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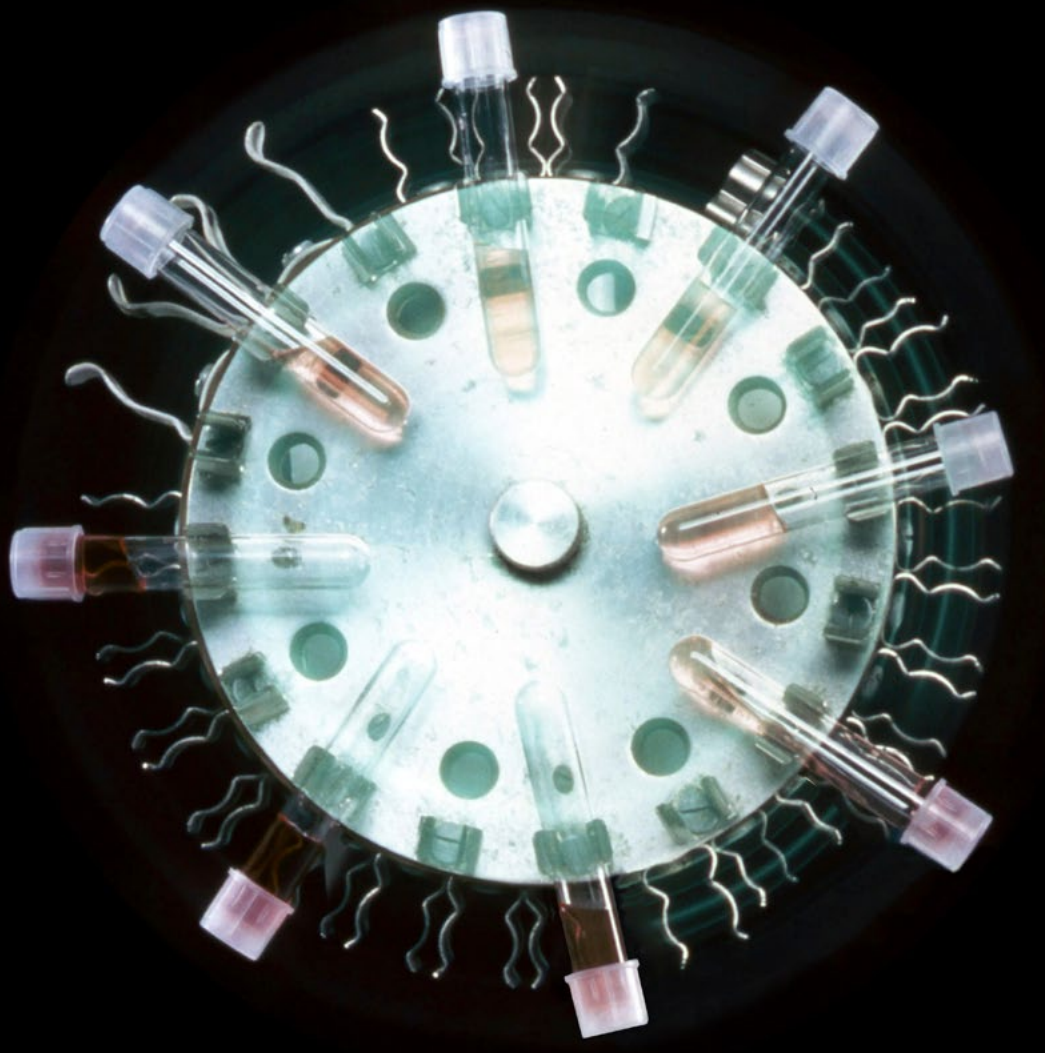

21st Century Health Care Challenges: A Connected Health Approach

Megatrends in Health care

To find out more about Deloitte Indonesia Life Sciences and Health Care, please scan the QR code below:

ABBREVIATIONS

ANNCEH	Australian National Consultative Committee on Electronic Health
APBN	National State Budget
APJII	Asosiasi Penyelenggara Jasa Internet Indonesia/ Association of Indonesian Internet Service Providers
APP	Australian Privacy Principle
ATA	American Telemedicine Association
ART	Assisted Reproductive Technology
ARV	Anti-Retroviral Virus
ASCOF	Adult Social Care Outcomes Framework
ASEAN	Association of Southeast Asian Nation
BPJS	Badan Penyelenggara Jaminan Sosial
CPME	Standing Committee of European Doctors
CPG	Clinical Practical Guidelines
CFR	Code of Federal Regulation
CGAR	compound annual growth rate
CMS	Centers for Medicare & Medicaid Service
CoPs	Conditions of Participations
CISS	Computer Information Security Standards
CFR	Code of Federal Regulations
CQRS	Calculating Quality Reporting Service
CP-IS	The Child Protection – Information Sharing project
CSS	Clinical Support System
CTG	Cardiotography
CoPS	Conditions of Participation
CMS	The Centers for Medicare & Medicaid Service
CSS	Clinical Support System
CUI	Common User Interface
DAQs	Digital Assessment Questionnaire
DARS	Data Access Request Service
DoS	The Directory of Services
DSA	Digital Signature Act
EHR	Electronic Health Records
EYS	expected years of schooling
ECA	Electronic Commerce Act
ECEG	Ethical Code Ethical Guidelines
ECG	Electrocardiogram
EDB	Electronic Development Board

EEA	European Economic Area
EHR	Electronic Health Record
EHealth	Digital Health or technology-based health care
EMR	e-Medical Record
EPS	Electronic Prescription Service
ERP	Electronic medical record Support for Public health
ETA	Electronic Transaction Act
ETP	Electronic Transfer of Prescriptions
FSMB	Federation of State Medical Boards
FDA	Food and Drug Administration (U.S. FDA)
FSMB	Federation of State Medical Board
GDPR	General Data Protection Regulation
GMC	General Medical Council
GPs	General Practitioners
GNI	Gross national income
GNIpc	Gross national income per capita
HAS	Health Science Authority
HDG	Health Data Grid
HDI	Human Development Index
HES	Hospital Episode Statistics
HHS	Health and Human Services
HIMSS	Health care Information Management and Support Services
HSCIC	Health and Social Care Information Centre
HIV/AIDS	Human Immunodeficiency Virus/Acquired Immunodeficiency Syndrome
HITECHT	Health Information Technology for Economic and Clinical Health
HHS	Health and Human Services
ICO	Information Commissioner's Office
ICT	Information and Communications Technology
IDI	Ikatan Dokter Indonesia
IKO	Indonesian Kalkulator of Oocytes
IVF	In Vitro Fertilization
ITT	Innovation and Technology Tariff Technical Notes
JKN	Jaminan Kesehatan Nasional/National Health Insurance
LE	Life expectancy
Kemenkes	Kementerian Kesehatan/Ministry of Health
KIS	Kartu Indonesia Sehat/Healthy Indonesia Card
MAS	Monetary Authority of Singapore
MMC	Malaysian Medical Council
MHealth	Mobile Health
MIMS	Monthly Index Medical Specialities
MYS	Mean years of schooling

NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NESAF	National eHealth Security and Access Framework
NEHTA	National eHealth Transition Authority
OECD	Organization for Economic Cooperation and Development
ODHA	Orang dengan HIV AIDS/People Living with HIV
PDPA	Personal Data Protection Act
PES	Prescription Exchange Service
PHFCSA	Private Health Care Facilities and Services Act
PHFCSR	Private Health Care Facilities and Services Regulation
PHI	Protected Health Information
PRO	Patients Relation Officer
PLHP	Personalized Lifetime Health Plan
PLN	Perusahaan Listrik Negara/State-owned electricity company
RAG	Research Advisory Group
RSPI	Rumah Sakit Pondok Indah
R1	Release One
R2	Release Two
SSA	Social Security Act
SMC Handbook	Singapore Medical Council Handbook
SCR	Summary Care Record
SIRS	Systemic Inflammatory Response Syndrome
SNTG	Singapore National Telemedicine Guidelines
SUS	Secondary Uses Practice
TPO	Treatment, payment, or health operation
TJC	The Join Commission
UK	United Kingdom
U.S. FDA	United States Food and Drug Administration
WHO	World Health Organization
Yankes	Pelayanan Kesehatan/Health Service

Foreword

With the fourth largest population in the world, Indonesia has a potential in the development of digital health technology (eHealth). The technology is expected to facilitate the people of Indonesian to gain health access more easily, which will be a benefit for more than 260 million people who lived in 17.504 islands spreadly in the country. Along with the growing eHealth industry in the country, Deloitte Indonesia, Bahar Law Firm, and Chapters Indonesia are starting to conduct a study on eHealth industry, which covers the industry growth, various type of eHealth business and services, applications, the use of technology as part of the hospital services, existing infrastructure, legal comparative studies in several countries, and a proposed road map of the eHealth development in Indonesia. The study is the first research publication on eHealth in the country, with the purpose to give inputs to the related stakeholders, specifically to the government to develop and strengthen the eHealth infrastructure for the common good.

The digital revolution in health sector is driven by eHealth development and innovation, which leads to the peer to peer approach that enable the users to share and looking for latest information, long distance-consultation with medical practitioner, which include e-prescribing, and sharing patient's health documents sharing. The digital health development will lead to open health technology, where the users are able to have open access to more convenient ways in approaching health services.

On the other side of the coin the peer to peer (P2P) technology has an issue on the data security that can give a serious impact in the technology utilization. This issue can make a serious impact in the eHealth business continuity. The team has conducted study comparation in infrastructure and regulation with other countries, where eHealth become part of the daily life and the result shows that the business, government, association, and other related stakeholders should work together to prepare proper infrastructure and regulation to protect the users (community) and business players in the industry.

We hope that the results of this study will be a valuable input for the relevant ministries to promote infrastructure improvements in the field of eHealth which aims to protect the interests of the community and future eHealth advancements. Looking at these problems, this paper aims to deliver an outlook and recommendation for Indonesian regulators, policy makers, academics, business owners, and users about the upcoming future trends in Indonesian health care system.

Deloitte Indonesia, Bahar Law Firm, and Chapters Indonesia

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CHAPTERS
Founded by Dr.Luthfi Mardiansyah in mid of 2017, Center for Healthcare Policy and Reform Studies (CHAPTERS), a non-profit institution, continue doing some studies on health care system in Indonesia, to educate people and provide analysis and insight to government not limited to KSP, Kemenkes, BPJS etc. CHAPTERS have conducted several public discussions including Media Gathering, Drug Procurement & Distribution System at JKN era , Kaleidoscope Indonesia Health Care System 2017, Indonesia Health System Outlook 2018 and Rare Diseases Forum recently in Sept. The vision of CHAPTERS is "To Dedicate our Outmost Expertise and Initiative for Better Healthcare Environment in Indonesia". Please visit our website www.chapters-id.com for more information.

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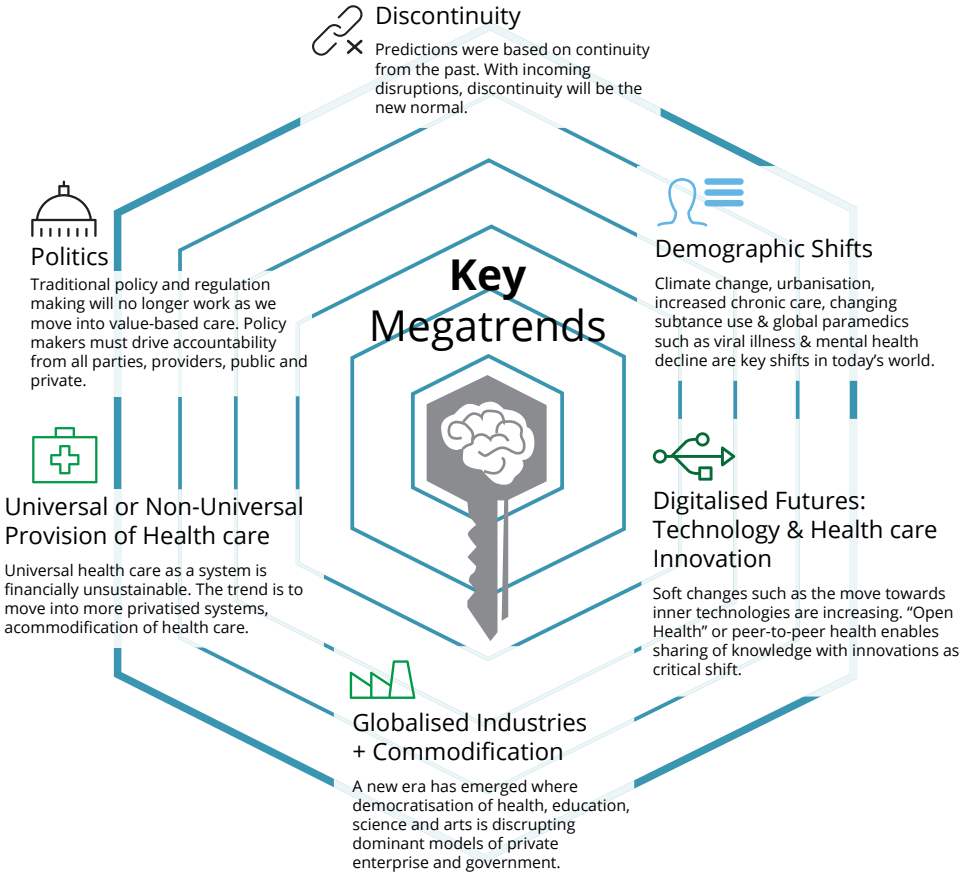
Introduction

The great forces in human and technology development that affect the future in all areas of human activity, which known as megatrends[1] in the John Naisbitt and Patricia Aburdene's famous book with similar title, seem very close to us now. Its keys that are predicted to be happened very soon are digitalized future (technology and health care innovation), globalized industries and commodification, universal or non-universal provision of health care, politics, discontinuity and demographic shifts. In terms of health care issue, the future are shaped by a convergence of drivers, needs and wants both in and outside of health care that will bring the future to a different way where we are now. There is a significant increase in the scope of possibilities for health care future – health care provision will no longer linear and continuous, predictable or immune from disruptive change.

In the side of digitalized futures, technology and health care innovation have led to "Open Health" or peer-to-peer health that enables sharing of knowledge with innovation as critical shift. A digital revolution in health care is speeding up. Telemedicine, predictive diagnostics, wearable sensors and a host of new applications will transform how people manage their health[2]. This is an evidence that health care change is not immune. There is most likely to occur that a convergence of trends will create discontinuous and abrupt changes in health care systems, no matter how advanced or rudimentary.

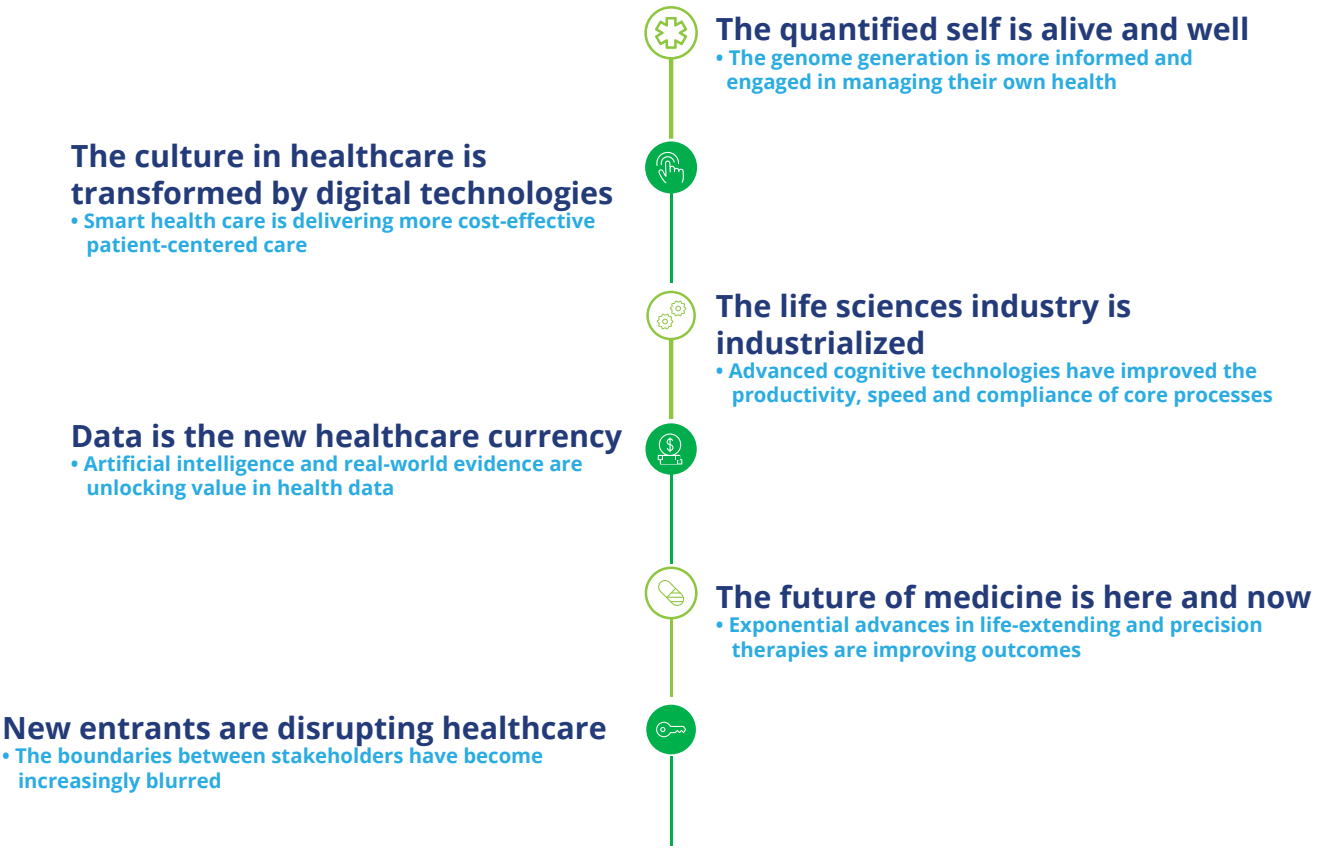
There is a rapidly growing number of health care innovations on the horizon that both excite and concern policy-makers. On the other hand, policies that shape health care are typically considered as conservative especially



[1] Naisbitt, J. and Aburdene, P., 1991. Megatrends 2000—Ten Dir ections for the 1990s. Megatrends 2000: Ten Directions for the 1990s.
[2] https://www.economist.com/news/business/21717990-telemedicine-predictive-diagnostics-wearable-sensors-and-host-new-apps-will-transform-how

in terms of traditional models of clinical practice and primary health care provision. Although the nature of health care is shifting dramatically away from these patterns of the past[3], providers, governments, large corporations, insurance companies, hospitals and the clinical caregivers themselves; all seem constrained by the dogma originating from attitudes and practices from the last century. Yet, there is considerable pressure from societies for providers to become more accountable, relevant and responsive while providing greater and more equitable access to health care and well-being. The response of this pressure varies -but it is generally subjected- to measures of costing, large corporate interests, traditional clinical practice models and the development of national policy.

2022 HEALTHCARE PREDICTIONS



Unlocking the opportunity of digital health

The digital age holds out the promise of innovative technology and business models. Most critically, internet and smartphone penetration is growing, and the technology infrastructure is moving to cloud-based services.

Along with the development of technology and the competition in business environment, managing health care has been changing. To be part of the competitive industry today, health care providers need to address the major changes that are driving patient behavior and adopt a customer service mindset. This emerging demand for customer centric care is driving innovation and transforming the patient-centered experience – from appointment scheduling to timely access to billing information and transparency in health care purchasing decisions.

[3] http://www.iftf.org/fileadmin/user_upload/downloads/hh/Report_U.S.Analysis_of_FutureHealthIndex.pdf

The proses is also manifested generally at the systemic level through peer-to-peer health and advanced wearables that allow direct personalized health information. Individuals are better informed about their symptoms and diseases they have and might have, and the availability of health care.

Expectations of health care and better outcomes for themselves are at their highest. Patients are true consumers, they understand they have options and use information and data about themselves and provides to get the best treatment at a time, place and cost convenient to them.

According to Forbes and Business Insider, the global health care industry will initiate a joint progression with the data analytics and technology industries. A research conducted by RNR Market Research forecasted a rapid and significant compound annual growth rate (CAGR) in the global telehealth industry of 27 percent by 2021.

Health care practitioners should keep in mind that medicine must always be patient-centric treatment, and technology is merely a tool to improve the patient's health outcome. This approach is not about purely relying on technologies or making decisions without referring to any data, but to utilize state-of-the-art technologies that improve health care services. Doing this way, professionals should also have time to provide the human touch.

What are the Differences Between Telehealth, Telemedicine, and eHealth?

We often use the terms of telemedicine, telehealth, and eHealth to describe the use of information technology system in health care industry to provide an easier access between health care providers and patients, especially from remote area. The terms are used to describe a broad concept within health care, the use of mobile and desktop technology for patient's health care self-management. All terms are used interchangeably but represent a different use of technology within health care[4]. However, is there any differences between those three terminologies?

Telemedicine is defined by the WHO as "the use of information and communications technology (ICT) to deliver health care particularly in settings where access to medical services is insufficient". The term **telemedicine** has historically been used to refer the use of electronic communications channel or mediums, as well as information technology to deliver clinical services to remote patients with the goal of improving a person health's status[5].

The broadest term in this comparison is telehealth. The term **telehealth** incorporates not only technologies that fall under "telemedicine," but also direct, electronic patient-to-provider interactions and the use of medical devices (e.g., smartphone applications ("apps"), activity trackers, automated reminders, blood glucose monitors, etc.) to collect and transmit health information, often with the intent to monitor or manage chronic conditions[6]. The use of telehealth also helps with developing and improving health-related education, health administration, and improving general public health[7].

In the United Kingdom and other European countries, the term 'eHealth' is also used to describe digital health and technology-driven remote health care. Barely in use before 1999; this term now seems to serve as a general "buzzword," used to characterize not only "internet medicine", but also virtually everything related to computers and medicine. The term was apparently first used by industry leaders and marketing people rather than academics. They created and used this term in line with other "e-words" such as e-commerce, e-business, e-solutions, and etc., the use of these terms is intended to convey the promises, principles, excitement (and hype) around e-commerce (electronic commerce) to the health arena, and to give an account of the new possibilities the internet is opening up to the area of health care[8]. The term **eHealth** is generally used to describe an even broader scope of digital information tools, ranging from electronic health records (EHRs), which facilitate the exchange of patient data between health care professionals.

[4] https://www.talkingmedicines.com/digital-health-terms-ehealth-mhealth-telehealth-telemedicine/
[5] http://electronichealthreporter.com/dividing-eHealth-telehealth-and-telemedicine/, accessed on 18 May 2018
[6] https://aspe.hhs.gov/system/files/pdf/206751/Telemedicinee-HealthReport.pdf, accessed on 18 May 2018
[7] http://electronichealthreporter.com/dividing-e-health-telehealth-and-telemedicine/, accessed on 18 May 2018
[8] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1761894/

EHealth may include computerized physician order entry mechanisms, e-prescribing, and clinical decision support tools, which provide electronic information about protocols and standards for use in diagnosing and treating patients to providers[9]. The concept of eHealth is not limited only to provide long-distance health care, but also to increase health care efficiency as a whole[10].

Telehealth Modalities

Telehealth can employ a multitude of modern technologies, transmitting information via text, audio, video, or still images to a range of medical specialists. This technology is relevant to a variety of disciplines including dermatology, radiology, and cardiology. With a simple internet connection, patients can conducting video conference with a health care professional half-way around the world or sending MRI scans result through email for medical analysis. More remarkably, without any face-to-face interaction, doctors can distantly monitor the blood pressure or glucose levels of a clinic's patients through a computer screen.

In the future of the health care industry, telehealth almost likely will involves four distinct domains of application those are commonly known as synchronous (live video), asynchronous (store-and-forward), Remote Patient Monitoring (RPM) and mobile health (m-Health)[12].

- Synchronous domain: A live and two-ways interaction between a person that could act as a patient, caregiver, or provider and a provider using audiovisual telecommunications technology. This form of service is also denoted as the "real-time" service and might function as a substitute for a real live in-person encounter when it is not possible.
- Asynchronous domain: A type of transmission of recorded health history, the examples are pre-recorded videos and digital images (X-rays and photos) through a secure electronic communications system to a specialist practitioner, who uses the information to evaluate the case or render a service outside of a real-time or live interface. As matched to a real-time physical visit, this type of service provides an access to the health data subsequently it has been gathered, and will involve communication tools such as a secure email.
- Remote Patient Monitoring: Personal health and medical data gathering from an individual in a certain location through electronic communication technologies, which is transmitted to a provider or occasionally through a data processing service in a different location for use in care and related support. This type of service allows a provider to resume tracking the health care data for a patient once they have been released back to their home or a care facility. This method reduces readmission rates.
- Mobile Health: When mobile communication devices such as cell phones, tablet computers and PDAs support health care and public health practice and education. Applications can range from targeted text messages that promote healthy behavior to wide-scale alerts about disease outbreaks.

Indonesia's Health Care Overview

Strong economic growth is leading Indonesia towards middle-income country status. The growth is unfortunately does not reflect in the government's budget allocation's national health budget, which is relatively low (2.9 percent of Indonesia's total gross domestic product (GDP) in 2014, or 5.0 percent of the National State Budget (*Anggaran Pendapatan dan Belanja Negara/APBN*)) in 2017 - leading to insufficient facilities and workforce needed for public services, and encouraging the growth of private health facilities[13]. Decentralization has also affected the capacity of the central Ministry of Health to maintain integration and alignment across the different levels of the health system[14].

However, Indonesia's health care spending is expected to be driven by aging and growing populations, developing market expansion, clinical and technological advances, and rising labor costs. As health care costs increases, the government is pushing health care affordability

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[9] https://aspe.hhs.gov/system/files/pdf/206751/TelemedicineE-HealthReport.pdf, accessed on 18 May 2018
[10] Ibid.
[11] https://www.hcs.harvard.edu/hghr/print/spring-2011/telemedicine-developing/
[12] Center for Connected Health Policy (CCHP)
[13] https://www.kemenkeu.go.id/apbn2017
[14] http://apps.who.int/iris/bitstream/10665/254716/1/9789290225164-eng.pdf

through universal health care insurance coverage (*Jaminan Kesehatan Nasional-Kartu Indonesia Sehat* (JKN-KIS)) even though implementation wise is challenging.

All of the efforts conducted by the Government of Indonesia (GoI) in health sector is part of the efforts to reach Indonesia's national target as written in the National Mid-Term Development Plan (RPJMN) 2015-2019, which is to make Indonesian people live healthier. Under this national target, there are six main goals of the programs which implemented during the range of time, namely: (1) to increase the maternal and child health status; (2) to increase disease control effort; (3) to increase access and quality of primary care and referral system, especially in remote, rural and disadvantage areas; (4) to increase the coverage and quality management of universal health care through Indonesian Care Insurance Coverage (*Jaminan Kesehatan Nasional - Kartu Indonesia Sehat*/JKN-KIS); (5) fulfillment of health care workers, medicines and vaccines; (6) to improve responsiveness of health care system. Few RJPMN indicators that is in-line with the implementation of eHealth includes:

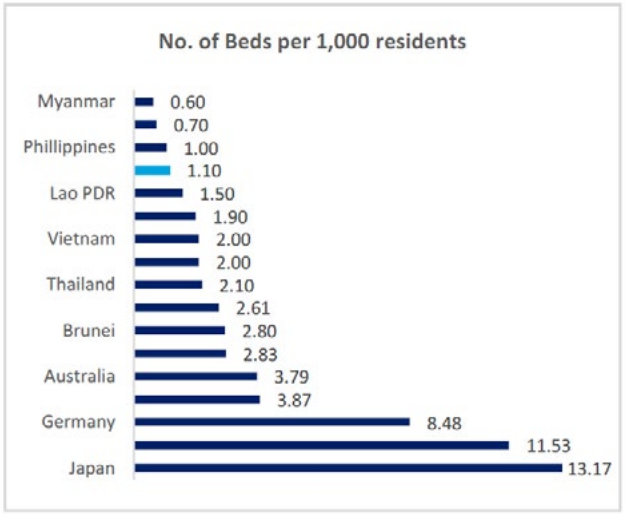
Indicators	Initial status	Target (2019)
Availability of accredited public primary care in districts across Indonesia	0 (2014)	5,600 (82%)
Availability of accredited regional public hospitals in cities across Indonesia	10 (2014)	481 (94%)
Coverage for national social security system (Sistem Jaminan Sosial Nasional / SJSN)	51.8 (2014)	95%

The following national target after 2019 is to provide all of Indonesian people access to qualified health service in 2025. This seems quite far comparing to the recent situation regarding health access.
With a population totaling around of 260 million individuals, Indonesia is now the fourth-largest country in terms of population size. The growth will continuously occurs, as stated by the United Nations (UN) that the population of Indonesia is estimated to exceed 270 million by 2025, exceed around 285 million by 2035 and another 290 million by 2045. Out of the population issue, Indonesia is often referred as the largest archipelago in the world with an estimation of 17,504 islands. The population growth rate of Indonesia between the year 2000 and 2010 stood at an average of 1.49 percent. Surprisingly, the growth does not spread evenly, the highest was in the eastern of Indonesia, Papua (5.46 percent) and lowest was in Central Java (0.37 percent)[15]. The rapid growth and the fact that Indonesia is the largest archipelago in the worlds makes it challenging to support and escalate the health care services, especially in remote areas of Indonesia.

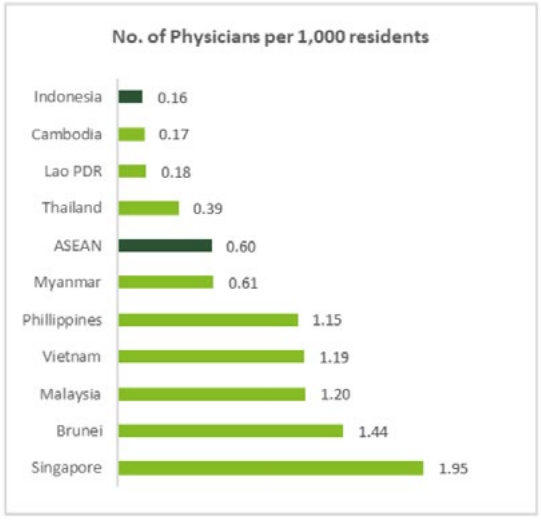
[15] https://www.indonesia-investments.com/culture/population/item67?

Other issue that raised, is the health care facilities and resources. Indonesia has a low number of beds compared to other countries in Association of Southeast Asian Nations (ASEAN)[16] and Organization for Economic Cooperation and Development (OECD)[17]. Some health care facilities are severely underfunded, and in many cases do not meet certain standards. Meanwhile, regarding health care professional resources in Indonesia, according to World Health Organization (WHO) data, as of in 2016, for every 1,000 residents, there are only 0.16 doctors available, this figure is lower than the average of countries in Southeast Asia (at 0.6 doctors for every 1,000 residents) and far lower than in the developed countries, such as Germany, which has 3.7 beds for every 1,000 residents. A critical note is that there are issues with accessibility and quality of health care, as hospitals and medical professionals are highly concentrated in big cities especially Jakarta. On the other hand, in accordance with the 9th Package of Commitments under the ASEAN Framework Agreement on Services (AFAS 9), non-Indonesian physicians and dentists are not allowed by the law to provide direct patient care unless it is under the auspices of "transfer of knowledge", such as training, social service, and research.

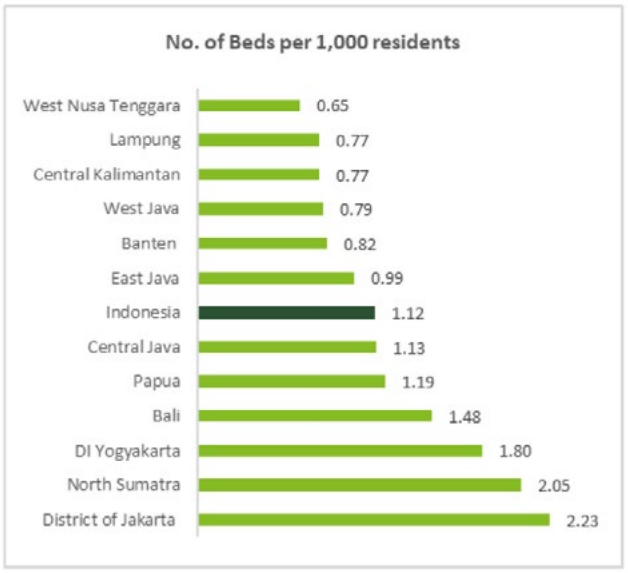
[16] Luthfi Mardiansyah's presentation in Deloitte Hospital Summit, 2017
[17] http://stats.oecd.org/index.aspx?queryid=30183, https://en.wikipedia.org/wiki/List_of_OECD_countries_by_hospital_beds



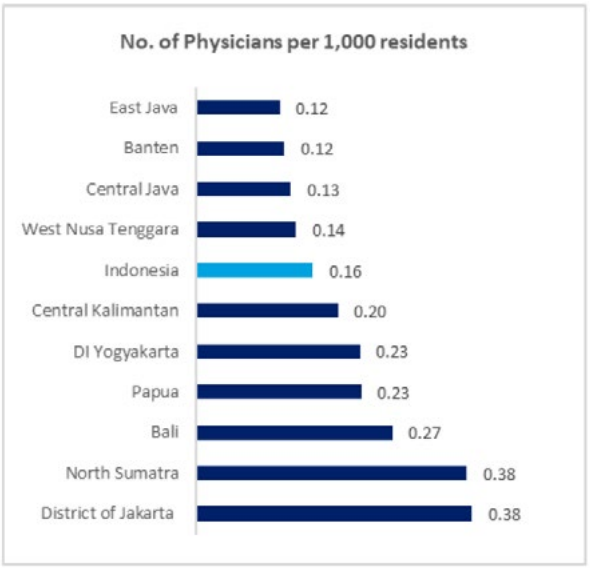
Source: Deloitte Hospital Summit, OECD, 2016



Source: Deloitte Hospital Summit, 2017 and Indonesia Health Profile, Ministry of Health, 2016



Source: Indonesia Health Profile, Ministry of Health, 2016



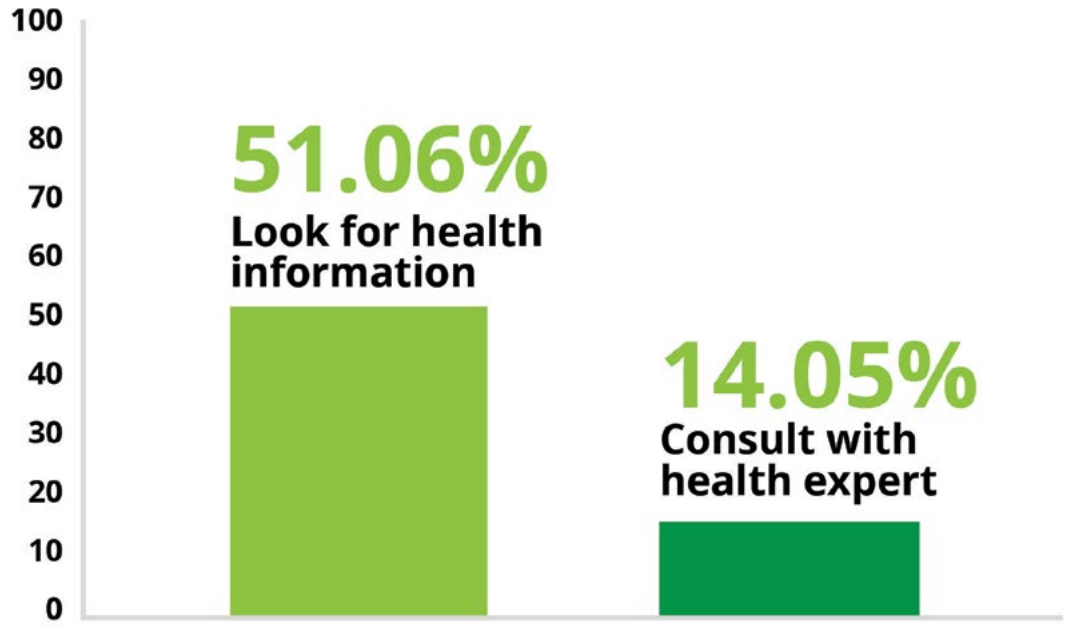
Source: Indonesia Health Profile, Ministry of Health, 2016

Lack of sophisticated health infrastructure in Indonesia has also been causing Indonesian's wealthy people to go abroad in seeking better medical treatments, as neighboring countries' health care providers are perceived as adequate to provide affordable high quality care and services. Notably, in trends with technological innovations, it has motivated some of those providers to develop the applications of telemedicine – targeting patients both inside and outside of their country (including Indonesia). Overseas countries with a more developed technology in health care such as Singapore, Malaysia, Japan, Australia, USA and Germany are also getting involved in health care provision in Indonesia - they are trying to meet the rising demand of high-quality health care facilities[18].

[18] International relation's within Indonesia's hospital sector, Dono Widiatmoko Ascobat Gani

Telehealth is going to be very beneficial for both the developer and consumer when it is successfully implemented in Indonesia. Dr. Nyoman Adhiarna, E-Business Director, Ministry of Communication and Information Technology said that eHealth is an interesting tools, as the digital-based health service application will benefitted the society. Indonesian population has been also utilizing internet for their health needs. For example, in regards of Indonesian internet usage specifically in health care sector, internet is utilized for browsing health information (51.06 percent) and to consult with health care professionals (14.05 percent)[19].

Internet Utilization in Health Care Sector



Dr. Nyoman Adhiarna E-Business Director, Ministry of Communications and Information, the Government of Indonesia.

"eHealth is an interesting tools, as the digital-based health service application will benefitted the society. However, Indonesia needs to speed up the issuance of ehealth regulation."

In the near future eHealth will not just appeal to the wealthier-end of the Indonesian populations, but also can benefit the poorer-end of the Indonesian populations – especially those located in underdeveloped rural areas. Hence, both public and private sectors in Indonesia are leveraging digital technologies. The government has implemented digital technology, particularly to reach patients in underserved areas and to better serve JKN participants. In private sectors, companies and startups in life science and health care are developing sporadically. They are leveraging digital technologies to improve health care service and accessibility, building patient centricity and data integrity, even to solve the occupational health future workforce crisis. The e-Business Director of the Ministry of Communication and Information Technology mentioned that there are three big issues in eHealth practice, which are user personal data protection, responsibility of the electronic system vendor on the information technology and electronic-based health services risk, and important role of the central data office. The following descriptions on the practice in Indonesia will show the development of the eHealth practice in the country.

[19] Teknopreneur.com, *Asosiasi Penyelenggaran Jasa Internet Indonesia* (APJII), 2017. *Infografis Penetrasi & Perilaku Pengguna Internet Indonesia.*

Dr. Nyoman Adhiarna E-Business Director, Ministry of Communications and Information, the Government of Indonesia.

"There are three big issues in eHealth practice: user personal data protection, responsibility of the electronic system vendor on the information technology and electronic-based health services risk, and the important role of the central data office."

Blockchain Technology in Health Care

Blockchain technology has the potential to transform health care system by simplifies data storage, increasing security, privacy, and interoperability of health data. Blockchain technology is a distributed system for recording and storing transaction records. It is a decentralized database capable of keeping secure and validated records of digital transactions. When new transactions take place, it will be grouped together with other transactions that occurred within a short time window, called a block, and sent out to that ledger's network and all digital health events are recorded in a way that does not allow for the data to be changed or recognized until it reaches the recipient.

Blockchain technology creates unique opportunities in health care ecosystem, especially brings improvement in Health Information Exchange. It enables disintermediation of trust in exchanging health data, reducing transaction and administrative costs by making the system more efficient, enhance security in protecting patient identities, sharing real-time data across parties and secure data access.

Although health care blockchain presents numerous opportunities for health care; however, it is still immature and cannot be immediately applied. Several concerns and challenges in its practicality have also arise: data anonymity, cost on establishing the technology, regulations and individuals' willingness in participating are still in questioned. Other than that, various technical, organizational, and behavioral economics challenges must be carefully analyzed before blockchain technology can be adopted by health care organizations nationwide.

[20] https://nasional.sindonews.com/read/1019210/149/makassar-sehat-dengan-home-care-telemedicine-1435804869; dr. HJ. Naisyah T. Azikin, M.Kes (Kepala Dinas Kesehatan Kota Makassar)'s presentation: Pelayanan Telemedisin Kota Makassar (Telemedicine Service in Makassar)

[21] https://nasional.sindonews.com/read/1019210/149/makassar-sehat-dengan-home-care-telemedicine-1435804869

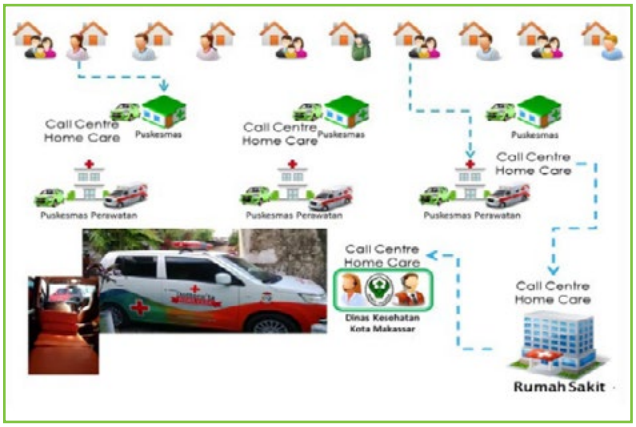
Current eHealth implementation

Public Sector

Indonesia Government's initiatives in digital health including:

1. **Makassar's 24-hour-homecare/ telemedicine and tele-radiology**
   The previous Makassar's city municipal, Ramdhan Pomanto, has initiated in implementing technology-based health care services for the sake of health equality in the city and its surrounding areas. Located in eastern Indonesia, Makassar introduced 24-hours-homecare service and telemedicine services[20] by its homecare service, health care force will come to patient's house, therefore increase the accessibility to health care professionals in the underserved areas. In its implementation, a transportation facility (Dottoro'ta) to take the patients to the health care service and vice versa is provided. Dottoro'ta is equipped with medicines, medical devices, oxygen tanks and a patient condition monitoring tool, that connects patients directly to a specialist through a wall room[21].

24-hour Health Care Service in Makassar



Telemedicine map in Makassar

[22] https://kominfo.go.id/content/detail/11490/siaran-pers-no-224hmkominfo112017-tentang-menkominfo-dorong-bpjs-manfaatkan-big-data-bentuk-transformasi-digital-model-bisnis-bpjs/0/siaran_pers

[23] https://www.bpjs-kesehatan.go.id/bpjs/index.php/post/read/2017/606/Ini-Strategi-RS-An-Nisa-Kelola-Keuangan

2. JKN Mobile

Badan Penyelenggara Jaminan Sosial (BPJS) *Kesehatan*, the provider of the National Health Insurance – Healthy Indonesia (JKN –KIS) program, is harnessing technology to create a better national health system to serve all Indonesians. This Mobile JKN application is a form of digital transformation business model by BPJS *Kesehatan* which started as an administrative tools used in BPJS office branches or health care facilities. It is then transformed to an app which allow their user to access it with no limited time (self service)[22].

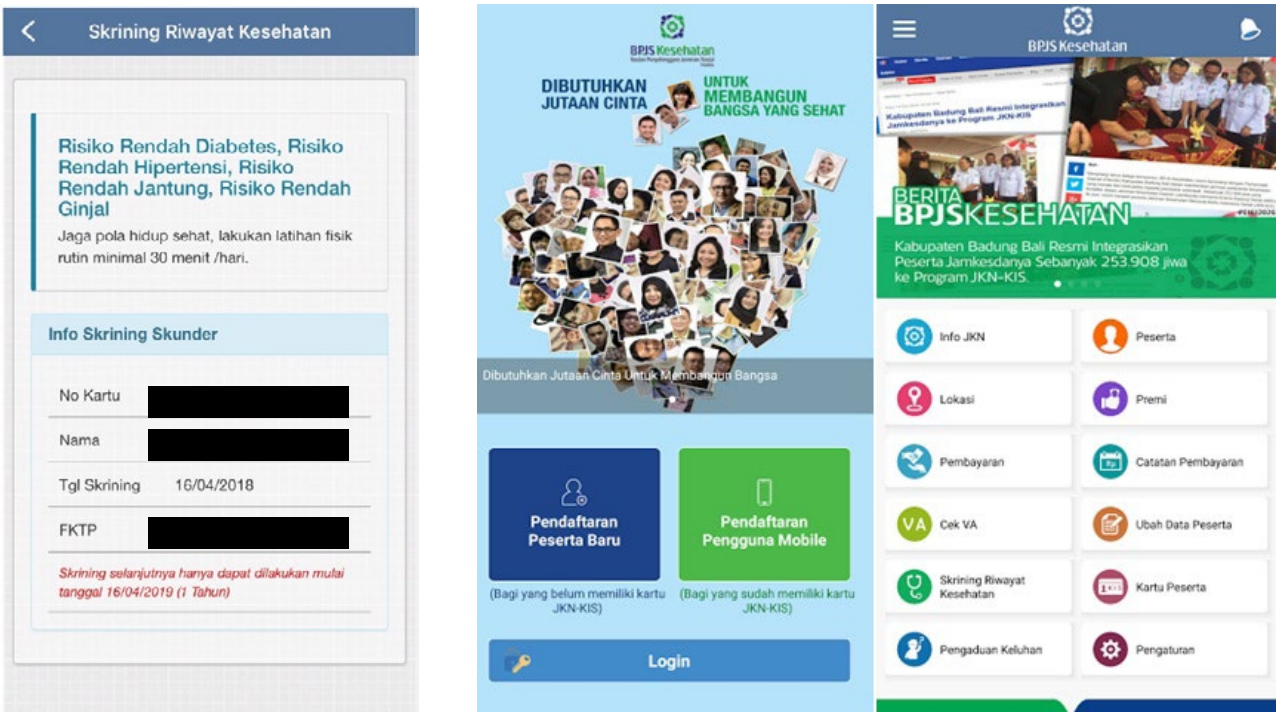
The development of the BPJS *Kesehatan* mobile application is part of their commitment in giving convenience and simplicity for an optimal experience. Through this application, users are able to access various information regarding JKN, which is managed by BPJS Kesehatan that is user friendly and snappy, anytime and anywhere.

Features that are offered to the users who is also the insurance consumers includes:

- BPJS general information
  Users are able to find their personal data such as their membership number, pin point and preview maps of health facilities based on branches and nearest available location.
- Invoicing
  Users can find their information regarding payments, such as virtual accounts, invoice notification and mobile payment.
- Selective health screening
  This health screening consists of 47 questions regarding eating habits, psychological symptoms, and exercise time, communicable and non-communicable diseases. This screening will be done yearly. From this questionnaire, BPJS (or the government) are able to estimate the risks for diabetes, hypertension, dyslipidemia, coronary heart disease, stroke, kidney disease and even mental disorder.

3. BPJS Digital Claim Verification (*Verifikasi Digital Klaim*/ Vedika)

To improve BPJS service and operation, BPJS launched BPJS Digital Claim Verification Software, that can be utilized to claim both inpatient and outpatient services. The application would be useful for hospital management, in terms of helping monitoring its JKN cost. Association of Indonesian Hospitals in Indonesia (Perhimpunan Rumah Sakit Seluruh Indonesia/ PERSI) and BPJS Kesehatan has agreed to support digital claim verification[24].

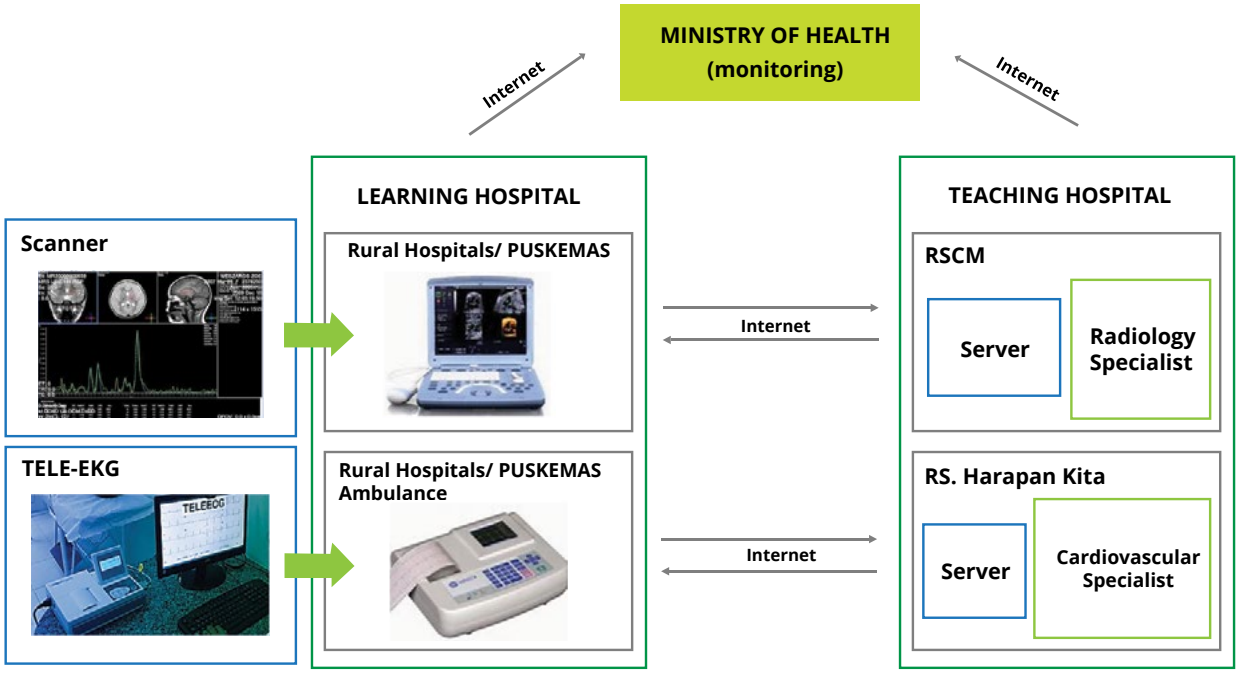


source: BPJS Kesehatran apps, taken 16 April 2018

[24] Hasil Pertemuan Perhimpunan Rumah Sakit Seluruh Indonesia (PERSI) bersama BPJS Kesehatan, 1 February 2018

4. **Digital Acquired Immune Deficiency Syndrome (AIDS) Application**[25]
In 2013, Indonesia's Ministry of Health, together with Indonesia AIDS Coalition (IAC), launched Digital AIDS Application. The initiative, which was run by people living with Human Immunodeficiency Virus (PL-HIV) (*orang dengan* HIV, AIDS (ODHA)), has the aim to support AIDS prevention programs. AIDS Digital contains information on services comprised of HIV testing, Anti-Retroviral (ARV) therapy, PL-HIV support groups, vertical prevention, sterile needle syringe services, methadone services and STI services. There are also online directories of agencies working on AIDS prevention programs such as Ministry of Health, Health Office, AIDS Prevention Commission, NGOs and also key population networks. This app beneficial in achieving the AIDS countermeasures program. AIDS Digital contains range of services from HIV testing, ARV therapy, PL-HIV support group, vertical prevention, availability of sterile syringes to methadone and sexually transmitting disease (STD) services. Also available, an online directory by partnering institution such as the ministry of health, publlic health office (*Dinas Kesehatan*), AIDS counting commission (*Komisi Penanggulangan* AIDS), non-governmental organizations (NGOs) and several key populations.

5. **TeleECG and TeleRadiology**
TeleECG and TeleRadiology are the two telemedicine pilot projects initiated by the Ministry of Health in 2012, with the concept of teleimaging and telediagnostic, specifically in referring the results of electrocardiography (ECG) and X-Ray. In 2013, there are 12 primary care facilities and 2 referral center hospitals (dr. Cipto Mangunkusumo National Central General Hospital (Rumah Sakit Umum Pusat Nasional (RSUPN) Dr. Cipto Mangunkusumo/ RSCM) & Harapan Kita Hospital) supporting both of the telemedicine. In its implementation, Radiology and ECG data from primary cares are transferred through a server to referral hospitals. RSUPN RSCM acts as TeleECG's referral center, while Harapan Kita Hospital plays a part as TeleECG's referral center[26].



source: Kebijakan Pemerintah Mengenai Telemedicine di Indonesia, 2013, Kemenkes.

[25] https://www.iac.or.id/portfolio/aids-digital/
[26] Kebijakan pemerintah mengenai telemedicine di Indonesia, 2013, Kemenkes

6. **P-Care BPJS**[27]
   P-Care BPJS is a web based application of patient information system that is provided by BPJS for primary care facilities to access data to BPJS server more easily. This application provide services including registration, diagnosing, therapy and laboratory services. This app is introduced back in 2014, and up until now it has a lot of tweaks that makes using this app seamless and easy, especially with the amount of BPJS user that keeps growing. It allows real-time and integrated patients' services between all levels of institutions.

7. **Application for Online Outpatient Registration**
   The Government of Indonesia's Ministry of Health launched a website-based queue management system. By accessing http://sirs.yankes.kemkes.go.id/, patient who is seeking outpatient treatment will be able to choose the hospital and physicians. After registering themselves, they will have a registration number, to be then presented to the targeted hospital. A total of 32 State-owned General Hospital Center (RSUP) in Indonesia have been included in the system.[28]

[27] https://www.bpjs-online.com/mengenal-pcare-bpjs-kesehatan/
[28] http://medan.tribunnews.com/2017/07/05/tak-perlu-repot-mau-berobat-rsu-p-ham-bisa-daftar-rawat-inap-secara-online?page=2

Private Sectors

Private sectors have more initiatives regarding the development of telemedicine, since it is believed to be the future to improve the promptness and accuracy of medical diagnostics and consultations in primary care[29]. It is most likely that users preference on using the digital health care application because of its practicality and convenience (see the box with title: How Does the Patients and Doctors Like eHealth Application? Page 72). Following information will describe on the Indonesian telemedicine development from private sectors:

1. **AloDokter[30]**
   AloDokter is a mobile application platform that focuses on giving high quality medical information that is easily understood by Indonesian-speaking users. Contents from diseases, drugs and daily difficulties that based on research are what AloDokter provides in their website and mobile app. This platform support users to take care of their own health and their families. Other features are included in the services, such as find drugs, doctors, hospitals, ask doctors and explanation of diseases.

2. **GO-MED**
   GO-MED is a mobile based application created by GO-JEK and Halodoc. It is one of the features that integrated within the GO-JEK application. GO-MED provide services which enables users to order their need of medicine via online application. Users can easily choose or input the product needed and the driver will directly buy the medicine and send it to the user.

3. **Gue Sehat[32]**
   GueSehat mobile app is the first online health community in Indonesia. This platform is also available in website form, it facilitates users to share their experiences regarding health issues, and users are welcome to write articles which will be sorted by their team. Their goal is to be the company that users trust to be their go to place to tell their story. They are also completed with self-diagnosing features, in-app health consultation, health and lifestyle guides and digital forums.

4. **HaloDoc and GoApotik[33,34]**
   Halodoc is a mobile application health care platform that unites patients, doctors, insurance, and pharmacies into one simple health care application. Halodoc has a vision to become the number one health care hub. It provides doctor consultation service by connecting general practioners, pediatrician, obstetrician-gynecologist, internists, and numerous other specialists; to patients at home through chat, voice call and video call. They work together with doctors who are registered by the Indonesian doctors' association (*Ikatan Dokter Indonesia*/IDI) and Indonesian Medical Counsils (*Konsil Kedokteran Indonesia*/KKI), who have a medical practice license (*Surat Ijin Praktek*/SIP and *Surat Tanda Registrasi*/STR). In addition, they provide tele-pharmacy service, by partnering with over 1,000 trusted pharmacies to deliver medicine to their customers' doorstep within an hour. Halodoc sells over-the-counter medication, vitamins, consumer products and prescription drugs. To order prescription drugs, customers are only required to take a photo of their prescription, then upload it for verification.

5. **Homedika[35]**
   Homedika is an app created by Indonesia Medika, a religious grass root-based organization based in Malang, which its members engaged in the collaboration of scientific fields and the applicable field with health interconnection to create innovative health products. Homedika is a technology-based social entrepreneur that connects health care workers and facilities with community/society in providing various health care services, with its motto: "Making Indonesian Health Services Integrated, Connected and Collaborated". Through the Homedika product, Indonesia Medika brings several services, including; teleconsultation (Med-Talk), Med-Chat and Med-Call; medical e-commerce site (Med-Shop); home visit

[29] Kemenkes RI, Kebijakan Pemerintah Mengenai Telemedicine di Indonesia, 2013
[30] https://www.alodokter.com/about
[31] https://www.go-jek.com/go-med/
[32] https://www.guesehat.com
[33] https://www.halodoc.com/
[34] www.goapotik.com
[35] https://www.indonesiamedika.com

(Med-Visit); emergency service (Med-Lance and Med-Quick); healthy catering (Med-Food); blood donor (Med-Blood); and health articles (Med-News).

6. **Homecare24**[36]
   Homecare24 is an online mobile app platform that provides 24 hours' in-home health care services, health care workers who are employed by this platform consists of licensed doctors and nurses. The services can be ordered straight from their website or application from smartphones and PCs, so users need to sign-up and then log in to get the services they want. Services can then be rated based on your preference.

7. **Indonesian Kalkulator of Oocyte (Indonesian Kalkulator of Oocytes/ IKO)**[37]
   IKO is a mobile application which predicts ovarium's biological age and the chance of pregnancy, by knowing patient's AMH (Anti-Mullerian Hormone) level. This Assisted Reproductive Technology (ART) is a result of Dr. dr. Budi Wiweko, SpOG (K)'s research, that found that AMH can be utilized as a biomaker of ovarium's biological age. IKO can be used as physician's reference guide when they provide consultation to patients with infertility disorders.

8. **K24 Klik**[38]
   K24Klik is the first online pharmacy store in Indonesia available in mobile app platform that provides several services, such as consultation, order and delivery for 24 hours a day, 7 days a week. K24Klik is claimed to be online pharmacy store that provides the most comprehensive pharmaceutical products. They also guarantee the authenticity of the medicines sold. The drugs ordered can be taken or delivered by users.

9. **Klik Dokter**[39]
   KlikDokter provides educational services, which provide excellent approach in terms of communications and information to the Indonesian speaking users in both medical and non-medical matters, such as beauty and general health-related information. They provide in-app and web consultation through live chats with general practitioners and specialized physicians.

10. **Medika App**[40]
    This mobile app lets the users find and book a consultation appointment with their preferable doctor at the nearest hospitals or clinics right at their fingers tip without any problem. The app also allow users to find, buy and book visits with additional promos and packages at their partnered clinics and hospitals. Other features including booking confirmation in 30 minutes, payment options with bank transfer or credit card right from the application, 12 months' installments and articles or information regarding beauty and health are parts of the service provided.

11. **Medico**[41]
    With their motto powering and empowering, Medico is a private cloud based management information system in web-based platform that is able to facilitate hospitals or clinics with a functional IT system that allows health care workers get updates on their patients remotely. Their product also has several special features to provide better services for patients and workers to minimize adverse effect and human-error such as drug interaction tracker, e-prescription, mobile management reporting, medical billing system and centralized inventory control.[42]

    Based on a report published in 2017, it was written that Medico has provided its compatibility with P-Care BPJS, which allows primary health care facility to achieve several indicator numbers requested by BPJS.[43]

[36] https://homecare24.id/tentang-kami
[37] https://www.researchgate.net/publication/323170359
[38] https://www.k24klik.com/tentang-k24klik
[39] https://www.klikdokter.com/pages/tentang-kami
[40] https://www.medika-platform.com/en
[41] https://medico.id/aboutus.html
[42] https://medico.id/index.html#learnmore
[43] http://www.beritasatu.com/iptek/468896-medico-kenalkan-fitur-integrasi-dengan-pcare-bpjs.html

12. MIMS Indonesia[44]

MIMS is a mobile based application that provide essential prescribing and drug reference guide. Established in 1963, MIMS is a multi-channel provider of drug information, medical education and services connecting health care communities working in 13 countries across Asia Pacific, which licensed in the UK. Their work empowers health care professionals to improve patient outcomes by facilitating knowledge exchange and better decision-making. Today, MIMS is present in 13 countries across Asia Pacific with approximately two million health care professional subscribers to its drug & resource portal, digital and print publications. The MIMS mobile application is available for free for android and IOS.

13. PesanLab[45]

Pesanlab is the Indonesian first online web based platform for ordering laboratory and medical checkup services, which based in Central Jakarta. Through Pesanlab, Jakarta resident can request bloodwork test service just as easy as booking a ticket. The services offered in this app are home service and lab online results.

14. Periksa.id[46]

This web platform helps doctors, clinics and hospitals to make everything multifunctional so that they can organized and control everything regarding patients, medical record and inventory more efficiently. This will affect the productivity and performance of doctors, clinics or hospitals, and when their productivity increases it will affect income and revenue.

15. Pro Sehat[47]

Pro Sehat mobile app provide easy access for the user to update vaccination status even without leaving home. In the in-app, the user can access services, such as carefree vaccination appointments and consultations in selected areas in Indonesia. They also provide other services including purchasing in-app medical devices, vitamins, herbals and medications.

16. RSPI Mobile[48]

RSPI Mobile is a free mobile application managed by Rumah Sakit Pondok Indah (RSPI) that is specially designed to facilitate patients in finding doctors and hospitals, and making hospital reservations. Using the application, patients will be able to access virtual member card, rate doctors, submit booking inquiry, as well as to be well informed about hospital's promotion program.

17. TeleCTG[49,50]

TeleCTG is a mobile application based medical technology start-up from Indonesia that developed a mobile cardiotocography (CTG) referral system. TeleCTG has been developed since 2015 by dr. Ari Waluyo, a Jakarta-based obstetrian-gynecologist, who have immersed himself in remote areas in order to provide medical assistance to mothers and children. The idea was arisen because the main factors behind pregnant women/mothers and children mortality cases is the fact that midwives in remote areas in Indonesia cannot identify fetal distress, as CTG devices are very costly. TeleCTG stands as a solution for a low-cost CTG device that can quickly deliver the output data from remote locations to obstetrician-gynecologist, who will then analyse the data and provide feedback.

[44] http://corporate.mims.com/about-mims/
[45] https://www.pesanlab.com
[46] https://periksa.id
[47] https://www.prosehat.com/tentang-kami
[48] http://www.rspondokindah.co.id/id/visitor-and-patient-information/information/detail/23/rspi-mobile
[49] telectg.co.id/
[50] https://www.linkedin.com/company/telectg

18. Sehati[51]

Sehati is a mobile application provided in Indonesian language that assist expecting mothers in monitoring their pregnancy through a standardized guidance and in making reservation for health check-up. Sehati was founded with the aim to improve newborns' health and nutrition, as expecting mothers often face lack of practical information and guidance about their pregnancy. The condition is also worsen especially with the fact that there are only about 3,500 obstetrician-gynecologist nationwide - who are also unevenly-distributed. Meanwhile, there are around 5 million new expecting mothers every year (1.7 percent annual growth). As a result, according to WHO, Indonesia is the top 9th of country with highest Low Birth Weight (LBR) newborns. The total of 15 percent of Indonesian newborns mainly suffer from low nutrition with weight <2.5kg, a rise from 10 percent in 2014. The vision of Sehati is a trilogy that aims to provide beneficial and educational information throughout a human's lifecycle through a web platform and complementary applications. "Sehati Kehamilanku" serves as the entry gate to the whole "Sehati journey" that initially focuses on "Kehamilanku" and will continue with "Anakku" and "Keluargaku". If the implementation of the system works well, the data that is gathered from the system can be a valuable source for the Government of Indonesia and the Local Government to provide proper approach for the health of the society. On August 2018 Sehati merged with TeleCTG into one application named Sehati TeleCTG and shifted its model business to the development of tehnology of the mobile application Sehati and the tools to check health pregnancies.

[51] https://sehati.info

eHealth Application		Products	
		Private	Public
	**Hospital Information System (Patient data management/ administrative stuffs)** • A system that process and integrate service flow in clinic or hospital in form of communication network.	• Medico • Periksa.id	• V-Claim BPJS • P-Care BPJS • Ministry of health outpatient online registration application (SIRS YANKES KEMKES) • JKN Mobile
	**E-prescribing** • Technology framework that allows health care professionals to write and send prescription electronically instead of using handwritten notes.	• HaloDoc • Prosehat	
	**Clinical decision support facilities** • Health information technology designed to provide health care professionals with clinical decision support.	• Tele-CTG • MIMS Indonesia	• Tele-ECG • Teleradiology
	**Patients health informatics** • A system that provides information for patients which facilitates the promotion of self-care, promoting healthy behaviors and peer information exchange	• Guesehat • Alo Dokter	• JKN Mobile
	**Clinical Information Providers** • Source for trustworthy and timely health/medical news and information	• MIMS Indonesia • HaloDoc • Alo Dokter • Guesehat • Sehati • Homedika	
	**Virtual health care teams** • A digital platform that allows health care professionals to collaborate and share information on patients	• ACAP Indonesia	
	Mobile health (wearable devices) • Smart electronic devices that can be worn on the body as implants or accessories.	• Fitbit® • Samsung Gear® • Apple Watch®	

eHealth Application		Products	
		Private	Public
	**Tele-pharmacy** • Delivery of pharmaceutical care via telecommunications to patients in locations where they may not have direct contact with a pharmacist.	• HaloDoc • K24Klik	
	**Tele-consultation** • Consultation by remote telecommunications, generally for the purpose of diagnosis or treatment of a patient at a site remote from the patient or primary physician.	• HaloDoc • Alo Dokter • Medika app • Tele-CTG • Homecare24	• Tele-ECG • Teleradiology • 24-hour-homecare service, hospital-to-hospital telemedicine and tele-radiology by targeting student hospital in remote areas.
	**Tele-rehabilitation** • Delivery of rehabilitation services via information technologies.		
	**Tele-laboratory** • Telecommunication facility that allows patient to get result of medical tests performed in a laboratory located remote from the patient.	• PesanLab	
	**Tele-radiology** • Transmission of radiological patient images (x-rays, CTs, MRIs) from one location to another.	• Tele-CTG	• Tele-ECG • Teleradiology Kemkes
	**Appointment scheduling** • Application that help patients to manage appointment across clinics and health care professionals.	• RSPI Mobile	
	**Research/Big Data** • Health information collected from single individuals to large cohort to allow all related health practitioners (parties) to work together to find evidence based solutions.	• IKO • ACAP Indonesia • Tele-CTG - Sehati	

eHealth Application Matrix

Application	Type	Government-or Private Initiative	Benefit	(Possible) Disadvantage
Mobile JKN	Mobile only	Government-initiative – provided by BPJS Kesehatan, a state-owned enterprise, which was initiated by Ministry of Health.	• Through the apps user can apply for JKN-KIS insurance • Users are able to find personal membership number, pin point and maps of health facilities and maps of health facilties and other information regarding insurance members; • The services that are available payment information virtual accounts, payment & health history, insurance status, invoice notification, complaints form, and mobile payment.	• The apps is only available in Indonesian. • The apps is only available for user who is registered.
GueSehat apps or. guesehat.com	• Mobile • Web-portal • Additional program of GueSehat is that they provide information in other social media, such as Twitter and Instagram.	Private-initiative (developed by PT. Anugerah Arkon Media)	• The apps provide detailed information on trending topic on health, presented in a fresh and interesting look, simple and smart, and colorful. • Info about man and woman's health symptom (the apps provides more than 350 symptoms information available on physical and mental health); directory (about hospitals, medical doctors, clinic, spa and massage, beauty, laboratory, gym and health club, restaurant, health practitioners), ongoing events. • Topics for the article: medical, beauty, lifestyle, sex and love, pregnancy, toddler life, discussion or chat forum on health topic.	In the "book" segment, we can only pick up available options, if not we cannot get info from there, but we can use "discussion forum" facility instead.

GoApotik	• Mobile application • Web-based via goapotik.com • Distribution service focusing on medicine or pharmaceutical drugs .	Private initiative – under Dexa Group (pharmaceutical and health care product producer)	• GoApotik provides services to distribute wide range of pharmaceutical drugs, goods from baby and beauty shop. • The GoApotik apps confirms that they only sell qualified and official goods, including prescription drugs. • GoApotik is a trusted partner of big e-commerce. • Payment to the merchant using official account of GoApotik through payment gateway.	
K24 Klik apps or k24klik.com	• Mobile application • Web based via www.k24klik.com	Private initiative by K24 Pharmacy	• 24 hours service and trusted products as it links to K24 Pharmacy. • The availability of health consultant and pharmacists. • Redeem doctors' prescription online. • Easy access, easy payment method, buyer can pay using Cash on Delivery / COD payments, Internet Banking, electronic money payments, ATM transfers and credit card payments.	Slow delivery (based on the K24 app review)

Halodoc apps or halodoc.com	• Mobile application • Web based via www.halodoc.com (the full services provided only through Halodoc mobile application)	Private initiative by Jonathan Sudharta	• Connects patients with licensed doctors for online consultation • Medicine delivery – partners with pharmacies and Gojek. • At-home lab test service – partners with Prodia, offers various lab test package • Halodoc wallet enables direct payment via application • Comprehensive information and articles about health, diseases, and lifestyle	

Challenges

Despite the benefit, the obstacle in implementing and developing a comprehensive eHealth environment in Indonesia can be perceived as massive, since Indonesia is still in the midst of their infrastructure development. Other than that, community acceptance, competence of the users, interoperability, and slow growth adaptation from the policy makers are other reasons that slow down the process even more.[52]

Infrastructure Limitation/Problems

Power Source

As per 2017, Indonesia's state electricity company (*Perusahaan Listrik Negara* / PLN) stated that Indonesia has 95.92 percent electrification ratio, superior to their initial target which is 92.75 by the end of 2017. This target is not based by a certain territory or area, instead it is based on how many houses that have access to electricity.[53] This percentage shows high numbers of ratio, but considering the vast area and magnitude of Indonesia population, this means that there are still 25 million people in Indonesia that do not have access to electricity, especially in the eastern region.[54] This was confirmed by PLN's statement which clarified that Eastern Nusa Tenggara and Eastern Papua only have electrification ratio of 60 percent.[55,56]

Communication Network

According to Association of Indonesian Internet Service Providers (*Asosiasi Penyelenggaran Jasa Internet Indonesia*/APJII), in 2017, more than 50 percent (or 143.96 million Indonesian populations) of the 260 million Indonesian have access to the internet[57]. Pertaining the amount of internet users, Indonesia is the fifth highest number of internet users in the world[58], after China, India, United States, and Brazil, but in terms of internet penetration, the country is considered to have low internet penetration compared to developed countries that has implemented more advanced eHealth technology. Other than internet penetration, digital health literacy and EMR implementation are several concerns which are still faced by internet users in the country. The other concern is regarding the challenge in connectivity. While fiber optic cables are going into the villages, actually in some areas, especially in rural areas, the stability of communication network is still not adequate for the implementation of digital health.[59]

A good news came from the Ministry of Communication and Information Technology, as they have confirmed that they are now in the process on the development of networks and infrastructure across its region through several programs such as Desa Broadband, Palapa Ring Program and Refarming 4G[60]. According to Dr. Nyoman Adhiarna, e-Business Director, Indonesian Ministry of Communications and Information, due to the wide and rapid innovation of eHealth practice, it cannot be managed in a special instrument. This will be a good sign that Indonesian people are able to use eHealth technology as part of their integrated health system in the near future. On the other hand, regarding the internet availability in the hospital in the country we still have to face unpleasant reality that only one out of 33 cities has 100 percent internet availability, while 14 cities of them have 80-99% availability, and the hospital in the five cities provide the percentage of under 59 percent internet availability (see the table 32).

At the moment there are several eHealth services, which provided by governmental institution, one of them is the JKN Mobile application, which can be utilized by all of the Indonesians, not only covered to those who live in the city areas, but also the ones lives remotely. This eHealth service provided by Badan Usaha Penyelenggara Jaminan Sosial - Kesehatan or BPJS Kesehatan, a state-owned enterprise on national social security service developed by the Indonesian's Ministry of Health. The service covers exchange of data

[52] Kebijakan Pemerintah Mengenai Telemedicine di Indonesia, 2013
[53] https://katadata.co.id/berita/2018/03/06/pln-targetkan-seluruh-wilayah-indonesia-dapat-akses-listrik-tahun-ini
[54] https://www.suara.com/bisnis/2017/06/07/140358/ada-25-juta-orang-indonesia-masih-tanpa-akses-listrik
[55] https://katadata.co.id/berita/2018/03/06/pln-targetkan-seluruh-wilayah-indonesia-dapat-akses-listrik-tahun-ini
[56] https://www.suara.com/bisnis/2017/06/07/140358/ada-25-juta-orang-indonesia-masih-tanpa-akses-listrik
[57] http://jakartaglobe.id/business/indonesia-143m-internet-users-2017-apjii/
[58] https://www.statista.com/statistics/262966/number-of-internet-users-in-selected-countries/
[59] Penggunaan Telemedicine di Indonesia, Kemenekes, 2013
[60] https://kominfo.go.id/content/detail/11490/siaran-pers-no-224hmkominfo112017-tentang-menkominfo-dorong-bpjs-manfaatkan-big-data-bentuk-transformasi-digital-model-bisnis-bpjs/0/siaran_pers

and information in attempts on expanding informatics application, public education and research, which supported by the Ministry of Communication and Information Technology in supporting the availability of system and technology information for the JKN – KIS, as mentioned in the press conference on November 15th, 2017.

Although there are many benefits in using eHealth technology that nowadays are enjoyed by the most of Indonesian especially in the big cities, telehealth is not yet integrated globally into existing health care systems. The reasons are vary: lack of proven large-scale operations, poor evidence base, inadequate implementation, lack of attention to the "soft side" of implementation (readiness, change management), and many others. Other than in Indonesia, reasons can be more pragmatic in other developing countries, including limited resources, unreliable power, poor connectivity, and high cost for the poverty-stricken person – those most in need. Telehealth is poised to improve health and health care in the developing countries, driven by both altruistic and profit motives. But on the other hand have the desired effect, telehealth must address very specific and evidence-based health "needs" of each facility, region, or country; the shortage of health workers and medical specialist services; and the required skills upgrading and training, allowing the developing countries to establish their own critical mass of experts. This condition will only be achieved by raising awareness, understanding, and ability regarding telehealth capability and limitations by the coordinated political and professional as well as by those who involved to guide public and private innovation and telehealth integration.[61]

[61] https://www.researchgate.net/publication/276337781_Telehealth_in_the_developing_world_current_status_and_future_prospects

Communication Device Availability in Public Hospitals in Indonesia[62]

No.	Province	Communication Device in Public Hospitals (%)		
		Telephone	Mobile Phone	Internet
1	Aceh	100	16.7	84
2	North Sumatra	94.4	11.1	72.2
3	West Sumatra	100	40.9	100
4	Riau	91.3	34.8	82.6
5	Jambi	92.3	7.7	84.6
6	South Sumatra	88.5	34.6	92.3
7	Bengkulu	76.9	23.1	61.5
8	Lampung	100	28.6	71.4
9	Bangka Belitung	100	0	85.7
10	Riau Islands	81.8	45.5	54.5
11	DKI Jakarta	100	36.8	94.4
12	West Java	100	34.8	97.8
13	Central Java	100	26.2	96.7
14	DI Yogyakarta	100	40.0	90
15	East Java	100	39.5	98.7
16	Banten	100	22.2	66.7
17	Bali	100	23.1	76.9
18	West Nusa Tenggara	100	22.2	88.9
19	East Nusa Tenggara	94.1	11.8	75
20	West Kalimantan	88.9	35.3	72.2
21	Central Kalimantan	93.8	37.5	87.5
22	South Kalimantan	100	20	89.5
23	East Kalimantan	95	20	95
24	North Sulawesi	75	12.5	68.8
25	Central Sulawesi	86.7	20	66.7
26	South Sulawesi	94.3	25.7	71.4
27	Southeast Sulawesi	66.7	20	66.7
28	Gorontalo	83.3	66.7	66.7
29	West Sulawesi	100	0	66.7
30	Maluku	85.7	28.6	50
31	North Maluku	75	8.3	58.3
32	West Papua	80	40	40
33	Papua	77.8	22.2	55.6
INDONESIA		93.6	27	82

[62] Kebijakan pemerintah mengenai telemedicine, kemenkes, 2013

Community Acceptance

At this time the most prevalent barrier to the implementation of telemedicine programs globally is the perception that the costs of telemedicine system are too high. In addition, some medical professionals have lack of technical expertise and have not put their trust on technology yet. This kind of fear is understandable, realizing that the risk of data loss, incorrect data input, connectivity problem, breaching medical ethics, etc. are still part of the inadequate daily health practice in the country. In addition to that the health care professionals may be passionate about telemedicine only if they are ensured that it is eligible according to Indonesia's medical ethics and regulations.

Human Development Index

Human development index (HDI) is a composite statistic (composite index) of life expectancy, education and per capita income indicators, which are used to rank countries into four tiers of human development. A country scores higher HDI when the three aspects: the life span, the educational level, the GDP per capita have high scores. The index is based on the human development approach, developed by Ul Haq, an economist from Pakistan economist. It is often framed in this index in terms of whether people are able to "be" and to "do" desirable things in life. Some of the examples include – doings: work, education, voting, participating in community life. It has also be noted that in the HDI the freedom of choice is central – someone who chooses to be hungry (e.g. During religious fast) is quite different to someone who is hungry because he or she cannot afford to buy food.[63]

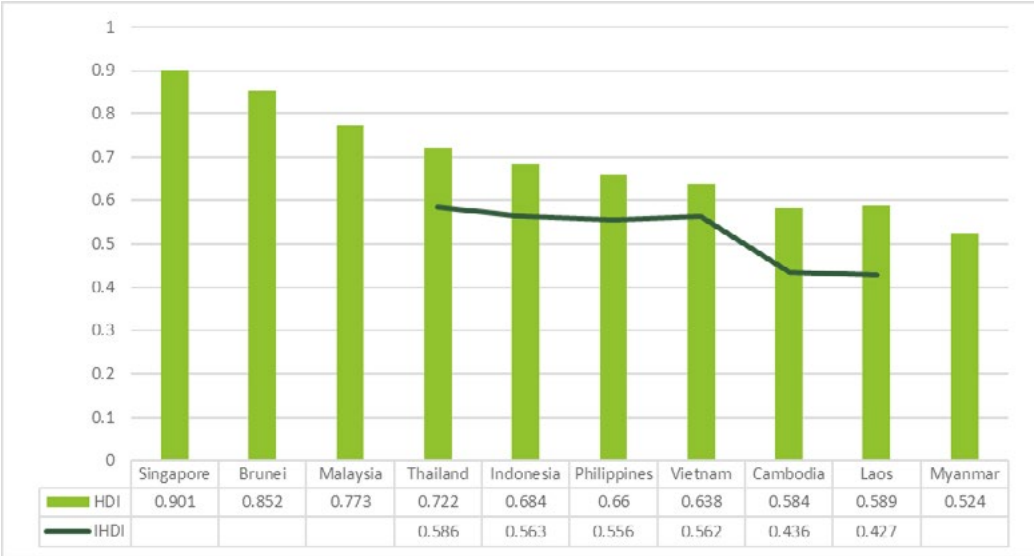
Published on November 4th 2010, the new method in calculating the HDI combines 3 dimensions:[64]

- Life expectancy at birth (LE)
- Mean years of schooling (MYS) and expected years of schooling (EYS)
- Gross national income (GNI) per capita (GNIpc)

The HDI has been criticized on a number of grounds, including alleged lack of consideration of technological development or contributions to the human civilization; focusing exclusively on national performance and ranking; lack of attention to development from a global perspective; measurement error of the underlying statistics; and on the United Nation's Development Programme (UNDP) changes in formula which can lead to severe misclassification in the categorization of 'low', 'medium' or 'very high' HDI.[65]

[63] "Human Development Index". Economic Times; "The Human Development concept". UNDP. 2010. Retrieved 29 July 2011.
[64] "Human Development Report 2010". UNDP. 4 November 2010; "Technical notes" (PDF). UNDP. 2013.
[65] Wolff, Hendrik; Chong, Howard; Auffhammer, Maximilian (2011). "Classification, Detection and Consequences of Data Error: Evidence from the Human Development Index". Economic Journal. 121 (553): 843–870. doi:10.1111/j.1468-0297.2010.02408.x

Human Development Index in ASEAN Countries[66]



	Singapore	Brunei	Malaysia	Thailand	Indonesia	Philippines	Vietnam	Cambodia	Laos	Myanmar
HDI	0.901	0.852	0.773	0.722	0.684	0.66	0.638	0.584	0.589	0.524
IHDI				0.586	0.563	0.556	0.562	0.436	0.427	

Table ..: Indonesia is in the fifth rank of HDI among other ASEAN countries in 2015

Indonesia's HDI in 2015 puts them in the "medium" category and ranked 113 out of 188 countries and territories. The HDI value is 30.5 percent, increased from its value in 1990. It reflects the progress Indonesia has made in life expectancy at birth, mean years of schooling, expected years of schooling and GNI per capita during the period. However, Indonesia's HDI falls when inequality is taken into account. Inequality-adjusted HDI (IHDI) is a measure of the average level of human development of people in a society once inequality is taken into account.[67]

Interoperability

Interoperability is the ability of a system to work with or use the parts or equipment of another system.[68] According to the Health care Information and Management Systems Society (HIMSS), in health care, interoperability is the ability of different information technology systems and software applications to communicate, exchange data, and use the information that has been exchanged. In practical, interoperability means the ability of health information systems to work together within and across organizational boundaries in order to advance the effective delivery of health care for individuals and communities. There are three levels of health information technology interoperability:

- **"Foundational"** interoperability allows data exchange from one information technology system to be received by another and does not require the ability for the receiving information technology system to interpret the data.
- **"Structural"** interoperability is an intermediate level that defines the structure or format of data exchange (i.e., the message format standards) where there is uniform movement of health care data from one system to another such that the clinical or operational purpose and meaning of the data is preserved and unaltered. Structural interoperability defines the syntax of the data exchange. It ensures that data exchanges between information technology systems can be interpreted at the data field level.
- **"Semantic"** interoperability provides interoperability at the highest level, which is the ability of two or more systems or elements to exchange information and to use the information that has been exchanged.[5] Semantic interoperability takes advantage of both the structuring of the data exchange and the codification of the data including vocabulary so that

[66] http://hdr.undp.org/en/composite/IHDI
[67] http://www.id.undp.org/content/indonesia/en/home/presscenter/pressreleases/2017/03/22/indonesia-s-human-development-index-rises-but-inequality-remains-.html
[68] https://www.merriam-webster.com/dictionary/interoperability

the receiving information technology systems can interpret the data. This level of interoperability supports the electronic exchange of patient summary information among caregivers and other authorized parties via potentially disparate electronic health record (EHR) systems and other systems to improve quality, safety, efficiency, and efficacy of health care delivery.

Hospital Management Information System: must exist and functional

In order to execute a future in the digital health technology, a functional hospital management information system (HMIS) in hospitals and clinics is a necessity. Today, Indonesian Hospitals both public and private hospitals are beginning to implement the technology in building their facilities and infrastructure, this transformation is part of paving the way to the world digitalization era. One of the most basic service that can be implemented in hospitals are through the hospital management system which integrates with the online CCTV. Other available service is the managed service provider for booking appointments.[69]

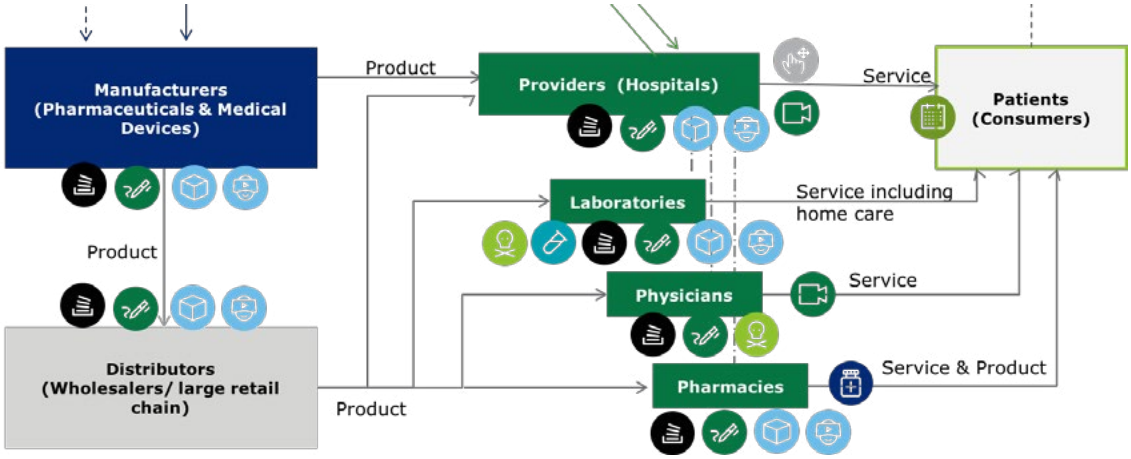
Hospital management information system is a computerized system that processes and integrates the flow of all business process and health care services in a coordinated network. This system provides reporting and other administrative procedure for a faster, precise and accurate information. In the future there is a possibility that this system can be used as an integrated system with the government institution and also the smart city program, which not only make an advance integrated hospital technology management system, but also an opportunities to provide a better care for the patients. These are few of the advantage in using Hospital management information system:[70]

1. Integrated hospital management;
2. Pharmaceutical stocks and multi storage floor stock can be lively updated;
3. In and out patient, single billing statement which covers all services;
4. Complete disease and nursing history (medical records) of patients that can be process and recalls automatically;
5. Diagnostic and operational statistical analysis for all patients with a standardized procedure by WHO;
6. Simplify budgeting process and realizing control;
7. Simplify both actual cash-flow and cash-flow plan;
8. Keeping data consistencies due to data sharing for both data master (patient, doctors, nurses, admin and pharmaceutical database) and transaction data;
9. Usage of data output from different modules as an input to avoid any process redundancies within parts of the hospital.

According to a 2017 report, there are only 52 percent of both public and private Indonesian hospitals which already have and implement this system. The considered as low numbers of eHealth technology use in the hospitals shows that the digital health technology is not yet well accepted and is still hampered. Although in the other side of the story, a support from the Indonesian Government on this issue has been shown that Indonesian Ministry of Health has implemented its regulation regarding the adaptation of HIMS from back in 2009 (Permenkes No 44 *Tahun* 2009).[71]

[69] http://www.yankes.kemkes.go.id/read-tahun-2018-semua-rumah-sakit-harus-sudah-punya-simrs-terintegrasi-2647.html
[70] https://media.neliti.com/media/publications/78723-ID-none.pdf
[71] https://gawaisehat.com/2016/12/01/baru-48-rumah-sakit-di-indonesia-yang-memiliki-simrs-fungsional/

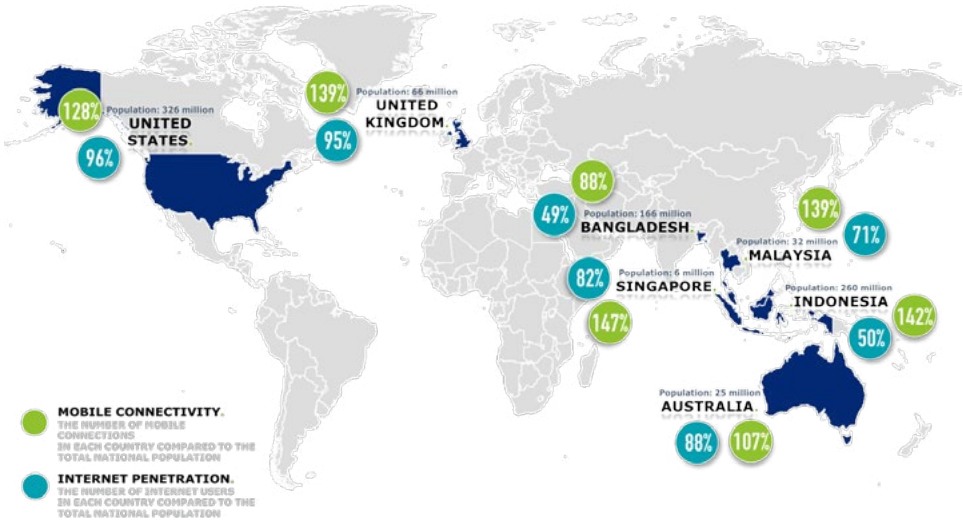
eHealth Practice Benchmarking: Comparison to Developed and Developing Countries



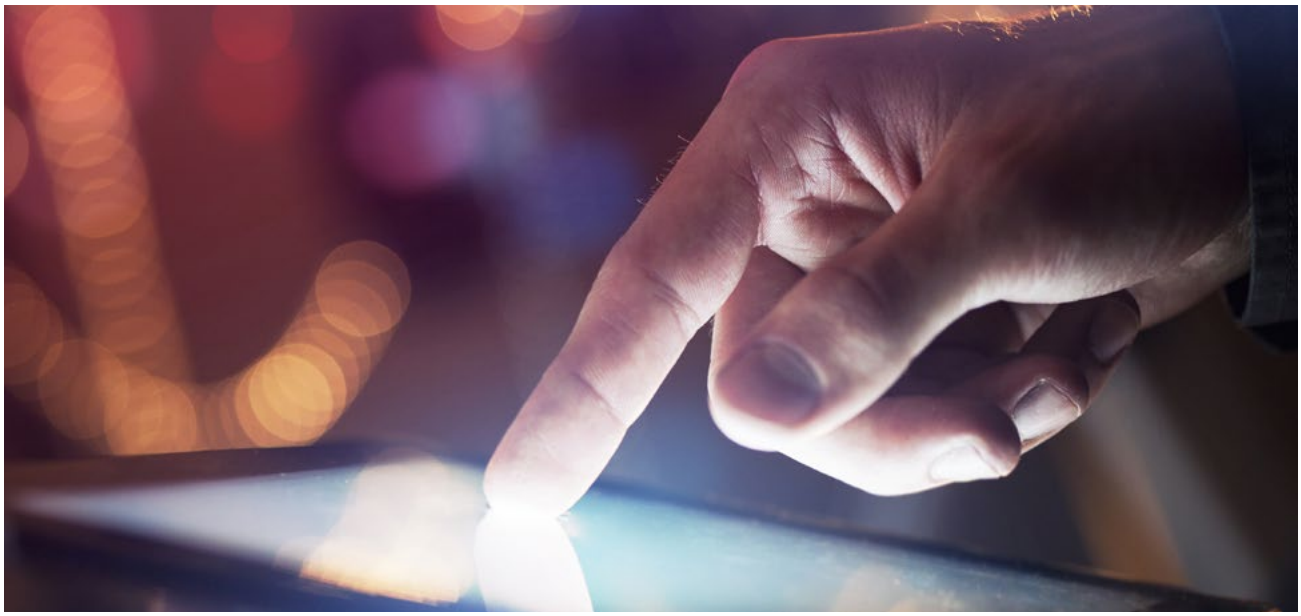
How eHealth has been incorporated across health care supply chain

Hospital Information System (Patient data management/ administrative stuffs)	Patients health informatics	Mobile health (wearable devices)
E-prescribing	Clinical Information Providers	Tele-pharmacy
Clinical decision support system	Virtual healthcare teams	Tele-consultation
Tele-rehabilitation	Tele-laboratory	Tele-radiology
Appointment scheduling	Research/ big data	

Visualization on internet penetration and mobile connectivity[72]



[72] https://www.internetworldstats.com/america.htm#us, https://www.internetworldstats.com/stats3.htm#asia, https://www.ofcom.org.uk/about-ofcom/latest/media/facts, http://www.btrc.gov.bd/content/mobile-phone-subscribers-bangladesh-january-2018, https://wearesocial.com/special-reports/digital-southeast-asia-2017, https://en.wikipedia.org/wiki/List_of_mobile_network_operators_of_the_Americas#United_States, http://www.abs.gov.au/ausstats/abs@.nsf/mf/8153.0



Singapore: Big data is watching and startups are on the rise

Our closest neighbor country has so far implementing this advance eHealth technology successfully. The philosophy of Singapore's health care system consists of three pillars. Firstly, the country is aimed to build up a healthy population with preventive health cares and to encourage healthy lifestyles. Secondly, Singapore also emphasizes personal responsibility towards healthy living through the "3M" (Medisave, Medishield and Medifund) system. Last but not least, the government has to keep the health care costs down by controlling the supply side of the health care services and providing heavy subsidies at public health care institutions.

In the system there are three main regulators playing roles: Minister of Health (MOH), Central Provident Fund (CPF) and Monetary Authority of Singapore (MAS). MOH oversees the provision and regulation of health care services. Specifically, it is in charge of promoting health education, monitoring the accessibility and quality of health care services, preventing and controlling diseases, allocating resources and specialists and administrating required licenses for health care establishments. CPF is a comprehensive and compulsory social security savings plan. It ensures working Singaporeans and permanent residents (PRs) to support themselves in the old age.

CPF has expended its objectives to meet the population's needs in retirement, housing, family protection, asset enhancement and health care. Workers and employers are required to make monthly contributions to the employees' CPF into three accounts, ordinary account, special account and the Medisave account. MAS, as Singapore's central bank, regulates the financial aspect of insurance sector. The Insurance Department of MAS administers the insurance Act, which protects the interests of policyholders and regulates insurers' activities, including registration and licensing requirements. Periodically, MAS provides directions and practice notes for regulating insurance activities[73].

The provision of appropriate Singaporean health care is becoming more challenging now. A number of factors are contributing to this: ageing population/changing demographics, increasing demand for health care services, changing expectations, relative shortage of health care professionals and caregivers, and shortfalls in health care facilities[74].

Moving towards a preventive and futuristic personalized health care provision, Singapore piloted the National Electronic Health Record (NEHR) that allows patient records to be shared across the health care ecosystem, both public and private health care providers. Also, to enable cost effective outcomes in treatments, better planning for health care services, and improvements in clinical quality, Singapore leverages Health Data Grid (HDG), a federated

[73] http://assets.ce.columbia.edu/pdf/actu/actu-singapore.pdf
[74] National Telemedicine Guidelines. January 2015.

or virtual database that will facilitate clinical research by enabling secure data access across separate health care databases that are located in different health care institutions[75]. The program provides timely information to support effective preventive health care and improves effectiveness in health care service delivery. In addition to that, using advanced data technologies, clinical researchers and doctors can derive from analyzing clinical and genetic data, thereby helping to shape potential new health care models for precision medicine. Beyond its use in the public sphere, Singapore has also identified Big Data and analytics as a key economic contributor for the future. The Singapore Economic Development Board (EDB) noted that in 2011 alone, more than 1.8 zettabytes of data were created, and this is expected to increase 50 times by 2020[76].

In the last decade, information and communication technologies (ICT) has made profound and game changing inroads into the health care sector, thanks to its strong startup ecosystem, advanced infrastructure and highly educated workforce. Singaporean national policy to promote the use of ICT across all sectors has also been extremely effective. Even, Singapore has public funding for ICT support of programs addressing national health priorities.[77] Some of the key eHealth initiatives are big data, data security, telehealth technology, wearables and hearables and internet of things. Not surprisingly, the rising startup and innovation hub leads Singapore to land at number one of the best startup cities[78]- even it outranked San Francisco, the city with Silicon Valley in its southern region. There are several ways of how the startups have been playing in the Singapore's region's health care systems.

DocDoc is developed to help the consumers to compare and book appointments - not just within their own country borders, but also across their country borders. Besides, there are a lot of startups like RingMD in Singapore that are trying to enhance consumer access to physicians through an online consultation solution. In line with that, LifeTrak Fitness Tracker is able to provide Electrocardiogram (ECG) accurate heart rate monitoring solutions, combined with accurate heart rate for precise calories, steps, and distance, plus clear-cut automatic sleep monitoring. Apart from that, Attune, the largest Cloud based health care IT service provider in the region, has pioneered Cloud based products designed to help the entire health care ecosystem. Attune's solutions seamlessly integrate Labs, Hospitals, Pharmacies, Blood Banks, Radiology, Medical Devices, Insurance Companies, and Accounting - resulting in increased revenues and operational efficiency. Attune's solutions can also be deployed across the spectrum of organizations – starting from single physician clinics to a network of health care providers making. This startup is Southeast Asia's highest-funded startup in digital health. Other startups that provide a similar service is Klinify, which provides a simpler and more user-friendly SaaS-based product for larger scaled clinics. Pertaining data aggregation platforms, there is MyDoc, which is building a network of laboratories, doctors and pharmacies through a set of services such as health screening follow-up tools for patients.

Over the years, Singapore has laid the foundation for a thriving ecosystem with its infrastructure of high-speed fibre optic network and extensive wireless links. In terms of infocomm manpower, Infocomm Media Development Authority (IMDA) works with industry and private organisations to spearhead the strategic use of infocomm in the various sectors including health care to meet the wellness needs of the population. Using wearables and IOT technologies, they explore extending medical care beyond the hospital premises to patients' homes and the community, where patients and those at-risk can be empowered to self-monitor their health vitals and seek medical help before they get seriously ill. A home infocomm system monitors selects chronically-ill patients through intelligent, embedded nano sensors. Fitness trackers, smartwatches, and other wearables will be supported by sensors installed across the nation to constantly transmit data[79]. Then, real time data on the patient's health conditions will be processed to activate alerts.

[79] http://www.himssasiapac.org/content-library/exclusive-articles/5-ehealth-initiatives-singapore-2015
[75] https://www.imda.gov.sg/industry-development/sectors/infocomm/healthcare-and-wellness/health-data-grid
[76] http://www.infocommguide.com/big-data-is-watching/
[77] http://www.who.int/goe/data/country_report/sgp.pdf
[78] https://www.forbes.com/sites/chynes/2017/08/09/singapore-tops-new-list-of-best-startup-cities/#136b5f7b167d

As the regulator of the telecom industry, IMDA also continue to promote a competitive market, while encouraging innovation that brings benefits to companies and consumers. Moreover, along with more pervasive use of data, IMDA also promotes and regulates data protection in Singapore through the Personal Data Protection Commission[80].

Telemedicine have been helping to address a number of current gaps in the system such as making health care resources (e.g. specialist services) more readily available in a timely manner to those who need it, bridging the constraint of distance and saving time and costs if this is done appropriately. Patients with mobility issues such as the chronically ill and the elderly will gain from the conveniences of telehealth. With the aim to prioritise telehealth services to support its ageing population, the government's health care technology provider, Integrated Health Information Systems, will launch new services that let elderly people consult a doctor through smartphones or other devices in their own home, which also allows telerehabilitation and vital signs monitoring[81].

Pertaining the regulation, in 2015, the Ministry of Health (MOH) issued a set of National Telemedicine Guidelines to guide health care providers in the safe and appropriate delivery of health care services through telemedicine. This is complemented by the Singapore Medical Council's (SMC) Ethical Code and Ethical Guidelines (ECEG) and accompanying Handbook on Medical Ethics issued in 2016 that set out the standards of care required of doctors practicing telemedicine. Based on the guidelines, the standard of care expected of doctors providing telemedicine should be comparable to what patients would receive in a face-to-face consultation. Doctors providing care via virtual platforms have a responsibility to ensure that the remote diagnosis made is accurate and that patients receive appropriate medical advice and management for their conditions. If in doubt, doctors should offer to see the patients face-to-face to conduct a physical assessment or refer the patient to the nearest clinic or health care institution[82].

Malaysia: Telemedicine Blueprint have been conceptualized – some have been implemented

Other neighbor country which is experiencing the implementation of ehealth technology is Malaysia. The country's health system is at a crossroads at the present. A 2016 report by the Harvard TH Chan School of Public Health concludes that "the health system faces new challenges in the face of a rapidly evolving context – characterized by demographic and epidemiological transitions, a shifting of socio-cultural environment, technological changes, and rising income levels, which have contributed to a nutritional transition, increasing health risks, and new user expectations." It also states that the lack of coordination between primary and secondary health care results in the overcrowding of government hospitals[83]. Although foreign doctors have been encouraged to take up employment in Malaysia, there is still a significant shortage in the medical workforce, especially of highly trained specialists; thus, certain medical care and treatment are available only in large cities. Recent efforts to bring many facilities to other towns have been hampered by lack of expertise to run the available equipment.

There were previous attempts at introducing a public insurance system called 1Care for 1Malaysia in the past, but this was eventually shelved. It is unclear whether there will be any new proposals for a public insurance system, but two things are certain: the costs of living are escalating, and a large proportion of Malaysians continues to depend on the public health care system. In terms of funding, the Malaysian government already contributes some 9.5 percent of its annual budget to health care, where RM26.58 billion is being allocated this year. This comes up to about 4.75 percent of the country's GDP, close to the WHO recommended proportion of 5 percent, but lower than the OECD average of 9.7 percent. But if the increase in health care spending continues at its current rates – increasing an average of 12-13 percent per year from 1997 to 2009 – this may not be sustainable in the long run.[84]

[80] https://www.imda.gov.sg/about/what-we-do
[81] https://govinsider.asia/innovation/singapore-picks-telehealth-to-support-its-elderly/, http://edition.cnn.com/2015/06/17/asia/telemedicine-in-singapore/index.html
[82] https://www.moh.gov.sg/content/moh_web/home/pressRoom/Parliamentary_QA/2017/Telehealth-Platforms0.html
[83] http://www.thesundaily.my/news/2018/01/18/sustaining-public-healthcare
[84] http://www.thesundaily.my/news/2018/01/18/sustaining-public-healthcare

Moreover, with a rising and ageing population, Malaysian government commits to the principles of universal access to high quality health care. In spite of that, a major problem with the health care sector is the lack of medical centers for rural areas, which the government is trying to counter through the development and expansion of a system called teleprimary care. This system is a tool for teleconsultation and distance learning in health care. With the tool doctors in the remote clinics are able to discuss the problem cases through teleconsultation with their colleaques in the hospitals using an audiovisual system. This system provides better care in the health centers without transferring the patients to the hospitals. Only patients with critical conditions are referred to the hospitals. This has not only reduced the number of patients referred to the hospitals, but it will reduce the cost which charges to the health care system. It will also provide a more comprehensive care to the patients in the health centres. The doctors in the health centers are also provided training and are also updated on the latest information and technology in medicine. This method of training has made doctors in the health care centers more efficient and satisfied[85].

Telehealth was also incorporated by the Malaysian government under the Multimedia Super Corridor (MSC) project, Telehealth Flagship. The project is one of the 7 flagship applications of MSC grouped under the 'Multimedia Development Flagship Application' and has long-term objectives towards Malaysia's Vision 2020. The project was intended to reshape the health care structure from illness focus to self-care emphasis by incorporating telecommunications, information and multimedia technologies. It is hoped that the health care services become more virtual, equitable, affordable, technologically appropriate, environmentally appropriate and consumer friendly, resulting in efficient health care delivery and enhanced quality of life.[86] The telehealth initiative has subsequently developed into a national eHealth system by integrating the different players in the health enterprise. Computer hardware and software vendors, system integrators, R&D organizations and relevant high-tech service providers are invited to join MSC project.

Malaysia's Telemedicine Blueprint "Leading Health care into the Information Age" and "Towards Excellence in Health Information Management" have outlined the concept to develop the most advanced health systems of the world by harnessing the power of information and multimedia technology. Amongst the pilot project applications that was launched was the Lifetime Health Plan (LHP), a personalized health care plan for the individual. Its objective is to develop a longitudinal health record of every individual and implement a proactive health plan thus enabling continuity in care. LHP was designed to provide a continuous medical care, informing the individual and health care providers with relevant medical information to maintain individual's state of health at the highest state possible at all times. In order to implement this project, there are sub-application that were conceptualized, namely Clinical Support System (CSS), Health care Information Management and Support Services (HIMSS) and Personalized Lifetime Health Plan (PLHP)[87]. E-HIMS is an electronic reporting system for the collection, collation and analysis of health information in MOH facilities. A web-based reporting system has been developed, which all health related data from MOH facilities, non MOH facilities and private sector are transacted to ensure timely and quality health information. The data is collected through e-forms applications provided by all hospitals, health office and clinics[88]. Malaysia planned to establish the National Health Data Warehouse which manages informations in compliance to health informatics standards which will allow evidence based health planning in the country[89].

[85] https://www.ncbi.nlm.nih.gov/pubmed/12109251
[86] https://www.researchgate.net/profile/Mohd_Hanafi_Mat_Som/publication/261028358_Telehealth_in_Malaysia-An_overview/links/584356c608aeda696815bf6e/Telehealth-in-Malaysia-An-overview.pdf
[87] http://www.moh.gov.my/images/gallery/publications/hi/HIMS%20Blueprint.pdf, https://www.researchgate.net/publication/261028358, https://www.researchgate.net/publication/12590822_Telemedicine_in_the_Malaysian_Multimedia_Super_Corridor_towards_personalized_lifetime_health_plans
[88] http://www.moh.gov.my/images/gallery/publications/hi/HIMS%20Blueprint.pdf, http://pik.moh.gov.my/himse.html
[89] http://www.moh.gov.my/images/gallery/publications/hi/HIMS%20Blueprint.pdf

In the country there are several teleconsultation startups being developed, i.e. DoctorOnCall.com.my, Malaysia's first and largest online consultation platform that provides services via chat, audio and phone calls, that delivers access to non-emergency medical care at anytime and anywhere, especially from the comfort of patient's own home. RingMD, that began in Singapore, is now also available to Malaysians. It allows video consultations which are encrypted end to end, so patients can securely text their doctors and the system allows the doctors to make clinical notes and provide prescribe medication. Other telemedicine ventures that work in almost the similar way, but provide website-based service, are u2Doc and Teleme. A benefit of Teleme that it has a good feature that the system has a tie up with pharmacies, which enable prescribed medicines to be delivered to the patient's doorstep[90].

Besides, to enhance the capability and knowledge of medical personnel, Continuing Professional Development (CPD) was established in Malaysia. There are many services provided in CPD, which will benefit the health practitioner, such as virtual library, modular distant learning (MDL), calendar of CPD events, online activity monitoring, online directory, complement competency assessment, and monitoring and evaluation of CPD[91].

In conclusion, health care delivery in Malaysia is in the process of improving its health system to have a better environment in the near future. At the moment there are more hospitals have been installed with applications of telehealth components. The government could also take initiative to encourage ISP providers to expand their operation in the rural areas and provide other essential infrastructure facilities[92].

Australia Health care Industry Value & Supply Chain

Australia's health care industry value, supply chain, as well as health care public policy are the best organized and regulated health care system in the world. The Australian government created a very sophisticated integrated health care system scheme in the form of Medicare, therefore allowing 100 percent of the total health care expenditure of the citizens and permanent residents are covered by the government health care programs and schemes including private-public partnership insurance schemes and health care facilities. Medicare was established in 1984 as the first well established Australian national health care system that is still operated until now. Medicare is a national health care system scheme that is eligible to all Australian citizens. However, Australian citizens who intend to receive Medicare services are required to pay a taxable amount of 2 percent to 2.5 percent of their monthly income to the Australian Department of Human Services (Medicare Levy). This is mandatory to all Australians, except those are considered as a low income citizen (annual income below A$ 21,335 or A$ 33,738 for seniors and pensioners).

Australia is a part of the Reciprocal Health Care Agreements (RHCA) that are in place with the United Kingdom, Sweden, the Netherlands, Belgium, Finland, Norway, Slovenia, Malta, Italy, Republic of Ireland and New Zealand, which entitle visitors from these countries to limited access to Medicare and entitles Australian residents to reciprocal rights while in one of these countries. According to the Reciprocal Health Care Agreements (RHCA), Australia's national health care scheme is the best among all of the RHCA members. Apart from all of the magnificent health care services that Australia have given, the Australian government has also established the Healthdirect program, a national public health information service that includes helpline (available 24 hours a day), an after-hours general practitioner (GP) helpline, the Healthdirect website (which provides free health information), a mobile device application, and a symptom checker (a guided, online self-triage tool allowing visitors to initiate their health enquiry online). Other than the Healthdirect program, the Australian government has also established the Australian National Consultative Committee on Electronic Health (ANCCEH) that deals with all of Australia's Telehealth related matters.

[90] https://new.medicine.com.my/2016/05/telemedicine-in-malaysia-coming-of-age/
[91] https://www.researchgate.net/publication/261028358
[92] https://www.researchgate.net/publication/261028358

In terms of size and area, Australia is a massive country and it is even considered as a continent. According to the World Bank data by 2016 Australia's total number of population have reached 24 million people that are scattered around in a massive are of 7,692,000 km2, because of the massive area that the country has and there are only a few Australian citizens compared to the country's size, most of the Australian citizens live in the big cities in the coastal area namely Sydney, Melbourne, Brisbane, Gold Coast and Adelaide. Due to these circumstances the Australian citizens are scattered around the country and not all of the cities in Australia have the best treatment and care knowledge for all of the existing diseases, thus for example, in certain cases people who lives in Brisbane who need the best and most intensive care for cancer still have to go to Melbourne just for checking up or even consultation. That is why telemedicine is necessary in Australia and have worked well in this country.

Telemedicine in Australia has been researched and developed since the late 1990's and more intensively in the early 2000's, the strong reason is as above explained, it is necessary to give a high quality and equal health care service towards all Australian citizens with a big possibility of health care cost reduction, which will benefit all stakeholders, especially the Australian government. The Australian National Consultative Committee on Electronic Health (ANCCEH) was established in 2004. It is the first telemedicine association in Australia and until now ANCCEH is still the main umbrella for telehealth related matters in the country, including the modern health care private-public partnership planning and schemes. ANCCEH is the leading telehealth association that represents the major ICT industry players and other stakeholder groups. The Committee contributes to the debate around the public and private health agenda in Australia with health promotion and provision of better health service through applications, and to support interactions with technology in order to improve efficiency, safety and productivity. As of 2012, ANCCEH has launched the Australian National Telehealth Strategy paper. The paper contains of ANCCEH's point of view in the importance of telehealth from national system perspective. Telehealth offers both public and private health system an opportunity to provide new models of efficient health care. ANCCEH's National Telehealth Strategy paper has received very positive feedback from the government, clinical providers and health industry players.

USA Health care Industry Value & Supply Chain

The health care industry value and supply chain in the United States of America (USA) are very well organized and regulated by the government, with 63 percent of the total health care expenditure are covered by the government health care programs and schemes. The US government created a couple of national health care system schemes such as Medicare, Medicaid (including state independent health care programs (SHIP)), State Children's Health Insurance Program (CHIP) and Veterans Health Administration.

Two main health care system schemes that are crucial for the government are Medicare and Medicaid. Medicare was established in 1965 alongside with Medicaid as the first United State (U.S.)'s national health care system at that time. Both national health care system schemes are not eligible to all U.S. citizens, as each of them have their own eligible requirements. Medicare is only available and eligible to the U.S. citizens who are 65 years old or older, under 65 years old with certain disabilities, and or have End-Stage Renal Disease. There are four parts of the Medicare: Part A (hospital coverage), Part B (medical insurance), Part C (combines Part A and Part B), and Part D (prescription drug coverage).

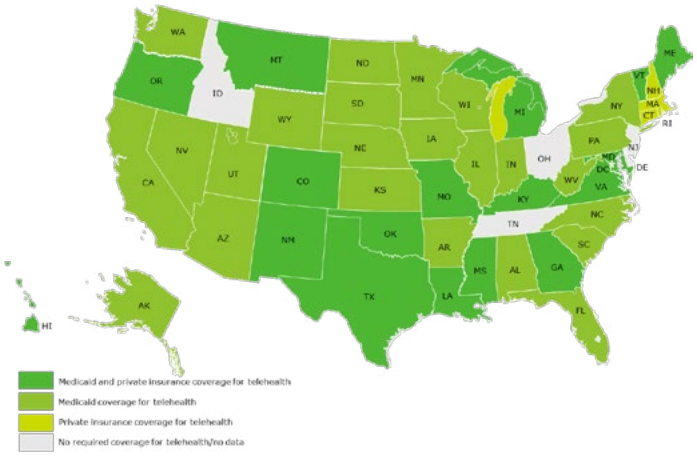
On the other hand, Medicaid determines the eligibility to register to the program, which mainly depends on the level of monthly income. The federal law requires the states to cover certain groups of individuals. Low income families, qualified pregnant women and children, and individuals receiving Supplemental Security Income (SSI) are considered as the mandatory eligible groups. States also have other coverage options and may choose to cover other groups, such as individuals receiving home-and-community-based services and children in foster care who are not otherwise eligible.

United States is a massive country both in terms of area and population. According to the World Bank, by 2017 United State's total number of population have reached 325.7 million, living around in a massive area of

9,831,500 km2. Due to this circumstances, the U.S. citizens are scattered around the country and not all of the cities in the U.S. are well developed - most of the well-developed cities in the U.S. are located in the west coast and east coast, such as New York City, Boston, Washington DC, Orlando, Seattle, San Francisco and Los Angeles. Compared to the coastal cities, the central part of the country is more underdeveloped in a way that massive number of their smaller cities have limited capabilities in their health care services. This require patients from the smaller cities to travel to other cities to get more proper and better health care services. As there are only limited number of hospitals and limited practitioners with special capabilities available in the smaller cities, telemedicine is necessary in the U.S. and have been working well in the country, even in some states that are covered by the health care national scheme and state health care program.

As telemedicine is perceived as crucial, it has been researched and developed since in the early 1990's in the United States. The American Telemedicine Association (ATA) which is the first telemedicine association in the U.S., was established in 1993 in Washington DC. ATA has a membership network of more than 10,000 industry leaders and health care professionals until now. It is a leading telehealth association and is helping to transform the health care ecosystem in the U.S. by helping the government improving the quality, equity and affordability of health care throughout the country. As of today, the practice of telemedicine has spread very rapidly and is currently integrated with the ongoing operations of hospitals, medical specialties departments, home health care agencies, private physician offices as well as consumer's homes and workplaces in the U.S. Thus, currently telemedicine has become a multi-billion-dollar industry. Every major hospital and health care system in the U.S. have leveraged telemedicine in order to transform and to re-invent their health care systems to be more practical, efficient and effective. In spite of that luxurious condition, telehealth is still facing a lot of challenges in the US, primarily regarding money and regulation. Reimbursement is commonly cited as a major barrier for telemedicine, where Medicare does not reimburse very much in the fee-for-service system. In addition to that, regulation issues such as regulation to practice, licensure and limitation of the system -where each state have its different system- also burdens the development of telehealth in the U.S.[93]

USA Insurance Covered Telemedicine Services Map



UK: Telehealth in Pharmaceutical Industry Value & Supply Chain

The pharmaceutical industry value and supply chain in the United Kingdom (UK) are very well organized and regulated by their National Healthcare System (NHS). The UK citizen have to pay a very massive amount of tax that is approximately 50 percent of their monthly wages, in which is included for their premium payment for the NHS services scheme. Consequently, all UK citizens does not have to pay anything else other than the monthly tax, to receive the best health care service whenever it is necessary. The free-of-charge health care services includes everything from consultation, diagnosis, surgery as well as pharmaceutical purchases.

Due to the involvement of the NHS in paying the cost of pharmaceutical products, NHS are putting an extensive attention towards the UK's pharmaceutical industry value and supply chain. As a result, UK pharmaceutical supply chain is encouraged to be very efficient and effective in executing its business operations. Most of the pharmaceutical products distributors and wholesalers are well integrated with the health

[93] https://www.nap.edu/read/13466/chapter/5#21

care service providers such as pharmaceutical retailers and hospitals, this is to reduce the number of mismanagement and keeping all parties intact with the whole management system. This lead to more efficient health care cost, as pharmaceutical products prices can be lowered.

Due to this phenomenon, pharmaceutical industry retailers and wholesalers enjoyed less profit margin. In return, pharmaceutical industry retailers and wholesalers will obtain patient outcome data that includes patients' feedback, experience and preferences. The data, which will be proceed into information, is valuable for their future business.

Over the past couple of years, from the market perspective, pharmaceutical industry in the UK have a slightly difference in consumer or patient preferences, as there is a massive growth of demand of home care and pharmaceutical product delivery. There have been a couple of emerging technology companies that provide direct-to-home pharmaceutical products delivery service by both web and mobile application basis. One of the most well-known company is Pharmacy2U, which is based in Leeds and was established in 1999. Pharmacy2U is the first mover in the industry, which has been approved by NHS. Its business model starts when the patient reaching out Pharmacy2U's general practitioners (GP) they want to consult with. Afterwards, Pharmacy2U's GP will review the consultation results and determine drugs should be dispensed and sent to the patient. In approximately in 24 hours, the medicines will reach the patients' doorstep.

In the wake of modern technology-based era, patients tend to be spoiled more and more due to the availability of tools that allow them to enjoy much simpler life. In brief, new business models that merge technologies (e.g. tele-pharmacy, that links business and consumer with a pharmaceutical industry as the supply side), suits really well with today's business world's necessities and customer preferences.

Predictions and strategic insights on Indonesian eHealth ecosystem development

Rising demand and associated spending in Indonesia are being fueled by an aging population; the growing prevalence of chronic diseases and comorbidities; development of costly clinical innovations; increasing patient awareness, knowledge, and expectations; and continued economic uncertainty. Meanwhile, governments and other stakeholders are trying to figure out the best path forward: Here's how much money we have to spend on health care, here's what we plan to do, here are the tools we need to provide high-quality care and services, equitable access, and optimal outcomes for patients at an affordable cost.

The problems that is caused by the alarming rate at which chronic diseases are increasing in Southeast Asia, coupled with the region's lack of access to quality and affordable health care, are unlikely to be solved with the use of traditional approaches. Rather than play catch-up with ever-increasing health care demand in a never-ending spiral, we should instead leverage on disruptive innovation to find new solutions to age-old challenges. Health care systems need to be proactive and focused on disease prevention, rather than reactive and focused on administering treatments during times of need.

eHealth Regulatory Issues

The use of ICT in health care raises a number of challenges related to legal, ethical and governance issues. These concerns and opportunities challenge not only patients and health professionals, but also the stakeholders of the implementation of eHealth, including academics, policy makers, industrialist, etc. As we have discussed about the least two mentioned issues in the aforementioned chapter, the issue about the legal approach will be discussed in this sub chapter.

Up to now, Indonesia does not have rules and regulations regarding digital health care system, so far the only tool, that developed by the Government of Indonesia related to the issue is teleconsultation and teleradiology guidelines or known as Hospital Pilot testing of Video-conference-based tele-medicine and teleradiology guideline (Rumah Sakit Uji Coba Program Pelayanan Telemedicine berbasis Video-conference dan Teleradiologi), which launched by the Ministry of Health. This is an unfortunate that any regulation regarding patient confidentiality and safety has not been launched yet. Although there are lack of legal and industry approaches from the ministries, the Ministry of Health acknowledged the development and promised its support and guidance for the key players of the industry. "Ministry of Health (MoH) have acknowledged and oversaw the rapid growth and development of eHealth in the country, we will guide the industry players and related parties of its practices and will supervise them," said dr. Slamet, MHP, Special Staff for Health issue and Globalisation, MoH.

dr. Slamet, MPH, Special Staff for Health issue and Globalisation

"Ministry of Health have acknowledged and oversaw the rapid growth and development of eHealth in the country, we will guide the industry players and related parties of its practices and will supervise them."

Regulation on eHealth in Indonesia

The Ministry of Health is in the discussion process on the legal status of the telemedicine and drafting a regulation on this. The existing Medical Practice regulation required face to face interaction as a compulsion. One of the point in the draft saying that the patient should be accompanied by a medical doctor, who is in charge with the patient. Essentially, the draft is trying to protect the patient from the disadvantage that might arise during telemedicine process.

Ministry of Health

"The Ministry of Health is having internal discussion on the legal status of telemedicine and preparing a draft on this. Essentially through the draft, we want to make sure that the patient are protected from the disadvantage that might arise during telemedicine process."

Important Factors to Implement Telemedicine in Indonesia[94]

- **ICT Infrastructure**
  An important step that needs to be done to organize eHealth practice in Indonesia aside of the regulation is the ICT (Information and Communications Technology) infrastructure. ICT infrastructure for health services includes the availability of networks and broadband throughout Indonesia. Indonesia's vast and scattered territory is one of the most difficult constraints in providing equitable infrastructure in Indonesia, ranging from doctors and nurses, interconnection and networking capacity, to basic infrastructure such as electricity and maintenance sites. Based on the aforementioned backgrounds, it is clear that the telemedicine is not only a single issue, but multisectoral one. On that account Ministry of Health should get supports from other parties and/or factors. One of those which is very important is infrastructure. In order to build great system of Telemedicine, all related factors must be standardized in advance in order to make it works well throughout Indonesia.[95]

  For eHealth wearable devices (also functioned as telecommunication devices) which are made, assembled, imported to be traded and/or used in the territory of Indonesia are generally required to be complied with the technical requirements under the technology authority through certification process (test and/or document evaluation). This provision indirectly requires the Electronic System Provider (ESP) for eHealth purpose in Indonesia to assure that the device vendor for its eHealth operation in Indonesia has obtained device certificates.

- **Diagnosis**
  In providing a diagnosis for the patient, the doctor should provide it based on the examination with the patient in accordance to his or her knowledge and expertise, and in accordance with the standards of medical practice. In the case of health services is provided through telemedicine, basically the diagnosis cannot be given by the doctor without a face-to-face meeting between the doctor and the patient.

  In some existing online health care applications, they provide a disclaimer stating that:
  1. IT-based health care application providers do not replace the role of physicians and / or health care facilities and the applications is not to replace face-to-face consultation functions.
  2. The physician who serves in the application is entitled to refuse for giving advise when the patient's case is assessed as an emergency case.
  3. Answering a question will not provide a working diagnosis or a definitive diagnosis. The diagnostics that can be written are only estimates of diagnosis or possible diagnosis that might be appealed.
  4. Answering a question will not provide definitive therapy in the form of medicines or medical action because there is no definitive diagnosis.
  5. Answering questions can only provide advice.
  6. All interpretations of the statements written in the answers to the patient's questions is entirely the responsibility of the patient.
  7. Users of the application service are strongly encouraged to always consult to a family physician or physician for self-medication before starting, altering or terminating an ongoing treatment therapist.
  8. The users are expected to consult with a doctor in the case of a medical complaint.[96]

- **Protection of Patient's Data**
  The point to be taken into account in the practice of health care is to maintain a complete and accessible quality of medical record, while maintaining patient confidentiality. In addition, documentation of patient's data is also required for the insurance of the respective patient.

[94] Zubairi Djoerban, "Telemedicine Menggagas Pengobatan Jarak Jauh di Indonesia", http://zubairidjoerban.org/telemedicine-menggagas-pengobatan-jarak-jauh-di-indonesia/, accessed on 24 November 2017.
[95] Interview with dr. Slamet MHP (Expertise on Technology-based Health care and Globalization of the Ministry of Health), 8 November 2017.
[96] Konsula, "Syarat dan Ketentuan", https://www.konsula.com/id/syarat-ketentuan, accessed on 24 November 2017 & Tanya Dok, "Syarat dan Ketentuan Konsultasi TanyaDok.com", https://www.tanyadok.com/ketentuan-ruang-konsultasi/, accessed on.

Please note that, in relation to the patient's medical record, this document shall be confidential and may not be shared to other party(ies) without the approval from the patients themselves. However, article 48 paragraph (2) of Law No. 29 of 2004 on The Practice of Doctor and Article 10 paragraph (2) on the Medical Record opens up the possibility for other party(ies) to access the patient's medical record. Those regulations stating that the patient's medical record may be disclosed in the event: (i) for the patient's health interest; (ii) request from the government for the law enforcement; (iii) request from the patient itself; (iv) stipulated under the prevailing laws; or (v) for research, education and medical audit so long it does not mention the identity of the patient.

Currently Indonesia is still not ready to apply eHealth because of it's under developed health infrastructure, lack of specific regulation on electronic health record. The only guidance is the Government Regulation Number 46 of 2014 on Health Information System, which is not enough to achieve a sufficient data center in state hospitals and community health centers in the region.[97]
Any organizations which serve as the ESP for eHealth in Indonesia shall (i) provide standard procedure of protection which guarantee security or confidentiality of patient's data (in the form of electronic information or documents); (ii) applying risk management upon any damage or loss arising out of electronic system operation; (iii) provide and carry out procedure and facility to protect electronic system from any interference and any material or immaterial loss; (iv) provide security standard covering procedure and system to prevent and overcome any thread or interference attempt.

In providing its electronic system for tele-health care purpose in Indonesia, basically the ESP is required to obtain corporate general license and if there is foreign capital participation, investment license from Indonesian Investment Coordination Board (BKPM) is also required (No requirement to obtain operation license from sectoral authority). In addition to that, registration as ESP is mandatory, which carries out services for public: owns web portal or online application through internet in order to offer its service, owns or provides electronic system with payment or financial transaction within, uses electronic system which process, manage, or store user's data, etc. As for any patient medical record which is in possession of the ESP, shall (i) be kept confidential, secure, complete, and available for the patients to amend, add, or update their records at any time by the ESP; (ii) be based on consent; (iii) be encrypted or stored by the ESP for certain period subject to health sector policy (at least 5 years if there is no retain period policy in respective sector); (iv) be stored in a data center required to be placed in Indonesian territory.

- **Informed Consent**
  Based on the provisions of Article 5 of the Decree of the Executive Board of the Indonesian Doctors Association No. 221 / PB / A.4 / 04/2002 on the Implementation of the Indonesian Medical Code of Ethics (Indonesian Medical Code of Practice) doctors are required to obtain informed consent prior to advising and/or acting to the patients and only allowed to give the service to the patient for the benefit of the patient. Then, if a physician is unable to perform an examination or treatment to the patient, then upon the consent of the patient or their family, the physician should refer the patient to a physician who has the expertise for it. Such provisions need to be applied and confirmed also in health care through telemedicine.

  Apart from that, an application provider stipulates in its terms and conditions that an application provider is not responsible for maintaining medical confidentiality of the user (patient). The background is by using the application, the user has given his consent and has notified the medical information open to the public unless the user uses features that provide private space between physicians and the user. However, if there is an occurrence that

[97] Dr. Mahesa Paranadipa, MH (,..,m), Kamis, 2 November2017.

user's data is being hacked, the application provider shall not be liable for this and shall be entitled to be relieved of any claims and damages incurred.[98]

Under the Electronic Transaction Law, any use of patient personal data via electronic system provided by ESP shall be based on the consent from the patient (provided by ESP) and shall be in line with the purpose made known to the patient at the time the data is collected. For example, should any use of data require a transfer or storage of personal data outside the jurisdiction, it would be best to inform such conditions to the patient and obtain the consent for transferring and/or storing such data in other jurisdictions. For reference in obtaining the consent through the provided online health system, it is necessary to note that Indonesian language is mandatory for (i) all kind of contracts (electronic or physical) involving Indonesian as a party (person or entity); and (ii) contents in the provided system electronic deployed in Indonesia.

- **Prescribing**
  Upon the issuance of this paper, there is no regulation regarding the e-prescription and related to the trading of drugs through online platform. The Medical Code of Ethics only stipulates that the physician shall deny to provide any form when attributed or reasonably suspected to be associated with his professional capacity in prescribing the medicines, including to influence the patient's or his family's wish to purchase or consume the medicines as he has received or is promised to receive commissions or profits of pharmaceutical companies. Nonetheless, an application provider determines that a health care provider does not guarantee that patients will be given with the prescription after the consultation using their application.[99] In addition, application providers also confirmed that physicians serving in the application provider will not provide definitive therapy in the form of medicines or medical measures because there is no definitive diagnosis.[100] On a separate note, currently, we understand that Indonesian National Agency of Drugs and Food Control is in the process to regulate regarding the trading of drugs through online platform. From the draft regulation, we note that only pharmacy may sell the drugs through online platform and the types of drugs are also limited.[101]

  Although there is no codified regulatory instrument regarding e-prescribing, for any future development, Electronic Transaction Law widely covers e-signature function as: (i) consent of the e-signer in an electronic agreement or contract (has similar legal enforcement as the manual signature); (ii) a media to identify a legal subject identity. To be effectively binding, e-signature shall at least comply with the following requirements: (i) confidential and only known by the owner of e-signature; (ii) the authority to use is only provided strictly for the respective e-signature owner; (iii) the e-signature owner may at any time notice any change to the e-signature after its execution; (iv) the e-signature owner may at any time notice any change of electronic information regarding the e-signature after its execution; (v) there are certain ways to identify the e-signature owner; and (vi) there are certain ways to indicate that the e-signature maker has given its approval to the related electronic system.

- **Medical Liability**
  There is no express regulation covers the provision of how far ESP liability upon any patient's data leak arising out of its provided electronic system failure. Generally, the ESP may be held accountable or sued by any person in the event of any loss arising from the provided electronic system. However, the ESP may limit its liability towards any claim filed if the ESP can prove its compliance under the prevailing law.

[97] Dr. Mahesa Paranadipa, MH (,..,m), Kamis, 2 November2017.
[98] Tanyadok, "Terms and Condition to Consult at TanyaDok.com", https://www.tanyadok.com/ketentuan-ruang-konsultasi/, accessed at 24 November 2017.
[99] Konsula, "Terms and Condition", https://www.konsula.com/id/syarat-ketentuan, accessed at 24 November 2017.
[100] Tanyadok, "Terms and Condition to Consult at TanyaDok.com", https://www.tanyadok.com/ketentuan-ruang-konsultasi/, accessed at 24 November 2017.
[101] Based on Indonesian Agency of Drugs and Food Control draft of regulation on Supervision of Online Drugs Distribution as of 14 December 2018.

- **Government Relation**
  There are several circumstances that Indonesian-based start ups working in eHealth issues, should pay attention for. One of them is that in the first place they should define the type of business they are getting into. This will be the first step for the business to smooth their process to get the buy in from the Government. In terms of relationship with the governmental agency, there are various types of health business in Indonesia, first is the type of the service (for instance whether it is directy related to public health), secondly, the type of the public health service (whether this is related to disease prevention and control, pharmacy and/or medical equipment). The business can be included one or more of relation types. In this case, the main issue is that although the service might get approval from the related ministry, the kind of business type will need informal approval of the health agencies in the ministry. There are four main agencies in the Ministry of Health, which the eHealth business can be associated with, namely:
  1. Directorate General of Public Health (Direktorat Jenderal Kesmas/Kesehatan Masyarakat)
  2. Directorate General of Health Service (Direktorat Jenderal Yankes/Pelayanan Kesehatan)
  3. Directorate General of Disease Prevention and Control (Direktorat Jenderal Pencegahan dan Pengendalian Penyakit
  4. Directorate General of Pharmacist and Medical Devices (Direktorat Jenderal Kefarmasian dan Alat Kesehatan)

By keeping good relationship with the above mentioned governmental agencies, the business is not only getting support from them, but on the other hand will serve as an update for the ministries on the development of health business landscape, this would also broadening the ministry's insight and awareness on the importance of infrastructure development in the eHealth business. The government relation will play a very important role of doing related health business in the country. And will lead to the success of the future of eHealth business in Indonesia.

Secondly, the business should also partner with the association related to the eHealth business. In this case IDI as the Indonesian association of medical practitioner (General Practitioner) has already developed the road map of eHealth in Indonesia. The discussion or partnership with the association will help the eHealth business to take part in the conversation of the roadmap. Besides IDI, there are other associations, which should be considered related to the type of business, for eHealth business, which provide services related to medical equipment, they should consider to have partnership, such as ASPAKI (Association of Medical Equipment Manufacturer), Gakeslab (Association of Medical Equipment and Laboratorium Companies), and PERSI (Association of Indonesian Hospital).

The third circumstance is to be able to have a relationship with other related ministries than the Ministry of Health. For TeleCTG, for instance. The business has built a partnership with Rural Ministry, as the service will cover pregnant mothers in rural areas as well.

eHealth Regulation in Australia

- **Definition**
  In Australia, health services using ICT is known as digital health that is defined as an electronic health information management to provide health services which is safer, more efficient, and more qualified. Digital health is used for the several health care systems in Australia, known as My Health Record, Telehealth, and Health care Identifiers Service.

- **Informed Consent**
  Informed consent is required when using an application, i.e. My Health Record. Before doctors upload patient health or a prescription into My Health Record, they need approval from the patient.[102] The approval would be sufficient with a statement or verbal consent by telling directly to the doctor or other health care providers.

  In this application, the patient will be given a choice regarding the types of information

[102] Australian Digital Health Agency, "Digital health and patient consent", https://www.digitalhealth.gov.au/using-the-my-health-record-system/maintaining-digital-health-in-your-practice/patient-consent, diakses 3 November 2017

which will be shown as per their request. Patients may also be informed with the health care providers who uploaded their data into this application and determine which health care provider that allows to access their accounts.

Basically, any collection, use, and disclosure of health information are authorized for the purposes of providing health care to the registered health care recipient and in accordance with the access controls will be set by the recipient. Other lawful conditions for collection, use and disclosures include the collection, use and disclosure: (i) for the management or operation purposes of the My Health Record system; (ii) whenever necessary to lessen or prevent a serious threats; (iii) authorized by commonwealth, state or territory law; (iv) for any purposes with the consent of the health care recipient; (v) for any purposes undertaken by a health care recipient regarding his or her My Health Record; (vi) for the purposes of indemnity cover for a health care provider; (vii) disclosure to courts and tribunals; (viii) disclosure for law enforcement purposes.

- **Protection of Patient's Data**
  Australia uses a national scale system called My Health Records as a digital data center media containing of patient health information. This application provides patient health information such as allergies, medical conditions and treatments, details of medicines given to patients, test reports or scans. The data and information can be accessed online by health care providers such as doctors, specialists, and hospital staff.

  My Health Records is officially governed by the law, My Health Records Act 2012. In order to obtain digitally recorded health data in My Health Records in most areas of Australia, the patient have to register in My Health Records website first. However this requirement does not apply Northern Queensland or the Nepean Blue Mountains residents, who listed in the Medicare insurance program, as they will be automatically enrolled into the My Health Records system. For residents who are not willing to put their data into My Health Records, they have to use opt-out rights. If the patient declares opt-out, patient data will not be recorded and entered into My Health Records system. Once a patient has enrolled himself in the My Health Records system, any information, health-care measures used and health-related data will be accessible to practitioners who provide health care and they can also upload health records in My Health Records.

  In addition, the use or disclose any patient data information is also subject to the Privacy Act 1988. In general, My Health Records Act 2012 deals on 3 (three) things:
  - Duties and functions of operator;
  - Registration provisions for patients and health care providers (individuals or organizations) who is willing to participate in the My Health Records system;
  - Privacy provisions (in conformity with the Privacy Act 1988), which governs that entities may access and use information in the My Health Records system, and sanctions may be imposed on the inappropriate use of My Health Records.

Patients who is willing to use My Health Records system is required to provide personal information such as full name, date and place of birth, and gender. Meanwhile, for health care providers must be registered in professional associations.

The law also stipulates regarding sanctions for unauthorized persons to access, use and disseminate the patient's health information in My Health Records. This violation might be subjected to sanctions in the form of 2 (two) years imprisonment, meaning that Australia is one of the countries which protect personal datas under Global privacy laws and regulations called Federal Privacy Act and Privacy Principles (APPs)
In addition, basically, registered health care providers in My Health Records may access and use such patient data or information in My Health Records for the purpose to provide health services, subject to the consent from the patient. If the registered health care provider is willing to upload the data or health information of the respective patients into My Health Records, registered health care providers must fulfill the requirements in which the uploaded data shall be approved by the relevant patient and has complied with the provisions of the

legislation, both at the national level and territorial level states. However, there is exceptions on the provisions of access and disclosure of health information related to a serious and public safety issue in which, the system operator is authorized to give permission to the health care provider to disclose related information.
A health care provider organization may apply to the System Operator of My Health Record. In that regard, such organization should apply this following steps: (1) has been assigned a health care identifier as in Health care Identifiers Act 2010, (2) comply with My Health Record Rules enacted by Commonwealth Minister for Health; (3) has agreed to be bound the conditions imposed by the system operators on registration. The Health Record Rules 2016 specifies, inter alia, such organization must take reasonable steps to ensure that they and their employees exercise due care and skill: so that any record is accurate, update, not misleading, not defamatory; and fit with purpose. Other requirements for such organization includes requirement to maintain interoperability, to provide assistance at the System Operator request, and tonly upload to a repository advanced care planning information. Further, persons may apply for registration as a repository operator, a portal operator, or a contracted service provider. For these kind of persons, they required to register with and should be linked to one or more registered health care provider organization, to only access My Health Record to the extent that they have been instructed to do so by a linked such organization, to notify the System Operator of certain things, such as inaccurate provenance information, error in a record, no longer linked with such organization, undergone material changes, etc. All those participants in My Health Record shall comply with security requirements as in The Health Record Rules 2016.

- **Credentialing and Privileging**
  In 2015, the Australian Commission on Safety and Quality in Health Care (the "Committee") publishes guidebooks on credentialing for health care providers and practitioners. Unlike the U.S. Government, the Australian Government does not regulate credentialing and privileging for a specific eHealth care provider. The rules on credentialing and privileging in Australia is applied for health care providers and practitioners in general (conventional, not IT based).

  Under the guidance, the Committee is responsible for credentialing and determining the scope of practice which shall be in accordance with the prevailing regulation, such as without any conflict of interest, discrimination, and not violating the privacy and practice of trade.

  In addition, the Committee is responsible for ensuring that health care providers understand their duties and responsibilities and do their duties and responsibilities in good faith, establishing policies and procedures to ensure that committee members do not have any conflict of interest in the credentialing and privileging process.

  To obtain credentials, practitioners or medical personnel is require to provide and fulfill the following requirements: [103]
  1. Details of work experience (as medical personnel), attached with its by evidence
  2. Details of educational and training data, along with relevant diplomas and certificates.
  3. Details of involvement in the clinical audit process, peer review activities and continuing medical education programs.
  4. Summary of climatic activity within the last 12 (twelve) months in all locations where the medical personnel provide health services, including patient location, type of provided, procedures, diagnostic records, and consultation results.
  5. Details of accreditation or award given by professional colleagues or associations relating to health care.
  6. Provide written consent for the Committee to conduct credentials and determine the scope of practice that will be provided to the respective individual or organization.

[103] Paragraph 8.6 of Standard for Credentialing and Defining the Scope of Clinical Practice.

Moreover, the Committee is responsible for verifying such data.

As for the ESP which provides electronic system for eHealth purpose, has to refer to general business establishment in Australia: business entity shall obtain recognition and registration, either from an Australian Company or a Foreign Company, before Australian Securities and Investments Commission c.q. Investors and Financial Consumers. This includes an obligation to obtain National Business Name Registration according to Business Names Registration Regulation 2011 AG. As the eHealth services dealing with personal data, business entity shall comply Privacy Act 1988 AG and Privacy Regulations 2013 AG through, for example, adopting code of practice. If it is categorized as a medical device, the supplier shall follow Therapeutic Goods Act 1989 AG. Apart from those, a business entity requires IPRs licenses (e.g. copyright, trademark, patent right, etc.)

- **E- Medical Record**
  The legislation on e-medical record is My Health Record Act 2012 which defines that record as the record of information that is created and maintained by system operator in relation to the health care recipient, and information that can be obtained by means of that record, including information in the register that relates to the health care recipient, other information connected in the record system to the health care recipient, and back-up records of such information.

  The Act 2012 substantively deals with registration of health care organization and the likes with the System Operator, including suspension, cancelation, suspension and variation of registration. Here, the System Operator must establish and maintain a Register. The authorization according to that Act 2012 is also equal to authorization of collection, use or disclosure for the purposes of Privacy Act 1988. To respond any complain, Privacy Commissioner has power to exercise investigation and do anything incidental. If data breach occurs/ aware, the health care provider information (all participants) shall notify the System Operator, or both Privacy Commissioner and the System Operator as the soonest. Further, the System Operator must not hold the record, or take the record, outside Australia, or process relating to the record outside Australia.

- **Medical Liability, Standards, and Malpractice Claim**
  Accreditation agencies in health care in Australia creates health care delivery standards in general which use electronic media. The following is the standards made by some accrediting agencies in Australia:

  1. National EHealth Security and Access Framework **(NESAF)**

     The NESAF, published by the National EHealth Transition Authority **(NEHTA)**, was established to provide guidance to all health care provider organizations, regardless of their organizational capacity or complexity of eHealth services. In general, NESAF provides guidelines for health care providers to establish and implement security systems to protect patient's data and other assets related to eHealth to ensure patient safety and privacy, which consists of:
     a. A set of principles that guide the implementation of eHealth.
     b. A framework that identifies controls over access and security.
     c. A risk-based approach to support the implementation of the framework, including analysis of gaps and risks which can be used by the organizations to assess the risk levels and compliance with the prevailing regulations.
     d. Toolkit that provides comprehensive relevant information regarding eHealth procedures, with security and access functions.

  2. Computer Information Security Standards **(CISS)**

     The Computer Information Security Standard (CISS) provides general guidance on the common practice by providing specific guidance to specific communities. This guidance provides risk evaluation and the way to increase the competency and capacity in computerization and information protection.

- **Malpratice**
  Patients may make claims for medical negligence or medical malpractice under Australian medical malpractice laws. Medical negligence or medical malpractice claims are made against individual health care providers as well as publicly funded hospitals that employ professional medical personnel.

  All participant in the My Health System (expert for the Operator of which), they shall maintain interoperability with that system, and if not compliance, the Operator may suspend the participant's access. On condition that a software/application is categorized as a "medical device", such software or application follows offences and civil penalty provisions relating to medical devices as in Therapeutic Goods Act 1989. Non-medical software/devices, however, do not follow such provisions, but effectuate in a software license agreement which partly is regulated by Competition and Consumer Act 2010 where in default the creator of software is responsible for services included in the software, subject to exceptions.

- **Prescribing**
  E-Prescriptions, or more commonly known as Electronic Transfer of Prescriptions (ETP) is an electronic prescribing management system of specialists, dentists, ophthalmologists, nurses etc.) for patients in Australia using an electronic system called Prescription Exchange Service (PES). Currently, there are two PES operating systems in Australia, namely eRx Script Exchange and MediSecure. Both of these PES operating systems have been approved by the Australian Government and are required to meet the prescribed standards relating to security and privacy. A pharmacy or medical practice may be connected to one or both of the PES systems.

  How e-Prescription works is a prescriber (doctor) makes an E-prescription, then E-Prescription is inserted into the PES system and automatically send to the intended pharmacist. The electronic prescription will be stored in PES and protected by PES system until the recipe is downloaded by the authorized pharmacist. The E-Prescription is then printed by a pharmacist. The prescription information contained in the e-prescription can be determined by scanning the barcode code contained in the e-prescription.

  E-prescribing is guided by National Requirements for Electronic Prescriptions v1.0 (DH-2625:2017). The end product of e-prescribing provides specification and guidance documents for software systems creating and processing prescriptions in electronic form. the DH-2625:2017 require the generation of e-prescribing must meet the following criteria, inter alia, (1) only health care professionals with the legal right to prescribe medicines can use the e-prescribing system to generate e-prescriptions; (2) the prescriber must be issued with a login and use that login to perform all action in e-prescribing system, (3) information about access to, use of and time of uses is preserved for audit and enforcement purposes; (4) the issuers of that login shall take reasonable steps to protect that login and ensure it is not used by another person; (5) on the display of e-prescribing system must show the particulars of the prescription required by legislations, obtain a final approval from the prescriber, including a unique identifier of the prescriber; (6)the prescriber must re-present his/her login when approving a e-prescribing for a drug of dependence or misuse; (7) any data of e-prescribing system shall be stored in a permanent and non-alterable.

- **Big Data for Research**
  Access to health information of patients or health care recipients can be obtained by health care provider or organizations who already assigned health care identifiers as regulated in Health care Identifiers Act 2010. In assigning such identifiers, the health authority (Chief Executive Medicare) may collect information from various sources for the purposes of assigning those identifiers.

  In a research activity, the Agency has official roles to evidence-based policy research for establishing and evaluating digital health. As for this purpose, private or other researchers may request research partnership with the Agency on condition their research are relevant with the Agency's priorities, which include public governance or performance rule 2016, the national digital health strategy, benefits attributable

to the My Health Record, the Agency corporate objective. Of which health strategy document, the Agency opens any innovation and scientific achievements in health care from entrepreneurs and researchers. As an example, that national strategy elaborates an example that mobile applications employ data mining methods to help diagnose asthma or pneumonia.

The specific legislation on research or big data on health care or eHealth, however, do not regulatory embodied by laws, except for APP (Australia Privacy Principles) as stated in Privacy Act 1988. APP delineates several basic principles for processing data where such processing shall be: (1) open and transparent ways: e.g. a clear expressed and up-to-date privacy policy; (2) giving option of not identifying individuals: anonymity and pseudonymity; (3) processing a strict necessary of data directly related to functions/activities; (4) destroying unsolicited personal data or de-identified; (5) notifying data owners about their data processing at or before the time of processing; (6) not using or disclosing the collected personal data for another purposes peculiar from primary purpose; (7) not using personal data for direct marketing, unless data is directly collected from data owners, under the scope of reasonability expectation of individuals, and respond an objection by a data owner at anytime; (8) not transfer personal data to the overseas recipients, unless permitted by laws or courts, and a data owner grants explicit consent; (9) not using a government related identifiers of an individual; (10) collected personal data must be accurate, up to date, and complete; (11) data controllers must adopt security measures to protect the data; (12) granting access right for data owners, right to correction, as well.

- **Cross-Country Practice**
  Australia does not explicitly regulate the disclosure of information or telemedicine practices across States in Australia. However, the prevailing laws regulates cross-border disclosure of personal information in Chapter 8 Australian Privacy Principle (APP) - Cross-border disclosure of personal information (APP 8). APP 8 create a framework for the disclosure of personal information across the borders. This framework generally requires health care providers to ensure that the recipients of information will use the health information in accordance with APP, and impose liability on the provider if the recipient of the information use the information inappropriately.

eHealth Regulation in the United States

- **Definition**
  Beside eHealth, another common terms in United States are telehealth and telemedicine. However, there is slight difference in the scope of services for those terms. Telehealth is a collection of tools or methods to improve health care services, public health, and health education using telecommunication technology. Telehealth covers a wide range of technologies and systems to provide virtual medical, health, and education services.[104] Telemedicine is the use of electronic communication and information technology to provide a clinical picture of the service when participants are in different locations (whether they are in remote areas, are of in an off-site location, or are online). Telemedicine has system that can be used by health care providers to extend not only face-to-face treatment practices. Telemedicine is often used when referring to traditional clinical diagnosis and monitoring delivered by technology. However, the term telehealth is now more commonly used because it describes a wide range of diagnosis and management, education, and other health care fields. This is including but not limited to, dental services, counseling, physical therapy, home health, monitoring and management of chronic diseases, disaster management, and consumer and professional education.[105]

- **Informed Consent**
  There are various requirements for the states in the United States (U.S.) related to informed consent in telemedicine practices.

[104] The Center for Connected Health Policy, "What is Telehealth", http://www.cchpca.org/what-is-telehealth, accessed 16 October 2017.
[105] Ibid.
[106] Teresa Iafolla, "Telemedicine & Informed Patient Consent: Done the Right Way", http://blog.evisit.com/telemedicine-informed-patient-consent-done-right-way, accessed on 13 October 2017

Some countries require informed consent from the patients before the treatment or telemedicine services are undertaken. However, several states do not require informed consent, and another states only require informed consent for certain forms of electronic communications (such as e-mail or text messages). Although informed consent is not required by several states in the U.S., but it is still the recommended best practice so far. Several organizations such as the Federation of State Medical Boards **(FSMB)** and the American Telemedicine Association **(ATA)** recommend that that the doctors should obtain informed consent to use telemedicine technology.

There are three components should be considered in creating informed consent:[106]

1. The language used in introducing and explaining the telehealth process should be in a manner that it is easily understood by the patient;
2. Describe the risks and benefits expected from telehealth services; and
3. Other information is required for the patient to have a complete understanding of the telehealth process (ie: available alternatives, referral information, etc.).

The following is the information to be included in the informed consent as recommended by ATA:

1. To inform patients about their rights when receiving telemedicine services, including the right to terminate or refuse treatment;
2. To tell the patients about their own responsibilities when receiving telemedicine services;
3. Have formal procedures to accommodate and resolve potential complaints or ethical problems that may arise as a result of health services (telecare);
4. Explain the potential benefits, constraints, and risks (such as privacy and security) of telemedicine;
5. Inform patients about what will happen in the event of a technological or equipment failure during a telemedicine session and an emergency plan.

Furthermore, the U.S. Food and Drug Administration's (FDA) has formulated a plan on informed consent, which contain several basic elements of informed consent as follows : (i) provide a description of the clinical investigation to be provided to the patient; (ii) provide a description of the risks and adverse conditions that may occur to the patient; (iii) the benefits of medical action to be performed on the patient; (iv) inform the patient regarding alternative procedures and treatments that may be beneficial to the patient; (v) confidentiality; (vi) medical compensation and treatment in the event of injury; (vii) contact numbers of the patient; (viii) a statement that the patient has voluntarily accepted a medical action.[107]

Patient consent usually captured on a paper consent. Electronic consent management enables this process to occur in a fully electronic manner (an electronic consent directive) and various laws, regulations, and policies for access and restrictions on sharing information particularly sensitive information are handled in an automated way health information technology (IT) system. In general, there are three phases in informed consent management:[108]

- Phase I – Consent is captured on paper forms and scanned into HER systems. These forms do not contain structured data. Provider staff must read and analyze the consent from before information is shared.
- Phase II – Consent may be collected on paper and then entered into an electronic format, on consent may be recorded digitally from the start using web portal or devices.
- Phase III – Consent is collected electronically and structured data is captured.

[106] Teresa Iafolla, "Telemedicine & Informed Patient Consent: Done the Right Way", http://blog.evisit.com/telemedicine-informed-patient-consent-done-right-way, accessed on 13 October 2017

[107] https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM405006.pdf, accessed on 24 January 2018.

[108] https://www.healthit.gov/sites/default/files/privacy-security/ecm_finalreport_forrelease62415.pdf, accessed on 20 May 2018

Title 45 of Code of Federal Regulations (CFR) (known as "45 CFR") basically stipulates that a patient's written consent need only be obtained by a provider once. The consent document may be brief and written in general terms. At a minimum, it must inform the patient that information may be used and disclosed for treatment, payment, health care operations (or TPO), state the patient rights to review the privacy notice, to request restrictions and to revoke consent, and be dated and signed by the individual or his or her representative.

However please note that the patient may revoke in writing, except to the extent that the covered entity has taken action in reliance on the consent, and the patient may request restriction on uses or disclosures of health information for TPO.

- **Protection of Patient's Data**
  Health care providers are required to comply with the provisions of the security implementation standards specified in Sections 164.308, 164.310, 164.312, and 164.316 of 45, Code of Federal Regulations (CFR) as follows:

  1. Administrative Security (§ 164.308 CFR)
     Health care providers should implement policies and procedures to prevent, detect, post, correct violations of security procedures, protect data, and apply authorization and approval systems from each party to each transaction. These efforts are implemented by applying risk analysis, risk management, sanctioning, and evaluation of information systems.

  2. Physical Security (§ 164.310 CFR)
     Health care providers should implement policies and procedures to limit physical access to existing electronic information systems and facilities while ensuring that the access is legitimate. These efforts are implemented by creating contingency operations, preparing security facility plans, establishing procedures for controlling access and validation, and controlling data storage including in the event of physical changes to the data.

  3. Technical Security (§ 164.312 CFR)
     Health care providers should implement technical policies and procedures for electronic information systems in order to safeguard electronic health information by granting access only to authorized persons or software programs. Implementation of this technical security is done by: (i) unique user identification; (ii) emergency access procedure; (iii) automatic logoff; (iv) encryption and decryption.

  4. Organization Security (§ 164.314 CFR)
     Safeguards against the organization of health care providers are made through agreements with the government on compliance in which the Government will define the security standards

  5. Required Policies and Procedures and Documents (§ 164,316)
     The health care provider shall adopt appropriate policies and procedures to comply with the government standards, specifications or requirements. Health care provider entities may change their policies and procedures at any time, provided they are documented and reported to the National Coordinator.

In addition, the Health Information Technology and Clinical Health (HITECHT) Act also provide a procedure for health care providers that violates the health data/information security provisions. In the event that the health care providers found any violation of the use of health data/information when accessing, modifying, recording, storing, removing, using, or disclosing information to a person's health data, they shall notify the owner of the health data/information. Such notice shall be made in no later than 60 days after they found such violation. The burden of proof of such violation is charged to the party who discovered the violation. They shall prove that the violation is not committed by them and they have notified the owner of the data/information in accordance with the provisions in the HITECH Act.

A notice of violation must include the following:
1. A brief description of the case, including the date of the violation and the date of the violation has been found (if applicable).
2. Explanation of the types of health data/ information which being violated (such as full name, social security number, date of birth, home address, account number, or disability code).
3. Steps to be taken to protect themselves from potential losses resulting from such violation.
4. A brief description of the entity involved in violation, to reduce the loss, and to protect against further violations.
5. Procedures for individuals to ask additional questions or information, which should include phone numbers, e-mail addresses, websites, and residential addresses.

Failure of the security provisions may be subject to sanctions as regulated in Section 1176 and 1177 Social Security Act (SSA). Section 1177 SSA stipulates that sanctions against violations might be imposed if:
1. Utilization of unique health identifier;
2. Obtain identifiable medical information of a person illegally; and
3. Disclose an individual's identifiable health information to others.

Failure of the above matters might be imposed by:
1. Fine maximum amounting to US$50,000 or imprisonment for not more than one year, or both;
2. If the defense is made by using false information, fine maximum amounting to US$100,000 or imprisonment for not more than five years, or both; and
3. If a violation is committed with a view to selling, transferring or using individually identifiable health information for commercial gain, personal gain or harmful cause, subject to a maximum fine amounting to US$250,000 or imprisonment not more than 10 years, or both.

In the case of a violation other than the action as stipulated under Section 1177 of the SSA, the applicable sanctions shall refer to the provisions of Section 1176 of the SSA. Section 1176 of The SSA stipulates sanctions in the form of fine. The amount of fine is vary in accordance with the violation.

- **Credentialing and Privileging**
  The national health organization in United States, i.e., The Centers for Medicare & Medicaid Service (CMS) is responsible for accrediting and validating the competence of medical personnel through credentialing and privileging. In the context of telehealth, if the CMS has to do the credentialing and privileging process which used an online health site provider in consultation, it will cause an administrative burden. To mitigate this burden, the Joint Commission (TJC) establishes a standard that allows hospitals to conduct its own credential and privileging. The provision also allows hospitals to receive services to make credential and privilege decisions for online health care providers.

  However, prior to 2011, the CMS rated these standards is in contrary to their current Medicare Conditions of Participation (CoPs). To address this, CMS made amendments to CoPs in July 2011 that allowed hospitals to be granted proxy credential and privilege powers. TJC followed a few months later by revising its standard rules in accordance with CMS (CoPs) rules. Provisions within the CoPs require that hospitals to have a credentialing and privileging process for all practitioners providing health care by not distinguishing the credentialing and privileging for practitioners who also provide eHealth/telehealth services. In addition, the CoPs also stipulates that hospitals are required to fully accept the credentialing and privileging made by an online healthcare provider (eHealth/ telehealth entity) for each practitioner on an online-based health service, and treat as practitioners as physically present at home.[109]

  Against these provisions, CMS through CoPs determines that between the hospital and

[109] Greg Billings (Senior Director of Center for Telehealth and e-Health Law), Telehealth Credentialing and Privileging Final Rule from Centers for Medicare and Medicaid Services, page. 1.

the online health care provider, a written agreement should be made. Through the written agreement, the organization should ensure that the processes and standards of credentials and privileges from eHealth service providers meets the CMS-defined standards and compliance with those standards is entirely the responsibility of eHealth health care providers. Moreover, the agreement must be determined that the organization ensures that in providing their services, the telemedicine entity is required to comply with all applicable CMS standards.[110]

To be able to take advantage of the credentialing and privileging process, there are requirements that must be fulfilled, among others:

1. There must be a written agreement between both parties (between the hospital and the telehealth service provider);
2. Hospitals which also act as telehealth service provider must be part of medicare participating hospital or telemedicine entity;
3. Telehealth providers obtain privileges from the hospital.
4. The telehealth provider holds the license issued by the country from which the hospital location is located.
5. The home hospital has an internal review of the telehealth provider's performance and provides this information to other hospitals.

- **Medical Liability, Standards, and Malpractice Claim**

  Through the HITECH Act, the planning, implementation, and oversight of the implementation of the eHealth program has been stipulated. Moreover, based on HITECH Act, the National Coordinator of the Office of Health Information Technology (Office of National Coordinator for Health Information Technology) was established under the Department of Health and Human Services **(HHS)**. The National Coordinator is responsible for the development of information technology in the field of health on a national scale.

  The main tasks for National Coordinators are to review and set standards and certification criteria for the exchange and use of electronic data and information recommended by the HIT Standard Committee for adoption by the U.S. Government.

  Moreover, the HITECH Act also stipulates clear provisions for the use of technology in eHealth applications, particularly in terms of electronic health records **(EHR)**. Before it is released and can be used by the public, the National Coordinator will ensure the feasibility and quality of EHR technology and establish certification of the technology.[111] For health care providers who is willing to adopt such technology, they will be charged by the National Coordinator in which the amount of the fee is adjusted to the condition of the health care provider. Funds generated from these technology adoption payments will then be allocated to smaller, low-income, and service providers in rural areas that are medically inaccessible.[112]

  Supervision on the quality of health services is also carried out at the state level. Government in U.S. State has the duty to administer and sponsor a health care program. Against this policy, the State Government is required to enter into an agreement with any health care provider, health planning or health insurance that the provider in the information technology system used must comply with the standards and specifications set by the Government.[113]

  In 2014, the telemedicine organization at the United States, the American Telemedicine Association **(ATA)** has developed a guideline for telemedicine services, namely: Core Operational Guidelines for Telehealth Services Involving Provider-Patient Interactions. The guidelines has been well received by the telemedicine community and adopted in various practices, and also used in research to

[110] Telehealth Resource Centers, "Credentialing and Privileging", https://www.telehealthresourcecenter.org/toolbox-module/credentialing-and-privileging, accessed 13 October 2017.
[111] Section 3007 (a) dan (b) HITECTH Act.
[112] Section 3007 (c) HITECTH Act.
[113] Section 13112 HITECH Act.

support the practice and development of telemedicine[114]. The guidelines is addressed to individual practitioners, groups and special practices, hospitals and health care systems, and other health-related service providers where there is telehealth interaction between patients and providers for health care purposes. The guidelines applied to healthcare providers and their patients residing in the U.S. territory. If one or both parties are not located in the U.S., the guidelines may be referred but should still refer to local guidelines.

Contemporary EHR system technology has significant limitations, and if these may cause harm, aggrieved individuals and enforcement entities have many legal resources. Plaintiffs whose alleged injuries are associated with EHR systems could sue health care providers for medical malpractice. Those who believe that their records have been improperly disclosed to third parties could assert privacy violation claims. In rare circumstances, providers accused of negligent EHR system use could face disciplinary proceedings (initiated by professional organizations), government enforcement actions, or criminal prosecutions.

Patients who feel that their care givers were negligent in treating them may assert medical malpractice claims. To prevail, the plaintiff must establish the four elements of negligence :(1) a duty of care owed by the defendant to the plaintiff,(2) breach of that duty through conduct that fails to meet the applicable standard of care,(3) harm or injury, and (4) a causal link between the injury and the breach of duty.

- **Prescribing**
  Each state has different provisions related to online prescribing or e-prescribing, whereas the majority of states claimed that a physical examination is required prior to prescribing. However, not all states require direct physical examination. The states that adopt the rules which require direct physical examination are New Jersey, Indiana, Tennessee, Colorado, and Idaho. There are also several states that prohibit online prescribing or e-prescribing for certain dangerous categories of medicines, such as California and Arizona. However, there are different restrictions on the two states. California prohibits the provision of online dangerous medicines without direct examination of patients and doctors, while Arizona determines that the prescription of such a dangerous medicine can be performed without direct physical examination between medical personnel and patients. Examination may be performed using telemedicine services and shall be supported by an EHR that meets the certification requirements as required by the Arizona Government.[115]

  Requirement of prescription or e-prescription by a pharmacist/practitioner is basically regulated under the 21 CFR.

  A pharmacist may dispense directly a controlled substance (listed in Schedule II of 21 CFR) that is a prescription drug only pursuant to a written prescription signed by the practitioner, except in the case of emergency. In the case of an emergency situation (as defined in 290.10 of 21 CFR), a pharmacist may dispense a controlled substance upon receiving oral authorization of a prescribing individual practitioner, provided that:

  (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner);
  (2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required, except for the signature of the prescribing individual practitioner;

  (3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which

[114]US National Library of Medicine National Institute of Health, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4934495/, accessed 16 October 2017.
[115] Health Current, "Controlled Substances", https://healthcurrent.org/information-center/e prescribing/controlled-substances/, accessed on 8 January 2018.

may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and

(4) Within seven days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered to the dispensing pharmacist. In addition to conforming to the requirements of the Code of Federal Regulation § 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner.

(5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance upon receiving an oral authorization from a retail pharmacist or an individual practitioner.

- **Payment**
  United States has the telemedicine financing policy in which states may provide reimbursement on telemedicine services provided that they meet state-of-the-art efficiency, economic and quality requirements. This provides an opportunity for states to define program criteria that earn reimbursements according to their policies.

Initially, Medicare only replaced the very specific health care costs that were provided through telemedicine with strict requirements. In recent years with the rapid growth of the telemedicine industry, Medicare has expanded the list of reimbursable telemedicine services, but still imposed many restrictions on the way healthcare is delivered.

Almost all the U.S. states (except Connecticut and Rhode Island) offers some form of reimbursement insurance for telemedicine under the state Medicaid program. Some state Medicaid programs provide widespread coverage for telemedicine reimbursement, without specifying the patient's location boundary or health care provider.

The American Telemedicine Association (ATA) released a comprehensive report on Medicaid state coverage for telemedicine:[116]

1. 48 Medicaid state programs include telemedicine
2. 24 states include telehealth for civil service work plans
3. 24 states and DC (Distric of Columbia) have no special requirements for patient location
4. 25 states recognize the patient's home as a place of origin
5. 82% of country of U.S. covering telemedicine as a whole, without limitation of distance between providers and patients
6. 15 states and DCs do not set limits on which health care providers can telemedicine

Medicare telehealth services may be provided to eligible Medicare beneficiaries even though the medical personnel providing telehealth services are not located in the same place as the beneficiaries. As a requirement, telehealth services must be provided through an interactive audio and video telecommunication system that provide in real time communication between beneficiaries and practitioners in different places. The CMS defines "qualified telehealth beneficiaries" as individuals registered under Medicare.[117]

[116] eVisit, "Telemedicine State Policy Landscape",https://evisit.com/state-policy-landscape/, diakses 20 Oktober 2017.
[117] Scott A. Edelstein and India K. Brim, Telemedicine: An Interactive Approach to Healthcare in the Wake of Healthcare Reform, page. 2.

Unlike Medicare, CMS has not yet officially mandated the coverage of telehealth services reimbursement under the Medicaid program. Each state has a policy to determine the reimbursement of health services covered by Medicaid, including telehealth applications. Medicaid will reimbursement of health services that meet state requirements. CMS has encouraged states to take advantage of this flexibility to create an innovative payment methodology for telemedicine services.

As provided by the § 54 CFR, a relevant entity may use and disclose 'protected health information' (PHI) for payment purposes. Payment is a defined term that encompasses various activities of health care providers to obtain payment or be reimbursed for their services and for a health plan to obtain premiums, to fulfill their coverage responsibilities and provide benefits under the plan, and to obtain or provide reimbursement form the provisions of health care.

In addition to the general definition, the § 45 CFR provides examples of common payment activities which include, but are not limited to determining eligibility or coverage under a plan and adjudication claims, risk adjustments, billing and collection activities, reviewing health care services for medical necessity, coverage, justification of charges, and the like, utilization review activities and disclosures to consumer reporting agencies (limited to specified identifying information about the individual, his or her payment history and identifying information about the covered entity).

- **Cross-Country Practice**
  Under Article 10 of the United States'constitution, the state is authorized to regulate the health, security and welfare aspects of its citizens. To be able to practice health care, every health worker is required to obtain a practical license from the state. In the case of telemedicine, the requirement to obtain a permit, the health worker shall ensure that its activities are legally valid. With Telehealth, the provision of health services is possible by health workers and patients in different places (states). Each state has its own rules. The majority of states have strict rules governing that any health worker providing inter-state health services must have a practice permit from the state where his or her patient is located. However, in the event of an emergency, such provisions may be disregarded.

  In addition, several states issue special permits or certificates related to the practice of telemedicine. There is also a state that does not specifically issue a specific telemedicine practice permit, but may issue a temporary medical license for a health worker from another state provided that the health worker meets the requirements.[118]

  For example, the State of Indiana in the code, IN Code, 25-1-9.5 health workers outside Indiana are not allowed to provide health services to Indiana residents without the express written permission to practice issued by the Indiana Professional Licensing Agency. The licensed health care professional of the agency is directly considered to be subject to the law in Indiana.[119]
  Different things are governed by the State of Mississippi. Based on MS Code Sec. 73-25-101, Mississippi regulates, acknowledges, and becomes a member of the Federation of State Medical Board **(FSMB)** that accommodates intravenous health care by allowing health workers to practice in other states.

eHealth Regulation in Malaysia

- **Definition**
  Malaysia uses telemedicine terminology for health services using ICT. The concept of telemedicine itself emerged in Malaysia since 1997 and has been regulated in the Laws of Malaysia Act 564, Telemedicine Act 1997 **(Malaysia Telemedicine Act)** which specifically defines telemedicine as a medical practice that uses audio, visual, and data communications. In addition to Malaysia Telemedicine Act, the definition of telemedicine by Malaysia Ministry of Health can also be found in Malaysia's Telemedicine Blueprint published on July 25, 1997, which stipulates that telemedicine means "far-reaching medicine." At the practical level, telemedicine refers to the practice of providing health services

related to telecommunications, information and multimedia technologies to connect participants in the health system.[120]

- **Informed Consent**
  Information consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action. In order to give informed consent, the person concerned must have adequate reasoning capacity and be in possession of all relevant facts at the time consent is given. This term was first used in a 1957 medical malpractice case by Paul G. Gebhard in USA.

  In relation to valid consent, the definition of valid consent is a voluntary agreement by an individual to a proposed procedure, given after appropriate and reliable information about the procedure, including the potential risks and benefits, has been conveyed to the individual. It is generally accepted that consent to be "valid" should be "informed". The requirements for obtaining valid consent are: (i) it must be given by a person with legal capacity and of sufficient intellectual capacity to understand the implications of undergoing the proposed procedure; (ii) it must be taken in a language which understood by the person; (iii) it must be given freely and voluntarily, and not coerced or induced by fraud or deceit; (iv) it must cover the procedure to be undertaken; (v) the person must have an awareness and understanding of the proposed procedure and its known potential risks; (vi) the person must be given alternate options to the proposed treatment or procedure; (vii) the person must have sufficient opportunity to seek further details or explanations about the proposed treatment or procedure; (viii) there must be a witness or interpreter, who may be another registered medical practitioner or a nurse, who is not directly involved in the management of the patient nor related to the patient or the medical practitioner, or any such person who can speak the language of the patient, to attest to the process during taking of the consent.

  According to the guideline by Malaysian Medical Council **(MMC)**, the main regulatory body of Malaysian medical practitioners, the relevant laws, regulations or guidelines relating to informed consent as below: (i) Mental Health Act 2001; (ii) Guardianship of Infants Act 1961; (iii) The Law Reform (Marriage and Divorce) Act 1876; (iv) Private Healthcare Facilities and Services Regulations 2006; (v) United Nations Convention on The Rights of the Child, 1989; and (vi) The Malaysian Medical Council Ethical Guideline on Audio & Visual Recordings.

  In general, there is not any procedure, examination, surgery or treatment may be undertaken on a patient without the consent of the patient, if she or he is a competent person. Consent of the patient must be obtained before the proposed procedure, examination, surgery or treatment is undertaken, except for emergency where the need to save life is of paramount importance. A medical practitioner is obliged to disclose information to the patient and to warn the patient of material risks that might happen before taking consent. Failure to obtain a patient's consent or disclose material risks may be interpreted as a failure of the standard of care which would be resulting in a disciplinary inquiry by the MMC or may be construed as a breach of duty of care and legal action constituted. The Federal Court of Malaysia has, in fact, reaffirmed in the case of Kok Chong Seng & Sunway Medical Centre v Soo Cheng Lin in 2017 that the legal standard for the provision of information to patients is the Rogers v Whitaker principle, i.e. doctors have a duty of care to disclose material risks. Patients who are young person (minors under the age of 18) do not have capacity to give valid consent. Consent may be gained from the minor's legal guardian. With regards to infants, medical practitioners should consult or obtain the consent of the infant's legal guardian, referring to Guardianship of Infants Act 1961. For patients who are incapable of, or impaired with, decision-making ability, consent may be obtained from a relative, next-of- kin or legal guardian of the patient. Complaints may be made to the MMC or MOH (Ministry of Health) which regulates the profession.
  In addition, Malaysian Personal Data Protection Act 2010 as at 15 June 2016 (PDPA): any personal data consisting of information as to the physical or mental

health or condition of a data subject (sensitive personal data) shall only be processed by a data user upon explicit consent of the respective data subject. Sensitive data processing for medical purposes is acceptable provided that it is undertaken by a health care professional or a person who under certain circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person was a health care professional.

Notification to and consent from data subject is also required for: collection and procession of any personal (including sensitive personal data), any disclosure (for purpose for which the personal data was to be disclosed at the time of collection of the personal data or a purpose directly related to the purpose at the time of collection), personal data transfer to a place outside Malaysia.

- **Protection of Patient's Data**
  The regulation of patient data protection in telemedicine is not regulated in the Malaysia Telemedicine Act. Thus, the implementation of patient data protection refers to the general rules of personal data protection, the Personal Data Protection Act 2010, as follows:

Regulation	Explanation
Protection of personal data (Article 6 paragraph 1)	Data controllers are prohibited: • process personal data without consent from data owners, in the case of personal data is not sensitive; or • process personal data in case the data is sensitive, except: (i) the data owner has given consent to process the data; or (ii) data processing is required.
The principle of security (Article 9)	Data handler shall, when performing the processing of personal data, to take practical steps to protect personal data against any unintentional defects, misuse, modification, access or disclosure, disclosure or destruction.
Right to correct data (Article 34)	Patients may request correction of false / inaccurate / incomplete personal data.
Right to accurate data (Article 22)	Patient may request correction of wrong / inaccurate / incomplete personal data.
Cancellation of data owner's consent to processing of personal data (Article 38)	• The owner of the data with written notice may withdraw the consent that he has made to the personal processing. • Compulsory data handlers, upon receipt of the above mentioned notice to cease processing of personal data. • If the controllers of data violated this article by keeping data processing subject to a fine of not more than RM100,000 or imprisonment for a period not exceeding one year, or subject to fine and imprisonment.

The existence of a special council to supervise the implementation of personal data protection (Article 47)	The Minister appoint a person or an institution as a Personal Data Protection Commissioner with the aim to supervise the implementation of the protection of personal data.
Rights in the event of a violation (Article 104)	Anyone who suffers a loss resulting from a violation of this rule conducted by a data controller has the right to file a legal action in the form of a written complaint addressed to the Personal Data Protection Commissioner.

Under the PDPA and the PDPA Standards 2015, organizations (including companies and internet providers) collecting and using personal data must ensure the security and data integrity of any personal data by implementing appropriate safeguards to prevent the loss, misuse, modification, unauthorized access or disclosure or alteration or destruction of the personal data it possesses, making the organization's obligation to establish internal standard operating procedures personal data management within the organization and comply with data protection principle in the PDPA.

PDPA Standards 2015 impose certain minimum standards to be adhered to by organizations (as the ESP) to safeguard and ensure the security and data integrity of the personal data being stored on any platform (whether physically or electronically (e.g. on a cloud)).

1. The key obligations under the security standards, among others:
   - Maintaining and limiting the right of access to personal data;
   - Setting limits upon the power of staff to access personal data;
   - Maintaining personal data records;
   - Potential risk management of ensuring that security procedures are in place and by controlling and recording incidences of data transfers;
   - Physical security standard as such monitoring access to data repositories, putting in place closed-circuit cameras and storing hard copies of personal data in locked cupboards.
2. The key obligations under the retention standards, among others:
   - Permanently disposed personal data once no longer required (including step of disposing data collection forms within 14 days of collection, unless the forms are subject to other legal requirement);
   - Remove the personal data which is no longer in use from the organization's database;
   - Prohibition of storing personal data in removable media devices without the written permission of senior management.
3. The key obligations under the data integrity standards, among others:
   - Ensuring that the personal data is accurate, complete, not misleading and up-to-date;
   - Making available (online and physical) forms for data subjects to update personal data and data users, including updating personal data immediately after receiving a data correction notice.

- **E-Medical Record**

  E-Medical Record (EMR) is classified as sensitive personal data since EMR is defined as a computerized record that can be accessed with concerned of patient privacy, confidential and security from multiple integrated system at any point of care within the health care organization. As EMR keeps sensitive personal information of the patient, data users are responsible and liable to ensure that the information are not leaks to other unauthorized parties and in compliance with PDPA and/or 2015 PDPA Standards.

  PDPA and 2015 PDPA Standards requires personal data to be:
  1. Processed and protected in any way (the Electronic medical record Support for Public health (ESP) to take practical steps) free from any loss, misuse, modification, unauthorized or accidental access or disclosure, alteration or destruction;
  2. Based on consent from the personal data subject.

PDPA applies to all personal data which is collected and used inside Malaysia, PDPA implying that personal data here in is personal data which is placed in territory of Malaysia. Regarding personal data transfer to any place outside Malaysia shall be restrictedly done to place as specified by the Minister of Science, Technology and Innovation, upon the recommendation of the Commissioner, by notification published in the Gazette. The ESP as personal data user shall take all reasonable precautions and exercised all due diligence to ensure that the personal data will not be processed in the recipient country in a way that would be a contravention of the PDPA.

- **Credentialing and Privileging**
  In terms of credentialing and privileging, there is a requirement that telemedicine service providers should be able to practice in Malaysia, which is set forth in Article 3 of Malaysia Telemedicine Act, as follows:
  1. medical providers that may provide telemedicine services are: (i) registered medical practitioners and have practice certificates; or a registered telemedicine practitioner from outside Malaysia who has a valid certificate of practice.
  2. any person providing telemedicine services in a manner contrary to this section, even if he practices outside Malaysia, shall be liable to a fine not exceeding RM500,000 or imprisonment for a period not exceeding five years.

  However, in relation to credentialing and privileging processes, the process is still within the scope of general health care delivery by the Ministry of Health Malaysia, hence there is no credentialing and privileging process undertaken specifically for telemedicine providers.

  There is not any requirement to obtain operational business license as the ESP who provide electronic system for eHealth purpose. However, the ESP which is classified as data user for health care and/ or insurance purpose shall be registered to the Commissioner of the Department of Personal Data Protection (the Commissioner). Failure to register of data user is an offence.

- **Medical Liability, Standards, and Malpractice Claim**
  The MMC regulates the professional conduct of all doctors, irrespective of whether they are practicing in the public, private, or voluntary sectors. The MOH enforces the laws regulating all private health care facilities, which include the voluntary sector. Although there is not any regulation related to the patients' rights in the public sector health care facilities, there are policies and procedures in place that protect their rights. For private sector health care services and facilities, the relevant regulatory law is the Private Health Care Facilities and Services Act 1998 (PHFCSA), which provides for: (i) the provision of medical care by a registered doctor; (ii) a grievance mechanism plan for patients using the premises of the private health care facility or service; (iii) the manner of assessing a patient's medical records and the manner of obtaining a patient's medical report by the patient, the patient's representatives, or a health care provider; (iv) the obtaining of a valid consent for a surgical operation or procedure; (v) the fees that may be charged by private health care facilities and services; (vi) matters relating to patients' rights in relation to health care services provided by any healthcare facility or service, including patients' privacy, confidentiality of information, and access to patients' medical reports and records; and (vii) the minimum standards and requirements for all health care facilities.

  There are quality standards prescribed in the PHCFSR for various aspects of health care. These quality standards support patients' rights, i.e. infection control; standards for obstetrical or gynaecological care, newborn nursery facilities, paediatric care, anaesthesia, surgical facilities and services, intensive care unit, emergency care services, pharmaceutical services, dietary services, rehabilitation facilities and services, specialist outpatient facilities and services, ambulatory care centres; special requirements for central sterilising and supply facilities and services, blood bank and blood transfusion services, haemodialysis facilities and services, radiological or diagnostic imaging services

and radiotherapy and radioisotope services; standards for private nursing homes and special provisions for hospice and palliative care services.

Grievance mechanism in private health care facilities:

- The licensee or person in charge of a health care facility has to provide a patient grievance mechanism plan which include the appointment of a patient relations officer (PRO) to serve as a liaison between the patient and the facility; the extent of decision-making authority given to the PRO; a method by which each patient will be informed of the PRO and how he or she may be contacted; and the documentation of all complaints.
- Any grievance against the facility may be submitted by the patient orally or in writing to the PRO or to any healthcare professional of the facility at any time. A complaint submitted to the latter has to be forwarded to the PRO by the next working day.
- The PRO is required to document all complaints received and resolve the matter. If the PRO cannot resolve the complaint, it has to be referred to the licensee or person in charge immediately or within three working days.
- The licensee or person in charge has to institute an investigation and provide a reply, which includes the result of the investigation to the complainant within 10 working days after the complaint was received by the licensee or person in charge.
- The report of the investigation to the complainant has to state that if he or she is dissatisfied with the reply of the licensee or person in charge, the complainant could refer matter to the Director-General of Health.
- The Director-General will then institute an investigation of the complaint and inform the complainant and the facility of his findings or any recommendations based on the findings.

For public sector health care facilities

There is not any specific law regarding the provision of health care or treatment in public sector health care facilities. However, there are policies and procedures put in place by the MOH and the boards of the University hospitals that protect patients' rights. Patients and their families can avail themselves of the grievance mechanisms that are in place in the public sector health care facilities. Complaints about a doctor can be made to the MMC; complaints about both private and public sector health care facilities can be sent to the Medical Practices Division of the MOH. Claim for medical negligence or malpractice on medical treatment can also be made through litigation process. Such claims are usually handled by Medico Legal Branch which will work along with the Attorney General's Chamber and the Law Advisor Office of the MOH.

A breach of the provisions of the PDPA (e.g. personal data leak or misuse) can result in a range of fines, imprisonment, or both. Especially for failure to comply with individual's personal data protection in section 9 of PDPA is an offence punishable by a fine of up to MR100,000 and/or imprisonment for up to two years. For the ESP as data user non-compliance with any of the security standards under the 2015 PDPA Standards may result in the ESP being held liable to a fine not exceeding RM250,000 or imprisonment not exceeding two years, or both.

- **Prescribing**

  Nearly all prescriptions in the country are written by hard, except for a selected few hospitals that utilize the e-prescribing system. This is because, as mentioned above, the eHealth project is ongoing and electronic systems in most aspects are expected to be available nationwide in 5 years.

  Relevant legislations (non-exhaustive):
  - Sale of Drugs Act 1952
  - Control of Drugs and Cosmetics Regulations 1984
  - Dangerous Drugs Act 1952
  - Poisons Act 1952
  - Medicines (Advertisement & Sale) Act 1956

  Any negligence or malpractice found on the part of doctors in prescribing may be complained or reported to the MOH or MCC who regulates the profession. Any negligence or malpractice found on the

part of pharmacists in prescribing may be complained or reported to the Pharmacy Practice & Development Division or the MOH.

Both digital signatures (stipulated under the Digital Signature Act 1997 (DSA)) and electronic signatures (stipulated under the Electronic Commerce Act 2006 (ECA)) are recognized in Malaysia.

1. E-signature
   Broadly defined as any letter, character, number, sound, or any other symbol or any combination thereof created in an electronic form adopted by a person as a signature. A signature of a person will be deemed as electronic signature if: (a) attached to or logically associated with the document; (b) adequately identifies the signer and his approval of the information to which the signature relates; (c) is as reliable as is appropriate given the purpose and circumstances for which the signature is required; (d) the means of creating the electronic signature is linked to and under the control of the signer only; (e) any change to the e-signature post signing is detectable; and (f) any change to the document post signing is detectable.

2. Digital Signature
   Defined as a transformation of a message using an asymmetric cryptosystem such that a person having the initial message and the signer's public key can accurately determine (a) whether the transformation was created using the private key that corresponds to the signer's public key and (b) whether the message had been altered since the transformation was made.

   The ECA does not preclude the use of digital signatures (as defined in the DSA) in electronic commercial transactions. As such, parties are free to choose to use a digital signature as an electronic signature in any commercial transaction.

- **Payment**
  Malaysia has a mixed health financing system. In the private sector, private health insurance is voluntary, with various premiums being charged on the basis of individual health status, type of health insurance, and coverage level. Meanwhile, public health services are funded through general taxation, with an annual health budget allocated by the Ministry of Finance to the Ministry of Health, where the proportion of revenues allocated to the Ministry of Health in the National State Budget (APBN) is decided every year. In addition, there is a scheme in which the workforce is formally employed for monthly contributions to the Employee Provident Fund and the savings will be distributed as pension and medical expenses. For public sector employees, they will get free access to medical services provided by public health providers. In relation to telemedicine, until now, there is no scientific paper or regulations regarding the reimbursement system for telemedicine services.

- Cross-Country Practice
  Relevant legislations and regulations:
  - Medical Act 1971
  - Medical (Amendment) Act 2012
  - Medical Regulations 1974
  - Medical (Setting of Examination for Provisional Registration) Regulations 2015

  Pursuant to the Medical Act 1971, any person (including non-Malaysian) who wishes to practice medicine in Malaysia needs to be registered with the MMC. The Council maintains a Medical Register for this purpose.
  Eligibility for registration and the process for gaining registration generally depends on:
  (i) The place where the applicant obtained his or her primary medical qualification;
  (ii) Nationality; and
  (iii) Professional background and experience

  Types of registration for foreign doctors who wish to practice medicine in Malaysia: (i) Full registration (with conditions) (section 14(3)); (ii) Temporary registration (section 16); and (iii) Specialist registration

  Registration applications are to be approved or refused by two Evaluation

Committees established by the MMC: (i) Evaluation Committee for Primary Medical Qualifications; or (ii) Evaluation Committee for Specialist Medical Qualifications.

Non-Malaysian applicants may have to undertake and pass certain medical exams and shall provide proof of efficiency in Malay (Malaysian language) and English as part of the requirements. As any other Malaysian doctors, cross country medical staff will be regulated by the Ministry of Health and the MMC and bound by all relevant legislations and regulations.

The Health Education Impact of eHealth for the Public

Since ehealth known by the public as part of the health industry, there is a change in the society related to health information. People used to depends on the doctor, media, or other formal channel of health information as the main resource of information. But since the eHealth era has arrived, health information is no longer known only in the consultancy room, but become information, which is publicly available. In one side this unavoidable shift has changed the role and the work nature of medical practitioner, on the other side the health knowledge sharing has opened the eyes of general public, as they become more aware on the importance of keeping good health, and always seek knowledge updates. In this case their thirst of knowledge has been met with the service that is provided by health applications, which always provide updated health knowledge as part of their services.

Several health applications for instance Gue Sehat, Alodokter, HaloDoc, Homedika provide various format of health information, which are accessible not only for people who are registered in the application, but for wider public as well. In this case the eHealth plays important role to strengthen health education and promotion in the society. This is important to enhance health understanding, but the people should also have the knowledge to choose which one is the scientific knowledge, and which one is not, and also the accuracy of the information as well.

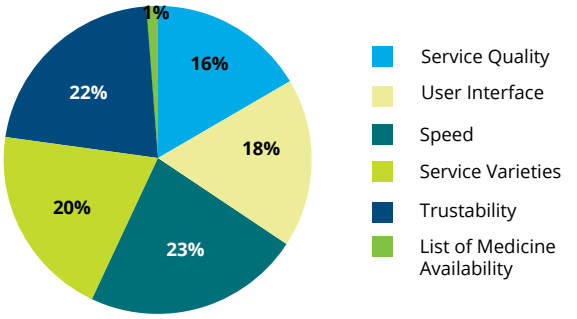
How Does the Patients and Doctors Like the eHealth Application?

A pair of surveys on the consumers of eHealth behavior towards the application have been conducted during May – July 2018.
The first survey which targeted to general public as participants reached 102 respondents. From all the respondents, 32.4% (33 respondents) of them have already used digital healthcare application while the other 67.6% (69 respondents) have not. From 33 respondents who already used digital health care application, the majority have use Alodokter (21 responses) and HaloDoc (12 responses). Meanwhile, other applications like Go-Med (2 responses), GueSehat, JKN Mobile, FatSecret, WebMD and Mayo Clinic can be assumed is less preferred (only one responses each).

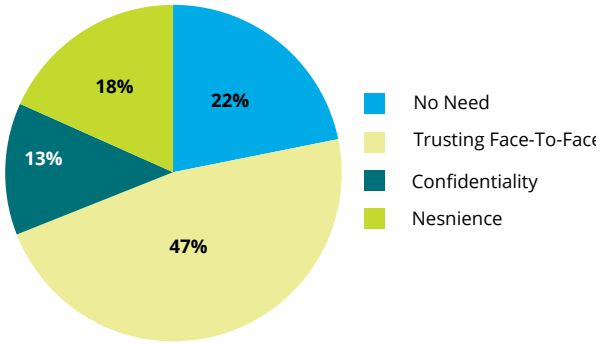
From the survey, practicality and convenience were the major reason of using digital health care application. While low cost and variety of choices came at the second place. The other reasons cover: higher reliability, obliged due to certain circumstances and as a source for getting second opinion. Based on the experience the respondents had, 84.4% were satisfied, while the other 15.6% of them were dissatisfied with digital health care application which they use. There were some concerns that the respondents have includes: data privacy, miscommunication, diagnostic accuracy, unexperienced doctors, and legal protection. However, issues regarding diagnostic accuracy was one which participants were most concern about.
Build upon the respondents, inputs for digital healthcare application platform varies range from improvement of service quality, user interface, speed, service varieties and reliability. The majority of the respondents (61.2%), have not use digital health care application due to the trust issue. Most of them believe that seeing medical doctors and do face-to-face consultation is much more reliable. Several other reasons for not using digital health care application include: the respondents did not know that health care applications were exist,

the feel of unnecessity, and issues regarding confidentiality. Meanwhile, several factors which can drive them to try to use the application were certainty regarding accuracy assurance, legal protection, data privacy, ease of use, and promotions.

Improvement Area
(General Public)

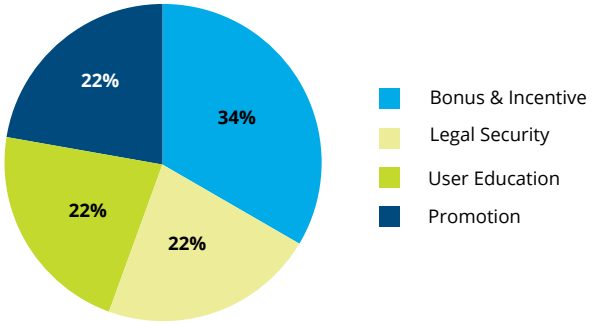


Reasons for Not Using Digital Health Applications
(General Public)

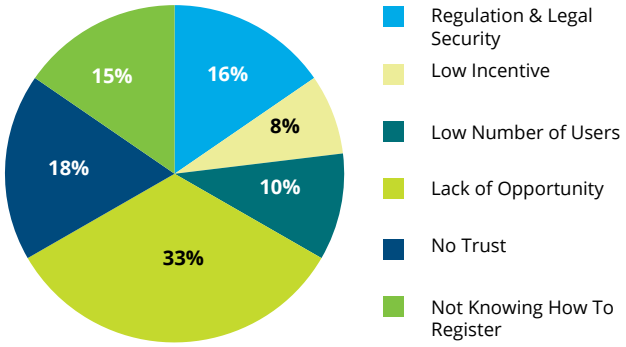


The second survey was responded by 27 medical doctors, 2 pharmacists and 2 midwife. The majority of the respondents never delivered service though digital application platform (26 respondents) while the other four delivers service through Alodokter (2 reponses), DokterChat, Telemed FKUB application with the main motivation of expand his service coverage via online application. The users of this application are 100% satisfied with the application which they use and have no concerns or issues regarding the digital health care application. However, in their point of view, the incentive given should be adjusted.

Improvement Area
(Healthcare Workers)



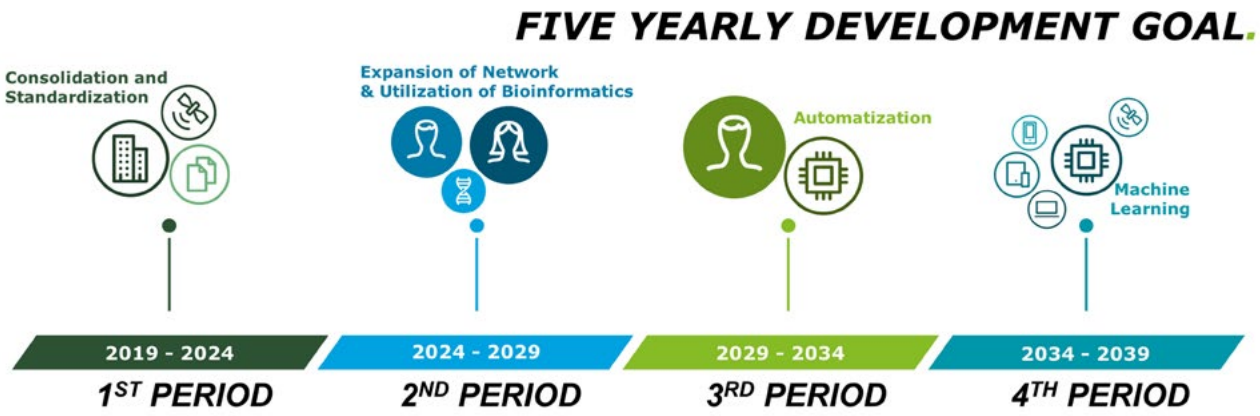
Reasons for Not Using Digital Health Applications
(Healthcare Workers)



While the others tend have not used the digital healthcare application platform mostly due to the lack of opportunity. In addition, some other factors include: the uncertainty of regulation and legal securities, the low-trust on digital or online application, small market number, unattractive incentive, and lack of knowledge on how to apply or join.
This survey does not produce any further discussions nor include any assumptions since the survey only aim to understand the market expectations from real users' point of view. Hopefully this survey can be used as a

Recommendations for Future eHealth Strategy

Indonesian eHealth Implementation Timeline Rules & Regulation



	2019 - 2024 1ST PERIOD	2024 - 2029 2ND PERIOD	2029 - 2034 3RD PERIOD	2034 - 2039 4TH PERIOD
Infrastructure	• Palapa Ring Project on progress - West project (100%) - Middle project (75%) - East Project (40%) • In the interest of broadband connection availability across Indonesia (34 Provinces) • Targeted to finish by the end of 2018, available for 2019. • Universal Healthcare Coverage is targeted to be fully implemented by 2019.	• Broadband connectivity is established across 7 main islands of Indonesia (Jawa, Sumatera, Kalimantan, Sulawesi, Maluku, Nusa Tenggara, Papua) • Palapa Ring Project supports in: - Apps growth especially for distant learning, telemedicine, e-government and other apps	• Infrastructure development in connectivity: - Smart home care - Telemedicine	
Data Storage	• Cloud (data storage) Accessibility is on progress (KOMINFO)	• Cloud storage available	• Cloud storage development and expansion	
eHealth Actualization	Smart hospital using Integrated Management Information System • Medical cloud: Integration across the health system (supported by BPJS) • Smarter access to health care facility, billing information and purchasing decisions • Smart and integrated 'wearables devices' and 'smartphone use as a medical device'	• Blockchain Implementation • Comprehensive historical medical record and current health condition. • Autonomous cars and drones for delivering medicine. • Insurance companies/ BPJS using IoT devices to monitor real-time lifestyle and diets	• Artificial intelligence/ chat-bot diagnostic device • Home diagnostic equipment for teleconsultation support.	• Robotic health care assistants • Augmented reality glasses, that allows doctors to view the patient's computed tomography (CT) scan and perform spinal surgery by projecting the patient's spine in 3D • Genomic database-based 3D printing to produce artificial organs for transplantation.
eHealth Actualization	• Mobile clinic program with telehealth car/bus • Utilization of Google trends for surveillance of epidemics and diseases • Digitalization in R&D/clinical research • Training and continuing medical education • "Smart pill" or "smart sensors" containers • Replacement of debit or credit cards with a unique biological identifier (e.g. fingerprint).	• Big data analysis-based drug R&D, e.g. in developing precision medicine. • Health map of infectious disease for epidemic protection: predicting patterns and putting up safeguards before the diseases takes out.	• Personalized and precise health treatment based on family's & individuals' genetic	Robo-lab: artificial intelligence guides the lab of the future. Machine learning automates the processes of pharmaceutical discovery and innovation.

Regulation and Policy	**Issuance of eHealth Roadmap** covering, among others: i. the definition of telehealth, telemedecine, tele-pharmacy, tele-consultation, tele-rehabilitation, tele-laboratory, tele-radiology and eHealth; ii. protection of personal data; iii. mobile health (wearable devices); iv. informed consent via wearable devices; v. business license, scope of services and liability for the stakeholders; vi. e-prescribing; vii. electronic system audit operation; viii. electronic certification; ix. credentialing and privileging; x. centralization of data; xi. sharing and standardization of data center; xii. system audit operation; xiii. medical procedure and claim of malpractice via electronic system, payment / billing system; xiv. insurance system integration; xv. clinical decision support system; xvi. health knowledge management by an authorized body or organization (hereinafter referred as "eHealth Matters"). **Codified Law of eHealth Practice in Indonesia** to provide the main legal referral and core principles of national eHealth by considering the prevailing conventional medical practice law and regulation as well as covers the eHealth Matters as mentioned above. **Amendment or Issuing New Regulations on specific matters, among others: (i) Conventional Medical Practice, (ii) Citizen Registration System, and (iii) Healthcare National Insurance (BPJS),** in order to support the enforcability of codified law of eHealth Practice in Indonesia as well as **Code of Conduct of Indonesian Medical**	**Amendment of eHealth Law and Regulations** covering the integrated citizen registration number online system (e.g. for integration or automatic linkage between citizen ID with medical records and insurance allocation), technology on autonomous cars and drones, specific standards of electronic system provided by electronic system provider, standard for electronic tools and devices used for data processing and connect to telecommunication network. **Guidance on blockchain** and technology to support ehealth system. **Regulation on Digital Signage Placement** in patient's mobile, personal computers, or digital wearable devices. Issuance of **Health map of infectious disease for epidemic protection.**	**Amendment of eHealth Laws and Regulations** covering artificial intelligence / chat-bot diagnostic device, biometric technology, personalized and precise health treatment, robo-lab, robotic healthcare assistants, 3D technology. This laws and regulations will set out the scope of services and liability for the stakeholders ("**Development of eHealth Matters**"). Issuance of **Guidance on the Development of eHealth Matters** to support the above regulation.

recommendation or to give a sight on what market really needs – which so that all stakeholders can work together and take part to create and improve the eHealth program.

1. Legal Provision in Indonesia, Malaysia, and Australia

eHealth Application		Indonesia	Malaysia	Australia
a.	Definition	The term "eHealth" in Indonesia is known mostly for the health digital application, which is famous because of the health awareness lately. Indonesia does not have specific rules and regulation regarding digital health care system yet, but the only regulation related is the teleconsultation and teleradiology guidelines (namely Hospital Pilot testing of Video-conference-based tele-medicine and teleradiology guideline or known as Rumah Sakit Uji Coba Program Pelayanan Telemedicine berbasis Video-conference dan Teleradiologi).	Malaysia uses telemedicine terminology for health services using ICT. Telemedicine Act 1997 ("Malaysia Telemedicine Act") specifically defines telemedicine as a medical practice that uses audio, visual, and data communications. In addition to Malaysia Telemedicine Act, the definition of telemedicine by Malaysian Ministry of Health can also be found in Malaysia's Telemedicine Blueprint published on July 25, 1997, which says that telemedicine literally means "far-reaching medicine."	Health services using ICT is known as digital health. Digital health is defined as an electronic health information management to provide health services which is safer, more efficient, and more qualified. Digital health is used for several health care systems in Australia, namely My Health Record, Telehealth, and Health care Identifiers Service.
b.	Language	Bahasa Indonesia is mandatory for: i. all kind of contracts (electronic or physical) involving Indonesian as a party (person or entity); ii. contents in the system electronic deployed in Indonesia.	There are no specific language requirements for any electronic system targeting or electronic contract involving the Malaysian market. Practically, most websites targeting the Malaysian market tend to be in dual languages, which are English and Malaysian National language (Malay).	No statutory requirements, though contracts are generally in English.

eHealth Application		Indonesia	Malaysia	Australia
c.	Informed Consent	In Indonesia Doctors are required to obtain informed consent prior to advising and / or acting to the patients and only allowed to give service to the patient for the benefit of the patient. In addition, any use of patient personal data via electronic system provided by electronic system provider ("ESP") shall be based on consent from the patient (consent form provided by ESP) and shall be in line with the purpose made known to the patient at the time the data is collected. This is required under Law No. 11 of 2008 regarding Electronic Information and Transaction as lastly amended by Law No. 19 of 2016 (Law 11/2008) and Government Regulation No. 82 of 2012 regarding Implementation of Electronic System and Transaction (GR 82/2012). For example, should any use of data require a transfer or storage of personal data outside the jurisdiction, it would be best to inform such conditions to the patient and obtain the consent for transferring and/or storing such data in other jurisdictions.	In Malaysia informed consent can be said to have been given based upon a clear appreciation and understanding of the facts, implications, and future consequences of an action. In order to give informed consent, the person concerned must have adequate reasoning capacity and be in possession of all relevant facts at the time consent is given. Failure to obtain a patient's consent or disclose material risks may be interpreted as a failure of the standard of care which would be resulting in a disciplinary inquiry by the MMC or may be construed as a breach of duty of care and legal action constituted. Malaysian Personal Data Protection Act 2010 as at 15 June 2016 (PDPA): Any personal data consisting of information as to the physical or mental health or condition of a data subject (sensitive personal data) shall only be processed by a data user upon explicit consent of the respective data subject. Sensitive data processing for medical purposes is acceptable provided that it is undertaken by a health care professional or a person who in certain circumstances owes a duty of confidentiality which is equivalent to that which would arise if that person was a health care professional. Notification to and consent from data subject is also required for: collection and procession of any personal (including sensitive personal data), any disclosure (for purpose for which the personal data was to be disclosed at the time of collection of the personal data or a purpose directly related to the purpose at the time of collection), personal data transfer to a place outside Malaysia.	In Australia informed consent is required when using an application, i.e. My Health Record. Before doctors upload patient health or an e-prescription into My Health Record, they need approval from the patient. The approval would be sufficient with a statement or verbal consent by telling directly to the doctor or other health care providers. Collection, use and disclosure of health information are authorized for the purposes of providing health care to the registered health care recipient and in accordance with the access controls set by that recipient.

eHealth Application		Indonesia	Malaysia	Australia
d.	Electronic System and Data Protection	In Indonesia the ESP shall: i. provide standard procedure of protection which guarantee security/ confidentiality of patient's data (in the form of electronic information/ documents); ii. applying risk management upon any damage or loss arising out of electronic system operation; iii. provide and carry out procedure and facility to protect electronic system from any interference and any material or immaterial loss; iv. provide security standard covering procedure and system to prevent and overcome any thread or interference attempt. Furthermore, in providing its electronic system for tele-health care purpose in Indonesia, basically the ESP is required to obtain corporate general license and if there is foreign capital participation, investment license from Indonesian Investment Coordination Board (BKPM) is also required (No requirement to obtain operation license from sectoral authority). Beside, registration as ESP is mandatory for ESP which carries out services for public: owns web portal or online application through internet in order to offer its service, owns/ provides electronic system with payment or financial transaction within, uses electronic system which process, manage, or store user's data, etc.	In Malaysia the implementation of patient data protection refers to the general rules of personal data protection, the Personal Data Protection Act 2010 in which data controllers are prohibited: (i) process personal data without consent from data owners, in the case of personal data is not sensitive; or process personal data in case the data is sensitive, except: (i) the data owner has given consent to process the data; or (ii) data processing is required. Under the PDPA and the PDPA Standards 2015, organizations (including companies and internet providers) collecting and using personal data must ensure the security and data integrity of any personal data by implementing appropriate safeguards to prevent the loss, misuse, modification, unauthorized access or disclosure or alteration or destruction of the personal data it possesses, making the organization's obligation to establish internal standard operating procedures for personal data management within the organization and comply with data protection principle in the PDPA. PDPA Standards 2015 impose certain minimum standards to be adhered to by organizations (as the ESP) to safeguard and ensure the security and data integrity of the personal data being stored on any platform (whether physically or electronically (e.g. on a cloud)). i. The key obligations under the security standards, among others: • Maintaining and limiting the right of access to personal data; • Setting limits upon the power of staff to access personal data; • Maintaining personal data records;	In Australia a health care provider organization may apply to the System Operator of My Health Record. In that regard, such organization must (1) has been assigned a health care identifier as in Healthcare Identifiers Act 2010, (2) comply with My Health Record Rules enacted by Commonwealth Minister for Health; (3) has agreed to be bound the conditions imposed by the system operators on registration. The Health Record Rules 2016 specifies, inter alia, such organization must take reasonable steps to ensure that they and their employees exercise due care and skill, so that any record is accurate, update, not misleading, not defamatory; and fit with purpose. Other requirements for such organization includes requirement to maintain interoperability, to provide assistance at the System Operator request, and to only upload to a repository advanced care planning information. Further, persons may apply for registration as a repository operator, a portal operator, or a contracted service provider. For these kind of persons, they required to register with and must be linked to one or more registered health care provider organization, to only access My Health Record to the extent that they have been instructed to do so by a linked such organization, to notify the System Operator of certain things, such as inaccurate provenance information, error in a record, no longer linked with such organization, undergone material changes, etc.

eHealth Application	Indonesia	Malaysia	Australia
		• Potential risk management of ensuring that security procedures are in place and by controlling and recording incidences of data transfers; • Physical security standard as such monitoring access to data repositories, putting in place closed-circuit cameras and storing hard copies of personal data in locked cupboards. ii. The key obligations under the retention standards, among others: • Permanently disposed personal data once no longer required (including step of disposing data collection forms within 14 days of collection, unless the forms are subject to other legal requirement); • Remove the personal data which is no longer in use from the organization's database; • Prohibition of storing personal data in removable media devices without the written permission of senior management. iii. The key obligations under the data integrity standards, among others: • Ensuring that the personal data is accurate, complete, not misleading and up-to-date; • Making available (online and physical) forms for data subjects to update personal data and data users updating personal data immediately after receiving a data correction notice.	All those participants in My Health Record shall comply with security requirements as in The Health Record Rules 2016.

eHealth Application		Indonesia	Malaysia	Australia
e.	Business License	In Indonesia the ESP is required to obtain business general license and if there is foreign capital participation, investment license from BKPM. No requirement to obtain operation license from sectoral authority.	In Malaysia no requirement to obtain operational business license as the ESP who provide electronic system for eHealth purpose. However, the ESP which is classified as data user for health care and/or insurance purpose shall be registered to the Commissioner of the Department of Personal Data Protection (the "Commissioner"). Failure to register of data user is an offence.	To operate business in Australia, business entity shall obtain recognition and registration, either an Australian Company or a Foreign Company, before Australian Securities and Investments Commission c.q. Investors and Financial Consumers. This includes an obligation to obtain National Business Name Registration according to Business Names Registration Regulation 2011 AG. As the eHealth services dealing with personal data, business entity shall comply with Privacy Act 1988 AG and Privacy Regulations 2013 AG through, for example, adopting code of practice. If it is categorized as a medical device, the supplier shall follow Therapeutic Goods Act 1989 AG. Apart from those, a business entity requires IPRs licenses (e.g. copyright, trademark, patent, etc.).

eHealth Application		Indonesia	Malaysia	Australia
f.	E-Medical Record	In Indonesia as for any patient medical record which is in possession of the ESP, it shall be (i) kept confidential, secure, complete, and available for the patient to amend, add, or update his/her record at any time by the ESP; (ii) based on consent; (iii) encrypted/stored by the ESP for certain period subject to health sector policy (at least 5 years if there is no retain period policy in respective sector); and (iv) stored in data center required to be placed in Indonesia territory.	In Malysia E-Medical Record ("EMR") is classified as sensitive personal data since EMR is defined as a computerized record that can be accessed with concerned of patient privacy, confidential and security from multiple integrated system at any point of care within the health care organization. As EMR keeps sensitive personal information of the patient, data users are responsible and liable to ensure that the information are not leaks to other unauthorized parties and in compliance with PDPA and/or PDPA Standards 2015. PDPA and PDPA Standards 2015 requires personal data to be: i. processed and protected in any way (the ESP to take practical steps) free from any loss, misuse, modification, unauthorized or accidental access or disclosure, alteration or destruction (see point 1.c above); ii. based on consent from the personal data subject (see point 1.b above). For personal data retention requirements please see point 1.c above. No express requirement to store personal data in Malaysia territory. However, since PDPA applies to personal data which is collected and used inside Malaysia, PDPA implying that personal data herein is personal data which is placed in territory of Malaysia. Regarding personal data transfer to any place outside Malaysia shall be restrictedly done to place as specified by the Minister of Science, Technology and Innovation, upon the recommendation of the Commissioner, by notification published in the Gazette. The ESP as personal data user shall take all reasonable precautions and exercised all due diligence to ensure that the personal data will not be processed in the recipient country in a way that would be a contravention of the PDPA.	

eHealth Application		Indonesia	Malaysia	Australia
g.	E-Prescribing	In Indonesia no regulation in telecommunication, digital, and technology sector specifying the use of e-signature in e-prescribing. However, Law No.11 of 2008 on The Information and Electronic Transaction as amended by Law No. 19 of 2016 on The Amendment of Law No.11 of 2008 on The Information and Electronic Transaction widely covers e-signature function as: i. consent of the e-signer in an electronic information/ contract (has the same legal enforcement/affect as the conventional signature); ii. a media to identify a legal subject identity. To be effectively binding, e-signature shall at least comply with the following requirements: i. confidential and only known by the owner of e-signature; ii. the authority to use is only provided strictly for the respective e-signature owner; iii. the e-signature owner may at any time notice any change to the e-signature after its execution; iv. the e-signature owner may at any time notice any change of electronic information regarding the e-signature after its execution; v. there are certain ways to identify the e-signer; and vi. there are certain ways to indicate that the e-signer has given its approval to the related electronic system.	In Malaysia nearly all prescriptions in the country are written by hand, except for a selected few hospitals that utilize the E-prescribing system. This is because, as mentioned above, the eHealth project is ongoing and electronic systems in most aspects are expected to be available nationwide in 5 years. Both digital signatures (stipulated under the Digital Signature Act 1997 ("DSA")) and electronic signatures (stipulated under the Electronic Commerce Act 2006 ("ECA")) are recognized in Malaysia. i. E-signature Broadly defined as any letter, character, number, sound, or any other symbol or any combination thereof created in an electronic form adopted by a person as a signature. A signature of a person will be deemed as electronic signature if: (a) attached to or logically associated with the document; (b) adequately identifies the signer and his approval of the information to which the signature relates; (c) is as reliable as is appropriate given the purpose and circumstances for which the signature is required; (d) the means of creating the electronic signature is linked to and under the control of the signer only; (e) any change to the e-signature post signing is detectable; and (f) any change to the document post signing is detectable. ii. Digital Signature Defined as a transformation of a message using an asymmetric cryptosystem such that a person having the initial message and the signer's public key can accurately determine (a) whether the transformation was created using the private key that corresponds to the signer's public key and (b) whether the message had been altered since the transformation was made.	In Australia E-prescribing is guided by National Requirements for Electronic Prescriptions v1.0 (DH-2625:2017). The end product of e-prescribing provides specification and guidance documents for software systems creating and processing prescriptions in electronic form. the DH-2625:2017 require the generation of e-prescribing must meet the following criteria, inter alia, (1) only health care professionals with the legal right to prescribe medicines can use the e-prescribing system to generate e-prescribing; (2) the prescriber must be issued with a login and use that login to perform all action in e-prescribing system, (3) information about access to, use of and time of uses is preserved for audit and enforcement purposes; (4) the issuers of that login shall take reasonable steps to protect that login and ensure it is not used by another person; (5) on the display of e-prescribing system must show the particulars of the prescription required by legislations, obtain a final approval from the prescriber, include a unique identifier of the prescriber; (6) the prescriber must re-present his/her login when approving a e-prescription for a drug of dependence or misuse; (7) any data of e-prescribing system shall be stored in a permanent and non-alterable.

eHealth Application		Indonesia	Malaysia	Australia
		Besides, Decree of the Executive Board of the Indonesian Doctors Association. 221 / PB / A.4 / 04/2002 on the Implementation of the Indonesian Medical Code of Ethics (The Medical Code of Ethics) only stipulates that the physician shall deny to provide any form when attributed or reasonably suspected to be associated with his professional capacity in prescribing the medicines, including to influence the patient's or his family's wish to purchase or consume the medicines as he has received or is promised to receive commissions or profits of pharmaceutical companies. Nonetheless, an application provider determines that a health care provider does not guarantee that patients will be given prescription after the consultation using their application. In addition, application providers also confirmed that physicians serving at the application provider will not provide definitive therapy in the form of medicines or medical measures because there is no definitive diagnosis.	The ECA does not preclude the use of digital signatures (as defined in the DSA) in electronic commercial transactions. As such, parties are free to choose to use a digital signature as an electronic signature in any commercial transaction. In non-ICT infrastructure perspective, Malaysia's pharmaceutical and pharmaceutical regulations, which are the Poisons Act 1952 (Revised 1989) and the 1951 Registration of Pharmacist Act (Revised 1989) are basis for e-prescribing practice. Hence, telemedicine must follow the conventional provisions on prescribing, where drug delivery should be carried out to the patient directly and there should be systems and mechanisms for detecting and verifying prescribing signatures present in e-prescribing.	

eHealth Application		Indonesia	Malaysia	Australia
h.	Clinical Decision Support System	No regulation in telecommunication, digital, and technology sector specifying clinical decision support system in Indonesia.	No specific regulatory measure (from IT/Communication sector) found in Malaysia.	In Australia, the supporting system for clinical decision include e-signature, eHealth interoperability framework, eHealth specifications and standards, secure messaging, and the National eHealth Security and Access Framework (NESAF). Each of those is governed by several recommendations documents. In e-signature, for example, a clinical document is assigned with three roles: author of the document, responsible person for the document contents/acts., and approver who signs approval of document's release. The mechanism for eSignature is operated by (1) assigning an identifier to organization and individual who deliver a patient care: (2) employing private key for the both care provider; (3) allowing a digital seal using those private keys to verify the sealing party and authenticity of a document/ message. (eSignature Final Recommendation v1.0 dated 12 March 2012)
i	Health Knowledge Management	No regulation in telecommunication, digital, and technology sector specifying health knowledge management.	No specific regulatory measure (from IT/Communication sector) found.	The principle coordinator for health knowledge management is held by the Australian Digital Health Agency (Agency). This agency already produced a clinical terminology list, Australian medicine terminology model, and pathology terminology and information model. For those, the agency provides online digital health training resources, digital health for pharmacists, and on demand training.
j.	Virtual Health Care Teams	No regulation in telecommunication, digital, and technology sector specifying assignment of human resources or certain facility to deploy a virtual health care.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found

eHealth Application		Indonesia	Malaysia	Australia
k.	Mobile Health (wearable devices)	No regulation in telecommunication, digital, and technology sector specifying wearable devices specification and certification/standardization for mobile health. However, eHealth wearable devices which are also functioned as telecommunication devices made, assembled, imported to be traded and/ or used in the territory of Indonesia are required to be complied with the technical requirements under the technology authority through certification process (test and/or document evaluation). This provision indirectly requires ESP to assure that the device vendor for its eHealth operation in Indonesia has obtained device certificates.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but the transmission of health care information shall comply with the Secure Messaging v.1.0.3
l.	Tele-pharmacy	No regulation in telecommunication, digital, and technology sector specifying the tele-pharmacy.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.
m.	Tele-consultation	No regulation in telecommunication, digital, and technology sector specifying the tele-consultation.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.
n.	Tele-rehabilitation	No regulation in telecommunication, digital, and technology sector specifying the tele-rehabilitation.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.
o.	Tele-laboratory	No regulation in telecommunication, digital, and technology sector specifying the tele-laboratory.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.
p.	Tele-radiology	No regulation in telecommunication, digital, and technology sector specifying the tele-radiology.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.

eHealth Application		Indonesia	Malaysia	Australia
q.	Hospital Information System (Patient data management/ administrative)	No regulation in telecommunication, digital, and technology sector specifying hospital information system.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.
r.	Research/ Big Data	The requirements imposed for using outsourced data processing service providers (third party) for patient profilling, marketing, etc: i. the ESP shall keep the patient data confidential, secure, complete, and available for the patient to amend, add, or update his/ her record at any time; ii. the data processing is based on consent collected by the ESP; and iii. the ESP shall have proper and speedy procedures to overcome any unexpected event to reduce the severity of any impact resulting from any incident, fraud or system failure	No specific regulatory measure (from IT/Communication sector) found.	Access to health information of patients/health care recipients can be obtained by health care providers/ organizations who already assigned health care identifiers as regulated in Healthcare Identifiers Act 2010. In assigning such identifiers, the health authority (Chief Executive Medicare) may collect information from various sources for the purposes of assigning those identifiers. In research, the Agency has official roles to evidence-based policy research for establishing and evaluating digital health. As for this, private or other researchers may request research partnership with the Agency on condition their research are relevant with the Agency's priorities, which include public governance/ performance rule 2016, the national digital health strategy, benefits attributable to the My Health Record, the Agency corporate objective. Of which health strategy document, the Agency opens any innovation and scientific achievements in health care from entrepreneurs and researchers. For example, that national strategy elaborates an example that mobile apps employ data mining methods to help diagnose asthma or pneumonia. The specific legislation on research or big data on health care or eHealth, however, do not regulatory embodied by laws, except for APP (Australia Privacy Principles) as in Privacy Act

eHealth Application		Indonesia	Malaysia	Australia
				1988. APP delineates several basic principles for processing data where such processing shall be (1) open and transparent ways: e.g. a clear expressed and up-to-date privacy policy; (2) giving option of not identifying individuals: anonymity and pseudonymity; (3) processing a strict necessary of data directly related to functions/ activities; (4) destroying unsolicited personal data or de-identified; (5) notifying data owners about their data processing at or before the time the processing; (6) not using or disclosing the collected personal data for another purposes peculiar from primary purpose; (7) not using personal data for direct marketing, unless data is directly collected from data owners, under the scope of reasonability expectation of individuals, and respond an objection by a data owner anytime; (8) not transfer personal data to the overseas recipients, unless permitted by laws/ courts, and a data owner grants explicit consent; (9) not using a government related identifiers of an individual; (10) collected personal data must be accurate, up to date, and complete; (11) data controllers must adopt security measures to protect the data; (12) granting access right for data owners, right to correction, as well.
s.	Consumer Health Informatics	No regulation in telecommunication, digital, and technology sector specifying consumer health informatics.	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.

eHealth Application		Indonesia	Malaysia	Australia
t.	Medical Liability	The ESP may be held accountable or sued by any person in the event of any loss arising from the provided electronic system. However, the ESP may limit its liability towards any claim filed if the ESP can prove its compliance under the prevailing law.	For private sector health care services and facilities, the relevant regulatory law is the Private Health Care Facilities and Services Act 1998 (PHFCSA), which provides for: (i) the provision of medical care by a registered doctor; (ii) a grievance mechanism plan for patients using the premises of the private health care facility or service; (iii) the manner of assessing a patient's medical records and the manner of obtaining a patient's medical report by the patient, the patient's representatives, or a health care provider; (iv) the obtaining of a valid consent for a surgical operation or procedure; (v) the fees that may be charged by private health care facilities and services; (vi) matters relating to patients' rights in relation to health care services provided by any health care facility or service, including patients' privacy, confidentiality of information, and access to patients' medical reports and records; and (vii) the minimum standards and requirements for all health care facilities. There are quality standards prescribed in the PHCFSR for various aspects of health care. These quality standards support patients' rights, i.e. infection control; standards for obstetrical or gynecological care, newborn nursery facilities, etc. For public sector health care facilities, there is no specific law regarding the provision of health care or treatment. However, there are policies and procedures put in place by the MOH and the boards of the university hospitals that protect patients' rights. Patients and their families can avail themselves of the grievance mechanisms that are in place in the public sector health care facilities. Complaints about a doctor can be made to the MMC; complaints about both private and public sector health care facilities can be sent to the Medical Practices Division of the MOH. Claim for medical negligence or	All participant in the My Health System (except for the Operator of which), they shall maintain interoperability with that system, and if not compliance, the Operator may suspend the participant's access. On condition that a software/app is categorized as a "medical device", such software or app follows offences and civil penalty provisions relating to medical devices as in Therapeutic Goods Act 1989. Non-medical software/devices, however, do not follow such provisions, but effectuate in a software license agreement which partly is regulated by Competition and Consumer Act 2010 where in default the creator of software is responsible for services included in the software, subject to exceptions. In terms of malpractice, patients may make claims for medical negligence or medical malpractice committed through medicare under Australian medical malpractice laws. Medical negligence or medical malpractice claims are made against individual health care providers as well as publicly funded hospitals that employ professional medical personnel.

eHealth Application		Indonesia	Malaysia	Australia
			malpractice on medical treatment can also be made through litigation process. Such claims are usually handled by Medico Legal Branch which will work along with the Attorney General's Chamber and the Law Advisor Office of the MOH. A breach of the provisions of the PDPA (e.g. personal data leak or misuse) can result in a range of fines, imprisonment, or both. Especially for failure to comply with individual's personal data protection in section 9 of PDPA is an offence punishable by a fine of up to MR100,000 and/or imprisonment for up to two years. For the ESP as data user non-compliance with any of the security standards under the PDPA Standards 2015 may result in the ESP being held liable to a fine not exceeding RM250,000 or imprisonment not exceeding two years, or both.	
u.	Payment/ Billing	No regulation in telecommunication, digital, and technology sector specifying payment/ billing method for eHealth practice. However, please note that registration as ESP is mandatory for ESP which carries out services for public: owns web portal or online application through internet in order to offer its service, owns/ provides electronic system with payment or financial transaction within, uses electronic system which process, manage, or store user's data, etc.	No specific regulatory measure (from IT/Communication sector) found. On the payment scheme, Malaysia has a mixed health financing system. In the private sector, private health insurance is voluntary, with varying premiums being charged on the basis of individual health status, type of health insurance, and coverage level. Meanwhile, public health services are funded through general taxation, with an annual health budget allocated by the Ministry of Finance to the Ministry of Health, where the proportion of revenues allocated to the Ministry of Health in the APBN is decided every year. In addition, there is a scheme whereby the workforce is formally employed for monthly contributions to the Employee Provident Fund, which the savings will be distributed as pension and medical expenses. For public sector employees, they will get free access to medical services provided by public health providers. Associated with telemedicine, until now there has been no scientific paper or regulations regarding the reimbursement system for telemedicine services. Thus, we have not been informed whether patients who have social health insurance can reimburse the fees that already paid.	eHealth strategy in Australia does not include provision on payment/billings as these issues might be addressed by other subject matter legislations. However, financing of health services in the Australia is done by Practice Intensive Program, which includes eHealth Incentives.

eHealth Application		Indonesia	Malaysia	Australia
v.	Collaboration, Partnership, Endorsement	No regulation in telecommunication, digital, and technology sector specifying collaboration, partnership, and endorsement.	No specific regulatory measure (from IT/Communication sector) found.	The agency has role on engagement, innovation, and clinical quality and safety of digital health for patients, consumers, and the health care providers. This agency has advisory committees, including Clinical and Technical Advisory Committee, Jurisdictional Advisory Committee, Consumer Advisory Committee, Privacy and Security Advisory Committee, Digital Health Safety and Quality Governance Committee, and Audit and Risk Committee.
w.	Cross Country Practice	No specific regulatory stipulates this matter.	Pursuant to the Medical Act 1971, any person (including non- Malaysian) who wishes to practice medicine in Malaysia needs to be registered with the MMC. The Council maintains a Medical Register for this purpose. Eligibility for registration and the process for gaining registration generally depends on: (i) the place where the applicant obtained his or her primary medical qualification; (ii) nationality; and (iii) professional background and experience. Non-Malaysian applicants may have to undertake and pass certain medical exams and shall provide proof of efficiency in Bahasa Malaysia and English as part of the requirements. Like all Malaysian doctors, cross country medical staff will be regulated by the Ministry of Health and the MMC and bound by all relevant legislations and regulations.	Australia does not explicitly regulate the disclosure of information or telemedicine practices across States in Australia. However, regulating cross-border disclosure of personal information in Chapter 8 Australian Privacy Principle ("APP") - Cross-border disclosure of personal information ("APP 8"). APP 8 create a framework for the disclosure of personal information across the borders. This framework generally requires health care providers to ensure that the recipients of information will use the health information in accordance with APP, and impose liability on the provider if the recipient of the information use the information inappropriately.
x.	Supervision and Provision	Ministry of Communication and Informatics.	The Ministry of Science, Technology and Innovation, Commissioner of the Department of Personal Data Protection.	Australian Digital Health Agency (established 20 Jan 2016, operated in 1 July 2016). An initiative agency formerly is NEFTA (National eHealth Transition Authority Ltd) operated from 2005 to 2015

eHealth Application		Indonesia	Malaysia	Australia
y.	Credentialing and Privileging	No specific regulatory stipulates this matter.	In terms of credentialing and privileging, there is a requirement that telemedicine service providers should be able to practice in Malaysia. However, in relation to credentialing and privileging processes, the process is still within the scope of general health care delivery by the Ministry of Health Malaysia, hence there is no credentialing and privileging process undertaken specifically for telemedicine providers.	To obtain credentials, practitioners or medical personnel require to provide and fulfill the requirement, among others: (i) details of work experience (as medical personnel), attached with its by evidence; (ii) details of educational and training data, along with relevant diplomas and certificates; and (iii) details of involvement in the clinical audit process, peer review activities and continuing medical education programs. As for the ESP which provides electronic system for e-Health purpose, has to refer to general business establishment in Australia: business entity shall obtain recognition and registration, either an Australian Company or a Foreign Company, before Australian Securities and Investments Commission c.q. Investors and Financial Consumers. This includes an obligation to obtain National Business Name Registration according to Business Names Registration Regulation 2011 AG. As the eHealth services dealing with personal data, business entity shall comply Privacy Act 1988 AG and Privacy Regulations 2013 AG through, for example, adopting code of practice. If it is categorized as a medical device, the supplier shall follow Therapeutic Goods Act 1989 AG. Apart from those, a business entity requires IPRs licenses (e.g. copyright, trademark, patent, etc.)

2. Legal Provision in Singapore, UK , and USA

Health Application		Singapore	UK	USA
a.	Definition	In Singapore, the terminology used in health services using ICTs is telehealth and telemedicine, as stated in the Ministry of Health: Telemedicine Guidelines Summary Card ("Singapore Telemedicine Guidelines Summary Card"). Telemedicine or telehealth refers to the systematic provision of health services through a physically separate environment between patients and healthcare providers, conducted through ICT. Furthermore, the exchange of information for clinical purposes between health care providers and patients via telephone, text messaging (SMS) or other similar applications (eg iMessage, WhatsApp) is also included in the scope and definition of telemedicine. In addition to defining telehealth or telemedicine, the same source also provides definitions of (i) tele-collaboration; (ii) tele-treatment; (iii) tele-monitoring; and (iv) tele-support.	The terminology used for health services using ICT in the UK is digital health, in which digital health has several sub-segments, namely (i) telehealth (a long-range health service using ICT between patient and physician); (ii) telecare (referring to the provision of health services using clinical data exchange between patients and medical practitioners); and (iii) mHealth (referring to mobile applications related to health).[121]	Beside eHealth, another common terms are telehealth and telemedicine. Telehealth is a collection of tools or methods to improve health care services, public health, and health education using telecommunication technology. Telehealth covers a wide range of technologies and systems to provide virtual medical, health, and education services. Telemedicine is the use of electronic communication and information technology to provide a clinical picture of the service when participants are in different locations (remote /off-site/ online). Telemedicine is the use of electronic communication and information technology to provide a clinical picture of the service when participants are in different locations (whether they are in remote areas, are of in an off-site location, or are online). Telemedicine has system that can be used by health care providers to extend not only face-to-face treatment practices.
b.	Language	There are no specific language requirements for any electronic system that targets or electronic contract that involves the Singaporean market. However, as English is the working language in Singapore, most websites that target the Singapore market tend to be in the English language.	As the common law system, the UK does not enact legislation on language, and even the English language does not have an "official" status in law. Nonetheless, the de facto official language of the United Kingdom is English which is used by 98% of the population.	There are no specific language requirements for any electronic system that targets or electronic contract that involves the States' market. However, as English is the working language in United States of America, most websites that target the States' market tend to be in the English language.

[121] UK Department of Health, UK Trade & Investment, dan National Health Services, The UK: Your Partner for Healthcare Solutions, Digital Health, accessed from https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/402227/Healthcare_UK_Digital_Health_Jan_2015.pdf on 31 January 2018.

Health Application		Singapore	UK	USA
c.	Informed Consent	The ESP as data user when handling personal data in their possession, shall take into account main concept of Personal Data Protection Act 2012 (PDPA), as follows: i. Consent – the ESP may collect, use, or disclose personal data only with the individual's knowledge and consent (with some exceptions, see point 2.q below); ii. Purpose – the ESP may collect, use, or disclose personal data in an appropriate manner for the circumstances, and only if they have informed the individual of purposes for the collection, use, or disclosure; and iii. Reasonableness – the ESP may collect, use, or disclose personal data only for purposes that would be considered appropriate to a reasonable person in the given circumstances. Under the Spam Control Act, any electronic message is unsolicited if the recipient (the patient or eHealth system user) did not request to receive or consent to the receipt the electronic message. Furthermore, the regulation of informed consent on telemedicine can also be found in the Singapore National Telemedicine Guidelines compiled by the Academy of Medicine Singapore, the Ministry of Health ("Singapore Telemedicine Guidelines").	UK has no specific rules regarding informed consent in the domain of telemedicine. Thus, the implementation of informed consent in the domain of telemedicine refers to the provision of conventional medical services established by the National Health Service. In this regard, the existing law on consent is Data Protection Act 1998 which is going to repealed by new Data Protection bill (on going enactment, dated 14 Sep 2017) along with GDPR (General Data Protection Regulation) on 25 May 2018. In the existing law, there are two basic conditions for consent where, for sensitive personal data (e.g. physical or mental health or conditions), the data owner shall have given "explicit consent", while for any personal data only requires data owner's consent. No legal definition, however, between consent and explicit consent in the existing law. Notwithstanding, GDPR and the Bill set out an informed consent shall be in a written declaration (e.g. not a pre-ticking box) giving before processing taking place, and shall be clearly presented in an intelligible and easily accessible form, using clear and plain language. As for 'explicit consent', GDPR does not elaborate in detail, but the Working Party 29 of the EU (European Commission) emphasizes the term 'explicit' refers to the way consent is expressed by the data subject where, in practice, a clear trail and explicit consent can be proven where the available options and the consequences have been made clear. For example, by two stages verification for a written consent.	There are vary requirements for the states in the U.S related to informed consent in telemedicine practices. Some countries require patient informed consent before treatment/ telemedicine services are undertaken. However, some states do not require informed consent. Some states only require informed consent for certain forms of electronic communications (such as e-mail or text messages). Although informed consent is not required by some states in the U.S., it is still the best practice recommended to do. Organizations such as the Federation of State Medical Boards ("FSMB") and the American Telemedicine Association ("ATA") recommend that doctors obtain informed consent to use telemedicine technology. There are three components to consider in creating informed consent in the USA:[122] 1. The language used in introducing and explaining the telehealth process in a manner that it should be easily understood by the patient; 2. Describe the risks and benefits expected from telehealth services; and 3. Other information is required for the patient to have a complete understanding of the telehealth process (ie: available alternatives, referral information, etc.). Patient consent usually captured on a paper consent. Electronic consent management enables this process to occur in a fully electronic manner

[122] Teresa Iafolla, "Telemedicine & Informed Patient Consent: Done the Right Way", http://blog.evisit.com/telemedicine-informed-patient-consent-done-right-way, accessed on 13 October 2017

Health Application		Singapore	UK	USA
		At point 1.6 of the Singapore Telemedicine Guidelines, it is stipulated that the patient shall be granted the freedom of making informed decisions. Thus, it is important for the patient, as in a conventional face-to-face consultation, to be informed of any details deemed important by the patient, and informed consent must be provided in accordance with applicable legislation.		(an electronic consent directive) and various laws, regulations, and policies for access and restrictions on sharing information particularly sensitive information are handled in an automated way health information technology (IT) system. Generally, there are three phases in informed consent management: (https://www.healthit.gov/sites/default/files/privacy-security/ecm_finalreport_forrelease62415.pdf) • Phase I – Consent is captured on paper forms and scanned into HER systems. These forms do not contain structured data. Provider staff must read and analyze the consent form before information is shared. • Phase II – Consent may be collected on paper and then entered into an electronic format, on consent may be recorded digitally from the start using web portal or devices. • Phase III – Consent is collected electronically and structured data is captured. Title 45 of Code of Federal Regulations (CFR or"45 CFR") basically stipulates that a patient's written consent need only be obtained by a provider once. The consent document may be brief and written in general terms. At a minimum, it must inform the patient that information may be used and disclosed for treatment, payment, health care operations ("TPO"), state the patient rights to review the privacy notice, to request restrictions and to revoke consent, and be dated and signed by the individual or his/her representative. However please note that the patient may revoke in writing, except to the extent that the covered entity has taken action in reliance on the consent, and the patient may request restriction on uses or disclosures of health information for TPO.

Health Application		Singapore	UK	USA
d.	Electronic System Protection and Protection of Patient's Data	Electronic Transactions Act 2010 ("ETA") generally provides obligation of security procedure for the purpose of verifying that an electronic record is that of a specific person or detecting error or alteration in the communication, content, or storage of an electronic record since a specific point in time, which may require the ESP to use algorithms or codes, identifying words or numbers, encryption, answerback or acknowledgement procedures, or similar security devices. According to PDPA, all contracts and transactions documents generally (also including online contracts) containing personal data shall be removed by the ESP (the ESP to cease retaining), as soon as the purpose for which that personal data was collected is no longer being served by retention of the personal data, and/or retention is no longer necessary for legal or business purposes. The data subject may ask the ESP to stop collecting, using, or disclosing their personal data, however by considering the above provision, the ESP is not required to delete or destroy the data subject's personal data and may retain it for as long as there are business or legal needs. From health care perspective, the arrangements on patient data protection are included in the Singapore Telemedicine Guidelines. At point 1.5 of the guidelines, it is stipulated that the confidentiality of patient information or data is one of the main issues in telemedicine practices. Accordingly, telemedicine providers shall ensure that patient information and data are protected through a patient's data confidentiality policy.	Regulatory landscape for e-System is GDPR and NHS Confidentiality Code of Practice 2003. GDPR requires the controller (or e-system operator) adopt data protection and security policies, technical certifications (subject to conditions), data encryption, and record keeping practice. Other responsibilities include (i) ensuring the ongoing confidentiality, integrity, availability and resilience of processing systems and services, (ii) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; (iii) process for regularly testing, assessing and evaluating the effectiveness of technical and organizational measures for ensuring the security of the processing. As for NHS Code of Practice, this only applies where the data is directly about patient to clinician. Such data follows a duty of confidentiality in health care system that requires to protect patient's information, inform the patient how their data is used, provide choice for the patient in disclosure of data, and improve better ways to safeguards confidentiality for patient (e.g. not tell unauthorized personnel how the security system operates, not breach security themselves, not share login, use a strong password, tracked access of data).	Health care providers are required to comply with the provisions of the security implementation standards specified in Sections 164.308, 164.310, 164.312, and 164.316 of 45, Code of Federal Regulations ("CFR") consisting of: administrative security, physical security, technical security, organization security and required policies and procedures and documents. In addition, the Health Information Technology and Clinical Health (HITECHT) Act also provide a procedure for health care providers that violates the health data/information security provisions security, physical ecurity, technical security, and organization security. Title 21 of Code of Federal Regulations (CFR) which is reserved for rules of the Food and Drug Administration/FDA ("21 CFR") requires the electronic system that support the electronic information for FDA- regulated clinical investigation to be secure with restricted access and should include methods to ensure confidentiality regarding the subject identity, study participation, and personal information after informed consent has been obtained. General requirements such as, encryption obligation upon the subject's information within an electronic system, unless the entity documents why encryption is not reasonable and appropriate in their specific circumstances and implements a reasonable

Health Application		Singapore	UK	USA
		Health providers are also required to comply with applicable regulations to ensure that patient health information is protected. In addition, other data retention requirements also exist for tax and other financial purposes.		and appropriate equivalent measure, is applied to the entity holding the subject's personal information under the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") (Public Law No. 104-191) or as for a business associate of a HIPAA-covered entity, the HIPAA Privacy, Security, and Breach Notification Rules is applied (45 CFR regarding Standards for Privacy of Individually Identifiable Health Information, Final Rule). This rule requires the relevant entity to take reasonable steps to limit the use or disclosure of and request for Protected Health Information ("PHI") to the minimum necessary to accomplish the intended purpose. The relevant entity's policies and procedures must clearly identify the persons or positions within the organization who need access to the information to carry out their job duties, the types of PHI needed, and the conditions appropriate to such access. (technicalhelp4u.com/The%20 Privacy%20Act.pdf)
e.	Business License	No specific regulatory measure (from IT/Communication sector) found.	Register eHealth business as a sole trader, limited company or partnership to Companies House of Department for Business, Energy and Industrial Strategy with tax payments (see Companies Act 2006; registration by online or post). Apply for license notification to process personal data on the Information Commissioner's Office (ICO). Adopting Confidentiality: NHS Code of Practice. Request guidance and advice to the National Institute for Health and Care Excellence (NICE) which is the body that provides national guidance and advice to improve health and social care < https://www.nice.org.uk/>.	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
f.	E-Medical Record	The PDPA does not expressly restrict the storage of data on the cloud. However, when personal data is stored by any means, the ESP has certain obligations that are outlined in the PDPA, such as ensuring the accuracy and protection of the personal data (see point 2.b and 2.c above).	The safeguards for e-Medical Records follows the organizational and technical measures in the GDPR and NHS Confidentiality Code of Practice 2003 as has been stipulated. Specifically, the UK's eMedical Record is SCR (Summary Care Records) used by authorized staff in other areas of the health and care system involved in the patient's direct care. At a minimum, the SCR holds important information about; current medication, allergies and details of any previous bad reactions to medicines, the name, address, date of birth and NHS number of the patient. SCR' users must have a smart card with the correct codes set to access the system. Patient's participation to SCRs is voluntary, and patients can opt-out or withhold from SCRs (if they do not want SCRs).	The HITECH Act stipulates the use of technology in eHealth applications, particularly in terms of electronic health records (EHR). Before it is released and can be used by the public, the National Coordinator will ensure the feasibility and quality of EHR technology and establish certification of the technology. For health care providers who is willing to adopt such technology, they will be charged by the National Coordinator in which the amount of the fee is adjusted to the condition of the health care provider. Funds generated from these technology adoption payments will then be allocated to smaller, low-income, and service providers in rural areas that are medically inaccessible. Federal law has been a driving force in Health Information Technology/ HIT's implementation and use by (among others) requiring federal agencies to use HIT and provide for its voluntary use by private providers, applying privacy and security requirements and penalties to HIT and required audits and enforcement, securing incentive payments through the Centers for Medicare and Medicaid Services (CMS) for professionals and hospitals that are deemed eligible based on their "meaningful use" of certified electronic health record (EHR) technologies. (https://www.cdc.gov/phlp/docs/datasharing-laws.pdf)

Health Application		Singapore	UK	USA
g.	E-Prescribing	ETA provides the electronic methods (such as e-signature) that can be used by people to indicate their intention with regards to electronic documents, which in this case health care provider's signature for e-prescribing purpose. A signature is defined as a method (electronic or otherwise) used to identify a person and to indicate the intention of that person in respect of the information contained in a record. Although e-signature have become increasingly prevalent in Singapore as more business move online due to convenience, certain contract must be signed by hand and cannot be signed electronically, these include, execution of a will, and any contract for the sale of transfer of immovable property or any interest in such property.	Until now the regulation and implementation of e-prescribing is still very limited. NHS Connecting for Health defines e-prescribing as "the use of electronic systems to facilitate and improve communications related to prescription or drug ordering, multiply options, and simplify administrative processes" GDPR and the UK Data Protection Act does not deal with e-prescribing, but the basic requirement for intermediary eHealth provider (e.g. apps) shall indeed follows the GDPR, NHS code of practice, Data Protection Act and Human Right Act. The UK only regulates e-prescribing for general practitioners and other health care professionals, namely EPS (Electronic Prescription Service). EPS allows prescribers to send prescriptions electronically to a dispenser (such as a pharmacy) of the patient's choice. Prescriptions must be generated and signed electronically by a prescriber before being sent to a patient's nominated pharmacy using their smart card. Apart from EPS, paper copies of electronic prescriptions (called tokens) shall be sent to the NHS Prescription Service at the end of every month.	Each state has different provisions related to online prescribing or e-prescribing, whereas the majority of states claimed that a physical examination is required prior to prescribing. However, not all states require direct physical examination. The states that adopt the rules which require direct physical examination are New Jersey, Indiana, Tennessee, Colorado, and Idaho. There are also some states that prohibit online prescribing or e-prescribing for certain dangerous categories of medicines, such as California and Arizona. However, there are differences between those two states. California prohibits the provision of online dangerous medicines without direct examination of patients and doctors, while Arizona determines that the prescription of such a dangerous medicine can be performed without direct physical examination between medical personnel and patients. Examination may be performed using telemedicine services and shall be supported by an EMR that meets the certification requirements as required by the Arizona Government. Requirement of prescription or e-prescription by a pharmacist/ practitioner is basically regulated under the 21 CFR. A pharmacist may dispense directly a controlled substance (listed in Schedule II of 21 CFR) that is a prescription drug only pursuant to a written prescription signed by the practitioner,

Health Application	Singapore	UK	USA
			except in case of emergency. In the case of an emergency situation (as defined in 290.10 of 21 CFR), a pharmacist may dispense a controlled substance upon receiving oral authorization of a prescribing individual practitioner, provided that: (1) The quantity prescribed and dispensed is limited to the amount adequate to treat the patient during the emergency period (dispensing beyond the emergency period must be pursuant to a paper or electronic prescription signed by the prescribing individual practitioner); (2) The prescription shall be immediately reduced to writing by the pharmacist and shall contain all information required, except for the signature of the prescribing individual practitioner; (3) If the prescribing individual practitioner is not known to the pharmacist, he must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a callback to the prescribing individual practitioner using his phone number as listed in the telephone directory and/or other good faith efforts to insure his identity; and (4) Within 7 days after authorizing an emergency oral prescription, the prescribing individual practitioner shall cause a written prescription for the emergency quantity prescribed to be delivered

Health Application		Singapore	UK	USA
				to the dispensing pharmacist. In addition to conforming to the requirements of 1306.05, the prescription shall have written on its face "Authorization for Emergency Dispensing," and the date of the oral order. The paper prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail it must be postmarked within the 7-day period. Upon receipt, the dispensing pharmacist must attach this paper prescription to the oral emergency prescription that had earlier been reduced to writing. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order. The pharmacist must notify the nearest office of the Administration if the prescribing individual practitioner fails to deliver a written prescription to him; failure of the pharmacist to do so shall void the authority conferred by this paragraph to dispense without a written prescription of a prescribing individual practitioner. (5) Central fill pharmacies shall not be authorized under this paragraph to prepare prescriptions for a controlled substance upon receiving an oral authorization from a retail pharmacist or an individual practitioner.
h.	Clinical Decision Support	No specific regulatory measure (from IT/ Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found. However, NHS Digital, a national information and technology partner of the UK Department of Health & Social Care, deliver technology-lead systems and services, inter alia, NHSmail, SCR, EPS, NHS e-Referral Service, Adult Social Care Outcomes Framework (ASCOF), The Calculating Quality Reporting Service (CQRS), The Child Protection - Information Sharing project (CP-IS), Common User Interface (CUI), Data Access Request Service (DARS), The Directory of Services (DoS), iView and iViewPlus, M-Connect 2, etc. <see https://digital.nhs.uk/services>	No specific regulatory measure (from IT/Communication sector) found.
i.	Health Knowledge Management	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
j.	Virtual Health-care teams	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found.	No specific regulatory measure (from IT/Communication sector) found.
k.	Mobile Health (wearable devices)	The Health Sciences Authority ("HSA") guidelines on telehealth devices as of September 2016 defines Telehealth Devices as all forms of devices, including hardware devices, software and mobile applications, used in the delivery of Telehealth services. Under this guideline, HSA propose only telehealth devices which are classified as medical devices to be subjected to medical device regulatory controls, including product registration. Telehealth devices which are classified as medical devices above are, for example, application used for measurement of heart rate and ECG – single measurements, software for prediction of low blood glucose level episodes in patients based on past glucose measurements and diet, application used for continuous measurement and monitoring of ECG and irregular heart rate management in cardiac patients, or application for measurement of blood glucose in whole blood and recommendation of medication dosage.	No specific regulations on mHealth, but, in April 2017, the NHS Digital launched a NHS Apps Library webpage that declares a small selection of digital health and care tools (or trusted patient-facing apps) to ensure they meet the high standard of quality, safety and effectiveness people expect from the NHS <visit https://apps.beta.nhs.uk/>. For mHealth developers who want to be listed in NHS Apps Library, they must pass the Digital Assessment Questionnaire (DAQs). DAQs assess several principal aspects such as digital tool information, indicators of effectiveness, regulatory approval, clinical safety, privacy & confidentiality, security, usability & accessibility, interoperability, technical stability, and change management. For example, an mHealth app shall have a clarity of purpose & intended use, a certification (OWASP Mobile AppSec Verification), encryption, approval from Care Quality Commission, Safety Standards (SCCI0129), etc. Digital tools, then, are labelled "NHS Approved" or "Being Tested in the NHS".	The Food, Drug, Cosmetic Act ("FD&C Act") provides basic regulatory framework. In FD&C Act, manufacturers' intended use of their product is a major factor of the definition of a medical device. If a manufacturer claims that its product is intended for use in the diagnosis treatment or prevention of disease, or is intended to affect human body, the product is subject to regulations on medical devices. The FD&C Act classifies medical devices into three categories based on the risks to human body: • Class I: Exempt from premarket procedures • Class II: Required to go through 510(k) notification. Marketable only after FDA clears the notification. • Class III: Clinical trial and approval by FDA required The FDA has published non-binding, but influential guidance applicable to wearable devices. The guidance list two categories of general wellness products:

Health Application		Singapore	UK	USA
		Guidance on Medical Device Product Registration: i. Immediate Route. Criteria: 2 reference agency approvals, 3 years marketing history with no major safety issues. Standalone mobile application (new) 1 reference agency approval and no major safety issues globally ii. Expedited Route. Criteria: 2 reference agency approvals or 1 reference agency approval + 3 years marketing history with no major safety issues globally iii. Abridged Route. Criteria: 1 reference agency approval iv. Full evaluation. No reference agency approval.	However, medical devices/ products are regulated and controlled by Medicines & Health care products Regulatory Agency. This agency assesses health care products in collaboration with several certification bodies, interalia, Amtac Certification Services Ltd (0473), BSI Healthcare (0086), Lloyd's Register Quality Assurance Ltd (0088), etc. This agency is importation from Directive 93/42/EEC of 14 June 1993 concerning medical devices (as amended), Commission communication in the framework of the implementation of the Council Directive 93/42/ EEC concerning medical devices, and the directive importation legislations in the UK, particularly, The Medical Devices Regulations 2002.	1) products of which the intended use relates to maintaining or encouraging a general state of health or a healthy activity without any reference to diseases or conditions; and 2) products of which the intended use relates the role of healthy lifestyle with reference to diseases or conditions. Given the rapid expansion and broad applicability of mobile applications, the FDA issued "Mobile Medical Applications: Guidance for Industry and Food and Drug Administration Staff" in 2015. In the Guidance, the FDA makes it clear that it does not intend to regulate mobile apps that may meet the definition of medical devices, but pose a lower risk to the public.
l.	Tele-pharmacy	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but NHS Digital may require mHealth app developers to comply with NHS Code of Practice and DAQs	No specific regulatory measure (from IT/Communication sector) found.
m.	Tele-consultation	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but NHS Digital may require mHealth app developers to comply with NHS Code of Practice and DAQs	No specific regulatory measure (from IT/Communication sector) found.
n.	Tele-rehabilitation	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but NHS Digital may require mHealth app developers to comply with NHS Code of Practice and DAQs	No specific regulatory measure (from IT/Communication sector) found.
o.	Tele-laboratory	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but NHS Digital may require mHealth app developers to comply with NHS Code of Practice and DAQs	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
p.	Tele-radiology	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but NHS Digital may require mHealth app developers to comply with NHS Code of Practice and DAQs	No specific regulatory measure (from IT/Communication sector) found.
q.	Hospital Information System (Patient data management/ administrative)	No specific regulatory measure (from IT/Communication sector) found.	No regulation in telecommunication, digital, and technology sector specifying on this issue, but a relevant system initiative by NHS Digital is HES (Hospital Episode Statistics). HES is a data warehouse containing details of all admissions, outpatient appointments and A and E attendances at NHS hospitals in England. This system gives benefits to monitor trends and patterns in NHS hospital activity, assess effective delivery of care, support local service planning, and so forth. Any disclosure or data mining to this database shall be kept anonymous with a strict statistical disclosure control to ensure that patient confidentiality is maintained.	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
r.	Research/big data	Any activities of using personal data for example for marketing purpose is allowed, provided that it complies with PDPA and ETA requirements (see point 2.c and 2.d above). Use of personal data without initial consent is allowed among others if: i. The use is necessary for any purpose which is clearly in the interest of the individual, if consent for its use cannot be obtained in a timely way or the individual would not reasonably be expected to withhold consent; ii. The use is necessary to respond to an emergency that threatens the life, health, or safety of the individual or another individual; iii. The use is necessary in the national interest, or for any investigation or proceedings; iv. Etc Disclosure of personal data without initial consent is allowed among others if: i. The disclosure is necessary for any purpose which is clearly in the interest of the individual, if consent for its disclosure cannot be obtained in timely way;	Partly provided by HES publications (monthly and annually). Health care research functions is facilitated by NHS Digital through RAG (Research Advisory Group). RAG brings the research community together to advance the use and effectiveness of NHS Digital's data and services. Group membership consists of senior representatives from across research, the third sector and NHS Digital. RAG has a sub-group, namely Future NHS Digital services for research - Innovation sub-group. RAG members are, interalia, Medical Research Council (MRC), Department of Health and Social Care (DHSC), Economics and Social Research Council (ESRC), Representative of academia (England), Charity sector, The Association of the British Pharmaceutical Industry, etc. In August 2017, NHS Digital supports Life Science Industrial Strategy written by scholars and professionals where areas for innovation include: remote data access environment (e.g. Sandbox concept), data donation	The 45 CFR establishes the conditions under which PHI may be used or disclosed by covered entities for research purposes. A covered entity may always use or disclose for research purposes health information which has been de-identified. The 45 CFR also defines the means by which individuals/human research subjects are informed of how medical information about themselves will be used or disclosed and their rights with regard to gaining access to information about themselves, when such information is held by covered entities. Under the 45 CFR, the relevant entities are permitted to use and disclose PHI for research with individual authorization, or without individual authorization under limited circumstances set forth in the 45 CFR. To use or disclose PHI without authorization by the research participant, a covered entity must obtain one of the following:

Health Application		Singapore	UK	USA
		ii. The disclosure is necessary to respond to an emergency that threatens the life, health or safety of the individual or another individual; iii. The disclosure is necessary in the national interest, or for any investigation or proceedings; iv. The personal data is publicly available; v. The personal data is disclosed to any officer of a prescribed law enforcement agency, upon production of written authorization signed by the head or director of that law enforcement agency or a person of a similar rank, certifying that the personal data is necessary for the purpose of the functions or duties of the officer., vi. Etc.	bank, support modernizing & improving clinical trials, data linkage, and secondments & placements. Moreover, the developers of mHealth app are obligated to involve and follow the Health Developer Network Information, a website to help developers create software for health and social care, including its forums and sites to get involved in the community thereof <see https://developer.nhs.uk/>	• Documentation that an alteration or waiver of research participants' authorization for use/disclosure of information about them for research purposes has been approved by an Institutional Review Board (IRB) or a Privacy Board • Representations from the researcher, either in writing or orally, that the use of disclosure of the PHI is solely to prepare a research protocol or for similar purposes preparatory to research, that the researcher will not remove any PHI from the relevant entity, and representation that PHI for which access is sought is necessary for the research purpose. • Representations from the researcher, either in writing or orally, that the use or disclosure being sought is solely for research on the PHI of decedents, that the PHI being sought is necessary for the research, and, at the request of the covered entity, documentation of the death of the individuals about whom information is being sought. The 45 CFR also permits covered entities to use and disclose PHI for research purposes when a research participant authorizes the use or disclosure of information about him or herself.
s.	Consumer Health Informatics	No specific regulatory measure (from IT/Communication sector) found.	No specific regulatory measure (from IT/ Communication sector) found, but CR also provide information for patients. Patients can ask to view or add information to their SCR by visiting their GP (General Practitioners) practice. Medical staff will ask patient's permission to look at his/her SCR (except in an emergency where a patient is unconscious, for example) and only staff with the right levels of security clearance can access the system. A patient can ask an organization to show a record of who has looked at patient's SCR - called a Subject Access Request.	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
t.	Medical Liability, Standards, and Malpractice Claim	The ESP as data user non-compliance with certain requirements (e.g. personal data requirements under the PDPA), a regulatory authority can require the ESP to comply with the applicable provisions and the authority can also impose fines and imprisonment if the requirements are breached. If the ESP as the electronic channel provider uses third party content online without obtaining the relevant rights, it could be exposed to claims of intellectual property infringement. There are statutory offences that could potentially be committed through the online publication of obscene material and can result in both imprisonment and fine. (Under the Undesirable Publications Act). For liability limitation of network service providers in Singapore, the government though ETA specifies that network service providers will not be subject to criminal or civil liability for such third-party material, in relation to which they are merely the host.	With regard to the Digital Apps Library, the named supplier listed is the entity solely responsible for the tool/app. NHS Digital or the approving body is not responsible or liable for any advice, or any other information, services or products obtained through the use of the tool/apps listed on the Digital Apps Library <https://apps.beta.nhs.uk/>. NHS Digital or the approving body has set standards for reviewing the tools/apps as detailed in this library, but NHS Digital does not mean that NHS Digital or the approving body has itself reviewed all aspects of the tool/app, or version of the same tool/app. The Digital Apps Library is intended to provide supportive relevant information only. It does not provide medical advice and it is not a substitute for a medical consultation. In terms of malpractice in UK, general malpractice lawsuits are addressed to the NHS and the NHS Trust, not individual doctors. In this case, NHS and the NHS Trust are responsible for their employees' negligent and negligent acts, including doctors and nurses. This responsibility arises from the maintenance tasks assigned by the NHS Trust to their patients. The adoption of this representative responsibility has resulted in a government policy known as the NHS compensation policy. Given this policy, the NHS may be liable for financial / medical damages for medical negligence / malpractice.	Through the HITECH Act, the planning, implementation, and oversight of the implementation of the eHealth program has been stipulated which includes clear provisions for the use of technology in eHealth applications, particularly in terms of EHR. Before it is released and can be used by the public, the National Coordinator will ensure the feasibility and quality of HER technology and establish certification of the technology. For health care providers who is willing to adopt such technology, they will be charged by the National Coordinator in which the amount of the fee is adjusted to the condition of the health care provider. Funds generated from these technology adoption payments will then be allocated to smaller, low-income, and service providers in rural areas that are medically inaccessible. Supervision on the quality of health services is also carried out at the state level. Government in the U.S. State has the duty to administer and sponsor a health care program. Against this policy, the State Government is required to enter into an agreement with any health care provider, health planning or health insurance that the provider in the information technology system used must comply with the standards and specifications set by the Government.[126]

Health Application		Singapore	UK	USA
				In addition, the telemedicine organization in the U.S., the American Telemedicine Association ("ATA") has developed a guideline for telemedicine services, namely: Core Operational Guidelines for Telehealth Services Involving Provider-Patient Interactions. Contemporary EHR system technology has significant limitations, and if these cause harm, aggrieved individuals and enforcement entities have many legal resources. Plaintiffs whose alleged injuries are associated with EHR systems could sue health care providers for medical malpractice. Those who believe that their records have been improperly disclosed to third parties could assert privacy violation claims. In rare circumstances, providers accused of negligent EHR system use could face disciplinary proceedings (initiated by professional organizations), government enforcement actions, or criminal prosecutions. Patients who feel that their care givers were negligent in treating them may assert medical malpractice claims. To prevail, the plaintiff must establish the four elements of negligence: (1) a duty of care owed by the defendant to the plaintiff, (2) breach of that duty through conduct that fails to meet the applicable standard of care, (3) harm or injury, and (4) a causal link between the injury and the breach of duty.

Health Application		Singapore	UK	USA
u.	Payment/ Billing	In terms of IT infrastructure in relation with payment, there is no specific regulatory measure (from IT/Communication sector) found. However, in terms of payment scheme, as in the US and EU, health care financing is generally done by reimbursement, in which the programs are divided into several forms, namely: (i) Medisave; (ii) Medishield; (iii) Medifund; and (iv) Eldershield. However, in the provision of telemedicine services, not all payments on services rendered receive reimbursement.	Tariff in health and social care is ruled by Health and Social Care Act 2012 where Article 115 of this law sets out "If a health care service is specified in the national tariff, the price payable for the provision of that service for the purposes of the NHS is such price as is determined in accordance with the national tariff on the basis of the price specified in the national tariff for that service." But "If not specified in the national tariff, the price payable of which services shall comply with rules provide for in the national tariff for that purposes" Of which national tariff, NHS published national tariff guidance for every two years. For this years, the in-force document is the 2017/18 and 2018/19 National Tariff Payment System containing a set of prices and rules to help providers of NHS care and commissioners provide best value to their patients. In regard to eHealth apps, NHS unveiled a supporting document to the 2017/18 and 2018/19 National Tariff Payment System, namely Innovation and Technology Tariff 2017 to 2019: technical notes ("ITT"). ITT was introduced to incentivise the adoption and spread of transformational innovation in the NHS. Approach of ITT is by using several mechanisms to fund innovation which meet the required theme specifications (from 1 to 6 themes). For themes (2,3,4,5), NHS guarantee automatic reimbursements to providers when a selected device, app or platform is used ("Paid for centrally by NHS"). For theme 1 provider will be reimbursed based on use.	

Health Application	Singapore	UK	USA
		For theme 6 provider are funded under the National Tariff for this innovation. Hereby, six themes of ITT category which NHS gives incentive are: 1. Guided mediolateral for episiotomy to minimize the risk of obstetric and anal sphincter injury (charged per use, GBP 16) 2. Reduction of bacterial contamination and accidental administration of medication (charged per use, GBP 2) 3. Prevention of ventilated associated pneumonia in critically ill patients (charged per use, GBP 150) 4. Web-based applications for the self-management of chronic obstructive pulmonary disease (charged per patient registration, GBP 20) 5. Frozen faecal microbiota transplantation (FMT) for recurrent Clostridium difficile infection (charged per patient use, GBP 95) 6. Treatment of lower urinary tract symptoms of benign prostatic hyperplasia as a day case (charged per spell, n/a as this not included in ITT but in National Tariff as above) NHS England will cover the costs of the innovations identified in ITT as outlined in each theme specification. Additional costs associated with implementation are not covered by the ITT and should form the basis of local discussions. <see https://improvement.nhs.uk/> Furthermore, regarding the reimbursement of telemedicine services,	

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			the NHS has provided a choice of 20 telemedicine programs that can be reimbursed automatically, such as MyCOPD, AliveCor and Pneux applications. Thus, it can be said that UK citizens do not have to pay anything related to health services, given the high taxes paid by UK citizens, where the free service includes all health services including consultation, examination, operation and all drug purchase.	
v.	Collaboration, Partnership, Endorsement	No specific regulatory measure (from IT/Communication sector) found.	NHS does not endorse the eHealth app listed in the Digital Apps Library. Medical staff and GPs, however, could endorse eHealth app for patients, but they reportedly reluctant to recommend an app as they do not want to be held contributory liable if app use to lead to patient harm in the health service since the GPs already held accountable for their prescribing decisions. The collaboration in eHealth innovation principally is facilitated by NHS and NHS Digital, including partnership with RAG or the Health Developer Network as above.	No specific regulatory measure (from IT/Communication sector) found.

Health Application		Singapore	UK	USA
w.	Cross-Country Practice	Singapore does not clearly govern telemedicine practices across countries. However, the Singapore National Telemedicine Guidelines provides that telemedicine providers originating or residing in Singapore are required to be registered and possess licenses originating from the competent entity. Furthermore, as to the qualifications of health-care providers, Article 13 paragraph (1) of the Singapore Medical Registration Act Chapter 174 also affirms that no one may practice as a medical practitioner or perform any action as a medical practitioner unless he is registered under the terms of this rule and has certificate for valid practice.	In the UK there is no specific regulation on telemedicine services conducted across countries, so in its implementation it refers to health regulations. In the UK itself, there is a special requirement for medical practitioners who wish to practice in the UK, which is required to be registered in full at the General Medical Council ("GMC"), or qualify for inclusion in the GMC specialist list. Although conditions apply to non-UK medical practitioners, there are differences in requirements between medical practitioners from countries that are members of the European Economic Area ("EEA") and medical practitioners from outside the EEA.	Under Article 10 of the U.S. Constitution, the state is authorized to regulate the health, security and welfare aspects of its citizens. To be able to practice health care, every health worker is required to obtain a practical license from the State. In the case of telemedicine, the requirement to obtain a permit, the health worker shall ensure that its activities are legally valid. With Telehealth, the provision of health services is possible by health workers and patients in different places (states). Each state has its own rules. The majority of States have strict rules governing that any health worker providing inter-state health services must have a practice permit from the State where his or her patient is located. However, in the event of an emergency, such provisions may be disregarded. In addition, some states issue special permits or certificates related to the practice of telemedicine. There is also a state that does not specifically issue a specific telemedicine practice permit, but may issue a temporary medical license for a health worker from another state provided that the health worker meets the requirements.
x.	Supervision and Provision	The Health Sciences Authority (HSA)	NHS is National Health Service <https://www.nhs.uk>, an executive non-departmental public body of the Department of Health and Social Care. Subsidiary of NHS is NHS Digital, a national information and technology partner of the UK Department of Health & Social Care <https://digital.nhs.uk/>	Department of Health and Human Services, Office of the Assistant Secretary of Planning and Evaluation.

Health Application		Singapore	UK	USA
y.	Credentialing and Privileging	Associated with credentialing and privileging, at present, there is no special permission for medical practitioners to practice telemedicine in Singapore. However, the Singapore Telemedicine Guidelines provides that telemedicine service providers originating or residing in Singapore are required to be registered and possess licenses originating from a competent entity. Furthermore, as to the qualifications of health care providers, Article 13 paragraph (1) of the Singapore Medical Registration Act Chapter 174 also affirms that no one may practice as a medical practitioner or perform any action as a medical practitioner unless he is registered under the terms of this rule and has certificate for valid practice.	In the UK alone, there are special requirements for medical practitioners who wish to practice in the UK, which is required to be registered in full at the General Medical Council ("GMC"), or qualify for inclusion in the GMC specialist list. Although conditions apply to non-UK medical practitioners, there are differences in requirements between medical practitioners from countries that are members of the European Economic Area ("EEA") and medical practitioners from outside the EEA.	The national health organization in the United States, i.e., The Centers for Medicare & Medicaid Service ("CMS") is responsible for accrediting and validating the competence of medical personnel through credentialing and privileging. In the context of telehealth, if the CMS has to do the credentialing and privileging process which used an online health site provider in consultation, it will cause an administrative burden. To mitigate this burden, the Joint Commission (TJC) establishes a standard that allows hospitals to conduct its own credential and privileging. The provision also allows hospitals to receive services to make credential and privilege decisions for online health care providers. Furthermore, CMS through Medicare Conditions of Participation determines that between the hospital and the online health care provider, a written agreement should be made. Through the written agreement, the organization should ensure that the processes and standards of credentials and privileges from eHealth service providers meets the CMS-defined standards and compliance with those standards is entirely the responsibility of eHealth health care providers.

Conclusion: Required Matters & The Importance of Regulation

Challenges in implementing telemedicine are substantial, and it varies from funding, regulations, adoptions and evidence of cost savings. Aside from costs, regulations and adoptions are things that should be solved in timely manner. It is reassuring for those entrepreneurs who enter telehealth in the 20th century, to understand that the Indonesian government's response is slow but surely accepting telemedicine.

As mentioned before, the existing medical practice regulation required face to face interaction as a compulsion. The government needs to provide regulation that make such telemedicine practice to be feasible to conduct but also protecting the patient from the disadvantage that might arise during telemedicine process. As to this condition, other than providing the regulations to support implementation of eHealth in Indonesia, the related stakeholders also needs to amend regulations which are contradictive to government's plan in developing eHealth implementation, such as Decree of the Executive Board of the Indonesian Doctors Association. 221 / PB / A.4 / 04/2002 on the Implementation of the Indonesian Medical Code of Ethics (The Medical Code of Ethics). Furthermore, a more detailed legal framework is also needed to allow the implementation of eHealth system, such as regulation on data protection, quality of care, liability and reimbursement, e-prescribing, patient confidentiality, and patient safety.

In addition, government also needs to set clear regulation on authorized body to supervise, monitor, control, and regulate eHealth practice in Indonesia as until today, the supervision of eHealth practice in Indonesia is divided under the Ministry of Health and the Ministry of Communication and Information.

In regards to government's support in eHealth implementation in Indonesia, Ministry of Health has confirmed its support on the eHealth issue, that the Ministry will work with other related ministries to implement the eHealth system in Indonesia.

dr. Slamet, MPH, Special Staff for Health issue and Globalisation, Ministry of Health:

"We are willing and trying to execute eHealth system in Indonesia by working together with other ministries, such as Ministry of Public Works, Ministry of Information and Communications, State owned Electricity Company."

Other than challenges caused by technical developments on eHealth platforms, we see that challenges caused by lack of regulatory framework in eHealth is also a big hole for the implementation of eHealth in Indonesia. With support from stakeholders, particularly the relevant ministries, we believe that the development and investment in eHealth will be boosted in timely manner.


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