

TO: MSSNY Officers, Councilors and Trustees

FROM: MSSNY's Legislative & Physician Advocacy Committee

DATE: November 1, 2018

RE: Resolution 66 – 2018 House of Delegates
Life-threatening Complications with Hip Replacements
Introduced by Dr. Edward Powers, as an Individual

The following resolution was referred to the Council by the House of Delegates. The resolution was forwarded to the Legislative and Physician Advocacy Committee for further study and recommendation for the Council's consideration.

RESOLVED, That the Medical Society of the State of New York (MSSNY) work for legislation and/or regulations, requiring physicians to identify (through the hip registry and other records) patients who have received cobalt/chromium metal-on-metal hip implants, and

- 1. To notify these patients of the dangerous medical conditions that have been associated with these implants (the costs of this research and the patient notifications to be borne by the manufacturers); and**
- 2. To conduct frequent serial testing of these patients' blood for cobalt and chromium levels (this testing also to be paid for by the manufacturers); and be it further**

RESOLVED, That the Medical Society of the State of New York ask the American Medical Association to establish more stringent guidelines for hip replacement surgery, to protect the public from the life-threatening conditions associated with cobalt/chromium metal-on-metal hip implants.

At the HOD, the Reference Committee heard mixed testimony on this resolution. On the one hand, there was testimony in support of the resolution due to concerns about complications with certain types of hip implants. On the other hand, there were concerns raised by some physicians regarding the imposition of a mandate on physicians to make patient notifications, as well as concerns with possible liability on those physicians. Moreover, it was noted by a representative of the New York State Society of Orthopedic Surgeons (NYSSOS) that not all types of cobalt chrome hip implants are harmful. Given the lack of consensus on this resolution, and the significant concerns regarding additional mandates, the delegates recommended that this resolution be referred to Council.

When this resolution was discussed at the September 6 meeting of the Committee, the sponsor of the resolution clarified that his goal was not to place a legal mandate on physicians to notify these patients, but instead to place the notification mandate on the manufacturers of these artificial hips. In response, there were comments from some Committee members that, practically speaking, for such a notification requirement to be placed on the manufacturer without also placing some responsibility on the physician who implanted the artificial hip. Committee members discussed their sympathy to the problem given the risks some patients may face, but were wary of legislation to require physicians to make this notification.

Concerns have also been expressed that calling for support for this proposal could also be perceived to be tacit support for legislation opposed (A.1964/S.3942) by the Orthopedic Surgeons that would require the provision of a 5-year warranty on electronic medical devices and implantable hip and knee medical devices.

In discussing this resolution with representatives of the NYSSOS, it was noted that the American Joint Replacement Registry (AJRR), a collaboration of medical societies, hospitals,

and manufacturers was established in 2010 to collect and disseminate data on hip and knee replacements that will lead to improved patient outcomes. AJRR is designated as a Qualified Clinical Data Registry (QCDR) by the Centers for Medicare & Medicaid Services (CMS), which helps facilitate quality reporting for MIPS compliance. The AJRR monitors advisory notices and makes notifications about specific implant recalls so that they can alert affected patients. By focusing on capturing data on primary procedures and revisions conducted in the United States, AJRR provides early detection capabilities for identifying poorly performing implants. This is helpful to surgeons, who need access to patient data so they can identify those at risk of poor clinical outcomes. The ability to compare patient data against national benchmarks improves patient follow up and intervention and enables more informed decision-making about at-risk patients and helps to reduce complications and revision rates.

Given the tools available to identify problematic artificial hips and other medical devices, instead of seeking a law that would mandate notification to patients for one particular type of hip implant, staff recommended and the Committee agreed, that MSSNY work with appropriate specialty societies to educate physicians and patients about risks and recalls generated through the AJRR QCDR. Information gathered from these QCDRs can then be used to inform physician judgment as to whether a particular patient should be notified.

It should be further noted that, during the October 18 Legislative & Physician Advocacy Committee meeting, there was a discussion of whether a resolution should be sent for to the AMA for its consideration at an upcoming House of Delegates meeting or, instead, a letter be sent to AMA to effectuate the intent of the second resolved calling for the AMA to work with the AAOS to increase the adoption of these musculoskeletal registries. The Committee concluded that, if this resolution is approved by the MSSNY Council, then a letter could be sent to the AMA, with a follow-up resolution to be sent next year if there is insufficient progress made to achieve the goals of this resolution.

RECOMMENDATION: That the MSSNY Council adopt the following substitute resolution in lieu of Resolution 66:

RESOLVED, that the Medical Society of the State of New York work with the NYS Society of Orthopedic Surgeons to educate physicians regarding existing clinical data registries that collect data regarding poorly performing implants to better assure physicians have necessary information to, where appropriate, inform their patients; and be it further

RESOLVED, that the Medical Society of the State of New York urge the American Medical Association (AMA) to work with the American Academy of Orthopedic Surgeons (AAOS) to increase the adoption of musculoskeletal registries so as to aid early detection capabilities of poorly performing implants and report to the public on clinical statistics, and inform quality improvement and educational activities.