Texas Diabetes Council Standards of Care Development and Update Subcommittee November 6, 2002 Wildflower Conference Room-Austin Airport Hilton Approved Meeting Minutes

The meeting was called to order by Jeffrey A. Jackson, MD, CDE, Chair at about 7:30 pm. Members present Curtis Triplitt, Pharm D; Craig Spellman, MD; Lance Sloan MD; Mohammed M. Bakdash MD (new member from Lubbock).

Most of the discussion time was spent on the Type II Diabetes Mellitus insulin algorithm with considerable progress, especially after Dr. Triplitt's suggested reworking by e-mail earlier in the afternoon. The draft will be re-discussed briefly at the morning meeting on November 7th, 2002, and will probably be ready as an action item for the January 30th, 2003, subcommittee meeting. The draft will be circulated to all committee members requesting their input, comments, critiques, and suggested revisions by early January. The algorithm will then be sent back to Dr. Irl Hirsch as a thought leader in the field for his additional suggestions.

The Type I Diabetes Mellitus insulin algorithm may also be ready by January 30th, 2003, and will include a box summarizing DKA management.

Dr. Spellman volunteered to work with Dr. Varma (and Dr. Riley) on the Glycemic Control Algorithm for Children/Adolescents, which is in development, but still compromised by the lack of FDA approval for oral agents in all age groups. Metformin apparently is approved down to age 8 or 10, and apparently rosiglitazone soon will be approved for use in > age 10, and pioglitazone will soon be approved for age 12 and over.

The anti-platelet therapy white paper was reviewed and is felt to be ready for an action item to the Health Professionals Meeting on November 7th am.

The Lipid Treatment Algorithm was looked at and the recommendation made to correct an inconsistency in the triglyceride column under the sub-categories triglyceride 200-399 mg per deciliter, non-HDL-C less than 130 mg per deciliter, eliminating the box to the left saying "TG less than 200 mg per deciliter" which is inconsistent and also considering a new box under the elevated LDL-C category "if LDL-C remains greater or equal 100 mg per deciliter add bile acid resin binder ³ or Ezetimide" (that being a newly FDA approved agent for cholesterol lowering) and to eliminate "history or no history of ASD," but to go right to a statin therapy if the LDL cholesterol is elevated in line with new evidence from the Heart Protection Study (July 2002).

There was discussion of more aggressive statin management of diabetics given the HPS results, but the decision was made to table that until subgroup analyses from the HPS are published looking specifically at diabetic patients in the study.

TDH/TDC disclaimer suggested by Dr. Sloan was reviewed and felt to be appropriate as an action item at the morning meeting.

Other subcommittee members E. Villagomez, P. Hollander, S. Varma, and B. Walz had notified the chair that they were not going to be able to attend. Barbara Walz is going to be working on the IV Insulin ICU/Perioperative Protocol for the next meeting.

Discussion was reasonably lively and quite productive. There is unanimous agreement that this type of meeting the night before the January 30th, 2003 regular committee meeting would be appropriate, same time and probably same place. We did note that the orlistat presentation by Dr. DeFronzo would be at the Health Professional Committee meeting November 7th am, and that our subcommittee would probably review a possible inclusion of orlistat in the glycemic control algorithm, and perhaps lipid algorithm at the next meeting. An obesity management algorithm is also in development.

Dr. Jackson adjourned the meeting at approximately 11:05 pm.

STANDARDS OF CARE DEVELOPMENT AND UPDATE ADVISORY SUBCOMMITTEE TEXAS DIABETES COUNCIL Moreton Building-TDH November 7, 2002

<u>Attendance:</u> Jeffrey A. Jackson MD CDE, Lance Sloan, MD, Craig Spellman MD, Curtis Triplitt Pharm D (Vice Chair),

TDH Staff: Luby Garza RS RD LD, Pat Black BA

<u>Absent:</u> Priscilla Hollander MD, Surrendra Varma MD, Barbara Walz RN CDE, Evangelina Villagomez RN CDE, Charles Reasner MD, William Riley MD

Dr. Jackson, Chair, called the meeting to order at 8:10 am and introductions were made.

Dr.Jackson opened the meeting by stating the Mission of the Subcommittee.

Mission Statement: To develop standards of care for patients with diabetes mellitus in the State of Texas and to continue to develop new clinical care algorithms and update existing algorithms which are evidence-based and unbiased to be recommended to the Texas Diabetes Council.

There was immediate discussion of this Mission Statement and whether it has changed over time. Dr. Sloan will examine that and make recommendations at the January 29th-30th meetings.

Dr. Jackson summarized the work of the committee the night before which met 7:30 pm to after 11 pm at the Austin Hilton. Three apparent action items appear appropriate to discuss and decide on:

1. White paper-antiplatelet agents. Dr. Triplitt who summarized the minor revisions since the last committee meeting presented this. This is the first of the series of white papers, which will provide the groundwork for a macrovascular disease prevention algorithm to be assembled in the future. It was decided not to include a 2000 or 2001 VA Study reporting 66% use of aspirin in diabetic patients. Regarding Plavix, no primary prevention evidence in patients with diabetes has been presented. The CAPRIE Trial constitutes a new reference 5 and the White paper can be updated once the CHARISMA Trial is published regarding primary prevention data. Age 30 was selected for

initiation of aspirin therapy according to ADA recommendations, but it will be reviewed whether this should be tied to certain duration of diabetes.

2. The present white paper was discussed and a motion was made by ______, seconded by _______ to approve the white paper for recommendation to the Health Professionals committee for further approval by TTC. It was approved unanimously. Revisions to the Lipid Algorithm were suggested (see attachment). A minor correction was made in the elevated triglyceride category on the right hand side of the algorithm, and presence or absence of ASD under the elevated LDL-C category was eliminated going straight to statin therapy with the suggestion of adding bile acid resin binder or ezetimibe if LDL-C remains elevated with a third footnote "if TG less than 200 mg per deciliter" was suggested. Suggestion was made to include "TLC" in the second box "abnormal FLP =TLC; control diabetes" "This was discussed and a motion was made by _______, seconded

by ______ to approve the revision. The motion was unanimously approved.

3. At the Health Care Professional Committee meeting in August, concern was raised regarding the need for disclaimer for the TDC/TDH to use at the Website. Dr. Sloan recommended a disclaimer derived from the National Kidney Foundation with the recommendation that this disclaimer used in whatever way and wherever the TDC and TDC legal council would recommend. The disclaimer is worded: "These guidelines are based upon the best information available at the time of publication. They are designed to provide information and to assist decision-making. They are not intended to define a standard of care, and should not be construed as one. Neither should they be interrupted as prescribing an exclusive course of management.

Variations in practice will inevitably and appropriately occur when clinicians take into account the needs of individual patients, available resources, and limitations unique to an institution or type of practice. Every healthcare professional making use of these guidelines is responsible for evaluating the appropriateness of applying them in the setting of any particular clinical situation".

Subsequent discussion was brief and a motion was made by ______, seconded by ______ to approve this disclaimer for recommendations to the Health Professionals subcommittee. It was approved unanimously.

Although Dr. Hollander could not attend the meeting, she did send a draft (see attachment) of a Type II Diabetes Prevention summary. Suggestions were made to specify the particular intervention, ie exercise, diet. It was mentioned whether to include a recent Chinese study, and also whether to include some older studies which were negative studies regarding the use of sulfonylureas-Dr. Triplitt thought that they were the Beford, Whitehall and perhaps one other study ? Strewer 1980, and Camarini from <u>NEJM</u> 20 years ago. There was also discussion about the Malmo Sweden Prevention Study regarding lifestyle. This prevention summary will be possibly ready for approval next meeting.

The Type II and Type I Diabetes Mellitus Insulin Algorithm were briefly discussed and updated drafts will be distributed to members with the possibility of having them as action items next meeting. The legend of abbreviations at the bottom left will be alphabetized, and glycemic control targets will be clearly listed. The intention of defining insulin deficient and less insulin deficient type II diabetes who are combination oral agent failures by level of hemoglobin A1C is intended to emphasize the likely need for multi-dose insulin therapy in the insulin deficient patients to obtain glycemic control versus the possibility of once daily pm or hs insulin, possibly being successful in those with less severe insulin deficiency.

Dr. Alen made an announcement regarding theBi-National Conference on Diabetes Mellitus: Improving Outcomes in his Hispanic Patients scheduled for McAllen, Texas, February 20-22, 2003.

Regarding the insulin algorithm, there was suggestion to bold NPH, Aspart, Lispro and Glargine since these are the generally more highly recommended agents. Reference to continuous subcutaneous insulin infusion in the footnote was suggested to be deleted.

Dr. Mo Bakdash, Endocrinologist in Lubbock, will be a new member of the subcommittee and did attend the prior evening meeting. Dr. Riley has not been able to attend meetings yet, and Dr. Jackson will check with him about whether he does want to be an active member of the subcommittee.

Dr. Spellman will be working with Dr. Varma and Dr. Riley on the Glycemic Control Algorithm for Children/Adolescents. Barbara Walz will be presenting a draft of the IV Insulin Protocol for perioperative and ICU management.

Luby Garza did distribute information on the Statewide Obesity Task Force which will be meeting November 22nd, 2002 to present a plan to the Board of Health and we did decide to work on a comprehensive overweight/obesity treatment algorithm as a future protocol which will be worked on by E. Villagomez and B. Walz and C. Triplitt as well.

Members are reminded to advise the Chair, Dr. Jackson, when they are unable to attend these meetings given our previously decided on policy regarding excused absences, etc.

Decisions regarding inclusion of Orlistat in any of the algorithms will be discussed at the next meeting.

The next Standards of Care Subcommittee Meetings will be January 29th 7-11 pm, probably at the Airport Hilton again for extensive discussion and revisions of the algorithms and decision regarding what action items will be recommended. The Regular Standards of Care Subcommittee meeting will be 8-10 am Thursday, January 30th, 2003.

Dr. Jackson adjourned the meeting at 9:58 am thanking all members and guests for attending, and actively participating in the productive meeting.

Respectively submitted,

Jeffrey A. Jackson, MD-Chair Substituting for Dr. Hollander-Recording Secretary