Cardiac Stents Teleconference
Key Questions Discussion
06/06/2008

Purpose:
The HTA program is considering an additional process step around defining key questions for our evidence review report. Before the HTA program finalizes the draft key questions, teleconference meeting was held to facilitate a dialogue about the key questions and any issues or questions that were raised during the public comment period.

Participants
1. HTA Program
2. Companies: Abbott Laboratories; Boston Scientific; MedTronic; Johnson & Johnson
3. Provider/Associations: American College of Cardiology; Society for Cardiovascular Angiography and Interventions; University of Washington
4. State Agencies: WA Labor & Industries

Introduction
To set context and address some public comments, a brief overview of the HTA program and its mission were given. See http://www.hta.hca.wa.gov/ for program information. In general, the program was given a directive to investigate technologies and pay for those that are proven safe, effective, and cost effective. This is accomplished by using a systematic reviewer to produce an evidence report and an independent clinical committee. Our program, similar to a "consumer reports" type service produces buyer's guidance where the focus is on information that a purchaser needs in order to make a good decision.

Comments Summary
Some overall comments are summarized here, with more detailed comments addressed in the key question categories below.

Several comments related to FDA approval and the interaction between the program's review and any FDA reviews, generally urging either that the program limit its questions to those posed by the FDA or stating that the FDA has already or is investigating this topic and thus this program's review is unnecessary.

- There are linkages between the FDA and our program, but we have different purposes which is why our questions and issues are different. First, the HTA is located in a government agency, like the FDA, but we aren't regulatory. Our mandate is to help the state make good health care purchasing choices. The FDA and agencies like Department of Health regulate industry and health care providers by issuing rules or requiring approvals to sell, manufacture health technologies or medical practice requirements. Therefore, the questions are very different – for regulation, the primary mandate is to ensure a basic and consistent level of safety. For purchasing, we are looking questions related to how to get the best value for the limited state resources we have. The second connection is that,

as part of our inquiry about a technology, we would always include information on FDA approval status, where approval is required.

Several comments related to the timing of this topic and generally indicated that it should be delayed for various reasons: there isn't any data; data to answer questions asked requires years to accumulate; data is being constantly updated; data on "real world" usage is forthcoming.

- Timing concerns are very typical for technology assessment work, and generally stem from market perspective and value differences. The program mechanism to account for this is the required consideration for re-review at least every 18 months.
- The criteria for selection are based on our statutory mandate to look at technologies where there are concerns about safety, efficacy, cost or potential cost to state programs.
- In this case, the dramatic rise in recent years in usage of stents and the variation in approach, primarily placement in off-study settings, is a primary reason this technology topic was chosen. Here, the technologies' use has spread to indications not originally approved, and the question is whether state agencies should continue to pay for all stent use. The program goal is to ensure an appropriate level of evidence before public agencies make a significant resource investment.

Key Questions –
For this topic, we are at the stage of finalizing our research questions that we will ask our technology assessment contractor to review. The program uses a standardized methodology for developing evidence review questions called by the acronym "PICO+".

PICO+ Categories

- **P**opulation:

The full stent topic for all indications and settings is too large a topic. We began to narrow the topic by focusing on intermediate disease patients (not emergency or asymptomatic). It appears from public comment that the term unstable angina may not be the best descriptor and it could inadvertently lead to certain studies that do address multiple stent placements being excluded. We will adjust the key questions and use the intervention description to narrow the topic and allow the evidence review vendor to segment the studies by population.

- **I**ntervention

We further narrowed the topic to look at patients with more complex indications. Single vessel, defined lesion placement is relatively well established and was the basis of stent approval. More complex indications include: multiple vessel; long lengths; small vessel; non-denovo; left main; ostial; full occlusion; acute MI situations. Of these, we focused on the multi-stent placements because this is a major portion of off -study usage, has study information available, and may be capable of translating to a purchasing decision.

- **C**omparator

The comparators are medical therapy (non surgical) or coronary bypass surgery. We will ensure that the evidence vendor reviews the COURAGE trial make sure that key questions do not inadvertently exclude this evidence

- **O**utcomes

The outcomes of interest are listed, in addition to those related to the safety profile; and any cost analysis. A question about impact on any defined sub-populations or patient groups is always included. No additional outcomes were suggested for inclusion.

Comments / Questions

Q: In the next 12 to 18 months more data will be available to do a better assessment of this health technology. Has a concern that this is not an effective use of state resources if the study would have to be re-done; consumer reports would wait until enough information to study.

A: The HTA program wants to pay for what works based on available evidence. There is a re-review process every 18 months. Consumer reports may note not enough data (e.g. reliability) but would include and rank. We need to make sure that as state purchasers we are focusing our limited resources at best use. If there are actionable, current studies that are forthcoming, they need to be shared with the program (rather than general reference to studies underway). They will be considered, but for this topic, it has already been subject to six months worth of public comment and we are currently in the process of finalizing key questions. Leah will review if submitted.

Q: Mitch Sugarman will forward to Leah studies about real world usage

Q: Thought this process was meaningful since he found the draft key questions confusing.

Q: Would like for this process to be done during the public comment period so people can interpret the information from our program before submitting their responses to the program.

A: Thanks, we will take the comments about this “trial process” and any others received after the teleconference into account.