

**MINUTES
HEALTH RESOURCES COMMISSION**

JANUARY 27, 2006

Members Present/Phone: Walter Shaffer, MD Chair; Paul Tiffany, Vice Chair
Dean Haxby, PharmD; Steve DeLashmutt, MD; Manny Berman; Lynn-Marie Crider; James
MacKay, MD; and Judith Wilson

Members Absent: Dan Kennedy, RPh; John Saultz, MD; Mark Yerby, MD

Staff Present: Kathleen Weaver, MD, HRC Director; Beth Zehr, HRC Assistant,

1. Call to Order and Roll Call—Walter Shaffer, MD

[A-019] The meeting was called to order by Chair, Walter Shaffer, MD and roll call taken. Dr. Shaffer introduced our newest member of the Commission, Judith Wilson, Director of Human Resources at Oregon Medical Peer Review Organization (OMPRO). Guests of the Commission are current applicants Bill Origer, MD Samaritan Health of Albany and Kate Merrill, MD of Providence in Astoria.

2. Approval of Minutes—Walter Shaffer, MD

[A-115] **Minutes presented were 10-20-05 and 11-18-05**

Corrections for 10-20-05 Minutes: October minutes were included once again to review a list of ideas the Commissioners came up with and corrected copy shared. Dr. Shaffer noted that the attachment showing ideas from the HRC Project Planning Group should be replaced with the HRC ideas. Minutes were approved in November.

Corrections for 11-18-05 Minutes: Allison Knight corrected the OMAP Update to name the drug purchasing program 340 B.

[A-170] **Action:** The 10-20-05 Minutes (Document 1) and 11-18-05 (Document 2) were unanimously approved with the revisions made as requested.

[A-184]

3. OMAP Update – Allison Knight, Assistant Manager of Program and Policy, OMAP

There have been changes in staffing at OMAP. Alison Little, MD is working as interim Medical Director until Walter Shaffer, MD begins his new position in March.

The federal budget should be passed and the signing of the reconciliation bill is likely to take place on February 2, 2006. There have been many changes in Medicaid financing, one being the formula on how to calculate the drug prices. Another change that will have a big impact on Medicaid is the elimination of the State's Medicaid Managed-care Tax. This tax is how OHP-Standard is funded. Currently, the OHP Standard population has been reduced to approximately 23,500 people. For the states that have this managed care tax, it will be phased-out by 2009. CNS does allow a managed care tax, but it has to be across all business lines, not just the Medicaid managed-care plans.

[A-215] Other changes in the federal legislation affecting the OMAP department (but not necessarily the Oregon Health Plan) are: (1) targeted Case Management Federal funds are being restricted, (2) 2006 budget is passed, and (3) OMAP is looking ahead towards the 2007 budget.

Oregon Health Plan and DHS are dealing with a significant budget issue due to case load forecasting. It's difficult to forecast a case load even though it was expected to be smaller from the previous biennium given Oregon's improved economy. The projections were underestimated and created a budget hole of \$170 million for DHS. More oversight has been budgeted from the Governor's office and the Department of Administrative Services (DAS). In just six months into the current biennium, DHS is short on funds. While no actions are being taken at this point, they're watching carefully.

[A-265] Another main focus is implementing Medicare Part D. There is a profound impact on the Medicaid program because of difficulties in implementation. Foremost is the difficulty with the data from CMS that does not accurately reflect dual eligible patients' status. In January some 12,000 dual eligible Oregonians were mistakenly being asked to pay the \$250 deductible and co-pays. The State stepped in to assume these charges so that patients would not have to forgo their medications. OMAP is currently working on recovering the deductible and co-pays from those plans while the State is ensuring patients their prescriptions.

[A-297] *Question: How will the overall impact of Part D affect the State? Will the States be paying back a larger expense? How much more will it cost the State?*

The "claw-back" is what the Federal Government is taking back from the States based on calculations of payments for assuming the pharmaceutical costs for dual eligibles. Oregon made estimates of what they thought the claw back would cost, and though they're on target, Medicare Part D for duals does eliminate the ability to manage costs per patient. Dean Haxby commented that the claw back effect starts at 95% percent dropping each year to 75% of estimated 2003 charges over 5 years. The claw-back, based on the year 2003, results in a higher payback to CMS if the States had implemented programs since 2003 to save money.

[A-340] *Question: Will the Federal Government pay back the money to the States for the problem of Part D that people face?*

Yes, though there are many restrictions, they recently issued a letter that they will reimburse the States, if the States are not able to recover from the plans themselves. It seems that the first step is for the State to collect money from the plans.

OMAP has been working overtime to accommodate the phone calls coming in for Part D issues. Dr. Weaver commented that Medicare patients on Oregon Prescription Drug Program (OPDP) may continue to use their prescription card but they have to keep track of their own deductibles, co-pays and expenses while they are in "the dough-nut hole."

[A-380] *Question: will the dual eligibles be assigned randomly to a plan in their area?*

Yes, many were enrolled to a plan for their area, but there was a substantial amount that was enrolled in inappropriate plans. Each were counseled and assisted to move to other plans. Many things about Part D implementations have been very difficult.

Many networking people such as State Health Insurance Benefits Assistance Program (SHIBA) volunteers have been a great help in assisting patients. The call support, OHP case workers, and pharmacists have persevered for several months to help implement these changes.

[A-500]

4. Drug Class Updates – Kathleen Weaver, MD

HRC Report Antiplatelets – (Document 3)

The HRC essentially approved the Antiplatelets report at the last meeting in November 2005. Some edits have been made at HRC request and the report is back for a final decision. Page 13 of the Antiplatelet report shows a new conclusion – bullet #5 and bullet #6.

[A-540] Dr. Shaffer requested a revision of the sentence in bullet #5 to read “the weakness of this report is there were no data reported on duration of treatment with Antiplatelet drugs.” Also stated was to omit the naming RAND-EPC to be the designated update reviewers.

[A-569] **Action: The HRC unanimously approved the Antiplatelet Report.**

[A-580] A written document was presented as public comment related to Antiplatelets from Aggrenox as their representatives were unable to attend. The HRC approved the document as public comment. Public Testimony was made open – no comments received.

[A-610] Inhaled Beta 2 Agonists Key Questions were presented to the HRC by Dr. Kathy Weaver. Since there is no subcommittee formed for this drug class, Dr. Weaver thought it best for the HRC to make comment on the draft Key Questions. After a brief explanation of this drug class and what the questions are aiming to conclude, Dr. Weaver requested comments from the HRC to be shared at the next Drug Effectiveness Review Project phone call, February 2, 2006. Discussions continued and questions answered, but the only alteration suggested was from Steve DeLashmatt, MD was to separate chronic obstructive pulmonary disease (COPD) from asthma [A-830].

[A-868] Public comment on Beta 2 Agonists was opened. Jennifer Brown from Sepracor pharmaceutical that makes Levalbuterol HCL, (Xopenex) – a short acting broncho-dialator testified. The key questions on the OHSU website are more up-to-date than what was presented for HRC. Xopenex is included in the more current B2A key questions. All of the Key Questions are looking at outpatient data only. ER hospital data and inpatient data are the best routes for a controlled study in results as these patients have the most severe condition. When the patient has brochospasm, it wouldn't be ethical to give a patient nothing or a placebo in a controlled study. When the HRC provides feedback, Ms. Brown requested the HRC consider this need to recognize inpatient and ER data. Specific studies have been performed within the ER using brand products vs. generic or older agents. COPD studies are best seen in hospital settings.

[A-975] *Question: James MacKay asked whether the HRC would ask OMAP if they needed only the outpatient use of these drugs, or if it would be better to include the inpatient and ER data.* Dr. Kathy Weaver responded that if the key questions included the inpatients and ER, it becomes a better and more useful report.

Dean Haxby, PharmD is interested to see acute asthma attacks and acute bronchitis excluded from key questions because it's such a large scope. Instead, focus on one drug versus another to find the best results of treatment.

Bill Origer, MD included that the scope of the study should focus on acute conditions separately from chronic conditions.

Dr. Walter Shaffer agreed that the HRC and OMAP will primarily need the information on chronic outpatient evidence. No other public comments were submitted.

[B-056] Antihistamines review has been underway with a full subcommittee at work. However, it was found that the draft version of the first update was better organized and included children. The subcommittee decided to delay all future meetings until the update report is released from the EPC (March 2006)

[B-075] *Standing Update Committee (SUC) Policy*

The Standing Update Committee is now reviewing all updated reports (as ruled by the HRC). The new HRC guidelines for the Standing Update Committee are to assemble at least two

members of the original subcommittee if there are anticipated major changes. In Dr. Weaver's efforts, she was able to contact only one original member in the area that was available to join the SUC. For this reason, an urologist was called on to complement the SUC for the Overactive Bladder drug review update #3. Dr. Weaver presented the name of Jeri Zoubek, MD and assured the HRC that her conflict of interest form and application would be reviewed before her serving with the Standing Update Committee.

[B-122] The HRC approved Jeri Zoubek, MD to serve with the Standing Update Committee for the Overactive Bladder drug class review.

[B-130] MedTap policy (Document #6) is reviewed in light of the HRC MedTAP on obesity management, drug and alcohol treatment, and disc surgery. The un-shaded part of this document was used in the past for health technology reviews and the shaded parts of the document are new additions to be approved. Dr. Weaver shared a power point presentation (slides are featured in Document #7). The Medicare Modernization Act through the AHRQ Effective Healthcare will provide systematic reviews on surgical vs. medical treatment of GERD, coronary artery stenting vs. CABG, and potentially will consider topics in obesity management. Dr. Weaver suggested we move with this project and be a part of the process. The benefits to using the AHRQ's Systematic Reviews are that the HRC could be involved in all steps including drafting the key questions, choosing topics for review, critiquing the reports, and sharing the results publicly. Dr. Weaver suggested forming an obesity subcommittee, having them draft key questions, and begin working with AHRQ.

[B-270] Dr. Weaver opened the discussion and the HRC asked for more time to review the "Medical Technology Assessment Program (MedTAP)" to discuss at the next meeting. Dr. Walter Shaffer shared a slight concern that the document is too specific and detailed that it could potentially be difficult to pursue. In our initial steps to begin reviews, we would want to follow a protocol, but maybe not such a specific protocol.

[B-334] Alison Little, MD of the Health Services Commission (HSC) attended the HRC meeting to compare the HSC process with the MedTap policy. Dr. Little had offered some assistance to Dr. Weaver for the MedTap policy review that was presented to the HRC during the meeting. Dr. Little went on to describe the HSC's process to maintain the Prioritized List and highlighted the differences between HSC and HRC policy.

[B-424] Dr. Weaver's additional comments from the PowerPoint presentation of the MedTap policy:

- Recommendations should fit into our standard for cost-effectiveness
- Disseminating the information publicly
- Evaluating and monitoring outcomes
- Updating information to keep current

[B-447] Paul Tiffany agreed this draft policy is a good road map. Dr. Walter Shaffer would like to continue to review this policy and be sure that this is the process we would like to follow. Dr. Weaver mentioned that reference to "guidelines" were intentionally deleted as not a part of the policy.

[B-500] Dr. Weaver and Dr. Little came up with an idea to receive some training through the Evidence-based Practice Center to learn to develop evidence reviews. OHSU through the Bio-informatics Center (BIC) will be teaching a course this Spring to sort, grade, and write evidence-based reports.

[B-570] The HRC agreed to continue reviewing and discussing the MedTap policy. The HRC decided not to adopt a policy that has not undergone complete review. Motion to accept the MedTap document was withdrawn.

[2A-005] Evidence-based Review on Obesity (Document #8) was shared with the HRC by Dr. Weaver. The document is a discussion starter for the HRC as it presents draft key questions to review together. Many different ideas were gathered and points to consider:

- Dietary supplements, non-pharmaceuticals
- Will we consider self-help groups? Non-physician supervised groups?
- Behavioral patterns should also be included
- “Medical” could mean all non-surgical treatment, medically supervised treatment, non-surgical treatment including self-help groups or commercial groups.
- Include dieting groups
- Bariatric surgery reviews alone will not give us the full scope,
- Limiting the scope may help us get our arms around the subject much better than the entire obesity management review.
- “Quick fixes” – focus on the information the public wants (diet pill, surgery, and group) list the quick fixes the population normally flecks to and address each.
- Surgical selection criteria – who really sets those standards as there are diverse results?
- If we’re collaborating with another group to form this technology review, then we should go with their efforts to include all the bariatric management treatments they propose.

Some editing points are to omit the word “endoscopic” as it’s the same as surgical. Key Question 1B seems redundant to 1A so, HRC agreed to omit 1B.

[2A-144] Dr. Weaver asked the HRC to consider the policy on Conflict of Interest in reference to obesity management. What should the opinion of a doctor that performs bariatric surgery be in our process? Would they be a voting member of a subcommittee or an advisor? Dr. Weaver gave three different suggestions:

- 1) that the HRC maintains the current policy, but the Conflict of Interest form would list affiliations regarding procedures as well as pharmaceuticals for those signing up for a subcommittee or a Technical Advisory Panel position.
- 2) those involved in bariatric surgery are non-voting members of a subcommittee.
- 3) those involved in bariatric surgery give only public comment when invited for public comment.

[2A-170] HRC agreed there is a need for bariatric surgeons input, testimony and that they be advisors to the subcommittee, but should not be a part of HRC’s MedTAP’s as outlined in the conflict of interest policy. HRC would encourage the participation of behaviorists, dietitians and nutritionists in the subcommittee as they are not likely to be as dependent on treatment of obesity as their primary financial support for obesity treatment.

[2A-199] Revising the Conflict of Interest form requires addition of Technical Advisory Program participant to be added to the document.

[2A-256] Dean Haxby, PharmD requested an addition for Key Questions 3 to include “evidence of safety” along with effectiveness.

[2A-261] Dr. Weaver commented that the preliminary work on obesity was from PEBB – Public Employees Benefit Board. Mark Helfand, MD from the Evidence-based Practice Center put together a report for PEBB on the statistics in obesity. PEBB used this information for determining their standards for coverage. The EPC report was merely statistical and not clinical. Is it possible for

the HRC to form a subcommittee to review the obesity report and offer a clinical view? Copies of this report for PEBB are available through Dr. Weaver.

[2A-307] The Meth Menace (Document #9) was shared with the Commissioners by Dr. Weaver briefly highlighting the topics in the document she wrote for the HRC. Much of the information is particular to Oregon. She also explained that the literature is slim and it may be that we're ahead of the curve looking for information on evidence that's not yet developed.

Guest, Bill Origer, MD added that we face another issue in Medicaid: is what we spend on drug/alcohol treatment effective?

Dr. Weaver suggested the HRC monitor the drug/alcohol treatment but place focus on our prescription drug reviews and obesity for the moment. Dr. Shaffer mentioned that the Governor has a task force on methamphetamine; we should include their information in our review. Judith Wilson also commented that the Oregon Medical Association started a task force on this issue. OMA is even debating whether to make methamphetamine a reportable disease so then people can more likely get treatment. On the other hand, would people avoid being diagnosed altogether?

[2A-374] The HRC had no objections to continue monitoring the drug/alcohol review but wait to embark on the work in the future The HRC would like to see an obesity subcommittee begin.

[2A-396] The leadership of the HRC is in transition. Dr. Wally Shaffer announced his resignation as Chair for the Health Resources Commission as he has accepted a new position as the Medical Director of Oregon Medical Assistance Program following Tom Turek's retirement. Dr. Shaffer commended Paul Tiffany for continuing to serve graciously with the HRC and announced that now it is time to find another to serve in his place as Vice Chair. Dr. Shaffer announced that the Commission elects its leadership, it's not appointed.

[2A-690-718] After a detailed discussion with much participation, the Commission elected James MacKay, MD as Chair for the HRC (temporarily – will revisit the subject when needed) and Dan Kennedy, RPh as Vice Chair for the HRC.

6. Meeting Adjourned at 4:30 PM

Documents:

1. Minutes 10-20-05
2. Minutes 11-18-05
3. HRC Draft Newer Antiplatelets Agents report
4. Inhaled Beta2-Agonists Key Questions
6. Medical Technology Assessment Program (MedTap)
7. MedTap slides and draft Conflict of Interest form for MedTap
8. Draft Key Questions on Evidence-based Review on Obesity
9. The Meth Menace document by Dr. Kathy Weaver

**MINUTES
HEALTH RESOURCES COMMISSION**

FEBRUARY 17, 2006

Members Present/Phone: James MacKay, MD, Chair; Dan Kennedy, RPh, Vice Chair; Dean Haxby, PharmD; Manny Berman; Judith Wilson; Walter Shaffer, MD and John Saultz, MD

Members Absent: Paul Tiffany, Mark Yerby, MD; Steve DeLashmutt, MD; Lynn-Marie Crider.

Staff Present: Kathleen Weaver, MD, HRC Director; Beth Zehr, HRC Assistant

1. Call to Order and Roll Call—James MacKay, MD

[A-001] The meeting was called to order by Chair, James MacKay, MD and roll call taken. HRC guest of the Commission and current Commissioner applicant, Bill Origer, MD Samaritan Health of Albany attended the meeting.

2. Announce HRC Election Results – Kathy Weaver, MD

Director, Kathy Weaver, MD congratulated and welcomed Dr. MacKay as our new Chair and Dan Kennedy as Vice Chair of the Commission.

3. Approval of Minutes—James MacKay, MD

[A-018] Minutes presented from 1-27-06 (Document 1). No comments or corrections were made.

[A-021] **Action: The 1-27-06 Minutes (Document 1) were unanimously approved.**

[A-022] An attachment to the minutes of 10-20-05 (Document 2) was presented. Dr. Weaver briefed the Commissioners on the document referring back to the HRC day retreat last fall where the Commissioners together gave input to topics the HRC should review in the next year. Document 2 is a list of some of those suggested projects. The Commissioners were satisfied with the list and intended to keep this on record.

4. OMAP Update – no update for this meeting, last month's items are current and no additions.

[A-037]

5. Drug Use Review (DUR) – Kathy Ketchum, MPA:HA, RPh

The DUR Board is mandated to advise the Medicaid agency about drug use issues. While the volunteer group of the DUR Board functions somewhat as a Pharmacy & Therapeutics Committee, they do no formularies. Relating to the evidence-based process, the DUR Board issues newsletters and publishes articles on newer drugs. Dr. Weaver remarked that DUR and HRC share objectives as noted that two members of the HRC subcommittee for Newer Sedative Hypnotics were invited as experts for the DUR Board for the Insomnia review. The DUR Board newsletter is distributed from OMAP along with the paychecks to providers each month. Newsletters are also publicly posted and on the web at http://pharmacy.oregonstate.edu/drug_policy/index.php?nav=newsletter. The Commissioners requested they be added to the DUR list serve.

[A-080] In regards to the HRC's work with the Newer Sedative Hypnotics, we had a subcommittee underway while the DUR Board was contemplating this same review. OMAP advised that they would not need an HRC review of the Newer Sedative Hypnotics at this time, however, the

HRC will revisit the NSH review at its first update report from the Evidence-based Practice Center scheduled for June 2006. Utilization of Newer Sedative Hypnotics has increased dramatically at nearly 60% in the last year; much of that increase due to direct-to-consumer advertising. Physicians and other prescribers are the target audience to educate because commercial health plans and OHP find these new drugs over-utilized, under-studied, and high-priced.

[A-120] The DUR Board searched the literature for trazadone or other older anti-depressants for insomnia for the sake of long-term safety in using those drugs. Unfortunately, the literature for insomnia with older medications is not helpful.

[A-124]

6. Drug Class Updates – Kathy Weaver, MD

Relating to the roster, Ruth Medak, MD has agreed to join the Standing Update Committee (SUC). She will be a great help as she is an internist and also specializes in cardiac drugs. Dr. Medak was a part of the HRC Antiplatelet subcommittee. She will be replacing Dr. Kathy Crispell, who asked to resign due to other priorities and work obligations.

[A-156] Dr. Weaver reported the intention to utilize the Antihistmine subcommittee for the upcoming Beta 2 Agonists subcommittee.

[A-176] Kathy Ketchum distributed the new 2006 pocket drug list. This list serves as a tool which helps to translate the evidence into practice. This is sent out to over 5,000 prescribers and pharmacies enrolled with OMAP as well as being available on the web at

http://pharmacy.oregonstate.edu//drug_policy/prescriber_tools/POCKETFinal.pdf

This list is helpful to providers as it shows the cost comparisons. This 3rd update of the list shows the prices next to the drugs are the retail prices OMAP pays, not showing rebates. The shading depicts the retail price, the white area is the lower 25% range of cost within a drug class and the medium shading depicts 25%-75% of the average price in a quartile.

[A-208] The Standing Update Committee met February 7th to review three different drug class reports. First, the *HRC Draft Report Overactive Bladder update #3 – (Document 3)* was discussed over the course of two meetings; the last meeting included Marian McDonaugh of the Evidence-based Practice Center, who presented the multiple new updates on this drug class. Jeri Zoubek, MD, urologist, and Michele Koder, PharmD of the original OAB subcommittee were asked to join in the Standing Update Committee for this particular review.

[A-223] Many new drugs were added to the OAB drug class within the previous year (list on page 6) which gave substantial changes to the EPC report. Reviewing 11 new trials added further to this report. Kathy Ketchum highlighted each consensus box and brought background explanations for each. As an overview, the Standing Update Committee added the new drugs to the HRC report, emphasized the inconsistent data, and re-emphasized those key questions where there was little or no evidence available.

This drug class is unique in that the evidence is inconsistent for efficacy and adverse events and what is effective may vary from patient to patient. Much reliance is given to clinical practice for empirical use. Public comment requested the HRC to advise for allowance for multiple options.

[A-341] Dr. Saultz surfaced an issue and question in regards to our drug reviews. We are currently comparing old drugs to new drug drugs. Safety of use for the drug are found in new literature, but also in experience of drug used for decades. There is a massive difference in the amount of post-marketing of drugs experience. Our process doesn't factor that in with the review of the literature. How long a drug has been on the market vs. how much has a drug has been used?

Dr. Weaver responded in agreement that we don't know the denominator. We have to rely on time (for instance, while adverse events may not be discovered in the first thousands of patients, after time and use, eventually, it's found in the first million).

Kathy Ketchum included the fact that our evidence-based review process is focused on both efficacy and effectiveness, but expands much broader to include observational studies for safety. The EPC is committed to finding the safety of Rx drugs.

[A-430] **Action: The HRC unanimously approved the Overactive Bladder #3 Report.**

HRC Draft Report Inhaled Corticosteroids update #1 – (Document 4)

The major change to this update is a move to reformulate inhalers to eliminate chlorofluorocarbons (CFC) as a vehicle as it punctures the ozone layer. Some products are discontinued and newer products are being added to this drug class. There is a problem with the literature in the dosage forms. EPC attempted to determine whether device and dosing differences have effect on outcomes. Since the available evidence was conflicting there are no firm conclusions.

[A-560] **Action: The HRC unanimously approved the Inhaled Corticosteroid #1 Report.**

HRC Draft Report Triptans update #3 – (Document 5)

The scope of this report has expanded to include more than oral products. Triptans now includes nasal and subcutaneous products. Our previous evidence on conventional tablets is no longer comparable as the release form of the medications changed. Some studies show that fast dissolving tablets compared to the conventional tablet show relief quicker and probably are at least as effective although the evidence is weak. Dr. Weaver stated that the EPC is not going to re-review any of the previous studies. The information we have now is all we can work with. An ongoing issue raised is the encapsulation of eletriptan so then we don't know how eletriptan compares to encapsulated comparators used in double blinded studies.

The cost and use of Triptans ranked high in Medicaid, and now it's uncertain where exactly it ranks with the loss of the dual-eligibles under Part D Medicare. While a consideration is made that a true migraine headache is not necessarily being experienced with all those patients taking triptans, a response is a good sign and lessens the trips to the Emergency Room. Again, all forms of triptans should be made available as there are different response rates for patients.

[A-798] **Action: The HRC unanimously approved the Triptans #3 Report.**

7. Med-Tap Program

Dr. Kathy Weaver brought the Med-Tap policy (Document #6) to the Commissioners for a final review to allow more time for them to consider the policy. There were mostly favorable comments however, a caution arose that it may be too prescriptive and too narrow a protocol for the HRC to follow. The shaded areas are new additions to the previous Med-Tap policy the HRC has used in the past.

[A-858] Alison Little, MD of the Health Services Commission was with us last month to overview the processes of such a policy and she suggested that the policy not automatically contain guidelines so it doesn't obligate us to review all guidelines.

[A-892] Chair Dr. James MacKay commented that the policy is straightforward, states what the HRC wants to do and how to do it. Document is appropriate for our work.

[A-902] **Action: The HRC MedTap Policy was unanimously approved**

Obesity - Dr. Weaver shared the revised key questions of the obesity management review (Document #7) and highlighted the changes made. Possible future additions may be in asking a key question “Do centers of excellence have better outcomes?” to discover whether facilities differ. Also, including medications along with surgery reviews will offer a broad scope for obesity management. Dr. Weaver noted that she intended to convene an obesity subcommittee in the next weeks ahead.

[A-987] Hanten Day, Research Analyst at Oregon Health Policy & Research presented some recent statistics on Oregon Bariatric Surgeries (also part of Document #7). All reported bariatric surgeries are based on Oregon hospital discharge data. The number of patients with Obesity Diagnosis information also includes two hospitals in SW Washington to gather the area population. While a few surgeries are cancer-related, those are noted on the chart and have remained consistent through the years while obesity-related surgeries have a rising trend of 400% in 10 years.

[B-064] Dr. Weaver commented the HRC might be interested in learning how many of the diagnosed patients are also diabetic. This will reveal whether patients are selected according to current guidelines. Also, the OHPR data will have more meaning if we have a sense of the geographic locations where bariatric surgeries are performed. Commissioners asked for the number of hospital locations that are performing bariatric surgeries. While the exact number can later be determined with a closer look, a majority of cases are done at Legacy, OHSU, Sacred Heart, and Merle West Medical Center. The named hospitals may have more to do with the surgeons who are in the area.

[B-087] The data is collected is by claims, CPT code, and hospital DRG code. The OHPR Research Unit uses the same process as the Agency for Health Quality and Research. (AHRQ) inclusion criteria for bariatric surgeries and their codes are listed on the memorandum page in the footnote. First all patients having the code of the bariatric surgery are identified. Then the cancer diagnoses coupled with those surgeries are separated for clear and valid statistics.

[B-120] There was noted a 17% decrease in total obesity-related surgeries from 2003 to 2004. Possible reasons for a decline in bariatric surgeries in 2004 may be the high out-of-pocket costs leaving people with a substantial debt. Medicare has adopted coverage in 2005. Commissioners questioned whether it would be managed care and utilization that denies coverage. Also, Dr. Flanagan retired in Eugene (a very active bariatric surgeon). The increasing popularity of adjustable banded laproscopic surgeries may account for the decline of obesity-related surgeries reported in 2004. Not all of these less invasive surgeries may be captured in hospital discharge data since some may be done in Ambulatory Surgery Centers. There are HMO's that no longer insure these procedures.

[B-151] What does the Commission do with this information? What's our purpose? The HRC would make a summary report and track the trend in bariatric surgery. This review might not have effect on the Oregon Health Plan (OHP) as the coverage for bariatric surgery is below the funding line (bariatric surgeries are only covered for co-morbidities). However, the Health Services Commission (HSC) is considering moving it above the funding line. PEBB and other employers are being pressured to cover these procedures, so there is interest to have guidance for what subgroups to cover, under what circumstances and what centers of excellence to utilize. Physicians as well as

insurers are interested in this unique information. The HRC would be fulfilling their role and reputation for providing evidence-based medicine in a public forum.

[B-214] There are no HRC funds for researching obesity management. One possibility is to have such a review done if OMAP decides to contract with the EPC to review for more than prescription drugs. Also, AHRQ, funded by the Medicare Modernization Act is discussing obesity treatments and will make their reports public.

The Commission must take into account that if our obesity report comes from an outside source, there may be less input for developing key questions. If the HRC uses the AHRQ Effective Healthcare process, there will be opportunity to have input on the questions.

[B-240] Dr. Saultz commented that when we're looking at drugs, we see a congruity in the product, study and literature. But with such projects of obesity management, the science about it is heterogeneous. The kind of expertise looking at this project will be harder to standardize. It will not be as easy to put the information, studies, and randomization together. When there is an actual practice of those patients who want surgery, can pay for it and do not have a contraindication there will be the group that gets the procedure that will not be randomized.

[B-294] Dr. Weaver added that the HRC would likely have to take an active role in producing a report along with the obesity subcommittee and not merely adopt the report. As discussed, professionals who perform bariatric surgery would not be a part of the subcommittee but invited to give testimony and reports on behalf of bariatric surgery. Ideal participants in the obesity subcommittee might involve a general surgeon or GI surgeon, and Endocrinologist, a General Internist, a Cardiologist, Gastroenterologist, Internal Medicine, Cardiac exercise professional, a Dietician, and a Psychiatrist. Dr. Weaver opened this to the Commissioners for comments regarding additional professionals. Commissioners thought to invite a lawyer, a bariatric management professional and a pharmacist into the subcommittee. It is intended to have the subcommittee members be a part of refining the key questions, grade and compare the evidence, and develop a report for the HRC. Commissioners agreed that reviewing procedures as well as the drugs we commonly do is a good direction for HRC.

Dr. Weaver included a Health Affairs article for the Commissioners' information. This article includes nation-wide info.

[B-426]

Methamphetamine –

Dr. Weaver brought to the Commissioners more information about the Meth problem. Oregon is now #1 in the nation on using and seeking treatment for methamphetamine. Small Meth labs were prominent in the state, but getting Sudafed behind the counter decreased the small meth labs by 70%-80%. Since then, a large quantity of Meth ingredients are arriving the U.S. from Mexico. The Meth problem is unique in that it spread from West to East. Also, children of Meth users are neglected, exposed to the harmful chemicals and often removed to foster care. The OMA task force concluded that drug addiction rehabilitation is effective, but the attendees need more than medical treatment; they need cognitive and social restructuring for at least a year thereafter. These needs are difficult for rehab programs to accomplish for the patient.

[B-530] DHS has said they can treat methamphetamine and its addiction, but lack the resources to do so. The HRC's question is: Are there methods of treatment that are better than others? If so, how do you direct people into those treatments? If there are no resources to get people into the treatments, then we're at loss to compare. At this point, the methamphetamine topic is for the Commissioners' information. The HRC work is focused on obesity and prescription drugs right now.

[B-548]

AHRQ-

The HRC is now looking into the work of the Agency for Health Research and Quality for their review on obesity management. Pharmaceutical literature is much more standardized and our future work with the treatment of obesity is “uncharted territory.” Commissioners asked for devices to look at for next HRC meeting.

[B-587] Dan Kennedy, RPh asked about our HRC charge concerning the switch of the dual eligibles to the Medicare. Kathy Ketchum reported that about half of OMAP’s drug costs are in Medicare. OMAP may still pay for some of the dual eligibles. Remaining in the Medicaid pharmacy costs are more children, more pregnant moms, and more people involved in OHP-plus. The federal government pays for all of Medicare except for the “claw-back” which is based on a drug utilization of Oregon’s 2003 data. The “claw-back” rate of payment does not decrease even if the state currently has less eligibles compared to 2003.

8. Meeting Adjourned at 3:30 PM

Documents:

1. Minutes 1-27-06
2. Minutes attachment for 10-20-05
3. HRC draft report – Overactive Bladder update #3
4. HRC draft report – Inhaled Corticosteroids update #1
5. HRC draft report – Triptans update #3
6. Medical Technology Assessment Program (MedTap)
7. Obesity revised Key Questions

**MINUTES
HEALTH RESOURCES COMMISSION**

MARCH 17, 2006

Members Present/Phone: James MacKay, MD, Chair; Lynn-Marie Crider; Judith Wilson; Steve DeLashmutt, MD; Bill Origer, MD, Kate Merrill, MD; Tony Melaragno, MD

Members Absent: Paul Tiffany, Dean Haxby, PharmD; John Saultz, MD Manny Berman; Mark Yerby, MD; Dan Kennedy, RPh, Vice Chair;

Staff Present: Kathleen Weaver, MD, HRC Director; Beth Zehr, HRC Assistant

1. Call to Order and Roll Call—James MacKay, MD

[A-001] The meeting was called to order by Chair, James MacKay, MD and roll call taken.

2. Approval of Minutes—James MacKay, MD

[A-004] Minutes presented from 2-17-06 (Document 1). Dr. MacKay questioned the accuracy of the statement made on page four that bariatric surgeries are covered by Oregon Health Plan when there are co-morbidities present. Dr. Kathy Weaver clarified that bariatric surgeries are in fact, below the funding line of the Oregon Health Plan's Prioritized List and would not normally be covered. A case-by-case basis can uncover the need for such a surgery with co-morbidity of condition in the funded part of the list that is adversely affected by morbid obesity. Changes to the minutes will be made by the HRC staff.

[A-033]

3. Drug Class Updates – Kathy Weaver, MD

Nicole O'Kane, PharmD, representing the Standing Update Committee of the HRC, presented the Angiotensin II Receptor Antagonists (AIIRA) also referred to as ARB's (Document #2). In the process of drug class reviews, many times a "class effect" occurs. This is where multiple drugs within the class having similar pharmacology, similar effect, but slightly different FDA labeling. Within the AIIRA drug class, it is suggested that "class effect" may play a large part.

Page 6 shows a table of the AIIRA drugs included in this review. The AIIRA's have shown to accurately reflect the FDA label indications. As for new evidence in this update, there were two major studies reviewed though they did not change any of the report's conclusions. The Standing Update Committee met March 7th to review the evidence and Mark Helfand, MD of the Evidence-based Practice Center, presented their AIIRA update #1. Overall, the Standing Update Committee found it only necessary to make clarifications, adding new information (on page 8) and some new findings in adverse reactions and did not change the conclusions from the previous report.

[A-070] Our aim is to use head-to-head drug data, but that is not available in the current literature. In the AIIRA class, much of the literature shows AIIRA's being compared to active controls, rather than the AIIRA drugs being compared to each other. Also, for ethical reasons, trials aren't performed comparing the AIIRAs with a placebo. The EPC has elected not to compare AIIRA's to the ACEIs. However, the AHRQ plans to produce such a report in the future comparing these two drug classes. On page 15, the Standing Update Committee included a note that with the losartan vs. atenolol trial, losartan increased the risk of strokes in black patients. They felt this was clinically important enough

to include in the report although atenolol (β -Blocker) wasn't included in the overall drug class review.

[A-095] Dr. Weaver stated that the shaded parts of the AIIRA Report are the updated parts of the report. For example, Table 1 on page 6, "Post MI" has a newly added column and Candesartan now has an indication for heart failure. It is noted on page 8, under New Findings, that there are updates to labeling changes initiated by the FDA. Written testimony on Micardis is submitted by Boehringer Ingelheim Pharmaceuticals for the HRC to consider and has already been reviewed by the Standing Update Committee.

[A-140] Dr. MacKay commented on the difficulty to determine the appropriate response to some of the studies. In his experience with hypertension trials, it was difficult to enroll high-risk patients, since most were already well treated. In some ways we seem to take these narrower studies of efficacy and globalize them, applying the findings to many other situations or patients.

[A-157] Briefing the HRC and newer Commissioners on the history of this drug class, Dr. Weaver explained that in the beginning, it was asked of the Evidence-based Practice Center (EPC) to compare AIIRA's to the ACEI's. At the time, the Evidence-based Practice Center considered that this would create too an extensive report. So, they separated these drug-classes into separate reports. The outcome resulted in a smaller, more readable report. But much of the literature compares AIIRA's to ACEI's and we lost the benefit of seeing head-to-head trials within this broader class. The comparison of ACEIs and AIIRAs would be more like a guideline as to which agent should be used.

[A-190] Dr. DeLashmutt questioned the reasoning for losartan to be included on Table 2 from page 17 of the report since losartan is presumably off the market. Ms. O'Kane verified that losartan is still on the market.

[A-219] Public comment was solicited, but none was made.

[A-275] Chair, Dr. MacKay asked Nicole O'Kane, PharmD for her recommendation for this report and in reply, O'Kane proposed to add the minor changes to the report with no changes to the final recommendations in the consensus or conclusion boxes.

[A-290] **The Health Resources Commission unanimously approved the AIIRA #1 report**

Returning to the beginning of the agenda, Chair James MacKay introduced the three new Commissioners: Bill Origer, MD, Katherine Merrill, MD, and Tony Melaragno, MD.

[A-326] **Action: The 2-17-06 Minutes (Document 1) were unanimously approved along with the changes requested.**

4. Drug Class Updates (resumed):

Targeted Immune Modulators report was presented to the Health Resources Commission by Dr. Steve Campbell, chief rheumatologist at the VA hospital in Portland. Dr. Campbell explained this drug class treated rheumatoid arthritis (RA), juvenile rheumatoid arthritis (JRA), ankylosing spondylitis (AS), and psoriatic arthritis (PsA). Crohn's disease was also included in this report as it shares some underlying immunology and physiology with the other diseases. Psoriasis was not addressed in this report primarily because the literature and studies became available after the cut-off date of the review. Next year there could likely be material on psoriasis.

[A-360] The Targeted Immune Modulators subcommittee met on January 18, February 13, and March 8, 2006. The subcommittee's draft report was presented to the HRC on March 17, 2006. Most immunosuppressant drugs work in a non-specific fashion. A commonality is the drugs' major dependence on cytokines – there are a group of 50 different molecules that play a major role in mediating the immune response and the information. The drugs appearing in this report basically

affect two of the major cytokines in the inflammatory cascade: Tumour Necrosis Factor and Interleukin-1.

Table 1 and 2 on pages 6 and 7 of the TIM report show the list of drugs included in this report. Many new studies and prescriptions have been released since this report was issued and the next report will appear differently. There is no doubt that these drugs are, or can be, efficacious; however, they are not universally efficacious, as not every patient improves with them. The controversy is not if the drugs work, but when the drugs ought to be used (i.e. used in late stage of the disease, used when all other medications have failed, or used initially). These issues were discussed among the subcommittee, although creating a guideline is not the work of the subcommittee or the HRC. Targeted Immune Modulators actually interfere with the body's natural immunity response and thus their safeties are of concern. Currently, it is known that these drugs are relatively safe. Few patients have become sick or died from these drugs, and overall they are quite effective. While it was initially hoped that short term use of these drugs would cure the disease, it has been shown that continuation of the drugs, lifelong, is necessary.

[A-449] The key questions for the TIM's compared the drugs within this class, but not compared to other classes of drugs. Unfortunately there are almost no direct comparative trials. The EPC report found primarily indirect comparisons. Dr. Campbell reviewed on the consensus statements from the TIM subcommittee for key questions 1, 2, and 3.

[A-496] These drugs interfere with the immune system and have the potential to cause infections (i.e. activation of tuberculosis), though not very commonly. Recommendation by the subcommittee is to generally not use these drugs for patients who have the co-morbidity of heart failure. There are tremendous variations within this drug class and they can be unpredictable. Thus it is reasonable to try another TIM for a patient if the first one fails.

[A-538] Dr. Weaver included that there are two drugs that were not discussed and are listed in Table 1 on page 6. Raptiva and Amevive are dermatology drugs and apparently do not work in psoriatic arthritis, but do work for psoriasis. They will be reviewed in the first update.

Infliximab, a kimeric type molecule, was usually only given when the patient was on Methotrexate because it was thought that the patients might create antibodies to the non-human protein in the molecule unless the immunosuppressant, Methotrexate, was continued. Most of the studies on RA include a combination of Infliximab + Methotrexate for efficacy. With the later use of infliximab for Ankylosing Spondylitis and Psoriatic Arthritis, the practice of using Infliximab alone was undertaken. So, while Methotrexate isn't a TIM, it appears in the conclusion since it has been used extensively in combination with Methotrexate (especially for RA)

[A-602] General discussion continued among the Commissioners regarding psoriasis and the TIM drugs; however, this discussion had no implication for any decisions or the outcome of this TIM report.

[A-726] Commissioner Crider commented the results must accurately state the limitedness of the research in the subcommittee's report that included TIM drugs compared to a placebo (example: 1A on page 10 of the TIM HRC report). Dr. Campbell explained the studies show the effectiveness of the drugs compared to a placebo; no literature revealed the evidence of the TIM drugs compared to one another.

Note:

[A-805] Public Testimony was solicited, but no comments were made.

[A-829] **Action: The HRC unanimously approved the Targeted Immune Modulators Report.**

Targeted Immune Modulators are moving along into their first update and the proposed key questions were shared with the Health Resources Commission. Dr. Weaver first described the

process of the key questions and reports. We have a vote among the other organizations in DERP and now have opportunity to better refine the key questions. The subcommittees of the HRC and the HRC themselves review the key questions and submit any additions or changes in order to have the best updated Evidence-based Practice Center report.

The Targeted Immune Modulators draft key questions (Document #4) have come to the HRC meeting in order to receive any input the HRC may have. Previous to the HRC meeting, the Targeted Immune Modulators subcommittee suggested:

- Adding Psoriasis and Ulcerative Colitis disease to the scope of research for the TIM drugs. The Drug Effectiveness Review Project (DERP) and the other U.S. organizations have agreed to include both diseases in their next report
- Including new drugs to treat Rheumatoid Arthritis: Rituximab (Anti CB 20), brand name Rituxan, and Abatacept (CTLA 4-Ig) brand name Orencia.
- Utilizing the Psoriasis Severity Area Index (PASI) scale
- Including co-morbidities with infections (such as strep) when psoriasis is treated
- Discovering whether the conditions stabilize or rebound when medications stop
- Comparison of methotrexate to other TIM drugs was suggested, however that change did not appear in the draft key questions. If there is evidence on this, it will be a part of the report anyway.

[A-978] With these additions in place, the HRC was asked to review and offer any other input to the TIM key questions (Document #4)

[B-000] Public comment was made open for the TIM key questions. One member of the public audience responded. Kelly Wright from Amgen spoke on psoriasis and the potential of rebound when the drug treatments are stopped. While rebound is a bone fide issue, Wright brought to the HRC's attention that relapse is also an issue for psoriatic patients. Rebound and relapse are two different scenarios that occur. Rebound is when a patient discontinues drug treatment and the disease returns with a flare, suddenly reoccurring and worse than before. Relapse is reoccurrence of the disease over time while on the drug. Rebound is usually more severe.

[B-023] In regards to combining methotrexate with other treatments, Medicaid patients, in particular, are more at risk for hepatotoxicity than the traditional managed care patients. This is likely due to the higher incidence of alcohol use by Medicaid patients. Some State Medicaid Departments have reviewed this drug class and their demography and have discovered this fact especially through the process of prior authorizations. With this information, there is a population factor to consider. While many times methotrexate is used in combination with TIM drugs, some other states have elected to study the drugs separately so as to better determine the TIM's. Best results will come when there are monotherapy head-to-head trials performed. Another challenge that exists and arose in conversation in previous meetings is, "what happens when a patient does not achieve a response with a TIM? Is it reasonable to suggest switching to another TIM drug or to different therapy?" While the practice is not uncommon, is the evidence available?

No vote was necessary for the Targeted Immune Modulators key questions. This served as an informational piece and the final product will come from the Drug Effectiveness Review Project.

5. Medical Technology Assessment Program (MedTap)

[B-080] Dr. Weaver shared the final document of the MedTap policy, as approved by the Health Resources Commission. This document is for the members to retain in their Commissioner notebooks and is our policy and procedure for the technology reviews that are underway (such as obesity management). Dr. Weaver uses this document as a tool to educate and inform the potential volunteers for a review project.

Obesity -

Obesity management subcommittee roster (Document #5) was shared in order to see those medical professionals who have agreed to serve on the new subcommittee, if approved by the HRC. Dr. Weaver gave some more background on each person listed on the roster. Discussions continued among the HRC for other possible recruitments for this subcommittee.

[B-192] Dr. Weaver asked the HRC as to whether we should form a new key question to discover by evidence whether bariatric surgeries are better performed in a clinic marked “center for excellence.” JAMA released an article by Bruce Wilstokes showing an increased mortality rates in Medicare and elderly patients having bariatric surgeries.

[B-244] As agreed in a previous HRC meeting, bariatric surgeons are invited to share public testimony. Document #5 shows some surgeons who are aware of the future HRC obesity management subcommittee and would likely come to give comment to the subcommittee. Discussions continued on multiple facets of bariatric surgery, weight loss, success stories, etc.

[B-408] Discussion turned back to the demographic roster for the Obesity management subcommittee. Dr. Weaver notified the Commissioners that she would like to add a consumer but not knowing how to go about it. A few commissioners suggested two consumer members: a consumer who succeeded at dieting with Weight Watchers or the like and a consumer who is satisfied with their bariatric surgery. On the other hand, Lynn-Marie Crider questioned whether we should include those patients who are real motivated on this issue or whether we add others from a health plan point of view. Dr. Bill Origer knew of someone from Regence to recommend.

[B-465]

Methamphetamine – (Document #6) An article was shared with the HRC merely for their information and later reading.

[B-471]

AHRQ- (Document #7) AHRQ is the Agency for Health Research and Quality. Studies the AHRQ has compiled and shown as effective health care. Dr. Weaver has been tracking their website updates and has participated in a phone conference for one of their prescription drug review. The AHRQ is involving consumers and practitioners in their process for evidence-based reviews since they are the same ones who refer to their reviews. An upcoming AHRQ review is comparing the older diabetic agents to the new diabetic agents. Though in our process with the Drug Effectiveness Review Project we are seeing the reviews of the TZD’s – Thiazolidinedione Anti-diabetic Agents, there is no annual update planned. The AHRQ reviews may become a more beneficial and continual resource to the HRC.

[B-506] It is not known at this time whether the AHRQ will review the evidence of obesity management methods though it has come up in discussion with much interest.

6. Northwest Pharmacy Management and Medical Director’s Meeting

Dr. Kathy Weaver recently attended this meeting and returned some information to the HRC. Another document shared with the HRC was the power point slides entitled, “Can We Really Trust the Scientific Evidence? What Are the Options?” by John Abramson, MD, March 10, 2006. On page four of this document, in the bottom slide there is a chart ranking the relationship between quality and Medicare spending; note where Oregon is ranked.

[B-556] A major point the presenter offered at the Northwest Medical Director’s meeting is that there is an academic/ industrial complex that exists. This may be because many of the studies are being funding and promoted by the pharmaceutical companies. Since the industry is very effective in influencing guidelines, Dr. Abramson studied the Adult Treatment Panel (ATP-3) guidelines and found that 25 million people worldwide take a form of Statins drugs and 13 million of those people are in the United States. There may be some slight benefit in those patients with

secondary prevention, but there really isn't the evidence to show that primary prevention was effective. Taking Statins was found to be less effective than exercise and diet. So, while the literature often compares the drugs, a deeper question is whether the drugs should be used at all and for whom? These are real issues the Commission needs to review to determine the value of this unnecessary cost. Also data shows that the Statins have risks. Dr. Weaver replied, "It's hard to make an asymptomatic patient better, but always possible to make them worse!"

[B-650] Delfini Group information was provided for the HRC for their reading. The Delfini Group offers critiquing tools, template and interventions for Pharmaceutical and Therapeutic (P&T) committees. This information is found to be helpful by to P & T committees as a way to find the evidence and not being persuaded by emotions or opinions.

[B-699] In closing, it was discussed that the next HRC meeting is scheduled for April 21st however, there will not be as many drug reports released until May. The HRC decided to pass over the April meeting and reconvene May 19, 2006.

[B-723] Chair, Dr. MacKay announced a thanks and farewell to Dr. Steve DeLashmutt and to Paul Tiffany for their many years of service to the Health Resources Commission for the State of Oregon. Dr. Kathy Weaver let the Commissioners know Justin Leonard is a potential future commissioner and his application is in progress.

8. Meeting Adjourned at 4:00 PM

Documents:

1. Minutes 2-17-06
2. HRC draft report – AIIRA update #1
3. HRC draft report – Targeted Immune Modulators
4. Key Questions – Targeted Immune Modulators update #1
5. Medical Technology Assessment Program (MedTap)
6. Obesity subcommittee demographic roster
7. NIDA InfoFacts: Methamphetamine
8. AHRQ key questions
9. Northwest Pharmacy Benefits Managers – Medical Director's meeting
"Can We Really Trust the Scientific Evidence? What are the Options?" John Abramson, MD
10. Delfini Group articles

**MINUTES
HEALTH RESOURCES COMMISSION**

MAY 19, 2006

Members Present/Phone: James MacKay, MD, Chair; Dan Kennedy, RPh, Vice Chair; Judith Wilson; Tony Melaragno, MD; Justin Leonard, JD

Members Absent: Dean Haxby, PharmD; Lynn Marie Crider; John Saultz, MD; Manny Berman; Kate Merrill, MD; Bill Origer, MD

Staff Present: Kathleen Weaver, MD, HRC Director; Beth Zehr, HRC Assistant

1. Call to Order and Roll Call—James MacKay, MD

[A-062] The meeting was called to order by Chair, James MacKay, MD and roll call taken.

The necessary quorum was not met; therefore, no final decisions were made on any documents. All documents not approved by the HRC will be brought to the following HRC meeting, July 7, 2006.

2. Approval of Minutes—James MacKay, MD

[A-096] Minutes were presented from 2-17-06 (Document 1). Dr. MacKay guided the HRC to move on with the meeting since there was no quorum available to vote on the minutes.

3. OMAP Update – Allison Knight, Asst. Manager of Program and Policy

[A-100] Allison reported that OMAP is awaiting approval for two waiver requests that were submitted to the CMS policy. One has to do with the changed premium policy for OHP standard clients in the expansion population which go into effect June 1st. This change will eliminate premiums for clients at or below 10% of the poverty level; this group makes up approximately 40% of the clients in the standard population. OMAP is also changing the internal policies with clients who still have premiums. OMAP was dismissing their enrollment from health plans after one month. Rather than taking a strict approach, the members will be dismissed from enrollment after their certification period is over. The Standard population continues to shrink (22,000) because new enrollment has not been open for over a year.

The other request on benefit reductions that came out of the last legislative session was submitted to CMS and awaits their approval. If the approval arrives, it will take four months to actually implement the changes and the earliest would be October 1st. The benefits reductions are on the fee-for-service program (which affects about ¼ of the OHP population) and applies a maximum of an 18 day limitation on inpatient hospital stays. OMAP is receiving indications from CMS that it may be approved. CMS continues to review the request in spite of feedback from stakeholders that it is a difficult policy.

The other benefit reduction is a minor modification to the over-the-counter drug policy since it is not a required benefit. Since there have been many other cost-savings approaches and OMAP has exhausted some options, the non-mandatory services are the few options where we can make cuts. Since over the counter medications are not required by OMAP to cover in their benefits, and the medications are more affordable than prescription drugs, it seems like the best option at this point. OMAP has formed a policy to continue limited over the counter drug coverage but is not as broad as it previously had been. Reductions have been made on the vision benefit for adults. Routine

vision checks and glasses are not being covered while eye diseases and greater needs will continue to be covered. Also, a restriction on the adult dental package is underway. The OMAP budget is based on having these reductions implemented by July 1, 2006. The reductions were intended to be only for this biennium, so efforts to restore these benefits are in the interest of OMAP for July 2007.

[A-178] One component of the deficit reduction act which was passed by the Federal Government in February 2006 had increased requirements of proof of US citizenship for all applicants to the Medicaid program. The law is effective July 1, 2006. Effects of the law were quite restrictive and CMS has published draft guidance for the states to implement these laws into the program. A subsequent letter from CMS showed some flexibility for enrollees who cannot produce a birth certificate, US Passport or other such legal documentation. OMAP really has no exact estimation on the overall impact of this law on Oregonians though it's thought to affect a large number of people. The Department is still waiting for final guidance.

The Health Services Commission, responsible for the prioritized list of covered benefits for OHP patients, are taking a look at how the current prioritized list is structured by direction of the Governor. The HSC is looking into creating a benefit package for the OHP Standard population that will be focused on preventative services and chronic care. The Prioritized List is in the initial stages of a long biennial review process that would be implemented in July 2008.

[A-245] Kathy Weaver, MD added to the discussion as she has worked with the Health Services Commission and the Medical Directors with the prioritized list. The Health Services Commission and legislature are looking at the whole prioritized list above the funding line. They are closely looking at evidence-based reason to support each line and particularly giving a higher priority to preventative services or chronic disease management than before. They are working to reprioritize and intend to have two different options of either having two separate lists or one list with two different funding lines. Obesity management reviews by the HRC will be shared with the Health Services Commission for the prioritized list. While both medical/behavioral and the surgical aspects of obesity management are below the funding line the Health Services Commission may consider adding treatments above the funding line.

[A-278] James MacKay, MD asked about whether the economics are considered in the prioritized list. While bypass surgery may be covered, hernias are not. But a few major surgeries on patients or treating cancers can really over-utilize the OHP funds. So, is the HSC looking at the expensive treatments and how to adjust?

Dr. Weaver commented that in the past HSC has at least looked into creating guidelines (such as chemotherapy with less than 5% chance of any response). But actually moving forward with that is a complex. HSC has met with opposition from oncologists in this example. It's often seen that many are cut out of OHP and left uninsured while a few are receiving expensive treatments. Progression to expand insurance would be a great movement.

[A-311] Clarification on limitations of hospital stay is 18 days per year (not per visit). The stay in the hospital past the 18 days will not be covered by OMAP, so prior to their admission the DRG checks the patient's available time allowed.

[A-334] It is still early in the budget process, it is hard to foresee what benefits will be funded. OMAP is planning to build its budget with the goal of the benefits restored for the next biennium.

[A-339] July 2006 may be the soonest for OMAP to report any new prescription drugs. The HRC has recently completed six drug classes (updated drug classes and an original drug class).

[A-347] OMAP has decided to participate in the MED Program (Medicaid Evidence Decisions) which is based at OHSU. OMAP's lead staff person involved in the MED Program is Wally Shaffer, MD, Medical Director for OMAP. Kathy Weaver, MD, Director of the Health Resources Commission will be the contact person for this project out of the Oregon Health Policy & Research (OHPR) office.

[A-362] The Governor's Healthy Kids Initiative is intended to expand coverage to Oregon children. Public meetings around the State have been conducted for the Medicaid Advisory Committee to receive input from the public, and then give recommendations to the Governor for a new plan. The proposed plan is an expansion of the Federal Poverty Level from the current 185% to 200% of the poverty level of the Oregon population. There is also an expansion of the Family Health Insurance Assistance Program (FHIAP) up to 300% of the Oregon poverty level. The State would contribute with a sliding contribution for the higher income level. Development of a pooled insurance product just for children with a sliding scale of premiums/benefits by family's incomes and available to all Oregonians regardless of income level is being considered.

[A-402] Medicare Part D issues are smoothing out. Some exceptions are still being funded on a month to month basis. OMAP covers Medicare Part D for the dual eligibles and expects the problems to continue but also lessen in the next several months. Compared to other state's experiences, Oregon managed the program tightly and did not spend funds on exceptions on the Part D coverage. Though Oregon didn't overuse funds on exceptions, it has taken a great deal of staff time and management. Patients faced much confusion in proper enrollment, especially dual eligibles who were switched programs without their knowledge, and subsequently had problems when asked for co-pays at the pharmacy. The State covered some of those issues while complete resolution was in process. The Federal government paid back the states for such costs up through June. This whole transition put patients and pharmacies at risk; patients for their health and having access to their prescriptions, and pharmacies at a financial risk. It also increased the workloads of insurance companies to learn, abide by, and implement the Federal laws. But this summer, the patients will be required to pay premiums and get nothing back until reaching a threshold of \$5,100. This dough-nut hole was intended to pay for the whole program. The average Medicare cost for patients is \$3,600 per year.

4. Drug Class Updates – Kathy Weaver, MD

[A-476] Jeanette Jansson, MS, RN, Chair of the Newer Antiemetics subcommittee of the HRC represented the Antiemetic subcommittee and presented the Newer Antiemetics report (Document #2). The Newer Antiemetic subcommittee met on February 9, 2006 and March 23, 2006 to review the EPC report which included 5HT-3 drugs and Substance P drugs. Populations included adults and children, post-operative nausea, chemotherapy induced nausea, radiation induced nausea, and pregnancy. Jeannette Jansson reviewed the key questions and conclusions relating to them (see Document #2). There were gaps in the research literature especially in the areas of pregnancy and in children. Though the HRC considers only good or fair quality studies, one poor study was included in the NAE report simply because it was the only study on dolasetron.

[A-665] Dan Kennedy, RPh noted that two drugs were not FDA approved for anything except chemotherapy. We precluded them from some indications. Dr. Kathy Weaver responded that Aprepitant is an add-on therapy, and never used alone.

As seen with previous drug classes, this drug class also is a review of Newer Antiemetics in comparison to one another. A more helpful review for OMAP would be to compare the Newer Antiemetics to the older remedies. Commissioners commented that some of these drugs listed may be going generic soon and will be of benefit to OMAP's selection of drugs for their formulary.

[A-747] Public comment was solicited. One comment was made that Zofran will be going generic sometime this year in November or December. Zofran is manufactured by Glaxo-Smith-Kline.

The HRC did not vote to approve the Newer Antiemetics report and agreed to vote on it when the next meeting contained a full quorum.

[A-770] Dr. Weaver shared the key questions on the Targeted Immune Modulators. Now in final form, the review will include psoriatic arthritis, ulcerative colitis, and two new drugs were added as requested. The TIM annual update #1 will be released January 2007.

[A-835] Report on Drug Effectiveness Review Project (DERP) Governance Meeting: Dr. Weaver reported on the discussions from the semi-annual meeting. DERP 1 was our three year contract and is concluding. There are now 16 states involved in this contract and DERP has completed 25 drug class reports. DERP 2 contract starts January 2007 which has some overlap of drug class reviews and reports from DERP 1. This new contract is another three year contract which includes 8-10 original reports. These reports could potentially be comparative drug class reviews, or perhaps reviews within a class (i.e. ACE vs. ARBS), or guideline reviews to determine which drugs to use first. Of these 8-10 reports, the DERP would like to publish three of them in order to give the DERP better visibility and ownership. The contract also includes twelve updates of the drug class reviews. Since there are 25 drug classes and only 12 updates, some classes will be excluded that generally do not have new information. The DERP will decide whether the report would be a large, medium, or small project and intend to reach a balance in determining which drug class reviews will be done. The DERP will also consider other resources in their decisions to update a class and utilize the AHRQ who will be conducting a review of the ACE's vs. ARB's, Beta Blockers, and NSAIDs.

[B-003] The MED program includes Jeannette Jansson, MS, RN and an evidence specialist. While the MED program is looking for a new specialist, Ed Clark, a retired radiologist, is filling in part time on clinical imaging. The project they are taking on now is assessing six major areas (topics) of Medicaid to determine where policies and resources could be created or shared. Beyond this year, the MED program will expand to receive on-going requests from the states. Much work will be done in referencing, research, compiling data, and investigating high cost items, etc. One main area in process is determining evidence-based research in MRI imaging, specifically of the head and spine, with PET scans following. Now that some states have started a pre-authorization policy for imaging, the MED program intends to gather those states' experiences and then consider criteria applicable for other states. Taking the example from the DERP model, the MED program will work to make information available to every state including interactive, searchable functions working on the internet. MED program will act as a bridge to other states so as to reduce workloads, offer sufficient tools, reliable research and share successes of other states to the states' needs.

[B-074] Jeanette Jansson was asked whether there are good studies available for medical equipment and medical procedures. Jansson responded that the MED program has been charged to create comparison studies when there are no other available reports. The MED program would be receiving a discount rate to access medical reports. The states, in turn, would pay a fee to the MED program to enroll in the program. The MED program not only shares the medical information with the states but will help decide what to do with the information, helping the states apply it to their local decision making processes and operating with it.

[B-107] Since Oregon is joining in this MED program contract, Chair, James MacKay, MD asked how the HRC will relate to the MED program. Dr. Weaver explained that it could be possible we request particular reviews and have the MED program investigate it. Otherwise, if the MED program is active in a study, then decide whether the HRC is interested to take it. Then, within the HRC process, activate a subcommittee to review literature and ultimately produce a report to disseminate.

[B-119] Jansson commented that the MED program addresses the states with why and how they change policies. Are state policies operational? Are state policies offering the right policies for the right reason? Discussion continued among the Commissioners of actual instances of new medical technologies being approved for Medicaid coverage that had poor evidence of effectiveness. States' responses have been motivated and interested in such a program as MED program. A current website for the MED program is <http://www.ohsu.edu/med/>. MED is different from DERP in that their information is not public. Though states will utilize the published information in the ways they see necessary, the MED program will not maintain a public website or distribute their information publicly outside the enrolled states. It is not certain whether they will at the least share listings of their current reviews.

(The Commission skipped to item #6 on the agenda)

6. Medical Technology Assessment Program (MedTap)

[B-200]

Obesity -

Dr. Weaver shared the draft roster for the Obesity subcommittee submitting it to the Commissioners for their approval. (See Document #5) No vote of approval was done, but the roster will be brought to the next HRC meeting.

[B-250] Dr. Tony Melarango commented that while the Commissioners are maintaining a standard of unbiased members on the Obesity subcommittee by excluding any bariatric surgeons, it would seem insufficient to conduct the subcommittee without any surgeon at all. Since surgical treatments are a main part of the assessment and risk factors to go along with surgeries, having a surgeon to address those key factors could be of benefit.

[B-310] The Draft Bariatric Surgery Report (Document #6) was distributed to the Commissioners to view the progress of the subcommittee's work. Dr. Weaver explained that the report is in progress and adverse events of the surgeries have not yet been reported. For now, the report follows the same model of our HRC drug class reports and includes the quality of evidence, the key questions, inclusion criteria (populations), interventions, and a clinical overview.

Statistics are showing that bariatric surgeries are increasing in Oregon. Dr. Weaver went on to explain a newer study from Australia she came across on adjustable laparoscopic band procedures. Though it was a short study of 2 years and involved only 80 patients, this was a one of few randomized controlled trials. Another one was a 10 year old Swedish study using different kinds of procedures.

[B-383] Dr. Tony Melarango shared that his group of physicians have proposed to NIH to do a study among diabetics. A surgeon had observed that a number of their bariatric surgery patients saw an improvement with their diabetes much quicker in than in weight loss. It's difficult to do more studies because the surgery procedure alone can cost up to \$27,000.

Dr. Weaver added that studies have shown hyper-insulin levels and the metabolic syndromes, found to improve. Dr. MacKay agreed to that since it's been well shown in diabetics to lose at least 10 pounds and there will be more control over diabetes.

[B-419] The question arose whether adolescents will be included in this study. While there is a great need for information on this and a growing interest among families and pediatricians, it's an area that needs more studies. We simply cannot make decisions where there is no evidence.

[B-453] Key Questions for the Bariatric Surgery report were brought to the attention of the Commissioners once more since they have been revised since their last approval. The difference is the key questions shared in March had four questions comparing bariatric surgery to medical

management, and the Obesity subcommittee chose to do two separate reports. The same key questions are now focused on first answering the bariatric surgery key question.

The HSC would like the HRC to have some recommendations about bariatric surgeries for their next meeting June 26, 2006 where they will look at a re-prioritizing the lines of the Prioritization List. Dr. Weaver asked the Commissioners to review the bariatric surgery report in an additional meeting if the Obesity Subcommittee could finish their report by their next meeting. Commissioners responded that they would rather consider the entire report before offering any considerations to the Health Services Commission. The HRC regretted that they could not make the deadline for the benefit of the Health Services Commission, but needed to do justice to the report. Also, the HRC will not want to share the evidence of surgeries alone, but will want to complete the review to show the comparison of bariatric surgeries to medical and behavioral therapies for weight loss.

[B-488] Dr. Tony Melaragno asked what would be the predicted outcomes of our bariatric surgery review if it reported a highly effective treatment. Would the State of Oregon then begin paying for bariatric surgeries to Oregon Health Plan patients? Allison Knight of OMAP answered that it would not be likely. The results of the bariatric surgery would fall into a non-funded category of the Health Services Commissions' Prioritized List. The Health Services Commission would also have to have a series of public meetings to come to decisions to implement what evidence the HRC found. Cost effectiveness compared to potential benefit becomes a consideration in medical treatments and prescriptions.

Dr. Weaver explained current policies in our MedTAP program (Medical Technology Assessment Program). If HRC reports an acceptance of a medical technology, then the Obesity Subcommittee in conjunction with the HRC will conduct a cost-effectiveness component by considering available policy relevant information and evaluating this technology's broader health care social and economic impact. Then the report will be submitted to the Health Services Commission for consideration.

[B-520] HRC Commissioners agreed that it will be an important meeting for the HRC when the final results of the obesity management review are submitted. Much consideration and discussion will come about from it since it is a complex review with variety of treatments. The weight loss and bariatric surgery issues are sensitive, highly political, and sometimes with emotion attached to it. This is evident as the HRC staffs have received comments and interest from a few surgeons and various groups nationwide. Medicare began approving bariatric surgeries as they had a deluge of people supporting these surgeries with their testimonials. Since this is all Medicare saw, they approved the surgeries. Perhaps the HRC will be faced with the same public comments and thus should treat the review very carefully and responsibly.

[B-581] More detailed statistics on Oregon bariatric surgeries were given the Commissioners in response to their questions from the last meeting. Hanten Day, Research Analyst at Oregon Health Policy & Research compiled a sheet to answer those questions. (See Document #7) One side of the page shows number of bariatric surgeries by hospital in alphabetical order. The reverse side of the page shows the hospitals performing surgeries by frequency. Legacy and OHSU are the only Centers for Excellence that was designated by Medicare. The evidence-based report from the EPC for the Public Employees Benefit Board did not resolve which types of bariatric surgeries should be done, but rather recommended the decision be left to the surgeon of a Center of Excellence when assessing each patient. OHSU generally shows 85% of their surgeries are Rue-en-Y's and Legacy shows higher percentages on the laposcopic band procedures.

[B-627] A possibility of why the bariatric surgery trends in 2004 are going down is because insurance companies tightened their policies on it. More patients are choosing to have their surgeries done internationally. Malpractice suits have possible entered into this factor as well, since more

attorneys are involved in the topic. Dr. Melaragno agreed to this having seen The Oregon Clinic not wanting to bear such responsibility or possibly poor reputation.

[B-643] Diabetes is also seen in the new set of statistics. The bottom row shows that close to a third of the bariatric surgery patients has Type II diabetes. It is likely that we see this in hospital data because insurances are using that as criteria for approval of such a surgery. The Commissioners were pleased to see Hanten Day's work and it was noted that hospital data from 2005 should be available in the OHPR office September 2006. Also, ambulatory data is not available since it is not required of the hospitals to report them. If bariatric surgeries are being done as an outpatient surgery, it is not being tracked.

5. HRC Future Projects

[B-674] Reprioritized Table (Document #4) for future reviews for the HRC was shared in a large packet of information. The packet contains articles, reports and studies pertaining to each topic listed on the front. These items listed were treatments the HRC has looked at before and there are new topics added to this list since Dr. Weaver has become aware of other systematic reviews underway where we may have access to free data. Though the HRC had settled on three topics to review (1. Obesity, 2. Methamphetamine, 3. Back/Disc Surgery), it is time to look at it again. Obesity management is underway; Methamphetamine recovery has little or no data on outcomes. HRC can now project ahead into some other options for MedTAP reviews and prescription reviews. Discussion moved along several different topics. Dartmouth Atlas papers are in the front of the packet and shows some common surgeries and where the variations in where they are performed around the State. The HRC is precluded from mental health drugs; however a potential review in depression treatments could involve items other than prescriptions. Emergency Room utilization is a huge topic and would be of benefit to many to have some literature on it. Unfortunately, no studies have really surfaced on the issue of Emergency Room use. Allison Knight of OMAP asked the HRC just what would they look at to study ER utilization. OMAP sees a high use of the ER for non-emergent conditions and wants to curb the problem. Dr. Weaver said it shows some patients have lack of access to health care, doctors, and non-emergent treatment. Dr. MacKay explained from an insurance perspective that there are three populations in the Providence health plan, one of which is Oregon Health Plan. OHP has approximately 850 visits per 1,000 members. Even with Providence insurance, the OHP patient will use the emergency room. For Medicare, there are about 300 visits per 1,000 and for commercial its 100 or 200 visits per 1,000 members. Speculation suggests OHP patients may have had trouble accessing their primary care doctor, are impatient, or have made ER visits a habit as more convenient and perhaps just part of their culture. Educating patients is the aim. OMAP now has an advice phone line for patients and hopes to create other ways to help.

[B-883] Commissioners were asked to review Document #4 and the various medical treatments and come back to the next meeting with a vote of at least three items which are most relevant, important, or of interest for cost savings for future HRC reviews. It would be likely that the HRC could take on two major MedTAP reviews each year. With new Commissioners on board, this is a good move to involve their perspectives.

[B-910] It was discussed that the next HRC meeting be re-scheduled for a combined June/July meeting. Many Commissioners could not attend the June 16th meeting. Later, by email, the Commissioners settled on July 7th, 2006.

7. Awarded Grant

[B-998]

Dr. Weaver told the Commissioners about a 2 year grant that OHPR applied for last fall offered by the State Attorneys General. OHPR was awarded \$400,000 over two years with options to re-apply for the grant following this two year period. A summary on this grant was shared with the Commissioners in their packet called, "Improving Professionals' Prescribing Practices." The goal in this project is to educate prescribers. We're working together with the Veteran's Hospital, who also was awarded the grant, to combine our efforts to reach prescribers. The first year would involve lectures and curriculum for students and prescribers. Later, web-based tutorials with CME credits will be implemented. The grant project will begin July 1, 2006 with plans to hire a project manager and a physician for the lectures. In the second year of the project, more education will be directed towards patients and consumers through public service announcements.

8. Meeting Adjourned at 4:30 PM

Documents:

1. Minutes 3-17-06
2. HRC draft report – Newer Antiemetics
3. EPC Key Questions - Targeted Immune Modulators update #1
4. Reprioritized Table of HRC future projects
5. Obesity subcommittee demographic roster
6. Obesity subcommittee draft report on Bariatric Surgery

MINUTES
HEALTH RESOURCES COMMISSION

September 8, 2006

Members Present: James MacKay, MD, Chair; Dan Kennedy, RPh, Vice Chair; Judith Wilson; Justin Leonard, JD; Bill Origer, MD; John Saultz, MD; Lynn Marie Crider; Kate Merrill, MD; Linda Lester, MD; Carol Blenning, MD; Wally Shaffer, MD

Members Absent: Manny Berman, Dean Haxby, PharmD; Tony Melaragno, MD; Ree Sailors, MSW

Staff Present: Kathleen Weaver, MD, HRC Director; Karen Eaton, HRC Assistant

1. Call to Order

Dr. James MacKay called the Health Resources Commission (HRC) meeting to order at 1:30 p.m. in room 112 of the Clackamas Community College Wilsonville Training Center, 29353 Town Center Loop East, Wilsonville, Oregon.

2. Approval of Minutes

At the bottom of page 1, insert “more” after “Deficit Reduction Act, it may actually cost *more*”. Justin Leonard, JD suggested taking out the three sentences that say “Currently the HRC is precluded from reviewing mental health drugs...consumers and other states,” and change “resolved the preclusion” to say “addressed the HRC’s review of HIV, Cancer”...and in the last line, “Practitioner Managed Prescription Drug Program,” would say “statutes”.

The HRC minutes were unanimously approved as amended for the 9-8-2006 meeting.

3. OMAP and PDL Update – Wally Shaffer, MD, Medical Director of OMAP

Dr. Wally Shaffer mentioned that OMAP has been renamed to The Division of Medical Assistance Programs (DMAP) which includes the Addictions and Mental Health Division, Children Adults and Families Division, Public Health Division, and Seniors and People with Disabilities Division.

Updates: The MED project OHSU Center for Evidence-based Policy is conducting a parallel project called the _____ to the DERP project for reviewing technology in general and has a web-based clearing house. He said the contract has not been finalized but when it is he and Dr. Kathy Weaver will have passwords and access to all the information on the web. Whatever is relevant will be immediately available. The contract for DERP 2 is in pre-final stages.

Dr. Shaffer passed out the new DMAP drug list pocket guide which is more than the planned drug list; it is policies the Oregon Health Plan has in place for the pharmacy programs. New on the PDL: 1) Several of the ACE inhibitors are newly generic - benazepril, enalapril, benazepril HTZ, enalapril HTZ, and lisinopril HTZ as well as quinapril; 2) inhaled drugs - least expensive are in white and more expensive drugs are in gray. In the white section on inhaled corticosteroids QVAR is the preferred low potency inhaled corticosteroid. Flovent is also on the preferred list and it is a high potency one; otherwise, the PDL is similar to the previous list.

Dr. Shaffer said that the drugs come up for review based on the HRC subcommittee reports. The HRC evidence-based reports on different categories of drugs are taken into account as the first step. The benchmark drug is determined as the least expensive of the drugs in the category that is deemed to be equivalent. Then other drugs within the category are added to the PDL if they meet that benchmark price. Whenever a drug becomes generic it does not automatically get added, but if it is recommended in the conclusion of the HRC report, then it is added. The list is reviewed quarterly. Dr. Shaffer said that if the benchmark drug was not generic and then became generic, it was unlikely it would go off the list.

It was asked if under oral hypoglycemics metformin was not included. Dr. Shaffer replied that the problem with diabetic drugs has been whether to compare drugs across categories or not. He believed that sulfonylureas were the drugs that were evaluated but did not think metformin was included in the reviews. Kathy Weaver replied that it was not in the original review of oral hypoglycemics nor did it make the new TZD review.

Dr. Shaffer said that DMAP gets a summary of ePocrates formulary use every quarter so the OHP drug list has been on ePocrates for at least a year. Oregon has almost 2500 total subscribers to the ePocrates Oregon Medicaid formulary, mostly physicians, but there are pharmacists and pharmacy benefit managers or medical and nursing students also included. Then there is a printout of users and although the number of subscribers has increased over the past year, this category called “Users” is lower and represents people who use the Oregon Medicaid formulary.

Dr. Weaver asked if the 2500 number was the number of ePocrates users who have asked for the OHP formulary to be added. Dr. Shaffer answered yes, both handheld or online prescribers and subscribers.

Dr. Shaffer said that the DUR board met and recommended restrictions on Actiq that require use to comply with the black box warning that includes use only for “breakthrough” cancer pain. There will be restriction on utilization that will translate into decreased cost from \$5000 to \$6000 a month.

4. Drug Class Program - Thiazolidinediones (TZDs) - Carol Blenning, MD

The subcommittee first met in the summer of 2005 and subsequently met four times in 2006, and consisted of four physicians, one physician assistant, and a pharmacist. They used OHSU’s Evidence-based Practice Center report, “Drug Class Review on Thiazolidinediones.” The subcommittee wanted to look at overall glycemic control comparing the two medications and also effects on macro- and micro- vascular complications. Rosiglitazone and pioglitazone are not currently approved for use in prediabetes or metabolic syndrome.

Key Questions 1a and 1b. Comments and questions were solicited.

Dr. Weaver said that a previous TZD, troglitazone, was taken off the market because of liver toxicity. Dr. MacKay stated that in monotherapy TZDs reduce A1C by one percentage point and asked if they are already on a sulfonylurea and the TZD is an add-on, what further percent reduction is expected. Dr. Blenning said that it was not more than 1% additional and that the TZDs are not usually a first line diabetic drug.

Key Questions 2a. and 2b. Comments and questions were solicited.

The question was asked why the two TZDs were compared to placebo or other active controls. Dr. Blenning said that they always try to find head-to-head comparisons such as, is there one drug that stands out from the rest, and if there is a difference, then that compels the commission to recommend the use of that one.

Dr. MacKay asked if there was any evidence that it does delay the onset of diabetes. Dr. Weaver said that in some ways the questions were premature. Dr. Blenning said that pioglitazone was part of the diabetes prevention trial and it was statistically significant in preventing the onset of diabetes. They ran into some issues that came up such as material that was available after the cutoff date talked about ophthalmic adverse effect.

Key Question 5, 6a, 6b and 7. There were no comments or questions.

Key Question 8. Comments and questions were solicited. Dr. Neilann Horner, GlaxoSmithKline (GSK), wanted to add more information specifically to the issue of what we know about additional decrease in A1C when rosiglitazone is added on to another oral hypoglycemic agent. Dr. Horner said that two publications recently came into the peer review domain, one December of 2005 and one January of 2006, the 2006 publication in Diabetes Obesity and Metabolism, the December publication in Clinical Therapeutics but both of those miss the cutoff for the report. Roughly 0.8% drop was seen when rosiglitazone was randomly added on to 10 mg bid glitazide. These studies were designed to understand what happens when we capitalize on complimentary mechanisms of action. When added to 1 gram or one half dose of metformin there was a 0.9% reduction with variability is about 10-20%. The metformin group was 300 persons per group. Phase 2 trials for Avandia, a combination pill of rosiglitazone and metformin was achieved May 19. Those trials were 50% Caucasian. Insulin resistance is of concern where Avandia is working uniquely vs. the other classes of drugs. The racial mix will be very important in understanding what that drug can offer type 2 diabetics. There is a large trial reporting in one week, a three-to-five year follow-up and impaired glucose tolerance with the endpoint being new onset type 2 diabetes plus death as the endpoint. They have another six-year trial that will be reported in December that is head-to-head metformin vs. glyburide vs. Avandia (rosiglitazone) in type 2 diabetics that have been diagnosed within three years.

Lynn-Marie Crider said she noticed that although the report cites clinically useful information from those studies, still does not help to compare these two agents against each other. Dr. Weaver said that DERP 2 would be comparing class-to-class and also looking at combination drugs that were not done in DERP 1.

Steven Stein, Takeda, said that some of the questions are not able to be answered with the current data. In one of the studies that was published after the cut-off point the patients, Hispanic women, were switched to pioglitazone and showed a delay in onset of new diabetes. The article was published in Diabetes in February 2006; research was done by Tom Buchanan, MD.

At the World Congress of Cardiology in Barcelona, there was a study with pioglitazone as a subset of a Proactiv study that came out last year showed a 47% relative risk reduction in secondary stroke vs. placebo. He said that certain cardiovascular specialists are showing interest

in this area and at the American Heart Association meeting coming up in Chicago there will be a late breaker announced by Takeda that will compare the effects of pioglitazone vs. glomiperide on the rate of progression of carotid artery atherosclerosis, a 400 patient study.

Dr. Weaver said that the TZD update would hopefully answer four of the Key Questions that had insufficient evidence and that this would be an update that would be good to send back to the original subcommittee instead of the Standing Update Committee because they would have the expertise there.

The Health Resources Commission unanimously approved the TZD report.

5. Drug Class - Proton Pump Inhibitors - Dan Kennedy, RPh

The Standing Update Committee met in July to review PPIs and Opioids. On page 6 are the new findings of the SUC. The review added children to the adult patient population. There were no new PPI drugs except omeprazole sodium bicarbonate mixture liquid which is the name brand Zegerid (omeprazole NaHCO₃.)

The comment was made that the FDA pregnancy categories are different; omeprazole is category C, others are all category D.

Comments and questions were solicited. On page 15 in the conclusion box, the spelling of “hypergastrinemia” needed to be corrected.

Public Comment: Diana Lein, Santarus, makers of Zegerid, the immediate release form of omeprazole wanted to point out that omeprazole was originally available in 20-40 mg. formulation as a powder for oral suspension. It is now also available in capsule form. They are considered the same drug. She said that the report brought up the point of “fussiness” of children in the studies that is a very difficult endpoint. This led to the question of looking at the question of gastric pH as an effective means of comparing drugs in this drug class. She said that the studies that they have were not included in the study questions in the review. However they do have three comparative studies that have been done. A hospital study published in the Journal of Critical Care Medicine looked at the reduction of risk of upper GI bleeding in critically ill patients using the powder for oral suspension through an NG tube. There was a loading dose on day one to get those patients to steady state then once-a-day dosing through the NG tube. The patients were NPO for the first three days of the study and they were able to maintain the median gastric pH ≥ 6 for the 14 treatment days in the Zegerid arm. This data was filed with the FDA. They now have an indication for the reduction of risk of UGI bleeding in critically ill patients. Theirs is the only PPI with that indication. It was not recommended that the capsule be broken apart and used through an NG tube because the powder for oral suspension was specifically formulated for that reason with suspension agents.

Ms. Lein said that more recently they have done two comparative studies looking at nocturnal acid control. In the first study, Zegerid was dosed prior to bedtime compared to pantoprazole. They showed a significant increase in gastric pH so the percent of the time the gastric pH was over 4 was significantly improved compared to the pantoprazole arm. On the last dose there was BID dosing of pantoprazole and their once-a-day dosing was superior to the twice a day pantoprazole dosing. This could be a potential savings benefit to an agency such as DMAP. The

pantoprazole was the standard formulation. In that study the pantoprazole was administered prior to dinner. It was recommended by the American College of Gastroenterology that PPIs be followed by a meal 30 minutes later to stimulate the parietal cells so you have an effective reduction of binding. The proton pumps need to be moved to the cell surface to be available for binding by the drug. If the drug was administered before you have that stimulation of the parietal cell, there would not be binding to the proton pump. She said in the hospital study those patients were NPO yet they still had significant pH control.

It was asked why there was a difference in pregnancy. Ms. Lein said it was her understanding that omeprazole is category C because there have not been any studies performed in pregnant women. Omeprazole has been used for a very long time and considered a safe drug. The adverse event rate of Zegerid is comparable to that of omeprazole. She said that they need to take into consideration that there is some sodium exposure from the antacid buffer but that would be taken into account by the clinician.

Tim Lemon, TAP Pharmaceuticals, said lansoprasole is Category B. Omeprazole was launched initially with a black box warning because of the overwhelming data that had been submitted not only from their product but also from Merck. Their black box warning was lifted by the FDA at the same time. When Prilosec and Prevacid were launched, 99.44% of patients did well on one or the other. He said that maybe Prevacid could be considered because they have a better category for pregnancy. TAP has capsules that can be opened up and put on applesauce or in apple juice and Prevacid solutab which can be used without water, placed on the tongue and easily swallowed. He said the granules are one-third the size of the capsule granule and the cost is 16% to 32% lower than any other PPI on the market. He said the dual-eligibles are those hardest to treat, the critically ill now being covered on the Medicare Part D plan. He said it is more important to consider the benefits of pediatrics and also the benefit of a safer rating in the category for pregnancy. The largest health plan in the state has lansoprasole as the exclusive product in its second tier. All others are non-preferred. OHSU has done the review and selected Prevacid as its only preferred branded product.

The commission unanimously approved the PPI update.

5. Drug Class Program - Opioids Update #4 - Dan Kennedy, RPh

Dan Kennedy said that extended release Hydromorphone was withdrawn because of its potential if taken with alcohol. They noted that constipation rates were higher with oral long-acting morphine than transdermal Fentanyl. They talked about methadone-related fatalities that go hand-in-hand with increased methadone use. They recognized that there is a new long-acting opioid that will be coming onto the marketplace before the next update. The conclusions of the report remain the same.

Public testimony: No comments were given from the public.

The commission unanimously approved the Opioids update.

5. Drug Class Program - Key Questions – Interferons/Hepatitis C - Kathy Weaver, MD

Dr. Weaver said that the key questions have been accepted by the DERP review process of the consortium of states already with input from hepatologists. She said there are actually two drugs

that will be considered, peg-interferon alfa-2a plus ribavirin and peg-interferon alfa-2b plus ribavirin.

Dr. MacKay commented that this is a very important disease. There was discussion that the comparison by phenotype is the important issue with treatment. Though the treatment is very expensive, if the shorter treatment works then that is very significant. Dr. Weaver said that she remembered when the HSC looked at HepC because it was below the funding line in the Prioritized List. The post-treatment data looked good then the remission rate of HepC started to erode with time. Now they are using combination interferon with ribavirin; it seems there is a more sustained response. Dr. Bill Origer commented that re-treatment may be good because there were folks who were treated with interferon only and is it worth retreating them with the combination product. Dr. Weaver said that the Key Questions include patient populations of nonresponders.

Public comment was solicited: Robert Cortez Jr. MD, Schering Plow, wanted to comment on Key Question 3 regarding the list of demographics. He suggested adding the weight > or < 75 kg because weight >75 kg is found to be a strong independent negative predictive factor in achieving sustained biological response. He said that in the largest study ever conducted in the U.S., WIN-R with almost 5,000 HepC patients enrolled, 2/3 or 67% of the patients were >75 kg and actually more than half were >85 kg. He said our report on the comparative sub-populations defined by patients that are above 75 kg would be important for 67% of the patients involved. There are two peginterferons on the market; the first on the market was peginterferon alpha-2b and it offers individualized weight-based dosing at 1.5 mcg/kg/week. Peginterferon alpha-2a is given as a fixed dose of 180 mcg/week and the FDA has recognized the problem with fixed dosing and has requested that the makers of peginterferon alpha-2a conduct a post-approval commitment study to evaluate higher doses of this drug in heavier patients. He said that as this would affect 67% of the patients Schering Plow asks that the category of weight > or < 75 kg be added to the list of patient subgroups that will be comparing effectiveness for the peginterferons.

Dr. Weaver asked if he thought that the obesity part is possibly non-alcoholic steato-hepatitis. Dr. Cortez answered that there are studies being done with NASH and also metabolic syndrome with insulin resistance that is a subgroup. He said obesity by itself even without NASH is still an important factor as is insulin resistance. The first head-to-head ideal trial is now closed to accrual and the initial results will start to come out in late 2007 and be final in 2008. Dr. Weaver said she would be happy to bring that up in the monthly DERP phone call. It is a lean weight but also BMIs will be important as well.

5. Drug Class Program - Key Questions – Inhaled Beta2-Agonists – Kathy Weaver, MD

Dr. Weaver said that these questions are based on what was done before with the other inhaled medications. We have some Canadians involved with some drugs available here and not in Canada and some available in Canada and not here. It might be interesting to compare because they are switching over to the HFA propellant vs. the older CFC that is environmentally contraindicated because of its effect on the ozone layer. Dr. Origer commented that when you are looking at methods of delivery, the difference in medication dosage between MDI and a nebulizer is different by a factor of 10 to 20. Dr. Weaver said that they did look at the inhaled steroids regarding medication delivery systems and that it gets difficult to measure the dose they

received or know if they used it properly. She commented that these studies get beyond efficacy into effectiveness because we want real life rather than scientifically controlled studies.

5. Drug Class Program – Rosters – Kathy Weaver, MD

Dr. Weaver is working on gathering people for the Beta 2-agonist subcommittee. Many on the roster have been on other subcommittees. She will recruit about eight people by the time the EPC report is ready to be reviewed.

There are already several people interested in the HepC committee, top two have already been on other subcommittees. The question is whether we should have hepatologists who in the past have been involved with clinical trials of one or the other or both of these drugs. Our Conflict of Interest says that one cannot do research in the last year and as we get to more detailed disease states it will be more difficult to get experts in those areas that are not involved with pharmaceutical research. She said that as long as the conflicts are stated up front all is well. She said she asked Ken Flora, MD, and Kent Benner, MD, to be involved. Lorren Sandt from HepC Challenge is interested. Sandt recommended Tina St. John, MD, who is on their board and an epidemiologist and lives in Vancouver. Mel Kohn, MD, is a state epidemiologist and pediatrician who also is on the Health Policy Commission Subcommittee on adolescent obesity and is very interested in being involved. Lynn Nishida, RPh, a pharmacist who has been with us previously, has been asked because we did not have a pharmacist for the Bariatric Surgery part.

6. MedTAP Program – Kathy Weaver, MD

Dr. Weaver introduced Linda Lester, MD, an endocrinologist at Providence, to present the MedTAP report on Bariatric Surgery.

Obesity MedTAP - Linda Lester, MD

Dr. Lester said that the MedTAP program was started in 1993, to direct the HRC to encourage the rational, responsible and appropriate allocation of health technology in Oregon. She said that the idea is that these reports will be used to inform and influence decision makers including consumers through collection analysis and synthesis of evidence-based medicine. In the spring of 2006 the HRC appointed the Obesity Management MedTAP to perform an evidence-based review and reports on 1) the use of Bariatric surgery for the treatment of morbid obesity in adults and 2) the comparison of surgical and non-surgical therapy for obesity. The most recent study shows that up to over 7.5% of the population has morbid obesity. Combinations of diet therapy, behavior modification, prescribed exercise programs, pharmacotherapy, and all their various combinations have only a modest degree of improvement in weight loss which is often not significant, is usually transient with a high recidivism rate.

The RYGB is now the most commonly performed Bariatric procedure in the United States, although the Laparoscopic Gastric Band and the Adjustable Gastric Band are increasing in prevalence. She said there is not the same number of data for both of these procedures. Over 120,000 procedures were performed in 2003 and that number is increasing.

Key Question 1. Questions and comments were solicited. Dr. MacKay asked if this was five years out. Dr. Lester said yes, that long-term follow-up is more limited, that some procedures are

relatively new and at least two-to-four years sustained weight loss with the newer procedures has been documented.

Dr. Weaver said that the Swedish study goes out 16 years but many of those surgical patients followed the longest were with procedures that are not performed anymore and the weight loss was not as great as with the newer procedures. Dr. MacKay said that it depends on which procedure you are doing and he does not believe there is any long-term data on the laparoscopic adjustable band. Dr. Lester said we do not have the long-term data as far as their outcome. Dr. MacKay said that you do not lose as much weight with the banding as you do on the RYGB.

Key Question 1b. Comments or questions were solicited. It was noted that “significantly” means compared to patients who did not get surgical intervention. Dr. Lester said that the percent that go from having type 2 diabetes to normal is in the 60% range which is significant. The data to show the decrease in diabetes onset/year goes from 0.15% of the surgical patients vs. 5% for non-surgical morbidly obese patients. Dr. Weaver said that it depends on the procedure but most of them reported an excess body weight (EBW) loss; averaged it would be 60% EBW sustained loss they have over three to five years.

Dr. Lester said that anything that produces a 20% weight loss in diabetics significantly improves diabetes or resolves it. With other therapies it has been hard to get that kind of weight loss. Dr. MacKay said the SOS will tell you not all diabetes went away and all did not improve so you might say “may resolve or improve” type 2 diabetes. Dr. Weaver said that part of the response depended on if it were a more recent onset of the diabetes that was more likely to respond than longstanding Type 2 Diabetes. Dr. MacKay said that the way it reads is that it resolves or improves it he is not sure that that has been proven. Dr. Lester said in a substantial number.

Dr. MacKay commented that he read in the SOS study that there were still a lot of diabetics left after the surgery. Dr. Lester responded that would be true of all of the subgroups here; hypertension, and hyperlipidemia, because they are looking at a somewhat diverse group, there are so many genetic components; hypertension would not go away with every patient. But there are a significant proportion of patients who do get either a complete resolution or a significant improvement, especially of type 2 diabetes. Dr. Weaver said that you could say, “There is strong evidence that Bariatric surgery resolves or reduces type 2 diabetes in a significant number of adult patients.” Dr. MacKay said that that would be fine.

Key Question 1c. Comments and questions were solicited. Dr. MacKay said that he keeps going back to the SOS study because in 10 years the hyperlipidemia improvement was not significant. Dr. Lester said she understood that for a majority of the patients it was sustained. Dr. MacKay said he thought the cholesterol levels did not change. Dr. Weaver stated that it depends on which lipids are measured. Dr. MacKay mentioned that in the SOS study hypertension is not significant either at two or 10 years. Hypercholesterolemia P value is 0.11 and 0.57. Dr. Lester said the question is whether we should divide out the lipid question into cholesterol and triglycerides.

Dr. MacKay answered that we need to be a little softer about stating “significantly improving” and that people do not go into this surgery for cholesterol issues. Dr. Weaver suggested that it could be stated, “There is evidence that Bariatric surgery may improve triglyceridemia.”

Key Questions 1f. and 1g. Questions and comments were solicited. There were none.

Key Question 1h. Questions and comments were solicited. Dr. MacKay said that he looked up the study in California and that clearly a very large group of people have the surgery and their hospitalization rate goes up in the first two years, and then on from three years. Before the surgery they had a mean hospitalization of 8%, then the year after it was 20%. He said there are a lot of complications and it is expected that they will come back to the hospital. Dr. Lester said that some of the more recent studies with lower morbidity and increased hospitalization rates have not been noted and that we will have to wait for an update on the data and perhaps will have the answer in the next update. Dr. MacKay mentioned that there are fewer complications with adjustable gastric banding. Dr. Lester said there are a couple of trends that are happening at the same time; improving surgical techniques and new centers opening, the newer centers will have poorer results than the older centers. Does having surgery with a less experienced surgeon, but a newer center with better techniques have an effect and how does that compare to what we had 10 years ago? Dr. MacKay said that it may be unknown with the newer techniques.

Dr. Lester asked if the evidence was insufficient and Dr. MacKay answered that it is insufficient for the newer techniques. Dr. Lester asked if **Key Question 1h** should be changed as insufficient evidence. Dr. Weaver felt that the subcommittee needs to discuss it. Dr. MacKay said that this is a very new process for them, that when they worked the pharmaceutical literature it was actually much clearer. There are randomized studies, they are blinded and the groups are all equal but this is more difficult to do and it is hard to evaluate the information. He said that a lot of the surgical literature is very biased.

Dr. Lester said that he Annals of Internal Medicine this last year has had excellent systematic reviews on Bariatric surgery. Dr. Weaver said she thinks a majority of the studies reviewed were uncontrolled prospective studies and although that kind of study design would not pass muster for pharmaceutical systematic reviews and is not as robust, the need for a control group in Bariatric surgery is maybe lessened by the fact that obesity and obesity-related comorbidities rarely improve or resolve spontaneously so that is why they can serve as their own control. The chance of their spontaneously losing their diabetes or their hypertension is near zero based on history. She thought it was great to have randomized controlled trials but did not know that they would ever get them for surgical procedures. The one RCT related to recent Bariatric procedures was the one that was done in Australia. It was a very good study in which O’Brien randomized the patients to a surgical or non-surgical group, but they were operating on people with BMIs ≥ 30 to 35. They felt that they could ethically randomize them because no one knew for sure what the outcomes would be. They used a cutoff point of BMI ≥ 35 and so that randomized study does not fit our criteria. She said she did not think they could wait for 20 years for enough observational data to make a rational decision and that morbidly obese patients are not going to be randomized. She thought it was important that they say, “Note the strength of the evidence.” She said there will not be randomized controlled studies done and that hopefully there will be cohort studies where there are well-matched controls.

Key Question 1i. Comments and questions were solicited. Dr. MacKay said that in the SOS study the primary outcome was change in mortality and this was not achieved. He said that was the thing they were really looking for and the study was negative, there was no difference in matched controls vs. ones who had surgery. In the Christou observational study, a Canadian study over 16 years says that all his patients did really well and this is how much weight they lost and then he said that he would match all those patients over the last 16 years with obese people out of our data bank in Canada and the only requirement was that they had not had a hospital admission for cancer, heart disease, or something in the last six months; they could have cancer or heart disease, they were not well-matched. He said that the study indicates that it helps mortality because it prevents cancer and that obesity surgery does not prevent cancer. He said the matched controls may have had cancer that it was a retrospective study, the matching was very poor and that is how they showed the mortality was less. He said he had to go back to the SOS study that says it was negative on mortality and he would disagree with the conclusion that it has been proven that it reduces mortality. Dr. Lester said that in the systematic review in the annals by Melinda Maggard there actually is data from their meta-analysis of several things that did show decreased mortality rates. Dr. MacKay said he did not know her or the analysis but looking at the studies they were using, they are inadequate studies, that the SOS study that held the most meaning did not show decrease in mortality.

Dr. Weaver said that study also goes back for a number of years where they are combining the older procedures and the newer procedures and those are lumped together. She said that Meggard's paper in the Annals of Internal Medicine was actually done for RAND which is another one of the EPCs using the same type criteria that the Oregon EPC does, so she felt better when she saw their conclusions. This was published in a medical not surgical publication; the original PEBB paper done by Mark Helfand that they based much of their conclusions on included quotes from Christou's paper directly and a lot of his findings were in their summary of systematic reviews. She said she might need to go back and talk to Mark Helfand about that. Dr. MacKay agreed it was something you could not draw any conclusions from, you could say that his patients did well and his surgical technique was good and their outcome was fine. Lynn-Marie Crider said that this is more complicated than what they have been doing and that they may need to know some additional things. She said she was looking at whether there are a certain studies that they need to examine and whether there are underlying things that would help us understand the quality of the studies that they look at. Dr. MacKay said that the report was not final, this was a rough draft of what the committee has done and they were trying to give them feedback.

Key Questions 2a. and 2b. Comments and questions were solicited. Dr. MacKay asked if the text of **Key Question 2b** which says that a 39.6% complication rate from the most recent AHRQ study should go to 40% in the conclusion for **Key Question 2b**. Dr. Weaver said that the thing about the AHRQ study is that they also included out-patient symptoms like dumping syndrome at 20%. They found out this was an intended consequence of the surgery and not an adverse effect. When people overate after they had those procedures they had dumping syndrome or nausea or vomiting. **Key Question 2b** may be more than the 10-20% which was what the PEBB study quoted. She did not know if we should go all the way up to 39.6%. Dr. Lester said that the AHRQ study included incisional hernia associated with the open procedures and that this would differ based upon which procedure it was. Dr. MacKay said that maybe that should be left out.

Dr. Weaver said the reason that they included studies beyond the PEBB study was that the EPC cutoff was 2004 and so much of the literature and important things that have happened since then particularly on the adverse side that they felt they could not really do an adequate report unless they included the newer literature.

Key Question 3. Comments and questions were solicited. The question was asked if this was pulmonary heart disease. Dr. Weaver said she thought they were referring to pulmonary hypertension; this was from the Washington study and they only had a few cases but a very high mortality rate.

Key Question 4. Comments and questions were solicited. Dr. Weaver introduced Som Saha, MD, Portland VA and OHSU general internist and health services research, member of the Evidence-based Practice Center, has done work with reviewing cost-effectiveness analyses, meta-analysis, and chairs the Health Outcomes Subcommittee of the Health Services Commission.

Dr. Saha commented on the outcomes data and the cost-effectiveness data. He prefaced his comments by saying that he reviewed the report and looked at some of the key studies. He said he would offer reasonable conclusions but no opinions about Bariatric surgery just opinions about the evidence and the quality of the evidence. Regarding the outcomes data there were two issues in judging the effectiveness of Bariatric surgery. For observational studies the obvious issue was that they were selection-biased, that people who undergo surgery are substantively different from people who do not undergo surgery, a very obvious thing. People who undergo surgery are typically healthier than people who do not undergo surgery for any given condition. The selection bias is one that is not to be underestimated. He said that huge lessons have been learned with hormone replacement therapy (HRT). They have thought for 15 years that they were reducing women's heart attacks with HRT until they did a randomized trial that showed that we were actually increasing myocardial infarction rates. He said that basing conclusions on observational studies of Bariatric surgery on the premise that there will never be a randomized trial is a little troubling, because there *will* be a randomized trial of Bariatric surgery. It is only unethical if they have proven that Bariatric surgery actually improves heart outcomes and that has not been proven. He said the studies to date have not shown improvement in the ultimate outcome which is mortality and quality of life.

He said this is a surgical intervention and even in the randomized trial setting there are issues. They thought that internal mammary ligation was effective because it was better than pills for people with chronic angina. Then they did a study in 1948 that compared internal mammary ligation to sham surgery and found there is no difference. The same thing happened about five years ago with knee arthroplasty for people with chronic knee arthritis; they thought forever that it worked because it seemed to be better than pills but then when they compared the surgery again there was no difference. He said there were a couple of reasons why that might be, the placebo effect, that people who do get surgery feel like they are doing better, and co-intervention meaning that people who get the surgery probably get more aggressive physical therapy. He thought that sham surgeries would be possible in the future because he thinks this will move to laparoscopic surgery altogether within the next five years and does not think open surgeries will be done much longer, laparoscopic surgeries seem to have much better outcomes.

Dr. Saha mentioned the three categories of outcomes; weight loss, amelioration of chronic conditions and future events. He felt that it was pretty clear from the evidence that these procedures are more effective at producing weight loss more than conventional therapy. There are not many randomized trials but the few randomized trials that have been done have looked at that outcome primarily and shown that there is weight loss sustained over two-to-five years. He did not think there was much question about that. He said there was the possibility of selection bias in observational studies but in the randomized trials you would have to posit that the people who were getting the surgery were aggressive about diet and exercise and it is hard to argue that the weight loss is not a real effect. He said he did not think many of the randomized trials really looked at amelioration. He felt that you would again have to posit that the people who were getting the surgery were getting aggressive about their diabetes because they got their surgery. He said the evidence may not be strong because strong evidence comes from randomized trials so to say any evidence from an observational study is strong evidence is ill-advised.

Dr. Saha also talked about mortality and morbidity (hospitalizations) where the selection bias is a large issue because these are observational studies. He said that regarding mortality, the study Dr. MacKay talked about was administrative data. He said with an observational study of mortality, the key issue is risk adjustment, i.e., how healthy were they to start with? He said they do not match by age and gender or BMI. As far as they know, the people who were in the non-surgical arm had 5 point higher BMIs. He said that they think that they probably did not have diabetes or cancer. He felt the mortality data at best insufficient evidence. The mortality data is core because of the selection bias issue and the absolute lack of controlling for risk. He looked at the annals article; he said they looked at mortality as post-operative and they do not really look at long-term mortality.

He thought it was interesting to see that in the comparison of two hospital groups, non-surgical and surgical, there were lower hospitalization rates for the surgical arm. He said that if there was a pre-post where they were taking the same people before they had the surgery and after the surgery, they actually had more hospitalizations after the surgery, which might be a nice illustration of how selection bias might be applied. He said that in two groups going forward, the people in the surgical arm had fewer hospitalizations because they were healthier. He said that in good studies of this sort there is adjustment for a lot of things, such as in hormone replacement therapy (HRT) they found that women who took hormones did better in terms of cardiovascular disease where they adjusted for aspirin, smoking, exercise, weight and they found that actually hormones were bad. They have learned that this is what we call the “healthy user effect;” people who are doing things for their health are healthy in ways that cannot be measured such as stress and self-efficacy. He thought that hospital visit data shows that if you take the same group of people before and after surgery, they actually have more hospitalizations after surgery; therefore, with two groups of people, non-surgical and surgical, the non-surgical are just sicker and that is why they are hospitalized more. He argued that the data is insufficient; the conclusion would be that there are more hospitalizations after surgery than before, maybe not surgery vs. non-surgery because that study showed pretty clearly that you do.

He felt that the cost-effectiveness studies were all really quite poor, there is insufficient evidence. He was able to look at only two of the cost-effectiveness studies but believed that they were the

two that everyone thought were the best studies. One was done for the British National Health Service, a 156-page document in the Health Technology Assessment database and the other one was published in the American Journal of Medicine. The reason he felt that those cost-effectiveness studies were worth less was the outcomes and the way that they linked them; they measured cost per quality adjusted life year. Quality-adjusted life year is just a combining of quality of life and life expectancy merged into one outcome measure. The way that they calculated their quality-adjusted life years or the way they looked at quality of life in order to determine quality-adjusted life it is necessary to understand the difference in quality of life between people who get the surgery and people who do not at those different time intervals.

Dr. Saha said that in the health technology assessment article they were only amplifying one study that really compared people who got surgery; 21 women who were asked about their quality of life at baseline, at one year, and two years. They found that the quality of life was better at one year and two years although they used a measure that was kind of funky. He said they did not use those data in their cost-effectiveness analysis but took quality of life data by BMI and said that if you get surgery your BMI goes down from 40 to 28 you have a quality of life improvement of such and such. He said the inherent problem with that is that they were not looking at quality of life for people who got surgery and did not get surgery; they were looking at quality of life for people according to their weight.

He said that if after surgery your BMI dropped from 40 to 28, that means your quality of life jumped and if you did not get surgery your BMI stayed at 40 and your quality of life did not change. He said that in these studies there is no accounting for the fact that you have cut into people's bodies. There is no accounting for the fact that they have more of all of these other symptoms. All of the quality of life is tied just to their BMI. He said that none of the adverse effects of the surgery are actually modeled in these studies. There are some costs about post-operative wound infections, etc., but they get the quality of life detriment in their scores without accruing any sort of quality of life. He said they have a quality of life increment without having any quality of life detriment because they now have dumping syndrome which is not an intended consequence; dumping syndrome happens when people overeat. Actually when people have dumping syndrome they often have to get rerouted because they cannot control their eating. Dumping syndrome is a consequence of overeating once you have surgery.

Dr. Saha said the British study did not give anyone a life expectancy advantage; they gave them the quality of life benefit of losing weight. The other study gave them a life expectancy benefit also. He said the reason that is problematic is that we do not know if there is a life expectancy benefit. He said for those reasons he would rate as poor both of those studies claimed to be the best in the review of cost-effectiveness studies that it is hasty to conclude that Bariatric surgery provides mortality benefit, reduces utilization or cost savings or even favorable cost-effectiveness ratio. Dr. Weaver asked if the evidence is insufficient and Dr. Saha affirmed that. Dr. Weaver said that part of the problem was that the DERP asked the EPC if they would do cost-effectiveness or analysis and they refused. Dr. Saha said that cost-effectiveness analyses need to have national guidelines so they can have an even playing-field across different types of interventions. He said that the mortality benefit or harm for Bariatric surgery is not known. They did the best that they could which was to assume no mortality difference because they do not know or to say they would give them a mortality benefit because they lost weight. He said that

cost data is hard to get and was typically achieved by expert opinion. One of the studies was British which costs have nothing to do with American costs. He felt that the literature in those two areas was insufficient to make any reasonable conclusions. Dr. Saha said that what they did not do was give them the quality of life detriment from the harms of surgery which are nausea, dumping, etc.

Bruce Wolfe, MD, professor of surgery at OHSU, co-chair of the NIH Consortium on Bariatric Surgery, commented that obesity research is a major component of the academic mission at OHSU and they are very anxious to bring this project to Oregon. Dr. Wolfe said that the desirability of prospective randomized class 1 data comparing equally matched patients to surgical and non-surgical therapy is something we would all like to have. He said that it would help to answer questions that a primary care or any physician or patient faces should they undergo surgery just because they have a BMI of 40 or greater. He said they spent the first six months at the NIH Consortium studying this phenomenon that arises as the result of a lack of sufficient data. The NIH identifies the key healthcare problems in the USA and then requests applications. They funded a specific program in which they allocated \$20 million to study Bariatric surgery because of the great public need for answers to the questions that were discussed in this meeting. This application process resulted in six university centers, a data center, and a whole cadre of NIH scientists who formed a steering committee. He said they spent the first six months examining exactly the kind of studies they could do and in particular how to go about conducting a prospective randomized trial. The conclusion was that it could not be done at this time or anytime soon, probably never.

Dr. Wolfe said there were a number of reasons that were specific to Bariatric Surgery that were being addressed here that did not occur with the examples given by Dr. Saha; in the past where treatments became popular and then a prospective randomized trial demonstrated that the treatments were not efficacious, such as the re-vascularization of the myocardium (Veinberg procedure), gastric freezing for ulcer disease, etc. He said that the reasons relate to the rules of human research which require informed consent. He said that in Bariatric Surgery there was an attempt at a prospective randomized trial in Denmark in the early days where they did not provide informed consent. That study was responsible for international outrage and is the reason that all journals now require certification of IRB approval before they will publish any research. He said that the patient who wants surgery will not consent to join the non-surgery group; the patients that are not seeking surgery could not ethically be randomized into an experimental arm that carries the risk that surgery does. He said they looked at offering surgery to patients who for economic reasons do not have access. That was decided to represent unethical coercion and was disallowed. He asked how the cohorts of patients who do not undergo surgery get accurately matched to the surgical cohort. The best-matched study was the Swedish obese study (SOS) which was done using operations that are now abandoned because they are not effective. Only 5% of the patients in the SOS had gastric bypass; 95% had vertical gastroplasty. The gastric bypass weight loss was 25% of excess body weight (EBW) and vertical-banded gastroplasty patients had 13-16% EBW loss. He said the weight loss that was reported by the SOS does not come close by about half of what the weight loss was in gastric bypass. He said there are additional benefits to rearranging the gut specific to type 2 diabetes that need to be taken into account; the complexities of these studies are great but the SOS study could not be relied on for

meaningful outcome data because the methods that were used are not pertinent to today's surgical techniques and procedures.

Dr. Wolfe said the Christou is the second-best paper in the literature for trying to match cohort control. The Flum study from Washington made no attempt whatsoever to exclude cancer and they agreed that there was no definitive data on which to base decisions so they would have to do the best they could with what was available. Dr. Weaver said the discussion had been very helpful coming from two different points of view. She thought it would be important to share really detailed minutes from this discussion with the subcommittee. She said that the people who testified at the subcommittee meetings were probably more in favor of surgery. She felt that Dr. Lester's was a very balanced look at the issues and her work with diabetics is acknowledged. She said the fact that diabetes has been shown to improve with gastric bypass even before the patient loses weight emphasizes that there is a real effect on diabetes as far as a rearrangement of the gut and that there is more going on than just the weight loss. The data for the other effects on hypertension, hyperlipidemia, and sleep apnea obviously could be affected by patient selection. The sub-committee appreciates the people who did come testify before the HRC.

Dr. Weaver wanted to invite any of the Commissioners who want to know more about this to come to the next subcommittee meeting on September 26th. Dr. MacKay stated that they need to be very careful of what they say and how they say it.

Dr. Saha said Bariatric surgery was one of the most promising options for the nation's number one health problem. He wants to look at evidence and then let the group decide. Dr. Weaver mentioned that when this was done before she was not with the HRC and it might be better to have the MedTAP develop the scientific report on the first 3 Key Questions, and have the full HRC reach a conclusion as far as the cost-effectiveness and value of the report.

7. Attorney General Grant – Kathy Weaver, MD

Dr. Weaver noted that the packet contained a one-page summary of our AG Grant and that in the future the AG grant would like to invite a commissioner from the HRC to be on the Technical Advisory Committee.

The meeting was adjourned at 4:40 p.m.

Documents:

1. Minutes 7-7-06
2. Minutes 9-8-06
3. Thiazolidinediones – Draft Report
4. Proton Pump Inhibitors Update #4
5. Opioids Update #4
6. Key Questions – Interferons and Beta2-Agonists
7. Rosters – Obesity, Beta2-Agonists, Hepatitis C
8. Bariatric Surgery
9. Bariatric Surgery Benefits
10. Improving Prescribers Practices

**MINUTES
HEALTH RESOURCES COMMISSION**

October 20, 2006

Members Present: James MacKay, MD, Chair; Dan Kennedy, RPh, Vice Chair; Judith Wilson; Bill Origer, MD; Lynn Marie Crider, MD; Dean Haxby, PharmD; Tony Melaragno, MD; John Saultz, MD

Members Absent: Manny Berman, Ree Sailors, MSW; Justin Leonard, JD; Kate Merrill, MD

Staff Present: Kathleen Weaver, MD, HRC Director; Karen Eaton, HRC Assistant

Also Attending: Wally Shaffer, MD; Ruth Medak, MD; Barbara Porter

1. Call to Order - James MacKay, MD

Dr. James MacKay called the Health Resources Commission (HRC) meeting to order at 1:30 p.m. in room 218 of the Clackamas Community College Wilsonville Training Center, 29353 Town Center Loop East, Wilsonville, Oregon.

2. Approval of Minutes – James MacKay, MD

The HRC minutes of 9-8-2006 were unanimously approved.

3. DMAP and PDL Update – Wally Shaffer, MD, Medical Director of DMAP

(020) Dr. Shaffer reported that there had been no changes in the PDL or other major changes at DMAP. He reported there were benefit reductions that will take place February 1, 2007; one involves drugs for the Oregon Health Plan (OHP).

4. Drug Class Program – Alzheimers (ALZ) – Dan Kennedy, RPh

(113) Dr. Weaver mentioned that the Standing Update Committee met on October 17. There were additions to Key Questions 1, 2 and 5. Razadyne is a new name for Galantamine (top of Page 5) but it is the same drug. There was discussion about separating out mild Alzheimers versus moderate-to-severe Alzheimers; this may be reflected in the key questions next time. Essentially this report is unchanged and it may be a year or two before it is updated.

Public testimony was solicited; there was no public comment.

The report was unanimously approved.

Statins – Dan Kennedy, RPh

(187) Mr. Kennedy mentioned that Key Question 2 had been changed. There were no new findings. The report was not approved.

(268)

5. MedTAP Program – Kathy Weaver, MD

6. DERP Governance Report – Kathy Weaver, MD

7. Attorney General Grant – Barbara Porter

Dr. Weaver introduced Barbara Porter who summarized the Attorney General Grant which she is serving as program director.

8. HRC Schedule 2007 – Kathy Weaver, MD

9. Next Meeting/Adjourn – James MacKay, MD

The next HRC meeting will be January 19th, 2007.

The meeting was adjourned at 4:30 p.m.

Documents:

1. Minutes of 9/8/06 meeting
2. Alzheimers Drugs
3. Statins
4. Bariatric Surgery – Draft Report
5. DERP Governance Report
6. HRC Schedule 2007