

NWX-HHS-AOA-1

**Moderator: Amy Wiatr
July 12, 2012
12:15 pm CT**

Coordinator: Welcome and thank you for standing by. At this time all participants will be able to listen only until the question-and-answer session of the conference. At that time if you would like to ask a question, you may do so by pressing star 1. I would also like to remind participants that today's conference is being recorded. If anyone has any objections, you may disconnect at this time. And now I will turn the meeting over to Ms. Amy Wiatr-Rodriguez with the Administration on Aging. Ma'am, you may begin.

Amy Wiatr-Rodriguez: Great. Thank you so much. Welcome everybody who's on today's webinar. I am Amy Wiatr-Rodriguez with the Administration on Aging which is within the Administration for Community Living, and I'll be moderating today's webinar: Connecting the Aging Network, Individuals with Dementia and Caregivers with Research Opportunities, which is the third in a three-part series.

This webinar series came about through discussion within AoA and our AoA funded programs such as Alzheimer's Disease Supportive Services Program, Older Americans Act Title III-E - National Family Caregiver Support Program, the National Alzheimer's Call Center, and Eldercare Locator

regarding how we could collaborate better with our colleagues at the National Institute on Aging and their funded programs such as Alzheimer's Disease Centers and the Alzheimer's Disease Education and Referral Center.

We're so pleased that some of the participants in those discussions are presenting today and others are featured on the other webinars in the series. Before I introduce our speakers, we have a few housekeeping announcements.

First if you have not already done so, please use the link included in your email confirmation to get onto WebEx so that you can not only follow along with the slides as we go through them, but also ask your questions when you have them through chat. If you don't have access to the link we emailed you, you can also go to www.webex.com, click on the Attend a Meeting button at the top of the page, and then enter the meeting number which is 665747298.

If you have any problems with getting into WebEx, please call WebEx technical support at 1-866-569-3239 especially if you do have technical difficulties.

As our operator mentioned all participants are in a listen-only mode, however, we welcome your questions throughout the course of this webinar. We'll try to answer those that we receive in breaks in between each presenter. You can use the chat function in WebEx by entering your questions and we'll, like I said, sort through them when we take a break between each presenter.

In addition after the presentations wrap up, we'll offer you a chance to ask your question through the audio line. And when that time comes, we'll have the operator come back on and give instructions as to how to queue up to ask your questions. Of course if there are any questions that we can't answer

during the course of this webinar, we'll follow up to be sure that we get them answered.

And if you think of any questions or other things afterwards, please use my email address. It's amy.wiatr@aoa.hhs.gov as well as many of the presenters today have included their contact information on the slides, and you can feel free to contact them as well.

As the operator mentioned, we are recording this webinar. We'll post the recording, the slides, and a transcript on the AoA Web site at aoa.gov as soon as possible, hopefully by the end of next week. And we will be sending out an email confirmation to everyone who registered when those materials are posted.

So our speakers today include Michelle Washko, Ph.D., Office of Policy Analysis and Development with ACL - the Administration for Community Living; Nina Silverberg, Ph.D., Program Officer for Alzheimer's Disease Centers with the National Institute on Aging; Diana R. Kerwin, M.D., Assistant Professor of Medicine-Geriatrics with the Cognitive Neurology and Alzheimer's Disease Center with Northwestern University Feinberg School of Medicine; Raj C. Shah, M.D., Assistant Professor of Family Medicine with Rush Alzheimer's Disease Center; Jennifer Watson, a Project Officer with the ADEAR Center with the National Institute on Aging; and Martha Tierney, Team Lead with the National Alzheimer's Contact Center with the Alzheimer's Association.

So at this point, I'd like to turn the presentation over to Michelle Washko with the Administration for Community Living for some welcoming remarks.
Michelle?

Michelle Washko: Thank you Amy and thank you to everyone who's participating, and I say that on behalf of the Administration for Community Living and the Administration on Aging.

The Aging Network, you know, should connect their clients, consumers, and organizations with researchers and research opportunities because it's in their best interests - our best interests. We all have a role to play and it's not just implementation of evidence-based practices, but in basic science and translation as well.

This translating research piece is a critical step in bringing the evidence-based results on what works out of the clinical setting and into community-based demonstration programs. And partnering is important as a way to close that knowledge gap between clinical research and practice.

If these relationships between research and community partners aren't nurtured and communication channels aren't promoted and developed, widespread adoption of evidence-based practice won't be achieved.

So with that thought in mind, what are the ways that the Aging Network can connect? And we'll be talking about this, you know, through all the presentations I'm sure.

First, reaching out to local universities, research institutes, organizations, and to your local Alzheimer's Disease Center which Nina's going to describe in detail.

Other things like getting to know what one another offers, looking for ways to partner like including Web site links to one another's organizations, establishing formal referral protocols. Even offering to speak at events for one

another or serving on advisory councils or committees, sharing information with clients and consumers that healthy volunteers as well as individuals with certain conditions or circumstances are needed for various research studies. These are all the types of things that you can do to be able to start to bridge that gap.

There are many resources to find out more about the types of research that is being conducted as well as risks and benefits of each and individuals can play a part and help making the next big breakthrough. And this is the message that I think on the community partner side of the house we really need to push and get through. Would you mind flipping the next slide?

Woman: Okay.

Michelle Washko: So the next slide, I'm going to talk about a few specific examples and opportunities. The first one is the Alzheimer's Disease Supportive Services Program. This program means to expand the availability of diagnostic and support services for individuals with Alzheimer's disease and related dementias for their families and their caregivers as well as to improve the responsiveness of the HCBS -- Home and Community Based Care System -- to persons with dementia.

This program funds Alzheimer's evidence-based caregiver interventions, Alzheimer's innovations, and dementia capable systems integrations -- I know a lot of titles -- through cooperative agreements that accomplish goals like piloting and translating the interventions, reforming the long-term services and supports programs to meet the needs of persons with this disease and their caregivers.

We currently have 55 funded programs in 30 states: the District of Columbia and Puerto Rico. And actually if you go to the next slide -- thank you -- you'll see a map of the total active ADSSP grants. This map is showing the number of active ADSSP grants by state. We at ACL-AoA especially encourage anyone working in states with active ADSSP grants to make sure that you're aware of programs available near you so that you can make appropriate referrals and work together with these programs when they're testing various interventions in the hopes that they'll have broader implementation in the future.

Next slide please. Thank you. The programs (unintelligible) space interventions which I mentioned just a little bit ago, they closely replicate specific interventions that have been listed through randomized control trials with results published in peer review journals. There are 26 grants in 16 states that are implementing these evidence-based models.

And some of the interventions that are being funded for this translational research include REACH, the New York University Caregiver Intervention and Savvy Caregiver. Many of these programs also struggle with recruiting eligible participants.

If you're looking at this and you're at a computer, by clicking on the red circled link next to Project Profile as indicated on the slide, you can get to the map on the next slide -- next slide please -- which contains specific profiles of the program or programs in each state. Clicking on the link brings you - this is the ADRC Technical Assistance Exchange which also includes the ADSSP Programs Technical Assistance Resource Center material. This map and the web link is adrc-tae.org. This can help you locate programs that are recruiting near you and get detailed information on each of the projects here.

Next slide please. So that's a specific project. The specific opportunity I wanted to mention is a joint Funding Opportunity Announcement or an FOA that was written and released - it was written between NIA and AoA and released last year. This particular translational research to help older adults maintain their health and independence in the community offers the opportunity to apply for an R01 or an R21 grant. The link on your slide will take you to the full announcement.

And just so that you know one project around ADRD was recently successfully funded and this FOA is still accepting applications on a rolling basis for the next two years. So that's all I wanted to mention today. Amy, I'll turn it back to you and thank you again for everyone who's participating.

Amy Wiatr-Rodriguez: All right great. Thank you so much Michelle. I think we did have one question coming in about the evidence-based programs. Can you kind of just give a sense for the Alzheimer's Disease Supportive Services Programs? They are evidence-based programs as well as some that are not. But that might be a question maybe, I don't know if Kate Gordon is with you?

Michelle Washko: Yes, she is. So what was the question?

Amy Wiatr-Rodriguez: The question was whether all of the programs under the ADSSP Program are evidence-based.

Michelle Washko: Oh, okay. Yes, I'll let Kate answer that.

Kate Gordon: This is Kate Gordon. I work with the Technical Assistance Resource Center for the ADSSP Program. And as Michelle mentioned that there are programs in multiple states, but only 26 of the grants that are in 16 states are what the Administration on Aging has titled the evidence-based programs. So those are

programs which have gone through randomized control trials and closely follow the fidelity measures for those programs.

There are however another set of grants - the innovations grants which may incorporate evidence-based practices, but they don't follow the same protocols. For example, they might be testing whether or not one of those evidence-based practices works in a population that was not tested in the original intervention or within the original research project. So there are some. The evidence-based programs follow the protocols as closely as possible and there are some innovations which are doing just that - innovative practices and going into new populations with those evidence-based practices.

Amy Wiatr-Rodriguez: Great. Thank you so much for that clarification. All right, we're going to move on to our next speaker which is Nina Silverberg with the National Institute on Aging. Nina, if you'd like to go ahead.

Nina Silverberg: Thank you Amy and thank you Michelle. I want to reiterate what Michelle said about how excited NIA is to be partnering with ACL and AoA not just in these series of webinars, but in lots of other ways and developing programs to help to connect the AoA community organizations with research centers.

We already do have some of our Alzheimer's centers working with local AoA offices and those have been really successful and productive and so we'd like to see that be expanded.

Again, I'm Nina Silverberg and I am the Assistant Director for the Alzheimer's Disease Centers Program and I'll be describing Alzheimer's Disease Centers as well as the ADCS - Alzheimer's Disease Cooperative Study.

You can go to the next slide. So we have approximately 30 centers on Alzheimer's disease, NIA funded centers across the country. The number changes depending on various funding situations, but basically it's nearly 30 across the country. You can see the map there.

Each Alzheimer's center has some common properties across all the centers and some unique properties focuses that they have for each individual local center. They all provide diagnosis and education services for patients and families as well as to physicians and other health care providers in their local community and sometimes more broadly especially because they each have web pages.

And later Jennifer Watson's going to be describing the NIA web page where you can get the information. It's listed here, but she's going to be describing some more detail about how to get information about participating in research.

Next slide please. So as I mentioned, there are some commonalities across all the centers. Each one has at least these five cores that I've listed here - an administrative core that takes care of the administrative business of the center which by the way includes for each center pilot research program. So they all are accepting proposals to do pilot resource to develop further research.

Each one has an education core and the education cores do outreach as I mentioned not just providing information to the community and connecting people to resources, but also information to physicians and other health care providers to help them keep up-to-date on the most current research in Alzheimer's disease.

They make opportunities available to participate in research available to as many people as they can and this is partly through providing talks and

community events. Recruitment costs are very high for research studies and this is a way to help connect the researchers with the community organizations. So we feel that the education cores are a very important part of the centers.

They each also have a clinical core which has a set of individuals who are followed annually with a uniform data set so we have the same information on all people across all the centers and then some unique information at each individual center.

They all have a data core so that they can make sure that the data are collected accurately and transmitted to the coordinating centers in Seattle for all of the centers. The data comes there for the informed data set. And then each center also has a neuropathology core that provides information to families on the diagnosis (and) autopsy.

So as I mentioned each individual center also has its own focus and I just put some examples on the slide. Some of them may be focused on other types of dementia and/or specific diverse populations. We have a couple with a focus on Down syndrome. And then most - I think all also conduct clinical trials and other clinical research.

Next slide please. So oh I just wanted to mention sorry before going on to the ADCS that the research topics at all of the Alzheimer's centers are very broad includes biological, clinical which may include imaging, research on diagnosis and the best way to convey diagnosis, other ethical issues, some study caregivers particularly. They all have some studies of neuropathology and contribute to the state of the art of research in this area.

So moving on for clinical trials and other clinical research, we have the Alzheimer's Disease Cooperative Study. This is an NIA funded collaboration and in a moment I'll show the map, but we have Alzheimer's disease collaborative study sites across the country. They overlap with the Alzheimer's centers, but there are many more sites for the study because they conduct multiple different research studies and they provide the infrastructure for other studies that aren't funded as part of the ADCS also.

They study therapies that include pharmacological and non-pharmacological. So for the drugs that they study, they primarily look at ones that might not be developed by the pharmaceutical industry. So it's a pretty unique focus.

Next slide. So as I mentioned, there are a larger number of ADCS sites that include all of the Alzheimer's centers plus others in Canada and others across the United States. Pretty good coverage across the country.

The sites sometimes change so don't stick with just what's on here as Jennifer will be saying you can get information on whether there is a site or another research site that we know of that's near you if it's not on this map. And then I think that's all I wanted to cover. Thank you.

Amy Wiatr-Rodriguez: Great. Thank you so much Nina. We're going to move on then and our next speakers are Dr. Diana Kerwin and Dr. Raj Shah. Dr. Kerwin is going to begin first in the next section and Dr. Shah is going to take the second half.

Oh and I'm sorry before we move on to that, we did have one question that came in. Perhaps this is for you Nina. And the question was were there any types of programs that you talked about in the different opportunities you

shared that were for people with Parkinson's since many of them have some form of cognitive impairment?

Nina Silverberg: Yes. NIH funds most of the Parkinson's research including the Udall Parkinson Centers through NINDS - Institute of Neurological Diseases and Stroke. We do have some of our Alzheimer's centers that also have Parkinson's as part of their focus and some of them actually are also locations for Udall centers and they collaborate and a couple of them actually are run by the same principal investigator for both the Alzheimer's center and the Parkinson's center. So there's a lot of interaction and there are some with a focus partly on Parkinson's disease research.

I guess I can give examples. One is the University of Pennsylvania, they also have a Udall center. And another is the University of Washington. Tom Montine is the Principal Investigator there.

Amy Wiatr-Rodriguez: Great. Thank you very much. All right. And if people need more information again beyond this feel free to email me and I can put people in touch with the right information. All right so we'll move on. Again as I mentioned Drs. Kerwin and Shah are going to be doing the next portion of our presentation. So I'll turn it over to Dr. Kerwin.

Dr. Diana Kerwin: Great. Thank you Amy. So Dr. Shah and I are going to divide up the next section to discuss clinical trials in a little bit more detail. We are both affiliated with an NIA funded Alzheimer's disease center. He's affiliated with the Rush Alzheimer's Disease Center and I'm affiliated with the Northwestern Alzheimer's Disease Center and we're both involved in the cooperative studies as well as some industry sponsored clinical trials at both of our sites.

And so the next two slides are actually our disclosure slides just indicating basically that I've received funding as the site principal investigator for studies, specifically the Alzheimer's Disease Cooperative Studies for ADNI.

There was an ADCS study also for Forest and with Lilly Laboratories and I've served on an advisory board for Neuronics and Pfizer and on the speaker board for Novartis Pharmaceuticals. And I've received funding from the Alzheimer's Disease Center which is the NIA funded center as well as support from the Illinois Department of Public Health Alzheimer's Disease Assistance grant. And on the next slide Dr. Shah has a list of his disclosures as well and I don't know, Raj did you want to say anything specifically?

Dr. Raj Shah: No. I think we both share and the slide is I think is self-explanatory as far as funding from national sources, research support from industry and then also I'm on the board of directors for the local Alzheimer's Association Greater Illinois Chapter. Thank you.

Dr. Diana Kerwin: Great. Thank you. So moving on to the next slide. So the discussion points that we're going to go over are really the basis for the large - for the Alzheimer's Disease Cooperative studies really the basis of the Alzheimer's disease centers is where we're trying to fill in the scientific gaps for Alzheimer's disease.

So some of the main points are going to be where are the gaps currently and how we diagnose the disease at this point in time, treatment, and prevention of Alzheimer's disease and then also why do we need to do clinical research in Alzheimer's disease. We're going to talk more about why these clinical trials and also studies looking at other interventions that may not necessarily be a medication intervention, but really to devise more what are risk factors for

Alzheimer's disease which can lead to more prevention interventions for Alzheimer's.

And then we'll be talking again specifically about what is clinical research, who should be involved in clinical research, and how can we work together to support clinical research through referrals and through cooperation between centers and also with the Aging Network.

You can go to the next slide. So I think many of you are very familiar with the statistics on Alzheimer's disease which are updated it's usually annually by the Alzheimer's Association.

Dementia due to Alzheimer's disease is really the leading cause of dementia in the United States in the 65 and older population. So that's why dementia and Alzheimer's disease are often used synonymously, but they aren't necessarily always the same.

There are other dementias that our centers will focus on such as frontal temporal dementias, but today we're going to be talking a little bit more specifically about Alzheimer's disease in particular just because it is the most common form in the United States.

There's about 5.4 million Americans with dementia due to Alzheimer's disease currently in the United States with about 15 million caregivers as well. And that's one of the things that I've learned as a physician diagnosing and caring for persons who had dementia specifically Alzheimer's disease is you really end up with two people, basically the caregiver and the patient. And this also carries over into clinical research.

Most of our clinical trials and clinical research on dementias and specifically Alzheimer's disease usually ask that there be a caregiver participating as well and accompanying the patient or the participant to the study so that we can get ancillary or informant information about how that participant is doing. So that's really a key piece to keep in mind when we talk about clinical trials.

Dementia right now due to Alzheimer's is the third most costly disease. Again when you combine in the cost of the diagnosis and treatment of Alzheimer's as well as the cost incurred by the caregiver through possibly lost wages, it really becomes a very expensive disease to care for and for society as well.

There's about \$200 billion that will be spent in direct and indirect costs for care in 2012 so about the third most costly behind heart disease and cancer. And Alzheimer's is the sixth leading cause of death in the United States. And by 2050 it's estimated that there will be at least 15 million more Americans who will develop Alzheimer's disease.

You can go to the next slide. So some of the gaps and some of the big issues that we're beginning to focus on with basically the direction of clinical research is to look at risk factors so that more prevention strategies can be developed. Right now prevention strategies are beginning to be formulated.

We're finding that the things that help protect the heart that are heart healthy seem to be brain healthy, but we really need to do a much larger brain focus in Alzheimer's disease prevention focus studies in order to really learn how much prevention we can instill by advising our patients when they're younger. When they're in the 40s and 50s what they can do at that point in time to prevent or delay their risk of developing a dementia due to Alzheimer's when they get into their 60s and 70s.

And we really - although we're advising patients at this point, we don't really have the evidence-base or the data yet and that's one area or gap that's going to be focused on in the next few years with clinical research.

One big area is about diagnostic testing. One of the - what I've seen in practice is one of the biggest barriers for caring for someone with Alzheimer's disease dementia is the barriers that the physician faces in diagnosis. Because we haven't had a blood test or simple single X-ray or biomarker that 100% can designate whether someone's memory loss is due to Alzheimer's disease, several physicians and families struggle with making the diagnosis very clearly or feeling that there's a certainty to the diagnosis which sometimes we see either the disease goes unrecognized or the disease goes untreated in that person because of that lack of certainty.

So one of the big areas of clinical research is something like the Alzheimer's Disease Neuroimaging Initiative or ADNI which is looking at just this question of what biomarker best predicts that someone's memory loss is due to Alzheimer's disease pathology and the certainty that that person will progress or will have that disease. And that's going to become more key as we develop more therapeutics that will really - that are disease modifying that will really push us to try to find persons with the earliest, earliest stages of Alzheimer's disease possibly to the point where they don't even have memory loss yet so that possibly if we give the medication at that point in time they won't ever develop any of the clinical symptoms of Alzheimer's.

But in order to find that person, we really need a biomarker that gives us a certainty that we would want to give - introduce a therapeutic intervention at that point in time.

Right now the diagnosis is really made after the person has memory loss that can be really quantified and evaluated usually by neuropsychological testing which is called now mild cognitive impairment or where they have memory loss and decline in their function which is actually the clinical syndrome of dementia. So we're really right now diagnosing the disease in a much later stage than what we would like to in order to develop more disease modifying therapeutics.

And then the last one is really the gap and cure for dementia due to Alzheimer's and that is going to really include the first two about prevention and diagnosis, but really the push to develop disease modifying therapeutics that really begin to address the underlying pathology and the underlying cause of Alzheimer's. And those are also gaps we aren't quite sure why people with Alzheimer's disease - although we know that amyloid plaque buildup is really the primary pathology, it still isn't clear as far as when, and where, and why that disease process begins that pathway and finding that will help us to develop a cure or really more disease modifying treatment. So there's a lot of work to do.

You can go to the next slide. So again just talking about some of the gaps. So what causes Alzheimer's disease? Well we know that age is a risk factor, but age is not something that we can really affect at this point. Age is a significant issue for the United States because we have become -- our health care system is so -- has become very good with cardiovascular disease and cancers that people are living much longer.

We also have a fast growing aging demographic in the United States with the 85 and older group, but we still haven't answered the question of why about, you know, 40% of persons over the age of 85 might develop a dementia due to Alzheimer's. But there's still a significant number of people who do not. So

it's not simply an aging-related disease although age is a risk factor, we do need to determine why is it that some people as they age will develop memory loss and dementia due to Alzheimer's and others will not.

And once we get to that, we will be able to develop more focused therapeutics and interventions and again the idea about risk factors for all Alzheimer's and what can modified. As I said age is a risk factor, but it's not a modifiable risk factor so it's not as helpful to us as more modifiable risk factors.

We are beginning to find things that people can affect in their middle life that are good disease modifying risk factors such as high blood pressure, diabetes control, body weight, what their diet, and what their exercise lifestyle is like in their mid-life can increase or decrease their risk of developing Alzheimer's disease later in life. But we still do need a very large and long-term study in order to determine exactly what is the right recommendations we should be making to patients to reduce their risk of Alzheimer's, especially if they have a family history of Alzheimer's knowing that we have already put them in a higher risk category, what exactly should we be telling you.

We almost need what's called is almost a Framingham study for - a Framingham study for the brain. Framingham was the study that was done for heart disease that really gave us all the information that we needed on how to prevent heart attacks. We need something very similar for Alzheimer's disease as well.

And then for the next point about markers to identify Alzheimer's before any memory loss or symptoms show up and again that's where studies like the ADNI study which is a undertaking by several centers internationally and really focused in the United States to identify as early as possible markers of

the disease so that possibly therapeutics can be introduced even before any memory loss occurs.

And then again what brings out the symptoms of Alzheimer's? How much disease does it take in the brain for one person to start to develop memory loss? And that does seem to differ. We do see that education affects or high intelligence sometimes that person may (need) a greater disease burden of Alzheimer's before they may show symptoms or someone without that might show symptoms earlier. And we are also finding some health disparities between races and ethnicities as far as when the disease presents itself. That needs to be looked at more closely.

And again what are accelerators of dementia due to Alzheimer's disease? There is some research that we know that sometimes anesthesia affects or head trauma, medications can sometimes basically accelerate the symptoms of dementia and that needs to be studied further as well.

You can go to the next slide. So research for Alzheimer's disease, I know in my clinic and I'm sure Dr. Shah would echo this as well when patients come to our centers - our NIA funded Alzheimer's disease centers, they're really coming for accurate diagnosis and for the educational aspects. But they're really coming as well for the research that's available to them.

Being part of a research study even if it's the clinical core where there's ongoing surveillance of a person on a research basis versus a clinical basis can be very helpful to patients and families feeling as though they're either contributing or they're helping to find out more about a disease that's really affected their love one and their family greatly.

So I do find that when we discuss research with our patients, it does help with the alleviation of fears. It does provide some hope again that they're contributing to furthering our scientific understanding of the disease. They're also when they do participate oftentimes clearing the path. They're really taking a little bit of control over a disease that sometimes feels as though our patients don't have a lot of control over. I think when they do participate they feel as though they're taking a little bit more control over the disease process and giving direction to them as well.

Giving them something that they can do beyond the usual clinical path that we give them, but something else that they can do to contribute and to give them some direction as far as if they go through the journey of their disease.

You can go to the next slide. So again for the research that we need to do, we need to look at preventative strategy. What can be done to prevent the buildup of the amyloid protein changes in the brain, but also other research that would be possibly more psychosocial, such as how do you buildup brain reserve. And that's where a lot of the research that's been done on exercise and on brain exercises, crossword puzzles, music therapy, social interaction. That research is just as important as sometimes the basic science and medication therapeutic development that we do for prevention as well.

What do we do for - we also need to do research on the early changes prior to disease diagnosis. Again ADNI and other studies that are looking at early biomarkers so that we can begin to detect persons who have early pathological changes in the brain, but no memory loss are going to be a key group that will be focused on for some of the intervention strategies that may come up.

If we can begin to find those persons and then knowing what we can do to prevent them from going to the next step of memory loss or decline of brain

function is going to be key. So doing biomarker studies is going to be very important as well as how do you then at that point in time prevent the progression or transition of that disease into a clinical syndrome.

For early disease stage for persons who already have early mild memory loss, what therapeutics, what interventions can we do at that point in time to either reverse or halt the progress. This is oftentimes multi-factorial between medications and cognitive therapy, exercise therapy, lifestyle interventions, and other disease modifying agents that may be developed as well that would be given at this point in time.

For the late disease states where possibly at that point medications may not be as useful, we still do need research on how can we improve quality of life. End of life care I think still has a broad range or broad area of research that can be done there as well.

How to reduce caregiver burden. We have a large, you know, a large field of research now that's developed showing us that our caregivers are really an at risk population for developing their own disease sets not necessarily dementia, but other things like depression worsening, high blood pressure. They often become ill during the course of caregiving for someone so they need to be a focus of research as well.

You can go to the next slide. So I'm going to talk a little bit about what exactly is clinical research. So this is actually defined by the NIH. And clinical research is really research that involves a particular person or group of people and it uses basically either biologic materials or human beings in research. A lot of this research can include looking at mechanisms of human disease.

So in our particular -- for this webinar we're talking about Alzheimer's disease -- so for our clinical research we're talking about either persons that have Alzheimer's disease, persons that are at risk for Alzheimer's disease but also healthy normal controls that can be looked at for us to understand why some people develop the disease and some people do not. So what are the mechanisms of the development of Alzheimer's disease. We need both normal healthy controls as well as persons that are either at risk or have the disease itself.

We're looking - we need, clinical research is also the basis for development of therapies and interventions so all of our drug developments, clinical trials looking at not just prescription medications but things like fish oil supplements or vitamin supplements or dietary or lifestyle interventions. That's all considered clinical research as well.

And then studies that develop new technology related to the disease are also clinical research. So if we're looking at a new diagnostic strategy, if we're looking at a device that might be an intervention strategy, or any other technology that are for diagnosis or for treatment that would also be considered a clinical research as well.

You can go to the next slide. So clinical trials are something that we oftentimes get a lot of interest in. The Alzheimer's Disease Cooperative Study does do a lot of clinical trials as well as industry sponsored trials looking at a specific therapeutic agent for development.

So clinical trials are really used to determine whether a medication or some other intervention whether it's exercise or doing crossword puzzles. Are they safe, do they work, are they effective in the disease process? So as I said this

can include medications, it can include other interventions to modify the disease such as diet, physical activity, cognitive therapy.

So clinical trials are research with human subjects that are used to develop or evaluate clinical lab tests as well. So we might do a clinical trial looking at again like the ADNI study where we're looking at biomarkers. That is considered a clinical trial although it's looking more at what is a diagnostic biomarker and what is the best diagnostic biomarker for us to use to predict that someone has a risk of development of disease and also high probability of the development of the disease. So that person might have a disease modifying agent given at that time.

You can go to the next slide. There's some key points about clinical trials that I like to talk about with my patients. Clinical trials are very important. It does need to be clear that it's not part of a clinical treatment plan. Clinical trials are still research although in our Alzheimer disease centers we oftentimes are doing all of these things simultaneously. We're doing diagnosis and a clinical treatment plan, education, and also research aspects. The research and the clinical care is really separate, and we do try to make sure our patients understand that. They can refuse or they can participate in clinical research, and it will not affect the clinical care that they will receive.

But it also shouldn't be considered part of the treatment plan. Medication and standard of care for their disease process really needs to be separately discussed and then when they decide to go into a clinical trial fully understanding all the aspects of what a clinical trial is and what it means.

In drug studies and in other, you know, behavioral interventions there is a placebo arm. So patients oftentimes, that may be the first thing that they ask. If they're going to take the time to participate in a clinical trial what is the

likelihood that they may receive the placebo, or the sugar arm, or the non-intervention arm of the study.

Most clinical trials are 50/50 where about half of the persons going into the study may receive the agents and half of them may not, but some of the studies are two-thirds, one-third where two-thirds receive the intervention and one-third do not. But it's very important that that be discussed.

And they also need to know that really the clinician that they might be speaking to or the research staff they're speaking to really usually has nothing to do with which arm they would be assigned to. This is usually randomly done and it's also blinded.

Clinical research is a commitment of time by the participant, and as I said the caregiver as well and family members providing transportation, but also the fact that all of our clinical trials or most of our clinical trials ask that a caregiver or an informant be present at all of the study visits as well.

So the benefits are that they are participating and many of our patients feel very, very satisfactory about their participation. But they usually understand that it doesn't necessarily directly benefit them as an individual, but the benefit will hopefully come to the next person down the road.

You can go to the next slide. So some of the clinical research or ongoing studies that we have going on are some such as something for risk factors. So genetic risk factors are becoming a very strong area of focus in research for Alzheimer's disease. Actually there was just an article this morning in the New York Times about a new genetic discovery and Rush Center is participating in the genetics initiative that I have a slide on that I can talk about more.

For diagnostics as I've mentioned a few times, the Alzheimer's Disease Neuroimaging Initiative which is now called ADNI 2. This is in it's I think fourth phase of this, this is a study that I think it includes over 70 sites internationally looking at biomarkers to try to help physicians understand what might be the best diagnostic biomarker to help them with diagnostic certainty that the person presenting in their office with memory loss has Alzheimer's disease pathology in the brain.

And that study has also been very helpful because it also provided a very large amount of imaging and serum and blood analyses that were available to researchers across the country that are doing ongoing research that have really helped us to further our understanding of the mechanism and the diagnosis of Alzheimer's disease.

And for treatment studies, there's a few treatment studies going on. We wanted to talk about one in particular which is Resveratrol and that is basically a non-prescription medication, but basically a supplement form that again is a clinical trial that was going on as well.

You can go to the next slide. So the genetics initiative which is going on at Rush is a trial to determine which genes play a role in late life Alzheimer's and learn more about the cause of Alzheimer's and how to prevent it.

Blood samples are collected from the participants and for eligibility you have usually two siblings who developed Alzheimer's disease after the age of 60 and one other family member over the age of 50 with memory loss or a family member over age 60 with no memory loss. Participants can be anywhere in the United States and basically the trial history requires one encounter every two years for follow up.

You can go to the next slide. The ADNI study I talked about is really to look at body fluids, genetics, and imaging that may help predict who's likely to develop Alzheimer's.

Right now we're currently enrolling individuals over the age of 55 with memory concerns and no diagnosis of dementia. They're followed with evaluations including blood, urine, and spinal fluid, and brain imaging and memory testing every six months and both Rush and Northwestern are enrolling in the ADNI study currently.

You can go to the next slide. And this Resveratrol study which is going on at Rush is a study to determine if Resveratrol which is a dietary supplement is better than placebo in delaying or altering the deteriorations of memory and daily function in persons with Alzheimer's.

Eligibility is persons over the age of 50 with Alzheimer's who do not have diabetes or taking warfarin. And the duration of the study is ten evaluations over a 52-week or one year period. You can go to the next slide. And with that, I think Raj you're going to take over from here.

Dr. Raj Shah: Great. Thanks Diana.

Dr. Diana Kerwin: Thank you.

Dr. Raj Shah: I appreciate the work you did in presenting some of the very important information about the disease and also with the basic sort of clinical research and clinical trials.

So just maybe take a step backwards and try to look at the bigger picture. What I wanted to do now that we have some of the basic understanding in place which is what Diana provided, I wanted to talk a little bit about who needs to be involved in clinical research for AD and then to start maybe showing how we all have to be connected including the Aging Network.

So, you know, and fundamentally when it comes down to research and always we tend to think about is that the relationship which is like a doctor/patient relationship, but really it's between the researcher and their participant or subject. But in reality we know it's actually a much broader team that requires a lot more resources and efforts to link those two groups together - the researcher and the person participating in the study.

And from the research side, you know, with the researchers there's an entire bevy of teammates that have to be involved not only including research assistants, and coordinators, and education and outreach personnel but also all the individuals that regulate the research and make sure it's safe and it's doing its best to protect individuals who participate and that includes institutional review boards and then other agencies that help to protect human subjects in research.

And then from the person side, I don't think most people make the decision just by themselves although you want to respect their autonomy. They usually - it's a very complex decision with a lot of information and they usually rely on their family members to help in making that decision. They rely on clergy, they rely on their community leaders, they rely on other health professionals they work with. And through that somehow magically after a lot of conversations back and forth eventually we get it so that person signs a formal consent to be part of a research project.

Now to connect the person and the researcher apart from the research staff and the families, there's an entire other network that has to be involved and those are the sponsors of the research that are providing some of the monitoring and physical and oversight responsibilities for the study. There's the individual health care providers in the medical system that are essentially acknowledging the need for more information to hopefully help with better patient care in the future.

There's a need for diverse communities and their community leaders to really acknowledge the need for their communities for participation in research to make sure that we can get you answers and help improve people's health.

And finally I do think the Aging Network plays a huge role because in many ways the Aging Network sees a significant amount of older adults through their programs, their caregivers and are offering other services through that network. And if frontline individuals can recognize that somebody may be a potential candidate to participate in a study, if they've gotten their treatment or are looking for more options having that connector is a wonderful addition and needs to be continued to be strengthened. And so it takes this entire village approach to essentially get clinical research to work.

And a lot of individuals when I give presentations ask me, you know, what are the real barriers to us finding an answer to Alzheimer's disease. And for many, you know, they say it must be the money. It must be not having enough funds. And funds are part of it, but I don't think that's the main reason.

And then other people will say well there's not enough ideas. We don't have enough new novel thoughts as far as what we can do to intervene and I really don't think that's the issue. There's a lot of thoughts and ideas and

infrastructure in place to generate more modifiable risk factors and interventions to help.

What we've been seeing not only in Alzheimer's disease, but in every disease in cancer, in heart disease, in pulmonary disease, in various conditions, the fundamental thing that seems to be limiting what is happening with developing new interventions that become part of clinical care is getting people to be willing to participate in studies and to at least be aware of that as an option for them as they progress through their condition or are concerned enough to be worried for not developing a condition like Alzheimer's disease.

So we have to do a lot to develop these networks and relationships so that we can help connect persons who may be eligible to participate in research with researchers.

And really how can we work together? And I think that's been the fundamental goal of this work on a national level between the Administration on Aging and also with the NIA and with advocacy groups such as the Alzheimer's Association and others is how do we help start making and building these bonds and helping each other out. And what I'd like to do is maybe talk about it at a slightly more state and local level and that's really what can we do on a day-to-day basis.

And so one thing from a research center as Nina explained in her presentation, look at your research centers that might be around you because fundamentally they realize that in order to make sure people are aware of options and opportunities there needs to be education about clinical research and they're there to provide some of those inputs on some of the details of research participation like we're doing today and then also to help answer questions to individuals and their families.

And so, you know, that's where the research centers can really help you -- the Alzheimer's disease centers, the core centers, and research centers to make those connections with participant -- persons that you are providing care to or client services to so that we can be out there in front of them and explain what's happening.

And then from the Aging Network, I think one of the big things is if we can encourage people to be more aware in acceptance of participation research in AD prevention diagnosis and treatment that would be helpful.

The Aging Network is much larger in many ways than what we are as researchers and approach many more people in a day-to-day basis. And is there a way that we can just encourage some message that supports people to look at the options of research in a positive manner and to weigh the risks, the benefits, and the alternatives so they can eventually make the decision that's right for the client or the person and their family. And so that's the great thing about the Aging Network is that potential to be out to see many people.

The other thing that I think is really important that the Aging Network can offer is you will meet older adults and their families for reasons that might not even have to do with cognition. It may be that they're looking for other resources in their community to be able to access such as, you know, getting help with their - reducing their bills for utilities or it might be other issues that they're coming to see you for, for services on transportation.

But what we're finding is where the research world is going is earlier and earlier, we want to eventually get to individuals that might not even be aware that they are at risk for developing the disease. Might not even be showing any symptoms of developing memory loss, but those are the individuals where

we want to really intervene to help with prevention studies that might be coming down the line or creating better diagnostic tests.

And together, if we can work together to make some of these connections bringing the knowledge and expertise for both groups hopefully we can help them connect the researchers to the persons and their caregivers over time.

And so what I thought in the next slide if I can give an example is a case example of maybe of a research project that's been ongoing nationally where there may be some options for some connections and I can give some examples locally as Rush is one of the centers.

So what I'd like to talk about briefly is a study called the Aspirin in Reducing Events in the Elderly study. It's a fundamentally simple question, but one that hasn't really been addressed. Aspirin is the most used medication worldwide. Many individuals will go to their local Walgreens and buy the bottle of 300 capsules of, you know, tablets - those little tablets of aspirin that cost less than \$5. And aspirin in many ways has done remarkable things for preventing a secondary heart attack or stroke when somebody has it.

And we have some data in people that are younger in their 40s and 50s that if you have risk factors for developing heart disease taking an aspirin can be beneficial at a low dose.

But the biggest users of aspirin are older adults and I was surprised as we got involved in putting the project together in a grant to the National Institute on Aging was that we haven't really fundamentally answered this question. If you're a healthy senior, if you're 70 years old and you're listening to the news where every week they're changing the recommendation on whether it's

beneficial to be on low-dose aspirin for preventive purposes or it can potentially cause more harm by bleeding, what decision to make?

And when individuals go to see their doctor - an older person goes to see their doctor and says, you know, hey doc, you know, I'm 70, I'm healthy should I really be taking a baby aspirin every day? Well the doctor's just helping to take information from what we currently have about the person and what we have data about to make the best decision. But it's not a fully complete decision that we have. We don't have enough data. And so the idea behind this was to actually conduct a clinical trial where half the group would get -- they're all healthy, but are over age 65 -- where they would get either an aspirin a day or a matching placebo and be followed over the course of five years on an annual basis in person and then with three-month phone calls to make sure that they're doing okay.

And we needed to see. We actually answered this question. If we look at the next slide what we found is we would need to follow over 19,000 healthy seniors. Now the plan to do this was to recruit about 13,000 in various centers in Australia and 6000 in the United States and this study was felt to be important enough in peer review process that it was sponsored by the National Institute on Aging. And really what was a unique feature of the study in the United States was to make sure that we included enough individuals to make the results identifiable to all Americans.

One of the things that's happening is that we have to realize that the United States and the aging population is getting more diverse and diverse over time. Unfortunately in most studies that are done with new treatments they exclude people in the older range of age so the people that might be using it the most, the fastest growing population, people over age 85, we may not have data as far as the medications, benefits, effects.

The second issue that might be happening is that we're not able to include all older adults. So whether they be African-American, Latino, Asian, Indian, American Indian, Eskimo, you know, we need to include all Americans so that when any American goes to see their doctor after the study is completed there will be results that can be referred to that population so that we can answer the best question for everybody.

Now this study is being done at 30 centers across the United States and more information can be found at the Web site that's included on this slide. But with that in mind what was really a difficult piece was to be able to - how do we get out in the United States to be able to make relationships so we can get the healthy older adults that might be willing to participate in the study.

And so on the next slide what I wanted to give is some information about how we started to maybe work together to put in this place. So some of the things that we as a research center did in the local Chicago area was to be able to make sure we could have a presentation about healthy aging and what we're understanding about it. What could help people to maintain disability-free longevity and to make that available throughout our community contacts.

And we made sure we were able as investigators and researchers and our staff was to be able to give community presentations and to answer questions one on one with a participant in their local environment where they might not be so intimidated by being in a hospital setting. And then we wanted to try to make it easy for people to access research options by talking with us and if they showed interest to finding out more when they met with us in their own territory and neighborhood.

And what we were able to do in the Chicago area is to actually - a strong community group for us was actually the senior centers that were run in the City of Chicago by the Area Agency on Aging that serves the Chicago area.

And in the next slide if we look at that, we essentially - we worked with the City of Chicago to really work with their frontline staff to at least get us in so we could evaluate individuals and come for presentations. So most centers on aging and in the Aging Network have these opportunities where older adults can come and get some education and information and we were able to link into that network and to work with community leaders to break down some potential barriers.

And then if we go to the next slide and I think by going together what we found is working in the Chicago region with the senior centers was that we needed to really start communicating between the leaderships of both what works and does not work. So like is it better to have our presentation after a health fitness class that was going on at the center to hopefully have more people present and then to be willing and consider a presentation.

And then also figuring out better ways that we could link the caregivers and persons at risk for AD and persons with AD to each group whether it be the resources in the Aging Network based on presentations at other places and then for the Aging Network to interact with us.

So if we go to the next slide. So how can we actively connect? Well, you'll be hearing in the next presentations about TrialMatch and ADEAR. So I'll leave that there. Nina in her presentation listed another option that was available which was the Alzheimer's Disease Information Network sponsored by the NIA Alzheimer's Disease Cooperative Study group and then there's also clinicaltrials.gov.

If we can go to the next slide. And here we just wanted to finish up and allow the other presentations to have more time and we included our contact information. So we appreciate your attention and look forward to hearing the other presentations.

Amy Wiatr-Rodriguez: Great. Thank you so much to both Drs. Kerwin and Shah. And our next presenter is Jennifer Watson with NIA. Jennifer?

Jennifer Watson: Good afternoon everybody. I'm Jennifer Watson from NIA and I'm the Project Officer for our Alzheimer's Disease Education Referral Center which we refer to as ADEAR. And I'm here to talk about some of the tools and information available to help people find out about participating in research to help make that connection between people, and families, and caregivers with research options as Raj and Diana were so eloquently speaking about. So we want to provide some of the tools to help make that connection.

So if you were on the webinar last month, I showed the ADEAR Web site which you see here. And as the lead federal agency for Alzheimer's research, NIA has a mission to keep the public informed about all aspects of the research and to connect people with the disease and families to available resources including clinical trials.

So as you can see here we feature research centers, the Alzheimer's disease centers that Nina spoke about, a clinical trial search function, and a way to sign up for email alerts to get regular updates about trials that are happening.

We're of course all very eager to better connect the Aging Network with information and resources to help people with Alzheimer's and other

dementias, their families, and others to find and participate in clinical trials and studies because literally research cannot move forward without them.

So today I just want to briefly show you our Alzheimer's clinical trials database is another tool you can use along with several other NIA and NIH supported resources.

Next slide. A good jumping off point for information on participating in Alzheimer's trials and studies is here on our research topic page on the ADEAR site. So this is just providing an overview and kind of a portal to a number of resources. So users can find links here about research and participating in trials, web content, publications, news, and related organizations, as well as links to clinical trials databases to find open studies.

And I just particularly wanted to highlight this fact sheet that NIA publishes called Participating in Alzheimer's Disease Clinical Trials and Studies. And it really gives a nice overview of what clinical trials are, why volunteers are needed, what the terminology means, what questions potential participants and caregivers should ask, how volunteers are protected, and more. And it's just kind of a handy piece to have and it's available free from the ADEAR Center and we would be happy to send you bulk quantities for you to have on hand for your users.

Next slide. So this is the ADEAR landing page to search Alzheimer's trials and visitors to the ADEAR Web site can go here to find current Alzheimer's, MCI, other dementia, and related clinical trials searching by specific geographic area or eligibility criteria or to find trials that are testing specific drugs or interventions including behavioral interventions or caregiver studies. So this database will - through this database they will get full information

about the trials that meet their criteria and it includes site contact information for each of the trials.

So you can see that there's a map. You can click on the state, you can use the search bar in the bottom right, you can look at new or featured trials. We're really trying to give people lots of different ways to find the trials that meet their criteria.

Right now there are more than 50 trials and studies in the database that are actively recruiting participants in the U.S. from large multi-site studies like the AD Genetic Study that Diana mentioned or the Alzheimer's Disease Neuroimaging Initiative -- ADNI -- which she also mentioned to drug trials conducted by NIA grantees and private companies to smaller pilot and behavioral studies.

So you can also sign up for email alerts as I mentioned before and we're also just launching an RSS feed so that people can be notified when new trials are added. So we're just refreshing this whole part of our site and are testing it this week so it will be fully available in the next week or so.

Next slide. Here is what a detailed page for each trial looks like. It's a lot of information to help a user learn more about the purpose of the study, what's being tested, the eligibility criteria meaning who can participate or what might exclude from participating, where the study will take place, how long it will last, and who to contact at each local study site to find out more.

We hope that by providing this information in a clear user-friendly way potential participants can make well informed decisions about participating in a particular trial or study or so that health care professionals have enough

information to talk with patients and make recommendations about participation.

Now I just wanted to point out that this is kind of an overlapping, but a different approach than the next service you're going to hear about - TrialMatch through the Alzheimer's Association. TrialMatch does more of the work of finding trials that match a person's eligibility criteria and we as the federal government aren't able to collect information about the person. So we're taking a different approach, and I think that both of those approaches work differently for different people. Some people like having lots of information up front and other people prefer to have more support and better help with matching themselves up to a particular trial.

But I think these are compatible, and we all have the same goal of helping the right people find the right trial for them and in promoting the progress of Alzheimer's research to find treatments or ultimately a cure.

Next slide. I also wanted to mention the very large NIH database clinicaltrials.gov. [Clinicaltrials.gov](http://clinicaltrials.gov) is the database that powers a lot of other clinical trials databases. It's a registry for clinical trials in the U.S. and around the world. With a few exceptions like pilot studies or non-drug trials investigators are required by law in the U.S. to register their trials here. So it's a fairly comprehensive database and it includes both ongoing and completed studies.

But because it's investigators who are posting the information, the records often include a lot of medical and scientific terminology at this point. So it's a huge database, it's very searchable, and it can be a little bit overwhelming for people who are really trying to find specific kinds of trials. So many specialized clinical trials databases including the ADEAR database and

TrialMatch retrieve information from clinicaltrials.gov as a source and then tailor the information to be more user friendly for the public. So I just wanted you to see sort of the source information.

It's pretty easy to search clinicaltrials.gov with the basic and advanced search functions which you can use to find trials by location, eligibility criteria, phase, etcetera. So it's a really good resource if you're looking more broadly.

Next slide. Another NIH resource that I really wanted to let you know about is called NIH Clinical Research Trials and You. This is a new initiative from NIH as a whole. So over the past couple of years recognizing that we share some of the same problems with recruiting participants to clinical research, many NIH institution centers came together to talk about raising awareness of clinical trials more broadly with the public and with health care providers.

Some upfront research shows that generally the public didn't know a lot about clinical trials or how to participate. But once they learn more, their impressions were positive.

So NIH has launched this large collaboration and campaign to promote research participation awareness and so far the efforts include a Web site which you see here. It's clinicalresearchtrials.nih.gov. And it incorporates personal stories and videos from participants in research including a great video that we were just able to upload from a volunteer at UT Southwestern Alzheimer's Disease Centers and also stories from researchers about their experiences in participating in and conducting research. So there's a real personal aspect to it that I think is persuasive to people who may not know a lot about research participation and what it might mean for them.

The site also includes links to general and population and disease specific information about clinical trials and they also have developed a few promotional materials like posters, flyers, and slides that can be downloaded and used in local sites. So there is also one as you see here on the slide that is a poster and flyer that are focused on Alzheimer's disease.

So the intent going forward with this initiative from NIH is to partner with organizations, research centers, and health care providers, and local communities to carry this message forward. And in recent developments, AMA has come on board as a partner and we're looking forward to expanding this effort to sort of lift all boats. So, you know, raising awareness across the board about participating in research and clearly the Aging Network would be a key part of that effort. So if you're interested in talking further about working together on the senior community, I would really be happy to talk with you further about this initiative.

Next slide. And then finally one last NIH resource that I, or tool that I wanted to let you know about is called researchmatch.org. And it's sponsored by the Clinical and Translational Science Awards or CTSA Program at NIH. And this is a registry that you can sign up and get some information about yourself and researchers who are conducting studies that need people like you can contact you directly about their study. So it's sort of bringing people who are possibly interested in participating in research together with researchers who have studies and matching them up together over time. So it's an easy tool for both to use and it's available and I would recommend taking a look at it.

So - next slide please. If you have any questions, please feel free to contact me through the ADEAR Center and the toll free number is here or the email address. Thank you so much for your time.

Amy Wiatr-Rodriguez: Great. Thank you so much Jennifer. This is Amy again and just in the interest of time, I think we're going to try to move right into Martha Tierney with the Alzheimer's Association. We do have a couple of questions that have come in, but I think maybe some of those questions might be answered during Martha's presentation as well and then we'll review the questions at the end of that as well opening up the call - the audio line. So if you'd like to go ahead Martha.

Martha Tierney: Okay. Thank you. And I can go probably pretty quickly. I can't imagine a better series of presenters to follow. So the Alzheimer's Association TrialMatch Program is a service that was launched in July 2010 in an effort to make clinical trial information more accessible to patients, caregivers, and to health care professionals.

Next slide. So it's our clinical trials matching service, we match individuals to clinical trials and then the other piece that we do is that we make sure that they're educated about any other Alzheimer's Association support programs and services that might be beneficial to them.

Next slide. So the prior presenters made a strong case that we need participants in order to move the science forward. The Alzheimer's Association's vision is a world without Alzheimer's. So efforts to get people into research are critical to that.

Another objective is to obviously increase the number of individuals enrolled in trials and studies and then also to provide the education and information that's understandable to the public and families and health care professionals.

And also the fourth piece is to educate caregivers and people with dementia about the Association support programs. That can range from sending them

basic print material about dementia to referring them to support groups nearby them. We have a lot of early stage engagement programs that we can link people to and then we have some safety services as well through the Association.

Next slide. So a quick overview of how TrialMatch works. People can go onto the TrialMatch Web site and there's a slide that has that coming up later. They'll go onto the Web site or they can call us and they can complete a profile either as a person with the disease, a healthy volunteer, or a caregiver. And physicians can go onto the TrialMatch Web site and view all of the trials in the database as well.

So once a person has completed their profile, that database then takes their information and compares it to the match criteria that's housed in the database and then it will present a list of trials that are potential matches.

Next slide. From that list of potential matches the individual can select the ones that they're most interested in and then they can connect with the TrialMatch Coordinator to get some more details about it and get some of their questions answered.

It's important to know that the system will match people to trials all over the country. So someone might be in Chicago and they go through their profile process and there's a list of 20 matches some of which are in Arizona and some are in Massachusetts. You know, there are some people who might travel that far for trials so we wanted to cast kind of a wide net and then let people determine for themselves what they're capable of doing.

And then number 4, over the following weeks and months TrialMatch Coordinators will follow up with the constituents to assist with any challenges

or questions that might come up. People run into bumps along the road. They may have a hard time getting into contact with the trial site or they may need help bridging that conversation between the trial site and their doctor and our follow-up calls can help with that. And then also when we follow up with people, we learn a lot about outcomes. Who got enrolled in a trial and what the process was like.

So as was mentioned earlier in the presentation constituents bring a lot of hope with them when they contact us. And the conversation that they have with our TrialMatch Agents helps them get any of their questions answered. We do a lot of kind of debunking of myths. It can be a tricky thing to work with that hope. The reality is that not everyone can match to a trial so the other piece that we are proud of is that we can link those people who might not match to a trial to our other programs.

Healthy volunteers who contact us, they can get a sense of empowerment. A lot of the healthy volunteers may have lost loved ones to the disease and they are searching for something that they can do to contribute and participating in research is something that's really important that they can do.

You can go to the next slide. So what does the TrialMatch database contain? The types of trials are mostly Alzheimer's trials, but also related dementia and mild cognitive impairment trials, some pharmacological and non-pharmacological studies, and we have trials that are in the U.S. and Canada. And as I had just mentioned, the questionnaire types -- the profile types -- are person with dementia, caregiver, other people filling something out on behalf of the person with dementia, or a healthy volunteer. There are approximately 140 trials in the database.

Next slide. This was also covered earlier in the presentation. The types of trials in the database: treatment trials, diagnostic studies, prevention trials, screening studies, and some quality of life studies. Those quality of life studies look at different ways to improve quality of life for people who have chronic illness or their caregivers or family members. I think Dr. Kerwin brought up the fact that a lot of caregivers can come up with their own health issues because of the stress of caregiving.

Next slide. Our listings come from clinicaltrials.gov and some come directly from researchers. We have a vendor that operates the database and manages that process. They go through clinicaltrials.gov and they vet all of the information for each trial to make sure that the TrialMatch database has current and updated contact names and numbers for the trials.

Next slide. So who can benefit? We all can benefit ultimately because we need to move the research forward so we can get rid of this terrible disease. Okay.

Next slide. So we're a friendly face ready to have a conversation to help people get linked up with research. We take people and they enter their criteria and they can get matched to trials. Let's see the captain picture. It's easy to navigate and then it's free.

The next slide. So we're funded by the Alzheimer's Association including all applicable studies and we don't have any preference to any sponsors and there's no fees. And the next slide has our contact information. I will finish up there.

Amy Wiatr-Rodriguez: Great. Thank you so much Martha. And thank you to all of our presenters today who shared such wonderful information. I'm going to ask our

-- since we do have a couple of minutes left -- ask our operator if she could get on and give the instructions for people who have an audio question. We also do have a number of questions that have come in through the chat feature. So after she gives the instructions while people are queuing up, we'll try to answer some of the web chat questions that have come in. So Gwen.

Coordinator: Thank you. At this time if you would like to ask a question, please press star 1. Please record your first and last name when prompted. To withdraw your request press star 2. Once again to ask a question, please press star 1. Please state your name slowly and clearly. Thank you.

Amy Wiatr-Rodriguez: All right and while we're waiting for those questions to line up, we had a question come in on the web chat from Tina who is asking for most clinical trials do participants need to live in the same state as the researcher? And I think that that was answered somewhat in the presentation, but if somebody would like to address that and confirm that again.

Woman: Well I think as Martha mentioned people are willing to travel for various trials and they have family members who live in other states and I think it's more up to the participant to assess whether that will work for them. It's not a requirement to live in the same state, but you do have to come for specific clinic visits.

Amy Wiatr-Rodriguez: Okay. Thank you. Another question came in from Jennifer who asked if the ADEAR search includes state level trials. In other words, ones supported by local foundations, universities, etcetera, that wouldn't be part of federal funding. She's wondering if there's one source that has all possible trials in one place.

Jennifer Watson: Yes. The ADEAR search includes everything we can find in clinicaltrials.gov plus any other studies that we can get information on and we are eager to have local foundations - state or local organizations submit trials to us. We would gladly put them in.

Amy Wiatr-Rodriguez: And I'm wondering if similarly on TrialMatch, I don't know. Martha is there - you mentioned that there is a way that if people are aware of other studies they are able to submit that as well; is that correct?

Martha Tierney: Right absolutely. So anything that's in clinicaltrials.gov is going to be in TrialMatch and then any researcher is welcome to contact us to get their trial on our database whether it's on clinicaltrials.gov.

Amy Wiatr-Rodriguez: Okay. And let me check in with our operator. Do we have anybody who's lined up to ask an audio question?

Coordinator: At this time there are no questions.

Amy Wiatr-Rodriguez: Okay. We still have - I know it's right at the hour, but we do have a couple of other questions that came in through the web chat. Let me see if I can find these. We have a question from Dolly asking about a particular - it sounds like a particular research or potential project going on. She's wondering if they are in there in any of the systems. I'm wondering if maybe if especially Jennifer and Martha if you could respond. Are people able to kind of look up and see whether the, you know, how different researchers are on? Like how they are listed or are there ways to check by state or whatever in terms of the various research studies that are in the systems?

Martha Tierney: In the TrialMatch database, there is a way to just look at all the trials. You would go to the TrialMatch Web site and then it prompts you. If there's a field

that says I am a new and you select from a dropdown. If you select I am a physician, the next page will give you an option. In the top bar you click on view trials and it shows every trial in the database. TrialMatch@alz.org is the email address and we'd be happy to look up a specific trial if you want to email that question.

Amy Wiatr-Rodriguez: Okay.

Jennifer Watson: And in the ADEAR database similarly the specific trial could just be searched or you could email ADEAR and we can help track down whether it's in the database or whether it could be added.

Amy Wiatr-Rodriguez: Okay wonderful. And let's see. There's another question that's come in about an article that was on CNN - CNN blog site or something about a rare genetic mutation protects against Alzheimer's. I guess this was a recent news article out there that one of our attendees is wanting to share about. I'm wondering if any of our panelists have any comment or anything that they'd like to make if they're aware of what that article is.

Dr. Diana Kerwin: Right. I don't know if you saw this morning. Yes, it was an Icelandic study that found a mutation that seems to be related to risk of Alzheimer's. So it's again I think just underscores the importance of the genetic research that we still have yet to do and each discovery in and of itself is very -- is wonderful and amazing, but I still think we -- there's still quite a bit of genetic information that needs to be collected. And I know that such as in ADNI they are doing a complete genetic analysis as well again looking for more of these genetic factors that will help further our understanding. But that was an article that was just released I think this morning in Nature.

Amy Wiatr-Rodriguez: Okay great. And I know we're running just a little bit over now. I think we'll pick one last question and maybe those of you who have sent in other questions we can try to respond to you afterwards. Just recognizing everyone's time. But the last question is from Tina again and she was asking do clinical trials last for one year or less or does it depend on the project.

Dr. Raj Shah: So this is Raj at Rush. So a great question, and I think the key answer is that every trial is different and has a different range of links and number of visits. But that's one thing that's always reviewed either on the sites or when you talk with the study staff. It's an important question to ask so you understand all of the time commitment and that information is always usually available even in the informed consent (or) in a study so. I hope that answered the question.

Amy Wiatr-Rodriguez: Okay great. Well unfortunately I think that's going to be the last question that we can take today. I want to thank everyone who's participated on today's webinar and especially to our speakers. Thank you to everyone who's asked questions to help us understand all the information that we've received today.

If people do think of any additional questions, if you have suggestions for future webinar topics, or if you'd like to share feedback on whether this webinar was helpful to you or not good, bad, or different suggestions for what we could have done to make it be better we do want to hear from you to kind of help us for future efforts.

You can email any questions or feedback to us at my email address. That's amy.wiatr@aoa.hhs.gov. We do want these webinars to be as useful as possible so please do send any suggestions you have. Again thank you all for

joining us. We look forward to having you with us for future events. This concludes today's webinar.

Woman: Thank you Amy.

Woman: Thanks Amy.

Amy Wiatr-Rodriguez: All right. Thank you everyone. Bye bye.

Woman: Bye.

Coordinator: This does conclude today's conference. Thank you for attending. You may disconnect at this time.

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