Praise for
The Future of Healthcare Transforming with Technology

"A comprehensive guide useful to all healthcare professionals who would like to understand the changing landscape of technology in the healthcare sector and its role in making healthcare more affordable and accessible."

– **Dr. R. S. Sharma, Chief Executive Officer, National Health Authority (NHA)**

"The interface of technology and the human touch has become the new normal across all healthcare practices. There is a compelling need for a scholarly reference which not only sheds light on the fundamentals of technology adoption, but also provides a comprehensive repository of constructive solutions. In this background, this book on technology and the health sector […] fills the requirements."

– **Dr. M. K. Ramesh, Vice-Chancellor, Rajiv Gandhi University of Health Sciences (RGUHS)**

"The book provides a great perspective of one of the most significant shifts happening around us – technology has evolved to create new models of healthcare that will radically change the model of care to a personalised, predictive and lifecycle engagement, rather than just treatment of episodic issues. The implications of technology in enhancing lives and reducing costs of care would be profound – the authors do a brilliant job in showcasing how multiple changes have come together to create the perfect flywheel – accelerated by the pandemic. Whether a hospital, insurance company, government or a corporation – each stakeholder is re-imagining how they engage with patients, and the future will probably be here sooner than we imagine!"

Mr. Prashant Tandon, CEO, Tata 1MG

"The use of technology in healthcare has not only raised the bar of patient safety, but also made healthcare cheaper, faster, accurate, more precise and within the reach of individuals. The benefits of adopting technology are ample – from improving patient care and experiences, to real-time information exchange, to flexibility for patients and clinicians. The way forward is to generate awareness of the latest developments on technology, embrace it effectively and reap the benefits."

– **Dr. Abhijat Sheth, President, National Board of Examinations (NBE)**

"In the digital era, successful technology integration into the healthcare industry will be entirely transformational. Encompassing technology with healthcare will augment treating illness, supporting health, creating efficiency and ensuring easier access at an affordable cost. This book will provide readers with a deep look at making the most of technology while also laying the groundwork for a redesigned healthcare industry."

Prof. (Dr.) Mahesh Verma, Chairman,
National Accreditation Board of Hospitals and Healthcare Providers (NABH)

"The use of modern technology such as telemedicine, AI, IoMT, nanotechnology, digital technology, drones and robotics, etc., is transforming healthcare delivery the world over. This book is an excellent effort to encapsulate all that one needs to know about the symbiotic relationship between technology and medicine and its immense potential in aiding and augmenting delivery of comprehensive healthcare to the population. The book, through its nineteen well-chosen chapters, is illuminating and impactful. A must-read for all medical professionals!"

– **Air Vice Marshal (Dr.) Sadhna S. Nair, VSM, Principal Medical Officer,**
Headquarters Training Command, Indian Air Force (IAF)

"Healthcare is likely to look very different in the future thanks to wide-ranging developments in technology. This book brings together an impressive group of authors to identify and explain the myriad ways in which this transformation will happen. Particularly distinctive is the range of technologies covered and their grounding in the Indian regulatory and policy context. This should be of great interest to healthcare professionals, students and policy-makers."

– **Rishikesha T. Krishnan, Ram Charan Chair Professor in Innovation and**
Leadership, Director, Indian Institute of Management, Bangalore

The Future of Healthcare Transforming with Technology

Edited by

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FOREWORD

We expect the healthcare industry to provide accessible, affordable, efficient and effective solutions to disease management. It is my belief that technology is an important enabler to deliver on these expectations. For example, the pandemic was a stark background against which the convenience of telemedicine took off, highlighting how technology can improve accessibility. It can transform our health systems into sustainable ones, accessible to all 1.4 billion Indians.

Many healthcare professionals see technology advancing extremely fast to the point where automation can replace human doctors, nurses and allied health workers. Who would say "no" to a robotic surgery, performed with technological precision to the nth degree and no space for human fallibility? On the other hand, what about the oft-quoted "human touch"? Both have their pros and cons, but I believe in a future with a combination of the two for the best healthcare.

Providing a range of lenses through which the utility of technology can be viewed in the health sector, this book delivers a health sector-focused comprehensive introduction to the world of technology, starting with the basics and moving onto the emergence of digital health platforms. In many cases, it goes beyond a mere introduction, transporting the reader to an exciting sphere of innovation that takes healthcare, healthcare delivery and health systems to new heights. The book also explores the profound effects of technology in its supportive role such as in hospital administration, big data analytics and smart healthcare to drive rapid change in the efficiency and effectiveness in the health sector. The sheer range of just what is possible in healthcare with technology is quite mind-blowing, with Artificial Intelligence, Virtual and Augmented Reality, Internet of Things, robotics and nanotechnology being just a few of the futuristic applications being covered in this book.

The inexorable march of technology will continue apace, and we cannot be left behind. Our healthcare professionals need to become familiar with

all these emerging technologies in order to stay relevant and enable the benefit to trickle down to the ultimate beneficiary – the patient. *The Future of Healthcare: Transforming with Technology* is an excellent survey of the direction the industry is taking.

It is my pleasure to pen the foreword for this publication, and I wish the editors all the best in their aim of preparing the health workforce for the transformation into the future of healthcare.

Mr. Kris Gopalakrishnan
Chairman, Axilor Ventures
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Dr. Alexander Thomas is the President of the Association of Healthcare Providers - India (AHPI), former President of the Association of National Board Accredited Institutions (ANBAI), and Founder-President and Patron of the Consortium of Accredited Healthcare Organisations (CAHO). He has effected far-reaching policy changes within the healthcare landscape at the national and the State level, pioneered numerous training initiatives, and received several awards for his contributions to the healthcare sector. His recent publications include books on communication, climate change, ethics and law, healthcare quality and white papers submitted to the Government of India.



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PREFACE

In today's world, technology plays a big role in our daily lives, including our consumption of healthcare. We are in an exciting new era where the advances being made in digital healthcare technologies and breakthrough innovations have the potential to improve the quality of healthcare while drastically reducing costs. Healthcare workers need to embrace these emerging technologies in order to stay relevant and achieve the dream of cheaper, faster and more effective healthcare solutions.

This book aims to empower healthcare workers by spreading awareness of this subject in the health sector. The contributors to this book have given their time and effort *pro bono,* and the book will be available online on an open access platform, free for anyone to download and read. The royalties from the print version will go to the Association of Healthcare Providers – India (AHPI) towards activities promoting awareness of technology in the health sector.

The process of putting together this book has been a valuable experience in itself. It has been a privilege to connect with the distinguished contributors, each of them experts in their own area of technology, and have them transfer their expertise onto paper for the benefit of colleagues in the health sector. As chief editor, it is my honour to thank each of them for contributing their knowledge and time to this project despite their busy schedules.

A complete list of chapter authors is presented on the next page, with their brief profiles available at the end of the book.

I would also like to record my deep appreciation for the valuable feedback and insightful comments provided by experts during our three-stage review process. The list of external reviewers is presented in the following pages.

I am indebted to **Mr. Kris Gopalakrishnan** for his thought-provoking foreword that skillfully captures the need for our nation's healthcare workers to take advantage of technology to deliver care.

This publication has been made available on an open-access platform thanks to the generous benefaction of **Mr. Sameer Mehta** of the **Mehta Medical Trust** (the charitable arm of Dr. Mehta's Hospitals) and the

Institute of Future Science (a think tank focused on enabling humankind to develop a safe, satisfactory and sustainable future).

Finally, I would like to thank my co-editors for the roles they played in developing this book in addition to contributing chapters in their areas of expertise. I am grateful to **Prof. S. Raghunath** and **Dr. Sandeep Bhalla** for laying the foundation by connecting me with many technology experts, evolving the structure of the book, and providing their valuable insight in bringing the manuscript together. My grateful thanks to **Ms. Divya Alexander**, who has been the centre of responsibility and operations, and the main architect of this project. I also thank **Dr. V. C. Shanmuganandan, Dr. Haresh Chandwani, Mr. Antony George and my colleagues in AHPI** for their support. The striking cover of the book was designed by **Mr. Yathish L. Shettigar**.

It was a pleasure working with our publishers, **Indus Publishers and ThinkMines Media**, and we are grateful to them for making the road to publication so smooth.

It is our hope that this book will present the power of technology as an asset in the quest to make quality healthcare accessible and affordable to all.

Dr. Alexander Thomas
Chief Editor

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On behalf of my co-editors, I would like to place on record our deep appreciation and grateful thanks to each of the contributing chapter authors and the domain experts who reviewed the manuscript. Their brief profiles are available at the end of the book.

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Section 1

AN INTRODUCTION TO HEALTHCARE TECHNOLOGY

Chapter 1

BUILDING BLOCKS: THE BASIC CONCEPTS OF HEALTHCARE TECHNOLOGY

Sandeep Bhalla and Haresh Chandwani

Introduction

Healthcare technology can be described as any software or IT tools designed to give new dimensions to medicine and treatments, enhance hospital and administrative productivity or improve overall quality of care provided. Health technology is defined by the World Health Organization as the "application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures, and systems developed to solve a health problem and improve quality of life." (WHO, 2007).

Healthcare is being driven by technology and will continue to be so for the foreseeable future. Healthcare has changed dramatically because of technological innovations and developments (Thimbleby, 2013), which include medical devices, IT systems, Artificial Intelligence (AI), cloud and blockchain and algorithms designed to support healthcare organisations, among others. The phrase "healthcare technology" commonly refers to the use of technologies developed for the purpose of improving any and all aspects of the healthcare system.

The goal of this chapter is to help readers understand the basic concepts of health technology. This chapter will

- Describe the importance of technology in healthcare and explain its basic concepts.
- Examine the benefits and applications of technology in healthcare.
- Provide an overview of the field of digital medicine, and explore how applications and digital therapeutics can bridge the gaps in healthcare.

The Importance of Technology in Healthcare

Many innovations have been developed in medicine over the last few decades. However, only a few have had the impact that is as comprehensive and far-reaching as digital technology.

Advances in computers and networks have increased treatment options and helped clinicians perform their jobs better.

Computer usage started to become popular in the 1960s, although they were initially too unreliable and expensive to be of much use for medical practice. As technology started to evolve, it led to cost reduction, standardization of data and formulation of policies, which led to the widespread use of technology in healthcare. Healthcare organizations were encouraged to adopt newer and innovative technologies for day-to-day practices such as record keeping and care delivery. Paper based medical records were digitized and converted to electronic health records, making health data much more accessible, easier, efficient and secure. It has now become standard practice to use electronic health records and other technologies when it comes to engaging with patients and creating treatment plans. Computers, mobiles, tablets and laptops have become just as common as stethoscopes. The biggest challenge with EHR is the large amount of unintegrated and unstandardised data that are accumulated. Healthcare organizations can use these large amount of data to improve practices and procedures, but may not yet have the tools to use it optimally and critically. The newer technologies based on machine learning such as Cloud, AI, block chain can help healthcare organizations to unravel the insights and patterns of data (IMB, undated).

As the health sector faces new challenges, technology solutions are emerging to help healthcare leaders improve performance across systems and manage costs. Healthcare technology streamlines the processes, improves the workflows and automates tasks at a pace that is not possible for humans alone. The providers of health systems and hospitals are therefore embracing the value addition of systems to improve patient care, reduce burnout and create better experiences for patients.

Basic Concepts in Health Technology

AI technology in healthcare: The incorporation of AI in healthcare can uncover insights from large collections of healthcare data for clinical decisions. It is impossible to analyse the accumulated data of healthcare organisations without AI. AI-enabled tools are useful in guiding treatment plans for various medical conditions by analysing large and complex data generated from various devices (*ibid.*).

Blockchain in healthcare: Blockchain technology offers the healthcare industry a user-centred experience where health information can be securely gathered, shared and verified along with clear functioning and structuring across diverse healthcare systems (*ibid.*). In healthcare, blockchain could serve as a substitute for traditionally distributed database management systems, which have generally been client-server databases with structured query language or relational input.

Cloud computing in healthcare: The concept of cloud technology is perceived by most people as nothing more than a storage place. Yet, the cloud does more than just provide data storage. It offers potential for automation and customisation of how data moves through the system. More security features are offered by hybrid cloud environments which aids organisations in maintaining HIPAA compliance and other regulations while giving them pliability if data need to be moved (*ibid.*).

Telehealth technology: During the pandemic, many healthcare providers started offering telehealth consultations, with the option of making healthcare appointments and paying for them online. Due to the convenience and flexibility of telemedicine, many choose to use it even after the pandemic, especially those patients who reside in remote locations, by using mobile or computer applications (*ibid.*).

Driving interoperability through technology: Interoperability refers to the potential for the seamless exchange of data across organisations and systems. This is crucial for driving the digital transformation of the healthcare industry. It creates advantages for providers and patients by making data uncomplicated and accessible without compromising privacy or security. Clinicians can work more efficiently as interoperability saves time used in accessing the data. Moreover, the cost of care can be decreased by reducing the number of repeated or unnecessary tests and helping clinicians to arrive at diagnoses at the earliest (*ibid.*).

3D printing: 3D printing refers to the automated process of building certain objects with the use of specialised software programs, machines and materials. It is used in prostheses, novel drug formulations, medical implants and bioprinting of human tissues and organs. Additionally, 3D printing also offers the advantages of more competent, customisable designs which are both cost-effective and time-effective. It allows medical companies to produce prototypes created with artificial tissue to practice before an operation.

There are also technologies and tests that are screened which in turn are used for diagnosis. For instance, using a test on a patient with a high likelihood of testing positive for a particular condition, is greatly affected by whether that test was used for diagnosing symptomatic patients or for screening asympomatic patients. Technologies are used for diagnosis and treatment as well; for example, coronary angiography is performed to guide percutaneous coronary interventions and technology is also used to diagnose heart disease. To restore normal heart rhythms electrical pulses are delivered and through implantable cardioverter defibrillators, life-threatening heart arrhythmias are detected. These technological purposes are supported through electronic health record systems (Goodman, 2014).

There are certain "hybrid" or "combination" technologies which combine major categories of technology devices with characteristics of drugs, for example: local drug delivery technologies (e.g., drug patches, drug inhalers, antibiotic bone cement, implantable drug pumps, and drug-eluting coronary artery stents); photodynamic therapy where laser-activated drugs are used (e.g., for targeted destruction of cancer cells); bioartificial organs and spermicidal condoms that combine natural tissues and artificial components, etc. There are also certain hybrid technologies that require complicated regulatory approvals. These test-drug combinations require clinical trials to test both clinical utility and safety and efficacy of the drugs (*ibid.*).

A certain technology may be used for investigating certain indications, established for some, and abandoned or outmoded for others, such as autologous bone marrow transplantation with high-dose chemotherapy for certain types of cancers. Once considered to be an outdaed technology, it might come back into use for a better defined or entirely different clinical purpose. At times, after their initial compliance into general practice, many technologies might undergo multiple step-by-step innovations (*ibid.*).

Digital technologies were used in a big way to support public health responses to COVID-19 worldwide, including case identification, contact tracing, population surveillance, and evaluation of interventions on the basis of mobility data and communication with the public. These rapid responses leverage billions of large online datasets, mobile phones, connected devices, relatively low-cost computing resources and advances in machine learning and natural language processing.

Connected care is defined as quality healthcare that is personalised and accessed through technology. It is the real-time, electronic communication between a patient and a healthcare provider (Talking Health Tech, 2020).

Some examples of connected care are remote patient monitoring, telehealth and email communication between treating doctor or clinicians and their patients.

Connected care is centred around the patient, their needs and their goals. Healthcare providers can remotely communicate with their patients through connected care using technology such as iPads, laptops and smartphones. Patients experience suitable treatment plans and appointments in connected care.

Various technologies such as hearables and wearables facilitate preventive healthcare. Sensors in these devices provide clinicians and patients data that enable patients to gain an understanding about cause and effect between their lifestyle choices and their positive or negative health outcomes (Talking Health Tech, 2020).

Benefits of Technology in Healthcare

Improving patient care and experiences: Using technology to capture and measure data across the system of patient care gives the institution a bird's-eye view of their own performance. It enables the organisation to continuously monitor and evaluate their results, giving them the opportunity to identify and fix gaps in the patient experience (IBM, undated).

Real-time information exchange: From patient to clinicians to payers, various groups should be able to access health records for various reasons. Earlier, organisations had to maintain different records for every individual. But new technology has made it easier to store digital patient records in a standardised and secure manner (IBM, undated).

Flexibility for patients and clinicians: Finding time for appointments can be a real struggle. Telemedicine and teleconsultation portals provide simpler ways for patients to communicate with the doctors. Wearable technology provides solutions for doctors to remotely monitor their patients' heart rate, blood pressure, and so on (*ibid.*).

Accelerated cost savings: Technology helps automate things that previously had to be done by people. Earlier, injections had to be given by nurses very often before the advent of infusion pumps; the infusion pump technology has automated the process. As a result, now a nurse's time is freed up for other activities. Once one infusion pump is programmed, it does not cost much to program them all. Using technology to make

technology helps in price reduction, increases the profit margin and market share as well. This allows the manufacturer to invest in more production and distribution technologies (Thimbleby, 2013).

However, it is imperative to notice that these benefits do not accrue to custom or rare problems that cannot be mass-produced. For example, an MRI scanner that can scan anyone in the same manner would be much more popular than one that needs to be tailor-made for specific conditions.

Big Data

Patients generate huge amounts of information in terms of *patient records* – from blood test results to X-rays. Replacing paper with electronic health records makes patient care more efficient and easier. In the future, the quantity of information will increase dramatically and more insights will become available as more patient data are collected.

When data on patient illness, treatments and outcomes are collected by computers, the valuable information on the effectiveness of those treatments, or relations between side effects and patient characteristics across whole populations is obtained. Huge amounts of data will be collected, hence the name big data. The incremental cost of adding one new patient will be essentially nothing once the infrastructures have been set up, and this economy of scale will drive further technical developments. Epidemiologists will also benefit enormously. However, the benefits to individuals are less obvious, except in the long run from big data's contribution to the progress of medical science more generally (Thimbleby, 2013).

Electronic Health Records (EHRs)

Electronic health records are an extremely significant advancement in the healthcare field. It facilitates a myriad of upgrades in medical treatment and diagnostics. EHRs enable fast information, recording, storage and transfer of medical files and efficient care integration, while in the past, medical records were handled inefficiently.

Genome Sequencing

Genome sequencing is essentially decoding an individual's genome. For this very reason, it is considered the future of healthcare. One of the biggest challenges in medical technology is equipping medical specialists to sequence the human genome. The information about the type of genetic progression carried by a particular segment of DNA is obtained through the sequence.

The genomic information is helpful in immediately isolating indicators and storing them for identification in future as well. It is also used to find the genesis and causes of disease and to achieve optimum health (RightPatient, 2021).

Remote Self-monitoring Tools

Remote self-monitoring tools can help patients save time on traveling to doctor's visits for specialised care. For patients who suffer from heart diseases, tools such as pacemakers are programmed to send data to health centres. There are also tools through which a patient's health can be monitored from hospitals regardless of distance for patients living with chronic conditions such as diabetes, hypertension and so on. Through these tools, patients with pre-existing conditions requiring keen and close monitoring can be monitored which halves the workload that would have otherwise been involved. The added advantage would be their ability to record this in data and billing as well (*ibid.*).

Telemedicine / Telehealth

Considering the dearth of skilled healthcare professionals in remote areas and unavailability of specialist care services for complex or chronic conditions like mental health illnesses, tuberculosis, HIV, hepatitis C, diabetes and other non-communicable diseases, technology can be used to make specialised medical knowledge accessible wherever it is needed to save and improve people's lives (*ibid.*).

In remote areas where patients don't have access to speciality care, patients can communicate with doctors virtually through their phones and computers.

- **Telemedicine**: Telemedicine refers to the provision of medical services for patients living in remote areas through utilisation of electronic tools and communication methods. Examples include virtual consultations and digital transmission of medical imaging.
- **Telehealth**: Telehealth technology enables the review, evaluation and diagnosis of patients remotely. Not only does it allow the provider to remotely identify real-time fluctuations in the patient's medical condition, it also allows them to remotely prescribe the appropriate medication.

Wearable Technologies

Technology has introduced wearable medical tools, and they are increasingly becoming popular in the healthcare sector. These wearables are a

category of electrically powered devices that could be implanted in the user's body, accessories, embedded in clothing or tattooed on the skin. They are microprocessor-powered and do not require any manual operation. They allow users to monitor their health and can receive and transmit data through the internet. The important data/information can be collected through wearable devices that will help patients and doctors evaluate and regulate the wearer's health (*ibid.*).

Health Technology Assessment

Health Technology Assessment (HTA) refers to the systematic evaluation of health technology in terms of its impacts or other effects. The main objective of HTA is to inform policymaking for technology in healthcare to enable decision-making at various levels, for example, the individual or patient level, the healthcare provider or institution level or at the regional, national and international levels. The consequences whether planned/unplanned, direct/indirect may also be addressed by Health Technology Assessment. HTA is conducted by an interdisciplinary team or group using analytical frameworks, drawing from a variety of methods.

Policy

As the use of IT systems and tools is increasing, privacy violations are also increasing rapidly due to easier access and poor management. Of late, one of the important topics in the healthcare is the concern of privacy. When organisations do not protect the privacy of people's data, it leads to breach of privacy. There are four types of privacy breaches, namely unintended disclosure by authorised personnel, intended disclosure by authorised personnel, privacy data loss or theft, and virtual hacking. Since the breach of privacy leads to high negative impact on both individuals and organisations, it is of the utmost importance to protect the security and privacy of patients' data. The exposure of sensitive health information can cause negative impacts on individuals' relationships, jobs or other personal areas. For any organisation, breach of privacy can lead to serious consequences such as loss of trust, loss of customers, monetary fines and legal actions. The U.S. healthcare legislation – HIPPAA (Health Insurance Portability and Accountability Act of 1996) includes two major rules – security and privacy of data. It also provides direction on how to use patient data. The security rule determines how to protect people's privacy, and the privacy rule protects people's rights to privacy.

How to Apply Healthcare Technology

From diagnostic centres to tiny health wearables, technology is an integral part of modern medicine. Technology as a whole has improved drastically along with new medical procedures and treatments. Patients enjoy the convenience of booking appointments online, and accessing their test results and health reports easily.

Here are a couple of illustrations of the areas where innovations in healthcare technology support new age advancements in healthcare.

Disease Diagnosis and Treatment

AI can be used to process data such as medical images for disease diagnosis and treatment. It can also assist clinicians in making diagnoses with more precision by developing disease models. For instance, it has been documented in one of the recent works from IBM Research that AI can be used to track the progression of neurogenerative illnesses such as Huntington's disease by recognising and interpreting brain activity patterns in MRI.

Medical Imaging

AI models and computers are particularly valuable in medical imaging as they can help turn pictures into numbers and detect trends. These innovations can help radiologists and other clinicians manage the large volume of images they have to review by identifying high-value findings and anomalies that can be brought to their attention.

Healthcare Operations

Many healthcare systems and hospitals are beginning to build on improvements they have experienced with electronic medical records and find other ways to systematically improve their operations. Mobile technology, analytics and cloud technology are a few of the technologies organisations are using to optimise their digital infrastructure.

Clinical Research

Technology is used by life sciences organisations to transform how clinical trials are being performed. Smart devices, telehealth visits and sensors are being used to support decentralised trials, making data collection easier and more efficient for trial participants (IBM, undated).

Use of Technology in Healthcare

There are seemingly endless uses of technology in the healthcare industry. Technology is being implemented in everything from surgery to cancer research and hospital administrative processes in order to improve efficiency throughout the industry. This makes the patient experience as painless as possible.

Administrative: To handle the growing administrative workloads, a whole host of software, tools and applications are used by hospitals. With the help of AI, administrative teams can streamline patient flows by doing everything from precisely calculating wait times to predicting peak busy hours for staff scheduling. On the other hand, apps can ask patients preliminary questions and prioritise schedules so doctors can use their time more efficiently (Daley, 2022).

Surgery: Surgery has witnessed some of the biggest improvements and progress over the years in terms of health tech efficiency. Robots are not the only technology that have invaded the operating room. However, robots can play a vital role by helping with a variety of operations ranging from minor non-invasive procedures to open heart surgery. These robotic surgical assistants could be in the form of small robots to giant arms used for various procedures. Virtual and augmented reality are assisting doctors and surgeons to better perform various important tasks, such as thoroughly explaining procedures to patients and practicing new surgical techniques (*ibid.*).

Drug development: The pharmaceutical industry is relying heavily on AI and machine learning to pave the way for drug research and development. In order to speed up time-consuming tasks like pinpointing certain chemical combinations that might help create the optimal drug and identifying patients who could best benefit from a particular drug trial, these tools (AI and ML) are currently being used in a variety of aspects across the pharma industry (*ibid.*).

Fitness: Of late, fitness has become a larger focus of the healthtech ecosystem. The industry has developed hundreds of apps, wearables and other tools that do everything ranging from tracking workouts to measuring sleep schedules, all in the name of increasing fitness and reducing preventable costs on the healthcare system (*ibid.*).

Diagnostics and error reduction: To tackle problems such as incorrect or overdue diagnoses, the healthcare industry is now using a variety of tech tools.

By introducing tech into pathology, genetics and other important diagnostic fields, healthtech companies have helped detect deadly diseases like cancer earlier and with greater accuracy than relying on humans alone (*ibid.*).

Mental health: One of the emerging sectors of healthcare truly benefiting from an influx of technology is mental health. Through exposure therapy, patients gradually train their brains to build up immunity to past traumas until those thoughts no longer negatively affect them. Virtual reality is seen as a bright light in the fight against PTSD, depression and even Alzheimer's. Telemedicine apps have made access to counsellors and healthcare professionals easier by opening the lines of communication and support, and reducing the need to wait for an in-person appointment during times of duress (*ibid.*).

Predictive Analysis

Predictive analytics can be referred to as a branch of advanced analytics that is helpful in making predictions regarding unknown future activities or events that lead to decisions.

Predictive analytics in healthcare can assist to identify early worsening signs of patients in the general ward and ICU, identify patients who are at risk in their homes to prevent hospital readmissions and prevent avoidable downtime of medical equipment.

Mobile technologies are evolving and changing the way providers deliver healthcare as patients demand more in the way of transparency, convenience and efficiency. Apps and mobile devices are significant for improving care coordination, increasing the level of patient engagement and managing chronic diseases, but the technologies could be made even more effective with better use of predictive analytics and data mining to help generate more actionable insights for providers (Watson, 2019).

Conclusion

The rapidly advancing rate of technological innovations have brought about a revolution in the healthcare sector. However, we need to ensure the use of mechanisms that focus on integrating technology with the needs of patients in a holistic matter, for healthier and happier patients. To sum up, the key takeaways from this chapter are that:

- Technology has the tremendous potential to improve the safety and quality of healthcare services.

- Providers who can use technology to leverage and amplify scarce resources to improve medical outcomes can position themselves for sustainability in the future.
- Several life-saving strategies have been certified through the use of technology in the field of medicine.
- Technological innovations will continue to transform healthcare, yet while technologies such as new devices, new drugs and treatments and so on will drive innovation, the human factors will remain an indispensable part of the care delivery process.

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Chapter 2

HEALTH DATA GOING DIGITAL: INDIA'S AYUSHMAN BHARAT DIGITAL MISSION

Divya Alexander and Alexander Thomas

Introduction

Data play a crucial role in a healthcare facility and in a health system, where it is generated, stored and shared daily to and from different sources. A patient's lab results go to the department where the treating doctor makes a diagnosis. A doctor's electronic prescription goes to the pharmacy where the pharmacist fulfils it. The ward sends information to the billing department in order for the complete invoice to be prepared. All of this, and other, information being sent and received comes under the category of "data," and since it relates to the health system, it is referred to as health data. Health data need to be interoperable and shareable in order for it to be useful, necessitating the need for health data standards.

The field of epidemiology uses health data to study health-related conditions in specific populations. The explosion of internet and mobile phone usage, especially social media usage, has led to a new subset of epidemiology, namely digital epidemiology, where traditional epidemiological studies and health-related research is conducted using new data and digital methods to provide insight into disease patterns, infectious disease monitoring and public health surveillance.

In India, the Ayushman Bharat Digital Mission (ABDM), previously known as the National Digital Health Mission (NDHM), aims to transform both personal healthcare and the study of population-wide diseases. Described as a "digital highway connecting various players across the healthcare system," the ABDM aims for a single unified platform where each citizen would have a unique health ID under which all their health records would be gathered: health data stored in a patient-centric single window in a standardised and interoperable format.

This chapter will

1. Introduce the concepts of health data and health data standards.
2. Examine the growth of digital epidemiology and its applications.
3. Provide an overview of India's Ayushman Bharat Digital Mission (ABDM) by outlining its history and purpose, a description of the ABDM ecosystem and the potential benefits as well its limitations and challenges to its implementation.

Health Data

Health data can be described as any data related to health directly (such as laboratory reports) or indirectly (such as health insurance claims forms), and is a very broad category that traditionally included Electronic Health Records (EHR), administrative data, claims data, patient registries, disease registries, clinical trials data, health surveys and so on. In recent years, health data have expanded to include health-related information captured from digital sources such as the following:

- Mobile applications: telehealth or telemedicine apps, audio-visual data, fitness apps that collect user health data for use in large-scale studies,
- Social media: Twitter, Facebook, Instagram and other social media app data that can be used for analysis,
- Internet of Things (IoT): remote patient monitoring through wearables such as smart watches, connected inhalers and so on,
- Big data: a large volume of unstructured and complex data (imaging data, genomics, electronic data) generated by humans as well as machines, that need to be mined before analysis.

The amount of data generated daily is enormous. To give the reader an idea of the sheer magnitude of this data: in 2018, 2.5 quintillion bytes of data were produced *every day* (Forbes, 2018) – 2.5 quintillion is 2.5 followed by 18 zeros! This number has only continued to grow since then. Imaging data is one digital source of big data in the health sector: new powerful imaging machines and scanners which can acquire images of a patient in less than a second have led to a data explosion for medical imaging data, resulting in data volumes that require vast quantities of storage, specialised applications and digital tools for mining and analysis (as well as clear regulatory guidelines on the standards for ownership, access to and analysis of that data).

Different departments within a hospital may use different formats or software to store their data. For example, a patient's cancer treatment plan may

be stored in digital text format in the oncology department, but the same patient's corresponding images in the radiology department might be stored on Pictures Archive Communication System (PACS), which is a different data platform (Traverso *et al.*, 2018). The usage of different data storage systems renders the data unusable by any other department, affecting its interoperability. This issue is called data fragmentation, and is one of the biggest issues to address when dealing with volumes of health data (*ibid*). The problem is multiplied when there is a requirement to use data from different institutions, where the relevant data are spread across all of them but not standardised. For data to be shared accurately, different IT systems with different infrastructures need to meet certain health data standards.

Health Data Standards

Health data standards establish rules for packaging the data for interoperability, that is, in order for it to be shared accurately. The lack of common data standards can cause problems in information sharing between different departments of a hospital (internal), and between different healthcare facilities (external). The chief obstacle to achieving this capability has been the haphazard adoption of data standards for organizing, representing and encoding clinical information so that the data can be understood and accepted by the receiving systems (Hammond, 2002).

As noted by Aspden *et al.* (2004), data standards are the principal informatics component necessary for information flow through any health information infrastructure. With common standards, clinical and patient safety systems can share an integrated information infrastructure whereby data are collected and reused for multiple purposes to meet the broad scope of data collection and reporting requirements more efficiently. Table 2.1 lists out important health data standards. Common data standards also support effective assimilation of new knowledge into decision support tools, such as an alert of a new drug contraindication, and refinements to the care process (Aspden *et al.*, 2004). Traverso *et al.* (2018) outlines the standardising of healthcare data as follows:

- Definition of data elements – determination of the data content to be collected and exchanged
- Data interchange formats – standard formats for electronically encoding the data elements
- Terminologies – the medical terms to describe, classify and code the data elements
- Knowledge representation – standard methods for electronically representing medical literature, clinical guidelines and the like for decision support

Table 2.1. Important health data standards.

Standards Development Organisation	Standard	Scope
Federative Committee on Anatomical Terminology (FCAT)	Terminologia Anatomica (TA)	Anatomy terms in English and Latin
Health Level Seven (HL7)	V2	Messaging protocol; several of the chapters of this standard cover clinical content
	v3 (RIM)	Information ontology; especially the "Clinical Statement" work aims to create reusable clinical data standards
	CDA Level 1-3	Information model for clinical documents (embedding of terminology standards in level 2 and 3); especially the Continuity of Care Document (CCD) specifications and the Consolidated CDA (C-CDA) specifications add detail to standards for clinical documents
	FHIR	Information and Document model; several parts of the core specification deal with clinical content
Integrating the Healthcare Enterprise (IHE)	Several integration profiles	Clinical workflows including references to clinical data standards to be used
International Organization for Standardization (ISO)	TS22220:2011	Identification of subjects of care
	21090:2011	Harmonized data types for information exchange
	13606	High-level description of clinical information models
	23940 (ContSys)	Health care processes for continuity of care
	14155	Clinical investigations
	IDMP	Medicinal products
National Electrical Manufacturers Association (NEMA)	DICOM	Medical imaging and related data
openEHR foundation	openEHR	Clinical information model specification

Table 2.1. (*Continued*)

Standards Development Organisation	Standard	Scope
Regenstrief Institute	LOINC	Terminology for lab and other observables
	UCUM	Standardised representation of units of measure according to the SI units (ISO 80000)
Personal Connected Health Alliance (PCHA)	Continua Design Guidelines	Collecting data from personal health devices
SNOMED International, formerly known as the International Health Terminology Standards Development Organisation	SNOMED CT	Terminology/Ontology for representing the electronic health record ("context model" = information model for SNOMED CT)
World Health Organization (WHO)	ICD-10/ICD-11	Disease classification
	ICF	Classification of functioning, disability and health
	ICHI	Health procedure classification
	INN	Generic names for pharmaceutical substances
	ATC	Drug ingredient classification
World Organization of Family Doctors (WONCA)	ICPC	Primary care classification

Source: Schulz, Stegwee and Chronaki (2019).

With the rise of personalised medicine, machine learning and big data have found multiple uses in the world of healthcare. Public and private bodies globally are attempting to maximise the use of digital infrastructure and instant connectivity to deliver health services more efficiently. Algorithms are capable of supporting diagnostic and therapeutic processes and offer added value for both healthcare professionals and patients. The field of big data, machine learning, deep learning and algorithm development and validation is often referred to as "data science" (Kubben *et al.*, 2019).

The "data" in clinical data science are rapidly expanding to include all the types of data mentioned in the beginning of this chapter. Clinical data science, to put it in simple terms, uses data science methods and insights to interpret clinical data for the ultimate aim of improving patient care. However, most healthcare professionals still consider the field of clinical data science as highly

technical and unrelated to their field, leaving many interesting and valuable opportunities unexplored (Chen and Asch, 2017). Chen and Asch posit that "combining machine-learning software with the best human clinician 'hardware' will permit delivery of care that outperforms what either can do alone" (*ibid.*). It could be the answer to fast and accurate first-time diagnoses, reducing the huge variance in healthcare costs and outcomes, and placing more accountability on people for their own health (Consoli *et al.*, 2019).

Digital Epidemiology

Healthcare workers will understand traditional epidemiology as the study of the distribution and determinants of health and disease conditions in specified populations. As a cornerstone of public health, it shapes policy decisions and evidence-based practice by identifying risk factors for disease and targets for preventive healthcare. Digital epidemiology, a new subset of the field, has emerged in recent years due to the rapid upsurge in internet and mobile phone usage and the increasing availability of big data, computing power, data analysis and artificial intelligence. In this subfield, traditional epidemiological studies and health-related research is conducted using new data and digital methods.

The term digital epidemiology is for epidemiology that uses data that were generated outside the public health system, that is, with data that was not generated with the primary purpose of doing epidemiology (Salathe, 2018). Another definition describes it as epidemiology that uses digital methods from data collection to data analysis (Park *et al.*, 2018). Examples of this data include search queries (many people search for health information online when they are ill) and social media posts (to share their results with their network). Descriptions of health problems, time-stamped and geo-tagged, are available. Thus, it is possible to study the health of a population in real time using such digital traces (*ibid.*).

While there is some controversy surrounding the non-traditional data sources that digital epidemiology relies on (including access, sharing and privacy issues), the broader context that it provides is valuable. For example, Wesolowski *et al.* (2012) analysed mobile phone call records as indicators of the travel patterns of 15 million mobile phone owners in Kenya over the course of one year. They combined the travel patterns with a detailed malaria risk map to estimate the movements of malaria parasites that could be caused by human movement. This information enabled detailed analyses of parasite sources and sinks among hundreds of local settlements. Bengtsson *et al.* (2011) used the position data of SIM cards from the largest mobile phone company in Haiti to estimate the magnitude and trends of population movements following the 2010 Haiti earthquake and cholera outbreak.

With the rise of artificial intelligence in medical research and new data-infrastructures in biological knowledge production, it has become easier to aggregate and use data from a wide range of sources and areas in medicine. Electronic healthcare records, digital infrastructures in hospitals as well as digital governance offer opportunities to unleash visions of automated reporting systems, efficient surveillance methods and seamless healthcare operations fuelled by digitisation (Garrety *et al.*, 2014; McFall, 2015; Topol, 2019).

Web-based data mining is having a revolutionary impact on the way we monitor global health outcomes and behaviours (Salathe *et al.*, 2012). Some types of infectious and chronic disease data can be captured from and disseminated in near real-time through an array of online sources including chat rooms, social networks, blogs, web search records and online news media. These online sources provide a picture of global health that is often different from the picture created by traditional surveillance systems (Brownstein *et al.*, 2008).

With the revolutionary aspect of web-based data mining comes another less savoury aspect, one that Antoinette Rouvroy calls "knowledge without truth" (Rouvroy, 2011), referring to how the web-based process bypasses the human knowledge and human contribution that provides a context for all these reservoirs of data. As Eckmanns describes,

> amid the widespread deployment of big data analytics and increasingly sophisticated algorithms for tracing the next outbreak, little critical assessment has been formulated by global health security theorists and practitioners on the ramifications 'digital' turn of health surveillance and the implications of big data and algorithmic surveillance practices on individuals, populations and states (Eckmanns, 2019).

Wrongly interpreted data may result in public health interventions that could cause harm. Hence, it is imperative to evaluate digitised health carefully.

Applications of Digital Epidemiology

With the proliferation of big data and machine learning, digital epidemiology can provide new insight into disease patterns, infectious disease monitoring and public health surveillance. Researchers can also use digital data to understand public attitudes, perceptions, and behaviours towards health issues. This is a new discipline in the area of big data, which promises faster detection of disease outbreaks and improved surveillance as well as reduction in administrative burden, among other things (Eckmanns *et al.*, 2019).

Data from search engines can now provide early warning of respiratory illnesses in local communities while data from social networking sites can provide early warning of vaccine refusal stemming from conspiracy theories or

other reasons. Google Flu Trends (GFT) is an early example of digital epidemiology, using search queries for the purpose of tracking influenza-like illnesses. In 2009, researchers from Google and the US Centers for Disease Control and Prevention (CDC) published a method to estimate flu activity by region using search queries (Park *et al.*, 2018). Online news media can provide a window into the emergence of pandemics weeks before it is brought to light by traditional surveillance. Similarly, data from social media could tell us about emerging trends in a wide range of health behaviours—for example, the uptake of new tobacco products—at the local and national level (Salathe, 2012).

With innumerable digital data sources, the pre-emption of health risks can be managed and analysed via an assemblage of innovative and evolving surveillance practices which combine multiple data sources and disease-tracking techniques, enacted at local, regional and global levels. Syndromic surveillance platforms and digital epidemic intelligence systems including ProMED-Mail, GPHIN, HealthMap, BioCaster, EpiSPIDER, and Google Flu Trends are examples of governmental technologies of overarching global health security practices, developed and installed in order to halt or preempt health risks (Eckmanns *et al.,* 2019). During the COVID-19 pandemic, several countries used GPS apps with Bluetooth to track coronavirus cases. India's Aarogya Setu app was one of them, augmenting Digital India, the government's flagship program to transform India into a digitally empowered society.

The Ayushman Bharat Digital Mission

History and Purpose

The growth of technology-enabled health delivery has led to the modernisation of several policy measures in India, particularly over the last few years. The National Health Policy, 2017, placed focus on the digitisation of the health sector, envisioning a digital health eco-system. In 2018, the NITI Aayog proposed a National Health Stack to develop the framework for such a system. In 2019, the National Digital Health Blueprint for the formation of this national digital health system was released, and it established the necessity of creating an organisation to execute its development. This organisation, the Ayushman Bharat Digital Mission (ABDM), also known as the National Digital Health Mission, was launched in 2020.

> "The vision of the ABDM is to create a national digital health ecosystem that supports universal health coverage in an efficient, accessible, inclusive, affordable, timely and safe manner, with the creation of a seamless online platform through the provision of a wide range of data, information and infrastructure services, leveraging open, interoperable, standards-based



Figure 2.1. The NDHM ecosystem.

Source: Official Govt. of India website [nha.gov.in/ndhm]

digital systems, while ensuring the security, confidentiality and privacy of health-related personal information" (National Health Portal, 2022).

The ABDM intends to create a holistic and comprehensive digital health ecosystem that will lay the foundation of a strong public digital infrastructure, digitally empower individuals, patients, doctors, health facilities and help streamline the delivery of healthcare services and related information. The ultimate aim is to strengthen the accessibility and equity of health services, including a continuum of care with the citizen as the owner of data (Figure 2.1).

As explained by the Director of the IT Department of the ABDM, Abhishek Kumar (eHealth Network, 2021), an important part of the ABDM is the creation of various online registries. Citizens, healthcare workers and healthcare facilities will have an identifier in the form of a Health ID, and become part of a repository of stakeholders in the health ecosystem of India.

- Health ID: a unique identifier for every enrolled individual in the ABDM system. The individual's electronic health record in the ABDM system, called a Personal Health Record (PHR) will be attached to the Health ID. A PHR can be managed, shared and controlled by the owner, differentiating it from EHR and EMR, which come under the purview of the healthcare facility.
- Health Professional Registry (HPR): a database of all the healthcare workers in India, facilitating the easy identification of health service providers.
- Health Facility Registry (HFR): a comprehensive repository of health facilities in India, both public and private, across different systems of medicine. It includes hospitals, clinics, diagnostic laboratories, imaging centres, pharmacies and so on.

Several digital healthcare solutions were already being effectively used in India's healthcare system even before the appearance of the COVID-19 pandemic. Two examples are ANMOL (Auxiliary Nurse Midwives Online, an app by the MoHFW to improve healthcare services to millions of pregnant women, mothers and newborns in India) and eVIN (the Electronic Vaccine Intelligence Network introduced by the MoHFW to strengthen the universal immunisation program in 12 Indian States). With the advent of the pandemic, digital health tools became even more important. The use of telemedicine skyrocketed. The Government of India used the Aarogya Setu app and the COWIN platform to steer public health interventions and deliver health services across the nation.

However, these digital tools are often developed in isolation for very specific purposes and rarely consider interoperability, thus restricting any broader usage of the data captured by these tools. Currently, the Electronic Health Records and Electronic Medical Records systems vary widely across the healthcare facilities where they are used, with no uniformity in data. This is where the ABDM hopes to change the landscape: using technology to standardise data formats and facilitate data sharing (interoperability), and thereby provide a single window for patient-centric healthcare. A patient would be able to access a complete and integrated healthcare history containing details of every hospital visit, medical test, result, diagnosis, treatment and medication prescribed, on a seamless online portal.

Benefits of the ABDM

The ABDM has been described as a "digital highway connecting various players across the healthcare system" (Preeti Sudan, Former Union Health Secretary, 2022).

Loss of medical records and the need for repeat tests will be minimised as citizens will have access to their complete medical history through digital health records. Ascertaining the availability of doctors, hospital beds and medicines will become easier with a single ecosystem helping citizens find the services they need efficiently.

Healthcare providers will also benefit from ABDM. Timely access to relevant digital medical records can help healthcare providers make better decisions in the interest of their patients. Providing teleconsultations can help them serve patients from far-off areas as well, and not just those in their vicinity.

Public health programme beneficiaries can also be provided services with greater ease with the support of a digital health ecosystem. Portability of benefits for beneficiaries can be carried out more efficiently.

The ABDM would not just enable the delivery of healthcare, but also be able to harness data for real-time public health decision-making. Policy-makers can also improve decision-making based on population-level health data in an anonymised and aggregated manner. Digital health records can also help doctors and patients seek follow-ups, obtain second opinions from specialists or avail of referrals, allowing for the development of integrated decision support systems which aim to maximise effectiveness and patient safety. Access to better data would enable better decision-making and targeted interventions. It will also enable geography and demography-based monitoring, allowing better programme design and delivery of services such as nutrition programmes in areas with high malnutrition, strengthening of vaccination programmes in geographical areas with low vaccination rates and so on. If implemented with adequate precautions, ABDM will revolutionise healthcare in the nation and go a long way in making Universal Health Coverage a reality for all our citizens.

Challenges and Limitations

Several concerns have been raised about the advisability of storing health data in the manner envisaged for the ABDM platform.

Data Privacy

Data privacy in the ABDM system has emerged as a major concern since it has been launched without having in place a comprehensive personal data protection legal framework nor an independent regulatory structure for health data protection. While it relies on the Personal Data Protection Bill for general privacy safeguards, that Bill has been pending in Parliament since 2019, leaving the ABDM to be implemented in a regulatory vacuum. In the absence of these crucial protections for data as sensitive as health

data, the enrolment of individuals in the ABDM should be purely voluntary, which on paper, it is. In practice however, it is being made mandatory in practice by hospitals for access to their healthcare delivery services (Rana, 2020). More recently, many users realised that those with Aadhaar-based enrolment on the COWIN platform were automatically registered for the health ID without their consent, as well as not having the option to opt out (Shrivastava, 2021). There is a worry that this data can be used for profiling and surveillance of citizens.

Data Security

The Internet Freedom Foundation in its analysis of the NDHM's health data management policy cautions that executives in the healthcare sector have recognized the cybersecurity risks posed by the ABDM, and notes that India has a past record of breaches of sensitive personal data like financial information and leakage of Aadhar numbers (IFF, 2021). For instance, in 2016, 3.2 million debit cards were recalled by various banks due to a data breach (Business Standard, Oct 2016). Any similar leak of sensitive health data collected as part of ABDM would cause severe and irreparable harm to millions of citizens which cannot be quantified or compensated in monetary terms. A few years ago, the mandatory linkage of Aadhaar cards to medical treatment for people living with HIV/AIDS was driving away patients from hospitals and Antiretroviral Therapy (ART) centres in Madhya Pradesh (Hindustan Times, 2017). In January 2021, a technology portal reported leaking of COVID-19 test results and personal information of thousands of patients, from the websites of multiple Indian government departments (IFF, 2021). For this reason, it is essential that independent technical experts scrutinize the technical design, and there should be full disclosure of all information that is necessary to conduct such an independent evaluation.

Inclusivity

Due to the digital divide, there have been questions about how the ABDM will empower the millions of citizens of India who live in remote areas without digital access. Language barriers are another obstacle.

Reliance on the Private Sector

In a country where less than 2.5% of the total GDP is spent on health, some argue that the real motive of the ABDM is to incentivise the private sector to

participate in India's healthcare system. It is seen as the government outsourcing healthcare services to private healthcare providers rather than focusing on improving public health infrastructure such as enhancing the availability of beds in the public sector, by using access to vast troves of health data as the proverbial carrot (CHRGJ, 2022). The growing reliance on private healthcare will further disadvantage people living in poverty.

Role of the State/State Capacity

Under the federal structure of the Constitution, health is a State subject and therefore state governments would also have the right to regulate this policy. The preparedness of states entails evaluation of their capacity (IFF, 2021).

Given that the implementation of ABDM is expected to improve access to healthcare and create data resources for policy-making and research, public participation in this initiative is crucial – its adoption by the Centre and States, by public and private entities and by individuals and decision-makers. Therefore, the incorporation of safeguards could potentially become a key building block for the success of the mission, by providing citizens with the controls required to protect their data while enjoying the benefits of integrated healthcare (CHRGJ, 2022). It is also crucial to analyse international experiences in order to learn from their achievements and mistakes.

Conclusion

With the proliferation of machine learning to analyse the large volumes of data being generated, digital epidemiology can provide new insight into disease patterns, infectious disease monitoring and public health surveillance, to name a few. Public and private bodies globally are attempting to maximise the use of digital infrastructure and instant connectivity to deliver health services more efficiently.

- This chapter introduced the subject of health data and health data standards, including the concepts of interoperability, big data, machine learning and clinical data science.
- The second section focused on digital epidemiology and its role in examining disease patterns, monitoring infectious diseases and public health surveillance.
- The final part of the chapter looked at India's Ayushman Bharat Digital Mission (ABDM) by outlining its history and purpose, a description of the ABDM ecosystem and the potential benefits as well its limitations and challenges to its implementation.

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Section 2

HEALTHCARE TECHNOLOGY FOR MEDICAL PROFESSIONALS

Chapter 3

THE FUTURE OF HEALTH: SMART HOSPITALS

S. Raghunath and Divya Alexander

Introduction

Over the last decade or two, the medical model has shifted away from disease-centric care towards a focus on wellness and prevention of disease, away from merely curative treatment to a more patient-centric model: managing health rather than simply treating disease. Health consciousness and practices that promote wellness, healthy lifestyles and disease prevention have become popular among the youth and the elderly. The growing need for personalised healthcare has found its answer in the digitisation of clinical care.

To meet this demand for precise and personalised healthcare, hospitals need to evolve in order to become smarter and more efficient. Hospitals that have been functioning for several decades need to upgrade in order to survive, gradually investing in new technologies to redesign the delivery of acute care, enabling them to reach out to other healthcare providers, and identifying activities that can be outsourced to others who can perform them more efficiently or effectively. In other words, these traditional hospitals need to transform into "smart hospitals."

The World Health Organization (WHO) estimates a shortfall of more than 18 million healthcare professionals globally within the next ten years (WHO, 2022). The increasing workload of doctors and medical staff makes a strong case for the conversion of traditional hospitals into smart hospitals to improve efficiency and the quality of patient care. Surveys have found that diagnostic and treatment errors are a major concern for both patients and physicians (Balogh *et al.*, 2015). New technologies such as Artificial Intelligence (AI), robotics, Internet of Things (IoT) products and others can improve diagnostic and treatment precision as well as enabling shared decision-making.

This chapter will

1. Provide a brief introduction to the new generation of information technologies that are revolutionising the health sector.
2. Use examples and case studies to illustrate how these technologies lead to increased efficiency, cost reduction and improved outcomes.
3. Explain the concept of smart hospitals and outlines the basic requirements for a traditional healthcare facility to become a smart hospital.

New Generation of Information Technologies

There are several new technologies that have enabled life-changing advances in healthcare delivery. Some of these are AI, IoT, robotics, 3D printing, augmented reality/virtual reality, genomics and telemedicine. These have become instrumental in controlling cost, generating efficiency, increasing precision, decreasing errors and improving outcomes. Each of these technologies is dealt with in detail in the subsequent chapters of this book. This chapter will focus on how these technologies have given rise to patient expectations of convenience, comfort and efficacy and what roles they play in a smart hospital.

Artificial Intelligence

Artificial Intelligence (AI) is a field of study that refers to intelligence displayed by machines that combine computer science and robust data sets to enable problem solving in a way similar to how humans think and solve problems. Computers that play chess or cars that drive themselves are examples of AI.

The confluence of big (clinical) data acquisition, rapidly growing computational power, advances in machine learning methods and cloud storage has fuelled the growth of AI in healthcare (Yu *et al.*, 2018). Automated medical-image diagnosis is one of the most successful domains of medical AI applications, with the fields of radiology, ophthalmology, dermatology and pathology benefiting hugely, as they rely on image-based diagnoses (*ibid*). With all these applications and more, AI has the potential to transform clinical practice (Table 3.1). For example, it is estimated that there will be a net deficit of over 5700 pathologists by 2030 (Robboy *et al.*, 2013). With AI applications that are able to detect prostate cancer from biopsy specimens, identify breast cancer metastasis in lymph nodes and detect mitosis in breast cancer, an automated system could mitigate this deficit (Yu *et al.*, 2018).

AI also demonstrates huge potential in Infection Prevention and Control (IPC). Its ability to detect transmission events during outbreaks and predict

Table 3.1. A list of current and potential AI applications in medicine.

Basic biomedical research	Translational research	Clinical practice
Automated experiments	Biomarker discovery	Disease diagnosis
Automated data collection	Drug-target prioritization	Interpretation of patient genomes
Gene function annotation	Drug discovery	Treatment selection
Prediction of transcription factor binding sites	Drug repurposing	Automated surgery
Simulation of molecular dynamics	Prediction of chemical toxicity	Patient monitoring
Literature mining	Genetic variant annotation	Patient risk stratification for primary prevention

Source: Yu, Beam and Kohane (2018).

high-risk patients can enable the development of tailored IPC interventions. It offers opportunities to enhance diagnostics with objective pattern recognition, standardise the diagnosis of infections with IPC implications and facilitate the dissemination of IPC expertise. An example of behaviour change delivered by AI applications is improved hand hygiene. However, staff can become dependent on automatic reminders, and it was noted that performance returns to baseline if the feedback is removed (Fitzpatrick *et al.*, 2020).

The advantages of using AI for IPC include speed, consistency and capability of handling infinitely large datasets. However, Fitzpatrick *et al.*, (2018) stress that many challenges remain: improving the availability of high-quality representative datasets and consideration of biases within pre-existing databases are important challenges for future developments. AI in itself will not improve IPC; this requires culture and behaviour change. Most studies to date assess performance retrospectively so there is a need for prospective evaluation in the real-life, often chaotic, clinical setting. Close collaboration with IPC experts to interpret outputs and ensure clinical relevance is essential (*ibid.*).

A comprehensive evaluation framework with common elements and interoperability is necessary to serve as a reference for AI-enabled clinical decision support system design and evaluation, with focuses on cross-disciplinary communication and collaboration. There is a pressing need to develop robust methodologies and empirically based tools for such evaluations (Ji *et al.*, 2021).

Clinical Decision Support Systems

Clinical Decision Support Systems (CDSS) are computer-based systems that use data, clinical knowledge and analysis to produce recommendations based on the patient's clinical condition in order to assist healthcare workers in decision-making. Robert Hayward of the Centre for Health Evidence (Pearlman, 2013) describes it as follows: "Clinical decision support systems link health observations with health knowledge to influence health choices by clinicians for improved healthcare."

Clinical knowledge, when converted to algorithms, can aid in making decisions in situations where clinical practice guidelines are ambiguous or unclear. CDSS can assist in decision-making at different stages by providing real-time information, data interpretation, diagnostics and prescriptions.

AI-based CDSS apply different techniques to improve healthcare quality and patient safety:

- Machine learning: computers that self-improve by learning from large amounts of data
- Computer vision: computers that understand visual data (image recognition) and can detect objects and classify images (useful in tumour detection, medical imaging, etc.)
- Natural language processing: computers with the ability to understand human speech by using unstructured data, gathering patterns and extracting its meaning (useful in aiding clinicians in diagnosis and symptom-checking)
- Knowledge graphs: a way of organising and merging information captured from different sources that enables computers to form knowledge about a particular subject (useful in developing diagnostic models and treatment models).

CDSS has its own challenges in being accepted by clinicians, as there is little understanding of the logic used by AI to deliver recommendations. The availability of technical support and administrative facilitation in the healthcare provider's environment are also issues that need to be addressed.

3D Printing

3D printing is a relatively new technology in smart hospitals. It involves the construction of a three-dimensional object designed on a computer and created or printed layer by layer. This opens up avenues for surgical teams to print out parts of a body such as prosthetic limbs or dental implants on

demand. In Hinduja Hospital, Mumbai, 3D printing was used to save the life of a man who had severe cranial trauma (skull fracture).

The patient, a 50-year-old man, was in a critical state, having lost a substantial part of the cranial bone, making it difficult to maintain hydraulic pressure and creating dangerous conditions for the brain. The major challenge was replacing the part of the cranium that was missing, as it was too deformed to be used. Moreover, a dummy (a customised model that replicated the current condition of the patient's skull) was required for surgical planning. The surgeons opined that if the lost part of the skull was not replaced immediately, the patient's condition would deteriorate rapidly. Standard bone plates would work, but sending it for customisation would be a time-consuming process.

A 3D-printing company, Imaginarium, rose to the occasion, churning out the potential of a cutting-edge technology in the best possible way. With in-depth knowledge of customised designing, the project used the data to create a virtual 3D model of the patient's skull in its current condition and was "sent for printing" for the surgeons to use as the dummy. After this, the lost part of the cranium was "printed" in titanium and placed on the patient's skull (Figure 3.1).



Figure 3.1. 3D-printed cranial bone used in surgery at Hinduja Hospital, Mumbai.

Source: Photograph taken by author.

The surgery was a success and the patient made a complete recovery, returning to his normal life.

Further afield in the University of Minnesota, engineers and medical researchers created silicon-made "scaffolding" that could benefit those with spinal cord injuries by restoring muscle control (Joung *et al.*, 2018). Cells were printed onto the structure, and then implanted into the patient's spinal cord, with a bridge between each cell. These and other examples demonstrate the potential of 3D printing in a hospital or healthcare facility.

Internet of Things

The Internet of Things (IoT) refers to an inter-related, internet-connected system of everyday objects that can collect and exchange data over a wireless network. Examples of IoT include wearable health monitors. Doctors, hospitals and healthcare providers are increasingly embracing the use of wearables and IoT products to monitor patient health, gauge responses to procedures, track chronic illness and identify geriatric issues. Some IoT solutions use AI to provide early warnings to doctors based on a patient's vitals.

Patient Monitoring Systems (PMS) refer to IoT technologies used by healthcare providers to monitor their patient's biological indicators. Remote PMS, used to monitor a patient's indicators remotely when they are outside the hospital (such as smart watches or telemedicine) are different from bedside PMS, which are used when they are within the healthcare facility (such as ECG machines). Remote monitoring results in increased freedom for patients, and useful insight for doctors in diagnosis and treatment as they can observe their patient's everyday lives.

The IoT on connected devices creates a data "lake," accumulating data from different data points. This enables further refining of the algorithms used to process data and sharpens data sense-making, the identification of the data patterns and the use of data to make decisions. The IoT system brings in proactive decision-making before the illness or disease imperils the patient's health.

Manipal Hospitals, Bengaluru, uses a remote monitoring solution linked to Google-owned Fitbit devices to track patients recovering from high-risk surgeries. The devices record patient data such as heart rate, oxygen saturation level, sleep quality, steps, and pain score, which are then shared with nurses and doctors over an online monitoring solution offered by a Singapore-based company called ConnectedLife. The monitoring solution is a customisable solution for each patient and can send patients reminders to take their medicines

or do physiotherapy on time. The solution can also send out alerts if it detects any major shift in a patient's physiological parameters. The patient's data are transferred directly to the doctor.

Robotics

Robotics is a field that involves the design, construction and operation of robots: machines that can assist humans. Robots are revolutionising healthcare in many different areas: fulfilling caregiving needs, providing social and physical therapy, performing surgeries, monitoring health indicators and keeping medical records, among others.

During the height of the COVID-19 pandemic, Fortis Hospital, Bengaluru, introduced the Mitra robots for COVID-19 screening. The initiative helped the hospital screen every single person who entered the hospital, including doctors, nurses, medical and non-medical staff. The robot interacted using facial and speech recognition and autonomous navigation to screen for COVID-19 symptoms such as fever, cough and cold.

The robotic screening was carried out in two phases. The first robot placed at the entrance of the hospital conducted basic screening, including a temperature check followed by a few questions on symptoms of cough and cold. If the temperature of that individual was found to be normal with no signs of cough and cold, the robot printed a hospital entry pass stating the screening results along with the name and picture of the individual. If any individual had a high body temperature or confirmed to the robot that he/she was experiencing a cough and cold, the robot printed a different pass for the flu clinic, where there was a second robot that connected the individual to a doctor, allowing a diagnosis to be made without any physical contact, and without exposing the other hospital visitors to potential infection.

In Wuhan, China, in the initial days of the COVID-19 pandemic, a hospital ward run entirely by robots was opened in order to protect its medical staff from the virus. The robots delivered food, drinks and drugs to the patients, and kept the ward clean. They only looked after patients who needed basic medical care. If patients' health problems became more acute, they were transferred to the human-run hospital. Some robots were described to have "a humanoid head, arms and upper torso but a wheeled base" (figure 3.2) while others looked more like "a box on wheels" (O'Meara, 2020). The machines could move around autonomously but were under the observation and control of staff outside the ward (*ibid.*).



Figure 3.2. COVID-19 patients at a smart hospital in Wuhan, China, with a robot from CloudMinds.

Source: AFP (2020).

Smart Hospitals

A hospital is "smart" when it improves patient care using optimised and automated processes, particularly the IoT, to connect medical devices to AI and data analytics. Smart hospitals usually deliver only critical high-value services within a value chain of supportive service providers such as major surgeries, intensive care, the management of severe trauma and treatment for other acute and complicated cases. On the other hand, preventive services and healthcare is provided in clinics, gymnasiums and even in patients' homes, while minor surgeries are completed in ambulatory care centres where there is a separate centre for diagnostic testing, including imaging and laboratory services (Chen *et al.*, 2019).

Smart hospitals automate numerous labour-intensive processes. They use a range of devices to upgrade operations and automate workflows in order to increase the productivity and accuracy of hospital care. Radiofrequency Identification (RFID), bar codes and other new sensing technologies can identify and track the use of assets and materials. Automated procedures and devices replace certain human activities in a range of care settings, freeing up the staff to spend more time on direct patient care. Automation is also used to improve the efficiency of many back-office and front-office processes. Web-based tracking of all patient services, electronic capacity allocation and

digital patient record management further improve the efficiency of hospital operations (*ibid.*). Leading hospitals in many parts of the world are already demonstrating what automation can do through mobile devices to allow for more efficient clinical operations. For example, when a patient reaches a critical condition, the Johnson Control's Code Blue Activation system can call up an emergency care team in just 24 seconds.

The COVID-19 pandemic has demonstrated how to deliver healthcare in the most contactless form possible, giving rise to the increasing use of telemedicine, mobile health apps for chronic disease monitoring or wireless biometric sensors that make remote sensing and diagnostics a reality. This enables the combination of telehealth and in-person care facilitating closer access, both physically and digitally, to patients. Virtual care at home may consist of various options such as on-demand virtual urgent care or virtual clinic visits, to technology-enabled home medication administration along with home delivery of prescribed medicines. Virtual care, as a complement to face-to-face interaction, will improve access, quality and affordability of care, while reducing unnecessary visits to healthcare facilities.

We are witnessing the use of online consultations and multidisciplinary team engagement to help hospitals become more patient-centric. Connected Electronic Health Records (EHRs), hospital automation and care coordination are delivering considerable savings. For example, some hospitals have online appointment scheduling, digital check-ins and test results sent through email. Robots and other technologies automate most of the complementary and supplementary services such as pharmacy, laundry and food delivery. This gives clinical staff more time to focus on patients. For example, the Cleveland Clinic in Abu Dhabi, UAE, uses digital apps to support treatment and pre-treatment procedures, and their patients use apps to communicate with the staff. During their stay, they use smart pads to access their information and daily plans, and to order food. At the time of discharge, the app sends prescriptions to local pharmacies before sending the patient his or her invoice.

As healthcare centres gain a deeper understanding of every patient, they can empower their patients to self-monitor (say wearables to track heart rates, monitor glucose levels and record exercise levels) and seek consultation for corrections required on any health parameter. These wearables can monitor each of the vital signs and can reduce the response-intervention time resulting in lower costs and reduced nosocomial infections. Meanwhile, the rapid growth and widespread adoption of mobile health technologies is increasing data flow and data collection which is very useful in designing treatment plans and rehabilitation programmes. Educating patients to participate in their own healthcare is an area of development in healthcare delivery called shared decision-making and studies have explained its benefits (Krist *et al.,* 2017).

Case Studies of Smart Hospitals and the Technologies Involved

Many hospitals in India use IoT, AI and other technologies in healthcare delivery:

Apollo Hospitals has launched a smart in-patient room automation system that uses an AI-powered triaging system to continuously monitor a patient's respiratory rate, heart rate and other clinical parameters remotely. Apollo has also deployed IoT-enabled smart health kiosks at several locations for screening and diagnosis of various health parameters in collaboration with Dozee. Dozee provides a contactless health monitor that tracks heart rate, respiration rate, sleep patterns, stress levels, cardiac contractions, apnea and more while patients sleep. Its AI algorithms enable early detection of any health deterioration. The health information can be accessed remotely by doctors/caretakers on Dozee's patient monitoring system and its app. Dozee also provides remote patient management and early warning systems to over 300 hospitals in India, using a combination of Ballistocardiography (BCG) and AI algorithms to determine a risk score for patients and provide early health deterioration warnings. BCG is a recording of micro-vibrations made by the human body due to the heart's mechanical activity such as the pumping of blood. Dozee integration with SpO2 (pulse oximeter) has proved instrumental in providing continuous remote monitoring to COVID-19 patients, keeping nurses and doctors safe from exposure to infection.

ConnectedLife, a Singaporean company, deploys an IoT-enabled sensor sheet, which when placed under a mattress on any bed, can capture BCG, respiration rate, blood pressure, oxygen levels, muscle twitches, temperature and other body movements of the person using it. The AI-based smart alerts system is designed to ensure that only relevant and timely escalations reach the doctor. With the growing emphasis on preventing disease progression comes the need for continuous closed-loop engagement with patients.

By combining medical-grade sensor technology (IoT) with AI, the ConnectedLife solution facilitates early detection and intervention for various common chronic conditions and enables continuous monitoring and personalised treatment to improve the quality of life and clinical outcomes of people living with chronic conditions such as Parkinson's Disease, orthopaedic conditions, congestive heart failure, diabetes and blood anticoagulation. The technology stack of ConnectedLife is highly modular, and can be customised to fit specific purposes. The company's COVID-19 solution with Fitbit, launched in a matter of months, is an example of how technology can be rapidly reconfigured, tested, hardened and brought to market.

Transforming Traditional Hospitals to Smart Hospitals

To begin the journey of transforming traditional hospitals to smart hospitals, **data transmission based on connectivity** is the key. There must be an agreed and accepted standard and structure for submission of information. There must also be rules for data collection, storage, transmission and usage. Data privacy must be maintained by creating a system that stores data securely. In smart hospitals, patients as well as hospital staff use interactive equipment to enable real-time data collection, tracking and transmission. In addition, clinical staff members are able to access the data through mobile devices to allow for more efficient clinical operations. There are hospitals that have transformed themselves in other countries that have their own electronic medical record system, virtualised data centres that collect and centralise information and mobile apps that allow the clinical staff and patients to access data within seconds.

The use of **data platforms** is a core requirement for smart hospitals. Data collected on patients, from their health monitoring devices or from their virtual or physical consultations will be available on these platforms, to ensure consistency throughout the patient's care journey. Policies will have to be in place to centralise the patient's data. Data platforms will promote closer collaboration among patients, clinics, insurance companies, laboratories, pharmacies, and specialist physicians, giving rise to quick responses and treatment based on analytics-based insights. Issues relating to interoperability and security of data remain to be addressed.

There are various models in which smart hospitals operate. One model is for smart hospitals to integrate data, store it and make it accessible to others. Another model is for government agencies to serve as data aggregators; the smart hospitals are then able to track the care received by patients at all healthcare facilities. The single-most-important element is connectivity. It is crucial because the hospitals must understand what happened before hospital admission, manage all inpatient care and monitor the post-discharge health condition.

Cyber security is an area of immediate concern relating to sensitive patient information on medical records. Hackers and online criminals are always snooping around hospital data and equipment. Those are the targets that are accessible when introducing a connected system like a smart hospital. Smart hospitals can be easy targets of cyberattacks like malware and Denial of Service (DoS) raids that take control of systems and devices, steal patient data (most likely to be sold on the dark web) and hold patient data hostage with ransomware. Since the COVID-19 pandemic, attacks on hospitals and health organisations have increased drastically, including this fatality triggered

by ransomware in Germany. During the pandemic in a hospital in Dusseldorf, Germany, a patient reportedly died from a virus. This was not the coronavirus – it was the hospital that was hit by ransomware, infecting 30 servers before causing a total system shutdown, leading to the loss of her life (BBC, 2020). Electronic health records, according to an FBI report, can be used to file fraudulent insurance claims, obtain prescription medication and advance identity theft. Health record theft also is more difficult to detect, taking almost twice as long to recognise as normal identity theft.

This attack was fatal, but not unexpected. Attacks on hospitals and other health organisations have dramatically increased during the pandemic. When they hit, they can cost lives. Hospitals often have limited cyber security, making them vulnerable to attacks. The University Hospital Brno in the Czech Republic faced a similar attack, but fortunately had no casualties (Porter, 2020).

If the devices are not configured correctly, tampering with drug delivery systems is another possibility. Human errors can continue to pose a challenge. With drug pumps, for example, smart hospitals, or more specifically their workers, deliver controlled doses of medications to patients. These systems prevent over or under-administration, but they have an override button for emergencies. There is a possibility, therefore, that someone could tamper with drug delivery, inadvertently or intentionally, which might have deadly consequences.

We realise that these technological advancements are not just projects for the IT department: the smart hospital involves participation between technologists and healthcare practitioners. Active collaboration is needed to protect smart hospitals and their smart systems as they can save more lives. Translating the smart hospital concept into reality relies on significant investment and a radical redesign of processes involving hospitals, clinicians and patients.

Conclusion

With the advent of information technology into every other sector, it was only a matter of time before it entered the health sector in a big way, with biotechnology-focused traditional medicine giving way to smart healthcare.

- Smart healthcare uses a new generation of information technologies, such as the Internet of Things (IoT), big data, cloud computing and Artificial Intelligence (AI), to remodel every layer of the healthcare system, making it more efficient, more convenient and more personalised.

- These modern information technologies are the foundation of a smart medical ecosystem with several dimensions including diagnosis, treatment, decision-making support and medical research (among many others) to enhance patient experiences.
- This chapter has provided an introduction to the new generation of information technologies that are revolutionising the health sector.
- It has illustrated how these technologies lead to increased efficiency, cost reduction and improved outcomes using case studies.
- It has examined the concept of smart hospitals and outlined the basic requirements for a traditional healthcare facility to become a smart hospital.

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Chapter 4

CONVENIENT CARE: THE RISE OF TELEMEDICINE

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Introduction

Accessibility and affordability are the two vital parameters that play a critical role in developing efficient healthcare delivery systems (Chhabra and Kohli, 2020). This becomes extremely important for developing nations with a large and growing population like India. The conventional method of delivering healthcare services and meeting the demand for a rapidly growing population through a hierarchical distribution method is itself a costly and challenging task for a country and the ruling government (*ibid.*). Hence, identifying a better methodology to meet the demand and supply of healthcare services in the fastest, safest and cheapest way is inevitable.

In the current era, digital and technological advancements have proved to be an efficient way to bring revolutionary changes across industries. The health industry has been successful in taking advantage of the mass digitisation shift by incorporating medical services such as preventive, diagnostic, therapeutic, patient education as well as self-management care through various telecommunication channels. This has been of immense significance during the COVID-19 pandemic of 2019 which limited patient mobility.

Telemedicine creates an opportunity by providing medical care, improved access to medical specialists and convenience to the patients all at low cost. Telemedicine services can reach anywhere, anytime using smartphone, tab and laptops; bringing close connectivity between healthcare specialists and patients. However, when we talk about tapping the internet's potential for telemedicine services, we are exposed to online threats and data security issues that hinder its mass adoption (Heston, 2018). This chapter will provide

1. The history of telemedicine and its development timelines.
2. The relationship between telehealth, telemedicine and their types.
3. The current status of telemedicine practices in India, with a comparison of pre- and post-COVID-19 scenarios.
4. An overview of telemedicine practice guidelines in India.
5. A SWOT analysis of telemedicine.

The History of Telemedicine

Telemedicine's quick emergence during the COVID-19 pandemic of 2019 may feel like it happened overnight. The coronavirus has clearly been a catalyst for our reliance on virtual care. Still, telemedicine has been around for quite some time. What may appear to be an unforeseen swell has actually been a slow burn. The conception and practice of using telecommunications technology to diagnose and treat cases have been around for decades. Some healthcare associations may feel outpaced by the new demand for video-conferencing-based consultancy. Others may be cautious of trusting what looks like a brand new technology. In the following sections, the history of telehealth will be explored, which happens to stretch back over a century (Sigmund Software, 2020).

Telemedicine Developments: A Timeline

Telegraph Transmissions during the Civil War

Communication across long physical distances was revolutionised with the invention of the electrical telegraph in the 1840s. The first major case of telecommunications for medical purposes came about a decade later when country miles of telegraph string were laid during the Civil War (PBS, 2014). The telegraph made remote wartime communication possible. It was used to order medical inventories and transmit casualty reports. The tech was so intertwined that telegraph carts generally idled right behind the front-line, transferring and entering information from the battleground as needed.

The Telephone Revolution

In 1876, Alexander Graham Bell was awarded a patent for his invention, the telephone, and the rest is history. This was the first step towards remote communication with medical professionals which they adopted quickly. Papers from a late nineteenth-century medical journal report the use of the telephone

to cut down on gratuitous office visits as early as 1879 (Lustig, 2012). The telephone allowed physicians to consult with their peers as well, improving the larger healthcare community.

When Radio Communication Emerged

Radio communication emerged at the turn of the century and was still a developing communication device in the 1900s. In 1928, Rev. John Flynn founded the Royal Flying Doctor Services (RFDS) in Australia, which became one of the primary telehealth services to have used the telegraph, radio and planes to deliver care in the remote areas of the country (Shampo and Kyle, 2005). Doctors consulted and diagnosed cases employing a combination of telegraph and radio communication, as well as flying in a healthcare provider to offer any necessary care. The RFDS entered international attention and considered the primary association to have conquered limited geographical access using telecommunications technology. Fast forward numerous decades, and radio communication became commonplace all over the world. The US army service relied heavily on telemedicine via radio to dispatch medical teams and choppers during the conflict between Korea and Vietnam.

TV and the Beginning of the Visual-based Telemedicine Era

When TV was invented, it made visual telecommunications a reality. This was a game-changing upgrade for early telemedicine practice. In the mid-1950s, the first attempt towards remote patient monitoring was made by the Nebraska Psychiatric Institute using closed-circuit television (AHRQ, undated).

By 1959, the institute offered various types of therapy, the majority of which was group and long-term therapy and medical student training at Norfolk State Hospital. In 1964, these two institutions started their first-ever video consultancy. Then, after three years, the primary comprehensive telemedicine system was put in to attach Boston's Logan Airport medical station to Massachusetts General Hospital. These events showed a potential reality towards remote diagnosis through interactive television (*ibid.*).

When NASA Pushed Telemedicine Forward

Telemedicine got its first big upgrade in the 1960s when NASA was on a mission to explore the possibilities of telemedicine in outer space. To find out, the United States and Soviets hooked animals up to medical observance

systems and sent them into space. After some time, NASA founded the Integrated Medical and Behavioural Laboratories and Measurement Systems (IMBLMS) program that was meant to develop a system that could acquire, display, analyse and record a wide array of medical, chemical science, microbiological and behavioural measurements and experiments designed to conduct a complete review of a human's well-being and operational capability (Simpson, 2021).

When the Internet Enhanced Telemedicine

Today, we live in the era of digitisation and rapid communication, all thanks to the high-speed internet connectivity that has changed our lifestyle forever. Today most things are interconnected, especially for the healthcare industry; the internet boom was like a technological breakthrough.

Along with the internet boom, the electronics and hardware industries were also booming to provide end-to-end support in the form of consumer electronics. The availability of various sensors, dynamic tools and computing technologies has given more opportunities to medical experts and engineers to explore the possibility of remote treatment.

Due to the unlimited possibilities with the Internet, telemedicine was revamped completely. Davidson and Santorelli (2021) have described the important factors as being:

- The faster Internet led to an efficient and quick transfer of data over a long distance in real time. As a result, telemedicine's speed and scope was forever enhanced.
- The widespread and low-cost Internet availability encouraged the mass adoption of digital technology that was needed to deliver telemedicine.
- Telemedicine is continuously improving and being refined due to the entry of various start-ups in this domain. However, powerful digital technology is still the foundation of a new era of telemedicine.

Telehealth and Telemedicine

Telehealth and telemedicine are often used synonymously. However, there is a difference between the two which is vital to understand. Telemedicine uses digital communications and information technologies to provide healthcare services to patients sitting at different locations. The term "Telehealth" is closely associated with telemedicine. The term "Telehealth" is often used to

represent a broader application of technologies to distance education, patient outreach and other applications wherein digital communications and information technologies are used to support healthcare services. Each form of remote healthcare services such as video consultancy, remote patient monitoring, data sharing and medical education is considered to be part of telemedicine and telehealth (Cranford, 2010). Telemedicine is not at all a separate healthcare ecosystem but it is a tool that could be used by healthcare experts to expand the traditional healthcare practices outside hospitals and clinics. Also, telemedicine provides a way to transform the healthcare ecosystem by encouraging consumers to participate in decision-making as well as new approaches to maintain a healthy lifestyle.

Types of Telemedicine

Store-and-Forward Telemedicine

The first type of telemedicine is known as store-and-forward telemedicine, also called "asynchronous telemedicine." In this type, the healthcare providers share health information data that may include lab reports, imaging studies and videos of the patient with healthcare experts sitting remotely (Chiron, 2021). The data transfer isn't done through normal digital platforms but from sophisticated, end-to-end encrypted secured cloud platforms to maintain patient data confidentiality. Store-and-forward telemedicine offers remote connectivity between patients, primary care and healthcare experts so that they could collaborate and review the information whenever possible. Store-and-forward telemedicine is considered when diagnosis and special treatments that include dermatology, ophthalmology and radiology are required.

Remote Patient Monitoring/Telemonitoring

The second type of telemedicine is telemonitoring. It enables healthcare experts to continuously monitor patients' vital health signs and activity remotely. Telemonitoring is used when care providers need to manage patients with high-risk conditions like heart problems, spinal ailments and so on (*ibid.*) or patients who were recently discharged from the hospital. Telemonitoring is especially useful for patients with chronic conditions. For example, a diabetic patient's blood glucose level needs to be monitored frequently; a spinal cord injury needs constant monitoring to avoid complications such as pressure ulcers or DVT (Tyagi *et al.*, 2019). The most

useful aspect of telemonitoring is that it can be done both conveniently and inexpensively.

Real-time Telemedicine

In this type of telemedicine, patients and healthcare providers use a real-time video-conferencing platform/software for health consultation, while the other types of telemedicine are used to enhance conventional in-person visits. It offers advantages by bringing primary care, urgent care and follow-up services online. Telemedicine platforms/apps are designed while safeguarding patients' privacy and protection to the highest level and to prove this, telemedicine companies must get Health Insurance Portability and Accountability Act (HIPAA) approval/local authority approval before offering their services (Chiron, 2021).

Current Status of Telemedicine

It is now clear that telemedicine is not a new technology but a continuously improving sector that has taken advantage of almost every innovation in the communication technologies and platforms of the respective decades. There are quite a few success stories where incorporation of telemedicine into the healthcare delivery system provided a fruitful outcome:

- **The telepediatric service in Queensland:** The service began in November 2000. It was developed steadily beyond its pilot phase and had integrated into the mainstream service. A centralised referral centre developed in Brisbane and is available to selected regional sites throughout Queensland. Telepediatric referrals are made easy by calling a toll-free phone number. A specialist response is guaranteed within 24 hours. Telepediatric coordinators provide full technical support. A video-conference call is established by a coordinator ready for the consultation with the regional clinician (referrer), the patient, and the family (Shampo and Kyle, 2005). Several secure and encrypted applications have been developed and studied in Singapore (Simpson, 2021; Emerson, 2020).
- In the United Kingdom (UK), in the orthopaedic domain, virtual fracture clinics are well established and are performing well, and were encouraged by the Royal College of Surgeons (RCS) Clinical Practice Guidelines, for a follow-up perspective (Shampo and Kyle, 2005; Simpson, 2021; Emerson, 2020).

- With the ongoing pandemic, the British Orthopaedic Association has, as per their BOAST guidelines, recommended the change-over of most if not all "non-essential" clinic visits to a virtual out-patient fracture clinic set-up (*ibid.*).
- Various successful telemedicine platforms have been established in India in association with the Indian Space Research Organization, such as Shankar Netralaya, Apollo, Mahatma Gandhi University of Medical Sciences and so on. Indian Spinal Injuries Centre has been running a telemedicine platform especially for spinal cord injured patients. This has been found to be very helpful considering the fact that the SCI consumers have mobility difficulties (Tyagi *et al.*, 2019).
- **Government initiatives that promote telemedicine in India**
  - The National Health Portal (NHP) provides information to citizens and stakeholders in different languages (currently six languages Hindi, English, Tamil, Gujarati, Bengali and Punjabi) to create awareness on the importance of good health, government programs and services in the health sector and so on. A voice portal with toll-free number 1800-180-1104 and mobile application are also available.
  - The Indian Space Research Organization (ISRO) through its Department of Space (DoS) had initiated a nationwide TeleMedicine (TM) programme in 2001 and provided telemedicine systems, hardware, software, communication equipment as well as satellite bandwidth for more than 384 healthcare centres with sixty specialty hospitals; connected to 306 remote/rural/district/medical college hospitals. 18 Mobile Telemedicine units were enabled for satellite connectivity to boost connected healthcare (Bhaskaranarayana *et al.*, 2009).

We are in the third decade of the twenty-first century; the application of telemedicine has already widened. Apart from doctor–patient remote connectivity and monitoring, new technologies like artificial intelligence systems use smartphones and various wearable sensors to accurately measure and record each event during a patient's health monitoring (Chhabra *et al.*, 2018; Tyagi *et al.*, 2019). The faster connectivity and high-speed data transfer have also allowed physicians to conduct a remote physical examination as well as remote surgery using a telerobotic system.

In 2019, we all faced the worst global health crisis in 100 years that forced the healthcare sector to widely switch to the digital mode of healthcare. This

is how the telemedicine sector saw a boost in recent times that played a critical role during the COVID-19 pandemic.

Healthcare agencies are now switching to high-quality video-based digital platforms to:

- Provide remote care directly to patients at their homes
- Enable real-time monitoring of patients' health and keep their practices open
- Assemble healthcare specialists virtually in case of emergency or special care
- Provide safety to healthcare workers and patients by reducing the chances of direct exposure.

The acceptance of telemedicine can be divided into three different phases using the Covid-19 pandemic as a marker.

Before COVID-19: Acceptance Barrier

We know that telemedicine is not a new concept and it has been around for decades. However, its acceptance and popularity didn't catch people's attention until recently when the COVID-19 pandemic hit the world hard. Before COVID-19, patients had to either live in or travel to that area where medical facilities were available. The physical presence of healthcare professionals was necessary for hospitals, labs and clinics. Limited numbers and hours of healthcare services were available (Pawar, 2021). Very few telemedicine services were approved to be delivered via real-time video conferencing. Telemedicine setup often required high up-front investment in platforms and hardware development. Some healthcare service providers were reluctant to adopt telemedicine, as they feared its perceived unreliability as a direct threat to their bottom line (Emerson, 2020).

During COVID-19: Telemedicine Transformation

It all turned around when the COVID-19 pandemic hit the entire world. The healthcare facilities suddenly witnessed patient surge as hospital beds were fully occupied and meeting experts was very difficult/risky. People were looking for alternative ways to connect with medical professionals which became the turning point for telemedicine mass acceptance. People and providers immediately started switching onto the digital mode of service delivery.

Telemedicine not only contributed to reducing the spread of the coronavirus, but also revolutionised service delivery. A number of

Table 4.1. The emergence of Indian telemedicine start-ups.

Startup	Launch Year	Presence	Types of Service	Number of providers on the platform
Practo	2008	15+ countries	Teleconsultation, online diagnostics, online pharmacy	2,00,000
1mg	2012	1000+cities	Teleconsultation, online diagnostics, online pharmacy, healthcare products	15,000+
MyUpchar	2016	200+cities	Teleconsultation, online diagnostics, online pharmacy, healthcare products	50,0000+
Lybrate	2013	80+cities	Teleconsultation, health information	1,00,000
DocPrime	2018	40+cities	Teleconsultation, online diagnostics	30,0000
mFine	2017	5+cities	Teleconsultation, online diagnostics	3,500+

telemedicine platforms flared up and performed well during that period in India (Table 4.1).

Why did telemedicine become essential? (Emerson, 2020)

- To offer necessary care for common ailments like cold and fever remotely without being exposed to COVID-19 patients.
- To provide mental health support
- To monitor COVID-19 patient's vital signs like heart rate and oxygen level, etc.
- To support patients on their lifestyle changes like immunity imbalance
- To reduce appointment costs, appointment delays and cancellations.

After COVID-19: The Future of Telemedicine

The year 2020 has transformed the global service landscape. Today both patients and service providers are aware about telemedicine. Though a

lot of education in the field is required, it could be difficult for them to go back completely to the conventional ways to avail telehealth facilities.

Since 2010, the healthcare market has grown about 12–15% per year including telemedicine. During the COVID-19 pandemic, the demand rose for skill-based jobs as health-tech professionals to develop the end-to-end infrastructure of the telemedicine network. IT and IoT domains witnessed huge hiring needs to meet 24/7 service demand. This could continue to grow even in the post-COVID-19 era as the providers are inclining towards using more cutting-edge technologies like Artificial Intelligence, Machine Learning, Data Science for accurate monitoring and predictive analysis (Loliwala, 2021).

The global telemedicine market is expected to grow at 38% while the Indian telemedicine market is expected to grow at 30% by 2025. Furthermore, India's healthcare market is expected to touch Rs. 37,000 crore in the financial year 2021–22 with a potential to create 1 lakh jobs approximately (*ibid.*).

Telemedicine Practice Guidelines in India

Earlier, doing telemedicine practices was challenging due to fewer regulations and guidelines which created speculation among the professionals regarding its legal validity. In common law, it is customary for the doctor to treat the patient only after clinically examining the patient (Mallikarjunaiah, 2020). A patient's health examination was considered as the first priority, without which the treatment may not be considered appropriate. Nevertheless, there was substantial confusion with regard to prescribing medication electronically as well. It was also felt that follow-up action can take place through telephone or any other medium of tele-communication technology, but the consultation had to be in-person only. At that time, India did not have dedicated law either prohibiting or regulating telemedicine. But the need became urgent in the COVID-19 pandemic to regulate telemedicine (*ibid.*). In March 2020, the Indian government launched telemedicine guidelines for the fair use of telemedicine practices that says "the professional judgment of a Registered Medical Practitioner should be the guiding principle for all telemedicine consultations: an RMP is well-positioned to decide whether a technology-based consultation is sufficient or an in-person review is needed. A practitioner shall exercise proper discretion and not compromise on the quality of care" (Medical Council of India, 2020).

We need to consider the following elements before beginning any telemedicine practices/consultation in India (*ibid.*).

i. Telemedicine should be appropriate and sufficient as per the context
ii. Identification of the registered medical practitioner and the patient is required
iii. Mode of telemedicine should be HIPAA compliant
iv. Patient consent should be taken before the consultation
v. Exchange of information for patient evaluation
vi. Types of consultation: first consult/follow-up consult should be mentioned
vii. Patient management: health education, counselling and medication
viii. Liability same as for in-person consultation.

Telemedicine applications can be classified into four basic types; according to the mode of communication, the timing of the information transmitted, the purpose of the consultation and the interaction between the individuals involved – be it RMP-to-patient/caregiver, or RMP to RMP.

- According to the mode of communication:
  - Video-based telemedicine facility, using video-calling apps such as WhatsApp, video platforms like Skype/Face time, etc.
  - Audio (Phone, VOIP, Apps, etc.)
  - Text-based:
    - Telemedicine chat-based applications like MFine, websites such as MDLive that provides 24/7 access, other internet-based systems, etc.
    - General messaging/chat platforms such as WhatsApp, Telegram, Facebook Messenger, etc.
    - Asynchronous (email, fax, etc.)
- According to the timing of information transmitted:
  - Any type of information related to in the form of video/audio/text can be exchanged.
- According to the purpose of the consultation (for non-emergency consult):
  - It is advisable to talk with any available RMP for the medical tests/diagnosis/treatment/counseling
  - Follow-up consult with the same RMP
- According to the individuals involved:
  - The telemedicine services can connect patients to an RMP on their respective platforms
  - A patient's caretaker can also use telemedicine services to connect with RMP to discuss on behalf of patient in some cases

- RMP may also use telemedicine services to discuss with a specialist (can be an RMP) in case of special care required or another RMP in case of handling multiple patients at the same time
- A health worker can also avail telemedicine consultation for a patient to connect with an RMP if required. In doing so, the worker can examine the patient and convey the findings to the RMP who could be sitting remotely. The health worker can easily explain/convey the advice given by the RMP to the patient.

SWOT Analysis of Telemedicine

Despite the strength that telemedicine holds, there are weaknesses, opportunities and challenges being faced. This section shall point out some of the aspects of SWOT analysis that could help the experts in keeping up with the pace of telehealth and telemedicine.

Strengths

- Accessibility of healthcare even at the remotest areas
- Affordability is at par with the traditional visits to the healthcare facilities (Pawar, 2021; Chhabra *et al.*, 2018)
- Saves the transportation time of the patients and their caretakers and hence doesn't compromise their livelihood (Chhabra *et al.*, 2018; Tyagi *et al.*, 2019)
- The value proposition is not only for patients but for healthcare settings too
- Indian Government's initiatives such as eSanjeeviniOPD.in, a free telemedicine service.

Weaknesses

- Patients feel that doctors should see them in-person for assured care.
- More relevant for follow-up and not for the first consultation
- Issues related to remuneration
- No health insurance coverage yet in India
- HIPAA and other regulatory compliances (Pawar, 2021)

Opportunities

- The long-existing problem of accessibility in Indian healthcare
- Affordable healthcare

- An increasing rate of technology adoption in millennials (Tyagi *et al.*, 2019)
- Increasing user base of smartphones (Chhabra *et al.*, 2018)
- Increasing internet penetration in remote locations (Tyagi *et al.*, 2019)
- Upcoming 5G network
- Supportive government policies and initiatives
- Healthcare providers scaling up in a new segment
- New medical device startups are focusing on remote diagnoses and mobile ATM-based healthcare services.

Threats

- Increasing incidences of data theft and other cybercrimes (Tyagi *et al.*, 2019)
- New policies and initiatives are government-dependent
- Possibility of abuse or misuse; hence, ensuring the privacy of patients in video consults is extremely important.

Conclusion

Telemedicine has proven to be an "effective practice of using communications technology to link healthcare providers to their patients and each other" by accessible and affordable means. People often get confused between "Telemedicine" and "Telehealth" which differ from each other. The chapter discusses the differences between the two terms and what they incorporate.

- Though Telemedicine has been present for a long time, the COVID-19 era acted as a catalyst that boosted its adoption amongst patients and healthcare providers. Hence this "new" practice of medicine has a long way to go.
- It has been found that a majority of patients seek internet help when they feel uneasy before going to medical professionals. In the future, the healthcare industry will be driven by patients' comfort and technology.
- The booming technologies like Artificial Intelligence, Machine Learning, Data Science, Augmented Reality and Virtual Reality will play a crucial role in more accurate and immersive healthcare experiences.
- The goal should be to make telemedicine more cost-effective, easily accessible, and evidence-based.
- The telemedicine supporting policies and initiatives hold the potential to become the fundamental rights to healthcare access.

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Chapter 5

THE VOCATION OF HEALING: CAREER PROSPECTS IN MEDICAL TECHNOLOGY AND RESEARCH

Suptendra Nath Sarbadhikari

Introduction

The goal of this chapter is to help the readers in choosing a career path in this field. The objective is that the readers should be able to demonstrate a clearer understanding of the career exploration process and how their own skills and interests match up to a chosen career path.

The associated learning outcomes are that the reader will be able to:

(i) Ascertain at least one career path they are interested in exploring further.
(ii) Evaluate their values, interests, strengths and skills.
(iii) Engage by cultivating a professional network and participating in informational interviews.
(iv) Implement a career path of either job or higher studies or research, by identifying and using relevant tools in the job and course search, including activating professional networks.

In the subsequent sections we discuss possible career paths, evaluation of your values, interests, strengths and skills; where to look for jobs, and, areas of specialisation in medical technology and research. These are followed by the conclusion.

Common and Specific Requirements for a Good Career

While a good grasp of the core specialisation is absolutely essential for getting a good job, going up the career ladder requires a few other attributes as well (Eastwood, 2021; Illinois Graduate College, 2021; SRG Talent, 2021; Abbott, 2019; Sarbadhikari, 2020).

Core / Essential Skills / Competencies

- Discipline-specific conceptual knowledge and skills. Some examples (details given in the next section):
  - Quality Assurance (QA)
  - Quality Control (QC)
  - Software as Medical Device (SaMD)
  - Manufacturing
  - Field Engineering
  - Research and Development (R&D) Design
  - Validation
  - Sales
- Communication skills, particularly for working in multi-, inter- and trans-disciplinary teams
- Research Aptitude and Skills – Lifelong Learning.

Desirable Qualifications

- **Professionalism**: It involves being reliable, setting your own high standards of expertise and experience, and showing that you care about every aspect of your job. It means being industrious and organised, and holding yourself accountable for your thoughts, words and actions.
- **Leadership and Management Skills**: Common ones include decision-making, particularly making tough decisions when a problem arises; communication; confidence; responsibility; vision and integrity.

We may alternatively classify the requirements for a good career in this field in the following manner:

Hard Skills

- **Research Methodology**: The specific procedures or techniques used to identify, select, process and analyse information about a topic.
- **Project Management**: The process of leading the work of a team to achieve all project goals within the given constraints; the use of specific knowledge, skills, tools and techniques to deliver something of value to people.
- **Data Analytics**: A process of inspecting, cleansing, transforming and modelling data with the goal of discovering useful information, informing conclusions and supporting decision-making.

Soft Skills

- **Communication**: The act of meaningfully transferring information from one place, person or group to another.
- **Flexibility** and **Agility**: Agility is the natural evolution of flexibility. While flexibility is considered as an operational ability, agility is a strategic ability that enables a firm or an individual to establish a strategic long-term vision. In fact, flexibility is an agility capability, among other capabilities such as responsiveness or speed.
- **Self-Motivation**: Our internal drive to achieve, produce, develop and keep moving forward.
- **Persistence**: The quality that allows someone to continue doing something or trying to do something even though it is difficult or opposed by other people.
- **Team Work**: The collaborative effort of a group to achieve a common goal or to complete a task in the most effective and efficient way.

Some of the possible career pathways are listed below.

Possible Career Paths

- Research and Development (Industry)
- Research and Teaching (Academia)
- Medical Writing/Content Creation
- Project Management (across a variety of workplaces)
- Servicing/Maintenance (Field Engineering) of medical equipment (Medical Device Industry or hospitals)
- Pre-sales and Marketing of Medical Equipment
- Sales of Medical Equipment
- Hospital Biomedical Equipment Management/Administration.

The common career pathways may include performing skilled technical work in the administration of specialised procedures and/or studies used for the diagnosis and treatment of patients.

The tests may include ultrasound, cardiac graphics and nuclear medicine. In general, one has to perform diagnostic testing in various clinical settings. Duties performed may include taking, developing and interpreting test results that will be reviewed by the physician. Further, summarising and communicating technical findings and using and maintaining technical equipment effectively. Work would most likely be working directly with patients, for

example, preparing patients for procedures, positioning patients and providing instruction.

At the **entry level**, one has to perform basic ultrasound, cardiac graphics and nuclear medicine procedures/studies. The employees are responsible for preparing the patients, adjusting conditions to achieve acceptable results, recording results and preparing a summary of technical findings. Employees present and discuss results with the provider. Additionally, they may have to train and monitor students.

At the **mid-level**, one has to perform more complex and/or specialised ultrasound, cardiac graphics and nuclear medicine procedures/studies. Employees are responsible for assisting others in interpreting results, monitoring safety and health control procedures, maintaining equipment, maintaining supply inventory, assisting in scheduling and evaluating new radiological procedures, equipment and methods. The job may include instruction of students and training of new employees. Employees may serve as lead worker and/or assist supervisor in human resources functions.

At the **advanced level**, one has to perform more complex and/or specialised ultrasound, cardiac graphics and nuclear medicine procedures/studies. Employees at this level supervise others and coordinate activities in a department or section. This career position may include training, evaluating and counselling others. Further, it may include developing and delivering educational programmes for staff and students.

Competencies Required

Knowledge: Technical skill and knowledge in medical diagnostic technology and the ability to learn medical diagnostic techniques.

Coordination: Work ability to follow specific procedures and instructions. Ability to perform routine tasks and to check work for accuracy. Ability to coordinate and maintain equipment, supplies and related resources.

Patient Care Ability: Ability to work with patients in a medical setting.

Data Collection/Analysis: Ability to observe, monitor, collect and record data. Ability to monitor, collect and assess the accuracy, validity and integrity of health data. Ability to interpret and evaluate results and create reports and/or presentations.

Instruction Ability: Ability to instruct and train employees, students, faculty and/or other clients by providing information, including appropriate procedures, practices and/or operation of equipment.

Human Resources Management: Knowledge of appropriate policies and procedures for recruiting, selecting, developing, counselling, disciplining and evaluating performance of employees to retain a diverse workforce.

A **clinical laboratory technologist** is a highly skilled professional who tests specimens for diseases. They usually work with doctors or other medical professionals to carry out laboratory tests and scientific analyses of specimens such as blood, urine and tissue samples. Thereby they generate data that helps physicians determine the best treatment for the patient. To perform the necessary lab tests, they typically use various lab equipment, including automated machines that can perform multiple tests at once.

The **job duties and responsibilities** of a clinical laboratory technologist include:

- Analysing the chemical constituents of a patient's body fluids
- Cross-matching donor blood for transfusions
- Determining blood-clotting abnormalities
- Testing blood for drug levels to determine the effectiveness of particular treatments
- Evaluating test results for accuracy and interpreting them for the physician
- Operating sophisticated lab equipment such as cell counters and microscopes
- Storing and retrieving equipment and chemicals according to the manufacturer's specifications
- Logging data from medical tests and entering results into a patient's medical record
- Discussing the results and findings of lab tests and procedures with physicians.

Clinical laboratory technologists work in a variety of settings, including the following:

- Hospital clinical laboratories
- Public health laboratories
- Commercial or reference laboratories
- Chemical or pharmaceutical industries
- Biotechnology companies
- Veterinary clinics
- Law enforcement and forensic laboratories
- Fertility clinics
- Teaching and research institutions
- Testing laboratories in the cosmetics or food industry
- Blood donation and transplant centres.

Medical laboratory scientists have a wide variety of responsibilities and duties, including the following:

- Examining and analysing blood, body fluids, tissues and cells
- Relaying test results to physicians
- Utilising microscopes, cell counters and other high-precision lab equipment
- Cross-matching blood for transfusion
- Monitoring patient outcomes
- Performing differential cell counts looking for abnormal cells to aid in the diagnosis of anaemia and leukaemia
- Establishing quality assurance programmes to monitor and ensure the accuracy of test results
- Overseeing the work of a medical laboratory technician.

The market for technological innovators in the healthcare field is expanding very fast. The dynamic healthcare device research and diagnostics industry needs people who are passionate about technology, want to make a global impact and save lives. Trans-disciplinary setups are necessary to develop the full potential of healthcare technology. While there are already some jobs available in this sector, the cutting-edge developments are opening up new career opportunities.

Conventionally, technology in healthcare means computers, patient databases, clinical apps and other administrative tools. However, advances in computing are regularly creating new markets for exciting innovations relying on next-gen technology. Computer-Aided Design (CAD) and 3D printing technology are making revolutions in medical technology, particularly for implants. An excellent open access review is available online (Fan *et al.*, 2020). 3D printing technology has been used for

- 3D skin (Pai, 2017)
- Drug and pharmaceutical research (Norman *et al.*, 2018)
- Bone and cartilage (Mori *et al.*, 2018]
- Replacement tissues (Yigong *et al.*, 2017)
- Organs (Ventola, 2014)
- Printing for cancer research (Knowlton *et al.*, 2015)
- Models for visualisation, education and communication (Qian *et al.*, 2018).

Equipped with ever-improving tools for data integration, Artificial Intelligence (AI), mobility, IoT (Internet of Things) enablement, wearables and robotics, medical technology firms are ideally poised to design next-gen solutions to the most pressing healthcare challenges, both current and evolving.

An excellent update on these applications and opportunities is available online (Bohr & Memarzadeh, 2020). A lot of newer possibilities are discussed in detail by Mbunge *et al.* (2021) and Haleem *et al.* (2022). Some examples:

- Internet of health things (Tsafack *et al.*, 2020)
- Wearable internet of things, IoMT (Haleem *et al.*, 2022)
- Cognitive internet of medical things (Swayamsiddha & Mohanty, 2020)
- IoNT*, and internet of mobile-health things (Pramanik *et al.*, 2020)
- Effective patient remote monitoring and tracking and virtual clinics (Seshadri *et al.*, 2020)
- Emotive Telemedicine (Akintunde *et al.*, 2021)
- Active Assisted Living (Taiwo & Ezugwu, 2020)
- Smart self-management and wellness monitoring and control (Choi *et al.*, 2018)
- Smart treatment reminders, compliance and adherence (Frangou *et al.*, 2005)
- Personalised and connected healthcare (PCHA, 2022).

In the near future, medical technology will aim to imitate human intellect and skills using machines, software and computer platforms. This will be possible because of advanced digital technologies, which make systems more productive and revolutionised. AI advances will lead to computing systems that can see, hear, learn and reason. All of these will be opening up new avenues for improving education and healthcare, addressing poverty and achieving a more sustainable future.

In the medical domain, scientists have cracked the human genome; learnt how to edit and splice DNA; introduced surgical robotics; designed wearable and implantable medical devices. They have also created new diagnostic tools that help physicians quickly and precisely diagnose everything from rare diseases to viral infections to heart diseases.

None of these exciting medical advances would have been possible without cutting-edge technology and the people who understand how to build it, use it and improve upon it. That includes people who have training and experience in bioengineering, mechanical and electrical engineering, software development, app development, information systems and many other skill sets that come with a tech degree. In other words, there is a need for team work, in a trans-disciplinary setup for healthcare technology to utilise its full potential.

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* IoNT (Internet of Nano Things) is the interconnection between nanoscale devices and the existing communication networks to perform tasks such as sensing, actuation and transmission via electromagnetic radiations.

Once you are confident of your core skills and knowledge, you need to look at the following factors before applying for any job.

Evaluation of Your Values, Interests, Strengths and Skills

Self-assessment is the process of identifying

- What matters most to you (Values)
- What you enjoy doing (Interests)
- Your knowledge and attitude (Strengths)
- What you are good at (Skills).

During graduate school, students usually acquire sophisticated skills in

- Research
- Problem solving
- Project management
- Communicating complex ideas.

Taking time to identify and articulate your skills is critical not only for successful career exploration but also for the creation of convincing résumés and cover letters. The knowledge gained during the self-assessment process also translates into greater self-confidence and savvier answers in interviews. The books by Basalla and Debelius (2014) and Bolles (2012) are excellent resources for trying these out.

One of the ways to find your strength/attitude/personality is the personality test based on Carl Jung's and Isabel Briggs Myers' typological approach. According to Carl Gustav Jung's theory of psychological types, people can be characterised by

- Their preference of general attitude: Extraverted (E) vs. Introverted (I),
- Their preference of one of the two functions of perception: Sensing (S) vs. Intuition (N)
- And their preference of one of the two functions of judging: Thinking (T) vs. Feeling (F).

The three areas of preferences introduced by Jung are dichotomies (i.e. bipolar dimensions where each pole represents a different preference). Jung also proposed that in a person one of the four functions above is dominant – either a function of perception or a function of judging. Isabel Briggs Myers, a researcher and practitioner of Jung's theory, proposed to see the Judging

(J) vs. Perceiving (P) relationship as a fourth dichotomy influencing personality type.

You can test your personality for free, using the above framework here: http://www.humanmetrics.com/personality or here: http://www.humanmetrics.com/cgi-win/jtypes2.asp

Where to Look for Jobs

There are various ways of finding jobs. Some of these could be:

1. Information from a friend or senior or teacher or a social network like LinkedIn
2. Searching through Google
3. Searching through job portals like Naukri.com
4. Searching directly through the websites of various academic institutes
5. Searching directly through the websites of various reputed companies dealing with healthcare/medical technology

Areas of Specialisation in Medical Technology and Research

While the different chapters of this book have given you an outline of the various disciplines, multi-disciplinary, inter-disciplinary and trans-disciplinary areas of health technology, this section will highlight some useful areas to focus your careers further.

Many technological innovations have been successfully applied right from the onset of the COVID-19 pandemic (Sarbadhikari & Sarbadhikari, 2020). One of the commonly overlooked areas of concern is the use of standards for meaningful exchange of health information (Sarbadhikari, 2019). Another area of concern is the application of safe and ethical technology for healthcare (Sarbadhikari & Pradhan, 2020). Patient safety and better health outcomes demand consideration of quality checks.

Quality Assurance (QA)

Quality assurance and quality control are complementary parts of a Quality Management System (QMS). Medical device engineers sometimes use the terms "quality assurance" and "quality control" interchangeably, but a clear understanding of the difference between these two processes can bring clarity to the overall structure of the quality process in any medical device company.

Quality assurance is proactive and process-focused. QA prevents flaws in the way a medical device is manufactured. Quality assurance takes place throughout the medical device manufacturing process. Quality staff look for problems in processes that might result in nonconforming products, and fix those processes that would otherwise cause defects.

QA occurs **throughout** the product lifecycle.

Quality Control (QC)

Quality control is reactive and product-focused. QC finds flaws in products after they have been manufactured but prior to distribution into the marketplace. Quality control tests products or batches of products to see whether they conform to product specifications. The goal is to catch defective products before they are shipped to the end user.

QC occurs **after** a physical product is ready to be shipped.

The combination of QA+QC is what gives your medical device company the greatest likelihood of attaining the highest level of quality.

Software as Medical Device (SaMD)

The Medical Devices (Amendment) Rules, (2020) is an Amendment to the Medical Devices Rules, 2017. Software as Medical Device (SaMD) is included in that Act. SaMD is software intended to be used for one or more medical purposes without being part of a hardware medical device, previously known as medical device software.

Manufacturing/Research and Development (R&D)/Design and Validation

Research and Development (R&D) are typically of three different types: Basic Research (where the objective is to fully understand one particular subject area, rather than in practical application); Applied Research (the investigation work necessary in acquiring new knowledge to create commercially marketable products and services) and Development Research (a systematic piece of project work that uses existing knowledge gained from research or practical experience for developing a new product, service or process).

The US FDA (2018), describes five stages for processing medical devices to prepare them for market. These stages form their Quality System Regulation (QSR), which governs "the methods used in, and the facilities and controls used for, the design, manufacture, packaging, labelling, storage, installation, and servicing of all finished devices intended for human use."

The FDA stages are as follows:

1. **Phase 1: Device Discovery and Concept:** Initiation – opportunity and risk analysis
2. **Phase 2: Preclinical Research and Prototyping:** Formulation – concept and feasibility analysis
3. **Phase 3: Pathway to Approval:** Design and development, including verification and validation to ensure the design output matches the specified design input
4. **Phase 4: Regulatory Review:** Final validation and product launch preparation
5. **Phase 5: Post-Market Device Safety Monitoring:** Product launch and post launch assessment.

You may choose to join the teams doing any of the above tasks in the various phases described above.

The Department of Health Research (2018) has already published Policy Documents for the Health Technology Assessment of (a) Safety Engineered Syringes, (b) Intraocular Lenses for Cataract Surgery and (c) Hemoglobinometers for Anemia Screening.

The Central Drugs Standard Control Organisation (CDSCO) of India has notified, under The Medical Devices (Amendment) Rules, 2020 (Government of India, 2020), that all medical devices manufactured in India or imported into India have to either be licensed or registered by 1 October 2021. If a medical device is manufactured or imported after 1 October 2021 without registration or license, it will be deemed to have been manufactured or imported in violation of Indian law, thereby inviting penal action.

Modern medical device development calls for upgrading Requirements Management (RM). RM denotes the capture, management, verification and maintenance of requirements information across the development process for safer, more effective medical devices. RM tries to manage complexity and improve quality by understanding the impact of changes across the medical device product lifecycle. It could mean the difference between life and death for vulnerable patients who depend on medical equipment to live. The factors of safety, reliability, security and quality control have to be kept in mind during RM.

Providing a medical device's compliance can be complex. Traditional document-driven models are not ideal for this purpose, either, as they can involve many discrete spreadsheets and other files that take a long time to retrieve, review and organise. The inefficiency of these workflows also complicates the traceability of development activities back to requirements.

In contrast, a centralised platform, with all key information in one place, can provide clearer insight into design controls for device requirements and related risks. Various software applications are available to gain real-time visibility into how design inputs have been met and verified, providing necessary evidence from the design control process, for better-informed decision-making and a more streamlined overall development process.

Next-generation medical devices have to be designed and developed with the following objectives in mind:

- Reducing healthcare costs
- Improving quality of care
- Personalising care for individuals
- Making it easy for healthcare consumers and physicians, nurses and technicians to use the devices available to them
- Ensuring regulatory approval.

That will require Design Thinking (Jamkar & Sarbadhikari, 2021), which is a human-centred approach to solving complex, ill-defined problems. Multidisciplinary teams come together to conceive of new products, solutions and business processes – asking questions like:

- Who will use this device?
- What is it that each different group of users want from it?
- How are different users struggling with devices available now?
- How can we overcome those pain points?

Then, ideate (brainstorm), plan and develop a prototype that can be used for experimentation, fine-tuning and making usable and adoptable widely.

Field Engineering

Field engineering involves working in coordination with the other departments, engineers and construction personnel when completing maintenance and equipment installations. A *field engineer* refers to the person you find actively working at job sites instead of in the office. He or she provides services to the clients. *Field engineers*, also known as field service technicians and equipment engineers, are specialist technicians responsible for inspecting and installing equipment and new technologies, directing crews or workers on site, and conducting research.

We discussed above some of the common pathways for starting a career in medical technology.

A career may start with one type of job and progress across various other types/specialisations of jobs throughout the career span. The career prospects for any individual, well trained and following the self-evaluation processes mentioned in the previous sections, will be growing in the near and distant future.

Most medical technologists employed in hospitals, private laboratories, physicians' offices, government agencies, industrial and pharmaceutical laboratories and university research programmes offer growing opportunities for employment advancements. The field offers advancement into supervisory, administrative, educational and specialty positions with experience and/or additional education. For honing up these additional skills (and attitude), the career seeker has to undergo further training. This training could be on-the-job, or acquired through external sources. Nowadays excellent MOOCs (Massive Open Online Courses) are available and they can provide this necessary value addition for climbing up the career pathways.

Conclusion

Medical or healthcare technology is a thriving and expanding industry. Therefore, job openings for tech-savvy employees who can help develop the next generation of medical devices and diagnostic tools, are in great demand and rising.

- Recession-proof, high-paying career opportunities do exist. Two industries where there is job security despite an economic downturn are healthcare and high-tech. These industries – and job opportunities within them – will continue to grow with evolving technology and the rapidly aging population, boosting demands for innovative new solutions that help people live longer, healthier lives.
- The fast-paced, innovative environment makes a career in medical technology exciting, challenging and never boring.
- The work experience is often emotionally rewarding as it is obtained by saving lives and improving the quality of life of people.
- Ongoing professional growth and development, particularly through networking, is encouraged in order to excel in this field.
- Choosing a specialisation, liking and excelling in it, as well as working on the other soft skills, attitude and values will make a candidate highly sought after in the job market. The excellence in knowledge, skills, attitude and values will transform the job into a flourishing and enjoyable career.

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Chapter 6

THE SKY IS THE LIMIT: CLOUD COMPUTING IN HEALTHCARE

Bernard L'Allier

Introduction

As the other chapters in this book have demonstrated, technology does have a profound effect on every aspect of the healthcare industry. All the technological innovations transforming the delivery of healthcare and the analysis of healthcare data require ever-growing quantities of computing power and vastly increasing storage volumes which traditional healthcare computing models cannot keep up with. Cloud computing is a key component of that revolution. This chapter will

1. Provide a brief overview of cloud computing and its evolution from traditional computing.
2. Analyse the current applications of cloud computing in healthcare and the future opportunities it offers.
3. Assesses the barriers to the faster adoption of cloud computing in healthcare.
4. Compares the specific Indian opportunities and challenges for cloud computing in healthcare.

What is Cloud Computing?

According to NIST, the US National Institute of Standards and Technology, cloud computing is a model for enabling ubiquitous, convenient, on-demand network access to a shared pool of configurable computing resources (e.g. networks, servers, storage, applications and services) that can be rapidly provisioned and released with minimal management effort or service provider interaction (NIST, 2011). Cloud computing allows for a much faster rate of

development and deployment of computer applications. Simultaneously, it also allows for the ability to scale those applications much more quickly without human intervention to meet sudden spikes in demand for computing power.

In a traditional datacentre, new applications can take years to develop, months to deploy and weeks to upgrade for additional capacity. This makes it impossible to run critical real-time applications such as telemedicine and AI diagnostic tools in a traditional computing environment, because sudden spikes in demand can lead to degraded performance and unavailability which could cause life-threatening real-world consequences.

Similarly, the revolution in Smart hospitals, with IoT and AI, has transformed patient care and also dramatically improved efficiency in non-clinical areas such as document management and logistics planning. This drives down the cost of healthcare and reduces the administrative burden on doctors so that they can interact with patients. However, it relies heavily on behind-the-scenes availability of reliable and scalable computing power to ensure that the tools in use remain online and responsive during peak demand.

Cloud computing is particularly important in driving down the cost and complexity of technology for smaller hospitals and clinics, particularly in remote areas where the lack of technology skills and the necessary physical infrastructure necessary to operate computers can be a critical barrier to technology-augmented healthcare. Due to this feature, cloud computing can serve as a strong lever for countries like India with large, diverse and widespread populations to increase affordable access to healthcare (Moghaddasi & Tabrizi, 2016). These benefits at the healthcare provider level are well understood and have created a broad consensus on the benefits of greater focus on and investment in cloud computing technology (McKinsey, 2021).

> Cloud computing is conducive to innovation in healthcare since it enables an organization to move from a capital-intensive model, with onsite server infrastructure, to an operation-based expense model using third-party service level agreements with Cloud Service Providers (CSPs). This transition allows healthcare organizations to save costs since they need not build a dedicated and secure IT facility and instead spend only for essential applications, hosted on a remote server with industry-level security features. (Raghavan *et al.*, 2021)

Cloud Computing Impact on Frontline Healthcare

Traditional computing in a hospital setting has played a small role in the frontline work of healthcare professionals interacting with patients. Computerised records and hospital administration systems have of course

driven significant efficiencies in healthcare, but until recently, doctor–patient interactions were not highly technological: the main role of technology was in driving medical research, digitising and optimising hospital equipment and improving the speed and accuracy of patient test results. Each of these has driven critical behind-the-scene improvements to healthcare outcomes, but have largely been invisible to patients and were not highly dependent on the availability of technology within the hospital setting.

However, this has changed dramatically in recent years with the many advances that have been covered in this book. Telemedicine, AI diagnostics, real-time patient monitoring through IoT systems and so on are becoming ever more advanced and ever more dependent on the availability of high-performance computing power to all corners of the hospital and beyond (in the case of remotely delivered healthcare). The real-time nature of these technologies mean that computing power must be always available (with real and sometimes deadly consequences for patients should systems be offline) and scalable on-demand as system overloads can again lead to outages and performance drop-offs.

This means that advances in these high-technology capabilities are critically reliant on the deployment of cloud-computing technology in a hospital setting. This is because traditional datacentre operating models, with a limited quantity of computing power designed to serve a number of non-patient facing processes which can survive periods of computing power unavailability, are no longer suitable.

Before COVID-19, the growth in the patient-centric use of technology was slowed by a conservative regulatory approach to technological adoption by most countries worldwide. Services such as telemedicine are relatively straightforward to set up and very familiar to a world which has enthusiastically adopted video calling for both work and personal use. However, in a medical setting, many concerns from both the practical (the perceived higher likelihood of an inaccurate diagnosis, to the logistics (concern over regulatory uncertainty, insurance coverage differences etc.) and the emotional ones (basic lack of familiarity with the use of technology in this setting by both doctor and the patient) significantly held back usage.

But post COVID-19, it became, in many cases, the only way to provide and receive care. Hence each of these difficulties were rapidly resolved to ensure that rules and norms were adapted to the requirements of an increasingly virtual world (Metzger *et al.*, 2021). This was a critical and necessary evolution of a technology that had already been designed and was awaiting widespread adoption. However, the surge in usage put sudden and intensive demands on healthcare provider computing resources which cloud computing helped to alleviate.

Cloud Computing in Medical Research

In research settings, the importance of cloud computing is every bit as important in supporting the ever-accelerating rate of development in medical science. As a pertinent recent example, the COVID-19 pandemic created an urgent pressure on researchers to find a vaccine at a much faster rate than ever before. They used cloud computing to drive the computer modelling which solved many of the complex problems to allow them to develop and test vaccines many times faster than before (McKnight and Jordan, 2020). This is just one high-profile example of the application of ever-larger quantities of computing power in accelerating the rate of medical research. Pharmaceutical companies increasingly use computing power not just to perform calculations but, through artificial intelligence and machine learning, to decide how to solve the problems that hold back drug development (Komarraju, 2021).

Similarly, cloud computing has been instrumental in modernising the way medical images are started and shared for manual collaboration among medical professionals and patients. It is the foundation for an increasing number of medical start-ups to provide AI imaging services which show great promise in reducing costs and improving patient outcomes (Hardy, 2019).

Barriers to the Faster Adoption of Cloud Computing

The benefits of cloud computing are already highly visible, but there remain a number of important barriers to more widespread adoption. These include:

Security Concerns

By its very nature, cloud computing increases the number of potential access points for healthcare data by creating centralised platforms with software-defined access (through Automated Programming Interfaces or APIs) to many users and applications. The openness of these systems and the sharing of data between applications is critical in supporting the positive outcomes which cloud computing enables, but of course, security becomes a critical concern. Of particular concern to regulators, healthcare providers and patients is the question of data security. Given the highly personal nature of healthcare data, security and confidentiality are of critical concern to patients. To ensure that the patient–doctor relationship runs smoothly, patients must have faith in the healthcare system to keep their data private (Al-Issa *et al.*, 2019).

Skill Shortages

The surge in demand for IT skills has made it harder for healthcare providers to retain and grow the capabilities they need in order to reliably

deploy cloud computing. Technology is not a core competency of hospitals, clinics or healthcare professionals. Due to the particular importance of any technology deployed in a healthcare setting (particularly any directly clinical healthcare applications), the high complexity and the IT skills shortage create a significant barrier to adoption. This makes healthcare technologically reliant on large investments of time and capital either through contracts with IT services organisations or through the direct hiring of IT specialists. Both of these routes carry long-term benefits but at a cost and complexity point which can be particularly difficult for smaller healthcare providers or those serving poorer patients, each of which are typically operating in a very lean way.

This makes private-investment-driven health technology spending heavily weighted toward larger hospitals serving wealthier patients with higher expectations of a modern service. Meanwhile, those providers and patients who could benefit the most from the adoption of technology are the least likely to see those benefits without significant government involvement to standardise healthcare technology and drive down the barriers to adoption.

Lack of Infrastructural Availability and Reliability

This is important in the supply of datacentres which drive cloud computing itself and the scale and reliability of the telecommunications network which makes that computing power accessible. In the healthcare context, where non-availability of systems can be a matter of life and death, this systems availability is of particular importance. As with the skills gap question above, this creates a particular challenge for poorer and more remote areas which, due to a shortage of healthcare professionals, could benefit the most from services like telemedicine. The absence of reliable infrastructure and the lack of patient money to generate demand for higher technology services, however, create a double disincentive which slows private sector delivery of healthcare technology into these areas.

These challenges create a number of barriers to wider and faster adoption of cloud computing in healthcare. Therefore, when healthcare technology investment is left to the free market, the benefits will only be very slowly adopted as healthcare providers take a conservative view of the return on their investment in healthcare technologies and the risk of greater regulatory scrutiny, hence slowing their overall investment, and focusing it strongly on pockets of greater wealth.

Further, even the slower rate of technology adoption would be unevenly distributed with investment driven by the budgets of larger healthcare providers serving wealthier patients while many of the most pressing opportunities outlined above will be underinvested.

Even more significantly in the long term, leaving cloud-computing approaches to individual healthcare providers would create data siloes which would make it much harder to achieve many of the exciting public health advances which become possible when healthcare data are centralised on a national scale. These possibilities are outlined in Chapter 2 and represent one of the most exciting opportunities for improvements in public health, but the scale and interoperability of the data sets is critical.

How to Address These Barriers

To address this challenge, many countries are taking a centralised approach to their healthcare strategy on cloud computing. Setting a common set of regulator-approved standards for the use of cloud computing in standards is the minimum requirement, but many countries, including India, have gone much further and planned healthcare platforms such as H-Cloud and the Ayushman Bharat Digital Mission.

The proximal goal of this platform is to drive standardisation and efficiency in the healthcare sector:

> The implementation of NDHM is expected to significantly improve the efficiency, effectiveness, and transparency of health service delivery overall. Patients will be able to securely store and access their medical records (such as prescriptions, diagnostic reports and discharge summaries), and share them with healthcare providers to ensure appropriate treatment and follow-up. They will also have access to more accurate information on health facilities and service providers. Further, they will have the option to access health services remotely through teleconsultation and e-pharmacy. NDHM will empower individuals with accurate information to enable informed decision making and increase accountability of healthcare providers (National Health Authority, 2021).

However, an explicit goal is also to support the more advanced use cases which critically depend on a strong and flexible cloud platform for their effective use:

> Emerging technologies such as Artificial Intelligence, the Internet of Things (IoT), blockchain and cloud computing provide additional opportunities for facilitating a more holistic digital health ecosystem, that can increase the equitable access to health services, improve health outcomes and reduce costs (National Health Authority, 2021).

Security concerns are explicitly addressed within the context:

> 3.8.5. "Health-Cloud (H-Cloud): The Health-Cloud will be built on the MeitY initiative of Government Community Cloud (GCC) or Virtual Private Cloud (VPC) with stronger security and privacy policies and infrastructure. Key data hub management services of the Mission will be deployed on the H-Cloud."
>
> 3.8.6. "Security and Privacy Operations Centre (SOC): All events on the Health-Cloud and the Health Network will be under 24x7 security surveillance ensuring every data byte is highly secure. This will be achieved through a Security Operations Centre (SOC). NDHM will establish a Privacy Operations Centre (POC) to help drive compliance on the privacy requirements, adherence to which is a must in the health sector. The POC will monitor all access to private data, review informed consent artefacts, audit services for privacy compliance, evangelize the privacy principles on which the building blocks of the Mission will be built and bring trust and strategic control in the usage of health data in the ecosystem." (National Health Authority, 2021).

Conclusion

It is critical that the wider healthcare sector invests in cloud computing and invests strongly in modernising their systems and their approach to managing computing infrastructure. All stakeholders (the government, healthcare firms and practitioners and patients) will see significant benefits in improved patient experience and better healthcare outcomes at lower costs if cloud computing is widely embraced and well implemented.

- This chapter has explored the increasing role of cloud computing in meeting the ever-growing computing requirements of the modern global healthcare system.
- It has examined some examples of the many and growing number of healthcare applications which critically depend on cloud computing and the benefits of adoption.
- It described some of the key barriers to wider cloud adoption and, in particular, the danger that shortages of skills and funding will limit its impact on the areas most in need of innovative technology solutions to solve critical healthcare shortages and cost barriers (particularly in the Indian context where a large, widely spread and low-income population receive little healthcare coverage).

- It examined the centralised approach that the Indian government has created to improve the impact of cloud computing on the overall Indian healthcare system.
- With this blueprint for central healthcare cloud planning, it is critical that the motion is well-funded and driven clearly by the Indian government with the goal of improving health outcomes for the whole population.

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Section 3

THE CLINICAL PERSPECTIVE FOR IT/MEDICAL DEVICE PROFESSIONALS

Chapter 7

DIAGNOSTIC DEVICES AND MORE: THE ROLE AND CONTRIBUTION OF MEDICAL DEVICES IN HEALTHCARE

Rajiv Nath

Introduction

Medical devices are any products or equipment used for medical purposes that are by themselves not medicinal in nature. Medical devices and equipment form an important part of healthcare delivery. Constant improvement and technological developments in the field of medical devices and equipment have helped doctors improve clinical results and quality of healthcare delivery. Increased use of digital technology is driving a new revolution in the medical devices sector, with a greater focus on improving delivery and user experience and bringing down healthcare costs. This chapter will

1. Examine the role of medical devices and its implications on the management of healthcare institutions and delivery of healthcare.
2. Describe the role of medical devices in healthcare interventions and its contribution to the new developments that we see in the field of medicine today.
3. Outline the steps being taken by the Government of India over the last few years to ensure the growth of a vibrant ecosystem for medical device manufacturing in India.
4. Share success stories in Indian medical devices manufacturing.
5. Examine the challenges in affordable access to healthcare in absence of indigenous availability.
6. Define the correct environment and support that will help India emerge as a globally competitive medical device manufacturing hub to support healthcare providers.

November 2019 saw the beginning of the Covid-19 pandemic that spread worldwide. The global crisis led to a disruption of international supply chains in February and March 2020 putting the spotlight on medical devices in India as never before, as the country went into lockdown. On assessing its meagre resources of COVID-19 critical medical devices as well as its woefully inadequate healthcare infrastructure, the country weighed its options to manufacture and ramp up manufacturing capacities of masks, PPE kits, ventilators, oxygen and oxygen delivery accessories, drug delivery and so on. This was not India's crisis alone – every country in the world was grappling with a supply chain crisis to access COVID-19 critical medical devices.

A flurry of phone calls from Department of Pharma, Department of Promotion for Industry & Internal Trade, NPPA and the PMO (Prime Minister's Office) sought data from AIMED (Association of the Indian Medical devices industry) on manufacturing capacity, list of manufacturers of COVID-19 critical medical devices, challenges and time to ramp up capacities without providing clarity on national needs and forecasts as the demand unfolding was unanticipated and unprecedented.

AIMED provided the Indian Government with a single point of contact access to domestic manufacturers and on behalf of manufacturers provided GoI responses on policy issues, information services, need for regulatory interventions of medical devices, guidance for quality certification (ISO, CE, ICMED QMS), while supporting and coordinating R&D by various academic and scientific institutions, encouraging innovations from member units, in its quest to position India to be the second factory in world for medical devices.

Making India Aatmanirbhar (Self-Reliant) in Medical Device Manufacturing

Prime Minister Narendra Modi's call for self-reliant Aatmanirbhar Bharat and the Government of India through its "Make in India" initiative relied heavily on the domestic manufacturers to meet the rising demand of essential healthcare equipment for the country, encouraging the Indian medical devices sector to become more self-reliant. The government-led interventions helped the medical devices industry scale up production rapidly. AIMED worked closely with the Government of India, that is, Department of Pharmaceuticals, Ministry of Commerce, NPPA & CDSCO as a facilitator between the government and the manufacturers

of COVID-19 critical medical devices, including gloves, masks, sanitisers, ventilators and oxygen therapy equipment, diagnostic and testing kits for Covid-19. AIMED assisted in ramping up capacity and addressing production bottlenecks in this national emergency to fight the pandemic during the complete lockdown period.

According to BW Business World, the medical device industry in India is estimated to mark a total of Rs. 77,539 crore (USD $11 billion) and ranks the fourth largest industry in Asia (Business World, 2022). India's medical device businesses, which accounted for more than 13% of the entire Asia-Pacific (APAC) medical device market in 2019, is expected to grow at a Compound Annual Growth Rate (CAGR) of 7.5% through 2025. The market is expected to increase at a CAGR of 35.4% from 2020 to 2025, reaching Rs. 352,450 crore (US$ 50 billion) (Verma, 2019). India's medical devices industry is poised for significant growth in the next five years (IBEF, 2022). The Indian medical device manufacturing industry is at the cusp of a great opportunity. Manufacturing growth in China has been challenged by many countries' resistance to buy Chinese medical devices.

Medical Devices Used in Healthcare Interventions

Medical devices are segregated into five major segments (Table 7.1):

Table 7.1. The five major categories of medical devices (AIMED compiled data from Department of Commerce, Government of India).

Consumables & Disposables include needles and syringes, drug delivery infusion and transfusion sets, surgical and wound dressings, sutures, contraceptives, etc.
Medical Electronics & Equipment include diagnostic imaging e.g. large equipment such as MRI, linear accelerator, x-ray machines or mid-sized ultrasounds, monitors, ventilators, etc. or smaller devices such as BP instruments, glucometers, thermometers and oximeters and even software and wearable monitoring apps.
Surgical and Medical Instruments such as endoscopes, tooth extractors, dental drills, surgical blades and knives, laparoscopy instruments, automated IVD analysers, etc.
Implants such as Orthopaedics and Prosthetics implants including knee implants, artificial joints, IOL, cardiac stents, heart valves, etc.
IVD Reagents and Test Kits include RT PCR test kits, rapid antigen & antibody test kits or point-of-care tests such as pregnancy tests, HIV test kits and cancer markers, etc.

Around 65% of the manufacturers in India are operating in the consumables segment and catering to local consumption with limited but rising exports. Large multinational corporations that mainly import lead the high technology end of the medical devices market in India with extensive warehousing and service networks.

Pre-COVID-19 there were approximately 750–800 domestic medical devices manufacturers in India, with an average investment of $2.3–2.7 million and an average turnover of $6.2-6.9 million (Verma, 2020). Post-COVID-19 these doubled to over 1600 manufacturers. There are six manufacturing natural "clusters" in the country. Additionally, medical device parks are being developed by States such as Andhra Pradesh and Telangana that have set up dedicated industrial parks for efficient domestic manufacturing at lower costs.

The Association of Indian Medical Device Industry (AIMED) is an umbrella association of Indian manufacturers of medical devices covering all types of medical devices including consumables, disposables, equipment instruments, implants, electronics and diagnostics. With a primary membership of over 350 manufacturers and additionally of over 200 associate members, AIMED represents the interest of over 1600 manufacturers of medical devices to address the manufacturer's problems. AIMED works closely with other product specialist vertical groups and associations such as OIMA for Orthopaedic Implants, ADMI for diagnostic manufacturers, AISNMA for syringes and needles manufacturers and PWMAI for preventive wear manufacturers to help make India Atmanirbhar.

The Role of Medical Devices and Its Implications on the Management of Healthcare Institutions and Delivery of Healthcare

Medical devices are an important component in the healthcare delivery system. Medical devices hold a key role in offering better screening, diagnosis and treatment of diseases along with restoration and monitoring of health indicators to boost prevention as well as for treatment.

COVID-19 has opened massive opportunities for the healthcare sector in tele-consultation, AI-based diagnostics and remote healthcare management. The healthcare sector has become more focused on innovation and technology over the past two years of change. Eighty per cent of healthcare systems are aiming to increase their investment in digital healthcare tools in the coming five years (Outlook, 2022).

Seventy per cent of the medical decisions and treatments are dependent on various diagnostics tests, and the corona pandemic has brought this backend diagnostics industry right into the forefront of the healthcare industry.

The IVD industry strives to develop tests and analyser platforms to address the need for precision and reliability, domestic production (self-reliant), affordability and reaching closer to Point-of-Care (POC).

The factors that are catalysing the growth of the Indian IVD market are – an increase of chronic diseases and a focus on POC diagnostics by consumers themselves.

The following trends recently emerged:

- **Telehealth** – This became an effective way to contain the spread of COVID-19 while still providing essential primary care. Wearable personal IoT devices can track vital signs. Chatbots can make initial diagnoses based on symptoms identified by patients. The Internet of Medical Things (IoMT) is an amalgamation of medical devices and applications that can connect to healthcare information technology systems using networking technologies. It can reduce unnecessary hospital visits and the burden on healthcare systems by connecting patients to their physicians and allowing the transfer of medical data over a secure network.
- **Testing and diagnosis** – Technology has improved the complexity and accuracy of screening. Portable/point-of-care devices have made it possible to improve diagnostic mechanisms at primary healthcare level, provide care at home and resulted in improved health outcomes and patient satisfaction. It has also improved access to quality healthcare in underserved and remote regions, while also making it possible for patients to avail of treatment outside traditional healthcare facilities.
- **Treatment and care** – Technological advancements in surgical equipment has enabled doctors to treat highly complex and critical cases and reduce the length of extended hospital stays. It has increasingly made it possible to perform elective and complex surgeries such as knee replacement, bariatric surgery, pain management in short stay/outpatient surgery centres. For example, laparoscopic surgery procedures remarkably improve outcomes and reduce length of hospital stays as well as costs of treatment.
- **Robotic surgery** – With enhanced precision, easier recovery and consequently less pain, robotic surgery has minimal scarring compared to open surgery, and allows surgeons greater flexibility especially with difficult-to-reach areas.
- **Restoration** – Rehabilitative centres and hospitals are making it easier for patients to recuperate and return to a relatively normal life with the help of advanced rehabilitative and assistive devices. Advancements in rehabilitative technology has also allowed people with disabilities to lead productive lives and fulfil their dreams.

- **Monitoring** – Advancements in health screening devices have enabled patients to monitor their health condition at home, keeping a close track on all major health indicators. Furthermore, smart devices are being increasingly used to remotely monitor patients and diagnose life-threatening conditions early, reducing the need for hospital visits and bringing down the pressure on the over-burdened healthcare centres.

COVID-19 – Opportunities and Challenges for the Indian Medical Device Industry

Due to low custom duty, India is importing Rs 46,000 crore of medical devices and is over 80–85% percent import-dependent (Nath, 2022). The Aatmanirbhar Bharat Abhiyaan was launched by the Government as a "Make in India" enabler which would help India emerge as a manufacturing superpower, a global manufacturing hub, a dependable manufacturer of quality products in the global supply chain and a global hub for providing skilled R&D manpower to other nations. With the objectives of reviving different spheres of the economy in the short term and insulating India from any future global economic downturn, the Atmanirbhar Bharat campaign seeks to make the Indian economy robust in the long run by scaling up manufacturing, accelerating infrastructure development, attracting investments and promoting a consumption-led growth.

The Covid-19 crisis has shown that the Indian medical devices sector can rise to the challenge. COVID-19 has shown the spirit of Indian entrepreneurs to Make in India rather than import into India. When imports were disrupted, specific devices detailed with quantified production shortages and a focused Inter-Ministry Group coordinating with domestic manufacturers via AIMED had addressed production bottlenecks and challenges so that capacity was not only utilised but also rapidly ramped up.

Due to geopolitical reasons, global investors have begun to show renewed interest in India. Our government has also seized the initiative and in a series of measures has reformed the country's foreign investment policy to allow higher levels of investment from abroad in diverse sectors. As a result, India has become one of the most open economies in the world and rightly positioned to attract large-scale foreign investments. The Indian government with Invest India spearheading the initiative has already chalked out plans intending to remove all roadblocks and offer tailor-made solutions to attract investment to make India a manufacturing hub for medical devices.

Chinese supply disruptions have been an opportunity for many markets to prosper globally and bridge the quality issues that existed previously. Manufacturing strategy shifted from "Just in Time" to "Just in Case." India

has a big opportunity of becoming a possible alternative for the devices as well as medical drugs.

Government Support and Achievements

The Atmanirbhar Bharat programme driving the self-sufficiency crusade of the government holds tremendous opportunities for foreign investors. From ever-increasing investment in medical device parks and clustering projects *vide* the medical devices park scheme with the view to develop world-class infrastructure and testing facilities, to the Production Linked Incentive (PLI) scheme allowing incentives on incremental sales on certain categories of high-end medical devices, such as

i) Cancer care/radiotherapy medical devices
ii) Radiology and imaging medical devices (both ionising and non-ionising radiation products) and nuclear imaging devices
iii) Anaesthetics and cardio-respiratory medical devices including catheters of cardiorespiratory category and renal care medical devices
iv) All implants including implantable electronic devices
v) *In vitro* diagnostics.

Each of these offers prospects wherein foreign investors can also participate and reap dividends in the long term. The Indian Ambassador to the United States cited the PLI scheme as one segment, among others, where US investors could contemplate investing, thus demonstrating that India is actively seeking FDI into these domestic Make in India programmes.

In the five years from 2015 to 2020, the country has received USD 600 million with major investments coming from Singapore, United States, Japan and Europe. The medical device categories that most attracted these investments have been equipment, instruments, consumables and implants. In May 2020, when the sector was navigating through the first phase of rough COVID-19 waters, Japanese investors had displayed interest in setting up a manufacturing base for *In Vitro* Diagnostic Device (IVD) and medical electronics in the country during their discussions with the Association of Indian Manufacturers of Medical Devices (AIMED). In fact, as part of the initiative, India is eyeing the potential of 200 joint ventures with foreign investors for nearly USD two billion and above as well as with 50 MNCs for the same amount, apart from looking to forge 1200 technical collaborations with Indian investors for nearly USD six billion. Similarly, several global med-tech companies did bring COVID-specific product designs and specifications from the United States into India to collaborate with Indian manufacturers.

The Government of India has additionally taken several steps to ensure the growth of a vibrant ecosystem of medical devices manufacturing in India over the past five years:

- It recognised Medical Devices as a sunrise sector under the Make in India campaign, 2014.
- The Medical Devices Rule of 2017 are considerably harmonised with international regulatory controls.
- In January 2020, the government set up a National Medical Devices Promotion Council to promote local manufacturing of high-end medical devices and attract investments in the sector.
- The Ministry of Health and Family Welfare has notified that medical equipment would qualify as "drugs" under Section 3 of the Drugs and Cosmetics Act (D & CA), 1940, from 1 April 2020.
- To boost domestic manufacturing of medical devices and attract huge investments in India, the department of pharmaceuticals launched a PLI scheme for domestic manufacturing of medical devices, with a total outlay of funds worth Rs. 3,420 crore for the period FY21–FY28.
- In June 2021, the Quality Council of India (QCI) and the Association of Indian Manufacturers of Medical Devices (AIMED) launched the Indian Product Certification of Medical Devices (ICMED) 13485 Plus scheme to undertake verification of the quality, safety and efficacy of medical devices.
- In October 2021, the government announced a plan to draft a new drugs, cosmetics and medical devices bill to increase the acceptability of Indian medical devices in the global market.

The Catalytic Role Played by Medical Device Parks and Emerging Scenario in India

After Andhra Pradesh MedTech Zone (AMTZ), an integrated medical device manufacturing ecosystem set up by the State government in Vizag three years ago, proved to be a major success during COVID-19 times, a lot of States have come forward and shown interest to establish medical device parks in their respective States.

More than 50 critical medical devices for COVID-19 care are produced in AMTZ's over 85 factories located there. The most recent inauguration of a foundation stone ceremony in December 2021 was by TransAsia for IVD Diagnostics & Translumina for Heart Valves. AMTZ has been supplying the bulk of the COVID-19 diagnostic kits, ventilators and surgical masks for the Indian market. The park will also see the roll-out of India's first locally produced MRI machines in the coming months.

AMTZ has been allowing domestic manufacturers to avail of world-class rapid prototyping, preclinical testing and certification services at very nominal rates and provided competitive advantage of low-cost leases and plug-and-play units as well as Gamma Radiation Plants and Common Warehousing Facilities.

The growing interest in such projects also saw 16 States, including Gujarat, Goa, Maharashtra, Odisha, Assam, Andhra Pradesh and Karnataka, among others, vying for the four medical device parks announced by the Central Government under its scheme for promotion of medical device parks last year. Under the scheme, the Centre will provide grant-in-aid to four medical device parks with a maximum limit of Rs 100 crore per park, or 70% of the project cost of common infrastructure facilities, whichever is less. In case of hilly States and the North-East, the grant-in-aid would be Rs 100 crore per park, or 90% of the project cost of common infrastructure facilities, whichever is less. The Rs 400-crore scheme is for the 2020–21 to 2024–25 period. Himachal Pradesh, Madhya Pradesh, Uttar Pradesh and Tamil Nadu are known to have won the race for setting up of four parks during 2021–22 and some others like Rajasthan, Maharashtra and Haryana are on the waiting list for the next round (Pandya, 2021).

Each of the medical devices park that are coming up not only attract huge investments to the tune of Rs 10,000 to 15,000 crore but will also provide direct and indirect employment to about 20,000 people in each mutually interdependent cluster created.

To ensure these Med Tech Parks thrive and don't remain green parks, AIMED recommended that the State government need a Capex Reduction Policy Model of low-cost rentals plug-and-play units, shared common manufacturing facilities and well-thought-out ancillaries and subcontracted manufacturing of parts and components and services. On the other hand, the Central Government needs to support with revenue supportive policies.

Cluster Development and Strengthening

Existing clusters of low-cost plastic disposables in Gujarat and Delhi NCR, surgical textiles based in Coimbatore, orthopaedic implants in Gujarat, Maharashtra & Delhi NCR, IOL in Tamil Nadu and Gujarat, medical electronics in Maharashtra, Karnataka and Tamil Nadu need to be strengthened by providing laboratories, research linkages with local universities, common R&D and tool room facilities, sterilisation facilities, regulatory support consultancy and training services, permanent exhibition/show rooms – conference sharing and start-up facilitating centres, etc.

Medical parks can be created with common product categories with common technologies so that they are specialised interdependent cooperative

clusters around key common raw material/component suppliers; for example, AMTZ at Vishakhapatnam in Andhra was envisaged to be focused on large capital medical electronics equipment with mother units of x-ray tubes to attract x-ray manufacturers and of magnetic coils to attract manufacturing of CT scan and MRI equipment and of EMC testing for aiding manufacturing of large medical electronic equipment.

Similarly, AIMED recommended Aurangabad in Maharashtra and Haryana, Karnal to focus on orthopaedic implants and surgical instruments by inviting and supporting a stainless steel alloy manufacturer instead of industry being dependent upon expensive imports from Sweden as well as a strategically located logistics hub for medical equipment online traders and for National Distributors considering its central distance to all parts of India; Chennai and Ujjain in Madhya Pradesh were recommended to develop medical devices park focused on instruments – medical electronics & IVD; Trivandrum, Kerala, to have a medical devices focused on latex and rubber technology with commonly shared zero discharge effluent treatment centre; for UP – Noida to focus on small consumer electronics and mid-sized electronics along with IVD reagents in collaboration with NIB; for Hyderabad, Telangana, to focus on medical electrical equipment and implants needing clinical research studies; for Bangalore, Karnataka, medical park to focus on embedded and standalone software, AI and IOT app-based products.

Prioritise Quality Checks and a Strong Ecosystem

To establish India as a dependable manufacturer of high-quality medical devices in the global supply chain and to vie for being the second factory in the world for medical devices, India needs to bring in a quality culture to maintain global standards in the quality of healthcare products. AIMED recommended that the Prime Minister constitute a Quality Advisory Council and a dedicated Principal Quality Advisor to the PM to evaluate the quality and standard of Indian products.

Such a dedicated team will ensure high-quality standards yet affordable medical devices, lend greater credibility to the quality of Indian medical devices, bring in innovation, incentivise the Indian manufacturers and enhance global competitiveness from Brand India.

For Make in India to thrive one needs a quality mindset of vertical product standards, horizontal process (and common product family), quality standards, specifications, voluntary standards setting and at times safer regulatory controls and demonstration of compliance with standards using test labs. These labs

are not only needed for tests but to benchmark evaluations and Research and Development studies.

The penal system in the Drugs Act is a disincentive for MedTech investors. The Act is not appropriate for innovative engineering products such as medical electronics. Consumers do need access to high-quality PPEs and ventilators. An appropriate legal framework as correctly envisaged by the NITI Aayog is awaited as a medical devices law that would decriminalise most oversights and regulatory lapses and will have risk-proportionate penalties. This will encourage new entrants to venture into medical devices – as being engineering products and not drugs.

In order to create an ecosystem for quality as part of Mission Aatmanirbhar Bharat to enhance the prospects of the Indian medical devices sector, the Quality Council of India (QCI) and the Association of Indian Medical Devices Industry (AIMED) have jointly come up with the Indian Product Certification for Medical Devices and launched a new scheme called the ICMED 13485 PLUS scheme which will undertake verification of the quality, safety and efficacy of medical devices to help Indian products gain a bigger share of the global market.

The initial ICMED Scheme as a voluntary Quality Management System (QMS) certification was launched for medical devices in 2016 to fill the then regulatory vacuum in the quality certification space for medical devices in the country and was a culmination of extensive discussions of 22 government departments and other stakeholder organisations with industry. It also helped to create an eco-system of certified competent quality auditors, QMS trainers and consultants, some of whom could be potential regulators.

The ICMED Plus scheme envisages quality management systems, along with product certification standards integrated with regulatory requirements. This scheme will be an end-to-end quality assurance scheme for the medical devices sector in India. It will go a long way in assisting the procurement agencies to tackle the challenges relating to the menace of counterfeit products and fake certification of CE, US FDA, ISO 13485 and NIOSH. This will also help in eliminating the circulation and use of sub-standard medical products, for example, mislabelled N95 masks instead of the BIS certified FFP2 masks or devices of doubtful origin that could prove to be serious health hazards.

ICMED Plus enables Indian manufacturers to not only provide medical devices products to consumers in India, but also compete globally by adopting global best practices for medical devices and enhancing the value for the end users.

As a step towards aiding public procurement and safeguarding private buyers and common consumers, ICMED Plus can be an enabler in reducing

regulatory oversights through a third-party independent certification system. This will reduce costs by reducing the need for international auditors.

Success Stories in Indian Medical Devices Manufacturing

In products like syringes and needles, I.V. Cannulas, surgical gloves, IOL (Intraocular lens), cardiac stents, hydrocephalus shunts, contraceptives, x-ray equipment, orthopaedic trauma implants and surgical blades, India is among the leading top five if not the top 10 producers in the world. Post COVID, the top 10 list has expanded to include oxygen therapy equipment such as ventilators, IVD diagnostic RT PCR kits, masks and PPE.

The leading manufacturers in the disposables category are HMD (Hindustan Syringes & Medical Devices Ltd.) for syringes and needles; Medico Electrodes for ECG disposable electrodes; Kanam Latex for surgical gloves, G. Surgiwear and in the consumables category, Romsons & Polymedicure for infusion sets and catheters and healthium for sutures and wound closures; in medical electronics in high-end equipment such as linear accelerators we have Panacea, in imaging equipment Allengers, GE, Siemens, IITPL and in ultrasound and oxygen therapy Trivitron, BPL, Skanray & Max; in hospital equipment, Midmark & Godrej for hospital beds, Remi for blood storage, Phoenix for neonatal incubators; in cardiac implants SMT, Meril & Translumina, in Intraocular Implants Appasamy & Aurolabs, in orthopedic implants Pitkar & Biorad; in instruments such as electrosurgical cautery Alan Electronics; in surgical blades HMD; in suture needles, Quality Needles, in IVD Transasia, Trivitron, Meril, Mylab, Mitra and Himedia are some of the leading manufacturers who compete successfully in India and globally. These companies are an inspiration for others to follow as these have succeeded in face of various initial marketing challenges as even if they were competitively priced they had to earn the trust of the medical profession based on quality and performance.

There are also some rising stars like Mylab & Black B 3 Bio riding on the RT PCR COVID-19 wave and Venus & Magnum riding on the FFP2 masks wave. Some start-ups to look out for are SS Innovation working on building India's first Robotic Surgery production initiative called Mantra; Times Medical Systems building MRI machines under the PICA brand; Robomed is another promising start-up that has introduced devices in asthma management, anaemia management and diabetes management with foreign collaboration; and Medorah Meditek manufacturing specialised stents for gastroenterology.

Cost-effective manufacturing strategies backed by integration of making one's own raw materials and components and investing in quality and technology allowed HMD'S DispoVan brand to wrestle control of the market in India and later internationally from firmly entrenched MNCs; SMT's cardiac

stents to be globally competitive and provide access to affordable cardiac care; Appasamy and Aurolabs to be cost-effective eye care entreprenuers. Many famous brands such as BD, Cooks, Boston Scientific, Smith & Nephew and Bausch & Lomb, etc. are being challenged to rethink their product portfolios and marketing strategies. Others such as GE & Siemens, having seen the writing on the wall, have started manufacturing their high-end equipment in India.

Hurdles Limiting the Growth of the Indian Medical Devices Industry

Imports of price-sensitive medical devices from China went up steeply by 75% from Rs. 5208 crore in 2019–20 to Rs. 9112 crore in 2020 (Mukherjee, 2021). This is a lost opportunity for Indian manufacturers to grow and compete globally but saw with dismay the dumping of Chinese imports when duties were slashed to zero per cent at the behest of importer dominant lobbies for COVID-19 critical items (Figure 7.1).

Sadly, these are the same Indian Manufacturers/Entrepreneurs, who, when imports were disrupted during Covid-19, were relied upon by the Government to meet the rising demand of essential COVID-19 items for the country, pushing the Indian medical devices sector to become self-reliant (Chopde, 2019).

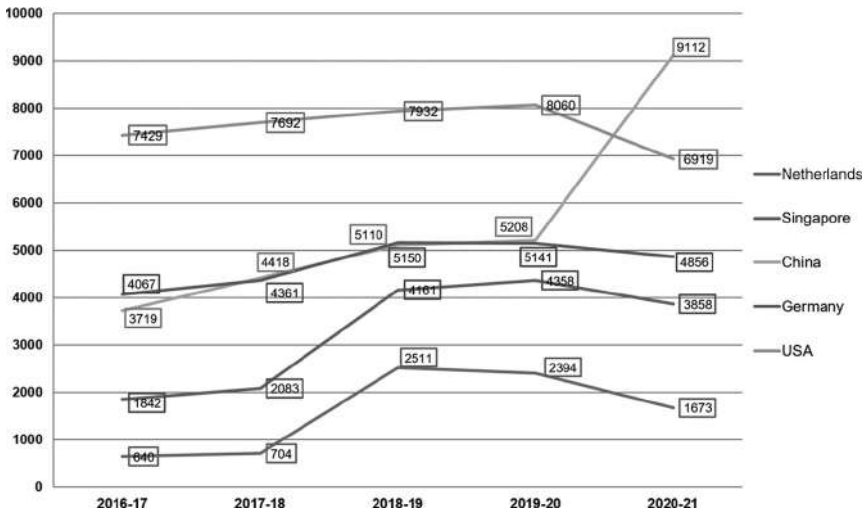


Figure 7.1. The top five sources of Indian imports over the last five years.

Source: AIMED compiled data from Department of Commerce, Government of India.

India's high dependence on imports of medical devices are due to:

1. Negligible basic custom duties of 0% to 7.5% on import of medical devices.
2. Almost 50 types of regulatory compliances in the form of license/registration/approvals for domestic manufacturing of medical devices as against 1 or 2 minor regulatory compliances for import.
3. No market access barriers in India for import from countries that impose such trade barriers against Indian exports of medical devices.
4. Lack of regulatory quality checking on second-hand import/dumping of medical instruments.
5. Ethical marketers are challenged by hospitals and retailers favouring usage of high MRP-labelled imports.

On other hand, the Department of Pharmaceuticals has recognised that in global competitiveness, indigenous manufacturers are negatively impacted by a disability of 12-15% (Nath, 2020) on account of:

1. Lack of adequate infrastructure, supply chain and logistics
2. High cost of finance
3. Inadequate availability and cost of quality power
4. Limited design capabilities and
5. Low focus on R&D and skill development.

Presently there is no mechanism to address these disadvantages in manufacturing of medical devices in India *viz*. a major economy. DBT, BIRAC and NITI Aayog and the office of Principal Scientific Advisor to PM have been working earnestly and successfully to create an eco-system for nurturing start-ups and incubators. But once they create a commercial product and must graduate to MSME entrepreneurs, the real challenge comes for these start-ups in the woods to survive and cope with the above 12–15% disadvantages and marketing challenges.

Policy-makers may consider that Indian investors are brand ambassadors. Unless local manufacturers are enthusiastic, the overseas investors will not come running. Before we can discuss external overseas tariff and non-tariff barriers, we need to address internal lack of tariff barriers and needless non-tariff export barriers internally.

Internally, Nominal Tariff Protection is sought for devices being made in the country and as a predictable tariff policy, so if capacity is added by a manufacturer there is assured nominal protection. This was done to establish the consumer electronics industry. To promote domestic medical device

Table 7.2. Import duties on medical devices in BRICS countries.

Import Duty on Medical Devices (HS Code 9018) in BRICS Countries					
Products/Countries	**Brazil**	**Russia**	**India**	**China**	**South Africa**
Medical Devices (HS Code 9018)	14%	up to 15%	Up to 7.50%	3.3%–17%	up to 20%

Source: AIMED-compiled data from the Department of Commerce, Govt. of India.

industry that will subsequently reduce India's heavy reliance on imports, the current Basic Import Tariff of 0–7.5% needs to be 15% for medical devices (the Bound Rate under WTO is 40% duty) and on their components to be initially at least 5% and next year 7.5% as a PMP (Phased Manufacturing Plan) Make in India Enabler.

Additionally, internal manufacturers face a unique non-tariff barrier of lack of availability of Free Sales Certificate from MOH&FW and CDSCO, without which capable and globally competitive Indian exporters are unable to register in markets such as China, Argentina, Mexico, etc.

Externally, India exporters face tariff barriers of up to 20% for BRICS countries as shown in Table 7.2.

Additionally, medical device exporters face non-tariff barriers of needing to seek regulatory approvals and registration in many countries. This not only delays the process, but is very expensive and increasingly complex, whether for export to Nigeria, Ethiopia, Brazil, Mexico, USA or Europe.

The Growth Factors

Availability of advanced and sophisticated medical technology is creating new markets/applications, increasing the dependence by doctors on advanced medical devices, and is leading to rapid obsolescence of existing medical technology thereby creating demand for replacement/up-gradation of products. The Government of India's focus on digital and increasing penetration of mobile and internet (eight-fold in the past decade), are other important factors contributing to rising awareness and demand. The advent of high-tech engineering innovations has led to the recent development of low-cost products that are at par with existing products on quality.

India's elderly population is to rise 41% over the next decade to touch 194 million in 2031 (Zompa, 2021). This would result in a much higher need for healthcare and thus medical devices, both at health facilities and homes.

The size of the population earning more than USD 5,000 per annum is estimated to increase to around 450 million (28% of the total population) in 2025. This is partly driven by increasing urbanisation in India, which is expected to reach 40% by 2030. In addition, health insurance coverage is also expected to cross over Rs 2 trillion by financial year 2030. As a result, the share of spend on healthcare as a percentage of total household spend is expected to increase manifold. Rising prevalence of chronic diseases results in a higher demand for healthcare services. Non-communicable diseases are expected to comprise more than 75% of India's disease burden by 2025, compared to 45% in 2010 (Deloitte, 2016).

The Road Ahead

The healthcare industry in India is projected to reach $372 billion by 2022 according to a report from Invest India (Verma, 2020). With overburdened hospitals, personalised homecare is likely to grow in 2022 as India continues to be amid the COVID-19 pandemic. Meanwhile, the government is also planning to increase public health spending to 2.5 per cent of the country's GDP by 2025 (*ibid.*).

The healthcare sector has become more focused on innovation and technology over the past two years of change. Eighty per cent of healthcare systems are aiming to increase their investment in digital healthcare tools in the coming five years.

The road ahead is full of opportunities. If within 2 years of COVID-19 pandemic, to address healthcare needs India could ramp up rapidly with high-tech innovative quality medical devices with conducive policies to encourage growth, the Indian medical device industry can achieve much greater success and make India the second factory in the world for medical devices.

The Indian Medical Device Industry is waiting for policy announcements on the following vital issues of Indian medical devices industry to end the 85% import dependence and an ever-increasing import bill of over Rs 46,000 crore so that affordable and dependable contribution to healthcare providers is assured (Nath, 2022).

- Consumer Protection: To ensure that ethical marketing is not disadvantageous, Trade Margin Rationalisation is needed and will also protect consumers from exorbitant pricing to ensure affordable healthcare access. MRP labelling needs to be enforced on Unit of Sale of Medical Devices by Customs and by a Trade Margin Cap Mechanism of maximum 75% Trade Margin between Ex-Factory/Import Landed Price (first point of sale) and MRP.

- Regulate all medical devices under a Patients' Safety Medical Devices Law separate from drugs to protect patients and aid responsible manufacturing.
- To create additional funds for PM-JAY healthcare scheme, a five per cent health cess needs to be applied on balance imported medical devices too. To address the 80–85% import dependency, in addition, a predictive nominal tariff protection policy should also be implemented as was done for mobile phones to ensure a vibrant domestic industry and competitiveness and price stability driven by competing domestic players.
- Additionally, the government may consider putting an additional 2% Infrastructural Development Cess on imports that could be used to provide budgetary support to Department of Pharma that has the mandate to promote manufacturing of medical devices; build infrastructure of existing clusters and NIPERs; help to make medical devices parks and finance further PLI schemes.
- Instead of 18% GST applicable on some medical devices that are not luxury goods, the GST needs to be a flat 12% for all medical devices. Also reducing GST to 5% is making Indian products non-competitive to imports as then manufacturers are unable to keep reduced ex-factory prices based on lower input costs net of GST.
- Incentivise the quality and domestic content in healthcare products in healthcare procurements by preferential pricing for Q1, for example, ICMED (QCI's Indian Certification for Medical Devices) instead of L1 (lowest price) to ensure that patients access acceptable quality.

Conclusion

- In this large black cloud of Coronavirus, the only silver lining to healthcare delivery was the major boost provided to indigenous manufacturing of (so far neglected) medical devices as these were critically needed for delivering vital healthcare
- From bringing in innovative new products to improving the existing ones, the Indian medical device industry is gaining traction for bringing unique propositions to address some of the challenges faced by the healthcare system during the pandemic.
- The COVID-19 situation has also simultaneously brought in a revolution in the Indian medical system's digital evolution and healthcare facilities.
- The Aatmanirbhar Bharat Abhiyaan is a "Make in India" enabler which will help India emerge as a manufacturing superpower, a dependable manufacturer of quality products in global supply chain and a global hub for providing skilled manpower to other nations.

- To establish India as a dependable manufacturer of high-quality medical devices in the global supply chain, India needs to bring in a quality culture to maintain global standards in quality of healthcare products.
- The Indian medical device industry is waiting for policy announcements on the vital issues of Indian medical devices industry to end the 85% import dependence and an ever-increasing import bill of over Rs 46,000 crore so that healthcare delivery can be affordable.
- The road ahead is full of opportunities. If within 2 years of COVID-19 pandemic, India could ramp up rapidly with high-tech innovative quality medical devices with conducive policies to encourage growth, the Indian Medical Device Industry can achieve much greater success and make India the second factory in the world for medical devices to support healthcare delivery in India and globally.

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Chapter 8

REMOTE HANDS: CONTROL SYSTEMS REQUIRED FOR IT AND MEDICAL DEVICE OUTCOMES

Anil Nileshwar and Gopalakrishnan Sriraman

Introduction

Measuring and managing IT and medical device outcomes is key to sustaining and improving healthcare organisations. With the increased complexity and scale of the health service ecosystem, digitisation of healthcare and connected medical devices, there is a need for a robust control system to meet cost, quality, efficiency and regulatory requirements. A well-defined organisation design and IT control system enables transparency, actionable insights and predictable outcomes to manage healthcare organisations. The latest technology developments like connected care, digitisation and the cloud offer new opportunities to enhance traditional control systems.

This chapter focuses on the evolution and advancements of control systems for measuring and managing IT and medical devices and will provide

1. A brief overview of management control systems, their components, types and deployment approach.
2. An examination of the role and benefits of control systems in measuring and managing Healthcare IT.
3. An exploration of the latest technology developments driving new generation control systems and their benefits.

Introduction to Control Systems

A *management control system* enables alignment of individuals and teams with the overall vision of the organisation. It drives proper structure, process and ensures that performance indicators are deployed across the organisation and are functional to meet the organisation's strategy. Application of control

systems helps organisations to improve service delivery and maximisation of generally scarce resources (Silva *et al.*, 2020).

An effective management control system has two distinct but complementing themes:

1. Structure – how organisations are structured, their scope, accountability and responsibility, dependencies
2. Process or set of standards and decision flows to establish purpose, allocate resources and manage outcomes.

The structure defines the system, and the process indicates what the system does. Both together ensure that each subsystem functions with clear objectives, follows a set of organisational standards, and contributes to meeting the organisation's overall purpose.

Types of Control Systems

A control system can be a formal or informal control system. A formal control system builds on well-documented rules and procedures that are strictly adhered to across the organisation. A medical device assembly system can be an example of a formal control system that follows a series of steps for device assembly and is subject to high regulatory compliance and quality assurance. Formal control systems rely on policies, procedures and work instructions.

The formal control system can be further classified into three types – Input Control, Output Control and Process Control systems based on the measures it focuses on, either the input ingredients for the system or the output the organisation generates, or the process it focuses on for the success of the overall organisation. Examples of formal control systems are cost accounting systems, FDA validation systems, Information Management control systems and so on.

The informal control system relies on behavioural values, culture and traditions. The informal system dramatically contributes to employees' overall organisational culture and motivation to align with corporate strategy. Examples are shared values, company behaviours, organisational culture, ethics and customs followed by management and employees. It is observed that informal control such as corporate ideology can be an important dimension of management control systems. The ability of ideological articulation to emphasise the organisations positioning gives the manager a powerful instrument of control in driving her team (Kraus *et al.,* 2017).

Successful organisations usually blend the informal and formal control systems to build strong performance culture to meet the strategy with measurable outcomes.

Change control systems are another type of system heavily used in regulated industries such as healthcare, medical devices and finance. These systems ensure stability, minimal disruption and continuity when a new change is introduced. Examples of change control systems are software patch management and hardware replacement in medical devices.

Process of Deploying a Control System

Control systems need to be designed and deployed considering the organisational needs, expected outcomes and culture. A typical process flow of deploying a control system is as follows:

Goal Setting

A control system deployment starts with identifying clear goals aligned to the strategy and vision of an organisation – this needs to consider various internal and external influenced success factors the organisation is impacted with.

For example, in a health service organisation the following may be the key goals:

- Ensure patient safety and providing first-time-right treatment
- Improve patient experience or patient satisfaction score
- Ensure zero deviation in regulatory and compliance domains.

These goals provide a direction and alignment with the overall strategy and mission of the organisation.

Establishing Standards

The organisation needs to identify the correct measures for each goal identified as a next step. These measures need to be Specific, Measurable, Attainable, Realistic and Time-Bound (SMART), providing clarity on what the goal is and what outcome is expected and measured.

Each goal may have multiple indicators; however, a select few critical Key Performance Indicators (KPI) need to be identified as must-have plans that, if met, provide predictability and confidence to leadership that the overall strategy and mission of the organisation are completed.

Another aspect that needs to be considered while setting goals is to ensure the plans are well cascaded across the organisation's hierarchy to impact and influence. This enables decentralised and collective goal unity; it is necessary to have tiered accountability and alignment of KPIs. The team structural

empowerment plays a vital role ineffectiveness of the management controls resulting in improved metrics (Baird & Baard, 2021).

- At the Board level, have a clear set of performance metrics that is more result-oriented, providing an overview of the organisation on the path to reaching its targets, the deviations to address – low-frequency metrics that give a summary of results
- At each department and team level – a set of performance metrics that are a mix of leading and lagging which contributes and rolls up to the Board level metrics – high-frequency metrics that help teams and departments to steer them to meet targets and act at the earliest moment when there is a deviation.

Monitoring and Evaluating

Establishing a reporting system that regularly monitors various KPIs is a necessary process. This traditionally requires a high level of bookkeeping and manual data collection. Data need to be collected for each of the measures from various sources and documented for all appropriate levels/departments. It requires formal routines and processes to be established and implemented.

Comparing Actual Results

The monitoring results need to be continuously processed compared with the standard target set for each measure. Organisations leverage the lean daily management process to compare and process the actual results against the target effectively.

For each measure the following attributes are processed:

- Actual result for the given period
- Standard target defined for the measure
- Gap between the standard and actual
- Trend of the actual results over the last few reporting cycles.

The gap needs to be further investigated for potential causes. Based on the investigation, the top contributors are identified and further investigated to determine the actionable root causes. Five-why and pareto principles are used for data-driven analysis.

Rectifying Deviations

Organisations need to ensure that they take required corrective action with a sense of urgency to meet the established standards. This may require various problem-solving techniques, including:

- PDCA – Plan-Do-Check-Act is an iterative procedure that helps drive continuous improvement to address the gap
- Gemba – going to the place where value is generated, talking to the real people involved, analysing the ecosystem and surroundings to investigate what and how things went wrong
- Applying 3C (Concern > Cause > Countermeasure) for simple problems that can be resolved on short notice
- Structured A3 problem solving if the problem is more systematic and requires time and effort to address. It provides a guideline and template for individuals and organisations which they strictly follow to define a problem, investigate, develop countermeasures, implement the fixes and ensure that the changes and improvements are sustained.

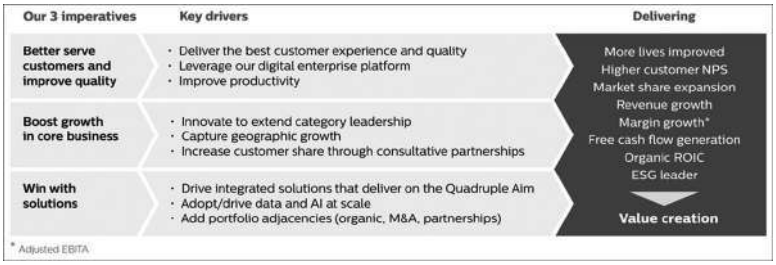
The effect of the management control system depends on culture, acceptance and adherence of the employees and may differ across organisations (Lopez-Valeiras, 2018), requiring a good change management strategy in the implementation of the control system.

Case: Strategy and Goal Alignment in Royal Philips–Large Healthcare Solutions Organisation

Royal Philips states the purpose of the organisation is to improve the lives of two billion people a year by 2025, including 300 million in underserved communities, rising to 2.5 billion and 400 million, respectively, by 2030.

Its strategy is to lead with innovative solutions that combine systems, intelligent devices, informatics and services and leverage big data – helping our customers deliver on the Quadruple Aim (better health outcomes, improved patient experience, improved staff experience, lower cost of care) and assisting the people in taking better care of their health at every stage of life.

Based on the strategy, it has identified critical drives and measures of value creation:



Also, it has broken down clear goals for each of its large domains.

Personal Health

- Delivering solutions that enable healthier lifestyles, personal hygiene, and living with chronic disease.

Diagnosis and Treatment

- Precision Diagnosis – providing intelligent, connected systems, optimised workflows and integrated diagnostic insights, leading to clear care pathways and predictable outcomes
- Image-Guided Therapy – innovating minimally invasive procedures in a growing number of therapeutic areas, with significantly better outcomes and productivity

Connected Care

- Driving better care management by seamlessly connecting patients and caregivers from the hospital to the home.

Each department of the organisation bases its performance system on measurable key performance indicators aligned to meet its overall strategy.

The company has also effectively leveraged a set of core behaviours it has put in place to build an informal control system that complements the formal perform-and-transform control system.

Core behaviours of the Philips system are

- Customers first
- Patient safety, quality and integrity always
- Team up to win
- Take ownership to deliver fast
- Eager to improve and inspire

With proper measures and the informal behavioural control system, the company aims to build its leadership in healthcare as a services and solutions organisation of this century.

Source: Royal Philips Annual Report, 2020

Control Systems for Measuring and Managing Healthcare IT

With the digitisation of healthcare, complexity and increased scale of operations, managing the IT systems becomes a challenge and success factor for the organisation. IT has become a driver rather than an enabler in driving patient experience, first-time-right treatment, and efficiency for hospitals. Hospitals and healthcare providers rely on IT right from patient experience, diagnosis and treatment, equipment and medical inventory, lab records, facilities management, billing and finances and so on. Hence, the availability, performance and user experience of these IT systems are critical and need to be well controlled and managed. Also, data privacy and regulatory and compliance requirements play a vital role in the sustenance of healthcare organisations.

The hospital management system provides streamlined procedures, better compliance, improved patient experience, cost control and efficiency (Gupta & Niranjan, 2020).

In addition to cost efficiency and utilisation, the healthcare providers are also opting to measure public value management, which takes into consideration the interests of stakeholders in the healthcare system and embraces a population-based prospective (Nuti *et al.*, 2021). It is also observed that the ownership and effectiveness of the employees improve with the implementation of a reasonable control system (King & Clarkson, 2015). There is a relationship between the use of the performance management aspect of the management control system and organisational capabilities leading to strategic choices, namely market orientation, entrepreneurship, innovativeness and organisational learning (Jean-François, 2006).

Steps to deploy a control system for Healthcare IT

- Identification of the goals and metrics – both functional and non-functional metrics for the underlying IT systems; some examples of the metrics are
  - Availability of the IT systems
  - End-user satisfaction survey results for the IT application
  - Incident fix SLA adherence
- Monitoring the IT systems for operational health and metrics, including CPU usage, memory, hardware life, software patch updates, security vulnerabilities, etc. Artificial Intelligence and machine learning-based monitoring tools play a vital role in real-time monitoring and healing.
- Comparing actual results against the targets – visualising the actual results and monitoring outcomes against the targets in digital dashboards, sending alerts and actionable insights to the stakeholders via automated emails or other communication channels.
- Rectifying deviation by doing problem management using the data insights and analytics.

In addition to the above, applying the proper control systems also helps improve the IT compliance and regulatory needs and reduces overheads with automated logs, reports and data sets.

Control Systems in Driving Medical Device Outcomes

The landscape of medical devices has transformed over the years from simple, standalone mechanical devices and instruments to digitised and connected devices and ecosystems. Technology advancements like the Internet of Things (IOT Sensors), software and hardware sensors, and big data analytics has countless possibilities to improve patient well-being, advance care and provide cost-efficient and targeted health services.

Some of the use cases where control systems-enabled connected medical devices can help are as follows:

- Improving underutilisation of high-cost medical devices by helping to forecast demand, supply and availability
- Addressing the challenge of unaccounted MedTech assets – enabling hospitals to locate the medical equipment and assets in real-time
- Central planning process on purchases, inventory management, tracking end-of-life hardware

- Driving efficiency in centralising decisions across networks of hospitals, using data analysis across various hospitals and improving the availability and routing of medical devices
- Improving machine service and support by automatically alerting service providers for parts replacement, breakdowns
- Enabling new business models like providing high-cost medical equipment as a service to hospitals where control systems can track the number of usage and charge hospitals dynamically on the same

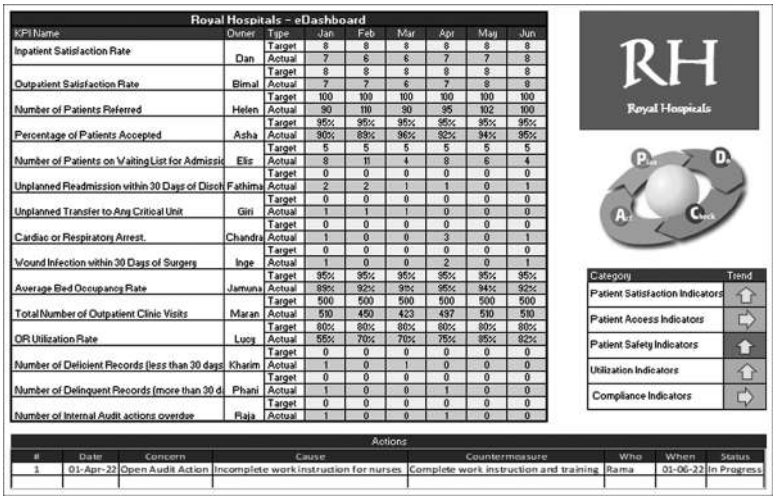
Control systems also play a vital role in patient care directly as the medical devices are embedded with more intelligence and capabilities such as

- SMART patient bed is embedded with controls and connected to various sensors and devices that continuously monitor the patient's vitals and interact with other systems in the hospital and alert the caregivers on specific thresholds and needs. These SMART patient beds are beneficial in-home connected care for the elderly where the elder members can stay at home. At the same time, they are continuously monitored and connected to caregivers to support them when needed remotely. This also helps address timely care for emergencies where the caregivers and doctors are immediately alerted when the control systems detect an anomaly in the vitals in the patient's bed.
- Another well-established use of the control systems in the MedTech field is the pacemaker. A pacemaker monitors the heart's electrical rhythm; when it detects an anomaly or absence of a natural electric pulse, it triggers a short, low voltage pulse to simulate the heart rhythm, saving human life.

Case – Measuring and Managing Performance in Royal Hospitals - A Simulated Case to Explain the Concept of IT Control Systems

Royal Hospitals is a leading super hospital chain with a network of 11 hospitals in five cities. The hospital chain has identified patient satisfaction, access and safety as focus areas to drive growth and contribute to quality healthcare. To achieve this, the hospital institutionalised a set of performance indicators for each hospital and deployed an IT-driven control system.

The eDashboard for Royal Hospitals for January to June in a calendar year.



Royal Hospitals – eDashboard

KPI Name	Owner	Type	Jan	Feb	Mar	Apr	May	Jun
Inpatient Satisfaction Rate	Dan	Target	8	8	8	8	8	8
		Actual	7	6	6	7	7	8
Outpatient Satisfaction Rate	Bimal	Target	8	8	8	8	8	8
		Actual	7	7	6	7	8	8
Number of Patients Referred	Helen	Target	100	100	100	100	100	100
		Actual	90	110	90	95	102	100
Percentage of Patients Accepted	Asha	Target	95%	95%	95%	95%	95%	95%
		Actual	90%	89%	96%	92%	94%	95%
Number of Patients on Waiting List for Admissic	Elis	Target	5	5	5	5	5	5
		Actual	8	11	4	8	6	4
Unplanned Readmission within 30 Days of Disch	Fathima	Target	0	0	0	0	0	0
		Actual	2	2	1	1	0	1
Unplanned Transfer to Any Critical Unit	Giri	Target	0	0	0	0	0	0
		Actual	1	1	1	0	0	0
Cardiac or Respiratory Arrest.	Chandra	Target	0	0	0	0	0	0
		Actual	1	0	0	3	0	1
Wound Infection within 30 Days of Surgery	Inge	Target	0	0	0	0	0	0
		Actual	1	0	0	2	0	1
Average Bed Occupancy Rate	Jamuna	Target	95%	95%	95%	95%	95%	95%
		Actual	89%	92%	91%	95%	94%	92%
Total Number of Outpatient Clinic Visits	Maran	Target	500	500	500	500	500	500
		Actual	510	450	423	497	510	510
OR Utilization Rate	Lucy	Target	80%	80%	80%	80%	80%	80%
		Actual	55%	70%	70%	75%	85%	82%
Number of Deficient Records (less than 30 days	Kharim	Target	0	0	0	0	0	0
		Actual	1	0	1	0	0	0
Number of Delinquent Records (more than 30 d	Phani	Target	0	0	0	0	0	0
		Actual	1	0	0	1	0	0
Number of Internal Audit actions overdue	Raja	Target	0	0	0	0	0	0
		Actual	1	0	0	1	0	0

RH Royal Hospitals

Category	Trend
Patient Satisfaction Indicators	⇧
Patient Access Indicators	⇨
Patient Safety Indicators	⇧
Utilization Indicators	⇧
Compliance Indicators	⇨

Actions

#	Date	Concern	Cause	Countermeasure	Who	When	Status
1	01-Apr-22	Open Audit Action	Incomplete work instruction for nurses	Complete work instruction and training	Rama	01-06-22	In Progress

- The hospital digitised various processes and data management using a Hospital Management System
- A simple mobile app was launched to capture information, including patient satisfaction and feedback
- Various departments of the hospital were connected with a Data Warehouse wherein the data from each department of the hospital were pushed to the data warehouse daily
- An analytical dashboard was built based on the data warehouse, which provides a 360* view of all performance metrics by department, hospital and the overall organisation.
- A Daily Management system was put in place in each department wherein the department members connect every week to review the metrics for their department, understand where they are missing targets and take required corrective/preventive actions
- A recognition system was implemented to reward and recognise the best department/hospital that can meet targets and drive best practices.

This eDashboard-based system helped the hospital chain drastically improve the performance and, most importantly, inculcate a sense of urgency and culture to drive improvements. It can quickly analyse the pattern and areas of concern and adapt to address the same to stay ahead.

- It can cascade the strategy better to its hospitals and departments with clear, measurable indicators
- Drive transparency across departments and hospitals, ensuring that the hospital leads can make better-informed decisions
- Bring accountability to the point of impact, driving decentralised ownership and decision-making
- Improve employee morale as the measures and metrics are predictable, and there is no ambiguity in data/fact-driven appraisals and recognitions.

Data Privacy Controls while Implementing a Control System for IT Healthcare

Healthcare IT systems gather and process high volumes of sensitive human data like personal information, disease information, electronic healthcare data records and so on. However, the privacy and security of these data are a concern, and any breach may have high negative outcomes for healthcare providers and individuals. Hence, these data need to be protected systematically and governed by a control system that adequately checks and ensures that the design and the processes are well implemented. Applying privacy, security, policies and standards in a systematic approach in the IT systems helps the healthcare organisations overcome this challenge (Puppala, 2016).

The National Institutes of Standards and Technology of the United States Department of Commerce has provided a detailed overview of security and privacy controls (NIST, 2020) that helps ensure the minimum needs on privacy and security are met. There needs to be a strong identity and access management control system that secures the healthcare organisation's data and IT assets.

Tools and controls that capture and record user information, manage digital identities and access controls

- A centralised system that governs the identity and access management, proactively monitors, and takes required preventive and corrective actions regularly
- Some techniques applied for securing IT systems are
    - o Single Sign-On – central authentication process that governs access across systems and software
    - o Multi-factor authentication – strengthens the user access with a combination of password, security token, facial or fingerprint-based authorisation

- Privileged access management maps users to specific roles in the system and provides access only to the relevant data and process for those roles – this ensures no unintended access to sensitive data even if the user has access to the system.

There need to be clear data privacy rules, guidelines and practices established in the organisation on who, what, why and how the data can be accessed and used. Training all caregivers, healthcare practitioners and support staff on data privacy awareness is a key so that there is no unintended data leakage or misuse.

Security Controls of IT Systems and Medical Devices

Medical devices are becoming advanced and interconnected with other devices and networks, through technology evolutions such as Bluetooth, wireless, Near Field Communication (NFC) and RFID. Securing medical devices and system from threats and hackers is a complex exercise that needs well-designed measures and control systems in place.

It starts with design wherein a threat modelling technique needs to be applied in identifying the possibilities of threats and how the design and architecture of these devices and systems can counter those perceived threats. Well-defined transaction protocols, encryption standards and hardening of the system need to be designed and implemented. As the threats and security issues evolve over the period, it is also necessary to continuously monitor, scan and act on security issues across the life cycle and usage of the systems with internal audits and reviews.

Medical devices like radiotherapy devices also contain hazardous materials that need careful management when decommissioning them as they may have unintended consequences including radioactive leakage.

A Reference Framework for Next-Generation Control Systems

With the advances mentioned above and increased complexity and business demands, we suggest Figure 8.1 as a reference framework for next-generation control systems.

Salient features:

- Input based on real-time data collection leveraging the Internet of Things on various parameters, multi-channel data entry from devices and systems, third-party feeds, and intelligence from service providers

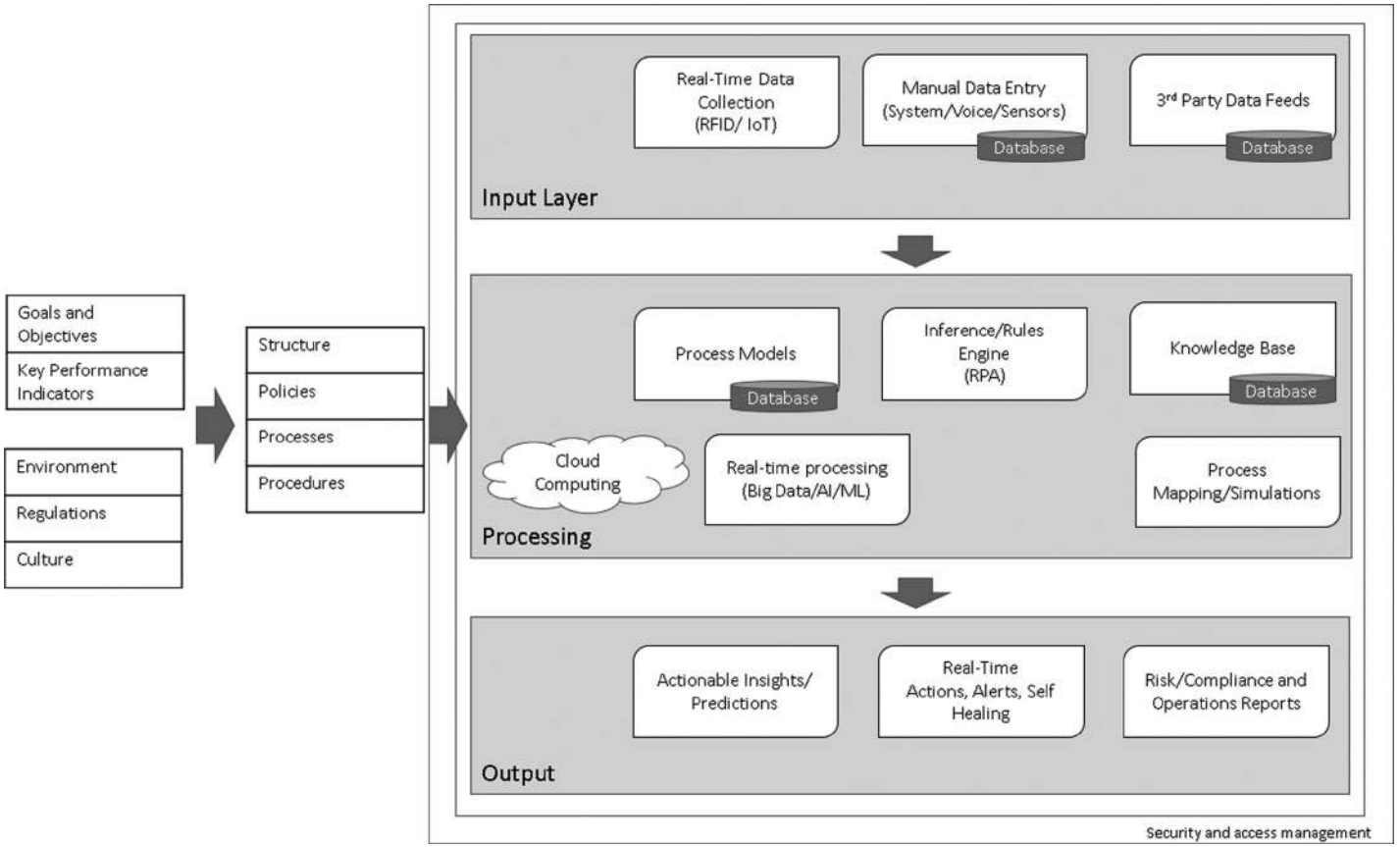


Figure 8.1. A reference framework for a next-generation control system.

Source: By Authors

- The goals, functional context, policies and procedures are standardised and fed to the system that adapts to the environment and regulatory needs
- Processing leverages cloud computing and big data analytics to drive high-volume data and uses predefined models and rules engine to simulate and validate scenarios and outcomes
- The outputs are actual-time actions and provides alerts when possible, offering actionable insights for faster decision-making and required regulatory and compliance reports
- Advancements in Information Technology and digitisation bring new capabilities and opportunities in building and managing control systems for their competitive advantage
- Digitization of organisations provides new ways to access, search, interact with and process data at lower cost, improving quality and increasing productivity
- Evolution of Big Data analytics – ability to analyse a large volume of diverse data enables companies to find insights, hidden patterns, correlations and trends that may aid in making better decisions
- Emergence of Data Science and AI enables organisations to obtain real-time intelligence, improve predictability, interpret complex data and aid decision-making
- The system should have robust security and access management in place for data and system privacy and security

Importance and Benefits of the Control System in Healthcare IT and Devices

- Healthcare organisations are consolidating and scaling up to stay competitive and relevant. As organisations scale, they need clear structure, process and monitoring mechanisms for sustainability.
- The domain of healthcare is expanding with preventive healthcare, wellness and homecare to new procedures and capabilities that require a data-driven E2E flow of analysis and maintenance, which requires an integrated control system that can enable and support practitioners to obtain a holistic view.
- Digitisation of the ecosystem and processes provide a huge opportunity to leverage control system processes and technology to stay in control, improve quality and customer-centricity and reduce operational costs.
- Regulatory and compliance requirements mandate well-documented procedures and systems, and evidence of the system is thoroughly followed. Control systems provide this ability and help organisations manage the cost of these overheads.

- Control systems help medical practitioners take out the operational and manual effort to track and monitor repetitive actions to focus on better outcomes.
- The healthcare administration can rely on control systems to control day-to-day operations with defined standards, which will improve the employee experience and build a predictable culture.
- A well-defined tiered system can help localise the accountability at each department and individual; this empowers and motivates the departments/individuals to stay in control as per standard, and also relieves the top management with time to focus on more priority areas instead of every operational action.
- Control systems create an atmosphere of order and discipline in the organisation, which improves employee morale.
- Clear standards and targets also provide a psychological pressure and sense of urgency, which will help departments and organisations to align the subunits and get the best out of them.

Conclusion

Control systems for measuring and managing IT systems and medical devices is an emergent field and is fast evolving with the latest developments in technology and networks, and increased complexity of medical devices and systems. These control systems help medical practitioners and hospitals drive quality, efficiency and cost control. Moreover, control systems help address new challenges related to data privacy, ethics and social responsibility requiring guardrails and regulatory oversight. IT systems and devices are not just information processing systems but becomes a core tool to provide more efficient and improved services and capabilities in healthcare organisations. With the highly regulatory and sensitive nature of these systems, there is a strong need for healthcare practitioners to be aware of and have basic knowledge of the control systems and the need to control IT systems and medical devices.

- Control systems play a vital role in managing IT and medical device outcomes.
- Management control systems ensure the organisation can reach its objectives predictably with transparent data-driven decision-making with goal congruence.
- Control systems are not optional but a must-have to manage IT and medical devices to drive efficiencies, quality and cost.

- Control systems play a vital role in meeting regulatory and compliance needs and also they ensure that the healthcare systems and devices are protected, meeting data privacy and security requirements.
- Technology developments create massive opportunities to improve traditional control systems by enabling real-time data analysis, predictive intelligence and self-healing alert mechanisms.

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Chapter 9

CALIBRATED FOR CARE I: QUALITY ASSURANCE IN MEDICAL DEVICE-BASED HEALTHCARE

Pawan Kapoor

Introduction

We are aware that no matter what, both the present and future of healthcare are and will be governed by the increasing use of medical devices. Without medical devices, it would not be possible for the healthcare providers to provide comprehensive healthcare to the population at large. Almost all the facets of healthcare, that is navigating pandemic such as Covid-19, conducting heart transplants, joint replacements, coronary angioplasty, providing assistive devices to the physically challenged and so on are dependent on the utilisation of medical devices. Medical devices are, therefore, all pervasive in the healthcare environment. They can be used by medical professionals for diagnostic, therapeutic, monitoring and rehabilitative purposes. They can be used by laypersons and healthcare recipients for monitoring their own progress as well as for assisting them in their daily activities.

If we understand that the future of healthcare delivery shall be dependent on medical devices then it also becomes imperative for the healthcare ecosystem to ensure that the procurement, utilisation and maintenance of these devices are governed by a robust quality assurance programme.

After the completion of this chapter, the reader will be able to understand and describe the:

(a) Concepts of quality as related to healthcare.
(b) Need for quality assurance in medical device-based healthcare.
(c) Components of quality assurance in medical device-based healthcare.

This chapter shall not focus on quality assurance activities that relate to the manufacturing of medical devices for which the guidelines have already been provided in the Medical Devices Regulatory Act – Regulations for Medical Devices, 2017, in India and by the WHO Regulations for medical devices.

Key Terminologies

In order to comprehend the contents of this chapter in the right perspective it may be useful to understand the key terminologies that are being used in the text.

Medical Device

The Global Harmonisation Task Force (GHTF, 2005) has defined a "medical device" to mean any instrument, apparatus, implement, machine, appliance, implant, *in vitro* reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of:

- Diagnosis, prevention, monitoring, treatment or alleviation of disease
- Diagnosis, monitoring, treatment, alleviation of or compensation for an injury
- Investigation, replacement, modification or support of the anatomy or of a physiological process
- Supporting or sustaining life
- Control of conception
- Disinfection of medical devices
- Providing information for medical purposes by means of *in vitro* examination of specimens derived from the human body and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.

Quality in Healthcare

The Institute of Medicine defines healthcare quality as "the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge" (IOM and Lohr, 1990). Quality in healthcare is however, more complex than this. It is dependent on the perspectives of the various stakeholders involved in healthcare. These include the recipients, providers and organisers of healthcare.

The **recipient's perspective** of quality is accessibility of care, its appropriateness and acceptability, its affordability, promptness with which care is provided, early diagnosis and treatment, early return to productivity and to be treated with concern, respect and empathy while maintaining privacy and confidentiality.

The **providers of healthcare** equate quality of care with technical performance. Their perspective is that they should be provided with adequate technology and resources commensurate with their skills and competency. They should be self-satisfied with the final outcomes of their clinical competence and each patient-care activity should add to their experience and skills. Finally, the patient should technically be cured or should attain a level of desirable comfort.

The **organisers of healthcare** perceive quality of care in terms of optimal and rational utilisation of available resources, maximum satisfaction to the user of the facilities, adequate delivery of all components under the health programmes and projects, compliance with treatment guidelines and protocols, proper maintenance of facilities and devices and an overall improvement in the health status of individuals, families, communities and population.

The **society perceives** quality in terms of accessibility, equity, cost effectiveness, transparency, extent of out-of-pocket expenditure and protection of health rights, especially those of marginalised and vulnerable populations.

Dimensions of Quality

If we see the perspectives of the stakeholders, we can arrive at certain dimensions of quality that are common to all (Levesque, 2013; Institute of Medicine, 2001). These are:

- Accessibility, that is, healthcare services are accessible and approachable when required.
- Affordability, that is, the healthcare services are provided at costs that can be catered to by the recipients of care.
- Safety, that is, freedom from unintended harm of healthcare interventions.
- Timeliness, that is, obtaining needed care in a timely manner by avoiding unnecessary delays.
- Efficiency, that is, maximising the healthcare benefits per unit of healthcare resource being utilised.
- Effectiveness, that is, outcomes achieved contribute to the overall positive change in the desired health status and behaviour of the recipients of care and the care is based on evidence-based process and protocols.

- Equity, that is, the care provided is equal irrespective of gender, caste, religion, sect and economic status.
- Patient-centric, that is, it meets the requirements of the patients as per their needs and preferences and the interaction ensures patient education and support.

Quality Assurance

As discussed before, quality refers to the ability of a product or service to meet its purpose or consumer need. Quality Assurance (QA) is a subset of the overarching quality management that focuses on processes that ensure quality. Quality Assurance emphasises providing confidence that quality requirements will be met. QA employs Quality Control (QC), that is, tools for evaluating quality as per the laid-down objectives, and the information derived by utilisation and analysis of these tools is used to certify that stated performance is in conformance with the identified quality standards based upon prevailing principles and practices. QA reacts to deviations in the system and processes to achieve the best possible outcomes. Let us take an example. QC tools help you to collect data that tells you the number of surgeries performed on erroneous sites or wrong patient per thousand surgeries or as a percentage of surgeries. QA involves strict implementation of the process of surgical safety checklist with due emphasis on time-out procedures to confirm the identity of the patient and site and type of surgery.

The interrelationship between Quality Systems, Quality Assurance and Quality Control is depicted in Figure 9.1.

Quality in healthcare is assured if the right patient is provided the right care at the right time using the right interventions by the right person at the right costs.

Quality Assurance in Medical Device-based Healthcare

It can now logically be deduced that QA in medical device-based healthcare implies ensuring availability and utilisation of the right medical device for the right patient at the right time for the right intervention by the right person at the right cost. Thus QA will ensure that processes are in place for acquiring the right medical device based upon the needs of the patient/user population. QA will ensure that processes require that such devices are available, accessible, affordable, safe, efficient and effective and will be utilised within the appropriate time frame focused on the individual needs of the patient/user population.



Figure 9.1. The relationship between Quality Systems, Quality Assurance and Quality Control.

The Need for QA

Many of us may feel that QA in medical devices is not required, and that it is just another fad of administrators, especially since the medical device manufacturers ensure that the devices are safe, and, for most of the major diagnostic and therapeutic medical devices, have a comprehensive maintenance plan. So what is the need for a QA system for medical devices? Let us examine these thoughts with some real-life examples which take place at regular intervals in various healthcare institutions but are generally either not reported or are subjected to a stoic silence on the adverse incidents discovered or reported. For the sake of confidentiality these real-life case studies have been modified while maintaining the core intent and content of the incidence or adverse event.

Case Studies

- Lab investigations of fasting and postprandial blood sugar as well as lipid profiles continue to show higher readings and many patients were put on anti-diabetic and statin treatments until one day, one of the affected individuals who got investigations done from another lab complained that his results from the same tests done at the other laboratory were showing normal results. On analysis, it was revealed that the laboratory analyser

had not been calibrated since its installation even once in the preceding five years. This had led to the wrong diagnosis and treatment.

- Many incidents were reported from the Intensive Care Unit and the Emergency ward of a reputed tertiary care institution that involved failure of a battery-powered defibrillator to discharge during cardiac emergency responses. This was revealed to be due to faulty recharging processes and lack of operational maintenance as a result of inadequate training of the concerned staff and there being no system of monitoring for Quality Assurance.
- There were orthopaedic plate failures due to the surgeon selecting the wrong size for the patient's weight. This was a selection problem due to inadequate training and knowledge.
- Case of motorised OT table: "While operating, the head end of the motorised operation table broke. Luckily, **the patient's neck was saved due to an alert resident.**" On analysis it was revealed that this incident could have been prevented if there had been a regular maintenance plan for the motorised OT table.

Patient Safety Studies

A study published in the *Journal of Anaesthesia* (Thomas & Galvin, 2008) revealed the following:

- Out of a total of 12084 incidents reported by 151 organisations,1021 incidents were associated with medical devices
- 185 incidents related to syringe pumps/infusion devices
- 164 incidents involved ventilators
- 107 incidents were elated to use of haemofilters
- 70 incidents involved the use of monitoring medical devices.

  Amongst all the afore-mentioned reported incidents, 29 incidents resulted in more than temporary harm to patients, 537 incidents were caused due to failure of medical devices or faulty medical devices and 358 incidents occurred due to incorrect setting or use of medical devices.

These case studies and reports suggest that there is a need to ensure that proper QA systems are in place to prevent and eliminate harm arising due to medical devices.

Assuring Quality in Medical Device-based Healthcare

To ensure and assure quality in medical device-based healthcare, it is essential to have a **quality assurance framework**. The Quality Assurance

framework shall focus on various structure, process and outcome measures that are necessary for medical devices (AHRQ, 2015).

The **structural measures** would involve having a multidisciplinary committee for medical device management that will be responsible for procurement, utilisation, performance management, planned preventive and corrective or breakdown maintenance and medical device audit. This committee will be supported by a biomedical engineering or a clinical engineering department. All process measures shall be laid down by this committee.

The **process measures** would include laying down the policies and procedures for procurement, performance assessment, planned preventive and corrective maintenance activities, incident reporting mechanisms, condemnation and disposal and medical device audit.

The **outcome measures** would be based upon various indicators like use coefficient for utilisation of medical devices, breakdown and response times for the maintenance of devices and incident report analysis for safety of medical devices.

Medical Devices Audit

The Medical Devices Audit is a periodic assessment and evaluation mechanism to monitor and to measure the quality of performance of the medical devices being used by the healthcare organisation with the aim of suggesting measures for improvement in the performance thereby assuring quality.

Why Audit?

At any given point of time, a substantial number of medical devices in the hospital may be non-functional or inappropriately utilised. The reasons could be:

- Procurement without a justifiable demand or need
- Overutilisation leading to equipment fatigue
- Inadequate or irregular preventive and corrective maintenance
- Lack or nonavailability of essential spares
- Electrical faults
- Lack of software updates
- Environmental conditions unfavourable for effective functioning
- Mishandling of equipment by untrained and unskilled workforce.

Medical device audit will ensure availability and better utilisation of equipment thereby assuring quality improvement and the judicious use of resources.

Who should Audit?

The Medical Device Audit should be done by a multidisciplinary committee (Equipment or Medical Device Audit Committee) in a manner that all medical devices are subjected to audit within the time frame of one year at least.

The recommended composition of the audit committee is as under:

- The Chief Operational Officer/Medical Superintendent/designated
- Head of concerned department
- Head/Representative of the Biomedical Engineering/Maintenance Department
- Representative from Procurement and Finance Departments
- Nursing Superintendent or representative.

Prerequisite for Audit

The following registers either in electronic or as a hard copy must be available for the audit to take place in a meaningful manner:

- Medical Device Inventory Register
- Medical Device Maintenance Register
- Medical Device Utilisation Records
- Medical Device-related incident reporting system records.

What Is the Focus of the Audit?

- To assess the current status of the medical equipment
- To analyse the records like healthcare device logbook, breakdown and preventive maintenance register, error and incident reporting records
- To ascertain the utilisation and performance of the healthcare device
- To suggest measures to optimally utilise the equipment for quality health services.

The Audit Process

The audit shall be based upon a checklist that will include all aspects related to procurement, installation where needed, maintenance, incident reporting, condemnation and disposal.

The **procurement and installation checklist** should focus on the following:

- Need assessment based upon community need, mission of the hospital, user requirements, cost effective, cost benefit and breakeven analysis
- Market analysis and literature review
- Risk-benefit analysis
- Technical and clinical specification
- Compliance with regulatory requirements
- Vendor analysis and tendering process
- Pre-installation activities
- Purchase and inspection activities
- Installation and user satisfaction certificate

The **inventory management** checklist should focus on the availability of the logbook which should have at least the following details:

- Unique identification number of the medical device
- Model number
- Serial number
- Source of procurement (manufacturer's details)
- Source of funding
- Cost per unit
- Date of installation if applicable
- Location of the medical device
- Warranty and guarantee if applicable
- After warranty maintenance contract with period and changes, if any
- Availability of spare parts inventory with biomedical engineering department, if any
- Current functional status.

The **equipment maintenance and usage** checklist should focus on the following parameters:

- Utilisation is as per manufacturer's recommendations
- The operational maintenance is as per the manufacturer's recommendation
- The medical device is being operated by qualified and trained personnel with requisite competencies to operate the medical device
- A planned preventive maintenance plan is in place
- A corrective or breakdown maintenance plan is in place
- A process is available for emergency repair of the medical device
- Response and down times are being collected and analysed for taking corrective and preventive actions

- Calibration is done at regular intervals based upon the usage of the medical device.

The **incident reporting and response checklist** will focus on the following aspects:

- Availability of an incident reporting mechanism in relation to a medical device
- Process of reporting a piece of medical equipment that is not functioning properly, which can include visual clues like smoking, sparking or display errors
- Process of response to an incident while using the medical device, which includes stabilising the patient, removing and securing of the incident causing device, completion of the incident reporting form and reporting to the manufacturer or the competent statutory bodies in case of serious adverse events
- A process for equipment recall that may be either related to the incident or has been done by the manufacturers in response to certain reported incidences elsewhere or manufacturing defects discovered after launch of the medical device.

The **condemnation and disposal checklist** should be based on the following parameters:

- Availability of a process for condemnation and disposal
- The process is carried out by a multidisciplinary committee
- The condemnation is either due to obsolescence of the medical device or it is being phased out as it is beyond economical repair and maintenance
- The disposal mechanism has parameters to be followed for auction, reselling the equipment after refurbishing the same or else it is being sold as scrap
- Safety issues are taken into consideration at the time of condemnation and repair specifically for radio imaging and laboratory equipment and devices.

Benefits of the Audit

The audit will help in

- Evaluating the utilisation and performance of the medical devices

- Providing inputs for planning of medical care device procurement in future
- Analysing the shortcomings (including downtime) in the utilisation of an equipment
- Providing suggestions for remedial measures, that is, corrective and preventive actions (including training to the users) so as to maximise the efficiency and effectiveness of the healthcare devices.

The healthcare device audit is an important tool for Quality Assurance of medical device-based healthcare.

Performance Measurement Indicators for Medical Device Management

The following **indicators** will be utilised for evaluating the performance of the medical device:

- **Use Coefficient (UC)**. It is used to calculate the utility of the equipment to the healthcare organisation and is given by the formula UC = N x100/ M, where N stands for the number of hours the medical device is utilised in a day and M stands for the maximum number of hours that the medical device could possibly be used in a day. An equipment or medical device having a use coefficient of less than 50% is considered an unsatisfactory investment. This is not applicable to life saving and emergency life support medical devices.
- **The Down Time Metrics or Indicators** (Sigga, 2022).
    - **Mean Time to Repair (MTTR)**. The MTTR represents the average time it takes to repair a medical device or equipment from the moment the medical device or a part thereof has failed to perform the intended function. The calculation of this indicator commences from the time the failure of the medical device or its part has occurred till the moment that the medical device functions have been fully restored to achieve the desired outcomes. MTTR is a measure of both the ability of a medical device to be repaired and maintained as well as the effectiveness of the maintenance functions. For example, the technician may possess the requisite knowledge, skill and competence to repair the medical device but if some parts of the device are highly complex or they have become obsolete and not freely available in the market, then MTTR could be prolonged due to the characteristics of the device itself and not due to the efficiency and effectiveness of the maintenance department. The

MTTR has several stages, that is, stage of occurrence of problem in a device, the stage of detection of the problem, stage of notification of the problem to the concerned department or technician, stage of diagnosis of problem, stage of rectification, stage of testing for correction and finally the stage of restarting for the intended use. The basic formula for the calculation for MTTR is as follows:

MTTR = Total Maintenance Time ÷ Number of Repairs

- **Mean Time Between Failures**, or **MTBF**. This unit of measurement of this indicator is hours. This indicator reflects the average time a medical device is functioning effectively between periods of failure. The higher the MTBF, the lesser is the downtime. MTBF can be measured by using the formula as under:

  MTBF = (Uptime Hours per Day × Total Days of operation)
  ÷ (Number of Breakdowns)

- **Lost Time** reflects the percentage of time that the functions of the medical device have been lost due to breakdowns over a specific period of time. It is measured by the formula as given below:

  Lost Time = (Time medical device is down ÷Total Time) ×100

  So, if a medical device is down 8 hours out of a 40-hour workweek, then 20% of the potential productivity time of that medical device is reflected as Lost Time. Lost time can also be interpreted as **lost revenues**.

- **Overall Equipment Effectiveness (OEE)**. This indicator reflects the overall functionality and reliability of the medical device and thereby its impact on downtime. The OEE calculation is based on machine availability, performance and quality. Availability is defined in terms of the percentage of time the medical device operates effectively when needed. Performance is reflected by the percentage of time the medical device functions at its peak use coefficient, and quality is reflected by the percentage of time the medical device is operational without any defects or errors. OEE is measured as under:

  OEE = Availability × Performance × Quality

An OEE of 80% is considered to be good but the best healthcare organisations strive for 96%.

Quality Assurance in IT-based Medical Devices

While most of the parameters for QA will remain the same as other medical devices, there are additional parameters that need to be looked into for software-based medical devices. There are innumerable software-based medical devices that have found their way as diagnostic, therapeutic or monitoring options. These have no doubt added value to the healthcare delivery but at the same time they too pose risks that could result in faulty diagnoses, wrong doses of drug administration, incorrect display of monitoring parameters and so on. It is, therefore, essential to have a built-in QA system for software-based medical devices that are used in healthcare. The QA programme for such medical devices needs to focus on the following (Khristich, 2021):

- **Thorough testing of medical software** including telehealth applications, mobile health apps, electronic medical records and health and hospital information management systems. The second set of software products that need to be tested includes systems and controllers that are responsible for the functioning of medical devices. These range from high-end hospital diagnostic equipment to personal AI-powered insulin pumps and asthma-monitoring and prevention devices. Under these circumstances the testing would involve both **software and medical device testing** to ensure that both the hardware and software are perfectly synchronised. The process should focus on a test plan with specific pass/fail criteria, a test protocol and verification and validation mechanism.
- **Ensuring compliance to regulatory and certification bodies**. The regulatory requirement for medical software Quality Assurance is the IEC 62304 standard, which is recognised internationally.
- **Testing for medical data exchange security**. Since the medical data will be used interoperably between many devices and systems, it is essential that confidentiality and security of data are maintained and never compromised. The predominant patient healthcare information transfer protocols/standards in the healthcare industry are:
  - ANSIX12EDI which is a HIPAA-regulated framework for healthcare-related record formatting and carrying out transactions on the organisational level, such as data exchange between hospitals and insurance companies.

- Health Level 7 (HL 7) which is another structured messaging unification protocol for bridging and interfacing multiple heterogeneous medical software systems that need to exchange clinical or administrative information, normally within a hospital, clinic or medical centre.
- FHIR (Fast Healthcare Interoperability Resources) that enables quick integration and interoperability between multiple data systems, including Electronic Health Records, mobile apps, medical devices, and more.
- DICOM (Digital Imaging and Communications in Medicine) standard that regulates all processes related to medical imaging information.

- **Ensuring system protection from security threats.**
  QA for IT-enabled medical devices needs to
  - Identify the system components that are most vulnerable for cyberattacks
  - Ensure that all necessary protection methods are in place
  - Ensure that the software code is meticulously assessed and does not contain serious security flaws or gaps.
  - Verify that no unauthorised access is possible
  - Check and test the internal network to make sure all layers and entry points are sustainable and hack-proof
  - Evaluate the protection of different components (such as mobile apps) against specific types of threats like jail breaking, rooting, man-in-the-middle attacks and others.

Conclusion

Quality in healthcare is an attribute of any product, service or device that ensures safety of the patients, visitors, staff, community and the environment. Technology definitely makes life simpler for both the providers and recipients of healthcare services. It results in better utilisation of the human, resources, earlier diagnosis of ailments, supports quicker clinical decision-making reduces human interventions, standardises care, supports round-the-clock monitoring of patient care especially in critical care settings, etc. With all its positive attributes, technology also kills, leads to adverse events and undesirable and unwanted outcomes, and above all, it adds to the cost. To offset the negative aspects of technology it is essential to have in-built Quality Assurance systems to ensure that the appropriate technology is available to all in a cost-effective and cost-efficient manner, and is put to effective use by trained and qualified personnel in

a timely manner. This chapter introduces the reader to the various concepts and dimensions of quality as applicable to medical device-based healthcare. This chapter emphasises the importance of having a Quality Assurance framework for medical devices with all its structural, processes and outcome measures. It also highlights the need for a medical device audit mechanism and the necessity for having performance-based measurement indicators for the management of medical devices. The chapter also addresses the requirements of IT-based medical devices specifically in terms of security, integrity and confidentialiy of data. It must be understood by the reader that medical devices are an aid to support patient care and therefore must be used with care and competence. Medical devices complement the tasks of the physicians and therefore their effective functioning for safe patient-centred care should be ensured through having a well-planned and designed Quality Assurance Programme for their appropriate and effective management.

- The medical devices industry is moving ahead in geometric progression. While there is no doubt that this rapidly advancing medical technology has added a lot of value to the healthcare ecosystem, it has also become a source of concern and risks. If not monitored for effective functioning, it can lead to serious errors and consequences.
- To ensure that medical devices-based healthcare is appropriate, affordable, available, safe, efficient, effective and patient-centric, it is mandatory to have a Quality Assurance system in place.
- The Quality Assurance system framework would require addressing all elements of structure, process and outcome measures.
- The Medical Device Audit, comprising various checklists related to procurement and installation, inventory management, maintenance, usage and incident reporting mechanisms, will be an important tool for ensuring that the right medical device is available to the right patient at the right time and operated by the right person and at right costs.
- For effective decision-making and evaluation of medical devices, the medical audit tool should be complemented by the use of various performance measurement indicators like use coefficient, mean time to repair, mean time between failures and overall equipment effectiveness.
- With the advent of Information Technology, a lot of additional parameters need to be tested, verified and validated. These parameters relate to both the software and hardware and must conform to the laid-down standards and protocols related to software development, its use and maintenance of its security and confidentiality features to prevent data theft and adverse consequences.

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Chapter 10

CALIBRATED FOR CARE II: QUALITY ASSURANCE IN IT-BASED HEALTHCARE

Ashvini Goel and Bagmisikha Puhan

Introduction

Healthcare is a sector which requires high levels of efficiency, and needs to deliver accurate, timely performance which invariably relies upon technology for reducing medical errors, deterring adverse drug reactions and improving compliance with practice guidelines, consequently improving patient safety. While reliance is placed on technology to improve the quality of healthcare delivered, it is also important to look into the efficiency of the very technology which enables delivery of healthcare. The present chapter is aimed at bringing to the fore:

- Basic concepts of quality and quality assurance in healthcare.
- The need for quality assurance in healthcare.
- The components of quality assurance in IT-based healthcare.

Throughout this chapter, there are discussions around the core concepts of quality assurance which overlap with the workings of the healthcare domain, especially focusing on aspects which are typical to the implementation of advanced technologies, for proliferation and augmentation of delivery of healthcare services to the last mile.

Understanding the Basics

Typically, for IT-enabled healthcare to be efficient and robust, data/information needs to be captured in a structured manner, as it is the building block for provision of accurate, reliable, clinically meaningful measures across the care systems. At the core of continued delivery of quality healthcare, lies Quality

Assurance (QA), which equips healthcare professionals and organisations with the tools to ensure excellent quality of care. The wide range of tools that come with IT systems, enable: (i) access to the most recent evidence-based clinical guidelines and decision support; (ii) improved patient care and safety; (iii) proactive health maintenance for patients; and (iv) efficient, coordinated sharing of clinical information with other providers through secure and private channels. With these objectives underscoring the adoption of IT in healthcare, it is imperative that there is quality care provided to the end users.

Quality in healthcare can be understood to be the degree to which healthcare services for individuals and populations increase the likelihood of desired health outcomes (WHO, 2022). Health service quality is difficult to define and measure, truly; for there are incongruous characteristics such as intangibility, heterogeneity and simultaneity. Without relying on any particular definition, it is important to consider a multidimensional approach that encompasses various healthcare stakeholders' needs and expectations.

This requirement is apparent in the sector, as we witnessed a shift from Quality Assurance to Quality Improvement, which builds upon the concept of measuring goals, and not just mere meeting of the thresholds which are essential to ensure quality in the ecosystem amongst the stakeholders. The entire process touches upon the perspectives that might be relevant to the (i) recipients of care; (ii) providers of care; as well as the (iii) care organisations.

Quality for Stakeholders

Care recipients: In enabling IT facilities in the healthcare sector, from a patient's perspective, there would be an expectation to have all information that is available about them, to be made accessible to them at one place, at one location. Additionally, as we move into a wellness model, the patient's data are bound to change over time, and this dynamic activity will also require prudence on the part of the provider to ensure that the data which are displayed are a comprehensive summary of the patient's health/medical journey. As one of the goals of QA is to realise continued care of the patients, the available data should be used effectively for follow-up, based on evidence-based prompts. Interestingly, where integrity of data is maintained with the help of IT, it also enables the service provider to provide support to patients across all conditions and health issues, and not limit it to any specific health encounter which has triggered a consult/visit to the Health Care Provider (HCP). Additionally, the patient should be in control of their own data, while being provided the option to input, as well as review and update any information with the help of digital health applications; this invariably assists the HCPs to manage expectations with respect to evidence-based prompts, and reminders that are generated of

this assimilation of datasets based on software-based digital Electronic Health Records (EHRs).

Care providers: For any health practitioner, in addition to what has been identified as essential elements for care recipients, one of the most rudimentary requirements for any care provider is to use digital data with the utmost ease. The look, feel and the level of automation, cannot be chaotic, but must enable the provider to seamlessly manoeuver through oceans of data, and manage the patient with least effort. As a problem-solving principle, Occam's razor states that *entities should not be multiplied beyond necessity;* any mismanaged information on the views that are afforded to the care provider is unwarranted. It defeats the very purpose of enabling swifter timelines, and focused care. Where QA is the focus, the care provider can provide the patient with a digital health education handout at the end of the consult; this could be achieved without provider interaction and can be the outcome of analysing trends based on patient data. One aspect where the HCP is heavily reliant upon the IT provider, is for increased efficiency where data are stored in a way and displayed in a manner that is actionable. Typically, reliance is sought on Clinical Decision Support Systems (CDSS) which are computer-based programmes, analysing data within existing health records to provide prompts and reminders to assist care providers in effective strategizing and increasing quality of care (CDC, 2021). This can be witnessed in the form of an evaluation, wherefore a particular blood result, if the provider is only presented with a threshold being breached for a particular parameter, for a particular timeline, it might save valuable time, and save the provider from sifting through volumes of data to identify which patient requires urgent attention as a part of the triaging process. Where a CDSS can remind providers for screening of cases of hypertension, prompting questions on medication adherence, there would be assistance provided for cardiovascular preventive care.

Care organisations: As large set-ups, for any Health Care Organisation, the consideration would be to enjoy benefits from the perspective of the HCO itself, the Healthcare Professionals, as well as the patients. In realising these quality goals, QA will stem from having a process for quality in place, conducting a self-assessment, assessing organisational gap analysis, then moving to enforcing QA principles and proceed for certification; this is easier said than done. However, to deliver a high-quality service in a measurable way, HCOs must have robust QA programmes. This focus will be premised on the basic principles of: (i) customer focus; (ii) quality; (iii) scientific approach; (iv) long-term commitment; (v) continual improvement systems; (vi) cross team coordination and team work; (vii) education and training. This addresses the requirement of providing direct medical services of diagnosis and treatment,

as well running indirect operations, like administration, billings and purchases. As HCOs also include payers, improved quality benefits in reduction of costs, and also identifying and addressing problems before they actually manifest or cause harm. IT-based digital tools enable the HCOs to cater for prospective and perspective planning to ensure Total Quality Management of healthcare provisioning activities.

HCOs must also ensure backup and recovery for all the datasets they manage; while physical backups have been considered viable, the cloud service providers are now coming up with solutions which are compliant with ISO standards and enable data to be available to the end-users during distressing events as well. All of this can be better implemented when the HCO relies upon modular, automated tools and functions which process voluminous data produced at the HCO. Scalability is integrated with the cloud service solutions, which also warrant that in case of a security event/natural disaster, the information which must flow to the clinicians or the patients, is not interrupted. These data solutions must be attended to and tested on a regular basis, enabling the personnel managing it to become familiar with the offerings, to ensure that there is nothing amiss in the implementation.

Dimensions of Quality in Healthcare

The commonly accepted dimensions of healthcare include, (i) patient **safety**; (ii) provision of **effective** services based on evidence; (iii) ensuring **timeliness** to avoid waiting times and harmful delays, with unnecessary escalations; (iv) using resources in an **efficient** manner (Mosadeghrad, 2012); (v) provision of care with an **equitable** objective, without letting prejudice and bias seep through disparate treatment on the basis of gender, ethnicity, socio-economic status and such other personal attributes of an individual; and, (vi) keeping the entire journey **patient-centred,** while ensuring affordability, accessibility and appropriateness of the services provided to them (Ossebaard and van Gemert-Pijnen, 2016).

To effectively assess the quality of any health system relying on IT services enablement, it is important to note that the enablers are not impeding the safety which it sets out to achieve. With constant involvement of collection of data, review of data, processing of data, it is for the digital tools to learn and also abstain from allowing any inaccuracy to seep into the algorithms which assist in clinical decision-making process. For instance, where a particular condition requires consideration of the *gender or age* of the patient, and the enabling tools have not been designed or attuned to such consideration, the results could possibly be disastrous, and end up causing actual harm to the patient. A QA programme will look through such aspects, and continue to improve

upon them, on the basis of the determination made by the HCPs, researchers, scientists and any trends which have been observed, to further improve the services.

Married to the idea of how data privacy and security works, it is also a matter of essential consideration that the data which are fed by the end user, the patient or caregiver, or the HCP, is not leading to a bias being caused in care delivery. As an equitable approach, it is essential that where medical science does not make determinations on the basis of a person' individual attributes, then such inferences must not be made by the HCPs, HCOs, as a matter of their individual assessment. It is important to note that in this interoperable digital healthcare network that is being sought to be created, there would be constant interactions between different systems, and a bias which is stemming from one place, may have bearing in another location too.

Interestingly, while personal attributes may not become the basis for patient evaluation and management, a patient-centred approach would mean that the patient's affordability, their individual circumstances, understanding of the situation, and cultural disposition, must be considered by the HCPs and HCOs, before any care is advised. The patients should be enabled to make decisions about their own care. It goes without saying that where efforts are put in a timely manner, all the stakeholders benefit from the same; the patients preserve their own health, the practitioners their line of treatment and advice, and the HCOs a lot of costs, demonstrating increased efficiency in their long-term commitment to quality.

With the effective adoption of QA into the healthcare systems, the outcomes would be specifically seen in the form of reliable Electronic Health Records (EHR), which would lead to efficient Clinical Decision Support Systems (CDSS). This would assist any HCO/HCP in forming an effectual care plan and may also further the cause of timely healthcare delivery. The objective of having quality care to be delivered to the end-users would resultantly boost customer confidence (Quigley *et al.*, 2011). This is a cycle of outcomes which can only be achieved through a robust quality assurance programme being adopted and executed by the care organisations.

Quality Assurance in India

Currently, in India (and abroad) every major HCO has some form of Health Information Exchange (HIE) services available, and implemented at an organisational level, or the network level. Specifically, the Indian government with its vision to have a well-defined healthcare architecture in the country, has been laying down the building blocks for the Ayushman Bharat Digital

Mission (**ABDM**), to enable the nation's public and private healthcare services including hospitals and other HCOs to electronically search, access, download patient information from sources beyond their own organisation or health system. This is premised upon compatibility amongst the systems, leading to a modicum of interoperability. In a heterogenous environment like India, where constant migration and relocation thwart ideas of assimilation of public health data, interoperable systems will not just empower the patients, but will also enable the HCOs and HCPs to manage patients and deliver care better.

Conventionally, QA has been conducted within a hospital preferred by a committee which was entrusted with the task of ensuring that any concerns with respect to a certain procedure or treatment are overcome by them collecting data to determine whether the minimum acceptable standard is reached or there exists a need to improve overall performance. The National Health Systems Resource Center has developed the National Quality Assurance Standards (NQAS), focusing on the specific requirements for public health facilities, as well as global practices. The NQAS broadly address matters related to: (i) Service Provision; (ii) Patient Rights; (iii) Inputs; (iv) Support Services; (v) Clinical Care; (vi) Infection Control; (vii) Quality Management; and (viii) Outcome (MoHFW, 2015).



Figure 10.1. Quality Assurance in healthcare.

The Need for Quality Assurance in Information Technology-based Healthcare

In assessing how QA is being adopted across organisations around the world, it is hard to miss that the focus is on prevention and well-being, as opposed to illness and treatment. With interoperable data and platforms enabling flows across individuals, populations, HCOs and HCPs, data are enabling real-time decisions about health. Globally, the focus on prevention and well-being has yielded in proactive and effective interventions, leading to decline in overall disease burden and spending, both at personal Out-of-Pocket (OOP) expenditure, as well as at the HCO level (may include payers, public and private players). Combining clinical data with other aspects about a person's genomic, biometric, behavioural and personal data, has also enabled targeted interventions in a timely manner. Following the thread of how we have moved away from a cure-based regime to one that is centred around the concept of "wellness," the patients monitoring their own health and medical conditions, have become significant participants of the healthcare delivery team. All of this is being made possible by the use of technology enablers, which are reliable, accurate and efficient.

ReMiND Project: we have witnessed that the ReMiND [Reducing Maternal and Newborn Deaths] Project, basing itself on an mHealth (mobile health) initiative, has helped several frontline Healthcare Workers (HWs) save lives. Exploiting upon interoperable network that was afforded by the Government of India, and data governance architecture made available to the users, HWs were able to monitor pregnant women better, leading to a projected decline in maternal and infant deaths. The project being patient-centred, witnessed that the women were more open to discuss several topics with the HWs than earlier. While this was undertaken at a community level, the same can be replicated across other locations, and at a larger scale, affording similar benefits to other demographics as well. While relying on the government issued guidelines, the digital application enables the HWs to take their clientele through a checklist of health behaviours, prompting them to counsel on any steps not being taken. The same app also allows the HW supervisors to help them monitor the HW's workload, identify any performance gaps, and problem solve around any challenges the HW faces in their operations (CRS *et al.,* 2016).

The Case of Therac-25

Even with the passage of a long time, this discussion from between June 1985 and January 1987, focusing on the computer-controlled radiation therapy machine, Therac-25, bears a lot of relevance to understand and appreciate

the benefits, as well as the limits of integrating technology seamlessly into the care delivery system. We will proceed with very focused discussion to assess why the need for QA in healthcare is ever urgent and stays at the core of care delivery and we will abstain from making any specific references to any particular aspect, as the accident was never officially investigated.

Therac-25 was designed as a dual-mode linear accelerator that could deliver either photons at 25 MeV or electrons at various energy levels and was produced by AECL (Atomic Energy Canada Limited). The machine relied upon software for monitoring the electron beam scanning plus mechanical interlocks (substituting earlier mechanical locks) for policing the machine and ensuring safe operation; furthermore, the computer was also responsible for the positioning of the turntable, and the patient. The machine was involved in about six accidents, in which patients were exposed to massive overdoses of radiation. As the software was suffering from several concurrent programming errors, the machines sometimes gave its patients radiation doses that were hundreds of times greater than normal, resulting in death or serious injury.

The issues stemming from this largely loomed around the paucity of software quality assurance at the manufacturing facility, the insensitiveness towards machine malfunctions that had consumed the HWs at the facilities, and the lack of documentation which was essential for the purposes of quality control (Leveson, 1995). The inadequate practices which plagued this incident include the following:

(a) Rigorous software quality assurance practices and standards were absent
(b) Extensive testing and formal analysis at the module and software level was not done; there was no regression testing conducted on the software to assess inadequacies
(c) The user manuals and other associated documentation required for the operators to manage were inadequate, and not in order
(d) The software did not have audit trails, and other ways to detect errors for verification
(e) There was no consideration made to the design of the software during AECL's assessment of how the machine might produce the desired results and what failure modes existed, focusing purely on hardware and asserting that the software was free of bugs
(f) AECL never tested the Therac-25 with the combination of software and hardware until it was assembled at the hospital.

In line with what has been discussed in the foregoing, these accidents went on to become a standard case study in health informatics, quality assurance, computer ethics and software engineering. The principles that we have

discussed insofar, pertaining to QA if applied to this particular case study, we could expect a remarkable change in the behaviour, or a possibly better outcome, if we put a positive spin to it. Nevertheless, as we have already indicated that there has been a gradual shifting of attitudes from quality assurance to quality improvement, one outcome that would have been useful is a gap assessment. This is the difference that is needed to be overcome in an overly connected and technology-intensive world of healthcare.

In an ideal scenario, the case study of Therac-25, with the emulated goals of QA (Madadipouya, 2016) would have fulfilled their contribution to quality improvement, if the following processes had been followed:

(a) Ascertainment of the suspected problem, by gathering further information on the same
(b) Examination of data assimilated at Step (a), above, and development of new measures for remediation and mitigation, as needed
(c) Setting goals and formulation of actions for improvement
(d) Implementation of actions for improvement, building upon the learning experience from the incidents so caused
(e) Continued assessment of progress and redefined actions for the purposes of implementation for improvement
(f) Monitoring of improvements for sustainability.

The pointers mentioned hereinabove are part of the requirements that would be expected of a quality healthcare system/care provider. This would also assist in achieving the desired outcomes *vis-à-vis* any patient, which forms the core objective of any quality assurance programme. Like any other IT-enabled service, the essence lies in identifying the problems and coming up with the necessary solutions to overcome the same. Early realisation of issues in an IT environment is essential to stamp out inefficiencies which can seep into the ecosystem, ranging from bugs to biases which would invariably result in inaccurate, inconsistent and unreliable outcomes. In the healthcare setup, this is a recipe for disaster, impacting the lives of many individuals, and disrupting the trust-based relationship that is forged between the HCOs, HCPs and the patients.

Components of Quality Assurance in IT-based Healthcare

Any IT system requires constant vigilance of the systems, the compatibility, availability and accessibility of the systems to all users. To this end, it is always important to have in place audit systems, to examine and evaluate the infrastructure, policies and operations of any organisation. This becomes all the

more relevant in case of IT systems and devices which are focused for care delivery.

The ***IT-based medical services audit*** is a periodic assessment and evaluation mechanism to monitor and to measure the quality of performance of the IT-based medical services being used by the healthcare organisation with the aim of suggesting measures for improvement in the performance thereby assuring quality. This becomes simpler where an entity maintains a risk register to prioritise risks and allocate resources for mitigation and remediation of those risks.

As any HCO, HCP consumes a lot of personal, and sensitive personal information of the end users. These qualify to be more than corporate assets and records, and the institutions need to ensure the integrity, security and continued availability of these data sets. This requires that the organisations are ever vigilant of the overall goals of theirs, which is quality care.

Objectives. The objective of any IT-based medical services audit is to evaluate the systems and processes in place, to ensure that the security of the data is preserved at all times. It cannot be stressed enough that for a sector which is data-driven, and where quality is measured by the outcomes, instances like clinical evidence data would thrive only upon accuracy and integrity of data. An IT audit also ensures that an organisation's risks are identified and any mitigation, or proposed remediation measures are put in place, to ensure that any action, may be performed *ex ante*. Furthermore, the entire process is put together to determine the level of compliance of the IT infrastructure with the statutory requirements, and the laws that are generally applicable or are specific to the sector. With the data privacy and security laws, and related IT laws becoming stringent by the day, it is important for the HCOs, HCPs, to ensure that they do not run afoul of the applicable laws, for the penalty provisions are expensive, and they pose a greater harm to the reputation that is weaved in, in case of a security incident/data breach.

Certain processes which are intrinsic to the purpose of managing data privacy and security of the systems, begin at the point of procurement itself. With the introduction of the European Union – General Data Protection Regulation,[1] the concept of a data protection impact assessment, has gained a lot of prominence. This comes at a stage where a new product, system or tool is proposed to be installed or on-boarded, to be integrated with any existing IT

1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

system solution; and is done with the objective of determining and assessing if the integration poses any risk, exposes any vulnerabilities or is susceptible to any incidents being paved into the existing systems. This is a process to identify risks prior to actual processing, and minimising such risks as early as possible. This process will extend to the stage of installation and integration of such tools, systems, devices to the existing ecosystem.

Maintenance of an IT system in the healthcare sector with the continued focus of having patient safety at its core, would require continuous monitoring, frequent audits and effective implementation and enforcement of the findings so derived from these IT audits performed on the systems. It is with the objective to ensure that the upgradation and replacements do not impact the confidentiality, integrity and availability of the data, that it becomes imperative for the care providers and organisations to conduct periodic IT audits. All of this goes into the QA programme, which strongly favours continued efficiency, and realisation of the primary goals of the organisation.

Equitable access to healthcare. It is a given that the advancement of technology, and increased integration of the same into the healthcare system, would entail additional costs on the part of the care providers, which would then trickle down to the end users, the patients. To improve health equity, it is essential that high-quality and effective services are available to the last mile, at their times of need. This also comes bundled with the fact that no additional cost is passed on to the end users; this becomes possible when issues relating to inequitable distribution of power and resources are managed better. For instance, where spending/budget can be allocated to the care delivery system, and where the care providers are able to efficiently allocate resources, without being wasteful about the costs that are being incurred by them towards resources which may be redundant, or not essential, the system may become relatively equitable. With investments being made cautiously, there could be an opportunity to bridge any divides existing between the urban and the healthcare infrastructure. This is not capable of change overnight, but requires considerable investment, monitoring and continued assessment of existing social and economic disparities which impedes equitable distribution and access to care.

The empowerment of women, and positioning of women in decision-making roles can influence issues related to gender inequity and may also bring in a more sensitive approach for addressing concerns persisting in the sector.

Monitoring Indicators

Quality care relies upon up-to-date and accurate data inventories to process and generate aggregated data sets, for improved performance levels. As with

any digital offering, consumer confidence is an integral component for eventual success. Unfortunately, in practice, it has been seen that previous incidents of data breaches across evolved jurisdictions such as the NHS in the United Kingdom (BBC, 2018) as well as in Germany (Pladson, 2019) have exposed sensitive information of millions of users, diminishing consumer confidence in these services. In order to ensure that there are no leakages or unauthorised accesses, it is important to ensure pilfering of health data does not occur owing to weak infrastructure, unfettered access being available to unnecessary personnel. To this end, monitoring of IT infrastructure, and preparedness will ensure that there are no concerns from the point of view of preserving, managing, and processing of data. There is an urgent need to develop quality checks/indicators for monitoring data incidents/breaches within the lifecycle, to filter out compromised data sets from further processing by the service providers.

In IT-based healthcare, indicators are required in order to realise the effective implementation of a QA programme. It has been seen that patient interviews and conversations are also a good determinant for both performance and safety monitoring, and they have also been considered as a good warning sign in recent tragedies. Safety indicators could be sourced from complaints, health and safety incidents, clinical audits, routine data, claims, inquests, administrative data and from direct and informal conversations with the patients and caregivers. Feedback from all stakeholders can be obtained with the help of digital app-based questionnaires and monitoring tools can be formulated based on the same.

There is no single measure for determining safety. Combining safety indicators, with how useful the services are to a user group, or a social group, makes a better case for enunciating equitable healthcare. This, however, will require specific inquiries to determine whether there is any actual construct, or inequalities in health between more and less advantaged social groups.

The performance measurement indicators for IT-based healthcare management are the same as those for medical device management and can be viewed on pages 138–139 in the chapter titled *Calibrated for Care I: Quality Assurance in Medical Device-based Healthcare* of this book.

Conclusion

To summarise, where security of patient data, secure and conversant interface of the applications, interoperability of IT-enabled devices, timeliness, and, efficient, seamless performance are key requirements of care delivery, *Quality Assurance* and testing and audits, allow care providers to deliver relevant solutions for any and all kinds of consumers/patients. Where data-driven

solutions and clinical evidence-based systems are coming to the fore, it is only complementing the fast-growing lifestyle medicine segment. All of this can be better realised, and public health can be better augmented by the *quality care* that is ensured by these measures being implemented.

It is important to note that QA programmes are not just designed to improve clinical outcomes of the organisations but are also aimed at effectively organising or reorganising the staff engagement in matters which contribute to the growth of the organisation as a whole.

This chapter aimed to provide basic aspects of quality assurance, and how organisations may learn to imbibe these concepts and raise the quality of delivered healthcare. This incessant urge for improvement of quality is deeply seated in the healthcare ecosystem, so, application of these necessary inputs will enable the healthcare sector to improve and derive optimum benefits from the quality initiatives.

Key Highlights. If you intend to launch a QA initiative, conduct a preliminary analysis by determining the following:

Step 1 – Review of clinical and managerial standards, norms, practices and processes; skill levels of the staff
Step 2 – Assess the quality of service currently provided, and patient and community satisfaction with the services
Step 3 – Examine the IT/information system, and evaluate the specificity, sensitivity, reliability of the indicators available
Step 4 – Assess the organisational hierarchy and QA programme.

As John Philpot Curran once said, "the condition upon which God hath given liberty to man is eternal vigilance," quality assurance is nothing but an extension of this adage, which would require us all to be vigilant of the choices that are made by every single stakeholder in the ecosystem. As a customer who expects quality care, they must put in their best efforts to make accurate descriptions and disclosures; the care provider is equally responsible to lend their ears, appreciate the stretch of the complaint and address the same; and the care organisation needs to make the facilities accessible, affordable and reliable. It is an ecosystem which requires a lot of inter-linkages, and these inter-linkages rely on a lot of assurance in form of what is put into the system, and what is derived of it.

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Chapter 11

TAKE CARE, BE SAFE: LEGAL ISSUES, PRIVACY AND SECURITY IN HEALTHCARE TECHNOLOGY

V. K. Singh, Sachin Gaur and Sanyam Khetarpal

Introduction

The Internet as we know has been around for almost 40 years. It started with connecting university computers and the enthusiasts behind them for trivial communication to what is serious business today, powering many industries from e-commerce to telemedicine in healthcare. Increasingly, it is not just humans behind the computers which are connected, but also machines, sometimes called the Internet of Things. Traditional medical devices which have been mechanical in nature or electromechanical devices have increasingly turned into computing machines from the benign stethoscope to an MRI machine. Software and connectivity is proliferating everywhere in the healthcare domain today. As they say in Silicon Valley parlance, "software is eating the world" (Andreessen, 2011).

The proliferation of software and connectivity has brought many gains to the healthcare industry, for example, use of artificial intelligence for assisted decision-making for clinicians, remote access and monitoring of healthcare/patient data to teleconsultations and so on. We have seen the sharp rise of digitalisation during the last two years of the COVID-19 pandemic globally. All these gains also come with rising concerns on safety and security of patients' lives and sensitive healthcare data. Collectively as a society we have not well understood the risks that digital healthcare brings with it and we are not well prepared to handle incidents. Over the years, major organisations have seen a data breach/cyber-security incident, giving us a glimpse of what lies ahead.

When it comes to the legal, privacy and security aspects of healthcare technology, our understanding is still entrenched in an era where healthcare delivery models were confined to a physical space and time with limited connectivity. New aspects related to information storage, who has access to it, how

it is processed and shared and other aspects of patient health information are being increasingly digitised and are no longer confined to the physical limits of the healthcare delivery centres.

This chapter will provide:

1. A description of the status quo on the topics of cyber security, privacy and the legal framework for readers to make an informed choice while planning, designing and building healthcare technology and connected health services, minimising the risk to patients' life and privacy.
2. A foundation of basic information security concepts.
3. An overview of issues that a practitioner may have to deal with in real life.
4. Emerging regulations and trends that will impact the sector in coming years, in order to help the reader plan steps in their own organisation accordingly to cope better with future developments.

Information Security Issues in the Health Sector

In the domain of (information) security, the triad of CIA, aka, Confidentiality, Integrity and Availability, are considered the fundamental pillars for providing security assurance (Figure 11.1).

It is no different in a hospital or healthcare setting; issues will lie in one of the domains whether violation of confidentiality, integrity or availability of the data.

Ransomware as an example of breach of confidentiality

The infamous ransomware cases over the last few years show that cybercriminals with sophisticated attacks infect hospital computers and take



Figure 11.1. The fundamental pillars for security assurance.

confidential (patient records or other billing information) data and extort money by threatening to make the data public.

> What is Ransomware?
>
> Ransomware is a malicious software which after getting into your computer encrypts all your data and locks you out of your own computer. It then demands payment of money in form of cryptocurrency to release the computer/data back to you.

Hospitals and care providers in general can start encrypting the data at rest in their premises. It will cripple ransomware attacks as the attacker then may not be able to make information public as it is encrypted. The other important step a hospital can take is to have a real time backup of their data, which means that a ransomware encrypting their data would not prevent them from continuing their operations and will enable the organisation to be resilient.

> We have surveyed over hundred hospitals in India and elsewhere over the last few years. We have found that none of them encrypts their data at rest and almost no one has a real-time back up of their data. Those who do back up their data, do it over a 48-hour or 7-day cycle. Hence, as of today, most healthcare organizations are vulnerable to ransomware attacks.

Integrity attacks can cause severe patient harm in the healthcare setting.

The other kind of attacks that we have not seen yet in a big way is the manipulation of healthcare information by a cybercriminal without the knowledge of the healthcare provider or the patient. For example, imagine information like allergies or blood groups of patients being modified. Any undesired change in this information could be life-threatening for the patient. As the healthcare staff may use it to administer therapies and drugs which may cause patient harm. Hence, the data integrity in certain contexts could be even more important than confidentiality.

> Xroad architecture from Estonia is a good example of underlying cyber infrastructure for building essential services. The architecture uses a blockchain-like approach to provide guarantees for data integrity. In our review of current Digital Health Policy Documents by the government of India, we have found a lack of emphasis on the topic of Integrity.

Denial of Service (DoS) attacks on an important public health service may disrupt the service

We have seen ransomware attacks where they have crippled hospitals as they corrupt their computers from operating as usual. The other possibility could be a nation state or a non-state actor planning a sophisticated distributed denial of service attack on important healthcare services. For example, if the vaccine scheduler or online vaccine certificate verification service is attacked and not able to operate as usual, it may prevent travellers' movements in airports or exercising other important participation which requires verification of the vaccine certificate.

> The world saw its first nation state level cyber-attack as early as the year 2007. On 25 April 2007, Estonia faced a distributed denial of service attack and most essential services were down for three days. Some estimates suggests that it has cost only 50,000 USD to organize the 2007 attack. Ever since then, we have seen the role of cyber-attacks getting bigger in every conflict that we have seen between two nation states. Hence, healthcare services need to consider this as a risk when the countries have a bigger conflict, cyber-attack on essential services may be the easiest and very first response from the adversary.

Possible Cyber Security Issues in the Health Sector

We mentioned various information security issues in a hospital setting above. However, a hospital increasingly is becoming a "Smart" hospital, which means a variety of machines are now talking to computer systems. For example: from the building management system controlling the air conditioning, water, oxygen and other utilities to diagnostic setups like MRI, X-Ray machines and other monitoring systems taking care of patient's health. Medical implants are also now becoming connected from a continuous blood sugar monitoring device or a pacemaker to an insulin pump; the connected technology is directly enabling the individual to manage their health on a day-to-day basis.

A cybercriminal or a novice hacker may be able to manipulate some of these systems and can create havoc in disrupting the normal operation of a hospital or the individual's life. For example, a false fire alarm in a hospital may disrupt an ongoing surgery in the operation theatre or manipulation of the X-Ray machine may create damage to the patient unintended. A malicious manipulation of the medical implants may actually kill the person concerned when it comes to disrupting pacemaker or an overdose of insulin with the insulin pump.

The medical device manufacturers are increasingly becoming aware of the issues and there are now guidelines available from various standards bodies like NIST and ETSI on avoiding pitfalls during the life cycle of connected devices in an organisation (ETSI, 2020).

Going forward, these cyberattacks will become even more prominent. As we have seen during COVID-19, a lot of the population went for remote care to contain the infection. We have also seen with the advent of 5G, remote surgery taking place for the first time (Loeffler, 2021).

Cyberattacks on such remote care setups can directly create patient harm and hence we need to pay increasingly more attention to these issues, when these technologies are designed, developed, deployed, maintained and decommissioned eventually.

Owning the Security Responsibility and Aiming for Resiliency

A responsible organisation should be ready for incidents. In the cyber-security world, a popular saying goes, "There are only two kinds of organisations, those who know they are being hacked and those who don't."

So when the incidents are unavoidable, how can an organisation be more resilient and ensure patient safety and security from cyberattacks? A strong adherence and compliance with the latest security advisories and standards may be the answer to minimise the damage from cyberattacks.

Figure 11.2 shows the NIST framework on safeguarding an organisation against cyberattacks. Most healthcare organisations in India today lack the ability to identify threats in advance, plan interventions to protect against the identified threats proactively, detect an attack and an effective response to it. The true resilience comes when the organisation has an ability to continue business as usual when under attack. For example, having real-time backups in case of a ransomware attack may save the day.

Who Owns the Patient Data? What Is the Responsibility of the Care Provider?

Healthcare organisations generate and store patient data linked to their health and treatment. The nature of healthcare data is considered sensitive and hence, from a global privacy regulation perspective, comes under tighter scrutiny. In India, in the past hospitals have collected, processed and even shared the patient data to third parties without the patient's consent. However, with the latest guidelines it is very clear that healthcare data are sensitive data, personally identifiable information is well defined and a care provider should take great care in storing this data for the purpose of maintaining the patient's

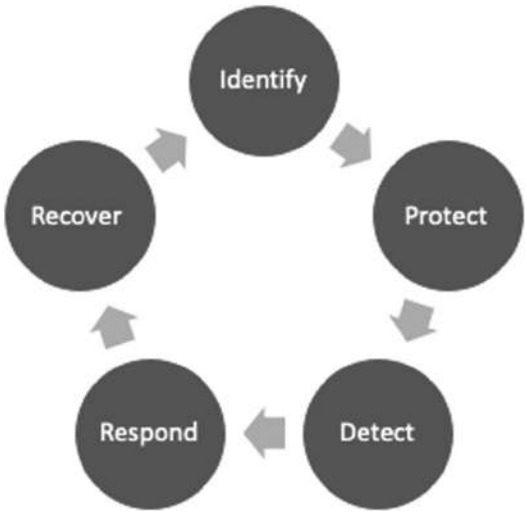


Figure 11.2. NIST cyber-security framework.

Source: NIST (2018).

privacy. The upcoming regulations from a data protection and privacy perspective define the role of a data-processing officer for a healthcare organisation like a hospital. It is a hospital's job to ensure that proper standards are being followed which ensures that there is no privacy violation when the data are being generated, stored and shared across the system. This means on a technical level a range of steps have been defined, such as segregation of Personally Identifiable Information from the rest of the medical data when storing the data; minimisation of the information being collected at first place; and, when sharing of information is required, proper steps being taken care for anonymisation.

There are big penalties on violation of these data protection and privacy rules globally and the healthcare organisations are expected to implement the latest international standards ensuring better security and privacy for healthcare data (ISO, 2016).

The huge potential of Artificial Intelligence in healthcare in improving access and quality of healthcare may result in great economic benefits for all parties involved. Having said that, all the innovation and progress is only possible when the data collected in the first place is with consent of the patient and patient being informed and involved on how the data are being processed at every step in the value chain. We believe that digital healthcare would take our society to a better quality of life but it requires strong ethical foundation

built on patient's consent and proper security and privacy during the entire life cycle.

The newly proposed National Digital Health Mission (NDHM, 2020) defines data policy, consent, security and privacy in detail. However, it still needs to be tested on the ground and there are still some open questions and issues to be handled. This topic is dealt with in Chapter 2 titled *Health Data Going Digital: India's Ayushman Bharat Digital Mission*.

Outline of Regulatory Structures Relating to Digital Health Data in India

In India, the current legal framework pertaining to e-health protection is governed by the provisions of the Information Technology Act, 2000, which propounds some degree of protection to the compilation, disclosure and transfer of sensitive personal data, which covers within its ambit medical records and history.

The healthcare sector can be thought of as a chariot, where the carriage comprises the healthcare workers and technology its wheels. The relationships should be effortless, if not exemplary, to improve productivity and efficient patient care. It is vital that the role of technology in the field of healthcare sector be clearly defined. The frequency of data breaches and cyber-security issues have become very common in today's time in all industries including the healthcare sector.

The likelihood of misuse of critical information belonging to patients often resonates with an important concern to prevent any sort of misuse of perilous information. Digital health data information can be related to physical or mental health, health service provided to an individual, information extracted from examining a body part, related to a clinical establishment used by an individual. It can be misused by unauthorised entities to make decisions about the physical and mental conditions, habits and orientations of persons. Therefore, data related to health is a sensitive issue and every now and then, a data breach story in every sector including the healthcare sector gains traction, making the confidential information of the patients vulnerable, and therefore there is a need to evolve standards for sharing healthcare data securely.

This is also important due to the fact that data sharing is to occur within the ecosystem. The approach in which data are shared, the protections/precautions that the persons sharing such data take before sharing are imperative.

After the onset of the pandemic, India among several other countries has seen the cusp of a digital revolution. The government realising the importance

of protecting digital data has proposed the Digital Information Security in Healthcare Act (hereinafter referred to as Disha), which peruses to provide for electronic health data privacy; confidentiality, security and standardisation; and creation of National Digital Health Authority and Health Information Exchanges.

Technology has been improving at speed, but the laws in India have not been revised at the same pace, leaving several aspects unaddressed. Taking note of this fact, the government has introduced the Personal Data Protection Bill, 2019, which applies to administering personal data where data have been compiled, disclosed, shared and processed in India. The scope of the legislation has been enlarged to apply to overseas companies processing personal data in connection with any business carried on in India, or any systematic activity of offering goods or services to data principals within the territory of India, or in connection with any activity which involves profiling of data principals within the territory of India.

Further, healthcare providers in India are increasingly using electronic medical records and electronic health records as the chosen technique of storing patient information. In fact, the rules of Clinical Establishments (Registration and Regulation) Act, 2010, mandate the "maintenance and provision of EMR for every patient" for the registration and continuation of every clinical establishment. In addition to this, the Ministry of Health and Family Welfare has introduced the Electronic Heath Record Standards, which was a uniform standard-based system for creation and maintenance of EHRs by the healthcare providers, in 2013, and was subsequently revised/notified in 2016.

Disha on the other hand lays down provisions that regulate the generation, collection, access, storage, transmission and use of Digital Health Data and associated personally identifiable information. According to the law, health data including physical, physiological, mental health condition, sexual orientation, medical records, medical history and biometric data is information that can only be the property of the specific person. It shall be the electronic record of health-related information about an individual and includes information relating to an individual's physical or mental health; donation by the individual of any body part or any bodily substance and so on. The legislation also entails the creation of a central regulator called the National Electronic Health Authority and various State Electronic Health Authorities to give effect to the provision of the law.

The law covers within its ambit clinical establishments (which includes hospitals, nursing homes, dispensaries, clinics, sanatoriums and pathology labs). Disha also proposes stringent penalties for defaulters in the nature of fine and/or imprisonment.

Global versus Local

The United States of America was one of the first to have enacted specific laws to protect personal health information related data by enacting the Health Insurance Portability and Accountability Act, 1996, which instituted the legal framework for privacy and protection of health information. This gives a patient sizeable authority over their protected information on health. The proposed Digital Information Security in Healthcare Act (Disha) is an Indian equivalent of the Act enacted in the United States.

Issues in Implementation of Digital Information Security in Healthcare Act

A grave issue with data collection and sharing is to obtain *informed consent* from the owner of the data. Another major concern will be effective enforcement of the provisions of Disha which, given the costs involved in implementing security solutions, may become a drain on resources for clinical establishments.

Electronically stored data are many times vulnerable to security breaches and therefore strict data security measures would need to be adopted. Sensitisation and protection of the rights of the citizens to privacy and security of their data is the foundation of Disha.

In terms of the Personal Data Protection Bill, health data being sensitive personal data requires the express consent of the individual for the data to be processed, whereas in terms of Disha, any use of digital health data for commercial purposes has been prohibited. This creates ambiguity between the legal provisions of the two laws. It is further interesting to note that both the Personal Data Protection Bill and Disha have overriding clauses in their specific drafts. Thus, if any conflicting provisions of any other law exist, then that conflicting provision would not be applicable. One can conclude from past precedents that in case of inconsistency between a special law and a general law, the provisions of the special law shall override that of the provisions of the general law.

The Way Forward

The technical issues of security and privacy in a healthcare organisation are complex topics and there are no straightforward answers. Only proactive implementation of latest security practices and an approach to resilience will ensure that care providers can fulfil their obligations, and it remains an aspiration. The proposed regulations and a concerted effort from the responsible bodies can improve the situation with time.

The jurisprudence surrounding data protection is still in its infancy in India. Both the Bills are yet to be enacted as a law by the both Houses of the

Parliament, and it will be interesting to see the shape and form in which they are both enacted. While the present law in terms of protection of health or personal data is more generic in nature, these laws shall bring out additional responsibilities on the data collection. With increasing globalisation, precise and effective definition of confidential information and related obligations are necessary for success in this increasingly competitive world. An enactment may not be a panacea, but will certainly add teeth to the existing laws.

Conclusion

We are still in the early days when it comes to preparing the workforce in healthcare for the wave of digital health that we are experiencing. The management of healthcare universities should introduce short courses for the coming generation while they are at the bachelor's level of education and also executive programmes for the existing workforce.

Having a strong foundation of the privacy and security topics will enable the healthcare professionals to deal with issues when they arise and also better manage and procure digital services from third parties.

Defining an information security policy for the organisation is a good starting point and also creating new job roles within the organisation like Data Protection Officer or Privacy and Security auditors may enable them to be ready for upcoming regulations that will govern the health sector.

The management of healthcare organisations should take cyber risks with same seriousness as they take patient safety from fire and other hazards in the hospital. Annual awareness/mock drills on such topics may enable an organisation wide awareness and readiness.

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Section 4

HEALTHCARE TECHNOLOGY FOR ALLIED HEALTH PROFESSIONALS

Chapter 12

NETWORKS OF CARE: DIGITALLY CONNECTED HEALTHCARE SYSTEMS

J. L. Meena and Piyush Chaturvedi

Introduction

The prerequisites to almost any significant improvement in health systems all over the world are robust information systems, carefully designed and widely deployed among key stakeholders. Unlike various sectors of economy, where enhancing productivity and minimising cost have been enjoyed now for some decades, the health sector in India is missing a significant opportunity to embrace technology as an important enabler of improved and more cost-effective healthcare delivery and finance.

India, of late, has excelled in its IT capacity, rapid adoption of mobile technologies and current roll-out of widespread broadband network services even to Tier-III cities. With the rollout of the Ayushman Bharat Digital Mission, the question arises of its adoptability. These technological advances will be enabling efficient, high-quality and low-cost healthcare services in India. This chapter will

1. Provide an overview of the major components and building blocks of digital health.
2. Describe the pillars of digital health.
3. Examine the impact of digital health in broadening the access of healthcare.
4. Explore the major gaps in digital health systems and their solutions.
5. Discuss digitally connected systems in countries across the globe.

The Major Components and Building Blocks of Digital Health

Before understanding digital initiatives in different countries, it is important to understand the building blocks of digital health systems (Figure 12.1).

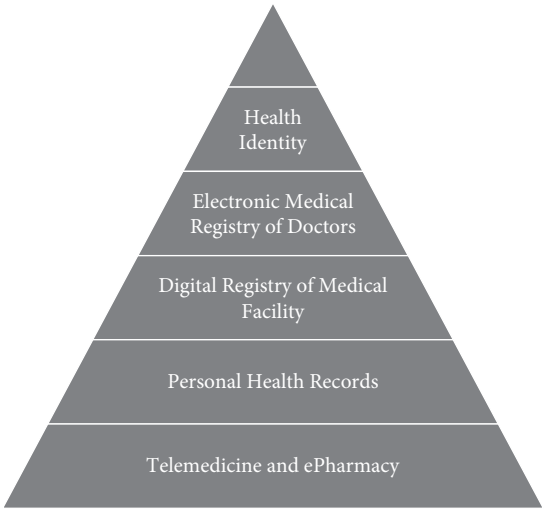


Figure 12.1. The major components and building blocks of digital health.

1. **Health identity:** Health identity can be a numeric or alphanumeric sequence which is unique to each individual. The main purpose of health identifier is to authenticate the individual. Health ID can be made more robust by linking it with various bio-authorisation parameters like finger print, retina scan and so on. The health identity is used for connecting the individual with various other components of digital health like health facility registry, personal health records, telemedicine, pharmacy, e-doctor and so on. The health ID because of its uniqueness stores and provides the ownership of health data of that individual.
2. **Electronic medical registry of doctors:** This component, as the name suggests, contains details of doctors such as name, qualification, name of institution of qualification, specialisation, registration number and so on. For any digital health system across the world it is important that it is updated from time to time.
3. **Digital registry of medical facility:** All the medical facilities in a country are registered under this component. The records are stored and maintained for both private and public facilities. The ownership of updating the information and its credibility lies on the medical facility. Medical facilities can be facilities can be hospitals (private, public or trust), dialysis centres, medical schools, polyclinics and so on.
4. **Personal health records:** During any medical incident (interaction of an individual with a medical facility) health information is generated. This information is recorded by the medical staff in a digitalised format. This

information generated during this interaction is called personal health record. The ownership of this record should preferably lie with the individual.

5. **Telemedicine and electronic pharmacy:** These are one of the most important components of the digital ecosystem. This component empowers an individual to consult a medical practitioner remotely via voice/video call. The importance of this component was emphasised during COVID-19. Along with providing ease of ordering medicines, e-pharmacy plays an important role in the extension of reachability of medicines in difficult geographical locations.

   Other components which play an important role in digital health include the **claim coverage platform** and the **national health analytic platform**. Claim coverage platforms include a variety of health insurance programmes at State level and national level funded by the government and private sector. National analytic platform combines information on multiple health initiatives and provides support in creating smart policy making. This may include various innovative technologies like predictive analytics.

The Pillars of Digital Health

To achieve the aspirational target of universal health coverage, the health industry needs to be rewired. In other words, the health industry has to be interconnected digitally to link the stakeholders (patients, providers, payers and governments), allow the flow of information and help in streamlining operations (Figure 12.2).



Figure 12.2. The pillars of digital health.

There are six pillars of digital health namely Governance Entity, Health Data Dictionary, Hospital Information Systems, Health Insurance Information Systems, Electronic Health Record, Health Data Warehouse and lastly Health Information Infrastructure.

1. **Governance:** Digital health requires a large number of technical components like hardware, software, cloud technology, network control centre, standards compliance and enforcement, implementation road map, certified training and upgradation of skills, establishing a help desk, maintenance as well as making a provision for regular upgradation of skills and technology. Apart from the technical components, non-technical elements would include innovative environment and culture to encourage Health Information Technology (HIT) vendors. The main responsibility lies in co-ordination, overseeing implementation, the procurement process and enforcement of standards.
2. **Health Data Dictionary (HDD) and master registries:** In order to communicate with each other the systems should use a common language. This would facilitate the various components of the healthcare ecosystem such as private and public sectors players in communicating with each other. Health Data Dictionary is a collection of those standards which together define the common language. The HDD process includes Unique Patient Identifier which is a universal coding syntax and semantics of each medical reference used. HDD contains formats of eClaims and eDischarge summaries.
3. **Hospital Information Systems (HIS):** The most important task is to effectively manage the facility clinically, administratively and financially. Hospital information systems have many functions in a modern healthcare ecosystem.
    a. They help in effectively managing the facility clinically, administratively and financially. Communications like eRefferals can play an important role to assure continuity of care.
    b. Communication with health payers can be made possible through eClaims as well as receive eProvider payments.
    c. The outputs are collated together to form the basis of Electronic Health records and Personal Health Records.
    d. Various statistics are provided to calculate the disease burden, compare outcomes across facilities and to provide epidemiological data.
    e. They create a health finance environment, where systems allow the creation of eClaims to be sent to the appropriate payer for fair payments.
4. **Health Insurance Information Systems (HIIS):** The payers have become a major partner in health as their roles and responsibilities have

increased in recent times. The HIIS is responsible for time-bound adjudication of claims. They are also responsible for making fair and timely payments to provider and beneficiary along with prevention of fraud and abuse. Advanced adjudication techniques can speed up the settlement process.

5. **Electronic Health Records (EHR)** for the clinicians and **Personal Health Records (PHR)** for patients: the EHR and PHR are the collection of information from various sources such as diagnostic results, discharge summaries, anaesthesia records, progress notes and so on.
6. **Health information infrastructure:** Interweaving of networks is clearly indicated to create a virtual health network which combines information from all possible sources (Pillars 1-5).

Impact of Digital Health in Broadening Access to Healthcare

Access to healthcare is defined as having timely use of health services to achieve the best outcomes. There are four components: coverage, services, timeliness and workforce (Table 12.1).

The use of various information and communication technologies in the health sector has led to major digital transformations. Some patients are not able to access healthcare services as they lack knowledge about the existence of such services, for example, being unaware that they are eligible beneficiaries of a government scheme. The digitalisation of healthcare helps bridge this gap. In a well-federated government healthcare scheme, a patient may be brought to the hospital and with the use of biometrics such as fingerprint/ facial authorisation, the hospital can see whether the patient is eligible for a scheme.

Table 12.1. Access to healthcare services and their components.

Coverage	Services	Timeliness	Workforce
This means access of an individual to healthcare services. A person having health insurance is more likely to receive medical care and a good health status.	It represents the availability of source of care which could be for screening, prevention, or treatment.	To provide a service at the time of need is defined as timeliness.	It is important to have a capable, qualified, trained healthcare professional.

There are many difficult terrains where it is impossible to provide healthcare services. Digital technologies such as telemedicine and video conference can help an individual to obtain basic consultation from a physician who is still hundreds of kilometres away. This was used on a very large scale during the COVID-19 pandemic.

Various situations such as lockdowns, siege, war, disability and so on restricts a patient's access to healthcare. Innovations such as artificial intelligence-based sensors, wearable devices, Internet of Things, blockchain, big data along with technologies like telemedicine and telehealth impact the access and delivery of healthcare.

Major Gaps in Digital Health Systems and their Solutions

To successfully bring about a transformation in the health sector, it is important that along with a prime focus on technical changes, importance is also given to complex adaptive change in human attitude and skills. Digital technologies should play an important role in increasing the productivity of health workers and patients. For example, if a hospital introduces a hospital information system but the staff is not acquainted with the system nor comfortable in typing out the details of patients, the overall productivity may decrease which would lead to increased dissatisfaction in the patients.

Many healthcare professionals understand the benefit of digital tools and solutions and use technology to benefit themselves and their patients. On the other hand, many health workers criticise the digital technologies in healthcare and complain that the technology interferes with their work. In some countries, healthcare workers don't have access to upskilling in order to fully utilise technology. Digitalisation plays an important role in legal, financial and organisational parts of work. However, in the case of missing safeguards, the threat to data privacy may lead to serious concerns.

The COVID-19 pandemic accelerated the update of digital technologies like teleconsultation, video consultation and online prescription and so on. The use of such tools allowed many countries better detection, prevention and treatment of the patient. The potential benefits of digital technologies in the health sector are numerous. Providing the correct information to the right people at the right time can improve care safety, efficacy and efficiency.

1. **The government's role:** The government should provide a foundation of trustworthy, ethical and human-centred digital transformation. This requires a reorganisation and proper strategy which would

pave the way for technology-driven innovation to form a framework of interconnected decision-making roles. A good digital strategy would lead to easy adaptability as well as simplify the work process keeping the patients' interest first.

Any digital transformation risks diversion of resources, leading to an ineffective system. To make a digital transformation successful, it is necessary that proper monitoring tools are established which would monitor the true impact on prevention.

To deal with the challenges stated above it is necessary to attain the knowledge and risk at initial stages of development and use of a new technology. Various advanced methods of systematic evaluation may be used. Currently pharmaceutical industries are using the same. Secondly, it is necessary to place regulatory safeguards to monitor digital technologies.

There are many examples where technology has hindered instead of helped. One major reason for this is complexity and inadequately designed processes.

2. **Human expertise and skill need to be advanced to enable digital technologies to add value:** Very few medical schools prepare a healthcare professional with the skills useful for adapting to digitisation. It is necessary that the education and training institutes teach various digital skills at a very initial level, and that a culture is created which would later allow an individual to easily adopt digitalisation. Continuous medical education courses should be available for healthcare professionals for digital upskilling.

   While we reap the benefits of digital technology for providing connections which have not been possible before, there are high chances of deterioration in the quality of social interaction. It is very important that an individual retains specific interpersonal skills. One of the most important interpersonal skills is patient-centred communication.

   Hybrid skill mixing is required to address the critical challenges in digital transformation. To address this challenge, a mix of various skills is required. For example, policy-makers, technologists, clinical leaders, managers should work together and understand each others' fields. Combined degree or hybrid programmes, for example, the use of technology, clinical practice, health policy management and ethics can be introduced for training.

3. **Existing models of health service delivery and the related legal and financial frameworks need to be adequately adapted in a timely manner:** It is very important that new approaches are explored along with ensuring timely revision of laws, payment systems and organisational frameworks. As mentioned above it is important that hybrid courses are designed to address the critical changes in digital

transformation. However, this would be unsuccessful if the demand and supply of such skills are not met. If there is high demand for digital technologists, there is a possibility that talented individuals like doctors would give up clinical practice to pursue a career in digital technology. It is important that a proper career path is available for all to meet the demand and supply.

Digitally Connected Systems Across the Globe

This section describes digital health initiatives in various countries across the globe.

The United States

The United States has an advanced digital health programme but it is segmented. The Office of National Coordinator (ONC) is the main government agency which is tasked with regulating health IT and digital health. The HITECH (Health Technology for Economic and Clinical Health) Act was passed in 2009 with the primary goal of establishing the use of electronic health records. HITECH was a part of the American Recovery and Reinvestment Act (ARRA) of 2009. An incentive was provided to the healthcare provider and hospitals for adopting and demonstrating use of EHR. These were governed by Centre for Medicare and Medicaid Services (CMS). HITECH also provided ONC the authority to develop and manage a certification programme, which stipulates requirement for Certified EHR technology. In 2006, Congress passed the 21st Century Cures Act. This Act helped to ensure that EHRs are interoperable and health data can be easily shared across systems which includes sharing data between various healthcare providers. The law also penalised private entities which were involved in information blocking. This means that information within the EHR should be retrievable by other authorised applications or health IT products without requiring any special coding. This framework which allows interoperability via use of API has been named Trusted Exchange Framework and Common Agreement (TEFCA). The health infrastructure in the United States is federated. It means that EHR software are deployed by the provider and the State determines whether to develop health information exchanges or not.

Another important component of US digital healthcare is HIPAA, that is, the Health Insurance Portability and Accountability Act. The body which oversees the enforcement of HIPAA is the US Department of Health and Human Services Office. This Act largely governs the protection, use and transmission of health data. Principally, the health data can be shared by the

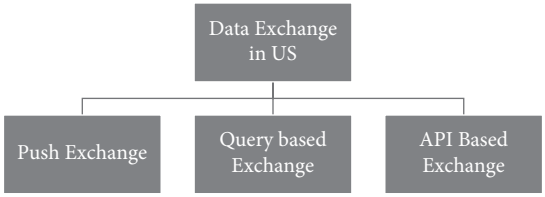


Figure 12.3. Types of data exchange in the United States.

healthcare providers and health insurers as long as it is done for treatment, payment and healthcare operations. An important point to note is that this exchange of information may take place without the consent of patient or any type of authorisation. State regulations in the United States vary and thus result in hinderance of data exchange. The Act HIPAA however provides rights to an individual to have a copy of their medical records in their preferred format. Health insurer data are used in health information exchanges for various clinical care purposes such as identifying the patient, prescribing medicines, ordering procedures and imaging, public health reporting and so on. Health insurers in the United States actively engage in data exchange for ascertaining patient identity and paying for the invoice of services.

Interestingly data are exchanged in the United States through:

1. Push Exchange: This mode of data transmission is used when a known recipient or destination system exists. Examples would be transfer of patient from one hospital to another, public health data submission, e-prescription, medical device communication, image exchange and so on.
2. Query-based exchange: If the information exists in many unknown locations, query-based exchange is used which runs a query across the healthcare system.
3. API-based exchange: To find specific information in EHR and extract the relevant data element – API-based exchange is used.

Patients can access their data through various means, one of which is "the insurance company portal." Patients also have access to view part of the information in their physicians' EHR through the patients' portal. These patients' portals allow access to medical list, lab records, vaccination records and so on. The patient portal also allows messaging with the doctor, nurse or provider organisation. The portal also has functionality of scheduling appointments or for requesting prescription refills. A study conducted in 2017 suggested that 52% of individuals were offered online access to their medical record by either

a healthcare or insurance provider (Patel and Johnson, 2018). Out of 84% of smartphone and tablet users, 44% have health or wellness apps (*ibid.*). Users would be able to access their health records through their preferred application as use of APIs is increasing. In recent advancements, Apple in partnership with various hospitals in the United States allowed its users the access to their health data on the Health Kit app on iPhones.

Australia

In 2012, Australia launched a national Personally Controlled Electronic Health Record (PCEHR). The system was relaunched in 2016 with the name of My Health Record. Initially an opt-in mechanism was used, but after relaunching an opt-out participation model was used. My Health Record creates a secure online summary though which a user can access their health records. It allows the user to control the access to health data. For example, the user can provide access only to the doctors/hospitals/dieticians who are involved in his or her treatment/care. This application has a capacity to store a broad range of document types including health summaries, e-refferals, discharge summaries, prescription and diagnostic and pathologic reports. This application My Health Record records the individual's clinical information from various hospitals, general practices, pharmacies, pathologists and so on. The information can be securely shared between various medical facilities depending upon the privacy setting of the individual on "My Health Record." Data from Australia Immunisation Register and Australian Organ Donor Registry is also captured in this application.

The application My Health Record can be accessed via National Consumer Portal (NCP) through the MyGOV platform or through the mobile application. It is important to mention that the development of this multi-channelled approach was carried out by the Australian Digital Health Agency. EMR is implemented in most of the Australian states and territories and its coverage is growing fast across the private hospital sector.

The Australian Digital Health Agency launched a new digital health strategy titled "Safe, Seamless and Secure: Evolving Health and Care to Meet the Needs of Modern Australia." Seven strategic priority areas were outlined in this plan. These were

1. My Health Record
2. Secure Messaging
3. Interoperability and data quality
4. Medication safety
5. Enhanced model of care

6. Workforce education
7. Driving innovation.

Data exchange in the Australian digital system takes place though a bilaterally agreed terminology and payload definition. Currently the bilateral information exchanges (exchange of information between a medical practitioner and the laboratory) supports pathology results, imaging reports, specialist referrals, discharge summaries and associated reports and letters.

The Australian government also operated the National Healthcare Identifiers Service which allows allocation and management of three types of identifiers:

1. Individual Healthcare Identifier (IHI): this is used to identify the people who are the subject of care
2. Healthcare Provider Identifier – Individual (HPI-I): this is used to identify the clinician who provided the care
3. Healthcare Provider Identifier – Organisation (HPI-O): this is used to identify the organisation under which care is provided.

The Australian Digital Health Agency also operates the National Clinical Terminology Service (NCTS) which provides national reference terminology to the industry in easily computable formats. These formats include SNOMED[1] CT-AU and Australian Medicines Terminology (AMT). Various tools and services are available to users: terminology server, online terminology browser, terminology mapping platform and national syndication server.

Hong Kong SAR

The journey of Hong Kong's digital healthcare is impressive as it was one of the few countries which had initiated digital health at a very early stage. Ninety per cent of inpatient services in Hong Kong is managed by the Hong Kong Hospital Authority with the help of 43 public hospitals and institutions. In 1995, HA first deployed the Clinical Management System (CMS) – which was a comprehensive and integrated EMR which had the capability of being interoperable across the whole of Hong Kong. It extended from primary to convalescent and community care. The focus was on supporting clinical care, improving clinical efficiency and quality. The electronic Patient Record (ePR)

1. SNOMED CT – stands for Systematized Nomenclature of Medicine – Clinical Terms. It is a standardized multilingual vocabulary of clinical terminology used by physicians and healthcare providers for electronic exchange of clinical health information.

was implemented in the year 2000, to provide a consolidated view of patient data in a single platform from all public hospitals.

Various digital solutions were rolled out from the year 2000 to 2010 to Hong Kong hospitals. Sharing of radiological imaging as well as sharing of detailed records with the private sector also took place during this time. HA became "filmless" in 2009. In 2010, HA saw a big iteration as they introduced their digital strategy of end-to-end Inpatient Medication Order Entry (IPMOE), dispensing and administration system.

In 2016, Hong Kong SAR launched the Electronic Health Record Sharing System (eHRSS) to support the exchange of health information across clinical services. This platform provides the infrastructure for two-way sharing of information between the public and private health sectors. In order to share the information, the consent of patients is mandatory. This application was developed in close collaboration with clinicians to consider clinical and workflow needs. This was done to ensure the system is user-friendly and sustainable.

The response to eHRSS has seen the participation of more than 730,000 patients in just two years by April 2018. eHRSS was rolled out in phases wherein during the first phase, development of a sharing platform connecting participating providers was created. The second phase involved development of Electronic Health Record Sharing System Ordinance (eHRSS Ordinance) which provides a legal framework for protection of data privacy and system security. The government is looking to increase the interoperability of the system where data can be shared securely and easily. Based on data available till July 2018, one-third of private clinics were connected to eHRSS. Outpatients' facilities are not available in eHRSS. eHRSS allows sharing of patient data between both private and public health sectors with explicit and informed patient consent. This is an opt-in system which patients may voluntarily participate in.

A component of eHRSS is the patient portal which allows patients to access and enter their health data; this component also provides the user functionality to define who can access their health record. The data are stored in the central data repositories to ensure performance, security and availability of data. Patient identification is done via Hong Kong Identity Card which is issued by the Immigration Department.

Japan

In Japan, the healthcare provider manages their own Electronic Medical Record (EMR) systems, and EHRs are not aggregated at a national level. Since 2000s at a local level, some areas have developed health record networks. This was done voluntarily by the healthcare institutions and local governments.

The Ministry of Health, Labour and Welfare (MHLW) is working to develop a nationwide network which would enable healthcare providers to share patients' medical information. The information categories of health data include paediatric check-up information collected by the local governments and specific medical check-up information and medication information collected by the health insurers.

The Health Information and Communication Standards (HELICS) Board takes up the task to verify the draft standards in the field of healthcare recommended by various academia. The MHLW after reviewing these standards, authorises them as national standards, and then promotes their use. Currently there are 17 sets of such national standards, which includes seven master codes and standard formats for information exchange.

Kingdom of Saudi Arabia

The Ministry of Health of the Kingdom of Saudi Arabia has identified eHealth to be a key enabler in order to implement this over 70 projects including implementation of primary care and hospital systems, provider and resident portals and supporting infrastructure. The personal health information in Kingdom of Saudi Arabia can be categorised into two major types:

1. A nationally coordinated platform was to be developed which would connect all government entities delivering healthcare including the Ministry of Health, defence and private hospitals. This includes the patient portal view of the universal health record. This will include access to:
   a. Provider entered information
   b. Patient entered information such as a medical report or allergies
2. Personal health information: This refers to information entered by the citizen and supports six specific models of care. Based on available information as of year 2020 it was under development by the Ministry of Health only for six conditions.

This record of this system would provide a lifetime longitudinal view of all health-related data for each individual. The eHealth Solutions Framework would be the backbone of the Kingdom of Saudi Arabia's digital health system and would illustrate the full range of IT solutions and capabilities necessary to develop a complete and robust unified health record. This system will use an opt-in model. The existing digital health infrastructure is a combination of centralised and federated, with good interoperability within an enterprise but limited interoperability between enterprises. Not all facilities

(hospital, primary healthcare and ancillary services) have digital health infrastructure, which is envisaged to be rolled out in future.

Until 2020 there was no current health data exchange, but a contract for Saudi eHealth Exchange (SeHe) and Saudi Health Insurance Bus (SHIB) has been signed. The project timeline is of 11 years which will be divided into multiple phases of implementation. It is envisioned that the health data exchange will occur through various registries, digital payment gateway, medical terminology services, management console, clinical data repositories, document repositories, patients and providers portals, eligibility and claims and payments management, and insurance portal. This data would be stored centrally.

During the initial phase the use cases for Saudi eHealth Exchange would be identification of patient; management of provider/organisation; coded lab orders; coded lab results; medication dispensing; medication prescription; encounter summaries; surgical notes; discharge summaries of mother and babies; general purpose discharge summaries; sharing diagnostic imaging; referral request/response; tele-radiology reporting; and immunisation records.

The Health Service Bus (HSB) determines the system-to-system incorporation channel to retrieve services implemented by the SeHe-SHIB programme. The HSB proposes a standards-based integration mechanism to the various healthcare and data management systems. One of the key functions of the HSB would be to map messages from one format to another data format, mapping across protocols, and data enrichment. It is expected that each HIE and EHR repository integrated to the SeHe and the SHIB platform will provide a set of services that will enable a user to submit a request for an EMR of a patient. One component of SeHe is the Patient Portal which is a web-based application that enables patients to interact with SeHe to access their EHR as well as management of the patient's record within the Patient Registry.

United Kingdom

The National Programme for IT in the NHS was launched in 2002, with the aim of reforming the way information was used in the National Health Service in England. Some parts of this national programme were delivered successfully while there were delays in developing and deploying the detailed care records systems.

In 2007, nhs.uk was launched, which happens to be the world's biggest health website receiving over 43 million visits per month. The website provides an overview of diagnoses and treatments as well as advice on self-care. In December 2018, the NHS app was launched to provide improved access for

patients to their healthcare record. This was done to expand the range of existing primary care services. Various features include the ability to book appointments, manage long-term conditions and order repeat prescriptions. A code of conduct describing data-driven health and care technology was published in the same year after thorough public consultation. Ten principles were described for the development and adoption of safe, ethical and effective data-driven health care technologies and a vision for digital data and technology in health. The National Health Service (NHS) in England provides patients with access to their GP records for a number of years. The mobile app developed allows real-time monitoring, the number of times records have been viewed; the number of GP appointments booked and cancelled; and the number of times prescriptions have been ordered. This level of analytics is unique in terms of understanding activity within the system.

Conclusion

This chapter has described the importance of various components of digital health and the pillars of digital health. It has also covered the digital health ecosystems of various countries across the globe. Some of these countries have a well-established digital health ecosystem whereas some are initiating their digital health journey.

- The major components and building blocks of digital health are Health Identity, Electronic Medical Registry of Doctors, Digital Registry of Medical Facilities, Personal Health Records and Telemedicine and Electronic Pharmacy.
- The six pillars of digital health are Governance, Health Data Dictionary, Hospital Information System, Health Insurance Information Systems, Electronic Health Records and Health Information Infrastructure.
- Digital health can broaden the access to healthcare with regard to coverage, services, timeliness and workforce.
- The major gaps in digital health systems are due to adaptive changes in human attitude and skills.
- The role of the government is to provide a foundation of trustworthy, ethical and human-centred digital transformation.
- Human expertise and skill need to be advanced to enable digital technologies to add value.
- Existing models of health service delivery and the related legal and financial frameworks need to be adequately and timely adapted.

- The chapter ends with an overview of digitally connected health systems in different countries around the world: the United States, Australia, Hong Kong SAR, Japan, Saudi Arabia and the United Kingdom.

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Chapter 13

THE PARAMETERS OF PRECISION: QUALITY MANAGEMENT IN HEALTHCARE TECHNOLOGY

Sanjeev Singh

Introduction

Nosocomial Infections (NIs) represent a major public health problem, with WHO estimates of 8.7% of hospital patients acquiring nosocomial infections on an average at any given moment and with more than 1.4 million people suffering from infectious complications acquired in hospital settings globally. These are preventable infections and therefore need to be addressed at the earliest (WHO, 2015). Patient safety in healthcare settings is the most targeted priority, with the majority of hospitals engaging in activities to improve the quality of care, safety and health outcomes.

Healthcare providers can use quality-improvement techniques and tools for a safer, more efficient, cost-effective system. Introduction of technology at various levels across healthcare, especially in aspects of infection prevention and waste management practices has changed the face of quality of care. The use of technology as tool helps to improve service performance considering all the quality parameters with respect to structure, process and outcomes in healthcare settings. Technology inputs play a crucial role in integrating various organizational functions and these innovations are driven by "market pull" and by "technological push." In need of continuous improvements, dynamic organisations use new technologies to achieve excellence. Therefore, innovative ideas are implemented throughout these development projects along with the organisation competitive strategies (Doll, 2018; Dey *et al.*, 2007; Haque *et al.*, 2018; Stone, 2009). This chapter will

1. Highlight the importance of technology in hospital settings and provide an overview of an array of technological inputs, put in practice or in research for developing, monitoring and maintaining quality healthcare.

2. Classify various technologies based on applications and systems, provide an overview of various technologies and products in the market as valuable adjuncts.
3. Provide an update on super technological advancements employed in hospital infection control and biomedical waste management practice to reduce the bio burden of hospital settings.

How to Identify the Indication for Technological Advancement in any Hospital Setting to Improve Infection Control and Biomedical Waste Management

Quality improvement is an ongoing effort to improve products, services or processes. These efforts can seek "incremental" improvement over time or "breakthrough" improvement all at once. It must have the three processes of corrective action, innovation and continual improvement. Any process can be improved through a multimodal FOCUS strategy as described below:

- **F** – Find a process that needs improvement
- **O** – Organise a team that knows the process
- **C** – Clarify the current knowledge of the process
- **U** – Understand the process and learn the causes of variation through various tools like 5-Whys analysis, fishbone diagram, driver diagram and so on
- **S** – Select the improvement opportunities based on priority matrix (selecting the high-impact low-effort interventions)

In the field of infection control and biomedical waste management, Kaizen is also a favourable system wherein small improvement suggestions on a daily basis involving every employee can lead to an improvement in the safety and effectiveness of the programme.

Each selected intervention should begin with a plan:

1. Determine what area(s) of improvement the facility needs to focus on and identify people/disciplines using or affected by the process.
    a. This can be achieved through mapping, flowcharting, pareto analysis, brainstorming, cause and effect diagram and evaluation matrix.
2. Make changes on a small scale as a trial
    a. Achieved through various techniques like experiment design, small group leadership skills, etc.
3. Check to see if changes are working by utilising control charts, graphical analysis, key performance indicators, etc.

4. Act to obtain the greatest benefit from changes through process mapping and standardisation.

This completes a single Plan-Do-Study-Act (PDSA) cycle. PDSA offers a data-based framework based on the scientific method. This simple yet powerful format drives continuous and ongoing efforts to achieve measurable improvements in the efficiency, effectiveness, performance, accountability, outcomes and other indicators of quality in services or processes which achieve equity and improve the health of the community. The need and the impact of a healthcare technology in improving the Infection Control and Biomedical Waste Management could be assessed as per this quality improvement strategy.

As the conventional methods are resource-intensive, requiring human resources, need for behavioural changes making it more time-consuming, the technological advancement can be considered as one of the high-impact, low-effort interventions. The novel technologies in the field of Infection Control and Biomedical Waste Management is described in detail in the following sections.

Mr. Shewhart, known as the Father of Quality, also amalgamated quality, science and technology. Shewhart was concerned about whether statistical theory serves the needs of industry. He exhibited the restlessness of one looking for a better way. A man of science who patiently developed and tested his ideas and the ideas of others, he was an astute observer of developments in the world of science and technology, which helped to take quality beyond standards.

Quality Management Using Technology in Infection Control

Classification of Technologies Based on Applications and Systems

I. Cleaning, disinfection and monitoring (chemical, light-activated, nanotechnology, robotics as systems) (Doll, 2018)

1. Antimicrobial surfaces
2. Antifouling and adhesive coatings
3. Antimicrobial textiles
4. Cleaning and monitoring technologies (hand hygiene monitoring)

II. Biomedical waste management technologies (thermal, chemical, radiation, biological, robotics and smart technology systems)

1. Waste collection, disposal and treatment

2. Waste reduction technologies

III. Mapping (promising future supertechnology innovations such as whole genome sequencing, microbiome research, etc.)

I.1. Antimicrobial surfaces and new technologies

Healthcare Associated Infections are on the rise. There are various causes that lead to increase in incidence of HAIs. These include environmental factors, material, measure, methods and manpower factors. This is depicted in the fishbone diagram given below (Figure 13.1).

Considering the increasing number of emerging infectious diseases, innovative approaches are strongly in demand. These innovative approaches can eliminate the need for human intervention and have sparked more research for real-world evidence. A wide range of technological products on antimicrobial coatings are either currently available as marketed products, or are in research stages. A few of them are discussed below.

Organic and inorganic antimicrobials: Some of these technologies are organic antimicrobials, released from the product (e.g. Microban ® contains Triclosan as the antimicrobial agent), whereas others rely on inorganic antimicrobials, most commonly the silver ion, copper and so on. These techniques which utilise diffusible antimicrobials continually deliver active compounds to the environment and therefore have the potential problem of inducing microbial resistance. Increased exposure of microbes to these compounds will inevitably lead to increased occurrences of resistance to the treatments, though at present there are few organisms which display resistance to Ag or Cu (Doll, 2018).

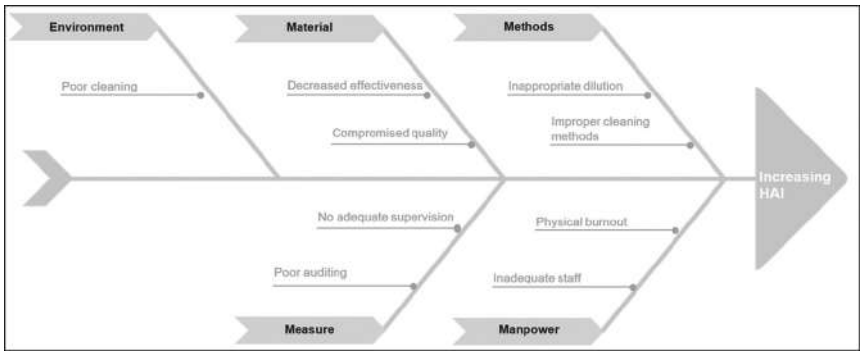


Figure 13.1. Ishikawa diagram for the reduction of healthcare associated infections.

Light-activated antimicrobial agents: Other technologies incorporated as an alternative method for disinfecting surfaces is the use of a coating that produces reactive radical species. These materials fall under the broad classification of light-activated antimicrobial agents. Unlike the antimicrobials, these have no specific target within a microbe, and therefore avoids the potential risk of microbes developing resistance to a microbicidal treatment. Principal coating types that produce these reactive species and act as antimicrobial surfaces include a photosensitiser immobilised in a coating and a titanium dioxide-based photocatalyst coating. These are being used to reduce environmental contamination in healthcare settings (Doll, 2018).

Latest nanotechnological advancements: This is seen to be helpful in creation of disks of aluminium 6063 studied on hospital and medical equipment and etching the disks with sodium hydroxide for up to 3 hours which changed the initially smooth, hydrophobic surface into a ridged, hydrophilic surface and showed combined antibacterial and antiviral properties with durable, nanostructured surface that has the potential to stop the spread of infections arising from physical surfaces in hospital settings (Hasan *et al.*, 2020).

I.2. Antifouling and anti-adhesive coatings

Another approach to microbial contamination of surfaces is to prepare a surface to which microbes find it hard to become attached. This strategy helps to prevent microbial adhesion to the device or surface in the first place (Page *et al.*, 2009). With both poly(ethylene glycol) coatings and Diamond-Like Carbon (DLC) films, the hydrophobic materials were shown to significantly reduce microbial adhesion to a sample submerged in a microbial suspension, even though each had their disadvantages. Recently it has been shown that polymers with zwitterionic head groups can be applied as surface coatings which inhibit biofouling of the surface. The new research interests lead to polymers like poly(phosphorylcholine) polymers, poly(sulfobetaine) polymers and poly(carboxybetaine) polymers. These zwitterion surfaces has shown promising results for coating medical devices such as catheters, because their biomimetic nature affords biocompatibility (by reducing attachment of human cells to the device) and also protect against bacterial biofilm formation which can lead to device-related infections (Page *et al.*, 2009).

I.3. Antimicrobial textiles

Through the Institute of Healthcare Improvement (IHI), a driver diagram is a good tool to understand the primary and secondary drivers to improve quality

care. One of the primary drivers in IHI Diagram is providing technology to reduce Healthcare Associated Infections, and antimicrobial textiles and surface disinfectants play a critical role.

These are functionally active textiles which may kill the microorganisms or inhibit their growth. Their use in healthcare settings are in the form of bandages, ear buds, scrubs, masks, lab coats, protective kits and so on. Advancements in technology have enabled both synthetic and natural fabrics to be used in antimicrobial textiles development. These antimicrobial properties are introduced to textiles by application of chemicals, metal-based nanoparticles, plant- and animal-derived compounds, dyes and mordants. These coated antimicrobial fabrics shows a narrow to broad range of antibacterial properties against bacteria, fungi and viruses. MIC and IC50 values can be used to evaluate the amount of antimicrobial compound to be coated, and therefore affects the price and efficiency of prepared antimicrobial textiles (Gulati *et al.*, 2021).

Studies in the clinical environment setting have shown reduction in the burden of important hospital microbes like Vancomycin-resistant Enterococcus from silver curtains and MRSA using quaternary ammonium impregnated provider scrubs. However, other studies have reported no difference in contamination rates, particularly from scrubs near the end of a healthcare worker's shift, or after several weeks of antimicrobial curtain use in an ICU. Therefore, the disparity in findings emphasises the need for future research directed towards exploring the potential use of different antimicrobial textiles (Doll, 2018; Gulati *et al.*, 2021).

I.4. Technologies in cleaning and monitoring

Inspite of challenges existing in achieving and maintaining adequate cleaning and disinfection in healthcare facilities, there is a need to consider the use of modern technologies designed to improve disinfection (Doll, 2018; Boyce, 2016). New technologies fall into several categories, and a few are included in the table below (Table 13.1).

New technologies: Adenosine Triphosphate (ATP) levels and fluorescent markers are new technologies introduced to assist in monitoring of cleaning. ATP levels represent the organic load or general cleanliness of a surface whereas the fluorescent markers are first placed on surfaces prior to cleaning and then reassessed with black light for their persistence after cleaning efforts, which are removed by manual cleaning (Doll, 2018).

Cleaning and spraying robots: Cleaning robots for hospital environments seem to be able to provide the innovation and are an integral part of disinfecting hospitals to remove germs and pesticides. Some of them include

Table 13.1. Technologies in cleaning and monitoring.

Technology	Inputs
New liquid surface disinfectants	***New disinfectants –*** improved hydrogen peroxide liquid disinfectants, peracetic acid-hydrogen peroxide combination, electrolyzed water, cold atmospheric pressure plasma and polymeric guanidine.
Improved methods for applying disinfectants	***Microfiber cloths*** or mops and ultramicrofiber cloths are newer methods for applying liquid disinfectants to surfaces.
Light-activated photosensitisers	***Light-activated photosensitisers*** such as nanosized titanium dioxide on surfaces and using UV light to generate reactive oxygen species that can disinfect surfaces.
New technologies	***Adenosine Triphosphate (ATP) levels and fluoroscent markers***
Robotics	***Cleaning and spraying robots and sanitiser dispensing robots***

Roomba cleaning robot (iRobot, Bedford, MA, USA) that uses intelligent navigating vacuum pump for dry/wet mopping; UVD robot (UVD Robots ApS, Odense, Denmark) is an ultra-violet radiation-based device used to disinfect hospital premises from microbes; Peanut robot (San Francisco, USA) is used to clean washrooms of hospitals by using a highly dynamic robotic gripper and sensing system; Swingobot 2000 (TASKI, South Carolina, USA) helps in cleaning hospital floors autonomously. Spraying/disinfection robots were remotely controlled to avoid hazardous contact with the disinfectant spray (Khan *et al.*, 2020).

Room Decontamination Touchless New Technologies

The touchless new technologies include aerosolised hydrogen peroxide, hydrogen peroxide vapour systems, gaseous ozone, chlorine dioxide, saturated steam systems, per acetic acid/hydrogen peroxide fogging, mobile continuous ultraviolet devices, pulsed xenon light devices and high-intensity narrow-spectrum (405 nm) light (Doll, 2018; Boyce, 2016; Weber *et al.*, 2016).

"Dry gas" vaporised hydrogen peroxide system utilises 30% hydrogen peroxide and has shown to be effective against a variety of pathogens, including Mycobacterium tuberculosis, Mycoplasma, Acinetobacter, C. difficile, Bacillus anthracis, viruses and prions, whereas the micro-condensation hydrogen

peroxide vapour system utilises 35% hydrogen peroxide, and is seen to be effective in eradicating important pathogens like MRSA, VRE, C. difficile, Klebsiella, Acinetobacter, Serratia, Mycobacterium tuberculosis, fungi, and viruses (Weber *et al.*, 2016).

Automated mobile ultraviolet light devices which emit UV-C continuously (254 nm) and placed in patients' rooms after patient discharge conduct terminal cleaning and kill the vegetative bacteria or spores. High-Intensity Narrow-Spectrum (HINS) light technology on the other hand uses visible violet-blue light (405 nm), targets intracellular porphyrins that absorb the light and produce reactive oxygen species. These are used as a means of disinfecting air and surfaces and hospital rooms. UV-activated titanium dioxide photo catalytic reactions are utilised to oxidise volatile organic compounds and airborne microorganisms (Weber *et al.*, 2016).

The above-mentioned new technologies can be used as valuable adjuncts but their relative effectiveness on cleaning, disinfecting and monitoring strategies, need future studies that directly compare newer disinfecting and monitoring methods to one another and with traditional ones.

Hand Hygiene Monitoring Technologies

Hand hygiene is the core strategy of infection prevention in the healthcare setting that is simple to perform. According to WHO analysis, adherence to recommended hand-washing practices is roughly 40% although studies have estimated a wide range of compliance (WHO, 2015). Compliance with hand hygiene is influenced by various factors as shown in the Ishikawa diagram below (Figure 13.2).

In order to improve compliance monitoring and feedback, technologies are essential (Doll, 2018). Quality improvement tools like direct observations are frequently used to assess the hand hygiene practices in a healthcare institution. This strategy is limited by high resource requirement, low number of observations and the Hawthorne effect. Certain technologies can be used instead of human resources for monitoring hand hygiene practices.

Technologies have been developed with fully automated monitoring systems which are capable of detecting hand hygiene events as healthcare workers enter and exit patient areas, and in some cases, may monitor all five of the WHO's Moments of Hand Hygiene. The data collected for individuals and systems are capable of transmitting real-time feedback data which acts as a reminder to perform hand hygiene when indicated (*ibid.*).

Devices that monitor and report hand hygiene events are another technological advancement such as the Deb Med Group Monitoring System, which

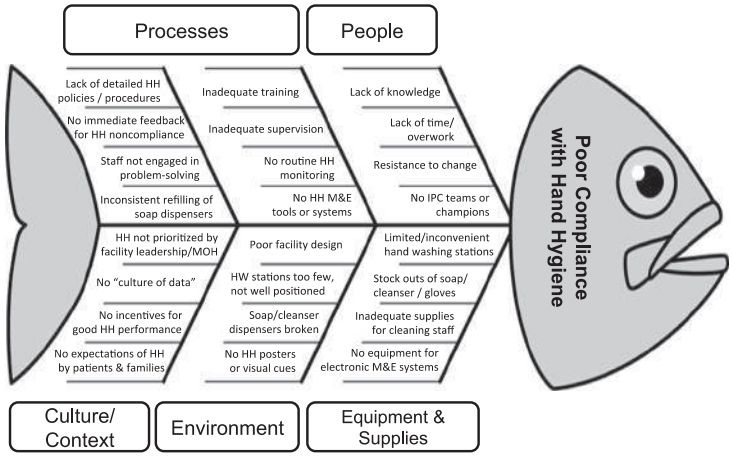


Figure 13.2. Ishikawa diagram displaying poor compliance with hand hygiene.

aims to improve healthcare worker hand-washing compliance. A compliance monitoring system device from GOJO Industries (maker of Purell hand sanitiser) tracks the number of times hand sanitizer dispensers are used, which helps to identify high and low compliance areas in the facility that can be used for staff monitoring and education (Doll, 2018; Masroor *et al.*, 2017; Marin, 2020).

Autonomously guided hand sanitiser dispensing robots are also introduced to reduce the infections on human hands and faces thereby introducing robotics in providing quality healthcare products in infection control and practice (Khan *et al.*, 2020).

II. New Technologies for Biomedical Waste Management

Biomedical Waste (BMW) are those produced during the diagnosis, treatment or immunisation of human or animal research activities, of which 10%–25% is hazardous, and the remaining 75%–95% is non-hazardous (WHO, 2018). The hazardous part of the waste presents infection risk to the general population and healthcare workers associated with handling, treatment and disposal of waste. Data from the Government of India from 1, 68,869 healthcare facilities indicate the total BMW generated in the country is 484 TPD (Tonnes Per Day). Unfortunately, only 447 TPD is treated, and 37 TPD is left untreated (Datta *et al.*, 2018). The untreated waste is dumped in landfills increasing the risk of infection in the community. This can be depicted using the 5-Why tool as shown in Figure 13.3.

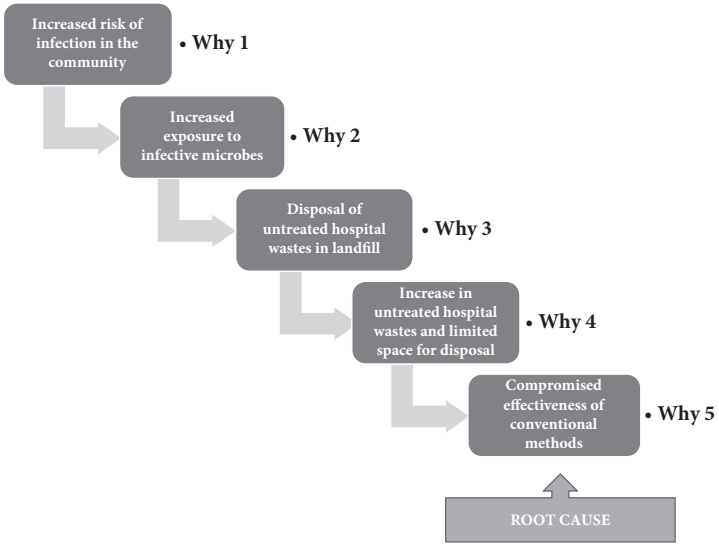


Figure 13.3. The 5-Why tool showing how untreated waste in landfills increases the risk of infection in the community.

This emphasises the importance of new technologies for biomedical waste management. The various new technologies for BMW disposal and treatment have been categorised and most of these products are still under research.

II.1. Thermal Technologies

Low heat technologies (operate between 93°C and 177°C): Microwaves and autoclaves are included under this technology. In autoclave, steam is used as a method for sterilisation. Air evacuation is more effective in autoclaves with a prevacuum or multiple vacuum cycles which are better. A shredder or grinder should be used if waste is to be made unrecognisable or reduction in waste volume is needed.

Medium heat technologies (operate between 177°C and 540°C): Reverse polymerisation and thermal depolymerisation are included under this type. Here the breakdown of the organic matter in BMW is done by the application of high-energy microwaves in nitrogen atmosphere, where the waste absorbs the microwave energy thereby undergoing chemical decomposition at molecular level (*ibid.*).

High-heat technologies (operate between 540°C and 8300°C): This includes mainly pyrolysis with types – oxidation, plasma pyrolysis, induction-based pyrolysis and lase-based pyrolysis. In pyrolysis oxidation, the organic solid and liquid waste vaporise at high temperature (approximately 594°C) leaving behind inert ash and glass and metal fragments. Plasma pyrolysis generate plasma energy using plasma torches which in plasma state, the ionised gas can conduct electricity, but due to its high resistance, the electric energy is converted to heat energy. A wide variety of waste can be destroyed in plasma-based technology – infectious waste, sharps, plastics, dialysis waste, hazardous waste, chemotherapeutic waste, chemotherapy waste and low-level radioactive waste with only one exemption of mercury. Low emission rate, inert and sterile waste residue and reduction in volume by 95% and mass by 80%–90% are some of the advantages, whereas high capital and operational cost along with limited lifespan of plasma torch were some of the disadvantages (*ibid.*).

II.2. Chemical Technologies

Chemical-based technologies in BMW disposal are currently under development. These chemical technologies are mainly indicated for treatment of cultures, sharps, liquid waste, human waste, laboratory waste and soft waste (gauze, bandages and gowns) and not indicated for volatile, semi-volatile organic compounds, mercury and radiological wastes (Datta *et al.*, 2018; Thakur & Katoch, 2012).

These are divided into two basic types: chlorine- and non-chlorine-based systems.

In chlorine-based systems, sodium hypochlorite or chlorine dioxide were used. It is shown lately to have toxins such as dioxins, halo acetic acid and chlorinated aromatic compounds released where sodium hypochlorite is used. Chlorine dioxide on the other hand is unstable, is a strong biocide and is used on site. Whereas in non-chlorine-based technologies, they use either gas, liquid or dry chemical to treat the biomedical waste. Many of these systems are in the market, such as Steri Ecocycle 104, which uses a portable chamber for collecting waste into which a per acetic acid-based decontaminant is added. Per acetic acid disinfects the waste after 10–12 min, and aerosolised pathogens are prevented from escaping by use of HEPA filter (Datta *et al.*, 2018).

Waste reduction chemical technology: Alkaline hydrolosis at a high temperature is used to convert human and microbial waste into a neutral aqueous solution. This technology is indicated for reduction of degradable bags, human waste and body fluids (Datta *et al.*, 2018).

II.3. Irradiation Technology

Ozone: Lynntech's technology for decontamination of BMW uses Ozone, which is a strong oxidant, and therefore helps to destroy microbes and converts molecular oxygen (Datta *et al.*, 2018).

High energy electron beam ionising radiation: These radiations produce free radicals which can cause damage to DNA and further damage to proteins and enzymes of infectious particles. This technology produces ionising radiation in the form of a beam of high-energy electron propelled at high speed to strike the target and is used to treat the infectious waste types, mainly human waste, laboratory waste, soft waste (gauze, bandages and gowns) and sharps. This method does not produce toxic emissions, no ionising radiation after machine switch off and has low operational cost. Disadvantages are present as there is no decrease in waste volume and shredders or grinders are needed for reduction (*ibid.*).

II.4. Biological Methods

Use of Enzymes: An enzyme solution to decontaminate medical waste is used and the resulting sludge is put through an extruder for waste removal. Another method is the use of biodegradable plastics for environmental BMW management. Many biomedical implants were built with biodegradable plastics which undergo biological degradation with microbial extracellular enzymes and therefore requires further research for large-scale economic manufacturing (*ibid.*).

Other Developing Biologic/Organic Disposal Methods

Bioremediation: Although incineration technologies are widely accepted across developed and developing nations, bioremediation techniques help to diminish the environmental impact associated with these processes, and develop bioaugmentation solutions that focus on using a special culture of microbes to break down pollutants with minimal environmental disruption (Kalyanam, 2017).

Hydrolytic bacteria have been known for their ability in reducing water pollution parameter values of organic waste. The non-pathogenic ones play a vital role in accelerating degradation of biomedical wastes. Hence, hydrolytic bacteria as bio-remediation agents are used in research to handle hospital wastewater, introduced thereby to resolve liquid biomedical waste problems (Ethica *et al.*, 2018).

II.5. Smart Bins and Robotics

Medical robots utilise state-of-the-art technology to carry out various tasks required for cleaning, sterilisation, transporting, nursing, rehabilitation and surgical applications (Ethica *et al.*, 2018; Stephina *et al.*, 2020).

Advancement of technology and research helped in the installation of robotic units for trash collection from different wards of the hospital and dumping in a particular destination, intimation of the notification of level of garbage filled in the smart bin (fully automated sensor-assisted bins) to the truck robot. With all these smart innovation technologies in place, the annual cost is likely to be reduced, turn-around time is likely to be improved, and contact of staff with BMW for disposal is reduced (Ethica *et al.*, 2018).

III. Mapping – Promising Future Supertechnology Innovations

An increase in the incidence of outbreaks are being reported across the healthcare institutes despite infection control measures. The root cause analysis points to lack of adequate technology to identify and target the specific strain of microbe causing the outbreak. This is depicted using the 5-Why diagram as in Figure 13.4:

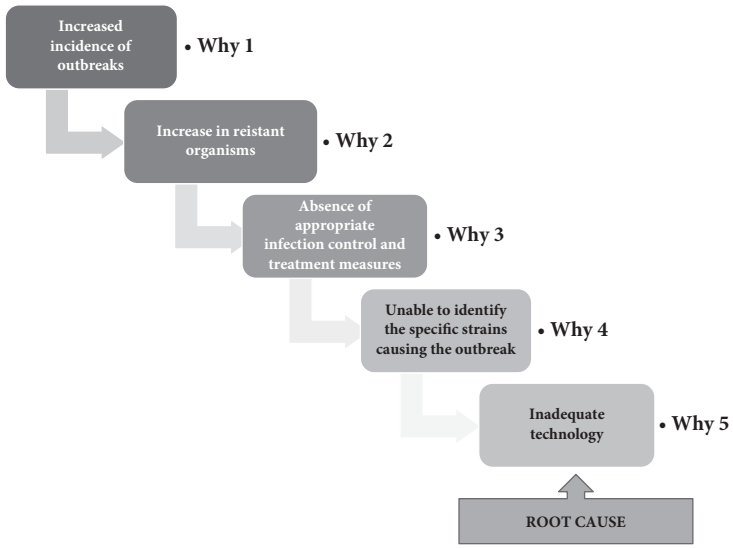


Figure 13.4. Root cause analysis for increased incidence of outbreaks despite infection control measures.

Whole Gene Sequencing (WGS): This technology is still growing and a number of challenges need to be addressed. Currently the phenotypic information is needed to inform genotypic interpretation and the data interpretation will constantly change over time. Lack of valid international reference platforms in this area still poses a challenge, although a few countries are investing in national database platforms. WGS is still used as a research tool although advancing rapidly and with many researchers using their own standards for data interpretation (Stephina *et al.*, 2020).

WGS has strengths such as detailed species identification, detection of antimicrobial resistance at the mechanism level, reproducibility and objective comparison of data. Combining information on species and antimicrobial resistance using WGS would be a particularly interesting advance in the monitoring of AMR on regional, national and international levels (*ibid.*).

Microbiome research: A microbiome is the community of the populations of microbial species living on or in the human body. The majority of the microbiota, and of the microbiome, is found in the intestines and this microbiome research as part of our immune system is rapidly progressing but has not yet emerged into a mature technology in relation to infection prevention and control of antimicrobial resistance. Microbiota-based intervention as a prevention strategy for AMR is innovative with beneficial potential. Faecal microbiota transplantation is an approved treatment against recurrent and refractory Clostridioides difficile infection in the United States. Although the mechanisms behind its efficacy is largely unknown, its applications in recent years have rapidly expanded (Stephina *et al.*, 2020; Berg *et al.*, 2020).

Conclusion

Quality has come a long way since its early steps from "guilds." Healthcare is no exception for quality. The quality movement is helping organisations improve and differentiate themselves from one another. If we are to be more successful at improvement in healthcare we must recognise that it embodies a science and technology encompassing a range of disciplines from quality tools to human psychology.

1. Quality tools and its implementation are just a means to an end and not the end. Given that the majority of our healthcare leaders and professionals have not been exposed to this science, we must address this deficiency through widespread education and training. We must realise

that, for healthcare to improve: "it is not enough to do your best; you must know what to do and then do your best."

2. Increase in healthcare-associated infections and antimicrobial resistance need immediate action to prevent the consequences.
3. Proper infection control and biomedical waste management practices play a crucial role in preventing and controlling hospital-acquired infections.
4. Conventional technologies used in these fields have certain limitations, thereby compromising the desired outcome which can be depicted using various quality management tools.
5. Application of these tools show us that the new technologies have a place in hospital infection prevention and waste management practice and therefore can be used as valuable adjuncts to existing evidence-based practices.
6. The evaluation of these new technologies is difficult to standardise and therefore call for more research in this area.

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Chapter 14

CREATION FOR CURE: SIMULATION AND ORGAN MODELLING

Shine S. R.

Introduction

The field of applied mathematical modelling of biological systems has developed tremendously during the last decade and continues to develop. The major reason for this development is the ability of these models to obtain data with much better resolution in time and space compared to modern invasive and non-invasive measurements. In addition, mathematical modelling of the dynamics can provide new insights into physiological mechanisms. The models will give qualitative and quantitative information of the function they predict and may also be used to suggest new experiments. Therefore, such models are necessary for improving the understanding human physiology and may help generate new physiological theories in the long term. Nowadays, an exponential increase in these models can be seen in the medical industry, where engineering has a significant role. The development of training simulators for doctors, nurses and technical personnel will be another area where these models play an important role in the future.

This chapter will provide background on the advances in organ modelling by discussing the modelling process. Details of each stage, information from case studies and limitation of the modelling process are included.

The learning objectives of this chapter are to:

1. Understand the basic principles associated with Computational Fluid Mechanics (CFD).
2. Analyse fluid mechanics models currently used for clinical research problems.
3. Identify specific diseases and how they are modelled using computational fluid dynamics principles.
4. Understand the advantages and limitations in the modelling process.

Computational Fluid Dynamics Basics

Computational Fluid Dynamics (CFD) is a powerful technique for analysing fluid flow, heat transfer and associated phenomena using computer-based simulation. CFD was initially limited to high-technology engineering areas but has become a widely adopted technique for solving complex problems in many fields, including biomedical engineering. The complexity of human anatomy and human body fluid behaviour has created many challenges to CFD research in the biomedical field. However, the technique is more accessible now due to high-performance hardware and software availability. By using this technique, medical researchers have gained more knowledge of body fluids and components and can make improvements for biofluid physiology studies and develop medical devices. CFD will provide an opportunity to simulate the conditions before real commitment and, therefore, improve design and direction in medical interventions.

The basis of CFD is the Navier-Stokes equations which include the expressions for the conservation of mass, momentum and energy. The equations are, (i) mass: change of mass = 0, (ii) momentum: change of momentum = force × time and (iii) energy: change of energy = work + heat. The differential form of these equations is converted into algebraic equations by using discretisation methods like finite difference, finite volume or finite element techniques. The domain is divided into a finite set of cells/mesh/grid volumes. The method of deriving the discrete equation using Taylor's series expansions is called the finite-difference method. However, most commercial CFD codes use the finite-volume or finite-element methods that are better suited for modelling flow past complex geometries. The finite-volume method is based on approximating conservation equations in finite-control volumes. This describes how the total amount of a physical quantity (mass, momentum, energy) is changed in the control volume. Over time, the conserved quantity is expressed as CHANGE = (AMOUNT ENTERING – AMOUNT LEAVING) + AMOUNT CREATED. Various steps involved in the finite volume method are shown in Figure 14.1. The finite volume method is popular in computational fluid mechanics because:

1. It enforces conservation in every control volume considered
2. It offers flexibility in terms of both geometry and fluid phenomena
3. It is directly related to physical quantities (mass flux, etc.)

The equations generated at every grid point are solved using computers for every grid resulting in information about the computational domain. Some commonly used CFD software are ANSYS FLUENT, CFX, COMSOL Multiphysics, STAR-CCM+, ICFD++, OPEN FOAM and so on.

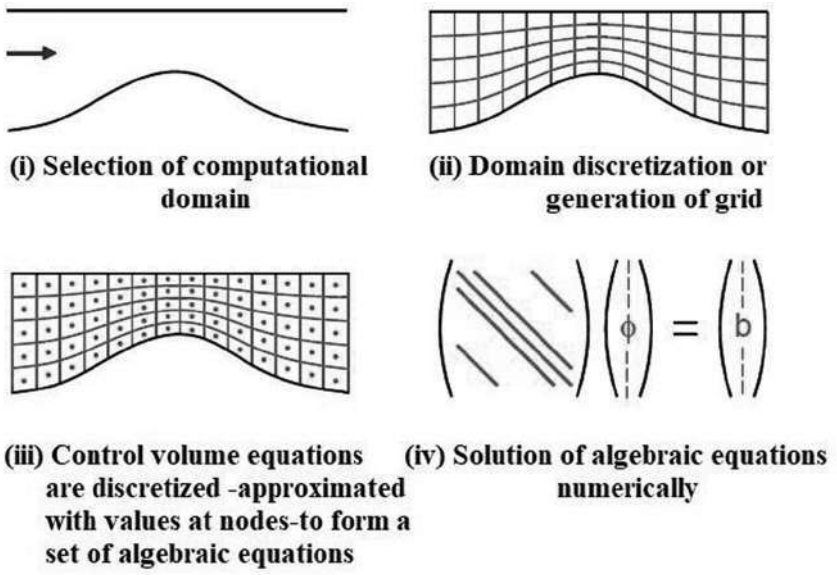


Figure 14.1. Various steps involved in the Finite Volume Method (FVM).

The building of a CFD model and its solution involves the following steps: (i) clinical imaging, (ii) segmentation and reconstruction of the geometry to generate the computational domain, (iii) selection of governing equations and boundary conditions, (iv) discretisation of the domain and governing equations, (v) solution of discretised equations using iterative methods and (vi) post-processing.

1. Clinical imaging
   Methods such as ultrasound, CT, MRI, X-Ray angiography and so on are used to obtain anatomical and physiological details of the organs. Sufficient quality data in a compatible format are desired.
2. Segmentation and reconstruction
   This involves the conversion of images into a 3D geometry to define a suitable computational domain. The anatomical motion is tracked using segmented regions when the data are obtained over a cardiac cycle.
3. Discretisation
   Depending on the required accuracy levels, the obtained geometry is divided into discrete volumetric elements or cells. For unsteady simulations, temporal discretisation will divide the solution into discrete time steps. This will be based on accuracy and numerical stability.

The Spatio-temporal discretisation must be done carefully to capture the required hemodynamics and optimise the available computational resources.

4. Selection of governing equations, boundary conditions and material properties

   Appropriate assumptions will be used to simplify Navier-Stokes equations. For example, steady/transient, single/multi-phase, laminar/turbulence, compressible/incompressible, Newtonian/non-Newtonian viscosity models and so on will be used to select the appropriate form of the equation. Boundary conditions are a set of applied physiological parameters that define the physical conditions at the boundaries of the desired computational domain. This is usually extracted from patient-specific data, population data, physical models or assumptions. The material properties will also be selected during this phase, for example, blood density and viscosity for the fluid model, arterial wall elastic properties for the solid domain for fluid-structure interaction problems and so on.

5. Solving

   The solver performs the actual computations, solving the discretised equations of the Navier-Stokes and continuity equations and proceeding incrementally towards a final solution ("convergence"). The solver may be using an appropriate discretisation method to discretise the governing partial differential equations. The solution of the discrete algebraic equations will generate the flow details (pressure and velocity field) over all elements at each time step at all discrete cells. A typical 3D cardiovascular simulation involves more than one million cells at every time step. For completing several cardiac pulses, hundreds or thousands of individual time steps may be required. Therefore CFD modelling is time-consuming and computationally demanding.

6. Validation

   The computed results must be validated against available experimental data of a specific experiment or analytical results. Generally, organ modelling cases involve comparison with data acquired during *in vivo* assessment or measured within an *in vitro* phantom.

7. Post-processing

   The CFD solver produces the pressure and velocity field over all elements at each step. This will be converted into valuable data of interest. This process is called post-processing. The computed results will generate the vorticity levels, recirculation regions, wall shear stress, Von Mises stress, pressure drops and so on for further analysis.

Figure 14.2 depicts the various processes involved in a Circle of Willis CFD simulation. The ring-like arterial structure which provides collateral blood supply to

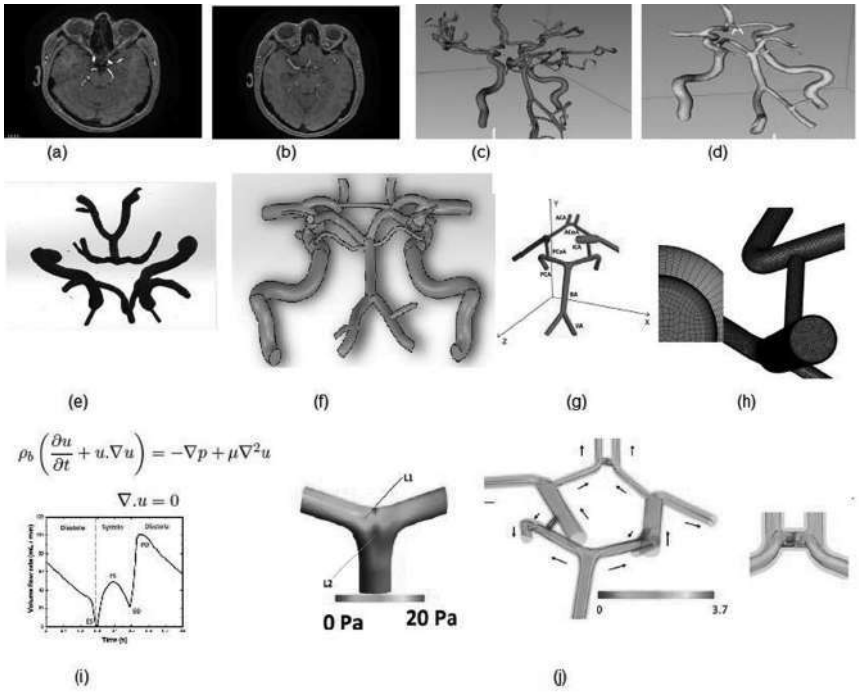


Figure 14.2. Steps involved in the computational modelling of the circle of Willis. This study examines the aneurysm initiation risk at various regions of CoW. (a) TOF MRA, (b) segmentation, (c) 3D model, (d) cropped STL geometry, (e) geometry building in CAD software, (g) idealised geometry built-in CFD pre-processor, (h) meshing of various sections, (i) governing equations and boundary conditions, (j) various results obtained from CFD post-processor, Wall shear stress at Basillar artery junction, streamline contour at COW during peak diastole, recirculation at anterior communicating artery.

the brain arteries is called the Circle of Willis (CoW). A 3-D model of CoW is reconstructed using a sequence of 2D data from the Magnetic Resonance Angiography images as shown in Figure 14.2 (c) and (d). The computational domain thus created is subdivided into many smaller elements used for flow simulations. Blood flow is assumed to be incompressible, non-Newtonian, and modelled using unsteady Navier-Stokes equations. Simulations are carried out for various cardiac cycles with an inlet velocity profile shown in Figure 14.2 (i). The estimation of the stress distribution within the wall obtained from the CFD model is shown in Figure 14.2 (j). This work demonstrates the most vulnerable locations for aneurysm initiation at the CoW.



Figure 14.3. A discrete representation with four equally spaced grid points for a 1D domain.

The Finite Difference Method

The fundamental laws of mechanics give the conservation of mass and momentum equations for a fluid. These are the governing equations used for the CFD simulation. Along with the energy equation, this will form a set of coupled, nonlinear partial differential equations. These equations are valid for the continuous domain, and therefore the flow variables are defined at every point. As analytical solutions are unavailable, approximate solutions are obtained based on computer-based methods. The method adopted is to replace the continuous problem domain with a discrete domain using a grid with each flow variable defined at the grid points. The governing partial differential equations and boundary conditions are approximated in the discrete domain in terms of the discrete variables. The discrete system is a large set of coupled, algebraic equations in the discrete variables. The solution of this discrete system involves a vast number of repetitive calculations, which are usually performed using the computer. An example of discretisation using the finite-difference method is explained below. Consider a 1D differential equation in a continuous domain as

$$\frac{\partial u}{\partial x} + u = 0; \quad 0 \le x \le 1; \quad u(0) = 1$$

A discrete representation of the system is shown in Figure 14.3 with four equally spaced grid points.

Since the governing equation is valid at any grid point, the equation for every point is

$$(\partial y/\partial x)_i + u_i = 0, \quad \textit{where } i = 1,2,3,4, \textit{ represents the grid points.}$$

Now for every grid pint, ∂u/∂x is approximated as an algebraic equation using Taylor's series as shown below.

$$(\partial y/\partial x)_i = \frac{u_i - u_{i-1}}{\Delta x} + Truncation\ error$$

Now excluding the error, the governing equation becomes

$$\frac{u_i - u_{i-1}}{\Delta x} + u_i = 0$$

Now the differential equation is converted to a system of algebraic equations. This method of deriving the discrete equation using Taylor's series expansions is called the finite-difference method. However, most commercial CFD codes use the finite-volume or finite-element methods, which are better suited for modelling flow past complex geometries. The equations generated at every grid point can form a system of four simultaneous algebraic equations in the four unknowns u_1, u_2, u_3 and u_4. Figure 14.4 depicts the above process.

The four algebraic equations will be

$$-u_1 + (1 + \Delta x)u_2 = 0$$

$$-u_2 + (1 + \Delta x)u_3 = 0$$

$$-u_3 + (1 + \Delta x)u_4 = 0$$

$$u_1 = 1$$

The number of algebraic equations obtained will equal the number of independent discrete variables. The discrete equations correspond to the grid points (or cells in the finite-volume method) in the domain's interior. Boundary conditions are specified for grid points (or cells) at the boundary. An iterative procedure finds the four unknowns u_1, u_2, u_3 and u_4. The iterations will be terminated when the residual falls below the specified convergence criterion. The convergence criterion for each conservation equation is problem- and code-dependent. In complex issues, the iterations converge slowly and, in some instances, may even diverge. Stability analysis determines the conditions for convergence of a given numerical scheme. A numerical method is referred

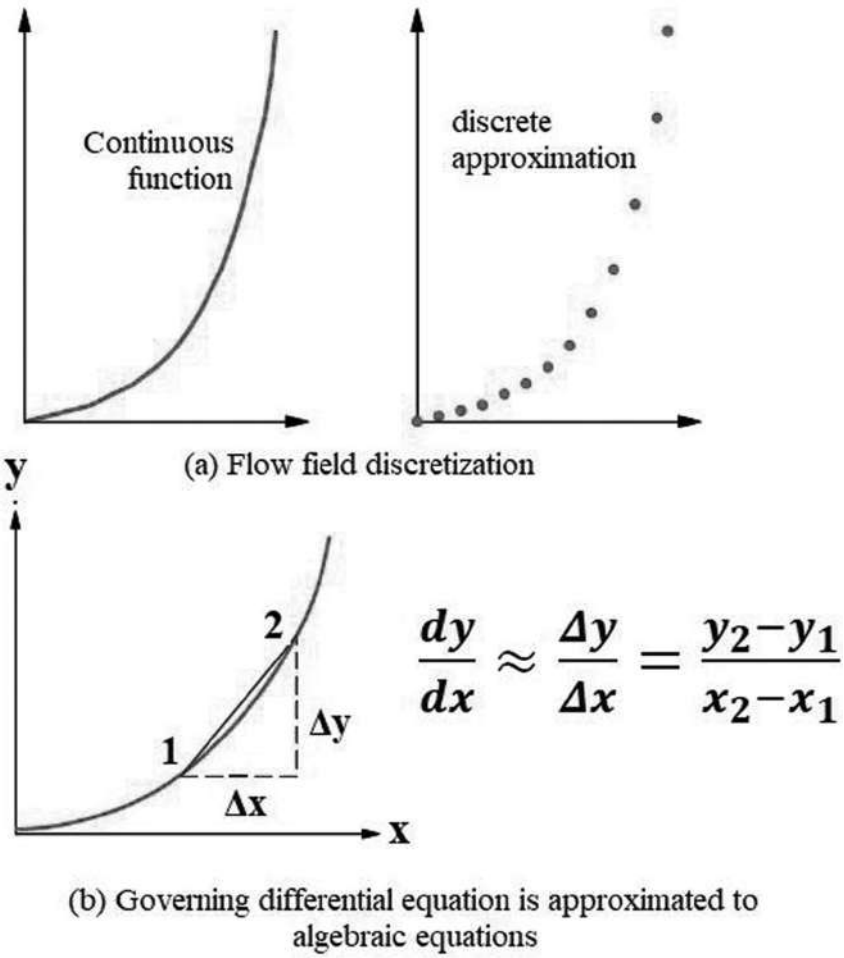


Figure 14.4. Basics of the Finite Difference Method (FDM).

to as being stable when the iterative process converges and unstable when it diverges. The non-linearity of the governing equations and non-linearities created by phenomena such as turbulence and chemical reaction for a fluid makes it challenging to obtain accurate numerical results for complex flows of practical interest.

Major Assumptions Used in CFD Modelling

One of the major assumptions used is the rigid artery walls. This usually leads to the prediction of higher wall shear stress, peak pressures

and so on. Pressure wave transmission at a finite speed of the elastic wall occurs with the elastic wall and reduces peak pressure during the cardiac cycle. As the vessel is large during peak flow, wall shear stress will be lower. Another assumption made is the smooth boundary for the fluid domain. Fluid-Structure Interaction (FSI) analysis uses the elastic wall to simulate vessel transformation during the cardiac cycle. FSI simulation requires information such as thickness and elastic modulus of the arterial wall. This information is difficult to obtain by most diagnostic devices, and therefore, many researchers use rigid wall assumptions. Blood viscosity is assumed Newtonian in larger vessels' simulations, though blood exhibits non-Newtonian behaviour. The fluid flow is generally considered incompressible and laminar.

Hemodynamic Parameters Calculated Using CFD

Various hemodynamic parameters are calculated from the computed flow results to obtain detailed information of the modelling organs. Wall Shear Stress (WSS) is the frictional tangential force on the arterial wall due to the blood flow. WSS is one of the most popular hemodynamic parameters used in CFD research. This parameter significantly affects atherosclerosis and plaque formation. The frictional forces contribute to biological reactions at the arterial walls. Oscillatory Shear Index (OSI) measures the directional changes of WSS during a cardiac cycle. This index is used to analyse the disturbances in the flow field. High OSI indicates flow-separation and reattachment and is usually used to identify regions susceptible to atherosclerosis. The Pressure Loss Coefficient (PLC) is used to calculate the resistance to blood flow in the arteries and calculated based on pressure loss in the blood flow as it passes through the artery. Relative Residence Time is calculated based on time-averaged WSS and is related to the time blood-bearing particles spent in different regions of the arterial walls.

CFD Modelling Applications in Medicine

The major outcome of the modelling is the availability of detailed hemodynamic parameters at a spatial and temporal resolution unachievable by current clinical methods. The detailed pressure, flow-fields and stress details are available, generating new insights into physiology and disease progression. The fluid mechanics details may be combined with cellular response to understand the disease initiation and progression. Some of the modelling applications likely to impact clinical practice in the recent future are summarised in Table 14.1.

Table 14.1. Summary of modelling applications in clinical practice.

Reference	Area	Clinical applications	Data and evidence	Potential clinical impact
Tu *et al.*, 2014; Morris *et al.*, 2015	Coronary artery disease and physiology	CT angiography-based models to compute physiological coronary lesion.	Good agreement between CFD predictions and standard data.	More access to physiological lesion assessment; models may be used for virtual stenting and enables optimal treatment protocol.
Georgakarakos *et al.*, 2011; Molony *et al.*, 2010	Aortic aneurysm	Detailed hemodynamic data for non-invasive imaging.	Outcome trials need to be done.	Predict aneurysm progression and risk of rupture and reduction in costs for follow-up imaging.
Schneiders *et al.*, 2015; Shine *et al.*, 2022	Cerebral aneurysm	Prediction of recirculation zones, wall shear stress, Von-Mises stresses, intra-aneurysmal flow, stasis.	Data available correlating the relation between hemodynamic parameters and aneurysm initiation, growth and rupture.	Risk prediction is possible. Putative treatments impact on local hemodynamics evaluated in silico.
Jiménez and Davies, 2009; Morlacchi and Migliavacca, 2013	Stent design	Prediction of stent induced hemodynamics.	Vessel remodelling with stents.	Optimal patient specific stent design possible.

Reference	Area	Clinical applications	Data and evidence	Potential clinical impact
Tang *et al.*, 2012; Kheyfets *et al.*, 2015	Pulmonary Hypertension (PH)	More knowledge of complex PH physiology. Non-invasive diagnosis possible.	Models demonstrated the difference between healthy volunteers and stratify PH subcategories.	Hemodynamic details help to reduce the requirement for right heart catheterisation. More knowledge regarding the structural changes contributing to increased PAP.
Trayanova, 2012	Modelling of heart function	Help to reveal how organ-scale arrhythmogenic phenomena and contractile dysfunction emerges from pathological effects.	Could explain many experimental observations.	Understanding of the mechanisms of atrial and ventricular mechanisms.

Case Study I: Coronary Artery Stenosis

The methodology adopted for fluid-structure interaction analysis of blood flow through a diseased arterial segment containing stenosis or dilation is described. This is based on the study conducted by Sandeep and Shine (2021). 3D models of various cases are obtained using different combinations of artery radius, the radius of stenosis/dilation and length of the diseased segment. The computational domain consists of a three-dimensional arterial segment with solid and fluid domains. The fluid domain consists of the blood path, and the arterial wall formed the solid domain. An element size of 0.0003 m was used for the fluid domain while the element size was fixed to be 0.0004 m for the solid domain, with the number of elements falling in the range of 920,000–820,000 and 78,620–21,000, respectively, for fluid and solid domains for different analyses. These optimum grid sizes were selected after a grid independence study. This is done to eliminate the influence of the number of grids/grid size on the computational results. The boundary conditions for the fluid domain inlet and outlet were time-varying pulsatile periodic velocity and pressure. The governing equations for the fluid domain were the unsteady mass and momentum equations. Various non-Newtonian viscosity models for blood, such as Generalized Power Law, Power Law, Carreau, Carreau-Yasuda, and Cross Model, are considered in the present study along with the Newtonian model. Two-way sequentially coupled transient FSI analysis was performed using a commercial CFD software ANSYS (2016). Ansys Fluent was used for the fluid domain simulation, and the pressure loads from this were transferred to the solid domain through an interface. The ANSYS Mechanical Solver solves the solid domain. The validation of the FSI model is done by comparing the results obtained for the wave velocity in simulation to that obtained analytically using the Moens-Korteweg equation. In contrast, the validation of the CFD model is conducted by comparing the simulated results to the experimental results available in the literature. The hemodynamics parameters such as velocity, pressure, WSS, arterial wall deformation and so on were obtained from the model at specific instants of pulse cycle like Early Systole (ES), Peak Systole (PS), Early Diastole (ED) and Late Diastole (LD). Significant changes in hemodynamic parameters were noticed in more stenosis cases than dilatation. Downstream stenosis showed significantly reduced wall shear stress which could cause more attachment of monocytes to the endothelium. Figure 14.5 shows the details of the study.

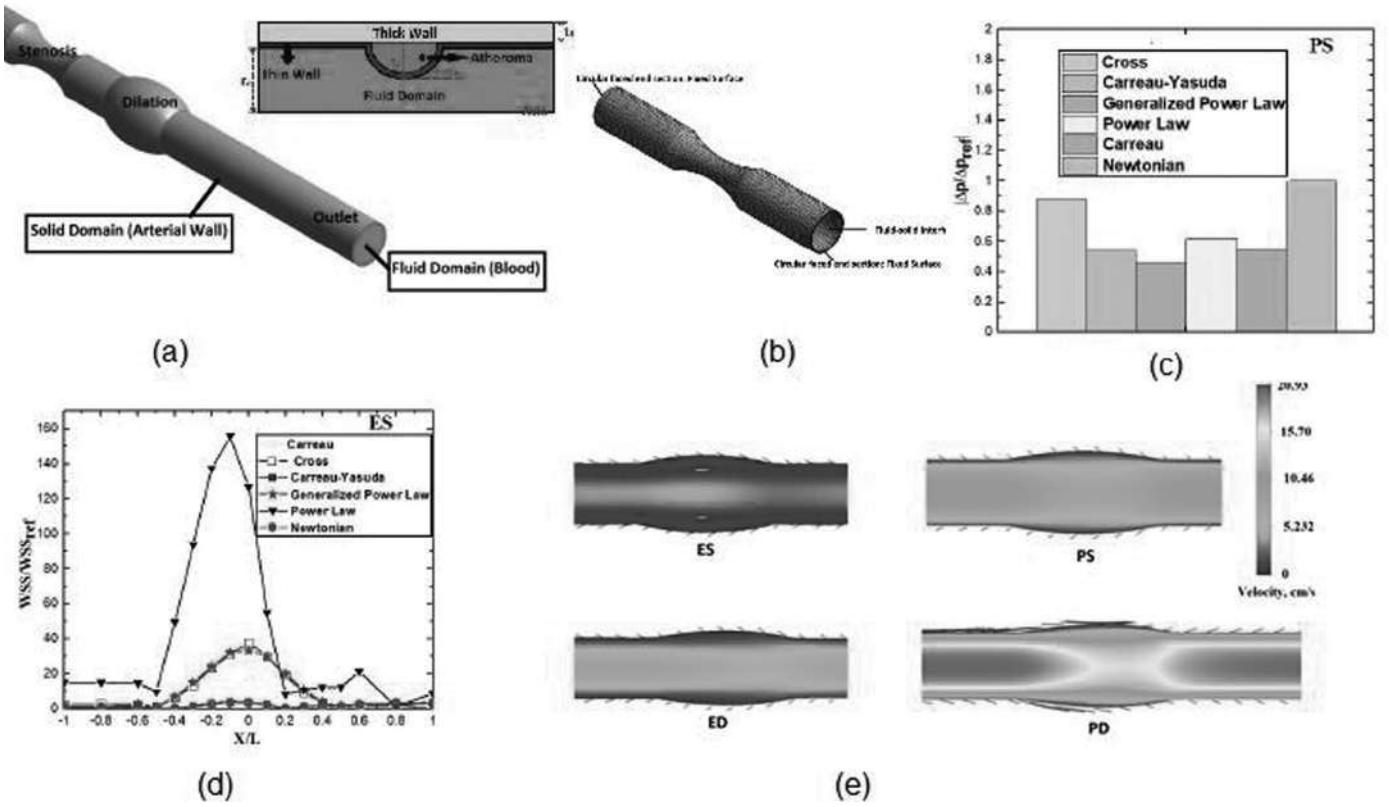


Figure 14.5. Details of the study conducted by Sandeep and Shine (2021). (a) Computational domain showing solid and fluid domain, (b) meshing of the solid domain, (c) comparison of non-dimensional pressure drop for various non-Newtonian models at peak diastole, (d) comparison of WSS prediction using different blood viscosity models, (e) velocity contour at the dilatation stenosis region during various phases of the cardiac cycle.

Case Study 2: Mathematical Modelling of Human Thermal Regulation

Thermal regulation models developed for predicting skin temperatures involve passive and active systems of the body. The passive system mainly depends on the body's individual characteristics such as height, mass, body surface area and fat percentage. The passive system consists of segments and sub-segments made up of simple geometries like spheres and cylinders. The head, face, neck, shoulders, thorax, abdomen, arms, hands, legs, feet and so on, will be considered separate segments. The heat transport mechanism between these sections is modelled using Pennes' bio-heat equation. Appropriate tissue material properties may be used while modelling the passive system. The body heat exchange with the surrounding is through convection and radiation, in addition to the evaporative heat loss.

Body temperature is controlled by a feedback system known as the active system. The active system generates thermoregulatory commands to regulate the body temperature based on the environmental condition. The thermo-regulatory commands are shivering, sweating, vasodilation and vasoconstriction. Evaporation for the skin will be modified based on the sweat command. Vasoconstriction and vasodilation commands are used to constrict or relax the arterioles near the body's surface to control heat transfer out of the body. This will control the blood flow to the skin layer and the skin temperature. Shivering command will increase metabolic heat generation. These thermo-regulatory functions are assigned to various nodes, generating heat flows. The model will be used to evaluate thermal comfort. The model will be capable of predicting the time-dependent temperature distribution in living tissue layers and evaluating thermal responses of the human body to environmental conditions. A representative diagram showing the human body's passive and active thermoregulation systems used is shown in Figure 14.6.

This model is very useful for planning human space flight travel. In a space environment, thermoregulation is critical for survival, especially in off-nominal operations. Various space agencies employ mathematical models to evaluate safety-of-flight issues in various human mission scenarios. Some of the scenarios analysed using thermoregulation models include (i) response of an astronaut wearing the crew escape-suit and liquid-cooled ventilation garment in the event of elevated cabin temperatures resulting from a systems failure, (ii) to devise the most effective mitigation strategy under off-normal conditions, (iii) analysis of metabolic loading during launch/entry operations that could occur in potentially extreme external environments, (iv) to predicting heat stress during Extravehicular Activity (EVA). EVA can create unusual environmental conditions such as incident radiation shining upon one side of the astronaut with the other side facing deep space, (v) to design,

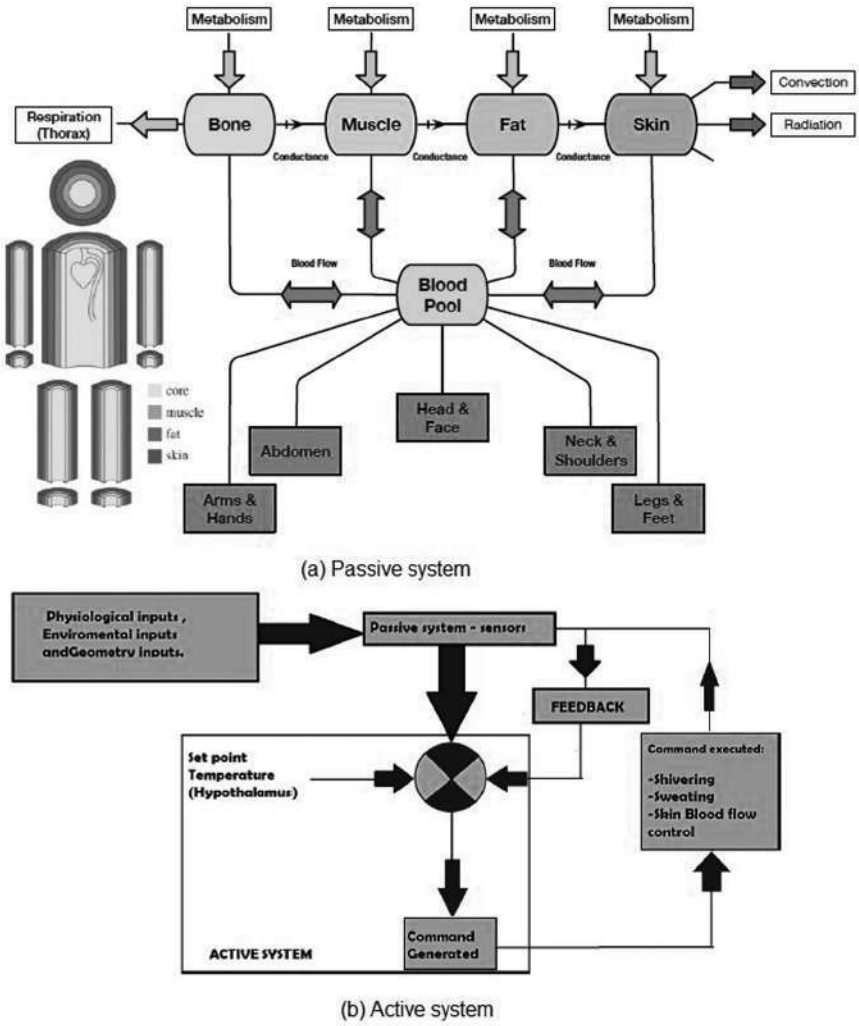


Figure 14.6. Components of a human thermoregulation model (a) passive system, representation of the interaction of different elements of the body, (b) schematic representation of the active system.

develop and test ECLSS (Environmental Control and Life Support Systems) designs, (vi) analysing current and future spacesuit concepts, (vii) analysis of various LCGs (Minnesota Advanced Cooling Suit (MACS-Delphi), Russian Orlan (Orlan), NASA Liquid Cooling Ventilation Garment, (viii) to use along with thermal comfort criteria to assess the effectiveness of local thermal management systems and so on. Another recent activity using these models is

suit architecture design for a crewed mission to Mars, which requires around 539-day stay on the surface, resulting in over 1,000 hours of Extravehicular Activity (EVA) per crew member. Current applications of thermoregulation models are summarised below.

- As a thermal analysis tool to support the development of the Space Suit System (SSS)
- To predict the human thermal response to the space flight environment
- In the development of UTCI: the UTCI equivalent temperature presents the air temperature of the reference environment that gives the same strain index.
- Medical applications: For example, a model was developed at Maastricht University, and Eindhoven University of Technology for predicting the response of patients during open-heart surgery (Severens *et al.*, 2007)
- For various thermal suit designs, cloth designs, etc.: The development of sweating manikins for measuring thermophysical properties of different clothing, sleeping bags, mattresses and so on, uses thermophysical models.
- Design of sports stadiums: Fiala model was used to design sports stadiums: for example, Stadium Australia used for the 2000 Olympics (Fiala and Lomas, 1999). The thermophysical model was used for predicting thermal stress on spectators under various roof designs.
- Improving thermal comfort car cabins: Models are used to predict the thermal responses of humans in the car cabin.

Limitations of the Modelling Studies

Currently, these models are used by two groups; (i) industrial, medical device developers to create low-cost, rapid prototypes, (ii) academicians to investigate various patient-specific scenarios. Clinicians are the emerging user group who require accurate and rapid results for treatment decisions. The studies are usually conducted with idealised geometries without considering the vessels' asymmetry and anatomical variations. Arteries will be modelled as ideal tubes with pre-determined curves. Efforts in imaging, image registration and segmentation algorithms in recent years may lead to more accurate input data and geometry generation. Most often, constant elastic properties of the arterial wall are assumed without considering the different elastic moduli of components that may be present (e.g. a vessel with plaque can have features such as fibrous cap, lipid pool, calcification, etc.). Blood is a complex fluid with shear-thinning and viscoelastic properties. The impact of blood's non-linear viscoelastic property is important for smaller arteries like coronary arteries.

Non-Newtonian shear-thinning is usually considered but not the viscoelastic property. Another challenge is the lack of relevant industry standards governing accuracy, reliability or validation. Currently, large volumes of clinical data available with hospital systems are inaccessible and restrictive. Channels of secure sharing of this anonymised patient-specific data with researchers may be established to ensure the growth of the subject. This will ensure long-term outcomes and clinical transition.

Future Directions

Nowadays, the benefits of organ modelling are being recognised by all stakeholders, including the regulatory authorities. More work is expected to enable model development with increased precision, speed and personalisation in the coming days. It is expected that these tools will be established in routine clinical practice with patient-specific models. However, efforts must be initiated to demonstrate the efficacy through large multicentre clinical trials. Next-generation doctors will require training to use these models for clinical decision-making and understand the principles, assumptions, methodologies and limitations. The emerging concepts like "Organ-on-a-Chip" use microfluidic platforms for organ testing under certain pathological and physiological conditions. The development of such devices requires extensive CFD simulations to study fluid flow, drug diffusion, heat and mass transfer. For example, Garcia *et al.* (2016) described the successful implementation of CFD techniques in transdermal drug delivery studies. CFD was used to determine microneedle insertion loads and fluid pressure distributions through the microneedle array. Similar is the case of "Lab-on-a-Chip" systems wherein an integrated micro-electro-mechanical system performs all biological and chemical processes stages.

Conclusion

The chapter presented an overview of the computational fluid mechanics principles, the various steps involved in the modelling process, assumptions, limitations, parameters derived from the models and so on.

1. Case studies are presented to understand the current status and role of CFD in the evaluation and treatment planning.
2. CFD is a valuable tool used in the design of surgical devices. The use of this technology for routine clinical practice may depend upon future investigations with more clinical data, sensitivity and validation studies, and a reduction in the speed of simulations.

3. The resolution of the current medical scanners needs to be improved to obtain accurate patient-specific flow conditions and wall properties.
4. Success will depend on more organised, coordinated and regular collaborations between clinicians and engineers.

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Chapter 15

THE SCIENCE OF REGENERATION: TISSUE ENGINEERING AND BIOMECHANICS

Arvind Ramanathan

Introduction

The goal of tissue engineering is to meet the rising need of patients for new treatments against injury-related and degenerative conditions. Humans have an extremely limited ability to regenerate/repair tissue (e.g. skeletal muscle and liver) often only in scenarios of small injuries. Therefore, loss of human tissue associated with cases of acute trauma, degenerative diseases and congenital defects would be greatly helped by construction of the required tissues from the same subject. This would diminish the need for transplantation-ready allogenic tissues and organs, and would eliminate the need for life-long medication that is required for preventing immune-rejection.

The overall approach used in tissue engineering is to develop replacement tissues or organs in the laboratory that can be used to substitute or promote regeneration of the respective organs *in vivo*. This is a rapidly developing area of biomedical research that has begun translating products into the clinic (Hoffman, Khademhosseini & Langer, 2019) despite numerous obstacles. The challenges in this field have been (i) a source of rapidly expandable and immuno-compatible cells, (ii) biocompatible synthetic or decellularised scaffolds that have the required mechanical and biochemical properties and (iii) generation of engineered vascularised tissues that can integrate with the circulatory system of the host. Assembling these building blocks under good tissue/cell manufacturing processes and ensuring economic viability have been major challenges in the widespread adoption of tissue engineering-based products in the clinic. This chapter will describe with examples the building blocks of engineering tissues, applications of engineered tissue in disease modelling, products from tissue engineering available in the clinic and final

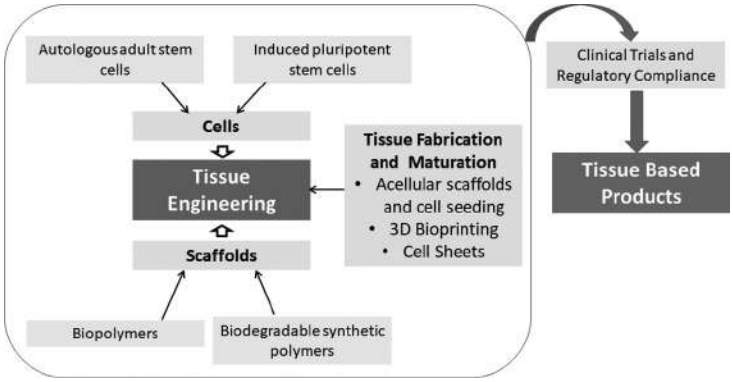


Figure 15.1. Building blocks of tissue engineering leading to tissue-based products for healthcare.

perspectives on challenges and the future of tissue engineering in the health sector (Figure 15.1). In this chapter you will learn about the following four points:

1. Building-blocks/components of tissue engineering.
2. Detailed technical considerations for building two tissues: (i) blood vessels and (ii) cartilage.
3. *In vitro* uses of engineered tissue in drug discovery and toxicity studies.
4. Examples of commercially available Tissue Engineered Products (TBPs).

The Three Building Blocks of Tissue Engineering

(i) Source of Cells – The fundamental building blocks of tissues are a characteristic set of cell-types that comprise each tissue. Prior to advancements in cellular reprogramming, tissue biopsies were the major source of cells, as in the case of skin biopsies where keratinocytes from the epidermis and fibroblasts from the epidermis could be obtained after dissociation using collagenase. These cells can be readily amplified in 2D culture. The earliest construction for tissue-engineered skin for grafting in patients with burns was done using this approach (Schlottmann, Bucan, Vogt & Krezdorn, 2021). The cells necessary for engineering other tissues such as skeletal muscle or neural tissue are not readily accessible from biopsies, and importantly, these solutions are not scalable. The isolation and culturing of human Embryonic Stem Cells (hESC) enabled the differentiation of these cells into tissue cells such as cardiomyocytes, liver, neurological tissue and so on, but direct applications in the clinic were limited due to ethical concerns.

The Nobel Prize winning technology to reprogram iPSCs (induced pluripotent stem cell) from tissue cells (Takahashi & Yamanaka, 2006) has been a major catalyst in solving this bottle neck. These "pluripotent" cells, like embryonic stem cells have the potential to form all three germ layers during differentiation, and potentially any cell type in our body. Using iPSC technology, cells such as Peripheral Blood Mononuclear Cells (PBMC) or dermal fibroblasts can be reprogrammed into pluripotent stem cells by the cellular expression of cellular proteins (four Yamanaka factors – Oct3/4, Sox2, Klf4, c-Myc). This technology has since progressed to allow the expression of these and other combination, of factors using viral vectors that do not integrate nucleic acids into the genome. Reprogramming into iPSCs has also been accomplished now with small molecules alone (Guan *et al.*, 2022). Such progress has been critical in allowing iPSCs to be safely used in a clinical setting since there is no change in the genomic sequence of donor cells.

Based on these steps, iPSC technology has widely enabled tissues to be engineered directly from patient-derived cells, which can avoid issues of immunological rejection that has been a major problem in traditional tissue transplantations. Patient-derived iPSCs have also been transformative in modelling of diseases that will be discussed in the following sections. It must be noted that efficient methods for deriving cells of interest for numerous tissues from iPSCs are yet to be discovered (e.g. cartilage) in which case mesenchymal stem cells or articular cartilage cells from patients are often expanded in culture as a source of precursor cells whenever necessary.

(ii) Biochemical Cues – Signalling molecules, which can be protein-based growth factors, lipids or other small molecules, are critical parts of the *in vivo* tissue environment. These biochemical signals control how cells maintain their stem-cell-like state, and how tissues maintain their molecular identity during growth and tissue differentiation. A comprehensive understanding of these signals has been key in turning patient-derived cells into appropriately arranged tissue cells. For example, maintaining iPSCs in their pluripotent state is controlled by numerous physiological signals including Fibroblast Growth Factor basic (bFGF) and hypoxia. The next challenge is applying appropriate signals to the stem cells in order to derive cells of the required tissues. The protocols for deriving tissue-specific cells from iPSCs involved identifying the germ layer (mesoderm, ectoderm or endoderm) that the tissue is derived from, and induction of cells into the tissue of interest by mimicking development. Where tissue cells are readily available from patients such as adipose cells or cartilage cells, they can be expanded *ex-vivo* and incorporated into tissue scaffolds described below.

(iii) Tissue Scaffolds – A critical step in engineering tissue is to provide a 3D environment that can provide the appropriate environment for growth and

integration of tissue resident cells derived from patient cells. Along with the biochemical cues that help tissue cells maintain their characteristics, biomechanical cues are equally important for tissues to form. The tissues in the human body can vary in stiffness from around 50 Pascals for brain tissue right up to approximately 4 Gigapascals for bone tissue (Cox & Erler, 2011). Providing cells with stiffness of their corresponding tissues is important in tissue engineering. In order to do this, numerous hydrogel scaffolds based on chitosan, gelatin, hyaluronic acid and so on have been used (Bachmann *et al.*, 2020). Some examples of this are provided in the next paragraph. Once appropriate scaffolds have been designed, the next step is patterning layers of scaffolds into tissue-specific arrangements. This is now routinely performed using 3D bioprinting.

There are numerous 3D bioprinting techniques, including those that deposit the scaffold polymer "ink" (as a viscous fluid) into the appropriate shapes and layers, followed by chemical or light mediated polymerisation. The biocompatible porous polymerised scaffolds, which have attachment sites for cells, are provided growth factors after which the cells can be integrated into the scaffold. In other approaches, the scaffold polymer "inks" are pre-mixed with cells and bio-printed as one unit to form the tissue of interest. After transplantation of these bioprinted tissues *in vivo*, the scaffold polymers degrade over time and are replaced by the extracellular matrix from the cells and surrounding tissue. With the emergence of 3D bioprinting as the approach of choice, other technologies for 3D arrangement of scaffolds including electrospinning, salt leaching, freeze drying and so on are less likely to advance.

Examples of Engineered Tissues

Described below are two examples of how the three building blocks (cells, biochemical cues and 3D scaffolds) can be integrated to engineer specific tissues.

(i) Blood Vessel – Approximately 400,000 coronary artery bypass grafts are performed in the United States every year (Bachar & Manna, 2022). For this and other arterial replacement procedures, there exists a significant demand for artificial arteries. Blood vessels are a circulatory system that infiltrate most tissues. Large blood vessels (veins and arteries) provide transport of biomolecules and cells to distant locations while small blood vessels (capillaries) provide oxygen and metabolite exchange inside tissues. Hence, the biofabrication requirements for these vessels is different with large vessels of sizes greater than 6 mm and small vessels at sizes smaller than 1 mm. The first blood vessel using endothelial cells, fibroblasts and collagen was created in 1986 (Weinberg & Bell, 1986), and since then there have been major advances

in bio-fabrication of this tissue for clinical use. Two basic challenges need to be overcome in bio-fabrication of blood vessels:

(i) Increasing cellular survival and arrangement of cells into their respective layers – smooth muscle cells in the middle layer and endothelial cells in the inner vascular layer. While using cellular scaffolds, even with the inclusion of biomolecules such as fibronectin and cell adhesion peptides, obtaining layered vascular tissues is a major challenge.

(ii) Tuning the mechanical properties of these dynamic tube-like structures to withstand the physiological pressure of up to approximately 3000 mmHg is critical to building functional blood vessels. Adult stem cells and autologous-induced pluripotent stem cell-derived vascular cells are the preferred source due to their ability to be expanded and regulatorily qualified. They have also sparked great interest due to their ability to minimise transplant rejection. The scaffold of choice is composed of biocompatible hydrogels that can encapsulate signalling molecules and proteins that guide formation of blood vessels. Bioengineering of hydrogels is a rapidly progressing field. The final goal is to find the material that can provide cues and mechanical support for the growth of vascular tissue, that can also be naturally degraded so as to be replaced by the natural extracellular matrix generated by vascular cells.

Bio-fabrication processes involve two main approaches: (i) seeding of cells into premanufactured scaffolds and (ii) 3D bioprinting of cells and scaffold materials simultaneously. An interesting approach to building blood vessels is via engineering cell-sheets. In this approach the cells that constitute the layers of blood vessels are each grown to confluence in 2D layers. In another scenario, all the different cell types are co-cultured on a substrate. The individual layers or a single layer with different cell types are then wrapped around a shaft or mandrel. This method is still evolving, but arrangement of smooth muscle and endothelial cells into individual layers remains a challenge.

Recent advances in 3D bioprinting have enabled the use of Computer-Aided Design (CAD). A printing technique that is particularly suited for building vascular tissues is the one using coaxial nozzles. This approach allows different cell types embedded into biomimetic inks to wrap into layers of tubular form directly. The final step is in the process of tissue maturation, where cells must be allowed to adapt to the 3D matrix to form cell–cell connections and start generating their own extracellular matrix. This is done in the presence of appropriate fluid flows and mechanical stresses to mimic physiological conditions. Today, numerous Tissue Engineered Blood Vessels (TEBV) using decellularised ECM or synthetic hydrogels (PolyLactic acid and Poly CaproLactone) are commercially available. A common problem that

should be monitored during implantation is graft stenosis. Lawson *et al.* (2016) conducted a Phase II clinical trial in 60 patients with end-stage Renal Disease, who were implanted with TEBV implanted with autologous endothelial cells. No immune reaction was observed, and successful grafting of endothelial cells was detected, clearing the way for Phase III clinical trials.

(ii) Cartilage – Articular cartridge is an important target for developing regenerative tissues, as intrinsic healing is limited due to its avascular nature, and left untreated predisposes patients to osteoarthritis (Francis *et al.*, 2018). Articular cartilage is the smooth tissue that covers bone ends at the joints, and the main component of this tissue is called the hyaline cartilage. Healthy cartilage is important for smooth movement and mechanical function of the skeletal system. This cartilage can be damaged by wear and by injuries like meniscal or ligament tears. Prior to tissue engineering, strategies to repair this tissue included Autologous Chondrocyte Implantation (ACI) and arthroscopic techniques such as inducing microfractures. The long-term results of the above techniques have been poor, and cartilage tissue engineering has emerged to provide a method to regenerate the tissue. In the bio-fabrication of this tissue numerous sources of cells have been considered. Chondrocytes (either autologous or from other sources) have limited availability and show donor site morbidity. Bone marrow derived mesenchymal stem cells have emerged as a ready, easily accessible/expandable and autologous source of cells. Optimal cell densities based on the size of the lesion are still being optimised. Biocompatible hydrogels with combinations of biomolecules that stimulate chondrogenesis growth (e.g. TGFbeta-3, bone Morphogenic Protein-2) can be used as scaffolds since the synovium *in vivo* might not have the required growth factors present.

Though it is clear that the engineered cartilage is stable *in vivo* in animal models, no long-term (greater than 12 weeks) studies have been performed. 3D bioprinting methods have been used to develop hand-held biopens that can deliver cells in conjunction with compatible hydrogels into the lesion site. These coaxial extrusion systems consist of an inner core of cells surrounded by the hydrogel layer. Tissue engineered cartilage are in active clinical trials. The clinicaltrials.gov website hosted by the U.S National Library of Medicine shows more than 400 ongoing or completed clinical trials of tissue engineered cartilage in patients. For example, long-term clinical trials are underway by a German firm (Novacart 3D) for treatments of defects in the knee of paediatric patients with closed epiphyseal growth plates. In this approach, autologous stem cells are harvested from the knee, expanded and manufactured for transplantation and patients are monitored over three years. The cartilage tissue engineering and transplantation field is now rapidly growing in

clinical use as judged by numerous ongoing trials (Francis *et al.*, 2018; Jiang *et al.*, 2020).

Tissue Engineering in Disease Modelling and Testing Drug-response *in vitro* (Skeletal Muscle as an Example)

Though numerous complex tissues such as skeletal muscle and liver are progressing rapidly in their tissue engineering, they are still in preclinical or early clinical stages of research in terms of providing tissue for transplantation (Jalal, Dastidar, & Tedesco, 2021). Even at these early stages, tissue engineering of tissues such as skeletal muscle, have provided platforms for bioengineering patient-specific "organoids" (smaller sized 3D arrangement of tissue resident cell types that mimic tissue function and disease pathology *in vitro*). These organoids, constructed using human skeletal muscle cells, have been effective in predicting drug toxicity and modelling the pathology of diseases such as Duchenne's Muscular Dystrophy (DMD) (Svobodova *et al.*, 2021). Skeletal muscle is one of the largest tissues in the body, which controls mechanical force generation, glucose, lipid metabolism and thermogenesis. The complex structure consists of a dense, orderly arrangment of contractile units, packed into myobundles that together make up the skeletal muscle. There is an increasing understanding of numerous cell types that comprise skeletal muscle, including tissue resident immune cells (e.g. macrophages, T-cells) and Fibro/Adipogenic Precursor (FAP) cells. The major cell type in building the contractile unit of skeletal muscle are the myoblast cells, that upon appropriate cues can differentiate into myotubes. The myoblasts are derived from quiescent tissue resident adult stem cells, called satellite cells, which are not abundant and reside beneath the basal lamina of the tissue. These cells are characterised by the marker-gene pax7, which upon injury activate into myogenic cells called myoblasts. A challenge in the bioengineering of skeletal muscle tissue has been the availability of sufficient biomass of myoblasts. The expansion of satellite cells into myoblasts is constrained by their limited proliferation capacity, and inefficient differentiation after a limited number of doublings. This constraint has been somewhat addressed by the arrival of iPSC technology, where stem cells derived from autologous cells can be converted into myoblasts by directed differentiation (Broer, Khodabukus, & Bursac, 2020).

In engineering this tissue it is important that scaffolds provide the mechanical and chemical cues for differentiation and sustenance of the tissue. Hydrogels like crosslinked fibrinogen and collagen can provide the stiffness of 12,000 Pa, similar to *in vivo* tissues. Another important consideration in building skeletal muscle tissue are the binary attachment points that mimic tendons, which can

be provided by constraining scaffolds between two points of surgical nylon or by forming ring-like structures around flexible Polydimethoxysilane (PDMS) posts. Since skeletal muscle is a highly vascularised tissue, it is important that vascular cells be integrated within the 3D tissue network that is currently being enabled. Though these engineered tissues can contract and generate force upon electrical stimulation, the current generation of skeletal muscle organoids also involve co-culturing with motor-neurons that have been shown to efficiently form neuromuscular junctions. Engineered skeletal muscle tissue have now been implanted and successfully integrated and vascularised *in vivo* using small mammals (Choi *et al.*, 2019; Gholobova *et al.*, 2020; Jalal *et al.*, 2021; Juhas *et al.*, 2014).

Translating this technology for transplantation into the clinic will require sustainable and qualified processes of growing sufficient biomass of cells from autologous sources. In the meantime, bioengineered skeletal muscle constructs have been used to predict toxicity of statin drugs in a personalised fashion using "myobundles" constructed from primary human myoblasts, either derived from biopsies or iPSCs. These myobundles have also been constructed in a 96-well plate format that enables drug screening. It has been found that force generation by organoids is directly proportional to calcium uptake from the sarcoplasmic reticulum, as measured by a dye-based and genetically driven fluorescent sensor of calcium. Based on these metrics, and from organoids derived from eight patients, the researchers were able to predict the toxicity effects of statins in each patient. This proof of principle shows that organoids generated from patients will be valuable in personalising statin prescriptions avoiding myotoxicity and choosing appropriate patients in clinical trials.

In another study, skeletal muscle organoids derived from normal subjects and patients suffering from DMD were generated. The ability of DMD myoblasts to form 3D skeletal muscle myobundles and generate force was limited, and structural deficits of these organoids mimicked those observed in patients suffering from DMD. This enabled the screening of drugs that were able to partially reverse these deficits. It is possible that organoids can also be applied for testing biologics in a personalised fashion, when the response to these expensive treatments is difficult to predict before treatment. Much like skeletal muscle, 3D Human Liver Organoids (HLO) have also been able to model liver diseases like Non-Alcoholic Fatty Liver disease (NASH) and predict drug responses for discovering and targeting available treatments (McCarron *et al.*, 2021).

Tissue-Based Products (TBP) Available for Clinical Use

The past few decades has seen the emergence of numerous TBPs (formulations of cells engineered into scaffolds) used for repair, replacement or regeneration

of tissues. As seen in examples from the previous paragraphs, TBPs may also be composed of biomimetic hydrogels in association with numerous biomolecules and signalling cues that are essential for tissue integration and vascularisation. The developmental stages of TBPs from basic discovery to trials to regulatory approval is a complex process that is beyond the scope of this book. It is worth noting that every jurisdiction has set regulatory structures and legislations based on the market that is being targeted. Below are a few examples (and by no means a comprehensive list) of TBPs that are approved for use in major markets:

(a) Apligraf (Organogenesis Inc. and Novartis AG) (Eudy, Eudy & Roy, 2021). Bioengineered skin substitute that is made using human dermal fibroblasts and Bovine Type I collagen, with an additional epidermal layer of cornified layer of human keratinocytes. Apligraf was approved for chronic leg ulcers and diabetic foot ulcers by the US FDA in 1998 and 2000, respectively.
(b) Stratagraft (Mallinckrodt). Allogenic cellularised scaffold, consisting of keratinocytes and fibroblasts in murine collagen (Gibson *et al.*, 2021). Stratagraft was approved by US FDA in 2021 for treating deep partial-thickness burns.
(c) Ossron is a regeneration therapy based on autologous bone cell-scaffold implantation for treatment of a wide range of bone defects (Kim *et al.*, 2009). This was approved in India in 2017 and South Korea in 2009.
(d) Novocart 3D (Aesculap Biologics). Chondrocyte cell suspensions embedded into collagen-chondroitin sulphate scaffolds (Jiang *et al.*, 2020). This was approved in the EU for articular cartilage repair in 2003.
(e) Heart Sheet (Terumo BCT) (Kurauchi, Kasai & Ito, 2020). Autologous skeletal muscle myoblast for treatment of patients with heart failure. This was approved in Japan in 2015.
(f) CardioCel (Admedus) (Musial-Wysocka *et al.*, 2019). Cardiovascular scaffold that enables tissue resident stem cells to regenerate/repair damaged cardiovascular tissue. This device is cleared for use in the United States (2014), Europe (2013), Canada (2014) and Singapore (2015).
(g) Aurix (Nuo Therapeutics) (Gude *et al.*, 2019). Hematogel consisting of autologous preparation of platelet-rich plasma gel for treatment of wounds, marketed in the USA since 2007.

Biomechanics

Biomechanics is an area of biophysics that deals with the mechanical (structural and functional) aspects of biological systems at the cellular, sub-cellular,

tissue and whole-body levels. It deals with the study of the physiological behaviour of cells and their movement, mechanics of biological fluids such as blood, soft tissue mechanics and growth, and development and motion of organs such as the heart and limbs. The general locomotion of living beings including competitive activities such as sports is studied in biomechanics. From a healthcare perspective, we will focus on tissues and organs, specifically in the context of rehabilitation and sports injuries.

Skeletal muscle can serve as an important model and context for the study of biomechanics. It is critical to understand how the internal structure of skeletal muscle fibres and their contraction can be optimised in various clinical contexts including promoting strength and posture. Skeletal muscle is composed of contractile muscle fibres along with connective tissue, blood vessels and nerves. These fibres are an organised unit of a series of contractile units, organised into macroscopic bundles that can generate force. Muscles are attached directly to bones via tendons. The ability of skeletal muscles to generate tension is controlled by the cycling of molecular motors composed of actin and myosin cross-bridges. The molecular mechanisms composed of cyclical hydrolysis of Adenosine Triphosphate (ATP), and transmission of nerve impulses via the sarcoplasmic reticulum are beyond the scope of this chapter. The contractions of skeletal muscle that generate force and tension are classified into (i) isotonic contractions, where there is constant tension with change in length, either eccentric (elongation) or concentric (shortening); examples are a dumbbell contraction or walking; (ii) isometric contractions where the length of the muscle does not change; an example is holding a bag; and (iii) isokinetic contractions with a constant rate of motion; an example is running on a treadmill.

An important concept in biomechanics is the concept of "load tolerance." Load is physical stress acting on anatomical structures within the body or imposed from outside (e.g. while lifting weight). The stress can be vibratory, kinematic (force) or kinetic (motion). Skeletal injuries, for example, can lead to biomechanical loading beyond the internal tolerance of the injured tissue. Measurement of these biomechanical factors is critical to clinical rehabilitation.

The quantification of force generation, loads and resulting movements are critical in accessing injuries such as skeletal muscle injury or acquired brain injury. Here, detailed camera and Electro-Myographic (EMG) measurements based on multi-joint movement – speed, distance and spatial path – are measured, to serve as biomechanical readouts of sensorimotor function (McCrea *et al.*, 2002). These kinematic and kinetic measurements are used to develop computational models that can describe, accurately and quantitatively, dysfunction in movement or force generation. These models serve to complement traditional clinical assessments to monitor injury and move patients more efficiently in their path to rehabilitation.

Post-stroke rehabilitation is an important example of how biomechanics can be applied in the clinic. Stroke is a major health problem affecting numerous countries, close to 15 million people worldwide, according to the World Health Organisation. Of these, 5 million die and another 5 million are disabled permanently (Nadeau *et al.*, 2013). Recovery of gait post-stroke is an important challenge that patients must overcome. Clinicians can use gait analysis based on observation and 2D/3D imaging. The biomechanical process of gait analysis for stroke patients emphasises gait speed (spatio-temporal parameters), kinematics and Ground Reaction Forces (GRF). The following are the biomechanical parameters of gait analysis:

(i) Spatiotemporal parameters are obtained using commercially available surfaces that have sensors below the patient's feet allowing real-time capture of parameters. Gait symmetry is calculated for right and left limbs in addition to velocity, stride length, cycle time and double support times. Hemiparetic individuals are those with weakness on one side of the body resulting in decreased gait speed (by about 25–50%) and changes in other spatiotemporal parameters as well such as gait cycle and step size.
(ii) Kinematics is a 3D description of movement including angular motions, linear velocities and accelerations. Participants are affixed with LED markers that are tracked using a camera-tracking system. Electromyography electrodes are often attached to skeletal muscle groups such as gastrocnemius and lateral hamstrings. Based on the location of the markers, anthropometric models are used to represent the subject and the motion of limb segments in 3D is recorded in real time, usually at 60Hz.
(iii) GRF and walking speed are calculated by measuring four parameters: the anteroposterior force, the vertical force, the mediolateral force and the total force. These parameters are associated with body mass and provide quantitation of how the centre of mass of the body is propelled during the gait cycle. This GRF analysis is valuable for accessing the gait pattern in stroke survivors.

Using these biomechanical parameters, the progress of post-stroke rehabilitation can be accurately monitored. Specifically, the post-stroke hemiparetic gait is characterised by reduced walking speed, gait asymmetry and decreased power transmission on the affected side. The change in these parameters can be measured to characterise individual clinical cases. This will help recommend and monitor progress during sensorimotor rehabilitation.

Conclusion

The field of tissue engineering is a rapidly evolving field that is beginning to yield numerous products and insights that will impact the field of healthcare. There has been success in the bioengineering of relatively simple tissues such as cartilage and epidermal layers of skin. Capturing the full complexity of tissues such as vasculature and larger tissues such as skeletal muscle and liver present challenges, including generating an economically viable, readily deployable biomass of various cell types. Though iPSCs have enabled the autologous generation of numerous cell types, engineering synthetic growth media and maintaining functional viability of cells during growth are important bottlenecks to address. It is quite clear that mechanical and biochemical signals from the extracellular scaffolds play a critical role in tissue function. A comprehensive knowledge of the extracellular cues and engineering of biomimetic scaffolds that incorporate appropriate concentration of these cues is necessary for the next generation of TBPs. Incorporation of 3D bioprinting at cellular, spatial resolution will be critical for appropriate arrangement of cells for building complex tissues. Efficient vascularisation, immune integration and integration of various cell types into tissue scaffolds will be required to meet the promise of tissue engineering in healthcare. Finally, streamlining of regulatory guidelines will enable the final step of translation of engineered tissue into the clinic. In this chapter, we have learnt about the following:

- Building blocks of tissue engineering: (i) source of cells, (ii) scaffolds and (iii) methods of bio-fabrication
- Examples of two bioengineered tissues: (i) blood vessels and (ii) cartilage
- Example of bioengineered skeletal muscle organoids for *in vitro* disease modelling and drug testing
- A brief list of Tissue-Based Products (TBP) currently available in the market.
- Biomechanics and its applications in the healthcare industry

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Chapter 16

MAKING VIRTUAL INTO REALITY: HOW AUGMENTED AND VIRTUAL REALITY ARE RESHAPING HEALTHCARE

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Introduction

The way we, as humans, consume information and interact with data is continuously evolving. The breakthroughs in computers and the advent of the internet have transformed digital technologies and their access. As has been the tradition with many technologies, Augmented Reality/Virtual Reality (AR/VR) development was driven by defence applications in the 1950s. It is quickly becoming mainstream, with consumer-grade devices and applications being launched over the last decade.

Due to the possible inherent risk to patients, the healthcare sector is cautious about adopting new solutions. However, the underlying technology landscape is fast changing. The patient benefit, clinical advantages and economics of AR/VR technologies hold immense prospects for healthcare. The current and future healthcare AR/VR solutions include a broad range of applications, from educating caregivers, training healthcare professionals, assisted surgery, telemedicine, physical therapy and treatments of phobias and other mental disorders. This chapter will

1. Introduce immersive technologies including augmented and virtual reality.
2. Describe the hardware and software technologies that are driving AR/VR.
3. Explain the role of AR/VR in healthcare through examples.
4. Explore the challenges of AR/VR technologies.

Augmented Reality and Virtual Reality (AR/VR)

Let us start by understanding immersive technologies. In simple words, VR enables interaction with simulated graphical environments using computer technology. Unlike traditional user interfaces such as joystick or mouse, VR places the user inside an experience or virtual environment. Instead of viewing a screen in front of them, the user is immersed in the 3D world and can interact with the same. Figure 16.1(a) shows an example of a virtual environment from a VR scene.

While VR enables interactions with the simulated environment, Augmented Reality (AR) enables interaction with the real-world environment (Dorner *et al.*, 2013). However, in AR, the objects in the real world are enhanced or augmented by computer-generated perceptual information. Figure 16.1(b) shows the human anatomy model realised over a person.

AR has three essential features: a combination of real and virtual worlds, real-time interaction and accurate 3D mapping of virtual and real objects. In AR, the computer uses sensors and algorithms to register the position and orientation of a camera. AR technology then superimposes computer-generated 3D graphics over a real world the user sees. In VR, the computer uses similar sensors and algorithms. Instead of locating a real camera within a physical environment, the position of the user's eyes is located within the simulated environment. If the user moves or turns the head, the graphics react accordingly. Rather than mixing computer-generated graphical objects and a

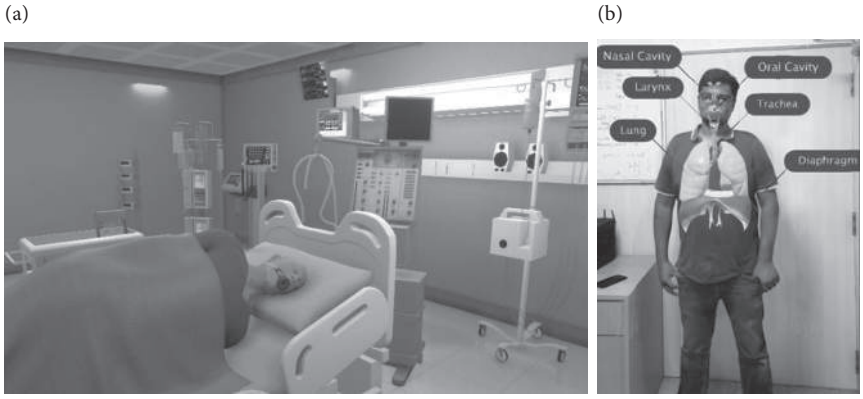


Figure 16.1. (a) A Virtual Reality scene as seen from a VR headset. (b) A screenshot from an Augmented Reality application showing the human respiratory system augmented over a person.

real scene, VR technology creates a convincing and interactive virtual world for the user.

Both VR and AR technologies sometimes include perceptual information across multiple sensory modalities such as visual, auditory (sense of hearing), haptic (sense of touch), somatosensory (pressure, pain, heat) and even olfactory (sense of smell). The goal of VR/AR technologies has been to provide immersive and near-real interactions in the virtual environment (Ha *et al.*, 2007). Multi-modal perceptual information improves immersion and takes the interaction closer to reality.

Our discussion clearly shows that VR and AR are based on the same computer graphics principles. While Virtual Reality creates an artificial environment to interact, Augmented Reality simulates artificial objects in the real environment. Mixed reality is another terminology commonly used in the field. We can think of Mixed Reality (MR) as the merging of real and virtual worlds to produce new environments and visualisations. Here, physical and digital objects co-exist and interact in real time. The interpretation of these technologies becomes apparent with the reality-virtuality continuum shown in Figure 16.2. Extended Reality (XR) is also commonly used in the field. It encompasses VR, AR and MR technologies. Since XR is an umbrella term, we will use XR to refer to the collective immersive technologies in the remainder of the chapter.

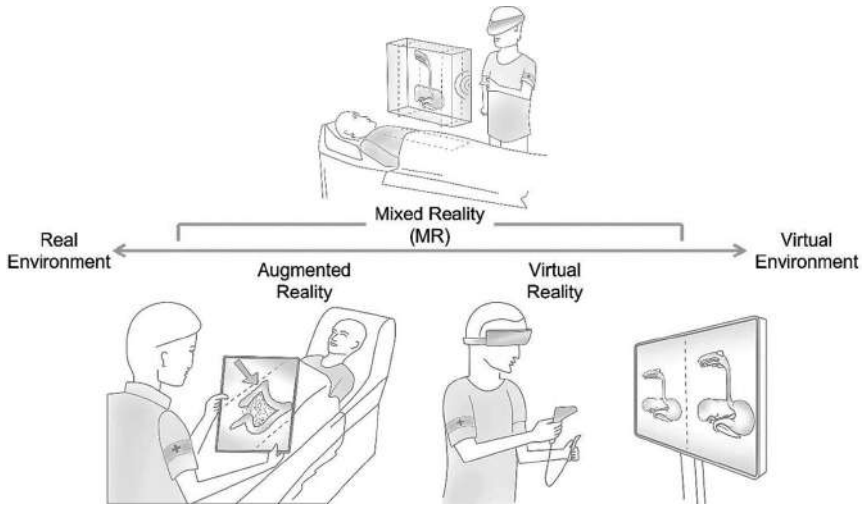


Figure 16.2. Real environment and virtual environment continuum: a concept proposed by Milgram and Kishino (1994).

Metaverse

Another paradigm that has taken prominence recently is Metaverse (Dionisio, 2013). In recent times, it has gained immense interest from videogame companies. However, the concept is not new; science fiction writer Neal Stephenson coined the term in 1992. Metaverse is a shared virtual reality space that users can access simultaneously using multiple devices. Because of the shared space, it holds great prospects for healthcare. Clinicians, patients and other stakeholders can come together on the meta virtual space for better access and improved care. This chapter will focus on XR technologies and treat Metaverse as a subset of XR.

The Technologies Behind AR/VR Solutions

This section will familiarise us with the hardware and software systems necessary for developing XR solutions.

Hardware

One of the first Head Mounted Displays (HMD) for AR/VR application was created in 1968 by Ivan Sutherland and Bob Sproull. It had complicated construction and restricted mobility. Ever since, the field has grown, and AR/VR headsets have become available for consumer use (Kugler, 2021). They require a computing unit to collect data from sensors and process output on display. Graphical Processing Units (GPU) are also commonly employed for high-quality display rendering. A variety of sensors such as Global Positioning System (GPS), accelerometers, cameras and infrared (IR) tracking devices help locate the user in the context of the simulated virtual environment, as well as the real environment. As many of these sensors are available on a smartphone, the use of the smartphone for AR modality is gaining popularity. Figure 16.3 shows examples of XR hardware devices with different modalities of use.

For head-mounted displays, one of the key differentiators in the AR/VR near-eye display is the use of optical combiners, illustrated in Figure 16.4(a). In most cases, AR systems require see-through possibilities. It is achieved either by optical see-through using optical combiners or video see-through using cameras on the head mounted display (See Figure 16.4(b)).

Combining real-world views with 3D graphics can be done by projecting the graphics through a partially reflective mirror and viewing the real world directly. This method is called optical see-through. Combining real-world view with 3D graphics digitally by taking video from a camera and merging it electronically is called the video see-through/pass-through method.

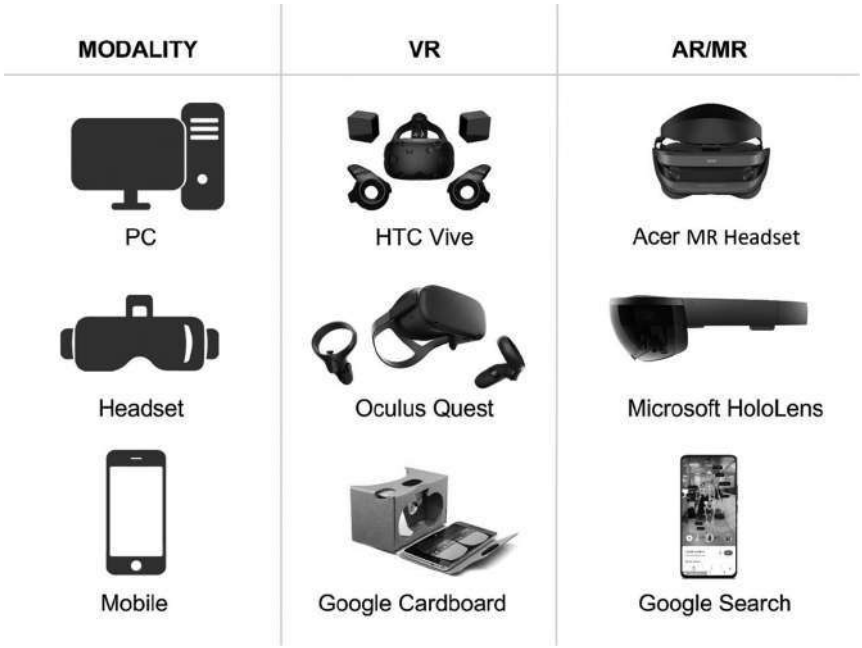


Figure 16.3. Hardware devices for AR/VR.

Software

The objective of AR/VR software is to design and render virtual experiences, referred to as scenes. These scenes are composed of virtual entities, and in many cases, they blend with real-world entities. Hence, when designing these scenes, it is necessary to understand the user's perspective on how they are expected to interact with the real and virtual entities in the scene.

The scene design process begins by creating mock-ups of the scene environment and how the user is expected to interact within the scene. In most cases, this is a textual or a pen and paper draft where a designer sketches out the basic elements of the scene. For example, to create a surgery room scene, the designer would create a mock-up of the surgery table, its placement relative to the instrument cart, which instruments are relevant, the lighting setup and so on. The main idea here is to convey the high-level objectives of the scene.

The scene designer then proceeds to engage a 3D modeller to create the necessary digital representations of the entities within the scene. These digital models are referred to as assets. This stage is referred to mostly as 3D modelling. 3D models, textures, animations and other art assets can be created using

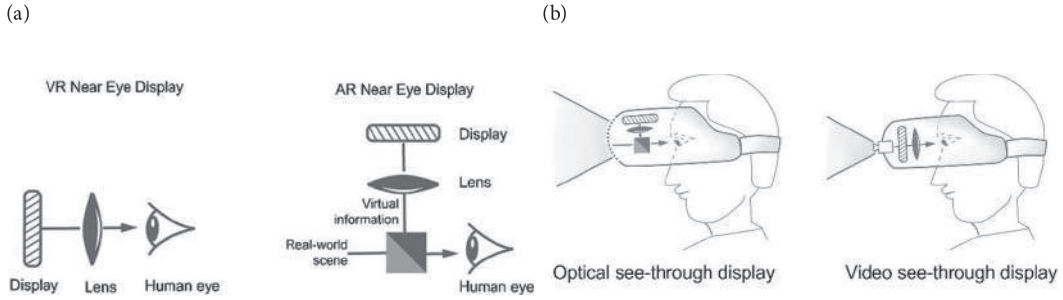


Figure 16.4. (a) Optical differences in VR and AR (b) Optical see-through and video see-through AR architectures.

Adobe products such as Maya or 3DS Max. Open-source 3D graphics software such as Blender is also popular for developing artwork for AR/VR. In our example, the modeller would create digital assets to represent the surgery table, the instrument cluster and so on. The modeller also designs the imagery and textures for these virtual objects.

The scene designer would then proceed to integrate these digital assets into a complete scene. Unity 3D and Unreal Engine are among the most popular AR/VR development scene design tools. The scene designer also decides other parameters including the lighting setup. One of the main functions of scene design is the design of user interactions with virtual entities. A basic expectation of interactive virtual entities is that they behave in a physically realistic manner. Hence, the designer needs to assign behaviour or response for the interaction of these objects in the virtual environment. These behaviours are often driven by physics simulation algorithms (referred to as a physics engine) that compute the interactions using laws of physics, usually Newton's laws. For example, in the surgery scene, if the designer decides to place a virtual pair of scissors in the scene with which the user could interact, then she would have to decide about the placement of the hinge joint and so on. When the user picks it up by one end, then the other end should dangle about the joint. This step of interaction design is tightly coupled with the underlying physics engine.

Scene design tools like Unity3D and Unreal Engine also have rendering technologies built into them. They build on the fundamental principles of lighting and computer graphics to deliver AR/VR imagery. This process of rendering is computationally demanding and requires specialised hardware (discussed above). These tools package the assets, physical properties, designed interactions and so on into an application that can be run on the hardware platforms discussed above.

At this point, it is important to register that XR technologies have their own set of challenges. Some people experience nausea, and others eye-strain from wearing head-mounted displays for long periods. The hardware is bulky and expensive, and the available applications are limited. Most applications lack multi-modal engagement, and the realism of VR systems is far from perfect. On the AR front, there are challenges in meshing and integrating virtual data with a real-world image. Latency and display lag are also issues for high-fidelity performance. Globally, research and development efforts are underway to solve these problems and provide an immersive experience for the user.

XR in Healthcare

Now that we understand the technology backbone of XR, let us look at its healthcare applications. Healthcare is an important sector for XR technology (van Genderen and Vlake, 2018). The AR/VR technologies market is maturing, with healthcare estimated to be the second biggest market after gaming for XR technologies. The excitement of clinicians around the technology and interest from the market shows XR's immense prospects for solving clinical problems. It will further be fuelled by advancements in technologies and increased collaboration among developers, researchers and physicians. Patient care is poised to get a boost with all these XR developments.

From the healthcare perspective, XR technology holds many advantages (Moro *et al.*, 2017), such as:

- Time and cost savings in educating physicians and caregivers
- Safe (for both clinicians and patients) training environment and mechanism for skill assessment
- Planning and rehearsing for medical procedures and surgeries
- Navigation aid and real-time data visualisation during surgery
- Remote medical assistance and collaboration for patient care
- Immersive treatment of challenging diseases (depression, phobias, etc.)
- Improved and faster response during rehabilitation and physical therapy.

The XR solutions for healthcare include a wide range of applications. These solutions can be broadly classified according to use-cases as education and training, diagnosis and planning, patient treatment, surgery and rehabilitation. Figure 16.5 illustrates the different use-cases of XR solutions in healthcare. We will explore these use-cases using examples. However, the applications are not limited; multiple AR/VR applications exist and many more are being developed for healthcare needs.

Education and Training

XR technologies have the most significant penetration in education and training for healthcare. Visualising the 3D human anatomy in an immersive way is possible with AR/VR. We already have solutions like Google's 3D search of the human anatomical system or a more complex holographic human anatomy model using Microsoft's HoloLens headset. Using these applications, a user can visualise everything from muscles to the tiniest veins in an immersive and interactive world. These technologies revolutionise medical

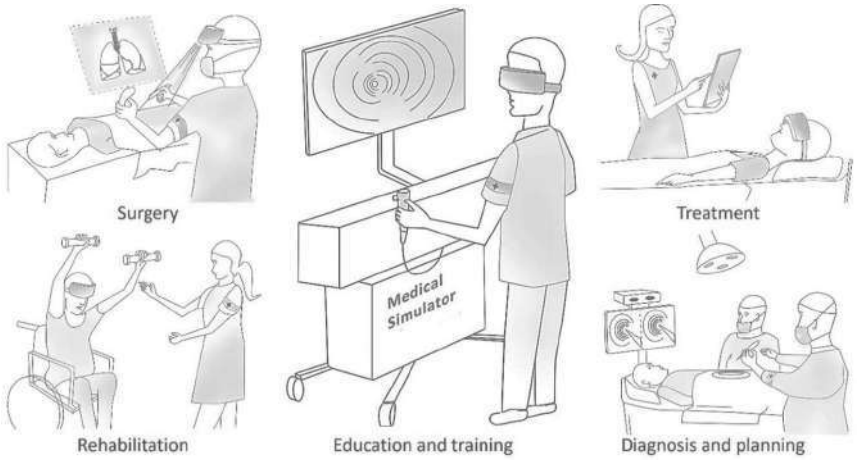


Figure 16.5. Illustration of XR solutions for different applications in healthcare.

education, as students can see and interact with these dynamic models instead of imagining from written descriptions or planar images in books.

Training in medical procedures using XR is also mainstream now. Immersive simulators have been integrated into several medical residency programmes. In one study, students trained on simulators were almost 30% faster in surgical dissections and made 80% fewer errors than their non-simulator trained counterparts (Grantcharov *et al.*, 2004). It is important to note that lack of training has serious safety concerns for patient care. A study published in the *New England Journal of Medicine* showed that lower-skilled bariatric surgeons had mortality rates five times higher than their high-skilled counterparts. Hands-on training is also essential (Seymour *et al.*, 2002). A study by the University of Michigan showed that 30% of surgeons could not operate independently after residency (George *et al.*, 2017).

Adopting simulation-based education has several advantages over the conventional 'see one, do one, teach one' learning. It provides for self-paced and self-directed learning with unlimited practice. Immersive simulations that have audio-visual and haptic feedback will help reduce the learning curve and achieve mastery of the skill. Just-in-time training with a VR interface also helps promote patient safety, especially during critical events.

Due to current technology challenges, open surgeries are difficult to simulate. The less restrictive scenarios in open surgeries require complex computations to simulate real-world surgeon–patient interactions. However, XR technology is more popular in Minimally Invasive Surgery (MIS). These MIS procedures restrict the interactions but require a high degree of skill

and hand–eye coordination. XR simulators for MIS procedures have shown great success in improving patient safety and being economical over the long run.

Example solutions: Simulators from Simbionix, CAE healthcare, Mimyk (Start-up), Medisim VR (Start-up), Merkel Haptics (Start-up).

Diagnostics and Planning

Medical imaging techniques have revolutionised diagnoses and patient care by allowing physicians to see the body's interior for clinical examination. Imaging modalities such as Computer Tomography (CT), Magnetic Resonance Imaging (MRI) and ultrasound images are commonly used by physicians for diagnosis or procedure planning. These imaging modalities manifest as planar images on the screen in most cases. Physicians must cognitively construct the 3D models of complex biological structures such as the brain, liver, spine and so on. XR offers an excellent alternative to these diagnostic methods. Clinicians can benefit from better spatial, distance and volumetric estimates using a 3D immersive environment rather than 2D screens (Bartesaghi *et al.*, 2015).

The progress made in XR technology has allowed for visualising complex anatomical structures or the specific 3D anatomical data for the patient being treated. These immersive visualisation solutions help in the planning of surgical procedures digitally. Medical errors are the third largest cause of death in the world. By enabling 3D visualisation and procedure planning, medical errors can be avoided. For example, consider complex neurosurgery where the instrument must be steered to a location without harming the tissue in the path. Surgeons can use immersive XR solutions to plan the navigation path digitally even before starting the procedure. There are also solutions that enable rehearsing of these procedures virtually. These planning and rehearsing techniques are shown to reduce errors and improve patient safety significantly.

Example solution: a VR planning system from Surgical Theatre, Cartosense (Start-up).

Treatment

Treatment is another area where XR technologies have shown immense potential. With XR solutions, patients can lower their pain and stress caused by medical procedures and conditions. These solutions help palliative care for painful treatments such as chemotherapy or for patients who suffer anxiety while undergoing other medical procedures.

XR is also used in the treatment of phobias or mental diseases such as autism (Lindner *et al.*, 2019). Some solutions allow children with autism to learn social skills. Several treatment methods use VR immersion to help patients get over the fear of heights, flight, animals and so on.

Example solution: a VR solution for palliative care from VITAS Healthcare.

Surgery

After training, surgery is one of the most active XR fields in healthcare (Satava, 1995). Immersive technologies can augment operation theatres with additional information during surgery. For example, consider a spine surgery where the patient's spinal structure is overlaid on the patient's body in the operation theatre. The additional information from the overlay helps the surgeon localise the spine structure and carry out the procedure safely. This additional information is usually drawn from pre-procedure imaging data such as CT. Apart from pre-procedure data, augmented information can also come from the real-time tracking of surgical instruments. Such assisted systems are common in minimally invasive procedures such as endoscope navigation, angio procedures, plastic surgery and dentistry (Farronato *et al.*, 2019). The real-time navigation information from tracking helps the surgeon control the instruments better and place the therapeutic instruments at the correct location. Apart from patient-specific information, assisted surgeries can help visualise the procedure better and eliminate the need for physical realisation of the anatomy.

Example solution: a see-through AR system from Xvision Spine System.

Rehabilitation

XR technologies are used in physical therapy or rehabilitation (Sveistrup, 2004). These technologies can help patients undergoing rehabilitation with long time repetitive routines. For example, the user can be slowly guided to perform repetitive routines after an accident or orthopaedic intervention surgery. These therapies can be more pleasant in an immersive VR environment. Moreover, a VR environment and 3D tracking of movements provide qualitative and quantitative feedback. The feedback allows for evaluating the progress of the treatment and correcting.

Example solution: a digital neurotherapeutics platform from Mindmaze.

Current Challenges and Future Opportunities for XR in Healthcare

Routine physical examination is usually the first point of interaction between healthcare professionals and patients. The physician proceeds with a series of steps to assess the patient's medical condition. XR offers significant opportunities and challenges for its use within the realm of such examinations. Let us take the general physical examination case to explore opportunities and challenges in XR.

VR in General Physical Examinations

In the application of Virtual Reality-based general physical examinations, there is a spectrum of opportunities and challenges. There have been significant advances in virtual reality application to simulation and training in these areas. Advancing these tools to clinical practice remains a challenge. However, the volume of general physical examinations is significant enough to justify the development of specialised technologies that make this process accessible. This is particularly true because general physical examinations are widely mandated for insurance and employment, among several other purposes. Such technologies can enable the application of quality healthcare practices at scale with significant opportunities for automation and standardisation. There are four primary modes of conducting a general physical examination (Swartz, 2020).

The first mode is an *inspection* where the physician looks at the patient or the body part in question to assess the general physical condition. Here, the current generation of XR technology can make significant immediate contributions where the patient's physicality can be represented in a virtual space. For instance, based on a real-time 3D reconstruction, using one or more RGBD cameras, it is possible to provide the physician with a virtual representation of the patient or a body part. Several years ago, such technologies already found their way into commodity gaming technology, such as the Microsoft Kinect gaming system. Such systems provide real-time gross reconstructions of players. While the technology pieces for such a modality are currently available, the challenge will be in providing a medically acceptable representation for assessment purposes.

The second mode is *palpation*, where the physician touches the body part to feel the size, consistency and texture of a body part. The technology to project such *haptic* feedback in virtual reality is significantly challenging. Several technologies, such as haptic gloves and haptic arms, have been developed. Here, the physician is virtually present next to the patient and can palpate the body

parts of interest. Furthermore, there is a significant body of work on haptic palpation simulation (Ullrich and Kuhlen, 2012). However, this technology is still premature from the perspective of it being two-way coupled in a virtual reality setting. Thus, the application of such devices is still in the research and concept stage.

The third mode is *auscultation*, where the physician places an auditory apparatus, such as the stethoscope, at various points on the patient's body to listen for anomalies. Current generation auscultation devices are relatively cost-effective. However, their integration into virtual environments, where their use is offered to a virtual physician, is currently not envisioned. The critical problem is in developing devices that can be manipulated in the context of the patient's physical reality by the physician within the context of virtual reality. There is a significant opportunity to extend low-cost medical devices such as stethoscopes to allow physicians to remotely articulate the device to get meaningful results from such devices. However, there will have to be some level of participation from patients to help in gross positioning and so on.

The fourth mode is *percussion*, where the physician taps the body parts of interest and feels and listens for fluid within organs or musculoskeletal reflexes. In physical examinations, it may involve the physician using their fingers or an instrument to carry out this examination. For this step, there are significant challenges in enabling the virtual physician to use one's fingers and get the precise haptic and auditory feedback required for the examination.

Safety and Security Aspects of XR in Healthcare

As XR systems communicate significant volumes of information between patients and healthcare providers, there is a need to ensure the safety and security of all participants and their data. While there are several risks of XR more generally, we focus here on this aspect of XR in healthcare.

Privacy in XR: confidential information is exchanged during any healthcare process such as examination and treatment. Extending this process to XR brings in the challenge of managing this information. XR sessions and the backend platforms need to have sufficient Information Technology (IT) checks and balances in place to ensure that there is no possibility of remote actors being witnesses to such confidential sessions. Implementing these checks is particularly challenging, as XR systems have evolved from gaming industries, where privacy concerns are of a lesser priority than connectivity and interactivity. XR sessions also need to consider the additional aspect that the users (both patient and healthcare providers) are immersed in a virtual world where they are less aware of their surroundings.

Familiarity with XR: the design of XR healthcare experiences needs to account for users who are generally not familiar with using these systems. Using the equipment for such sessions should be intuitive and straightforward. These considerations come under the realm of design thinking, where the process of educating the user is through interactive user flows and kinaesthetic actions rather than dry technical descriptions.

Limitations of XR: as a nascent technology, decision-makers need to be aware of the limitations of XR. Ultimately, all perception through XR is some form of digital reconstruction of the physical world. For instance, the representation of colour is often subject to significant transformations, even in natural lighting. Performing a medical diagnosis based on the colour representation does have in-built inaccuracies that the physician must be aware of before forming an opinion. Furthermore, given the heterogeneity of hardware and software systems that must coordinate to deliver an XR session, the representations can vary significantly across XR sessions. In general, the risks of such representations need to be understood and communicated upfront to all stakeholders.

Conclusion

At the beginning of the chapter, we asked whether AR/VR technologies are changing how clinicians and healthcare professionals care for patients. We started by understanding the terminologies used in immersive technologies. We explored the hardware and software fundamentals that enable the development of XR solutions. We looked at the advantages XR offers to solve clinical problems. These benefits were illustrated using examples classified according to use-cases. Although XR has challenges, the opportunity for solving clinical problems is immense. From this understanding, we conclude that XR is already reshaping healthcare and is poised to play an even more significant role in patient care.

- AR, VR, XR and MR are immersive virtuality technologies built on computer graphics principles.
- While VR immerses the user into a completely virtual environment, AR creates an overlay of virtual content.
- Advancements in hardware and software have enabled rapid development and adoption of XR technology.
- Healthcare is one of the most significant areas for XR technology.
- XR offers several advantages to healthcare in areas of training, planning, diagnoses and treatment, surgery and rehabilitation.

- Safety and security risks are to be considered while developing XR solutions for healthcare.
- XR technology offers immense opportunities to solve clinical problems and is poised to become mainstream in healthcare.

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Chapter 17

PROGRAMMED TO HEAL: HEALTHCARE ROBOTICS

Sameer Mehta and Venkatesh Munikrishnan

Introduction

Medical robotics is a relatively young field. The first robots were introduced globally in 1985 for surgical assistance via robotic arm technologies for a brain biopsy. India waited over 20 years for the first case of medical robotics (surgical intervention), for a radical prostatectomy in 2006 at AIIMS, New Delhi (Dogra, 2012). While robots are emerging as key components in fields such as automotive and industrial manufacturing, pharmaceutical manufacturing, and logistics and warehouse management, they are only now coming of age in the field of medicine and healthcare.

Today, robots are used in pharmaceutical and biotech drug manufacturing and discovery, surgical assistance, and in the form of care robots, exo-skeletons and hospital service robots. India today has over 100 patient-screening, telemedicine and cleaning robots, and over 70 surgical robots installed, with the most popular being the da Vinci Surgical System. One of the most significant game changers in a country like India, where healthcare infrastructure and clinicians are below WHO standards, is the capacity to undertake telemedicine and telerobotic surgery where the specialist doctor or surgeon may be sitting thousands of kilometres away from the patient.

This chapter will

1. Describe the areas of robotics in healthcare, and specifically in hospitals.
2. Examine the penetration of medical robots in Indian hospitals.
3. Explore the benefits of medical robots in healthcare.
4. Enumerate the different types of surgical robots across specialties.

The use of robots in the pharmaceutical, biotech and logistics industries do not fall under the scope of this chapter.

Types of Robots

Some key terminologies used in this chapter are explained below:

- Robots – any automatically operated machine that replaces human effort, though it may not resemble human beings in appearance nor perform functions in a human-like manner (Moravec, 2022).
- Artificial Intelligence (AI) – the ability of a digital computer or computer-controlled robot to perform tasks commonly associated with intelligent beings (Copeland, 2022).

Robots have different levels of penetration across multiple areas of healthcare across the multiple settings of the value chain.

- Drug discovery robots (rapid drug trials)
- Robots involved in pharmaceutical manufacturing
- Diagnostic guided robots with automation
- Surgical robots
- Customer touch or hospital robots; for example, telemedicine, concierge medicine, drug dispensing robots, cleaning robots
- Care or therapeutic robots; for example, rehabilitation
- Autonomous mobile robots
- Social robots

Robots have had significant penetration within drug and biotech discovery, and drug and consumable production. Surgical robots have had strong penetration and interest from across the clinical ecosystem: there are over 6500 deployed with Da Vinci (from Intuitive Surgical) accounting for 90% of this market. However, India only accounts for around 75 hospital installations – partially due to the cost, clinical training and limited benefit of labour arbitrage.

More recently during the COVID-19 pandemic, many hospital automation robots made a significant entry in telemedicine, drug dispensing and cleaning, with nearly 1000 robots installed across India. As customer convenience expectations, labour challenges and care setting logistics increase, this sector is expected to grow significantly.

Robots Are Big Business

The global medical robotic market is estimated at US$ 16.1 billion in 2021 and expected to grow at a compound annual growth rate (CAGR) of 17.4% from 2022 to 2030 (Grand View Research, 2022). Many of the world's top players have entered the medical and surgical robot space including Google,

IBM, Microsoft, iRobot Corporation as well as more familiar healthcare players like Intuitive Surgical, Johnson & Johnson, McKesson Corporation, Medtronic, Smith & Nephew, Stryker Corporation and so on.

Robotics in Clinical Healthcare

The introduction of robotics in the healthcare landscape is bound to have a lasting impact on how healthcare is delivered across the world. While complete automation is possible in certain clinical areas, the majority of the impact will be through augmenting surgical skills and technique in the operating room (Martin, 2020). This field of surgical robotics has undergone major changes in the last decade. Several specialty specific robotic systems have been introduced and even become mainstream.

What Is a Surgical Robot?

A surgical robot assists surgeons during surgical procedures. Robotic surgery is typically minimally invasive surgery and is also known as keyhole surgery. The current benefits of robotic surgery include enhanced visualisation owing to the 3D interface, tenfold magnification, better accuracy, precision, dexterity with wristed instruments (with 7 degrees of freedom), tremor filtration, scaled motion, haptic corrective feedback and improved ergonomics for the surgeon during procedures. These advantages help surgeons to perform precision surgery through smaller incisions. Surgical robots give surgeons full control over the camera for visualisation of the target area and perform the necessary manoeuvres with reduced tissue handling. The robotic instrument tips are much smaller and more dexterous than a human hand. They can record and filter out a surgeon's natural hand tremor and rescale movement to increase precision and reduce the chance for error. The advantages and disadvantages of robotic surgery are outlined in Table 17.1.

The Surgeon-Robot Interface

Typically, robotic surgery can be classified as either (a) supervisory-controlled, (b) tele-surgical or (c) shared-controlled. The supervisory-controlled approach is the most automated of the three methods. The RoboDoc from Integrated Surgical Systems Inc. is an example of a supervisory-controlled system used in orthopaedic surgeries. The initial planning and registration phase creates a 3D model using common imaging methods such as Computer Tomography (CT) scans, Magnetic Resonance Imaging (MRI) scans, ultrasonography, fluoroscopy and X-Ray scans which will best suit the patient. After the robot is positioned, the robot finds the best fit between the model and reality. The

robot then automatically cuts the bone to just the right size for the orthopaedic implant and the surgical procedure is performed.

The tele-surgical approach allows the surgical robot to be tele-operated, that is, operated from a distance by a human surgeon. The Da Vinci Robot from Intuitive Surgical is one of the most popular surgical robotic systems in the world and uses the tele-surgical approach. The robot and the surgeon are usually within the same operating room. Tele-surgery is also possible across larger distances. However, problems such as time delays (i.e. network latencies) and the available bandwidth (i.e. the amount of information that can be transferred per unit time) are challenges that need to be addressed.

The shared-controlled approach refers to the technique by which the robot can not only be tele-operated but can also resist the operator's intended movement using haptic feedback if the robot deems that it would not be beneficial.

Robotic Surgery Platforms

Use of Robotic Surgery in Surgical Specialities

There are several robotic platforms which are currently available for clinical use. The Da Vinci robotic system is the most widely used platform in the world. The newer platforms Hugo RAS from Medtronic or Versius from CMR

Table 17.1. Advantages and disadvantages of robotic surgery platforms.

ADVANTAGES	DISADVANTAGES
Stable platforms	Higher costs
3D vision	Larger equipment footprint
10x magnification	Longer operative time
Tremor filtering	Limited access
4 robotic arms	
Shorter learning curve	
Articulated wristed miniaturised instruments with 7 degrees of movement	
In-built Firefly technology which helps assess tissue viability	
Less physical stress on the surgeon thus increasing his or her professional longevity	

Surgical offer several different advantages which may make them attractive to prospective users.

Urological Surgery

The field of urological surgery has led the way for the adoption of robotics in daily surgical practice and research. Robotic surgery for prostate cancer (Robotic Radical Prostatectomy) has become the gold standard and is the most commonly performed robotic procedure around the world. The removal of the prostate gland for cancer from the bony pelvis presents a challenge to traditional laparoscopy; the robotic technique offsets these difficulties. Robotic surgery has been used for almost every urological procedure with excellent clinical outcomes.

Orthopaedic and Spine Surgery

The field of Orthopaedics and Spine Surgery presents a unique opportunity for robotic surgery. Some of the most commonly performed orthopaedic procedures include joint replacement with prosthetics and placing pedicle screws in spine surgery, both of which involve precise planning. There are several different varieties of robotic assistance such as Mako from Stryker and Mazor X Stealth from Medtronic. A Computerised Tomography (CT) scan before the surgery is used to plan exactly how much bone should be removed and to aid in maximising the accuracy of the alignment and placement of the implant. During the surgery, the robotic arm ensures that this plan is followed exactly – so that just enough but not too much bone is removed.

One of the most difficult aspects of joint replacement surgery is placing the individual components of the artificial joint in the best possible alignment. The robotic arm provides tactile, visual and auditory feedback to assist the surgeon in achieving the desired orientation, which can enhance stability and mobility. Similarly placing pedicle screws in spine surgery needs precise planning and placement. The use of robotic-assisted placement reduces the amount of tissues that need to be dissected and enhances recovery from the procedure.

Cardiac Surgery

About half of all robotic cardiac cases are coronary artery bypass procedures, the remainder being mitral valve and concomitant procedures. Several reports confirm low perioperative complication rates, reduced transfusion requirements, shorter ventilation times, reduced intensive care and overall

lengths of stay, diminished postoperative pain, faster return to normal activities and greater overall patient satisfaction.

Robotic cardiac surgery will evolve with higher-resolution visualisation, smaller instruments with lower profiles allowing for finer motor control and coordination, and the incorporation of haptic feedback into the platforms to facilitate faster, smoother operations, with consistently reproducible results. Continued innovation in robotics will undoubtedly translate into even broader application in cardiac surgery, with potential for its use in thoracic aortic procedures, paediatric cases and even in conjunction with transcatheter valve therapies.

Gastrointestinal Surgery

Robotic-assisted oesophageal surgery allows for improved visualisation, dexterity and precision, which are especially beneficial in a confined space like the chest. In upper abdominal surgery, the main advantage of robotics seems to be in procedures where better visualisation and highly fine dissection is required. Robotic surgery has its own well-documented learning curve, however, and reserving it for complex cases may not allow surgeons to gain familiarity with and confidence in this technology. As the technology evolves, the use of single-incision robotic thoracic surgery will offer additional benefits such as a smaller single incision and reduced pain. Ultimately, this progress will continue to lead to safer, less painful and oncologically sound operations for patients.

Colorectal Surgery is well suited for robotic assistance as it involves multiquadrant (the abdomen can be divided into nine different quadrants) surgery in the abdomen. Robotic Colorectal Surgery has clinically similar short- and long-term outcomes for patients compared to laparoscopic surgery but may decrease conversion rates, allow smaller, less painful incisions and improve technical ease for surgeons (Spinelli *et al.*, 2017). Robotic surgery can be a helpful adjunct during pelvic surgery, given the confines of the bony pelvis. Its use has been described in procedures for inflammatory bowel disease, pelvic organ prolapse and rectal cancer. The laparoscopic approach to rectal cancer may offer limitations in the pathologic adequacy of the resection while the robotic technique offers enhancement in the quality of surgery performed, particularly with its 3D visualisation, magnification and wristed instruments.

Gynaecological Surgery

The robotic surgical platform in gynaecology has allowed clinicians to improve their surgical abilities enabling general gynaecologists to overcome challenges

that are associated with laparoscopic surgery, and gynaecologic oncologists to perform more complex surgeries on uterine or ovarian cancer including dissections in retroperitoneal spaces.

Robotic Surgery Disadvantages

Robotic surgery presents several challenges. The robotic platforms have a larger footprint compared to standard laparoscopic equipment. The Operating Room (OR) suites need to accommodate the surgeon console, the robotic arms and the bedside carts. The limited OR space will be a constraint to many healthcare providers. The robotic platforms and the arms will need more space for movement during surgery to access the surgical field (Lanfranco *et al.*, 2004). A trained bedside assistant is required to perform a variety of tasks, including docking and undocking, instrument exchange, introduction and retrieval of surgical supplies (sutures, needles, staples, clips, gauze pads, etc.), and in some situations, provide additional exposure.

Another primary concern for surgeons is the absence of haptic feedback. Haptics is defined as the tactile feedback from the console to the surgeon's hand. Loss of touch sensation combined with the strength of robotic arms might lead to technical errors, increased operative times and learning curves. Lacking touch sensation feedback might lead to excessive use of force when handling tissues and cause inadvertent damage. Like with any other device that demonstrates advanced technology, the robotic platform has shown higher costs when compared with other approaches. The implementation of robotic surgery in an institution requires the purchase and maintainence of robotic supplies, both of which carry a significant economic burden for institutions. A systematic review showed that the robot results in higher costs of purchase and maintenance, as well as longer operative times. However, when a high number of robotic surgeries are performed, the procedure can be cost effective.

Risks from Surgical Robots

Increasing numbers of procedures are being performed using robotic-assisted platforms. Despite its benefits, procedure-specific complications occur in surgery including the preoperative, intraoperative and postoperative periods. Robotic surgery has no technology-specific surgery-related complications, but equipment malfunction and poor surgeon training might be associated with impaired patient safety (Muaddi *et al.*, 2021). Optimal equipment maintenance with continuous surgeon and robotic team training are essential to avoid complications. Regular audits on equipment failure and complications should be reported promptly to improve patient outcomes.

Conclusion

Robotic penetration across the world will grow significantly over the next ten years both globally and especially in India. Today, the surgeon operating at the console has to be physically located in the same operating suite as the patient and the bedside assistant. With the development of tele-surgery using robotic technology and incorporation of faster wireless network technology, distant remote surgery has become a true possibility. The evolution of simulation, virtual reality and augmented reality into robotic surgical systems will enhance the surgeon's capabilities in the near future.

We will also see the rise of indigenous robotic surgery and automation systems being developed and sold within the country, which should increase clinical and end user customer awareness of the benefits of robotic systems. With the rise of 5G communication availability and inflation of labour costs across the nation, we expect to see significant uptake of robots for surgical assistance, drone delivery and tele-medicine systems. By 2030, there should be well over 1000 surgical robots across India, including in many tier-II cities and government hospitals. By 2050, robotic penetration could represent over 15% of annual hospital capital costs with more than five robotic systems in large accredited hospitals and over 100,000 robotic systems across hospitals. Further, we expect robotic systems to have some interesting penetration across other areas of the value chain, with over 80% drug delivery using drones, autonomous vehicles and logistic transport systems.

This chapter has provided an overview of robotics in healthcare and the medical field:

1. It has explored the penetration of robotics across multiple areas of the healthcare value chain.
2. It has described the use of robotics in surgery specialties, including a description of the advantages, disadvantages and risks.

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Chapter 18

BEYOND BOUNDARIES: TECHNOLOGY FOR CARE ACROSS THE HEALTHCARE CONTINUUM

Kiran Mazumdar-Shaw

Introduction

Technology has played a truly transformative role in India's development. A country that had no phones in the 1970s has vaulted into one of the largest and fastest-growing markets for smartphones, with the number of users projected to reach 1 billion in 2026 (Business Standard, 2022). Technology can be a game changer for the Indian health sector. It can help leapfrog the traditional linear model and take healthcare to the next level. Telehealth and adaptive intelligence solutions can lower the barriers between hospitals and patients, thereby improving access to care and enhancing overall patient satisfaction, particularly in Tier II and III cities in India. Building a robust digital architecture that supports data platforms and data networks across the country will enable India to fulfil the vision of the national health policy: promoting wellness, universal access and affordable care for all citizens. This will entail policy changes to facilitate strong private innovation that can be deployed on public digital infrastructure for overall societal good.

As technology disruptively and rapidly transforms diagnosis, treatment, tracking and eradication of disease, tomorrow's healthcare will have no resemblance to what exists today. Advances in digital healthcare technologies and breakthrough innovations promise to not only improve the quality of healthcare but drastically reduce costs too. Smart and connected health has been proven to be one of the most effective strategies towards providing better healthcare at reduced prices. For India, technological innovations can deliver affordability and accessibility, enable preventive approaches and deliver value across the complete spectrum of the healthcare ecosystem.

To enable technological leapfrogging, India will need to focus on four areas: technology in pharma; genomics and nanotechnology; research,

production, storage and delivery; and e-pharmacies and telemedicine. This chapter will

1. Describe how technology is rapidly transforming the drug discovery and development process of the pharmaceutical industry.
2. Discuss how the pharmaceutical industry is leveraging genomic methodologies and tools to predict, diagnose and prevent diseases.
3. Obtain an overview of how digital tools are being implemented to create a stable, secure and responsive information technology backbone for pharma companies.
4. Understand how digitalisation is leading to improved efficiency in manufacturing and quality operations while enabling cost optimisation.
5. Recognise the impact of e-pharmacies and telemedicine in improving pharmaceutical services delivery in India.

Technology in Pharma

Technologies such as Artificial Intelligence (AI), automation and the Internet of Things (IoT) have percolated almost every aspect of healthcare today from drug discovery to drug development, thereby consequently improving the patient experience. Big data analytics are helping to catalogue, characterise and compare the properties of millions of compounds in silico, enabling researchers to speedily and affordably find the best drug candidates for a target.

The availability of genetic information, together with other phenotypic as well as medical information, is helping identify new drug targets by linking particular genes and their products to individual diseases. In addition to genomic data, other -omics data have moved into the spotlight. Proteomics and metabolomics, as well as epigenetics and an integrated view of all of these disciplines, are gaining more and more traction. The impact of lifestyle choices is also starting to be factored in.

On the other end of the spectrum, Electronic Health Records (EHRs) and other patient-related information in registries, hospital administration databases and payer databases are helping establish real-world evidence for the effectiveness of a particular medicine. Seventy-six per cent of Indian healthcare professionals are using EHRs in their hospital practice (eHealth, 2019).

We are witnessing a convergence of translational research in biomedicine, with disciplines such as public health, epidemiology, infectious disease modelling and data science all intersecting. Researchers today are relying on multiplexed data sets to make drug discovery and development more innovative, cheaper and faster. The multidisciplinary approach demands a reimagining of biomedical innovation.

Data Science

Drug discovery is capital-intensive, research-intensive and IP-intensive with inherently long gestational timelines. First, researchers must identify a potential therapeutic target. Then, a drug that acts on that target must be developed, purified and tested, both on cells in a petri dish and in living animals. In order to be approved, this new drug must meet rigorous safety specifications and pass through highly controlled phases of human testing. It could take up to a decade for a new drug to complete the "lab to market" journey, and cost over USD 2.5 billion (Spalding and Cortez, 2018). With a "1 in 10" success rate, the global pharmaceutical industry is looking at data science to enhance the probability of success and shorten timelines. Data science enables the pharmaceutical industry to throw off the shackles of the conventional one-drug-one-target-one-disease model of healthcare innovation, which is inefficient, expensive and time-consuming.

Drug discovery research today is bringing together cross-disciplinary teams comprising biologists, chemists, clinicians and data scientists. Data scientists draw on their expertise in computer science and statistics to sift through gargantuan virtual databases of molecular and clinical data to zoom in on likely drug candidates that treat key mutations. Bioinformatics, a specialised branch of data science, incorporates knowledge derived from genomics, proteomics and other biological disciplines into drug discovery and drug design in order to come up with revolutionary ideas for new molecules. In the wake of the novel coronavirus pandemic, scientists have extensively used Artificial Intelligence (AI) and data analytics tools to find treatments for COVID-19 quickly.

Artificial intelligence can analyse and generate new research hypotheses from increasingly massive datasets. This technology is speeding up the process of running scientific studies and drawing conclusions from them, including novel ways of developing safe and effective vaccines against diseases such as COVID-19. The Harvard T.H. Chan School of Public Health and the Human Vaccines Project launched the Human Immunomics Initiative in April 2020 (Harvard Gazette, 2020). This initiative is leveraging AI models to accelerate vaccine development by virtually testing potential vaccines and predicting which therapies might work best across populations.

The pandemic has led to the creation of several analytics platforms to systematically collect clinical, laboratory and diagnostic data from different sources globally, harmonise it and make it available for researchers worldwide to accelerate COVID-19 research and clinical care. This approach may help answer other research questions and serve as a model for addressing future public health emergencies. Data analytics can also be used to predict clinical outcomes, inform clinical trial designs, support evidence of effectiveness,

optimise dosing, predict product safety and evaluate potential adverse event mechanisms.

The Mazumdar Shaw Center for Translational Research (MSCTR), is working closely with clinicians at the Mazumdar Shaw Medical Center (MSMC) to facilitate translational research that will contribute to early detection, diagnosis and treatment of various human diseases by analysing the data generated through patients being treated at the hospital. Data science is therefore ushering in the next wave of drug innovation by promising to transform every stage of the new drug discovery and development process.

Digital Therapeutics

Going forward, we are likely to see increased demand for therapies that are patient-focused, data-driven and digitally enabled. Patient care will move to non-clinical settings driven by technology and connectivity, even as accelerated adoption of digital therapeutics empowers patients with point-of-care management.

Digital therapeutics can help people with diabetes by updating blood glucose levels in real time and sending patients alerts and notifications on the timing and quantity of their next dose of insulin. This technology can also help in connecting devices, where insulin is automatically released into the blood stream once the device detects spikes in the patient's blood sugar level. Digital therapeutics can make disease management a seamless and continuous experience for the patient.

As care delivery using digital technology becomes more pervasive, we are likely to see standard treatment guidelines becoming common. The availability of large statistically significant datasets would empower doctors to benefit from the power of big data in choosing the best treatment protocol for their patients.

Biocon Biologics' Global Collaboration with Voluntis on Digital Therapeutics for Insulins Aims to Personalise Treatment for Type 2 Diabetes Patients on Insulin

Biocon Biologics and digital therapeutics company Voluntis have in 2020 entered a global collaboration to develop and distribute a unique digital therapeutic solution that has U.S. FDA clearance and a CE mark to help manage the treatment of Type 2 diabetes with Insulin Glargine. The deal will make *Insulia* available to many Biocon Biologics' biosimilar

insulin users, and in the process, help transform personalised care in Type 2 diabetes.

Voluntis' *Insulia* is a prescription-only software medical device available on the web and on mobile app platforms and is intended for use by healthcare professionals and their Type 2 diabetes patients to support insulin titration for long-acting insulin analogs, such as Insulin Glargine.

Biocon Biologics aims to transform the lives of people with Type 2 diabetes by creating universal access to high-quality insulins at low costs, while also pairing its products with technologies that personalise treatment. The combination of affordable pricing with Voluntis' digital therapeutic capabilities will help drive a paradigm shift in Type 2 diabetes management, enable better patient outcomes and reduce costs to healthcare systems.

Digital therapeutic products, such as Insulia, have the potential to facilitate remote patient management and personalised treatment through high-quality, safe and effective data-driven interventions.

Genomics and Nanotechnology

Genomics

Genomics has created a new breed of life scientists and researchers who look at disease in a very different way from their older peers. It is no longer about treating symptoms but about understanding disease at a cellular and genetic level to deliver personalised diagnostics and therapies.

The seeds of personalised medicine were sown in 1998 at Mayo Clinic, Rochester, U.S., when a team led by Dr. Weinshilboum made a ground-breaking discovery that explained why a childhood leukaemia drug, Azathioprine, which proved efficacious in most children, caused fatality in some. The fatality was pinned down to a missing enzyme, TPMT (Thiopurine Methyltransferase) which led to the build-up of the drug and caused acute bone marrow failure. The missing enzyme was attributed to a faulty gene and thus began the era of "pharmaco-genomic medicine." Since then, a large number of commonly used drugs have been known to have variable responses thus questioning the "one drug fits all" approach taken by pharmaceutical companies.

In the West, genomic testing has become part of the healthcare lexicon as the cost of genomic testing has come down steeply. Today, whole genomes can be sequenced at a fraction of the cost of what it took to complete the sequencing of the first human genome. Genomic tests are being used in many key areas such as disease prevention, diagnosis and treatment.

Whole-genome sequencing has become a common tool for pathogen identification and tracking, establishing transmission routes and outbreak control. To study viral transmission and evolution using genome sequencing, the U.S. government set up the SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology and Surveillance (SPHERES), while the UK government established COVID-19 Genomics UK (COG-UK). India set up INSACOG as a national multi-agency consortium of genome sequencing laboratories in December 2020 to detect new mutant variants of SARS-CoV-2 in the country. In September 2021, the Indian government brought in private sector laboratories to significantly scale up genomic surveillance in the country to detect new coronavirus variants.

Genomic medicine is already making an impact in the fields of cancer, rare diseases and certain infectious disease. Targeted genome-editing technology like CRISPR CAS9 is allowing scientists to edit genomes with unprecedented precision, efficiency and flexibility for treating diseases. CRISPR, which provides a precise and cheap technology to "repair broken genes," will make it possible to treat several thousand inherited disorders caused by gene mistakes, most of which have no cure, such as Huntington's disease and cystic fibrosis.

Mapmygenome, a Hyderabad-based start-up founded by Anu Acharya, is offering a full range of tests to identify an individual's genetic predisposition to lifestyle, metabolic, cardiovascular, ocular, skin and hair, orthopaedic and gender-specific conditions. Combining genetic report and health history with genetic counselling, Mapmygenome helps people reduce health risks through lifestyle modification.

Advances in technology can further bring down the costs of genome mapping and gene editing, making these medical advances more accessible and affordable for patients in India.

Wider participation from stakeholders and scientific experts in both public and private sectors will increase the development and dissemination of genomic methodologies and tools for prediction, diagnosis and prevention of disease and contribute to improving the health of the nation.

Improved infrastructure and technology utilisation across channels can deliver faster and more integrated data and metadata to assist in using genomics surveillance for public health responses to fend off future waves of COVID-19 or other pandemics.

Nanotechnology

Nanomedicine, which combines nanotechnology with drugs or diagnostic molecules, holds tremendous scope in addressing specific healthcare needs.

Nanoscale devices smaller than 50 nanometers can easily enter most cells, while those smaller than 20 nanometers can move out of blood vessels as they circulate through the body (National Cancer Institute, 2022). Their small size allows them to readily interact with biomolecules both on the surface and within cells. Their ability to gain access to so many areas of the body allows nanomedicines to better target specific cells or tissues. Nanoparticles can also be engineered to transport and deliver or release drugs over long periods of time. For example, nanotechnology-based methods and materials have been developed for the early detection and diagnosis of cancer, as well as for treatment of the disease. Nanomedicine is also being used to treat HIV. Long-acting injectable nanoparticles that work as antiretrovirals are reducing the frequency of doses for HIV patients.

As this field advances, the research into integrating nanotechnology within medicine will enable development of innovative treatment regimens with lower dose frequency and less maintenance, which will assist with progressing the quality of patient care.

The Government of India, through its various agencies, is funding nanotechnology research in the country as it has applications in imaging, diagnosis and drug delivery as well as in combatting future pandemics. Agencies such as the Department of Science and Technology (DST), Council of Scientific and Industrial Research (CSIR), Defence Research and Development Organization (DRDO), Department of Biotechnology (DBT), Indian Council of Medical Research (ICMR) and Jawaharlal Nehru Centre for Advanced Scientific Research (JNCASR) are fostering research, skilling human resources, working with international partners and strengthening capacity for creating nano-enabled technologies.

In October 2019, the Government of India issued "Guidelines for Evaluation of Nanopharmaceuticals in India" to delineate quality, safety and efficacy assessment of novel nanoformulations. The guidelines are intended to provide transparent, consistent and predictable regulatory pathways for nanopharmaceuticals in India.

At that time, the government said that Indian researchers would be facilitated to undertake research in line with the regulatory guidelines.

> "The guidelines apply to the nanopharmaceuticals in the form of finished formulation as well as Active Pharmaceutical Ingredient (API) of a new molecule or an already approved molecule with altered nanoscale dimensions, properties or phenomenon associated with the application of nanotechnology intended to be used for treatment, *in vivo* diagnosis, mitigation, cure or prevention of diseases and disorders in humans," the government said in an official release (Press Information Bureau, 2019).

The guidelines will facilitate translational research in line with the regulatory requirements. The guidelines will facilitate decision-making by regulators for clearance of newer products based on nanotechnology, and also by researchers to obtain clearance for their products to launch in the market. End users will also be benefited by the quality assured of anticipated products in the market in accordance with the guidelines, it added.

Research, Production, Storage and Delivery

Many pharma companies in India, including Biocon, are trying to re-imagine the ways of working with the right set of technologies and innovations to usher in digital transformation within their organisations. Adopting industry 4.0 covers the whole gamut, from paperless records and automation of important processes, to implementation of Augmented Reality/Virtual Reality or advanced analytics and robotic process automation. Companies are automating some of the key processes that are carried out manually via robotics or advanced systems and rolling out dashboards across functions. Digitalisation is allowing these pharma companies to apply technology and gain better insights for decision-making with an objective of creating a highly patient-centric organisation. Fit-for-purpose technologies are increasing compliance, introducing efficient ways of working, reducing time to market and augmenting data security. The right digital tools are also allowing companies to unify and analyse data to gain meaningful insights and evolve towards unified and harmonised information at one's fingertips.

Pharma companies in India are already reaping the gains of digital technology use across the value chain.

Quality

Quality teams are implementing a digital platform called TrackWise, an electronic Quality Management System for GMP that brings all quality processes together in a single place and helps automate them.

The Scientific Data Management System is an automated data repository that automatically imports diverse data generated by instruments, scientists and outside sources into a centralised data repository. This information can easily be searched, communicated and shared.

The Laboratory Information Management System offers an efficient data management solution. By replacing manual data logging and maintenance, it decreases human error and provides a more accurate information system to support various decisions. It also provides an audit trail that automatically reduces the time taken for manual auditing.

The Validation Lifecycle Management System provides a paperless validation solution to digitise equipment qualification and Computer System Validation-related qualification.

R&D

Replacing paper-based processes with electronic workflows are improving efficiency, collaboration, compliance and data security. The Electronic Lab Notebook software offers the unique combination of experiment automation and procedure control in R&D laboratories.

Clinical Trials

To manage ongoing clinical trials, digital platforms enable sponsors to obtain consent remotely. It also empowers patients to take informed decisions through interactive multimedia engagement. These platforms also enable faster recruitment of sites and patients as well as remote monitoring of clinical trials.

The Electronic Trial Master File System allows for real-time management of all Trial Master File documents and processes and helps sponsors, CROs and sites work together to accelerate trials.

Data Analytics

Various Data Analytics tools in use by pharma companies today enable the distilling of information from a large bank of data related to efficacy, tolerability, safety profile of the investigational drug and patient safety. These analytical and visualisation tools improve the efficient management of information, simplify propositions, improve understanding of data connections and trends, and enable quicker decision-making.

Supply Chain Management

To continuously improve the efficiency of supply chain processes, pharma companies have introduced process automation. They are also deploying e-auction technology to engage chemical and solvents suppliers, resulting in transparent bidding and procurement decisions. These systems are being equipped to handle purchase order automation for market-volatile and price-sensitive material categories.

The deployment of the Digital Approved Supplier List tool is reducing documentation time and effort and providing information in real time.

Manufacturing

The execution of Online Factory Assessment Testing of new equipment is mitigating delays, while Augmented Reality (AR) tools in Drug Products manufacturing are re-designing the employee training experience, improving data capture, increasing adherence to SOPs and reducing human errors.

The "Remote Eye" technology platform allows remote viewing of manufacturing facilities in real-time to replicate physical inspection by regulatory teams.

E-Pharmacies and Telemedicine

To achieve universal health coverage by 2030, India will have to double its number of qualified health professionals. The latest National Sample Survey Office (NSSO) data show India has 20.6 doctors, nurses and midwives per 10,000 population and no more than 5.9 allopathic doctors. It lags behind the WHO 2006 recommendation of a minimum of 22.8 health workers, including 10 doctors, per 10,000 population. It is well below WHO's revised 2016 norms for 44.5 healthcare workers per 10,000 population, which is needed to achieve the UN's Sustainable Development Goals and universal health coverage. To get around the shortage of qualified health professionals, India will need to leverage digital health tools such as telemedicine and e-pharmacies in a big way.

Prime Minister Narendra Modi has launched the National Digital Health Mission, which makes every Indian eligible to voluntarily sign up for a Health ID, which can serve as a unified interface for all the healthcare records of an individual. The digital Health ID initiative can help India develop a universal healthcare system based on Electronic Health Records (EHRs) and e-Health Centres. This topic is covered in Chapter 2 titled *Health Data Going Digital: India's Ayushman Bharat Digital Mission*. Digital technology can provide innovative and effective solutions to help maintain good health in patients of chronic disease after the diagnosis is made or surgery is performed (Figure 18.1).

Having control of their own data through EHRs will empower patients and enhance their ability to easily identify what is in their best interest. Availability of longitudinal EHRs will make it easier for doctors and healthcare workers to a customised overview of everyone's journey. Investment in building a robust digital architecture will support healthcare platforms and networks across the country.

Technologies such as the use of voice-enabled records are emerging as a global best practice for improving the ease and reliability of data capture. One such app is mSakhi for frontline health workers in India. It is an open source

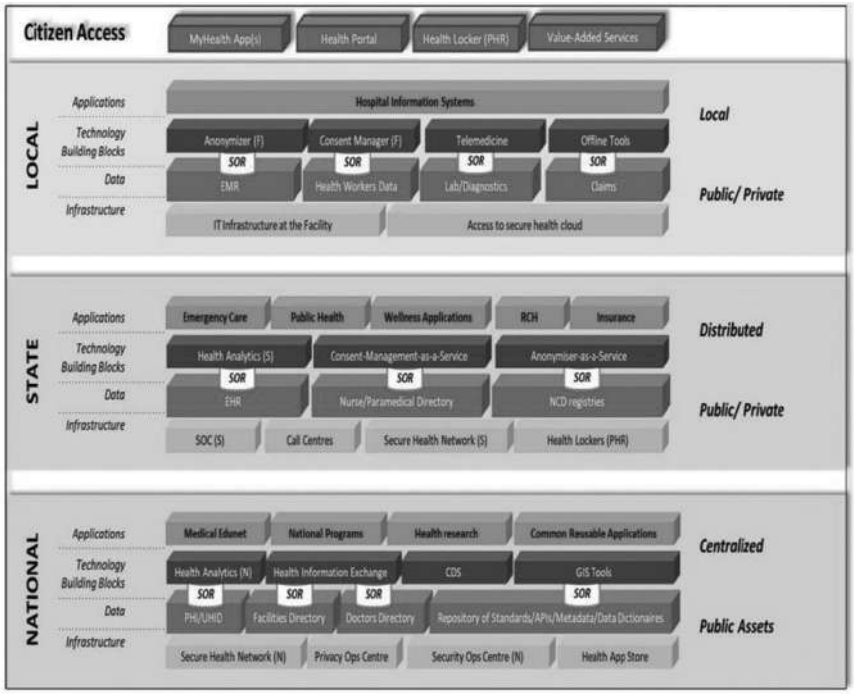


Figure 18.1. Federated architecture of the NDHM.

Source: National Health Authority

Android application that has helped digitise multiple paper-based tools and enabled health workers to gain access to the most up-to-date training, stay connected and report essential data.

Thanks to innovative start-ups, there is a wealth of available and in-development innovative technology which can fundamentally transform the way healthcare is delivered in the country. Moreover, mobile and point-of-care technology-enabled testing and screening modalities are replacing the more expensive traditional methods that require immobile equipment and specialist human technicians. Armed with such hand-held, affordable technological innovations, ASHA workers can provide screening, wellness and disease awareness services in remote areas of the country.

E-Pharmacies

During the COVID-19 pandemic, e-pharmacies ensured uninterrupted supplies of quality medicines at the consumer's doorstep. With increasing

mobile internet penetration and consumer literacy, e-pharmacies have grown rapidly over the past five years. In India, there was a lot of initial resistance to e-pharmacies. However, with COVID-19 creating opportunities for use of technology in daily life, e-pharmacies have become almost indispensable. Realising the critical role of online pharmacies during the crisis, federal and State authorities in India issued orders recognising medicine delivery through e-commerce as an essential service. Moreover, the Government of India is reportedly working to bring a new law to monitor new retail avenues and regulatory demands that have emerged in recent years. The proposed new law will replace the existing Drugs & Cosmetics Act, 1940, and will comprehensively address areas such as medical devices, hospital equipment, e-pharmacies and so on, according to media reports (Dey, 2021).

On the back of rapid advancements in technology and logistics services, e-pharma services are now spreading beyond urban areas. A FICCI study has projected that 70 million households are likely to use e-pharmacies for their medicines by FY25.

In addition to improved availability, online pharmacies introduce an additional element of safety. Handwritten prescriptions have often been known to lead to problems related to poor handwriting and wrong doses. In addition, the medications provided by the pharmacy are dependent upon the availability of the appropriate brands (which is influenced by channel margins, etc.). With the right kind of regulations, online pharmacies can eliminate many of the inadequacies in the last mile delivery of drugs.

Going forward, the government should articulate simple and clear rules that allows innovation to thrive in the e-pharmacies space, which will ensure the timely availability of affordable medicines in even the remotest parts of the country.

Telemedicine

The implementation of a modern ICT-based healthcare system in India will help leverage modern diagnostics in primary healthcare for early detection and treatment, with telemedicine bridging the deficit of specialists at the primary care level. Such a system can also be used for cloud-based data collection to collate epidemiological and patient-centric data to profile and map the disease burden at the level of the smallest administrative unit. A robust mobile phone infrastructure that allows fast and cost-effective data sharing will allow well-trained specialists to treat patients in far-flung, distant parts of the country using telemedicine.

Comprehensive databases and disease registries will enable better evaluation of the incidence and diversity of diseases at an epidemiological level

and thereby allow for more effective healthcare interventions. This can, in turn, ensure equitable access to healthcare services of assured quality, safety, efficacy and cost effectiveness to all sections of the society.

An ICT-based health delivery model will need strong integration between primary and tertiary care providers. Also, linkages need to be established between health research and national health programmes to ensure that research findings are leveraged in decision-making in public health.

The power of ICT and medical technology in the public healthcare sector can bring in transparency, efficiency and accountability, leading to a more effective healthcare system.

The pandemic has nudged both patients and doctors into adopting telemedicine solutions and moving to online consultations. In fact, data show a dramatic increase in the volume of telehealth visits in 2020 as patients sought to safely obtain outpatient care over the Internet.

The Medical Council of India, in partnership with the NITI Aayog, has released the Telemedicine Practice Guidelines, 2020.

Telemedicine can prove to be a game changer for healthcare delivery in India.

BOX: Biocon Foundation's eLAJ Smart Clinics Helping Strengthen Primary Healthcare Delivery in Rural Areas

Primary healthcare is a vital strategy that remains the backbone of health service delivery. Keeping this objective in mind, Primary Healthcare Centres (PHCs) were envisaged as a critical component to improving care at the grassroots level, providing promotive and preventive healthcare services as well as health education. As of 31 March 2019, India had a network of 24,855 PHCs in rural areas and 5,190 UPHCs in urban locations. These centres epitomise last-mile healthcare delivery, covering maternal and child health services, all major national health programmes, along with the provision of free essential drugs and diagnostic services.

Primary healthcare services overlap with those of Universal Health Coverage (UHC). However, UHC in the Indian context is a work in progress. Despite notable progress in the past three to four decades, there are still gaps in the PHC delivery system. Common challenges include shortfalls in infrastructure, supplies and personnel, resulting in poor quality of care. Owing to these gaps in PHC services, people either seek healthcare in outpatient departments of government hospitals or mostly go to private hospitals. The consequences of weak primary

healthcare are evident in poor health outcomes, delayed care and expensive hospitalisations leading to increased out-of-pocket expenses. The COVID-19 pandemic has brought these gaps into the spotlight, highlighting the need for renewed and innovative steps to address the multi-level challenges.

The NITI Aayog, in its vision paper titled "Public Health Surveillance by 2035," outlined three major threats to public health including Noncommunicable Diseases (NCDs), re-emerging and new communicable diseases and antimicrobial resistance. The report highlights several challenges including a limited focus on NCD surveillance with a need for a comprehensive picture that would combine health records with periodic surveys for risk factors and disease prevalence.

The report goes on to suggest that a predictive, responsive, integrated system of disease and health surveillance would be founded on robust electronic health records and data analytics with advanced health informatics.

Against this background, it is evident that multi-level interventions are required on a sustained basis. The adoption of Electronic Health Record (EHRs) or Electronic Medical Records (EMRs) by healthcare providers can ensure more effective and comprehensive delivery of care. Collection, storage and use of medical records would ensure evidence-based care and accurate and faster diagnosis, which in turn would translate into treatment at lower costs, increasing efficiency, avoiding unnecessary investigations, reducing errors and enabling robust analytics. Furthermore, EHR systems help in maintaining the continuum of care and public health surveillance by assessing disease trends and disease profiles of different communities. It empowers decision-makers to assess and manage interventions, thus providing the possibility of enormous advances for public health practice and policy. Therefore, EHR systems are of paramount importance in improving patient care and outcomes at all levels.

With these objectives in mind, the eLAJ Smart Clinic programme was rolled out by the Biocon Foundation in 2016, in partnership with the Government of Karnataka, as a proof of concept to demonstrate the potential of Information and Communication Technology (ICT)-based tools to refine the quality of healthcare. The eLAJ programme was structured with the perspective of supporting the PHCs, by leveraging

technology to improve data capture, enhance quality of care, and specifically address the burden of NCDs.

Developed in-house by Biocon Foundation, this real-time health information system has been adopted in three private clinics of Biocon Foundation, and twenty government PHCs in Karnataka, through a Public–Private Partnership (PPP), catering to a population of more than one million across seven districts of Karnataka.

Focused on individual patient needs, the innovation stores patient records and facilitates seamless information flow to improve physician productivity and operational efficiency. It promotes opportunistic screening in routine clinical practice. These eLAJ clinics utilise trained laboratory technicians, haematology and biochemistry testing equipment and other high-quality diagnostic capabilities.

The eLAJ dashboard improves analytical capabilities as it organises massive amounts of information into actionable insights in real time. The longitudinal patient data facilitates preventive actions against NCDs and enables risk factor surveillance.

As part of the eLAJ model, frontline workers securely capture demographic and clinical data at the community and household levels, thereby enabling syndromic surveillance. In keeping with the NITI Aayog's Vision 2035, rather than episodic interventions, our eLAJ centres are focusing longitudinally on quality and outcomes of care.

Apart from the provision of EHRs, the focus has also been on improving human resource availability and enhancing diagnostic capabilities.

In keeping with the NITI Aayog's vision 2035, the scope of the EMR is being expanded to include standard treatment guidelines and training modules for oral cancer screening as well as NCD surveillance formats, which also aligns with the National Health Mission Guidelines. To improve traction on the EMR services, data entry operators are used at the point of registration and clinical examination. Additionally, advanced laboratory diagnostics, handled by the foundation-appointed lab technicians, can perform more than 50 tests for comprehensive primary healthcare delivery.

The eLAJ model has proven to be relevant, agile and robust in its response to the pandemic, and the several lessons gleaned will be incorporated to enhance the services and serve the communities in an outcome-oriented, equitable and inclusive manner in the post-Covid world.

Conclusion

The COVID-19 crisis has accelerated the digitisation of several sectors, from e-payments to e-commerce and e-learning to e-government. The pandemic saw the advent of mass scale platforms like CoWin and Arogyasetu that have combined mobile phones, individual IDs and OTP-based verification to capture key diagnostic, vaccination and outcome data, which are perhaps the most advanced databases in the world. Software and data analytics have enabled us to track and trace COVID-19 infections and vaccination doses as well as re-infections linked to sequenced variants, providing us with strong surveillance-based COVID-19 management. This has truly spearheaded digital disruption in healthcare delivery which must continue beyond the pandemic. We must leverage these powerful digital platforms beyond COVID-19 to manage both communicable and non-communicable diseases in real time.

The pandemic has accelerated innovation, catalysed technological breakthroughs and created a fertile environment for the emergence of low-cost innovations anchored in affordability and accessibility. At the same time, it has forced changes in consumer behaviour, persuaded doctors to become tech-savvy, prompted pharma companies to invest in digital therapeutics and pressured governments to bring in more flexible healthcare-related regulation. The accelerated digital transformation will see greater implementation of new technologies in the healthcare industry next. Greater use of digital technology in the delivery of healthcare can not only provide consistent level care at a larger scale, but can also make healthcare accessible to the most economically disadvantaged individuals in the population.

India will need to make exponential investments in R&D, manufacturing and digital transformations to become a global pharmaceutical innovation hub as well as achieve its vision of self-reliance in pharmaceuticals and biopharma. It is here that the government can play a key supporting role. To reap the benefits of technology, India will need to make a coordinated effort in terms of policy, technology and finance with the ultimate goal of ensuring universal access and affordable care to all Indians. With the right kind of policies and fiscal incentives, the health sciences and healthcare industry can emulate the IT industry's success and transform India into technology-led leadership in healthcare.

- Artificial Intelligence, Automation and Internet of Things have percolated to almost every aspect of healthcare, from drug discovery to drug development.

- Data science is enabling the pharmaceutical industry to throw off the shackles of the conventional one-drug-one-target-one-disease model of healthcare innovation.
- Genomics has led to the understanding of disease at a cellular and genetic level to deliver personalised diagnostics and therapies, and is already making an impact in the fields of cancer, rare diseases and certain infectious disease using genomic information about an individual as part of their clinical care.
- Nanomedicine, which combines nanotechnology with drugs or diagnostic molecules to improve the ability to target specific cells or tissues, also holds tremendous scope in imaging, diagnosis and drug delivery as well as in combatting future pandemics.
- Digitalisation can help companies become more efficient in terms of execution, cost, level of accuracy and speed. It can make them future-ready.
- Digitalisation and automation are enhancing productivity, improving quality, increasing safety, speeding up delivery, reducing turnaround times and cutting manual intervention and errors.
- Application of data analytics will provide superior insights for better decision-making with an objective of creating a highly patient-centric organisation.
- With increasing mobile internet penetration and consumer literacy, e-pharmacies have grown rapidly over the past five years.
- With the right regulations, online pharmacies can eliminate many of the inadequacies in the last-mile delivery of drugs.

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Chapter 19

CUTTING-EDGE CARE: FUTURISTIC HEALTHCARE TECHNOLOGIES OF THE NEXT DECADE

Ajit Isaac

Introduction

This chapter explores the role that health technologies play in creating scalable and sustainable healthcare ecosystems in the next decade. The need to create quality healthcare infrastructure is critical and must be achieved quickly without compromising the safety and quality of care. While keeping the patient at the core of this concept, this chapter explores the advent of ethical, scalable, affordable and transparent healthcare technology innovations. The learning objectives of the chapter are to:

1. Study the emerging trends in futuristic technologies.
2. Explore the impact these technologies will have on patient care, drug development and healthcare capacity building.
3. Discuss the impact of digital health technologies on the future of medical specialties.
4. Use future state healthcare models to examine how futuristic health technologies can improve access to quality healthcare for all and work towards the sustainable development goals of ensuring universal health coverage, better health and well-being, and access to support during health emergencies.

Futuristic Technologies for Healthcare

The world was brought to its knees with the COVID-19 pandemic in 2020. While some countries had stable and robust healthcare systems to accommodate the health requirements of their residents, several developing countries witnessed their healthcare infrastructure crumbling before their very eyes.

At a time when healthcare technologies are advancing rapidly and several futuristic technologies are on the horizon, how prepared are we to welcome them? Whether we accept it or not, futuristic health technologies are set to change the face of healthcare as we know it, making it more accessible, safe, reliable and more importantly, affordable.

The COVID-19 pandemic brought a new wave of challenges and perspectives to our existing healthcare systems. What "was" before the pandemic is not what "is" or "will be" in the future. The healthcare industry was one of the few industries that had to evolve while holding the burden of the pandemic along with its existing burden of care, and enabling humanity to see the light of day.

While the pandemic exposed the raw skeleton of healthcare systems across the globe, it has also been instrumental in accelerating several technologies and bringing them to fruition in a shorter time than anticipated. Today, there have been significant advances in technology that can support the high demand for access to healthcare and the need for digitisation and protection of healthcare data. With more and more people accepting the integration of technology in healthcare, several new technologies have come to the fore.

With newer technologies entering the healthcare space, it is important to keep up with the latest trends and integrate these into our existing healthcare system. At any point in time, the focus of healthcare technology is to improve the accessibility of care, improve the performance and productivity of healthcare processes and teams, improve efficiency at all service levels and ensure the security of data while keeping it accessible and reliable.

Health Technology Innovations

AI-Driven Healthcare

The human mind is the most superior one on the planet. While humans are busy teaching machines to become humans, machines are already adept at analysing and deducing inferences from their data. When the speed of the machines is combined with the human mind, the processes become faster, more reliable and much more efficient than is humanly possible. This is how AI is a value addition. A simple example of the potential of AI is how IBM Watson can ready over 400 million documents in just 15 seconds (Das, 2016).

Apart from speed, AI can be used to develop applications to help clinicians and radiologists make precise and accurate decisions, suggest treatments and drugs that have therapeutic potential for a patient and help in data mining from existing health records to improve healthcare service delivery.

AI technology has advanced rapidly in recent years, and this trend will continue. While AI-drive healthcare technologies help greatly with diagnostics and detection of diseases, its applications extend much further. For example, IBM Watson, an AI platform, is suitable for both business and healthcare (including custom medical software solutions).

AI has a high chance of becoming the primary health tech trend in future years.

- **Computed Tomography (CT) scan analysis**: AI algorithms can swiftly process CT scans of thousands of patients, evaluating pneumonia patterns caused by COVID-19, compensating for a shortage of skilled human resources in this field. Imaging COVID-19 was established as a deep learning model for automated detection of COVID-19 patterns on CT scans. It is also used for confirming existing diagnoses or enriching research data.
- **Machine learning in biopharma:** From potential medication for the treatment of obsessive-compulsive disorder to possible cures for rare and dangerous diseases, promising formulas have been discovered because of AI-enhanced lab experimenting. Many innovative projects use AI and machine learning methodologies to augment chemical experiments and medical drug research, including molecule modelling and simulation of chemical reactions under multi-factor environments.

  AI has been integrated with advanced CT scan machines to help detect pneumonia in post-COVID-19 patients. Microsoft's Project InnerEye, a radiotherapy AI tool, speeds up the process of the 3D contouring process, bringing down the process time from hours to minutes.

  Another example of AI's prowess is Project Hanover, a Microsoft AI system developed to catalogue biomedical research papers from PubMed. This reduces the time for clinicians to go through several thousands of papers before arriving at a diagnosis and prescribing the most effective drugs for a patient.

  US pharma giant Pfizer is working with IBM's Watson AI and uses machine learning in their immuno-oncology study to understand how the human body's immune system fights cancer.
- **Robotics to automate hospital workflows**: With start-ups investing hundreds of millions in the development of AI projects, including different robotic systems, it will help with the shortage of nurses and clinicians due to the pandemic and bring down the hiring costs of hospital staff.
- **Symptom checker chatbots**: Chatbots are now widely used across the healthcare and medical consulting industries. It is accessible 24/7 online

on multiple devices and capable of preliminary medical diagnostics and health advice based on a patient's symptoms. It can also be integrated with patient portals at hospitals and clinics.

- **AI against COVID-19**: Cutting-edge technology like AI helped us stay ahead of the curve during the several waves across the world. From scanning media sources to determine real-time outbreaks of COVID-19 cases to machine learning advances deployed in vaccine development, AI has been a boon during the COVID-19 pandemic.

  AI has also been instrumental in vaccine development in a very short period, thermal screening for identifying symptomatic individuals, facial recognition software that helped identify individuals even with a mask and flagging people who did not wear a mask where it was mandatory (Tsymbal, 2022).
- **AI for mental health:** AI is not just beneficial for improving a patient's physical health but has also been helpful in mental health services. Researchers at MIT and Harvard have used AI and machine learning to track symptoms and mental health in people during the COVID-19 pandemic. Using a highly efficient AI model, the researchers were able to analyse thousands of online Reddit messages to find topics and answers related to suicide, loneliness, depression and so on. This helped the researchers with the ongoing trend in large populations (Low *et al.*, 2020).

Nanomedicine

Nanomedicine is a new branch of medicine that uses the knowledge and tools of nanotechnology for the prevention and treatment of diseases. It uses nanoscale materials, such as biocompatible nanoparticles and nanorobots to diagnose or treat living organisms. This technology is also now used to treat many genetic, oncologic or auto-immune diseases on a cellular level, including tumours, arthritis and so on.

Advances in several allied health fields such as genetics, molecular and cellular biology, material science, biomedical engineering, proteomics and so on have contributed to the development of nanomedicine that deals with the physiological processes at a nanoscale level.

Nanomedicine carries huge potential for the future of healthcare as the cellular functions naturally occur at the nanoscale. It is also interesting to note that biologically significant molecules like water, antibodies, glucose, receptor proteins, enzymes and haemoglobin are all within the nanoscale. For this reason, several researchers and scientists are currently working on treatments, devices, tools and instruments that deploy nanotechnology in medicine to improve the efficacy, sensitivity, safety and personalisation of care provided to patients.

Using nanotechnology in medicine shows the potential to improve the bioavailability of drugs, reduce the toxicity of drugs and chemicals, improve dosage response of the drug, and increase solubility compared to conventional medicines used.

Nanotechnology can be used to design drugs that provide controlled release of the required dosage in response to a trigger that is remotely placed or site-specific. An example of this property of drugs manufactured using nanotechnology is a mildly acidic environment inside an inflammation or tumour tissue that can be used to trigger the release of the said drug.

Nanomedicine offers several advantages over conventional medicines:

- It has the potential of being a non-invasive tool for diagnostic imaging, tumour detection and drug delivery.
- It is likely to show improved efficacy and safety over conventional medications.
- Drugs with low bioavailability can now be directed towards the target site using nanomedicine.
- The large surface area and higher reactivity of nanoparticles allow dose reduction of drugs, which subsequently improves toxicity profiles and patient compliance.
- The greater surface area of nanoparticles also increases the saturation solubility, dissolution rate and intracellular uptake of the drugs, thereby enhancing their efficacy.
- By combining encapsulation, release modalities and surface modifications, drugs manufactured using nanotechnology may have seven times greater efficacy than their bulk counterparts.
- Targeted nanoparticles can be used to transport large doses of drugs or therapeutic agents into malignant cells without damaging the healthy surrounding cells.
- Multifunctional nanoparticle complexes can allow for simultaneous non-invasive targeting, imaging and treatment monitoring.
- Multifunctional nanoparticles with fluorescent dyes provide *in vivo* imaging of biological events that occur during drug administration and diagnostic labels for the early detection and localisation of tumours.
- The latest research is also focused on developing magnetic nanoparticles that target both diagnostic and therapeutic agents.
- Nanotechnologies have been used in genetic and biological analysis using devices that assess molecular biomarkers. These tests using nanoparticles are quicker, more reliable and cost-effective than other diagnostic alternatives.

Existing research shows the tremendous potential of nanotechnology and nanoparticles in the diagnostic, imaging and therapeutic segments. Diagnostic

devices developed using nanotechnology are much more sensitive and can detect the earliest signs of metabolic imbalance, often indicating chronic illnesses such as obesity and Type 2 diabetes.

Continued updates and advances in nanotechnology can lead to better and more affordable technology that opens up avenues for enabling the routine practice of personalised medicine, especially in treating diseases such as cancer.

Though nanotechnology has been around for a few years and several drugs using this technology have been approved and marketed, several drugs are still under clinical trials or preliminary testing. Nanomedicine offers tremendous potential for early diagnosis, safer and more effective and personalised treatments, with accessible and affordable healthcare costs. Nanomedicine can revolutionise healthcare within the next decade.

Internet of Things (IoT) and Internet of Medical Things (IoMT)

Wearables and IoT-based technologies are becoming increasingly popular and have dominated the wellness space in recent years. This sector has grown significantly with companies like Fitbit, Garmin and Apple entering this space with their wide range of fitness trackers and smartwatches. What began with helping people lead healthy lives and motivating them to stay active, have today become tools used for telehealth and telemedicine technologies, enabling easy integration with various software and applications. This led to the development of IoMT.

In 2021, there were around 12.2 billion devices connected to the internet (State of IoT, 2022). According to industry estimates, the medical and wearable devices market will reach USD 94.2 billion by 2026 (Markets and Markets Report, 2021). Recent times have seen significant innovation in Medtech and the emergence of numerous connected medical devices that can generate, collect, analyse and transmit data. IoMT comprises this connected infrastructure of medical devices, software applications and health systems and services.

IoMT is a promising sector with the potential to grow exponentially in the coming years. There are several IoMT solutions out in the market today that provide the option to design and customise one's IoMT system according to one's needs.

- **Wearables and Mobile Apps in Medical Practice**

Remote health monitoring and wellness apps enable synchronisation with wearables such as pulsometers or fitness trackers. One can collect data through the sensors in the wearables and analyse one's health conditions such as pulse, body temperature and blood pressure.

Wearables are one of the most revolutionising inventions of current times and have given the healthcare industry several new dimensions to collect data, analyse data, obtain data points directly from individuals, maintain data security and gather deep insights into people's lifestyles and how it affects their health.

The ability to virtually monitor an individual's health throughout the day was unthinkable before wearables were introduced. While some people choose to avoid these devices, a survey by Deloitte found that nearly 41% of participants owned a smartwatch (Deloitte Insights, 2022).

Wearables provide different data points such as an individual's heart rate, physical health determinants like blood oxygen levels, number of steps walked, the type of exercise performed and so on. Blood oxygen saturation levels can be detected using pulse oximeters. The ability of wearable devices to monitor these levels in the wearer throughout the day enables them to send a warning when the levels fall below a certain mark. Wearable devices can send SOS messages to the caretaker or the individual's physician and save lives!

The latest wearable devices use photoplethysmography, which enables the device to measure variations in an individual's blood composition and volume. Constantly monitoring and storing the vital health parameters of an individual can shed light on the risk for certain diseases, the progress of treatment and prevention conditions.

While watches and fitness trackers primarily dominate the wearables segment, smart hearing aids and biopatches are also being used. AI has been used in smart hearing aids to improve noise cancellation and isolation.

- **Smart autonomous devices in healthcare**: With the pandemic outbreak, the exposure to infection risks has risen in the healthcare sector. Autonomous robots or self-moving smart devices are a boon to the medical staff, reducing their workload and exposure time.

Apart from the uses of IoT in healthcare, another revolutionary concept is that of smart pills. Smart pills transform IoT into the internet of bodies and are essentially edible electronic devices with pharmaceutical uses and provide valuable information about the patient's body. The first smart pill to be approved by the FDA was released in 2017 (Wamsley, 2017).

Smart Implants

In the coming years, we can see more implant-related technologies, including **3D bioprinting technology** and neural implants entering the healthcare market globally. Smart implants can improve the efficiency of regenerative

medicine and patient rehabilitation and can be a cure for different disabilities that have previously been considered incurable.

Smart implants are implantable medical devices with one or more sensors that can pick up on sensory input and have the inbuilt intelligence to respond (e.g. drug release or stimulation electrode). Besides these features, smart implants are also equipped with telemetry or communication between the implant and the outside world. Common examples of smart implants are pacemakers, cochlear implants, neural probes and so on (Ip and Yang, 2014).

Cochlear implants and pacemakers have been around for a couple of decades but are constantly evolving with advancing technology. What is interesting to note is that these smart implants are also reducing in size. Other latest smart implants include smart drug delivery systems and flexible retinal implants.

The ideal smart implant should be small in size, allow for minimally invasive implantation, consume minimal power (to avoid overheating of tissues and shortening of battery life), and be biomimetic (to reduce allergies or foreign body reactions), hermetic and biostable for the entire duration of the implant.

Smart implants or implantable devices were earlier used for treatment purposes. However, there has been a shift in the landscape of implantable smart devices, and these are now being used for long-term monitoring in patients before or after surgery. Smart implants enable the early detection of adverse events and minimise post-operative complications by eliminating the "wait and watch" approach common with conventional post-operative care. Regardless of the success of developing smart implants, there is still a long way to go.

Telemedicine

One technology that was unanimously adopted globally healthcare was telemedicine. Telehealth and telemedicine gained immense popularity in 2020 and 2021 and have become standard practice. Internet, videoconferencing, streaming and other technologies used for communication have all been adapted to enable healthcare services remotely. Telehealth has also been used to educate patients and clinicians as and when required. This topic is discussed in Chapter 4 titled *Convenient Care: the Rise of Telemedicine.*

Virtual, Augmented and Extended Reality in Healthcare

Virtual, augmented and extended reality are technologies that have extensively been used in industries like gaming. Today, these technologies show tremendous potential in medical education, diagnosis and treatment compliance.

Computer-generated or augmented reality offers an additional dimension to medical diagnosis and education. A computer-rendered layer of additional information or virtual objects is added to the real world with augmented reality solutions. Students or healthcare professionals can use augmented reality to access information and reports while working with patients, in a hands-free mode, via voice command or with supportive data appearing automatically. Virtual reality solutions give medical students an integrated and real-time situation where they can practise without a hospital setup or actual patients. Extended reality is a broader umbrella term that includes augmented, virtual and mixed reality that is turning out to be exceptionally beneficial to the healthcare industry – from enabling surgery assistance to improving telehealth applications. This topic is dealt with in Chapter 16 titled *Making Virtual into Reality: How Augmented and Virtual Reality Are Reshaping Healthcare.*

Big Data and Analytics at the Centre Stage for Disease Prevention

Data has little value without analysis. While preliminary data analysis is possible with existing technology, the increasing volume of healthcare data that has accumulated in recent years requires big data processing. It can be analysed and interpreted to gain medical insights using AI/ML algorithms. Analytics like this can help with chronic disease prevention and long-term treatment regimens. Big data can also help formulate plans for pandemic prevention.

As technology advances, so is the amount of healthcare data being collected. What healthcare organisations now need is an efficient way to use these massive arrays of anonymised data to spot medical patterns and trends that allow researchers and scientists to determine new correlations between demographics, economy, ecology, climate and several other factors on individual and population health.

When sufficient data are available to scientists, it can be processed as big data and fed into AI or ML algorithms for analysis and interpretation. This big data analysis can provide us with some medical insights that we did not have access to earlier. Big data analytics provides opportunities to diagnose and prevent chronic diseases and suggests the most suitable treatment plans for them.

Big data analytics has been instrumental in allowing healthcare bodies to use predictive modelling to estimate the next possible COVID-19 wave or the emergence of virulent strains of the virus in a country, region or the entire world.

Most people may think that big data requires enormous data sets to run analysis. However, simple data sets obtained from medical software and Electronic Health Records (EHR) are sufficient to analyse and infer.

Integration of Healthcare Systems with Big Data and Data Silos

One of the top business priorities in the medical industry going forward will be to develop secure multi-cloud solutions capable of linking siloed data with healthcare systems and managing, storing and mining large volumes of data for meaningful insights. This topic is dealt with in Chapter 19 titled *Cutting-Edge Care: Futuristic Healthcare Technologies of the Next Decade*.

Interoperability and Data Sharing among Healthcare Entities

Each clinic often has its database containing the medical history of its patients. If a patient seeks treatment from a different healthcare practitioner, then in most cases, they undergo complete diagnostics each time, resulting in double-spending on procedures. Interoperability enables a universal database for a patient, accessible by any clinic that treats that patient. It can provide a comprehensive medical history of the patient allowing for more effective diagnosis and treatment. It is made possible by leveraging cutting-edge technologies such as platform integration, APIs and blockchain. The topic of interoperability is dealt with in Chapter 2 titled *Health Data Going Digital India's Ayushman Bharat Digital Mission*.

Here are some examples of how different countries across the world are ensuring interoperability and data sharing using technology in healthcare:

- Authorities in the United States are encouraging healthcare organisations to move from an enterprise-centric approach to a patient-centric one and maintain patient records jointly.
- The European Union has encouraged and introduced cross-border interoperability and enhanced data protection for patient health records. This will give patients the freedom to seek the best possible care across the EU.
- Several Asian and African countries have also begun adopting an interoperable framework to make medical data and healthcare records easily accessible when patients need them. With suitable regulations, managing healthcare and patient data safely becomes easy.

With the latest advances in software, cutting-edge solutions enable platform and API integrations that allow the scaling of open systems. Along with

interoperability, the healthcare industry is likely to utilise blockchain technology for data storage and transmission in the coming years.

Precision Medicine

Precision medicine is an emerging approach to disease treatment and prevention that considers individual gene variability and environmental and lifestyle differences in an individual. This approach allows doctors and researchers to evaluate and predict more accurately which preventive or therapeutic strategy works best for an individual suffering from a disease and determines whether the approach will work for a group of people with the condition.

Precision medicine ensures that personal diagnostics are accurate and treatment is efficient. Precision medicine is developed by leveraging cutting-edge informatics technologies to effectively capture and analyse patients' real-life data and generate accurate diagnoses and treatment plans. It is in contrast to the "one-size-fits-all" approach used in conventional treatment and believes that just like each individual is different, so should the approach be for treating their disease or condition.

While the term precision medicine appears newly coined, this concept has been around in healthcare for several years now. The best example of this approach is blood group testing: a person who needs a blood transfusion is given blood from a donor whose blood type matches the recipient, to reduce the risk of complications. However, what has changed now is that precision medicine is currently supported by data, analytics, predictive models, AI and machine learning – all of which have made personalised medicine more specific, accurate, safe, efficient and affordable.

It is important to understand that precision medicine's application in our daily lives is currently but with ongoing research, its scope will only increase in the coming years. However, cutting-edge technology and facilities are required to effectively capture and analyse real-life data collected from patients and provide accurate diagnoses and prescriptions. Precision informatics arising from this technology is said to be secure, interoperable and can serve all stakeholders including service providers, payers, pharma companies and others.

Future-State Innovative Healthcare Delivery Models

Health Delivery Organisations (HDOs) globally are grappling with long-standing healthcare affordability, access and quality issues. Existing care models do not support their efforts to adapt and evolve for the future. It focuses primarily on physical health, location and payment models over consumer needs, making the customer experience fragmented and transactional.

Care Model Innovation

Many of the issues posed by today's delivery methods can be reduced/eliminated by using innovative care models. In our view, future-state models will:

- Be consumer-centric
- Make healthcare holistic to include spiritual, mental and emotional components
- Place increased emphasis on the social determinants or drivers of health
- Shift focus from acute care to prevention and well-being
- Change from standardised clinical protocols to personalised medicine
- Transition payment models from volume-based to value-based/outcome-focused and drive financial, operational and performance improvements
- Enable seamless physician–patient and physician–physician interactions
- Automate, align and integrate connections among all functions and stakeholders.

In addition to providing a more effective and pleasant patient and clinician experience, care model innovation can help bend the HDO cost curve by lowering fixed and variable costs.

Care model transformation is not an easy job and requires a multiyear and multistep approach. The organisation leaders need to define the future-state delivery model, assess the gap between the enterprise's current state and desired future state, prioritise and sequence initiatives to invest in and develop, and implement, monitor and measure each initiative.

Digital Health Technologies and the Future of Medical Specialties

We have often heard that the technology of the future will replace doctors and other healthcare staff. Surveys conducted at different times state that most people believe that technology will replace about 80% of what doctors do (Khosla, 2012). However, we believe that healthcare technologies will give rise to an entirely new breed of doctors who will use technology to lighten their workload while they focus on being good physicians and clinicians.

According to the Medical Futurist (TMF), applying new-age technologies can accelerate tasks involving the collection, analysis and interpretation of information, such as diagnostics in general or radiology/pathology in particular (TMF, 2019).

In today's technologically advanced era of e-physicians, face-to-face communication skills, digital literacy, interdisciplinarity, data sourcing,

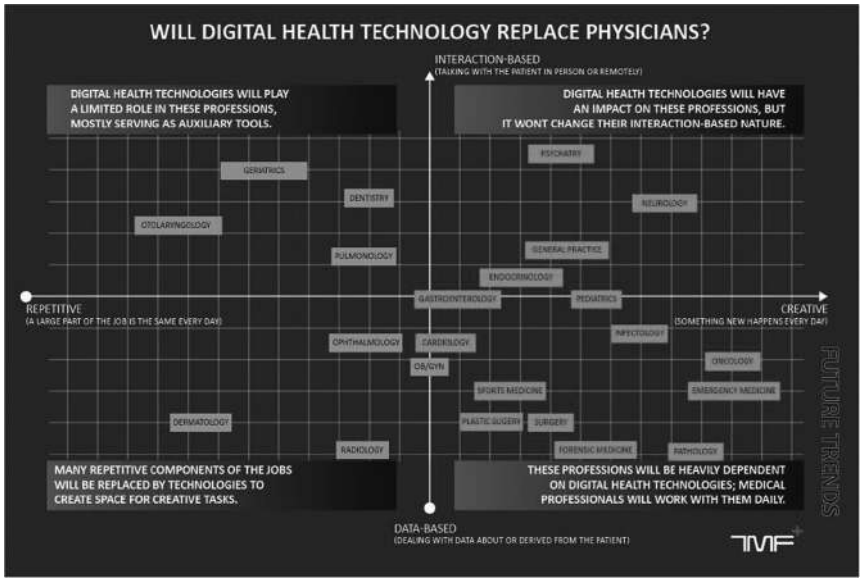


Figure 19.1. How digital health technologies will affect different specialities.

Source: The Medical Futurist

transforming data into insights, and so on, is at the core of practicing medicine (Figure 19.1).

Here is what the future of medicine could look like for different specialities:

- **General Practice**

General physicians enjoy the trust of their patients, but when they have a busy practice, it leaves them very little time to spend on each patient's diagnosis. Wearable devices and sensors can stream constant information about their patient's health and flag or raise the alarm when something is amiss.

These health-tech devices will also ensure that GPs provide adequate care to those who need it when they do. At the same time, these devices also help doctors monitor their patients' lifestyles, flag those at high risk of developing chronic illnesses and monitor those undergoing treatment.

Digital health assistants and chatbots are easily usable health technologies that can ease a physician's load and help them in triaging their patients.

- **Paediatrics**

Paediatrics is challenging as most doctors run busy practices with very little time for a baby and the mother. Using wearable devices or sensors on the

mother and the baby helps them monitor health parameters rather than basing their diagnosis on the symptoms provided by the mother or the father.

Advanced genetic technologies like CRISPR enable the removal or elimination of problematic genes to treat several genetic conditions, even before a baby is born, to ensure a healthy life later.

- **Radiology**

Existing technology has already led to many helpful devices and tools for radiologists. Today, deep learning algorithms, AI and ML have all been used to create advances in the field of medical imaging. For example, DeepMind, an AI created by Google, is better than radiologists in detecting breast cancer (CNBC, 2020).

While many presume these health technologies will replace radiologists soon, it seems unlikely. These technologies will be adept at taking over repetitive or tedious tasks, leaving radiologists to look at more exciting tasks.

IBM's newly launched algorithm called Medical Sieve has qualified to assist clinicians in radiology and cardiology. This algorithm can scan hundreds of radiographs in seconds and recognise benign and malignant lesions and other abnormal findings, while the radiologists can focus more on more complex cases.

Apart from algorithms, AI and ML, the field of radiology has also seen some recent advances in digital health. With the latest machines like the Philips Lumify and the Clarius Portable Ultrasound, the accessibility and ease of scanning have been taken up by a few notches. The latest technology in the field of radiology is fast-moving, with great potential to improve diagnosis for patients.

- **Ophthalmology**

The field of ophthalmology has had some sophisticated technologies such as retinal implants and bionic eyes to restore vision in people who have lost it. These technologies have been constantly upgraded since the first bionic eye surgery in 2015. What began with treating age-related macular degeneration to improve vision led to neural implants used in a clinical trial that resulted in the partial restoration of vision for six people (Guardian, 2019).

A brain implant in Spain allowed researchers to restore rudimentary vision in an individual with toxic optic neuropathy (Fernandez *et al.*, 2021).

Apart from paediatrics, CRISPR technology has shown tremendous potential in all other aspects of medicine, including ophthalmology.

Several smartphone-based applications and sensors use the phone's camera to detect underdeveloped areas of the eyes. While Personal Vision Tracker measures an individual's refractive status, including routine conditions like near- and far-sightedness and astigmatism, EyeQue Insight can help determine visual acuity.

- **Oncology**

Oncology is largely looking forward to prevention, early detection, targeted and precise therapies and personalised treatments. Cancers continue to be an enigma. While oncologists have many of these illnesses under their information radar, several aspects of how they occur, gene interactions that lead to them, why they recur and so on, are still under study. Oncologists need to customise their treatments based on a patient's genetic background, family history, nature of the tumour and other factors.

Genome sequencing has been a boon to oncology as it can determine genetic and blood biomarkers for improved diagnosis. Companies like GRAIL are in the process of developing fluid biopsies that are essentially blood tests to detect cancer at a very early stage. Doing so will reduce the burden of diagnosis on the diagnostic setups and make these tests easily accessible and available to most populations.

Most of the global tech giants like Google, IBM and Microsoft have start-ups that are building AI solutions to create personalised treatments for all types of cancers that are more effective than traditional treatments available today. Philadelphia-based company Oncora Medical has developed software that provides comprehensive and in-depth data and imaging to help oncologists improve their processes and patient outcomes.

- **Dermatology**

The skin protects all the internal organs while bearing the brunt of external and internal factors. Routine factors such as the amount of sleep, stress or sun exposure can affect skin health. Health technology has penetrated the field of dermatology to monitor skin health. For example, SkinVision is a smartphone app that allows doctors to remotely monitor their patients' suspicious moles, and call them in when a more in-depth evaluation is needed.

Most people rush to their dermatologist when they experience a rash, lesion or abnormal spots, leading to long queues at the clinics. With software applications like idoc24, patients can now send pictures of their skin lesions that they are worried about and receive medical advice online, making it a win–win for both the dermatologist and the patients.

IBM's ML has achieved a 76% accuracy in diagnosing melanoma, which is 5.5% more than a human dermatologist's accuracy of diagnosis (Codella *et al.*, 2017). Today, several advanced machines are available that can take a 360-degree scan of the entire body and identify any abnormal lesions.

The field of 3D printing has helped develop living skin with blood vessels, a breakthrough for burn and acid attack victims or those with issues like ulcers and diabetes.

- **Emergency Medicine**

Time is crucial in medicine, especially in medical emergencies or disaster situations that require an urgent response, prompt treatments and the doctor's ability to improve outcomes. Healthcare innovations are, therefore, a boon to emergency medicine.

Medical drones have great potential in emergencies as they can transport vital drugs, vaccines and other medical aids to inaccessible areas immediately. The ability to transport Automatic External Defibrillators (AED) directly to people who have suffered a heart attack before an ambulance arrives can save several lives daily. These technological innovations have been tested in Africa, Canada and the Netherlands.

Portable, hand-held diagnostic devices like the AliveCor can provide doctors with vital information about an individual in a medical emergency and prompt them to take the required actions immediately. Other technologies that can change the face of emergency medicine include driverless ambulances, which can ease the load off emergency services in a crisis.

- **Gastroenterology**

Nanotechnology has prompted gastroenterologists to look beyond the stomach and the GI tract. Innovations like the PillCam, a pill-sized camera, allows doctors to visualise the small intestine, oesophagus, colon and other parts of the GI tract without sedation or any other invasive procedures. With this technology, diagnosing and treating GI issues is easy, and specialists can focus on innovative ways to treat their patients effectively.

Food scanners are a revolutionary innovation that can provide insights to doctors and patients. This can help people with food allergies and dietary restrictions. TellSpec is a hand-held food scanner that tells patients about the ingredients and nutrients present in a food plate. This is made possible because of an AI-based food analysis engine. There are several gluten and nut sensors available on the market.

- **Epidemiology**

Epidemiology is the backbone of healthcare, without which most clinicians and healthcare bodies would be flying blind. It becomes difficult for clinicians to filter out relevant information about several diseases and outbreaks. AI, ML and automation have helped create online dashboards that aggregate results and use predictive modelling to enable healthcare professionals and bodies to determine the most suitable course of action to stop the spread of the disease, understand treatment outcomes, recovery rates, mortality rates, modes of transmission, etc.

AI and robotics can help us prepare for and manage outbreaks like the Zika virus or the COVID-19 pandemic. For example, doctors in a hospital in the United States used a robot with a screen and stethoscope to collect the vitals of suspected and infected COVID-19 patients to minimise exposure of the healthcare staff. In a hospital in Shanghai, robots were deployed to disinfect the hospital to keep cross-infection levels to a minimum.

AI has been and will continue to be instrumental in predicting and preventing infectious disease outbreaks. A Canadian company called BlueDot sent out the first alerts about the COVID-19 pandemic even before the CDC and WHO (Wired, 2020). This was possible because BlueDot used airline data, information in news reports, animal disease outbreak data and ongoing trends.

- **Surgery**

With time, tools and advanced diagnostics and imaging techniques, surgery has become more specific, minimally invasive and precise. As more advanced technology is being deployed, surgery is set to become more data-driven, robotic and artificially intelligent in the coming years.

Digital health technologies are already finding their place on the operating table. The surgical robotics industry is said to boom, with the market said to reach USD 12.6 billion by 2025 (PR Newswire, 2018). While robots are already a part of surgical operatories, surgeons can now carry out superior precision operations with their help. Technologies like VR, AR and 5G are bringing about drastic and prominent changes in the field of surgery. Imagine being able to perform emergency surgery from thousands of miles away! With healthcare technology advances, it seems that working from home might be possible for surgeons too.

Conclusion

Technology, digitisation and automation are an integral part of healthcare and medicine today. This chapter provided an overview of futuristic trends in healthcare:

- While technologists are doing their best to incorporate the latest advances into routine medical practice, clinicians need to upgrade their skills and learn new ones to make the best use of the technology they have at hand today.
- Integrating the latest technology with the clinical acumen of clinicians can improve disease outcomes and enable the early detection and prevention of several diseases.
- Technology cannot replace doctors, but it can disrupt how they practice medicine.
- To upgrade our existing healthcare systems, we must repair what is broken and incorporate the latest technologies available to us.
- The future of medicine, healthcare and the pharmaceutical industry is brimming with potential and opens the doors for more innovations in the coming years.

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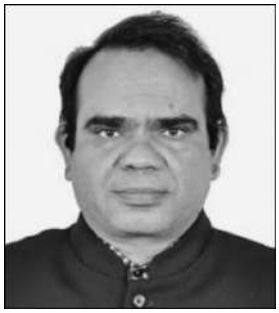


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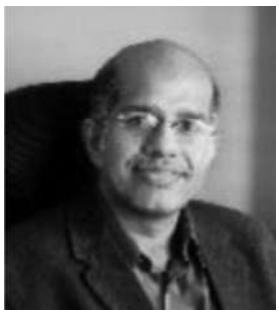


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