

STATEMENT Regulation and Virtual Healthcare

PURPOSE

- 1. IAMRA's Purpose is to promote effective medical regulation worldwide by supporting best practice, innovation, collaboration and knowledge sharing in the interest of public safety and in support of the medical profession.
- 2. One of IAMRA's strategic goals is, 'creating a global community of medical regulators by expanding IAMRA's membership, partnerships and impact, and increasing value to members.' In support of this goal, IAMRA develops policy statements which may be of assistance to members as they navigate the challenges and competing priorities of regulating the medical profession in their own jurisdiction.

BACKGROUND

- **3.** IAMRA does not promote a particular model of medical regulation, recognising that models are influenced by the structure of the health care system, the legal framework in which regulatory authorities operate and the resources available. Nevertheless, Medical Regulatory Authorities (MRAs) have a shared objective: to protect patients by employing effective regulatory tools to manage risk, to ensure that doctors are fit to practice and to contribute to the provision of high-quality healthcare.
- 4. This statement is a response to the rapid adoption of virtual healthcare as a result of the COVID-19 pandemic. Early in the pandemic, many MRA's found themselves in a position where their existing policies on virtual healthcare/telemedicine were no longer fit for purpose in an environment where such delivery models were widely encouraged and proliferated rapidly. Suddenly, it was necessary to balance historical objections to virtual healthcare with the clear advantages of the model in the circumstances of a serious pandemic.
- **5.** For the purpose of this Statement:
 - Virtual Healthcare is defined as a medical service provided by a registered/licensed doctor to a patient via information and communication technology (text or audio -with or without visual contact) without in-person contact with the patient;
 - *In-person,* is defined to mean that the doctor and patient are physically present in the same location.
- 6. MRAs are encouraged to have a policy that addresses the key regulatory issues arising from the provision of virtual healthcare, recognising that this mode of health service delivery is likely to retain its new-found prominence in many health systems after the pandemic is controlled. Virtual healthcare as a stand-alone, episodic service may not meet expected standards, but if provided as part of an integrated healthcare service in conjunction with in-person healthcare, has the potential to offer patients access and choices otherwise unavailable to them.

GUIDELINES FOR THE DEVELOPMENT OF A VIRTUAL HEALTHCARE POLICY

7. The details of MRAs' policies will vary according to their local laws and practices, but should, as a minimum, address the positive and negative aspects of virtual healthcare and practitioners' legal, professional and ethical obligations in this context. A virtual healthcare policy should address:

a. The primacy of patient safety¹

A policy on virtual healthcare should address the primacy of patient safety and in addition:

- i. may state the importance of balancing the positive and negative aspects of virtual healthcare, recognising that it is another way of providing healthcare, not a distinct service in its own rightⁱ.
- ii. may state the MRA's preference for hybrid (in-person and virtual) healthcare in an integrated service, in which the doctor has, ideally already established an in-person relationship with the patient, with reference to the <u>positive aspects</u> of virtual healthcare including:
 - patient access to health services and convenience;
 - equity in the provision of health services;
 - patient and practitioner safety, particularly in the circumstances of an epidemic where, for example, it is desirable to screen patients' symptoms before having them attend in-person;

and noting that the following risks of virtual healthcare may need to be mitigated:

- limited ability to fully assess the patient, both as a baseline and on an ongoing basis, may result in harm to the patient, particularly if the doctor does not have a physical location which the patient can attend;
- continuity of care may suffer with resultant harm, if patients access unconnected doctors for virtual and in-person health services;
- patients' technology literacy and access to technology may disadvantage them if in-person services are not available;
- the provision of virtual healthcare for patients in a jurisdiction where the doctor is not registered/licensed may impede MRAs' abilities to hold them accountable for the care they provide.
- iii. may require that doctors who are registered/licensed with an MRA and who provide virtual healthcare to patients located in another jurisdiction to:
 - establish, as a professional obligation, whether they are required to be registered in that jurisdiction, as well as any broader requirements such as collaborating with a registered/licensed doctor in the same jurisdiction as the patient;
 - practice according to the standards, codes and guidelines of the MRA with whom they are licensed/registered.

¹ IAMRA's Statement on the Independence of Regulation and the Primacy of Patient Safety concludes: *To the extent that it is possible within the structural and legal framework of the Medical Regulatory Authority, IAMRA supports and encourages all Medical Regulatory Authorities to maintain their independence and make patient safety their primary concern, especially when faced with pressure on the integrity of effective regulation.*

b. Registration/licensure

Doctors providing virtual healthcare should practice according to the registering/licensing MRAs' policies, guidelines, codes and standards, including cooperating with the MRAs' complaints process and may also be expected to:

- i. comply with the registration/licensing requirements of every MRA where their patients are located. This policy provides the most indisputable and binding requirement on doctors practicing virtual healthcareⁱ;
- ii. have and maintain appropriate professional indemnity protection in every jurisdiction where their patients are located.

Alternatively, MRAs should set out in a policy, the circumstances in which registration/licensure is and is not required when doctors, not registered/licensed by the MRA, provide medical services to patients located in the MRA's jurisdiction.

c. Ensuring the standard of virtual healthcare

Doctors providing virtual healthcare should be expected to:

- i. ensure they have sufficient training and competency to provide virtual healthcare;
- ii. ensure the provision of a defined standard of care. When the risks associated with in-person healthcare or the unavailability of in-person healthcare outweigh the risks associated with virtual healthcare, then it may be necessary to define a new standard of care – for example, one that does not require a physical examination of the patient;
- iii. take reasonable steps to ensure that the consultation is provided safely, securely, and privately;
- iv. disclose their identity, location and registration/licensure status to the patient;
- v. take appropriate steps to confirm the identity of the patient using a standard protocol;
- vi. explain in plain language, the appropriateness and limitations of the particular type of virtual healthcare being offered;
- vii. obtain, document and maintain all aspects of informed patient consent, including financial consent and consent for the virtual consultation;
- viii. assess patients' presenting condition and the appropriateness of a virtual consultation. In circumstances where and in-person consultation is required, for example when it is essential that a physical examination is conducted, within a reasonable timeframe, doctors should be expected to make suitable arrangements to see the patient in person or refer them to a doctor who can do so;
- ix. offer and provide appropriate patient follow-up, including arrangements for the management of adverse events and emergencies arising from treatment and review of investigation results;

- x. communicate with other healthcare professionals as appropriate;
- xi. have an emergency plan for referral to an acute care facility for treatment when this is necessary for the safety of the patient. The emergency plan should include a formal, written protocol appropriate to the virtual healthcare services being provided;
- xii. uphold high standards of professional conduct.

d. <u>Medical records and the privacy, confidentiality, security of and access to patient information</u>

Doctors providing virtual healthcare should be expected to create and maintain a medical record to the required standard and to comply with all the registering/licensing MRA's requirements for the privacy, confidentiality, availability, retention, transmission and security of patient information. These obligations should be identical to those applying to the provision of in-person medical services.

e. <u>Prescribing Practices</u>

Doctors providing virtual healthcare should be expected to:

- i. conduct an appropriate assessment in accordance with the MRA's standards of care before prescribing any drug;
- ii. ensure that their prescriptions comply with the legal standards and requirements that apply in the location where the prescription will be dispensed;
- iii. give consideration to the patient's ability to obtain the prescribed medication;
- iv. be aware of and comply with the registering/licensing MRA's requirements pertaining to controlled substances and substances that can be abused.

Medical Regulatory Authorities are encouraged to maintain a policy on Virtual Healthcare. The aim of such a policy should be to foster the positive aspects of virtual healthcare, recognise its limitations, ensure patient safety and provide guidance to practitioners.

ACKNOWLEDGEMENTS

- Federation of Medical Regulatory Authorities of Canada, Framework on Telemedicine,
 2019
- The report commissioned by the General Medical Council (UK): Europe Economics, Regulatory approaches to telemedicine, 2018
- Medical Council of New Zealand statement, Telehealth, 2020

References

POLICY STATUS: Statement on Regulation and Virtual Healthcare

Governing Authority IAMRA Board of Directors

Approval Authority Members General Assembly

Responsible Officer Executive Director

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Date of Last Revision Not Applicable

Statement on the Independence of

Related Policies Regulation and the Primacy of Patient

Safety

ⁱ Europe Economics, Regulatory approaches to telemedicine, 2018

⁺ Unless otherwise indicated, this policy will still apply beyond the review date.