Clinical Research Coordinator Workshop

Optimizing the Consent Process In Cognitively Impaired Volunteers

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3.21.2024

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Objectives

- Increase knowledge of the terminology and diagnosis related to cognitive changes.
- Identify common health conditions that affect memory and cognition and the implications these may have on study participation.
- Outline strategies for improved consenting practices in volunteers with cognitive changes.

Case study Mr. V

- Mr. V is an 84 y.o. retired attorney, recently diagnosed with mild cognitive impairment accompanied by his daughter who lives locally and visits him 5 days/wk. Records review-diagnosis is accurate. On Aricept x 4 mos, tolerating well. Daughter does the majority of the interaction and is interested in clinical trials at GT/immunotherapy. Consent given at the clinic visit is 40 pages. When the study coordinator calls him in follow up he states:

  "My doctor told me this treatment will help my memory and you are recommending it for me?"

- How should you proceed with the consent process?
- If he participates who should sign the consent?
- What are the issues with diminished capacity in this scenario?

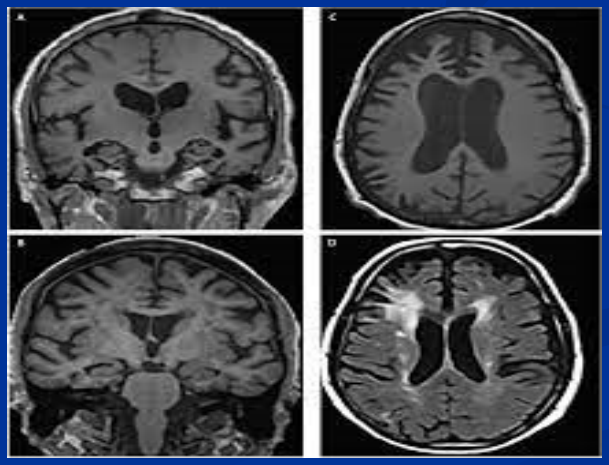
Typical Memory Changes with Aging

Subjective:

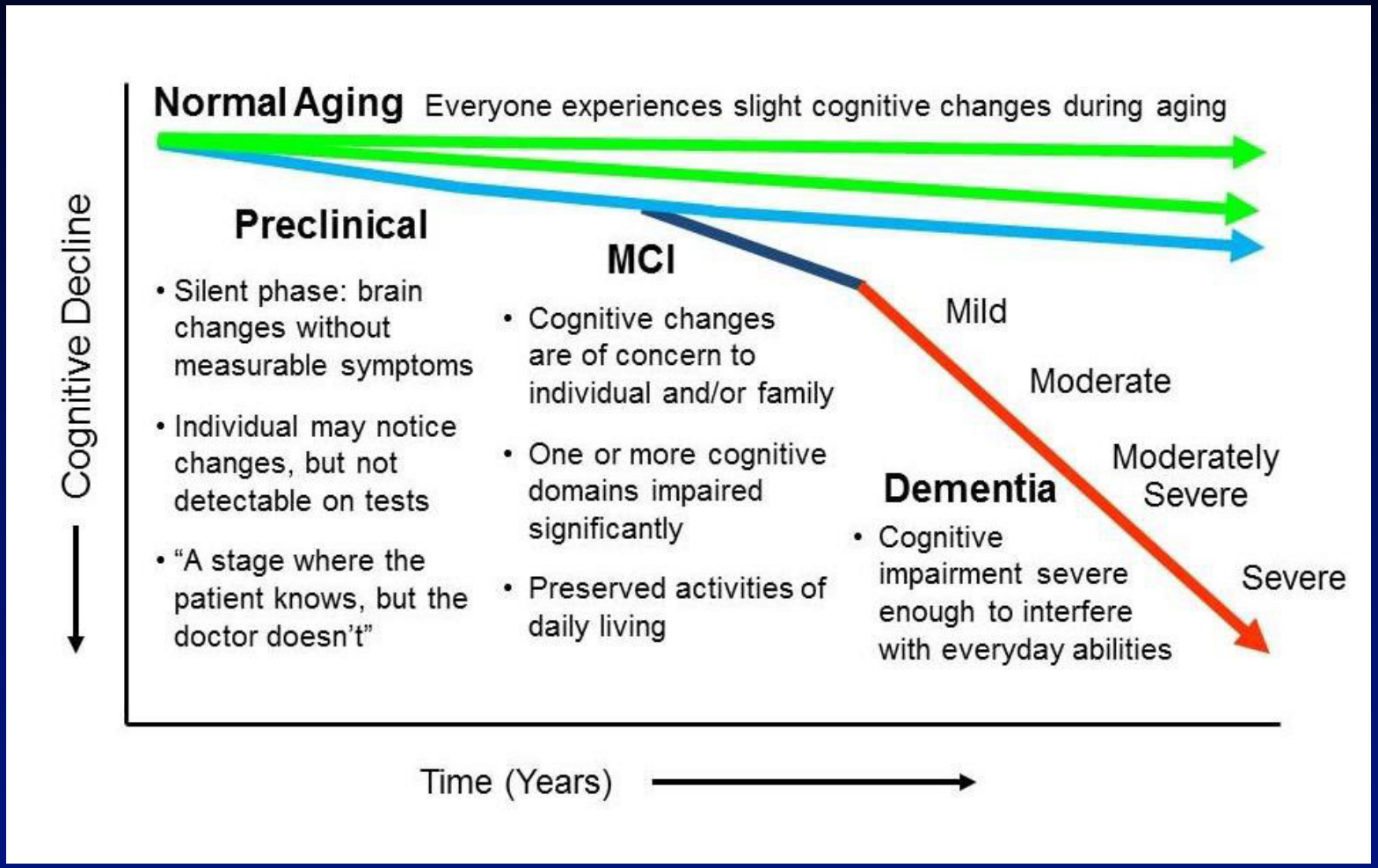
- Problem with remembering names and numbers
- Changes in attention (more trouble multi-tasking)

Objective:

- Slight decline in encoding
- Slight decline in retrieval (free recall and “finding a word”)
- Brain MRI –Atrophy and white matter changes



What is Mild Cognitive Impairment?



Why do I Need to Know about Mild Cognitive Impairment (MCI)?

- 16-20% of adults age 60 and older have MCI
- NIH policy initiatives to include older people in studies
- Cognitive deficits are often dismissed as normal aging.
- Patients may lack insight as to their cognitive changes (increasing risk for safety issues)

What are the Symptoms of MCI ?

- Memory loss noticeable to family and friends without clear functional decline
- Increased reliance on reminders, lists, prompts, ques
- Often very insidious in onset and can last 10-15 years
- Risk of conversion to AD is 5-15% per year, however not all cases convert

How is Normal Aging Different from MCI?

Criterion	MCI	Normal Aging
Subjective decline	Present or absent	Present or absent
Cognitive impairment by testing	Impaired for age	Normal for age
Independence in daily activities	Normal	Normal

MCI Types and Treatments

- MCI Subtypes classified by type and number of cognitive domains
- Amnestic type (repetitiveness) is most likely to convert to AD
- Other subtypes may be seen in vascular disease, diabetes, MS, parkinsons, TBI, depression, anxiety and many other diseases
- FDA approved therapy Leqembi for MCI (with biomarker evidence of AD pathology) not yet available at GT
- Many therapies in the pipeline, we need these volunteers!

Conditions Contributing to Memory Changes

Mental health issues- depression, anxiety, alcoholism d drug abuse

Illnesses & infections that stress your body (often a temporary change)

Endocrine problems (poorly controlled hypothyroidism or diabetes)

Medications- pain, bladder, benzo's (xanax), antianxiety (valium) (assess benefit vs risk) chemo

Insomnia- sleep is the7thvital sign!

Head trauma

Cognitive Evaluation

Primary care clinician, Geriatrician, or Neurologist

- History of problem, physical exam, bloodwork, vision and hearing referrals
- Basic cognitive test (MMSE or MOCA)
- CT or MRI Brain (looking for other causes, AD does not show up on these brain scans)
- Sleep evaluation if indicated
- Psychiatric evaluation if indicated
- Initial referral to Neurologist if indicated
- Neuropsychometric testing if indicated
- FDG PET scan or Amyloid PET scan and spinal tap if indicated

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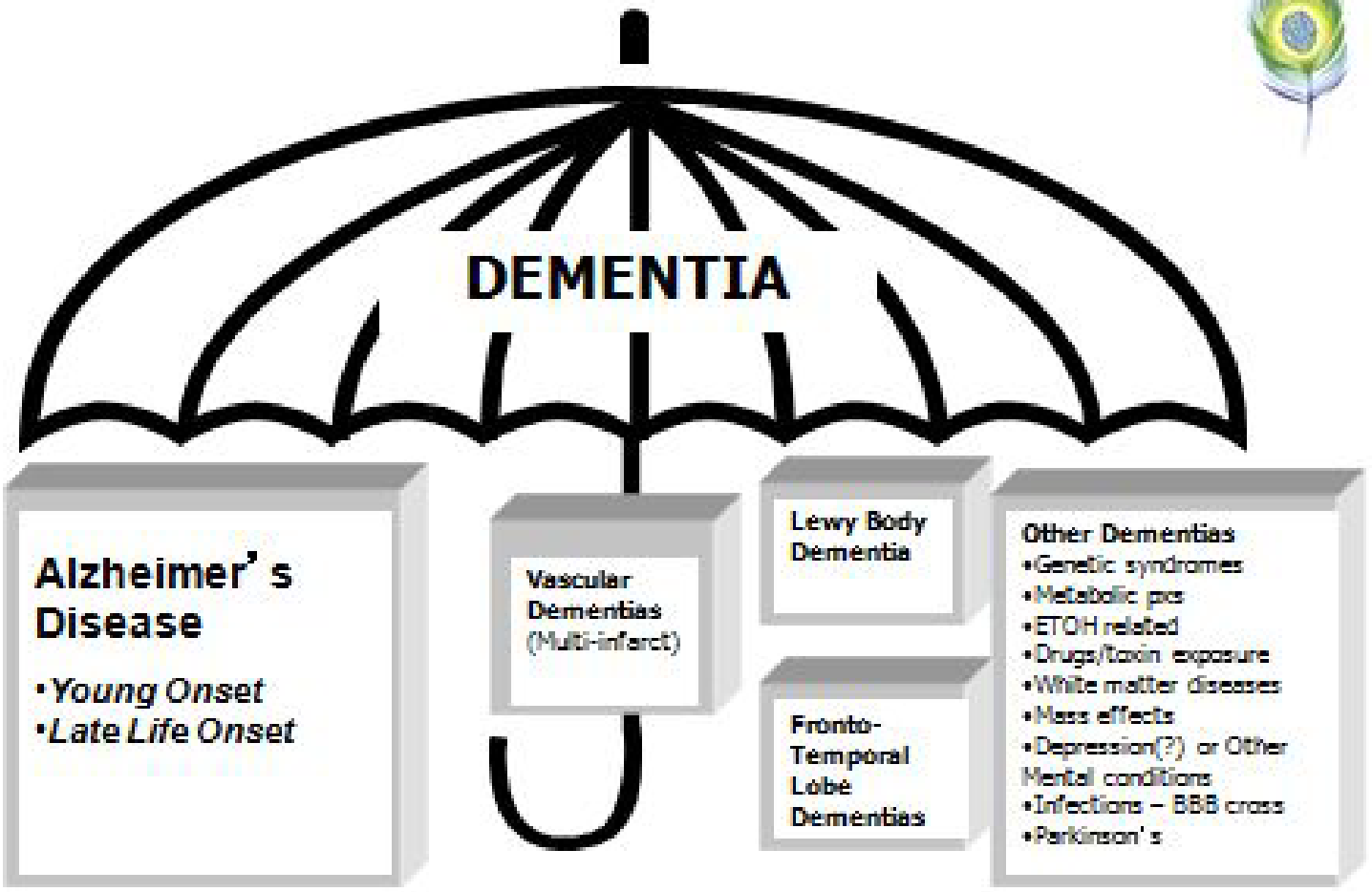

Consenting Volunteers with Cognitive Changes

- Determine where they fall on the spectrum of memory changes and the likely cause of the problem.
  - Interview with family and/or evaluation by clinician
  - Delay screening if it is an acute problem
- A diagnosis of MCI or dementia does not confer decisional incapacity.
  - Depends on the complexity of the study
  - Informant or study partner must be involved.
- Study must have IRB approval for including subjects with impaired decision-making capacity.

Benefits to Improving the Consent Process

- Respects autonomy
- Increases efficiency of the IRB
- Reduces legal liability
- Improves recruitment into studies

Strategies to Optimize Consenting

- Simplify the study materials for your targeted volunteers and study partners. (Consenttools.org *)
  - Plain language
  - Format the text so it is easier to read
  - Short paragraphs and short sentences (15-20 words in length)
  - Use an active voice
  - Avoid acronyms and abbreviations
  - Less is more, focus on most relevant
  - Use the same terms consistently
  - Increase the white space and margin space
  - Use “what will I do?” tables

*Bioethics Research Center (2024) *ConsentTools*. https//consenttools.org/

Engage Your Stakeholders

- Volunteers, family members, health care team
  - Involve an informant from the initial assessment
  - Ask clinicians to introduce the idea of research early on (newsletters, luncheons, websites, visuals)
  - Ask for feedback from patients and caregivers.
  - Don’t exclude complicated family networks, embrace them!
  - Obtain the medical record to determine if there is a diagnosed memory problem (and what type)
  - Be aware of items needed for sensory support (hearing aides, glasses)
  - Determine the volunteer’s level of insight for their diagnosis
  - Plan for multiple contacts: schedule extra time for reviewing consent with the PI or study clinician and family members.

Deliver Information Slowly

- Teach Back Method
  - Use a caring tone of voice and attitude.
  - Display comfortable body language and make eye contact.
  - Ask the patient to explain back, using their own words. Use non-shaming, open-ended questions.
  - Avoid asking questions that can be answered with a simple yes or no.
  - Emphasize that the responsibility to explain clearly is on you, the provider.
  - If the patient is not able to teach back correctly, explain again and re-check.

Teachbacktraining.org

(Healthcare Advancement IHA 2023)

Assess Comprehension

- The capacity to understand a study can be assessed by standardized tools:
  - UBACC form on consenttools.org
    - 10 items with scoring instructions
  - Institutions may have their own tools
- For studies with more risk consider involvement of a patient advocate who can provide an independent assessment.
- Document the decisional assessment results in the research record.

What is a Legally Authorized Representative?

- LAR is someone appointed to serve as a surrogate or proxy decision maker when the patient is unable or no longer able to provide informed consent.
  - A DPOA is a legal document appointing an LAR for Health Care and may also include finances.
  - Some states do have specific forms for appointing an LAR for medical research, but usually a DPOA for health care covers medical research.
  - If the patient has not appointed (or won't) name a LAR, refer to local laws for the hierarchy of who qualifies.
  - Institutional IRB's may also have their own specific guidelines.

State Requirements

- Requirements vary by state as to who can serve as a proxy in the absence of a DPOA .
- Code.dccouncil.gov (CH 22 Health Care Decisions)

  Substituted consent in order of priority:
  - Court appointed guardian or conservator
  - Court appointed intellectual disability advocate (if within their scope)
  - Spouse or domestic partner
  - Adult child
  - Parent
  - Adult sibling
  - Religious Superior
  - Close friend
  - Nearest living relative

Is an LAR Needed?

- A diagnosed memory problem does not confer decisional incapacity. It depends on the complexity of the decision.
- Even when participants lose the ability to consent to a complex research study, they may retain the ability to appoint an LAR.
- Capacity is task specific- a clinician can render a decision about capacity to do certain tasks (serving as a juror, driving, managing finances and living alone).

Strategies for Coping

- Encourage the patient to use memory enhancing strategies
  - external: VM, emails, timers, memory book
  - internal: implementation intentions (see it and say it or make it meaningful) and retrieval practice

- Encourage Autonomy and define responsibilities of the informant and/or caregiver.

- Give feedback to the patient and informant

What will happen in the future?

- Persons at risk for MCI will be diagnosed and patients will be more educated as to their specific cognitive changes
- Consent/teaching will be individualized/targeted toward “problem areas” of cognition.
- Patients and CG will have more of a voice as a class
- Emphasis on more inclusion (asymptomatic, increased diversity, more health problems)
- More remote consenting and use of apps for tracking.
- More regulations, more complexity in studies and more documentation!

Case Study Mr. V

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Resources

- Anderson, Nicole D, Murphy, Kelly J, Troyer, Angela K Living with Mild Cognitive Impairment , Oxford Univ. Press, 2024
- Alz.org: for education, on line tools, resource finder
- https://dacl.dc.gov/page/iona-senior-services-resource-guide: for an online directory of resources in DC
- AARP.org: free advance directives by state
- Dementiacarecentral.com: caregiving and planning for legal matters
- https://www.nia.nih.gov/health/advance-care-planning/getting-your-affairs-order-checklist-documents-prepare-future

Thank You!

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And thank you to the CRU Team!