

MINUTES

Evidence-based Guidelines Subcommittee
Meridian Park Community Health Education Center, Room 117B&C
19300 SW 65th Avenue, Tualatin, OR
June 5, 2014
2:00-5:00pm

Members Present: Wiley Chan, MD, Chair; Beth Westbrook, PsyD, MPH; Leda Garside, RN, MBA; Som Saha, MD, MPH; Bob Joondeph, JD; Eric Stecker, MD, MPH.

Members Absent: Steve Marks, MD, Vice-Chair; Vern Saboe, DC

Staff Present: Darren Coffman; Cat Livingston, MD, MPH; Jason Gingerich.

Also Attending: Alison Little, MD (CEBP); Shannon Vandergriff (CEBP); Erika Zoller, (CEBP), Barbara Morrow (Astellas), Bill Struyk (Johnson and Johnson), Sue Miller (Astellas), Stephen Heitner, MD (OHSU, appointed expert for Nuclear Cardiac Imaging).

1. CALL TO ORDER

Wiley Chan called the meeting of the Evidence-based Guidelines Subcommittee (EbGS) to order at 2:09 pm.

2. MINUTES REVIEW

No changes were made to the April 24, 2014 minutes.

Minutes approved 6-0.

3. STAFF REPORT

Coffman reported that, prior to the May VbBS meeting, staff has discovered that putting intensity and duration limits on mental health services may conflict with Federal Mental Health parity regulations, which created concerns about the limits in the Evidence Evaluation on Applied Behavior Analysis for Autism Spectrum Disorder. Staff will present a revised recommendation to VbBS which summarizes the evidence on intensity and duration but does not create a hard limit. Staff believes it is allowable to have language requiring an evaluation to ensure that progress is being made. The Evidence Evaluation will eventually need to come back to EbGS to align the two documents. Chan asked about EIBI, as intensity is part of the definition of therapy. Coffman said that EIBI could be described but that the language on absolute limits would be removed. He acknowledged that the onus would be on the CCOs to interpret medical appropriateness in individual cases using a consistent methodology. The subcommittee discussed how parity really applies, and tried without success to identify similar services in the physical health field that are provided for many hours per week for long periods of time; however, there are certainly expensive medications that might be used for long periods of time. The group also discussed how cost effectiveness considerations might fit into parity.

4. REVIEW OF PUBLIC COMMENTS

A) Ablation for atrial fibrillation

Alison Little reviewed the draft coverage guidance, including the evidence and clinical context. Livingston reviewed the GRADE table. Saha asked about the row on atrioventricular (AV) ablation versus rate control where individual pharmacotherapy was ineffective. This seems contradictory. Livingston said that she was hoping to get clear guidance on the best sequence of therapies based on the AHRQ report. There is no way to derive that kind of pathway from the evidence. In this case, if a patient fails to benefit from rate control medication, the question is whether to try ablation or additional rate control. Stecker said that it would also be an option to tolerate inadequate heart rates, or to prescribe additional drugs. However, he said that for elderly patients, ablation is preferable to multiple drugs. Saha asked Stecker whether rhythm or additional rate control would be preferred for a patient who fails rate control. Stecker said some studies show you don't need to do rate control as aggressively as was done in the past—a rate of 100 to 110 may be ok. Depending on the heart rate, you may try rhythm or add a pacemaker and AV node ablation. For the elderly, he said quality of life is better with AV ablation. For younger patients you might try rhythm control before implanting a pacemaker for life. Saha asked what the threshold for rate control was and whether the studies in our report included the more relaxed rate control levels. Little said that in general a resting heart rate of 90, or 130 with exertion was considered as needing treatment for most of the studies. After discussion, the subcommittee modified the recommendation on ablation to allow coverage with patients who have inadequate rate control that makes them symptomatic or puts them at risk for left ventricular systolic dysfunction.

Chan observed that transcatheter pulmonary vein isolation would also be an option for patients who fail rate control. Westbrook asked whether the preference for this treatment differs from hospital to hospital. Stecker said the treatment is preference sensitive based on many factors, including, but not limited to, financial factors. There is not enough evidence to add additional nuance about the choice between these therapies. Chan asked what the purpose of the coverage guidance is. Stecker said one potential would be to address heterogeneity of care; another would be to identify treatments with an unfavorable balance of benefit and risk. There is not sufficient evidence to do either of these. Another possibility is to address when to choose rate versus rhythm control. There is data for elderly patients showing that the strategies are equal from a mortality standpoint, except that hospitalization rates vary.

Saha said the pulmonary vein isolation (PVI) recommendation reads as if a surgeon should not do PVI during another cardiac surgery but should complete the first procedure then do a transcatheter PVI procedure instead of doing it all at once. After discussion the subcommittee changed the language to clarify that PVI is recommended for certain patients undergoing other cardiac surgery, but transcatheter PVI could be done as a standalone procedure in patients not undergoing other cardiac surgery.

The subcommittee discussed whether to require failure of both rate and rhythm control medications before transcatheter PVI. Little said most studies required failure of both, though one trial did not include a trial of rhythm control. Stecker said the practice guidelines have recommended a trial of antiarrhythmics. After discussion the group decided to require a trial of antiarrhythmics.

The subcommittee also decided to separate the recommendations about transcatheter PVI and PVI during other cardiac surgery since the populations are different. [CL1] The subcommittee then discussed the Maze procedure. Members decided to remove the language about risk of mortality, as standard care would include weighing the risk of mortality during surgery. Stecker clarified that the historic Maze procedure is rarely done, with current practice being more like a PVI plus Maze. In addition, the subcommittee decided to recommend Maze only at the time of other cardiac surgery, due to risks of the procedure. Livingston asked Little to confirm that this aligns with the entry criteria for the trials.

The subcommittee made corresponding changes to the rationale section, working from a handout provided at the meeting. They also removed the last three rows of the GRADE table comparing rate versus rhythm control, along with related evidence, because the evidence to support detailed treatment approaches is lacking and can be left to the surgeon.

There was no public comment.

A motion was made to put the coverage guidance as modified out for public comment.

Motion approved 6-0.

HERC COVERAGE GUIDANCE

AV node ablation is recommended for coverage only in persons with inadequate ventricular rate control resulting in symptoms, left ventricular systolic dysfunction or substantial risk of left ventricular systolic dysfunction. Coverage is recommended only when pharmacological therapy for rate control is ineffective or not tolerated (*weak recommendation*).

Transcatheter pulmonary vein isolation is recommended for coverage for those who are persistently symptomatic despite rate control medications and antiarrhythmic medications (*strong recommendation*).

Pulmonary vein isolation is recommended for coverage at the time of other cardiac surgery for patients who are persistently symptomatic despite rate control medications (*weak recommendation*).

The Maze procedure is recommended for coverage at the time of other cardiac surgery for patients with significant symptoms from atrial fibrillation (*weak recommendation*).

B) Nuclear Cardiac Imaging

Dr. Steve Heitner, the appointed expert for this topic, introduced himself and said that he has no conflicts of interest. Little presented the draft coverage guidance, based on the Washington Health Technology Assessment report on Nuclear Cardiac Imaging. Livingston reviewed the GRADE framework.

There was discussion about ETT vs ECHO vs SPECT and it was determined that the indications for ETT vs ECHO were outside the scope of this coverage guidance. There were concerns that the cost analyses produced conflicting results, the potential harm of radiation is hard to quantify, and the risk of angiography (increased referrals due to false positives) may be inadequately accounted for.

Heitner clarified that in certain patients ECHO versus nuclear is not equivalent. For instance, in morbidly obese patients where acoustic windows are difficult to obtain, the accuracy of the stress ECHO goes way down and stress nuclear imaging would be preferred. He described several other cases where alternative tests might be preferred. Stecker shared that it is common for inappropriate testing modalities to be ordered (for example an exercise treadmill test on a wheelchair bound patient) and more appropriate tests may need to be done. Institutional expertise is also deemed to be a factor in preferred imaging testing. Using a nonpreferred test may result in risk to the patient and cost from additional testing and procedures.

The subcommittee chose to change the references to harm from radiation to “potential harm” as no evidence has been presented that the amounts of radiation used in these tests produces actual harms and an angiogram would include a higher dose of radiation.

The subcommittee chose to not recommend SPECT for screening. They chose to recommend against coverage for SPECT for diagnosis or risk stratification unless stress ECHO results would be suboptimal or would be contraindicated. Heitner provided a list of patient conditions for which ECHO would be suboptimal or contraindicated:

- 1) Preexisting cardiomyopathy or regional wall motion abnormalities
- 2) LBBB
- 3) Paced rhythm
- 4) Unsuitable acoustic window due to body habitus
- 5) Need for pharmacologic stress agent but contraindication to administration of dobutamine

The group decided to add these instances as appropriate for coverage of SPECT. Reference to a guideline was also recommended to assist clinicians and medical directors to justify when SPECT may be preferable to ECHO.

The subcommittee then moved to discussion of PET scanning. It was agreed that the evidence was insufficient at this time and recommended noncoverage.

A motion was made to approve the draft coverage guidance as modified and put it out for public comment. **Motion approved 6-0.**

HERC COVERAGE GUIDANCE

PET is not recommended for coverage for screening or diagnosis of coronary artery disease (CAD) (*strong recommendation*).

Single photon emission computed tomography (SPECT) is not recommended for coverage for screening of CAD (*strong recommendation*).

SPECT is not recommended for coverage for diagnosis or risk stratification of CAD (*strong recommendation*)—except in patients for whom stress imaging is required and stress ECHO is contraindicated or would provide suboptimal imaging.*

**i.e. pre-existing cardiomyopathy, baseline regional wall motion abnormalities, left bundle branch block, paced rhythm, unsuitable acoustic windows due to body habitus, inability to utilize dobutamine in a setting where exercise is not possible or when the target workload is not achievable*

6. ADJOURNMENT

The meeting was adjourned at 5:00 pm. The next meeting is scheduled for September 4, 2014 from 2:00-5:00pm in Room 117B&C of the Meridian Park Hospital Community Health Education Center in Tualatin.