Report of the Medical Council Working Group on Telemedicine

April 2021

Comhairle na nDochtúirí Leighis
Medical Council

About the Medical Council

The Medical Council is the regulatory body for doctors. It has a statutory role in protecting the public by promoting the highest professional standards amongst doctors practising in the Republic of Ireland.

The Council has a majority of non-medical members. The 25 member Council consists of 13 non-medical members and 12 medical members. The Council receives no State funding and is funded primarily by doctors' registration fees.

The Medical Council maintains the Register of Medical Practitioners - the Register of all doctors who are legally permitted to carry out medical work in Ireland. The Council also sets the standards for medical education, training and lifelong learning of registered medical practitioners in Ireland. It is charged with promoting good medical practice and provides professional and ethical guidance. The Medical Council is also where the public, profession and services may make a complaint against a registered medical practitioner.

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Foreword

The role of the Medical Council is to protect the public as they interact with medical practitioners, as detailed in the Medical Practitioners Act (2007). The Council established a working group to examine regulatory issues relating to emerging telemedicine practice. The group explored how telemedicine is used in other jurisdictions and considered developments in telemedicine that have occurred in light of the COVID-19 pandemic.

In March 2020, just 4% of the population had engaged with telemedicine, but as the pandemic took hold it drove a fivefold increase, with 21% having used the service by October.

The impact of the pandemic and its associated public health restrictions made the use of telephone and video consultations much more relevant, with many doctors and patients alike, engaging in this new way to care for patients for the first time. In recognition of this the Medical Council produced guides on the use of telemedicine for both patients and doctors.

Accessing healthcare from the home can in particular help those living in rural areas with limited access to transport and those seeking after hours medical support among others. However, like any service, in order for it to be effective in its role of meeting patients' needs, it must be implemented appropriately with the correct supports, structures and guidelines in place. Given the appropriate resources, the COVID-19 experience shows that telemedicine can continue to be developed as a service in line with best practice, strengthening the health service, protecting patients and supporting doctors in turn.

This report highlights areas for further consideration including the registration process, doctor education and training, data protection, patient privacy, the governance framework and legislative landscape. Consideration must also be given to the role of doctors providing telemedicine outside of their jurisdiction and the associated validation of registration, education and training.

The safe and effective integration of telemedicine into the Irish health service requires a strong governance framework, overarching care delivery and the appropriate education and training. The introduction of electronic health records and national unique health identifiers would further ensure safe patient care.

Positive feedback relating to telemedicine, from both practitioners and patients, means that although it will never replace traditional face to face interaction entirely, it could be used to complement existing services into the future.

Medicine and patient care is constantly evolving and embracing new methods, treatments and technology. The use of telemedicine is an exciting new chapter in modern medicine provided it does not negatively impact upon the therapeutic relationship between patient and practitioner. With the right supports, governance structures and oversight, the benefits of telemedicine to patient care and patient safety can be realised. However, like with all new developments, the patient must remain our primary focus.

Mr Paul Harkin

Chair of the Telemedicine Working Group
Member of the Medical Council

Dr Rita Doyle

President
Medical Council

Executive Summary

The Telemedicine Working Group was formed by the Medical Council to consider the impact on patient safety, and regulation of the medical profession with the increasing reliance on telemedicine. The work of the group had an increased importance as both patients and the medical profession had widespread telemedicine use thrust upon them with the COVID-19 pandemic.

A literature review took place and a thematic analysis was conducted, identifying the key themes across the literature as related to telemedicine such as efficacy, minimising contact, connecting rural and disadvantaged communities, accessibility, cost and future direction. 1,454 records were identified as part of the review.

The overwhelming consensus is that telemedicine is effective across a wide range of clinical situations when used appropriately. Throughout the literature, it was observed that telemedicine facilitates connectivity in disadvantaged communities, minimises face-to-face contact and patient movement, is less costly for patients and clinicians and also holds significant potential for expansion and evolution moving forward. Notwithstanding the positive aspects of virtual care that were observed, and indeed prominent in literature, concerns were raised regarding patient privacy and data sharing. Contradictory evidence was accessed with respect to the impact of virtual care on the patient-clinician relationship, though most articles accessed argued that this relationship was not diminished as a result of using virtual care. More prevalent in the literature, however, was the sentiment that telemedicine should never be an outright replacement for face-to-face consultation in future, instead being utilised as one method in a comprehensive approach to care, while currently minimising any potential spread of COVID-19.

A review of international regulatory approaches to telemedicine identified a number of key trends and concerns around confidentiality, patient consent and patient safety issues.

Through a consultative forum which was held with a number of practitioners with experience of telemedicine both within Ireland and internationally and a stakeholder survey these issues were raised again, in addition to education, framework for telemedicine, the legal landscape in telemedicine, prescribing, doctor work burden and fatigue, lack of physical examination, communication, practical challenges and regulation.

On two occasions, public opinions research was conducted on behave of the Medical Council. Between the first research carried out in February and March 2020 and the second carried out in October 2020 it was identified that there was a fivefold increase in telemedicine usage, mainly due to the impact of COVID-19 on the health service, from 4% to 21%.

The working group identified that both the public and the medical profession were seeking guidance and supports on the usage of telemedicine to receive and deliver care. The Medical Council, through the Telemedicine Working Group, published a guide for patients and a separate guide for doctors with practical tips and advice for telemedicine consultations.

Issues relating to Irish legislation and EU Directives on cross border care were considered as were recent legislative changes following BREXIT.

Role of the Working group

The Function of Council under Part 2, Section 7, sub-section (2) (i) of the Medical Practitioners Act 2007 relate to "specifying standards of practice for registered medical practitioners, including the establishment, publication, maintenance and review of appropriate guidance on all matters related to professional conduct and ethics for registered medical practitioners".

The Telemedicine Working Group was formed to consider the impact on patient safety, and regulation of the medical profession with the increasing reliance on telemedicine. It had an increased importance as both patients and the medical profession had this thrust upon them with the COVID-19 pandemic. The Telemedicine Working Group sought to examine issues relating to telemedicine, with regard to commercial and non-commercial telemedicine. It examined telemedicine used in other jurisdictions. In its workplan, the group examined medical regulation issues relating to; registration, patient safety, and professional conduct & ethical guidance. To inform outputs, research was undertaken incorporating: an international review, consultation with the medical profession and patients to ascertain the use of telemedicine in practice; incorporating positive aspects and shortcomings in telemedicine as a means to deliver safe, quality patient care.

The membership of the Telemedicine Working Group comprised a mix of Council and external members. See membership at Appendix A. The working group held regular meetings over a 12-month period. Members contribution provided an insight as they shared their experiences of telemedicine, during COVID-19 and working in other jurisdictions where telemedicine was already integrated into the provision of patient care and treatment. The Telemedicine Working Group:

- Considered a systematic search of the literature observing the positive and negative aspects associated with telemedicine in 2020 – compiled by the Research Section of the Medical Council.
- Undertook a consultative forum with invited representation from varying medical experts to inform the working group of their experiences of the use and importance of telemedicine, particularly given its increased use during the COVID-19 pandemic.
- Produced a patient information booklet on telemedicine and an information booklet for doctors on telemedicine.
- Commissioned Behaviour & Attitudes Limited (a Market Research company) to conduct public opinion research on telemedicine (from the patient perspective) – an initial survey was conducted in March 2020 (pre-COVID-19) and the follow-up survey was undertaken in late October 2020.
- Considered guidance on telemedicine (December 2020) that has been provided in other jurisdictions - compiled by the Research Section of the Medical Council.
- Initiated a consultative process with stakeholders in December 2020. This was by way of a survey that was issued to key stakeholders which included Postgraduate Medical Training Bodies (PGTBs), working group members, patient advocacy groups, the Mental Health Commission, the Pharmaceutical Society of Ireland, and the Data Protection Commission amongst others.
- Sought legal opinion to contextualise Irish and European Law on the practice of telemedicine by the medical profession within and external to Ireland and the EU.

- Examined the impacts of Brexit legislative changes on the delivery of some telemedicine services.
- Produced this report and recommendations to the Medical Council.

Introduction

The impact of COVID-19 has resulted in the rapid growth in the use of telemedicine in patient care.

As Public Health guidance indicates that all efforts should be made to reduce face to face contact, telemedicine consultations provide an alternative to an office or clinic visit for many patients.

Research completed in early March before the introduction of the first set of COVID-19 public health restrictions, showed that only 4% of the population had ever engaged with a telemedicine service.

Since the onset of COVID-19, the rapid changes in the way healthcare is delivered has resulted in an increase in its use, with 21% of the population having now experienced telemedicine. Telemedicine is particularly useful when it is part of an existing system for providing patient care.

Background to Telemedicine

Telemedicine is a term coined in the 1970s, meaning 'healing at a distance' (Strehle & Shabde, 2006). In general terms, telemedicine is defined as a medical service provided remotely via information and communication technology. Telemedicine can be applied to consultations, diagnosis and treatment. Telemedicine should be seen as another way of providing healthcare, rather than as a distinct medical service in its own right.

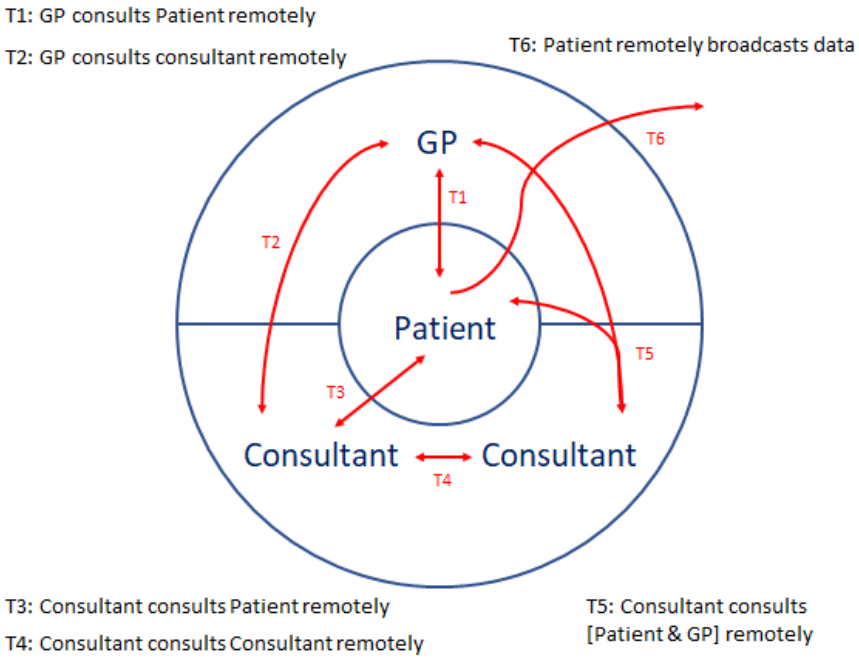
Telemedicine can be used to reduce exposure to infection, including coronavirus, by enabling both patients and clinicians to consult while in isolation. It can also increase organisational resilience by protecting the workforce and enabling support to be provided from different geographical locations (Ahuja et al, 2020).

Many doctors already use some form of information and communications technology when providing care. The impact of COVID-19 has meant that telemedicine has now become an integral part of medicine. Telemedicine can:

- help patients who are vulnerable receive necessary care
- provide patients with more convenient access to care
- provide ease of access for those in isolated locations
- allow for more comprehensive delivery of services after-hours
- allow for more efficient use of limited health resources

The conceptual framework (in Figure 1) relates to telemedicine and how telemedicine revolves not just around the patient and the general practitioner (GP) but the patient, the GP and the consultant with multi-faceted interactions between them. The diagram was drafted as a visual to aid discussion on some elements of telemedicine (Irish Medical Council, 2020, p 3).

FIGURE 1. *THE CONCEPTUAL FRAMEWORK OF TELEMEDICINE*



As with a face-to-face consultation, the principles of care within telemedicine are the same (Irish Medical Council, 2020, p 4):

- High-quality patient care is the priority.
- The use of telemedicine does not alter the ethical, professional or legal obligations of doctors, regardless of how the doctor-patient interaction occurs. Doctors must comply with the Guide to Professional Conduct and Ethics which sets out the principles of professional practice that all doctors registered with the Council are expected to follow.
- Doctors are responsible for determining the appropriateness of telemedicine to support the best outcome for their patients, considering their patients' context and symptoms.
- Patient privacy and confidentiality of personal health information must be protected.
- Care standards for practice, such as evidence-based best practice, should be carried through to care delivered via telemedicine.
- As with face-to-face appointments that require the use of interpreters, the presence of family members or a carer, or other aides; those same supports should be arranged for telemedicine consultations.

Definition of Telemedicine

The Guide to Professional Conduct and Ethics for Registered Medical Practitioners (Amended) 8th Edition 2019 provides a definition for telemedicine:

> ***Telemedicine describes the delivery of health care services through information and communication technologies to promote the health of individuals and their communities.***
>
> ***It involves the exchange of information between doctors and patients, or between doctors and professional colleagues, for the diagnosis, treatment and prevention of disease and injuries, and for research, evaluation and continuing education.***

Literature Review

A systematic search of the literature observing the positive and negative aspects associated with virtual care in 2020.

Introduction

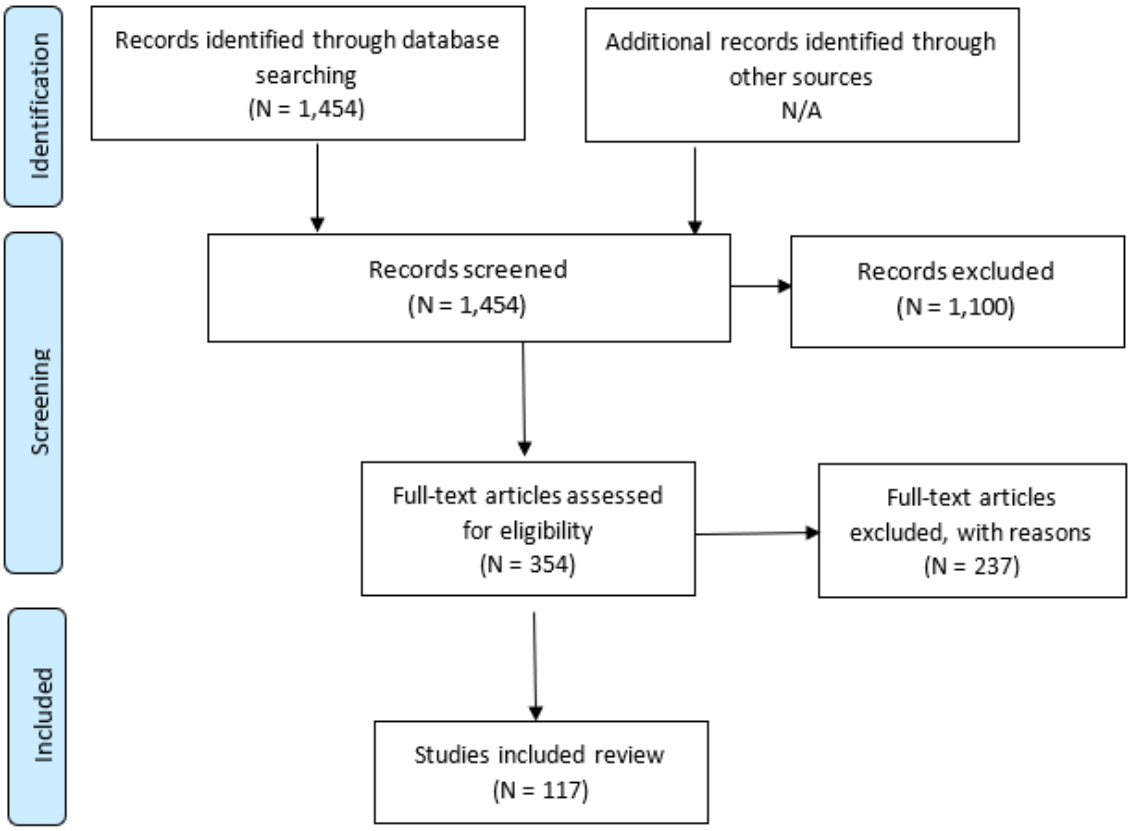
According to the WHO, telemedicine is 'the delivery of health care services, where distance is a critical factor, by all health care professionals using information and communication technologies for the exchange of valid information for diagnosis, treatment and prevention of disease and injuries, research and evaluation, and for the continuing education of health care providers, all in the interests of advancing the health of individuals and their communities' (WHO, 2010, p 9). The WHO deemed that telemedicine fulfils four key purposes, including:

1. Providing clinical support;
2. Overcoming geographical barriers, connecting users who are not in the same physical location;
3. Using of various types of ICT;
4. Improving health outcomes.

This report on the literature is presented against the backdrop of a global pandemic which has affected physical human interaction. The World Health Organization declared COVID-19 a Public Health Emergency of International Concern on the 30th January, before upgrading it to a global pandemic on the 11th of March. At the time of writing, living with COVID-19 is very much a part of day to day life, for both clinicians and patients. In addition, COVID-19 has required the medical profession to put in place measures to ensure patients receive treatment, while avoiding in-person visits and face-to-face consultations where possible. This prompted the Medical Council Executive to use a systematic approach to review the literature assessing the positive and negative aspects associated with telemedicine following the outbreak of COVID-19.

Search Strategy

A systematic approach was taken to searching the literature using the PRISMA guidelines. Pubmed, JAMA, EBSCO and the BMJ were searched using the search terms 'telemedicine', 'telehealth' and 'virtual care'. For inclusion were articles observing the perceived pros and cons associated with virtual care. Only articles published between the 31/12/2019 and 06/08/2020 were considered for review. A total of 1,454 articles were retrieved. Following analysis of titles and abstracts, 354 articles were considered for review. Two-hundred and thirty-seven (N = 237) articles were excluded for not meeting the inclusion criteria, leaving a total of 117 studies for inclusion. A PRISMA flow diagram provides graphical representation of citations reviewed and decisions made.



Thematic Analysis

A thematic analysis was conducted. The key themes identified across the literature as related to telemedicine were;

- Efficacy;
- Minimising contact;
- Connecting rural and disadvantaged communities;
- Accessibility;
- Cost;
- Future direction.

Efficacy

Telemedicine was observed to be effective in diabetes care, treatment of cardiometabolic diseases, osteoporosis management, ALS symptom management, urological conditions, epilepsy, aftercare for patients with heart failure, therapy, retinopathy, dentistry, management of many musculoskeletal conditions and physical rehabilitation.

From a patient perspective, effective virtual care was predicted by factors such as ease of access, effective scheduling and effective communication (Elliot et al., 2020). It was also observed that patients were keen to engage with telemedicine, particularly as an option to support traditional care

models. Telemedicine encouraged patients to become more active in their treatment and was observed to have a positive influence on patients' state of health and understanding of their care.

From a clinician perspective, telemedicine was regarded as efficient, with no associated increase to workload when compared to face-to-face consultations. The evidence suggests that telemedicine facilitates effective communication. Panda et al., (2020) observed that 96% caregivers were satisfied with the quality of medical advice they were able to provide using virtual care.

Notwithstanding these observed benefits, there exists some scepticism as to the practicability of telemedicine from a surgical standpoint. Challenges with diagnosis were observed, particularly with telephone consultations (Olwill et al., 2020). Additionally, there were concerns that telemedicine could diminish the therapeutic alliance between patient and clinician, with Costanzo et al., (2020) advising that the use of telemedicine may have a negative emotional impact on patients due to the lack of face-to-face contact, thereby negatively impacting therapeutic effectiveness.

Minimising Contact

Telemedicine facilitates clinical support at a distance, thereby assuring continuity of care (Boehm et al., 2020; Loeb et al., 2020), reduces face to face care (Vecchione et al., 2020), limits the risk of viral transmission (Al-Shamsi et al., 2020; Fieux et al., 2020) and reduces the burden placed on hospitals. Hashim et al., (2020), Catanese et al., (2020), Singh et al., (2020) and Sutherland et al., (2020) cited the elimination of viral transmission as a benefit of virtual care.

Bhatia et al., (2020) and Rodriguez-Socarrás et al., (2020) both identified that telemedicine minimises unnecessary care, while Aguilera et al., (2020) observed that telemedicine affords the opportunity for clinicians to immediately disseminate information.

Babbage et al., (2020) observed that virtual care is predictive of patients making independent health care decisions, acknowledging that the use of technology can make care more accessible and increase patient autonomy. The potential damage to the patient-doctor relationship was highlighted by Babbage et al., (2020), with Jiménez-Rodríguez et al., (2020) arguing that the use of telemedicine can potentially create a perceived psychological distance between clinician and patient.

Connecting rural and disadvantaged areas

Virtual care was described by Schwamm et al., (2020) as collapsing 'the barriers of time and distance', entailing a ubiquitous accessibility. Lavin et al., (2020) added that telehealth services and virtual clinics offered accessible disease management pathways for patients living in health resource limited areas. Gohari et al., (2020) concluded that travel could be reduced by a minimum of 26.5% and a maximum 85% for those in rural communities

Babbage et al., (2020) specifically referenced that access to virtual care technology can be limited in rural communities. Contreras et al., (2020) anticipate that telemedicine will mature due to the proliferation of interconnected consumer health devices and high-speed 5G data connectivity in the coming decade, representing a distinct disadvantage to those without access to such resources.

Accessibility

Two individual barriers to accessibility were identified, including privacy and familiarity with technology. Privacy was a concern for the younger cohort, while familiarity with technology was a

concern primarily for an older cohort. Singh et al., (2020) acknowledged that widespread use of telemedicine and emerging apps has the potential to lead to data privacy breaches. They advise balancing the dual principles of erring on the side of collecting and using data conducive to the protection of lives, while cautiously working to prevent the potential for abuse by developing new rules and regulations against the misuse of this data, particularly during times of public health emergencies (Singh et al., 2020).

Reed et al., (2020) observed that patients aged 65 years and over were less likely than patients aged 18 to 44 years to choose telemedicine. Lam et al., (2020) observed that telephone was the preferred method of contact for an older cohort. Lame et al., (2020) observed that barriers to engaging with virtual care in older adults was primarily due to difficulties with hearing and communicating, while 38% of older patients were unwilling to use telemedicine owing to inexperience with technology.

Cost

When compared to face-to-face care, Schieltz et al., (2020) observed that telehealth services predicted similar reductions in deleterious health behaviours in patients, at a significantly lower cost. While technology can reduce the cost of healthcare for some, the costs associated with installing, maintaining and servicing certain technology can be massive on a private individual.

From a preoperative standpoint, Bridges et al., (2020) determined it was unclear whether virtual care would be financially favourable for hospital systems, due to factors such as the institution's needs, patient population and surgical cancellation rate.

Future direction

With respect to the future directions in care that telemedicine could predict, in cataract care, Lin et al., (2020) determined that utilising a patient-centred streaming system adaptable to a changing environment will ensure cataract services evolve into a robust practice model for the future. Gujral et al., (2020) made a similar assertion with respect to diabetes care, arguing the future of diabetes care may shift toward a hybrid model combining in-person visits and telemedicine. It is notable, however, that Gujral et al., (2020) followed this statement by underlining the key role that the research community will play in gathering information on the impacts of virtual care on diabetes treatment and outcomes with a view to improving shortfalls in the system as they arise. The importance of research into telemedicine was additionally referenced by two studies with both Vecchione et al., (2020) and Catanese et al., (2020) arguing that diagnostic and therapeutic algorithms must be explored to ensure the highest quality of continued care. Most notably, irrespective of advancements or perceived advantages, Bianchi et al., (2020) determined virtual care should never replace face-to-face visits with a clinician entirely.

Conclusion

The year that was 2020 will be remembered as one of significant societal, political and social upheaval. Nonetheless, the restrictions resultant from the COVID-19 pandemic have necessitated innovation from a variety of fields, including that of medicine. It is therefore advisable that the lessons learned, and the best practice observed, be carried forward and further developed in time, combined with best practice prior to COVID-19, with a view to protecting patients seeking care and supporting doctors in practice.

Overwhelmingly, the consensus is that telemedicine is effective across a wide range of clinical situations when used appropriately. Throughout the literature, it was observed that telemedicine facilitates connectivity in disadvantaged communities, minimises face-to-face contact and patient movement, is less costly for patients and clinicians and also holds significant potential for expansion and evolution moving forward. Notwithstanding the positive aspects of virtual care that were observed, and indeed prominent in literature, concerns were raised regarding patient privacy and data sharing. Contradictory evidence was accessed with respect to the impact of virtual care on the patient-clinician relationship, though most articles accessed argued that this relationship was not diminished as a result of using virtual care. More prevalent in the literature, however, was the sentiment that telemedicine should never be an outright replacement for face-to-face consultation in future, instead being utilised as one method in a comprehensive approach to care, while currently minimising any potential spread of COVID-19.

International Regulatory approaches to telemedicine

In March 2018, the General Medical Council (GMC), in the UK, published research it commissioned, conducted by Europe Economics, titled "Regulatory approaches to telemedicine". The research reviewed regulatory approaches to telemedicine around the world. The following definitions of telemedicine are drawn from this report.

Definitions of telemedicine

United Kingdom

- Care Quality Commission (CQC - 2017) - Healthcare services that provide a regulated activity by an online means. This involves transmitting information by text, sound, images or other digital forms for the prevention, diagnosis, or treatment of disease and to follow up patients' treatment (p. 2)

New Zealand

- Medical Council of New Zealand (MCNZ, 2020), Telehealth: the use of information and video conferencing technologies, to deliver health services to a patient and/or transmit health information regarding that patient between two or more locations at least one of which is within New Zealand (MCNZ, 2020, p. 2)
- Video consultation: Where the doctor and patient use information and video conferencing technologies to communicate with each other and visual and audio information are exchanged in real time, but the doctor and patient are not physically present in the same consultation room. Video consultations can be conducted between a doctor and patient in the presence of their general practitioner or other health practitioner or it can be conducted with no medical support at the patient's end (MCNZ, 2020, p. 2).

Australia

- Medical Board of Australia (2020) – Technology-based patient consultations are patient consultations that use any form of technology, including, but not restricted to videoconferencing, internet and telephone, as an alternative to face-to-face consultations (p. 1).
- Allied Health Professionals Australia (2020) - (Telehealth) broadly refers to the use of technology to communicate with, and deliver health services to, consumers without the need for face-to-face contact with a health professional (p. 3).

Canada

- Canadian Medical Association - Virtual Care (2020) has been defined as any interaction between patients and/or members of their circle of care, occurring remotely, using any

forms of communication or information technologies with the aim of facilitating or maximizing the quality and effectiveness of patient care (p. 3).

- College of Surgeons and Physicians Ontario – Telemedicine (2014) is both the practice of medicine and a way to provide or assist in the provision of patient care (which includes consulting with and referring patients to other health-care providers, and practising telemedicine across borders) at a distance1 using information and communication technologies such as telephone, email, audio and video conferencing, remote monitoring, and telerobotics.

Registration

- The GMC is responsible for registering UK doctors and licensing those who wish to practise medicine, but cannot require doctors outside the UK to register with the GMC, even if they provide remote medical service to a patient in the UK (GMC, 2018, p. 16). The CQC (2017) state that those who intend to provide telemedicine must apply to them to secure registration for the regulated activities they intend to deliver. They continue, adding that providers must satisfy that the care and treatment provided will meet the requirements of the Health and Social Care Act 2008 and its associated regulations (CQC, 2017, p. 3).
- The Medical Council of New Zealand's statement on the provision of Telehealth applies to doctors registered in New Zealand and practicing telehealth in New Zealand and/or overseas; as well as doctors who are overseas and provide health services through telehealth to patients in New Zealand. (MCNZ, 2020).
- AHPRA state that if a practitioner is registered with the relevant profession's National Board under the National Registration and Accreditation Scheme and are based overseas, AHPRA and the National Boards consider that they can provide telehealth services to patients based in Australia (p. 1).
- As per the Canadian Medical Association (2020), all medical regulatory bodies in Canada have some form of standard or policy on licensure requirements for physicians providing telemedicine/telehealth services, but there exists variability across Canada. Saskatchewan offers a specific telemedicine licence and New Brunswick enables physicians from other jurisdictions to provide telemedicine services to its residents. British Colombia, Ontario, Nova Scotia and Newfoundland & Labrador do not specify that a physician licensed outside the province must be licensed in their jurisdiction to provide telemedicine (CMA, 2020, p. 8).

Patient consent

- The Medical Council of Ireland's Guide to Professional Conduct and Ethics to Registered Medical Practitioners (2019) further provides that practitioners ensure patients have given their consent to conduct the consultation through telemedicine and consent to any treatment provided (43.3, p. 32).
- In their PMS digital healthcare providers document (2017), the CQC prompt practitioners to ensure consent is obtained and specifically directs that patients be informed and consent to their interactions being recorded (p. 12).

- The Medical Council of New Zealand's (2020) statement on the provision of Telehealth directs that the patient's consent be sought before the telehealth service is provided (p. 1).
- The Medical Board of Australia (2020) direct practitioners to apply the usual principles for obtaining a patient's informed consent, protecting the patient's privacy and protecting the patient's rights to confidentially (p. 2).
- The Canadian Medical Association (2020) direct practitioners empower patients to make informed decisions regarding their health by communicating with and helping the patient (or, where appropriate, their substitute decision-maker) navigate reasonable therapeutic options to determine the best course of action consistent with their goals of care; communicate with and help the patient assess material risks and benefits before consenting to any treatment or intervention (p. 5).

Confidentiality

- The Medical Council of Ireland's Guide directs that if a practitioner provides telemedicine patient privacy be protected through effective security measures that protect patients' privacy by following the Guide's sections on confidentiality in paragraphs 29 and 33 (43.3, p. 32). The Guide also states that compliance with data protection principles be ensured in the transfer of any personal patient information to other jurisdictions (43.3, p. 32), that every effort to ensure that any notes made about a patient are placed in the patient's medical record with their general practitioner as soon as possible (33.3, p. 27) and that the patient's GP be informed of the consultation (43.3, p. 32).
- The GMC's Regulatory Approaches to Telemedicine Requirements applicable to the provision of telemedicine includes: ensuring the same standard of care as that of face-to-face healthcare; ensuring that telemedicine is an appropriate method of delivering healthcare; ensuring that sufficient information regarding a patient's medical history and current condition is available for diagnosing and/or treating patients; ensuring confidentiality, safety and security of the exchanged information (sometimes including the technical aspects of it); obtaining a patient's consent for this method of providing medical services (sometimes paired with a requirement to provide an overview of what the patient can expect from a teleconsultation or tele-treatment); and confirming a patient's identity and maintaining medical records.
- The Royal Australasian College of Physicians Telehealth Guidelines and Practical Tips (2012) document outlines that Telehealth consultations should be private and confidential, and physicians should have processes in place to facilitate confidentiality as per standard face-to-face consultations (p. 11). The guidelines offer specific advice to protect patient privacy including:
- Having a system to ensure that there are no interruptions at the specialist and patient ends of the consultation;
- Ensuring patients participating in the telehealth consultation from home do so in a quiet room where they will not be disturbed;
- Alerting other staff at their practice location that they are conducting a telehealth consultation and asking not to be disturbed;

- If a consultation is to be recorded, storing the recording securely and ensuring privacy and confidentiality is maintained;
- When choosing videoconferencing hardware and software for telehealth, considering the security features of the telehealth system to ensure the technology used facilitates privacy and confidentiality;
- Maintaining appropriate storage of all reports provided for, or generated from, the telehealth consultation;
- If there is a valid and clinically appropriate reason for the recording of a consultation, fully informing the patient and receiving their consent. (p. 11).
- Canadian Medical Association's Code of Ethics and Professionalism (2018), directs that practitioners fulfil their duty of confidentiality to the patient by;
- keeping identifiable patient information confidential;
- collecting, using, and disclosing only as much health information as necessary to benefit the patient;
- and sharing information only to benefit the patient and within the patient's circle of care.
- Exceptions include situations where the informed consent of the patient has been obtained for disclosure or as provided for by law (p. 5). It further directs that practitioners avoid health care discussions, including in personal, public, or virtual conversations, that could reasonably be seen as revealing confidential or identifying information or as being disrespectful to patients, their families, or caregivers (p.5).

Key challenges

- Access to patients' long-term medical records —ensuring that sufficient information regarding patient's medical history and current condition is available for diagnosing and/or treating the patient;
- Identification of the patient, including some key characteristics such as age, gender, body weight etc. — confirming a patient's identity as well as access to medical records;
- Healthcare based on an asynchronous (i.e. not real-time), text-based relationship (e.g. questionnaires or standardised emails) — sufficient medical information is obtained before forming a diagnosis or starting treatment.
- Requests for confidentiality being potentially abused by patients to avoid sensitive information being shared between the remote doctor and their primary healthcare provider — which is closely matched by the concerns of the USA and Canadian regulators that telemedicine increases the risk of patients being treated in isolation of other healthcare services they receive. This could be mitigated by a requirement to provide telemedicine only in cases of a pre-established face-to-face relationship between the patient and the doctor, or a physical intermediation from another healthcare professional at the location of the patient.
- In some jurisdictions, telemedicine has been practised for many years and appears to be relatively common. The relevant regulation is still evolving as new applications of telemedicine bring new risks and challenges which regulators aim to address.

Emerging Themes from a Consultative Forum

On the 13th October 2020 a consultative forum was convened over Zoom with invited representatives from varying fields of medicine. The group informed the Telemedicine Working Group of their experiences of the use and importance of telemedicine, particularly given its increased use during the COVID pandemic.

Emerging themes from the consultative forum were categorised into 4 main areas:

- Education;
- Patient safety and confidentiality;
- Framework for telemedicine;
- Legal landscape in telemedicine.

The salient points relevant to each category were noted and these are detailed below.

Education:

- More difficult for a doctor to make a connection and show empathy with a patient in a telemedicine consultation;
- Web-side manner is very different to bed-side manner and a framework is needed to learn new skills and support doctors;
- Pitfalls for doctors that have not been properly trained in video consultations;
- Telemedicine is a tool and it needs to be used correctly;
- We should be facilitating appropriate integration of telemedicine into patient care;
- While Attend Anywhere[1] works very well , no formal training has been provided in its use. This could be a concern and those who are reluctant to use the technology are more likely to be at risk;
- Education and infrastructure within telemedicine consultation is important.

Patient safety and confidentiality:

- More difficult to make a connection and show empathy with a patient in a telemedicine consultation;
- Telemedicine brings confidentiality issues - Need to adhere to best practice concerning safety, cautioning that you can't guarantee a telemedicine consult cannot be heard just by the patient alone (there may be others in the room);

[1] Attend Anywhere is a web-based platform for virtual clinics, that offers a secure private online waiting area for patients and provides video and audio conferencing, screen sharing and messaging during clinical consultations (HSE, 2020)

- Technical issues could be a reason for a complaint, for example a signal drop or lag could increase risk of misinformation;
- There have been patients prescribed medications that may not have been prescribed if they had been seen face to face;
- GPs are safety-netting a lot;
- Web-side manner is very different to bed-side manner and a framework is needed to learn new skills and support doctors;
- New private patients are a challenge as they often don't see a phone consult as a consult and are therefore reluctant to pay for it.

Framework for telemedicine:

- Consider operating a framework of telemedicine such as in Ontario – with local community hubs and registered offices that can be governed appropriately and utilized by referring physicians and sub-specialists;
- We should be endorsing an electronic medical record in Ireland;
- We should be endorsing a national unique identifier in Ireland;
- We should be facilitating appropriate integration of telemedicine into patient care;
- No point in re-inventing the wheel, we can learn from the United Kingdom (UK), colleagues in Ontario and Australia, where e-records, unique identifiers and telemedicine are in use and is seen as the norm;
- Roll-out is highly contingent on infrastructure and how information moves within a system;
- Telemedicine is a tool and we need to see where it sits in the architecture of medicine. Infrastructure is so important;
- Telemedicine is here to stay and we need to keep pace with it.

Legal Landscape in telemedicine:

- A lack of clarity from legal perspective where the law has not kept abreast of the rapid changes with regard to electronic prescribing, noting it is a grey area when it comes to scheduled 2 and 3 drugs
- The law has not kept pace with the post-COVID environment, as a regulator we should advocate that the Department of Health keeps pace with legal requirements regarding e-prescribing

Public opinions research

Public opinion research, commissioned by the Medical Council before the introduction of the first set of COVID-19 public health restrictions (February/March 2020), was undertaken by Behaviour & Attitudes (B&A), an independent Market Research company. Follow-up research took place in October 2020.

February/March 2020 Research

The first set of research involved fieldwork carried out between 27th February – 10th March as part of one of B&A's face-to-face Barometer (Omnibus) surveys. Overall, 1,016 adults aged 16+ were interviewed in-home, face-to-face, with the sample population-representative in terms of gender, age, social class and region.

The findings showed that only 4% of respondents had ever engaged with a telemedicine service, the majority with a doctor as opposed to a nurse or other healthcare provider.

The use of telemedicine was primarily in the context of obtaining a repeat prescription (particularly female and younger participants) or in the event of a cold or flu diagnosis (particularly male and younger participants). Failure to get an appointment with a GP was more likely to prompt or mobilize older and particularly female patients to choose telemedicine. A substantial number of younger adults reported that they might consider the use of telemedicine where they needed to obtain a sick note.

For those who had availed of telemedicine, it was largely in the context of a repeat prescription, or in cases of cold & flu. Users of telemedicine tended to have become relatively frequent users of the service, with an average of about two and a half times over the past year noted.

3 out of 4 were prescribed medicine with about half mentioning antibiotics. Benzodiazepines or sleep medicines were prescribed to 15% while 18% were prescribed painkillers. It should be noted that these numbers are from a low base cohort of 35 respondents and so are comparatively low to the larger study cohort.

Most respondents (92%) who had used telemedicine believed that the service they accessed was based in Ireland. Just 15% suggested that they checked the Medical Council's website to see if the doctor they had interacted with was on the register.

October 2020 Research

In light of the changes brought about by COVID-19, particularly in relation to the public's ability to visit and consult with their doctors, it was decided to update the telemedicine-related aspect of this study in October 2020.

As a result of the escalation of restrictions on movement beyond Level 2/3, it was necessary to undertake this second element of research online, rather than face-to-face. As with the Spring survey, the sample involves a nationally representative survey of just under 1,000 adults aged 16 and over, and using identical gender, age, social class, region and area of residence quotas.

There was a five-fold increase in use of telemedicine since the start of the lockdown in March. 21% of respondents reported having used it compared to just 4% in March. Separate research conducted by B&A in September 2020 had this figure at 19% (IPU &IPHA, September 2020). Most respondents reported accessing telemedicine by telephone, with relatively smaller numbers using video-delivered alternatives.

The use of telemedicine was substantially elevated between 25 - 50 year olds, among middle class adults and those living in Dublin and Leinster. There was no notable gender difference. Other studies have highlighted that patients in their 20s and 30s were more anxious about attending telemedicine? appointments than older adults (IPU & IPHA, September 2020). There was a greater likelihood of older adults (Age 50+) having used telemedicine to access their regular GP or specialist, while younger patients appeared to have primarily used telephone/video call services operated by medical insurers.

The reasons reported for using telemedicine have changed substantially in recent months. Telemedicine reported to be used by 3 in 10 respondents to access a regular medical consultation. Older and female patients were more likely to avail of telemedicine for repeat prescriptions whereas younger patients appeared to be integrating it into their everyday GP engagement more readily (i.e: for colds and flu, to get a sicknote etc.) A fifth of those who reported to avail of telemedicine say it was for a COVID-19 referral/consultation.

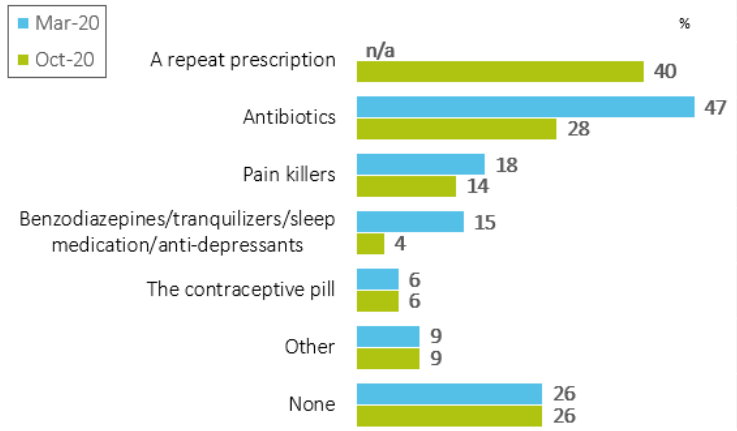
1 in 6 respondents indicated that they used telemedicine because they could not get an appointment with their regular GP. However, the number of respondents indicating that they visit their GP frequently are notably reduced since March. Most respondents suggested that they have only used telemedicine on a limited basis: few are multiple or more frequent users. Nonetheless, most indicated that they would continue to use telemedicine more frequently in the future and for many it would appear to broadly address their needs, although just a third indicate that it 'meets my care needs'. Four out of five said that they are satisfied with the telemedicine service they have used, with slightly more tentative responses by men, those living in Dublin and to an extent the Leinster region.

The majority of respondents suggested that they are likely to use telemedicine more frequently in the future (55%), with a fifth (21%) saying that they are unlikely to. Those who say that they are less likely to be frequent users tend to be elderly, from less affluent backgrounds and female more so than male.

Prescriptions

More than 7 in 10 (72%) were prescribed medication via telemedicine consultation, with non-prescription much more likely in the younger cohort (Figure 2). Repeat prescriptions were the most common requirement followed by antibiotics and painkillers. Being prescribed anti-depressants online occurred at a relatively low level.

FIGURE 2. *WERE YOU PRESCRIBED MEDICATION?*

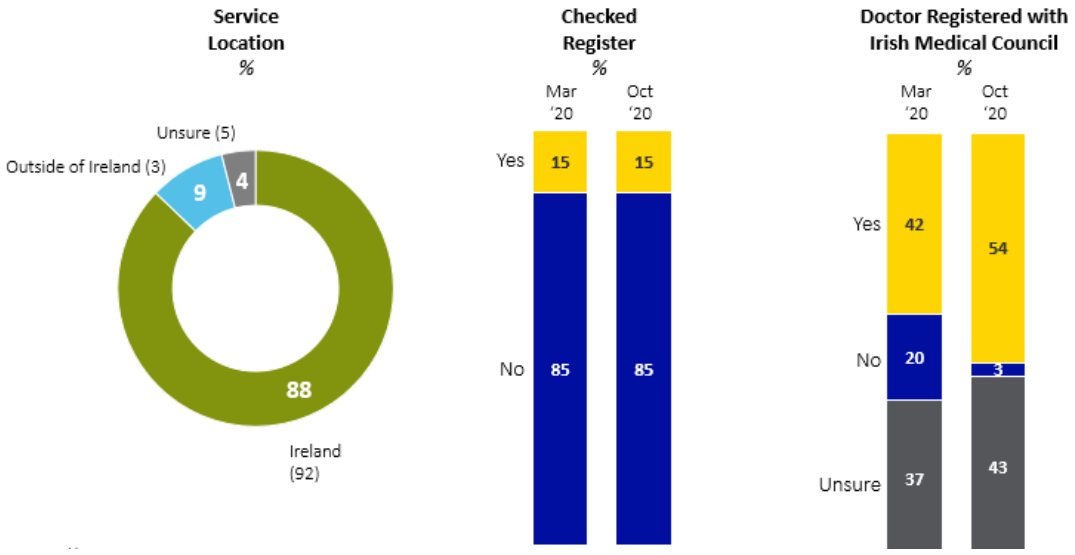


	Gender		Age				Social Class	
	Male	Female	U35	35-49	50-64	65+	ABC1F	C2DE
	101	*117*	*71*	*80*	*46*	*21*	*127*	*91*
	%	%	%	%	%	%	%	%
A repeat prescription	35	44	27	38	51	63	37	43
Antibiotics	22	33	34	29	30	8	26	30
Pain killers	20	9	12	16	20	7	10	20
Benzodiazepines/tranquilizers/sleep medication/anti-depressants	4	3	5	5	2	-	2	6
The contraceptive pill	2	10	12	6	-	-	8	4
Other	10	8	6	11	12	9	10	8
None	32	20	34	26	13	20	26	25

Location of doctor

The vast majority of respondents who used telemedicine indicated that the GP they consulted was based in Ireland (Figure 3), although a low proportion actually checked this. Of those who did check, most satisfied themselves that the GP was registered with the Irish Medical Council.

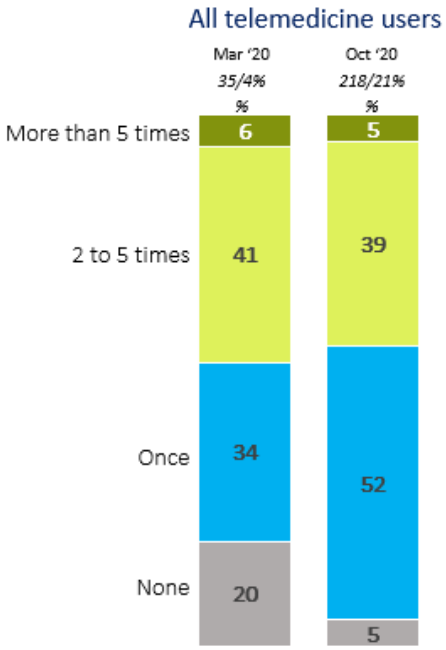
FIGURE 3. *GPS FROM IRISH MEDICAL COUNCIL REGISTER?*



Number of times telemedicine used in past year

Almost five times as many respondents used telemedicine by October 2020 than was the case in March 2020 (Figure 4). For most however, they have consulted once, with about 2 in 5 having done so more frequently.

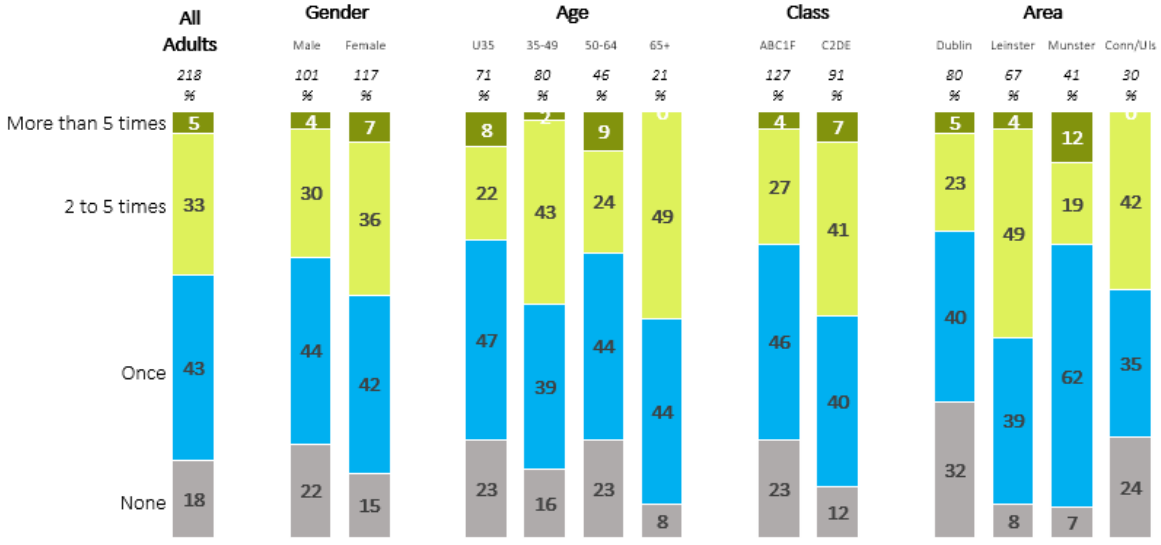
FIGURE 4. *NO. OF TIMES ACCESSED TELEMEDICINE SERVICES IN PAST YEAR X DEMOGRAPHICS?*



		Demographics			
		More than 5 times	2 to 5 times	Once	None
Male	%	3	40	50	7
Female	%	6	38	53	3
U35	%	7	28	57	8
35-49	%	2	46	48	4
50-64	%	5	37	52	6
65+	%	6	47	47	-
ABC1F	%	3	37	53	6
C2DE	%	6	41	50	3
Dublin	%	2	29	60	9
R.Leinster	%	4	53	42	1
Munster	%	10	30	60	-
Conn/Uls	%	5	43	43	9

As before, most respondents indicated that they have used telemedicine only once, but about 1 in 3 have been more frequent users (Figure 5). These more frequent users tended to have been more concentrated in middle age and working class rather than middle class.

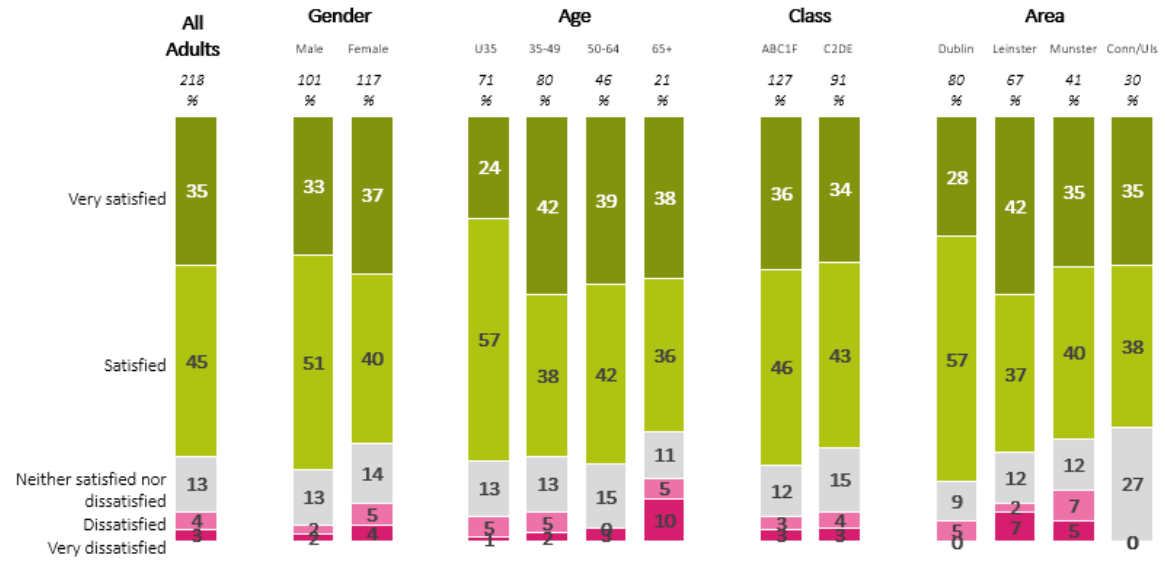
FIGURE 5. *NO. OF TIMES ACCESSED TELEMEDICINE SERVICES SINCE COVID X DEMOGRAPHICS?*



Satisfaction rates with telemedicine

Satisfaction with telemedicine services was broadly high amongst women and older adults (Figure 6). Notably those outside of Dublin tended to have been broadly happier with telemedicine services. There is no notable difference between social class, but those who were disappointed tended to have been older, working class and not in the Dublin region. Nonetheless levels of dissatisfaction are low.

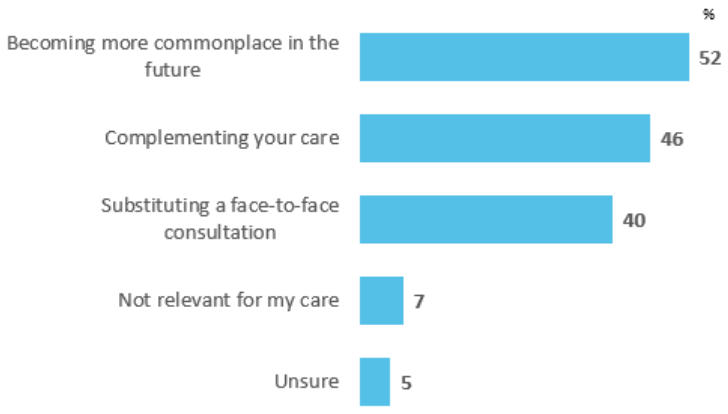
FIGURE 6. *SATISFACTION WITH TELEMEDICINE SERVICES X DEMOGRAPHICS*



Attitudes to telemedicine and perceived benefits

Those who used telemedicine were very likely to regard it as something that was likely to grow in the future, as potentially complementing their care (Figure 7). For two in five respondents, it was thought that it may substitute for a face-to-face consultation.

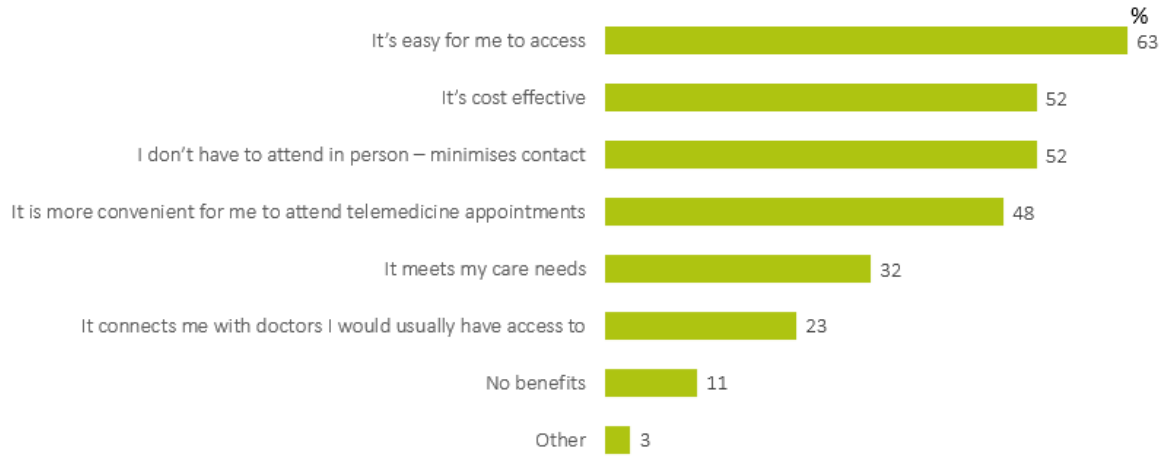
FIGURE 7. *ATTITUDES TO TELEMEDICINE*



Gender		Age				Social Class	
Male	Female	U35	35-49	50-64	65+	ABC1F	C2DE
101	*117*	*71*	*80*	*46*	*21*	*127*	*91*
%	%	%	%	%	%	%	%
52	53	43	55	53	66	52	53
54	39	52	45	35	48	54	35
40	39	42	36	42	43	33	48
5	9	5	9	8	4	6	7
3	7	6	4	4	7	6	4

Perspectives of telemedicine were broadly very positive, with up to half expressing that they were happy that they did not have to attend a particular practice. Half of respondents indicated that telemedicine was more convenient for them. However, only 1 in 3 agreed that it necessarily met their care needs. For 1 in 4, it connected them to doctors that they wouldn't otherwise have been able to access (Figure 8).

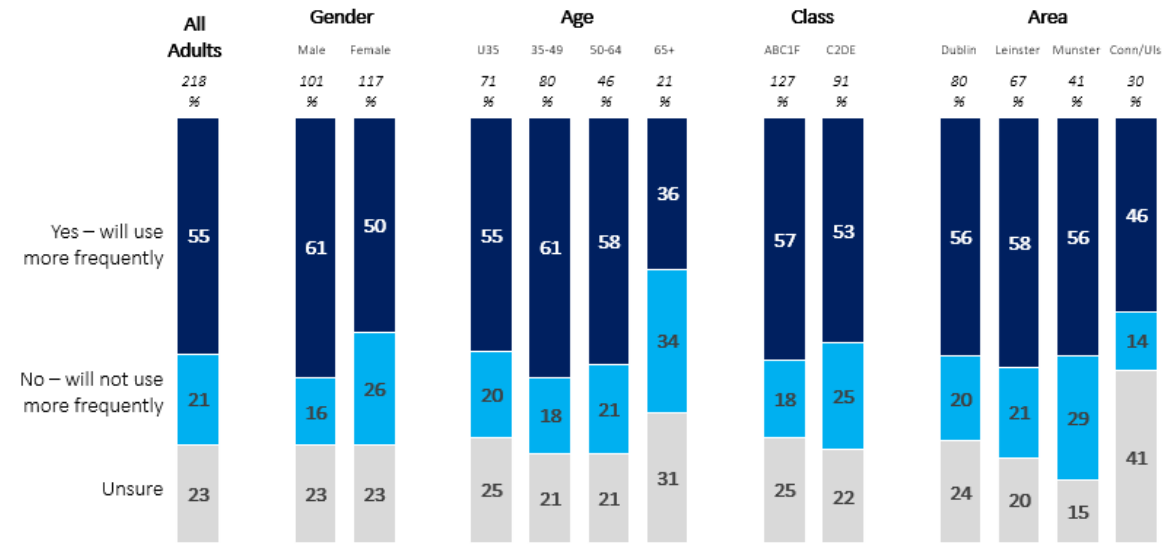
FIGURE 8. *BENEFITS EXPERIENCED IN A TELEMEDICINE CONSULTATION*



Older patients were more likely to be critical of telemedicine, placing less value on convenience or the perceived cost-effectiveness. Ease of access appeared to be less of a driver for them too. Younger patients tended to note a greater breadth of benefit.

The vast majority indicated that they were likely to use telemedicine more frequently in the future, with older adults somewhat more uncertain overall (Figure 9).

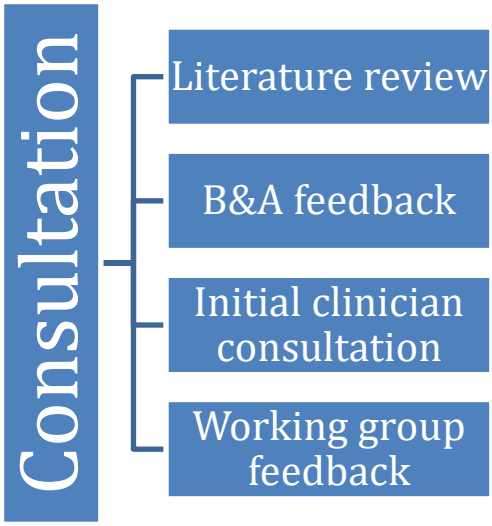
FIGURE 9. *TELEMEDICINE: FUTURE INTENTION X DEMOGRAPHICS*



Stakeholder consultation

In order to inform the Working Group and build a picture of stakeholder perspectives on telemedicine, a consultation process was undertaken informed by the principles outlined in the Consultation Principles & Guidance (2016) document. This took the form of a survey, using a mixed methods approach, including quantitative and qualitative data collection opportunities to maximise capture of relevant stakeholder perspectives. The survey was informed by a number of sources, outlined in figure 10.

FIGURE 10. *CONSULTATION PROCESS- DATA SOURCES INFORMING SURVEY DEVELOPMENT*



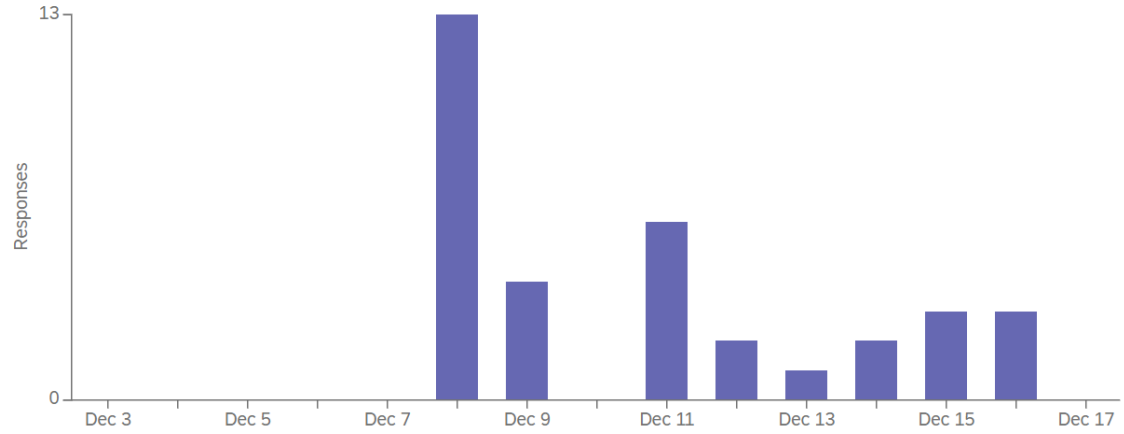
Method

In total 85 key stakeholders were identified. These included:

- Postgraduate training bodies;
- Working group members;
- Patient advocacy groups;
- The Mental Health Commission;
- The Data Protection Commissioner;
- The Pharmaceutical Society of Ireland.

The survey issued on Tuesday 8th December, with a listed closing date of the 14th December. However, to capture as many responses as possible, and to allow for additional responses, the survey remained open and data was drawn down on Friday 17th December. The survey was hosted online by Qualtrics, with qualitative/quantitative response options available.

FIGURE 11. *RESPONSE PATTERNS OBSERVED BETWEEN THE 8TH AND 17TH OF DECEMBER 2020*

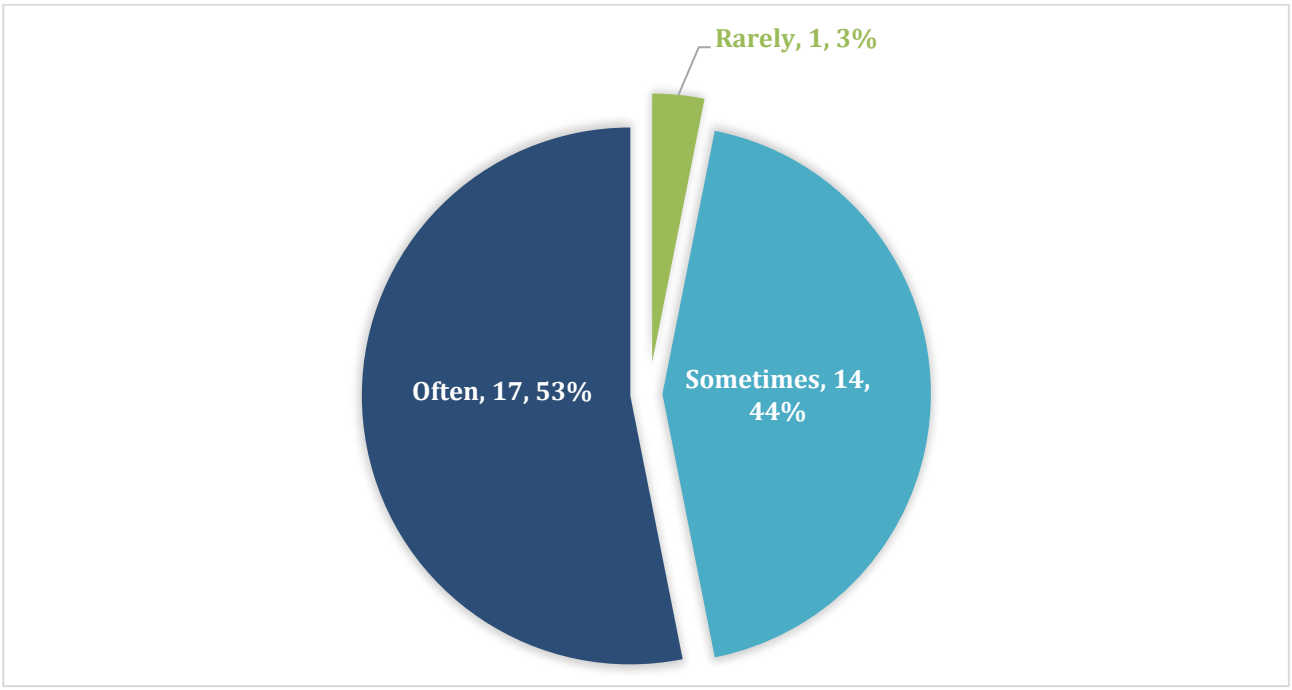


In total, there were 32 respondents, representing a 37.6% response rate. The survey had an 83% completion rate for all of those who started the survey.

Results

When surveyed, the majority of respondents (97%) felt that telemedicine sometimes or often met the care needs of patients.

FIGURE 12. *IN YOUR OPINION, HOW OFTEN DOES TELEMEDICINE MEET THE CARE NEEDS OF PATIENTS?*



In response to this question, 18 qualitative answers were additionally received. It was noted that, as in the quantitative data, telemedicine did not always meet the care needs of patients. It was often a cursory or transactional step in care.

Feedback reflected that face-to-face consultation is important in doctor-patient communication. It was noted that elements of traditional face-to-face communication in a telemedicine consultation are absent, providing challenges in interactions in practice.

Follow-up face-to-face consultations were reported as being required in some instances following a telemedicine consultation. While physical examination was an important element of the face-to-face interaction, dealing with issues that the patient may deem private or sensitive was not perceived as always appropriately attended to via telemedicine. History taking and its importance was emphasized by two respondents.

One respondent reported that effectiveness is determined by patient need, complexity and context matched to appropriate telemedicine methodology. Respondents noted, in particular, how telemedicine could meet the needs of patients with chronic conditions.

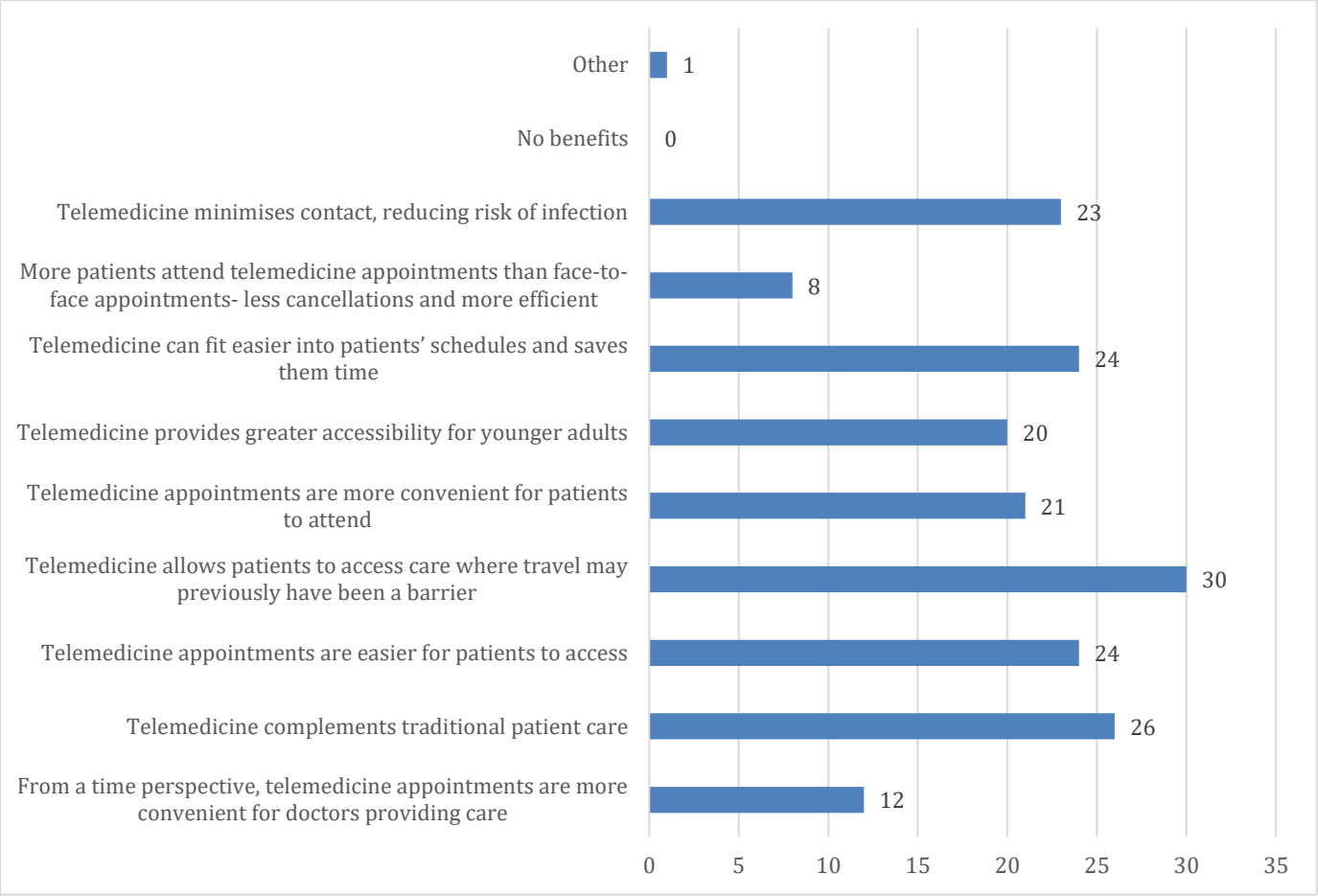
Telemedicine was also reported to be suited to follow-up and outpatient appointments for patients that had to travel a prohibitive distance.

Two respondents focused on the role of telemedicine in the practice of medicine and noted that it is a tool in supporting patient care, or an adjunct to traditional treatment. It was also noted that this is a method used broadly internationally and that reflecting on the experience on more established practice internationally would be beneficial.

Only one respondent expressed feeling that there was no difference between telemedicine consultations and a traditional, face-to-face consultation. Its acceptability to patients currently was also reported by one respondent to be borne out of necessity rather than patient preference or demand.

Stakeholders were also asked about the benefits of telemedicine that they perceived, drawn from the literature search, working group feedback and initial clinician consultation online. The most commonly agreed-with benefit (by 94% of respondents) was that telemedicine allows patients to access care where travel may previously have been a barrier. All statements and number of respondents that agreed with these is described below on figure 13.

FIGURE 13. Q2 - WHAT ARE THE BENEFITS THAT YOU PERCEIVE OF TELEMEDICINE IN IRELAND? PLEASE SELECT ALL THAT APPLY:



One participant chose the "other" option and noted that *"telemedicine offers potential for maximising utilisation of doctors resource eg Patient living in Dublin can assess a registered doctor in Donegal, Kerry indeed UK.",* somewhat in line with the previously mentioned item regarding patient access to care where travel was previously a barrier.

Eleven participants also responded with qualitative feedback to expand on the above, clarify, question and also balance out the proffered benefits with challenges met in practice.

Two respondents also clarified that they felt that as in question one, telemedicine and its suitability was dependent on the patient, the context, their care needs and other factors, so not always suitable.

Conclusions

Through consultation, it was identified by participants that a comprehensive approach was needed to inform the group, examining multiple stakeholder perspectives and systemic issues. Participants described telemedicine as a tool in supporting patient care, or an adjunct to traditional treatment. It was often a cursory step in care, but suited to patients with chronic conditions, review consultations and communicating results. However, the suitability of telemedicine was dependent on the patient, the context, their care needs and other factors. It was also noted that this is a method used broadly internationally and that reflecting on the experience on more established practice

internationally would be beneficial. Participants also described the acceleration of telemedicine use for pragmatic reasons with the onset of the pandemic, indicating that the current picture of pandemic pressures and telemedicine are often inextricable.

Key findings included:

When surveyed, almost all respondents (97%) felt that telemedicine sometimes or often met the care needs of patients. Stakeholders also agreed (94% of respondents) that telemedicine allows patients to access care where travel may previously have been a barrier. Challenges in diagnosing and prescribing via telemedicine emerged as the most frequently agreed with challenge presented by telemedicine (30 of 32 respondents, 94%).

97% of respondents agreed that it presented a new way of working with clinical colleagues and teams that are geographically distant. The area of flexibility in terms of both working options for some doctors and delivery of care was also agreed with by 81.3% of respondents.

The majority of respondents (81.3%) agreed, 6.3% disagreed and 12.5% were undecided with regard to the statement: “A national electronic medical record would support the success of safe telemedicine integrating with regular care”. Similarly, the majority of respondents (84.4%) agreed, 9.4% disagreed and 6.3% were undecided with regard to the statement: “A national unique health identifier would support the success of safe telemedicine integrating with regular care”.

Following this, consultation participants were asked, in their opinion, what is needed to fully integrate telemedicine into safe and effective healthcare in Ireland? In total 28 respondents (87.5%) respectively agreed that this would require a strong governance framework overarching care delivery and doctor education and training to learn new skills in engaging effectively in telemedicine consultations. Additionally, 27 respondents (84.4%) agreed that identifying areas where telemedicine is appropriately positioned within the practice of medicine and employer support (where appropriate) in telemedicine service provision would be required.

When given the opportunity to expand on quantitative answers, stakeholders took the opportunity to describe some of the challenges experienced, benefits and opportunities presented by telemedicine in Ireland. Areas explored focused on communications; lack of physical examination; prescribing; doctor work burden and fatigue; patient perceptions of telemedicine as care; practical challenges; education and regulation.

Communication

Feedback reflected that the face-to-face element in consultations is important in doctor-patient communication. It was noted that elements of traditional face-to-face communication in a telemedicine consultation are absent, providing challenges in interactions in practice. While physical examination was an important element of the face-to-face interaction, dealing with issues that the patient may deem private or sensitive were not perceived as always appropriately attended to via telemedicine. Quality, accurate patient history taking, and its importance was also emphasized.

Lack of physical examination

The lack of physical examination in a telemedicine consultation and support was also noted as an area for regulatory concern and risk, especially with potential for misdiagnosis and associated complaints.

Prescribing

Prescribing was cited by respondents as an area of high-risk in telemedicine practice, with stakeholders noting changes in practice now being mismatched with legislation, while technology such as electronic patient records is not operationalised to support appropriately. The model of prescribing and the associated legislation both presented difficulties in the context of telemedicine. Doctors in private practice were raised as an area of concern, in particular in the area of safe and appropriate prescribing. A suggestion is proffered involving a ban from Council on advertising by such providers.

Doctor work burden and fatigue

Many qualitative responses related to the additional work and time-consuming nature of engaging with patients through telemedicine with additional administration, scheduling and follow-up work. While the literature examined noted efficiencies of telemedicine, this was not a feature of telemedicine as experienced by participants. A difficulty in concentration when practicing telemedicine and fatigue was noted in responses received. Participants described how challenging and tiring practising telemedicine is and how this is not how they previously practiced or intended initially to primarily practice. This was noted to be broader than just the experience of doctors but across other healthcare professionals. It was reported that there is also a level of personal preference and practice suitability to telemedicine, with varying levels of impact on operation.

Patient perceptions of telemedicine as care

Telemedicine acceptability to patients was reported by one respondent to be borne out of necessity rather than patient preference or demand. There was also a perceived sense that some patients were less likely to view a telemedicine appointment in the same way as a face-to-face appointment. Respondents emphasised the potential for patient autonomy in terms of consultation meeting times and self-management of chronic conditions, with doctors, their colleagues and patients working together. Any time saving efficiencies that may be garnered were noted to be likely on the part of the patient rather than the doctor. While confidentiality was an issue in a number of responses across the consultation, a respondent noted the emergence of a new generation of patients who are digitally native, less comfortable with the process of engaging in a clinic face-to-face and comfortable with engaging via telemedicine.

Practical challenges

There were challenges reported with technology, connectivity, access and associated administration. The need for practical technological resources to support this, in particular broadband and Wi-Fi were described as necessary going forward. The platform used in telemedicine consultations was one that raised concern. There was uncertainty as to the lack of standardisation currently and the potential for communication and confidentiality issues that this raised. The institution of a single, common platform to address the concerns raised was suggested to respond to this. Electronic health records and national unique health identifiers were also described at having the potential to support safe regular care and telemedicine, along with minimising duplication and resources. Confidentiality and the ethics of this were also raised as potential challenges in operationalising both electronic health records and unique health identifiers. The interoperability of pre-existing systems was alternatively suggested. Additionally, the issue of guidance for both doctors and patients was raised by respondents, which has already been addressed by the group.

Education

Respondents noted that there is learning required systemically to respond effectively to change in practice driven by the rapid acceleration in use of telemedicine, but that this was possible and may lead to benefits across practice. The theme of appropriate education and training in a new era of telemedicine practice was also raised. The current context of practice and limited learning opportunities for junior doctors were also queried. For those pre-specialist registration, particular attention was also described as necessary. Doctors presenting their Medical Council Number was suggested as a potential act of good practice. It was suggested that there would be much to learn for the Medical Council in responding to the challenges that telemedicine would present. In dealing with complaints, the regulator would meet challenges due to a lack of experience and evidence base.

Regulation

The issue of telemedicine regulation across jurisdictions was also of concern to a number of respondents. Regulation of doctors in private practice in this context was also raised. The validation of registration and education and training across jurisdictions was an associated concern in terms of professional regulation across the spectrum of healthcare practitioners, while it was noted that guidance was required for health technology devices more broadly. The limitations of indemnity and current regulatory flexibility beyond the bounds of the pandemic were queried by respondents. It was suggested that greater legal protection would be required going forward. Associated ethical concerns including support persons to patients in consultations, empathy in communications and protection of children and vulnerable people were also raised as issues to be considered by the regulator. This highlights the complexity of the issues at hand.

These key themes expand on the literature examined and provide an insight into the experience of stakeholders in Ireland in the context of telemedicine acceleration and delivery in a pandemic. While this may not be reflective of all stakeholder experience and the context of practice post-pandemic, it provides insights into some of the challenges and opportunities presented currently. Investigating this and providing leadership was very much appreciated by stakeholders as expressed in feedback, and further developments to support doctors and protect patients would be welcomed in the same vein.

Regulation & legal framework

Challenges in regulating telemedicine

The Telemedicine Working Group sought legal advice in relation to telemedicine services and in particular, in relation to the Medical Council's registration requirements in respect of medical practitioners providing telemedicine services. Set out below is a summary of the relevant EU and Irish legislation. In addition, preliminary regulatory advices including the identification of potential risks associated with the Council's current registration practice and proposed steps to resolve these risks are also provided.

Under Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, doctors providing telemedicine services are considered to be providing services in the EU Member State in which they are established. Such doctors are required to comply with the legislation, including the regulatory requirements, of that Member State only. The Irish implementing legislation has only partially transposed the Directive's provisions on telemedicine. This has resulted in a lacuna in the law in Ireland in relation to telemedicine services. This lacuna has given rise to the Medical Council's current registration practice which advises that medical practitioners providing telemedicine services to patients in the State should register with the Council in order to maintain public confidence in the profession.

If the Directive was held to have direct effect, its provisions would apply in place of the lacuna in the law. This could result in the Council's registration practice being contrary to the applicable law in Ireland as the Directive would be the applicable law. While the Directive provides that the provisions on telemedicine will have a broader scope of application, they have only been transposed in Ireland in the context of the reimbursement of cost of treatment. The Implementing Regulations therefore do not give full effect to the Directive.

The Medical Practitioners Act 2007 provides generally for the registration of medical practitioners in Ireland. Section 37 provides that an unregistered medical practitioner shall not

a) practice medicine or

b) advertise the practitioner's services as a medical practitioner

To "practise medicine" is defined in Section 2 of the Act as "to engage in the practice of medicine". Accordingly, the 2007 Act imposes a broad obligation on any doctor who engages in the practice of medicine to register with the Council.

The *Guide to Professional Conduct and Ethics* sets out the Council's current registration practice and provides that "if you provide telemedicine services to patients within the State, you should be registered with the Medical Council. This is to maintain public confidence in telemedicine."

It is not clear from the language in the Guide whether it is the medical practitioner and/or the patient(s) which should be within the State for the registration policy to be applicable. It appears that current issue of the Guide may not be compatible with the spirit of the Directive and EU law.

Regulation of individual doctors who provide telemedicine services

Doctors providing telemedicine services can be categorized as follows:

- Doctors providing telemedicine services in Ireland to patients in Ireland
- Doctors providing telemedicine services from Ireland to patients in the EU or patients based in third countries
- Doctors who are based in the EU providing telemedicine services to patients in Ireland, but who are established in another EU Member State
- Doctors who are based in third countries and are providing telemedicine services to patients in Ireland

Doctors providing telemedicine services in Ireland to patients in Ireland.

It is clear that where a doctor is providing telemedicine services in the State to patients in Ireland that this doctor is engaged in the practice of medicine under the Act and must be registered with the Council.

Doctors providing telemedicine services from Ireland to patients in the EU.

In terms of EU law, the Directive provides that "in the case of telemedicine, healthcare is considered to be provided in the Member State in which the healthcare provider is established". The "Member State of treatment" for telemedicine services is therefore, the Member State in which the healthcare provider is established. Therefore, where a doctor is providing telemedicine services to patients in the EU from Ireland the doctor must be registered with the Medical Council.

Doctors providing telemedicine services from Ireland to patients in third countries.

In terms of doctors providing telemedicine services from Ireland to patients overseas, this is an issue that has recently arisen in respect of a doctor from the United States who made an enquiry in relation to whether they required registration to provide telemedicine services to patients in the United States while the doctor living in Dublin for a period. The advice, based on analysis of the Act, was that the doctor should be advised to register with the Council taking into account the relevant legislative provisions in the Act. Specifically, section 37 of the Act provides that an unregistered medical practitioner shall not

(a) practise medicine, or

(b) advertise the practitioner's services as a medical practitioner.

The issue which arises is that section 37 of the Act is drafted in very broad terms. Therefore, the safest position legally is to advise doctors in this category to register with the Council. It was noted from the legal advice, that Council may wish to consider from a policy perspective whether this is the best approach.

Doctors based in EU Members States providing telemedicine services to patients in Ireland.

Where doctors are practising medicine in other EU Members States and providing telemedicine services to patients in Ireland, for the purposes of the Directive the healthcare is considered to be provided in the Member State in which they are established. So, if a doctor is proving telemedicine

services from France to a patient in Ireland, then the doctor is established in France and regulated by the French regulatory authorities. Due to the fact the Directive has not been implemented correctly in Ireland there is currently a lacuna in Irish law. The Guide currently provides that "if you provide telemedicine services to patients within the State, you should be registered with the Medical Council. This is to maintain public confidence in telemedicine."

While the Council does not require a doctor, who is established in another Member State and providing telemedicine services in Ireland to register with the Council, telling a doctor that they should register may create some risks from a legal and policy perspective. Furthermore, if the provisions of the Directive were held to have direct effect, its provisions would apply over and above the national legislation. This could result in the Council's registration practice being contrary to the applicable law in Ireland as the Directive would be the applicable law. It could be relied upon by a doctor challenging the Council's decision that such a doctor should be registered with the Council.

In circumstances where doctors are being told they should register, this may mean that certain doctors may chose not to register, while others chose to register. This could lead to an inconsistency of approach in terms of the registration of such doctors. The Medical Council needs to consider its registration practices from a policy perspective taking into account issues such as patient safety and the public confidence, together with the ability of the Council to take regulatory action in relation to doctors based outside of the jurisdiction in terms of fitness to practise and maintenance of professional competence.

Doctors who are based in third countries and are providing telemedicine services to patients in Ireland

To date, the Medical Council has not received many enquiries from doctors based in countries outside the EU in relation to the provision of telemedicine services in Ireland.

Council may want to consider applying the approach as set out in the Guide to Professional Conduct and Ethics, which would be to tell such doctors that they should register, or Council may want to take a different approach. This is a legal and policy issue that the Council shall have to consider.

The issue that requires consideration is (i) whether the Council could require doctors providing telemedicine services to patients in Ireland to register with the Council, taking into account the broad definition of "practise medicine" in the Act or (ii) whether the Council lacks the jurisdiction to require such doctors to register in circumstances where such doctors are not located in the State. This position is currently unclear under the Act. Furthermore, the issue of third countries is potentially more complicated than the EU position where there is no uniform approach among countries to the issue and in circumstances where the standards and practices of training vary among third countries.

BREXIT

The Minister for Health amended the Medicinal Products (Prescription and Control of Supply) Regulations 2003 (as amended), to enable the recognition of prescriptions written in the UK by registered medical practitioners, registered dentists and registered nurse prescribers, including midwife prescribers, for dispensing in the State. The Regulations came into effect on 1 January 2021.

The prescription must meet the same legal requirements, as those already in place for a prescription issued by a relevant practitioner practicing in another EEA state. The original prescription must be presented in the pharmacy. A fax or scanned copy of a prescription is not a legally valid prescription. This will be on the provision that the prescription has not been issued with a view to enabling the supply of a medicine by mail order and the prescription has not been issued by means of information society services.

Medicinal Products (Prescription and Control of Supply) (Amendment) (No. 6) Regulations 2020

With the United Kingdom's exit from the EU and the ending of the transition period on 31 December 2020, there have been changes to the legality of prescriptions written by online doctors based in the UK.

As mentioned, amendments to the Medicinal Products (Prescription and Control of Supply) Regulations published by the Department of Health (S.I. No. 614 of 2020) enable the continued recognition of hard copies of medical prescriptions written by doctors, dentists and nurse prescribers based in the United Kingdom; however online prescriptions or prescriptions written by UK-based prescribers for the purposes of enabling mail order supply issued to people living in Ireland are no longer valid.

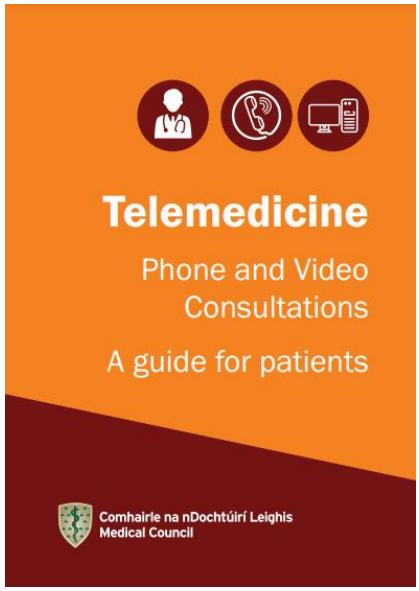
The regulations prevent prescriptions being issued by information society services (ISS) or cross-border telemedicine services, based in the UK or other third countries. Therefore, if a teleconsultation is carried out by a UK-based doctor for a patient living in Ireland as part of a telemedicine service (even if accessed through an Irish website), neither a digital nor a physical prescription will be acceptable.

The current Brexit deal covers trade, not services, and a teleconsultation was regarded as a service with a third country.

Guides to Telemedicine for doctors and patients

The impact of COVID-19 has resulted in the rapid growth in the use of telemedicine in patient care.

The Working Group identified the challenges that patients may face when engaging in a telemedicine consultation. It was recognised that the shift to delivering patient care via telemedicine came almost overnight and that a guide for patients and doctors would be necessary.



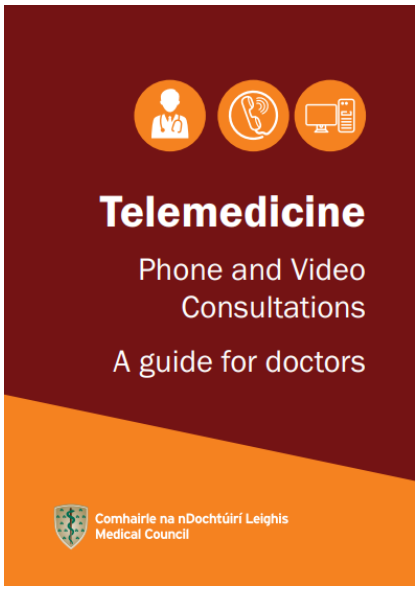
Guide for patients

The Working Group, supported and endorsed by the Medical Council, produced a guide to help patients understand what is involved in a telemedicine consultation. It explains how such consultations work, what they can expect from a telemedicine consultation with a doctor and what patients can do in preparation for the consultation to help ensure the doctor can provide the appropriate care.

Guide for doctors

Many doctors already use some form of information and communications technology when providing care. An increased shift towards telemedicine since the start of the COVID-19 pandemic has meant doctors have had to adapt to a new way of working.

The impact of COVID-19 has meant that telemedicine has now become an integral part of medicine. Telemedicine can help patients who are vulnerable receive necessary care, provide patients with more convenient access to care, ease of access for those in isolated locations, allow for more comprehensive delivery of services after-hours and allow for more efficient use of limited health resources. Telemedicine is particularly useful when it is part of an existing system for providing patient care.



In response to this, the Medical Council released an online resource for medical practitioners on telemedicine. The guide, which is available on the Medical Council's website, contains information and practical advice for doctors who now utilise telemedicine systems for a large number of their consultations.

Recommendations

Registration and Regulation

- It is recommended that the Medical Council should, via its Ethics Committee, give consideration to reviewing the current guidance on Telemedicine and highlight that telemedicine consultations must meet the same ethical standards as traditional face-to-face consultations.
- It is recommended that the Medical Council should, via its Registration and Professional Competence Committee, examine this report and liaise with key stakeholders to address regulatory actions identified in this report to enhance patient safety around telemedicine.
- The Medical Council should review its registration practices from a legal and policy perspective in relation to the issues identified in respect of the different categories of doctors who provide telemedicine services. Doctors providing telemedicine services can be categorized as follows:
    - Doctors providing telemedicine services in Ireland to patients in Ireland
    - Doctors providing telemedicine services from Ireland to patients in the EU or patients based in third countries
    - Doctors who are based in the EU providing telemedicine services to patients in Ireland, but who are established in another EU Member State
    - Doctors who are based in third countries and are providing telemedicine services to patients in Ireland
- The Medical Council should, in developing its policy, engage with other healthcare regulators and organisations to ensure there is a consistency of approach as regards the development of telemedicine policies in Ireland. This could include for example the establishment of a group of healthcare regulators and other health organisations to discuss common themes and issues.

Doctor Education & training

- It is recommended that Postgraduate Training Bodies develop clinical guidelines on telemedicine usage specific to their speciality.
- It is recommended that Postgraduate Training Bodies provide a level of ongoing education and training in the skills required for the use of telemedicine, especially with regard to issues of communication and patient consent.
- It is recommended that Medical Schools assess the extent to which they prepare students for medical practice using telemedicine.

Practice

- It is recommended that certain drugs, such as benzodiazepines, Z-drugs and opioids should only be prescribed via telemedicine in limited situations.

- It is recommended that doctors should clearly provide patients with their name and Medical Council number at the beginning of each telemedicine consultation, especially where no previous relationship exists.

Infrastructure

- It is recommended that telemedicine usage be explored further in the development of the future of healthcare delivery in Ireland, including the use of supported telemedicine consultation hubs at primary care settings to support patients accessing secondary level care with the support of a doctor or nurse to assist with physical examinations.
- The need for electronic records and a unique patient identifier have become more acute during the pandemic and development should be prioritised.

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Appendices

Appendix A

Membership of the Telemedicine Working Group

Mr Paul Harkin - **Chair**

Ms Vicky Blomfield*

Dr Muiris Houston

Dr Erica Maguire**

Dr Mark Murphy***

Mr Joe O'Donovan*

Dr Sinead O'Gorman*

Mr Jim O'Sullivan*

Dr Andree Rochfort*

Dr Patricia Walsh*

*Joined 28th September 2020

**Dr Maguire stepped down 7th September 2020

***Dr Murphy stepped down 8th December 2020

Appendix B

The appendices listed below are available as standalone documents published at the same time as this report and available on the Medical Council website.

- Telemedicine: A systematic search of the literature observing the positive and negative aspects associated with virtual care in 2020 (September 2020) - compiled by the Medical Council Research Team

- Telemedicine – Stakeholder Consultation Report (December 2020) – compiled by the Medical Council Research Team

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