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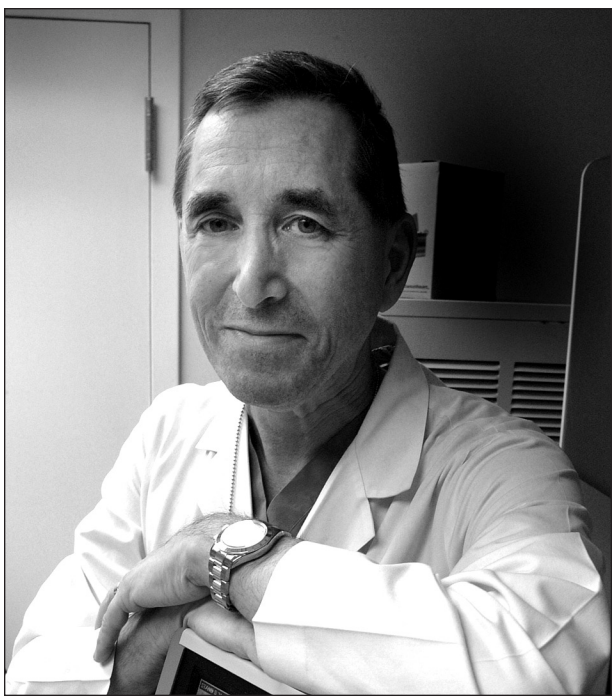
EDITORIAL

A Note from the Editor-in-Chief

Lawrence D. Devoe, M.D.

Welcome to the January-February 2020 Editor-in-Chief's page. This editorial column will focus on two articles that expose problems in how obstetrician-gynecologists deal with information and misinformation that could be important in their care of patients.



Lawrence D. Devoe, M.D., Editor-in-Chief

In This Issue

- ***Provider Knowledge, Comfort with, and Training on Genetics Screening and Diagnostic Testing: Assessing Educational Needs***
  A. Delgado, J. Schulkin, R. Kaji, and C. J. Macri

  The authors used a survey tool to evaluate doctors, residents, nurse practitioners, and midwives regarding their ability to counsel patients who received genetic screening and diagnostic testing. They found that the minority of those surveyed either had formal training or continuing medical education in this topic area, although the majority were interested in becoming better educated on such topics.

- ***Analysis of the Food and Drug Administration MAUDE Database for Approved Devices in Obstetrics and Gynecology***
  J. M. Maurice and S. Galhotra

  This retrospective study looked at the accuracy of death and injury reports over a two-decade interval that were stored in the Manufacturer and User Facility Device Experience (MAUDE) database for approved devices for obstetric and/or gynecologic care. When comparing raw to subsequently adjusted data, the authors found significant drops in adjusted death and injury reports with substantial overestimates in both

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categories, with a ten-fold greater overestimate for device-related injuries when compared to device-related deaths.

Editorial Comment

While Delgado and colleagues conducted their survey in a single institution, it is an academic medical center in which the state of knowledge, awareness, and subsequent comfort in understanding, interpreting, and counseling patients receiving genetic screening and testing should be reasonably high. As the number of patients who are either offered or undergo such testing is increasing on an exponential basis due to the proliferation of specific screening tests and expanded screening panels, it is quite likely that OBGYN providers at all levels will see them more frequently in their practices. Although it may not be reasonable to expect these individuals, who are often responsible for ordering genetic tests, to perform at the same level as specially trained and experienced genetic counselors, they will often be the first providers to whom patients return once their test results have been received.

Problems often may begin with routine genetic screening for conditions like hemoglobinopathies, cystic fibrosis, spinal muscular atrophy, and Fragile X but may extend well beyond these conditions in the near future. This situation is exacerbated by the current shortage of trained genetic counselors, who typically populate university medical centers and are not likely to be found in community hospitals. Once physicians and nurses complete their formal training, unless there is a requirement to update their knowledge in the area of genetic screening and testing, they will continue to fall behind as a group. Studies like this one provide a possible path on an institution-by-institution and provider-by-provider basis to identify such knowledge gaps and develop accessible education programs on-site to improve this situation. We need to accept the inevitable: medical care is becoming increasingly driven by genomics. The sooner our professional organizations recognize this trend, the sooner the implementation of educational programs to address these needs and the mandates for providers to keep updated will become reality.

Maurice and Galhotra's paper is even more disturbing as manufacturers, physicians, and patients can be affected by reporting errors for serious adverse events that appear to be device-related. The MAUDE website is available to the public through the FDA's website, www.fda.gov. When one opens the MAUDE homepage, a number of disclaimers are made, including the following:

- The search feature is limited to adverse event reports within the past 10 years.
- The data cannot be used in isolation to determine rates or changes in rates of events over time or between devices.
- Determining cause-and-effect relationships between devices and events may be difficult.
- A medical device report submission and its FDA release does not mean that the device caused the event.

What the authors found in their study was the clear potential for error, in this case overestimation of rates of death and injury to a greater magnitude than these MAUDE disclaimers would suggest. It also supports the author's conclusion that there should be a national device registry with more accurate statistical analyses. While this is laudable in principle, the problem with such voluntary reporting systems is that they have inherent bias, under- and over-reporting of adverse events, may exhibit long delays between events and their reporting, and have built-in limits as to how much information can be provided for any event. In short, it may take years before a medical device approved through premarket approval or 510(k) equivalence surfaces as dangerous enough for product warnings or recalls. Physicians who use FDA-approved medical devices may or may not receive timely information on problems with these devices and, in turn, may be reluctant to report them to MAUDE. The word to the wise: if you use an approved medical device frequently, keep in touch with the company representative, watch for ACOG news items or bulletins, and visit MAUDE at least annually.