

Aging and Adult Dependent Care Committee (AADCC)

September 21st, 2021

WebEx

2:00 PM to 4:00 PM

Attendees:

Carla Alvarez Mells
Louie Brennan
Tammie Edwards
Debbie Henken
Dawn Lea
Jill Bartholomew
Brittany Patterson

Rusty Mason
Cooper McLendon
Chris Gaines
Martina Lavrisha
Jenny Jones
Joe Balintfy

Mark Rubert
Leon Reynolds
Virgilio Bundoc
Ryan Gonzalez
Dan Xi
Quandra Blackeney

I. Welcome and Introduction

A. Welcome and Introductions

Madhav Thambisetty, MD, PhD is a Board-certified neurologist with sub-specialty training in cognitive/behavioral neurology and sleep disorders. He completed both residency and fellowship training in the Department of Neurology at Emory University School of Medicine in Atlanta. Prior to training in Neurology, he was awarded a PhD (DPhil) in Clinical Pharmacology from the University of Oxford where he pursued doctoral studies on a Felix scholarship. His PhD thesis examined the role of synaptic remodeling in the actions of anti-depressant treatments. In 2004, he was awarded a research fellowship by the Alzheimer's Society of the United Kingdom to pursue research into 'Blood biomarkers of Alzheimer's Disease' at the Institute of Psychiatry, King's College, London. He was elected to the Emanol Lee medical research fellowship at St. Cross College, Oxford in 2004. In 2016, he was awarded the Norman Geschwind prize in Behavioral Neurology by the American Academy of Neurology (AAN). He is currently also an Adjunct Associate Professor of Neurology at the Johns Hopkins University School of Medicine.

II. Special Guest Presentation

A. Madhav Thambisetty, MD, PhD, Senior Investigator and Chief, Clinical and Translational Neuroscience Section, Laboratory of Behavioral Neuroscience, National Institute of Aging: "Aducanumab: post-approval debates, dilemmas, and decisions"

Dr. Thambisetty served on the FDA advisory committee related to the conditional approval of aducanumab. In his presentation, he shared the implications of the approval for patient care and anticipating the future.

- i. In the 100 plus years since Alzheimer's was described up until June of this year, there have only been four FDA approved treatments and they are only symptomatic treatments only and do nothing to stop the progression or reverse the trajectory of the disease once it has started.
- ii. Aducanumab is the first drug in 18 years to be approved by the FDA but there has been debate as to if it had met clinical efficacy. This is the first time that the FDA has gone against its own advisory committee. In 2015, Biogen started two separate, but nearly identical clinical trials about a month apart.

Each trial recruited approximately 1,600 participants in the early stages of Alzheimer's. In December 2018 the company carried out a pre-specified futility analysis and would look at the data to see if there were signs to continue the trial. In March 2019 it was determined that neither trial had a realistic chance of meeting the primary goal of slowing cognitive decline. However, after subsequently looking at a larger data set, one trial was positive for slowing decline while the other trial was not. Based on analysis of the larger dataset, Biogen sought FDA approval for licensing aducanumab in October 2019.

- iii. In November 2020. The FDA's clinical reviewer stated that the data supporting efficacy of the drug was "exceptionally persuasive". However, the FDA's statistical reviewer disagreed. The advisory committee of 11 members voted overwhelming against approving the drug stating there was no clear evidence for efficacy. In June 2021 the FDA approved aducanumab under an accelerated program requiring a post-approval study by Biogen. Side effects observed in the trials also included brain swelling and microhemorrhages. One of the common symptoms associated with brain swelling is confusion, which is usually already a major problem in an Alzheimer patient. The drug also costs about \$56,000 annually and may not be covered by insurance.
- iv. In June 2021 after the drug approval, Dr. Thambisetty had a patient that was in the moderate to severe stages of Alzheimer's. The caregiver who was the patient's son asked when the patient could be signed up for the new Alzheimer's drug. Dr. Thambisetty provided the caregiver his assessment about the lack of clear efficacy of the drug in Alzheimer's, side effects and financial implications. Moreover, as the drug had only been tested on patients that were in the early stages of Alzheimer's disease, this patient would not match those in the clinical trials. The prescribing label on the drug was subsequently updated to specify that it be used only in patients with state mild cognitive impairment or mild dementia stage of disease.
- v. Dr. Thambisetty hence determined that the patient was not eligible to receive aducanumab due to their advanced disease stage, past history of stroke, and doubtful clinical efficacy of the drug. The patient and caregiver agreed with the decision.
- vi. The drug also costs about \$56,000 annually and may not be covered by insurance or Medicare. An independent evaluation of the cost by the Institute for Clinical and Economic Review (ICER) determined that the cost was too high and an unfair price. ICER recommended that a fair pricing would be around \$3,000 per year. There are currently no patient assistance programs to help with cost.
- vii. Dr. Thambisetty's concern is also that Biogen has up to 10 years to collect data and they company may take all 10 years to do so. This combined with the high cost to patients and no certainty if the drug works or not is worrying. He anticipates that other drugs will soon come up for regulatory approval from the FDA that work in a similar manner to remove brain amyloid. Two such drugs have been given breakthrough therapy status by the FDA which means they are prioritized for review and may receive regulatory approval in the next 1-2 years.
- viii. Dr. Thambisetty also anticipates that amyloid-lowering drugs that had been previously abandoned by companies may be revived since the FDA's approval of aducanumab was not based on clinical benefit but the ability of

the drug to remove brain amyloid.

III. Updates

A. AADCC Project Listing Updates

- i. **Stakeholder Engagement & Benchmarking-Chris**
 - On September 14 the first meeting of NIH Stakeholder Groups consisting of The NIH Child Care Board, NIH Health and Wellness Council, NIH Well-Being Ambassadors, Aging and Adult Dependent Care Committee, and Nurses Wellness Committee met for the first time to identify common goals and foster collaborations amongst the groups. From that meeting. A stakeholder team channel was created. Sharing of resources such as webpages, and contacts. Future regular meetings were also established if other committee members would like to attend.

- ii. **ORS Website- Debbie, Melissa, Chris, Mark**
 - It was suggested that the resources tree (tree of resources) be added to the website. It will feature links to various items that would be of assistance to staff. The tree can be featured on the website to provide a lot of different information on one page.

- iii. **AADCC Branding and Communications- Mark**
 - The group have met to discuss the framework for the PowerPoint presentation slide deck. The slides will be provided to committee members so they can be used when presenting information about the AADCC committee and what the committee is doing and can be modified depending on the audience. Hoping to have the template by the end of October. The committee is asked to review and provide input.

- iv. **Adult Care Support Listserv- Martina**
 - Request for feedback sent in August to the 350-400 listserv members and received no feedback. It is hard to tell if persons are satisfied with the listserv or if persons are not sure on topics to share. Chris will also remind other stakeholder groups to help promote the Adult Listserv. Sharing with coworkers can also raise awareness. Chris will investigate the history of the listserv. He will see when the list was started and when membership numbers were increased and figure out why. There is a listserv for the Federal Workplace Health Collaborative and information can shared and drive more persons to the listserv from other agencies. Chris will speak to the collaborative in regards.

AADCC members were instrumental in posting a wide variety of topics weekly with intermittent dialogue ensuing. Some of the topics related to health observances for that month or increasing awareness of AADCC. We are working on increasing the number of subscribers.

- v. **Communications Calendar- Sonia & Ryan**
 - No major updates but will continue to keep the calendar up to date with specific aging and adult specific events but also cross promoting events. They will also have specific goals set for the communications calendar by next meeting. They will also check the possibility of linking the calendar with OneNote.

- vi. **Health Screenings Calendar- Dawn & Virgilio**
 - The group has done the research and identified the health screenings and created a list. It is more a matter of creating a visual format that is easy to read. This item is pending for a creative person that can assist. Making the list downloadable so that people could place on their refrigerator. Ideas and suggestions are welcomed. Debbie suggested sending the raw list out to the listserv to inform the recipients of what is being worked and take suggestions to make it look better. Mark mentioned that the National Library of Medicine have two pages of screenings for men and woman age 65 and older.

- vii. **Future Webinar Topic-Virgilio**
 - The group would like to find approximately two to three speakers a year for not just committee members but NIH-wide webinars. Sharing a request for suggestions on the listserv could be an option. Chris informed the group that the process of making the presentations 508 complaint for the website is ongoing. Dr. Thambisetty's presentation was already captioned via WebEx and will be immediately posted.

- viii. **Newsletter- Chris**
 - The letter will be coming out in October and will be dedicated to Work and Family Month and promoting the activities for the month.

- ix. **FEVS Data-Debbie & Dede**
 - The group found that there were three questions relevant to the AADCC. One question showed that only 1.4% of NIH'ers have used or participated in Work-Life programs. Which is a reminder to keep the communications up. OHR provided that the average age of a NIH employee is 56.3 years old, but the group will look across the last 20 years and determine if that average is changing across time. Once the group meets with OHR. This will help lobby for additional resources and get more people involved.

- x. **IC Environmental Scan-Chris**
 - The Health and Wellness Council will be working with the Well-Being Ambassadors to put together an inventory of all the wellness, well-being, work-life, and dependent care supports in the various IC's. This was done approximately four years ago but the group is looking to update due to IC's providing specific support to staff. The goal is to create a repository of information and share best practices.

IV. October Work and Family Month-Jill, Chris, Cooper

- A. October is Work and Family month. The last week of the month is focused on retirement and those with adult and dependent care issues. A nutrition for healthy aging will take place on October 26. A hospice and palliative care webinar will also be posted once captioned. The presentation on the new Alzheimers drug will be featured as well. The AADCC slide deck will also be included if ready in time.

V. Upcoming AADCC Membership Drive

A. Co-chair solicitations are due October 15

- i. Both Dawn Lea and Martina Lavrisha will continue their membership on the committee. Cooper McLendon and Jill Bartholomew term as co-chairs will expire at the end of December and are seeking nominations for new co-chairs. Jill and Cooper will shadow the new co-chairs in the beginning to assist in the transition. They both will also remain on the AADCC.

VI. Open Discussion

- A. Today, September 21, is World Alzheimer's Day

VII. Announcements and Adjournment

- A. The next meeting will be December 14th