DADS/DSHS EXECUTIVE FORMULARY COMMITTEE MINUTES
October 29, 2004

The Executive Formulary Committee convened on Friday, October 29, 2004 in Room 107D - CO Building 1. The meeting was called to order by Dr. Morgan, Chair at 9:36 a.m.

Janet Adams, MSN, RN, CNS	√	Bernardo C. Tarin-Godoy, M.D.	√
Rosha Chadwick, R.Ph.	√	Robert L. Ward, D.O.	√
Erlinda Devera, M.D.	√	Robert Kifowit	Absent
Emilio Dominguez, M.D.	Absent	Kenny Dudley	Absent
Jeanna Heidel, Pharm.D.	Absent	Mike Maples	Absent
Robin Mallett, M.D.	Absent	Pat Martin	Absent
Jack McCoy, M.D.	√	Earl Matthew, M.D.	Absent
Victoria B. Morgan, M.D.	√	Camille Hemlock, M.D.	√
Ann L. Richards, Pharm.D.	√	Nina Muse, M.D.	Absent
Dan Still, Pharm.D.	√	Steven P. Shon, M.D.	√
Cindy Sturdivant, B.S.N., R.N.	√	Vacant Center Position	

Guest Present: Sharon Tramonte, Pharm.D., San Antonio State School, Barbara Otting, RN, Lynn Crismon, Pharm.D., Denise Scofield, Pharmacy Student

Roll Call, Introductions and Announcements

It was announced that Dr. J R. Van Norman, Medical Director of Austin Travis County MHMR Center has submitted his resignation to the Committee effective August 11th. Dr. Shon will be meeting with the Center MHMR Medical Directors in the afternoon and will request volunteers to fill this slot.

The web site to access the Drug Formulary and other mental health program web pages is:

http://www.dshs.state.tx.us/mhprograms/

Approval of Minutes of April 16, 2004

On a motion of Dr. Ward, seconded by Dr. Tarin-Godoy, the minutes of the April 16th meeting were approved as previously distributed. The Committee did not meet in July due to time constraints with work on the new pharmacy system WORx™ taking a priority and a limited agenda.

Adverse Drug Reaction Reports

The Executive Formulary Committee received many adverse drug reaction reports from several facilities. In the first report, a 9-year-old patient developed leukopenia with an ANC of 1,000/mm^3 after receiving amoxicillin/potassium clavulanate (Augmentin®). The patient had a normal WBC upon admission. After the Augmentin® was discontinued, the WBC and ANC improved.

A 45 year-old female patient with a history of being HIV positive, hepatitis C and asthma, had a history of decreasing WBC with increasing doses of olanzapine (Zyprexa®). The patient developed leukopenia/agranulocytosis when the dose of olanzapine was increased. The olanzapine was discontinued and the WBC/ANC rebounded to normal.

A 52 year-old female patient was rapidly titrated up to 200 mg/day of clozapine (Clozaril®) in one week. The patient developed leukopenia and neutropenia. The labs returned to baseline four weeks after discontinuing the clozapine.

A 61 year-old male patient on oral haloperidol (Haldol®) and haloperidol decanoate developed signs and symptoms of neuroleptic malignant syndrome. The oral haloperidol was discontinued and the patient was treated with bromocriptine (Parlodel®) and recovered.

A 36 year-old male patient had been stable as an outpatient for many years on haloperidol (Haldol®) decanoate 100 mg every 4 weeks. The patient was changed to aripiprazole (Abilify®) and decompensated. The patient received several emergency medications [risperidone (Risperdal®) M-tabs 2 mg, lorazepam (Ativan®) 2 mg PO, ziprasidone (Geodon®) 20 mg IM, lorazepam 2 mg IM] on the first day and the several emergency medications on the second day [risperidone (Risperdal®) M-tabs 2 mg, lorazepam (Ativan®) 2 mg PO, haloperidol (Haldol®) 10mg IM]. Patient developed signs and symptoms of neuroleptic malignant syndrome. Patient was treated with IV fluids, bromocriptine, dantrolene (Dantrium®), sodium bicarbonate and furosemide (Lasix®).

A 50 year-old male patient treated with valproic acid (Depakene®) and olanzapine (Zyprexa®) developed leukopenia after the addition of mirtazapine (Remeron®). The mirtazapine was discontinued. No follow-up labs were obtained as the patient was discharged from the hospital.

A 13 year-old female patient treated with divalproex (Depakote®), olanzapine (Zyprexa®) and sertraline (Zoloft®) had their divalproex dose increased and three days later their ANC was 1,300/mm^3. The patient previously had ANC levels that were within normal limits. The divalproex was discontinued and the ANC rebounded.

One facility submitted four adverse drug reaction reports on patients developing hypoalbuminemia in patients receiving divalproex (Depakote® ER –three cases and Depakote® - one case). In two cases, the divalproex was discontinued and the albumin rebounded. In another case, the divalproex was discontinued and follow-up labs were not obtained. In the other case, the divalproex was decreased and the albumin increased.

A 53 year-old female patient on oxcarbazepine (Trileptal®) developed hyponatremia two weeks after initiation of therapy. The hyponatremia improved when the drug was discontinued.

Proposed changes to DSHS Standard Formulary Memo

Dr. Shon presented the memo from Dr. Bell (Deputy Executive Commissioner for Health Services) regarding proposed changes to the Drug Formulary. The purpose of the memo was to seek guidance and present recommendations regarding the use of cost containment strategies for state hospitals and Community Mental Health Centers (CMHC) using the Formulary. Dr. Shon made the clarification that this issue also applies to the MR facilities. Dr. Bell made the following recommendations:

1. The Executive Formulary Committee should research the potential savings to be realized by including generic pharmaceuticals in the Formulary and encouraging their use when clinically appropriate.
2. DSHS, through their Formulary Committee, should revise the formulary for medications utilized at the state hospitals and by the CMHCs using the Pharmacy and Therapeutics Committee and the PDL (preferred drug list) as a guideline for the revisions. The goal should be to curtail the use of more expensive medications when a less expensive alternative is clinically appropriate in the management of the patient. The Committee is encouraged to research and utilize strategies that have been implemented by health maintenance organizations to control the expenditures for psychotropic and other medications.
3. DSHS should research opportunities for savings through implementation of control systems, such as automated clinical pathways, to ensure the appropriate and efficient use of pharmaceuticals within the mental health system of services. DSHS should seek the expertise of a contractor to evaluate what might be utilized with the current system of monitoring drug utilization that is in place or whether a new system needs to be created.

In reviewing these recommendations, the Committee noted that the use of generics has already been implemented. In July 2000, Dr. Shon distributed a memo regarding the consideration of medication acquisition cost in medication selection within a TIMA stage. In addition, this memo addressed the use of generic clozapine. A follow up clarification memo was distributed in August 2000. The Drug Formulary lists drugs by generic names. For years, facilities have been purchasing generic drugs when possible.

Dr. Shon noted that HB 2292 developed the PDL (preferred drug list) and authorized the HHSC to expand the PDL to the general revenue funds. In discussing the PDL with Dr. Bell, Dr. Shon noted that the PDL supposedly looks at effectiveness and safety. In light of this, it was suggested that the development of monitoring parameters to follow the safety of the atypical antipsychotics would be an appropriate substitute for implementing a PDL.

The third issue addressed the implementation or clinical pathways and contracting with a vendor to monitor drug utilization. The mental health facilities have implemented TIMA, which is a clinical pathway. Dr. Shon noted that currently there is a working relationship with The University of Texas College of Pharmacy and they would be an excellent resource for drug utilization.

On a motion of Dr. Ward, seconded by Dr. McCoy, it was recommended that three work groups be formed to address these issues. The following groups will be appointed:

1. To address the generic issue a work group consisting of Dr. Tramonte, Dr. Hemlock and Dr. Richards will be appointed. Dr. Tramonte will serve as the leader. This group will research the current expenditures for the use of generic drugs versus name brand drugs by therapeutic category. In addition, the group will investigate the possibility of updating the memos previously distributed by Dr. Shon.
2. The second group will address the development of guidelines to address safety issues with the use of atypical antipsychotics. This group will use the current audit criteria along with the recent published articles on monitoring atypical antipsychotics. This group will consist of Dr. Tarin-Godoy, Dr. Ward, Dr. Still and Dr. Richards. Dr. Ward will take the lead with this group.
3. The third group will address the drug utilization issues and will work with The University of Texas College of Pharmacy. The members of this group include Dr. Crismon, Dr. Richards, Dr. Hemlock, Dr. Tramonte and Dr. McCoy. Dr. Richards will facilitate this group.

The goal is to have all the work completed by January 14th so that it can be discussed at the next Committee meeting.

Atypical Antipsychotic Audit Criteria

The update of the atypical antipsychotic will be incorporated into the workgroup previously

established to update the guidelines to monitor safety issues with the use of these agents.

Nutritional Supplements, Herbal Products, Medical Food

Previously, the Executive Formulary Committee has opted to not include herbal products and nutritional supplements to the Drug Formulary. Currently, there is another category that is recently receiving attention and that is medical food. By definition of the FDA, a medical food is prescribed by a physician when a patient has special nutrient needs in order to manage a disease or health condition, and the patient is under the physician's ongoing care. The label must clearly state that the product is intended to be used to manage a specific medical disorder or condition. An example of a medical food is a food for use by persons with phenylketonuria. Medical foods are not meant to be used by the general public and may not be available in stores or supermarkets. Currently, the FDA does not regulate medical foods. The Committee did not make any recommendations to add these types of agents to the Drug Formulary.

New Drug Applications

(Please refer to Attachment A for the monograph and application that was considered when determining action by the committee.)

duloxetine (Cymbalta®) - discussed by Dr. Still

Duloxetine is a selective serotonin and norepinephrine reuptake inhibitor. It is indicated for the treatment of major depressive disorder and the management of diabetic peripheral neuropathic pain. For major depressive disorder, duloxetine should be administered at a total dose of 40 mg/day (given as 20 mg BID) to 60 mg/day (given either once a day or as 30 mg BID) without regard to meals. As with all antidepressants, patients need to be monitored for clinical worsening and suicide risk.

Following discussion, on motion of Dr. Tarin-Godoy, seconded by Ms. Chadwick, the request to add duloxetine (Cymbalta®) to the formulary as an antidepressant was approved. The Formulary CheckList was completed.

Tarvil® - discussed by Dr. Still

Tarvil® is a medical food that is indicated for the dietary management of tardive dyskinesia in males. Tarvil® has demonstrated some promise as a treatment option in two small studies of short duration, conducted and published by the same investigators. Since this is a medical food, the Committee did not consider the addition of this product to the Drug Formulary. Facilities can purchase Tarvil® for patients that have a clinical need. This product can be purchased through mechanisms already established to obtain supplies.

Quarterly Non-Formulary Drug Justification Report

The non-formulary drug report for the last two quarters was reviewed. With the new agency, the facilities should be divided into two groups. One group should reflect the hospitals and include Austin State Hospital, Big Spring State Hospital, Kerrville State Hospital, Rusk State Hospital, San Antonio State Hospital, North Texas State Hospital, Waco Center for the Youth, Rio Grande State Center and El Paso Psychiatric Center. The other group should include Abilene State School, Austin State School, Brenham State School, Corpus Christi State School, Denton State School, Lubbock State School, Lufkin State School, Mexia State School, Richmond State School, San Angelo State School, San Antonio State School, and El Paso State Center. The Committee noted that lovastatin (Mevacor®) was requested numerous times. The Committee will review the addition of lovastatin to the Formulary in the future.

Top Ten Non-Formulary Drug Justification Review for FY04

Dr. Tramonte will present this review at the next meeting.

Restrictive Formulary/PDL Issues

The restrictive Formulary/PDL issues will be covered in the work group led by Dr. Ward under the "Proposed changes to DSHS Standard Formulary Memo" section of this meeting.

Consolidation of Prescribing Psychotropic Rules - MHMR

The Prescribing of Psychoactive Medication Chapter 415, Subchapter A was published with an effective date of August 31, 2004. A copy was distributed to the Committee.

Thioridazine (Mellaril®) Purchases

Dr. Tramonte reviewed the thioridazine purchases for FY04. During this year, sixteen of the facilities bought $14,577.45 worth of thioridazine.

Polypharmacy with Atypical Antipsychotics

Previously, it was recommended that a report be obtained from BHIS to determine the number of patients on more than one atypical antipsychotic for both the MH and MR side. This has not been completed. The Committee recommended that facilities be surveyed to determine what individual facilities are doing to monitor for polypharmacy.

Memantine (Namenda®) Literature and Medication Error Review

When memantine was added to the formulary, it was on the market for less than a year. As a result, the Committee reviews the literature six months after it has been added to the Formulary for adverse drug reactions and medication errors. Dr. Tramonte did not find any reported issue in the literature.

Formulary Review Schedule

The revised Formulary Review Schedule for the next three years was reviewed and approved.

Formulary Table Reviews

Dr. Still reviewed the psychotropic tables listed in the Drug Formulary. For the antipsychotics, Dr. Still recommended that the haloperidol (Haldol®) dose be changed from 100 mg/day to 40 mg/day. Even though the package insert allows a dose of 100 mg/day, this dose is rarely used in current practice. On the motion by Dr. Still, seconded by Dr. Tarin-Godoy, the recommendation to change the haloperidol dose to 40 mg/day was approved. For the mood stabilizers, Dr. Still recommended that the maximum dose for topiramate (Topamax®) be 1600 mg/day instead of "not determined." On a motion of Dr. Still, seconded by Dr. Ward, the recommendation to change the maximum dose of topiramate to 1600 mg/day was approved. Since nefazodone (Serzone®) was deleted from the Formulary, it was deleted from the antidepressant table.

Drug Formulary 2005

Dr. Tramonte presented the 2005 Drug Formulary book. The book will include all the changes made as a result of this meeting. Dr. Tramonte noted that tall-man characters were used for those drug names that it has been recommended. On a motion of Dr. Ward, seconded by Dr. Still, the recommendation to approve the Drug Formulary 2005 was approved.

Proposed Drug Deletion List - Psychotropic Agents

The Committee did not receive any comments from the field about the proposed deletions for the psychotropic agents. On a motion of Dr. Ward, seconded by Dr. Devera, the motion to delete the psychotropic agents was approved.

Drug Formulary Sectional Review- **Antidiabetic Agents**
Antidotes/Deterrents/Poison Control Agents
Antihistamine Agents
Antineoplastic Agents
Blood Modifying Agents

Dr. Tramonte provided the review of the antidiabetic agents with her recommendation. Attachment B. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment B). Dr. Tramonte recommended the addition of insulin aspart (NovoLog®) to the Formulary.

> Insulin aspart is a rapid-acting human insulin analog. It is homologous with regular human insulin with the exception of a single substitution of proline at position B28 with aspartic acid. Insulin aspart has an onset in 15 minutes, peaks in 40 to 50 minutes and has a duration of 3 to 5 hours. It is used to cover meals for the diabetic patient. Attachment C.

On a motion by Ms. Chadwick, seconded by Dr. Tarin-Godoy, it was recommended to add insulin aspart (NovoLog®) to the Formulary. The Formulary CheckList was completed.

Dr. Tramonte recommended that metformin (Glucophage®) ER 750 mg tablet be added to the Formulary.

Dr. Tramonte recommended the deletion of the following dosage strengths/formulations.

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
Chlorpropamide	Diabinese®	Tablet: 100 mg, 250 mg	None
Glyburide	Micronase®, DiaBeta®	Tablet, micronized: 4.5 mg	Tablet: 1.25 mg, 2.5 mg, 5 mg Tablet, micronized: 1.5 mg, 3 mg, 6 mg
Tolbutamide	Orinase®	Injection, diagnostic: 1 g	Tablet: 250mg, 500 mg

On a motion of Ms. Chadwick, seconded by Dr. Tarin-Godoy, the motion to delete these products was approved. Feedback will be obtained from the field.

Dr. Tramonte provided the review of the antidotes/deterrents/poison control agents. Attachment D. The comparative cost index and dosage availability of these agents was reviewed (included in
Attachment D). Dr. Tramonte recommended that oral glucose be added to this section. On the motion of Dr. Ward, seconded by Dr. Still the recommendation to add oral glucose to this section was approved.

Dr. Tramonte provided the review of the antihistamine agents with her recommendation. Attachment E. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment E). Dr. Tramonte recommended the deletion of the following:

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
Fexofenadine	Allegra®	Capsule: 60 mg	Tablet: 30 mg, 60 mg, 180 mg

On a motion of Dr. Still, seconded by Dr. Tarin-Godoy, the motion to delete this product was approved. Feedback will be obtained from the field.

Dr. Tramonte provided the review of the antineoplastic agents. Attachment F. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment F). Dr. Tramonte made no recommendations for this section. The use of the aromatase inhibitors will be reviewed at a future meeting.

Dr. Tramonte provided the review of the blood modifying agents with her recommendation. Attachment G. The comparative cost index and dosage availability of these agents was reviewed (included in Attachment G). Dr. Tramonte recommended the addition of dipyridamole/aspirin (Aggrenox®) to the Formulary.

> Aggrenox® is a combination product of the extended release dipyridamole 200 mg and immediate release aspirin 25 mg. The antithrombotic action of Aggrenox® is the result of the additive antiplatelet effects of dipyridamole and aspirin. Aspirin irreversibly inhibits platelet cyclo-oxygenase further inhibiting thromboxane A2, a potent inducer of platelet aggregation and vasoconstriction. Dipyridamole inhibits platelet aggregation by several mechanisms including inhibition of the uptake of adenosine into platelets, in vitro and in vivo, in a dose-dependent manner. This inhibition results in stimulating platelet adenylate cyclase and increasing platelet cyclic-3', 5'-adenosine monophosphate (cAMP) levels. Attachment H.

There was no motion to add dipyridamole/aspirin (Aggrenox®) to the Formulary.

Dr. Tramonte recommended that addition of enoxaparin (Lovenox®) 120 mg injection to the Formulary. On a motion by Ms. Chadwick, seconded by Dr. Tarin-Godoy, it was recommended to add enoxaparin (Lovenox®) 120 mg injection to the Formulary.

Dr. Tramonte recommended the deletion of the following:

Generic Name	Brand Name	Dosage forms to be deleted	Dosage forms still available
Iron dextran complex	Imferon®	Injection: 50 mg/ml	none

On a motion of Ms. Chadwick, seconded by Dr. Tarin-Godoy, the motion to delete this product was approved. Feedback will be obtained from the field.

Sectional Review for January 2005

The analgesic, antiemetic/antivertigo, sedative/hypnotic and anticonvulsant agents will be reviewed at the next meeting.

Other Issues

Dr. Tramonte noted that the FDA has requested that manufacturers of all antidepressant drugs include in their labeling a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with these agents, and additional information about the results of pediatric studies.

Eli Lilly Canada has issued a "Dear Healthcare Professional" letter regarding the use of olanzapine (Zyprexa®) IM. The package insert in Canada has been updated to include information about the co-administration of olanzapine IM with other drugs (administered parenterally or orally), such as haloperidol, lorazepam, midazolam, and chlorpromazine. The combination can induce hypotension, bradycardia, respiratory or CNS depression. The update was based on the review of post-marketing surveillance adverse event reports where serious adverse events including deaths, have been reported. These serious events have been associated with the improper administration of olanzapine IM, most of which were either in combination with oral olanzapine in a total daily dose greater than the maximum recommended by the product monograph, or in combination with other drugs listed above. The Committee recommended that this information be disseminated to the field.

Dr. Tramonte reported that a generic citalopram (Celexa®) is about to be launched.

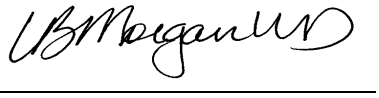
Dr. Tramonte noted that State Schools could have a problem with labeling issues with certain products during the ICF-MR survey. For example, ferrous sulfate comes in multiple dosage strengths (300 mg, 324 mg, 325 mg). Having one dosage strength and using a label for another dosage strength can lead to deficiencies on the ICF-MR surveys. As a result, some state schools are adopting policies to allow dosage strengths within a range. This might apply to phenobarbital.

Next Meeting Date

The next meeting was scheduled for February 4, 2005.

Adjourn

There being no further business, the meeting was adjourned at 1:58 p.m.

Approved: 

Victoria B. Morgan, M.D., Chairman

Attachments

Attachment A:	New Drug Monographs
Attachment B:	Antidiabetic Agents Class Review & Cost Review and Alphabetical Listing
Attachment C:	Insulin aspart (NovoLog®) Monograph
Attachment D:	Antidotes/Deterrents/Poison Control Agents Class Review & Cost Review and Alphabetical Listing
Attachment E:	Antihistamine Agents Class Review & Cost Review and Alphabetical Listing
Attachment F:	Antineoplastic Agents Class Review & Cost Review and Alphabetical Listing
Attachment G:	Blood Modifying Agents Class Review & Cost Review and Alphabetical Listing
Attachment H:	Dipyridamole/Aspirin (Aggrenox®) Monograph

Minutes Prepared by:
Ann L. Richards, Pharm.D.
Rosha Chadwick