THE ROLE OF CLINICAL DATA IN POSTMARKET SURVEILLANCE OF CARDIOVASCULAR DEVICES

WORKSHOP SUMMARY

The American College of Cardiology (ACC) and the Center for Devices and Radiological Health (CDRH), FDA, jointly sponsored a workshop on postmarket monitoring of cardiovascular devices on February 2-3, 2000 at the ACC Heart House, in Bethesda, MD. The ACC and FDA were joined by the Health Industry Manufacturers Association in organizing this workshop entitled, the Role of Clinical Data in Postmarket Surveillance of Cardiovascular Devices, chaired by John W. Hirshfeld, Jr., M.D., FACC and Larry G. Kessler, Sc.D. The two-day workshop was a collaborative effort that resulted from an earlier meeting, held during the ACC Annual Scientific Sessions in New Orleans, in March 1999. The March 1999 workshop prompted discussions with clinicians and others on the need for a universal system to collect surveillance data on cardiovascular devices that would serve the needs of clinicians, FDA, industry, and others. The participants recommended a follow-up session to explore the issues during a more in-depth, two-day meeting.

The February 2000 workshop brought together a diverse group of constituents from government, industry, and the clinical community, in an effort to explore challenges in postmarket surveillance of cardiovascular devices and strategies for improving performance monitoring of such devices. The opening plenary session provided an overview of perspectives and current activities for each of the three major constituencies. Assessment of roles and responsibilities, as well as relationships with other constituents were important objectives of the workshop, in order to explore potential collaboration in developing a mutually beneficial mechanism for postmarket surveillance of cardiovascular devices.

The presentation included a “strawman” for an enhanced approach to postmarket surveillance that outlined the needs of government, industry, and the clinical community, as well as overall requirements for employing extant databases in support of current postmarket surveillance activities. Each of the three constituents is committed to ensuring safety and effectiveness of devices. However, recognizing that concerns exist, including confidentiality, scope of regulatory authority, diversity of existing databases, and data accuracy, the strawman highlighted the need for collaborative effort, additional funding, and modification of current databases, so that the needs of various constituents might be met. The following is the strawman concept that was proposed:

- Clinical registries should be used to meet needs/interests of all three constituents
- Registries need to be modified to include product-specific information in context of patient disease management
- Manufacturers’ sales representatives could promote participation in clinical data registries as part of servicing accounts

- Funding is needed from new mechanisms/sources

- Funding from industry should be based upon a beneficial business case:
  - Generate value-added information for manufacturers on product use, market context, outcomes, etc.
  - Share responsibility of data collection
  - Reduce redundant costs and gain economies of scale

- Funding from Government could be through grants, contracted services, or Cooperative Research And Development Agreement (CRADA)

After discussion of the strawman proposal by the constituent panel and the audience, participants met in breakout sessions, organized according to three major categories of cardiovascular devices, with the charge to focus on one device type within each group, to attempt to develop concrete suggestions for future directions. The categories included: interventional (stents), surgical (heart valves), and anti-arrhythmia (defibrillators, pacing leads, pulse generators) devices. Existing registries and other databases served as models for discussion. Each breakout session explored specific opportunities or unmet needs in postmarket surveillance, and identified obstacles, potential solutions, probable benefits, and implementation strategies for database approaches as they apply to a particular device.

All three breakout groups agreed that there is opportunity to establish a system for the collection and management of information which would be helpful in meeting specific goals. These goals include, 1) improving patient management through rapid access to postmarket data and outcomes (particularly rapid identification/evaluation of device problems), and 2) eliminating redundancies among current data collection activities. Discussion also addressed the collection of data on unapproved or "off-label" uses of devices. It was emphasized that registry data on off-label uses may not be used to subvert the Investigational Device Exemption (IDE) regulations. However, high-quality clinical registries can serve as valuable sources of data for assessing device performance in the postmarket setting and when appropriate, potentially expedite the time to market, by providing device reviewers confidence in similar or previous versions of a product, and the knowledge that systems exist for vigilance, once a product enters the marketplace.

Specific opportunities included the following:

- Use extant registries in support of, not replacement for, current postmarket surveillance mechanisms. Registries provide opportunities to collect data from a broader population of patients and physicians than do current surveillance mechanisms, and could be used to identify device performance trends, inappropriate off-label use, and hypotheses for follow up studies.

- Develop standardized data elements, including definitions of risk factors related to devices and device applications

- Collect long-term data on significant events, quality of life/functionality, and quality of care

- Monitor actual practices and practice bias, for both on-label and off-label use of devices

- Reduce overall cost of data collection by eliminating unnecessary redundancies that may exist among current systems

- Use technology as appropriate, to enhance data collection while containing costs

The breakout work groups also identified a number of constraints that need to be addressed:

- Maintaining confidentiality of patient, physician, and corporate data

- Ensuring data consistency, reliability, and accuracy

- Establishing a means of ensuring joint control over the data

- Ensuring that the cost of data collection is outweighed by the benefits

- Confronting potential liability issues

The workshop concluded with summary presentations by each of the breakout session chairs on the deliberations in each device area, and discussion of potential next steps in the process of developing a postmarket surveillance system to meet the needs of all stakeholders. These consisted of the following recommendations in closing the workshop:

<u>Potential short-term activities</u>

- Broader involvement by industry, clinicians, and related organizations such as third party payers, Health Care Financing Administration (HCFA), Veterans Administration (VA), Agency for Healthcare Research and Quality (AHRQ)

- Communication with colleagues and stakeholders to identify current sources of data, unmet needs and opportunities to reduce redundancies in data collections

- Identification and prioritization of unanswered clinical practice questions and additional research opportunities

- Reexamination by FDA of least burdensome approaches as they may involve postmarket surveillance

- Pursuit of opportunities using information technologies, such as on-line data entry and bar coding, to enhance data collection methods

- Development of data collection methods that address issues of privacy and data confidentiality and also that ensure compliance with patient confidentiality laws

- Further definition of incentives for the government, clinical community and industry to participate in data collection activities

Possible future initiatives

- Further development of the strawman proposal, and exploration of options, including, 1) establishment of a national cardiovascular database, 2) creation of a limited model based on current efforts in one device area, or 3) construction of a postmarket surveillance system for a newly marketed technology

- Development by HIMA of a model document of agreement between industry and clinical societies, for the registry to provide data needed by industry

- Enhancement of the rapidity/validity of the MDR system, for improved early warning

- Exploration of the role of the ACC National Cardiovascular Data Registry (NCDR), with respect to potential upgrades/modification, and sources of funding

This workshop was a significant first step in identifying opportunities for a mutually beneficial system for postmarket monitoring of cardiovascular devices. Implementation of the workshop recommendations will require a cooperative investment by all constituent partners. Successful strategies and solutions to address unmet needs and overcome obstacles in postmarket surveillance can substantially contribute to improved patient outcomes through use of safe, effective medical devices.

The FDA welcomes the submission of comments on this summary and expressions of interest in participation in related postmarket activities. The agency is particularly interested in comments on current methods of data collection and analysis for postmarket monitoring of cardiovascular devices, how current methods could be improved through the use of registries or other alternative mechanisms, and the priority of the above workshop recommendations.

Comments should be submitted by June 1, 2000 to Anita Rayner by e-mail at arb@cdrh.fda.gov or telefacsimile at (301) 594-0050.