

Meeting Minutes
Texas Council on Alzheimer's Disease and Related Disorders
Meeting Minutes – February 8, 2018; 11:00 a.m.

Texas Department of State Health Services
1100 W. 49th St., Austin, TX 78756
Tower Building, room T-607 (on the 6th floor)

Council Members Present

Debbie Hanna, Chair
The Honorable Clint Hackney, Vice-Chair
Rita Hortenstine
Valerie J. Krueger
Toni Packard
Laura DeFina, MD
Kathlene E. Camp, PT, DPT
Ronald Devere, MD
Marc Diamond, MD
Terrence Sommers
Vaunette Fay, PhD
Ana Guerrero Gore
Char Hu, PhD

Council Members Absent

Francisco González-Scarano, M.D.

Guests Present

Carleigh Baudoin, Department of State Health Services (DSHS), Health Promotion and Chronic Disease Prevention Section (HPCDPS)
Robin Chapman, Health and Human Services (HHSC), Assistant General Counsel
Ricardo Howard, DSHS, HPCDPS
Carolyn Pittman, DSHS, Stakeholder Relations
Carolyn Bivens, DSHS, Stakeholder Relations
Rachel Jew, DSHS, HPCDPS
Jordan Hill, DSHS, Government Affairs
James Crowson, Attorney General's Office
Munro Cullum, Texas Alzheimer's Research and Care Consortium (TARCC), UT Southwestern
John Hart, UT Southwestern
Bruce Jones, UT Southwestern
Richard Elbein, Alzheimer's Association
Melissa Sanchez, Alzheimer's Association
John Harris, Alzheimer's Association
Delia Jervier, Alzheimer's Association
Cacie Waters, Alzheimer's Association
Meg Barron, Alzheimer's Association
Aaron Gregg, Alzheimer's Association

Program Staff Members Present

Lynda Taylor, DSHS – HPCDPS

1. Welcome/Call to Order/Roll Call/Excuse Absent Members

Debbie Hanna called the meeting to order at 11:17 a.m. Lynda Taylor certified roll, and a quorum was present. Ms. Hanna asked Council members to excuse absent members. Dr. Devere moved that absent members be excused. Ms. Hortenstine seconded the motion. All were in favor, and absent members were excused.

2. Introduction of New Members

Ms. Hanna reported that several new members were present at this first meeting of 2018 and asked Council members to introduce themselves.

3. Approval of Council Minutes from the May 18, 2017 Meeting

Ms. Hanna asked Council members to review the minutes from the May 18, 2017, meeting. Mr. Hackney moved that the minutes be approved. Dr. Devere seconded the motion. All were in favor and the May 18, 2017, meeting minutes were approved.

4. Information on Texas State Plan on Alzheimer's Disease Development

Ms. Hanna provided an overview of the history of the state plan, noting that the plan concept was instigated by the Chronic Disease Department at the Texas Department of State Health Services (DSHS), where the Alzheimer's Disease Program is managed. She reported that over a period of eighteen months, prior to Carleigh or Lynda's involvement in the program, more than 180 volunteers physically came to Austin to participate in four planning meetings. Ms. Hanna noted that there were separate sub-committees, called goal groups, each working on a specific area of the plan. She noted that further, the committees were disaggregated on content and worked through conference calls or, in the case of the Dallas group, there was a concentration physically in that area that met several times in person. Over an eighteen-month period, goals, strategies, objectives, and tasks were outlined, and the state plan came together.

Ms. Hanna reported that the raw document went through the review and approval hierarchy at DSHS, and lastly up to Commissioner Lakey's office, who is now the Vice Chancellor for Health Affairs at UT System. Dr. Lakey approved the state plan, with minor edits, and 1,000 copies were printed and distributed to certain legislative offices, healthcare facilities, and Area Agencies on Aging. The plan was launched at the DSHS, with many distinguished speakers presenting, including Dr. Kenneth Cooper, one of our famous, and most famous older Texans, who presented to the group on healthy living and brain health and living well.

Ms. Hanna noted that over the years, the plan has been a volunteer effort, and remains so today, noting that the plan is not expired; nor is it milk on the shelf in the refrigerator with a "use-by date". Ms. Hanna stated that the plan belongs to the state of Texas - it is the Texas plan.

Ms. Hanna reported that programmatically, the Council is moving forward on the state plan, as noted in the Council's 2016 Biennial Report, and explained that plan work has slowed down somewhat, as we are devising a plan to incorporate the national movement, dementia friendly states, into the Texas plan goals, and because the department has been going through a recodification of their master plan inside the department.

Ms. Hanna clarified that the Partnership is the master group of about 185 individuals (the database is maintained by Lynda) who have volunteered their time over the last five to six years to working on the plan, and reported that Ms. Baudoin, as Lynda's supervisor and the Chronic Disease manager, will be working with the volunteers on a timeline, in an appropriate way, to reconvene the Partnership, and will guide the plan through the volunteer process with the help of not only Council members, but anyone in the room. Ms. Hanna reported that it was a very laborious task to recruit volunteers, develop the plan, get it approved, printed and distributed, and noted that last month she was in a legislative office and a copy of the state plan was sitting on a desk – noting it lives – it's not expired, and it's still on the website for everybody to see. Ms. Hanna expressed her hopes that Council members and guests will be a part of the collaborative planning process when the department rolls out the timeline.

5. Dementia Friendly Communities

a. Information on the national movement

Ms. Hortenstine provided an overview on how the dementia friendly concept was introduced to the Texas Council, noting that in the Council's effort to confront the compelling issue of Alzheimer's disease and the complexity of the aging population, the Council invited Olivia Mastry to speak at a Partnership meeting several years ago. Ms. Mastry is the guiding light and one the individuals who helped develop the movement called "Dementia Friendly America". She is an attorney out of Minneapolis with a Master's degree in public health.

Ms. Hortenstine explained that dementia friendly living is a national, multi-sector, volunteer-driven, grassroots initiative aimed at reducing the stigma of people living with Alzheimer's disease, as well as creating public awareness, and helping individuals to stay in their homes longer, thereby maintaining their quality of life. Ms. Hortenstine reported that following Ms. Mastry's presentation, the Council voted to incorporate the concepts of dementia friendly into the state plan, making Texas one of the major leaders in incorporating this concept and showing that enhancing public awareness can help improve the quality of life for people living with Alzheimer's, and their caregivers.

Ms. Hortenstine explained that throughout that first year, the Care group chairs of the state plan met via conference calls or planning sessions, and in the spring of 2017, presented a preliminary document that introduced science and early diagnosis into care planning. She reported that late last October, Dr. Alan Stevens, a highly regarded and also a sought-after speaker for his work in caregiver support, was invited by the NIH to serve on their planning committee and to speak at a dementia caregiving summit, which launched Texas once again into being one of the states that is using innovative methods for addressing caregiver challenges.

Ms. Hortenstine ended by saying that as the Council moves forward with the state plan, working with experts in different public health sectors, TARCC, and other stakeholders, she feels very confident that we will again be the leaders in developing a template for communities at large, including urban and rural areas, so that we can have a dementia friendly community within their environments.

b. Update on activities to provide education on dementia friendly communities

Ms. Taylor reported that she has education materials on dementia friendly communities and that she has started work on a guidebook that outlines some of the principles to include in dementia friendly that we want to communicate through education pieces in Texas, based on the Dementia Friendly America information. Ms. Taylor reported that moving forward, a review of the education material is in order, and as Ms. Hanna noted, that the agency is reviewing processes and strategies moving forward to inform the work we will do on dementia friendly. Ms. Taylor reported that she has wonderful ideas to share with Texans through an educational platform and possibilities to include people through educational webinars. She noted the need for this information to be presented in a user-friendly way.

Ms. Hanna stated that Lynda and Carleigh, as state-appointed members by virtue of their employment, will be of great help in professionally guiding this effort. Ms. Hanna reported that Lynda is specifically attached to the Alzheimer's Disease Program, while Carleigh has some responsibility in varying levels for childhood obesity, school health, asthma, nutrition and wellness, tobacco, diabetes, cardiovascular disease, comprehensive cancer, kidney disease and, lastly, Alzheimer's disease, with expertise in all ages, from early childhood to aging. Ms. Hanna noted that Carleigh and Lynda are very skilled at developing good volunteer cores, listening to volunteers, and moving state plans forward. Ms. Hanna noted that it is not a requirement that the Texas Council have a state plan, which is possibly why one wasn't developed until 2010/2011, as at that time, the department was focusing on Councils that had a statutory requirement to create state plans. Ms. Hanna noted that Carleigh will be the leader in advancing the state plan.

Ms. Baudoin reported that the agency has undergone a transformation where it now looks across the agency strategically to see how the plan aligns with other priorities across the

agency, and noted that she will continue to communicate about this and the status of the state plan going forward.

6. Biennial Report 2018

a. Overview of Biennial Report development process and timeline

Ms. Hanna reported that the Biennial Report is a state mandate that the Council and the department produce, and asked Ms. Taylor to provide an overview. Ms. Taylor reported that the Council submits a report to the Governor, the Lt. Governor, the Speaker of the House, and Legislature prior to September 1st in every even-numbered year, and noted that in order to meet the deadlines, the work on the report has begun. Ms. Taylor reported that the Council is making its recommendations for fiscal years 2019 and 2020, and is working with the Texas Alzheimer's Research and Care Consortium (TARCC) to provide information for the report. Ms. Taylor noted that the Alzheimer's Disease Program within the Chronic Disease Branch works administratively with the Council to prepare the report, along with the Health Promotion and Chronic Disease Prevention Section, the Community Health Improvement Division, and the External Relations and Government Affairs departments.

Ms. Taylor stated that before June 1st, the Chronic Disease Branch and the Alzheimer's Disease Program will need to have a complete and formatted draft report from the Council for internal review, to include the Council's final determination of its recommendations and activities. Ms. Taylor stated that by June 1, a draft of the report goes to the Section Director for review, and by July 1st, a draft goes to the Division office for review and edits as necessary. The final report is due July 15th to External Relations and Government Affairs.

Ms. Hanna noted that the report is prepared on a state prescribed template, but that in prior years, the report was a little more extemporaneous, with unique covers and colors so the Council could distinguish themselves. She noted that over the years, mandates have been added to update language requirements, understandability, and website posting to be accessible to people with disabilities.

Ms. Hanna referenced eight recommendations (below) for priority discussion, noting that the Council can add to, edit or remove from. Ms. Hanna reported that as an advisory Council, we do not have the authority to recommend to the legislature which items we think should be funded and at what funding level, but rather, we proffer these recommendations as items we believe to be important.

1. Sustain and support ongoing coordinated AD research.
2. Increase collaborative research among Texas AD researchers.
3. Continue support for quality long-term care.
4. Expand community-based programs and services.
5. In collaboration with DSHS, related departments, TARCC, stakeholders, and related organizations update the *Texas State Plan on Alzheimer's Disease* to

reflect dementia-friendly concepts, support mechanisms, and enhancement of the research enterprise in Texas.

6. Engage in strategic collaborations.
7. Expand local caregiver services and supports.
8. Create communication partnerships with related state agencies to inform and educate on support, services, and best practices for the AD and related disorders communities.

The following discussion ensued on the recommendations:

Dr. Devere stated that he would like to address the use or overuse of medications, particularly antipsychotics, which is a crisis in the care of Alzheimer's patients. He noted that the treatment for dementia in facilities, and even at home, is a major crisis now because of the tremendous use, not just of antipsychotic drugs, but sedatives and tranquilizers. Dr. Devere referenced an audit done by the state of Texas that showed the overuse of medications in Texas facilities was 25%, vs. Hawaii at 10%. Dr. Devere stated that the only thing this Council can do is to get the word out and that perhaps, we could add this as a recommendation that medications, particularly antipsychotics, should be used minimally.

Dr. Diamond stated that item #8 is rather long, and duplicative, but could easily be edited to include minimizing the prescribing of prescriptions/antipsychotics.

Ms. Camp reported that a lot of times the request for medication is coming from the caregivers or the nurses, so maybe we need a training/educational alternative approach to deal with the issues of the anxiety and the agitation that leads them to request the anti-anxiety medication. Dr. Devere reiterated that the doctors are approving and writing the orders.

Ms. Krueger suggested we educate the families so that they understand what the medications are and can approve the use of them, or not.

Mr. Sommers suggested that recommendation #8 can actually be divided up, to include who is being trained and who's received the training.

Ms. Hanna asked the Council to refer to recommendations #1-7 and asked members to provide input, as we need to craft language to go into the minutes.

Dr. Diamond noted that #1 and #2 are somewhat redundant, and stated that 'Support ongoing coordinated AD research'(#1) and 'Increase collaborative research among Texas AD researchers'(#2) could be condensed into a single idea, as it's basically supporting research and collaboration.

Ms. Hanna asked if we are supporting research, are we supporting it whether it's collaborative or not. Dr. Diamond stated that coordinated, sort of means collaborative – that to him it means multiple investigators working.

Ms. Hanna noted to delete recommendation #2.

Dr. Fay noted that #2 could mean collaborative within the state where #1 could mean collaborative within an institution. Dr. Diamond stated yes, but that why not just say collaborative AD, just for brevity, or say collaboration, meaning even intra- and inter-institutional collaboration in the state of Texas.

Dr. Camp asked if a subheading should be included that would address how the researchers can access the research that's going on and/or the results or be informed of what is being started, so that they can build on it rather than duplicate it.

Ms. Hanna asked if we needed exact language today.

Ms. Chapman stated that this is a Council report, and that the Council either today or at another meeting is going to need to approve recommendations, and noted that there can be some wordsmithing, but substantively the Council is going to need to approve it.

Dr. Diamond suggested as a general idea, the fewer recommendations, the better, and the shorter the better. He stated that #5 is hard for him to understand in a quick moment.

Dr. Fay noted that in a lot of ways #5 and #8 are very close to each other.

Dr. Diamond noted he sees the following general ideas:

- We want to advise about prioritizing research that could be intra-institutional and inter-institutional.
- We want the community to be educated, which could be law enforcement, and civic engagement in terms of how other things are organized in a community with regard to dementia, but outside the healthcare realm.
- We want advice on long-term care issues, so this could go to management.
- We want strategic collaborations, which I'm not sure what it means – perhaps engaging the private sector with the concepts and academia or care in trying to promote innovate ways to deal with things.

Ms. Hanna noted that recommendation #5 and #8 could all be part of #6. Dr. Diamond agreed, stating that if you shrink them down, you get those more to bite size pieces.

Ms. Hanna suggested we adopt, as written, #1, #3, #6 and #7, and asked members who have a specific area of interest, to explain why your issue is not within the parameters of those, briefly stated four recommendations.

Dr. Diamond stated that it's always hard to write by committee, and suggested that someone take the lead to condense the discussion into general points. Ms. Hanna asked if that was a motion. Dr. Diamond stated that it was a motion. The motion reads items #1, #3, #6 and #7 be adopted as written for the purposes of your report. Discussion will continue on any member's specific items: law enforcement, medication, collaborative research, access to data, etc., to determine if we have missed including them. Ms. Chapman asked if "discussion" means they

occur at a meeting. Ms. Hanna noted they will be discussed now. Dr. Devere seconded the motion. Ms. Hanna then opened it up for discussion.

Dr. Fay asked if engaging and strategic collaborations, takes in #5. Ms. Hanna noted it actually could take in #5 and #8. Dr. Fay stated that under that objective or plan, that in the explanation, we could include the interagency collaboration on the Texas state plan for Alzheimer's disease. Ms. Hanna stated correct.

Dr. Camp noted that under the dementia friendly strategy initiative, there are a lot of legal and community steps, of which the dementia friendly initiative is going to encompass.

Dr. Diamond stated that you could break this down to three categories - research, creating an environment around in the community outside the medical community (but this relates to law enforcement, civic life), and the long-term care issues, or even a medical approach to current therapies.

Dr. DeFina noted that she had broken this down into four buckets, which are research, treatment (which covers that bigger picture that you're trying to get words around right now), long-term care, and then all of the community-based things.

Dr. Fay noted that her thought is when you try to be too brief, or try to lump too much together, then you don't identify out and get any plans around medication management or education. She stated that in looking at these four elements, she would remove the long-term care issues, as that's a whole bucket and a half. She also noted that the community-based issues are separate.

Ms. Taylor reiterated that this is a report of the Council and that the Council authors the report with the content. She stated that there's a difference between that, and the department helping to put the content together, which is what they will be doing. She stated that if the Council votes on what the recommendations are at this high level, then after the meeting, the department will appropriately determine ways to find how to expand on each of these so that it is similar in style to the 2016 report.

Ms. Hanna then reported that Lynda will take the 2016 report and access as necessary the previous reports and construct the document on the template. Ms. Taylor will then ask for input primarily from me to summarize the accomplishments at a later date, the activities and accomplishments of this Council over the last two years.

Ms. Taylor then provided a review of the 2016 Biennial Report sections with the Council.

Ms. Hanna stated we have a motion and a second on the table. All those in favor of the motion to include 1,3, 6 and 7 as the recommendations of the Council for the 2019-2020 Council's recommendations please signify by saying aye. There were eleven ayes, none opposed, two abstentions (Dr. Fay and Gore) The motion passed.

7. Texas Alzheimer's Research and Care Consortium (TARCC)

Ms. Hanna explained that one of the privileges of the Council is the capacity to add worthy Texas medical schools to the membership of TARCC to participate in collaboration with other member schools. Ms. Hanna provided an overview of TARCC membership, noting that the enabling legislation included four schools; the University of North Texas Health Science Center at Ft. Worth, Baylor College of Medicine, UT Southwestern, and Texas Tech Health Sciences Center. Since then, the Council has increased TARCC membership through the addition of the University of Texas Health Sciences Center San Antonio (the springboard for TARCC's Hispanic cohort), the Texas A&M University Health Science Center, and the University of Texas at Austin Dell Medical School. Ms. Hanna reported that two applications for TARCC membership will be presented and voted on separately.

- a. *Consideration and possible action on applications for TARCC membership, including opportunity for applicants to present, offer information, and respond to Council questions relating to applications*

University of Texas Medical Branch Galveston

Dr. Munro Cullum presented the letter of application for TARCC membership from UTMB Galveston's Dr. Tagliatela and reported the following: The institution of UTMB is making neuroscience and the brain a priority for the next ten years. UTMB Galveston is very excited to be focused on Alzheimer's disease and related disorders, has over \$15M in grants in this area, and have published several papers over the last 10 years. UTMB has the Mitchell Center for Neurodegeneration and Neurodegenerative Diseases, and new clinical programs that follow over 600 patients per year with known or suspected dementia. With their emphasis in their number of faculty with NIH grants and other institutional organizational grants that are contributing to research in this area, they are very excited to be potentially joining TARCC and collaborating with other existing TARCC institutions. In looking through their portfolio of accomplishments and what they bring to the table it looks quite impressive. They have a very collaborative group. Dr. Tagliatela has reached out to Dr. Cullum personally indicating an interest in participating in TARCC and utilizing our data as well, and that he personally recommends and supports their joining.

Dr. Diamond moved that UTMB Galveston be included in TARCC membership. The motion was seconded by Mr. Hackney. The motion was voted on and passed unanimously, UTMB Galveston was admitted to TARCC membership. Dr. Cullum will let Dr. Tagliatela know that UTMB Galveston is now a TARCC member institution.

University of Texas Health Science Center at Houston

Dr. Diamond stated that he would like to make a similar case for the University of Texas Health Science Center at Houston, and noted the following: They look similarly strong with the Mitchell Center in the McGovern Medical School. Their emphasis is a bit more on translational research and biomarker discovery, looking at biomarkers and risk factors for the development and markers of progression in Alzheimer's disease and related disorders. They have taken in about \$20M in funding over the last the last 10 years, and have published over 200 papers in that amount of time. They are particularly interested in developing PET imaging, the

physiologic imaging of the brain to look for amyloid and potentially tau markers of the disease process in the brain in vivo, and have a very active memory disorders and dementia clinic as well. Dr. Diamond stated that they also reached out and indicated a strong interest in wanting to be part of TARCC and be collaborative as TARCC moves ahead.

Mr. Hackney moved that the UT Houston Health Science Center be included in TARCC membership. Dr. Fay seconded the motion. The motion was voted on and passed unanimously, UT Houston Health Science Center was admitted to TARCC membership. Dr. Fay will let Drs. Soto and Rodrigo know that they are now TARCC members.

b. Consideration and possible action concerning consortium activities related to recommendations from research and scientific steering committee and Scientific Director

1. Ethnic composition and funding of the TARCC cohort

Ms. Hanna introduced Dr. Munro Cullum, the Scientific Director at TARCC, who holds the Blumenthal Distinguished Professorship in Clinical Psychology, and was UT Southwestern's first board certified neuropsychologist when he joined the faculty in 1994. Dr. Cullum is active in medical training and research and has worked with the Dallas Cowboys and Dallas Stars for nearly 20 years in the NFL and NHL concussion programs. Dr. Cullum along with Dr. John Hart, who holds a joint appointment in UT Dallas and UT Southwestern, authored a JAMA paper on the incidence and prevalence of dementia and depression in aging athletes. Ms. Hanna reported that it's available on the internet and suggested members read it, noting we are hearing about this on the news every day.

Dr. Cullum thanked members for the opportunity to present. He reported that in its ten plus years of existence, TARCC has been a multi-institutional organization, with all member institutions contributing clinical and biospecimen data to a central repository and then sharing in collaborative research using those data. He reported that TARCC has been very, very successful in its recruitment and that the total number of subjects is now over 3,600 patients, which include individuals with Alzheimer's disease as a primary diagnosis, people with mild cognitive impairment (that sort of transitional stage in between normal aging and AD), and then also a nice cohort of healthy aging individuals as well for comparison to allow for scientific studies to be done in a variety of ways.

Dr. Cullum noted that one of the important points of TARCC is that roughly 40% of the TARCC cohort are Hispanic, which is significant because we really don't know as much about the development of mild cognitive impairment, and the risk factors for Alzheimer's and dementias in individuals of Hispanic ethnicity. He reported that Dr. John Hart is actually working now on a fascinating analysis from the TARCC data suggesting that the predictors for the onset of disease and progression may be different in individuals of Hispanic background. And, interestingly, Texas is unique in contributing to this literature so far as we have one of the few large cohorts of non-Caribbean Hispanics. Most of the studies done in the Hispanic individuals are Caribbean

Hispanics, so our cohort is actually different, and they may be different neurobiologically as well. So, we've got 40%, which is really unique.

2. Investigator Grant Awards (IGP)

Dr. Cullum stated that TARCC now has a true database of over 3,600 cases of which about 1,600 represent individuals that are still actively being followed, and that some of these patients are being followed now for 10 plus years, giving us a lot of rich clinical and biologic data. He reported that a review of TARCC has been done pretty much annually by our external review panel, and on several occasions, the review panel has recommended that TARCC maybe consider going in a little bit different direction by making more use of the data – one of their concerns. Another recommendation was to take a deeper dive into the diagnostics in these different groups, such as brain imaging, a more detailed biological characterization of the subjects that are in the research database, and then looking at the productivity from the various sites using TARCC data (our external advisors noting it was reasonable, but not impressive). Dr. Cullum stated that we thought it was time to make a shift in TARCC, now that we have mature database, and actually move to an investigator grant-based program, where we would maintain the structure of TARCC, the database of TARCC that we have already acquired and will continue to curate, but now open up, especially with the addition of our new sites in Houston and Galveston, to other institutions being able to submit applications for their best science.

Dr. Cullum reported that TARCC as an organization can look at the best science from all of our Texas medical schools being submitted, and then submit those to an external review panel, get their recommendations for what is going to help advance Alzheimer's disease and related disorders and maximize the scientific utilization of the TARCC database. He reported that this is the direction we chose to take by sending out a Request for Application to all the TARCC institutions as well as other academic institutions across the state encouraging applications, and noted TARCC is still in the process of receiving applications.

Dr. Cullum reported that TARCC has received one completed application so far, but the deadline isn't until February 15th, and that all the different schools are working actively on putting together what they think will be the best projects. When these are reviewed by our external reviewers, one of the grading points will be, just like NIH, is a numeric rating for the quality of the investigators, the science of the project, and the opportunities that will lead to other things, such as the environment, etc. Dr. Cullum reported that there will be extra points given in the review for utilization or building upon the TARCC cohort, as we want to see this rich database now utilized in a greater extent, and noted that they are looking forward to seeing the applications, and seeing if we're asking for the best science from all these great institutions. He noted they will be looking at the applications as they come in later this month.

Hispanic conversion

In addition, Dr. Cullum reported that given the richness of the Hispanic cohort, we want to maintain that piece of TARCC, so one of the focus areas for the RFAs specifically asks for people to apply for projects that will utilize and build upon and continue our Hispanic cohort, preferably across multiple sites. This will be one unique feature that we do have a goal of continuing that cohort and actually expanding it to enhance the diagnostic end of things. He noted that Alzheimer's is primarily a clinical diagnosis, but that the field is moving toward utilization of more and more biological markers of disease, such as beta amyloid and tau that can be obtained from cerebral spinal fluid, and in some cases, through brain imaging.

He noted we want to make sure that we are diagnosing all the cases in the Hispanic cohort to the extent possible, and really maximizing that, and that we are proposing that neuroimaging become a part of that cohort and that blood-based in addition to cerebral spinal fluid-based markers be obtained as well. Dr. Cullum reported that this was specifically asked for in the request and that they are aware of at least one institution that is collaborating with three other TARCC sites in submitting such a proposal.

D. Hanna asked Dr. Diamond to speak to the expanded protocols for diagnostics and to the evolution of the cohort which is now leading us to imaging and the collection of cerebral spinal fluid.

Dr. Diamond reported that we've known about Alzheimer's disease for over 100 years, with the pathology that was described 100 years ago still standing true today, and noting it's still pretty much the gold standard. Dr. Diamond explained that the problem lies with making the diagnosis before death, when you can't analyze their brain tissue under a microscope. He reported that historically, diagnosis was done by taking a careful history and a neurological exam, and if you were really, really good at that, and maybe did some standard imaging, you could probably be right at best 85% of the time. This meant that 15% of the time it was being called Alzheimer's when it wasn't Alzheimer's, or they were missing it.

Dr. Diamond noted that since that last decade or so, new ways have evolved that use a technique called PET, which involves the infusion of a very harmless and tiny amount of a radioactive material that labels the accumulation of protein in your brain of amyloid beta, which is one of the key components of Alzheimer's. He noted that it is now approved and that no drug companies are doing any trials without incorporating this into the diagnosis because, if someone doesn't have that signal, they essentially do not have Alzheimer's.

Dr. Diamond reported that in last week or so, there was a major publication in *Nature*, showing that a blood measurement could be made that would tell with very high accuracy whether someone had the protein accumulation in their brain. He reported that there's another protein that accumulates in Alzheimer's, it's called the tau protein, which we can measure in spinal fluid, noting we still don't have a great imaging agent for that, but that it is moving forward. Dr. Diamond explained that the science is fast approaching a time when we can come very close to

the accuracy that a neuropathologist would have but on a living patient, which has a lot of implications for how we make the call about whether someone has the disease or not, also answering important issues about how we use these tests that are pretty expensive.

Dr. Diamond explained that the imaging of the brain to see the amyloid beta protein costs about \$6,000 to make a diagnosis, which is quite expensive. He noted that blood tests could be done much more cost effectively, but that the bottom line is that as we study Alzheimer's disease, we have to incorporate these new methods, figure out how to use them most effectively, and would really like to make other more easy-to-use methods that are going to be just as accurate.

Dr. Diamond finished, noting that all of this is very important, because just as we are making all of these new advances in diagnosis, there are actually new therapies coming on, including new therapies in clinical trials. He stated that unfortunately, all of them are going to be very expensive, and will involve infusions of antibodies or other infusions into the nervous system, which is quite involved. Dr. Diamond stated that we have to pick the patients who receive these treatments with great accuracy, otherwise we will break the bank. Dr. Diamond stated that for the current therapies coming down the pike, it will be critical for us to have the ability to pick out patients with a precise diagnosis.

Dr. DeFina requested a clarification as to whether or not we are going to continue collecting data on the 3600 people that were in the longitudinal part of the TARCC study, or, now, use the existing data and move forward with adding people in the Mexican American category. Dr. Cullum stated that we will largely discontinue most of the current cohort and consider that a set database, unless some of the proposals actually require an ongoing study of some of the TARCC participants. Dr. Cullum reported that as a special sub-category, we are determined to make sure that the current Hispanic individuals in the cohort are continued in some collaborative fashion, but only involving the sites that are interested and are able to participate in continuing to contribute to this.

Dr. DeFina requested a clarification regarding the investigator grants, and asked if there is some infrastructure maintenance for the database and the staffing behind it, that isn't institutionally specific. Dr. Cullum stated yes, that there will be a central TARCC funded maintenance of the biobank as well as the database. Dr. Cullum reported that Dr. Bruce Jones has been instrumental in overhauling the TARCC database, as one of the issues is that when TARCC started, it was done in the database Microsoft Access program, which was the hot database at the time. He noted it is now lukewarm and not the most user friendly for all sites. Dr. Cullum reported TARCC is now getting informatics experts at UT Southwestern, free of charge, to basically translate our existing Access database into a much more modernized, dashboard-based system, which should be released in couple of months. This will greatly enhance all the TARCC sites, and all the investigators' abilities to utilize the data.

Dr. Diamond asked how many applications for the IGP have been downloaded. Dr. Jones reported that as of two weeks ago, we were in the 300s.

Dr. Fay asked if the information collected through the research done via the proposals will be added to the TARCC database. Dr. Cullum reported that those who are funded will be asked to contribute to the TARCC database, so that it will grow.

Dr. Hu inquired about available funding. Ms. Hanna reported that for the biennium, TARCC was funded at \$9.3M.

Dr. Fay asked for clarification on the parameters of the grants. Dr. Jones noted apply for either an investigator-initiated grant at \$200,000 in direct per year for one to four years, or like a regular grant. If they were a junior investigator, they could do a \$100,000 in direct for the same period, but it would be like a smaller project for someone who was just starting out.

Dr. Fay asked if we have a new investigator category. Dr. Jones reported yes.

D. Hanna reported that this is a continuation of a program we did previously, called the Investigator Grant Program (IGP). Senior investigator awards went to North Texas, a quarter of a million dollars, and Dr. Huda Zoghbi at Baylor, very well regarded. And then, five or six young investigator grants. Ms. Hanna reported that the final reports from that round of awards are due in August of this year.

Dr. Cullum noted that for applications that come in and overlap or might benefit from a collaboration, we will reach back to them and encourage them to combine forces, as well.

Dr. Diamond asked for clarification on the nature of the applications. Dr. Cullum reported we are emphasizing the Hispanic cohort, including modern biomarkers, looking at biomarker predictors of progression in general, new advances in neuroimaging techniques, new technologies that might assist with caregivers and caregiver support, use of technology in the detection and monitoring of dementia as well. Dr. Jones added that we have got biomarkers of disease onset and progression, multi-dimensional diagnostic prediction models, advances in neuroimaging, advances in assessment of cognitive decline, use of technology to aid in detection and monitoring of behavior, use of technology in advancing dementia assessment monitoring in their caregiving, advances in caregiving with a focus on collaboration and innovation, advances in therapeutic interventions, studies in MCI and AD in Hispanics. And then we had a special emphasis on proposals involving more than one TARCC site and those that utilize the existing TARCC database or that build upon the existing Hispanic cohort.

Dr. Diamond asked if someone wanted to collaborate with the private sector, would that be okay. Dr. Cullum stated he believes so, but noted that there would be issues around proprietary development of equipment or devices or whatever.

Dr. Cullum then reported that TARCC is going to be overhauling the steering committee. Ms. Hanna reported that by statute, each member school sends to the Council, the name of someone from their institution to participate on the steering committee. She noted that over time the steering committee has evolved, and that the Council has never failed to appoint anyone that the university wanted to be on the steering committee. She reported that initially,

the steering committee was comprised of more administrators, and that one of Dr. Cullum's goals is to try to make sure that the steering committee members are researchers, so that everyone talks the same language on the phone calls.

Dr. Cullum stated that we recommend that there be an annual appointment for the steering committee, rather than an indefinite term for everyone, which gives us the opportunity to change the committee composition for those who may not be participating.

Dr. Diamond asked how TARCC's shift from just dispersing funds to a set number of places to one where there's sort of competitive grants will affect the steering committee. Dr. Cullum reported that they are currently addressing this - figuring out what the steering committee is actually going to do, aside from hearing updates about what the grants are, and hearing the projects and the updates. He noted that one of the charges for steering committee members will be to help, not in a micro-managerial way, but to oversee the research of the projects that are going on at their institution. He reported that during the first iteration of the grants program years ago, there was not as much oversight in terms of required annual or even several-times-a-year reports on progress updates, so that will be tightened up and the steering committee members will be utilized that way also.

Ms. Hanna reported that it was actually the recommendation of the external group that Texas carve out a unique spot for ourselves, by converting to primarily a Hispanic cohort, which led to these discussions. She noted that there are many other cohorts in the nation, some of which are more generously funded, but that TARCC's special niche is the Hispanic cohort. She noted that this is due in large part to the work of Sid O'Bryant at North Texas and Don Royall's recruiting at UTHSC-SA. Ms. Hanna explained that some of our TARCC sites, such as Baylor College of Medicine, cannot get any Hispanic subjects, normal controls, MCIs, but they can get ADs, so Munro and the group decided that participation in the Hispanic cohort had to be voluntary, because we weren't going to be punitive to anybody because they couldn't get Hispanics.

Dr. Cullum then added that one of the other things implemented during the process of further refining the existing database, was to establish a compliance committee last year at Debbie's request. Dr. Jones and Dr. Hart were part of this committee, so we had neurologists, neuropsychologists and other clinicians from our sites review all of the TARCC cases, looking just through the database, to see what diagnosis would we come up with as a compliance committee, and how that matches up with the diagnosis that was made each of these sites as well. The good news is that the diagnostic accuracy was quite high, our consistency was quite high across the TARCC sites. He noted we now have a, sort of dually-diagnosed, cleaned up TARCC database for the first time. So, we added that level of quality control so that investigators mining the database in the future will rest assured within the clinical framework and, anyway, they can have more confidence in the clinical diagnoses that were made.

Ms. Gore asked how the designation of the University of Texas Southwestern Medical Branch was determined, as the data center. Ms. Hanna reported that Texas Tech was designated in the legislation as a “data center,” and they asked us not to give it to them because it would have meant gearing up in a way that they could not handle. She reported that Mr. Crowson from the Attorney General’s office was at the first meeting in about 2005, when the steering committee members from the schools recommended that the money for Alzheimer’s research be used to create a longitudinal cohort, which required both a sophisticated data center and a lab tissue bank, freezer capacity to store, audit and maintain the genetic materials. She noted that initially, it was blood and a cheek pull for DNA, and now it’s just biomarkers.

Ms. Gore asked if anyone else has been able to step into those shoes since 2005. Ms. Hanna reported that no one else has wanted to or has ever come forward asking to do it. Ms. Gore asked if they will also manage the IGP grant award process. Ms. Hanna explained that the first manager of the IGP program was Texas A&M Health Science Center, but with the expansion of the RFP, and the kind of proposals that we expect to get, that Southwestern has a lot more go power to manage it. She noted that A&M is not objecting to not being asked to manage the second round of grants.

Ms. Chapman inquired if this is a new designation that needs to be voted on - for Southwestern to manage the IGP grant award process. Ms. Hanna stated that yes, we need two separate motions: one to approve the grant, one to manage the data.

Dr. DeFina moved that UT Southwestern manage the investigator grant program grants award process in a manner and amount with the parameters and conditions relating to the awards consistent with the highest scientific standards possible. Dr. Diamond seconded the motion. The motion was voted on and passed unanimously.

Ms. Hortenstine moved to approve the TARCC plan as proposed that converts the cohort to the voluntary site participation grant funded enrolling and studying Texas Hispanics. Dr. Devere seconded the motion. The motion was voted on and passed unanimously.

A discussion ensued about the TARCC appropriation. Ms. Hanna reported that the Council does not receive any direct funds, nor does the Department of State Health Services receive any funds for TARCC research. She noted that because the Legislature created Alzheimer’s disease consortium in Article III of the state budget under Education, that our funds are trusted to the University of Texas at Austin to the office of President Greg Fenves. She noted that when they accepted the rider for our appropriation, they were not even a member of TARCC, and did this as an accommodation to the Council. She explained that the University of Texas at Austin writes the checks, pays the bills, and handles all the money – the Council not Department touches and money related to the research effort.

Ms. Hanna reported that TARCC contracts are managed by the Grants and Contracts office at UT Austin, and that they work with AG's office on the contracts and approving the distribution of funds. Mr. Crowson reported that as a trustee, UT Austin has no say over what the money goes, they just write the checks. Ms. Hanna noted that when TARCC makes purchases, such as freezers to store samples, they deal directly with UT and it has to be purchased in accordance with state purchasing standards.

Ms. Gore asked about vacant positions on the Council roster. Ms. Hanna noted that the vacant spots on the roster are actually non-voting members within state agencies, which we depend on state agencies to keep filled.

8. Time and date for next Council meeting

Ms. Hanna reported that the Council is required to meet twice a year and asked members that if they already know of unavailability this fall to let Lynda know. Ms. Hanna noted that we try to avoid busy times, such as the Austin City Limits Festival. She noted that several people on the Council travel extensively, so that finding compatible dates can be difficult. Ms. Taylor will find four dates for a fall meeting and poll Council members on availability.

9. Public Comment

Dr. Devere stated that he did not want to leave the message that antipsychotics and sedatives should not be used in dementia treatment, but noted that there is great potential for medication errors with multiple physicians and hospitals treating the patient.

10. Adjourn

Clint Hackney moved that the meeting be adjourned. Dr. Faye seconded the motion. The meeting was adjourned at 1:12 p.m.