

ARTICLE

CIRCLES FOR ASSESSMENT OF COGNITIVE IMPAIRMENT

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**ABSTRACT:** Cognitive impairment (“CI”) represents major healthcare cost and societal issues. As populations age in developed countries, these issues are receiving increased attention on the clinical, scientific and legislative levels. <sup>1</sup> The first step in any CI treatment is recognition, and then an assessment of its nature and severity. Recognition and assessment are the responsibilities not only of neuropsychiatrists and geriatricians, but of all clinicians.

However, conducting standardized clinical evaluations and follow-up measurements presents a number of challenges. These include expertise, staff time, caregiver involvement, integration of lab results and imaging, IT systems, cost, co-morbidities and reimbursement.

Circles help address these challenges. A current Circle use case involving the remote delivery of the MoCA assessment <sup>2</sup> is presented at the end of this Article.

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## BACKGROUND

### The Nature and Impact of CI

#### General

The prevalence of subjective cognitive decline in the U.S. among adults aged 65 years and older is 12%, and 11% among adults 45-64 years of age.

Global healthcare costs in 2019 attributable to cognitive impairment were estimated at \$213 billion. Direct social care costs accounted for another \$450 billion, and the cost of informal care was estimated to be \$650 billion. <sup>3</sup>

Moreover, various forms of CI are closely correlated to a number of co-morbidities. <sup>4</sup>

In all developed countries with aging populations living longer, these numbers will only increase significantly. <sup>5</sup>

#### Alzheimer's

Cognitive impairment categories include Alzheimer's, mild cognitive impairment, subjective cognitive decline, vascular cognitive impairment <sup>6</sup>, and others. <sup>7</sup>

The dominant CI category is of course Alzheimer's. Statistics from the Alzheimer's Association <sup>8</sup> include:

- ❖ Between 2000 and 2019, deaths from stroke, heart disease and HIV decreased, whereas reported deaths from AD increased more than 145%.
- ❖ Unpaid dementia caregiving was valued

at \$340 billion in 2022. Its true costs, however, extend to family caregivers' increased risk for emotional distress and negative mental and physical health outcomes.

- ❖ Average per-person Medicare payments for services to beneficiaries aged 65 and older with Alzheimer's or other dementias are almost three times as great as payments for beneficiaries without these conditions, and Medicaid payments are more than 22 times as great.

Proper assessment and treatment of CI thus have enormous population health, federal budgetary and societal implications.

### Clinical Evaluations

#### General

In the U.S., primary care physicians ("PCPs"), surgeons and other healthcare professionals are actively encouraged by their medical societies to look for signs of CI. CMS reimburses CI evaluation as a part of an annual wellness visit. <sup>9</sup> There is extensive literature addressing approaches to CI identification and evaluation. <sup>10</sup>

However, PCPs are often hesitant to investigate potential cognitive decline in their patients; many will do so only when family members raise the topic.

Moreover, many PCPs perceive limited referral options for patients which may

exhibit CI. PCPs often feel they do not possess the expertise necessary to educate their patients about possible treatment options.

**Standardized Assessments**

Several CI assessments tools have been developed. These include MoCA <sup>11</sup>, IQCODE <sup>12</sup>, Mini-COG <sup>13</sup> and QDRS <sup>14</sup>. One can expect many more assessments to be developed.

However, most PCPs – and even many specialists – are uncertain as to which is the appropriate assessment tool to use. Moreover, assessment of CI patients often requires caregiver involvement, which may call into question the accuracy of returned scores in the absence of proper controls.

Assessment through telehealth poses additional challenges.

**Treatment Protocols**

Many individuals are reluctant bring up possible CI symptoms with their healthcare professional. (And, as

mentioned, many PCPs and other “frontline” clinicians are reluctant themselves to investigate potential CI.) This is unfortunate since, as with many conditions, early detection allows for a broader variety of treatment options, or at least risk reduction. <sup>15</sup>

Currently, three cholinesterase inhibitors are approved for mild to moderate Alzheimer’s <sup>16</sup>. A drug currently approved by the FDA to treat symptoms due to moderate to severe stages of Alzheimer’s is memantine (Namenda®).

Other drugs are under investigation, and CI patients are often encouraged to consider clinical trials.

**Support Groups**

Besides major groups such as the Alzheimer’s Association and their local chapters, there are many dozens of local CI support organizations. <sup>17</sup> There are also dedicated support groups for caregivers, which of course play a pivotal role in effective CI assessment and treatment. <sup>18</sup>

**CHALLENGES WITH ASSESSMENTS AND TREATMENT PROTOCOLS**

**Introduction**

By the very nature of CI, assessing and treating it – or at least reducing its associated risks –pose a number of particular challenges. These go well

beyond the sheer number of individuals suffering from CI, the necessary involvement of caregivers, and co-morbidities which can result from CI.

**Recognition of CI**

In its early stages, cognitive impairment is often dismissed as forgetfulness or an inevitable part of aging. As mentioned, PCP and other healthcare professionals may be reluctant or insufficiently trained to assess CI, let alone conduct an informed discussion with patients.

Although much remains to be learned, it appears that early assessment may make a difference for a patient’s longer-term prognosis.<sup>19</sup>

**Training and Education**

Emergency room HCP’s and primary care physicians are often the first to see a patient with CI. Due to co-morbidities often associated with CI, non-neurological medical specialists such as cardiologists also frequently encounter CI.

As mentioned, these “frontline” healthcare professionals may not be trained to assess CI, or properly discuss it with their patients. Indeed, they are often reluctant to do so, and patients are reluctant to bring the topic up.

Even for neuropsychiatrists and other CI specialists, relevant medical science and treatment options (e.g., biologics) are often advancing too rapidly to remain current.<sup>20</sup>

**Caregivers**

Perhaps more than for any other condition, caregivers play a critical, and nuanced, role in CI assessment and treatment. They are often the first to bring CI symptoms to the attention of a healthcare professional and even the patient him/herself.

Initial and ongoing CI assessments typically rely on a caregiver’s support. On the one hand, the caregiver cannot prompt or otherwise influence the patient’s answers. In a telehealth context, it is often the caregiver who needs to log onto a telehealth portal on behalf of the patient, and assist with other technical aspects.

Moreover, the caregiver him/herself is generally an important part of a risk reduction or treatment protocol. Finally, the treating clinician needs to be alert to the health of the caregiver as well as of the CI patient.

**USING CIRCLES TO ADDRESS KEY CI ASSESSMENT AND EDUCATION CHALLENGES**

**Introduction**

A “Circle” integrates the technical platforms and processes allowing any healthcare professional to generate clinical,

scientific, and financial value from their everyday cases.

Key Circle elements include (i) clinical grade technology, (ii) minimal burden for

the provider and patient, (iii) inherent collaboration within and across institutional and national boundaries, (iv) publication/influence, and (v) cost-effectiveness.

Circles are ideal for clinicians, whatever their specialty, in assessing, monitoring, and treating cognitive-impairment patients. Further information is provided at the end of this article.

**CI-Specific Circle Use Cases**

**CI Assessments**

The observational protocol component of a Circle typically contains separate sections for pre-clinical, clinical, and long-term outcomes assessments. The nature of data to be collected in each section is determined by the clinician, often in conjunction with peers or a clinical/scientific expert.

In the field of cognitive impairment, Circles can incorporate any standardized assessment tools, such as MoCA, IQCODE, Mini-COG and/or QDRS. Alternatively, the clinician can modify these, or develop his/her own assessment scoring.

If desired by the clinician, RegenMed handles the remote delivery of the assessment.<sup>21</sup>

**Integration of All, But Only, Relevant Data**

CI assessment, risk reduction and/or treatment data may include lab results, imaging, self-reported evaluations, broader

health metrics (sleep, exercise, etc.), information on status of co-morbidities, and of course original clinical data.

EMRs may capture some but not all of this information. Moreover, they will capture a good deal of information which is irrelevant.

Each Circle is designed for a specific indication, treatment protocol, and outcomes assessment scoring. The clinician and his fellow Circle Members can thus easily capture, aggregate, verify and analyze all of the necessary data, without unnecessary or confusing artifacts.

**Multiple Healthcare Professionals**

CI patients often see more than one specialist, in addition to their primary care physicians. Each clinical encounter yields information potentially relevant to CI assessment and treatment protocol design or adjustment.

However, those providers frequently do not have the time meaningfully to communicate with each other. Also, they may be utilizing different EMR systems. More critically, those systems are not set up to collect the data most relevant to cognitive impairment decisions.

Circles inherently support collaboration among all providers involved in the care of a CI patient.

### Caregiver Use Experience

Caregivers can have their own Benchmarc™<sup>22</sup> accounts to track a patient's reports and progress. Digital consents forms also allow patient approval of caregiver PHI access.

The clinician can also include a separate caregivers survey in the observational protocol, to further strengthen the involvement of the caregiver in the patient's risk reduction or treatment plan.

### CI and Real-World Evidence

Approaches to cognitive impairment assessments, risk-prevention and treatments are fast evolving. Real-world evidence is an essential part of the developing medical science, as well as its clinical translation.

Regulators, legislative bodies, and payers recognize the potential of real-world evidence to improve healthcare outcomes and reduce costs.<sup>23</sup> This has led to a proliferation of registries<sup>24</sup> and study designs -- pragmatic, quality improvement, observational, and other.<sup>25</sup> A corollary is the requirement for more inclusiveness and diversity in clinical trial design.<sup>26</sup>

Circles thus develop and extend clinically significant standards of cognitive impairment care.<sup>27</sup> Importantly, they can be utilized by large academic medical centers, as well as smaller practicing dealing with CI patient populations.

### Overall Circle Benefits

#### Technology Platform and Processes

Circles utilize the clinical grade<sup>28</sup> and patented<sup>29</sup> clinician-facing [inCytes™](#) and patient-facing [Benchmarc™](#) platforms.

They include patient and caregiver enrollment, long-term outcomes capture, report generation, publication, single and multi-center administration, publication, industry funding, IRB support and other integrated capabilities.

The Circles user experience emphasizes patient engagement, comprehension of medical conditions and proposed treatment paths, and long-term compliance.

#### Scalability

Circles support the identification, onboarding, and active involvement of providers within and outside of institutional and regional boundaries.

Their inherent flexibility accommodates efficient data collection from the small patient panel of small practices, as well as patient populations of virtually any size.

#### Further Information On Circles

[Circle Overview](#)

[Circles/What Is A Circle](#)

[KnowledgeBase](#)

[LinkedIn Corporate Page](#)

[Latest](#)

[Contact Us](#)

USE CASE

A leading U.S. neurologist has designed and implemented a Circle focusing on patients suffering with moderate cognitive impairment. He is utilizing the MoCA assessment tool, which is administered through RegenMed by MoCA certified personnel quarterly for at least one year. Lab results and other clinical information will be included in each patient record.

In addition, the Circle Founder will be enlisting other neurologists and CI specialists from around the world as Circle Members (essentially co-investigators).

The Circle Founder will regularly report to all Circle Members on protocol design elements, as well as statistically significant correlations arising from the aggregated Circle datasets.

CONCLUSION

Cognitive impairment, in all of its manifestations, is one of this century's most pressing healthcare, economic and societal issues.

Evidence-based approaches to CI assessment, risk reduction and treatment are sorely needed. These goals are complicated by the very nature of CI, the

frequent presence of co-morbidities, the relatively undeveloped nature of CI science, and the importance of caregivers as extensions of healthcare providers.

Circles are already helping clinicians in their efforts to address these challenges efficiently.



## FOOTNOTES

- 1 See <https://aspe.hhs.gov/reports/risk-costs-severe-cognitive-impairment-older-ages-key-findings-our-literature-review-projection-0>,  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10357114/>,  
[https://www.thelancet.com/journals/lanepi/article/PIIS2666-7762\(22\)00168-5/fulltext](https://www.thelancet.com/journals/lanepi/article/PIIS2666-7762(22)00168-5/fulltext).
- 2 <https://www.verywellhealth.com/alzheimers-and-montreal-cognitive-assessment-moca-98617>.
- 3 <https://alz-journals.onlinelibrary.wiley.com/doi/full/10.1002/alz.12901>. See also  
<https://www.ahajournals.org/doi/epub/10.1161/01.STR.0000017878.85274.44>,  
<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5657516/>.
- 4 <https://www.cdc.gov/aging/publications/chronic-diseases-brief.html>
- 5 <https://www.cdc.gov/aging/data/subjective-cognitive-decline-brief.html>.
- 6 <https://www.heartandstroke.ca/stroke/what-is-stroke/vascular-cognitive-impairment>.
- 7 See this list from one major academic medical hospital system  
<https://www.mountsinai.org/care/neurology/services/cognitive-disorders>.
- 8 <https://pubmed.ncbi.nlm.nih.gov/36918389/>.
- 9 <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/preventive-services/medicare-wellness-visits.html>.
- 10 See for example <https://www.nia.nih.gov/health/assessing-cognitive-impairment-older-patients>, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4119094/>,  
<https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/cognitive-impairment-in-older-adults-screening>, <https://www.facs.org/for-medical-professionals/news-publications/news-and-articles/bulletin/2023/september-2023-volume-108-issue-9/cognitive-screening-in-older-patients-may-help-optimize-outcomes/>,
- 11 <https://mocacognition.com/>.
- 12 <https://www.alz.org/media/documents/short-form-informant-questionnaire-decline.pdf>.
- 13 <https://mini-cog.com/>.

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- 14 <https://www.guidetolongtermcare.com/images/The-Quick-Dementia-Rating-System.pdf>.
- 15 See for example <https://my.clevelandclinic.org/health/diseases/17990-mild-cognitive-impairment>.
- 16 Galantamine (Razadyne®), Rivastigmine (Exelon®) and Donepezil (Aricept®). [Lecanemab \(Leqembi®\)](#), and [aducanumab \(Aduhelm®\)](#) have also been approved by the FDA for the treatment of early Alzheimer's disease.
- 17 <https://www.alzheimersla.org/>, <https://www.caregiver.org/resource/mild-cognitive-impairment-mci/>, [https://www.alz.org/cacentralcoast/helping\\_you/support-groups](https://www.alz.org/cacentralcoast/helping_you/support-groups).
- 18 <https://alzfdn.org/caregiving-resources/alzheimers-and-dementia-support-groups/>.
- 19 [https://www.alz.org/alzheimers-dementia/what-is-dementia/related\\_conditions/mild-cognitive-impairment](https://www.alz.org/alzheimers-dementia/what-is-dementia/related_conditions/mild-cognitive-impairment).
- 20 <https://www.nia.nih.gov/about/advances-alzheimers-disease-related-dementias-research>.
- 21 For example, RegenMed handles MoCA benchmark and post-clinical assessments for some Circle founders.
- 22 <https://kb.rgnmed.com/what-is-benchmarc>.
- 23 See for example [FDA, Real World Evidence, FDA, Post-Market Surveillance Programs; The 21st Century Cures Act; NIH Grants Program For Real-World Studies; Expect To See More RWE-Based Regulatory Decisions](#), Robert Califf, FDA Commissioner; [Use Of Real-World Evidence In Regulatory Decision Making](#), European Medicines Agency.
- 24 See [Registries for Evaluating Patient Outcomes: A User's Guide: 4th Edition](#), Agency for Healthcare and Quality and Research, U.S. Department of Health and Human Services.
- 25 See [Pragmatic Trials](#), NEJM, Ford and Norrie, [Quality Improvement Projects and Clinical Research Studies](#), Faiman, and [Quality Improvement In Practice](#), Backman.
- 26 See for example, [Diversity and Inclusion In Clinical Trials](#), NIH; [Why Diverse Clinical Trial Participation Matters](#), Schwartz et al, New England Journal Of Medicine.
- 27 See [Transforming Medicare Coverage: A New Medicare Coverage Pathway for Emerging Technologies and Revamped Evidence Development Framework](#), Fleischer et al., Center For Medicare and Medicaid Services; [Center For Clinical and Translational Science/Product Development Pathways](#), Mayo Clinic. [What Is The Evidence For Our Standards Of Care?](#), Turka et al, The Journal Of Clinical Investigation.
- 28 HIPAA, GDPR, Part 11, FHIR HL7 Compliant. Scalable. All data and edits fully auditable.
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Multilingual. Real-time 24/7 accessibility by patients and clinicians from any device in any location. Robust role, permission, clinician branding, and other customization settings

- <sup>29</sup> U.S. patent number 11720567, *Method and System For Processing Large Amounts Of Real-World Evidence*.