Global Medical Technology Alliance
Innovating for a Healthier World

JOINT PRINCIPLES ON MEDICAL DEVICE REPRESENTATIVE RE-ENTRY INTO HEALTH CARE FACILITIES DURING THE COVID-19 PANDEMIC

Background

The Global Medical Technology Alliance ("GMTA") member associations represent companies that develop, distribute, and manufacture medical devices, diagnostics, and digital health technologies that are vital to diagnosing and treating COVID-19 patients around the world.

In response to the COVID-19 pandemic, many national and local health authorities recommended interim cancelation or delay of "elective" surgical procedures, which includes non-urgent but medically necessary procedures. Physicians and health care organizations have responded appropriately and generally delayed "elective" cases around the world. Health Care Industry Representatives ("HCIRs") that represent medical technology companies, both manufacturers and distributors, are often called upon by clinicians to provide this support in patient-care or restricted areas of a Health Care Facility ("Facility"). Although some HCIRs have been called upon during the pandemic to support procedures essential for COVID-19, many HCIRs primarily support "elective" procedures and have not been requested to enter facilities until recently. As facilities resume elective procedures based on their local circumstances, GMTA members are committed to supporting the needs of patients who have had their procedures delayed.

GMTA member associations support the principles offered below concerning the re-entry of HCIRs into health care facilities to facilitate patient access to the medically necessary care that they have delayed with evidence-based criteria for protecting patients, clinicians, and HCIRs from COVID-19 transmission. Alignment around these principles will further consistency in safety and testing protocols and lead to improved compliance. It will also ensure that HCIRs, who provide technical support to improve patient outcomes, are adhering to relevant national and local safety standards. Greater consistency will also improve the ability of HCIRs to provide support for technology used in procedures when and where needed with minimal impediment or delay.

GMTA member associations are closely collaborating with medical societies, hospital associations, and other groups representing the interests of patients, facilities, and clinicians, both domestically and abroad, to promote adoption of these principles.

Prevailing Assumptions and Objectives

As the aim is to provide current, evidence-based recommendations, we anticipate that the principles may be updated to integrate improvements in the understanding of COVID-19 and the capabilities and availability of other resources such as diagnostic testing. These Principles are intended to account for: (1) the need for patient care; (2) the limited availability of Personal Protective Equipment ("PPE"); (3) the capabilities and availability of diagnostic testing; (4) the current understanding about COVID-19 disease and immunity; (5) the lack of an approved vaccine; and (6) the application of local laws, regulations, and official/health authority guidelines, which shall prevail in the event of any conflict or inconsistency with these Principles.

The Principles seek to minimize the transmission of COVID-19 to patients, clinicians, and HCIRs, in a manner that protects patients first, while also protecting clinicians and HCIRs in a way that (1) conserves the use of limited PPE for the priorities where such PPE would be most needed, (2) avoids unnecessarily duplicative, inefficient, or otherwise wasteful activities or expenditures, and (3) meets the obligations of both providers and suppliers. Consensus in the health care community toward best practices decreases confusion, improves compliance, and prioritizes provider access to limited PPE.

GMTA Joint Principles

1. Roles and Limitations of the HCIR in Health Care Facilities ("Facilities")

An HCIR may represent a medical device manufacturer or a distributor of one or more device manufacturers. By virtue of their training, knowledge, and expertise, HCIRs, in connection with the surgical device used in a procedure may:

- provide technical assistance to the surgical team;
- expedite the procedure and facilitate the safe and effective application of surgical products and technologies;[1]
- provide on-site product/technology expertise to the perioperative team and help clinicians make critical, real-time choices.[2]
- support the clinical/operating room team to ensure that the appropriate range of necessary devices and accessories are available during a procedure, especially when dealing with medical technology that involves multiple devices, different sizing specifications and/or accessories; and
- serve other roles that include: training Facility staff on the safe and effective use of medical devices; delivering, installing, maintaining, servicing/repairing medical devices; updating device-related information and guidance; and programming and calibrating implant devices among others.

At all times, the role of the HCIR is subject to the following controls and limitations:

- HCIRs should enter and be present in the clinical setting only at the request of and under the supervision of the presiding Health Care Professional ("HCP");
- HCIRs should be transparent that they are acting on behalf of the Company in a technical support capacity for the relevant device used in the and only in respect of approved indications; and
- HCIRs should not interfere with a HCP's independent clinical decision-making.

2. Social Distancing and Safety Precautions

- HCIRs entering all areas of the Facility should take safety precautions in accordance with prevailing national and local public health recommendations (e.g., regarding handwashing and face coverings) both to protect the individual HCIR and others in the Facility.
- Facility social distancing and safety policies applicable to staff should apply equally to HCIRs accessing the same areas of the Facility.

3. COVID-19 Testing and Screening

- Facility screening procedures applicable to staff should be equally applicable to HCIRs entering the facility, including but not limited to screening for symptoms, close contact with COVID-19 cases, etc.
- Facility testing policies for HCIRs entering both restricted and non-restricted areas should follow current national and local priority recommendations for COVID-19 diagnostic testing for Facility staff.
- Any required COVID-19 diagnostic testing of asymptomatic individuals should only be

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[1] American College of Surgeons, Revised Statement on Health Care Industry Representatives in the Operating Room, October 1, 2016, https://www.facs.org/about-acs/statements/91-industry-reps-in-or

[2] Association of periOperative Registered Nurses, AORN Position Statement on the Role of the Health Care Industry Representatives in Perioperative Settings, https://www.aorn.org/-/media/aorn/guidelines/position-statements/posstat-personnel-health-care-reps.pdf (For example, some implant systems include hundreds of component options with certain nuanced variations that can be most efficiently and effectively communicated by an on-site, interactive resource and advisor)

implemented in accordance with applicable national and local health authority requirements or guidance.

4. Elective Procedures and Crisis-Level Emergency Surgical Procedures and Personal Protective Equipment ("PPE")

- Consistent with national and local regulations and health authority guidance, HCIRs can work with HCPs and facilities with videoconferencing capabilities in their operating rooms/procedure suites to provide virtual support in surgical cases where remote attendance does not compromise patient safety, medical outcomes, or privacy.
- Since Facilities establish the case-specific administrative and engineering infection prevention controls, Facilities are best positioned to determine the proper PPE for individuals that are present in the room for a particular procedure according to relevant health authority requirements or guidance ("Proper PPE").[3]
- Surgical case scheduling and prioritization policies should account for the sufficiency of PPE inventory, including Proper PPE for any HCIRs essential to an "elective" procedure.
- Facilities operating within a crisis-level capacity[4] may require HCIRs essential to emergency surgical and other invasive procedures to provide their own PPE if the facility is in short supply to the extent this practice is consistent with applicable national and local regulations and guidance.
- HCIRs and Facilities should follow national and local health authority guidance for conserving PPE and infection control regarding the use, reuse, and decontamination of any PPE, whether supplied by the Facility or by an HCIR.

5. Training and Education regarding COVID-19 Safety and Precautions

- HCIRs are trained on general infection prevention and control within procedural settings.
- HCIRs should have an understanding of national and local health authority guidance for COVID-19 infection prevention and PPE use (including donning and doffing).
- HCIRs should have an understanding of Facility policy related to COVID-19 safety principles.
- Training and education are a shared responsibility. The HCIR's employer has a direct interest in ensuring that their representatives are trained to conduct their activities safely, and the Facility is best positioned to educate and train on the site's specific policies and procedures.
- Virtual training and education should be encouraged where possible to minimize contact with other individuals.

[3] Proper PPE may include some combination of respiratory protection, masks, face shields, eye protection, gowns, head covers, gloves, shoe coverings, or coveralls.

[4] Crisis Capacity operations (made necessary by a catastrophic disaster) involve adapting spaces, personnel, or supplies in ways which are not consistent with usual local standards of care to provide the best possible care to patients given the circumstances and resources available.