

# Mental Health Drug Workgroup

## 4/01/05

### 2:00 – 4:00

## Meeting Minutes

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Meeting Started at 2:00

### To Dos and Agreements

#### Agreements:

1. Workgroup members will send assignments for EBM reviews to MAA prior to the discussion for distribution to members.
2. The workgroup agreed that no “clinical only” meeting is needed. MAA will meet with DSHS agencies every other week to review data and discuss internal processes. Decisions will be made in the full workgroup meetings.
3. **Members need to review the scheduled meeting dates distributed by Ms. Harambasic.** There will be a meeting on April 29<sup>th</sup> from 2-4.
4. The workgroup will request help in literature searching through MAA. “Dr. Barnhart at Harborview will assist us in literature pulls and reviews. Please submit reviews through Ms. Jonell Blatt”
5. Dr. Avery reviewed the use of antiepileptic medications for in agitated dementia. The work group agreed that anti-epileptics have “C” level evidence. Dr. Avery will work on a “rare” exception when other “FDA labeled” medications fail for dementia with agitation.
6. MAA stated that for the anti-epileptics, given the history of abuse/misuse, PA tools will be used to get control of “off label” use. However, once provider’s demonstrate EBM use of medications, MAA may switch to EPA or covered while monitoring the utilization.
7. Literature reviews from PubMed are adequate and can include both US and international studies.
8. That communication and education should start with efforts to get providers to use diagnostic codes on the script to improve patient safety and administrative simplification

#### Completed To dos:

1. The UW and Dr. Sullivan will be available to review and rank the statistical validity of our reviews.
2. The term observation study is unclear. From Dr. Santa: **Observational Studies** are studies in which participant or physician preference determines whether a participant receives treatment or control. Observational studies have variables that are observed rather than manipulated. See attached email for further details. MAA will use more precise terms for EBM such as randomized, cohort, prospective, retrospective, controlled, case series, case studies, quasi-experimental, and blinded to more accurately reflect a study design.
3. Dr. Martin will be available for the up coming P&T meetings (Sept and Oct 2005) with a contract to represent the Washington State Psychiatric Association.
4. The sequence of the DUR and P&T will continue to have the DUR follow the P&T meetings. The agencies will have utilization numbers available for the P&T upon request. DUR meetings will attempt to review drug classes in the months before a P&T PDL drug class decision.
5. The MAA spoke the WSPA and Mr. Shafer is reading the minutes but does not have time to attend. There is a great deal of activity on Part D in the pharmacy community at this time. MAA will review the mental health workgroup decisions/minutes at the quarterly WSPA meetings.

6. MAA is developing Part D communications for Medicaid clients. Interested parties should call David Hanig at MAA (360 725 1322).
7. The corrected assignment are as follows:
  - a. The groups reviewed the diagnosis and chose the following for an EBM review of “off label” use:
    - i. Use of Topimax in metabolic syndrome (Dr. Martin)
    - ii. Indications for the use of Neurontin or gabapentin in ETOH and Substance Abuse (Dr. Resse)
    - iii. Use of Neurontin or gabapentin medications for sleep and headaches. (To be discussed at next meeting) (Dr. Jackson and Tomisser)
    - iv. Use of Neurontin or gabapentin medications in anxiety (Dr. Farmer)
    - v. Use of antiepileptic medications as adjunctive therapy in mood stabilization (Dr. McGamery)
    - vi. Use of antiepileptic medications for in agitated dementia (Dr. Avery)

### **New To Dos**

1. MAA will look into other sources of literature reviews, as the drug companies may not be able to supply “off label” literature. Dr. Sullivan from UW has agreed to review complex evidence designs and statistical analysis.
2. The Refill definitions include a proposal to look back 180 days to align with the typical 90 day scripts. Agencies will look at the last script in a drug class to determine refill. A DOC meeting will look into defining a refill process across DOC and MAA.
3. Drs Thompson and Farmer will continue discussions on linking RSN and MAA data. MAA will look into linking at the Mental Health agency level
4. MAA will send to the workgroup the Missouri experience for review prior to our Washington State questionnaire discussions on SSRI and Second generation. Workgroup members are encouraged to read the findings before the next meeting.
5. MAA will send provider letters to the Mental Health Workgroup prior to communication/education efforts. ”Should the group wish to add their names to the communication please send your approval”
6. The workgroup will define a broad communication/education list to inform stakeholders. Members commented that there should be targeted communications and face-to-face discussion with outlier providers.
7. The workgroup will continue to look into methods to connect Diagnosis and Prescriptions (e.g. educating providers to include an ICD9 or DSM4 code on the script)
8. The workgroup will complete the anti-epileptics “off label” EBM reviews at the next meeting April 15, 2005
9. MAA’s PA staff will begin asking pharmacies to record the diagnosis and tracking the codes into the POS system
10. Partners in Crisis to develop a list of jails and key contacts for education/communication efforts within two weeks
11. Dr. Avery will work on a “rare” exception when other “FDA labeled” medications fail.

## **Old Business**

### **Review of Minutes**

The group reviewed the minutes. There needs to be a correction to the March 4<sup>th</sup> minutes in that SB6088 does not set a timeline for PDL implementation. Further analysis shows that the agencies have had delays in implementation due to programmatic issues and stakeholder requests. These delays have reduced the projected savings from the SB6088 fiscal notes. MAA

established timelines in the SB6088 fiscal notes that were reviewed by leg staff, governor's office, and OFM. Minutes from the March 18<sup>th</sup> meeting will change trails to trials.

**MAA reviewed the work to date and discussed completed work (see completed to dos).**

### **Can we have a clinician only meeting?**

The Workgroup discussed the proposal from Western State for a clinical only meeting. MAA is currently meeting with DSHS agencies to review internal policies and MAA mental health data. Western State believes this is an adequate review of clinical data internal to MAA. One drug company asked whether outside material is discussed and MAA answered no. The workgroup agreed that decisions would occur in the mental health workgroup. Just a reminder that our edits need to be agreed to and in place by June 05.

### **How are the "Off label" EBM progressing?**

Western state is having difficulties in finding articles for Neurotin and sleep. One member is looking at older reports for anti-epileptics as adjunctive therapy in mood disorders. Next meeting will do the analysis of adjunctive therapy for mood stabilization. Some drug companies commented that they could only pull articles for their drugs. One drug company commented that they could not pull "off label" literature. MAA will inquire as to whether the UW can assist with literature reviews. The committee reviewed the March 18<sup>th</sup> notes and MAA reminded that the group should consider:

- Demonstration of good evidence from more than one source,
- Rationales for good clinical use for PA/EPA/Covered criteria,
- Demonstrations of "no equally effective lesser cost" alternative
- Best practices and clinical rationale of tried and failed
- Processes to ensure clients coming off medication prescribed for "off label" indications are titrated off to ensure no side effects.

## **New Business**

### **Use of gabapentin medications for in agitated dementia** by Dr. Avery

Dr. Avery did an excellent brief review of "off label" for agitated dementia. The Medline search was from 2000 to present. There were seven papers with an N=73. There were five positive results and two no effect. 50 of 73 patients improved. Tolerability was good with little dropout. Effects appear to wear off after time; however, it is unclear if this due to lesser drug effectiveness or disease progression. In general, this is a "B" to "C" rating and other medications should be tried before Gabapentin. The workgroup discussed that lack of good clear evidence and the availability of lesser cost alternatives for this indication. Dr. Avery commented that in "rare cases" all other alternatives may fail and Gabapentin might have a role as a last resort. Dr. Avery will develop a "step therapy" that includes lesser cost alternatives and a process for "rare" exceptions.

### **Anti-epileptics – Education and Communication**

MAA will provide letters used by Dr. Chiles in TX and CA for templates in education/communication. The workgroup asked to review the letters prior to MAA sending.

Some commented that they have knowledge of some practice variances in the community and suggested that MAA contact those providers. Names were shared in confidence with MAA. The workgroup wished to have a broad distribution list for education and communication to include:

- ❑ Partners in Crisis to develop a list of jail commanders and consultants
- ❑ Mental health discharge coordinators
- ❑ Medicaid health plans (Molina and CHPW)
- ❑ Public and private mental health hospitals, providers (MD, ARNP, PA), pharmacies, associations (WSPA, WSMA, WAIM, WAFP), Compass health
- ❑ Targeted communication to outliers

MAA commented that the current education/communication program can and will target the top prescribing providers either in face-to-face academic detailing or letters. MAA commented that with good PA/EPA criteria from the workgroup there could minimize client disruption.

### **How do we improve the relationship of diagnosis to prescriptions?**

There was much discussion related to PA activity at the point of service and determining the clinical condition. The workgroup agreed that a diagnosis on the script is a good start and would add to patient safety efforts. Some worried that a written diagnosis might have a stigma attached. All agreed that using ICD9 and DSM4 codes could be an alternative. MAA suggested that it could track the efficiency of diagnostic codes from Seattle RSN to the MAA database. MAA reminded the workgroup that the pharmacy system only can put diagnosis in on an actual claim that the pharmacy has inputted for MAA consideration. MAA will discuss with Compass Health how a pilot codes moving from scripts to the MAA database. MAA will begin asking the pharmacies about collecting diagnosis with PA calls. Some asked both how MAA does PA on non-enrolled client requests. MAA stated that if they are not enrolled we cannot process claim. Some asked about a holding system for requests. MAA may have some system for “holding” requests with the new MMIS system in 7/07 but processes to ensure refills and timeliness are good starts for the workgroup.

### **What about Duplicate SSRI use?**

Western state commented that the claims data is showing some patterns of poor choices of combinations both for SSRI and Second Generation combinations. MAA will share the data at the next meeting. Early returns of the questionnaire are similar to the Missouri experience. The group should review the Missouri outcomes to compare to Washington. Western state noted that dosing, often low doses seem frequent in combinations. The workgroup heard that old DUR activity had agreed on stops for prescribing 2x FDA dosing. The group thought an edit for 2x doses a reasonable safety edit and will review with the questionnaire reports.

**From:** John Santa [mailto:santaj@ohsu.edu]  
**Sent:** Monday, April 04, 2005 11:26 AM  
**To:** CHILDSA@dshs.wa.gov  
**Cc:** ThompJ@dshs.wa.gov  
**Subject:** Re: OHSU definition of observational studies

Siri/Jeff,

**Observational Studies** (from our Toolkit): Studies in which participant or physician preference determines whether a participant receives treatment or control. A study in which variable are observed rather than manipulated.

Let me expand with a more functional definition. Observational studies "observe" the effects of an intervention. As a result a variety of biases are in play since the who, what, when, where and how of observation introduces bias. There a number of observational designs---case/control, cohort, cross sectional analysis etc. Each has its pros and cons. Cohort studies are usually thought of as the best of the observational designs since they are prospective---you follow people forward rather than relying entirely on retrospective information. Cross sectional studies are usually thought of as least reliable since they have no controls however they can be persuasive if they cover large populations in a comprehensive way----the Mayo Clinic for example has a registry of all the patients they have seen in Olmstead County, and Kaiser has a 5% sample of all of their patients for virtually all of their care.

Observational studies are useful for identifying a potential problem or a potential solution. Their limitations however are such that it is rare that one would want to make large population decisions based on them unless they are also done on a large population. Observational studies major advantage is that they can be done quickly and cheaply (though if one really does them well on a large population they can be quite expensive). I think most decision makers feel that an important conclusion from an observational trial that affects a large population needs to be confirmed by a randomized controlled trial to confirm the conclusion.

RCTs manipulate the intervention in terms of time, place, population to reduce bias---this may reduce the generalizability (external validity) of the findings but improves the internal validity---what you know to be true is true for a smaller population but you are more certain it is true.

Ideally observational trials and RCTs agree---sometimes they don't---estrogens, anti-arrythmics etc. In those cases, the most likely explanation is the observational trials had a bias that was not appreciated or there are subpopulations with different results that was not appreciated. Since observational trials are subject to so many biases you cannot be certain whether the bias or subpopulation led to the observational trial result.

Hope this helps

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>>> "Childs, Siri" <CHILDSA@dshs.wa.gov> 04/03/05 8:20 PM >>>

John, will you please give us your definition of what an observational study is. Also, please explain what you mean by a registry.

This is the workgroup's request, but my request for more information about the registry.

Siri