Commentary

Expecting the Unexpected: How Regulators Can Prepare for Serious Events

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Introduction

At a time when the world continues to be gripped by one of the most significant pandemics in history, medical regulators are understanding, more than ever, the potential for effective regulation to impact on the local provision of health care, as well as health care across national and international borders. It has never been more important to work together, share experience and information and strive for regulatory best practices.

The pandemic has put a new focus on the work of the International Association of Medical Regulatory Authorities (IAMRA), which was formed in 2000 and today includes members from more than 100 countries around the world.

In addition to offering various resources for medical regulators, including convening biennial international conferences, IAMRA develops consensus statements based on collaborative input from multiple

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international regulatory agencies—helping regulators navigate a wide variety of key issues. Previous statements have been published on issues ranging from physician health and wellbeing to the accreditation of medical education.[1]

At its 13th International Conference in Dubai in 2018, member organizations spoke about a variety of difficulties they have experienced responding to serious local or regional events such as natural disasters, civil unrest, refugee crises and catastrophic weather events. Members related situations where assistance from much-needed medical personnel from outside their jurisdiction could not be mobilized sufficiently quickly. Others spoke of aid organizations sending physicians of unknown standing to their jurisdiction without any reference to the regulator. There were some positive experiences as well, such as the assistance provided by the Federation of State Medical Boards (FSMB) in the United States in the aftermath of Hurricane Katrina. Given the level of interest and the ubiquity of members' concerns, IAMRA embarked on the development of a statement designed to provide guidance to help regulators prepare for and manage such events.

With the arrival of the COVID-19 pandemic in 2020, the draft statement was revised to address more directly regulators' preparedness for pandemics. The statement was approved by the Management Committee and in October 2020 a final version was released, titled "Statement on Regulation During a Serious Event Such as a Disaster, Epidemic or Pandemic."[2]

The recommendations of the statement, summarized here, are accompanied by a brief history of the establishment and growth of IAMRA and its role as a global forum for the exchange of information and ideas in the medical regulatory community.

Background: IAMRA and the Rise of Global Regulatory Collaboration

In May 1994, the FSMB, under contract with the U.S. Department of Health and Human Services, planned and hosted the first International Conference on Medical Regulation in Washington, D.C. Participants came from Australia, Canada, Ireland, New Zealand, South Africa, the United Kingdom and the United States. Observers attended from Egypt, Israel, Mexico and Taiwan.

Designed to initiate dialogue among the attendees, the conference focused on the status of medical regulation in the participating nations, examined current research and identified future research needs. The attendees concluded that regulatory issues are not unique to any one nation (a sentiment that holds true today) and decided to hold a second conference in Australia in 1996, beginning a pattern of biennial conferences that continues, albeit having been disrupted in 2020 by the COVID-19 pandemic.

In September 2000, medical regulatory authorities from Australia, Canada, Ireland, New Zealand, South Africa, Sweden, the United Kingdom and the United States formed the International Association of

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Medical Licensing Authorities, which was formally incorporated in 2004 in the State of Texas as the International Association of Medical Regulatory Authorities (IAMRA). The IAMRA Secretariat continues to be supported by the generosity of the FSMB.

Membership in IAMRA in the "Member" category is open to medical regulatory authorities and to national associations of medical regulatory authorities. The term "medical regulatory authority" (MRA) refers to an organization recognized by the government of a specific country or jurisdiction as being responsible for the regulation, and/or registration/ licensure of medical practitioners whereby such practitioners are entitled to practice the profession of medicine.

Membership in IAMRA in the "Partner" category is open to organizations that have a nexus to IAMRA: 1) as indicated by direct contribution to the quality and integrity of the practice of medicine and therefore medical regulation, through activities such as medical education and assessment (undergraduate and postgraduate), credentialing of licensed/ registered practitioners; or 2) by virtue of directly regulating health care professionals other than the medical profession.

IAMRA's vision is "that everyone around the world is treated and cared for by safe and competent doctors." Its 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."[3]

IAMRA recognizes that effective regulation makes a vital contribution to patient safety. Most MRAs have a similar objective: to protect patients by employing effective regulatory tools to manage risk, to ensure that physicians are fit to practice and to contribute to the provision of high-quality health care. The challenge for medical regulators is to create relevant and effective systems that can respond to the rapidly changing environments in which physicians work, changes in health care and communication technologies, evolving health care delivery systems and—as is increasingly apparent—the emergence of pandemics and catastrophic climate or weather events.

Given the mobility of the medical workforce, IAMRA also recognizes that the impacts of medical regulation can be felt across the world: What happens in one jurisdiction has the potential to affect another, both positively and adversely. Facilitating interconnectedness and collaboration is the mechanism by which IAMRA fosters best practices and collegiality in medical regulation.

Membership in IAMRA has grown steadily and today IAMRA has more than 100 members from every world region. IAMRA's biennial conferences are valued by members as opportunities to learn from, and connect with, other MRAs.

The COVID-19 pandemic resulted in the postponement of the 14th International Conference in Johannesburg in September 2020. However, IAMRA has worked hard to maintain connections with and between its members during this challenging period.

IAMRA does not promote a particular model of medical regulation or dictate how MRAs should operate, recognizing that regulatory models are influenced by the structure of the health care system, the legal framework in which regulatory authorities operate and the resources available. Within IAMRA's membership, many different models of regulation and degrees of independence and autonomy are represented. In view of this, one of IAMRA's objectives is to provide resources to assist members as they navigate the challenges and competing priorities of regulating the medical

profession in their own jurisdiction. Statements on key regulatory issues are a cornerstone of IAMRA's resource development. Recent statements have addressed Independence in Medical Regulation, Continued Competency, Physician Health and Wellbeing, Prescribing Drugs of Dependence, Research and Accreditation of Medical Education.

Preparing for Serious Events: A Summary of IAMRA's New Statement

In 2018, IAMRA's 13th International Conference was held in Dubai, UAE. It was apparent that there was considerable interest in the role of medical

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regulators in the management of natural disasters or other serious local, regional, or global events. At that time, discussion focused on regulatory responses to issues such as refugee crises and catastrophic weather events.

Following the conference, IAMRA's Management Committee, with leadership from its new Chair, Dr. Kgosietsile Letlape, agreed that a statement should be developed to encourage MRAs to prepare for and assist other MRAs during serious events. The statement was drafted during 2019 and in early 2020 it was revised in light of the issues emerging from the evolving COVID-19 pandemic. It was always IAMRA's intention that "serious events" would encompass epidemics and pandemics, but the particular challenges of COVID-19 sharpened the focus of the statement, which was released in October 2020.

The World Health Organization (WHO) defines *disaster* as:

"A serious disruption of the functioning of a community or a society at any scale due to hazardous events interacting with conditions of exposure, vulnerability and capacity, leading to one or more of the following: human, material, economic and environmental losses and impacts."[4]

A disaster may be natural (e.g., hurricane, flood, fire) or manmade (e.g., war, social unrest, terrorist attack).

The WHO defines *epidemic* and *pandemic,* respectively, as:

"The occurrence in a community or region of cases of an illness, specific health-related behavior, or other health-related events clearly in excess of normal expectancy"[5] and "A worldwide outbreak of a disease in humans in numbers clearly in excess of normal."[6]

These definitions do not address issues such as population immunity or disease severity, so seasonal influenza may be classed as an epidemic, or even a pandemic, but it may have minimal impact on the health care system or MRAs.

For the purpose of the statement, a "serious event" is one where there is significant impact on the capacity of the health care system, and physicians in particular, to manage the health care needs of the general population or those directly affected by the event. The event may lead to MRAs having to change the way they work and could even have a direct impact on an MRA's staff and/or infrastructure.

In IAMRA's statement, MRAs are encouraged to develop their own protocols that address the key

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issues and their priorities in response to a serious event. Ideally, such protocols would be developed in collaboration with government or non-government agencies, such as the Ministry of Health, Civil Defense, Police, NGOs, neighboring MRAs and other health professions' regulatory authorities, in order to be part of a broader disaster/event management plan.

During a serious event, MRAs may find themselves under pressure in relation to any of their key regulatory processes, potentially compromising their ability to regulate effectively. Individuals, organizations or governments may seek to exert their influence in relation to issues such as the medical workforce;

there can be considerable tension between maintaining standards and recruiting/licensing an expanded medical workforce in response to a perceived need.

To the extent that it is possible within the local structural and legal framework, IAMRA supports and encourages all MRAs to maintain their independence and make patient safety their primary concern.[7]

IAMRA recognizes that MRAs' serious event protocols will, by necessity, vary, but suggests that a protocol could address:

A. Invoking, Communicating and Revoking Application of the Protocol

1. The power to invoke the protocol, e.g., a decision of a quorum of Board/Council members.

2. The circumstances in which the protocol may be invoked, e.g., declaration of a state of emergency or epidemic lockdown due to the event's impact on the provision of effective health care.

3. A strategy for communicating with stakeholders, including other MRAs, that the protocol has been invoked.

4. The circumstances in which the Board/Council may revoke the application of the protocol.

B. Registration/Licensure Decisions

Medical regulation involves a number of processes aimed at ensuring that physicians are fit to practice. Of particular relevance during serious events are the processes whereby registration/licensure is granted to physicians.

MRAs may be called upon to facilitate the expeditious registration/licensure of physicians who are recruited or volunteer to assist, but do not hold registration/licensure with the MRA. In addition, MRAs outside the area of a serious event may be called upon to facilitate the registration/licensure of physicians within the event zone by prioritizing confirmation of the good standing for physicians wishing to practice in the affected area.

A "serious events" protocol could address:

1. Delegation of authority to grant registration/licensure.

2. Prioritization of applications directly related to the event, and the target timeframe from receipt of a complete application to registration/licensure.

3. Pre-recognition of international aid organizations likely to bring personnel to the event zone.

4. Registration/licensure criteria (see below).

5. Category and terms of registration/licensure (see below).

6. Prioritization of requests for certification of good standing from other MRAs affected by the event. (Registration/licensure generally requires that the physician requests a Certificate of Good Standing or equivalent from the MRAs, whether they are, or have been, registered/licensed. MRAs may wish to expedite the provision of this certification when a serious event arises in another jurisdiction.)

7. Maintenance/enhancement of the medical workforce, e.g., registration/licensure of recently retired physicians or senior medical students co-opted to provide assistance.

8. Arrangements for certification of training for students/trainees whose training and assessment may be disrupted by the event.

C. Registration/Licensure Criteria and Categories

When developing criteria and the processes for processing registration/licensure applications during a serious event, the MRA should plan to work quickly and flexibly to facilitate the provision of effective health care services, but at the same time, ensure that patient safety is not put at risk by allowing emergency health care to be provided by physicians with inadequate expertise, or by physicians that are not in good standing with other MRAs.

MRAs may consider granting registration/licensure in a specific, event-related category and may also consider requiring registered/licensed physicians in any event-related category to practice under explicit conditions, e.g.:

1. Working only within a defined clinical setting and/or for an approved international aid organization.

2. Working with a defined scope of practice.

3. Working only as part of a multi-disciplinary team.

4. Working under the direction of an approved supervisor.

5. Time-limited registration/licensure.

MRAs may wish to consider criteria that include requirements for the physician seeking event-related registration/licensure:

1. To have a defined role that is directly relevant to managing the serious event. This includes physicians taking over the roles of other physicians to enable them to manage the serious event.

2. To be already registered/licensed by a pre-recognized, competent MRA, and be in good standing with that MRA.

3. To be invited or supported by a competent authority, e.g., a government hospital, or a pre-approved, international aid organization.

4. To provide a certified copy of their primary medical qualification, specialist qualification, details of their current registration/licensure and a declaration that they are not subject to any outstanding fitness-to-practice concerns.

5. To provide evidence of any insurance that may be required to be held by physicians practicing in the MRA's jurisdiction unless arrangements are in place to indemnify physicians licensed/registered for the purpose of the serious event.

D. Standards of Practice

The COVID-19 pandemic has shown that practices that were unthinkable or deemed unacceptable before 2020 needed to be introduced in response to the emerging disaster. Many MRAs have found it necessary to reassure health care professionals that if it is not possible to adhere to usual guidelines and protocols, they will not be judged harshly, as long as they act, as best they can, in the interest of their patients.

During a serious event, MRAs may also find themselves under external pressure to support — or at least, condone — alternate modes of practice, such as telehealth or off-label treatments in the absence of adequate scientific evidence. A serious events protocol may provide a framework for managing these demands by addressing:

1. Systems for the rapid development and dissemination of guidance on practice issues arising from the serious event, e.g., the ethics of prioritization and resource allocation; standards or protocols for testing, diagnosis and treatment; use of new technologies and practices, experimental treatments; self-care under pressure.

2. Standards of care, i.e., how the usual standards of care expected of physicians can be adjusted and communicated in response to the serious event.

3. Waiver or deferral of certain requirements for renewal of registration/licensure, e.g., annual continued competency/CPD requirements.

E. Business Continuity Arrangements:

In anticipation of circumstances where the MRA itself is impacted by office closure or staff shortages, a serious events protocol could address:

1. Governance arrangements and delegations. This may include delegation of some or all functions to another MRA with which prior agreement has been reached.

2. Priority services in circumstances where there is insufficient capacity to maintain all the MRA's usual services.

3. Working from home (WFH) arrangements, including criteria for invoking WFH, staff communication systems, information technology requirements including hardware, software, system support and security.

4. Staff wellbeing.

5. Stakeholder communication regarding new business arrangements.

6. Return-to-office criteria and logistics.

In addition to the guidance provided above, the "Statement on Regulation During a Serious Event Such as a Disaster, Epidemic or Pandemic" concludes with the following:

"Medical Regulatory Authorities are encouraged to develop a protocol to assist in the event of a natural or manmade disaster, or a serious epidemic or pandemic affecting the provision of healthcare within their jurisdiction or in other jurisdictions.

"The aim of such a protocol should be to enable the MRA to achieve business continuity, maximize efficiency, work quickly to support physicians, and facilitate the provision of responsive, safe and effective health services."

Conclusion

In recent times and in many places, the health care system has been tested to its limits and, in some cases, has faltered under this stress. However, IAMRA is aware that MRAs have demonstrated remarkable agility in adapting to the impact of the COVID-19 pandemic. Around the world there are many examples of MRAs that have, for example, adapted their registration/licensure policies to accommodate students and recently retired physicians in the workforce, maintained business continuity with staff working from home and even conducted hearings using videoconferencing, adjusted their examination and accreditation requirements, and rapidly disseminated guidance on standards of care and practice issues arising from the pandemic.

It is IAMRA's sincere hope that when the pandemic is behind us, MRAs that have not already done so will develop protocols to prepare them to manage more rapidly and effectively the next, sadly inevitable, serious event that may pose very different challenges. Despite the adaptability demonstrated by so many MRAs during the COVID-19 pandemic, preparation is key and there is always something to learn and something to improve.

DESPITE THE ADAPTABILITY DEMONSTRATED BY SO MANY MRAs DURING THE COVID-19 PANDEMIC, PREPARATION IS KEY AND THERE IS ALWAYS SOMETHING TO LEARN AND SOMETHING TO IMPROVE.

COVID-19 vaccines and treatments offer new hope for the future, but in the meantime, the pandemic continues to devastate populations, particularly in less developed nations. It is vital now for medical regulators to learn from their collective experience and seek new strategies to prepare for a world in which more pandemics are likely. We believe IAMRA's statement on preparedness for serious events is timely and offers a strong foundation to help in this effort.

IAMRA is committed to assisting medical regulatory authorities in any way it can, and will continue to facilitate collaborative learning and the interconnectedness of medical regulatory authorities around the world. ∎

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