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## Risks, Benefits of Emerging Heart Valve Replacement Technique Not Fully Understood

Press Release Date: August 2, 2010

A newer, less invasive method of heart valve replacement shows promise and may be appropriate for patients who cannot tolerate traditional open heart surgery, but research is needed to understand its potential risks and benefits, according to a new study funded by the Department of Health & Human Services' (HHS) Agency for Healthcare Research and Quality (AHRQ).

The report finds that percutaneous heart valve replacement, a procedure in which a replacement valve is implanted through a catheter rather than by open heart surgery, is a realistic option for some patients with heart valve disease, especially older or sicker patients. The report found that percutaneous heart valve replacement may be a safe and effective alternative to open heart surgery, especially in the short term, for those patients. However, information is lacking on the potential long-term benefits and risks of this procedure, particularly compared with open heart valve replacement surgery. The report did not conclude that any of the seven valves studied is safer or more effective than another.

The report was produced by the Duke Evidence-based Practice Center for AHRQ, a leading Federal agency conducting comparative effectiveness research. Results of the report were published online today in *Annals of Internal Medicine*. Heart valve disease—a narrowing of the heart valve—is blamed for approximately 20,000 deaths a year.

"As the U.S. population ages, the number of patients with heart valve disease will increase, so more Americans will need options for safe, effective heart valve replacement," said AHRQ Director Carolyn M. Clancy, M.D. "This report identifies what is known about this emerging procedure and where the research is lacking to give patients more options about their treatment."

Conventional heart valve replacement is a well-established procedure, with approximately 95,000 open heart surgeries performed per year for patients with severe narrowing of the heart valve. However, as many as one-third of patients with severe heart valve disease are considered too high risk for open heart surgery, in which patients typically are under general anesthesia for three to six hours, are hospitalized for 5 to 6 days, and require recovery time of 12 weeks. These patients would likely benefit from a less invasive option.

The report found that percutaneous heart valve replacement is a good option for patients at high risk for traditional surgery because of advanced age or illness. Approximately 92 percent of patients who received a percutaneous valve survived the procedure; of those, 86 percent survived for at least 30 days, the report found.

Catheter-based valve implantation was first reported in 2002. Just one device, the Medtronic Melody Transcatheter Pulmonary Valve and Ensemble Delivery System, currently has approval from the U.S. Food and Drug Administration. This device was approved in January 2010 under the Humanitarian Device Exemption program. Percutaneous heart valve replacement surgery has been available in Europe for nearly 2 years.

The report identified 62 published studies representing a total of 856 patients, as well as additional studies not yet published. However, researchers were unable to make direct comparisons between percutaneous valves and traditional surgical replacement because of differences between patient groups receiving the treatments. Clinical trials that may allow direct comparisons are currently underway in the United States.

*Percutaneous Heart Valve Replacement* is the newest technical brief from AHRQ's Effective Health Care Program. Technical briefs are rapid-turnaround reports that summarize key issues regarding emerging treatments, highlighting where more research is needed, and where research may be sufficient to warrant a full systematic comparative effectiveness review. The Effective Health Care Program represents a leading federal effort to compare alternative treatments for health conditions and make the findings public to help doctors, nurses, pharmacists and others work together with patients to choose the most effective treatments.

In conjunction with the new report, AHRQ will soon publish plain-language summary guides about heart surgery for patients, clinicians and policymakers. Summary guides on numerous clinical topics and other information and background on the Effective Health Care Program can be found at <http://www.effectivehealthcare.ahrq.gov>.

For more information, please contact AHRQ Public Affairs: (301) 427-1998 or (301) 427-1855.