Effective Health Care

Safety and Quality of Cardiac Rhythm Devices
Nomination Summary Document

Results of Topic Selection Process & Next Steps

- Safety and quality of specific cardiac rhythm devices does not fit within the domain of the Effective Health Care (EHC) Program because this topic represents a regulatory issue better suited for other federal domains, such as the United States Food and Drug Administration (FDA). No further activity will be undertaken on this topic.

Topic Description

Nominator: Individual

Nomination Summary: The nominator wishes to see guides developed for physicians and patients that present the safety and quality of various cardiac rhythm devices, including pacemakers, implantable cardioverter-defibrillators (ICD), cardiac resynchronization therapy (CRT) devices, and leads. The nominator states that these guides should be developed from FDA information, warning letters, and the AdvaMed Guide.

Staff-Generated PICO:
Population(s): Patients with arrhythmias and/or heart failure who are candidates for device therapy
Intervention(s): Cardiac rhythm devices, including pacemakers, ICDs, CRTs, and leads
Comparator(s): The above devices compared between manufacturers
Outcome(s): Safety (e.g., number, class, and trends of recalls over time; FDA warning letters; premature battery depletion; loss of therapy); quality (e.g., percent cumulative probability survival; longevity estimates versus real performance), cost (e.g., cost-benefit relationship between product price versus quality and safety); patient quality of life; and rates of follow-up

Key Questions from Nominator: None

Considerations

- Cardiovascular devices make up a large portion of recalled devices in the US. The increase in recalls and advisories in recent years has significant implications for clinicians and patients. Patients, their families, and physicians are faced with a challenging decision that involves weighing the risk of device malfunction with the risks involved with device removal and replacement. Managing patients with

device and lead advisories is becoming a more common practice for specialists in this field. The Heart Rhythm Society and the European Cardiac Arrhythmia Society have produced guidelines for patient care in the setting of an advisory.

- Recently, the FDA's 510(k) device approval process has been scrutinized after several problems with malfunctioning devices. In 2009, they began action towards reevaluating the current 510(k) process, including the production of two reports in August 2010. The reports were conducted by the FDA's Center for Devices and Radiological Health (CDRH). Detailed recommendations are provided in these reports, including a recommendation that CDRH build upon public databases to include meaningful, up-to-date information that supports good decision making, promotes the safe use of devices, and improves upon the current database by including summaries of FDA review decisions, current labeling, and photos. The reports can be found at: http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHReports/ucm239448.htm.

- In addition, the FDA has requested the IOM to review the 501(k) process. The expected IOM report titled *Public Health Effectiveness of the FDA 510(k) Clearance Process* is due in mid-2011. Specifically, the IOM committee will answer two main questions:
  1. Does the current 510(k) process optimally protect patients and promote innovation in support of public health?
  2. If not, what legislative, regulatory, or administrative changes are recommended to optimally achieve the goals of the 510(k) process?

- This topic is a better fit with the domain of the FDA rather than the EHC Program due to the nominator's interest in outcomes based on FDA information, including the number and trends of recalls over time, numbers of FDA warning letters, and incidence of premature battery depletion outcomes. Therefore, no further action will be undertaken on this topic within the EHC Program.