32nd European Partnership for Supervisory Organizations in Health Services and Social Care (EPSO) Conference with focus on Asia-Pacific (APAC)

TAC Working Group Meeting Report

22nd June 2022: Pre-Conference Working Group Meeting

The 3rd EPSO Tele-Digital Health, AI, Cybersecurity (TAC) Working Group Meeting was held on 22nd June 2022, prior to the main conference and was chaired virtually by Mr. Kevin Freeman-Ferguson, Head of Service Review, Healthcare Improvement Scotland and Ms. Janet Ortega, Head of Integrated Care and Inspection for General Practice, Care Quality Commission (CQC), UK. The Chair introduced the TAC working group and its aim to bring together collaboration across different economies for the improvement of regulation of services and for sharing intelligence and information about online healthcare. He also indicated that delivery of healthcare goes beyond geographical boundaries with online services, with many providers being outside of Europe.

The three EPSO Blueprint draft discussion documents - (a) the blueprint to support the delivery of safe and high-quality care by Telehealth, (b) the blueprint for the supervision of artificial intelligence in healthcare and (c) the blueprint for cybersecurity in healthcare - were distributed to members of the working group meeting. The members and third parties who attended the 3rd TAC working group meeting were tasked with reviewing the documents and to add relevant sections pertaining to their economies in order to complete the documents. Each of the blueprint documents was discussed in the 3rd TAC working group meeting as follows:

1. Blueprint to support the delivery of safe and high-quality care by Telehealth:

This session involved three speakers. Professor James Kingsland, Clinical Excellence Network Digital Healthcare, DICE UK, joined in virtually updating on the Digital Clinical Excellence Forum (DICE). Ms. Kertti Merimaa, Advisor and Head of eHealth Interoperability, dealing with standardization and data exchange, Ministry of Social Affairs, Estonia; and Professor Carl Moons, Julius Center, UMC Utrecht; Director, Health Innovation Netherlands (HI-NL), University Medical Center Utrecht, The Netherlands. Prof. Moons and Ms. Merimaa presented in-person on the developments in Estonia and the Netherlands, respectively.

1.1. Developments in the UK:

1.1.1. Introduction of DICE (Digital Clinical Excellence):

The DICE Forum, set up in March 2019, is an independent organization and network that incorporates online clinical service providers from across the UK. It aims to support clinical care improvements and safety in digital healthcare, as well as to develop consistency in quality and safety through digital care standards. It does not have any commercial focus or activity. Currently, it supports around twenty-two organizations ranging from large corporations with services around the UK to independent primary care providers with custom-made services. Online consultations by doctors and pharmacists are relatively new and digitalization of primary care has only accelerated in recent years. DICE evaluates the quality and safety of online consultations, focusing on patient-doctor interactions, as well as providing education and training programmes. The consultation skills training programme included rules of handling patient information, data privacy and protection, adapting new ways of working and treating patients, and 5G connectivity to support real-time monitoring. Overall, the programme was well received, including by senior clinicians, as it enables understanding new ways of working online and interacting with new technology.

1.1.2. Challenges:

The main issues faced include data protection matters, legality of online consultation issues, managing delivery platforms, and the need to standardize such platforms. In addition, technical competencies and communication skills are required to meet the needs and expectations of patients in a digital environment, especially for consultation and the process to transfer patients from one clinician to another.

The major challenge was to find the right balance between face-to-face and online services as there are always those who prefer face-to-face interaction.

It was observed that even in this digital era, what patients value in terms of service quality does not change. Patients, independent of delivery mode, value availability, accessibility, responsiveness, good communication skills, interpersonal attributes of care/compassion, continuity of care, range of on-site services, and technical skills of staff with more importance given to humanistic factors.

1.1.3. Future Plans:

The future plans are to design health services based on the demographics of the patients in terms of their age or generation they belong to. As each generation ages, their values changes and needs grow more complex, altering their needs for healthcare services. The needs of the younger generations growing up with technology and highly digitally dependent would be different compared to the baby boomers who may prefer face-to-face consultations. As we look across generations, when one looks at the expectations of online consultations, the tech-savvy folks are entirely dependent on technology and expect it. Surprisingly, for specific areas like financial advice or career advice, the younger generation still wants it face-to-face. The question remains, what are the expectation once this younger generation ages and have more complex care needs. Will their needs for services also change and align with that of the baby boomers and pivot to favor face-to-face interactions?

Thus, as Maria Antoinette says, “There is nothing new except what has been forgotten”. Beyond predicting the new normal, it is important to ensure that we are all well-prepared for it.

Another topic to address is education and training for clinicians who face difficulties to conduct online consultations.

1.1.4. Key Takeaways:

- Digitalization of healthcare has accelerated;
- Necessity to strike the right balance between face-to-face and virtual consultations;
- Need to study the outcomes of virtual consultations;
- Importance of people-centered factors when it comes to service quality of online consultations;
- Need to tailor the healthcare services to the population, especially based on generations;
- Need to educate and train the clinicians in the effective use of technologies.

1.2. Developments in Estonia:

1.2.1. Introduction of Telemedicine (TM) Platform in Estonia:

TM can be considered synonymous to telehealth, which is “healing at a distance” or remote healthcare services. As per WHO definition, TM is the “delivery of health care services, where distance

is a critical factor, by all healthcare professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation and for the continuing education of healthcare providers, all in the interest of advancing the health of individuals and their communities".

For Estonia, the goal for the next 10 years is to integrate patient-centered care and TM facilitates this, especially in terms of convenience for patients in rural areas. The regional availability of TM creates more equal options for patients. Patients' direct involvement with their choices also results in a larger responsibility for their own health, increasing user familiarity and confidence. Estonia made extensive efforts to define what TM is and the services focused on to avoid uncertainty about services offered. A lot of effort was required to clarify the different services available and to differentiate them for patients.

Attitudes toward TM have changed with the COVID-19 pandemic. Prior to COVID-19, many specialists were not eager to use TM and health insurance did not cover TM usage. However, more providers and users are now more confident in and open to using TM. In addition, insurance allows TM as a claimable service. This has led to a boom in the uptake of TM.

In Estonia, the requirements for telehealth services are the same as for in-person care in terms of the content of consultations and the protection requirements. Telehealth services are used only when appropriate for the patient and it is necessary to assess the patient's technical readiness as well as to obtain the patient's consent to use TM and their personal data. If patients prefer face-to-face consultation, they should be able to receive it.

Currently, in Estonia, the following 3 services provided to patients are reimbursable by the Estonian health insurance fund, which is the main buyer of publicly funded healthcare services:

1. ***Teleconsultation:*** Around 10% of all ambulatory appointments are based on teleconsultations. Nearly 30% of psychiatric care appointments were through this mode during COVID. Monetary incentives were provided to healthcare professionals who used video consultations tools during COVID.
2. ***Teletherapy:*** This is only provided by video and is commonly used for speech therapy, physiotherapy and psychotherapy. The updake is very low (only 7.4% of psychology care appointments remotely) as it is rather new and not many professionals are offering this service. So far, the patients' feedback has been positive.
3. ***Telemonitoring:*** Predominantly driven by the private sector, but Estonian health insurance fund is looking for different paying models to bring it to market. Healthcare providers are reluctant to take up these solutions, especially solutions that are not reimbursed.

1.2.2. Future Plans:

A pilot project to accelerate the introduction of user-friendly TM services is in progress. The pilot project involves funding of one million Euros to four pilot projects to develop telemonitoring solutions. For these pilot projects, the focus was on service design for last year while the focus for this year will be to roll out the new service designs to live patients. The four pilot projects are as follows: two general practice projects and two specific projects, respectively:

A. General Practice Projects:

1. My health journey, which helps to digitalize care plans for primary care doctor, specialist and patient;
2. Digital triaging service;

B. Specific Projects:

3. Connect care which supports cancer patients;
4. Monitoring Soriasis from afar.

For all four projects, multi-disciplinary teams composed of healthcare providers, technical and academia partners were set up. An impact analysis was mandatory to determine the uptake, and any problems that had risen for the healthcare providers and patients. Finally, a paying model to reimburse healthcare providers who utilize the four services would also be established. If these solutions prove to be useful, it would be scaled up for all over Estonia.

1.2.3. Challenges:

- Difficulties to find healthcare providers who did not have any conflict of interest to develop and test the product as the pool of healthcare providers within Estonia is very small;
- Small circle of specialists;
- Lack of clarity in the roles of different parties, namely the technical partner, healthcare provider and academia, i.e., the academic was more in the background, while the healthcare provider took control of the whole project which may have led to biases.

1.2.4. Observations/Results:

The uptake of services/solutions in the past 5-6 months was relatively high, with an exception for cancer patients where only 12 out of 100 places were filled as patients in the cancer project were quite old and had difficulties in using smart devices, including email.

1.2.5. Key Takeaways:

- Patients are the drivers for new models of healthcare services and their feedback is essential for developing new service models especially when the literature is limited;
- 75% of specialists think that video consultation is good, but the number is smaller when looking at older specialists;
- Specialists and doctors are more reluctant than patients to try out new services;
- Need for empowerment and training of specialists as they seem to lack sufficient digital skills; how does the specialist communicate with the patients on where to focus on.
- Need for appropriate and intuitive tools like specialized telecommuting platforms compared to common platforms such as skype;
- Importance of international and national guidelines and exchange of best practices – very important for the specialists to see the evidence;
- Telemedicine offers flexibility and convenience at lower costs if targeted and managed properly.

1.3. Expert Thoughts from The Netherlands:

- Telemedicine will be needed even more in the future as we get older and healthier, thereby prolonging our lifetime leading to more sick people at some point of time;
- Patient history taking can easily be done via teleconsultation and not much of a difference would exist whether it is done virtually or in-person;
- The issue around testing exists in the Netherlands whether the testing is done by the patient itself or the doctor remotely:

- When it is a self-test done at home by the patient itself, patients query whether the testing will be as good and accurate as compared to the tests done by a doctor in the hospital;
- When it involves a remote testing (blood test, images) and physical examination, healthcare professionals query whether they are as good as when the patient is in front of them or whether they are going to miss something when it is performed remotely.

- Lack of evidence that telemedicine is as good as face-to-face consultation bears the risk of misdiagnosis. Doctors are worried that they would have to be legally responsible if they make mistakes which they wouldn't have made if they had seen the patient in-person.
- Lack of evidence to show that TM is as good or even better than the normal consultation can be even more dangerous when treating patients with terminal illness as doctors are more afraid in case their diagnosis is wrong.
- Healthcare professionals' business model is changing, which leads to two further questions:
  - How to ease the transition?
  - How to reimburse when healthcare professionals incur losses due to this change in the business model?

1.4. Session Discussions:

1.4.1. The current situation in other economies:

1.4.1.1. Singapore:

Singapore rolled out a regulatory sandbox in 2018 and gathered data from TM consultants. From a risk perspective outlook, data from over 10,000 consultants during a period of 2 years showed that there were no adverse outcomes from TM itself. The learnings from the sandbox were translated into an electronic training platform and TM providers had to go through the training. The training also included information on the existing legal protections, the advice that doctors should provide and the platforms that can be used. Those who completed the training are put on a volunteer list which is uploaded onto the Ministry's website for the public to use. As far as reimbursement is concerned, patients can be reimbursed through their medical savings account. Patient feedback is also very important and in Singapore, it is looked at from the professional angle, that is how to equip the doctor to offer the service professionally rather than from a patient's point of view.

Points to Ponder:

- Methods of gathering evidence to assess if there is equality in outcomes;
- Ways to gather patient feedback.

1.4.1.2. Malta:

Prior to COVID-19, telemedicine was not accepted whereas, today, service users are seeing telemedicine differently and are also forthcoming to use such services. The government is also working on improving the public feedback channels.

As part of the training required for practitioners, Malta has just introduced a Master's degree in digital health which enables the participants to improve their knowledge on systems and practices.

1.4.1.3. Estonia:

Estonia is looking at the patients' experience through different angles by analyzing PREMS – Patient reported experience measures and PROMS – Patient reported outcome measures. They are also looking at the healthcare system level ~~an in~~ whether hospital admissions are moving up or down.

Currently Estonia is reassessing the skills needed for healthcare practitioners in order to improve the training curriculum for healthcare professionals including doctors, nurses and support specialists and also to adapt to the changing modality of service provision.

1.4.1.4. Australia:

Telemedicine is practiced as a substitute for a proportion of in-person care and the two modes are usually not mutually exclusive and exist in a blended model. It would be difficult to do direct comparative studies as there is a need to choose appropriate patients. Hence, it may not be possible to say that telemedicine is as good as conventional consultation; however, we can reduce the risk with appropriate guidelines in place.

1.4.1.5. Cambodia:

Cambodia has prepared a strategic plan for digital health and has started to work on the same. They would like to learn more about the infrastructure required based on research from experts at the conference.

1.4.1.6. Scotland:

In contrast to Australia where most of the services are blended and not operated on a wholly online service model, in Scotland, there are a number of services that are provided without a physician present. This makes it difficult for the medical providers to provide an in-person assessment when it is required for the patient's wellbeing.

1.4.1.7. Latvia:

Due to two severe COVID-19 waves, many people could not attend in-person services, hence teleconsultation was introduced as part of the primary care system and the economy saw a surge in teleconsultations. It was also included to be eligible for reimbursement. During lockdowns, the economy saw a surge in teleconsultations.

2. <u>Blueprint for Cybersecurity in Healthcare:</u>

2.1. Scotland:

For Cybersecurity, there are only two golden rules – (i) we either stop a cyberattack or (ii) we learn to manage, should there be an attack. About 30% of cyberattacks are user preventable. Scotland did experience a massive cyberattack in the environmental regulation sector which took months to sort out staff data. Soon after the attack, work could continue due to the technical competence of staff and retained knowledge. In contrast, in healthcare, this is not the case as doctors will not be able to care for patients without the relevant patient data. Hence, having a solid backup of data is critical to ensure that one is able to retrieve all the necessary data as fast as possible.

In the aforementioned case, even with all the backups, it took almost 6 months to build up a new system. Once the new system was re-established, increased effort went toward retraining of staff with focus on upskilling their digital practices ranging from good file naming protocols to proper file storage. Likewise, the healthcare professionals also need to be upskilled in relevant digital skills.

2.2. Bahrain:

Bahrain's experience in the industry revealed that 85% of attacks are from internal users. Hence, Bahrain follows the General Data Protection Regulation (GDPR) European standards where hefty penalties are imposed in the event of data breaches. Circulars are also used to warn employees of phishing emails and to stay vigilant. Security by design and privacy by design are the key principles on which they operate. It is important to consider security and privacy when designing system and security has been the foundational consideration at the inception of any new system in Bahrain. Companies are advised to detect a cyberattack early to allow for necessary rectification and follow-ups as required.

The biggest challenge for digital health is the Internet of Things (IoT) which poses greater cyber security risks. IoT devices are small, ubiquitous, have limited onboard power and storage, and most of them are sold in stores without proper built-in security protocols. Without proper built-in security measures, data can be easily siphoned. Hence it is necessary to ensure that device manufacturer have all the precautions ready to ensure that devices will not be compromised and ultimately affect patient safety.

At homes, if everyone sticks to default credentials (without changing the password), devices could also be used to wage disruption on infrastructure. A few years ago, there was a case where 300,000 IoT devices were used to attack a government website.

2.3. Singapore:

Following a cyberattack at one of the healthcare clusters that resulted in data leak, a huge revamp of systems and regulations in Singapore occurred. As a public healthcare system that is critical to the continuity of care for essential services, electronic medical records are designated as critical information infrastructure and come under the Cyber Security Agency Act. Mandatory technical safeguards are put in place to ensure that the electronic medical record system is guarded.

Cybersecurity Essential Guidelines have been issued to layout the different processes, policies and people protection that need to be implemented. Licensees are requested to abide by these guidelines as much as possible. Singapore is currently trying to see how to convert these guidelines into law as once it is translated into regulation, providers have to abide by it or else enforcement actions will be taken against them.

User behavior is very important and Singapore for example undertakes phishing exercises – in essence testing of how many people accidentally fall for a phishing email. Outcomes of such studies are shared.

Not just IT systems, but also medical devices are taken into consideration as medical devices will impact how telemonitoring and tele-devices will be utilized.

2.4. Estonia:

In addition to IoT devices, legacy systems are increasingly to various threats. With the growing number of hospital systems and networks, this is something that economies need to look into and, also, invest in the national infrastructure.

3. <u>Blueprint for the Supervision of Artificial Intelligence (AI) in healthcare:</u>

This session started off with a presentation by Professor Carl Moons on the development of the Dutch Guidelines to promote the development and introduction of safe, effective and transparent AI in healthcare.

3.1. Artificial Intelligence-based Prediction Algorithms:

Prof. Moons explained that AI is used widely in hospitals and primary care, for example, in pathology, reading of images, or predicting algorithms. AI can be part of the field of medicine, but not every telemedicine is based on AI.

Prediction algorithm is an important topic as now the world appears to be overwhelmed with it. Every existing prediction model seems to be redeveloped with AI or machine learning, as it is now feasible and people do have the data. Prediction algorithm can be defined as any combination of 2 or more variable predictors (input) that convert these values of these variables into a risk or probability (diagnostic) of either having something or developing a particular outcome within a certain time (prognosis). Prediction models are not new in healthcare, whether it is embedded with AI or not. APGAR score which is the most frequently used prediction algorithm was introduced as early as 1951.

The Ministry of Health at the Netherlands had tasked Prof. Moons and his team to develop guidance and quality criteria for AI-based Prediction Algorithm (AIPA) in healthcare. AIPA is a data driven model that provides an individual's probabilistic predictions of current presence or future occurrence of a possible outcome. The developed guidelines requested by MOH are based on the published review of quality assessment tools.

3.2. Regulatory Pathways for AI in England:

Mr. Moritz Flockenhaus highlighted that the Care Quality Commission (CQC) regulates health and social care providers who provide care services in England and do not regulate products or software. As per England's regulatory approach, the legislation of 2017, any clinical evaluation must be carried out by a person as opposed to AI. Hence, the only company that registered for developing an algorithm to interpret chest X-rays (service) was informed that all images analyzed by the AI still need to be reviewed by a clinician at their end.

Points to Ponder while regulating services using AI:

- Need to review the entire regulatory process in UK to see if software developers needed regulations;
- Prepare suitable questions to be asked by the inspection staff during inspection;
- Information that is required for notification processes;
- Incorporation of the AI providers in the new assessment framework and regulatory approach;
- Develop ratings for AI developers and integrate those ratings into the wider system level assessments;
- Standard Operating Procedures to be developed when collaborations between different agencies take place, whether they are regulating products, services or a combination;
- Establish data protection routes.

3.3. Motivation for Developers of AI to abide by the guidelines:

Dr. Raymond Chua, Deputy Director of Medical Services (Health Regulation Group), Ministry of Health, Singapore indicated that the AI guidelines is not yet a law in Singapore. Using a sandbox approach, MOH invites the roll of new services and technologies allowing for the collection of data for

such services. This is a more collaborative approach and allows services to roll out within the stipulated guidelines of the sandbox parameters. Based on the data collected, a better understanding would be reached to establish regulatory parameters. In collaboration with the developers, MOH (Singapore) drafts the regulations in and co-creates the training.

When it comes to new technologies, the expertise is provided by the the industry itself and no mentorship is imparted by the regulators. The major advantage for the developers participating in the sandbox is that they will know how the service is going to be regulated ahead of their peers in the field and they can also contribute, nuance and shape the regulations. Those not in the sandbox may find it more challenging to comply with the regulations.
