The Use (and Abuse) of Governmental Databases

Government has become increasingly interested in the details of medical practice. Large quantities of relatively crude data are being accumulated by various agencies. Manufacturers of medical devices are required to report complications related to their products to the Medical Device Reporting (MDR) database maintained by the Food and Drug Administration (FDA). In this issue (see page 1221), we can read a summary of the complications related to central venous catheters that were reported to the FDA from 1984-86.

It is unlikely that anyone could object to data that would be useful to physicians who insert central vascular catheters. Scott’s review of the technique is reasonable and informative. Yet, we have to ask, what is the value of the MDR database? In the two years covered by the study, the author estimates that 5.5 million central venous catheters were placed. Neither he, nor we, have a way to determine the actual number of complications during the study period. Obviously, the true complication rate is underestimated in the MDR system. Given the potential situational and even psychologic reasons that determine the reporting of an individual event, there is no way to decide whether the proportions of the various reported complications represent a valid description of the true population of complications. For example, the rate of infection, the most serious complication commonly associated with central vascular catheters, is reported as “negligible.”

It is clear that if the MDR database identified a particular mode of mechanical failure or even a systematic physician error, such information would be useful and should be promptly disseminated to both physicians and manufacturers. Could this “simple” database be misleading? We can conceive of situations in which the overemphasized report of a complication with a low probability of occurrence could lead a physician to avoid a useful technique that has a high probability of benefit. Further, extrapolation of biased data to a larger population could result in erroneous conclusions regarding the number of patients at true risk for complications from a given procedure.

We believe this description of the MDR database is a relatively innocent example of what may be a greater problem for physicians in this country. There are many other existing or planned Federal medical databases, each of which is a nicely computerized mass of data, that the government may analyze and report without any real regard for such scientific practices as controls or appropriate statistical caveats. For example, the DHHS is mandated by Congress to establish a national data bank on malpractice claims and licensure actions. While there are clearly useful purposes to having such information, the potential for misinterpretation and statistical bias is apparent. Another recent case in point is the Federal government’s release of the hospital mortality rates of Medicare beneficiaries, with little attempt to correct for variation in patient selection, trauma, emergency cases, etc. Currently, DHHS has proposed a preliminary study to “rate” all doctors who treat Medicare patients on the quality of their care.1 It is not clear whether this represents a naive attempt to provide consumers with data or a broader political agenda. Dr. William Roper, administrator of the Health Care Financing Administration (HCFA), stated that in addition to studying how to make doctors more effective, the government will use the data to “steer” Medicare patients to those physicians whom the study revealed practiced “quality medicine.”

It is apparent that American physicians will be increasingly subjected to further governmental data collection and reporting. The appropriate use of health care data can enhance our ability to deliver the best and most cost effective medical care at minimal risk to our patients. We who practice medicine must respond through our local and national organizations by insisting that this critical process be done in an intelligent and constructive manner.

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Reference


Tube Thoracostomy Drainage
An Alternative in the Management of Giant Bullae?

In this issue (see page 1289), Uyama and associates report a single case where it appears that tube thoracostomy was successful in alleviating the symptoms of expanding giant bullae. MacArthur and associates1 have described in detail the technique and experience in 35 patients. The method of cauerostomy with suction and drainage was proposed by Monaldi