

Accelerating Brain Health Technologies: A Public-Private Partnership Action Plan

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Abstract

Chronic brain disorders, prevalent in aging populations, disproportionately impact marginalized and underserved communities. Introducing artificial intelligence/machine learning (AI/ML)-powered Clinical Decision Intelligence Applications (CDIAs) offers a promising solution to improve brain health and health equity. However, the sustained adoption of such technologies requires significant improvements in clinical workflows, personnel training, ethical considerations, financial models, regulatory compliance, and governance structures. To address these challenges, the Brain Watch Coalition advocates forming a public-private partnership to build trust and validate the effectiveness of AI/ML-powered CDIAs. This perspective outlines challenges and recommendations for establishing a purpose-driven public-private partnership: to demonstrate the long-term viability and ethical deployment of CDIAs within real-world healthcare settings and to establish a framework for ensuring equitable access to innovative brain health solutions. This initiative is a critical step towards enhancing patient outcomes, modernizing healthcare systems, and effectively managing the growing burden of chronic brain disorders across global populations.

Keywords: Alzheimer's, Dementia, Public-Private Partnership, Mild Cognitive Impairment, Brain Health, Healthcare System Industry, Healthcare Supply Chain Management, AI/ML (Artificial Intelligence/Machine Learning).

Introduction

Cognitive impairment and dementia remain a significant concern for the global healthcare system. There are six main factors contributing to this issue. First, the incidence of dementia is increasing, and it is estimated that there will be over 50 million people globally affected by 2050 (1). Second, providing care for these individuals costs approximately \$1.3 trillion globally (2). Third, detecting cognitive impairment outside of specialty care clinics is challenging, leading to delays in delivering putatively effective interventions (3). Fourth, there is an inadequate workforce to manage the current demand for healthcare and social care services (4). Fifth, care services are fragmented, and clinical care options are not coordinated, making it difficult for healthcare consumers to evaluate quality and value (5). Finally, cognitive impairment lasts for an extended period, and the nature of clinical and social care services options are uneven and variable (6).

New treatments for brain disorders, such as Alzheimer's disease (AD), are expected in the next five years despite ongoing debate about their effectiveness, safety, and cost. A second wave of interventions is in development that may offer greater benefits. However, healthcare systems face significant challenges in handling the current prevalence and new cases of Alzheimer's and related disorders (AD/ADRD) and providing timely access to diagnosis, treatment, and care for individuals with cognitive, functional, and behavioral impairments. This challenge is particularly acute for vulnerable populations without adequate access to quality brain healthcare.

Developing and deploying affordable and accessible brain health technologies for detecting, diagnosing, assessing, managing, and treating chronic brain disorders face significant regulatory, ethical, financial, and technical hurdles (7). The United Nations, World Health Organization, and other stakeholders are working to enhance

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legislation, regulations, and rules to address research and development gaps in promoting brain health and healthy aging (8, 9). With the experience of the COVID-19 pandemic, world health policymakers are becoming increasingly aware of the need to improve and fortify healthcare system preparedness, supply chain, and capabilities to evaluate new interventions, devices, and services (10-14). Challenges in providing quality healthcare are compounded by several stressors on healthcare providers (15, 16). Given these needs and challenges, exploring whether AI/ML-powered health technologies can offer solutions.

The Brain Watch Coalition working group sought to identify possible recommendations and implementation methods for learning health systems (17) that leverage existing US clinical health infrastructure. The public and consumer health goal will be to expedite and forge sustainable pathways for affordable, appropriate, and equitable access to health care, particularly among under-represented and under-served communities at the most significant risk for cognitive, behavioral, and functional impairments due to chronic brain disorders (18).

Healthcare System Preparedness, Electronic Health Information, and Bioinformatics

The landscape of healthcare is changing rapidly, particularly for brain health, Alzheimer’s disease, and related disorders. The COVID-19 pandemic has hastened the forecast that there could be significantly fewer healthcare systems in the coming two decades (19, 20). In the case of Alzheimer’s disease and related disorders, blood-based biomarkers focused on pathologic features of the condition have become a viable possibility and an essential priority for aiding detection and diagnosis. Although tremendous focus is now on discovering, qualifying, and validating these assays, some debate remains about the actual use case for these tools in differing clinical settings (21). Specifically, there has yet to be a clear consensus on when these tools may transition from triage to confirmatory diagnostic assay and when this will occur for specialists and general practitioners.

Electronic health information (EHI) and bioinformatics innovations offer promising solutions to help healthcare systems cope with these challenges while improving the quality of life for older individuals. Artificial intelligence/

machine learning (AI/ML)-powered clinical decision intelligence applications (AI/ML CDIA, or CDIA) have the potential to identify patterns and prediction horizons that can indicate an increased risk or presence of cognitive, functional, and behavioral impairments, a group that can be conceptualized as the cognitively vulnerable. These prediction horizons can range from 1 to 3 years before a dementia diagnosis, which empowers medical professionals to intervene earlier and provide possible treatment plans for at-risk cognitively vulnerable individuals (22). In addition to detecting those at risk for unrecognized cognitive impairment and dementia earlier, CDIA may also improve brain health and patient outcomes (23). By providing aid for more accurate diagnoses and better treatment plans, these algorithms can help reduce the number of hospitalizations due to dementia-related complications. Furthermore, they can help reduce costs associated with long-term care by promoting brain health and providing options for early interventions among the cognitively vulnerable that may slow or even prevent disease progression.

Despite the potential benefits of CDIA,-just like any novel technology—their ethical and responsible implementation in the healthcare system is a key challenge. Successful adoption is not guaranteed unless the interests of key stakeholders are represented and addressed. Previous studies have mainly focused on the technological aspects of CDIA but often fail to consider the use case of a particular technology and the context of the healthcare system’s environment to support innovation. This includes the human factor for both people providing and receiving health services.

The following outlines the challenges and recommendations to accelerate the sustainable deployment, implementation, and adoption of new CDIA to sustain and enhance brain health for health consumers across differing populations and healthcare settings. Specifically, we aim to explore two key questions: 1) What are the determinants of the perceived characteristics of CDIA adoption in healthcare systems? 2) How can healthcare systems maximize their readiness for adoption? In doing so, we focus on developing a framework to fit better the specifications and unique challenges healthcare systems face. While traditional technological innovations are characterized by relative advantage, compatibility, and ease of use, CDIA

adoption will be shaped by four primary areas of evidence development: trust, improvement in clinical care, revenue optimization, and health equity and research.

Healthcare System Enterprise Challenges

Outdated R&D model

Healthcare systems are facing challenges in adopting commercial technology at a relevant pace. Innovations from non-commercial research and development organizations are rarely integrated into a commercialization adoption pipeline. Traditional technology developers tend to focus on near-term requirements that are solution-oriented rather than broadly defining healthcare gaps that can help advance technologies. This may be one of the reasons why healthcare systems struggle to apply leading technologies to their enterprise systems effectively.

Long timelines and inflexible execution

Healthcare systems often have to deliver systems to meet requirements defined decades earlier. It is difficult to insert new health system technology to effectively respond to dynamic changes in the marketplace, regulatory changes, technological opportunities, and advances in medical care macroeconomic and supply chain disruptions. Hardware-centric models are slower and integrated less effectively than software-centric models that can be rapidly updated.

The Valley of Death

The «Valley of Death» refers to the funding gap between the research and development phase and the commercial adoption of a technology or service. Though funding is the primary issue, regulatory compliance and risk management can also delay economic stability for new technologies (24). Healthcare system investments often fail to generate sustainable revenue due to challenges in transitioning from prototypes to production contracts. Long timelines, program constraints, and disconnected ecosystems are among the challenges faced by technology companies developing viable products or services for healthcare systems.

Workforce protection

Some healthcare workforce members are hampered by a bureaucratic culture of compliance and oversight, resulting in a challenging environment for innovation. Unfortunately, creative problem-solving and measured risk-taking are not often rewarded. Additionally, there is a shortage of individuals with technology industry backgrounds in senior leadership roles in healthcare systems.

Program centered adoption

Many large healthcare system technology developers offer closed proprietary solutions for major systems, which hinders interoperability and responsiveness to changes in operations, threats, and technologies. Open system architectures that conform to defined interface controls are rarely adopted, which limits the ability to incorporate innovative technologies.

Cumbersome reporting

Justification documents for novel healthcare system technologies by payers and regulatory agencies can be lengthy and inconsistent, making it difficult for healthcare system management to understand how best to deploy new technology responsibly.

Differential understanding of emerging technology potential

Healthcare systems need help to adopt new technologies like information technology, biotechnology, and quantum information due to a lack of or differential understanding among various healthcare system stakeholders. Given the complex and different performance measures that sustain a healthcare system, as these technologies mature, it becomes more challenging to implement and leverage them effectively.

Change management

Change management refers to an organization's structured approach to transitioning individuals, teams, and the organization from the current state to a desired future state. In health technology adoption by health systems, change management must address institutional resistance to change, regulatory compliance, interoperability, disruption to workflow, training, leadership championship, and workforce acceptance/adoption. Change management is a continuous process that identifies barriers and determines mitigations as the innovation integrates into the health system.

Not-invented-here

Internal technology teams are often reluctant to adopt or purchase external technologies, solutions, or innovations, often due to a belief that in-house developed solutions are superior. This reduces the opportunity to adopt validated and generalizable tools. Additionally, the team may need more bandwidth in terms of time or personnel to incorporate new technology and maintain and support its users.

Top Recommendations to Accelerate Responsible and Sustainable Adoption of CDIA's

The authors recommend that leaders and stakeholders take high-priority actions to accelerate the adoption of healthcare system technology innovation.

Specifying a Capability Portfolio Model/Requirements Document

Developing a standardized language for identifying use cases in health technology assessment tools is essential. A concise, standard document should provide high-level information on overarching, joint, enduring capability needs and key mission impact measures. This document should focus on the intended outcomes of health technology and the needs of healthcare providers, clinicians, consumers, and healthcare systems. Such a portfolio document specifying overarching model requirements for the organization would enable leaner program requirements and shape future research and prototypes among all stakeholders involved in healthcare system operations. Moreover, it is essential to establish a standardized set of portfolio strategies and processes that include roadmaps, success measures, contract infrastructure, and architectures. This enables faster deployment, implementation, and adoption of programs. Portfolio contracting strategies should promote a robust industry base by encouraging continuous competition, iterative development, supply chain risk mitigation, greater participation of nontraditional companies/organizations, commercial service acquisitions, and generation of economies of scale.

When considering portfolio strategies, it is recommended to break down large program implementations into smaller, modular tasks. Common platforms, components, and services should be used, while commercial solutions

should be maximized to help optimize interoperability. Portfolio strategies should prioritize scaling and aligning prototypes, experimentation, and testing infrastructure. Investment in a standard suite of engineering tools, platforms, and other techniques can ensure interoperability, cyber security resilience, and responsible sustainability.

Consolidate Program Elements

Creating a standardized list of deployment and implementation program elements is crucial to expedite the implementation of new technologies into existing healthcare systems. These elements should include simplified budget submission and consolidated components for cost, schedule, and performance trade-offs. This standardization would streamline the integration process, eliminating the need for a complete system restart. Additionally, the prototyping and deploying of new systems that fulfill critical areas should be prioritized. By identifying best practices for justifying activities within a standardized capability set, we can further enhance the efficiency and effectiveness of technology integration in healthcare systems.

Modernize Healthcare Systems to Align with the Technology Industry

A pre-competitive team should create a streamlined framework for reviewing and documenting the healthcare system's acquisition and adoption of health technologies for healthcare systems. This team's role would include integrating commercial practices into early program phases and collaborating with the health technology industry, capital markets, and other stakeholders to develop rapid funding tools that synchronize with commercial innovation cycles. The team should develop a swift health system needs evaluation and validation process involving feedback from various healthcare stakeholders. This process will decentralize decision-making, allowing validation of commercial solutions by officials not tied to a single organization within a healthcare system. The team will also collaborate with industries to gather information for acquisition programs and test, deliver, and iterate for scalability. Success measures should include developing funds to help more entrants cross the Valley of Death, increasing transparency about healthcare system priorities, identifying commercial pathways, and providing guidance and training for the workforce to acquire new

technologies rapidly. The team should also measure resources saved and efficiencies gained from central repository information from traditional and non-industrial bases like market intelligence technology landscape analysis and due diligence on companies.

Strengthen the Alignment Among Capital Markets, Health Technology Companies, and Healthcare Systems

The global capital markets are crucial for healthcare system innovation and the adoption of new technologies, yet they remain underutilized. Programs that enable capital market-backed companies to participate and new pathways for healthcare systems to secure funding from capital markets for essential healthcare system information technologies should be expanded to optimize these resources. There is a need to expand grant models. For example, in the US, innovative small businesses should have the flexibility to propose federal funding assistance for Phase Three SBIR development activities to the US Department of Health and Human Services after successful Phase Two performance. As with other US Federal departments, including the Department of Defense, this recommendation offers a new strategic financing mechanism to bridge the funding gap in technology transfer to real-world settings.

Increasing competition is also necessary, which can be achieved by broadening the range of health technology firms competing for grants and other non-diluted means of funding. Tools must be developed to drive widespread technology adoption that leverages external capital markets to fund R&D pilot projects. Moreover, a portion of grant «indirect costs» should be allocated to support commercial readiness efforts.

Success measures should include a notable increase in capital market funding for health technology companies, more companies successfully crossing the «valley of death» stage, faster integration of commercially developed technology, increased production contracts from non-traditional businesses, and more touchpoints with cutting-edge technology. An example of this could be a venture capital-backed company showcasing a unique capability, which gets expedited to the SBIR phase three, commences full-scale production and successfully navigates through the challenging early stages of growth.

Encourage Technology Companies to Collaborate with Various Types of Healthcare Systems Through Incentives

Increase government-directed incentives and broaden access to capital markets for small and disadvantaged healthcare businesses, including technology startups and nontraditional health technology. Make credit loan authorities available to other agencies, departments, and healthcare systems, and include purchase commitments and loan guarantees. Work to reduce risk and increase incentives for companies seeking to scale production of critical technologies. Decrease barriers to entry for healthcare businesses. Establish a working group with large health technology companies and nontraditional technology companies to incentivize technology startups in the healthcare industry. Explore cooperation with larger health technology companies to scale the integration and production of healthcare system tools, creating a sustainable advantage in healthcare system innovation.

Establish Bridge Funds for Successfully Demonstrated Technologies

Seed funds will facilitate accelerating and scaling successful demonstrations for healthcare technologies and capabilities. Success measures include increasing the number of demonstrations successfully transitioned to healthcare systems and incentivizing companies to demonstrate.

Identify, Deploy, and Scale Successful Innovation Adoption Paradigms from Other Industries

Form a team to create a model replicating successful approaches and incorporating lessons from rapid adoption. Hire an experienced leader with technical acumen, product management skills, a clear vision, a vast network, and a five-year commitment. Provide success measures and examples of previous successful implementations.

Modernize Healthcare System Requirements for Delivery of the IHI Quadruple Aims

To modernize healthcare systems, we need to convince clinicians about the value of CDAs for patient care. Otherwise, they may not use them as intended. Also, we need to standardize and streamline the process of creating and approving

requirement documents. To achieve this, we should establish a pre-competitive team to set deadlines, create comprehensive requirements, and involve stakeholders in testing and feedback. The team should balance managing services and capabilities while allowing for individual programs. It should also enhance training programs and ensure that policies, guidance, and templates are available online in a dynamic and accessible format. We need to convince clinicians about the value of CDIA for patient care. Otherwise, they may not use them as intended.

Conclusions and Next Steps: Brain Watch Coalition Sandbox for Clinical Decision Intelligence Applications

Many healthcare systems hesitate to adopt innovative technology due to internal and external factors. One solution to this issue is to create sandbox environments that allow for live testing, leading to faster adoption. AI/ML technologies must have safeguards and considerations for real-world scenarios when developed in isolation. This results in delayed adoption and the need for increased trust in AI/ML-based clinical decision intelligence.

The sandbox approach aims to create authentic test environments that safely simulate the operations of an entire healthcare enterprise system. This provides all stakeholders with a risk-free testing ground to evaluate various aspects of clinical operations, such as workforce productivity, quality measure assessment, financial efficiency, and other regulatory or statutory requirements that impact a healthcare system's operations. Expanding on the Machine Learning Technology Readiness Levels (MLTRL) framework will be crucial (25). In addition, the effectiveness of these programs can be significantly improved by creating partnerships between the public and private sectors. These partnerships can offer the required assistance, resources, and knowledge to accelerate the adoption of AI/ML technologies in healthcare systems. Moreover, they can establish a collaborative atmosphere that encourages innovation, sharing of knowledge, and mutual development. It is also critical that the sandbox approach includes healthcare experts in the health issues of interest and healthcare end-users to ensure that approaches are well-informed and well-received. Establishing a CDIA Sandbox represents a significant stride towards accelerating the transition of innovative models and algorithms

from the research and development phase to tangible product implementation within the clinical healthcare system.

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Conflict of interest

Ara Khachaturian is an Officer and director of the Campaign to Prevent Alzheimer's Disease (PAD 20/20) and; Officer, director and employee of Khachaturian and Associates; Founding executive-editor of Alzheimer's & Dementia, The Journal of the Alzheimer's Association (retired), Founding executive-editor of Alzheimer's & Dementia: Translational Research & Clinical Intervention (retired), Founding executive-editor of Alzheimer's & Dementia: Diagnoses, Assessment & Disease Monitoring (retired); Executive Officer and Director, Brain Watch Coalition; Senior Research Fellow, University of Nevada Las Vegas, National Supercomputing Institute & Dedicated Research Network; Received payments through organizational affiliations for grants, contracts, consulting fees, honoraria, meeting support, travel support, in-kind research/professional support over the last 36 months from the Alzheimer's Association, Alzheon, Clinical Trials Alzheimer's Disease Conference, Davos Alzheimer's Consortium, Eisai, Inc., Eli Lilly & Company, High Lantern Group, International Neurodegenerative Disorders Research Center, and Serdi Publishing. The Campaign to Prevent Alzheimer's Disease thanks the generous support of Eisai, Inc., Eli Lilly & Company, Alzheon, and the donors of Prevent Alzheimer's Disease 20/20 for the unrestricted educational support of this working group.

Authors' contributions

All authors contributed equally to the conceptualization, formal analysis, and writing review and editing. Ara S. Khachaturian, PhD, Brittany Cassin, MBA, Glen Finney, MD, and Louis Tripoli, MD, contributed equally to the methodology and project administration. Ara S. Khachaturian, PhD contributed to the funding acquisition, resources, and writing the original draft.

Ethical standards

Ethical standards used to produce this consensus manuscript include transparency in methodology, maintaining objectivity, and avoiding conflicts of interest. Contributors adhered to principles of honesty, provide accurate and reliable data, respect intellectual property rights, and ensure that the consensus represents a balanced and fair view of the topic, reflecting the collective agreement of all contributors.

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