20 min. In each session, the patient will start the app that automatically connects to the clinician web portal. The patient will then insert the mobile phone in the waist pouch and attach it around their waist. The clinician will instruct the patient to perform the tasks (balance, TUG, chair rise, range of motion) while the mobile app captures the motion data and automatically uploads it to the web portal for storage and further analysis. At **T2** and **T10,** patient questionnaires will be administered to assess the usability of ARIADNE. In addition, at **T10** a clinician focus group will be conducted.

Outcome and data analysis: At the completion of the study, the following aims will be achieved:

Primary Aim (a): *assess desirability and usability of ARIADNE*:

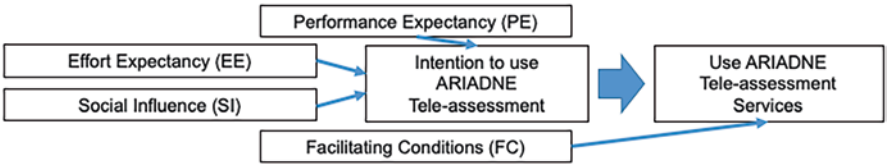

Fig. 8.4 UTAUT as an organising structure, relating to users' perceptions of tele-assessment

The Unified Theory of Acceptance and Use of Technology (UTAUT) will be used, as the theoretical framework underpinning the research, to understand and empirically test the factors that influence the end-users' acceptance and adoption of the tele-assessment services in THR and TKR patients (see Fig. 8.4). The UTAUT includes four determinants; performance expectancy (PE), effort expectancy (EE), social influence (SI) and facilitating conditions (FCs), which can explain 70% of the variance of behavioural intentions [27], while other models explained approximately 40% of technology acceptance [28]. It has been widely adopted in different areas including mobile health such as to investigate the intention to use Physical Activity Apps [29], but to our knowledge, there is no published study applying UTAUT to the investigation of tele-assessment use intention in joint replacement patients. To specify, PE refers to the services of the clinician in the clinician–patient interaction in tele-assessment. EE refers to patients' perceived ease of interacting with physicians in tele-assessment. SI refers to the impact of other people's feelings, views and behaviours on the behavioural intention of patients interacting with clinicians in telehealth. FC refers to users' perceptions of their ability to perform the behaviour and measure the degree to which the tele-assessment fits with their existing values, previous experiences and current needs. Each determinant includes related questions with a five-point Likert-type response format that ranged from "strongly disagree" (1) to "strongly agree" (5) to measure each construct covering the variables in the research model. The UTAUT will be completed at **T1**, **T8** and **T10**. Separate analyses will be conducted for older and younger groups of participants to test usability and efficacy across all age levels.

Primary Aim (b): *assess reliability using MDC*:

The outcome measure for each postural and functional task is calculated by processing the motion sensor signal from the mobile device. The outcome measures are the hip and knee joint maximum range of motion, the magnitude of body sway for the postural balance test, the time taken to complete five repetitions of the sit-to-stand manoeuver test and time taken to complete the TUG and 40-m fast-paced walk tests. The pre-surgery-1 session will be used for the validation study. A video camera will simultaneously record the patient's performance during the postural and functional tasks. The range of motion and time taken to complete the task measurements collected from the video analysis will be regarded as the gold standard in this study. Measurement consistency between the tele-assessment platform and the reference condition will be compared using two-way random-effects intra-class correlation.

Reliability and MDC will be analysed from the tele-assessment outcome measures (described above) when comparing outcomes between the pre-surgery-1 and the pre-surgery-2 sessions. The reliability will be estimated using repeated-measures analysis of variance and the intra-class correlation coefficient. Standard error of measure (SEM) and MDC will be calculated utilising the same methodology as our previous study using IMU measurements in gait [22]. SEM will be calculated as $SD \times \sqrt{1 - ICC}$, where SD is the standard deviation of all scores from the participants. SEM is also presented as a SEM% by dividing the SEM with the average of the test and retest values. The MDC will be calculated as $SEM \times 1.96 \times \sqrt{2}$ to construct 95% CI. The multi-level analysis will be used to test for significant differences across younger and older age groups separately for THR and TKR patients. This is an intention-to-treat method that allows for irregular assessment measures, allowing for the control of other variables as needed.

Primary Aim (c): *evaluate if ARIADNE is fit for purpose*:

Empirical evidence shows that users will not simply accept and use the technology if it does not fit their needs and improve their performance [30, 31]. Hence, to assess the fit for purpose of ARIADNE, we apply *task-technology fit*, the degree to which a technology assists an individual in performing his or her task. To measure the level of "fit for purpose" of ARIADNE, during the focus group session conducted at **T10**, we will ask clinicians to compare their experience with ARIADNE to that without tele-assessment; i.e. as per their normal delivery of care. This will enable us to understand key task characteristics, how the technology supported those tasks, and whether clinician users perceived ARIADNE to perform better, as good as, or worse than face-to-face assessments.

Secondary Aim (a): *The cost-effectiveness of the tele-assessment model*:

The costs associated with tele-assessment will be assessed using a societal perspective. To provide some comparison with standard care, an "average cost per patient" will be derived from historical records (to estimate the mean number of visits and time spent delivering the consultation) and including travel costs that would have been relevant to the participants if they underwent face to face consultations. Estimation of the costs of full implementation of tele-assessment at Western Health outpatient clinic may also be conducted.

Secondary Aim (b): *Determine ARIADNE's ability to support better access, quality and value*:

We will assess patient-reported measures regarding ease of access, clinician-reported measures of quality of clinical outcomes as compared to past records of results from past face-to-face consults, and cost-effectiveness as considered in Secondary Aim (a).

8.6.4 Ethics

Approval will be obtained from Swinburne University of Technology Ethics in Human Research Committee, followed by a Research Governance application to Western Health.

8.6.5 Sample Size

Sample size was calculated using the G*Power software tool [32] for repeated Analysis of Variance test (2 × 5, age groups × tele-assessment sessions, allowing for 50% completion of ten possible assessments) for both THR and TKR participants. This analysis is based on the tele-assessment postural and functional outcome measures (2 × 10, groups × tele-assessment sessions). Cohen's effect size was based on a previously published RCT that investigated the effectiveness of tele-rehabilitation as a supplement to rehabilitation in THR and TKR patients [33]. Patients that received standard care reported an improvement of 1.5 s in TUG having 9.0 ± 2.4 s and 7.5 ± 1.6 s in pre and 3 weeks post-surgery testing, respectively. For the chair rise test an improvement of 3.9 s was found from pre and 3 weeks post-surgery, 17.1 ± 6.2 s and 13.2 ± 2.3 s, respectively. Further, subjective parameters on function using the Western Ontario and McMaster Universities Arthritis Index were found to be 24.8 ± 16.4 and 13.9 ± 14.3 for pre and 3 weeks post-surgery, respectively. The Cohen's *d* effect size using the above data was calculated to be 0.73, 0.83 and 0.71. Using a 0.7 effect size ($f = 0.35$), $\alpha = 0.05$, and power = 0.80, for a repeated-measures ANOVA 15 participants are needed in each age group, for both THR and TKR participants (60 total). Having 20% dropouts 72 participants in total will be recruited for this study.

8.6.6 Identified Risks

Risk #1—Poor desirability and reliability of the tele-assessment platform: the tele-assessment platform is built for the purpose of assessing joint replacement intervention postural and functional control outcomes. Thus, it is important for the platform to be desirable and reliable. This risk is mitigated from findings of previous studies on the desirability and reliability of using IMU in measuring the postural and functional performance of the proposed tasks in a range of population types including healthy older adults [24, 25], Parkinson disease [13], multiple sclerosis [14] and TKR [26], with very good to excellent desirability and reliability. These studies and the systematic review [25] used mobile phone motion sensors, suggesting that mobile phones are non-inferior compared to the other postural and functional measurement techniques. Furthermore, our unpublished preliminary experiment validating our tele-assessment knee range with the gold standard video analysis showed excellent correlation ($r = 0.98$) and very good agreement with a clinically acceptable bias of 5.4° with 17.3° and −6.4° for upper and lower 95% confidence bounds respectively.

Risk #2—Security of the data: to increase data security the data will be stored on Nectar cloud and will be backed up daily. Nectar is an online infrastructure for researchers to store, access and analyse data remotely and is managed and funded by the Australian Government through the National Collaborative Research Infrastructure Strategy.

Risk #3—Participants can feel directionless and overwhelmed with the technology: to reduce participant anxiety with the digital technology, the patient advocate team member, will provide coaching and mentoring support to participants, enabling them to optimise self-management.

Risk #4—Falls, limited space and poor environmental set-up at home or difficulties to attach the phone to the ankle and/or waist: patients' home visits will occur to inspect and set up the testing environment and reduce potential hazards.

Risk #5—Poor Internet connection: the necessary Internet connection will utilise the mobile device's Internet access provider. Data collection is performed using the app installed on the patient's mobile device, thus a poor network will not disrupt data capture and quality.

8.7 Results to Date

The assessment of the fidelity, efficacy and fit for purpose of the developed ARIADNE solution requires many stages and is thus a longitudinal study. On the receipt of ethics approval, initial phases of the design science research methodology have been conducted with a small group of patients and clinicians respectively to fine-tune the solution. This is an important key step to ensure high clinician and patient use as well as ensure the developed solution will support the required needs for rehab of THR and TKR patients. The ARIADNE solution now has patient and clinician approval and based on a small pilot study demonstrated the ease of use and fit for purpose. While not statistically significant, this directional data provides support to progress to the next phase with confidence. The next key step is to conduct a large-scale clinical trial to capture key data around the impact of the solution to support THR and TKR patients in their rehabilitation. Once the clinical trial is concluded it will then be possible to address issues around the deployment of the solution into appropriate clinical contexts.

8.8 Discussion

ARIADNE is designed to remotely capture, analyse and interpret body motion using the accelerometer and gyroscope motion sensors embedded in today's mobile phones. The mobile phones we have today have three-axial accelerometers and gyroscope components. The accelerometer allows the measurement of linear acceleration in three orthogonal directions (x, y and z) and the gyroscope allows the measurement of angular velocity in the x, y and z axes. The linear acceleration and angular velocity signals can be processed and used to analyse body motion and further provide interpretation of the movement quantity and quality, such as level of stability during quiet standing. The ability to remotely connect to patient mobile phones and capture accelerometer and gyroscope data creates new opportunities for

clinicians, sports trainers and engineers to remotely quantify and analyse the performance level of any posture and/or movement task.

ARIADNE is comprised of three components including the mobile phone app, web-based application and a cloud database. The objective of the mobile phone app is to capture accelerometer and gyroscope data at 100 Hz and to upload the data to the cloud database. The objectives of the web-based application are to provide the examiner (clinician and sports trainer) with a web browser platform to remotely connect and control the mobile phone app, instruct the mobile app to upload the accelerometer and gyroscope data to the cloud database and perform data analysis for further interpretation and reporting of the level of performance.

8.9 Conclusion

Our designed solution, ARIADNE, represents a novel and unique approach to telehealth rehabilitation in orthopaedic care for THR and TKR patients. To date, current telehealth solutions in this space do not address tele-assessment, which means that there is a significant limitation in the current post-operative critical 12-week period for THR and TKR patients. Hence, ARIADNE not only addresses this key void, but it also serves to potentially help address a major conundrum facing healthcare delivery around THR and TKR; namely, the fact that current services will be unsustainable by 2030. Moreover, our solution is consistent with 2018 MoC recommendation [7] for "Innovation in service delivery model." By including a co-design approach and assessing ARIADNE as fit for purpose, we will have a unique tele-assessment solution that can be used for THR and TKR patients and potentially beyond, thereby also serving to leapfrog Australian telehealth initiatives. If the results of the clinical trial provide a positive endorsement for ARIADNE, then we would have successfully developed a unique teleassessment solution that addresses a key gap in post-surgical recovery for THR and TKR patients.

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Chapter 9
Telehealth Implementation: A Synopsis of Patients' Experience of Clinical Outcomes

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9.1 Introduction

Telehealth can be defined as the strategic implementation of telecommunication technologies in healthcare to improve wellness [1]. The technique has relied on videoconferencing platforms, mobile apps, wearable and monitoring sensors for remotely collecting information and providing healthcare services to patients [2]. It has been used for managing chronic disease conditions and real-time monitoring of patients using the seamless acquisition of blood pressures, electrocardiogram (ECG), oxygen saturation (SpO2), heart rate, temperature and respiration [3–5]). The role of telehealth in maintaining wellness and reducing the cost of healthcare has been strongly promoted by many researchers who have published myriads of scientific articles of the applications in different areas of medicine. These clinical trials and reviews show the applications of this technique in managing different disease conditions while new telehealth platforms that boast of several capabilities such as remote monitoring and diagnosis of complex disease conditions are

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springing up continuously. The benefits of telehealth are not in doubt, especially in this time of social distancing due to COVID-19. Thus, the use of telehealth as a viable alternative to the traditional face-to-face healthcare services in many instances cannot be overemphasised. As research shows that lack of interest in the use of the technique is a huge burden to the health system that stands to save more than $101 M in the emergency department with only 1% adoption rate [6]. With only one in ten Americans being interested in telehealth pre-COVID-19 and a modest expectation of 15–20% adoption in 2020, it is not surprising that the social isolation resulted in 257–700% increased use [7] as billing and privacy restrictions were relaxed to enable patients to access insurance. This signifies that the future of telehealth in effective healthcare implementation cannot be ignored, especially when 5–20% of patients admitted in hospitals have the potential of contracting other infections [8].

The very rapid uptake of telehealth driven by the infection control considerations to control COVID-19 has outpaced evaluation methods for the technology, particularly in comparison to in-person consultations.

Although the health outcome obtained from telehealth has been shown not to differ significantly with in-person hospital visitation [9], in some instances, some experts have argued that the readiness of the telehealth implementation hinges on adopting a platform and training of healthcare professionals, integration of EMRs, patient education and acquisition of the necessary hardware for the participating patients [10]. Others believe that the implementation of telehealth should be a work-in-progress that will keep maturing with time. However, the business module of telehealth is driving investors into developing new technologies to maximise gains prior to the flooding of the market. These expectations have caused researchers to ramp up publications on telehealth strategies, the enabling technologies and the ever-increasing applications in numerous healthcare contexts. Yet the evidential outcomes of these technologies from patients' experiences of their effectiveness have received minimal attention particularly for what is regarded as 'difficult conversations' related to life-threatening illness and complex treatments like those involved with cancer.

At least part of the problem is the failure to fully characterise all of the dimensions of the in-person consultation prior to considering what effect telehealth might have on those aspects.

It remains difficult to explain with some degree of certainty how telehealth technologies are helping patients in self-management of chronic conditions to advance their quality of life despite complex health challenges. Despite the overwhelming belief that telehealth is the next big revolution in the healthcare industry, it is worthwhile to understand what telehealth strategy works and in which healthcare context.

To understand the patients' experience of the clinical outcomes of different telehealth strategies and the enabling technologies for managing different disease conditions, we decided to draw information from different academic literature. Hence, showing the synopsis of patients' experience of clinical outcomes in varying clinical trials. This knowledge will be vital for integrating efficient telehealth strategies for managing different disease conditions into the mainstream healthcare system.

9.2 Scope of Telehealth Applications in the Clinical Context

The ever-growing scope of telehealth has patients, doctors and hospitals relying on many techniques for the implementation of healthcare. Figure 9.1 shows some of the telehealth strategies, enabling technologies and the expected outcomes for efficient maintenance of wellness at a distance.

Televisits have afforded patients dwelling in remote locations with the opportunity to have specialist attention following teleconferencing, telephone conversation, or by using any of the specialist telehealth platforms. Tonyushkina et al. [11] showed that televisit is a well-accepted strategy for minimising doctor's appointments for patients with diabetes type 1 because the A1C levels were under control after replacing 3 of the 4 yearly doctors visit with televisit. Telerounding has also been shown to be evolving significantly with the advances in the enabling technologies of telehealth. Some experts have touted it as a cost-effective technique for pre-operative care although there is no difference in the hospital factors and mortality of patients managed with robot-guided telerounding [12].

With the advances in telecommunication technology, surgeons can use robots remotely to perform surgical procedures on patients via telesurgery, thus providing a panacea for the shortage of surgeons especially in remote and rural communities [13]. Telesurgery also boasts of timeliness of operation by eliminating the geographical barriers that hinder real-time surgical interventions while enhancing surgical accuracy and ensuring the safety of surgeons. Similarly, the presence of video conferencing and advanced telehealth software in operating rooms have enabled telementoring and teleproctoring of surgeons who reported increased confidence for laparoscopic surgery with excellent robotic skills [14]. Remote mentoring of robot

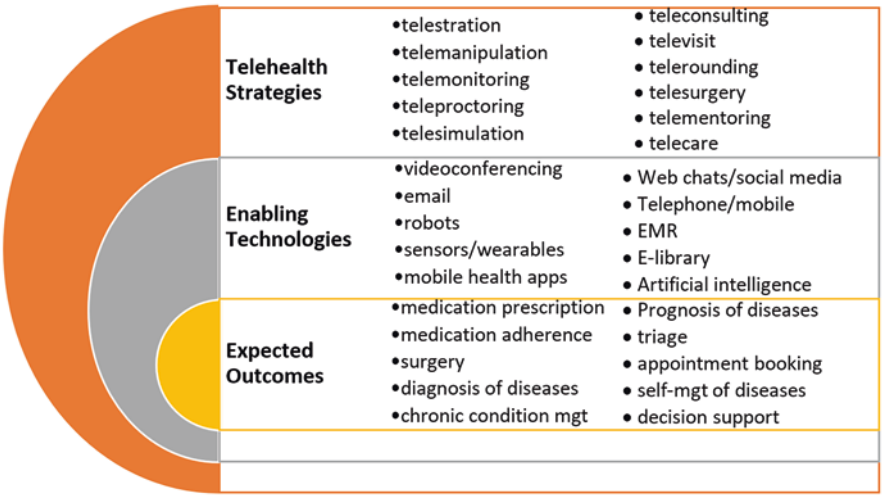

Fig. 9.1 Summary of some telehealth strategies utilised for managing the wellness of patients at a distance

manipulation during telesurgery is also increasing with enhanced accuracy of surgical procedures compared with human-operated surgery [15].

9.2.1 Cardiovascular Diseases

It is pertinent to use telehealth for acute cardiac, stroke and rehabilitation services, especially to reduce the risk factors for patients in rural and remote Australia because they are at higher risk of mortality because of limited specialist care [16]. The case of full-scale implementation of telehealth in acute care is well-known to result in efficient diagnosis and treatment of cardiac conditions through electronic transmission of ECGs, remote rehabilitation [17] and exercises [18]. This has resulted in reducing mortality [19, 20], which has plagued rural and remote dwelling Australians whose risk of mortality due to chronic heart conditions increases with the increase in location to major clinical hubs in the major cities [21]. With numerous evidence pointing to the potency of telehealth in cardiac rehabilitation services [22, 23], the adoption in rural and remote hospitals and in-home monitoring will inevitably help to reduce cardiovascular-based mortalities because of early identification and interventions [16].

9.2.2 Surgery

The goal of telehealth application in surgery ranges from providing improved access to specialist surgeons by patients in rural and remote communities to the efficiency of surgical procedures [13, 24]. Similarly, there is increased support for patients who receive specialist pre-operative and post-operative care at a reduced time due to the elimination of travel times [25]. There is also a higher tendency of carrying out high-quality surgery due to the collaboration between medical centres in real time [26, 27] while damages to healthy tissues are minimised due to the precision of the robots, hence quickening patients recovery time [26].

9.2.2.1 Pre-operative Assessment

Specialist surgeons can rely on video conferencing for pre-operative examination with the aid of a local consulting physician who can provide specific information for the decision on the progression of the disease condition and the urgency of surgical telemedicine can help in optimal decision support about for surgical procedures to forestall complications as non-essential procedures are on hold due to the effects of COVID-19 [28–30]. Patient assessments can be done remotely through a series of self-assessment questions to obtain temperature, blood pressure and pulse rates. Digital stethoscopes with the associated mobile apps have also been used for

remotely obtaining lung and heart sound, murmur and afib analysis and electrocardiogram (ECG) [4, 5]. Clinicians have also incorporated radiographic images, ultrasounds, laboratory reports and ECG and skin images for severity assessment of certain diseases in pre-operative assessments of surgical procedures using telehealth.

9.2.2.2 Post-operative Monitoring

Video conferencing and pictures are very viable for post-operative monitoring of surgical patients, especially for detecting complications [31]. Telephone calls were effectively used to substitute standard post-operative clinical visits for selected ambulatory surgery patients after hernia and appendectomy with no complication recorded for cholecystectomy and 4.8% for herniorrhaphy [32]. The preference for telephone pre-operative monitoring was inspired by convenience and time savings of 74.2–99.4 min when compared with pre-intervention pre-operative visits [33, 34]. Patients who were pre-operatively monitored by emails after arthroscopic rotary cuff surgery were satisfied with the strategy after safe monitoring for 2, 6 and 12 weeks [35].

9.2.3 Urology

Numerous telehealth techniques such as televisit, teleconsultation, telesugery, telerounding and mobile app image sharing are currently in use in urology [2]. Numerous studies point to the effectiveness of telehealth in urology because of the comparative effectiveness with face-to-face visits, especially for post-operative care [36, 37]. Telesurgery has also become predominant with many small invasive procedures related to bladder cancer, prostate and kidney, example is percutaneous nephrolithotomy [38]. Some of the works on telesurgery have been based on verbal guidance and telestration direction [15] to enhance telemanipulation of robots to improve the accuracy of operations, which were shown to be more accurate than human operations [39].

9.2.4 Psychiatry

The survey of mental health professionals in regional South Australia [40] was necessary to ascertain the challenges and advantages derived from telehealth especially with the advances in digital telehealth facilities. There was an enhanced quality of service that culminated in improved consultation due to the good communication between users and resultant improved work output in mental health assessment for the review of involuntary detentions. Thus, staffs were better able to do case conferencing and consultation with the guardianship board on different patients' need and

other administrative issues such as discharge planning and narrative therapies. It was also easier to support staff educationally via therapeutic trainings and peers supports while hospital staff meetings with the psychiatric health management boards improved. Similarly, Pratt et al. [41] concluded that a 6-month telehealth intervention for comorbid psychiatric patients resulted in improved efficacy of self-management of conditions with improved knowledgebase. Thus, resulting in lowered blood sugar levels for those that are diabetic and reduced care needed for the patients with bipolar disorder and major depression. For patients with post-traumatic stress disorder and depression, lack of familiarity with telehealth technology caused them a poor response to the treatment because of limited confidence [42], despite the positive impact of the technique on the treatment. Unfortunately, a nurse-led augmented telehealth treatment for depression in primary care did not show any improvement in medication adherence [43].

9.2.5 Ophthalmology

The key requirements for effectiveness in managing the visual health of the populace will rely on the telehealth strategy for offering triage [44], maintaining patients-physical engagement, medication recommendation, scheduling of future appointments and appraisal of care plans [45]. Imperatively, the telehealth visit cycle will involve scheduling, diagnosis following the health history evaluation, visual acuity from mobile apps [46] and intraocular pressure checks with finger tension patients. Although this procedure may not give a good accuracy, it may provide a guide for the assessment of the condition of patients. Ancillary testing can also be done with commercial or free apps for muscular diseases evaluation while relying on video visits for the examination of external adnexal, pupil, motility, alignment, anterior segment, iris and corneal light reflexes [47]. This strategy with significant self-management education can suffice for preventing diabetes-associated visual loss [47].

9.2.6 Cancer

All medical consultations have some common dimensions, but the consultation with a cancer patient is widely regarded as having a particularly strong psychosocial component given the gravity of issues that are often discussed particularly in the context of treatment with palliative intent and end-of-life care.

Most patients in these consultations are accompanied by carers who are a critical part of the care team and whose body language reactions to the content of the conversations is sometimes difficult to determine in a teleconference where the camera is obviously focused on the patient. Consultations involving a significant number of

family members which often occur in the context of cancer treatment are even more difficult to manage.

A critical part of any cancer consultation is the process of 'turn taking', where the practitioner and the patient usually give non-verbal cues to indicate the end of their contribution to their part of the conversation and the opportunity for the other party to start their contribution. These cues are substantially attenuated in a teleconferencing situation and much more difficult to read and thus affect the quality of the consultation.

Much of the focus of evaluation in cancer consultations is the effectiveness of information transfer from the practitioner to the patient and the elicitation of patient preferences by the practitioner. These verbal exchanges are usually faithfully recorded by Telemedicine, but the non-verbal dimensions to these exchanges are often difficult to record.

During these conversational exchanges, a process of trust is concurrently and hopefully developing in the patient for the practitioner. It is not clear from the published literature that this process of trust development is enhanced or attenuated by telemedicine processes.

A key part of modern cancer services is the decision-making by a multidisciplinary meeting, where different types of cancer specialists discuss cases and come to consensus recommendations about the management.

Telehealth makes these meetings much easier to convene and function and provides the possibility of national or international experts participating enhancing quality.

9.2.7 Other Disease Conditions

Table 9.1 summarises the effects of using telehealth for managing some selected chronic disease conditions, such as diabetes, chronic obstructive pulmonary disease (COPD) and cancer.

9.3 Intelligent Supports for Quick Outcomes in Telehealth

Although telehealth has been used for different forms of patient care, the implementation of artificial intelligence (AI)-based support for intelligent decision is gaining ground [59, 60] because of the quick decision support that is revolutionising caregiving. Notwithstanding, the importance of quality decision support frameworks cannot be overemphasised [61]. To this end, the promotion and use of high-fidelity data and techniques to develop these architectures with high true positive and true negative rates will be vital for effective health management. Researchers have implemented the strategy in different forms with Molina et al. [62] integrating EMR and telehealth services for managing epilepsy by ensuring an intelligent detection of

Table 9.1 Some studies (ST) detailing patients' experience of telehealth strategies (TS) and the enabling technology (ET) used for managing chronic diseases(DS) such as diabetes, chronic obstructive pulmonary disease (COPD) and cancer

ST	TS	ET	DS	Summary	Outcomes	Remarks
Davis et al. [48]	Telecare	Telephone, video conferencing	Diabetes	A 1-year randomised trial for a remote self-management of diabetes in rural South Carolina using 30 participants and 10 groups that received 13-sessions of telecare or usual care showed a reduction of glycerated haemoglobin in the telecare group from 9.4 ± 0.3 to 8.3 ± 0.3 (in 6 months) and 8.2 ± 0.4 (in 12 months). Those on usual care, the glycerated haemoglobin changed from 8.8 ± 0.3 to 8.6 ± 0.3 (in 6 months) and 8.6 ± 0.4 (in 12 months)	Reduced level of glycerated haemoglobin	Telecare using telephone and videoconferencing resulted in a better comprehensive self-management of blood glucose level than the usual caring method for patients with diabetes
Ciemins et al. [49]	Telecare	Video conferencing	Diabetes	A 16-week study of 667 participants in a diabetes prevention program showed that 15 rural communities connected via video conferencing have 34.6% compared to 33.5% face-to-face urban participants who lost 7% of their body weight. Similarly, 50% of those on telehealth lost 5% of their body weight as against 47% who used face-to-face intervention	TP body weight loss that is comparable with the CC technique	There was a comparative weight loss for both categories, thus, making a very good case for cost minimisation with telehealth
Vadheim et al. [50]				894 participants were monitored over a 7-year period for body weight loss in diabetes prevention program		

Davis et al. [51]	Telemonitoring	Mobile app	Diabetes	The impact of remote patients monitoring for managing diabetes was tested in a 12 months trial of 171 participants with an HbA1c of >7.0% and a significant difference in their baseline readings of 2.6–23.5% was observed after 3, 6, 9 and 12 months	Reduced HbA1c	There is efficiency in using remote patient monitoring for self-management of diabetes
Calvo et al. [52]	Telemonitoring	Sensors	COPD	A 7-month randomised trial of 60 COPD patients with post-bronchodilator forced expiratory volume (FEV1%) predicted at <50 and age > 50 years and on long-term oxygen therapy but are not smokers. There was a significant difference in the intervention group (telehealth participants (TP)) and those on conventional care (CC) as follows: Emergency visits (TP: 20; CC:57), hospitalisation (TP: 12, CC:33), length of stay in hospital (LOS) (TP: 105, CC: 276) and non-invasive mechanical ventilation (TM:0,CC:8)	Reduced emergency visits, hospitalisation, LOS and use of mechanical ventilation	Telehealth is vital for managing elderly multiple comorbid COPD patients and helps to reduce the cost of healthcare

(continued)

Table 9.1 (continued)

ST	TS	ET	DS	Summary	Outcomes	Remarks
Nield and Hoo [53]	Telecare	Video conferencing	COPD	22 participants with COPD (mean FEV1% predicted = 56) were randomly monitored for 12 weeks to understand their response to pursed lips breathing and 16 completed protocol (9 telehealth, 7 control)	Social support and dyspnoea assessment—(visual analogue scales for intensity and distress, modified Borg) after 6-min walk distance and shortness of breath assessment	There was a decrease in dyspnoea and increased social support for the participants that utilised real-time video conferencing
Tabak et al. [54]	Teleconsulting	Web apps	COPD	Examined the use of telehealth for primary and secondary care by checking ambulant activities, real-time coaching, web exercise programs and self-mgt of exacerbation among 29 participants for 9 months	Clients' satisfaction with care is high but adherence to exercise is low (21%). There was a better dyspnoea measure with telehealth	The role of healthcare professionals in patient's adherence to telehealth is crucial
Soriano et al. [55]	Telemonitoring	Sensors	COPD	Clinical trial of 237 COPD patients (FEV1% predicted <50) having at least 6 weeks without exacerbation. There was no statistically significant difference in the primary efficacy analysis leading to emergency visits and hospital admissions for both the control (CC) and intervention (TP) groups. The same case was found with the number of exacerbations in 12 months	The use of telehealth remote monitoring did not reduce hospital admissions or emergency visits of the patients	The number of hospitalisation and emergency visits was not changed through telemonitoring

Head et al. [56]	Telemessaging	Mobile app, sensors	Cancer	44 stage II head and neck cancer patients undergoing chemotherapy and/or radiation were clinically tried with a telehealth support device for self-management of symptoms by addressing 29 different symptoms and answering 100 questions to support education and response while soliciting for 3–5 daily questions to measure outcomes. The telehealth device was used for 86.3% ± 15.0 of the total days of the study	Satisfaction with telehealth utilisation for managing cancer symptoms. Declined quality of life score due to symptoms during treatment but returned to normalcy after treatment	Using telehealth to support patients in the period of pain and declining quality of life due to cancer treatment is vital for self-management of symptoms to alleviate the burden on the health system
Galiano-Castillo et al. [57]	Telerehabilitation	Web apps	Cancer	Randomised trial of 81 breast cancer patients (stage I to IIIA) using 6-months exercise regime. There was a significant improvement in global scores for health status, cognitive functioning ($P < 0.001$) and arm symptoms ($P < 0.01$) as well as pain severity ($P = 0.001$) and pain interference ($P = 0.045$) of the intervention group compared with the control group. The trial also shows that handgrip, abdominal, back and lower body strength ($P < 0.001$) and total fatigue ($P < 0.001$) improved for the intervention group	Quality of life – brief pain inventory, the handgrip dynamometer, the isometric abdominal test, the back dynamometer, the multiple sit-to-stand test and the piper fatigue scale	The use of telerehabilitation will improve the adverse effects of breast cancer survivors while maintaining their quality of life

(continued)

Table 9.1 (continued)

ST	TS	ET	DS	Summary	Outcomes	Remarks
Myers et al. [58]	Telecare	Video conferencing	Cancer	The study focused on 61 stage I–III breast cancer survivors reporting cognitive issues 2 months to 5 years after chemotherapy. They received psychoeducation-based cognitive intervention in 6 weekly 2.5 h session for 12 months. The intervention group showed improvement in cognitive function 6 and 12 months of using the therapy	The perceived cognitive function of breast cancer survivors improved	Psychoeducation-based rehabilitation of breast cancer survivors can help cognitive problems after chemotherapy

EEG signals from the patients. This framework that was configured in OpenMRS platform helped neurologists to make quick health assessments on the patients with a 65–75% time savings when compared with the manual signal assessment. Eggerth et al. [63] showed that the integration of intelligent decisions into medication adherence management is vital for quick analysis of patients' compliance. Intelligent decision support also interphases with EMR via loop telehealth to facilitate collaborative management by relevant stakeholders for proactive caregiving [64, 65]. Intelligent decision support for medication adherence through real-time monitoring and prediction of risks with vital signs can be a useful strategy for quick decision about patient's wellness status and therapeutic effects management [66]. Unfortunately, Alghamdi et al. [67] showed that improved medication adherence was not achieved through telemonitoring and text messaging, whereas other studies supported improved medication adherence with other forms of telehealth monitoring strategies requiring constant reminders [68, 69].

9.4 Challenges of Telehealth Application

Removing distance barriers to telehealth is vital for enhancing the wellness of the community if sufficient electronic and telecommunication infrastructure can be available for the various kinds of medical services to be undertaken remotely [70]. The numerous challenges facing telehealth are summarised in Table 9.2.

9.5 Implications for Theory and Practice

There is overwhelming evidence from the reviews to support the efficacy of telehealth in managing various diseases such as cardiovascular diseases, mental health problems, diabetes, COPD, degenerative eye conditions, cancer etc. This advantage is pronounced for patients in rural and remote communities, which do not have immediate access to specialist services and have higher mortality rates [19, 20] that are decreasing especially for cardiovascular conditions [17, 21].

The major advantages in telehealth for rural and regional communities accrue to the patient in terms of reduced travel time and cost to access highly specialised services that are non-procedural as procedural services still require in-person attendance with the current state of robotics.

Governments have invested substantially in the development of specialised health services in regional centres.

If in-person health services of a non-procedural nature are regarded as equivalent in quality to those delivered by Telehealth it may result in withdrawal of non-procedural specialist services from regional and rural centres and concentration in Metropolitan centres.

Table 9.2 Summary of key challenges

Key challenges	Description	Reference
Infrastructure	• Lack of critical infrastructure for health service provision in remote and rural communities is hampering the smooth running of telehealth	Rashvand and Hsiao [70], Rosenbaum [7], Saleem et al. [45]
Safety challenges	• Safety of client managed by telehealth can be compromised due to poor clinical decisions necessitated by poor inferences • Staff training on the use of some telehealth technologies is posing a barrier to their implementation in some regional health centres • Security and privacy of cloud-based platforms	Rashvand and Hsiao [70], Ellimoottil et al. [2], Newton et al. [40], Jin and Chen [71]
Legislative bottleneck	• Legislative bottlenecks are preventing the wide implementation of telehealth as many nations, states and territories have conflicting requirements for the management of patients' health records	Rashvand and Hsiao [70], Ellimoottil et al. [2], Newton et al. [40]
Cost	• As most of the technologies on which telehealth are built are not yet matured, investors are not always willing to invest on such infrastructure and services for fear of inadequate financial returns	Rashvand and Hsiao [70], Ellimoottil et al. [2], Newton et al. [40]
Waiting time	• Due to the COVID-19 pandemic and struggling capacity of the current infrastructure, the waiting time for patients increased • The healthcare professionals may spend more time in acquiring patient's history due to poor narratives that sometimes cannot be quickly interpreted because of the inconsistencies with the established norms for clinical assessments of clinical conditions	Rosenbaum [7], Saleem et al. [45], Blue et al. [72]
Scepticism	• Many patients are hard to convince about the efficacy of telehealth, thus, making it difficult to win them over • Organisational business strategy adopted in several health contexts	Ellimoottil et al. [2], Trux [6], Newton et al. [40]
Quality of service	• There is a tendency for a decrease in the quality of examination patients get especially when the quality of video transmission is poor for locations with limited telecommunication infrastructures • The delay in transmission could be a recipe for poor information delivery and subsequently poor health outcome. This can be worsened during poor weather or technical problems with the telecommunication infrastructures • Interoperability of electronic medical records (EMRs) and challenges of seamless communication with telehealth platform	Park et al. [73], Sahin et al. [74], Blue et al. [72], Jin and Chen [71]

The improvement in the quality of life is also evident in patients with chronic conditions subjected to self-management care via telehealth as diabetes prevention programs conducted for satellite patients achieved the same level of body weight

loss (5 and 7%) as face-to-face patients [49, 50]. There was also evidence of an enhanced reduction in HbA1c levels and other biomarkers for telehealth patients compared with those using the conventional practice of face-to-face doctor visitation ([51, 75]). As a result of these positive patients' experiences, it may suffice to implement telecare with videoconferencing and/or mobile apps as the enabling technology to manage diabetes in regions of high prevalence to improve wellness and reduce the cost impact to the healthcare sector.

The importance of adapting less complex telehealth enabling technologies was clearly shown by the inability of patients with limited knowledge of telehealth technologies to complete clinical trials and benefitting from the health management information proffered [42]. Some health experts are also having problems with telehealth technology due to their complex navigation platforms, thus, many are discouraging the patients about the potency of the technology despite the numerous advantages. To this end, some of the complex telehealth platforms may be preventing the adoption despite the cost associated with the integration process. It may therefore be beneficial for developers to focus on using mobile apps with minimal features or use manipulation strategies that will rely more on scanning barcodes for information retrievals [76]. Health professionals relying on these platforms can be able to manipulate reports easily and retrieve medical images in time to facilitate diagnosis.

Inclusion of educational modules about the various disease conditions targeted by telehealth is very vital for achieving the anticipated wellness of the patients. Evidence from this study suggests that proper education is necessary for managing the symptoms of chronic conditions during and after treatments such as chemotherapy and radiation [56, 57]. This was further proved by patients suffering from major depression and bipolar disorder that had improved wellness (reduced care) through self-management education and reduced blood sugar level for diabetic patients with mental illness [41].

Although most of the telehealth outcomes are encouraging as patients in some instances have similar health outcomes with telehealth as with face-to-face hospital visitation, the hindrance caused by insufficient telecommunication infrastructure in rural and remote communities is enormous. Health professionals who can only rely on telehealth for covering a vast expanse of rural communities were met with poor-quality networks that impaired the service delivery [40]. In light of this, getting telehealth to achieve more milestones in wellness will involve efficient telecommunication services [3], that will boost communication between the health professionals and patients. This will promote intelligent telehealth in diagnosis, prognosis, medication adherence, collaborative decision support and quick recovery for patients [26, 60, 63, 76]. Similarly, the challenge posed by the fragmentation of electronic medical records (EMRs) and the poor interoperability of most hospital systems [77], and the impact on smooth telehealth implementation can be mitigated with the cost-effectiveness of the open EMR platforms [78].

9.6 Limitations

We made a concerted effort to address patients' experience of clinical outcomes from telehealth by reviewing the findings of numerous studies in the literature. Although the study tried to incorporate the results from many papers addressing the subject matter especially the focused disease conditions and clinical practices, we know that some studies must have been omitted. Given the fact that the practicality of exhausting all the known literature in a given area is not possible, we affirmatively believe that the information in this study represents patients' experiences of clinical outcomes from telehealth and will provide invaluable information for policy implementations.

9.7 Conclusions

As the cost of healthcare is increasing all over the world and managing wellness is becoming gradually more difficult, one of the sure ways of expanding access to healthcare is telehealth. Despite some of the challenges facing telehealth implementation such as limited telecommunication infrastructure and the cost of developing and running a successful platform, the technology still remains the true option for self-management of many chronic diseases and maintaining the quality of life of rural and remote dwellers.

This study relied on the information from the literature to show how telehealth has helped patients maintain wellness or manage chronic and debilitating conditions by analysing numerous clinical trials and other articles on telehealth strategies, enabling technologies and patients' experiences of the clinical outcomes. This evidence-based study confirmed that the use of telehealth services improves self-management efficiency and glycaemic control in patients with diabetes. It also helps individuals undergoing diabetes prevention programs to lose body weight at the same rate as people using face-to-face services lose theirs following some regimented programs. People with mental illness and have diabetes were also able to have reduced blood sugar levels following a telehealth education program that controlled their anxiety levels. The advantages of telehealth for pre-operative and post-operative surgical care were also outstanding with results of patients' satisfaction and ease of identification of complications after surgery compared to those obtained via face-to-face care. Patients with COPD were able to reduce the number of emergency visits, hospitalisation, use of mechanical ventilators and LOS after telecare, whereas cancer patients undergoing chemotherapy and radiation treatments had increased quality of life due to their ability to understand the symptoms and the management strategies of the sickness.

It is obvious that telehealth still has obvious challenges that are hampering the widespread implementation, but the progress made so far through the intervention in monitoring, mentoring, rehabilitation, surgery and caring is sufficient to open

new healthcare frontiers for implementation. Thus, a systematic investment in the needed infrastructures, the simplification of the telehealth software and the improvement of EMRs' interoperability and democratisation will define the next phase of adoption of the technology. Since the legislative bottlenecks surrounding data privacy and security are gradually easing and the security of data transmitted through the platforms is improving, there is bound to be an enhanced acceptance of the technology. This will inevitably give room for greater investments in the infrastructure facilities, hence guaranteeing greater access to the populace.

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Part III
People and Policy Considerations

Chapter 10
Disrupting LATAM Digital Healthcare with Entrepreneurship and Intrapreneurship

Luis E. Fernández

10.1 Digital Health Overview

Now more than ever, technology has played a massive role in how we deliver safe and accessible healthcare services to patients around the world. The implementation of digital tools and systems in both healthcare organisations and companies provides the right set of circumstances to enable healthcare professionals to do their job better, faster, safer and with a wider scope.

Since the accessibility of personal computers in the early 1990s [1], the world has been constantly innovating to shorten the gap between patients-healthcare professionals, make smarter decisions by using data and provide accessible service to the community through Digital Health applications [2].

According to the US Food and Drug Administration (FDA) [3] and the drug treatment agency (DTA) in the UK, there are six categories in which Digital Health applications can be divided into [4]:

- Telehealth
- Health Information Technology
- Digital Therapeutics
- Personalised Healthcare
- Devices, Wearables and Sensors
- Mobile Health

Although it may seem that Digital Health applications are expensive projects to develop, through the "Startup Movement", the world has discovered a feasible and popular channel in which intrapreneurs and entrepreneurs can validate a specified hypothesis in a shorter period and with a lower budget. According to the Journal of

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mHealth's Global Digital Health 100 Award, there is a huge market niche that's being addressed by Health tech/Digital Health startups today.

10.2 The Startup Movement and Method Overview

The access to personal computers and the boom of the dot.com era brought a world of possibilities to solve problems in every sector. Companies such as Amazon and Uber have disrupted traditional business models and methodologies, offering results that reduce inefficiencies, costs and increase quality for customers and business owners.

Over the past decades, individuals and groups of people have used this technology as an inexpensive basis to innovate, producing solutions with limited funding that can create a huge impact and value on our society. The popular phenomenon of venturing to create a business under a high level of uncertainty is often referred to as "create a startup".

Eric Ries's book *The Lean Startup* [5] describes a framework under which one or more individuals can create a startup by following an adjusted set of principles that are similar to those included in the Scientific Method (Fig. 10.1).

To prove if a startup's product or service will be successful, its value proposition needs to be centred on an established hypothesis that has been designed to challenge the customer's or user's usual behaviour. For example, if a startup's product or service was related to electronic health records, the hypothesis would most probably be related to enhancing performance improvement in medical practices and/or increasing patient outcomes by using the product in a certain process.

After carefully designing a hypothesis, a startup builds a product or service that serves as a vehicle to challenge it, but because funding and other resources are likely limited, the venture needs to make smart decisions on product/service development. Ries describes this as the Minimum Viable Product/Service development process, which is basically creating a solution with sufficient features to attract early adopters that will offer the needed feedback to improve and scale.

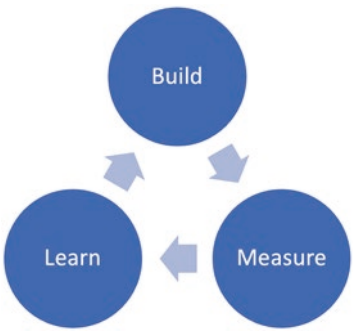

Fig. 10.1 The build-measure-learn loop as described in Eric Ries's *The Lean Startup* [5]

Table 10.1 Examples of challenges faced by digital health products/services

Digital health application	Example of a challenge
Telemedicine	Connectivity
Electronic health record	Privacy
Digital sleep improvement	Accuracy
Personalised health recommendations using AI	Liability
Smart watches	Traceability
Symptom monitoring through smartphones	Timing

The Value Proposition Canvas (VPC) developed by Dr. Alexander Osterwalder [6] can help a startup create products/services that are centred around the customers' needs. The VPC will help illustrate the customer's usual activities and pinpoint the "pains" or "symptoms" he/she is experimenting with because they're not using the startup's product/service. After making a list of both the activities and the pains, a startup must validate these assumptions through customer engagement, surveys and focus groups; not doing so may result in imprecise product/service design which will eventually lead a startup to a pivoting process and probable failure. After validating the customer's usual activities and pains, a startup can now focus on designing the product/service features that will provide value to the customer, saving them time and money.

Although being an entrepreneur in any sector can be very tough, Health tech/Digital Health startups face additional challenges that make it even harder for a product/service to reach the market (Table 10.1).

Since most health tech/digital health startup products/services are related to diagnose, treat or rehabilitate patients, they might have to comply with additional medical device regulation that requires additional funding and time to successfully launch into the market.

10.3 Entrepreneurship and Intrapreneurship

In entrepreneurship, the founding team is responsible for the ideation, operational framework, product/service development, funding, marketing, sales, legal and other process groups that lead to the startup becoming a formal company. In this type of venture, the team operates freely at their own pace and with their own rules. On the other hand, intrapreneurship refers to the innovation process within an established company, who provides resources and guidelines so that a team can deliver a result that either enhance an existing product/service or creates a new one. If the product/service developed in an intrapreneurship scenario is successful enough, it's common for the venture to evolve into a spinoff; a part of a company that has been sold to create a new one.

In both cases, the team members share the startup mindset (uncertainty, adaptability, awareness and leadership skills) and they also use the same startup principles, methodologies and tools previously mentioned. However, an entrepreneur will receive all the rewards and has a much higher risk than an intrapreneur, as the former one will not be risking neither time nor money. Regardless of the risk level, it is very common to see both project classifications competing in the healthcare market.

10.4 Health Tech/Digital Health Startup Ecosystem in Chile and Mexico

As mentioned in the abstract, most of the medical devices used in Latin America are imported from foreign nations, with countries like Mexico importing more than 80% of the medical technology used in hospitals [7]. With the rise in the accessibility of technology and inspiration from popular startup regions such as Silicon Valley, Latin American entrepreneurs and intrapreneurs have been working hard to deliver much more affordable and LATAM-oriented solutions [8, 9].

10.5 The VSZ-20-02 COVID-19 Mexican Emergency Ventilator Case

Due to limited critical COVID-19 equipment and complications in international logistics caused by the pandemic, the healthcare sector suffered one of its biggest crises in history [10]. Mexico was one of the most affected countries due to its large percentage of imported medical devices, outdated regulatory procedures related to emerging medical technology and lack of a well-established medical device industry [11].

When Mexican entrepreneurs and intrapreneurs witnessed the lack of mechanical ventilators for critically ill COVID-19 patients, multiple individuals (Biomedical and Non-Biomedical Professionals) gathered to assess the possibility to create ventilators to help their country. Although more than 30 ventilator initiatives were detected by the Mexican Society for Biomedical Engineering (SOMIB), almost all of them failed to deliver due to a simple motive; building a ventilator that will be used on patients is not just simply building a machine that pushes air through a circuit.

In 2020, a group of private companies and the Salvador Zubirán National Institute of Health Sciences and Nutrition gathered to develop an emergency ventilator to fight the deficit of these devices nationwide [12].

After months of hard work, the VSZ-20-02 emergency mechanical ventilator received a temporary emergency approval by the Mexican FDA COFEPRIS and built over 200 units to be sold at a lower price than foreign devices available in the

market ($12,000.00 USD in comparison to an average price of $60,000.00 USD per ventilator from recognised manufacturers).

The VSZ-20-02 Emergency Ventilator Project can be categorised within the entrepreneurial scope since several groups of professionals worked together to prove that the national industry holds the potential to develop the needed technology for clinics and hospitals in Mexico. Although most of the manufacturing team had not worked on medical technology projects before the VSZ-20-02 project, the ventilator succeeded to meet the regulatory criteria to obtain a temporary authorisation from COFEPRIS. Its success was due mainly because of the participation of several medical device specialists, consultants, healthcare professionals, regulatory agencies and universities. The project had a hypothesis, was built with limited functionality that targeted specific COVID-19 therapy needs and allowed Mexican hospitals to save over 70% of their budget when purchasing a ventilator for COVID-19 purposes. To evaluate both its functionality and feasibility, as well as to correctly maintain each unit, a third-party service provider was hired to offer preventive and corrective maintenance, user training, customer support and register any customer interaction that involved a ventilator unit in a CMMS software [13]. The collected data will be evaluated in 24 months to conclude if the ventilator could go under further development to enhance its functions and compete in the market with a wider scope [14].

10.6 Innovation Within a Company (Intrapreneurship)

Curious enough, the CMMS platform was donated by a startup (TINC) that emerged within a service company. Due to the lack of Latin American-focused CMMS solutions, a Clinical Engineering (CE) outsourcing company (Biomedica en Línea) [15] developed an asset management platform to be used in the 35 hospitals in which they were offering CE outsourcing services. The main purpose of this platform was to standardise CE processes among their customers, which would then give them the opportunity to generate enough data to create tailored reports for each customer (saving thousands of dollars in administrative labour). The platform was so successful that it eventually became a company of its own, offering a job to more than 20 professionals in Mexico that led them to win multiple international entrepreneurial competitions, raise a USD $300,000.00 investment round and offer their SaaS services to +700 customers in nine countries.

10.7 Proposed Role for Universities in the Startup Movement

Innovation begins in a classroom filled with enthusiastic students and experimented professionals (teachers). From 2012 through 2017, a survey was conducted in a private university in Mexico to assess final projects developed by last semester's

students. The intention of the survey was to conclude what percentage of those projects could be potentially used as a Minimum Viable Product/Service to help the community. The results concluded that only 7% of the 72 projects were targeted to a real community need.

Universities can have a huge and very productive role in the entrepreneurial process if only professors would (1) include assessing real customer needs in their project criteria, (2) were trained in the VPC/Lean Startup methodologies and (3) made enough emphasis in the Scientific Method for research.

One of the Top-Class Entrepreneurial Accelerators worldwide, Start-Up Chile [16], offers entrepreneurial teams an opportunity to develop their business idea into a startup under a proven mentoring process that includes networking, business model ideation, pitch practice and an equity-free seed fund of USD $40,000.00. Since its creation in 2016, Start-Up Chile has accelerated 1960 startups and has reached a USD $2.1B valuation, becoming one of the Top Ten accelerators in the world and the most important in Latin America.

If only the universities would focus more on solving real issues among their communities instead of randomly asking the student to develop a research essay to meet a milestone of a final project, many of these projects could be funded by programs like Start-Up Chile, which can help them turn their university project into a startup that will evolve into a successful business that generates value.

10.8 Conclusion

Latin America holds the potential of becoming a leading industry in medical technology [17], from university classrooms to manufacturing companies that export their products internationally. The Startup Era is slowly (but surely) emerging in Latin American countries [18], and with the clear example of scarce health tech solutions during the COVID-19 pandemic, economies will start looking at startups as the next solution to enterprise problems. With much lower operating costs, great talent, young energy and the recognition of the Biomedical Engineering profession healthcare regulations, disruption in the traditional healthcare model is happening through a systematic process that will require Venture Capital and Governments to start re-shaping their ways much faster than they thought [19].

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Chapter 11
Data for Social Good: A Tripartite Approach to Address Diabetes Self-Care and Patient Empowerment

Nilmini Wickramasinghe and Steve Goldberg

11.1 Introduction

One of the biggest burdens for healthcare systems globally is the exponential growth of chronic, non-communicable diseases such as diabetes [1–4]. In 2019, approximately 463 million adults (20–79 years) were living with diabetes [5, 6]; by 2045, it is estimated that this will rise to 700 million**.** The proportion of people with type 2 diabetes is increasing in most countries while 79% of adults with diabetes are living in low- and middle-income countries (ibid). The greatest number of people with diabetes are between 40 and 59 years of age, and 1 in 2 (232 million) people with diabetes are undiagnosed (ibid). Diabetes is responsible for 4.2 million deaths (ibid) and is a major cause of blindness, kidney failure, heart attacks and lower limb amputations. In the United States alone, diabetes caused at least USD 760 billion dollars in health expenditure in 2019—10% of total spending on adults (ibid). More than 1.1 million children and adolescents are living with type 1 diabetes and more than 20 million births (one in six births) are affected by diabetes, while 374 million people are at increased risk of developing type 2 diabetes (ibid). Clearly, these alarming statistics serve to underscore the depth and magnitude of this silent epidemic of diabetes, and the dearth of globally effective approaches to curb its continually rising incidence and impact.

Succinctly, diabetes mellitus (diabetes) is a metabolic disease due to several causes characterised by hyperglycaemia (high blood sugar) resulting from defects in insulin secretion, insulin action or both [5]. The chronic hyperglycaemia of

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diabetes is associated with long-term damage, dysfunction and failure of various organs, especially the eyes, kidneys, nerves, heart and blood vessels [7]. The vast majority of cases of diabetes fall into two broad categories (ibid). In one category, type 1 diabetes, the cause is an absolute deficiency of insulin secretion. In the other, much more prevalent category, type 2 diabetes and gestational diabetes, the cause is a combination of resistance to insulin action and an inadequate compensatory insulin secretory response (ibid).

Early detection and proactive management of diabetes are thus essential [8]. In this regard, a critical treatment imperative is to improve the control of diabetes by providing patients' monitoring to enable better assessment and control of blood glucose coupled with appropriate support and feedback regarding effective diet and exercise regimens [9–11]. This strategy also serves to prevent and/or limit the onset of further and unpleasant complications associated with poorly managed diabetes [8]. It is vital that a cost-effective solution that is convenient to both patients and clinicians, and least disruptive to patient lifestyle, be adopted [10]. However, given the escalating numbers of people developing diabetes (made more problematic by the rapid rise in developing countries primarily due to the adoption of westernised diets coupled with reduced physical activity) is reaching a crisis point for healthcare delivery. This indicates that current approaches to management are falling short.

As there is no cure, diabetes requires daily self-management with attention to regulating blood sugar through a balance of diet (supply of carbohydrate) and exercise (demand for carbohydrates), regardless of whether or not an individual is also using pharmacological therapeutic agents to enhance their insulin supply and/or cellular uptake [8].

To address this healthcare and community predicament, the Data for Social Good Cloud Innovation Centre powered by Amazon Web Services (AWS) at Swinburne University of Technology, Northern Health and Inet International, Inc., Canada, together with academics and healthcare professionals, are developing a unique flipped healthcare model (i.e. where the patient takes more responsibility, becomes an active participant who is empowered to manage their health based on being better informed) [12] for providing patients with type 2 diabetes support for self-management and patient empowerment. This is the first such initiative in the Southern hemisphere and is a unique approach, bringing together key yet very disparate stakeholders, a large international IT solutions organisation, an SME (small- to medium-sized enterprise) IT vendor, a large healthcare organisation and academe to:

(a) *Serve society*—by addressing a critical healthcare priority that affects 1 in 3 people and cost billions of dollars annually.
(b) *Involve stakeholders*—by bringing together patients, healthcare professionals, healthcare organisations with IT and academe as well as other key healthcare stakeholders such as government, and payers.
(c) *Impact stakeholders*—by working together to co-design a technology solution to enable people with diabetes to flourish while living with diabetes as well as supporting healthcare providers to provide superior, patient-centred care and reduce healthcare costs.

(d) *Value both basic and applied contributions*—by harnessing tools and technologies of the Internet of Things (IoT) to develop a new theoretical framework that will enable applied research to impact a pressing and current issue effectively and successfully.
(e) *Value plurality and multidisciplinary collaboration*—by bringing together all key stakeholders and working together to solve the pressing dilemma.
(f) *Subscribe to a sound methodology*—by applying Amazon's innovation approach and enfolding around these key principles of Design Science Research Methodology, co-creation and user-centred design.
(g) *Provide broad dissemination*—by using many forms of dissemination, including Amazon press releases, hospital and research networks, social networks and patient advocacy organisations to ensure the advancement and uptake of knowledge and practice in this space.

The proposed approach serves to underscore the importance of adopting a responsible style to design, development and deployment of a robust, personalised yet culturally sensitive IS/IT (information systems/information technology) solution to support individuals with diabetes will prove to be beneficial in addressing the current crisis. The following presents the key steps in the design and development of this solution "SAPIENT", the first stage of this longitudinal research project.

11.2 Background

Jimenez et al. [13] have noted that currently there are over 300,000 health apps available in the market targeting a variety of user needs from weight loss to management of chronic conditions, with diabetes being the most commonly targeted condition. Separately, we conducted a simple assessment of several of these Apps using a Google search and examining patient/user reported feedback to develop a flavour for the strengths and limitations of these Apps. Specifically, we examined the top 60 iOS and Android mobile apps used for monitoring diabetes based on user ratings available at the time of review and noted the following:

– 41 are free apps
– 19 require some form of payment
– The cost of paid apps ranges from $0.99 to $86.99
– 50 are Android-based
– 10 are iOS-based
– Of the 53 Android-based and 10 iOS-based apps, 6 are both iOS- and Android-based

Tables 11.1 and 11.2 present summaries of the data compiled around specific features.

A key point to note is that none of these leading apps provided ongoing behaviour support and reinforcement nor was their provision for cultural nuances,

Table 11.1 Classification of the key features of diabetes mobile apps

Feature
Alcohol consumption management
Automatic synchronisation
Bluetooth connectivity and compatibility with other apps and devices
Carb intake and sugar level analysis
Data backup and export
Doctor's report and appointments
Expenses management
Health and medication analysis
Lab report inclusion and prescription management
Location monitoring
Meditation, thoughts and behavioural management
Nutrition, exercise and health tips
Report modification
Scheduling and reminders
SharePoint and networking
Smart assistance

Table 11.2 Summary of number of features present in surveyed apps

Number of features	% of Apps
1	28
2	8
3	15
4	22
5	10
6	5
7	7

religious and/or ethnic preferences around diet and exercise; rather, it was assumed that everyone subscribed to a typical meat and vegetable diet.

Given that diabetes management is an ongoing, lifetime endeavour, especially given the lack of existence of any cure or known solution for a foreseeable cure, sustained behaviour modification around lifestyle, diet and exercise is an essential aspect to achieve successful and long-term blood glucose management [8]. Therefore, it is unsurprising that the current apps on the market are not significantly successful in supporting long-term management for patients with diabetes. Moreover, another aspect to be noted is that these apps pay little if any attention to cultural and/or religious sensitivities around food choices and recommendations and/or exercise activities. It is not possible to ascertain that co-design featured significantly as this point was never mentioned but this also means we cannot assume that it did not occur just because it was not mentioned; thus it is prudent to believe it is highly likely that co-design was not a significant factor in the design and

development of the examined apps. Finally, this chapter contends that by drawing upon the more recent advances in analytics (such as artificial intelligence (AI) and machine learning techniques), it should be possible to design and develop a digital health solution that can support diabetes self-management by providing real-time feedback and decision support to individuals regarding better diet and exercise choices based on their current blood glucose levels when interpreted in the context of their actual current and recent food and diet choices.

Hence, the following sets about to design a more tailored, precision diabetes self-management tool to address this apparent void. The research question guiding the study is: *How can we combine the advances in digital health, in particular mobile health solutions and data analytics, to support a personalised yet culturally sensitive self-management support for individuals with type 2 diabetes to enable ongoing tight blood glucose control and thereby superior diabetes management*?

11.3 Method

As noted by Jimenez et al. [13] and confirmed not only by our own assessments of the extant literature but also by previous work [9], the ambiguity of app selection and the wide variability in key features of the apps recommended for diabetes management create many difficulties for patients when trying to select the most appropriate and effective app to help them achieve optimal self-care of their diabetes. Moreover, it appears that these apps fall short of providing sustained benefits [9, 13]. It is critical, then, to involve key stakeholders; patients, clinicians and technology leaders to define the key features an app should have for it to be classified as a "diabetes management" app (ibid). Taking this into consideration and motivated to address a serious and significant healthcare issue; namely diabetes management, we thus, assembled a multi-dimensional team including leading clinicians (endocrinologist, diabetic nurse, diabetic educator and dietician as well as senior health professionals), a large public hospital in Victoria, Australia that has an extensive and heterogeneous diabetic patient population, AWS Cloud Innovation team, an SME IT vendor who has had over 20 years of designing mobile solutions for diabetes and an academic team consisting of individuals with clinical expertise in diabetes and glucose control, digital health, IS/IT and behavioural science. In this way, we were confident that the team had the necessary expertise, knowledge and skills to address the design, development and deployment of a suitably robust technology solution that would be fit for purpose.

This research project represents the first AWS Cloud Innovation Collaboration (CIC) in the Southern hemisphere and it subscribes to a rapid idea-to-realisation format incorporating Amazon's "working backwards" technique [14] that has been used and proved to be successful, coupled with design science research methodologies, co-creation and user-centred design principles. The project consisted of several sequential phases that also required numerous iterative steps within and across the respective phases.

11.3.1 App Development

The initial build phase was conducted over a 10-week period on the securement of appropriate ethics approvals. The objective of this phase, which is consistent with Amazon's *working backwards* mechanism that is applied to Amazon new product development projects, was to apply rapid development to complete a conceptual prototype. This conceptual prototype was then used to facilitate discussions with user groups to ascertain key features and needs required of the solution, so it would indeed be fit for purpose. Figure 11.1 depicts the essential stages within this key phase.

To build the conceptual prototype, the key stages included multiple site visits, semi-structured interviews with patients and clinicians, as well as working with IT team members to design and develop the essential elements of the conceptual prototype. Key deliverables at this stage included identifying important person/patient types or personas around age, gender, cultural sensitivities, likes and helpful features for patient users and key clinical imperatives for the clinical users. Standard qualitative and quantitative techniques were used including focus groups, semi-structured interviews, surveys and hermeneutic analysis to gather the necessary data.

11.3.2 App Validation

Once the conceptual prototype was deemed appropriate by both clinical and patient users then the next phase was the build stage of the functional prototype. On the development of the functional prototype a test phase is now in progress. The test phase consists of two key parts. The first part involves unit testing to ensure the solution provides the correct results when dummy data is entered, and the second part is a clinical trial with 100 patients to assess usability, feasibility, fidelity desirability, viability and establish proof of concept. The clinical trial involves a two-arm

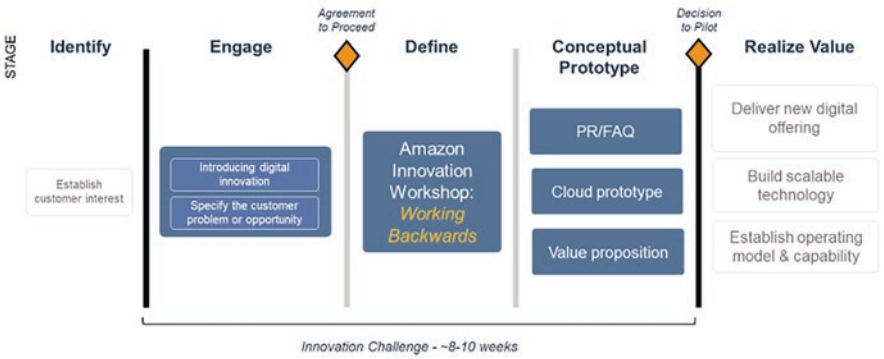

Fig. 11.1 Phase 1 with associated stages

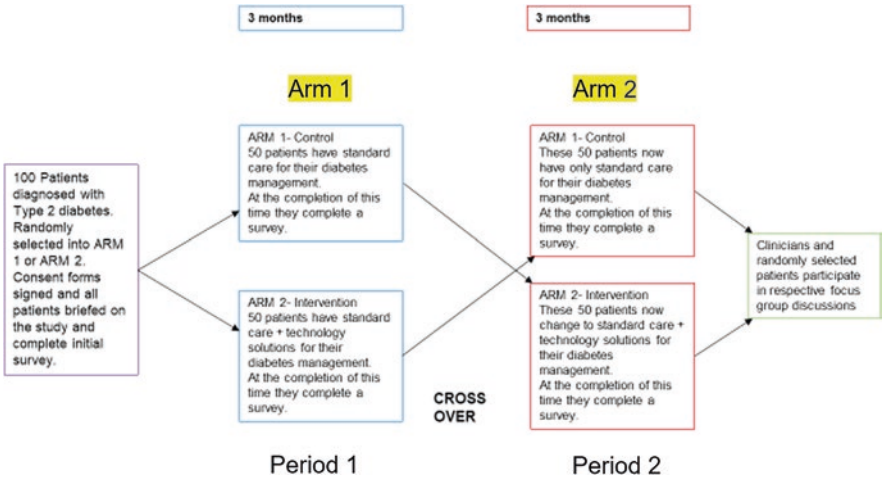

Fig. 11.2 Study design for the clinical trial

cross-over trial of 6 months, with cross-over taking place at the 3-month mark (refer to Fig. 11.2). One arm of the study will have standard care plus the built solution while the other will have just standard care. At the 3-month cross-over mark the two arms will inter-change. This is necessary to assess haemoglobin A1c levels (HbA1C), an objective measure of blood sugar control [15]. Cross-over trials are deemed a most appropriate research design to test solutions of this nature; namely when a technology solution is introduced to enhance or augment standard care [16]. At the start, cross-over point and conclusion of the clinical trial both patient and clinician users complete a short survey regarding the use of the solution. During the course of the clinical trial patient blood glucose, diet and exercise are monitored and at each 3-month mark HbA1C is measured, to enable assessments of the fidelity, desirability and viability of the built solution. In addition, at the end of the clinical trial a subset of patients and all clinicians will partake in focus groups respectively to discuss the solution, enhancements and other issues.

11.4 Results

In following the prescribed "working backwards" approach of Amazon, a first essential step is the development of an infographic that captures all the key aspects around the problem domain. Figure 11.3 presents the developed infographic. This

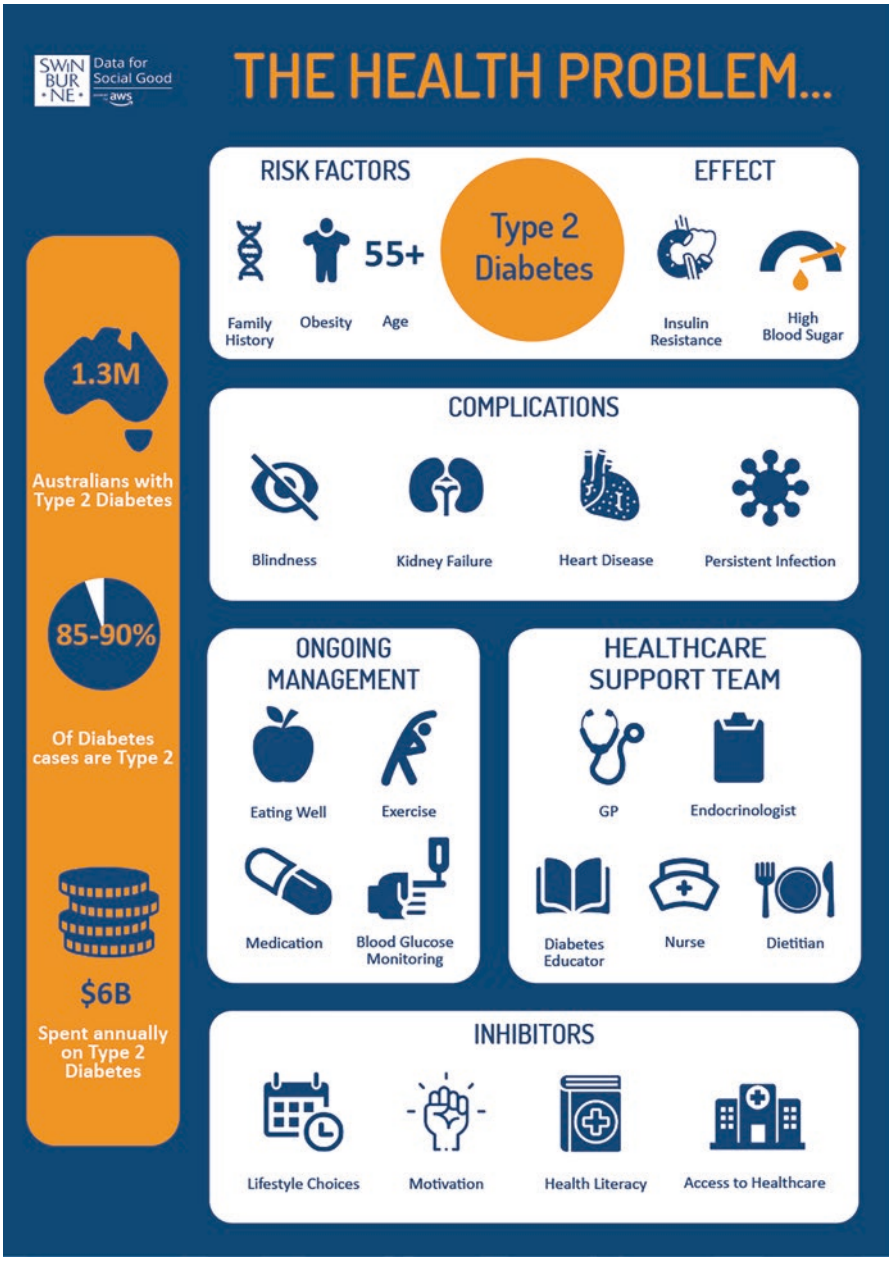

Fig. 11.3 Diabetes infographic

infographic was used to communicate between all users (patient and clinician) critical aspects of the problem domain and its far-reaching implications. Specifically, in the case of diabetes, there is the cost for the healthcare system, the impact on

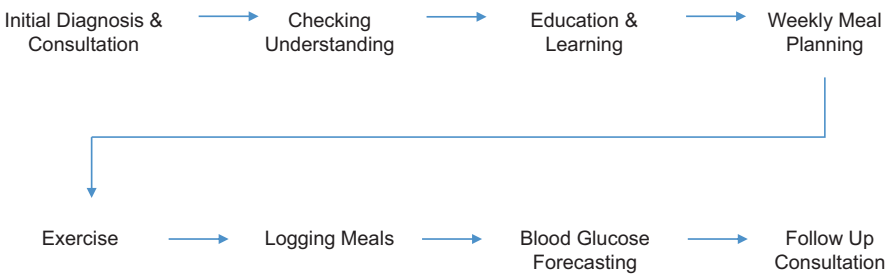

Fig. 11.4 Conceptual prototype

clinicians and most importantly the impact on patients especially if left untreated or poorly managed. The developed infographic also captures key inhibitors.

The conceptual prototype called "SAPIENT" was developed within the 10-week rapid design phase, as presented in Fig. 11.4. Although not explicitly demonstrated in the conceptual prototype, this solution is powered by a very sophisticated analytics engine. The analytics are required to support the integration of patient anthropometry, daily blood glucose measurements coupled with exercise activity and food intake to then predict and thereby advise to the patient suggested food and exercise choices that will ensure best blood glucose levels and thus guide them in achieving the best and sustained management of their diabetes. Cultural sensitivity is reflected in the food choices that are developed, keeping in mind the patient's ethnicity, religious beliefs and/or allergies and food preferences. Moreover, in the course of time, personal preferences will be learned and thus can also be recommended. The sophisticated analytics to support this is designed in collaboration with AWS and their Data for Social Good group.

In addition to subscribing to the "working backwards" approach of Amazon, the study also adhered to a design science research methodology coupled with co-creation and user-centred design framework. It is important to note that in this context there are two key user groups: patients (and their carers) and clinicians and both groups' inputs were considered. Design science is becoming an important research paradigm especially if the desire is to design and develop high fidelity, useful and usable solutions [17]. Moreover, Hevner and Wickramasinghe [18] noted that for healthcare contexts, the use of a design science research methodology (DSRM) is especially prudent when fine-tuning innovative solutions; and thus, it was incorporated when moving from the conceptual prototype to design and develop the functional prototype. Table 11.3 maps the cycles of DSRM as used to develop the built prototype.

The developed conceptual and functional prototypes respectively have several unique features including being culturally sensitive and supporting ethnic diversity and being tailored to individuals needs around their diabetes management. Moreover, the built prototype provides educational and behaviour change support coupled with guidance around good diabetes care for medication management, glucose control, diet and exercise. This is achieved through nudge features, the ability to support serious games [19] and/or interact with users chosen social network. The power of nudge solutions, coupled with serious games and the ability to

Table 11.3 Design science research guidelines

Design science research guidelines	SAPIENT
Guideline 1: Design as an artefact	SAPIENT—a convenient and innovative mobile solution to support patient and clinical users and enable diabetes self-management and monitoring to ensue is developed after iterative discussion with clinicians and patients. It also has the potential to support a value-based care agenda as it can increase timely patient access, has the potential to increase quality of care and has the potential to reduce costs of care by preventing more serious problems from occurring
Guideline 2: Problem relevance	To address the need for continuous and superior monitoring and management of type 2 diabetes patients. To provide in a timely fashion anywhere, anytime key data to facilitate better decision making. To provide an appropriate technology solution that can support self-management of diabetes for patients and support for clinicians
Guideline 3: Design evaluation	Clinicians and potential patient users were included at various points in the design and testing of the solution. In addition, hospital representatives were consulted to ensure the solution complied with all government requirements for technology solutions interacting in medical research. In particular, patient and clinician feedback enabled the solution to be tailored to the Australian healthcare context. Key examples included ensuring the scale to measure blood glucose levels were correct, since different scales are used in different countries; the correct names of the medications were enabled; appropriate legal requirements met and message included such as "if you have any concern please contact your health professional [number provided] immediately"; while patient-users provide insights into the look and feel from their perspective on how they would like data displayed. In addition, we tried to gather critical insights around cultural/ethnic and/or religious preferences regarding diet and exercise choices. All these aspects were addressed before the solution was used in the study
Guideline 4: Research contributions	In this study, users' perspectives of the mediating role of the solution are explored
Guideline 5: Research rigor	Theoretical foundations and conceptual models drawn from information systems, chronic disease management protocols, healthcare quality and safety were used to inform the development cycles to evaluate SAPIENT in clinical contexts
Guideline 6: Design as a search process	In this project, the design was essential to be correct to meet with ethics requirements in healthcare studies and to ensure full and complete risk mitigation in such a context
Guideline 7: Communication of research	Internal communication: Presented the technology and clinically-oriented users through focus groups, simulations exercises, brainstorming meetings, as well as technical and managerial meetings External communication: Progress and findings are reported in relevant health and IT forum

interact with one's chosen social network has been shown to enable and support desired and sustained behaviour modification [20]. In addition, at all times clinicians have oversight of the essential clinical metrics so can assess if the patient is in need of essential medical treatment, thus ensuring the solution is medically responsible at all times.

Initial results and feedback from patients on the conceptual prototype were very positive. In particular, patients commented on simplicity and ease of understanding as well as the ability to have the important information readily accessible. Similarly, clinician users were very supportive and enthusiastic, noting that the proposed solution addressed all clinical considerations from their perspective in a convenient fashion.

Reflections on the rapid conceptual build phase with both clinician and patient participants identified some noteworthy comments as follows:

1. Patient 1—*it was nice to be heard and have my concerns listened to*.
2. Clinician a—*while it has been a very full on day, this is best given we are so time poor. I can focus on this and also see where it is going quickly…. I am really pleased with the approach and look forward to seeing the built solution*.
3. Clinician b—*it is great to work with such a strong and diverse team. I think we have captured the key features…. I am sure it will really help us*.

11.5 Discussion

There is little doubt that diabetes is a significant global problem. In today's information age, we should expect that IS/IT can play a pivotal role to ameliorate the current crisis around diabetes and more importantly support better care and self-management so that those who suffer from this serious, unpleasant, chronic, non-communicable disease can enjoy high-quality life. We decided to address this significant void by setting out to answer the research question *How can we combine the advances in digital health, in particular, mobile health solutions and data analytics to support a personalised yet culturally sensitive self-management support for individuals with type 2 diabetes to enable on-going tight blood glucose management and thereby superior diabetes management*?

To answer such a question requires a rich and complex longitudinal project. Critical steps include the assembling of a robust and skilled multi-dimensional team, the design and development of an approximate conceptual prototype which is then developed into a functional prototype that can then be tested at both the unit level and in a clinical trial. Only once all these steps have been completed can we evaluate the success of the project.

Based on the results to date, the solution is rated highly by the clinician and patient users in terms of usability, acceptability and functionality. Results from the clinical trial will serve to confirm the success of the solution with regard to patient compliance, patient satisfaction, level of glycaemic control and clinician satisfaction. Once all these benefits are assessed, it will be then necessary to unpack how and why it supports value-based care and provides a better approach to combating diabetes, a pressing global healthcare priority that has far-reaching individual and societal implications.

At this stage, we have completed most of the key steps in the development of the prototype except the completion of the clinical trial. Hence, we cannot state if the

project is successful. However even at this stage, this research in progress study highlights many essential contributions for theory and practice and most importantly in terms of critical factors to ensure responsible IS design, development and deployment to address a global social priority as follows: In terms of practice, it demonstrates the benefits of collaborating with a multi-dimensional team of clinicians, IT vendors and researchers. Without such a skilled team it would not be possible to effectively and appropriately design and develop a solution to address this complex and wicked problem. Next, it highlights that especially in healthcare, it is important to recognise that there exist multiple user groups, most typically patients and clinicians, and both groups' needs and requirements must be identified. Moreover, while neither of these two groups is homogenous, the heterogeneity of the patient-user group is an important factor to consider when providing suggestions around diet and exercise. In particular, it is vital to be sensitive to cultural/ethnic and/or religious preferences and/or requirements. Designing solutions with either an explicit or an implicit view that one size fits all with regard to diet and exercise is not only problematic in the context of diabetes but also irresponsible because it unintentionally contributes to the significant chasm around health inequality with regard to individuals of different cultural/ethnic and/or religious backgrounds and their ability to access appropriate food choices that also are appropriate from the perspective of their diabetes management plan.

From the perspective of theory, it demonstrates the benefits of subscribing to solid research methodologies and design principles such as DSRM coupled with co-creation and user-centred design but also incorporating successful techniques from practice such as Amazon's "working backwards" approach. In this way, we have developed a "flipped" healthcare model where the patient takes part in designing the solution that is best suited for their care but we also have taken key steps to ensure a designed solution is not only useful and usable but also of clinical value. Today, we can see many apps developed to address various healthcare issues but we caution that when such solutions are developed without sufficient rigor and healthcare domain expertise they are highly likely to do more harm than good, albeit the harm is naturally unintended, it is nonetheless irresponsible rather than responsible because ultimately in healthcare a mistake can mean the difference between life and death.

This study does also have a significant contribution to highlighting an important area with regard to IS research and that is its role in outlining an IS study that is focused on enabling a "better world". Given the number of people globally currently suffering, as well as those projected to suffer, from diabetes in the next 5 years alone there is broad recognition that diabetes is a serious global health concern. Of note, this health concern has far-reaching implications not just for the patients and their families but also for the care team and healthcare workforce implications, healthcare funding and society at large. Hence, we believe this study highlights critical aspects of how an information systems research initiative can strive to enable a better world as follows:

(a) *Serve society*—type 2 diabetes affects one in three people and cost billions of dollars annually so by focusing on designing and developing a superior technology solution that supports self-management and patient empowerment, that is

clinically valid, addresses behaviour modification and is culturally sensitive, indeed serves society.

(b) *Involve stakeholders*—in this project we have brought together patients, healthcare professionals, a large healthcare organisation, a global organisation AWS and an SME together with academe as well as other key healthcare stakeholders such as government, and payers. In fact, it is unusual for clinicians to collaborate with a leading IT vendor and patients on a project, and we refer to this as a tripartite approach.

(c) *Impact stakeholders*—by working together to co-design a technology solution to enable people with diabetes to flourish while living with diabetes as well as supporting healthcare providers to provide superior, patient-centred care and reduce healthcare costs we are making progress to beneficially impact all key stakeholders.

(d) *Value both basic and applied contributions*—by harnessing tools and technologies of the Internet of Things (IoT) we have developed a theoretical framework by combining DSRM with co-creation and user-centred design together with Amazon's "working backwards" approach to enable the rapid design and development of a technology solution that is fit for purpose to impact a pressing and current issue effectively and successfully.

(e) *Value plurality and multidisciplinary collaboration*—by bringing together all key stakeholders and working together to solve the pressing dilemma we have been able to combine diverse types of inquiry to facilitate the development of a solution to address the complex and wicked healthcare problem of diabetes management. Moreover, by recognising a "one size fits all" solution is not appropriate in the context of people suffering from diabetes and thus incorporating cultural, ethnic and/or religious sensitives to food and/or exercise we are also recognising plurality with the solution and helping to reduce rather than increase health inequality issues.

(f) *Subscribe to a sound methodology*—by applying Amazon's innovation approach and enfolding around this the key principles of Design Science Research Methodology, co-creation and user-centred design we have subscribed to existing sound methodology but also leveraged this and developed a more suitable methodology for designing solutions for complex healthcare contexts.

(g) *Provide broad dissemination*—by using many forms of dissemination, including Amazon press releases, to ensure the advancement of knowledge and practice in this space we plan to disseminate our findings on completion of the clinical trial.

11.6 Conclusions

This study describes a unique approach to combating a pressing and significant healthcare and social problem; namely diabetes. By bringing together industry, healthcare and academe to co-design a solution together with patient and clinical

users that is fit for purpose, the study highlights not just a specific example of responsible IS Research for a better world but also and perhaps more importantly a model or blueprint for performing sound IS research that can benefit society, which we hope that many will choose to adopt. We believe that by having a multi-dimensional team of academics and not just IS researchers to co-design a digital health solution together with industry, clinical experts and patient users, we are more likely to develop solutions that are fit for purpose, appeal to both clinical and patient users and deliver better clinical outcomes. We note that working in such a multispectral team brings with it its own challenges as individuals and/or groups have specific approaches and need to become flexible and nuanced in other members' styles and protocols, but our experience is that when all have the same shared goal, trying to address a key healthcare priority, there is a willingness to work together to develop a successful solution.

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Chapter 12
Realising the Healthcare Value Proposition of Better Access, Quality and Value of Care by Incorporating the Social Determinants of Health with Digital Health

Nilmini Wickramasinghe and John Zelcer

12.1 Introduction

Healthcare systems in most OECD countries are facing major challenges as they try to deliver on a healthcare value proposition of better access, quality and high-value care. There are many factors that combine to increase demand and contribute to the rising costs of care, including an aging population, longer life expectancy and a rise in chronic conditions [1]. This situation is most stark when we look at the United States. When comparing healthcare performance across high-income countries, the United States most notably ranks the lowest [2]. In contrast, the United States is generally above average with respect to care process measures, which include prevention, safety and patient engagement [2]. Again, however, the United States ranks relatively low with respect to indicators relating to access, care coordination, avoidable hospitalisation and information flow between healthcare providers and social service providers [2, 3].

One essential factor to facilitate more effective and efficient care delivery is around tailoring care and reducing disparities [2]. To realise such a goal, it is necessary to focus on aspects that add value while simultaneously removing areas that do not directly impact patients and/or do not add value. By focusing on care coordination and engaging patients, it is possible to be successful in this regard [1]. Improvements in care coordination that focus on chronic conditions as well as the elimination of unnecessary and low-value services, reduce over-prescription of antibiotics and analgesics coupled with reducing unnecessary surgeries, have

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shown that it is possible to save up to $271 billion [1]. The key stakeholders of healthcare—doctors, payers, regulators and healthcare administrators—are all focused on improving quality, access and value in care delivery [4]. One way to do this is to increase the role of primary care, especially with respect to prevention as is noted in the literature [3, 5]. Furthermore, we have witnessed a significant adoption and diffusion of expensive digital health solutions [5]. However, this fails to take into account social indicators which also have a bearing on prevention and better healthcare outcomes [6] and thus only serves to exacerbate the cost of care without addressing improvement to the quality of care or better access, and hence the healthcare value proposition is pushed further from attainment [7–11].

The situation has become bleaker in the COVID-19 pandemic when we have witnessed people in lower socio-economic communities being more severely affected and having less access to necessary care [12]. While the association between socio-economic and behavioural determinants has been noted by care providers to have a germane impact on outcomes, it is still to be seen if this view will be recognised in healthcare reform initiatives [3, 6].

12.2 Social Determinants of Health

Patients' social and physical environments have a strong impact on their relative health and wellness and as such, are recognised as critical aspects of the social determinants of healthcare (SDOH) [11]. Figure 12.1 depicts these key areas which are the main aspects that impact people's work and living activities. Thus, if specific SDOH is improved, it is not just an individual who will benefit but rather it is possible to ameliorate specific disparities relating to healthcare and in so doing, the likelihood of reducing unnecessary hospital visits also increases [3, 7, 8].

To summarise, the SDOH comprises economic and social aspects that, taken together, impact people's health status and ability to recover. Thus, they make up the health-promoting factors from one's working and living environments and directly impact the risk of contracting a disease or infection as well as one's ability to recover [7]. For example, if one lives in a location that has no running water, it is highly likely that infection will occur versus if one has clean water. Hence, by systematically examining these factors one by one, it is possible to identify solutions to ameliorate such conditions and thus ensure a better level of health and care might ensue [3].

Therefore, we focus on the key social determinants of health with a view to map these against healthcare delivery challenges of access, quality and value so that we can then model this and identify the key factors and their relation to individual patients' outcomes [3].

From this, we can also construct a framework to assist in the identification and evaluation of current determinates to then assist with the design and development of a solution set to address the current situation [3]. Next, we integrate this with the key tools of digital health to show how we might transform specific healthcare contexts

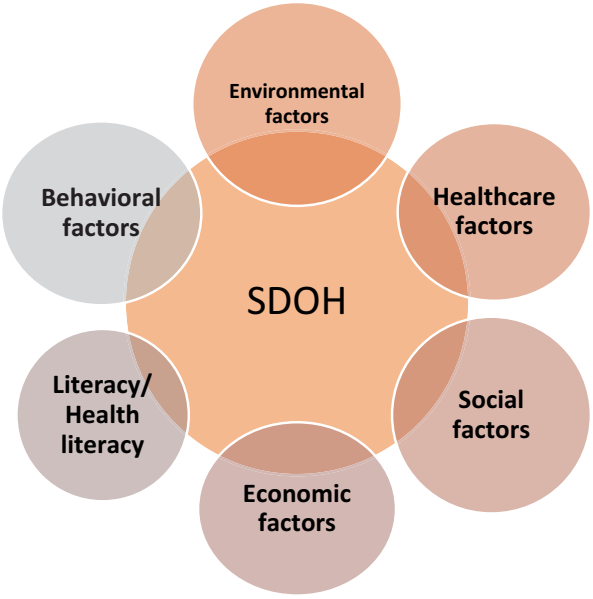

Fig. 12.1 Five determinant areas of SDOH (adapted from [11])

to enable better healthcare ecosystems which in turn will then support the realisation of the aspired healthcare value proposition.

We contend that without critical consideration of the social determinants of health coupled with digital health solutions, it will not be possible to realise the desired healthcare value proposition. To address this key void and answer the research question; "How can we incorporate the social determinants of health and digital health solutions to enable and support better healthcare outcomes and the realisation of the healthcare value proposition of better access, quality and value?", we proffer the *value cube* model (Fig. 12.2).

12.3 Method

This research will adopt a qualitative research methodology to answer the posed research question and by so doing, develop a suitable model. The research has several phases including performing a substantive review of relevant literature to identify and assess aspects of clinical and non-clinical determinants of health [3]. We included studies that emphasised identifying the subcomponents within healthcare determinants. These components actively apply to patients' lifestyles under different categories of health determinants. In addition, we assessed the major digital health capabilities and finally the impacts that could be realised if the necessary building blocks are put in place. From this, we develop our value cube model (Fig. 12.2).

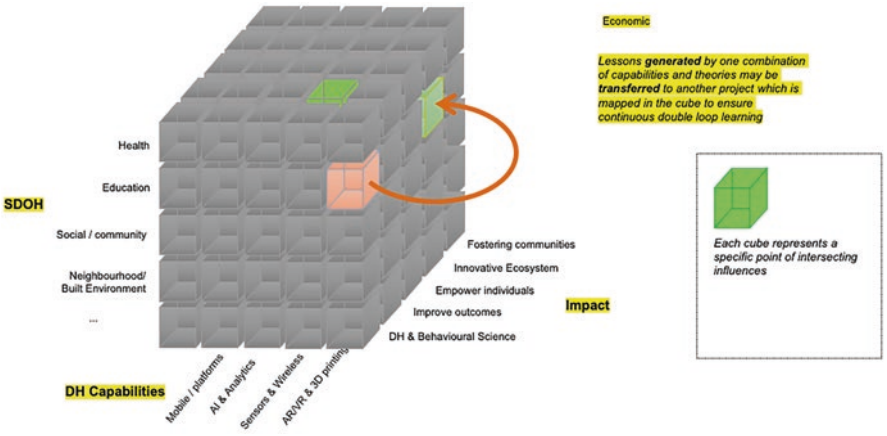

Fig. 12.2 Value cube

12.4 Digital Health Powered Through Health 4.0

The application of advances in digital technologies, such as mobile and platform solutions, analytics and artificial intelligence (AI) as well as high-speed computing and networking, has brought significant gains to various industries in terms of effectiveness and efficiencies as well as enabled mass customisation [3].

Since the early part of this new millennium, Industry 4.0 has been spearheading much of this advancement [12]. Industry 4.0 is enabled via the technologies that make up the Internet of Things (IoT) and Internet of Systems (IoS) [12]. When Industry 4.0 is applied to healthcare, it is often called Health 4.0 and relates to the digitisation of healthcare and the application of IoT to healthcare contexts [12, 13]. Specifically, the relevant technologies in Health 4.0 include analytics and AI, augmented, mixed and/or virtual reality, mobile and platforms, sensors, 3D printing and/or enterprise-wide systems such as EMRs (electronic medical record systems) [3, 13–15].

Returning to the SDOH, the role of Health 4.0 is as an enabler for trying to address the disparities. A case in point can be around health literacy; via a mobile solution that provides advice and information around a chronic condition such as diabetes and what might be a good food choice versus a less appropriate food choice can be very powerful and yet convenient and relatively inexpensive to an individual in a lower socioeconomic situation. Thus, it is the contention of this chapter that Health 4.0 plays a pivotal role in enabling an amelioration of most if not all the factors that are connected to the SDOH and thus can have a critical role to play moving forward [3].

12.5 Impacts

Returning to the value cube presented earlier, we identified several key impacts (refer to Fig. 12.2) which we now discuss in turn.

(a) **Fostering Communities**

Due to various cultural norms and differences in socio-economic level, there exist variations in health equity and healthcare delivered across different communities [8, 16]. Taken together these factors also affect relative health literacy [8]. By developing targeted and tailored strategies to ensure a high level of health literacy for all communities it is then possible to address some of these current voids [16].

(b) **Innovative Ecosystems**

As the recent COVID-19 pandemic has clearly illustrated, ecosystems that are able to respond and adapt quickly have been able to manage more effectively and be less affected by the pandemic. Thus, it becomes necessary to ensure that ecosystems are prepared and ready for dealing with various types of emergency and disaster scenarios [17].

(c) **Empowering Individuals**

Today, when health and wellness are affected much more by chronic conditions rather than infectious disease, it becomes essential that individuals are empowered in their own health and well-being activities. Mental health, diabetes and obesity are examples of chronic conditions that can either be avoided or at least better managed if individuals are empowered and take an active role in their health and wellness management including following a suitable diet and maintaining appropriate physical exercise regimens [18].

(d) **Improving Outcomes**

Delivering high-value, quality care also includes trying to mitigate risks, avoid adverse events and prevent unplanned readmissions. To address these aspects, advances in analytics have demonstrated that it is possible to a priori identify possible high-risk patients so that preventative measures can be initiated which will serve to ensure higher clinical outcomes ensue [19].

(e) **Digital Health (DH) and Behaviour Modification**

An essential aspect of managing various chronic conditions, such as diabetes and obesity or programs to address medication adherence, is to address behaviours that exacerbate the condition—for example, eating the wrong foods. In particular, as this is an ongoing requirement, it is essential that patients have the necessary support. Technology solutions, most notably a plethora of apps, have been developed to include nudge strategies and serious games which serve to focus on reinforcing positive behaviours and minimise negative behaviours in a gentle, non-judgmental, non-punitive approach [20].

12.6 Discussion

The presented value cube model (Fig. 12.2) is proffered as a suitable model to assist in addressing various public health issues in which the social determinants of health can be a major factor impeding the realisation of better care. For example, if we apply the value model to the COVID-19 pandemic, it is possible to relatively rapidly assess how best to design and develop a technology intervention that can have maximum benefit. Specifically, as has been the case, when designing a mobile solution to remind and support people on the three public health steps for precaution (hand sanitising, mask-wearing and social distancing where possible), the knowledge (or at least appreciation) of the individual's or group's education, health status, social or community surroundings and built environment become relevant factors to consider in the design of a suitable solution if the solution is to then have high fidelity with respect to providing support that can be useful and useable in a sustained manner for greatest impact. Hence, this example illustrates the role of the value cube in supporting primarily the education angle via a simple mobile solution in order to realise the impacts of improving outcomes. Figure 12.3a highlights this in yellow.

The proffered value cube can also be used to realise a shift and impact multiple aspects including empowering communities and individuals, improving outcomes as well as changing behaviours as the next two case vignettes illustrate. While the two vignettes are different, the components of the value cube of relevance are highlighted in blue in Fig. 12.3b.

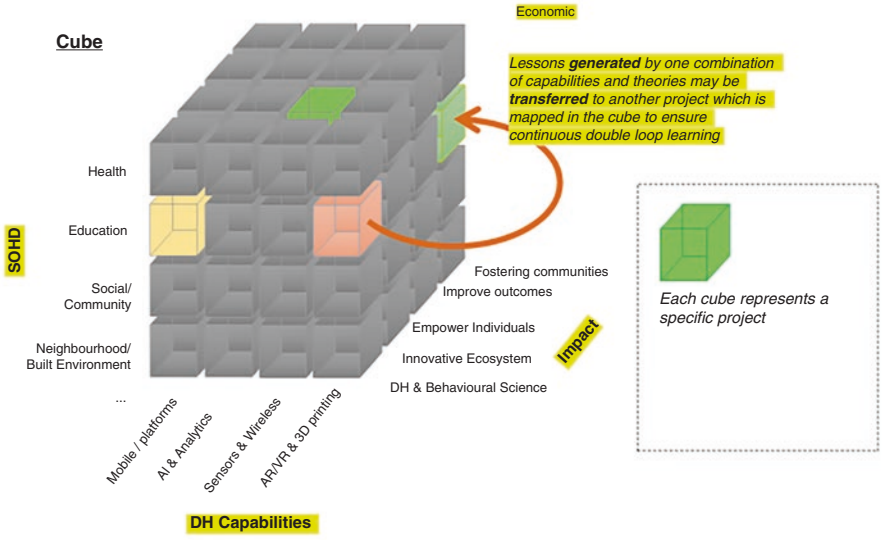

Fig. 12.3 (**a**) Model I for smarter health communities. (**b**) Model II for smarter health communities

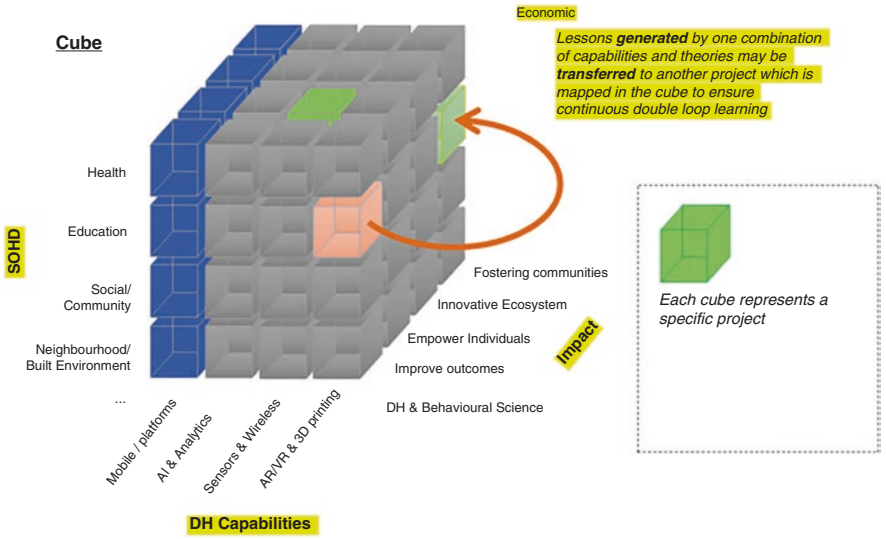

Fig. 12.3 (continued)

A study conducted in South Side in Chicago, Illinois [21] that focused on the design and development of an appropriate technology solution to support African Americans and Hispanics with respect to diet and exercise to decrease the individuals risk of developing diabetes is a case vignette that serves to illustrate the benefits of the cube to provide both descriptive needs and prescriptive recommendations. For instance, in this region, the average level of education is at best high school graduation, while the general health status is poor, and the level of health literacy is also low. Community influence in the form of gang activity is prevalent and the built environment is in general not supportive. Thus, in developing the appropriate digital health solution to provide high impact with respect to fostering communities and empowering individuals, as a first step it was necessary to engage individuals and build their awareness. Given the relatively low level of education and health literacy, this was done using gamification based on "local" heroes and villains, being sure to use language that was culturally appropriate and used.

Similarly, in a study to develop a diabetes self-management solution for the catchment of patients served by a public hospital in the northeast of Melbourne, Australia [22], the solution is being developed with due consideration to food preferences including halal and vegetarian options, high use of graphics and multilingual capability.

12.7 Conclusion

As 2020 ends, globally we are still trying to get control of the COVID-19 pandemic. Many things have become apparent with the pandemic. One such area is the inequalities of care and the failure in general of public health initiatives to rapidly address the COVID-19 crisis. We contend that one aspect that could help in this regard is a focus on the social determinants of health and how a better understanding of these, combined with leveraging possibilities from digital health solutions, can result in meaningful and impactful initiatives that can empower individuals, foster communities, modify behaviours and thus improve outcomes. By examining case vignettes, we have illustrated some of the benefits of the proffered value cube. Our future work will serve to empirically test the cube in a variety of contexts to demonstrate not just its benefits but also its generalisability and thus its full potential to support the realisation of better public health initiatives.

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Chapter 13
Why Do You Want Me to Use This EMR?

Amir Eslami Andargoli, Helen Almond, Dominic King, Jonathan Schaffer and Nilmini Wickramasinghe

13.1 Introduction

For the last 10 years, the digital transformation of healthcare delivery for all [1] is typically highlighted by the implementation of an EMR (electronic medical record). However, research to date, mainly from the United States [2, 3], suggests that while investment in the EMR is significant, the return on this investment, patient satisfaction, nurse and clinician satisfaction is rated as poor at best. Moreover, EMR systems do not (and arguably should not) mimic the actual clinical care processes used routinely by nurses and clinicians, making adoption even more challenging. Anecdotally, it is noted that nurses often question "You want me to use this EMR"?

Digital transformation in healthcare delivery is here to stay. However, the transformation can only be successful with the expected benefits achieved if health and care providers and users adopt, adapt and embrace such electronic solutions. As nurses provide the majority of inpatient healthcare, this research has focused on them. Specifically, the benefits and detriments of the adoption of EMR systems for nurses are evaluated, thus assisting in proactive development to responses when they question the benefit of an EMR.

For more than two decades, the transition from paper-based systems to digital records systems has been advocated by payors, patients and providers globally [4]. The goals were to increase the efficiency and efficacy of healthcare delivery while

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decreasing waste and error, increasing the value of the services provided and improving clinical outcomes [5]. These efforts require healthcare professionals, including nurses, to adopt EMRs [5]. The importance of nursing attitude and expectations to the successful implementation and ongoing use of an EMR is well documented [4].

Technological change is a constant in today's workplace, especially the healthcare workplace. The burden of EMR implementation on nursing practice and the complexities of how the technology is adopted in nursing remain poorly understood [6]. However, as the largest healthcare profession, nurses are regarded as key drivers towards the move from paper-based to electronic systems [4]. The importance of their participation in decision-making, development, implementation and evaluation of EMR is now being realised [6].

The barriers to nurses' adoption and use of the EMR are broad and varied. Sockolow, Liao, Chittams and Bowles [7] identified barriers, which included cumbersome system functionalities, lack of interoperability and hardware issues. It has been argued that these frustrations and dissatisfaction continue to be precipitated by low awareness, uncertainty, resource burden, low access to sufficient resources, uncertainty of impact on patient outcomes or alignment with patient preferences and reduced confidence about nurses own ability to perform tasks with an EMR [8]. All of these elements impact the nurses' work stress and health, further complicating EMR use [9].

To determine nurses' acceptance of the implementation of an EMR system and fully engage them in the decision-making, development, implementation and evaluation of the EMR, three important foundational domains require better understanding: (1) issues at the system level (e.g. system usability; interoperability systems and integration; standards; limited functionality/missing components), (2) user–task issues (e.g. systems to meet nursing needs) and (3) environment issues (e.g. lack of user training, the attention of educators, managers, policymakers) [5]. As a solution, human-centred frameworks need to be identified and established to understand EMR use and satisfaction for nurses.

The research question considers "how can we encourage nurses to use an EMR and develop foundational skills required of a Nurse Informatician?". To answer the question, it is necessary to first apply rich theories in the information systems domain, helping us segment and understand critical issues impacting nurses with respect to EMR use. The application of relationship equity theory (RET) is proposed as the optimal theory.

13.2 Method

This study used the narrative review process, proposed by [10], to investigate the factors that affect nurses' perceptions of EMR acceptance.

Utilising this approach, a series of keywords (("EMR" OR "Electronic Medical Record" OR "EHR" OR "Electronic Health Record") AND ("Nurse") AND

("Acceptance" OR "Adoption")) were used to search the catalogue of studies in the Scopus database.

The search focused on journal articles that included these keywords in either their titles or abstracts or keywords, published between 1990 and 2020 in English. The study excluded articles without an empirical basis.

The initial search retrieved 300 articles, of which only one focused on nurses was included. By reviewing all relevant references and sources from the retrieved articles, other available documents on other sources were reviewed.

13.3 Findings

Given that most EMR/EHR adoption studies were undertaken from the perspective of physicians, only a limited number of studies were found that adopted a nurse's perspective [11]. As nurses are a key group of stakeholders using EHR/EMR technologies directly, they play an important role in the success of those technologies [12]. The lack of acceptance of EHR/EMR, even in mandatory settings, suggests that the development of negative perceptions toward technology by nurses could lead to lack of usage and unwillingness to learn new functionalities of the systems [11]. Investigating and understanding critical factors with regard to the adoption and utilisation behaviour of these systems could benefit designers and implementers and improve the utilisation of them [11, 12].

The literature review found only 14 studies that investigated factors from a nurse's perspective. Table 13.1 shows the critical factors identified in the adoption of these technologies by nurses. Perceived usefulness, or lack thereof, was seen as the most common barrier to the adoption of EHR/EMR systems by them. This comes as no surprise because the technology acceptance model (TAM), or a variant of it, was used as a theoretical model for conducting these studies. Another interesting observation was the lack of qualitative studies in this field, with only one study out of fourteen captured in our review.

In this qualitative study, [13] used semi-structured interviews to investigate the critical factors in the adoption of EHR by nurses, who considered themselves as digital laggards. This study used FITT framework (Fit between the Individual, Task and Technology) as a theoretical lens. This study found the lack of user-friendliness, integration with workflows, training and the system's excessive time demands, as the main reasons for their being unable to meaningfully use the system.

These results, when taken collectively, highlight the need for more qualitative studies so that the role of context may be considered more fully. The context in these studies can provide a deeper understanding of the barriers and facilitators in the adoption of e-Health technologies. This could assist developers, implementers and policymakers to design and put into place new systems in various settings, which are more effective in terms of cost and time—both critical factors for a more rapid rate of adoption of them.

Table 13.1 Critical factors in the adoption of EMR/EHR from Nurses' perspectives

Adoption barriers and factors	EHRs	EMRs
Individual factors	Lack of digital skills [13], Gender, age, experience expectancy [14]	
Psychological factors	Fear of usage [15], self-efficacy [16], perceived ease of use [15], perceived usefulness [11, 12, 16] attitude [16], privacy [15], security [15], attitude [17] behavioural intention, effort expectancy, performance expectancy [14]	Perceived usefulness, attitude, behavioural intention [18] Perceived ease of use, perceived usefulness, self-image [19] Behavioural intention, effort expectancy, performance expectancy, self-efficacy, attitude [20]
Environmental factors	Physical security [21] Work environment [22]	Social influence, facilitating conditions [19]
Organisational factors	Leadership [15], experiences of users [11, 15], leadership and experienced users, training and education [13] Involvement in planning and implementation [17]	
Financial factors	Cost of implementation and maintenance [15], incentive [15]	
Legal factors		
Technical factors	Design [23], decision support tools [23], training [15], user-friendly interface [15], communication [15], interoperability [15], usability [11], ICT Infrastructure, Internet access [21], usability [20]	Compatibility, security, accuracy, reliability [19]
Time	Productivity [23], workload [15], Workload and productivity [13]	

13.4 Application

The literature review showed the majority of studies used either TAM or the unified theory of acceptance and use of technology (UTAUT), one of their extensions, which brings into question whether other factors, not included in the above-mentioned models, were being addressed. Therefore, we propose to investigate the suitability of Relationship Equity Theory (RET) in studying EMR adoption by nurses.

Application of Relationship Equity Theory (RET) falls into the area of the social sciences and originates from the works of Adams [24, 25] and Homans [26]. It is a dynamic process in which each participant's perception may change over time [27].

According to RET, in any social exchange, when participants to the relationship perceive that their share of the output, or gain, is not proportionate to their input, they experience an unpleasant emotional state [25]. RET, therefore, is uniquely suited to the evaluation of the approach of nurses to the EMR.

This research aims to apply RET, providing a better understanding of both the adoption and utilisation of EMR by nurses and the potential consequences of an EMR on nurses. Adoption of an EMR should be considered as a change process. The introduction of them in the hospitals does have an effect on the dynamics of existing relationships.

Joshi [28] extended RET in the development of his Equity Implementation Model (EIM) which describes the process of organisational information systems implementation and adoption. They argued, introducing new systems to an organisation may lead to changes in the inputs required by the users. It would be expected that a new system might, on the one hand, demand more inputs, such as effort in learning a new system, whilst, on the other hand, decreasing other inputs in the general areas of effort and manual work.

Similarly, outcomes, the introduction of a new system may lead to the changes for the better, such as job satisfaction, but may negatively affect outcomes by the fear of losing one's job, more tension and conflict.

According to the EIM [28], there are three levels of application:

- *Self:* One's own perception about the changes in the net outcomes, expressed as net changes in equity status.
  Adopting and using EMRs may increase the inputs required. For example, adding to participants' workloads may cause them to feel as though they have less control and flexibility over their activities. In turn, this may demand new skills and effort on their part. Therefore, if outputs, in comparison to inputs, do not proportionately increase, then nurses may feel distressed.
- *Self and the employer:* The change in relative outputs of one's self versus the relative change of outputs accruing to the employer.
  At the second level of application, the focus is on the nurse's perceptions of fairness in sharing the benefits. If nurses consider that the EMR brings greater benefits for the hospital rather than for themselves, they may feel dissatisfied.
- *Self and other users:* The change in relative outputs of oneself versus the change in relative outputs accruing to other users.
  At the third level of application, the focus of consideration is that of the nurse whose basis for comparison is between him or her and other groups of users, including other nurses, clinicians, lab staff and others. If nurses perceive that their relative outcomes are less than those of other users, they may feel distressed. For example, if they feel using an EMR has added to their workload, but clinicians are reaping the benefits, they feel unjustly dealt with. Equally, if they feel other nurses, using the system, do not enter data correctly, they have to spend their time and effort to correct the information, they may feel aggrieved and distressed.

13.5 Discussion

Advances in Information and Communication Technology (ICT) provide many opportunities within the healthcare industry. However, unless the systems are actually adopted and used appropriately by all stakeholders, any potential benefits arising from these systems will remain elusive and will not be achieved, [29, 30]. It is noteworthy in itself that there is a large body of literature addressing Health Information System (HIS) failures arising from either a lack of system uptake or issues in their implementation [31–34]. These failures range from individual, physiological, environmental, technical, legal, financial, cultural, organisational, structural, political and behavioural [30, 35, 36]. From the nursing perspective, these are interpreted as interoperability and hardware issues [7], lack of awareness, uncertainty, resource burden, the uncertainty of the impact on patient outcomes or alignment with patient preferences and lack of confidence [8]. In this connection, as adoption of technologies is in reality a change management process, the adoption should be treated as such [37, 38].

Nursing is in and of itself, a challenging occupation, and the activities nurses perform are vital for improving healthcare safety, efficiency, quality, effectiveness and satisfaction [39]. Nurses work in highly complex environments, and they must perform a wide range of cognitive and physical activities [40]. The range of activities expected of nurses has been illustrated by Hendrich et al. [39], who demonstrate nurses' time is spent on: Documentation (35.3%), Care coordination (20.6%), Patient care activities (19.3%), Medication administration (17.2%) and Patient assessment including reading vital signs (7.2%). In theory, a HIS can assist nurses to improve their practices by reducing non-value-added activities [41]. However, the impact of EMR implementation on nurses has not been studied thoroughly [41].

13.6 Conclusion

Hospitals are environments where a matrix of social exchanges occurs, and the dynamics of the relationships between the internal stakeholders and with external stakeholders are complex and subject to change over time [42–44]. Applying RET could assist in understanding the impact of EMR and the complexity of the relationship of nursing within a complex health environment.

This study postulates that RET can provide a better understanding of both the adoption and utilisation of an EMR by nurses and the potential consequence of an EMR on nurses. RET is relevant to any social setting and essentially can be applied when there is any sort of exchange taking place [25]. Adoption of any EMR should be considered as a change process where the introduction of them, into hospitals, does affect the dynamics of existing relationships. This research represents the first phase of a longitudinal project. This will serve to shed further light on this important area that impacts nurses, all healthcare providers and users alike.

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Chapter 14
Leveraging Information Technology in Pharmacovigilance: Benefits for Pharmacists and Pharmaceutical Companies

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14.1 Introduction

The development and use of medications aim to alleviate suffering and ailments. However, they can be associated with adverse side effects or adverse drug reactions (ADRs), leading to physical and psychological harm, of which many could be prevented [1]. Severe ADRs can cause an overload in hospital admissions and increase health expenditure, with studies showing 3–7% of all hospital admissions are the results of an ADR, causing a heavy burden on the national healthcare systems [2]. In the United States, serious ADRs were the fourth to sixth causes of death in hospitalised patients, extended hospital admissions and increased the cost of treating these patients.

All medications have adverse effects; however, many that are new are not detected until drug commercialisation. Therefore, it is crucial to have strategies to monitor drug safety [3]. This can be achieved by drug surveillance or pharmacovigilance (PV), with its main goal of public health safety [3].

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14.2 Background

14.2.1 Pharmacovigilance (PV)

PV is the science and activities involving the detection, assessment, understanding and prevention of adverse effects and other drug-related problems [4]. The data are derived from multiple sources, these include case reports within the medical literature, spontaneous ADR reporting to national PV centers, post-marketing clinical and epidemiological studies or data generated from prescriptions and medical claims monitoring [5]. However, one of the most widely used forms of PV is spontaneous ADR reporting (SAR) made by healthcare professionals (HCP) [3].

14.2.2 Spontaneous ADR Reporting (SAR)

Spontaneous ADR reporting (SAR) was developed in the 1960s following the thalidomide tragedy [6]. In 1951, it was initially marketed as an effective antiemetic for morning sickness during pregnancy, thousands of pregnant women took the drug to relieve their symptoms [7]. Initially considered safe, however, the drug was responsible for a significant number of serious birth defects, accounting for more than 10,000 children and led to the death of around 2000 children [6, 7]. Following unyielding pressure from the media and the public in November of 1961 Thalidomide was taken off the market, after almost 10 years [7].

In 1968, ten countries, including Australia operating a national PV services, decided to collaborate under the administration of the World Health Organization (WHO) and launched the WHO Pilot Research Project for International Drug Monitoring [8]. In 1971, a resolution of the twentieth World Health Assembly laid the groundwork for the WHO International Drug Monitoring Programmed (IDMP) [9]. Today, PV agencies in 72 countries collect, process and evaluate case reports of suspected ADRs submitted by healthcare professionals (HCPs) [9]. The information from these reports is also submitted to the WHO's central data processing agency, that is, Uppsala Monitoring Centre (UMC) in Sweden, for inclusion in their international database [9].

14.2.3 The Problem of New Drugs

The prescription and supply of medications are intended to relieve ailments and suffering, as such, HCPs generally trust that the administration of drugs at the appropriate dose, for their registered indications, will result in safe use [3]. However, all medications have adverse effects and some of these may not be detected until post-marketing. Due to the limitations of pre-marketing clinical trials, many aspects of

drug safety cannot be known until a drug is widely used in a broad range of medically complex patients [3].

During the clinical trial phase, generally, the number of subjects exposed to the investigational product is approximately 1500–2000 subjects [6]. Here, only the most common ADRs can be detected, unfortunately, rare ADRs such as those with an incidence of less than 1 in 500 may not be detected [6]. Furthermore, the participants in the clinical trial are generally highly selective, in accordance with the study protocol; therefore, sample may not necessarily represent the broader population that will eventually require the drugs [10]. Therefore, certain adverse events may not occur until these novel agents are used in, for example, very young, elderly or very ill patients with concomitant diseases, as these patients are often excluded from clinical trials [6]. The true safety profile only emerges over time and as the drug is used in a broad range of patients, some with medically complex situations. For these reasons, HCPs must be alert to the chance of new adverse drug events (ADE) [11].

14.2.4 Adverse Drug Events (ADEs) Versus Adverse Drug Reactions (ADRs)

ADE is an umbrella term that encompasses the harm that results from both an ADR and a Medication Error (ME). ADRs describe any response to a drug that may occur during the use of a pharmaceutical product that may or may not have a causal relationship with the drug, that is noxious and untoward [12]. MEs are the result of imperfect human intervention or human error, including poisoning and other problems associated with the manufacture, distribution and therapeutic failure that results from under-use of medicines or failure to prescribe medicine when indicated [13, 14]. According to the WHO, a definition for an ADR is: “any response to a drug which is noxious, unintended and occurs at doses used in man for prophylaxis, diagnosis or therapy of disease or modification of physiological function” [12].

14.2.5 Voluntary Versus Mandatory Reporting

Pharmacovigilance is predominantly based on SAR made by healthcare professionals (HCPs), consumers and pharmaceutical companies [4]. The reporting of suspected ADRs is mandatory for all pharmaceutical and medical device companies; however, it is voluntary for HCPs and consumers. The primary purpose of SAR is to provide early warnings or “signals” of previously unrecognised drug reactions or toxicities [3].

SAR systems accept reports for all drugs at all stages of their life cycle, as soon as they are in use and on all patients regardless of the age or disease state with no limits on the medicines involved, making SARs a very effective PV tool for

highlighting problems with new drugs compared to other PV tools, for example, published case reports within medical literature, post-marketing clinical and epidemiological studies or data generated from prescriptions and medical claims monitoring[3]. Furthermore, SAR is a relatively inexpensive PV tool to operate, as it only requires the investment of well-trained staff and basic technical equipment such as computers or telephones [3].

14.2.6 The Problem of ADR Under-Reporting

Currently, underreporting by HCPs is the major limitation associated with spontaneous reporting systems and a global problem. A systematic review conducted in the European Union estimated that only 6% of all ADRs are reported [3]. It is important to note that under-reporting of ADRs delays the identification of drugs with triggering alert signals and thus imposes a threat to public health. HCPs have expressed several reasons for hesitating to report suspected ADRs. These included, but were not limited to, insufficient knowledge of ADR detection and reporting, time constraints due to workload, and lack of incentives [1]. Another factor that may also account for underreporting is the respondent's motivation [15].

14.2.7 Strategies to Improve ADR Reporting

To improve ADR reporting, several interventions have been developed and evaluated to overcome the barriers perceived by HCPs that prevent ADR reporting. Some of these interventions include [16]:

- Improving access to ADR reporting forms (e.g. distributing the reporting forms to increase availability).
- Facilitating the reporting processes (e.g. computer links)
- Improving the reporting form (e.g. original reporting form modified to a reporting card)
- Educating HCPs about ADR reporting.
- Improvement of feedback to reporters (e.g. information is sent to the reporter once the ADR report is evaluated)
- Incentives for reporting (e.g. financial or bonuses such as educational credits)

14.2.8 The Need to Improve ADR Reporting

No single activity has been shown to achieve a sustained increase in the quantity or quality of ADR reports [16]. In fact, a systematic review looking at the strategies to

improve ADR reporting found that most studies applied more than one type of intervention, making it challenging to isolate the individual impact of each intervention strategy in the final results [16].

Another important factor is the duration of the effect of the intervention. Some studies which have analysed the duration of effect, that is, the length of time the resulting effect is sustained from the date of the intervention, estimate a maximum duration of 3 years. As such, there continues to be a need to overcome the problem of under-reporting by HCPs. It is commonly agreed that continual and consistent interventions are required to maintain ADR reporting systems as most interventions have a limited effect over time [17]. Molokhia et al. concluded that using electronic health data combined with other methods of ADR reporting can enhance the efficiency of PV. As healthcare systems are becoming more digitised in both primary and secondary care, there is great potential to explore these information systems for ADR reporting [18]. Furthermore, improvement in the current ADR reporting methods in Australia, including analysing the effectiveness of underused or innovative methods, is crucial to improve patient safety and public health.

14.2.9 ADR Reporting in Australia

While medicines can contribute to significant health improvement, they can also have adverse effects and cause serious harm. It's estimated that close to 250,000 Australians are hospitalised each year due to an ADE, of which half could have been prevented [19]. Furthermore, approximately 400,000 Australians present to the emergency departments as a result of medication-related problems, with 50% of medication-related problems being preventable [20, 21]. The total Pharmaceutical Benefits Scheme (PBS) expenditure for medication-related problems is estimated at 15%, that is, close to $1.4 billion per annum [19].

14.2.10 The Reporting Processes

In Australia, the regulatory authority, that is, Therapeutics Goods Administration (TGA), receives information on suspected ADRs and medication error reports directly from healthcare professionals (such as physicians, pharmacists, nurses and others) and consumers (such as patients, family members, lawyers and others) [17, 22].

The TGA makes drug safety decisions by regularly reviewing available information which originates from suspected ADR reports. In the preliminary evaluation, the goal is to assess the likelihood of an association between the reaction and the health product [22]. Typical information which must be taken into account includes the frequency, severity, plausibility, quality of the information contained in the ADR reports, amount of product used, the time needed for the appearance of the reaction,

underlying diseases, simultaneous use of other medications and evidence of disappearance or reappearance of the reaction once the product was discontinued or reintroduced [8]. Additional investigative studies and consultations with other regulatory agencies are often necessary to confirm the product-ADR relationship [22]. If action is needed, the TGA may require changes or additions to product labelling, dosing or removal of products from the market [22].

14.2.11 ADR Reporting Rates to the TGA

In 2017, the TGA received approximately 18,600 reports of adverse events [23]. Of these adverse event reports received, approximately 54% (9998) were from sponsors; 18% (3441) from State and Territory Health Departments (reports of adverse events following immunisation); 10% (1879) from hospitals and hospital pharmacists; 7% (1201) from consumers; 6% (1170) from community pharmacists; 3% (579) from general practitioners (GPs); and 2% (359) from other sources [23]. The latest TGA reports for the source of notification of medicines and vaccines adverse reactions 2019–2020 show that Healthcare Professionals (HCPs) contributed approximately 19% [24]. It is important to take note the reporting of suspected ADRs is mandatory for all pharmaceutical and medical device companies; and voluntary for HCPs and consumers [3].

14.2.12 Community Pharmacist: Most Accessible of HCPs

HCPs are the key source of ADR reports, as consumers will generally discuss their medication-related problems with them; however, due to the voluntary nature of ADR reporting for HCPs, its effectiveness is undermined. Community pharmacists are drug experts and are employed by pharmacies. They may work at a pharmacy within a supermarket or big-box retailer, or they may work at an independent pharmacy and some own their pharmacy. Some pharmacies are open late and on weekends, so community pharmacists may have to work evening and weekend shifts. As such, community pharmacists are the most accessible of healthcare providers, the most frequently visited, and usually, the first point of contact regarding medication-related issues as anyone can walk into a retail pharmacy and request to speak to the pharmacist. Furthermore, if the agent causing an ADR was likely to be available in a community pharmacy, the patients are more likely to consider it necessary to inform or discuss any new ADRs with their regular community pharmacist or return to the pharmacy where they initially purchased it. Therefore, pharmacists are uniquely suited to detect, document and report any suspected ADRs to the regulatory authorities. However, under-reporting of ADRs by community pharmacists is a major issue. Factors that influence pharmacists reporting ADRs may include, insufficient knowledge of ADR detection and the reporting process; lack of time within their daily practice, or lack of financial incentives [15, 25].

14.2.13 Why Community Pharmacists Must Report

A survey into the habits of medicine use of Australians estimates more than nine million people take a prescribed medicine every day, with eight million taking two or more prescribed medicines in a week [26].

In Australia, there are 5822 community pharmacies, with an average person visiting a community pharmacy 18 times each year, in both metropolitan as well as rural and remote locations [27]. Community pharmacies are easily accessible with the majority open after-hours, including weekends. In capital cities, 97% of consumers are no further than 2.5 km from a pharmacy [28]. In regional and remote areas, 65% of people are within 2.5 km of a pharmacy. As such, community pharmacies are the most frequently accessed health destination with over 462 million individual patient visits annually. The total 2020 PBS prescription report volumes was 216.7 million prescriptions dispensed by community pharmacies [29]. Furthermore, a pharmacist is among the most trusted profession, with 84% of adults trusting the advice they receive from the pharmacist, according to a public opinion survey [27]. Furthermore, in a 2012 FIP Pharmacist Workforce Report, a global sample revealed that, on average, 55% of pharmacists were found to work in a community pharmacy environment, where they can face events based on ADRs or other drug-related problems [4].

As community pharmacists are the most accessible of healthcare providers, the most frequently visited, and usually the first point of contact regarding medication-related issues as anyone can walk into a retail pharmacy and request to speak to the pharmacist, community pharmacists are uniquely suited to detect, document and report any suspected ADRs to the regulatory authorities [25]. In fact, a study to assess the frequency of adverse drug events (ADE)-related admissions during a prospective medical record review of patients admitted to a metropolitan tertiary referral hospital, suggest within clinical settings, the cost of employing more pharmacists to detect and rectify ADEs earlier may reduce overall hospital costs by minimising patient morbidity and length of stay [21]. However, factors that influence pharmacists reporting ADRs may include; insufficient knowledge of ADR detection and the reporting process; lack of time within their daily practice; or lack of financial incentives [15, 25].

14.2.14 Why Do Community Pharmacists Lack Time to Report

Raymond Li et al. investigated the knowledge, perspectives and practices of ADR reporting by community pharmacists in Australia. The study showed that non-reporting community pharmacists indicated that lack of time was the most significant barrier to reporting ADRs. This is also consistent with studies conducted overseas [25]. A cross-sectional study to identify the barriers to ADR reporting amongst community pharmacists practicing in the United Kingdom reported that 46% of community pharmacists attributed to lack of time as a barrier to reporting.

Training and information about what to report, as well as access to information technology to do the ADR reporting system, were identified as potential facilitators to improve reporting of ADRs [30].

In Australia, the most significant barrier to reporting ADRs is the lack of time, partly because the community pharmacists' roles have increased beyond dispensing medicines, with added responsibility and complexity [25]. Community pharmacists now provide vaccination services, health checks and professional services such as MedsCheck Program, home medicines reviews, dose administration aids and clinical interventions [31]. Another factor contributing to lack of time is having to manually complete a separate ADR reporting form which is both time-consuming and comes with a higher degree of error [31]. Therefore, one of the priorities to improve ADR reporting rates by community pharmacists would be to shorten the time it takes to complete the reporting process [25].

A systematic review on the use of information systems for the promotion of ADR reporting proposed that it would be useful to develop systems to assist HCPs to complete ADR reporting within electronic health records as this approach presents as an efficient method to increase ADR reporting rates [1]. This can be achieved by making the reporting forms more accessible and utilising any auto-population features available from existing information in the dispensing software to allow community pharmacists to report ADRs directly to the TGA via their dispensing software [25].

14.3 Technology in Pharmacovigilance

14.3.1 Role of PV Systems for Marketing Authorisation Holders

Digital transformation is the adoption of digital technology to transform services or businesses [32]. This can be done by replacing manual processes or non-digital processes with digital processes or changing older digital technology with newer digital technology. It is no secret that health information technology (HIT) has significant potential to not only transform the healthcare system but to also support continuous quality improvements [32].

The adoption of TeleHealth, artificial intelligence (AI)-enabled medical devices and electronic health records are just a few concrete examples of how digital transformation in healthcare is completely reshaping how individuals and HCPs interact with each other, how data is shared among providers and how decisions are made about our treatment plans and health outcomes [33].

As more receive regulatory approvals and a massive amount of data is generated daily, pharmaceutical companies and sponsors of clinical trials have mandatory obligations to collect the large and growing volumes of safety data, for which much of this data includes individual case safety reports (ICSRs), medication errors,

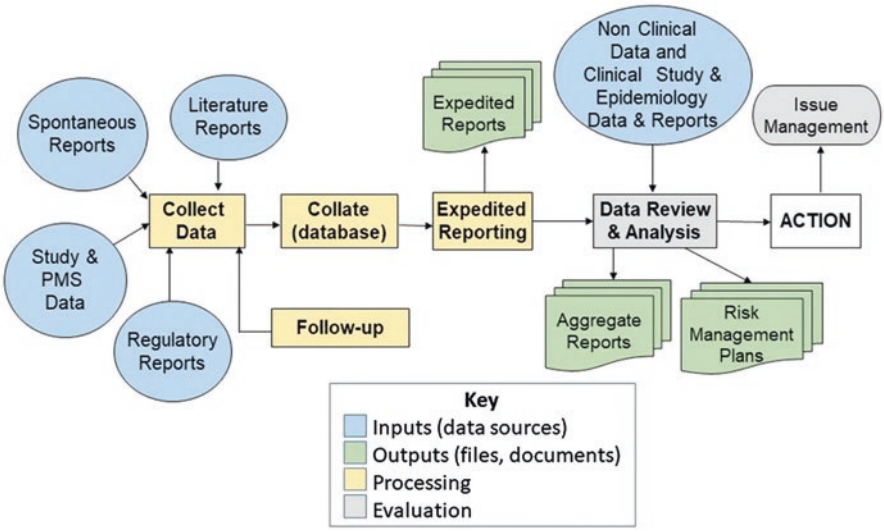

Fig. 14.1 Typical workflow process of an ICSR for a MAH (Reprinted from Lewis, D.J., & McCallum, J.F. [36]. Utilizing Advanced Technologies to Augment Pharmacovigilance Systems: Challenges and Opportunities. *Ther Innov Regul Sci*. 54:888–899, Figure 1. https://doi.org/10.1007/s43441-019-00023-3, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

product quality complaints and exposures to medicines during pregnancy [34]. PV being a highly regulated sector requires careful planning and management. As such, the pharmaceutical industry faces significant challenges when it comes to deploying and utilising advanced information technology (IT) [35].

As the Marketing Authorisation Holders (MAHs), that is, a company or other legal entity that has the authorisation to market a medicine, set up their global PV strategies, more effective PV processes are required [35]. ICSR is an adverse event report for an individual patient and a source of data in PV. ICSRs are reports originating from healthcare providers and consumers [36]. These are collected, organised, formatted and assessed in accordance to set standard processes as shown in Fig. 14.1 [36].

HIT provides an opportunity to add value to the traditional, paper-based PV processes. To better manage PV activities, MAHs require technologies to collect, characterise and evaluate ADR reports.

14.3.1.1 Big Data

This includes the large and growing volumes of computerised medical information available within electronic health records, drug monitory registries or even medical claims data [34]. These are generally collected routinely during administrative processes and clinical practice by different healthcare professionals, for example,

clinicians recording their patient's medical history, healthcare claims or pharmacists dispensing prescriptions. Other sources of big data may include, social media, online channels and informative systems for spontaneous ADR. The development of powerful computerised tools that can process and analyse big volumes of information for predictive purposes offers great opportunities to study and monitor, drug use and safety on wider scales and in greater detail [34].

14.3.1.2 Natural Language Processing

Big data by itself is useless; for it to be useful, it has to be correctly analysed and interpreted. Therefore, MAHs have to filter the high volumes of noise to stay on top of all the post-marketing safety signals that emerge across the Internet and digital resources [37]. This can be done through the use of artificial intelligence (AI), a branch of Natural Language Processing (NLP) that helps computers understand, interpret and manipulate human language [36, 38]. Therefore, NLP can help to identify adverse events, risk factors or health outcomes from the data available within sources such as EMRs, scientific literature, patient forums, social media and other online communities. It is important to remember that findings generated using big data require robust clinical interpretation and critical judgment. In no way can the process of drug safety signal detection, refinement and validation be fully automated without expert assessments [38].

14.3.1.3 Cloud-Based Solutions

As the volume of data continues to grow, pharmaceutical companies will need technological solutions that can allow them to quickly scale up and manage large datasets [36, 38]. This can be achieved and simplified by cloud-based technology that allows MAH to benefit from the ability to store and analyse the large amounts of data stored. This provides better cost efficiencies, by enabling MAH to work with large amounts of data without compromising the quality, security and data privacy [39].

14.3.2 Automation: The Way Forward

Automation of PV processes can provide quick and effortless high-quality safety data, thereby improving the evidence available for timely assessment [36]. This requires MAHs to evaluate their operations and their impact on productivity, operational costs, quality, compliance, audit readiness and then implement IT systems aimed at addressing process improvements [39]. These technological solutions should enable the MAH to make end-to-end safety processes more efficient and eliminate redundant steps that add no value [36].

The PV automation process involves several stages or levels. This can start with basic automation, robotic process automation, to cognitive computing and ultimately AI, with each transformation requiring less human involvement [39].

14.3.3 Stages of PV Automation Process for a MAH

1. Basic Process Automation

This involves automatically tracking and monitoring set tasks or continuous metrics collection, for example, literature tracking tools [39].

2. Robotic Process Automation

This involves reducing or eliminating any manual task, resulting in automatic entry, processing and analysing safety of data into a safety database or system [39].

3. Cognitive Process Automation

This is often combined with robotic process automation. To provide the required outcome it leverages on NLP to help humans drive the final decisions [39].

4. Artificial Intelligence (AI)

This involves very minimal or no human interaction, allowing data scientists and analysts to construct algorithms that can enable them to learn to make predictions through Machine Learning (ML). These algorithms detect patterns in big data, improving over time and learning from the data feeds [36, 39].

14.3.4 Leveraging Technology for PV Transformation

While IT systems and applications can automate ICSR processing, reporting activities and offers a great opportunity for digital transformation in PV, the overall process still requires much human intervention and manual effort, particularly in the areas of case intake and data entry [36]. It should be noted that many of the issues surrounding PV systems are not entirely IT problems, but rather issues in the manual processing or the users managing the systems, for example, the repetitive and deterministic nature of these processes [39]. Tools, including IT solutions, must be implemented in the context of addressing such process improvements and organisational needs. Therefore, technologies such as robotic process automation leveraging (NLP and ML) through AI to move beyond basic automation thereby limiting the amount of human intervention needed, provide great opportunities. Utilising automation in processing ICSR will not only result in costs reduction and accelerate processing, but also eliminate the chance of human error and improve quality and accuracy [39].

14.4 Role of PV Systems in Healthcare

One of the most common interventions in the healthcare systems is the use of medicine, which comes with associated problems and misadventures [35]. Two significant factors contributing to medicine misadventure are gaps and time delays in communication; however, digital transformation can provide the necessary tools to piece together a fragmented healthcare system [35].

It is well recognised that IT has entered and transformed the world of healthcare and medicine, connecting health information, ensuring that information is accessible to patients, HCPs and caretakers on time and ensuring work proceeds with higher quality, efficiency and at a lower cost [40]. The integration of PV databases within healthcare systems appears to be an effective way to improve the knowledge of drug safety as Electronic Health Records (EHR) contain a lot of information about ADRs, which is not always shared with the MAH or regulatory authorities [36].

ADR underreporting from HCP is a major issue undermining the effectiveness of PV, resulting in latency and inconsistency, despite this, it is still considered as the most valuable method to detect drug safety problems [18]. Most of the drug safety decisions made by the Regulatory Authorities are triggered by spontaneous ADR reports made by HCP [9]. Therefore, it is important to achieve the greatest number of ADR reports possible together with high-quality data.

The promotion of ADR reports among HCPs is key and requires regular reminders as well as the development of tools to facilitate this duty [1]. Tools used in PV are continually evolving, worldwide information systems (IS) to promote ADR reporting or to detect ADRs in healthcare institutions have been tested and used, these include the development of online reporting forms, the inclusion of electronic reporting systems into the hospital Information, direct hyperlinks to online reporting forms, software's that allow voluntary and automated detection of ADRs, tools that analyse clinical databases or web sites that actively inform healthcare professionals [1].

There are clinical and economic benefits to incorporating information systems in patient care. However, user dissatisfaction and resistance to health information technology can prevent optimal use of such systems [41].

14.4.1 Health Information Technology in Community Pharmacy

Community pharmacists started to use computer systems as early as the 1970s [42]. The first systems were designed for dispensing, billing and reimbursement purposes. Since then, applications have been extended to include a wide range of administrative and medication management functions such as identifying and intervening drug-related problems, for example, drug interactions, dosages, ADRs or compliance [42].

Patient care services in community pharmacies are divided into three main categories:

1. Electronic health records, including electronic prescribing and clinical decision support systems.
2. Health information technology in medication management.
3. Additional community pharmacy applications, including the internet and use of social media in communication on medicines [43].

Community pharmacies in Australia have shown a great willingness to adopt innovative technologies to offer the highest standard of pharmacy and healthcare services, whether those innovations are technological, systematic or strategic in nature. Some technologies that have been adopted include [44]:

14.4.1.1 PBS Online

Online claiming for Pharmaceutical Benefits Scheme (PBS) was piloted by a small number of pharmacies in 2004 and was followed by an independent evaluation. Medicare implemented the recommendations of the evaluation report and rolled out Online Claiming for (PBS) medicines with 99.4% of pharmacies utilising PBS online daily [44].

14.4.1.2 eRx Script Exchange

This is an industry-driven partnership focused on Electronic prescribing and transfer of prescriptions, designed and built for doctors, pharmacists and patients. With over two hundred million prescriptions dispensed every year in Australia, and pharmacists dispensing on average 100–200 scripts a day, electronic prescriptions provide a significant opportunity to strengthen patient safety and confidence in dispensing medication [44].

14.4.1.3 My Health Record

In recent years, Australia's health system has embarked on an ambitious transformation journey, a patient-controlled electronic health record system, which for pharmacists involved genuine, online, real-time interconnectivity with consumers and other healthcare providers [45].

In the area of digital health, no other profession has done more than community pharmacy in terms of investing its funds to support the challenging transition to a Digital Health model [44]. However, the Australian government also has a key role in ensuring that disruption in the health sector is managed in a way that delivers maximum benefit for patients and is sustainable for healthcare providers.

As such for community pharmacies, it is imperative that business processes are streamlined with effective change management and adequate resources to ensure the digital transformation can deliver optimal benefits to community pharmacies and these can be passed onto the consumers. As mentioned earlier, PBS Online is a great example of innovation reinforced with effective and incentivised change management [44].

14.4.2 Current PV Technology Available to Australian Community Pharmacies

In Australia digital disruptors of the healthcare system are being driven by the opportunity to enhance a patient's access to the health system through the new healthcare ecosystem, that is, shifting from an organisation to a patient-centric model of healthcare service delivery to facilitate collaborative, multidisciplinary and cross-organisational healthcare delivery processes medication [44].

Spontaneous ADR reports made by HCPs can be made using paper, telephone and by e-mail to the TGA or online through the TGA website [25, 46]. To allow for a faster and more convenient way for community pharmacists to report ADRs directly to the TGA via their dispensing software instead of having to manually complete a separate ADR reporting form. In June 2014, GuildLink, an Australian pharmacy software company created a program called GuildCare [25, 47].

Through electronic recording, the program is designed to assist pharmacists with the delivery of professional services and support, including medication management programs, compliance and adherence programs. The GuildCare programs achieve this by helping pharmacists guide their patients to take the right medicines, at the right time, for the right length of time, helping medication compliance and adherence to their prescribed treatment [48].

To assist with spontaneous ADR reporting, GuildLink created an Adverse Events Recording module within GuildCare. This enables pharmacists to electronically document and submit ADEs presented within pharmacy to the TGA [25, 47]. The GuildCare module is linked to the TGA's adverse event reporting web service; as such, pharmacists can easily record ADEs with all the necessary information and where required can also submit to a patient's medical practitioner almost instantly [25]. GuildCare Adverse Events Recording module can record three types of Adverse Events:

- Adverse Drug Reactions
- Problems with Medical Devices
- Medicine Deficiencies or Defects

Soon after the availability of GuildLink in June 2014, the TGA received 254 reports from community pharmacists by September 2014 via the GuildLink portal. The rate of reporting was almost as high as the total number of reports received from community pharmacists for the entire year of 2013 [25]. This suggests the measures to simplify the ADR reporting process using information systems may have been

well received. However, the total number of ADR reports made by pharmacists fell again in 2015, indicating the need for constant encouragement and reminders to maintain ADR reporting rates, and possible system evaluations [25]. It is important to note, measures to encourage and facilitate ADR reports, for example, setting reminders in the dispensing software were considered a popular method in addition to education programs and having patient information automatically populated from the dispensing software into a form ready for submission [25].

14.4.2.1 Assessment of GuildCare Adverse Events Recording Module

To date, the GuildCare Adverse Events Recording module is the only HIT that provides early and spontaneous electronic reporting of ADRs to the TGA through the engagement of community pharmacists with consumers in the pharmacy [49]. As discussed earlier, in June 2014 after its release, the reporting rates from the TGA indicated GuildCare was well-received, as the total number of reports by community pharmacists to the TGA between June 2014 and September 2014 was nearly as high as that for the entire year of 2013. However, despite the positive start, the numbers declined again in 2015 [25]. To date, there has been little discussion about factors affecting the adoption and/or long-term use of the GuildCare Adverse Events Recording module.

There are several challenges and concerns when it comes to the integration and adoption of patient care services and information technology into community pharmacies.

Organisational Some of these include, the lack of IT skills and proficiency; differentiation of the community pharmacies; some pharmacies may focus their business model on increasing dispensing and product sales, and other pharmacies may choose to develop their business through the provision of cognitive pharmaceutical services (professional services) [50]. Furthermore, whilst HIT is often said to improve "quality of care" or improve "work efficiency", obtaining detailed outcomes resulting from specific HIT functionalities are hard to measure and anticipate as the implementation of innovative tools often require fundamental changes to operational processes and many organisations do not attempt this [51].

Technical These include factors such as HIT that don't fit the community pharmacists' needs. Here, it's important that the system not only fits the organisational purpose and business strategy but also the clinical need of the end-users. For many community pharmacists, time is of the essence and any initiative that slows down key clinical tasks or work practices is likely to be strongly resisted, despite improving overall organisational efficiency. Another factor influencing HIT adoption may be the lack of standardisation of systems across multiple institutions [50]. Furthermore, it's important to note despite national and international guidelines for ADR reporting and management, in Australia, there is no gold standard system that has been established at the individual healthcare facility level, which may result in significant interinstitutional variability with respect to the timing and/or nature of ADR reporting [52].

Social Often not a focal point, however, the expectations and benefits/values of the HIT can influence the end-user's (community pharmacists) attitude and motivation to use the tool. Therefore, understanding the user's concerns or resistance and incorporating this input into the design, training and support, could influence user acceptance.

Taking the aforementioned into account, a contributing factor leading to HITs that don't appropriately meet the needs of community pharmacists or limit their use within organisations could be the lack of usability testing during implementation. This is crucial for system improvements and a vital step for end-users, as it examines, for example, community pharmacist's workflow and how they achieve their end goals, thereby ensuring the usability of systems, HITs or business intelligence systems, remain optimal for end-user and organisational purpose [53].

14.4.2.2 Sociotechnical Theoretical

To understand the factors that influence the diffusion of innovation, adoption or users' perceptions of value towards digital health, several sociotechnical theories on how humans use technology must be considered [54]. Many of the theories are drawn from other disciplines such as sociology, each theory focuses on different aspects of the users' experience of technology [54].

Activity Theory and Task Technology Fit (TTF) are the contending theories that appear to best assist with providing an appropriately rich theoretical lens in which to analyse the key aspects of GuildCare Adverse Events Recording Module and ADR reporting by community pharmacists.

1. **ADR reporting**

Activity Theory is a descriptive approach that explains human practices in the social context. Since the design of information systems should consider the viewpoints and behaviors of users in a social context, Activity Theory has been demonstrated to be valuable in the field of information systems [55]. As shown in Table 14.1 Researchers may use information system as a tool, the user as the subject, the user's goal as the object and the user's workplace environment as the community when using Activity Theory [56]. This perspective can be adopted in this study when analysing the reporting of suspected ADRs to the TGA. Activity theory can also be used to explain the dynamics of the pharmacy and the stakeholders.

2. **GuildCare Adverse Events Recording Module**

The tools component of activity theory can be further explained through the theoretical lens of task technology fit (TTF). This theory argues that technology needs to be willingly accepted as well as fit well with the users and their corresponding tasks to prove its effectiveness. This is a powerful model as this analyses the adoption and behavior use of innovative technology [57]. In the context of the GuildCare Adverse Events Recording module (the tool), we can assess the Tool component of Activity theory through the lens of TTF. The tool needs to help with the task at hand, that is, reporting suspected ADRs by community pharmacists and if it does the job really well then there is a strong fit.

Table 14.1 GuildCare ADR reporting through the lens of activity theory

Components	Activity theory
Subject	Reporting suspecting ADRs to the TGA pharmacist and patients
Objects	Pharmacist and patients
Outcome	Patient safety
Tools (TTF)	– Computer – GuildCare—Adverse events recording module and internet = connecting tools – Community pharmacy work
Community	Physical collaboration occurring in the pharmacy between the pharmacist and patient. Community face-to-face with interaction
Rules	TGA/WHO

14.5 The Future

In the Raymond Li et al., pharmacovigilance survey, community pharmacists in Australia suggested a way to shorten the ADR reporting time would be to have the reporting forms electronic and provide auto-population features from within the dispensing software and automatically populated patient information from the dispensing software into an ADR report ready for submission, with 91.8% of respondents, that is, "community pharmacists", agreeing with this statement [25]. Despite this, considering GuildCare Adverse Events Recording module, had an initial positive response (adoption), attributed to the increase in the number of ADR reports to the TGA by community pharmacists between June 2014 and September 2014 [25]. The reporting rates were nearly as high as that for the entire year of 2013. However, despite this the reporting rates fell again a year later, suggesting the measure by GuildLink may have initially been well accepted by the end-users, however, further investigation is needed to understand the subsequent drop in reporting rates, to identify strategies to increase and maintain the ADR reporting. As discussed previously, several strategies have been studied and shown to have positive results in reporting rates by HCP. Yet the evidence of sustained improvements after these interventions, remains a significant challenge [49].

Further research to identify specific barriers to ADR reporting by pharmacists, for example, in the community pharmacy setting, would be crucial, as they provide opportunities for the development of interventions. These include mobile apps and software that integrate within existing databases. First, usability studies to assess pharmacist acceptance or use PV technologies can be done to better understand the strengths, weaknesses, facilitators and barriers to technology acceptance and long-term use [58]. Second, as new technologies roll out, implementation activities generally take priority; however, although time-consuming and costly, investments in evaluation activities to monitor real-time, longitudinal data and continuously assessing existing and anticipated organisational needs and user workflow are always beneficial for long-term use and success of HIT [51]. This can allow technology companies to capture user feedback and problems as they arise and respond to them on time, and to identify when systems need improvements or when they have become obsolete and need new solutions [51].

14.6 Conclusion

Pharmacovigilance has the potential to meet the challenges of new therapeutics (including vaccines) with increasing range and potencies; however, there are challenges, issues and concerns involved in implementing and adopting modern pharmacovigilance systems. As drug experts who are specifically trained in this field, community pharmacists are the most accessible health professionals and play a crucial role in maintaining health systems by ensuring rational and safe use of medications.

ADR reporting rate by community pharmacists in Australia is low even though the vast majority believe they have a professional obligation to report. The most significant barrier to reporting ADRs is lack of time and this can be addressed by simplifying the current reporting procedures and utilising information systems. It is important to understand community pharmacists' requirements and needs when developing HIT systems for ADR reporting, including the theories which could contribute to making the innovation and development process work better and identify internal and external factors influencing its adoption.

The successful adoption of HIT by community pharmacists for ADR promises to deliver improved post-marketing surveillance, improved public health safety and reduced global health costs through early signal detection, efficient and timely reporting of ADRs, process automation and better data management. Therefore, careful planning and ongoing critical evaluation of processes are central to the successful implementation of major health information technology in pharmacovigilance.

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Chapter 15
Scoping Mobile Clinical Decision Support Systems to Enhance Design and Recording of Usage Data Effectively: A Suggested Approach

Nalika Ulapane and Nilmini Wickramasinghe

15.1 Introduction

Clinical decision-making is a unique process that involves the interplay between knowledge of pre-existing pathological conditions, explicit patient information, nursing care and experiential learning [1]. Through literature, it can be seen that clinical decisions can mainly be viewed through two categories: (1) Diagnostic decisions (i.e. determining "what is true?"); and (2) Treatment planning decisions (i.e. determining "what to do?") [2]. Clinical decision-making involves high cognitive and critical thinking capabilities and mistakes in clinical decisions can contribute to medical errors. Medical errors are often described as human errors in healthcare [3]. According to a 2016 study from Johns Hopkins Medicine [4], medical errors are the third-leading cause of death in the United States. The projected cost of these errors to the US economy has been approximately $20 billion, 87% of which are direct increases in medical costs of providing services to a patient affected by medical errors [5]. Medical errors have been said to increase average hospital costs by as much as $4769 per patient [6]. Thus, clinical decision-making stands out as a crucial factor contributing to quality healthcare and it is of importance to support making the best clinical decisions.

An established way of supporting clinical decision-making is the implementation of Clinical Decision Support Systems (CDSS). CDSS of various capacities have emerged over time, and as of now, some systems that function in the form of Smartphone apps even have emerged [7]. Currently, various CDSS of different

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functionalities such as diagnostic assistance, treatment planning assistance and diagnostic plus treatment planning assistance have been introduced to healthcare [2]. The majority of these CDSS are technology-enabled and present some unique technology-related as well as socio-technical challenges, such as concerns about performance and fitness for purpose, cost of implementation, privacy and data security, surveillance capitalism, scalability and expandability, policy and legislative challenges and slow adoption and uptake [7, 8]. Moreover, some clinical practice-related concerns regarding CDSS, such as having the best information available, avoiding alert and trigger fatigues and enabling ease and efficiency in updating systems, and more generally, having seamless integration with clinical workflows have also been identified [2]. As such, it becomes important to design CDSS in ways such challenges are alleviated. Moreover, alongside the emergence of diverse CDSS and also increasing demand for better quality healthcare, there tends to be a rise in the need for the use of digital health capabilities to not only support making better clinical decisions and making CDSS smoothly integrate with clinical workflow, but also to enable the capture of data to lay the foundation and support data-driven advancements in healthcare [9].

To facilitate the better design of CDSS and also to enable data capture to be meaningful for data-driven advancements in healthcare, an important first step we see necessary is to have a structured approach to scope out different CDSS we encounter according to their limits and capabilities. Such a scoping can serve as a useful guide for designing, improving and also planning meaningful use of data that may be produced. However, such a scoping strategy has not yet been well established in extant literature. As such, we attempt to contribute to that void by presenting in this chapter a strategy to scope (or classify) CDSS based on criteria we find useful by trying to answer the following research question: How can CDSS be scoped (or classified) according to their limits and capabilities, in a way that is meaningful to guide the CDSS design and development and also enable exploitation of CDSS usage data?

We try to answer the aforesaid research question by first taking a perspective that views CDSS as "*Inquiring Systems*" [10]. As an *Inquiring System* can essentially be viewed as a *System* having clear and well-defined *Inputs* and *Outputs*, our perspective helps us to construct a useful scoping (or classification) of CDSS, by making use of the differences of the components that compound the CDSS we view as an *Inquiring System*. We then go on to pick certain criteria we see as useful from literature, and also our experience in an ongoing Australian study [11] involving a Smartphone App-based CDSS [12], to draw up a systematic criterion through which CDSS can be scoped. Next, we demonstrate how the scoping can be put into practice via a case study using the CLOTS Smartphone App-based CDSS [12, 13], and we conclude by mapping out the available data capture opportunities for CLOTS and also discussing some noteworthy limitations.

15.2 A Perspective of Viewing CDSS as *Inquiring Systems*

Inquiring Systems studied at length by Churchman [10] can be interpreted as "*Systems*" that can be put into practice to solve a problem or to find a satisfactory answer to a question. Going with that interpretation of "*Systems*", *Inquiring Systems* will have *Inputs*, *Outputs* and a *Process* in between. The *Output* of an *Inquiring System* is "*true knowledge*", or at least knowledge that is best agreed upon. A distinctive feature of *Inquiring Systems* is that they contain elaborate mechanisms for "*guaranteeing*" that only "*valid*" knowledge is produced as *Outputs*.

CDSS, too, can in a way be interpreted in an architecture similar to that of *Inquiring Systems*. A CDSS will have a user (i.e. a clinician) who will be providing some inputs into some information system comprising of hardware and software components, and when the system is designed, implemented and used accurately, this information system will produce some "*verified*" and "*valid*" knowledge or recommendations and the likes as the output that is most appropriate to the input provided by the user (i.e. the clinician). Along this line, we propose the perspective illustrated in Fig. 15.1 that characterises CDSS analogous to the three components of an *Inquiring System* (i.e. (1) Input; (2) Process and (3) Output) in accordance with what was described earlier. In the next section, we discuss how the components of a CDSS as per Fig. 15.1 can be used to scope out different types of CDSS encountered.

15.3 A Strategy for Scoping CDSS

To propose our strategy of scoping CDSS, we draw links from the Chapter written by Wasylewicz et al. [2] and our experience gained in working with an ongoing Australian study [10] involving the CLOTS App. As part of their work, Wasylewicz et al. [2] have summarised the different types of CDSS that can be encountered. Wasylewicz et al. [2] is one of several articles we reviewed in search of such knowledge, and we found that our views that have been partly shaped through our experience with the CLOTS App-related work, found considerable overlap with what is reported by Wasylewicz et al. [2]. Therefore, we base our strategy of scoping CDSS

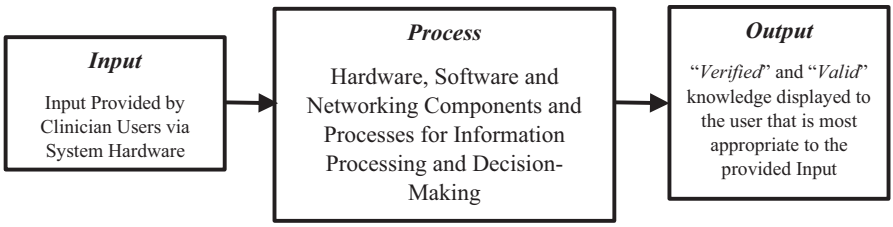

Fig. 15.1 A perspective of viewing CDSS as *Inquiring Systems*

on how CDSS have been classified by Wasylewicz et al. [2], and for a couple of points, we propose strengthening factors coming from our experience with CLOTS App. Thereby, we present in this chapter a fairly robust strategy of scoping CDSS according to their attributes and capabilities, and limitations, as such a scoping will be a beneficial foundational step in planning out the design and development of CDSS and also improvements to existing CDSS.

The classification of a CDSS as per Wasylewicz et al. [2] spans mainly across four themes. The themes are: (1) System Function; (2) Way of Communication; (3) Decision-Making Process; and (4) Human–Computer Interaction. We provide details of the four themes in the coming paragraph, and we provide a rubric summarising the scoping strategy at the end of this Section in Table 15.1.

Under the *System Function* theme, Wasylewicz et al. [2] identify that a CDSS can be classified to be a (a) Diagnostic Assistant tool; (b) Treatment Planning Assistant

Table 15.1 Rubric depicting the strategy for scoping CDSS. Normal text shows points drawn from Wasylewicz et al. [2]. Bold text shows the points added by us

Theme number	Theme	Categories	Description
Theme 1	*System Function*	*Diagnostic Assistant Tool*	A tool that assists in the diagnosis
		Treatment Planning Assistant tool	A tool that assists in treatment planning
		A Diagnostic as well as Treatment Planning Assistant tool	A tool that assists in both diagnosis and treatment planning
Theme 2	*Way of Communication*	*Passive Communication*	A tool that comes to play only if and when a user (i.e. a clinician in this context) needs to use the tool and calls upon it
		Active Communication	A tool that has the capability to issue triggers and can tell users (i.e. clinicians in this context) what to do
Theme 3	*Decision-Making Process*	*Flowchart based*	A tool that produces outputs governed by a Flowchart-based architecture
		Decision tree based	A tool that produces outputs governed by probability driven Decision tree-based architecture
		AI-based decision support based	A tool that produces outputs governed by some form of Artificial Intelligence
		Other forms of decision-making processes	A tool that produces outputs by a means that cannot be classified according to the above three
		Flexibility to add more classifications	**Numerous classifications can be drawn within this theme, and the above three listed out are not the only provisions. Practitioners will have the flexibility to draw out classifications of different form**

(continued)

Table 15.1 (continued)

Theme number	Theme	Categories	Description
Theme 4	*Human–computer interaction*	Connected to EMRs	A tool that can pull out data from an EMR and/or can push data into an EMR
		Not Connected to EMRs	A tool that is in no way connected to an EMR
		Has facility to record CDSS usage activity	**A tool that is connected to some form of electronic memory and the memory is enabled to record the usage activity of the CDSS**
		No facility to record CDSS usage activity	**A tool that may or may not be connected to some form of electronic memory and has no way to record the usage activity of the CDSS**
		Accessible on Mobile/ Handheld devices	**A tool that makes the CDSS accessible on Mobile/Handheld devices only (including the likes of Smartphone Apps)**
		Accessible on Stationary devices	**A tool that makes the CDSS accessible on Stationary devices only (e.g. Desktop computers)**
		Accessible over a combination of both Mobile/Handheld devices and Stationary devices	**A tool that makes the CDSS accessible on both Mobile/Handheld devices as well as Stationary devices**
		Flexibility to add more classifications	**Similar to Theme 3, numerous classifications can be drawn within this fourth theme as well. Practitioners will have the flexibility to draw out classifications of different form**

tool; or (c) Diagnostic as well as Treatment Planning Assistant tool. Our experience with CLOTS finds good agreement with that classification. A key difference we see between *Diagnostic Assistant* tools and *Treatment Planning Assistant* tools aligns with the components *Input* and *Output* we identified in our *Inquiring System* perspective in Fig. 15.1. We see that if a CDSS is a *Diagnostic Assistant* tool, it is quite likely to take *Symptoms* of patients as a part of the *Input*, and provide a *Diagnosis* as part of the *Output*, which means, on the contrary, a *Treatment Planning Assistant* tool may not rely too much on *Symptoms* as part of input and might not output a *Diagnosis*. That could be a useful hint for someone to determine whether a CDSS they look at is more toward the *Diagnostic Assistant* side, or whether it is more towards the *Treatment Planning Assistant* side, as there could be key differences in the *Inputs* and also the Outputs of CDSS depending on which category a CDSS falls into.

The second theme is *Way of Communication*. In this theme, Wasylewicz et al. [2] identify two classes to which a CDSS can be classified into as to say a CDSS might belong to either the (a) Passive Communication class or (b) Active Communication class. *Passive Communication* here means that a clinician consults a CDSS in question when they need it. *Active Communication* on the other hand simply means that the CDSS has the capability to issue triggers and can tell clinicians what to do. This classification too coming under the theme *Way of Communication* can be considered fairly clear cut and straightforward similar to the classification under the first theme.

The third theme is *Decision-Making Process*. In this theme, Wasylewicz et al. [2] focuses primarily on the inside of the *Process* part of a CDSS we identified in our *Inquiring Systems* perspective in Fig. 15.1. As such, Wasylewicz et al. [2] identify several classes such as (a) Flowchart-based; (b) Decision tree-based; (c) AI-based decision support-based; and (d) other forms of decision-making processes that can be comprised within this theme. While our experience and learnings agree to a good extent with this theme and classes as Wasylewicz et al. [2] have seen, we would like to also add that given the advancements of Computer Science of late, there can be numerous other classifications that can be formed under this very theme, and therefore the classes can have flexibility going beyond the four classes (a), (b), (c) and (d) listed in this paragraph.

The last theme is *Human–Computer Interaction*. This theme, too, like the third theme *Decision-Making Process*, or rather, even more than the third theme, can be quite broad and can have the flexibility to have different classifications within. It is not very straightforward to give a clear-cut classification within this theme, as this theme relates to the technological aspects, capacities and limitations of a CDSS. Thus, we can only give indicative examples of some classifications that can be formed within this theme. Wasylewicz et al. [2] give the following example, as to whether a CDSS is: (a) Connected to Electronic Medical Records (EMRs); or whether a CDSS is (b) Not Connected to EMRs. We agree with that example. But, since we also see the flexibility within this theme, we also would like to introduce the following classification. One classification is based on whether a CDSS has: (a) Facility to record CDSS usage activity or (b) No Facility to record CDSS usage activity. Another classification is based on the devices on which users can access the CDSS. Here we would like to introduce a case for Smartphone Apps. Therefore, we would introduce our next classification based on whether a CDSS is accessible on (a) Mobile/Handheld devices, (b) Stationary devices or (c) a combination of Mobile/Handheld devices and Stationary devices.

Table 15.1 summarises the aforesaid scoping criteria, forming somewhat a rubric. This table can be useful for practitioners to use as a guide to scope our CDSS to help plan and manage design, development and improvements to CDSS. In Table 15.1, what appears in the normal text is what we have picked from Wasylewicz et al. [2]. What appears in **Bold** are the additions we propose. In Sect. 15.4, we present a case study in which we apply the proposed scoping strategy to the CLOTS App-based CDSS.

15.4 Case Study (CLOTS Smartphone App) on Using the Proposed Scoping

In this section, we report the results of a case study we conducted with the CLOTS Smartphone App-based CDSS [12, 13] that is involved with an ongoing Australian study [11]. In this case study, we demonstrate how the scoping strategy proposed in Sect. 15.3 is applied to the CLOTS App and what comes forth as the result. At the end of this section, we also map out an outline showing what kinds of data can be captured from this system.

15.4.1 CLOTS App Overview

CLOTS is a Smartphone App functional on both Android and iOS platforms. The App has been developed by the Peter MacCallum Cancer Centre in Victoria, Australia, CLOTS [12, 13] and provides easy-to-follow (flowchart based) algorithms for: (a) calculating surgical thromboembolism risk of perioperative patients; (b) pre- and post-surgery anticoagulant drug management; (c) warfarin reversal; and (d) haematological optimisation. As such, CLOTS is essentially a four-model system, that supports clinical decision-making for the prevention of thromboembolism in perioperative patients. This App is currently used by the Peter MacCallum Cancer Centre in Victoria, Australia. The App is based on a risk-stratified thromboprophylaxis protocol of which the development and assessment have been published in [13].

15.4.2 Scoping of CLOTS App

In this subsection, we demonstrate the application of our scoping criteria (in Table 15.1) to the CLOTS App.

Firstly, as said in [12], CLOTS is designed to be used surrounding surgery. By using and redeveloping the App ourselves, our experience too affirms that view. Through using the App, we have seen that this App is quite clearly, none other than a "*Treatment Planning Assistant*" tool according to our scoping criteria described before. As a justification to our judgment, we can confirm that the App does not take as input any details about "*Symptoms*" of patients, for example, and does not produce as the output any "*Diagnosis*", going along with our explanation in Sect. 15.3 in which we argued that whether or not "*Symptoms*" being taken as input to a CDSS and "*Diagnosis*" being produced as the output can be a distinctive feature in determining whether a CDSS is more of a "*Diagnostic Assistant*" tool or more of a "*Treatment Planning Assistant*" tool.

Table 15.2 Scoping of the CLOTS App-based CDSS by applying the scoping criteria presented in Table 15.1

Theme number	Theme	Categories
Theme 1	*System Function*	*Treatment Planning Assistant tool*
Theme 2	*Way of Communication*	*Passive Communication*
Theme 3	*Decision-Making Process*	*Flowchart based*
Theme 4	*Human–Computer Interaction*	Not Connected to EMRs
		No facility to record CDSS usage activity
		Accessible on Mobile/Handheld devices

Second, we can confirm that CLOTS plays a role only when clinicians take out their smartphones and decide to consult CLOTS, and CLOTS in no way generates anything of the nature of triggers or warning alarms that would interfere with clinical workflow. As such, CLOTS can quite easily be scoped as a "*Passive Communication*" CDSS.

Thirdly, on having closely studied each of the four models embedded in CLOTS, we see the underlying decision-making process of CLOTS to be "*Flowchart*" based. CLOTS App does not have within itself any probability calculation-based *Decision Tree* architecture or any other *Artificial Intelligence* or *Other Forms* of decision-making according to our scoping criteria.

Coming onto the last theme, CLOTS in its current form can be confirmed to have "*No Connection to EMRs*". Then, along the same theme, we can confirm that CLOTS in its current form does not record any data or usage activity. Thus, CLOTS falls under the "*No facility to record CDSS usage activity*" category. Lastly, the most obvious point we can conclude on is the last point of whether CLOTS is a "*Mobile/Handheld*" tool, or a "*Stationary*" tool, or a mix of the two. CLOTS being a Smartphone App, the CDSS created by CLOTS essentially becomes a "*Mobile/Handheld*" tool-based CDSS.

As such, the scoping of the CLOTS App-based CDSS can be presented as in Table 15.2. Thus, Table 15.2 stands as an example of what an output looks like when the proposed scoping strategy is applied to any CDSS.

15.4.3 A Data Capture Outline for CLOTS App

In this section, we further discuss how the proposed scoping strategy can be used to make improvements to CDSS and also even be used to design and develop new CDSS. We take the same case of the CLOTS App to demonstrate this case.

Now, we have presented the current scoping of the CLOTS App in Table 15.2. Now suppose, we intend to improve CLOTS App and this targeted improved version of CLOTS would fall into a different scope to that in Table 15.2. Table 15.3 shows the new scoping of the targeted improved version of CLOTS. Simply said,

Table 15.3 An example improvement for CLOTS App-based CDSS by changing its scoping compared to that in Table 15.2

Theme number	Theme	Categories
Theme 1	*System Function*	*Treatment Planning Assistant tool*
Theme 2	*Way of Communication*	*Passive Communication*
Theme 3	*Decision-Making Process*	*Flowchart based*
Theme 4	*Human–Computer Interaction*	Not Connected to EMRs
		Has facility to record CDSS usage activity
		Accessible on Mobile/Handheld devices

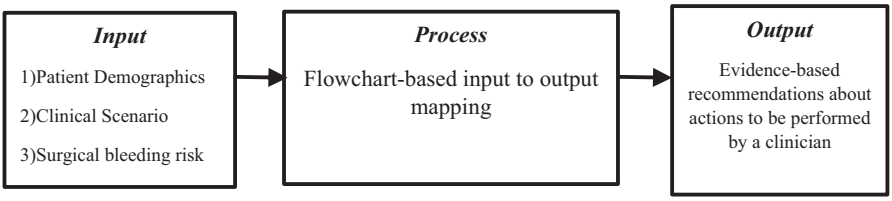

Fig. 15.2 CLOTS App-based CDSS mapped onto the *Inquiring Systems* perspective

the intended improvement is to enable recording of App usage data, in contrast to having no provision to record data in the original scoping shown in Table 15.2.

With the aid of the new scoping and our perspective of viewing CDSS as *Inquiring Systems* (recall from Fig. 15.1), we now go on to show a mapping of data capture opportunities for the CLOTS App as an example.

Recall from Sect. 15.4.1 that CLOTS is essentially a system that supports clinical decision-making for the prevention of thromboembolism of perioperative patients. Thus, CLOTS App is a tool to be used by perioperative clinicians to support in their clinical decision-making in regard to managing thromboembolism in surgery patients. As per our *Inquiring Systems* perspective, we find that the CLOTS App can be mapped out as in Fig. 15.2.

According to the mapping in Fig. 15.2, and our scoping in Table 15.3 targeted at improving the CLOTS App, we can conclude that there is no data to be recorded in the *Process* component as per the structure of the CLOTS App since the Process within the app is a simple flowchart-based input to the output mapping process. Thus, the process of decision-making has already been coded into the App and also can easily be verified.

Then, the data that is available to be recorded happen to be what is entered as *Input*, and also for the sake of completeness, what the App gives as the *Output*. In addition to those, since CLOTS is a Smartphone App, there is an additional data point that is available for recording, which is the mobile device identifier of the device in which a clinical uses the CLOTS App. CLOTS App is quite likely to be used in a clinician's personal Smartphone they use at work. In that case, it needs to be clear that the device identifier will only be a string of characters unique to a

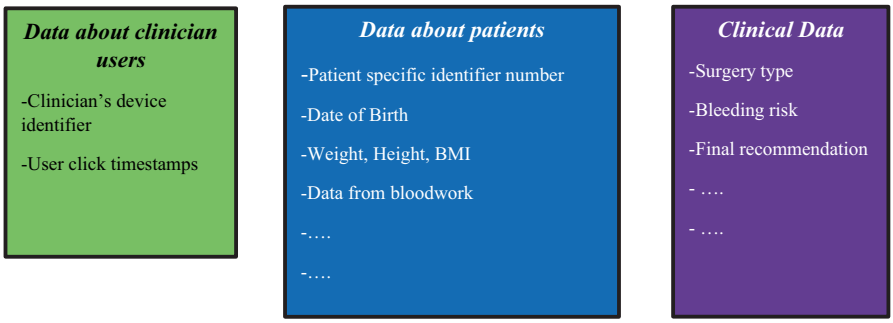

Fig. 15.3 Example data points available for recording from the CLOTS App-based CDSS; colour codes are given to be consistent with Fig. 15.4

particular device (e.g. a particular Smartphone), but that does not necessarily mean that the identifier will be able to reveal the identity of the clinician user. Thus, if the device identifier is recorded, the clinician user will still remain anonymous. Further special arrangements will be required to reveal the identity of the clinician user.

With that additional data point which is available to be collected about the clinician user, we see two human stakeholders about whom data will be available. The two human stakeholders are: (1) The Clinician User and (2) The patient. We propose any other data that is being generated outside in relevance to those two human stakeholders to be categorised into one category; in the light of the CLOTS App, we name that third category "Clinical Data". Along with that breakdown, we can now categorise data types coming from the CLOTS App to be threefold: (1) Data about clinician users; (2) Data about patients; and (3) Clinical data. With that breakdown, in Fig. 15.3 we illustrate some example data points that are available to be collected from the CLOTS App. It should be noted that Fig. 15.3 does not show all the data points and it is not possible for authors to list all the data points because there are too many. In this example, the authors only report some selected data points as examples. With those data points, since we take into account the data available about the clinician users, we will also be able to record the timestamp of clicks in the App performed by clinician users. Since that timestamp also becomes a data point that is recordable, that data point is indicated as "user click timestamps" in Fig. 15.3.

The data breakdown in Fig. 15.3 leads to a clinician-centric data model for the CLOTS App. This data model could be extended and generalised for other Smartphone App-based CDSS or even outside the scope of Smartphone Apps. A simple representation of this clinician-centric data model is given in Fig. 15.4. Figure 15.4 shows the data model only with respect to one clinician user. A database that records this data can have the facility to save data according to such a model for multiple users. In the next section, we go on to discuss the critical issues, barriers and enablers that come to the picture when pursuing such a direction of data recording.

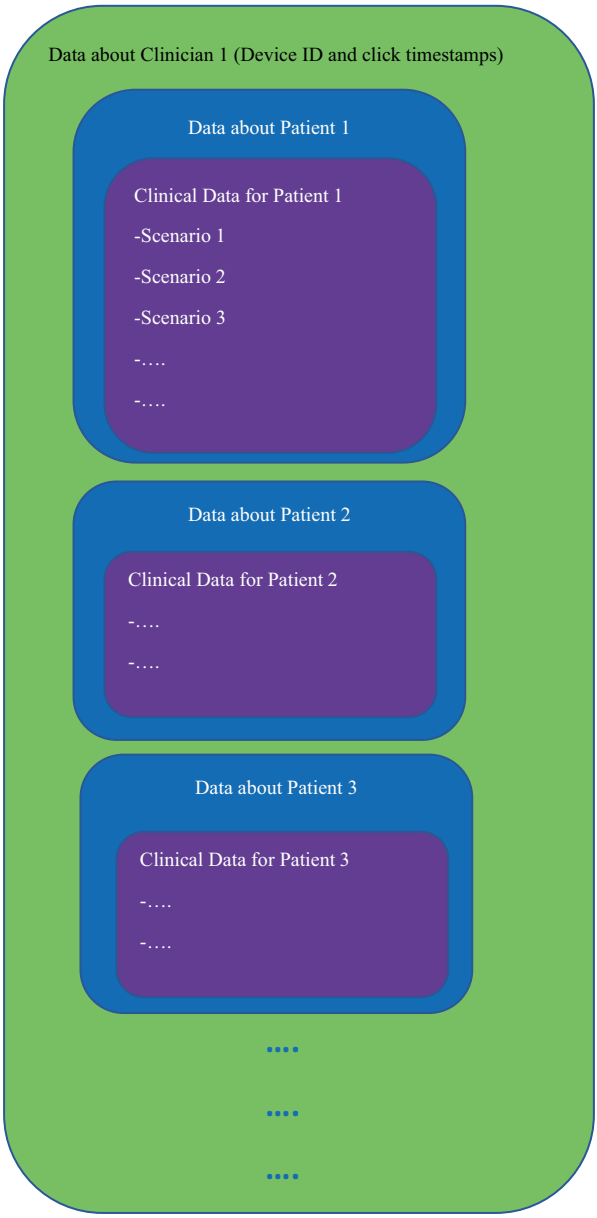

Fig. 15.4 Illustration of cascaded clinician-centric data model for CLOTS App. Interpretation should be: Under one clinician there can be several patients saved, and under each patient there can be several scenarios saved according the what the clinician has queried in the CDSS

15.5 Discussion

One of the first questions that usually gets asked when endeavouring a direction of data recording like this is, why is this done and what is the purpose behind this. To answer that question, we have to look comparatively at the option of not recording data versus the option of recording data.

The issue with not recording data is that when a CDSS tool such as the CLOTS App is introduced, we will have no way of finding out whether the tool is actually being used by the intended users (clinicians in this instance). Now, since a technology innovation is usually invested in healthcare to achieve some improvement in healthcare delivery, if the intended users end up not using the technology, which altogether undermines the effort on improvement. Therefore, it is important to have some objective and independent measure to learn about the usage (or lack of it) when a technology innovation has been introduced. Data recording in the proposed manner becomes a key enabler of having such an objective measure. On having such an objective measure, we can think of many incremental developments to improve even further. However, if not having an objective measure to start with, there will be no measurable available to even think of further developments, improvements, or even collecting evidence to support a reversal of technology solution that may be not suiting the intended purposes. Thus comes the rationale behind supporting recording data against the option of not recording data.

It is also well known that data recording adds whole new layers of complexity and risk as well, which could altogether be avoided if we decide to not record data at all. Previous works have found out that with data recording comes some critical issues such as concerns about performance and fitness for purpose, cost of implementation, privacy and data security, surveillance capitalism, scalability and expandability, policy and legislative challenges and slow adoption and uptake [7, 8]. However, with the rationale presented just before, we see that recording of data has benefits as well by creating the launchpad for potential further improvements as well. Thus, the more beneficial way forward seems to be a support of data collection, along with maximum efforts to counter the risks and limitations, and also the effort puts into advocacy of awareness about risks and limitations and not resorts to the simpler and less progressive option of not recording data at all.

Then, coming back to the work of this chapter, what we presented was a way to scope CDSS of different capacities. Our scoping strategy was bounded by four themes, namely: (1) System Function; (2) Way of Communication; (3) Decision-Making Process and (4) Human–Computer Interaction. We presented subcategories under each of those themes along which a CDSS can be scoped and also presented an example of how scoping of a CDSS can be done across those themes and categories using the CLOTS App as a case study. Although the four themes in the scoping strategy are fairly rigid, the subcategories coming under the themes can be fairly flexible and has space of tailoring to match a wide variety of CDSS. The purpose

behind introducing this way of scoping is to facilitate a more systematic approach to the design, development, assessment and improvement of different types of CDSS. On one side, our way of scoping enables a better understanding of the limits and capabilities of an existing CDSS, and on another side, the scoping can be used as a guide to design, develop and assess new CDSS, and also propose improvements to existing ones.

Along that direction of proposing improvements to an existing CDSS, we selected a case study which is carried out under a presently undergoing Australian study that involves the CLOTS App-based CDSS [11]. The existing version of CLOTS App has no facility to record data or usage activity. Therefore, the improvement we scoped was enabling the recording of data. We presented the existing and proposed (or improved) scoping in Tables 15.2 and 15.3 respectively. Then we went on to view CLOTS App aligning with the *Information Systems* perspective (recall from Fig. 15.1) we discussed initially and thereby went on to identify the data points which can be collected. The data points coming from CLOTS App were then identified under a threefold categorisation. This categorisation included the three categories: (1) Data about clinician users; (2) Data about patients and (3) Clinical data. Although this categorisation is quite tailored to the CLOTS App, this categorisation has some main themes that are quite generic providing the ability for this categorisation to be tweaked and adoptable to apply to different types of CDSS. In the remainder of this Discussion, we discuss some critical issues and ways to work around them when recording data under the threefold categorisation presented in this work. The next phase of our discussion unfolds as Subsections devoted to: (1) Issues regarding capturing data about clinician users; (2) Issues regarding capturing data about patients and (3) Issues regarding capturing clinical data. We discuss the issues and possible solutions under the socio-technical perspective of Technology, Process and People issues.

15.5.1 Issues Regarding Capturing Data About Clinician Users

Technological Issues: A connection to an external database storage will be necessary. Alongside external data storage, the risks of data theft will have to be accepted, and evolving countermeasures will have to be adopted. A primary measure doable will be ensuring the stored data are de-identifiable. Another crucial issue will be that a reliable wireless data connection will be required when connecting to an external database. In case the wireless data connection is lost, using the CDSS may be still possible, but data recording will not happen.

Process Issues: No major process issues are foreseen. No interference to clinical workflow will be caused as recording clinicians' information (i.e. user's device

identifier and usage timestamps) can be automated. However, users may have to accept some usage terms and conditions on their first time of using.

People Issues: People issues might arise regarding consent to recording CDSS usage activity. Since this is a CDSS, it is desirable to mandate recording usage activity and not allow an option to opt out. As said before, personal human identifiers should not be recorded for privacy.

15.5.2 Issues Regarding Capturing Data About Patients

Technological Issues: A connection to an external database storage will be necessary. Alongside external data storage, the risks of data theft will have to be accepted, and evolving countermeasures will have to be adopted. A primary measure doable will be ensuring the stored data are de-identifiable. Another crucial issue will be that a reliable wireless data connection will be required when connecting to an external database. In case the wireless data connection is lost, using the CDSS may be still possible, but data recording will not happen.

Process Issues: There can be points where clinicians have to manually enter data points and that will take some additional time. The alternative to spending that additional time, will be recalling something from memory, and risking any uncertainty or memory fog. But, since using a CDSS, in any case, will be optional, if a clinician is certain about a decision or can recall from memory, they will not have to spend time on the CDSS. In the event of such certainty or memory is absent, investing that extra bit of time in manually inserting data can be seen as a worthwhile investment.

People Issues: Since we are dealing with CDSS and the sole users are expected to be clinicians, there can be errors in manually entering data into the CDSS. A way to alleviate that challenge is to link with an EMR and cross-check or import the necessary data points required for the CDSS. However, there can be systems that do not have the facility to connect to a CDSS, for example, the CLOTS App (see scoping in Tables 15.2 and 15.3). In such instances, there can be errors in manually entered data. In the event of having no connection to EMR, the responsibility of the accuracy of entered data would lie on the clinician users. In regard to recording, the database will record all and any data entered into the CDSS, and the database will have no way of verifying accuracy. Therefore, in the technology design, overriding any data in the database or recalling data into the CDSS from the database should not be allowed because we have no guarantee that the data that have been entered manually into the CDSS by a single clinician, is error-free. Instead of overriding and recalling, manual data entry should be allowed every time the CDSS is used, and data entered and every single time should be recorded independently. Recording data in that manner may help in post-analysis-based auditing and identifying trends of mistakes and usage habits that can evolve, and countermeasures can eventually

be advocated via persuasion and/or training. Since this involves recording data about patients, the question about patient privacy would arise as well. To address that concern, the data available to record about patients should not involve personal identifiers. That measure will be a strong factor to ensure privacy to patients.

15.5.3 Issues Regarding Capturing Clinical Data

Technological Issues: A connection to an external database storage will be necessary. Alongside external data storage, the risks of data theft will have to be accepted, and evolving countermeasures will have to be adopted. A primary measure doable will be ensuring the stored data are de-identifiable. In the context of clinical data, they by default are unlikely to have personal human identifiers. Another crucial issue will be that a reliable wireless data connection will be required when connecting to an external database. In case the wireless data connection is lost, using the CDSS may be still possible, but data recording will not happen.

Process Issues: There can be points where clinicians have to manually enter data and that will take some additional time. The alternative to spending that additional time, will be recalling something from memory, and risking any uncertainty or memory fog. But, since using a CDSS, in any case, will be optional, if a clinician is certain about a decision or can recall from memory, they will not have to spend time on the CDSS. In the event of such certainty or memory is absent, investing that extra bit of time in manually inserting data can be seen as a worthwhile investment.

People Issues: As said under issues regarding capturing data about patients, errors can occur where manual data entry is necessary. In regard to clinical data, not all points may be verifiable through an EMR either in an instance there is the ability to connect to an EMR. But as said before, examples like CLOTS App will not have the ability to connect to an EMR. Furthermore, when it comes to clinical data, there can be some decision points where the clinician has to make on their own. In such instances, technology-wise in the design aspect, factors like screen clutter or overpopulating the screen, or providing too many options at once, have to be avoided. In a backdrop such aspects are addressed through design, once again; if a mistake happens, the responsibility will once again direct towards the user clinician. In regard to recording, the database will record all and any data entered into the CDSS. Overriding any data in the database or recalling data into the CDSS from the database should not be allowed. Instead of overriding and recalling, manual data entry should be allowed at every time the CDSS is used, and data entered and every single time should be recorded independently. Recording data in that manner may help in post-analysis-based auditing and identifying trends of mistakes and usage habits that can evolve, and countermeasures can eventually be advocated via persuasion and/or training.

15.6 Conclusion

This chapter proposes a way of scoping CDSS. The purpose of proposing this scoping is to facilitate a more systematic means to understand different types of CDSS and also to enable designing, development, assessment and improvement of CDSS. The proposed scoping involved viewing CDSS in an *Inquiring Systems* [10] perspective (recall from Fig. 15.1), and also scoping out under different categories listed under four themes (recall from Table 15.1). We also present a case study with the CLOTS Smartphone App-based CDSS [12] to show how the proposed scoping can be applied to CLOTS App and also scope out an improved version of the App. The scoped out improved version of the CLOTS App in our case study involved enabling recording CDSS usage data. We then went on to discuss how such a data capture task can be mapped and analysed through the scoping as well as the Inquiring Systems perspective and concluded by presenting how issues and challenges can be foreseen, and also mitigation tactics can be planned guided by the structure provided by our proposed scoping and perspectives. Some noteworthy issues and also prospects in regard to recording usage activity were discussed under the socio-technical metric of Technology/Process/People issues. We expect the presented scoping and perspectives can help technology designers/developers and also clinicians in better understanding different types of CDSS and also to plan the design, development, assessment and improvements to CDSS in a more systematic manner.

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Part IV
COVID-19-Pandemic Focus

Chapter 16
Better Pandemic Preparedness with the Intelligence Continuum

Nilmini Wickramasinghe

16.1 Introduction

COVID-19, the global pandemic that has caused devastation and chaos around the world in 2020 and continues to plague nations in 2021, is an example of yet another emergency and disaster scenario that has been poorly managed. These scenarios necessitate rapid and effective crisis management, including appropriate hospital and emergency/trauma in-hospital medical services, firefighting, disaster-related law enforcement operations, coupled with superior decision-making capabilities [1–3]. Different local or national agencies typically provide such services which in turn result in a variety of operating plans, rules, standards and regulations that govern them [4]. This creates a significant problem with respect to gathering and storing of data as they reside in disparate databases (ibid). In contrast, there is an interdependent nature with respect to such scenarios and decision-making which is only based on a few of these data elements that will only provide a partial picture at best, resulting in suboptimal decision-making (ibid). It is vital to collect multi-spectral data, analyse these data in aggregate to develop a comprehensive picture if one is to facilitate superior, prudent and timely decision-making (ibid). The critical success factors in such an approach include embracing the tools, techniques, tactics and technologies of the knowledge economy [3–11].

This chapter, thus, serves to examine how we can apply the tools, techniques and processes of the knowledge economy, supported by digital health solutions, to be better prepared to contend with pandemics in the future. To do this, previous work-around knowledge management and the intelligence continuum must be presented and its relevance to the current focus outlined.

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16.2 Background

To understand and appreciate the role for applying the tools, techniques and processes of the knowledge economy, it is necessary to first understand the intelligence continuum [12] and related aspects of data mining and knowledge discovery.

16.2.1 The Intelligence Continuum

The Intelligence Continuum, developed by Wickramasinghe and Schaffer [12], consists of an assembly of crucial tools, techniques and processes of the knowledge economy, such as data mining, business intelligence/analytics and knowledge management which, when taken together and then applied to a generic socio-technical system of people, process and technology in a systematic and ordered fashion, will enable superior decision-making to ensue [4, 12].

The power of this approach is drawn from the ability to systematically analyse multispectral data simultaneously. The intelligence continuum (developed by Wickramasinghe and Schaffer, 2010), which essentially applies in a systematic fashion key artificial intelligence and machine learning tools to disparate and multispectral data sets, can be applied to the output of any generic information system [4]. By doing so, the results can then be reintroduced into the system and combined with further inputs to develop a continuum of analysis (ibid). This means that the intelligence continuum not only supports the generation of data and its analysis to provide a "diagnosis" but it can also, through the ability to reintroduce findings into the cycle, provide a "prescriptive" solution (ibid).

This unique model supports and enables the ability to analyse large volumes of disparate, multi-spectral data with the specific focus of supporting superior decision-making (ibid). This is made possible by combining key tools, technologies and techniques of the knowledge economy with advances in machine learning and analytics so that the model can indeed provide the necessary support (ibid). Further, this model supports the interaction with domain experts to ensure appropriate results and the best solutions can ensue. Hence, it is logical to apply the intelligence continuum to emergency and disaster scenarios such as pandemics. Such scenarios are typically complex, unstable and unpredictable environments where there are many unknowns or the decision-maker is in a position of information inferiority and yet must make decisions that have profound and long-term implications. In dynamic and complex scenarios, as we are witnessing with COVID-19, because events are chaotic and haphazard, decision-making is typically suboptimal. In such a context, by applying key tools and techniques around knowledge discovery, as is the case when the intelligence continuum is used, it is possible to extract critical insights from large and multispectral data in a timely fashion (ibid). By doing so, it is also possible that decision-makers can make better decisions and thus chaos is reduced with the result that the disaster is lessened or eliminated [4].

16.2.2 Data Mining

As the Information Age continues, we are generating more and more volumes of data. Data are the essential raw material; however, to make these data valuable and meaningful it is essential to mine and process the data; much like raw minerals and gold need to be refined and processed to provide their full value and utility. Data mining is a technical process that utilises techniques from computer science, specifically artificial intelligence and machine learning, and applies them to data to assist with sense-making and extraction of critical information from heterogeneous databases and data sets [13–16]. Such multispectral data are often present in emergency contexts such as with COVID-19, when data were being generated in real-time in many different contexts. Hence, the ability to quickly make sense of and identify key insights from these data in a timely fashion is essential and thus the reason why data mining can be useful in such contexts.

Typically, data mining consists of traversing several steps from identifying target data to cleaning it, processing it and then utilising it for decision-making [16–20].

Thus, succinctly stated data mining is the non-trivial process of identifying valid, novel, potentially useful and ultimately understandable patterns from data [16].

16.2.3 Business Intelligence/Analytics

A more sophisticated technology-centric approach, like data mining, is the area of business intelligence and business analytics [12]. These are knowledge-generating and support the cyclic nature of the intelligence continuum [12]. Business intelligence (BI) involves a combination of a variety of analytic decision-support tools to identify meaningful insights into data [5, 12]. Often BI utilises a hierarchy approach with regard to using these respective tools in which the first layer consists of extraction and formatting tools often called data-extraction tools [12]. These tools are typically used to collect data from existing databases for inclusion in data warehouses and data marts. The next level of the BI hierarchy is known as warehouses and marts [12]. Because the data come from so many different, often incompatible systems in various file formats, the next step in the BI hierarchy consists of formatting tools that are used to "cleanse" the data and convert it to formats that can easily be understood in the data warehouse or data mart [12]. Next, tools are needed to support the reporting and analytical techniques that are known as enterprise reporting and analytical tools [12]. OLAP (online analytical processing) engines and analytical application-development tools that make up this layer are used to analyse data and perform modelling and trend analysis [12]. The next layers include intelligence tools to work with people and support their decision-making [12].

16.2.4 Knowledge Management

Knowledge management (KM), a management discipline that has become significant in today's knowledge economy, focusses on resolving business problems principally concerned with trying to increase efficiency and efficacy of core business processes while concurrently enabling and fostering innovation [3, 5]. Specifically, KM focusses on combining germane organisational data, information and knowledge to create business value and enable an organisation to capitalise on its intangible and human assets so that it can effectively achieve its primary business goals as well as maximise its core business competencies [3, 5, 6]. This is done by relying on various tools and techniques [3, 5]. Many note that knowledge creation or generation is the critical step and has the most impact on supporting superior decision-making [3, 5].

16.3 Knowledge Generation and Dynamic Environments

In dynamic, complex and unpredictable environments, data, information and knowledge are essential to make sense of and support sound decision-making [21, 22]. In this regard, the gathering of information precedes the transformation of information into useable knowledge [21, 22], while the rate of information collection and the quality of the collected information have a major bearing on the quality (usefulness) of the generated knowledge [23] and ultimately the soundness of the decisions made [24, 25]. Thus, to be meaningful, the widely dispersed and apparently disconnected (or irrelevant) data must be processed into coherent information so that the latter must then be rapidly converted into a knowledge-base which in turn, serves as the foundation for goal-oriented interactions with the environment within which decision must be made (e.g. [5, 24, 26–29]).

To achieve an appropriate or optimal level of awareness requires appropriate and timely extraction of key insights from multi-spectral data [29]. An efficient and effective method to do this systematically is via a network-centric perspective [30]. Specifically, network-centric operations simultaneously support action space awareness and information superiority and have been found to be particularly beneficial in healthcare contexts when too often time is of the essence to save lives [30]. To understand the fundamentals of network-centric operations, one needs to understand the OODA Loop (Fig. 16.1), the cornerstone and driving philosophy of all network-centric operations [29, 31, 32]. The application of the OODA Loop and the connected concept of OODA thinking is particularly beneficial for effective, efficient and real-time extraction of critical multi-spectral data and have been used in many contexts such as healthcare, business and military operations [1–3, 31–34] and thus are proffered in this chapter as being equally suitable for decision-making as well as enabling a state of better preparedness in the context of pandemics.

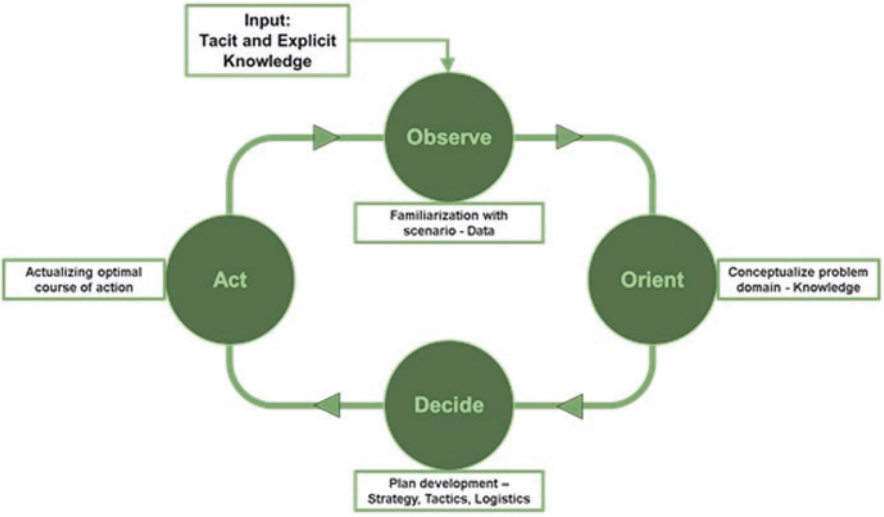

Fig. 16.1 The OODA Loop adapted from [12, 31, 32]

The OODA Loop consists of four interrelated stages: Observe, Orientate, Decide and Act, which has a temporal dimension [12]. Stage 1 Observe requires the gathering of multispectral, implicit and explicit inputs [ibid]. Stage 2 Orientate then converts these inputs into coherent information [ibid]. Then the sequential Decide (knowledge generation) stage identifies appropriate courses for action, and finally the Act (practical implementation of knowledge) stage is where the chosen decision is enacted [12]. The outcome of the decision impacts, in turn, the starting point (Observe) of the next revolution in the forward progression of the loop [12].

16.4 Application of IC and OODA Loop to COVID-19

The COVID-19 pandemic has caused catastrophic devastation to the world in 2020 with more than ten million Coronavirus cases in the United States and over a quarter of a million deaths [35] by the end of 2020. Moreover, this virus has caused significant impacts on the economy and healthcare facilities. The first clusters of pneumonia related to COVID-19 were reported in the Hubei province, China in December 2019 followed by a declaration of public health emergency of international concern (PHEIC) by the World Health Organization (WHO) in January 2020 [36–41], and on 11 March 2020, the WHO declared the COVID-19 outbreak as a global pandemic. As noted by the Centers for Disease Control and Prevention (CDC) in March 2020 [36, 37], older adults comprised a significant number of hospitalisations and ICU admissions. While older adults contributed to 31% of the infected population, they accounted for 45% of hospitalisations and 53% of ICU bed occupancy [36, 37].

Aside from prevention, the most commonly used treatment for COVID-19 patients is considered to be supportive care [38–40]. Furthermore, since the start of the pandemic, COVID-19 has not only spread globally to all areas of the world but several mutations also have already occurred.

Many studies confirm that more comprehensive data are required regarding COVID-19 patients to best optimise resource planning and identify vulnerable populations [38–41]. Deploying accessible applications for self-reporting of symptoms and identifying avoidable hotspots rely on robust data gathering systems [38–41]. Due to limited resources and the extent of COVID-19 spread, many countries do not have the opportunity to experiment with different strategies and they must adopt methods that will produce the most optimal outcomes [38–41]. Clearly, the world was caught by surprise, and efforts to control the COVID-19 pandemic have all been reactionary.

On closer examination of the events in 2020, what is a unifying and concerning aspect is how unprepared the world in general was to deal with the pandemic and how slow decision-makers globally were to take necessary steps. In short, suboptimal decision-making took place and there was an inability to identify rapidly critical data, pertinent information and germane knowledge. This chapter proffers the previous model of the intelligence continuum coupled with Boyd's OODA Loop as an appropriate framework to assist decision-makers in such emergence and disaster scenarios.

Specifically, the first step of Observe would ensure that key decision-makers, by applying the intelligence continuum to data and information that was being generated about cases of pneumonia and its rapid spread in Wuhan in December 2019, could evaluate the level of a potential threat. By doing so objectively and with robust analysis of critical data, it would then be possible to move to the Orient stage of the OODA Loop. In this stage decision-makers would start to evaluate relative risks and consequences; for example, should borders be closed, what public health information and warnings should be shared and what resources need to be made ready. From the Orient stage the next step is to formulate Decisions to be made at the macro, meso and micro levels regarding policy, deployment of resources and support, need to develop a vaccine and how best to contain the spread and eradicate the virus. Finally, in the Action stage, sound and appropriate courses of action would result.

However, when we analyse the recent COVID-19 pandemic and how it has been handled to date, we notice a common theme being a lack of preparedness and readiness. Clearly, we cannot go back in time but moving forward there are key lessons to learn and hopefully a better state of preparedness will ensue for the future.

16.5 Discussion and Conclusion

The impact of COVID-19 will likely be felt across the world for several years after the pandemic. While the pandemic was unexpected, it should not mean countries are unprepared for emergency and disaster events like pandemics and it is paramount that part of the recovery process focusses on having a better state of preparedness in the future.

The preceding has proffered the intelligence continuum model coupled with OODA Loop thinking as a suitable framework to enable a better state of preparedness to be reached. Given the advancement of our digital technologies, especially with Industry 4.0 including mobile and wireless, analytics, sensors and platforms, it should be possible for countries and communities to not only build back better but also to establish a better state of preparedness not just for pandemics but also for all emergency and disaster events. The Intelligence Continuum offers the perfect organising framework to strategically and systematically apply these technological solutions to enable the full benefits of knowledge extraction and prediction to ensure and thereby support better preparedness and readiness as well as decision support, especially in the context of a pandemic Such an approach should be considered a strategic necessity for all governments and policy-makers since one thing is for certain: COVID-19 will not be the last pandemic, emergency or disaster scenario to impact the globe.

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Chapter 17
COVID-19 Response in Australia and the United States (March–August 2020) and the Key Role for Digital Health: A Tale of Two Countries

Foluke Ajiboye and Nilmini Wickramasinghe

17.1 Introduction

Coronaviruses are a family of RNA viruses that usually cause mild respiratory disease in humans. In December 2019, a cluster of pneumonia cases of unknown aetiology centred in Wuhan, China, was reported by Chinese authorities. The first case diagnosed with the novel coronavirus (2019-nCOV) in the United States was on 21 January 2020, and by 4 February 2020, a total of 293 persons were under investigation for nCOV in the United States (see Fig. 17.1). Eleven of those were confirmed nCOV cases [2]. According to US Food and Drug Administration (FDA) (2020), "CDC activated its Emergency Operations Center for COVID-19 in the US on January 21, 2020. Using an incident management structure, CDC works in coordination with World Health Organization and other countries as well as with state and local partners in response to the pandemic". The Centers for Disease Control and Prevention (CDC) issued a Level 3 travel ban for nonessential travel to Mainland China on 27 January 2020. Since then the number of cases has increased. The first case of 2019-nCOV in Australia was announced to the general public through a media release on 25 January 2020 (see Fig. 17.2). The patient had just arrived from mainland China. The Department of Health further informed the public of the plans implemented to reduce the risk of transmission such as educating the general public about the possible pandemic and that officials will be stationed at the airport to support and inform passengers arriving from China. A telephone line for reporting to the authorities was made public by the time the second case was identified on 29

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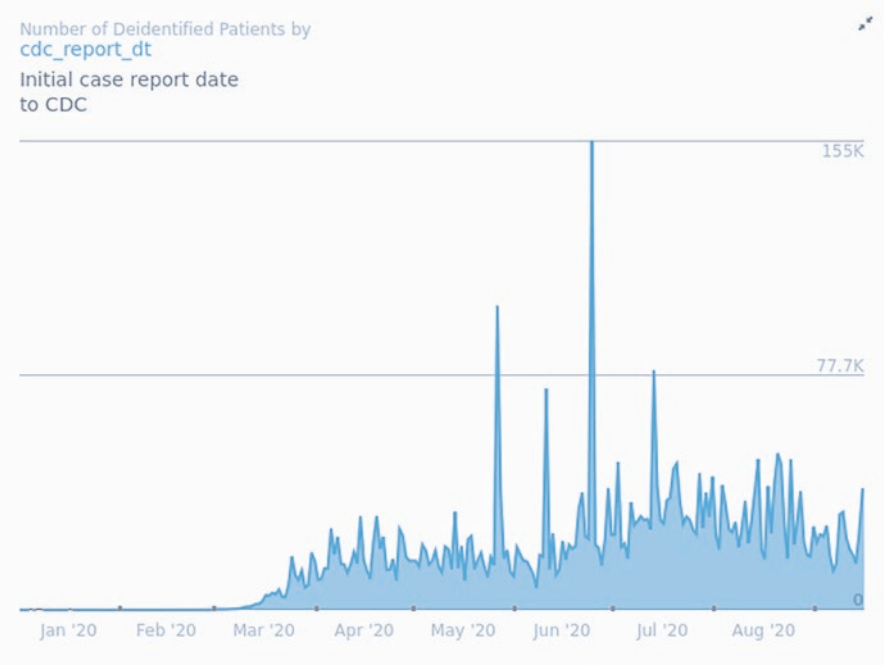

Fig. 17.1 Initial case report date of COVID-19 cases in the United States. Patient-level COVID-positive cases reported to US states and territories reflecting the earlier of the Clinical Date (date related to the illness or specimen collection) or the Date Received by CDC. (Source: CDC [1] [https://covid.cdc.gov/covid-data-tracker/#demographics])

January 2020. Timely reporting of new cases, contact tracing and surveillance are crucial in preventing the spread and mortality from COVID 19, hence the need for technological tools to create awareness and facilitate timely reporting of new cases to trigger response systems put in place by the healthcare authorities.

17.2 Methods

Review of the literature, grey literature and social media on COVID-19. Google searches were performed for relevant articles on government responses on COVID-19 as well as websites of public health organisations such as CDC, WHO, FDA and Australian Government Department of Health. References from identified publications were reviewed. Key themes, identified a priori, such as the spread of virus, number of cases and strategies to prevent spread, and then many emergent themes, such as contact tracing and telehealth, were used to help identify and analyse the literature in a systematic fashion. The goal was to develop a set of guidelines that would ensure we can be more prepared to combat future pandemics and thereby

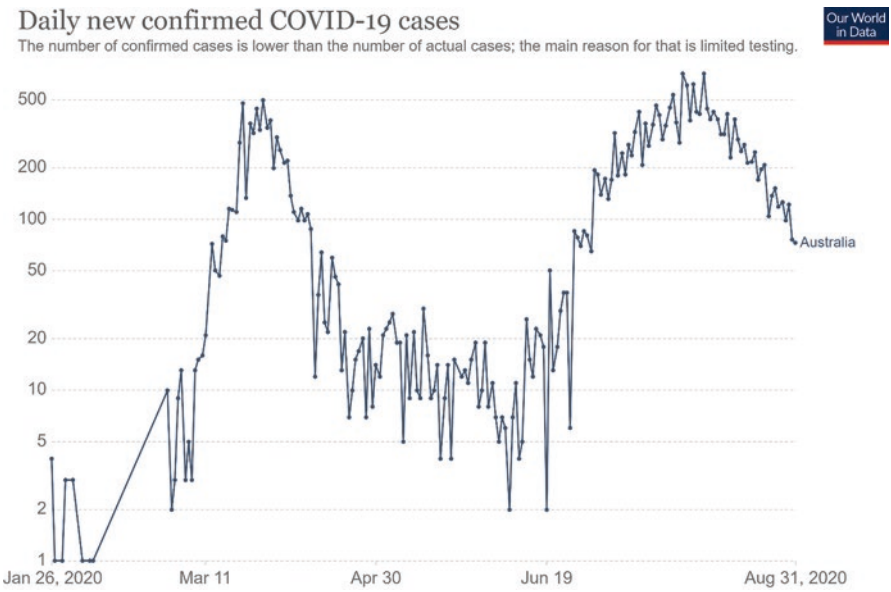

Fig. 17.2 Daily confirmed COVID-19 cases in Australia. Patient-level COVID-positive cases reported to national authorities showing a sharp increase from January 2020 to March 2020. (Sources: Johns Hopkins University CSSE [3]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

answer the research question, "how can we best prepare ourselves to be ready to combat pandemics and other emergency and disaster scenarios?"

17.3 Background

The recent coronavirus infection, COVID-19, is a SARS-CoV-2 disease that causes mild to severe respiratory illness, especially in immunocompromised individuals. Studies show that transmission is through respiratory droplets that are produced when an infected person coughs, sneezes or talks, droplets are subsequently inhaled or contacted by another person nearby to the infected individual. The virus is easily spread from person to person, the spread is facilitated through shorter distance, less than 6 feet apart and longer contact time. The virus may also be transmitted through other ways such as touching a surface or through an object that has the virus on it. According to the CDC [2], symptoms reported include fever, cough, shortness of breath or difficulty in breathing, fatigue, muscle or body aches, headaches, new loss of taste or smell, sore throat, congestion or runny nose, nausea or vomiting and diarrhoea. Patients become symptomatic 2–14 days after exposure to the virus. Testing for COVID-19 can be done by a diagnostic viral test to determine if a person has a

current infection. This includes molecular tests like the RT-PCR test that detects the genetic material of the virus and the antigen test that identifies proteins on the surface of the virus. Past infection can be detected through antibody tests [5]. There is currently no treatment for the disease, and prevention is the main strategy to control the spread of the disease. This is done by avoiding close contact with infected people, the use of a face mask to prevent droplet inhalation and spread, frequent hand washing and rigorous cleaning and sanitising of surfaces that are frequently touched. There are ongoing clinical trials to develop vaccines for COVID-19. The use of monoclonal antibodies and antivirals to hasten recovery is also being explored.

17.4 Assessments and Evaluations

Based on the literature reviewed the following summarises key assessments and evaluations for both the Australian and the US actions towards addressing and trying to stem the spread of COVID-19.

In both countries, the total number of cases has seen a steady increase since March 2020, as seen in Table 17.1.

The aim is to determine why these numbers have continued to increase and to examine response strategies and policies in place in the United States to prevent this rise in number of cases. Australia, on the other hand, was shown to have had a better control of the curve initially, in which a plateau was reached between April and June 2020. In July 2020, the cases started to increase again, doubling the number of cases recorded in June (see Figs. 17.2, 17.3, 17.4, 17.5, and 17.6). The increase in number was mostly attributed to people not observing the lockdown measures in place as seen in Melbourne (BBC, 2020). A review of Australia's COVID-19 response showed that in March 2020, as the cases began to increase Australia created a National Cabinet to coordinate and deliver a consistent response to COVID-19.

Table 17.1 Total number of cumulative cases of COVID-19 (monthly): United States versus Australia

Month	United States Total number of cumulative cases, monthly	Australia Total number of cumulative cases, monthly
31 Mar 2020	164,620	4557
30 Apr 2020	1.04 million	6746
31 May 2020	1.77 million	7185
30 Jun 2020	2.59 million	7767
31 Jul 2020	4.5 million	16,303
31 Aug 2020	6 million	25,670

Source of data: EUROPEAN CDC [6]

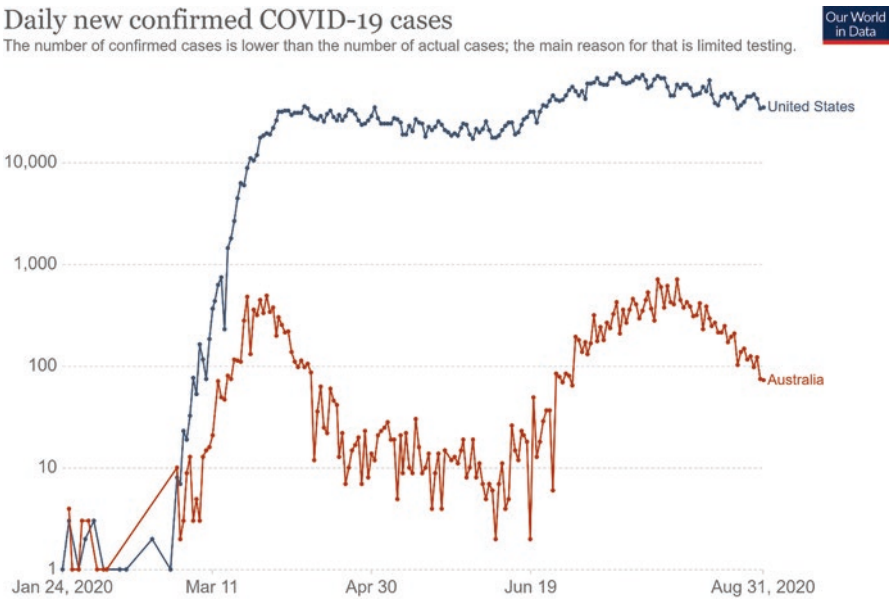

Fig. 17.3 Daily new confirmed COVID-19 cases. Shows the COVID-19 curve for Australia and the United States, with a plateau/decrease in new cases between April 2020 and June 2020. (Sources: Johns Hopkins University CSSE [3]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

"The Australian Prime Minister and all state and territory leaders (the equivalent of governors) agreed that the 'wartime' cabinet would meet regularly (sometimes daily) via secure video-conferencing to make decisions about health, education, public safety, social services, and infrastructure. Its members are all elected officials responsible to their own parliaments and constituents (the nation's Chief Medical Officer also participates in meetings). Members come from both major parties but have agreed to work together as a united team to protect the lives of Australians" [7]. Within a week of the formation of the National Cabinet, restrictions on social gatherings began, followed by business shutdowns a couple of days afterwards. According to Duckett and Stobart [8], four key ways in which Australia achieved some success in flattening the curve during the timeframe studied were by: "Formation of national cabinet that set the same standard for the country regardless of state, Closure of international border and setting a mandatory two-week quarantine for all international arrivals, Public acceptance of spatial distancing and the use of Telehealth".

The Australian system is not without its shortcoming as the largest single source of initial infection was from the cruise ship that was allowed to un-board passengers showing symptoms of the virus. The 700 cases constituted 10% of the nation's COVID cases at the time [8]. Other shortcomings noted by Duckett and Stobart [8] are that Australia was slow to close its border to other nationals except for foreign

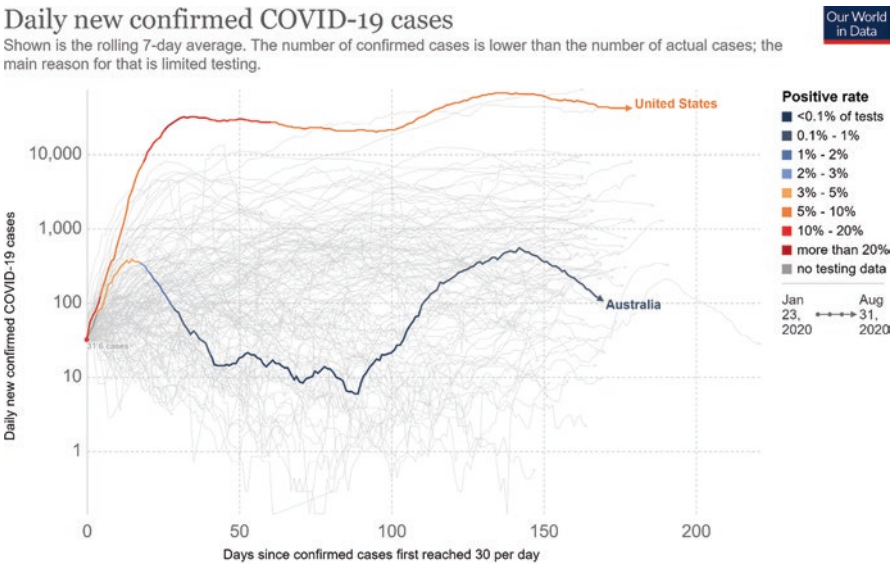

Fig. 17.4 Daily confirmed new cases showing the COVID-19 curve for Australia and the United States, with a significant drop in new cases in Australia between April 2020 and June 2020 compared to the United States. (Sources: Johns Hopkins University CSSE [3]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

nationals coming from China, the health system was also not prepared for a pandemic scale response and, finally, there was an unclear strategy resulting in confused messages such as sending children back to school a month after the initial short closure.

In the United States, some have argued that the response to the pandemic was slow, resulting in the high number of cases seen from the beginning of the pandemic to date (see Table 17.1). According to Just Security [9], "in late November to December 2019 U.S intelligence warned of a cataclysmic and out of control disease in Wuhan, China". It appeared that no actions were taken immediately to prepare in the event of spread into the country or to prevent spread into the country. Even after the first COVID case in the United States, strategies were not immediately implemented to mitigate the spread of the disease, for example, the mandatory use of face masks in public places did not go into effect until 31 May 2020. The healthcare structure in the United States may have also played a role in the rapid spread of the disease. In the United States, policy responses regarding COVID-19 are being made at the state and local/county levels resulting in different levels of restrictions across the country with interstate travel restrictions not necessarily in place in the initial months of the pandemic. This resulted in further spread of the disease from places with little restrictions to places that have strict restrictions in the United States, thus increasing the spread of the disease and curve. The numbers continued to rise in the United States due to issues such as lack of healthcare insurance for all citizens,

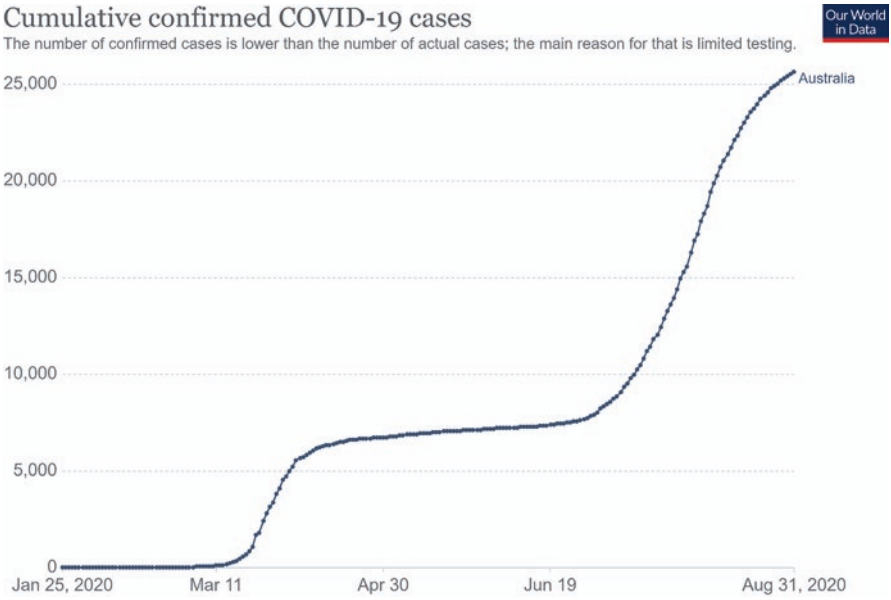

Fig. 17.5 Cumulative confirmed COVID-19 cases—Australia. An initial rise in the number of cases in March 2020 and a flattening of the curve between April 2020 and June 2020; thereafter, a steady rise in the number of COVID-19 cases. (Source: European CDC [6]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

resulting in reduced or no access to healthcare for some individuals even prior to COVID-19. There is also a disproportionate increase in COVID-19 cases among minority groups in the United States, and according to the CDC [2], "Long-standing systemic health and social inequities have put some members of racial and ethnic minority groups at increased risk of getting COVID-19 or experiencing severe illness, regardless of age" (see Fig. 17.7).

17.5 Key Policy Responses

Government policy responses were also reviewed using the Oxford COVID-19 Government Response Tracker (OxCGRT). It uses 18 indicators to measure government policy responses (see Box 17.1). According to Hale et al. [10], in the United States, this is further subdivided into the following: "(1) containment and health index [see Fig. 17.9] showing how many and how forceful the measures to contain the virus and protect citizen health are (this combines 'lockdown' restrictions and closures with health measures such as testing policy and contact tracing); (2) an economic support index, showing how much economic support has been made available (such as income support and debt relief); (3) a stringency index [see

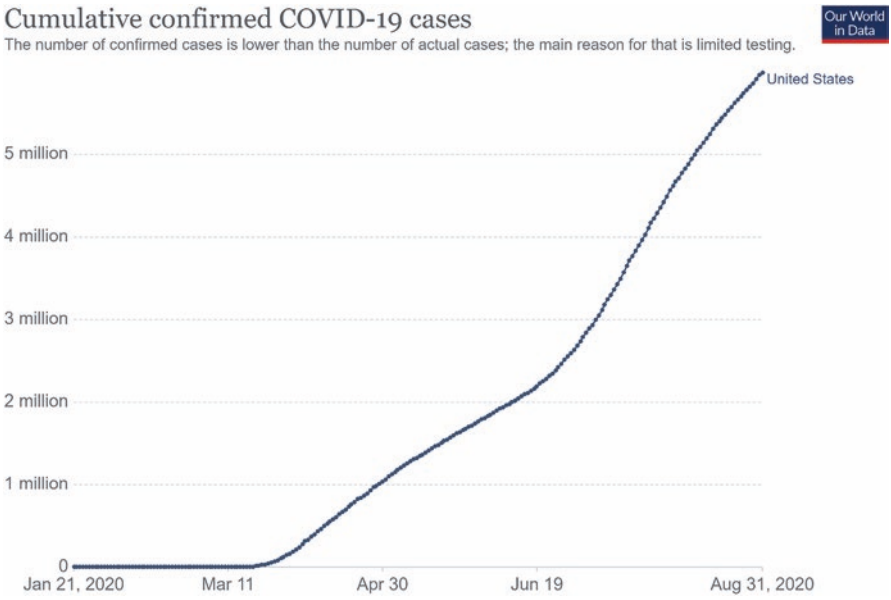

Fig. 17.6 Cumulative confirmed COVID-19 cases—USA. A steady rise in the number of cases from March 2020 to August 2020. (Source: European CDC [6]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

Fig. 17.8] that records the strictness of 'lockdown style', closure and containment policies that primarily restrict people's behavior; (4) an overall government response index which records how the response of states has varied over all indicators, capturing the full range of government responses".

A higher score indicates a stricter response; for example, a score of 100 equals the strictest response (Fig. 17.8). According to Hale et al. [10], "this does not

Box 17.1 OxCGRT Indicators—Policy Indices of COVID-19 Government Responses

Containment and closure

C1 School closing
C2 Workplace
C3 Cancel public events
C4 Restrictions on gathering size
C5 Close public transport
C6 Stay at home requirements
C7 Restrictions on internal movement
C8 Restrictions on international travel

(continued)

Box 17.1 (continued)

Economic response

E1 Income support
E2 Debt/contract relief for households
E3 Fiscal measures
E4 Giving international support

Health systems

H1 Public information campaign
H2 Testing policy
H3 Contact tracing
H4 Emergency investment in healthcare
H5 Investment in COVID-19 vaccines

Miscellaneous

M1 Other responses

(Source: Oxford COVID-19 Government Response Tracker (OxCGRT). https://github.com/OxCGRT/covid-policy-tracker/blob/master/documentation/codebook.md)

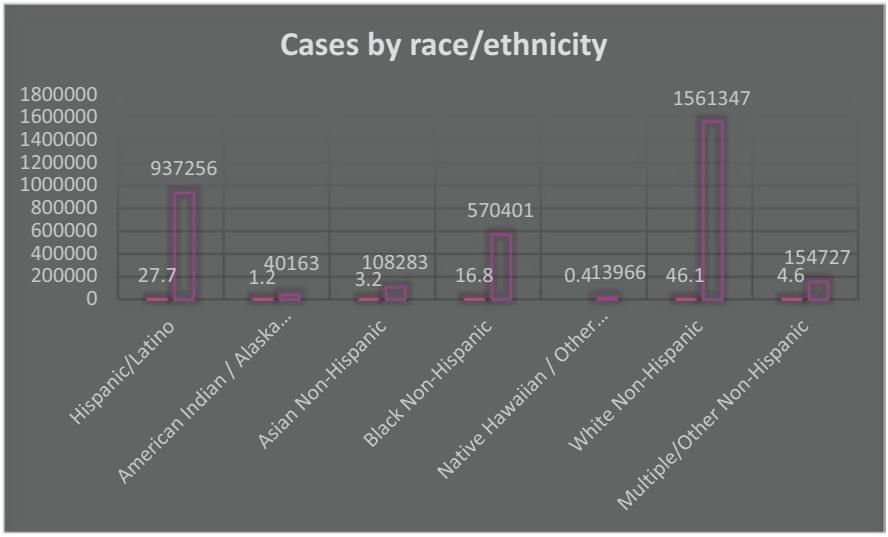

Fig. 17.7 Cases by race or ethnicity in the United States. There is a proportionate increase in COVID-19 among minority groups due to long-standing systemic health and social inequities in the United States (Source: CDC [1] [https://covid.cdc.gov/covid-data-tracker/#demographics])

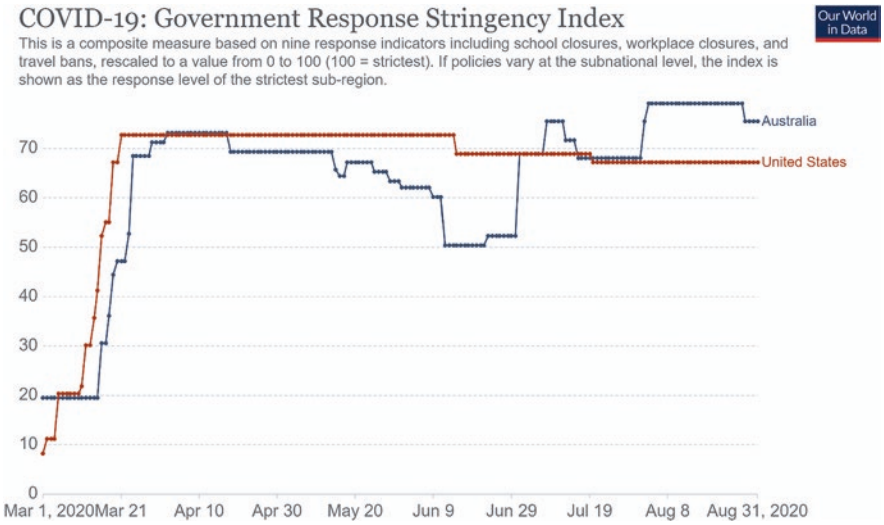

Fig. 17.8 COVID-19: Government Response Stringency Index. In the United States, varying policy responses at the subnational level may be responsible for the difference in score after July 2020 compared to Australia. (Sources: Hale et al. [10]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

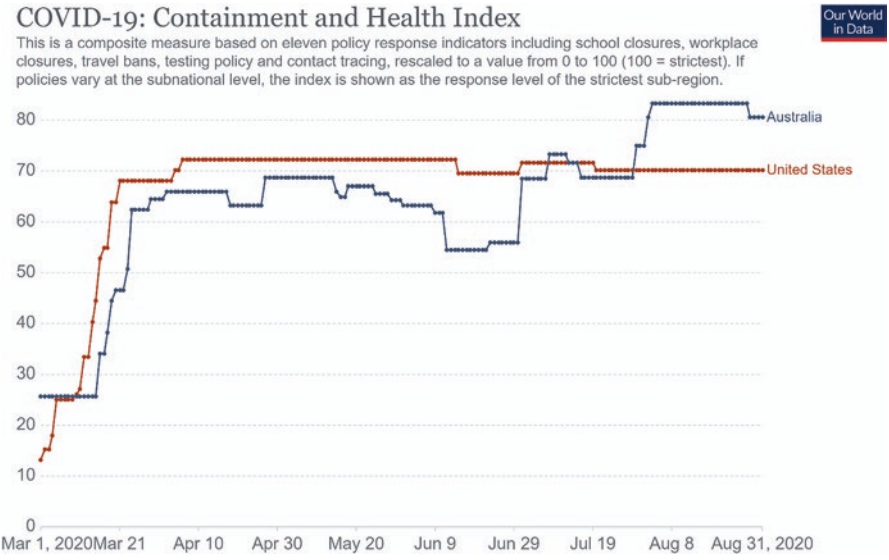

Fig. 17.9 COVID-19: Containment and Health Index. Graphs indicate a robust response based on the containment and health index score in both countries after June 2020. (Sources: Hale et al. [10]; Ritchie et al. [4]. Published online at OurWorldInData.org, licensed under the terms of the Creative Commons Attribution 4.0 International License (http://creativecommons.org/licenses/by/4.0/))

measure or imply the appropriateness or effectiveness of a country's response. A higher score does not necessarily mean that a country's response is 'better' than others lower on the index".

Robust responses in the United States are defined as those states that achieve a Containment and Health Index score of at least 60 (Fig. 17.9). While a lasting response was one in which the Containment and Health Index score remains within 10 points of the maximum value achieved by the state for at least 60 days [10].

17.6 Contact Tracing

Contact tracing is one of the mitigation measures adopted to control the spread of the virus. The concepts are to "trace and monitor contacts of infected people to notify them of their exposure and support the quarantine of contacts" [2]. Trained professionals begin case investigation by supporting patients suspected or confirmed cases of infection by the virus. Those patients are required to recall close contacts to them who would also have to be immediately contacted, notified and tested for the virus. It is important that everyone involved in the process is educated about the disease, mode and risk of transmission and the need to separate themselves from other people to prevent further spread of the disease. The process of contact tracing can be overwhelming for everyone involved and can be faster and more efficient using digital contact tracing tools for COVID-19. They could be tools for case management or exposure notification [2]. Case management tools can help the healthcare professional to generate a notification to contacts and electronic surveys for patients to self-report recent contacts triggering other contact tracing processes. They are also used to manage notification workflows along with other alert health systems. Exposure notification tools are used to notify people about potential exposure by sending messages or alerts on their smartphones. It provides referrals for patient follow-up. It also reminds the patient of locations or recent events. Aggressive efforts in contact tracing are one of the best strategies to reduce spread in workplaces and schools. The creation of exposure monitoring devices or smartphone apps for use in these places is essential for accurate identification of contacts. These devices transmit encrypted short-range wireless signals which are picked up when individuals wearing them are within range, they vibrate team members are too close to each other. Such devices are already available for use at workplaces by team members who wear small wireless device to remind them to stay at least 6-feet apart from others by vibrating when too close. According to Estimote [11], "these devices remember direct contact interactions, when an employee develops symptoms, they can push a button which is interconnected to a contact tracing dashboard to report their status. The organization can generate a report to protect team members by notifying direct contacts of possible exposure and need for quarantine". As schools reopen, easing of lockdown measures and restrictions, there is an urgent need to invest in exposure monitoring and notification devices for use among students and team members in workplaces. The Apple-Google exposure notification system is

being adapted by states in the United States, for sending COVID-19 exposure alerts to smartphones. It is important to highlight here that without advances in digital health, it would not be possible to design, develop and rapidly deploy the types of contact tracing that have been used.

17.7 The Role of Telehealth

Telehealth can be defined as the use of videoconferencing technologies to conduct a medical consultation where audio and visual information is exchanged in real time between the healthcare provider and patient. Remote communication technologies include apps such as FaceTime, Telephone, Google Hangouts, Skype and Zoom. In the United States, the Coronavirus Preparedness and Response Supplemental Appropriations Act was signed into law on 6 March 2020, and among other expansions in healthcare during the Pandemic, it allowed Medicare beneficiaries access to telehealth services in the United States. The Centers for Medicare & Medicaid Services issued an 1135 waiver that relaxed rules regarding virtual visits allowing more access to healthcare and promoting social distancing.

In a press release by the Australian government on 11 March 2020, through which a comprehensive $2.4 billion health package was unveiled to protect its citizens, $100 million of the fund was allocated for telehealth services. The Australian government identified that telehealth service will help reduce the spread of the virus and immediately implemented it starting 13 March 2020. This timeliness of this intervention has been attributed to the initial containment of the spread in the country. As the pandemic continues to ravage, telehealth services is one of the strategies to deliver healthcare to most of the population and contain the spread of the virus. It is also a means of protecting patients and healthcare providers.

17.8 Conclusion

The preceding review of literature is neither exhaustive nor complete. This is mainly due to the fact that the analysis was timed almost in real time as things were developing. However, in spite of these limitations, the reviewed literature serves to provide us with key insights from which we can develop guidelines from the lessons learned to date.

The initial response during a pandemic is one of the determinants of the level of containment of the spread of the disease. Upon notification of any outbreak, an immediate unified nationwide response plan must be implemented, this should involve notification of the general public about the disease through the media, healthcare facilities and over the internet. This calls for a healthcare reform in some parts of the world to require enforcement of a unified nationwide strategy during pandemics such as COVID-19. An overview of the response plan should be rolled

out to the public in a timely fashion with proper education of the public through articles, pamphlets and relevant websites. Smartphone apps for education and self-reporting should be made available once an outbreak has been confirmed. Adequate funds must be provided to execute the proposed mitigation plan. Public health surveillance must begin immediately to identify cases and possible contacts. The use of technological tools to enhance this process is crucial to the success of the strategies to combat the disease. Telehealth will expand access to healthcare for more people and it will protect patients and healthcare providers from the risk of exposure. The issue of stigmatisation is also reduced as patients with symptoms can secretly seek medical attention without fear of others around them being aware of clinic visits. Funds must be promptly released for large-scale production of case management and exposure notification tools for public use. In certain instances, there may be a need to provide telephone service to the elderly, at-risk individuals with co-morbid conditions and people of low socioeconomic status that otherwise cannot afford such smartphones.

In the United States, there was a delay in the implementation of mandatory use of face masks, due in part to unclear messages from politicians to the public rather than strict guidelines from public health officials about the use of face masks. There must be a strong coalition of public health officials nationwide who would stand firm and enforce guidelines to be followed during pandemics such as this. Governments must ensure the provision of personal protective equipment (PPE) to the public at little or no cost. Test kits must be readily available and test centres accessible nationwide, which is key to early identification of cases especially in asymptomatic patients. It is important to ensure that contact tracing is enhanced by the use of case management and exposure notification tools. Tracing every case contact and ensuring mandatory quarantine or self-isolation is one of the effective strategies to contain disease spread. School and workplace closure should be mandated until the disease spread is under control as easing these restrictions was shown to bring about another increase in the curve. Even with a mitigation plan in place, school reopening for in-person attendance has been another avenue for the spread of the disease. Remote learning through virtual classes is effective in reducing the spread of the disease among students worldwide. The same can be said of adults in the workforce, as most companies have transitioned employees to work remotely. COVID-19 cases have continued to rise worldwide despite efforts to contain the virus. The world is waiting for an answer to end the pandemic. The answer comes through science and technological innovations such as vaccines. There are ongoing clinical trials to develop a vaccine that gives hope to end this pandemic.

As 2021 approaches, the rollout of several vaccines has begun. This is clearly a key step in the journey to conquer COVID-19. Indeed, the need for a vaccine is vital; however, it should not be at the expense of developing robust, effective and efficient strategies and protocols to ensure communities, nations and the world are prepared and ready to combat pandemic and emergency and disaster scenarios. What has been evident is the critical role for digital health at multiple levels including contact tracing, telehealth, support to rapidly develop and mass produce a

vaccine and then to the efficient logistic support needed to rapidly deploy the vaccine to all populations whether in rural, remote or metro locations.

This chapter has served to capture key findings from various sources of literature during the 2020 COVID-19 pandemic. In so doing, it has enabled the development of important guidelines to be developed from the lessons learned that can serve as an essential resource for the future in the pandemic, emergency and/or disaster scenarios. We close by calling for further work in this regard so we can ensure we are always as prepared and ready as possible to meet such devastating and deadly challenges as COVID-19.

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Chapter 18
Digital Tools as Optimising Enablers of Quantitative Medicine and Value-Based Healthcare in a SARS-CoV-2/COVID-19 Pandemic World

Duane F. Wisk

… I will fulfill according to my ability and judgment this oath and this covenant.
… I will apply dietetic measures for the benefit of the sick according to my ability and judgment. I will keep them from harm and injustice.

Hippocratic Oath

18.1 Introduction

SARS-CoV-2 is the virus responsible for the disease COVID-19. It is the most significant global pandemic since the 1918 influenza (Spanish flu). Starting in 2019 and to the present in 2021, we have seen the SARS-CoV-2 virus spread rapidly. Now, more contagious variant mutations have continued to spread across the globe. As the population vaccination rate continues to rise in the United States, it is now becoming a pandemic of the unvaccinated. As of this writing, there are five *variants of concern* (VOC) [1]. These include the Alpha (B.1.1.7, emerged in the U.K.), the Beta (B.1.351, emerged in South Africa), the Gamma (P.1, emerged in Brazil), the Delta (B.1.617.2, emerged in India) and most recently Omicron (B.1.1.529). Delta has two mutations, the L452R and like the Beta a K417N. It is up to 115% more transmissible. It is the dominant variant worldwide as of this writing, but Omicron is rapidly displacing Delta in Africa. Early data suggest that Omicron may more effectively evade immunity as evidenced by the reinfection rate. Of concern with Omicron over Delta are the changes in the Receptor Binding Domains (RBD of G339 D, S371L, S375F, K417N, N440K, G446S, S477N, T478K, E484A, Q493R,

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G496S, Q498R, N501Y, Y505 H) and 19 other changes that also are where monoclonal antibodies bind [2]. In addition, there are emerging Variants of Interest (VOI) and Variants of High Consequence. These include the Epsilon (B.1.427, B.1.429), Zeta (P.2), Eta (B.1.525), Theta (P.3), Iota (B.1.526), Kappa (B.1.617.1) and Lambda (C.37). The longer the large pools of unvaccinated populations continue, the greater the opportunity for these mutations to occur. These mutations are suspected to decrease in the efficacy of binding by antibodies and vaccines while increasing the R_0. This global pandemic has shaken the very core of global healthcare and economies as we know it. Unlike the United States, developing countries are struggling to get a supply of vaccines to their populations. The pandemic is taxing the global system to the point of collapse during the peak of cases has caused a serious rethinking of the fundamental care delivery system itself. Omicron is now creating a second major wave and may again, as in 2020, tax the hospital system, but this time in two ways. First, bringing new Omicron admission to the hospital, and second, the backlog of patients with non-COVID illnesses, when combined together may again stress test the system to a failure point. So it begs the question in 2022 whether the current system is prepared to manage this and future pandemics? It has also caused an intensive retrospective examination of the *structural* underpinnings of this system and whether it is capable of meeting sudden unforeseen capacity demands.

18.1.1 Form Follows Function

The phrase "form follows function" was coined in 1896 by architect Louis H. Sullivan to refer to tall office buildings [3]. It still has utility today when referring to the design, planning, construction and implementation of digital healthcare structural tools to improve healthcare functional processes. Unfortunately, all too often in healthcare, the reality is that this truism is inverted. The function is forced to follow bad form. With the advent of the American Reinvestment and Recovery Act (ARRA) in 2009, the movement to modernise healthcare information systems resulted in the enactment of a measure called the Health Information Technology for Economic and Clinical Health (HITECH) Act. It proposed the meaningful use of interoperable electronic health records as a key national priority. During the subsequent three-stage implementation program, incentives and penalties led to a plethora of *electronic health record* (EHR) vendors flooding the U.S. marketplace. Providers rushed to avoid Medicare reimbursement reductions for failure to achieve milestones. This, in turn, led to billions of dollars in EHR deployments, whose form often failed to meet the functional needs of physician providers or add advanced (artificial intelligence [AI]-driven) clinical decision support (CDS). In Fig. 18.1, the top workflow shows a manual (non-CDS) clinical process. The bottom workflow demonstrates insertion points for AI to provide an opportunity to optimise a clinician's workflow.

While digitisation has many potential upsides, there are several functional process mismatches that persist as a result of inadequate digital infrastructure form.

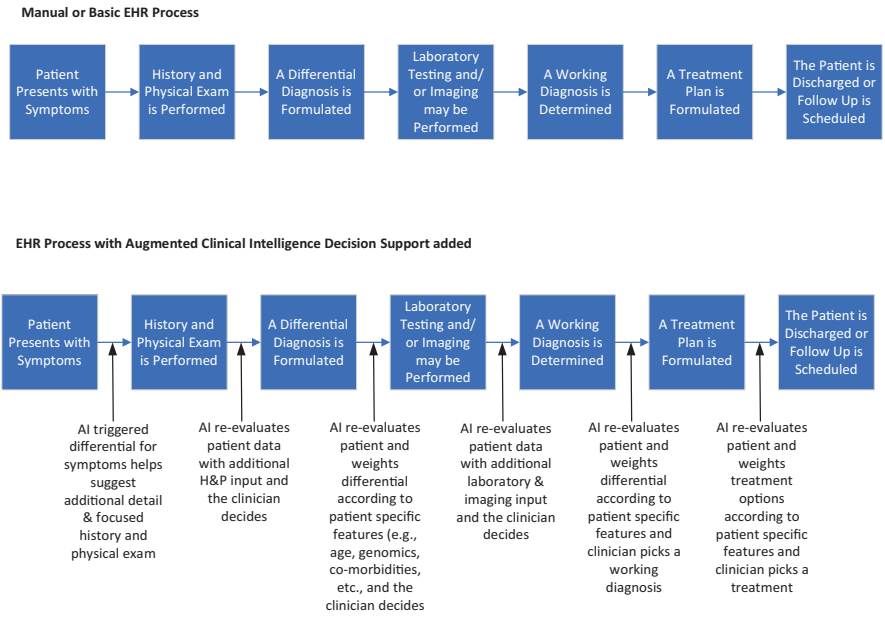

Fig. 18.1 Manual process versus points of AI opportunity to optimise workflow (source: author)

They include inconvenience and inefficiency leading to a significant loss in productivity, loss of time and money, increased malpractice exposure, increased anxiety on the part of patients leading to degraded communication, and flawed data entry and corrupted patient records, as well as privacy breaches and network cybersecurity gaps. In the case of flawed data, patient-matching technology shortfalls and the *universal patient identifier* (UPI) dilemma have led to patient errors due to identity confusion. For example, if John Doe, Sr. is confused with John Doe, Jr., this can lead to serious morbidity or even mortality. Suppose that John Doe, Sr. has no drug allergies, but John Doe, Jr. is allergic to penicillin. John Doe, Jr. is having a surgical procedure that is preceded by the administration of IV penicillin as a matter of preoperative guidelines. If he has an anaphylactic reaction to penicillin, it can be potentially fatal. This demonstrates how an operative procedure, which is considered routine in a patient with a low-risk profile, has the potential for a catastrophic medical error.

This process gap described in the previous example that led to the medical error has many root causes. One of the most significant contributors is system design. Such designs can be traced back to the evolution of the collection of healthcare data, the primary function of which was billing. Subsequent digitisation efforts, including electronic medical records, were a by-product of the primary function. Early attempts at standardising medical record data elements began with the American College of Surgeons in 1928 [4]. With the introduction of Medicare and Medicaid in 1965, healthcare systems were needed to keep track of the billing and

reimbursement demands of this new form of government health insurance. This was made possible by the advancements in computer systems in the 1960s, and as a result, the first hospital-based electronic medical records systems burst onto the scene in 1965 [5]. Some physician systems emerged in the early 1970s.

However, the advent of the personal computer in the early 1980s was another inflection point. With a much smaller form factor and lower cost, these features led to the more widespread use of billing systems in physician offices by the late 1980s. The rapid growth of these systems into the clinical area did not occur right away. This delay in expansion to areas other than billing and finance was hampered by issues of security, lack of standards and cost. The HITECH Act, combined with advances in computer technology, led to accelerated development and adoption of EHRs, with a sevenfold increase in usage from 2008 to 2015 in general medical hospitals [6]. The key takeaway is that software designers served financial process goals. Clinicians have been and are still largely forced to deal with systems whose workflow is not matched to how they ideally practice day-to-day. This creates a dysfunctional workflow for them that does not optimise patient care. Furthermore, the lack of content standards between EHR software vendors significantly retards interoperability efforts as of this writing. Finally, this chasm between the workflow process of providers (e.g. physicians as expensive data entry clerks, rather than medical decision-makers) and software design limits acceptance and advancements of digital clinical tools. These tools need to be reengineered from the ground up to be provider process and patient-centric, to optimise value-based care.

18.1.2 Digital Structure Can Enable the Healthcare Process Through Quantitative Medicine Leading to Value-Based Purchasing

The lesson experienced, but not learned, is that form still does not optimally follow function. Form or digital structure is not optimally driven by process. Clinicians must design software and make the rules for how they are best utilised. The government's push for meaningful use resulted in EHR vendors hastily jamming clumsy systems into the workflow of healthcare providers. The care process was digitised but often exacerbated the mismatch between a normal manual workflow and new forced digital workflow processes. This caused significant industry-wide loss of productivity [7]. Provider throughput of patients fell off. Such mismatches can not only lead to substantial reductions in productivity but also reduced effectiveness of patient interactions (e.g. clinical staff staring at screens and not giving attention and eye contact to patients) and, at worst, medical errors. The doctor–patient interaction suffered. Medical *scribes* have emerged as workforce multipliers, thereby offloading the data entry task for clinicians. Once trained, these scribes enhance provider productivity and the quality of the doctor–patient interaction. This process is not perfect, but a step in the right direction as clinicians become more comfortable with these process dynamics and training of such staff advances. In addition, voice

recognition systems such as Dragon have continued to advance in speed and accuracy. This acts to supplant data entry tasks, especially for narrative clinical summaries that are primarily free text, unstructured data.

Challenges remain, however. Workflow function, as expressed in day-to-day clinical patient care processes, must become the primary directive in designing next-generation EHR systems. Billing should be a subordinated function of the clinical workflow. It can always be derived from a well-documented clinical care process record. The reverse is not true. Advances in artificial intelligence and machine learning have created text search engines to look at text or search billing records for patterns that may portend significant clinical conclusions. However, this method makes such knowledge engineering possible but not highly efficacious. As an industry, healthcare is on the verge of a major inversion of not only the healthcare information technology (IT) sector but also in how care is delivered and paid for. Armed with disruptive innovation, asymmetric competitors will start delivering solutions that arise out of the clinical process as the central driver. In the medical software design world, the patient is the sun with other stakeholders as the planets. Only then will digital structure truly enable the care process. As this medical software technology inversion emerges, with it comes the structure to drive value-based care and medical care advances in ways not imagined.

One of those unimagined ways is through a new field formally defined as *Quantitative Medicine* (QM). Bits and pieces of this field are and have been done for years. However, it should now be a separate and distinct field of study that brings multiple skill sets to bear with a focused purpose. The Science Council (sciencecouncil.org) defines a scientific methodology to include the following: "Objective observation: Measurement and data (possibly although not necessarily using mathematics as a tool)". Live Science (livescience.com) defines mathematics as the science that deals with the logic of shape, quantity and arrangement. When the science of mathematics is overlaid upon the science of medicine, the combination is a new field of medicine. This will formally become a separate discipline and field called *Quantitative Medicine*. This field is defined as the science of objective observation that includes measurement, data and the expression of clinical care processes as mathematical expressions. As with all mathematical expressions, they will be objects that can be manipulated and studied through research. The power of appropriately leveraged digital tools will permit the rapid development and growth of *quantitative medicine* in a way that allows for the widespread application of quantitative comparisons of care outcomes. Therefore, meaningful development of *quantitative medicine* is a prerequisite structure for the execution of effective *value-based care outcomes* and the remuneration systems that pay for such care.

18.2 The U.S. Healthcare System Today

> The U.S. system of ***financing*** healthcare is routinely viewed as the bogeyman of health policy—as an example of how ***not*** to structure a nation's health system. Uwe E. Reinhardt [8]

18.2.1 SARS-CoV-2/COVID-19 Pandemic's Impact on Public Health, Health Information Behaviour, Research and Clinical Care

The world as we knew it ended in 2019. This world was one where defects in the system, although glaring and widely discussed, did not get exposed as the "canary in the coal mine" as an impending system collapse. This did not happen until the pandemic system stress test. Public health systems have, over recent years, seen their funding cut, while concurrently being asked to deliver more services with fewer resources. This reduction in public health, population health and preventive services has resulted in the system being already taxed at a time of a pandemic emergency when it needed to be functioning optimally. Today, in general, health information-seeking behaviour has been kicked into high gear by users worldwide. This desperate search for medical information has risen dramatically at this global level due to a once-in-a-100-year pandemic. Research into the natural disease history, pathophysiology, diagnosis, treatment and vaccine development has been rapidly energised at a governmental level last seen with the "Manhattan Project" during World War II [9]. This research has, in turn, fuelled the diagnostic and treatment knowledge base of the clinical care guidelines. Despite this rapid acceleration of research and the disease knowledge base, during the pandemic, this dissemination of diagnostic and treatment information has been sporadic, inconsistent and often contradictory. This tendency holds true even in the medical community, which was sprinkled with misinformation. Information dissemination was not optimised locally, regionally, nationally or globally since the onset of this disease. Some reports have placed the start of the pandemic in Wuhan, China as early as August 2019. Although much progress has been made in the utilisation of digital records to improve the value of care, the SARS-CoV-2/COVID-19 pandemic sheds light on just how much farther we need to go in the global medical community.

18.2.2 Healthcare: A Commodity-Based Reimbursement System

As discussed, healthcare IT is not structured around the care process as the first order of business. Therefore, it has no way to accurately derive the value of the care process and the subsequent value of the outcomes. As a result, despite the U.S.

legislative foundation and mandates, there is no way that successful value-based purchasing programs can be fully operationalised. This means that the current system of *commodity*-based payment will continue, along with a smattering of unsuccessful or minimally successful experiments in value-based purchasing. The Center for Medicare and Medicaid Innovation (CMMI) was a division spawned from the ACA as a foray into the experimental world of new payment and care delivery models for Centers for Medicare & Medicaid Services (CMS). The primary goal has been to lower costs without taking a hit on care quality, also known as *value* (Quality/Cost) [3]. There has been a steady upward trend of prices in the U.S. healthcare system. These price increases have arrived without concomitant care outcomes that are superior to other developed countries that spend far less of their gross domestic product (GDP) on healthcare. This is when comparing benchmarks of leading quality indicators (e.g. maternal and infant mortality). It is the mission of CMMI to reverse that trend. The enigma is to design new models that increase quality, while either cutting costs or at least holding costs at the same levels. The Congressional Budget Office projected billions in savings from these care delivery and payment models by 2026, but of the 37 tested by CMMI, only two have been certified by CMS for expansion.

The result is that the long-standing current market reimbursement mechanisms, largely driven by CMS first, remain largely unchanged. Therefore, the predominant mechanism of a commodity approach to healthcare services and products remains unchanged [4]. Medicine is a highly complex and individualised service industry, and no two patients are alike. Yet, all providers are compensated like purchasing coal. In this commodity-based healthcare marketplace, all providers are treated as equal, all outcomes are the same, all patients share the same preferences, medicine is one service line, and therefore, all payments for those services in a *fee-for-service* market should be the same. The same procedure gets paid the same for every provider. In other industries (e.g. cars, appliances, etc.), you can go online and check ratings that benchmark the value of the product or service. In healthcare, the technology is not in place structurally to deliver such "Consumer Reports"-style guidance on who should take out your gallbladder given your unique clinical presentation. That's not to say one shouldn't be able to or that there is not the technology to calculate that type of outcome comparison. In a patient-centric design, one should be able to compare outcomes uniquely matched to the demand of the individual patient.

18.2.3 Zero-Sum Healthcare Competition Is "SICK"

When thinking about the characteristics of a market governed by *zero-sum competition*, it is easy to remember by using the acronym "SICK". "S" stands for shifting costs to other stakeholders. "I" stands for increasing bargaining power against other stakeholders. "C" stands for cost reductions when patients self-ration (e.g. due to high deductible). *Self-rationing* reduces costs by not consuming services against reserves in the short term, lowering quality and ultimately increasing long-term

costs. These long-term cost increases occur when diseases progress farther before an intervention is begun. “K” stands for keeping restrictions on patients and their choices, which again often reduces the quality of care in the long term.

There is much debate about how to accurately compare the healthcare systems of developed countries globally. The U.S. system has been much maligned for its very high-cost relative to the size of its economy [10]. This is because these high investment costs do not return proportionately high outcome returns on key care benchmarks, when compared to other countries. There continues to be an ongoing dialogue about the best financing mechanism for care globally. The socialised, single-payer, societal-level of medical care versus a combination of government and private insurance financing of healthcare is a debate that continues to rage on. The truth never seems to reside in either of the two extremes, but often the debate is based on the wrong issue. The question is not which entity structure is the correct financing mechanism, but rather are the funds being spent to purchase high-value services or products? The problem is that there is no current way to easily measure total aggregate cost while simultaneously measuring the actual quality of the outcomes. Therefore, it is impossible to measure the overall value at an individual or population level by a single disease or with multiple comorbidities grouped together. The digital technological capacity is there to answer these questions, but it has not been applied in this way. Figure 18.2 demonstrates the dynamic between those that receive healthcare, the entities that fund that care and the flow of funds to the providers of care. The default mechanism to pay or insure individuals or populations is to pool funds that are sufficient to absorb the risk for a risk pool or population of patients. A discussion of these different pooling mechanisms is beyond the scope of this writing, but the takeaway is that historical use of actuarial tables is only an educated guess about the probability that the reserve pools are sufficient to cover all claims for the insured population.

Although new models are constantly being proposed and tested, Fig. 18.3 illustrates the stakeholder relationships from Fig. 18.2 with respect to three specific variables. Those variables are on the left y-axis represent the degree to which savings accrues to the payers of care. The x-axis demonstrates the level of provider financial risk incurred. Finally, the right y-axis reflects the level of restriction on patient freedom of choice. These historical models have revealed how trying to purely restrict care or have providers share risk has temporarily reduced costs (the denominator in the value equation) by restricting care to patients or shifting risk onto providers. However, this low-hanging fruit in the cost reduction quest has run its course. Now the real work begins in adding value by improving quality (the numerator in the value equation). This requires that the relationship between stakeholders in a healthcare commodity-based payment marketplace shift to a value-based approach. Since a value-based purchasing system is yet to be implemented, the result is a continuation of cost-shifting among stakeholders.

Ideally, the patient is looking for freedom in choosing providers and care options. The providers want to deliver care for services rendered without financial risk. The payer has insurance pools or reserves they want to protect. This is the push-pull dynamic that exists among stakeholders. Figure 18.4 illustrates that for for-profit

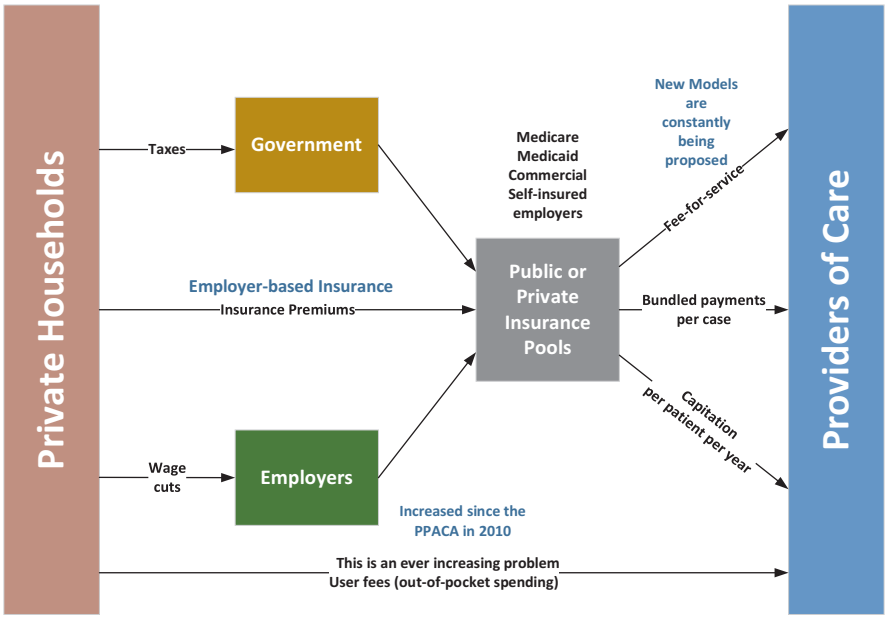

Fig. 18.2 U.S. Healthcare Financing Model (Adapted with permission of Princeton University Press, from *Priced Out: The Economic and Ethical Costs of American Healthcare*, U.E. Reinhardt, 2020; permission conveyed through Copyright Clearance Center, Inc. [8])

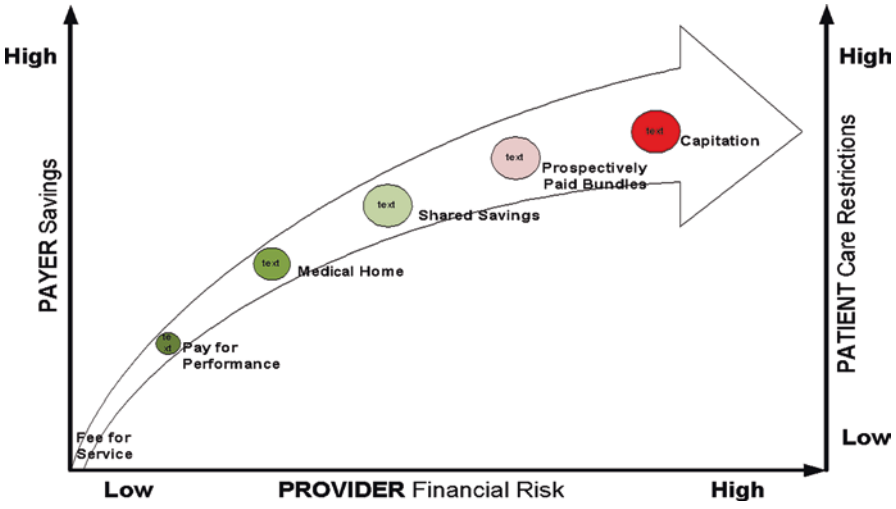

Fig. 18.3 Cost-shifting relationships between U.S. healthcare stakeholders (source: author)

insurance companies to maximise profits, it must minimise the consumption of reserves that reflect unused premium dollars. The most effective way to do that is to invest in preventive care for members. The difficulty is that the insurance company

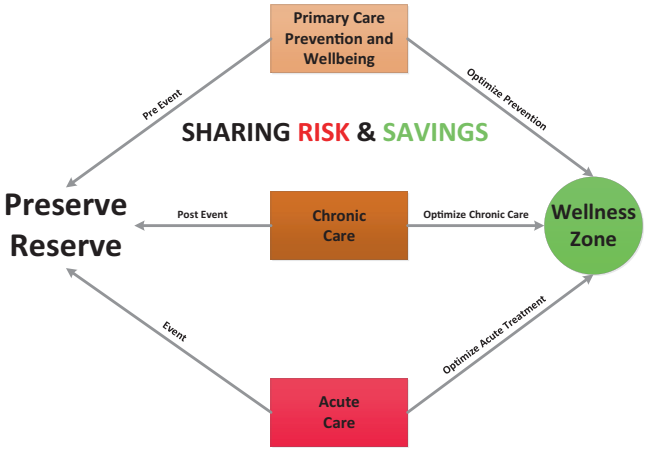

Fig. 18.4 Care continuum and the emphasis on maintaining insurance reserves (source: author)

may not maintain the relationship with the member beyond a year. Any investment in wellness may be recouped by another insurance company that may insure the patient the following year. As a result, this market dynamic will remain a cost-shifting dynamic, until the value of care outcomes is rewarded in a meaningful way so that providers provide the continuity of care that insurance companies may not be able to. This will occur when actual outcomes can be measured, analysed, reported and paid for to align the incentives of all stakeholders around the actual value of the care provided. The digital tools, process structure and people orientation need to be put into a value-based model for this to occur. This is a complex, tedious and long-term implementation process. However, it is possible today with current digital technology, applied appropriately to the care process and managed by individuals with the correct vision and skillset to operationalise it.

18.3 Value-Based Healthcare in a Population

The health of an individual is a complex physiologic interplay. Measuring the value of that interplay is even more complex. When you scale such adequate measurement and precisely quantify it for a population, the level of complexity seems daunting and, at first glance, insurmountable. That is, of course, if your expectation is to do it right. If your expectation, however, is to get it mostly right or close enough, then you have the current system of global medicine, measurement and monetisation of that medicine. In the final analysis, it is about managing expectations.

18.3.1 *Understanding Value in a Healthcare Context for a Population*

The complexity of a population is daunting but seemingly incalculable for all the numerous relationships in a marketplace. Figure 18.5 illustrates the bidirectional transactions that occur in a marketplace between payers of healthcare and providers of healthcare services and products. As alluded to previously, aggregate *total costs of care* are impossible to calculate with current infrastructure. This diagrammatic transaction schematic illustrates all the dynamic process relationships that exist for a population. Each arrow refers to a process that entails a resource transaction. To adequately account for total costs, all those monetary exchanges in the marketplace have to be accounted for in a reliable way. In this way, the value of each of those individual populations can be tracked and then aggregated to calculate the total cost and net value. This means that the purchasers understand what exact value they are receiving on the demand side. On the supply side, hospitals, doctors and suppliers are measured for actual value created and compete with each other based on the quantifiable value. As such, value accrues to the purchasers (*value-based purchasing*) and the value rises among competitors, with weak competitors falling out. New digital tools must be utilised to measure, analyse, report and calculate remuneration proportionate to the actual level of value-based outcomes achieved. This then becomes a very simple conceptual virtuous continuous cycle of the three R's: Record, Report and Reward.

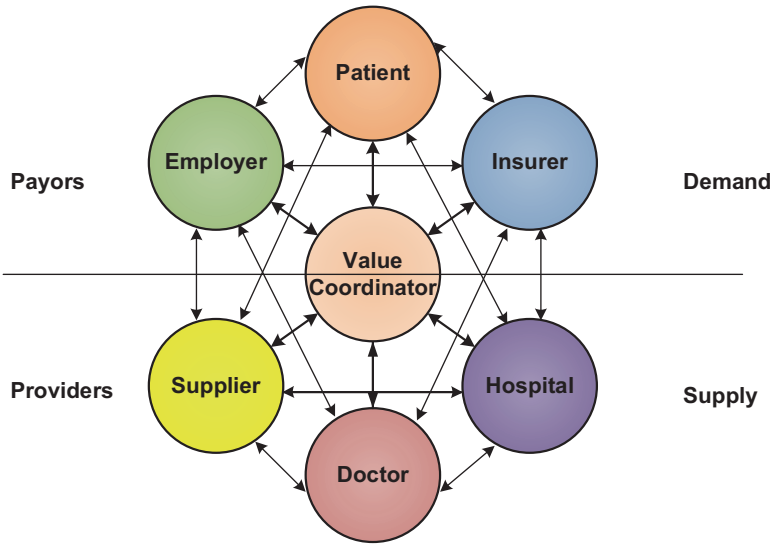

Fig. 18.5 Representation of all the bidirectional relationships and transactions between marketplace stakeholders relative to a value coordinator (source: author)

18.3.2 Value-Based Competition Is Positive Sum

For the first time since the passage of the PPACA, value-based purchasing programs can actually be operationalised when powered by digital tools driven by disruptive innovations. Commodity is replaced by value-based. An entirely new generation of leaders will emerge to look at the healthcare industry through an entirely new lens. They will cut ties with legacy technology that must be swept aside and rebuilt *de novo* with the right architecture for the user. Asymmetric competitors with no ties to such systems are solely focused on solving the "Rubik's Cube" of how to design, build and operationalise a new ecosystem based upon this architecture. This industry inflection point will create a domino effect on all stakeholders simultaneously by enabling *value-based outcomes* measurement. The switch is suddenly flipped for value-based competition and the jettisoning of a *commodity-based zero-sum game* marketplace. The result is a positive-sum environment that fosters competition on measurable outcomes. Figure 18.6 shows the stark contrast between a commodity and a value-based marketplace for patients and providers. In this environment, the best competitors rise to the top and patients benefit. As these competitors improve, they earn even more market share because they are delivering a better quality of care at a lower cost (quality-adjusted prices fall) [11]. These competitors work to differentiate themselves through their products and service offerings. The market expands and more patient needs are met and more effectively. Niches in the market are filled with disruptive innovators that use new technologies and business methodologies to create differentiation and superior user value.

18.3.3 Characteristics of a Value-Based Global Healthcare Marketplace

This model will spread precipitously and globally as it is discovered that the cost curve can finally be substantially bent upstream. Unending cost escalations were the norm for the past four decades, with per capita spending increasing 31-fold. This pattern can be traced back to the cost-plus reimbursement system for hospitals, cost insensitivity by providers and patients and significant growth in treatment options, which led to a steady escalation in prices. Price was equated with quality, but without precise quantification and accountability, there were no checks and balances in the system. The healthcare industry evolved in a way unlike other industries in a capitalistic value-based product or service society. As a result, healthcare follows a traditional "Field of Dreams" view of supply-side economics, where you build it and they will come. This means to keep producing more products and capacity, then market those products and services like crazy to drive consumption. In the United States, the *certificate of need* (CON) program was established first in New York in 1964 and then advanced federally in 1974 [12]. This process requires a legal document justifying the need for acquisitions, expansions or creations of healthcare

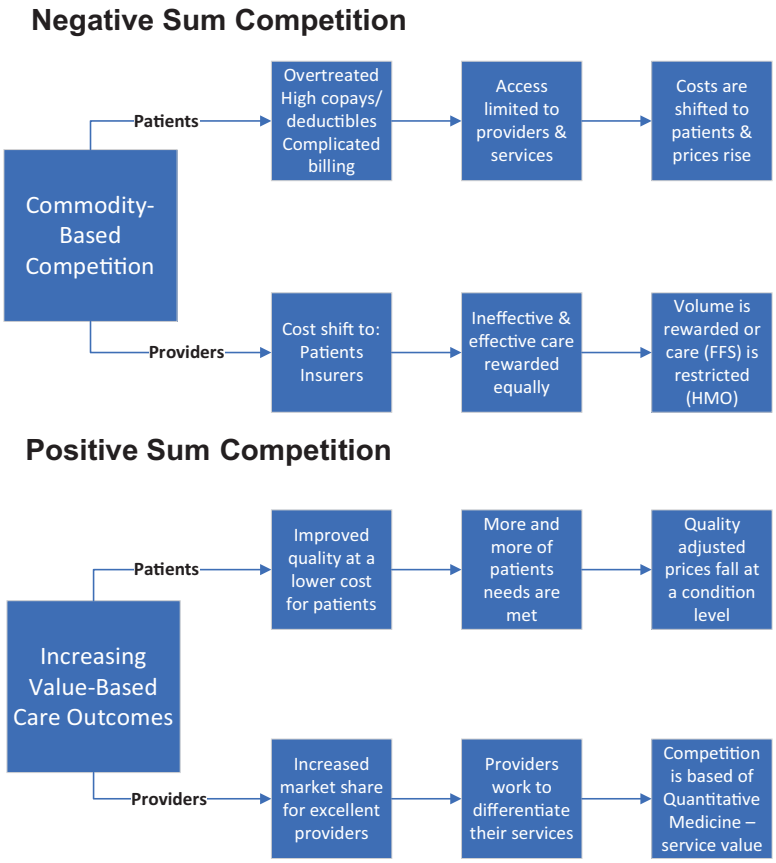

Fig. 18.6 Comparison between a market driven by commodity versus value-based forces and the effects on patients and providers (source: author)

facilities. Despite this gating legislation, facilities mushroomed along with volume, prices, and, consequently, costs.

Fast forward to today, and we live amid an economy in which *globalisation* has produced global competition for goods and services in all other industries [13]. Measurement of the value of these goods and services leads to quantification of value and, therefore, competition based on those value features. With the proper process-enabling digital tools, healthcare will be pushed in the direction of globalisation. Once strictly a local business, healthcare will no longer be governed by local or even regional benchmarks of performance, but rather global ones. Once adjusted for severity of illness criteria and other factors, the postoperative infection rate in Memphis, Tennessee, will be the same expected top benchmark rate in Memphis, Egypt. In other words, value-based outcomes as equally measured by digital tools, then analysed and reported, will be a global standard of excellence benchmark.

18.3.4 Access Barriers, the "Triple Aim", and the PPACA

Access to care has been a serious problem in the United States despite great wealth and care. Poor access takes three forms. Access can be limited due to geographic constraints, where there is a limited number of providers, other services or facilities (e.g. critical access hospitals). Despite the passage of the PPACA, another serious access issue relates to being uninsured. As of 2019, 10.9% of the population, or 44 million adults in the United States, did not have health insurance [14]. Furthermore, another 38 million adults in the United States do not have adequate insurance. In total, it means that one in five Americans, or 20% of the U.S. adult population, has either no insurance or is underinsured. For those that are underinsured, high out-of-pocket costs result in these patients self-rationing. These populations are not getting the "Triple Aim" that Dr. Donald Berwick and the group articulated in 2008: improving the patient experience of care, improving the health of populations and reducing the per capita cost of healthcare. The "Triple Aim" was core to the PPACA passed in 2010. Again, the progress, despite a legislative mandate spearheaded by CMMI, has not been significant. It is another cornerstone in the argument that structural changes in medicine, measurement and money are necessary to reinvigorate the execution of value-based care. The lack of structure is the key barrier and major explanation for the lack of progress towards value-based care when seemingly every other barrier has been eliminated.

18.3.5 An Effective Sequence for Successful Healthcare Market Change

So just what are those structural changes and what sequence of structural implementation is required? Putting the medical, measurement and monetisation infrastructure in place is foundational to successfully facilitating disruptive value-based medical care outcome innovation. Such innovation will allow the reorganising of existing market processes around a new, value-based service paradigm. It can be matched up with the traditionally thought of three key business process areas of people, process and product. *First*, the people are the patients and the providers. In an *E-Health* marketplace, the patient is the key user and therefore driver of a *pull economy*. Patient-centric care must be the primary focus in value-based care. Physicians must be reorganised around patients, care guidelines, outcomes measurement and continuous improvement in a quantifiable structure that enables the process. *Second*, the process is the complete care cycle. The industry must pivot to precisely quantify care outcomes and that starts with precise measurement. New disruptive measurement systems must exactly codify an audit trail of what care was actually provided. A global healthcare industry must answer questions of how the care conformed or diverged from the global guidelines. If care does diverge, is the care approach incorrect, or if there are improved outcomes, is this due to innovation

or advancement of the guidelines? *Third*, the product is a measurable, analysable and fairly compensatable care outcome. These separate processes are really three categorically distinct initiatives that synergise to optimise the overall value-based care process scaled to any population or market size, including global.

18.4 Global Healthcare Transformation

In his award-winning 2005 book, *The World Is Flat: A Brief History of the Twenty-First Century*, Thomas Friedman outlined how globalisation has changed core economic concepts [13]. That same flattening is on the horizon for the healthcare industry, which historically lags behind other traditional industries in advancement. This is ironic, given how we think of medicine as so technologically advanced. Despite this general public notion of medicine, it is still by and large a fragmented, siloed and information technology-impaired industry. Digitisation of electronic medical records did not become more widespread in the United States until a law made it happen. Even that digitisation is a very rough start. This digitisation was the first pillar to be put in place in the globalisation process. The second pillar was a global pandemic that, by necessity, forced contactless interaction with providers in the seeking of medical services. The table has been set for a significant global inflection point.

18.4.1 Globalisation of Healthcare Value

As mentioned, the healthcare economy will increasingly become a globalised healthcare ecosystem. Reorganisation of providers, digital measurement, analysation and the payment systems that emerge from that knowledge engineering will together catalyse that evolution. Specifically, healthcare will begin to take the form of other industries that have long functioned under a value-based competitive model. As such, healthcare competition will gradually shift to a global playing field until it finally reaches a tipping point and exponentially emerges into this completely new value-based global order. A significant impetus in achieving this tipping point has and will be the advancement of digital tools. These tools will, for the first time, permit widespread big data measurement, storage, analysis and reporting of the exponentially burgeoning terabytes of healthcare data.

18.4.2 Movement Away from the View of Healthcare as a "Local Business"

Medical care has always been thought of as a service you obtain and measure quality and cost locally. For many years, this was true due to proximity, familiarity and traditional doctor–patient relationships. Slowly, that doctor–patient bond has been eroded. Maybe your doctor joined a larger single or multispecialty group to share calls or overhead. Maybe the physician joined a big health system or academic teaching centre. In some cases, your doctor just retired. You may get on a plane to have a special surgery only performed at a major academic centre of excellence in another state. The SARS-CoV-2 and COVID-19 pandemic caused restricted access and you may have had to resort to a *telehealth* visit with a doctor you don't even know. Whatever the reason, medical care has evolved from the general practitioner who may have delivered all of your kids to a telehealth ear, nose and throat doctor thousands of miles away. It's not your grandparent's pure local business anymore.

18.4.2.1 Pull Economics

Globalisation and digital technology advancement go hand-in-hand. Supply-side economics has given way to demand-side economics and the consequent shift to a pull economy. In such a market, the producers of healthcare services and products are increasingly responding rapidly to consumer demands on a direct basis. This response is facilitated by the growth of digital tools. The SARS-CoV-2/COVID-19 pandemic further pushed digitisation a quantum leap forward in just 1 year. Suddenly, in response to the face-to-face restrictions of the care process, CMS made significant regulatory changes that loosened restrictions on interstate commerce to healthcare providers across the United States. CMS modified rules for coverage and payment of virtual services [15]. A new page was quickly turned in the digital transformation and a telehealth story, characteristic of a two-sided E-Health marketplace [16]. Pull economics demand a precise understanding of customer needs. This understanding can only be gained through optimised communication with the customer. The growth of social media and digital communications tools has accelerated that process.

18.4.2.2 The Two-Sided E-Health Market

In healthcare, that customer is the patient and represents one side of the rapidly expanding, two-sided E-health marketplace. The other dominant side of that market is the provider—specifically, the physician and their *workforce multipliers*. These two sides will once again restore the doctor–patient bond from decades ago, just not via the same structure. As with social media platforms, users will form the core symbiotic relationship that is used to embody the relationship with your general

practitioner. As digital tools permit a more accurate measurement of the value generated by each side of a two-sided E-health market, the value of this two-sided E-health relationship will only increase. This is not to say that other stakeholders will not still play a part in this marketplace but rather that they will no longer play the central role. Hospitals may actually move from a central health system part of the marketplace to becoming commodities in a global ecosystem. The patient-centric model will finally become a full-blown market reality as a result of advancements in digital tools that effectively enable and optimise it. As the marketplace evolves through digitisation and telehealth offerings, the patient/doctor symbiosis will evolve and grow into an even more symbiotic form. Just as social technology has eliminated physical boundaries, this E-Health evolution will also have no geographic limitations. Genomics, epigenetics, precision medicine, medical tourism and a whole host of as-yet-undiscovered offerings will further globalise into an ecosystem similar to platforms in other industries. The measurement of how well providers make an effective interpersonal connection with their patients will be a yardstick by which patients judge their providers. For example, effective follow-up with patients by clinical staff makes a big difference in outcomes. This followup used to be a phone call from the provider's staff. Now communication has broadened to many vehicles, such as text, email, chat, video conferencing and telehealth visits. There will be no limit to how successful providers and their staff try to connect with their patients. AI and other digital tools can be leveraged to drive reminders to caregiving and clinical staff as to when and how is the best way to connect with the patient.

18.4.2.3 From PCs to Platforms to Global Healthcare Multi-platform Ecosystems

As described earlier, information technology has come a long way from the billing PC found in physician offices in the 1980s. Today, we see the emergence of many more platforms and network-centric solutions. These are all initial steps to the development of a sophisticated Global Healthcare Multi-platform Ecosystem (GHME) [6]. The advancement of this E-health world will produce an environment where precision medicine will result in bespoke diagnostics and therapeutics. Such interventions will optimise the value of healthcare for the individual patient. Patients will have access to information customised to their individual needs in such a way that reduces medical errors resulting from "cookie-cutter" approaches to therapeutics or inaccurate diagnoses. Patients will be precisely matched to not only the exact treatment they need but also to the best providers to deliver that precise treatment that they individually require. For example, if a patient has a workup that indicates a very specific condition requiring an orphan drug or a rare procedure only performed successfully at a certain medical centre in the world, then that patient can be matched with that provider and treatment. This happens similarly with the organ donation and matching process. This is optimal value-based care. Resources are always limited in some way, so this optionality will still have economic implications

and therefore financial constraints that once again gate access. This scenario is possible with available technology, but this technology is not structurally in place or applied to this customised approach.

18.4.3 Structural Change and the Three Process Spheres

Structural change will ultimately touch the three spheres of people, process and product. The core people are the patient and provider. Patients will be reorganised to be placed with their health information at the centre of the ecosystem. Pull economic rules dictate how and when they are connected to anyone (users and partners) they choose in the ecosystem [17], but they will be the gating function to availability of their health information. That information will be their medical avatar or "*digital double*". Providers will be reorganised through digital connectivity into second-generation clinically integrated global networks. This structural reorganisation is also about information reorganisation that is reshaping the business world as machines, platforms and crowds [18]. It will occur efficiently as driven by pull-economic forces within the GHME environment. The digital structure will allow for rapid dynamic and organic changes within that ecosystem that adjust interactions as driven by demand from users [19]. Again, this is not a new business dynamic, just new to the healthcare industry. Finally, this will rapidly drive remuneration that naturally arises from a more exact calculation of risk through actual measurement, rather than probability approximations from actuarial tables. Insurance plans can be more customised at not only a group level but also down to an individual level. Patients will demand an improved premium structure that naturally emerges from more accurate data used to more precisely calculate member risks for consuming certain services and incurring costs.

18.4.4 The Three Spheres of Process Change

The functional domains of medicine exist in three worlds. World one is where medical care is delivered. World two is where care is measured. World three is where care is paid for. All three of these worlds have their roots intertwined, but these interrelated processes remain stagnated relative to other industries with respect to the rate of advancements. The SARS-CoV-2/COVID-19 pandemic proved that the industry could make great advancements in a surprisingly short period of time. Operation Warp Speed surprised the medical community and general public with its unprecedented short-term success for vaccine development and deployment. This initiative proved that rapid change can occur under the right environmental circumstances. This success was a harbinger for an industry inflection point in the three spheres of process change.

18.4.4.1 Sphere 1: Medical Care Outcomes

The idea of integrated clinical care teams is not a new one, but advanced digital tools will take this to another level. Human beings make mistakes due to errors in thinking and doctors, as people are no different. Doctors are not machines and as such have feelings that influence decision-making [20]. Machines with no feelings, on the other hand, cannot replace a doctor's intuitive cognition, but they can augment it to help mitigate errors. Specifically, *Augmented Clinical Intelligence Decision Support* (ACIDS) will take early decision-support solutions to an additional level. These solutions combine the intelligence of the medical community as a collective genius to support an individual provider's medical decision-making at the point and moment of care [21]. The next generation of electronic medical records will be a further inversion of current systems. This system will mean a reengineering from process inhibitor to process facilitator. The EHR will now closely mirror care processes and facilitate productivity. Additionally, EHRs will more accurately reflect a complete audit trail of what actually happened in the care process. ACIDS will not only be at the point of care but more importantly at the moment of medical decision-making to facilitate increasingly more accurate diagnosis and treatment. That accuracy is driven by a process that mitigates medical errors. Placed in the middle of the workflow, it will serve to increase the efficiency and therefore velocity of the care process. Overall, the medical care outcomes will be put into a virtuous continuous improvement cycle that is the goal of interaction management interventions.

18.4.4.2 Sphere 2: Measurement of Care Outcomes

Next-generation EHRs will be designed to create a more precise audit trail to determine an accurate value of the care process with respect to quality and cost. Ideally, there will be a reciprocal relationship between quality and cost, whereas when quality improves, then the cost will decline. This can result from many process interventions, but the most notable will be the result of error mitigation methodologies. Human beings are not perfect machines and as such our ideal goal is to reduce errors down to as low of a level as is humanly possible. It all starts with measurement, as you cannot correct process errors of which you are not aware. Therefore, EHRs must first mirror processes precisely, and the measurement systems must collect complete and accurate data about that process. Quality improvement efforts then undertake ongoing evaluations and audits of those processes to promote continuous improvement through process change. The next generation of EHRs will perform this task at a higher level of accuracy.

18.4.4.3 Sphere 3: Monetising Care Outcomes and Competing on the Value of the Outcomes

You can only bill and collect for what you actually perform. Therefore, you must first perform the best care, then measure that care precisely and then be paid fairly. Such a payment system will incentivise providers to continue to raise the performance bar. The sequence of changing the current system and driving out unnecessary costs starts with providing the best care, followed by measuring completely and paying accurately and fairly for what care outcomes are achieved. Providers have for decades achieved phenomenal care, but then are guilty of not recording that performance completely. This made billers frustrated when trying to code for written charts that did not properly reflect what was done. The pendulum swung a little in the other direction since EHRs offered an "exception charting" feature. If you felt that you did a complete exam, you could press a complete exam button that would spit out a voluminous amount of text reflecting the most complete history or exam you could imagine. This was easy to bill for, but sometimes a press of a button produces documentation of actions (historical or examination-related), all of which were not necessarily performed. This led to inaccurate records, overbilling and increased liability. Although systems are improving in this regard, they still do not accurately or smoothly reflect or facilitate the optimal care processes.

18.4.5 Prerequisite Structural Changes

The medical community wants to cross the river to a world of value-based medicine. The river represents the obstacle or gap to bridge to process change. A structural bridge will be required. That bridge is measurement technology. Advances in infrastructure that adequately measure the care process will permit care and payment advancements. This bridge has yet to be adequately built. Therefore, adequate measurement systems are not yet in place and there is as of yet no crossing that river to a value-based care shore.

18.4.5.1 A Patient-Centric Model as the Key Function

A key design element to this structure is overlaying an immutable template of a patient-centricity to the design process. For example, if a new measurement technology is being designed, then each feature of that technology should be checked against an ideal template of *patient-centricity*. It should first pass this checklist as to whether it improves the adequacy of measuring the patient's experience throughout the care process. A patient-centric, functionally driven process must have the patient at the centre of all activities. All of those activities must be geared toward making *all* aspects of the healthcare experience clearly and unequivocally better for patients. For example, patients are suffering from the disease but also from the costs causing

illness to their financial health. Sixty percent of personal bankruptcies in the United States resulted from medical bills [22]. All activities, both medical and financial, will be increasingly judged by patients in a pull economy and those judgments will be posted on *social media*. All stakeholder processes will be driven by the litmus test of patient-centricity. Doctors, hospitals, insurers, government employers and suppliers do not exist without the patient. Now is the time when the market completes its inversion from a non-patient-centric structure.

The explosion of social media further emphasises the power of the consumer in today's marketplace. These social technologies that facilitate network relationships among users are a powerful factor in a patient-centric marketplace. Websites and applications are appearing all the time for patients with chronic diseases. They serve their users from multiple dimensions. They can be a support group, allow for the exchange of treatment experiences or may simply just help to uplift spirits and provide hope. In general, this dimension of the marketplace has driven a growing need for channels for health information-seeking behaviour. The result is raising the bar on health literacy. In a Global Healthcare Multi-Platform Ecosystem, many of these patient networks will grow and become an increasingly powerful force in shaping care globally. Mutual support, in general, expands population and individual empowerment. These users pull technology and technological advancements to them, causing significant and often rapid market shifts. The needs and desires of users shape the market. For the first time, patient-users shape the market directly, actively and in near real-time. An entire chapter can be devoted solely to the social technology digital solutions and their effect on E-health and healthcare in general. For now, we will note that these social technologies will play an instrumental part in a truly patient-centric marketplace.

A Patient-Centric Model Drives Building New Care Infrastructure

We have talked about how the actual care process must be improved from a provider's standpoint, but we have not described improving the patient experience. A patient-centric model has often been aspired to, but rarely accomplished. A view from the patient's functional standpoint must be utilised to reengineer all structural care processes. In most cases, this will involve abandoning old inadequate structures and starting completely de novo. Inpatient and outpatient systems rarely reflect a patient's health information-seeking behavioural process. In addition, bilateral communication is not well reflected and the patient historical information acquisition process is still too one-size-fits-all. These functional and process challenges remain because the primary immutable directive is still not "the patient comes first". Systems often remain inflexible. As a result, patients are forced to participate in a process that is often quite different depending on the setting. The settings vary not only from inpatient to outpatient, but also from one inpatient or outpatient health system to another, as patients may increasingly drift from one organisation to the next for their various care needs. Patient loyalty has been on a steady decline over the years. This is a major factor in how many different organisations you may

interface with, especially in large urban settings. E-health will further enable this migratory behaviour in the near future, until a new Global Healthcare Multi-platform Ecosystem takes a firm hold. Pull economic forces will mold this new healthcare world order, to closely match a patient's day-to-day functional healthcare process needs. Providers that are deaf to this new order will find patients increasingly deaf to them. The competitors that best match their services to a patient's functional care needs will draw disproportionate market share to them.

18.4.5.2 The Form and the Three M's of Infrastructure

The three M's of infrastructure begin with the three functional processes that the infrastructure is built to serve. These are the three spheres previously described that include *Medicine*, *Measurement* and *Monetisation*. Each of these functional process spheres requires infrastructure that supports a patient's unique needs and catalyses the care process. *Medicine*, or the medical care process, requires structure. Doctors need stethoscopes or ECG machines to assess the heart's function. They also need digital infrastructure tools, such as clinical decision support, as much as a stethoscope. An ECG checks the heart's electrical function, whereas the clinical decision support tools augment the physician's cognitive function. Likewise, the *measurement* process, so instrumental in quality improvement processes, requires infrastructure to collect data from the care process. A cardiothoracic surgeon replaces a heart valve and the echocardiogram measures the ejection fraction of blood as a quantitative measure of cardiac muscle function post-surgery. This number is reported as a percentage and can be used to compare the effectiveness of surgical intervention or the surgeon's performance as compared to their peers. Finally, the care process and the costs associated with it must be transformed through *monetisation* as remuneration to providers of care. The functional payment process needs infrastructure to perform a conversion of the above care process to a functional billing and payment process. This functional conversion process (quantitative medicine) requires sophisticated digital tool infrastructure to make this complex transformation a reality. This technology infrastructure is the least mature and therefore has the potential for the most growth and impact.

Medical Infrastructure

What kind of medical care is produced by the top-performing competitors? The answer: exactly the care that each patient needs and wants. The medical process needs to be supported by a structure that optimises this demand from the consumer in a pull economy. For example, patient histories will be tailored to the needs of the individual. This means eliminating barriers of language, vernacular and terminology, advocacy, billing, diagnosis explanation, procedure risks and benefits, learning the track record of performance information and so on. Although it sounds extensive, this level of information infrastructure is readily available in other

transactions, including repairing your automobile or online banking. Sometimes the medical service bar is so low that individual patients have lowered their expectations for what reasonable care and care-related services look like. Cancer patients are often desperate and afraid to challenge the system because they are afraid of not getting the life-saving attention they need. Therefore, every structural component that supports the patient's functional needs must be designed, built and operated with those needs at the centre. This means building waywardness, web applications, patient gowns, biometrics, wearables and so on [23]. Yes, technology must be built to help providers to offer better care, but it must also be designed first to help patients receive the best care and care experience.

Measurement Infrastructure

An adequate measurement process has features of *precision*, *accuracy*, *reliability*, *validity*, *repeatability* and *reproducibility* [24]. Medicine currently lacks the infrastructure to perform all these functions at a granular level for all patients, in all settings, even for a handful of key diseases that drive most healthcare costs. Such a ubiquitous and widespread measurement system infrastructure must be built to advance care and reimbursement methodologies. The significant presence of unstructured data in medicine is here to stay for the foreseeable future. Although not an impenetrable barrier to precise measurement and knowledge engineering, it does mitigate an efficient and effective process. Continuing innovation in digital tools (e.g. AI-driven text search engines) has begun to break down barriers, but they are not going away in the near term. Drop-down menus for patient histories still do not match the nuances and complexities of a well-dictated patient narrative. As a result, there are blind sides and gaps in the measurement of care processes and patient experiences that innovations will solve. With respect to the patient-centric approach, measurement must get much better. Patients still by and large are resigned to taking what they are given. In the SARS-CoV-2/COVID-19 world, we have experienced significant public health-driven restrictions not only to movement, but also access to care [25]. This access extended to significant restrictions while receiving care (e.g. deliveries without the expectant father present). The patient experience took a significant hit in 2020, as did the accurate measurement of that functional process. This will now spark accelerated change through innovation.

Monetisation Infrastructure

The complexity of financial markets today is astounding, and the technology infrastructure that underpins these markets is similarly impressive. These transactions are based on a more than adequate measurement and reporting process. Healthcare infrastructure lags far behind the financial industry with respect to leveraging information technology. Monetisation must be based on outcomes that are produced as a result of an accurate audit trail of the care process. Unfortunately, an individual can

get a more precise audit trail of their 401 K performance than they can with their care performance. For this to become a reality, providers need to have their care outcomes accurately measured and fairly compensated for. In addition, provider care outcomes are also significantly affected by patient compliance. The best diagnostic and treatment process is only as effective as the patient's will to accept and optimally participate in it. Patients must also have skin in the game. With the development of vaccines for COVID-19 and the continuing work on vaccines for the rapid development of variants, it would seem that the journey to herd immunity is well on its way [26]. The problem is that acceptance, even by healthcare workers, is irregular. Therefore, compliance directly affects outcomes for which providers are being compensated and not necessarily in control. This makes the monetisation methodology more complex. It emphasises digital tools to assist in facilitating and improving the patient communication and education process. It also means that an accurate measurement process should account for the lack of patient compliance in calculating remuneration for the provider care outcomes. A similar system is in place for calculating the severity of illness within a patient.

18.4.6 A Patient-Centric Model as an Immutable Operational Mandate

A patient-centric approach cannot merely be a marketing slogan or casual intention. It must be an aggressive industry-wide immutable mandate. This mandate is cemented by payment systems that reward providers that do this well. It is also cemented by the demand for an educated user that can compare provider service values. These are the pull economic forces that govern other industries today. In healthcare, this will be the emerging E-health marketplace. Although in its infancy as a strategy, this slogan is gaining momentum as an operational plan.

18.4.6.1 From Buzzword to Operational Obsession

Buzzwords do not drive functional care improvements or profits. In the near future, for providers to survive or thrive, they must deliver value-based care and it must be patient-centric by definition. Those competitors that grasp this will have organisations where this operational obsession permeates every aspect of patient care delivery. Social media will mirror those organisations that succeed or fail in this obsession. The market will reward or punish those providers proportionate to their level of success or failure in this pursuit.

Patient-Centric Medical Care

The discussion thus far has pointed out the significant impact of the role that a patient garners in a pull economy. The emergence of this two-sided E-health market will drive care to be measurable, ratable and therefore comparable. Optimising the care process is tantamount to a provider's success. This significance has been underemphasised beyond talk in the operational setting, to the extent that care is not primarily driven with the patient at the centre of the process, even at the date of this writing. The justifications and arguments to do so are numerous and compelling, including that patient-centric care should be an immutable operational mandate. Successful organisations in the future will do just that and use advanced digital tools to enable it. Functional care processes will look and perform much differently in 10 years. In the value equation, technical quality is in the numerator, but so is patient satisfaction. We can improve the medical care outcomes by more accurately measuring both and using that improved measurement process to drive improved medical care quality improvement efforts.

Patient-Centric Measurement of Care

Patients are increasingly seeking metrics of the care process. Patients cannot know if the right intravenous solution is administered at the right rate or for the right problem, but they do know whether or not their providers are kind, personable and thorough. They also know whether their broken leg gets better and when they can again walk normally. Simple tests of the accuracy of the care measurement systems are still failing today. This is not an indictment of healthcare professionals, who are dedicated, compassionate and experts at what they do. Instead, this is a reflection primarily of the tools and the system within which they provide care. That system is still broken, as reflected by continually rising costs. Measures to cut costs by eliminating the low-hanging fruit and restrictions of care have largely already been done. The remaining frontier in cost reduction will come from improvements in the care itself. All quality improvement efforts start with good measurement systems. These effective measurement systems still are largely absent in healthcare, as opposed to other industries. For instance, take a tour of an automotive assembly plant and observe digital boards next to lines that reflect production rates, error rates, safety, injury rates, and so on. The feedback is measured, in real time, instantly reported and reflected in "just-in-time" production processes. Finance does this similarly, but at breakneck speeds compared to healthcare systems. Millions of stock trades occur each second, and a fraction of a second is meaningful in a war where competitors play a nanosecond game. The more volatile markets are, the more important time becomes. Healthcare does function under these constraints, but could borrow lessons learned. This high-speed technology can be co-opted to improve measurement, analysis and reporting of the clinical care process.

Money Paid to Providers That Optimises Patient-Centric Care Value

Providers need to be paid proportionately to how closely they meet patient expectations. These expectations should be the highest quality care at the lowest cost. As prices become more transparent and care outcome results more readily available, patients will expect accountability from providers. Part of this accountability, especially as copays and deductibles continue to rise, will also be in the form of feedback when a patient's expectations are not met. System infrastructure will be built in the near future to make this a reality. Extending the lesson from traditional finance further into healthcare finance is a logical step. In finance, computer systems make buying and selling decisions in split seconds, then execute them in the precise order required and track the entire transaction process precisely [27]. These exchanges are global, so transactions must be time-stamped from different time zones. That order is critical to the sorting and profit-making process in trading. Wall Street, therefore, is obsessed with time, because time is money. These systems are 10–12 years ahead of healthcare computing systems. Again, nonetheless, the lessons learned from manufacturing and finance can be applied to healthcare. These systems can be built de novo around the patient and the delivery of value-based care. These measurements, ordering, analysing and reporting methodologies are a natural fit for healthcare. Healthcare is a complex system, but amenable to the same types of financial engineering as Wall Street. Conversion of a care process to a mathematical representation of that process is the next frontier and therefore the main challenge for healthcare. Digital tools will enable and be a catalyst for this conversion as providers navigate that brave new world called *quantitative medicine*.

18.5 Clinical Care Transformation

Providers of medical care are dedicated and caring individuals. The job of a clinician is a very difficult one to do well and requires a special skill set that not all people have the capacity to perform, even if they wanted to. However, providers are human. Human error is an inevitable reality because people are not perfect and, as such, do not perform perfectly every time. This is not to say that perfection should not be strived for in the care of human life. The reality is that errors will happen and the goal should be to mitigate them as much as possible, by any means possible. This is where a system's view of the error mitigation process is useful. Digital systems can be designed and implemented, so as to assist the human provider to reduce the existence and severity of medical errors. Such infrastructure can transform the care process as we know it and improve overall value.

18.5.1 IOM Report, Medical Errors and Bending the Outcomes Curve

For the medical industry to transition to a fundamentally value-based structured marketplace, a transformation will be required. One of the biggest transformations will occur in the advancement of root cause analysis in care quality improvement efforts. Figure 18.7 illustrates the multifaceted nature of human process errors. Tracking is impossible without digital measurement systems. Care process redesign is then accelerated by accurate root cause analysis and system changes. Putting excellent people into a broken system is not an optimal use of resources. It is better to train excellent people to work within an excellent and constantly improving system enabled by digital measurement tools. The system should be constantly evolving, so as to optimise the care process from both sides of the two-sided E-health relationship. The 1999 Institute of Medicine report "To Err is Human" triggered efforts nationwide to improve patient safety. Medical errors require rework to fix them, which is more expensive than getting it right the first time.

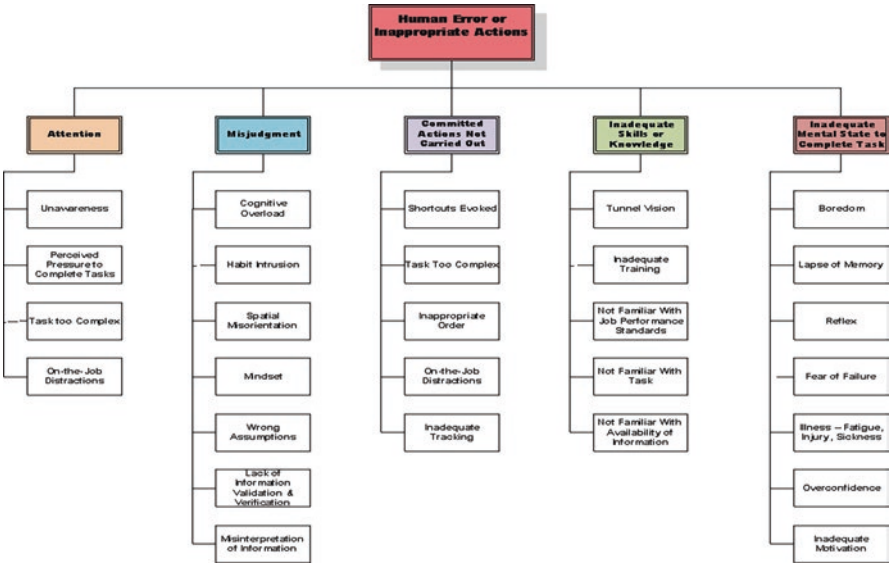

Fig. 18.7 Categorical representation of human error root causes (source: author)

18.5.2 Mitigating Medical Errors Improves Value by Improving Quality

In a *commodity-based reimbursement system*, there is not a strong provider incentive to radically improve care. That is because irrespective of the medical care outcomes, remuneration will be the same. Coal, as a commodity, is created the same and therefore economically equal. Imagine if suddenly all care is measured and the error rate for care by each disease is reported by every provider to purchasers. Additionally, their entire compensation was based on a rank order of performance. Now, the payment system is restructured around a *value-based meritocracy*. Care is tracked for outcomes. Outcomes, specifically, are measured and root causes of poor outcomes are tracked back to medical errors that may have triggered a cascade or domino effect as illustrated in Fig. 18.8. What flows from an error in the care process is rework to fix that error. That error lowers the quality of the care, the satisfaction of the patient with their care experience, raises the risk of morbidity and mortality and ultimately produces higher costs associated with rework, morbidity (e.g. short- and long-term disability) or even death.

The market is suddenly "cardioverted" or shocked into an obsession with ways to improve value. The best way to do that is upstream, where the most profound effect on bending the quality and cost curve resides. This then converts the entire care supply chain to innovate to this new reality. Just as the HITECH Act and the PPACA shocked the system into looking at value rather than just volume, so the emergence of reimbursement systems that demand this model drive technology. In the 1980s, we saw the PC revolution in doctors' offices and the emergence of digitisation, albeit primarily with respect to billing systems. After the HITECH Act and the PPACA, we saw a rapid rollout of EHRs that primarily just recorded care and, in some cases, improved certain aspects of it [28]. In the future, we will see these digital tools assist in the migration to a value-based care market, where technology is a strategic and competitive weapon linked to provider survival. Therefore, the

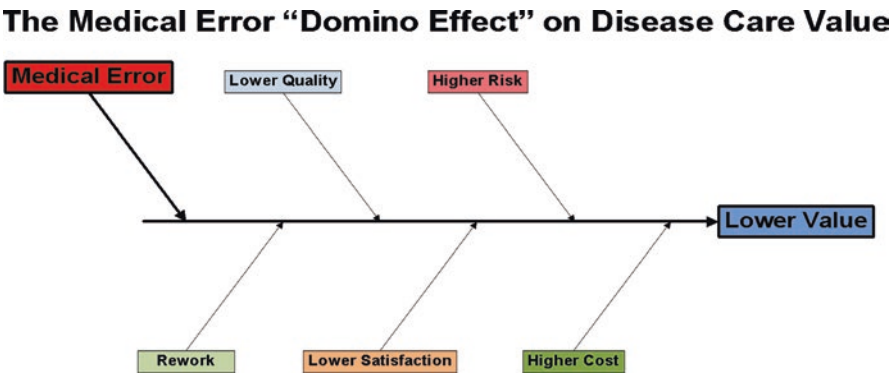

Fig. 18.8 Cascade of downstream process issues that result from a medical error (source: author)

future is high value-based outcomes that are produced by the most technically skilled providers utilising the most advanced digital toolsets.

18.5.3 A Proposed Error Reduction Methodology

The advanced digital toolset must focus on quantifying the idealised care process as it would exist absent artificially imposed constraints from poorly designed technology. Today, this technology is often workflow-adverse. The result is the introduction of inefficiency, as a result of clumsy data collection tools. These tools often assign data entry tasks to people whose training is optimised not for these tasks, but rather for medical decision-making. Picture for a moment a courtroom, where it was suddenly decided that meaningful use of courtroom documentation meant mandatory digitising of those records. Furthermore, to prevent poor translation of the spoken word, it was decided that transcription should be assigned to the lawyer as the originating author. What would be the ensuing workflow issues? Analogously, why did anyone think that adopting this process in the field of medicine would go much better? Instead, the tools need to be designed to dovetail smoothly into an idealised manual process, so as to not impair that process, but rather to improve it. Let people do what they are best trained to do. That process consists of the three main process components of diagnosis, treatment and the velocity of those two functions. The workforce of providers and their workforce multipliers should be the first to have this manual process optimised. Then, the manual process should be viewed by clinicians to decide what tools and in what part of the process those toolsets could be introduced to improve it.

The improvement in the clinical care process should focus on the three key elements of care. Those are diagnostic accuracy, treatment accuracy and the velocity of those two combined processes. The rows in Fig. 18.9 list these three variables against three interventions in the columns. These interventions are *workforce reorganisation* (e.g. integrated practice units, workforce multipliers, etc.), interaction management (e.g. lean, six sigma, constraints and change management) and augmented clinical intelligence (e.g. combining AI tools to create a clinical decision support layer of the EHR). The last column of Fig. 18.9 suggests the potential benefits of combining these interventions (columns) with the three categorical aspects of the clinical care process (rows) to produce superior patient care outcomes (e.g. improved value of care).

The four traditional improvement processes of Lean, Six Sigma, Constraints and Change Management (less utilised in healthcare) can then be optimised by the digital data collection platform. This platform produces the needed information to fuel those quality improvement methods. These methods are people tools that collectively serve as an *Interaction Management System* (IMS) that works together to improve people processes. Accurate data is critical to making good decisions with these methods and digital tools are critical to accurate data collection. In that regard, diagnosis and treatment are improved with augmented clinical intelligence tools

	WORKFORCE REORGNIZATION	INTERACTION MANAGEMENT	AUGMENTED CLINICAL INTELLIGENCE	OUTCOME
DIAGNOSIS	Diagnosis team as prospective and retrospective resource to focus on ehancing correct diagnosis	Lean, Six Sigma, Constraints and Change Management tools used to improve accuracy	Analytics & database used at the medical decision making moment enhances accuracy	**Reduced errors and rework associated in achieving the accurate diagnosis**
TREATMENT	Integrated disease treatment teams focused on treatment that also uses care mulitipliers	Lean, Six Sigma, Constraints and Change Management tools used to improve selection and roll out	Analytics & database use all along the treatment process improves effectiveness	**Reduced errors and rework in the selection & implementation of the treatment process**
VELOCITY	Heightened focus on integration and coordination of resources to increase velocity	Lean, Six Sigma, Constraints and Change Management tools used to improve cycle time	Root cause analysis driven by continuous use of analytics improves process optimization	**Increase speed of error free diagnosis and treatment process**

Fig. 18.9 The interplay between medical care process (left column) and interventions (top row) and net outcome effects (right column) (source: author)

that are built into the EHR to enhance these two care processes. This assists with error mitigation by attacking errors upstream at the point and moment of care that results from provider medical decision-making.

18.5.4 The Clinically Integrated Network (CIN) and the SARS-CoV-2/COVID-19 Pandemic

The healthcare industry has seen a flurry of mergers and acquisitions (M&A) over the years, but the proclaimed benefits of improved quality and reduced costs have largely failed to materialise. Instead, in a zero-sum commodity-driven market, these moves have primarily served to increase market share, increase bargaining power, more effectively cost-shift, control patients and their choices, maintain broadline strategies and raise prices. Physicians have been increasingly forming larger groups and becoming employees of health systems or publicly traded companies. This is all about to reverse, as the provider/clinical integration adapts to the patient-centric marketplace on a local, national and global level. The SARS-CoV-2/COVID-19 pandemic, out of necessity, pushed interstate care rule changes that marked a tipping point in E-health. The domino effect of this tipping point has not begun to fully manifest itself.

18.5.4.1 The Magic of Collective Clinical Digital Genius (CCDG)

Innovation is a team sport. No one genius usually sits in a lab where a "Eureka" hits them nor does a solitary person produce a revolutionary breakthrough [29]. Nobel prizes are often given to groups that simultaneously or collaboratively make breakthrough discoveries. Medicine has evolved from ambulatory solo practices at the turn of the last century to hospital and ambulatory, to large physician groups and multi-specialty practices, to mega groups (for-profit and non-profit) and health systems. Mergers and acquisitions in healthcare have yet to produce clear and unequivocal benefits in quality improvement, cost savings or the general public good. CINs have the opportunity to do just that. Digital infrastructure can catapult a new form of collaborative physician group into the forefront. This is the second generation of *Clinically Integrated Network* (CIN). The SARS-CoV-2 and COVID-19 pandemic has ripped off the Band-Aid on system flaws, thereby exposing inefficiencies and limitations. Lockdowns did buy enough time by flattening the curve on disease transmission, thereby reducing the number of potential hospital admissions to a level just below a system breaking point. However, there were significant gaps and irregularities in diagnostic and therapeutic information dissemination. Granted, this was a novel virus and the learning curve was steep at first. It also reminded us that public health is an amalgamation of medical, social, economic and political influences. The net effect on medical care is a function of the balancing act of those influences. The existence of multiple CINs could have assisted in the more efficient management of this pandemic, especially if powered by advanced digital tools. This second generation of CIN will emerge from within and upon a new healthcare digital multi-platform ecosystem. The ecosystem is not the CIN but rather the enabler of advancement in CIN functionality. This enabling will be the "magic dust" that enhances the effectiveness of provider collaboration and serves as the glue to integration through functional and structural interoperability. Each provider's genius contribution to the whole CIN is multiplied through a symbiotic new order of provider integration.

18.5.5 CIN Implementation and Functional Care Transformation

The concept of integrated care teams or units is not new. When taken at scale, this concept is represented by a CIN. The scale can be local, regional and national. There have been examples of this already with insurance models (e.g. Kaiser, Intermountain Health, etc.), health systems (e.g. Trinity, HCA, Mayo Clinic, Cleveland Clinic, etc.) and non-profit and for-profit physician groups (e.g. The Permanente Medical Group, Mayo, Team Health, etc.). These groups represent business and technology platforms that have made strides in clinical and operational efficiency. However, although there has been progress, no group or group model has emerged as a shining example of how to unlock the enigma of operationalising value-based purchasing.

18.5.6 The CIN and a Value-Driven Disease Market Architecture

Architectures, such as those illustrated in Fig. 18.10, have attempted to solve the seamless and interoperable integration of providers and care processes. The organisational, process and digital platforms have still fallen short in moving the needle on significant value-based or purchasing-based organisational outcomes. Care is still, by and large, *fragmented* and *siloed*. Progress has been iterative, but isolated and in very small increments. As alluded to by the reports from CMMI initiatives, the quality and cost needle has not made a quantum leap to a new level. Otherwise, we would have seen widespread adoption of that breakthrough model. Each of us today has a story that reflects this reality about the care we or loved ones received. Insiders in the industry, likewise, have their own bevy of examples of when the proverbial right and left hand did not know what the other was doing. More times than not, this is a system error and not a provider error. For example, assume that Dr. Smith provided perfect care regarding their piece of Mrs. Jones' care process. However, Dr. Smith did not convey those results perfectly to Dr. Brown, who was responsible for another portion of Mrs. Jones' care process. The care by Drs. Smith and Brown, although perfect in their own right in isolation, may affect their other provider's decision making, so as to not be ideal when looking at Mrs. Jones overall health status. Net value-based care is not only the aggregate of total costs, but also

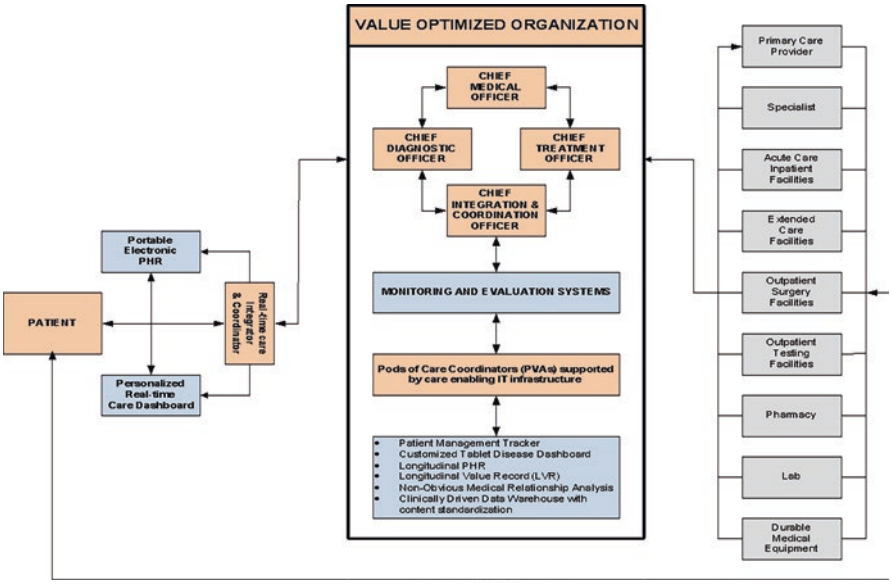

Fig. 18.10 Hypothetical CIN architecture that is patient-centric utilises quantitative medicine, with a focus on value-based outcomes (source: author)

more importantly the aggregate of total quality of care provided to each individual patient throughout the full cycle of their care. The CIN should be of such a provider architecture, so as to facilitate the highest care value.

18.5.7 The CIN, Value-Based Care and SARS-CoV-2/ COVID-19

Taking this analogy and applying it to the ongoing pandemic has significant utility in understanding current gaps in the U.S. healthcare system and provides insights on the ways to bridge those gaps. As mentioned, a well-oiled CIN would have offered utility in providing value-based care for COVID-19 patients. This did not happen, so gaps occurred and these gaps became newsworthy stories. The CIN would have been useful in one major area: the dissemination of consistent and up-to-date information about diagnosis and treatment.

18.5.7.1 Testing, Measuring COVID-19 Natural Disease Progression and the Utility of Provider Integration

The *natural disease history* from SARS-CoV-2 (the virus) exposure to COVID-19 (the disease) through convalescence can be tracked through testing. Figure 18.11 represents a matrix with columns consisting of exposure day, symptomatic or asymptomatic, status-stage or significance, type of test and conclusions. Of note, the antigen test is not included in this chart, as not all these tests were available at the onset of the pandemic. As time passed, more options for disease testing were developed and made available. There was enormous variability across the two-sided market of patient and provider about what the natural disease history looked like, what tests were available when to use them, how to interpret them, how to act on those results, when to act on those results and how that action may actually impact the patient with respect to the natural course of the disease. Although a plethora of research was conducted and prepublication, preliminary and published results flowed in a continuous stream, its effective dissemination was a totally different issue altogether. There was also significant variation in how the information was utilised by both the patient and provider. This variation led to disparities in care as a result of not only information dissemination but also of a uniform approach on the part of providers. Furthermore, disparities are exacerbated by the issues of access, testing and social determinants of health. A well-functioning CIN powered by state-of-the-art digital tools can go a long way in closing the gap in these disparities.

Day	Symptomatic	Asymptomatic	Status-Stage/Significance	RT-qPCR	Paper	IgM	IgG	Comments
No exp	-	-	No exposure to SARS-CoV-2	-	-	-	-	Virus naïve
-27 to -2	Pre-symptomatic	New	SARS-CoV-2 exposure	-	-	-	-	False negative
-3 to 0	Pre-symptomatic	New	Early infection	+	+	-	-	Shedding virus
0 to 14	Symptomatic	Current	Current Infection - Recent	+	+	+/-	-	Shedding virus
12 to 26	Symptomatic	Current	Current Infection - Mid-stage	+/-	+	+/-	-	Worsening
12 to 21	Symptomatic	Current	Current Infection - Late-stage	+/-	-	+/-	+	Not shedding transmissible virus
14 or later	Recovering	Recovered	Previous Infection - Recent	+/-	-	-	+	Not shedding transmissible virus
96 or later	Recovered	Recovered	Previous Infection - Recovered	+/-	-	-	+	12% of symptomatic & 40% of asymptomatic no longer have IgG

Assumptions:

Day **0** is day of symptom onset in group that gets symptoms.

Asymptomatic never develops symptoms and shed virus an average of 19 days.

Presymptomatic becomes the symptomatic group.

You'll get some overlap in days because not everyone has the same course.

97% of presymptomatic develop symptoms in 14 days, average 5-6 days after exposure

A few % of tests are false positives. PPV depends on population prevalence of the disease.

If 5% of the population has disease, and test is 99% specific, 20% will be false positive

5

Fig. 18.11 Temporal relationships between patient SARS-CoV-2 exposure, symptoms, disease stage and testing (source: author)

18.5.7.2 The CIN, Prevention and SARS-CoV-2

Such a well-functioning system composed of a CIN and its IT platform can be utilised to analyse how to best address a disease like SARS-CoV-2 and COVID-19. To do this, it is helpful to look at the entire spectrum of patient care not only for an individual but also from a public health and population perspective [30]. This is a longitudinal view along the natural disease historical course. Figure 18.12 illustrates a public health view of disease management. This view is one of prevention. There are three categories of prevention. The first is primary prevention, which means preventing the occurrence of disease in the first place. The current pandemic is a race to vaccinate the population and achieve herd immunity that will ultimately extinguish the disease. The second type of prevention is secondary prevention. This is the early detection and intervention before much of the significant disease effects can express themselves as serious morbidity. Finally, tertiary prevention is when the disease is well established and these morbidities require medical interventions aimed at reducing the severity of illness.

In the case of SARS-CoV-2, the battery of patients cared for by the CIN is tracked for risk factors to contracting a moderate or severe case of COVID-19. As COVID-19 is a disease affecting the ACE-2 receptor, all patients in the network with ACE-2 receptor-vulnerable organ system diseases (e.g. lungs, cardiac, brain, kidneys, etc.) should be culled from the relational database, flagged and alerts sent to the primary care and other treating clinicians. They should be more closely monitored for early disease symptoms, patient education about the disease and benefit from vaccination and tracking of completion of vaccine dosing. Vaccine acceptance and rates among various patient populations, as well as the healthcare workers who treat them, are variable. The highest death rates have been in nursing homes. Of the overall mortality numbers, nursing home residents have made up 40–70% of the deaths before vaccine distribution. This contribution to overall mortality statistics did not drive

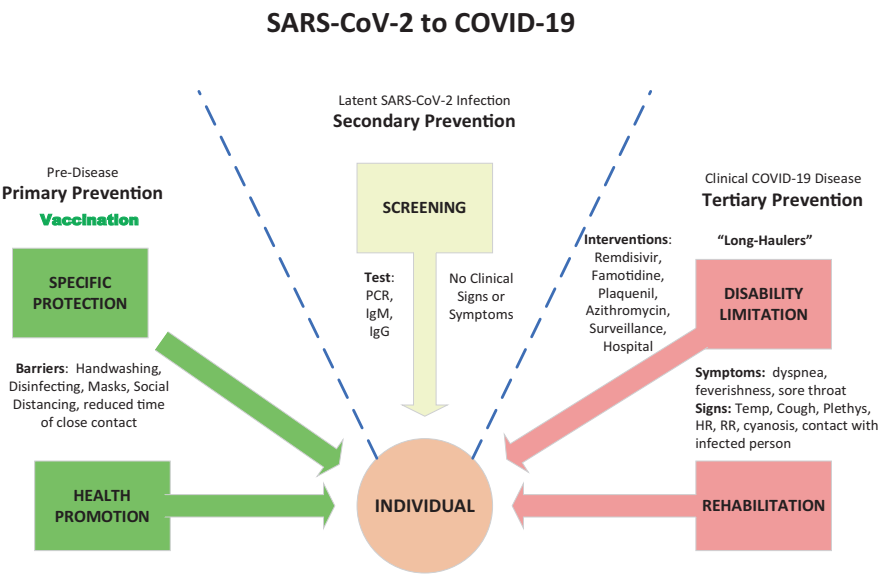

Fig. 18.12 Relationship between SARS-CoV-2 and COVID-19 disease natural history and the three phases of prevention (source: author)

nursing home-ancillary medical staff vaccination acceptance and compliance. Healthcare workers in nursing homes have vaccination rates of only between 30 and 60%. The CIN patient population, as well as the healthcare workers that staff their office, can be part of the primary, secondary and tertiary preventive process only if the digital tools are leveraged to optimise this continuum. Digital tools that enable process, when utilised in conjunction with change management methods, have a higher potential to drive stakeholder acceptance of key initiatives.

18.6 Measurement Transformation

People measure what they care about, whether it's stepping on the scale in the morning to check your weight or checking your tire pressure before a big road trip. The accuracy of the measurement process is of great importance with certain critical metrics. Radiation levels in a nuclear power plant control room or blood pressure in patients in intensive care units reflect critically important metrics. To enable value-based care outcomes, we must transform current measurement systems of the care processes.

18.6.1 Measurement as a Value Enabling Information Tool (VEIT)

Specifically, those tools are leveraged to measure the actual care process. That measurement should be part of a premeditated quality improvement process, which uses the data to quantify which care process elements are value accretive and which are devaluing. Since care is longitudinal and continuously cyclical, accurate measurement should occur continuously all along the entire cycle of care. Measurement in medicine is being exponentially accelerated in both the inpatient and outpatient settings, catalysed by changes in regulations (CMS) and advances in technology. CMS is changing remuneration to accommodate *Remote Patient Monitoring* (RPM) [31]. Technology is advancing to allow for precise, accurate and timely remote monitoring through sophisticated sensor development coupled with AI embedded in the devices, which are independent and integrated with cloud-based analytics. The independent distribution of technology into the IT environment is creating a "distributed-intelligence" web of devices. Driving measurement, data storage and machine learning down to the patient's wearable device level will elevate the effectiveness of the measurement process. Immediate change is now distributed down to a real-time sensor response level that was not previously technologically possible. Such a scenario would be with a patient that receives a cardiac medication, such as a beta-blocker. This medication to reduce blood pressure affects heart rate. Wearable devices that can detect the person's heart rate usually make on-demand measurements. These are discrete, rather than continuous. However, the medication is best adjusted using measurements that may be best detected at night during sleep, when the heart rate may drop the most. To accurately determine the heart rate trend line necessary for dosing adjustment, measurements must be at night when the patient can't voluntarily trigger a reading. A sensor that can be triggered into a continuous mode when an intermittent read detects a drop below an acceptable benchmark level would be of major clinical value. It is far more beneficial to the clinician to therapeutically adjust medication dose to know the lowest heart rate. Clearly, the usual method of adjusting medication every 3 months as a recheck in the office with a single discrete measurement is not ideal.

18.6.2 Measurement of a Disease's Longitudinal Natural History

Measurement of various physiologic parameters should be aggregated to obtain not only a more complete view of the patient's health status at a moment in time for a single body system, but also over time for multiple systems. Public health information systems would benefit from a population-level automatic data collection and aggregation by information technology [32]. Again, let's use the cardiovascular status of a patient as an example. A patient with heart failure may reach a tipping point

and require hospital intervention. Once discharged, a significant concern for the patient, treating physician, hospital and insurance company is readmission within 30 days. Although RPM is utilised with heart failure, the RPM has just begun to scratch the surface of what is possible. It is not only important to monitor such patients for a "stack" of multiple physiologic parameters, but also for medication compliance, understanding of treatment regimen and communication with the safety net of care providers. That said, there are other factors that have come into play with the SARS-CoV-2/COVID19 pandemic. Infectious disease plays a significant role in the exacerbation of cardiac disease and there are more heart attacks during influenza season [33]. The pandemic has also correlated with an uptick in cardiac events. It would be helpful to have other physiologic indicators in addition to the usual cardiac metrics that would be a signal of a change in physiologic status. This signal could be for infectious diseases that could be detected even before standardised laboratory testing. This signal could portend not only of infectious disease, but also an infectious disease that significantly increases the probability of a new cardiac event or an exacerbation of a pre-existing cardiac condition, such as heart failure. Figure 18.13 shows the relationship of primary (green), secondary (blue) and tertiary (red) prevention along a disease timeline of the natural disease course. The goal is to prevent the disease from occurring, thereby improving the quality of care the most. If this is not possible (e.g. a vaccine is not developed for the infectious agent), then emphasising detection as early in the preclinical time period as possible has the greatest chance to mitigate the rate of disease progression, as well as its severity. This saves costs to the system by improving the quality of clinical care. Therefore, in the population or individual health longitudinal schema, the best strategy for significant improvement in quality of life, health status and therefore cost reduction, is putting more emphasis on primary and secondary preventive efforts.

18.6.3 Measurement and the Population Clinical Care Process

As wearables take over the individual measurement process, data on each person will increase significantly. Ultimately, it will create a more and more detailed digital representation of who we are as unique physiologic beings. Each of us will have our "digital double" or "medical avatar". At a population health level, this will be a collection of anonymised digital representations that enable population and public health to be better optimised. Often this optimisation is focused on a single disease. The purpose is to study the effectiveness of a provider or institution's compliance with treatment guidelines and the associated performance benchmarks. These measurements are disease-oriented for a discrete period, such as postoperative infection rate or readmission. They can also be used for discrete testing, such as HbA1c for the measurement of longitudinal control of therapy in patients or populations with diabetes. The problem is that patients are complex. Therefore, discrete, finite and episodic measurement, even though longitudinal, does not contain enough data

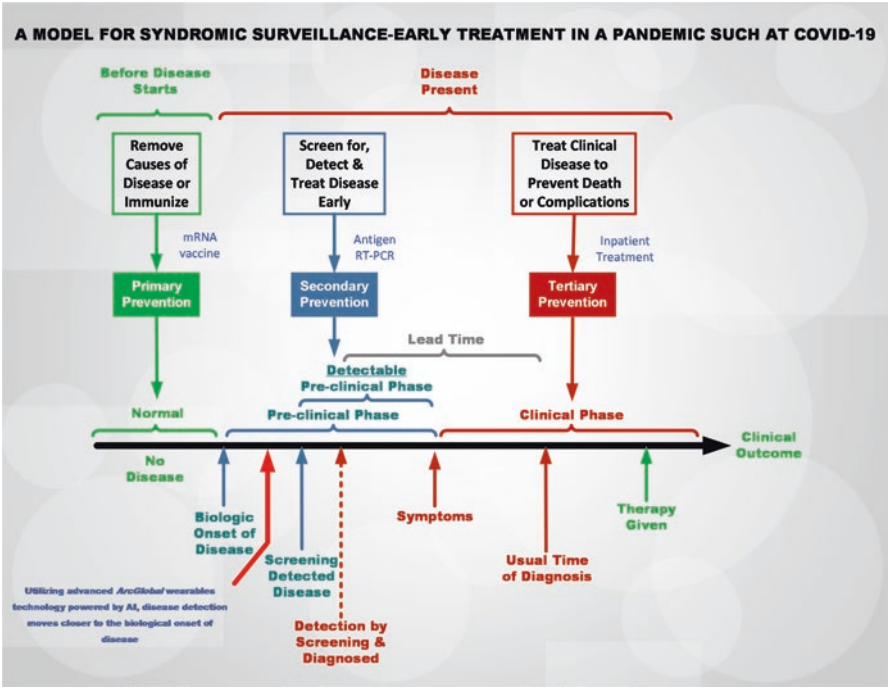

Fig. 18.13 Relationship between the natural disease course of SARS-CoV-2 and the use of an advanced ArcGlobal™ wearable technology to detect disease prior to traditional laboratory testing and close to actual biologic onset of COVID-19 (Source: *Gordis Epidemiology, 6th ed.*, David D. Celentano and Moyses Szklo. Copyright © 2019 by Elsevier, Inc. All rights reserved. Adapted with permission of Elsevier B.V. through PLSclear)

points of a single metric (or metrics in general) to paint a complete picture of the patient's health status. AI and machine learning can connect some of the dots, but such inferential statistical methodologies have significant limitations with accurate predictions. The more accurate path is to add more metrics with more continuous data measurement. It would also be helpful to add more metrics that are shown to be symbiotic in accurately measuring a patient's overall health status, physiologic equilibrium and early dysregulation of that equilibrium.

18.6.4 An Integrated Healthcare Measurement Model

An integrated healthcare measurement model is the answer and it must be multi-system and multivariate. As we have described, it should be longitudinal along the full cycle of a patient's care process. In short, this is a complex measurement system. Figure 18.14 illustrates primary, secondary and tertiary care phases from another perspective. This is the more traditional nomenclature of acute illness,

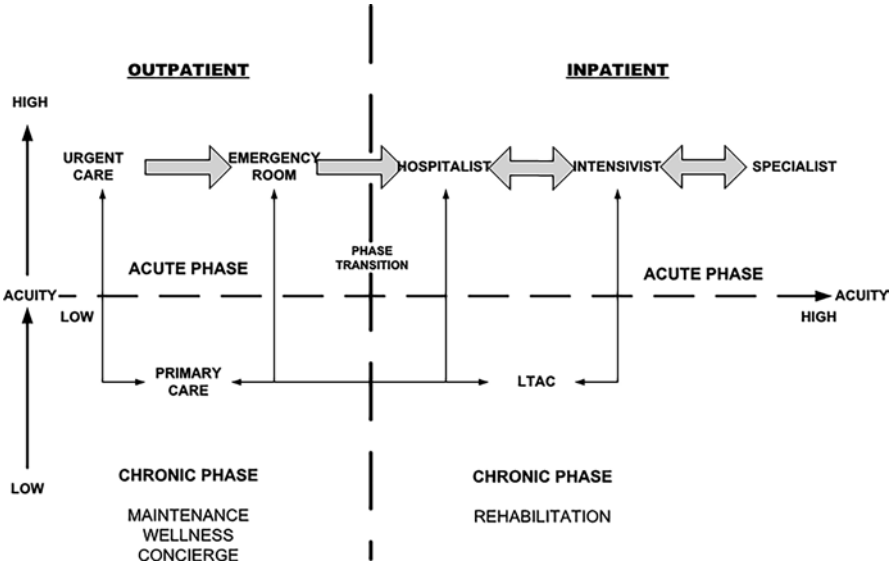

Fig. 18.14 Measurement of the clinical care process and the outcomes that result from that process in multiple settings and patient states (source: author)

chronic illness, outpatient and inpatient care. It also overlays a scale of acuity. The "phase transition" is the result of the failure of secondary prevention efforts to prevent a physiologic tipping point from acute self-limiting low acuity of illness to chronic higher acuity debilitating illness of tertiary prevention. The division between the three phases of prevention is not distinct boundaries, but rather a continuum of iterative subtle physiologic changes over time in each unique individual. The goal is to build a system of remote patient monitoring (RPM) digital tools that collectively make up an individual surveillance system for each person. Patients are a unique and complex system. To advance secondary prevention we need better digital syndromic surveillance tools that push early detection farther into the beginning of the pre-clinical phase. In doing so, we can detect early changes in the physiologic pattern or rhythms unique to each human being. This is their digital energy or homeostatic fingerprints. This early detection of a disruption in one's normal rhythm can lead to significantly earlier interventions that bend the secondary prevention curve much farther upstream. Consequently, it is not an intellectual stretch to imagine that each of our individual physiologic systems expresses disease initiation and progression differently. This depends on our genomics, age, race, sex, environmental exposures, lifestyle, nutrition, stress and a myriad of other factors that influence disease expression. The digital future of medicine involves improved monitoring, a measurement that will significantly influence diagnostic accuracy, treatment accuracy and velocity of these two aforementioned processes.

Again, our human systems are complex, and no two patients are exactly alike. We cannot manually track these unique nuances of each patient due to the limitations of the human mind. However, augmented intelligence will marry the human

mind and machine to permit a journey into a better understanding of how to better customise care to each individual patient.

The medical care diagnostic and treatment process is filled with reductionism and heuristic thinking that is often a by-product of the search to make the practitioner's life faster and more efficient. "Cookie-Cutter Medicine" is a reflection of this tendency. Depending on the setting, such an approach works most of the time. However, in an emergency room (ER) setting, unless the practitioner maintains a high index of suspicion, an outlier will be missed and lead to diagnostic or treatment error and/or reduction in care velocity. As patients move from care setting to care setting, the risks and complications in the care process vary widely. A complex patient, such as one with multiple comorbidities, can magnify their risk significantly. For example, if they land in a complex care setting, such as a busy trauma ER on a Saturday evening in the summer, the recipe for escalating error is present.

18.6.5 Complex Systems Demand Precise Measurement

We have established that patients are *complex systems* and that different settings have their own inherent complexity. In medicine and with the treatment of patients, we are constantly dealing with the physics of physiology. The material goes through phase transitions, such as from liquid to gas, or in general a change between different states of matter. Figure 18.15 is another representation of primary, secondary and tertiary prevention. This diagram combines the variables of acuity, cost, complexity and setting. This model can be used at an individual or population health level to analyse the continuum of care and a natural disease course. This becomes even more challenging when viewed from the perspective of a patient with multiple co-morbidities. Physiologic systems and materials move through different "states". In the prevention model of public health and medicine, we try to deal with individuals and populations in the primary prevention stage. The goal with primary prevention is to avoid a transition from a disease-free state to the development of early disease, but without clinical manifestations (secondary prevention). The goal of secondary prevention is to limit or slow disease progression from asymptomatic disease to chronic symptomatic disease state. In each case, the mission is to slow the disease progression. When viewed at such a system level, an individual or population's health status must be accurately measured to fully grasp a snapshot of their current physiologic state and design measures to slow the development of the disease or disease progression once a disease manifests itself. For instance, pancreatic cancer is a very rapidly progressing disease once diagnosed. The reason is that it is not detected until the late stages of the disease. Imagine if a multi-metric physiologic measurement system could detect a dysregulation that was statistically predictive of early pancreatic cancer. Under these circumstances, treatments could be devised and applied at a time when the disease may be curable or its natural history curve bent upstream to slow progression and prolong the number of quality life years. Genomics and epigenetics, when coupled with such a precise physiologic process measuring system, could become a bellwether for a new field of diagnosis

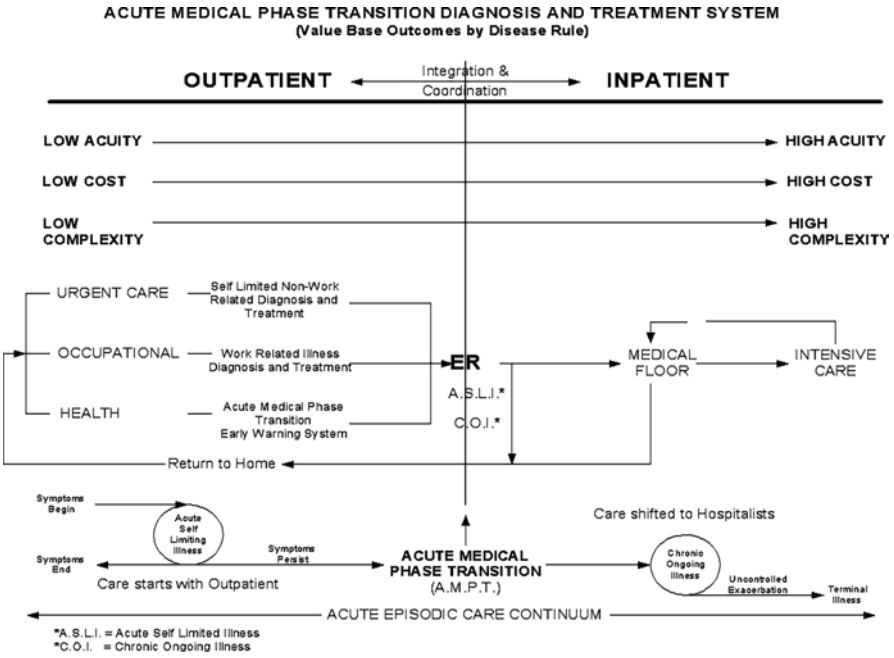

Fig. 18.15 The complexity of the constant balancing in physiologic systems between maintaining wellness, repairing and system failure in the form of chronic disease (source: author)

and treatment. Together, all these realities speak to the need for better digital tools to collect, measure, analyse and report on the status of both the individual health and that of a collective population. It also demonstrates that health status functions on a primary, secondary, tertiary prevention continuum. The current healthcare system emphasises interventions of the tertiary prevention phase. We must shift to a broader view of the longitudinal clinical care continuum.

18.6.6 Measurement of the Full Longitudinal Clinical Care Cycle (LCCC)

There are technologies currently in the developmental stages to deliver exactly such a system. Results are preliminary but promising. Such a system should be integrated closely with an individual patient and population's full cycle of care longitudinally throughout a lifetime. At the centre of the care cycle is measurement. The measurement process includes not only data collection and storage but also analysis all along the entire continuous process. These digital tools can provide the patient with precise feedback at any step in this virtuous cycle. This is where medicine is optimised by advanced digital tools that promote knowledge engineering and directly impact patient lives.

Fig. 18.16 The continuous virtuous cycle of care and its relationship to centralised and continuous measurement, analysis and reporting of that care process (Adapted from Appendix B The Care Delivery Value Chain, Delineating Types of Care Delivery Activities, from "Redefining Healthcare" by M.E. Porter & E.O. Teisberg (2006) [product# 7782-HBK]. Republished by permission Harvard Business Publishing)

Figure 18.16 represents a continuous cycle that could involve an acute, self-limiting illness that has a finite end. This has been the case with most patients that have had COVID-19. Most patients have asymptomatic or mild symptoms with a short LCCC. Other patients with COVID-19 may be "*long haulers*" or Post-Acute Sequelae of SARS-CoV-2 (PASC) that suffer a trigger of a viral-induced autoimmune process, resulting in persistent symptomatology and a long LCCC [34]. They will need ongoing monitoring and treatment until hopefully liberated from that cycle by a new therapeutic discovery that breaks the autoimmune cycle. In the interim, continued precise measurement contributes to an accurate assessment of the patient's health status, optimises available treatment and maintains the patient in the best health status, while awaiting definitive treatment. This, consequently, represents a virtuous and continuous optimal cycle of value-based care.

18.6.7 The Necessity of Clinical Decision Support Systems (CDSS)

Future medical school candidates go through a rigorous admission process that screens a candidate for general intelligence, memory, aptitude for the sciences and people skills. Medicine combines math, physics and social science with practical, in-the-field problem-solving about life and death issues for a real person. Being a doctor means balancing all these skills. The greatest challenge of medical school is not the depth of the subject matter in each field, but rather the breadth and sheer volume of the material covered. No physician, regardless of how brilliant, retains and is able to regurgitate all that learned knowledge all the time. As the old Chinese proverb states, "The faintest ink is more powerful than the strongest memory". In addition, collective genius outperforms singular genius. This reinforces the case for *Clinical Decision Support* (CDS) becoming standard fare and embedded in all EHRs.

18.6.8 Augmented Clinical Intelligence (ACI) Plus CDSS Equals Augmented Clinical Intelligence Decision Support (ACIDS)

Going forward, CDSS (Clinical Decision Support Systems) will become defined as *Augmented Clinical Intelligence Decision Support* or ACIDS. One of the clearest ways this assumption was tested was with chess. Figure 18.17 illustrates the clear-cut advantage of man plus machine. The "Deep Blue" competition proved to be the beginning of the end for human-versus-computer matches [35]. Today, most chess grand champions play computers only to train for competitions, because humans never win. Although playing chess is different from treating patients, there are a few key takeaways. First, computers are unbound by any habits, whereas people bring preconceptions or biases to the problem-solving table. The example of heuristic thinking or taking mental shortcuts is a prime example. Heuristic thinking is a double-edged sword. It can lead to efficiency and speed in daily patient care, but at the same time, it can lead to oversight by making a false assumption about the array of presenting symptoms. Augmented intelligence brings together the best of both worlds.

In this world, the domain expertise of both is brought to the table. The computer partner utilises computational speed, mathematical skills, multiple deep domains and large data sets. The human partner brings visualisation and intuitive reasoning. Computers of today are just not, and may never be, capable of intuition, given that computers are only as good as the human programmer. This ACIDS support tool, embedded into the clinical measurement and analytical processing component of differential diagnosis and treatment selection, will *augment* medical decision-making to improve accuracy, precision and velocity in a way not possible without it.

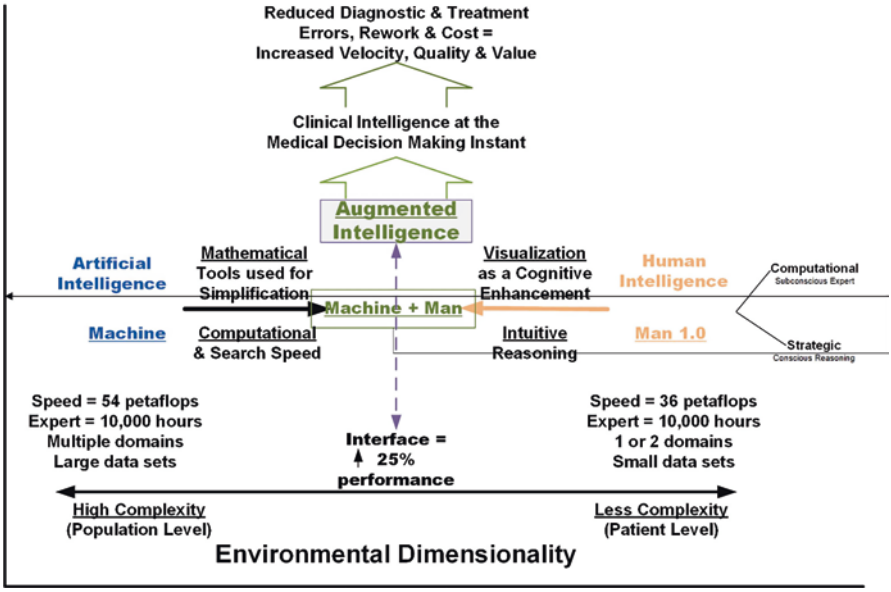

Fig. 18.17 The featured advantages of man, machine and man + machine in an augmented clinical intelligence decision support (ACIDS) model (source: author)

It will also improve interoperability between clinicians and patients and between clinicians themselves. It will be a two-sided E-health workflow optimiser. More accurate diagnosis and treatment, especially with patients that have multiple comorbidities, will improve the value of care.

18.6.9 ACIDS and the Complex Patient

The benefit of marrying augmented intelligence and clinical decision support is no more poignant than in patients with multiple chronic conditions. From a healthcare economics standpoint, 5% of the patient population makes up 50% of the spending [36]. Twenty-five percent of spending occurs in the last 3 years of a person's life. The question becomes how much of this spending is high value? The answer is made more straightforward when one considers that most of this spending is on patients with chronic medical conditions. A single chronic medical condition can be a complex case-management challenge all by itself. However, when one adds three, four or five chronic conditions to the same patient, the optimal care guidelines for the management of simultaneous comorbidities become a challenge. Figure 18.18 shows a hypothetical patient with three chronic conditions. In this case, the comorbidities are diabetes, congestive heart failure and emphysema. This is not an unusual patient scenario. It is not very difficult to look up evidence-based guidelines for

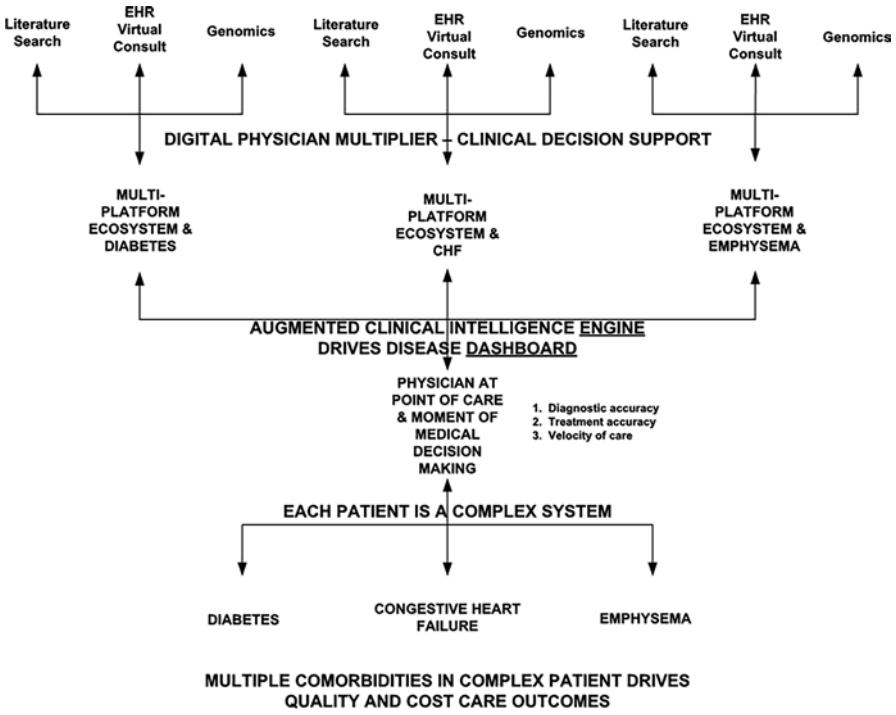

Fig. 18.18 The complex patient, the physician, ACID tool, plus digital tools of telehealth, genomics EHR integration and machine learning-driven literature search (source: author)

each of these diseases. It becomes much more difficult to find an evidence-based guideline that combines all these diseases into a combined algorithm or pathway. The final challenge is to customise this pathway to the individual patient who may present in such a way that is not familiar and challenges the intellect of even the most astute primary care provider or specialist.

Quantitative medicine is defined as the use of advanced mathematics and physics in the analysis of patient disease care. As was alluded to earlier, medical school is more about volume than delving into the physics of physiology at a graduate level. The complexity of the math and physics of a PhD in the subject can border on what very few people can abstractly comprehend. Doctors in their daily patient care practice do not regularly delve into this area. That does not mean advances in mathematics and physics cannot be leveraged in medicine and embedded into everyday clinical decision-making by the ACIDS approach. The following example is of a clinician whose patient presents with diabetes, congestive heart failure and emphysema. He is seeing this patient in his office for a follow-up from hospitalisation for congestive heart failure. The patient's hospitalisation occurred after his wife passed away, when he started eating salty and sugary snacks, stopped using his inhaler for his emphysema and took his medication intermittently. His regular visiting nurse had COVID-19 and he had not been visited by anyone since his discharge from the

hospital. He was supposed to have RPM equipment installed in his house, but the system did not have automated alerts. It also relied on the visiting nurse, who had been sick, to check on the patient. The physician is running behind for the day and does not have the time to organise the case, review the discharge notes, check on medication or check the status of the visiting nurse's notes.

As a result, the physician spends most of the visit typing his own notes into a tablet computer without even looking up at the patient. This is a complex patient with diagnostic, treatment and social issues and his treatment requires homework before the patient hits the exam room door. RPM, patient communication tools, integration of hospital discharge summary and visiting nurse and pharmacy alerts are tasks that can be done in the background by clinical decision support systems. These systems can provide recommendations to the clinician at each step of the pre-visit, visit and post-visit follow-up. Documentation into these systems can be built for use by scribes that are specially trained to work with a given physician to optimise the documentation process. This frees the physician to be the *medical decision-maker* by reviewing visit summaries, labs, radiology reports and other pieces of summary data and then drilling down as necessary. As a general internist, he may wish to do a telehealth consult with the cardiologist or endocrinologist. The ACIDS may present him with recent research articles cross-referenced as relevant to this patient's precise clinical conditions and presentation. The clinician will use clinical deductive and inductive reasoning and experience to reach the best conclusions diagnostically and therapeutically. If the clinician functions within a second-generation CIN, then this scenario results in a care process integrated seamlessly with the digital infrastructure, provider network and interaction management resources to optimise the care process.

18.6.10 GHME with Seamless Integration and Interoperability

The Global Healthcare Multi-Platform Ecosystem (GHME) is an environment within which the CIN functions. There are many healthcare platforms today, but no common network-centric architecture that systematically binds them all together into a process, care and two-sided pull economic environment. The CIN may be local, regional, national or global. The GHME will provide the infrastructure to digitally bind providers and patients together at any scale. It will invert the current market completely away from a view of medicine as a local business. The pandemic led to the near absence of volume in a face-to-face setting, thereby forcing the dependence on telehealth and telemedicine. This spawned an explosion of telehealth providers in an already crowded market. Seamless integration and interoperability remain primarily intra-network to an individual vendor and there isn't much inter-network integration and interoperability.

Figure 18.19 demonstrates a hypothetical architecture that blends multiple platforms into a single interoperable ecosystem. At one layer you have the data warehouse layer in the cloud. In another platform, you may have the machine learning

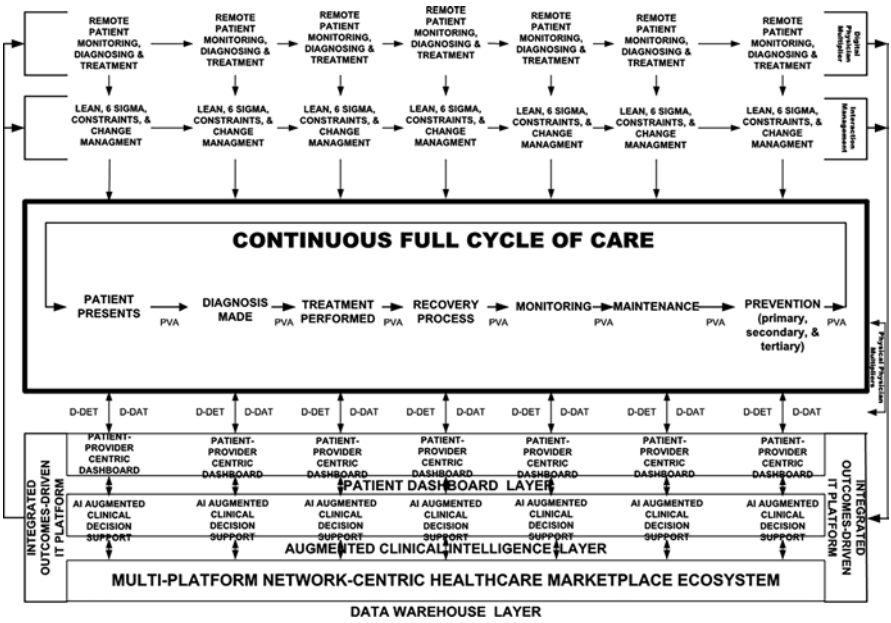

Fig. 18.19 A small slice of the interoperable multi-platform ecosystem, interaction management layer, digital physician multiplier layer and the continuous cycle of care (source: author)

and AI tools from one or more vendors. Another platform may be the EHR vendors that seek to perform some or all of the aforementioned functions and provide a bundled solution. The actual full cycle of care, both inpatient and outpatient, may represent one or more of these EHR vendors. HIEs may function in one or more states in an effort to provide a repository for this disparate patient data. Another platform may help manage the interaction management efforts (e.g. lean, etc.) that seek to optimise the care process. Another platform may manage the RPM and telehealth components that attempt to integrate with some of the EHR vendors. Meaningful use has certainly accelerated this adoption of digital platform solutions. And yet we continue to fax patient information between providers and health systems. Even today, patients continue to start their care encounters by filling out patient histories, signing authorisation forms for procedures and billing in some of the largest health systems and in the largest cities in the United States. The siloed and fragmented care continues and is accompanied by siloed and fragmented platforms. This is digitisation, but not optimisation.

A number of start-ups are seeking to build platforms that meld all these diverse platforms or networks with "patchwork" solutions that will create temporary fixes to fundamentally flawed architecture. The *Office of the National Coordinator for Health Information Technology* (ONC) began to make strides in 2020 towards standardisation and therefore interoperability [37]. However, the vision and path are still not clear. What is clear is that for a given CIN, all the providers must be functioning on a common information multi-platform ecosystem, where interoperability and a

seamless environment are given. Within that environment, the ACIDS system is the keeper of care guidelines for single and multiple diseases, or, in other words, the clinical glue for the network of clinicians. This glue binds not only primary care providers together, but also specialists to primary care providers and specialist to specialist. This is the seamless reference in an operational sense to day-to-day functioning. As CINs become global and compensation mechanisms less geographically constrained, the globalisation of medicine will be accelerated, as well as *value-based global healthcare purchasing*.

18.6.11 GHME Architecture and Security

Earlier, it was mentioned that social media could be a chapter all by itself. The same holds true with security threats to a global healthcare ecosystem. We have all heard stories of hospitals being held hostage by cyber-criminals locking information systems down and demanding ransoms for their release. The healthcare industry is particularly prone to such attacks primarily because it contains so much valuable information [38]. These systems contain medical records, insurance information, financial information, prescription information and other very personal data. What also makes these systems a prime target is all the chinks these systems have in their cyber armour. First, many of these systems are outdated. Second, as such, they lack tight access controls. Third, devices (e.g. laptops, tablets and mobile devices) are appearing everywhere within these systems, thereby creating a sieve in the wall of cybersecurity. Fourth, due to poor protections on email addresses, phishing attacks are prevalent. Fifth, information security awareness is low, and attitudes about security are loose. Therefore, the overall process, no matter how tightly built, is not followed by many key people. The security is only as good as the weakest link, that being people. As a result, security will remain a serious issue in the development of any healthcare platform. EHRs are an enormous development in the pursuit of digitisation. They also remain a major blind spot for security. These systems, unfortunately, do not have the same regulations and standards regarding privacy and security among all vendors. Consequently, security in the evolution of a global healthcare multi-platform ecosystem will have major security and privacy issues along the way of planning, development, implementation and maturation of these systems for the foreseeable future.

18.6.11.1 The Hierarchal Emphasis

The Global Healthcare Multi-Platform Ecosystem, with its embedded Augmented Clinical Intelligence Decision Support system layer, forms the foundation upon which a global CIN will be built. Such a seamless, interoperable system does not exist today. The two-sided E-health market, combined with the COVID-19 pandemic, was the first domino in a market paradigm shift. It has provided the

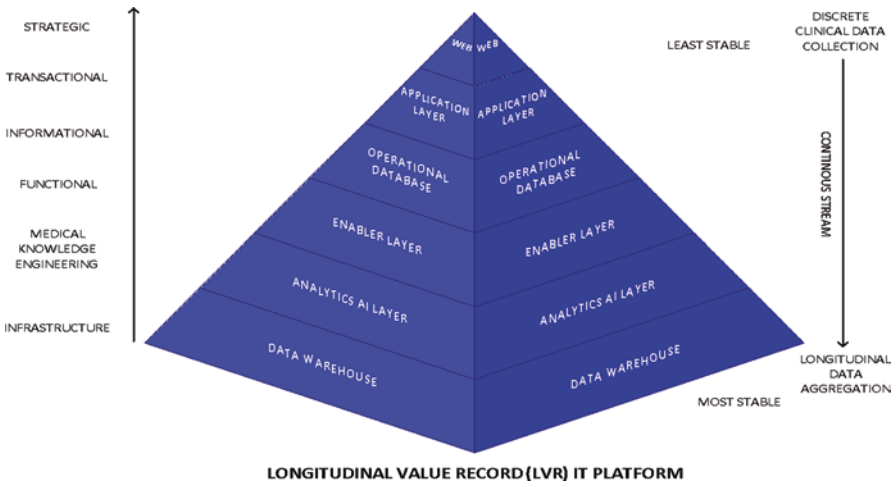

Fig. 18.20 Reciprocal relationship between digital solutions, stability and strategic value in the overall longitudinal information architecture (source: author)

functional impetus for the form to follow. It will be created by the demands of a pull economic setting that was kickstarted by the pandemic. Figure 18.20 illustrates some of the components of that ecosystem that will eventually form a worldwide multi-platform network-centric interoperable ecosystem. It will shape the new infrastructure through iterative change created by disruptive technology companies that have the vision to match patient-centric needs to care workflow products. These products will simultaneously match the needs of the other side of the market, which is the provider. Structured and unstructured data will be reorganised and optimised. As a result, it will then be efficiently utilised by big data structure, artificial intelligence, relational database demands, optimised user interface and the changing nature of human medical information-seeking behaviour in a post-pandemic world. The additional major factor is that all stakeholders' needs and transactions on both the supply and demand side will be quantified. This is the age of Quantitative Medicine. A patient-centric marketplace and the measurement of all the ensuing interactions will be measured and quantitatively analysed. This quantification of care, resulting from precise measurement, will finally lead to a standardised monetisation model of the quantified care outcomes and the dawn of true value-based purchasing.

18.6.12 The GHME and the Globalisation of Healthcare

Standardisation of quantified care outcomes will not belong to one government or be geographically constrained, any more than $E = mc^2$ is one nation's unique equation. Instead, the globalisation of medicine requires the standardisation of

measurement methodologies, the systems to execute those methodologies and the remuneration mechanism to cement such process and system change. The overall marketplace will be made possible by the emergence of a GHME. The CIN can operate globally if the infrastructure enables that geographic functional reach. Financial systems have achieved this for global markets, and medical transactions and operations will follow suit. The technological capacity is there, just not the operational application of that technology. Again, the process must be measured with precision and validity in a way not much functionally different than a financial trade. What's lacking with the emergence of a GHME, unlike the financial markets, are agreed-upon standards that will catalyse interoperability. With interoperability, measurement can become more widespread. The final hurdle will be the movement towards *Quantitative Medicine* (QM). Quantitative Medicine, or "mathematical medicine", will be a new discipline or scientific methodology, by which the care clinical process is translated into a mathematical expression of that process. The care process can then be numerically represented. This numerical representation can be utilised to rate outcomes and compare provider or product performance. Medicine now is liberated from the commodity-based competition. Current high-level comparisons of care outcomes are just crude proxies for a precise measurement of actual care outcomes. These crude provider ratings of today will be replaced by precise mathematically based performance indexing. This then allows the creation of an accurate and fair payment system that spurs a care outcomes meritocracy as well as a value-based purchasing environment.

18.7 Monetisation Transformation

Paying for value is baked into the DNA of most industries, but medicine is not one of them. It is not that payors don't want to pay, especially the government. After all, value-based purchasing is codified in the PPACA. Rather, current systems aren't designed to calculate what that value is. That's because measurement systems can't measure it. You can't pay for what you don't know, so you guess and put aside enough in reserves to make sure you can pay all the claims that are made against those reserves. Also, since you don't really know the value of the service delivered quantitatively, you pay everyone the same amount, like a commodity. Everyone knows what a commodity is, because all commodities (e.g., copper, crude oil, wheat) are the same. Is medicine a service commodity? If it were, then medicine is all just one business, all doctors are equally as competent, they all produce exactly the same outcomes and all patients need and want exactly the same things. If this were true, then paying all providers the exact same amount would make sense. The reality is that this is just not the case. So, what's stopping the industry from transforming into a value-based purchasing marketplace? The answer is Quantitative Medicine (QM) and the structure that supports it.

18.7.1 The Complexity of Healthcare Measurement

The human organism and its multiple physiologic processes are very complex. Measurement of these processes is also an extremely complex task. Therefore, transforming the scientific measurement into a financial calculation is likewise daunting. However, without this transformation, there is no tangible way to calculate the value of a single disease outcome. So, too, there is no real way to compare providers' performance in producing diagnostic and treatment outcomes. This provides a partial explanation for the failure of healthcare to transition to quantitative medicine. There are primarily four main reasons why this transition has not occurred. First, to repeat, medicine is very complex. That complexity is driven by the complexity of individual human physiology, even without the presence of one or more diseases. This complexity is greatly magnified at a population health level. The industry has to have ample motivation to begin to take on the wholesale precise measurement of this complexity and there has not yet been such ample motivation. So, second, there has been no incentive to do so. That has begun to change with the passage of the PPACA. The problem is that the incentives with pilot CMMI programs have not been sufficient. Simply put, the reward to overcome the costs of resources expended in value-based purchasing programs has not been a driver of change. Even the penalties have not been sufficient incentive. Third, even if the rewards are sufficient, there has not been sufficient infrastructure in place to enable the transition to QM. The discussion of measurement points out that the technology is certainly sophisticated enough to enable this transition and is just not being utilised in healthcare to any large extent. That said, the cost of abandoning sunk costs in existing legacy technology implemented post-meaningful use is greater than financial rewards associated with investing in entirely new infrastructure. Fourth, the vision for reassembling those technologies into a new GHME is not clear to a majority of stakeholders, even with sufficient resources to begin that investment in infrastructure. Without the vision, infrastructure, significant incentives and long-haul motivation to tackle the complexity, the QM era will not begin in earnest.

18.7.1.1 The Individual Perspective

The individual patient should by now have accrued more benefits in the post-PPACA era. Having insurance is not a guarantee that you will use it, especially if there is a financial barrier to do so. For example, it is discovered that you need your gallbladder removed due to worsening gastrointestinal symptoms. Previously you did not have insurance, but now you have gone to the healthcare marketplace and purchased a high-deductible policy. The laparoscopic surgery is quoted at $8300, but you have a $5000 deductible health plan and decide to wait. In the meantime, you have an acute attack of cholecystitis that was not initially diagnosed. By the time you're admitted to the hospital, you've developed pancreatitis as a complication and are admitted to the intensive care unit. You survive, but are left with chronic pancreatitis

and a total hospitalisation cost of over $100,000. Just having insurance is not the entire picture if the patient has a high deductible and is underinsured.

18.7.1.2 The Public Health and Population Health Perspective

Penny-wise and pound-foolish applies not only to the vulnerable individual, but also at scale. Insuring populations takes the individual problems and magnifies them for a population. Insurance reserves are that company's way of hedging that risk. The public health perspective is also a population health view from a governmental agency standpoint. So, the insurance company and public health agency both have a population perspective, but with different long-term incentives. The long-term view of a public health department has numerous other variables that make its overall view much broader in scope than the profit-driven population health view of an insurance company. The SARS-CoV-2/COVID-19 pandemic has brought that reality into very clear focus. As a governmental agency, a public health department's scope of responsibilities includes preparing for and responding to an emergency, such as a global pandemic, where the focus is to prevent the spread of disease (e.g. a salmonella outbreak at an egg producer). In addition, the responsibilities include providing adequate infrastructure, promoting healthy communities (including healthy behaviours), assuring health services (e.g. immunisations) and protecting against environmental hazards. As funding had been gradually declining for health departments prior to the pandemic, the monitoring and measurement that goes hand-in-hand with these activities become more challenging [39]. Effective and adequate monetisation of population and public activities have been highlighted as critical during the current global crisis. How we can and need to do that better as a global society has been brought to the forefront.

18.7.1.3 The Research Perspective

The process of producing multiple effective vaccines within a year has been nothing short of remarkable during this global pandemic. The groundwork for this "overnight" success was laid over years of research into mRNA and viral vector technologies [40]. The reality is that vaccines are not huge profit-makers for pharmaceutical companies. Overall, the global vaccine industry, which is research-intensive, was just $24 billion prior to the current pandemic. That number is only 2–3% of the trillion-dollar worldwide pharmaceutical industry [41]. By contrast, the complementary and alternative medicine market, much of which is not well-researched and therefore unproven, is valued at well over $82.27 billion globally in 2020 [42]. Without governments "pre-paying" for COVID-19 vaccine research and development, the world would not be in such an optimistic position today. There have not been a lot of new antibiotics developed in recent years. Antibiotic development also does not have significant financial incentives for the pharmaceutical industry and as a result, many large companies have left that industry [43]. This is, despite the large

uptick in antibiotic resistance, both in the inpatient and outpatient settings. Conducting Phase 1, 2 and 3 studies is an expensive proposition for many reasons, not least of which is that even after billions in investment, a promising drug in early trials may turn out to be unusable and need to be abandoned after later testing. The research industry must undergo a new phase of digital infrastructure development in coordination with the provider community that improves the efficiency of research and ultimately the monetisation of scientific advancement.

18.7.1.4 The Financial Perspective

Medical care, public health and research are all inexorably linked by the ability to finance all these activities. The financing must be cost-effective to produce a positive return on investment for all stakeholders concurrently in the short and long term. These stakeholders include patients, employers, insurers, providers, hospitals and product suppliers. To accomplish this, the market must convert to a value-based monetisation model, also referred to as value-based purchasing. We have already discussed that this means that value-based outcomes have to be measured. The last piece of the puzzle is the transition to quantitative medicine. The mathematical translation of medical care processes from a value-based measurement perspective will transform the financial perspective of the medical industry. This is the next great frontier to be explored and conquered. The GHME will provide the nexus between medicine, mathematics and physics in quantifying medicine. The digital audit trails of the care process that exist today will be considered neophytic and archaic in 10 years. The healthcare industry estimates its costs because no one really knows or is walking the path to calculating the true total costs of the care process.

18.7.2 The Total Cost of Care

The total cost of a service or product is not a complex concept. For example, say you get into an automobile accident. You escaped injury, but your vehicle was not so lucky. You take it to the repair shop and the insurance company sends an estimator. They estimate the total cost of repairs. The body shop accepts that estimate and begins work, or they refute it, line item by line item, in great detail. They know the exact cost of replacement parts and the labour required to complete the repair with those parts. As the work is begun and progresses, it may require additional unforeseen labour or parts. The cost of a healthcare service or product, on the other hand, is a very complex answer to a simple concept. Of course, the human body is much more complex than a car repair. If your "body" gets into an accident and needs body work, you may get some estimates, depending on your insurance. If you don't even have insurance, you may get a "cash" discount. At the end of the day, no one really knows how much all your "body" repairs cost by the end of the care process. In the healthcare industry, it's all just continuous "estimates".

18.7.2.1 Calculation Across the Entire Care Delivery Value Chain

The path to QM goes through calculating the total cost of care, and the path to calculating the total cost of care goes through the measurement of every step of clinical care. That means measurement of every step, irrespective of the care setting. That requires interoperability of measurement systems, which at present are EHRs. The lack of content standards impedes such interoperability and therefore comprehensive and meaningful value-based process measurement [44]. Figure 18.21 demonstrates that everything starts with the continuous care cycle. This cycle is the longitudinal process of a patient's life. It is the embodiment of patient-centricity. Interconnected to the cycle should be the continuous monitoring of a patient's physiologic status. This status is the internal ecosystem of a person's body. Each of the different systems works in a complex interplay to maintain homeostasis. Infectious disease, cancer or trauma can disrupt this intricate interplay of systems. The monitoring systems of yesterday and today are not real-time in that monitoring. As technology dives deeper into the wearable world, this monitoring will detect not only what we have come to know as the usual metrics, but also new metrics yet undiscovered that will detect dysregulation of these systems far in advance of current measurement and detection devices.

This current lack of infrastructure provides a significant barrier to measuring disease and care processes. This makes calculating accurate total costs of care currently incalculable. Without a representation of the longitudinal aggregation of all discrete costs along the value chain of care, outcomes cannot be compared and value for that outcome cannot be assigned. The absence of calculated care values will be an ongoing barrier to effectively and fairly operationalising value-based provider compensation models that have widespread acceptance.

18.7.2.2 Every Value Chain Step Must Add Value

If the GHME were in place and mature, then the focus should be to ensure that the *entire care value chain* is measured. The value chain shown in Fig. 18.21 lines up well with the public health view of the primary, secondary and tertiary prevention diagram discussed previously. The difficulty in practice is not identifying the steps, but rather instituting and maintaining an adequate measurement process. Although there are many quantitative components to the care process in the form of structured data, there is also a large degree of qualitative and unstructured data. Therefore, in measuring the care process value-chain, we are measuring nominal, ordinal, interval and ratio data. For the care measurement process to be adequate, it must produce data that are valid, accurate, reliable and precise. Anyone with experience in the healthcare quality improvement process knows that achieving an adequate measurement process with current infrastructure is challenging for many of the reasons already articulated in this chapter. Therefore, it follows that if the care-value chain process is not well measured, then creating accountability and improvement of the value-creation process is difficult.

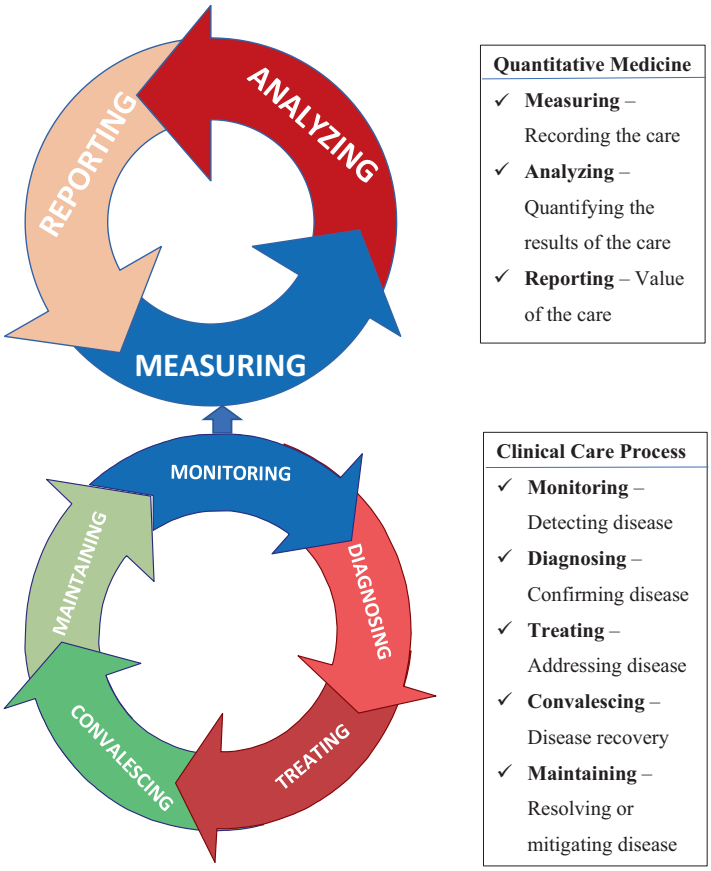

Fig. 18.21 The clinical care process value–chain relationship between patient and provider (Adapted from Appendix B The Care Delivery Value Chain, Delineating Types of Care Delivery Activities, from "Redefining Healthcare" by M.E. Porter & E.O. Teisberg (2006) [product# 7782-HBK]. Republished by permission Harvard Business Publishing)

18.7.2.3 Interconnecting the Care Value Chain to Value Creation and Clinical Care Outcomes Remuneration System (CCORS)

The ultimate question is if we can't adequately measure the process or optimally improve it, how can we pay the top-performing providers fairly and equitably? The answer is that we can't and won't until such infrastructure is in place to adequately measure the value chain, the value creation process, move the provider market away from commodity to a value-based purchasing model and consequently strongly incentivise innovation and improvement around value-based care outcomes. Figure 18.22 illustrates the simultaneous three processes in an ideal value-based care model. That cycle drives the next concentric circle: the continuous caring for an individual longitudinally across their entire life-cycle. At the centre lies an adequate

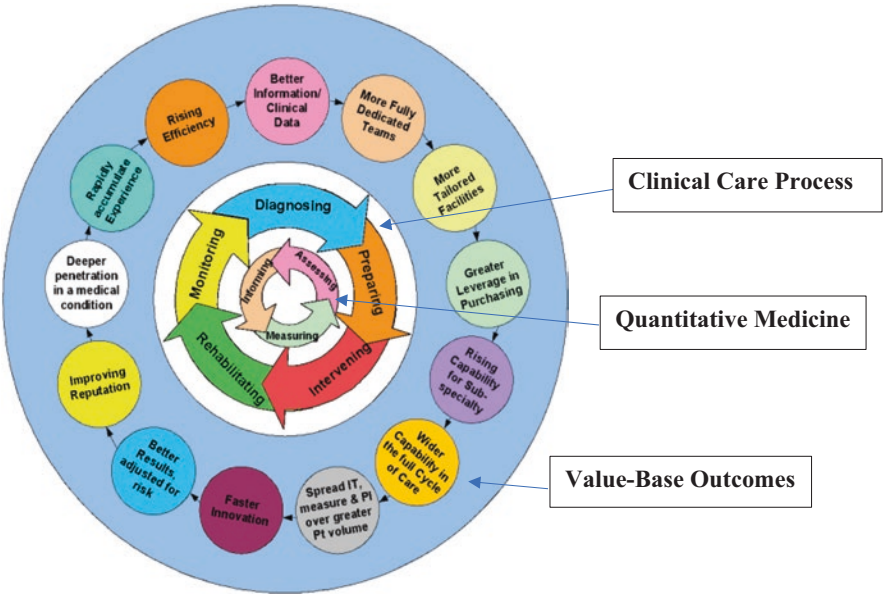

Fig. 18.22 The interrelationship between the clinical care process, quantitative medicine and the resultant value-based care marketplace (Adapted from Appendix B The Care Delivery Value Chain, Delineating Types of Care Delivery Activities, from "Redefining Healthcare" by M.E. Porter & E.O. Teisberg (2006) [product# 7782-HBK]. Republished by permission Harvard Business Publishing)

measurement process. Finally, the outermost circle represents the virtuous marketplace cycle when you aggregate all the individual patients to a population and marketplace level where value-based competition occurs. Such a cycle is well-established in other industries, but for reasons previously outlined, has not emerged as the dominant healthcare model. Value-based competition aligns incentives in the entire marketplace around value. Cost shifting, possible when prices and processes are not transparent, will not happen in a highly measured and performance outcomes-reported market. In this environment, purchasers of care are fully aware of what they are getting for the money. This is especially true in a fully functioning two-sided E-health marketplace. If a hospital or provider has a high infection rate, or worse yet mortality rate, for a given surgical procedure, then why would enlightened patients, employers or governments continue to sanction and purchase that care?

18.7.2.4 The Carrot, Stick or Something Else: The CMS and CMMI Enigma

The answer is that purchasers still haven't figured out a working value-based purchasing alternative. We have alluded to failed or modest CMS pilot outcomes tested by its innovation arm of CMMI [45]. More than 40 pilots later, the U.S. healthcare

market has not figured this out. This is despite carrots (bonus incentives) and sticks (performance penalties). Much has been written about how anaemic the incentives and penalties were. If the incentives are weak, providers largely ignore signing up for such bonus programs because they are more work than they are worth. The same thing goes for the penalties. If, however, the penalties are too harsh, then providers vehemently protest and the resultant uproar crushes such initiatives. The reality of a paradigm shift is in part the size of incentives and penalties, but also the necessary infrastructure to create successful change. There is an argument that substantial incentives and disincentives will spur such change, but only if enough foundational infrastructure is in place to allow successful disruptive innovators to force the market into a value-based paradigm shift.

18.7.2.5 Value-Based Payment Methodology

Measurement infrastructure should be adequate all along the value-creation chain. Figure 18.23 lists the categories to be measured, which of course represent the full cycle of care that involves any stakeholder that influences that care process. As stated, the measurement should be longitudinal. It should cover the entire supply side. It should be present in every setting where the patient receives care. It should, therefore, measure the diagnoses, treatment and speed of treatment for each disease, and, if indicated, for more than one disease in an individual patient.

If the value of the care outcomes is precisely measured, analysed and reported for every provider, then downstream payment methodologies become less relevant. Most of the more recent payment models, such as capitation, act as proxies for a true value-based payment system in action. Since the care measurement process is inadequate, cost becomes the focus. This is because the goal of insurance profit-making is to collect premiums, stockpile reserves, keep operating costs at a minimum and mitigate claim payments as the primary mechanism to preserve reserves. In a commodity-based fee-for-service market, the more a provider does, the more they get paid. The danger is the provider's incentive to push too many services (e.g. blood draws in a cancer patient) on their patients. With capitation, on the other hand,

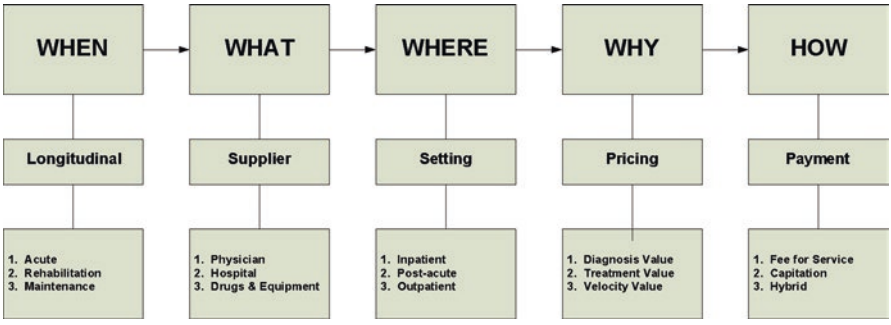

Fig. 18.23 The functional categories of a monetisation model (source: author)

providers are at risk for cost overruns and are therefore incentivised to not push services (e.g. too few blood draws in a cancer patient). If, however, all care outcomes are closely measured, analysed, tracked, reported and compared to ideal guidelines, then payment can be structured in a variety of ways. That is because the payment model is not cost-driven, but rather driven by outcomes that are of the highest measurable value. This is what quantitative medicine will mean.

18.7.2.6 Outcomes, the Total Cost of Care, Pricing and Payment

This brings the argument back full circle to the measurement of outcomes, calculating the total cost of care, creating a premium pricing model and restructuring provider payment accordingly. This also requires the revisiting of diagnosis, treatment and velocity of care. Figure 18.24 diagrammatically illustrates the influence of each of the care process variables on true aggregate costs. Today we can only make guesstimates about what those total costs of care are. This is the pseudo-science of actuarial tables that are probability estimates (guesses) about costs and diseases in populations [46]. These guesses try to predict medical loss ratios and premium price points [47]. Revisiting these three components of the care process also leads us back to the root causes of human error. Assume an ideal world, where the care process is quantified by an adequate measurement system. This digital environment has a measurement system that is valid, accurate, reliable and precise. This measurement system continuously measures the accuracy of diagnosis, treatment and velocity of care. The results are aggregated in time.

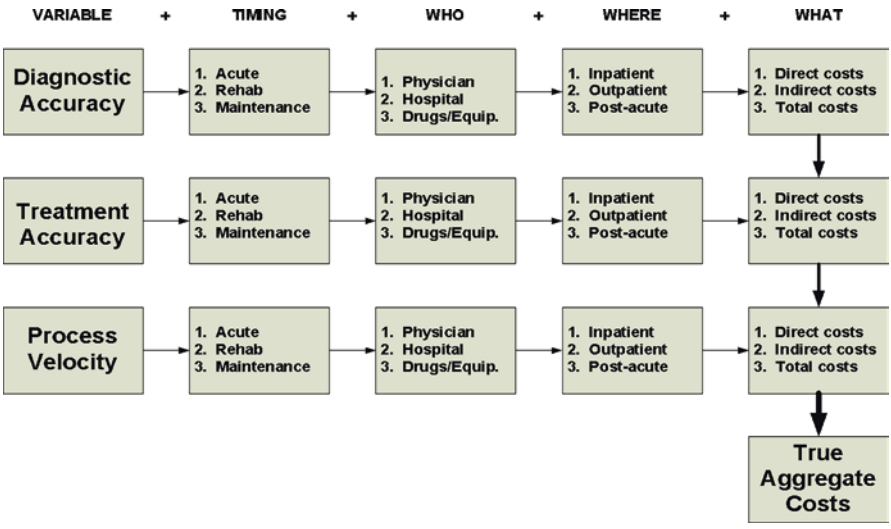

Fig. 18.24 An overview of the complexity in accounting for the total cost of care in relationship to the three variables impacting quality (source: author)

This diagram illustrates how these three variables of the care process are comprehensively tracked to create an audit trail. That audit trail leads to a cost aggregation and total cost calculation representing the quantitative financial component of money invested in caring for a patient or a population by each disease. Note that total costs include not only direct medical costs, but also indirect costs that are often overlooked or never calculated. In the United States, there are four different payor categories of care, which are government (e.g. Medicare, Medicaid), commercial health insurance, workers' compensation and auto insurance. With respect to the impact of indirect costs, take an example of a worker injured on the job. This falls under workers' compensation insurance. The small contributor to costs is the primary treating provider. From a medical cost standpoint, specialists (e.g. orthopaedics), imaging (e.g. MRI) and procedures (e.g. surgery) make up the largest share of medical costs. Lost time and therefore lost wages due to total disability (temporary or permanent) are also a major portion of costs. However, indirect costs in the form of partial disability are major, but often unmeasured costs. For example, an employer runs a ten-person machine shop. One of the workers injures his dominant right arm. He has run a CNC machine for the past 20 years that requires the use of his right arm. He is 10% of the workforce, but his machine represents 30% of the company's revenue. No one else in the company can do his job and training a replacement could take up to a year, provided they can find the right person. This loss of productivity costs the company a significant loss in revenue, and, potentially, a customer. This is an unmeasured indirect cost in healthcare.

18.7.2.7 Costs Flow Directly from Care Outcomes

The total cost of this CNC machine operator is dramatically reduced by high-value care. Taking the example further, let's consider two opposite scenarios with two outcomes and calculate the impact on a company's cost for each. In scenario one, the patient goes to the clinic. The patient is 55 years old. He is diagnosed with a right shoulder strain. He is put on over-the-counter medication and asked to recheck in 2 days. In 2 days, he returns, but is not feeling better and is put on partial restrictions for the use of his right arm. He is told to recheck in a week. In a week, he returns and complains that he feels much worse. The restrictions are continued and he is put in physical therapy for 3 weeks and placed on prescription medication. He returns in 3 weeks and is worse yet. He is told to not use his right arm at all and to continue therapy for another 3 weeks. He returns to find his shoulder "frozen" with limited movement. He is sent to a specialist who performs surgery and the patient is left with a permanent disability, for which he receives a settlement from the company. This scenario equates to hundreds of thousands of dollars of true aggregate costs. In the other scenario, the patient is seen Monday, the day of the injury. The primary care doctor diagnoses a rotator cuff tear, labral tear and biceps tendon tear. The patient is sent for a magnetic resonance angiography (MRA) that confirms this diagnosis the next day. The primary care doctor refers the patient to an orthopaedic surgeon, who does surgery on Friday of that same week. The patient makes a full

recovery with total cost of care at $40,000—a significant savings in both direct and indirect costs. These two scenarios poignantly illustrate how costs flow directly from value-based outcomes, good or bad. The probability calculation of the risk for future similar patients in a population risk pool is much more accurate if the entire care measurement process is adequate, thereby creating a methodology for quantitative medicine.

18.7.2.8 The Journey from Measurement to the Mathematical Representation of Care Outcomes as a Basis for Care Outcomes Performance System (COPS) and Provider Performance Indexing (PPI)

Quantitative medicine will become a field in and of itself that bridges the gap from where medicine is today to the world of a value-based outcomes medical marketplace. As has been outlined, that journey begins with the construction of the first pillars of a GHME. One of those pillars is an EHR with inverted architecture from current offerings. The next generation of EHRs will be designed, built and implemented with an architecture that enables patient-centric care, optimally matches provider clinical workflow, maximises an adequate care measurement process and supplies data to artificial intelligence and machine learning digital tools that can translate clinical care processes into mathematical expressions of value-based care outcomes. These expressions of disease outcomes will form the basis of a Care Outcomes Performance System (COPS). This system will calculate mathematically the actual value of the outcome of care by one or more providers involved in the patient's entire care process. Such measurement and analysis will be both discrete (e.g. a self-limited episode of care such as a surgery) and longitudinal. This system will produce a *provider performance indexing* (PPI) by a single disease or in a patient with multiple comorbidities. With such a system in place, performance between providers and hospitals can be compared. This ushers in the dawn of a true, fair rating of provider performance. These formulas will adjust for concrete factors that directly affect such indexing, such as the severity of illness. Ratings will settle into a standardised comparison that will pass through continuous and multiple iterations of adjustment as they evolve into a de-facto standard for the healthcare industry. As in other industries, such a value-based payment system will promote value by rewarding excellent providers. Patients will benefit in a way and at a scale that they have not before. Excellent providers will draw more market share to them. As with the previous case example, as care quality improves, errors are reduced, rework declines and costs go down. Low-value providers will fall out of the market. Providers will seek to differentiate themselves from other competitors as the old commodity structure melts away. The two-sided E-health market will exponentially increase, fuelled by disruptive innovation and asymmetric competition. Customers will pull more and more value to them as their needs are more carefully assessed and met by providers. All of this is catalysed by a value-based quantitative medicine driven by the "New Math" of healthcare.

18.7.2.9 The Emergence of the "New Math" of Value-Based Reimbursement

Quantitative medicine is by definition *mathematically* based. Everything in the environment around us can be represented by mathematics and physics, provided the discoveries of those processes have been made. Medicine has lagged behind other disciplines and industries. In 1970, per capita spending was $363 per person. In 2019, that number had risen to $11,582 [48]. As a result of the social distancing and delay or cancellation of elective services necessitated by the SARS-CoV-2/COVID-19 pandemic, there was a historic decrease in health services spending. The issue of access again came into play, but just not due to inadequate supply, lack of health insurance or self-rationing due to high out-of-pocket costs. As we emerge from this global pandemic, digital health has gotten a jump-start to a new level, due to access issues. This will, in fact, be a rapid segue into the GHME, depending on whether digital healthcare providers recognise and seize the shift. If they see it as a way to change care, through a measurement and remuneration paradigm shift, then change will be rapid. If, however, vendors merely see this as an extension of the current commodity-based market and do not advance products and services to a value-based methodology [49], then the rate of change will plateau or even stagnate. Wall Street is obsessed with providing data with a competitive advantage and competitive promotion to drive investment activity. That advantage drives spending on technology that buys transactional processing speed. These investments in technology are at least 10 years further along than in healthcare. "Machine" trading driven by artificial intelligence and machine learning can be co-opted to the healthcare industry. These digital tools will power the "New Math" of quantitative medicine. This new math will become the field of Quantitative Medical Mathematics (QMM). QMM is required to power a reliable calculation of the value of care outcomes. These calculations will enable the development of new value-based care outcome remuneration. This will trigger tangible, reproducible and sustainable value-based reimbursement. In a market where incentives for all stakeholders are aligned around standardised value, value-based competition will finally, in a real sense, cut the chains of commodity-based reimbursement. Once free, the two-sided E-health market will lead to global competition for patients and, thus, the globalisation of healthcare.

18.8 Conclusion

1. The U.S. Healthcare System is pricing itself out of the market of the average patient, leading to reduced access and self-rationing of care.
2. Value-Based Healthcare has been the law of the land since the passage of the PPACA in 2010, but the *major barrier* is that there isn't the necessary *infrastructure* to deploy value-based purchasing programs.

3. Current legacy infrastructure serves as a barrier to the widespread adoption of a *quantitative medicine* approach to transformation.
4. To *facilitate* a global healthcare transformation, the form must follow function and the functional goal is a patient-centric healthcare system supported by the transformation of the three M's of *Medicine, Measurement* and *Monetisation*.
5. *Quantitative Medicine* will *facilitate* the transformation of medical care, measurement and monetisation.
6. The three M's are linked to the three R's of *Record* medical care, *Report* the results of that measurement and *Reward* by monetising value-based care outcomes that create a marketplace meritocracy.
7. *Medicine* requires clinical care transformation, which in turn requires the structure of a CIN to reorganise providers and their care process around the patient and value-based outcomes utilising a *quantitative medicine* approach and advanced digital measurement tools.
8. *Measurement* transformation requires the structure of a healthcare platform ecosystem that is seamlessly interoperable for all stakeholders and functions through the lens of *quantitative medicine* to measure, analyse, index and report value-based care outcomes by disease.
9. *Monetisation* transformation requires the structure of disruptive innovative payment mechanisms that are enabled by the cutting-edge technology of the platform ecosystem to utilise a *quantitative medicine* approach optimised by digital measurement tools.
10. Finally, it is necessary that the Medicine (CIN), Measurement (Platform Ecosystem) [50] and Monetisation (Value-Based Purchasing Systems) be deployed as separate, but combined parts of a single larger *quantitative medicine* system that works in unison to facilitate and transform the delivery of healthcare to individuals and populations.

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Chapter 19
The Internet Hospital in the Time of COVID-19: An Example from China

Jianqiu Kou, Zhengzhong Yan, and Nilmini Wickramasinghe

19.1 Introduction

With the spread of COVID-19 across the world, many countries are currently experiencing cases of respiratory disease, severe pneumonia and even death caused by the outbreak of this virus [1]. Since the sudden outburst of COVID-19, the original off-line medical treatment model has been threatened, and a great deal of demand for remote medical treatment has emerged. On 4th February 2020, the National Health Commission of China issued the "Notice regarding the high quality delivery of Internet diagnosis and consultancy services in the prevention and control of the pandemic", which encouraged the adoption of information technology to assist the COVID-19 epidemic research and diagnosis [2]. The support role of telemedicine in terms of strengthening data collection and analysis, innovative diagnosis and treatment models, and improving service efficiency had been strengthened [2]. Furthermore, more attention should be paid to the regulation and security issues in promoting Internet treatment and consultation. Many hospitals were also actively engaged in the Internet hospital diagnosis and treatment business and have achieved certain benefits. In the prevention and control of COVID-19, Internet hospitals showed unique advantages in maximising the use of medical resources, reducing the gathering of people and avoiding cross-infection. Its construction, transformation and application are of great significance for public health [3].

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19.2 Background

In recent years, the Internet hospital as an emerging innovation delivering outpatient service has been developed rapidly in China [4]. Internet hospitals were launched in 2013 and there were already 68 Internet hospitals by March 2017 in China [5]. The Internet hospital model has the potential to improve the quality and accessibility of medical services [6]. On the other hand, many Internet hospitals were not mature and there were also some problems such as the scarcity of online doctors, medical quality supervision and medical insurance coverage [5].

19.2.1 The Contents of Internet Hospital

"Internet + medical" refers to the integration of the traditional medical industry and the new generation of information technologies represented by the Internet, cloud computing, Internet of Things (IoT) and Artificial Intelligence (AI) [7]. This formed a new service format to improve the innovation ability and efficiency of the medical industry [7]. The Internet hospital is a kind of medical service model which is based on the Internet platform [5]. It can provide online medical consultation, electronic medical records, online prescription, medicine delivery, medical assessment, remote rehabilitation, medical education and health information [5].

In China, with the popularisation of the Internet and the smartphone, the Internet hospital model is a kind of emerging innovation to provide a convenient medical solution to overcome physical obstacles and time limitations [4, 5]. Some Internet hospitals were operated by Internet companies and pharmaceutical supply companies, whereas some Internet hospitals were operated by traditional physical hospitals [5]. From the perspective of patients, they have a high degree of satisfaction with Internet hospitals because of the convenience, low cost and free choice to clinicians [4].

19.2.2 Related New Technology

Some emerging technologies such as the Internet of things, cloud computing technology, Big Data, 5G Communication Technology and Artificial Intelligence are in the application or trial stage for the construction of Internet hospitals [7]. From the perspective of medical institutions, the application of Internet of Things is very important to hospital informatisation construction. Through the scientific use of the Internet of Things technology, some of the innovations of hospital management and clinical treatment mode can be realised. For example, there were some innovative attempts in clinical assessment and nursing care management adopting the Internet of Things technology [8]. As an emerging technology, cloud computing technology

can realise the flexible deployment that cannot be realised in traditional hospital information systems. In the process of constructing the Internet hospital, cloud computing technology is used to improve service efficiency so as to enable patients to acquire high-quality and convenient medical services [9]. Big data is a fast and diverse mass information asset that requires cost-effective and innovative forms of information processing to enhance insight and decision-making and has shown its significance in the healthcare field [10]. 5G refers to the fifth generation of mobile communication technology. It is an extension of 4G and also the latest generation of cellular mobile communication technology [11]. With features such as high speed, large broadband and low delay, 5G will bring great changes to medical treatment [11]. Artificial Intelligence (AI) is a branch of information technology that intends to imitator human thought and learning processes as well as information storage processes. Artificial intelligence also has the possibility to improve medical quality [12].

19.3 An Example of an Internet Hospital Case Against COVID-19

In the situation of the global spread of COVID-19, people turn to Internet hospitals to solve their health issues. This section demonstrates the application of Internet hospitals against COVID-19 with a case example. The selection of the case study was based on the objective of this research which is to explore the research question: *How can Internet hospitals be used in response to COVID-19 and their effectiveness?* The selected case is the Internet hospital of Jiangsu Province Hospital of Chinese Medicine which has the largest number of cases of Internet diagnosis and treatment in Jiangsu Province by May 2020.

19.3.1 The Case Hospital

The case study for the application of the Internet hospital was launched in Jiangsu Province Hospital of Chinese Medicine (Affiliated Hospital of the Nanjing University of Chinese Medicine). This hospital was founded in 1954 and is a well-known, large-scale, first-class comprehensive hospital of traditional Chinese medicine in China. This hospital is the National Clinical Base of Traditional Chinese Medicine and the International Training Center of Acupuncture and Moxibustion. There are 58 clinical wards and 2500 beds for inpatients. In 2019, the number of outpatient visits had exceeded 5.85 million, ranking seventh among all the hospitals in China.

The difficulties and problems encountered in the daily operation of the hospital forced the hospital management to seek new ways of development. The first

problem was to resolve the contradiction between the large amount of outpatient service and the relatively inadequate service capacity. The outpatient volume of the hospital was very large, and the outpatient building has been used for nearly 20 years, which is far from matching the huge outpatient volume in terms of physical conditions. Therefore, it was necessary to provide online channels to expand time and space and improve the patient experience. The second problem was the contradiction between the scarcity of high-quality medical resources and the increasing demand. In recent years, hospitals have established the medical consortium, and all the member units of the medical consortium have a great demand for grassroots services provided by skilled experts. However, the resources of experts were very limited, so the hospital hoped to build a platform. Therefore, medical resources can be effectively allocated to the real needs through the platform to alleviate the imbalance of resources to a certain extent.

19.3.2 The Construction of the Internet Hospital

Based on the physical hospital and with the adoption of Internet technology and the mode of "Internet + medical treatment", the Internet Hospital of Jiangsu Provincial Hospital of Chinese Medicine has built a service platform combining off-line and online. The Internet hospital was launched in August 2017, and now patients can receive online consultation, online prescription, online payment, medicine delivery and other services through the Internet hospital with their computers or smartphones.

The functional modules of the Internet hospital of Jiangsu Provincial Hospital of Chinese Medicine included platform service, outpatient process optimisation, online consultation, management service, outreach service and other modules. According to different application scenarios, the web, WeChat and APP versions were provided. According to the roles of users, versions for patient, doctor and management were provided. The function design diagram is shown in Fig. 19.1.

The optimisation of the outpatient process fully integrated online and off-line processes and minimised the invalid waiting time of the patients while improving patient satisfaction. Before the patients see a doctor, they will make an appointment through various online channels and then come to the hospital at the scheduled time. After the medical treatment, the patient can pay directly online. Afterwards, the patient has the option of medicine home delivery and the medical examination report can be checked through the mobile phone.

The online consultation module realised the remote diagnosis and treatment for patients. A doctor communicates with the patient via the online video at the appointed time. The doctor may prescribe medicine for the patient and the medicine can be delivered to the patient's home. If the patient needs further examination, the system can make an appointment automatically, so the patient can go to the hospital for examination at the appointed time. This function saves substantial time for patients and improves patient satisfaction. The whole process of online consultation is shown in Fig. 19.2.

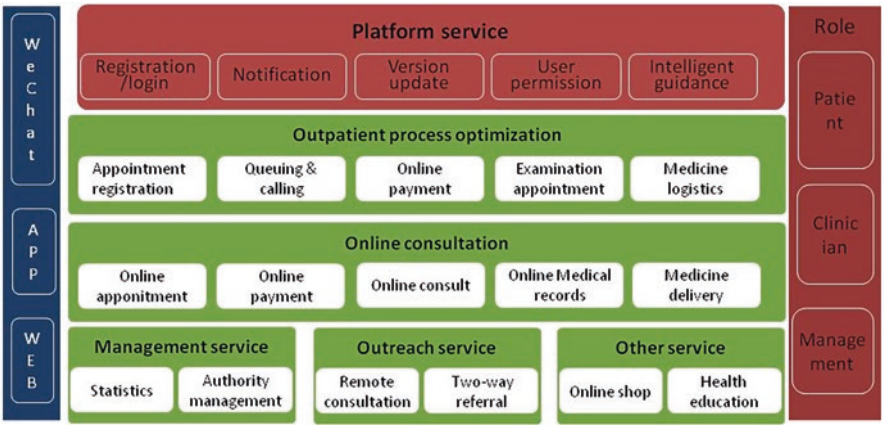

Fig. 19.1 Function design diagram of the Internet hospital

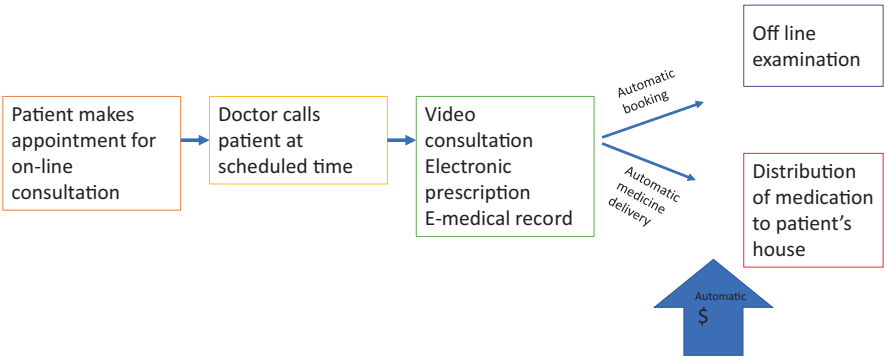

Fig. 19.2 The process of online consultation

Remote consultation for medical institutions included domestic and international consultation. In China, remote consultation is mainly aimed at community hospitals, assistance hospitals and cooperative hospitals. International remote consultation is one of the highlights of the Internet Hospital of Jiangsu Provincial Hospital of Chinese Medicine. By the end of 2019, the hospital had launched remote consultation cooperation with TCM clinics in nearly 20 countries, including Switzerland, Australia and the United Kingdom.

19.3.3 Applications Against COVID-19

This Internet hospital has played a major role in the COVID-19 prevention and control. Clinicians cooperated with the frontline medical teams in Hubei Province and carried out academic exchanges with medical professionals overseas through

the Internet hospital platform. Many patients with chronic illnesses had received medical consultation and medicine delivery through online consultation.

Affected by COVID-19, the medical consultation and medication for patients with chronic diseases had become a serious problem. In February 2020, at the early stage of the outbreak of COVID-19, Professor Wu, the vice president of Jiangsu Provincial Hospital of Chinese Medicine said:

> *The epidemic in Nanjing, Jiangsu province is not very serious. Therefore, in addition to focusing on the diagnosis and treatment for COVID-19 patients, it is important to pay more attention to the treatment and medication of patients with chronic diseases. After all, there are a large number of patients with chronic diseases. They cannot go to the hospital because of the epidemic, so it is urgent to consider how to solve their actual difficulties and ensure their health.*

Jiangsu Province Hospital of Chinese Medicine had taken many measures to increase the service capacity and quality of online consultation. First of all, more skilled doctors were arranged for online treatment every day to meet the needs of patients. Second, the procedure of online consultation had been optimised continuously, including the express delivery of substitutes of traditional Chinese medicine, online payment for health insurance, electronic invoices and online medical record inquiry. All these actions had improved the satisfaction and experience of patients with online consultation. Meanwhile, the number of patients treated through online consultation per day had already surpassed 300 while the number was only around 50 in 2019.

19.4 Discussion and Conclusion

The Internet hospital is developing rapidly and will provide more intelligent functions such as big data analysis, artificial intelligence application and precision medical service in the future [5]. This innovative mode has shown its significance for public health especially during the period of COVID-19 pandemic. Internet hospitals in China provide examples for other countries to follow. On the other hand, the Internet hospital mode is not mature at this stage and there are still a lot of issues needed to be resolved. Medical quality supervision and medical insurance coverage are all problems that need the government to offer a solution. For the patients, they need to familiarise themselves with making appointments before medical consultations. In addition to this, due to the scarcity of skilled doctors, the question of balancing doctors' workload and patients' needs also should be paid attention to [13].

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Epilogue

Our book has served to present a miscellany of papers that focus on notable examples of utilising, incorporating, designing and conceptualising roles for technology to enable and support superior healthcare delivery and wellness management. The rapid pace of the advancements in technology is exciting and a hallmark of this decade and century. Never more than now has healthcare delivery needed to draw upon these developments to provide high-fidelity, high-quality and high-value care to all. The recent COVID-19 pandemic has served to highlight for us all how fragile, dynamic and uncertain our healthcare systems can be. However, our digital health solutions hold the promise and potential for a better tomorrow.

Clearly, this is still a very nascent domain and many issues around health literacy, policy, privacy and security, not to mention the direct and subtle as well as far-reaching implications for the various stakeholders (patients, clinicians, healthcare organisations, regulators, payers and the community at large), are yet to be fully understood or identified. Moreover, it is impossible, in one book, to capture all activities even slightly, let alone unpack critical issues in depth. We do hope, however, that this volume serves as a catalyst to ignite and inspire more thinking, research and focus as well as funding to support key initiatives in digital health from idea to realisation.

These are challenging times as we come out of the COVID-19 pandemic and begin to operate in a new normal. None of us know with certainty what the future will hold, but it is safe to suggest that technology will play a central role, and digital health holds many possibilities, often only limited by our imagination, for delivering high-value, patient-centred quality care for all. The future is, thus, both exciting and challenging. We can participate to ensure that superior technology solutions can

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provide high-value, patient-centred quality care. We trust that on the completion of this book, researchers, scholars, practitioners, consultants and the general public will all have a better understanding of how the technologies of the Internet of Things (IoT) can be harnessed to provide superior healthcare delivery and wellness management and will rise to the challenge of starting to build a better health and wellness environment for tomorrow, today.

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