

MINUTES

EVIDENCE-BASED LIST TASK FORCE

Tuesday, June 17, 2003

Members Attending: Eric Walsh, MD, Chair; Kathy Savicki, LCSW; Jono Hildner.

Members Absent: Bryan Sohl, MD, Dave Arnold.

Staff Attending: Darren Coffman; Carole Romm, RN; Laura Lanssens.

Others Attending: Paul Potter, MSW, Cascadia Behavioral Healthcare; Diane Lund, Oregon Health Forum; Marylou Hazelwood, RN, Office of Medical Assistance Programs (OMAP).

I. Call to Order

Dr. Eric Walsh called the Evidence-based List Task Force meeting to order 1:36 p.m. in Room 326 of Emma Jones Hall at Oregon Health Science University (OHSU). Darren Coffman noted attendance. Mr. Coffman also reminded the task force that Dave Arnold had given his resignation from the HSC and would no longer be attending as a member of the task force.

II. Goals of the Meeting

Dr. Walsh informed the task force that the goals of the meeting. The first is to “road test” a methodology that might be used when assessing new technologies and new treatments that come before the Health Services Commission (HSC) for consideration. The task force will report back to the HSC at their July 24th meeting on how useful this methodology may be in the future.

A second goal is to discuss how to apply the methodology existing, commonly used technology. The third goal is to determine what level of evidence the HSC should accept as deserving of their approval for both new and old technology.

Dr. Walsh thought that such a methodology could be easily applied to most new technologies that come along but may prove more difficult for existing ones.

III. Review of Sources of Clinical Evidence

Darren Coffman briefed the task force on a meeting that he and Bruce Goldberg, MD, Administrator of the Office for Oregon Health Policy and Research (OHPR), had with Mark Helfand, MD, Director of the Oregon Evidence-based Practice Center at OHSU. Dr. Helfand looked over a list of sources that the task force had reviewed at its last meeting. He identified four additional sources that the task force should consider adding:

1. CMS Medicare Coverage Advisory Committee (MCAC)
www.cms.hhs.gov/ncdr/mcacindex.asp
2. Canadian Coordinating Office for Health Technology Assessment (CCOHTA)
www.ccohta.ca
3. Bandolier www.jr2.ox.ac.uk/bandolier
4. ECRI www.ecri.org

Also Dr. Helfand thought that the HSC should consider giving extra weight to three particular sources:

1. National Institute for Clinical Excellence (NICE) – United Kingdom
www.nice.org.uk/cat.asp?pn=professional&cn=toplevel&ln=en
2. CMS Medicare Coverage Advisory Committee (MCAC)
3. Canadian Coordinating Office for Health Technology Assessment (CCOHTA)

The reason for giving these three sources special consideration is that the decisions made by these bodies directly relate to coverage decisions. This is not the case with other sources of evidence-based research such as BMJ Clinical Evidence, where they simply publish their findings for others to use as they see fit. NICE and CMS both have public processes, and CCOHTA to a lesser extent. Dr. Helfand acknowledged that political considerations may play a factor in some coverage decisions, but that this happened less than 20% of the time and that they original evidence-based reports should still be available for review.

Dr. Walsh said that the HSC would be interested in Dr. Helfand's suggestions as he is the head of the Evidence-based Practice Center at OHSU and frequently works with many of these entities being looked at as sources.

IV. Review of Methodologies for Evaluating Studies on Clinical Effectiveness and Discussion of What Constitutes Good Evidence

Carole Romm gave a brief overview of the different methodologies the various sources used for evaluating the levels of evidence. They ranged from a very detailed A-D grading system used by the Centers for Evidence-Based Medicine to the unstructured account given on a review-by-review basis by BMJ Clinical Evidence. The task force members felt that the experts performing the reviews for all of these sources were better

at determining their validity than they were and that they wouldn't come to a conclusion about the technology one way or the other without a reasonable level of evidence.

V. Work Session on Defining a Process for Incorporating Clinical Evidence into Prioritized List using Selected Clinical Examples

Carole Romm proceeded to walk the task force through process of using the Internet sources identified for selected technologies.

A. Oral glycoprotein IIa/IIIb receptor inhibitors for secondary prevention of ischemic cardiac events

Evidence was found on both the BMJ Clinical Evidence and NICE websites indicating that this drug is not only ineffective when used for this indication, but is also harmful to the patient, causing increased mortality and morbidity. Evidence was also known to exist on the ACP website. However, a password is necessary to gain access to that material and it was not available. This is a good example of a service that could be removed from the list.

B. Bypass surgery for peripheral atherosclerosis

Only the BMJ Clinical Evidence website included research on the use of bypass surgery for peripheral atherosclerosis. The study indicated that surgery did not increase lifespan or decrease the rate of amputation compared to other conservative measures and concluded that this treatment is of unknown effectiveness. Since other treatments are available that are shown to be effective this may be a service the HSC should consider removing in the future, but it is not as clear-cut as with the glycoprotein inhibitors.

C. Essure procedure for female sterilization

No mention of the new female sterilization technique called Essure were found on any of the Internet sources. The only information found was located on the manufacturer's website, www.essure.com. This does not meet the task force's requirements as an unbiased source and cannot be considered.

VI. Next Steps

The task force agreed unanimously that the process outlined at the May 22nd meeting should be recommended to the HSC. Dr. Walsh will report on these recommendations at the Commission's July 24, 2003 meeting. At that time it will be determined if further meetings of this task force will be necessary. He imagined that incoming Medical Director Dr. Alison Little would likely take the lead on finding evidence-based reviews to

bring forward from the sources identified. Mr. Coffman thought that this work would take the place of the biennial review work done by the Health Outcomes Subcommittee.

VII. Adjournment

Dr. Walsh adjourned the meeting of the Evidence-based List Task Force at 3:21 p.m.

Eric Walsh, MD, Chair

MINUTES

EVIDENCE-BASED LIST TASK FORCE

Thursday, May 22, 2003

Members Attending: Eric Walsh, MD, Chair; Kathy Savicki, LCSW; Jono Hildner; Dave Arnold; Bryan Sohl, MD.

Staff Attending: Darren Coffman; Carole Romm, RN; Laura Lanssens

Others Attending: Tom Turek, MD and Marylou Hazelwood, RN, Office of Medical Assistance Programs; Tina Kitchin, MD, DHS Seniors & People with Disabilities group; Alison Little, MD; Diana Jones, Oregon Health Policy & Research (OHPR); Andrew Glass, MD, Health Services Commission (HSC); Lisa Gilliam, Schering-Plough Pharmaceuticals.

I. Call to Order

Dr. Walsh called to order the Evidence-Based List Task Force at 12:35 p.m. in Room 104, of Meridian Park Hospital Community Health Education Center, 19300 SW 65th Avenue, Tualatin, Oregon. Darren Coffman noted attendance.

II. Chair's Report

Dr. Walsh indicated that the purpose of the Evidence-Based List Task Force is to go through the Prioritized List on a line-by-line basis in order to find potential savings for the Oregon Health Plan through the use of evidence-based research. This may result either from the elimination of pairings from the list or through the establishment of additional guidelines.

He indicated that his review of the materials with staff showed a lack of information of procedural based services, most evidence-based research is in the field of prescription drugs. While Dr. Bruce Goldberg (OHPR Administrator) and Dr. Kathy Weaver (Health Resources Commission Director) have indicated that it would be appropriate for the HSC to look at excluding coverage of prescription drugs where evidence shows them to be ineffective, there are significant obstacles. First and foremost, prescriptions do not include the ICD-9 code, making it difficult to implement coverage decisions based on the diagnosis. One way around this is to require a prior authorization (PA) on the drug and ask for the diagnosis at the time of the phone call. OMAP allows for a five-day emergency supply of a drug while a PA is being obtained. Dr. Andy Glass said that HealthNet currently PA's about 25-30 drugs. Dr. Walsh also indicated that instituting quantity limits is another method of restricting the use of drugs.

Darren Coffman said that at the request of the HSC, language has been added to HB 3624 which specifies that the Commission consider “effectiveness and cost-effectiveness” in establishing the rankings on the Prioritized List of Health Services.

Dr. Walsh summarized the day’s discussion to be focused on three areas:

1. What tools should be used in determining a treatment’s effectiveness?
2. What levels of evidence are acceptable?
3. How should new services be dealt with?

III. Medical Director’s Perspective

Dr. Alison Little said that she did not have any comments at this point in time but would interject her thoughts as the discussion progressed.

IV. Sources of Clinical Evidence

Carole Romm directed the task force to a list of sources for evidence-based research that she had compiled (see Table 1). This list is a combination of the sources initially given by Dr. Weaver and those sent by Dr. Jeff Thompson. Ms. Romm then weeded out those websites that she did not feel were conducive to the needs of the task force.

TABLE 1

SOURCES OF INFORMATION FOR EVIDENCE-BASED HEALTH TECHNOLOGY ASSESSMENT

- a. BMJ Clinical Evidence <http://www.clinicalevidence.com>
- b. Evidence-Based Practice Centers (EPC) www.ahcpr.gov/clinic/epc
- c. Cochrane Collaboration www.cochrane.org/cochrane/revabstr/mainindex.htm
- d. University of York nhscrd.york.ac.uk
- e. Agency for Healthcare Research and Quality (AHRQ) www.ahcpr.gov
- f. Dartmouth Atlas www.dartmouthatlas.org
- g. Center for Evidence-Based Medicine www.cebm.net/searching.asp
- h. National Guideline Clearinghouse www.guideline.gov
- i. Health Technology Assessment Programme – United Kingdom <http://www.hta.nhsweb.nhs.uk/ProjectData>
- j. Institute for Clinical Systems Improvement <http://www.icsi.org>
- k. National Institute for Clinical Excellence (NICE) – United Kingdom www.nice.org.uk/Cat.asp?pn=professional&cn=toplevel&ln=en

The task force established the following criteria for a source to be considered valid for their use:

- research must be current either by either initially being done or updated within the last three years

- has no vested interest in the outcome of the research
- uses accepted methods of research based on the outcomes of *multiple studies*
- represents scientific literature

V. Existing Evidence-Based Studies

Carole Romm led the task force through a handout on existing evidence-based studies from her initial search of five different sources, with BMJ Clinical Evidence serving as the primary source. This first search was only done for services appearing on a line item on the Prioritized List, which falls in the top 25% according to average per-member per-month (PMPM) costs. No evidence-based studies existed for many of these line items.

The task force proceeded to look through the document, paying particular attention to those services where evidence for a treatment showed it to be “unlikely to be beneficial” or “ineffective or harmful.” It was decided that if a treatment results in a “trade off between benefit and harms” that the service should still be included on the Prioritized List with the clinical decision left to the physician and patient as to what is appropriate for an individual case. A treatment of “unknown effectiveness” can be considered for possible elimination or limitation through a guideline if there are known treatments that are “beneficial” or “likely to be beneficial,” unless the treatment is found to be a part of established lines for standard therapy. In this case a requirement of the use of step therapy may be appropriate for consideration.

VI. Discussion of Process for Incorporating Clinical Evidence into Prioritized List

An initial framework for a process was discussed as follows:

1. The HSC examines pooled data from one of the recognized sources/websites
2. Exceptions be allowed for rare diseases
3. The HSC be willing to look at new sources/websites for use as they are identified, and
4. Evidence against the effectiveness of a treatment be used to take a service off of the list and evidence for a treatment’s effectiveness be used to initially place it on the list.

VII. Methodology for Assessing New Treatments & Health Technologies

Dr. Walsh would like to see the Commission use the same process as discussed above in determining whether new treatments/technologies be placed on the Prioritized List.

VIII. Next Steps

The next meeting will serve as a work session to further develop this process. A computer will be hooked up to the internet with the screen projected for the task force to see what information is available for selected treatments. Some potential examples to use as treatments, which are unlikely to be beneficial or shown to be ineffective or harmful, are:

- glycoprotein IIb/IIIa receptor inhibitors for the secondary prevention of ischemic cardiac events or the treatment of unstable angina
- routine ultrasound screening in late pregnancy (> 24 weeks)
- non-surgical treatment or the use of a short cephalocondylic nail (vs. a sliding hip screw device) for treating extracapsular hip fractures
- intensive behavior therapy for attention deficit and hyperactivity disorder
- bypass surgery for peripheral atherosclerosis
- knee replacement in obese people
- beta blockers and certain other prescription drugs for the treatment of anxiety disorders

Staff will work with Dr. Walsh in selecting one drug-based therapy and one procedural-based therapy to use during the work session. Essure, a new method for female sterilization in an outpatient setting will serve as an example of a new technology to work through.

In addition, Kathy Savicki agreed to look at websites on evidence-based research as it applies to mental health treatments. Carole Romm will also develop a crosswalk for equating the findings of the various websites (e.g. “unlikely to be beneficial” may equal level C evidence on another site).

IX. Adjournment

Dr. Walsh adjourned the meeting at 3:06 p.m. The next meeting of the Evidence-Based List Task Force is scheduled for Tuesday, June 17, 2003, 1:30 p.m. to 3:30 p.m., Room 326, in Emma Jones Hall at OHSU.

Dr. Eric Walsh, MD, Chair