ACE OVERVIEW FOR NEW AND EMERGING HEALTH TECHNOLOGIES

Overview of Clinical Applications of Telemedicine

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This overview presents independent research by the ACE. It is not a systematic review, but rather a rapid overview of the technology and the available evidence based on a limited literature search. It is not intended to provide recommendations for or against the particular technology. The views expressed are those of the author and not necessarily those of the ACE, or the Ministry of Health.

Summary of Key Points

- Telemedicine is the delivery of healthcare services through information and communication technologies. It is a multi-dimensional concept that reflects its capability to reform healthcare delivery, reconstruct social interaction and reorganise traditional healthcare structure.
- Key modes of telemedicine service delivery include store-and-forward telemedicine, hospital-based real-time telemedicine and home-based telemedicine.
- The number of clinical applications for telemedicine are wide and varied while the technologies supporting telemedicine are novel and evolving.
- The Health Sciences Authority (HSA) has implemented a Regulatory Guideline for Telehealth Products, categorising them as medical devices and subjected to similar regulatory approval pathways as other medical devices. However, regulation of cyber security risks from network-enabled medical devices, international licensure and cross-institute credentialing may present some challenges.
- Telemedicine is proposed to provide health system benefits by creating a centralised database for better patient management of chronic conditions, decentralise healthcare delivery from hospitals to home, extend speciality care to primary care facilities, and provide on-site triage to prevent unnecessary referrals.
- Some evidence indicates that telemedicine may result in improved patient outcomes for a few clinical applications, which includes remote patient monitoring, communication and counselling for some chronic conditions and psychotherapy for behavioural health.
- It has been suggested that the effectiveness of telemedicine is dependent on the disease severity and trajectory of the population studied, the telemedicine application used, and the healthcare system and provider involved.
- Despite the high upfront cost, telemedicine has been proposed as potentially cost-effective due to better utilisation of healthcare resources and encourages preventative healthcare to support a value-based healthcare model.
- Main barriers to implementation include medico-legal liabilities, technological and infrastructure interoperability, data protection and confidentiality of patient's medical records, cost of implementation, reimbursement and subsidies, and digital literacy.

I. Background

Telemedicine is broadly defined by the World Health Organisation as the delivery of healthcare services across distance by healthcare professionals through information and communication technologies (ICTs) for the diagnosis, treatment and prevention of diseases and injuries, research and evaluation and continual education of healthcare providers to improve the health of individuals and communities.[1] The term telemedicine was first conceptualised in the 1970s to describe the use of ICTs to overcome geographical barriers in providing medical services to the medically underserved population and has recently been considered to improve healthcare delivery by coordinating and optimising geographically remote resources.[1] Telemedicine, together with health informatics, e-learning and electronic commerce, fall under the broader category of eHealth, which in turn is classified under digital health alongside mobile health (mHealth) and emerging technological advances such as artificial intelligence, genomics and big data.[1,2] To date, no single definition of telemedicine exists, and telehealth is often used synonymously with telemedicine. Telehealth is generally used as an umbrella term to encompass both clinical and non-clinical applications such as health research, education and administration while telemedicine often refers to clinical, patient-oriented applications.[3] For the purpose of this overview, the focus will be on telemedicine as defined by the delivery of healthcare services through ICT transmissions.

During the MTAC meeting in July 2019, telehealth was nominated as a potential topic of interest for horizon scanning and was subsequently shortlisted for further review considering the overarching clinical applications and impact that it can bring towards improving patient care and the healthcare system. Over the past decade, there has been an increasing implementation of telehealth programmes globally.[1] More recently, the COVID-19 pandemic has accelerated the need for telemedicine beyond baseline demands in Singapore, with telemedicine provider MyDoc reporting an increase of 160% in daily users since the start of 2020.[4] With the wide range of telehealth applications in various medical specialities and a lack of a defined scope during the nomination phase, an overview was developed to provide a broad view and understanding of telemedicine, with emphasis on its clinical applications, impact, implication and challenges in the Singapore healthcare system. This overview aims to better inform the committee for further scoping of potential telemedicine topics for review.

II. Technology

Telemedicine is a multi-dimensional concept that reflects its capability to reform healthcare delivery through the use of technology, reconstruct social interaction from a physical to an electronic encounter and reorganise traditional healthcare structure.[5] The adoption of telemedicine holds the potential to transform the landscape of healthcare to one that would allow convenient, continuous and connected mode of care. Increased interest in telemedicine is evident from a longitudinal bibliometric analysis of telemedicine, which revealed a shift from technical concerns towards specialised clinical and discipline-specific interest in the contemporary epoch, suggesting a transition from technical challenges to greater clinical utility of telemedicine.[6] Telemedicine serves as an adjunct to traditional medical practices and does not represent a separate medical entity. It disrupts traditional healthcare delivery pathway by allowing rapid exchange of information, improved access to specialist services, reduced need for face-to-face consultations and ensures optimal use of healthcare resources.[7] The service delivery of telemedicine is achieved through three broad categories, which includes store-and-forward, hospital-based real-time telemedicine and home-based telemedicine.[1]

Store-and-forward telemedicine leverages on digital tools for the acquisition, storage and asynchronous transmission of medical information for review by healthcare professionals across time and distance. This extends patient's access to speciality care and has been widely utilised in dermatology[8] and ophthalmology[9] for the transmission of medical images for making diagnoses. Hospital-based real-time telemedicine services, or tele-consultation, provide synchronous interaction between patients and healthcare professionals through video conferencing, reducing the need for face-to-face consultation. Tele-consultation can also function either in a synchronous manner or through asynchronous means. Home-based telemedicine extends medical practices to the home setting and is known as tele-monitoring, where electronic or medical devices allow remote recording and monitoring of biological parameters which can be uploaded to a monitoring system that is accessible by healthcare professionals. Tele-monitoring is often used to manage chronic diseases to enable early detection of medical problems and provide timely treatment for patients, ensuring that care is provided at an appropriate time and place in the most appropriate manner.[10]

The number of clinical applications for telemedicine are wide and varied while the technologies supporting telemedicine are novel and evolving. Tele-monitoring has been demonstrated to be implemented in various clinical fields such as cardiovascular, hematologic, respiratory, neurologic, metabolic, urologic, obstetrics-gynaecology and drug therapy.[11] Certain clinical applications such as tele-dermatology can be performed via synchronous tele-consultations or asynchronous store-and-forward system. Additionally, synchronous video conferencing and remote monitoring of non-physiological parameters such as sensory and motor functions allow for tele-rehabilitation.[12] The wide range of clinical applications and versatility of telemedicine, together with the profusion of nascent technologies and medical devices supporting telemedicine, indicates a potential for high degree of diffusion and disruption of many standard healthcare practices.

III. Regulatory Considerations

With the digitalisation of healthcare, software is increasingly used for medical purpose in telemedicine and are addressed by regulatory authorities to facilitate its adoption to promote healthcare innovations. Various regulatory bodies have implemented market authorisations for software as a medical device (SaMD), in line with the recommendation by the International Medical Device Regulators Forum,[13] as well as for software that is part of a medical device.

In Singapore, the Health Sciences Authority (HSA) has implemented the Regulatory Guideline for Telehealth Products where telehealth products, defined as hardware devices or software and mobile applications that provides healthcare services over physically separate environments via ICT, will be classified as medical devices and subjected to conventional HSA regulatory pathways if it is intended for medical purposes.[14] Such telehealth products include hardware such as remote surgical systems and software such as software-embedded remote patient monitoring device, mobile medical applications that transform a mobile platform into a regulated medical device and standalone mobile applications. Similarly, the United States Food and Drug Administration (FDA) and the Therapeutic Goods Administration (TGA) in Australia maintain regulatory oversight on software medical devices according to existing regulatory pathways for medical devices, with the FDA focusing on software[a] as an accessory to a regulated medical device or to transform a mobile platform into a regulated medical device[15] while the TGA considers all medical device software that is an integral component of the physical hardware part of the device and is collectively regulated.[16] In the European Union (EU), the European Medicines Agency (EMA) regulates medical device software that have fulfilled both the prespecified definitions of software and medical device, whether used alone or in combination, under the Medical Device Regulation or the In Vitro Diagnostic Medical Device Regulation.[17] Also, regulatory controls by HSA, FDA, TGA and EMA on such software medical devices are commensurate with its risk classification.

Among the various regulatory bodies, fast track regulatory approval exists for SaMD. Under the HSA's Regulatory Guideline for Telehealth Products, Class B and C standalone mobile applications qualify for the Immediate Registration Route if it has been approved by at least one of HSA's reference agencies with no known safety issues globally in the last three years or since the launch of the medical device.[14] In the United States, the FDA has introduced the Digital Health Software Precertification Programme to streamline regulations for software and is currently limited to SaMD as a pilot programme, with intentions to include software embedded in medical devices in the future.[18] Also, SaMD are currently regulated under prevailing TGA regulatory pathway for medical devices and it intends to seek new regulatory guidelines as current risk classification systems tend to underestimate the potential risk of SaMD.[16] Likewise, Health Canada has launched the Digital Health Review Division to improve targeted review and market access time for SaMD.[19]

The issue of cyber security of both software in a medical device and SaMD was addressed in the Postmarket Management of Cybersecurity in Medical Devices guidance by FDA in 2016, where it recommended that manufacturers should monitor, identify and address cyber security vulnerabilities and provide suitable mitigation strategies as part of their post-market management of medical devices.[20] Currently, identification and management of cyber security risks associated with software medical devices are addressed in a draft guideline published by HSA, which aims to provide clarity on regulatory requirements for software medical devices in its entire life cycle from product development to post-marketing.[21]

On the other hand, the regulation of telemedicine practice does not fall under the purview of HSA and there is no specific regulation to govern the use of telemedicine in Singapore to date. Instead, various initiatives and guidelines have been developed. The National Telemedicine Guidelines (NTG) was launched by the National Telemedicine Advisory Committee in 2015 to provide a framework to guide the implementation and delivery of telemedicine through recommended practices on clinical standards and outcomes, human resources, organisational framework and technology and equipment.[22] The Ministry of Health (MOH) launched the Licensing Experimentation and Adaptation Programme (LEAP) regulatory sandbox in 2018 to provide a controlled environment to develop innovative medical services, and telemedicine is the first medical service to be classified under LEAP.[23] This provides the groundwork and foundation for MOH to establish a regulatory framework under the Healthcare Services Act,

[a] The United States FDA currently classify software as both software in a medical device (SiMD) and software as a medical device (SaMD), which are similarly regulated in accordance to its risk classification.

which will supersede LEAP for the regulation of telemedicine services in the third quarter of 2022. Also, the Singapore Medical Council (SMC) has revised its Ethical Code and Ethical Guidelines (ECEG) in 2016 to provide guidelines on responsible telemedicine practices. Doctors currently providing tele-consultation are recommended to take reference from the SMC ECEG 2016 and the NTG.

Across various regulatory bodies, the issue of licensure remains largely unsolved as health practitioners may often only be able to practice telemedicine in his or her own jurisdiction. In the United States, a licensing board governs each state, and doctors have to apply for multiple state licences to practise telemedicine across state borders, which serves as a barrier for cross-border telemedicine. To streamline licensing in multiple states, the Interstate Medical Licensure Compact in the United States was enacted to circumvent licensure issues across states.[24] In Singapore, the NTG recommends that doctors intending to provide cross-border telemedicine services should adhere to licensing requirements imposed by the country that the patient resides in.[22] Also, credentialing is required for doctors practising telemedicine in the United States in addition to licensing requirements.[25] The issue of credentialing was not explicitly addressed in the NTG and the question on whether a healthcare professional has to be credentialed at both the organisation providing the telemedicine service and the remote institution receiving it in Singapore should be explored.

IV. Current Development in Singapore

Stage of diffusion	Clinical applications
Investigational	Unclear
Newly entered	Tele-monitoring
Nearly established	Tele-stroke, tele-rehabilitation, tele-consultation
Established	Tele-ophthalmology

Various nationwide telemedicine pilot programmes have been launched in Singapore's public healthcare institutions (PHIs) as part of the nation's telemedicine initiative. The Integrated Health Information Systems (IHiS) has launched the Smart Health Video Consultation, Smart Health TeleRehab, Smart Health Vital Signs Monitoring and the tele-stroke network, while the national tele-ophthalmology network was launched by the Singapore Integrated Diabetic Retinopathy Programme (SiDRP) at the Singapore National Eye Centre (SNEC) Ocular Reading Centre (SORC). Tele-consultation services from private healthcare providers have also been launched under the LEAP regulatory sandbox programme. Each of these telemedicine initiatives are at varying degree of diffusion in the local healthcare setting.

Among the various telemedicine initiatives, tele-ophthalmology is well established and widely utilised. The tele-ophthalmology programme was introduced by SiDRP in 2010 to provide a real-time diabetic retinopathy screening at the primary care setting, which includes all 21 polyclinics, in order to improve grading consistency and reduce referral rates to tertiary eye care. From the cost-effectiveness perspective, the use of tele-ophthalmology is dominant over the preceding family physician-based system.[26] An automated artificial intelligence-based system to streamline retinal image grading is currently in the pipeline.[9]

Tele-stroke, tele-rehabilitation and tele-consultation are currently in the developmental phase and are nearly established. The tele-stroke network, launched in 2011, serves to provide remote acute stroke care from a centralised team of neurologist at the National Neuroscience Institute (NNI) to healthcare providers from Changi General Hospital (CGH) and Khoo Teck Puat Hospital (KTPH), with further plans to expand the tele-stroke network to more PHIs.[27] At the same time, efforts to reduce the door-to-needle time for thrombolysis through optimisation of the tele-stroke workflow is ongoing.[28] The Smart Health TeleRehab was launched in various PHIs, nursing homes and community care partners in 2017 as a nationwide tele-rehabilitation pilot programme by IHiS and T-Rehab, which is a start-up from the National University of Singapore.[29] An increase in the uptake of tele-rehabilitation was reported at CGH, KTPH, Yishun Community Hospital and Alexandra Hospital, with 15 to 20 per cent of outpatient speech therapy conducted by tele-rehabilitation at Tan Tock Seng Hospital in 2020.[30] In addition, tele-consultation services for primary care and specialty care are provided by both private and public healthcare providers. Eleven private healthcare practitioners have been regulated under LEAP for the provision of tele-consultation services as part of a pilot programme since 2018.[23] In the PHIs, the Smart Health Video Consultation was launched in 2017 and has been introduced at various PHIs and 31 community care partners, with plans for further expansion to Ng Teng Fong General Hospital, SNEC, NNI and the National Healthcare Group Polyclinics.[31]

Tele-monitoring was recently introduced and is in the early stage of diffusion. As part of the Smart Health Vital Signs Monitoring scheme, a nationwide tele-monitoring pilot programme known as the Primary Tech-Enhanced Care was launched in August 2020 across the three polyclinic clusters – National Healthcare Group Polyclinics, National University Polyclinics and SingHealth Polyclinics – with an initial focus on the Home Blood Pressure Monitoring Programme and longer term plans to incorporate other chronic diseases and to include primary care partners.[32]

V. Expected Impact on Healthcare

There is a global evolving demographics and transition in healthcare focus towards an ageing population with increased life expectancies.[33] In Singapore, the leading burden of diseases are cardiovascular disease, cancer, mental disorder, diabetes and kidney disease, which account for an increasing demand of healthcare services.[34] The implementation of telemedicine allows continuous remote patient monitoring and improved access to healthcare which can facilitate patient-centred care and continuity of care,[1] with a potential for better health outcomes, better utilisation of healthcare resources and cost savings. Through various clinical applications, telemedicine provides a potential to tackle the present challenges in the healthcare system.

Impact on patients and healthcare delivery

Tele-monitoring engages patients in the ownership and self-management of their health, allow continuous monitoring by healthcare professionals and enable identification of early symptoms for prompt response and treatment.[35] Home tele-monitoring for chronic diseases was shown to produce positive clinical outcomes in a systematic review including studies on pulmonary, cardiac, hypertension and diabetes conditions, with patients reporting high level of acceptance and satisfaction with the tele-monitoring systems.[36] Positive health outcomes from tele-monitoring have been demonstrated through reduced blood pressure in hypertension,[37] early cardiovascular event detection with implantable cardiac device,[37] reduced heart failure-related hospitalisations and all-cause mortality,[38] and improved glycated haemoglobin control in patient with type 2 diabetes.[39] Moreover, improved health outcomes might be attributed to reduced fragmentation of care through a centralised database of patient-generated data that can be accessed by qualified healthcare providers.[40]

Tele-monitoring also allows for on-site patient triage to reduce unnecessary hospital visits and hospitalisations.[35] Reduced emergency department visits, hospitalisation and hospital length of stay were demonstrated in patients with pulmonary or cardiac diseases undergoing tele-monitoring.[35,36] Tele-monitoring also promotes a shift of patient care from healthcare institutions towards patient empowerment, encouraging preventative healthcare. Telemedicine-mediated self-management of chronic conditions was found to be non-inferior to usual care in diabetes, heart failure, asthma, chronic obstructive pulmonary disease and cancer, suggesting that telemedicine is a safe and viable approach for self-management of chronic diseases, particularly in heart failure and type-2 diabetes.[41]

Furthermore, store-and-forward services and tele-consultation provide a potential to extend speciality care to primary care facilities and improve access to care. Various studies have reported the success of tele-stroke[42] and tele-ophthalmology,[43] where patients were able to receive speciality care from a remote healthcare institution. Furthermore, reviews on tele-dermatology supported its use as a triage tool to prevent unnecessary referral to speciality care.[8] As tele-consultation reduces the need for face-to-face visits, travel and waiting time for patients and their caregivers are consequently reduced, leading to greater convenience and indirect cost savings. In terms of health outcomes, a comprehensive overview by the Agency for Healthcare Research and Quality (AHRQ) reported that asynchronous and synchronous tele-consultation were generally non-inferior compared to usual care in acute and chronic care settings. Tele-consultation was found to likely reduce intensive care unit (ICU) and hospital mortality in the remote ICU, reduce patient time in the emergency department, reduce mortality for heart attack patients and improve access and clinical outcomes in the outpatient setting.[44]

In addition, telemedicine can also be used for rehabilitation through virtual reality or video conferencing means. Tele-rehabilitation has been investigated in health conditions such as cardiopulmonary diseases,[45] musculoskeletal conditions[46] and stroke,[47] with a consensus supporting tele-rehabilitation as a non-inferior approach compared to conventional rehabilitation sessions. By leveraging on tele-monitoring devices, routine data can be obtained from wearable kinematic sensors or electromyography sensors for muscular activity detection, allowing rehabilitative processes to be monitored for timely feedbacks.[12] Time savings from the use of tele-rehabilitation was also reported in a pilot study on tele-rehabilitation for stroke patients conducted in Singapore.[48]

Notably, evidence of health outcomes have to be interpreted with caution as most telemedicine studies are observational, vary in strength of research methodology and used inconsistent outcomes measures which limit the ability to reach definitive conclusion.[44] A Cochrane review has also suggested that the effectiveness of telemedicine is dependent on the disease severity and trajectory of the population studied, the telemedicine application used and the healthcare system and provider involved.[49] Although promising, further rigorous and multi-site studies of telemedicine are required for better assessment of its impact on health outcomes.[44] Nevertheless, an evidence map based on high quality systematic reviews was developed by AHRQ to inform potential and mature telemedicine applications that are expected to impact healthcare. Substantial evidence appears to consistently support the effectiveness of remote patient monitoring and communication and counselling for chronic conditions, and psychotherapy for behavioural health (Table 1).[50] Figures A1 and A2, and Table A1 in the Appendix provides a detailed evidence map of the clinical effectiveness of various telemedicine applications.

Table 1: Evidence categories for telemedicine topics

Category	**Topic**
A	Remote patient monitoring for chronic conditions#
A	Communication and counselling for chronic conditions*
A	Psychotherapy for behavioural health
B	Consultation for various clinical reasons
B	Applications of telehealth for acute/ICU care including remote patient monitoring and tele-monitoring
B	Maternal and child health
C	Triage for urgent and primary care
C	Applications in paediatrics (managing chronic serious conditions)
C	Applications relevant to the integration of mental and physical health
C	Impact of tele-dermatology on patient outcomes
C	Impact on cost and utilisation

Category A: Topics that have a body of evidence in the form of several systematic reviews that can be used to inform decisions according to AHRQ's assessment. For these topics, there is a sizable quantity of evidence and some consistency in the conclusions and it seems unlikely that new studies in the near future will overturn the conclusions supporting the effectiveness of telemedicine.

Category B: Topics that would benefit from new or additional systematic reviews. For these topics, there appears to be enough primary studies to constitute a body of evidence, based on AHRQ's assessment of excluded reviews, reviews in progress, and primary studies.

Category C: Topics with few primary studies completed to date and are less likely to constitute a body of evidence that could support policy decisions. Systematic reviews in these areas would risk being small and inconclusive until more primary research is done.

Chronic conditions in the included reviews that reported benefits from remote patient monitoring include chronic obstructive pulmonary disease, heart failure and diabetes.

* Chronic conditions in the included reviews that reported positive benefits from communication and counselling include cardiovascular disease (secondary prevention) and diabetes.

Adapted from Totten et al. (2016).

Impact on healthcare system

Telemedicine is a disruptive innovation that may significantly transform the way healthcare is delivered, shifting patient care away from healthcare institutions. Coupled with improved patient outcomes and reduced unnecessary speciality care visits with on-site triage, telemedicine allows for better optimisation and utilisation of healthcare resources for more patients at lower costs.[36] Consequently, this may contribute to a more efficient and sustainable healthcare system.

Besides, telemedicine challenges the notion of clustered healthcare systems. It has been suggested that the distribution of healthcare demands is not homogenous in clustered healthcare systems, and telemedicine provides a potential to create a quasi-cluster to better distribute healthcare demands.[5] In Singapore, the three integrated healthcare clusters – Singapore Health Service, National Healthcare Group and National University Health System – serve as one public healthcare system. The use of telemedicine may promote better cross-cluster collaboration in the delivery of healthcare services across the entire continuum of care.

VI. Impact on healthcare cost

With reduced unnecessary hospital visits, improved health outcomes (especially in chronic conditions) and better utilisation of healthcare resources, telemedicine has been proposed to be a cost-effective tool to both patients and healthcare providers.[5] Patients would expect short-term savings from reduced travelling time and long-term savings from improved health outcomes. From the perspective of the healthcare provider, better healthcare utilisation from telemedicine can improve efficiency and lead to potential cost savings. As mentioned previously, tele-monitoring can serve as a form of prophylaxis by promoting patient engagement and ownership of their health. Coupled with the availability of patient-centred data from tele-monitoring tools, it allows healthcare providers to better manage chronic conditions and promote value-driven outcomes to achieve a value-based healthcare model.

However, currently most economic evaluations on telemedicine are based on small sample sizes, short time horizon, inconsistent cost estimate methods and lack of randomised controlled trials.[51] These result in ambiguous conclusions surrounding the cost-effectiveness of most applications of telemedicine, with a large number of reviews reporting inconclusive or irresolute cost-effectiveness of telemedicine in various clinical functions.[50] A local cost-effectiveness analysis of the national tele-ophthalmology-based diabetic retinopathy screening programme resulted in a cost saving of S$29.4 million over a lifetime horizon when compared to family physician-based assessment, with similar quality-adjusted life years reported for both groups.[26] Besides, benefits from telemedicine may present as a potential strategy for achieving a sustainable healthcare system. This would require better cost estimates from data on long-term routine use of telemedicine, which may capture its impact on patient experiences and their health outcomes, healthcare resource utilisation and the health system as a whole.

VII. Implementation Issues

For the full potential of telemedicine to be realised, it will require technological configurations, standardised normative standards and protocols, human resource reorganisation and new organisational structure.[5] Herein lies various implementation issues that serve as barriers towards the adoption of telemedicine in the healthcare system. Additionally, there are certain risks inherent with the use of telemedicine that should be considered.

Medico-legal liability

The pervasive use of telemedicine may increase the chance of misdiagnosis, particularly in store-and-forward and synchronous tele-consultations where diagnoses are made without face-to-face assessment. Studies in tele-dermatology indicated a need for more studies to support its clinical application in the diagnosis of lesions,[52] while major diagnoses were found to be missed in a direct-to-consumer tele-dermatology study conducted with simulated patients.[53] Moreover, equipment malfunction of telemedicine tools such as tele-consultation platforms, robotic tele-surgery systems or remote patient monitoring devices may result in delayed diagnosis or failure to treat, potentially leading to medical malpractice.

Both misdiagnosis and malpractice arising from telemedicine practices may lead to patient harm and present medico-legal liabilities on the doctor’s part. Furthermore, malpractices arising from international telemedicine services may also complicate legal proceedings as multiple jurisdictions are involved. Such medico-legal liabilities might serve as a barrier towards the adoption of telemedicine by healthcare professionals and could be mitigated through proper staff training on video conferencing and technical troubleshooting during the transitionary phase towards telemedicine. In addition, careful judgement on the limits of technology has to be made on the part of the healthcare provider to ensure that the clinical condition of the patient is suitable for telemedicine without any compromise in quality of care as compared to face-to-face consultation.[22] As a reference for equipment malfunction, the EU has passed the Product Liability Directive which states that the manufacturer shall be liable for damages caused by a defective product.[54]

Technological and infrastructure interoperability

A crucial step towards telemedicine is the establishment of technical interoperability among ICT equipment for proper and efficient delivery of telemedicine services. This creates an integrated standardised system to allow for seamless medical record entry and retrieval, and effective digital communication by all stakeholders across the full continuum of care. Technologically, the Picture Archiving and Communication System and the National Electronic Health Record provides a centralised digital platform of medical records keeping and sharing. To further improve infrastructure interoperability, it would be necessary to update legacy systems in both public and private healthcare institutes to a common standard for integrative telemedicine solutions to be realised. Recommendations from the NTG proposed the use of standards-based equipment to ensure interoperability of systems.[22]

Data protection and confidentiality

Digitalisation of healthcare may pose a risk in cyber security and data confidentiality. Telemedicine often requires a two-way transfer and storage of sensitive medical data between patients and healthcare providers. A lack of safeguards for data privacy, storage and transmission can pose risk on private health information. The Personal Data Protection Act 2012 (PDPA) and SMC ECEG serves to protect individual healthcare information through proper data encryption and safe data handling practices. Although encryption of video conferencing or data transfer between healthcare providers can be implemented using ICT systems and software in a controlled environment, security risk are present when one end of the communication involves the patient. Personal devices such as smartphone or computer may contain security flaws and present privacy concerns. Furthermore, cross-border telemedicine might exacerbate issues of data security and can constitute potential medico-legal issues and privacy risk when personal data are transferred out of Singapore and stored on an overseas database or server. This might occur with telemedicine platforms that provide tele-consultation services with overseas-based doctors. The PDPA prohibits the transfer of any personal data out of Singapore with the exception that the overseas organisation is able to ensure a same degree of data protection.[55] Regulations on the use and storage of personal medical data associated with international telemedicine practices have to be carefully deliberated.

Cost of implementation

High upfront cost of implementing telemedicine may pose as a significant barrier, however this should be considered in the context of the potential downstream cost saving from its perceived benefits. These costs include building technological and infrastructure networks, equipment maintenance and staff training. The American Hospital Association reported that the implementation cost of the telemedicine program for the Veterans Health Administration in 2012 was US$1,600 per patient per year, with an estimated cost savings of US$6,500 per patient or US$1 billion in system-wide savings in the same year.[56] Despite this, the financial burden of implementing telemedicine services may still be a barrier especially in smaller practices.

Reimbursement and subsidies

Funding and reimbursement have been reported to be a major barrier of telemedicine in various developed countries.[57] Restrictions imposed on fee-for-service reimbursement for telemedicine services creates an inertia towards the adoption of telemedicine.[58] Furthermore, the transitory nature of telemedicine funding programmes and additional telemedicine duties for waged employees without a corresponding pay raise might hinder staff retention and telemedicine adoption.[58] In Singapore, the pivot from a fee-for-service model towards a value-based healthcare model through bundled payments and value-based reimbursement could set a precedence for implementing telemedicine in the PHIs. Conversely, from the patient's perspective, fees arising from the use telemedicine services might act a barrier towards its utilisation. The use of the Community Health Assistance Scheme (CHAS) subsidies and MediSave for telemedicine services for selected chronic conditions were permitted by MOH on a time-limited basis during the COVID-19 pandemic to encourage video consultations.[59]

Digital literacy and ease-of-use

As the burden of disease and usage of telemedicine lies predominantly with the elderly population, there may be barriers towards its acceptance and utilisation. A review found challenges in the use of telemedicine by older patients in terms of poor hearing and vision, cognitive impairment, enmity towards an absence of physical contact and lack of assistance from family members.[60] Furthermore, the degree of ICT literacy can be varied in this population which might impede the uptake of telemedicine who would otherwise benefit more from the use of telemedicine services. User-centred designs can be considered for telemedicine applications or devices for better ease-of-use for the older population, while more training in digital health can be provided to bridge the digital gap.

Risk of overloaded healthcare system

The convenience of telemedicine may encourage overconsumption of healthcare resources and create additional workload for healthcare providers. This may be further exacerbated with continuous remote patient monitoring which generates a large volume of information, with the potential to create additional burden for healthcare professionals. Innovative processes can be used to apprise healthcare providers on aggregated patient's data while a technology-enabled triage system screens and manage the large volume of information.[61] Additionally, workflow reorganisation may be needed to prepare the healthcare system for the adoption and delivery of telemedicine. This can include appropriate training to fill skills and knowledge gaps, revised human resource policies and proper delegation of telemedicine-related responsibilities.[1,22]

VIII. Expected Future Developments

There is a preponderance of ongoing research to assess the clinical and cost-effectiveness of telemedicine across a wide range of clinical use. A search on ClinicalTrials.gov yielded more than 700 ongoing clinical trials involving telemedicine or telehealth.[62] Also, the emergence of the COVID-19 pandemic has seen a surge in telemedicine usage.

On the technology front, telemedicine is evolving with the advent of emerging medical technologies, creating an immense potential for healthcare to be decentralised through the Internet of Medical Things (IoMT), which provides an interconnected and interoperable infrastructure between healthcare systems and medical services.[63] The emergence of IoMT is supported by advances in innovative medical technology that drives the development of new and network-enabled medical devices which can collect, store, analyse and transmit data, creating disruptive enablers for telemedicine.[63] Current developments include digital stethoscope and pulse oximeters that can be connected to a mobile phone for physiological readings to be captured and transmitted to healthcare providers. Wearable technologies are expected to be the mainstay of emerging medical technologies to augment telemedicine, such as a self-powered triboelectric wearable for cardiovascular monitoring[64] and an inkjet-printed conducting polymer tattoo electrode for long term brain electroencephalography monitoring.[65] Furthermore, tele-therapy and tele-rehabilitation involving virtual and extended reality technologies could shape the future of mental health and rehabilitation respectively. A step forward to robotic-assisted surgeries, remote robotic tele-surgery may be incorporated into routine surgical practice in the future.[5]

Moreover, the incorporation of artificial intelligence (AI) technology into healthcare presents a myriad of possibilities to enhance the workflow of telemedicine. AI has been used to interpret retinal images in tele-ophthalmology[9] and radiological images in handheld ultrasound systems.[66] Future use of AI in telemedicine could allow AI-assisted remote patient monitoring to detect exacerbations in chronic conditions, AI-guided diagnosis and AI-enabled health information optimisation with big data analytics and neural networks. Furthermore, the synergy between AI and IoMT allows large datasets derived from medical devices and wearables to be reduced, aggregated and analysed to provide clinically meaningful outputs. With healthcare designated as one of the five sectors of the National Artificial Intelligence Strategy, it is expected that AI will continue to play a synergistic role in advancing the capabilities of telemedicine in Singapore.

Blockchain technology has also been proposed as a new model for exchange of health information in the era of telemedicine by increasing security and interoperability of health data.[67] The immutable nature of blockchain could allow exchange of health information between various stakeholders in a secure and accountable manner.

IX. Additional Information

A multitude of ethical considerations exist with the digitalisation of healthcare. While telemedicine may improve access to healthcare services, it can also lead to issues surrounding equity and fairness in access in instances where digital technologies are not developed for patients suffering from rare diseases or when certain populations are excluded due to digital illiteracy.[68] Secondly, patients should be aware and notified of the risks associated with telemedicine and participation should be voluntary, while the same level of care should be provided to patients who do not wish to engage in telemedicine. Informed consent should be obtained regarding the privacy risks from long-term digital storage of personal health data, as well as the extended risk to their family members in situations when genetic data are collected in telemedicine practices.[68]

Furthermore, telemedicine may alter social interactions in medical practice. The doctor-patient relationship comprises an empathetic component that requires understanding of the patient and tailoring treatments to their needs, and a technical component which involves expert medical knowledge.[69] Telemedicine disrupts the empathetic component, as non-verbal cues such as body posture may not be adequately perceived. Similar to the NTG, guidelines from the American Medical Association recommended that a valid doctor-patient relationship should be established before the provision of telemedicine services.[22,70] Moreover, socio-ethical issues may arise from the conveyance of bad news through remote means and this should be avoided as it disregards the dignity of patients and puts them in a vulnerable situation.[68]

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Appendix

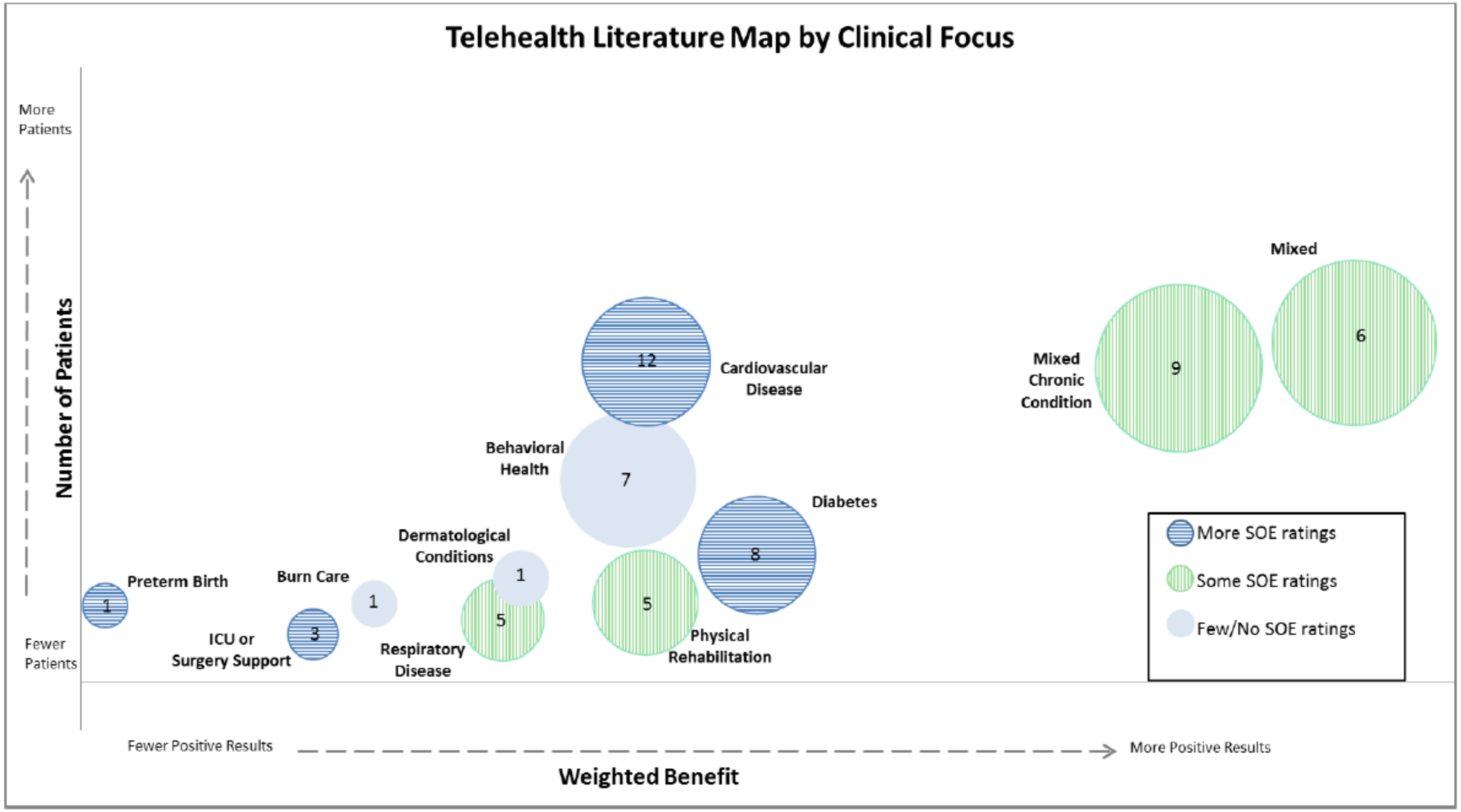

Figure A1: Telehealth literature map of systematic reviews by clinical focus. Bubble size reflects the unduplicated number of individual studies included in the systematic reviews regarding the particular clinical focus while the numerical digit within each bubble represents the number of systematic reviews. The bubble size is proportional to the number of studies for each clinical focus. The colour of the bubble represents the number of systematic reviews with strength of evidence (SOE) reported. Relative weighted benefit is calculated by weighting the overall conclusion of each review by the number of studies in the review. Bubbles to the right indicate more positive findings while bubbles to the left represent findings that are unclear or found no benefit. *Adapted from Totten et al. (2016).*

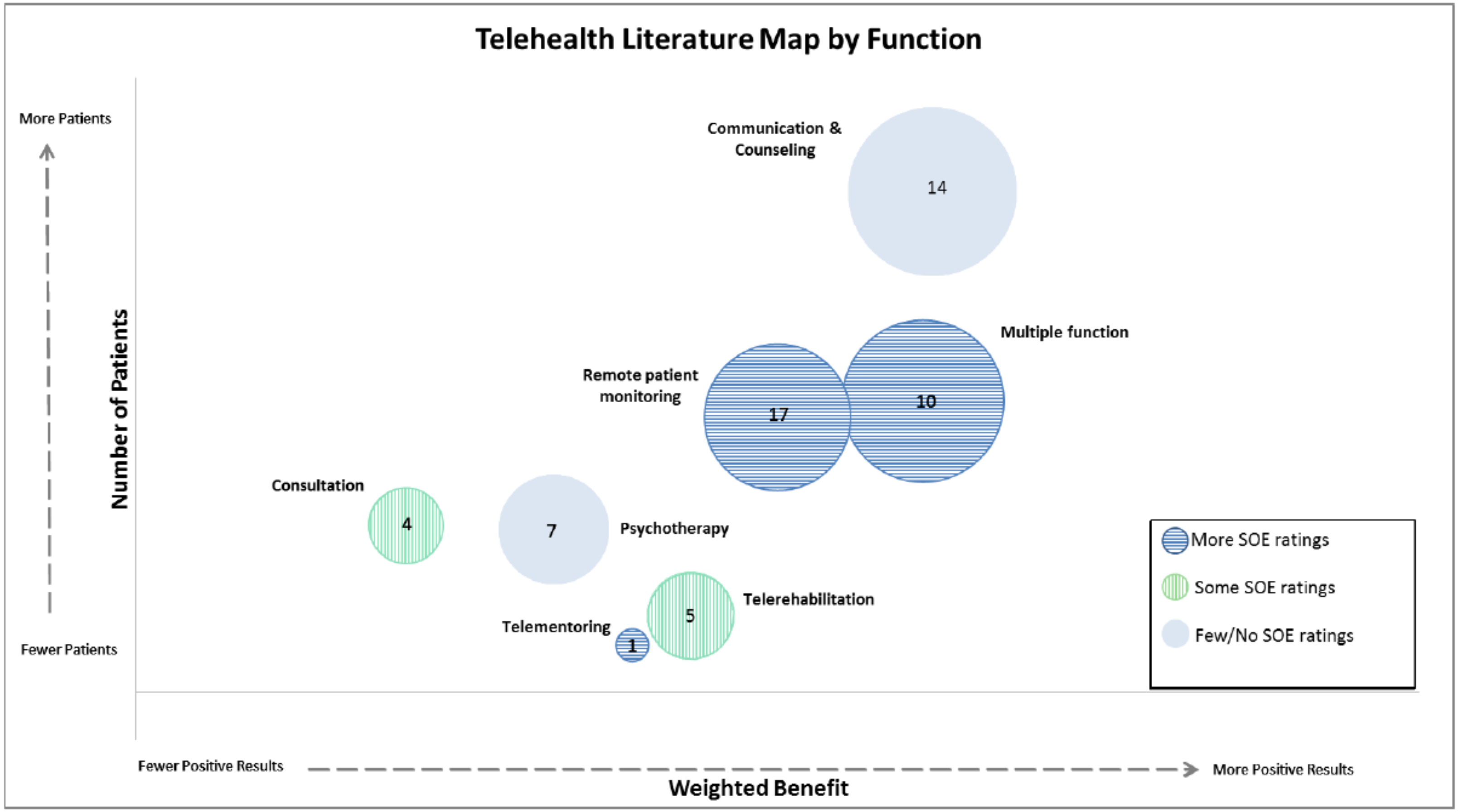

Figure A2: Telehealth literature map of systematic reviews by telehealth function. Bubble size reflects the unduplicated number of individual studies included in the systematic reviews regarding the particular telehealth function while the numerical digit within each bubble represents the number of systematic reviews. The bubble size is proportional to the number of studies for each telehealth function. The colour of the bubble represents the number of systematic reviews with strength of evidence (SOE) reported. Relative weighted benefit is calculated by weighting the overall conclusion of each review by the number of studies in the review. Bubbles to the right indicate more positive findings while bubbles to the left represent findings that are unclear or found no benefit. *Adapted from Totten et al. (2016).*

Table A1: Selected systematic reviews of telehealth for chronic conditions that reported positive benefits

Clinical Focus of Systematic Review	Author, Year Number of RCTs/Total Number of Included Studies (n/N) Telehealth function	Selected Results: Clinical Outcomes	Selected Results: Cost and/or Utilisation
Chronic Obstructive Pulmonary Disease	Kamei, 2013 7/9 Remote Patient Monitoring	• Mortality: No significant difference (5 trials) • Fewer disease exacerbations (2 trials)	• Fewer hospitalisations (6 trials) • Fewer emergency department visits (4 trials)
	McLean, 2011[≠] 10/10 Remote Patient Monitoring	• Higher quality of life (2 trials) • Mortality: No significant difference (3 trials)	• Fewer hospitalisation (6 trials) • Fewer emergency department visits (3 trials)
Heart Failure	Conway, 2014 11/11 Remote Patient Monitoring	• Reduced all-cause mortality (RR 0.62; 95% CI 0.50 to 0.77; p<0.0001)	• Fewer heart failure related hospitalisations (RR 0.75; 95% CI 0.63 to 0.91; p=0.003)
	Dang, 2008 9/9 Remote Patient Monitoring	• Lower mortality in 3 studies (not significant in 4; not reported in 2)	• Fewer heart failure related hospital admissions: 6 of 9 studies (1 trend towards increase; 2 not reported)
	Kotb, 2015 30/30 Remote Patient Monitoring	• Lower mortality (OR 0.53; 95% CI 0.36 to 0.80)	• Fewer heart failure related hospitalisations (OR 0.64; 95% CI 0.39 to 0.95)
	Seto, 2008 4/10 Remote Patient Monitoring	• None reported	• Reduced direct costs compared to usual care in all 9 studies that analysed heart failure (range 1.6% to 68.3%). Attributable to reductions in hospitalisations. • Lower patient costs: 1 study reported reductions in travel costs
Secondary Prevention: Cardiovascular Disease	Widmer, 2015 28/29 Communication and Counselling	• Reduction in cardiovascular outcomes, weight, body mass index and Framingham risk score. • No improvement in blood pressure.	• None reported
Implanted Cardioverter Defibrillators	Parthiban, 2015 9/9 Remote Patient Monitoring	• Not significantly different from office follow up. • Reduction in all-cause mortality in 3 studies with daily transmission verification (OR: 0.65; p=0.021) • Reduction in appropriate shock (OR 0.55; p=0.002)	• Similar hospitalisation to office follow-up

Diabetes	Liang, 2010 11/22 Communication and Counselling	• Improvement in clinical outcomes (22 trials)	• None reported
	Saffari, 2014 6/6 Remote Patient Monitoring	• Improvement in HgA1c	• None reported
	Toma, 2014 34/34 Communication and Counselling	• Improvement in clinical outcomes (HgA1c, blood pressure, triglycerides and total cholesterol)	• None reported
Mixed Chronic Conditions	Tran, 2008 18/34 Remote Patient Monitoring	• Improvement in clinical outcomes for diabetes (12 trials) and heart failure (5 trials) • Improvement not seen in chronic obstructive pulmonary disease – 1 study reported higher mortality	• Fewer hospitalisation and emergency visits • More primary care and speciality visits
	de Jong, 2014 15/15 Communication and Counselling	• Improvement in clinical outcomes (5 trials) • Improvement in symptoms (5 trials) • Positive psychosocial outcomes (5 trials)	• Physician visits: No significant difference (2 trials)

RCTs: randomised controlled trials, CI: confidence interval, RR: relative risk, OR: odds ratio, HgA1c: haemoglobin A1c.

Mixed chronic conditions: Reviews that included studies on conditions such as asthma, hypertension, diabetes, chronic pulmonary obstructive disease and kidney failure.

≠ Two individual studies are repeated in these reviews.

Adapted from Totten et al. (2016).