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GUEST EDITORIAL

Ethically Problematic Medical Device Representation

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Ethical issues in physician-industry and academia-industry relationships have focused largely on the financial nature of these relationships. It took very little time after solutions to transparency regarding financial conflicts were introduced, however, before the medical community was presented with a new and equally challenging situation involving the medical device industry.

In 2018, the North American medical device market was valued at $169.3 billion USD, comprising the largest sector of the $425.5 billion USD global medical device market (Fortune Business Insights 2019). To date, ethics discourse surrounding medical device representatives (MDR) has been concerned with their role in the operating room (Bedard et al. 2014; Gagliardi et al. 2017; Grundy et al. 2018; Pollner et al. 2019; O'Connor et al. 2016). However, a new pipeline is giving some MDRs direct access to patients through visits to their homes, interactions with families in waiting rooms, and presentations to advocacy groups. It is no secret that this is occurring in the world of novel neurotechnologies for the treatment of a range of psychiatric and neurologic disorders such as drug resistant epilepsy in children, and is resulting in instances of inappropriate MDR interactions with families. While this horse has already left the barn, this is not a time for bioethicists to be complacent. Ethics concerns abound (Box 1).

The first concern is about oversight and access to patients and families, the means by which patient contact lists come into the hands of the MDRs, and the privacy of protected health information. We ask whether families consented to the release of their information to MDRs, in what form, and with what rights. We further note and challenge the absence of oversight over pressures on MDRs to meet device sales quotas.

Visit timing and messaging is a second ethics concern. Patients may receive visits from MDRs before they are assessed clinically for suitability for a given intervention. Some of these patients may not even be candidates for a procedure endorsed by an MDR, vagus nerve stimulation for example, but are left with the impression that the procedure was the most appropriate and least invasive. This may occur even where more than one reasonable treatment option is available. When choice for one treatment over another seems to be compelled rather than informed, the risk of inappropriately raised expectations is high and proper treatment may be delayed. Vulnerability is substantial: having a child with drug resistant epilepsy, for example, may expose a family to suggestion, and the mere suggestion of a singular treatment option has the potential to introduce conflict and erode trust in the health care team.

The third issue relates to clinical boundaries. Some MDRs have begun to refer to themselves as "therapeutic consultants," by comparison to "industry representatives" in pharma. This MDR term does not explicitly reveal a relationship with the medical device industry and the vague use of the word therapeutic suggests that the representative has a role in clinical care. MDR counsel about a device in the pre-operative setting may be mistaken for that of a treating professional.

MDRs provide many practical and meaningful services, such as training and informational resources, and can be a valuable resource to the surgeon and health care team in and out of the operating theater. Direct recruitment and advocacy for targeted interventions should not be among them. This is a time and place for anticipatory bioethics. The potential for harm unequivocally outweighs any foreseeable benefits, and the imperative for action is now. Until data about this evolving and currently indefensible practice are available to suggest otherwise, and evidence-based regulatory oversight is implemented, we urge that direct MDR access to patients end. Just as bioethicists did

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Box 1. Ethics considerations.

Ethics concern	Considerations
Access to patients	• Transmission of personal health information • Lack of access oversight, documentation, and reporting • Access quota pressures • Unspecified methods for acquiring consent for access to private information and rights of consenters
Messaging and health implications	• Timing of visits and interactions with and recommendations of healthcare team • Conflict of interest in treatment selection process • Delays in proper treatment
Clinical boundaries	• Limited transparency regarding MDR role • Confusions about MDR expertise

with conflict of interest the pharmaceutical industry, we must intervene expediently and forthrightly to make this happen without further delay.

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