REPORT OF THE ORGANIZED MEDICAL STAFF SECTION
GOVERNING COUNCIL

OMSS GC Report D
(I-24)

Subject: Inclusion of Patient Safety and Environmental Stewardship in CSAPH Report *Improving Research Standards, Approval Processes Post-Market and Surveillance Standards for Medical Devices* (OMSS Resolution 2-I-23)

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Referred to: OMSS Reference Committee (, MD, Chair)

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INTRODUCTION

At its 2023 Interim Meeting, the OMSS Assembly referred Resolution 2-I-23, Inclusion of Patient Safety and Environmental Stewardship in CSAPH *Report Improving Research Standards, Approval Processes Post-Market and Surveillance Standards for Medical Devices*, for report. The resolution asked the AMA to:

1. Develop policy that specifically addresses concerns about the design, use, and maintenance of reusable medical devices in the context of the growth of antibiotic-resistant microbes, as it threatens patient safety

2. Develop policy that specifically addresses single use/disposable medical devices with regards to 1) adverse environmental consequences (material use and medical waste), and 2) the balance of fiscal expense vs. patient safety concerns

3. Advocate for an augmented recommendation on medical devices that addresses patient safety as it intersects with fiscal and environmental considerations to the U.S. Food and Drug Administration's Center for Devices and Radiological Health and advocate for its incorporation into the Center's policies regarding approval and continuance of medical devices.

DISCUSSION

The key directive of Resolution 2-I-23 is to task the AMA with developing policy that can help to manage the tension between environmental sustainability and patient safety as it relates to single-use and reusable medical devices. The AMA currently lacks robust policy on this subject and what policy does exist relates largely to support for existing federal guidance on reprocessing of existing durable medical equipment and general acknowledgements of the AMA's responsibility to ethically consider the environmental impact of the practice of medicine. Developing practical, specific recommendations for single-use or reusable medical equipment has not historically been an item of policy interest for the AMA.

At the same time, the AMA has recognized the risks associated with antibiotic-resistant microbes and the need for careful, effective procedures to keep patients as safe as possible when receiving care, particularly care delivered in a surgical or other inpatient setting. Indeed, presence of antibiotic-resistant microbes leading to the shutdown of surgical suites as well as dental, endoscopic, urologic, podiatric, optometric and sleep study venues is well[1] documented[2] as is the relationship between these events and the use of inadequately reprocessed reusable devices, resulting in greater expenses for healthcare facilities, physicians, and patients.

Implementation of effective policy to manage both safety and environmental obligations requires, almost by definition, the existence of an industry standard. Unfortunately, there does not seem at this time to be a universal standard or rubric for evaluating the costs and benefits of single-use and reprocessed reusable medical devices relative to the potential for risk and cost to patients, though there are some public[3] attempts to craft such a standard. This in and of itself is potentially problematic. Without a recognized industry standard approach that has been evaluated and carefully considered by physicians, the creation of standards is falling to private industries[4] which are free to develop and propagate their own standards with or without the input of the physicians that regularly use the materials.

In addition to the environmental and safety concerns, it is also important to consider the economic impacts at play. While spending on medical devices remains a relatively small piece of overall health spending, there are signs of growth. In 2021, medical device spending increased at an average annual rate of 5.8 percent[5], just slightly behind the overall rate of 6.1 percent. Inflationary pressure is expected[6] to continue to push spending higher in the coming years. While all healthcare facilities must be mindful of costs relative to revenue, facilities and practices where margins are thinnest, such as rural and other underserved areas, may have an even more sensitive calculus to consider, particularly as the risk of closure of services or full shutdowns may be greater without careful consideration of cost-effectiveness.

A successful standard is one that considers safety, environmental sustainability, and economic responsibility in equally appropriate measure. Physicians undeniably must be at the forefront of determining any industry standards related to use of these materials, however it is not a task that can be accomplished by physicians, or even the healthcare sector, alone. Determining a careful standard will require cross-sectional inputs from the healthcare sector and the physicians who lead it as well as environmental experts and financial cost benefit analysts who can contribute.

## CONCLUSION

The creation of a “gold standard” for single-use and reusable medical equipment that considers both the environmental impact of a changing world and the safety needs of patients is a task that’s time has come. Unfortunately, determining those exact standards for patient safety and environmental stewardship is beyond the scope of the Organized Medical Staff Section. However as the representative facilitators between medical staff and healthcare facilities, the OMSS is in a unique position to spur the development of better standards of care that also consider the needs of physicians and the literal work environment physicians practice in.

The OMSS Governing Council believes the best path forward lies in encouraging the AMA to take the lead with other key national stakeholders in developing a “cradle-to-grave” lifecycle assessment[7] tool that can evaluate single-use and reusable medical equipment, both in isolation and combination, to help make determinations about the best possible products and applications. Such tools are commonly used in a variety of industries and are generally well-accepted[8] as reasonable and responsible assessments for product use.

Finally, while Resolution 2-I-23 initially sought to directly address the Council on Science and Public Health's (CSAPH) Annual 2023 report on research standards improvement, given the passage of time since that report and the still outstanding need for policy addressing the issue of environmental stewardship and patient safety, the OMSS Governing Council does not believe it is necessary to amend the CSAPH report in order to achieve the resolution's goals.

RECOMMENDATION

The OMSS Governing Council recommends that the following be adopted in lieu of Resolution 2-I-23, and that the remainder of this report be filed:

1. That the AMA work with such stakeholders as is sensible to develop and/or confirm a comprehensive cradle-to-grave life-cycle assessment for single-use versus reusable medical devices factoring safety relative to cost effectiveness and environmental impact.

2. That the AMA advocate for federal regulation on medical devices that addresses patient safety as it intersects with fiscal and environmental considerations and promotes the use of a "gold standard" life-cycle assessment for single-use and reusable medical devices.

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