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Meaningful Lives As We Age

The 5-Cog Paradigm: An Innovation to Improve Detection and Management of Impaired Cognition in Primary Care

Applications from the GSA KAER Toolkit for Brain Health
Momentum Discussions Podcast from the Gerontological Society of America

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Announcer:
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Jen Pettis:
Welcome to this GSA Momentum Discussions Podcast episode titled, *The 5-Cog Paradigm: An Innovation to Improve Detection and Management of Impaired Cognition in Primary Care*. Momentum Discussions highlight topics experiencing great momentum in the field of gerontology. We are grateful to Genentech, Lilly, Eisai, and Otsuka for their support of the *GSA KAER Toolkit for Brain Health* and today's podcast episode. My name is Jen Pettis, I am the Director of Strategic Alliances at the Gerontological Society of America (GSA), and I am pleased to serve as the host for today's Momentum Discussion. I am delighted to be joined by Dr. Joe Verghese, a professor in the Saul R. Korey Department of Neurology, the Murray D. Gross Memorial Faculty Scholar in Gerontology, and the Chief of the Divisions of Cognitive and Motor Aging at Albert Einstein College of Medicine. He is also an attending physician in the Department of Neurology and the Chief of the Division of Geriatrics for the Montefiore Health System.

Jen Pettis:
Earlier this year, Dr. Verghese and his colleagues reported the results of the 5-Cog study in Nature Medicine. This study was funded by the National Institutes of Health's (NIH's) National Institute of Neurological Disorders and Stroke in collaboration with NIH's National Institute on Aging. The 5-Cog study is part of the Consortium for the Detection of Cognitive Impairment – or DetectCID. I am delighted to have this opportunity to chat with Dr. Verghese who led the 5-Cog study.

Dr. Verghese:
Thank you very much, Jen. It's a pleasure to join you today.

Jen Pettis:
Dr. Verghese, in the paper recently published in Nature Medicine, you and your colleagues discussed barriers to implementing routine screening and related care processes in primary care. What are some of those barriers?

Dr. Verghese:
The rapidly aging population in the U.S. and throughout the world has resulted in a rise in the number of age-related diseases, including dementias, like Alzheimer's disease, and cognitive impairment in general among the older population. Most patients who have cognitive concerns or cognitive impairment are seen by primary care physicians, which is where most dementia diagnosis takes place. Varying surveys indicate that in up to 50% to 80% of dementia cases, the diagnosis is missed in primary care clinics. Many barriers account for this. The barriers are found at the level of the screening instrument, the primary care physician, the patient, and the healthcare system.

There are multiple barriers to cognitive screening and associated care actions in the primary care setting. Screening instruments are lengthy and require specialized training or personnel. Many require clinicians to administer these tests, and many are not free. Another major barrier is that when the clinician has completed these screening tests and a normal or abnormal result is indicated, there's often no guidance on the next steps that the clinician should take. The United States Preventive Services Task Force (USPSTF) suggested in their recommendations, from a year or two ago, that there was no evidence for either the benefits or harm of doing routine cognitive screening in older patients. A big difference between those recommendations and our study is that we focused on patients with cognitive concerns, a large population of up to 40% in our primary care settings, a population not targeted by the USPSTF recommendations.

At the physician level, primary care physicians are too busy. They don't have time to do elaborate screenings and often struggle with multiple priorities. It's said that on average in the U.S., a primary care physician gets to spend between 15 to 17 minutes with a patient, during which time they address up to six medical issues. A patient might have come with a sprained ankle or a cough, and then you're adding on cognitive screening and dealing with that in a limited time. At the system level, our systems don't account for the rising tide of cognitive concerns and impairment among older patients. While there are some preliminary attempts to enable clinical screening and appropriate reimbursements, it's not widespread. It's not available in all centers. These are some of the multiple barriers to cognitive screening and associated care actions in the primary care setting.

Jen Pettis:
Dr. Verghese, next, can you address the unmet needs around detecting cognitive impairment in Black and Hispanic individuals in particular?

Dr. Verghese:
That is a serious problem and concern. Most cognitive tests and screening instruments have been developed in Caucasian populations. They are inappropriately applied to underserved minorities like African American or Hispanic populations. For instance, a widely used cognitive screening test in primary care, the Montreal Cognitive Assessment (MoCA) showed that recommended cut scores developed for White populations were inappropriately high in Hispanic and African American populations. A lower rate of literacy in marginalized communities was another barrier in the screening process. In our population, we have a lot of patients who have a high school or less than a high school level education, and many tests require you to have a degree of literacy, thereby excluding candidates with low literacy.

Cultural differences and understanding are another testing barrier since examples used in the test items developed in one population may have a completely different meaning in another population. For instance, in our primary care clinic, test questions developed for White populations addressed cognitive concerns in these populations. The same questions used in Hispanic or African American populations were more related to depressive symptoms than cognition. A degree of cultural sensitivity needs to be applied. The approach to screening developed for communities with resources needs to be different than that applied to underserved minorities.

Jen Pettis:
How does the 5-Cog cognitive detection tool address those unmet needs you discussed and those issues with the underserved populations?

Dr. Verghese:
The 5-Cog takes less time. As the name suggests, it takes only five minutes to complete. It's quick; it's easy to train. We've trained community health workers, social workers, and undergraduate students to administer the test. It's been an easy process to train people. The 5-Cog is given before the patient sees the primary care physician. In a clinical setting, the screening can be done by a community health worker, a licensed practice nurse, or an administrative staff member. Office staff can also be trained to give it, reducing the burden on the primary care physician. The other important element to realize about the 5-Cog is that it is not just a screening test alone, it is paired with recommendations.

It's the 5-Cog Paradigm and the approach that we are promoting. Once a patient has the test, a series of recommendations are generated to guide the primary care physicians in the next step, thus eliminating another barrier. The 5-Cog questions are picture-based. The questions are designed to be applied to different populations. I've been asked if the 5-Cog test is only applicable to Hispanic or African American populations because in our clinical trial, we had over 90% representation from those communities. However, that's not the case. The 5-Cog is intended to be utilized by all populations, races, and ethnicities. Unlike many other cognitive tests, it is also applicable to underserved minorities.

Jen Pettis:
You mentioned the detection tool itself, the screening portion, was done before the patient met with the provider. Tell us about the elements of the 5-Cog, who conducted the test, and how it was conducted when the screening was used during this study.

Dr. Verghese:
The 5-Cog consists of three tests. The first test is called the Picture Based Memory Impairment Screen. This is a visual memory test. It consists of four pictures in different categories presented to the patient to identify. For example, the pictures may include a hand, a grape, and a bicycle. The patient is asked to identify each picture and then we give them the categories to cue them. For instance, after they've identified all the pictures, we would ask them which picture is of the body part, and they're supposed to say hand, or they are asked which is a fruit, and they're supposed to say grape. Once they've learned that, we put aside the pictures and move on to the other two parts of the 5-Cog.

The second part of the 5-Cog is another picture-based test where you match abstract symbols to numbers. They're given a series of symbols for which they have to write the appropriate numbers underneath, and we see how many they can do in 90 seconds. This is called a symbol-match test. This test is a non-memory domain because the picture-based memory impairment screen is a memory test, and people might have other non-memory impairments early in cognitive decline.

Over the last two decades, we realized there are non-cognitive manifestations of cognitive decline. Traditionally when we think of dementia, we think of it as a cognitive issue with memory problems and executive function problems. However, other non-cognitive manifestations have been described as poor sense of smell or hearing. An important marker is walking slowly. We've shown that people who walk slowly are at increased risk of dementia.

We proposed a pre-dementia syndrome that identifies people at high risk of converting to dementia called the Motoric Cognitive Risk Syndrome. The Motoric Cognitive Risk Syndrome is a combination of cognitive complaints plus slow gait. We capitalize on this finding to include slow gait as a screening test because we were identifying people with cognitive concerns. If you identified that they also had a slow gait, they more or less met the criteria for Motoric Cognitive Risk Syndrome. Those are the three tests. To identify Motoric Cognitive Risk Syndrome, we take the patient into the hallway and ask them to walk a fixed distance in different settings. It could be either 8 feet or 10 feet. We marked it on the floor, and they were timed walking this distance. We have cut scores that determine whether a patient walks slowly or not.

Similarly, we have cut scores on the Picture-Based Memory Impairment Screen and the simple match. After the patient finished walking, we brought out the pictures that we had shown before, and we asked the patient to recall them. If they can't recall the pictures freely, we give them the category cues. There's a scoring that's developed to account for how they get these, how many items they get, and how many items they need cueing on. The 5-Cog is those three tests. Abnormalities on any one test are enough to trigger recommendations because we believe that being abnormal on all three tests might suggest a high degree of impairment. We think it's important that even if you have abnormalities on any one test, that's good enough.

Dr. Verghese:
Before we implemented these tests in the primary care clinic, we had lots of consultations with primary care clinicians. The feedback that we received was that they wanted to ensure that they did not miss a true case of cognitive impairment. In other words, they wanted the tests to have a high sensitivity. To prevent a case of cognitive decline from being missed, our recommendation is that if the screening result is negative then the older adult should be retested a year later. When you're having patients with regular follow-ups, it's possible to miss a patient. The detection might be delayed for a year, but still discovered very early in the course of cognitive decline.

Jen Pettis:
You mentioned that the 5-Cog Paradigm combines the 5-Cog with an electronic medical record (EMR) embedded clinical decision tree. Can you tell our listeners about the paradigm and the outcomes of implementing it?

Dr. Verghese:
The 5-Cog Paradigm is the combination of the 5-Cog screening test, which are those three tests that I described, plus a set of electronic recommendations. Broadly, there are two sets of recommendations. There's either a screen positive, which means that you had an abnormal performance on one of those three tests, or a screen negative, in which case you cleared all three tests. The test is administered in our setting by a community health worker who gives the three tests and compiles the results into our electronic medical record system. We've worked with the electronic medical record system programmers to create an alert. During a patient visit, an electronic alert pops up on the primary care provider's screen notifying them of the patient's results of the 5-Cog screening paradigm test, whether the result was positive or negative.

If the tests were negative, the patient had no issues on all three tests, and the physician was informed of the negative results and the patient's cognitive concerns (because cognitive concerns were the reason that they were administered the test), in which case, we would recommend repeat screening in a year. If the test was positive, then there are a different set of recommendations. We would say that this patient was at a high risk for having either mild cognitive impairment (MCI) or dementia. It's important to know that tests like 5-Cog are not diagnostic tests, these are screening tests. They don't provide a diagnosis; they indicate that somebody is at risk. We were very careful in not saying that this can be used for diagnosis. That's the same with any other screening tests like the MoCA, Mini-Cog, and many other tests that have been developed. These are all screening tests.

Some of the recommendations we make are to consider assigning a diagnosis of either MCI or dementia after further testing is done, send the patient for further evaluation, or consider doing laboratory investigations to rule out causes of cognitive impairment. Dementia is not the only cause of cognitive impairment. Cognitive impairment concerns could arise because patients are depressed, have sleeping issues, or have anxiety. The primary care physician needs to consider these other possibilities. Finally, these recommendations were not prescriptions for primary care physicians. These were just recommendations so they could choose to follow up, given we were only doing a five-minute test. Most primary care physicians have been seeing their regular patients for years. They know much more about the patient than a five-minute test can relay.

Dr. Verghese:
However, they might not have had time to address some of these issues or the patient might not have expressed their cognitive concerns. This is a way of alerting the primary care physician and then guiding them if they need help in the next step. In our study, we had a positivity rate of about 40% on the 5-Cog. Of all the patients who were administered the 5-Cog, about 40% had an abnormal result on any one of those three tests. The primary care physicians took some action in about 40% of those patients. In the majority of the patients that had a positive result, they decided not to act. The reasons might be because they know the patient much better than we do. They took action, they noted the abnormality, but then decided that they knew what the reason was, and it was probably already being addressed or they had a plan to address it. It's important to note that primary care physicians use their judgment in making patient decisions, and this is just a way of assisting them in making these decisions.

Jen Pettis:
How was the patient acceptance and the clinician feedback about the 5-Cog Paradigm? I'm interested to hear what they had to say.

Dr. Verghese:
It's interesting. They had differing perspectives. For the patient, we went back and asked patients about their experiences. While the actual clinical trial was taking place, we did get informed consent from the patients, and then they went on to have the test. However, we didn't want to disrupt the clinician flow so as soon as the 5-Cog was complete, they went on to see their primary care physician. When we followed up with patients a few months later, many didn't recall taking the 5-Cog. In that way, I think it's a good thing because it wasn't an obstruction or a barrier. It's something that was done that they felt was part of the routine clinical procedure. Some of the patients who had the positive results did recall having the test done or the results they discussed with their doctor.

We didn't do a deep analysis of the harm that the 5-Cog could cause, but from our experience in administering it, nobody had a harmful effect. Nobody developed severe anxiety or had blood pressure problems from having taken the test. When we examined the primary care physician's notes, there was no mention of that, but it's important to note that when we did the test, we informed them that we were passing the results on to their primary care physician. The actual diagnosis of either MCI or dementia was done by the primary care physician taking into account the 5-Cog and other evaluations that they did. We didn't track the effect of informing the patient of the diagnosis, but other studies have shown that, if it's not done properly, it can cause harm in some patients.

When we designed the 5-Cog Paradigm we received integral feedback from the primary care physicians because we involved them before starting the clinical trial. We had primary care physicians on our team, which was a great help. I'm a neurologist, and I've done dementia care for over 20 years, but my care is done in a specialty clinic, which is a completely different world from primary care. Having primary care clinicians and primary care staff partners was very important to the success of our study. They helped design the way the 5-Cog Paradigm was administered. Most of them had very positive views and opinions about the 5-Cog and felt it helped their flow.

Jen Pettis:
Finally, Dr. Verghese, what's next for the 5-Cog? How can others use it in research and practice and what's next for the study team?

Dr. Verghese:
I should mention that the 5-Cog clinical trial that we completed had really impressive results, even if I may say so. The 5-Cog Paradigm improved dementia care threefold. The way we defined the study, dementia care improved by including new diagnoses, appropriate investigations for cognitive impairment, referring patients to specialists, and ordering prescriptions. The diagnosis rate went up about five or sixfold in the 5-Cog arm of MCI and dementia. Physicians also made other diagnoses like cognitive loss. The only outcome that wasn't different interestingly between the 5-Cog arm and the control arm were prescription rates. Even though the prescription rates were higher in the 5-Cog arm, only about 1% or so patients in the 5-Cog arm had prescriptions from primary care physicians.

I think there are quite a few reasons, which could include that the primary care physicians needed more time to evaluate the results and complete the series of investigations. They did refer a small portion of patients to specialists. They may have been waiting for the specialists to finish their evaluation or start treatment. There might be some physicians who do not believe that the currently available medications work. There might be many reasons for our current trial. We are trying to do a deeper dive into some of those reasons because as new diagnostic tests and therapeutic options for Alzheimer's and other dementia become available, this will be an issue. After all, in specialty clinics, we will only be able to deal with the tip of the iceberg of a growing dementia problem in this country.

We need to empower primary care for clinicians and clinics to deal with dementia, which includes ordering the right tests and starting treatments. This issue needs to be looked at in great detail. In order to address some of these issues, we have received funding from the National Institute of Health for a pragmatic clinical trial which we are doing in partnership with Indiana University. My co-principle investigator is Dr. Malaz Boustani, a geriatrician with an accomplished team of investigators. We will involve six primary care clinics in the Bronx and 16 primary care clinics in Indiana. We'll have a mix of urban, suburban, and rural area clinics. We'll have different populations, including African American and Hispanic populations on both sides, with probably more in the Bronx. We'll have rural populations in Indiana.

We are going to test out the 5-Cog Paradigm in a more real-world setting, which will apply to many parts of the U.S. and hopefully worldwide. Half of these randomized clinics will receive the 5-Cog Paradigm, which will be the cognitive screening test administered by community health workers before patients see their primary care physician, and the other half of the clinics will provide their usual care. We are going to compare these types of clinics that are assigned to both arms and see if our primary outcome of a diagnosis of MCI and dementia differs between them. But we'll also look at some of the other care indicators like, are physicians ordering the right tests for cognitive impairment. Are they doing referrals? Are they starting treatments for cognitive impairment? We started the clinical trial about a year or so ago. We've completed enrollment in two of the 22 sites, so we still have some ways to go, but we hope to complete the clinical trial by 2027.

Dr. Verghese:
In addition to this, we also have an implementation component of the clinical trial. We examine implementation barriers at the level of the clinic, the physician, and the patient to better understand how we can improve care in a primary care clinic. The final piece we are doing, which I think is important for studies like this, is partnering with health economist, Dr. Dustin French at Northwestern University in Chicago, to look at cost-effectiveness issues regarding the 5-Cog. Can we afford to implement the 5-Cog? The 5-Cog was designed as a pen-and-paper test but can be upscaled in digital apps or electronic systems by having made one major change to it. Instead of requiring community health workers to measure gait speed, we've substituted that with a questionnaire that assesses gait. The 5-Cog or the 5-Cog 2.0, as we like calling the current version, includes two picture-based tests and a questionnaire. It makes it even easier to administer in primary care settings.

Jen Pettis:
Dr. Verghese, Thank you so much for your time. Most of all, thanks to you and your team for this amazing work. Thanks to those who listened to this episode of the podcast, we hope that you found it informative and enjoyable. Thanks again, Dr. Verghese.

Dr. Verghese:
Thank you so much for having me, Jen.

Announcer:
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