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Brain Health Living Labs

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Abstract

We call on geriatric brain health care providers, executives and entrepreneurs to embrace our Brain Health Living Lab model-a user-centered, iterative ecosystem, integrating concurrent clinical care, research and innovation processes.

Keywords

Innovation; technology; entrepreneur; brain health; late-life; mental health; living lab; psychiatry

INTRODUCTION

The current brain health crisis in the United States of America sees rising rates of late-life dementia and depression with massive personal and economic costs. Current approaches to screening, diagnosis, treatment, prevention, and treatment access are inadequate. Further, health care is in creasingly being pushed toward tele-or remote settings, where possible. Despite the large number of emerging technologies (e.g., apps, wearables, sensors, robotics, and pharmacogenetic tools), there are precious few examples of evidence-based and scalable innovations to address these issues. We suggest the collision of these needs and opportunities necessitate a fundamentally different approach to care. New solutions informing this care will require envisioning a brain health clinic of the future that acts as a care provider and test bed for innovation.

In imagining the future of care, it is helpful to think about the following design questions: *What would it look like if care was seamlessly bridged remotely between in-clinic visits, with smartphone devices, sensors, brain imaging, and multi-omic technologies? How would the clinical and scientific understanding of brain health conditions be improved if a more robust feedback loop were developed between research, care and innovations into the real-world, enabling the world to become the laboratory? What would care look like if it were designed from scratch by partnerships with the patient, biomedical engineers, clinicians, family members, and others working in tandem with each other? How might such a model address the care needs of the most vulnerable populations (e.g., economically deprived groups or older adults), most demanding care settings (e.g., nursing homes) and the types of socio-environmental stressors (e.g., loneliness, isolation) that are not always considered the domain of the medical sciences, despite clear evidence of their harmful health impact?*[1,2]

Currently, approaches to technological innovation for brain health disorders are not adequate. Solutions developed for adult populations are not optimized for the unique design challenges of late-life (e.g., less digital literacy, less access to smart devices and broadband, and unique sensory and motor difficulties).[4–7] There is also a common failure to translate evidence-based data and solutions (e.g., randomized controlled trials) into pragmatic, real-world care.[8–10] There is a noted loss of innovations through the "valley of death" (the solution development period after the discovery phase and before the commercialization phase) – meaning the potential of new solutions is often not realized.[8] Existing clinics do not allow for rapid and sophisticated technological innovation.[3] There are several insufficiently responsible innovations, which can have unintended negative consequences on brain health.[11] Examples include the adoption of interventions with inadequate evidence of effectiveness and/or safety and limited privacy protection of some interventions. Of particular concern are those which rely upon social media platforms which have been shown to be associated with risk for cyber-exploitation and political polarization, and which propagate issues such as psychological distress.[11,12] Novel innovations need to be tested in a more controlled setting and either optimized or flagged as inappropriate for clinical use.

We suggest the brain health field can benefit from the living lab model. The European Network of Living Labs defines Living Labs as *"a user-centered, open innovation ecosystem based on a systematic user co-creation approach, integrating research and innovation processes in real-life communities and settings"*.[13] Living Labs are both clinical practice-based organizations that facilitate and foster open, collaborative innovation, as well as real-life environments (such as the home) where both open innovation and user innovation processes can be studied and subject to iterative refinements and where new solutions are developed. Living Labs operate as platforms for deep collaboration and Design Thinking–a concept we will later explore in greater depth. This operates among patients, families, research organizations, companies, cities and regions for joint value co-creation, rapid prototyping or validation to scale up innovation and businesses. We note exemplars of a Livings Labs in other areas of medicine. In the Netherlands, a 3-year Living Lab project was established, named eLabEL, to unravel the slow implementation of eHealth solutions in primary care, and to optimize the implementation of such solutions.[14] In this Living Lab, patients, health care professionals, small- and medium-sized enterprises (SMEs), and research institutes collaborated to select and integrate fully mature eHealth technologies for implementation in primary health care. Seven primary health care centers, 10 SMEs, and 4 research institutes participated. The large-scale implementation of eHealth seemed to depend on the efforts of and interaction and collaboration among four groups of stakeholders: patients, health care professionals, SMEs, and those responsible for health care policy (health care insurers and policymakers). Recently, Rodriquez-Villa et al.[15] outlined the structure for a Mental Health Digital Clinic and empirically profiled the formation of such a clinic at the Beth Israel Deaconess Medical Center in Boston, MA. The Digital Clinic seeks to integrate technologies such as smartphone apps and sensors directly into care and has an emphasis on the therapeutic alliance, measurement-based care, and shared decision making. This Digital Clinic has developed a well-articulated implementation process adapted from the Replicating Effective Programs Framework.[16] In Canada, BaieSaint-Paul, a rural Emergency Department in, Québec, recently announced the formation of a Living Lab.[17]

They launched three pilot projects including a quality of work life program, a computed tomography implementation study and telemedicine in ambulances. Other possible solutions will be evaluated and prioritized including in situ simulation, care protocol, telemedicine, point-of-care ultrasound, helicopters and drones. The Living Labs model has not yet been refined in the context of brain health.

We propose a Brain Health Living Lab model as a model to optimize the speed and efficacy of innovation development and deployment. We suggest a Brain Health Living Lab is a user-centered, iterative, open-innovation ecosystem, operating in a clinical-academic setting, integrating concurrent clinical care, research and innovation processes within a public-private-consumer partnership. By leveraging the Brain Health Living Lab model, patients, caregivers, families, medical, allied and community health care workers, health coaches, technology innovators, engineers, entrepreneurs, researchers, and policymakers can collaborate and grapple with brain health challenges around the world within a connected community setting. This collaboration should occur during the selection, integration, implementation, and evaluation of brain health tools and interventions based on evolving and emerging technologies. This lab model can be integrated into current brain health clinic infrastructure. We believe this diverse, inter- and transdisciplinary approach is critical and will yield many unanticipated improvements and advances, especially in developing the brain health clinic of the future.[18] This approach is unique to current clinical-academic settings for a number of reasons: it is a systematized approach to this work, and it involves a wider array of professionals (e.g., including engineers, entrepreneurs).

There are clearly unique considerations for Brain Health Living Labs. These are best explained by considering the core components of Brain Health Living Lab design, which include frameworks from human-centered Design Thinking, responsible innovation in neurotechnologies, stakeholders, translational medicine and implementation science, and unique funding opportunities. Table 1 outlines unique considerations within these components.

Design thinking is an established systematized approach to find a solution for a real need using an iterative method which will facilitate creating and maintaining momentum of Brain Health Living Labs. The fundamental philosophy of Design Thinking is to empathize–fully understand the perspectives, emotions, needs, and motivations of individuals for which one is designing–and reframe a problem, so that one can innovate faster using systematic methods. The core components of design thinking include: Empathize, Define, Ideate, Prototype, and Test. A recent systematic review[19] of intelligent assistive technologies (technologies leveraging on computing capabilities, robotics, and machine intelligence for assistive purposes) noted that only 40% of current intelligent assistive technologies are designed through user-centered approaches.

An Implementation Science understanding of Brain Health Living Labs development is critical.[20] A recent systematic review[21] identified factors that influence the acceptance by seniors of technology for aging in the postimplementation stage. The results show that acceptance of technology in the postimplementation stage is influenced by 36 factors, divided into six themes: concerns/problems regarding technology (technical errors, etc.), experienced positive characteristics of technology (e.g., ease of use factors, privacy implications), expected benefits of technology (e.g., increased safety, companionship, increased security, etc.), need for technology (e.g., perceived need to use), social influence (e.g., influence by peers, family or surroundings), and characteristics of older adults (e.g., past experiences/attitudes, physical environment). With careful consideration, many of these factors can be managed. A recent commentary[22] proposed helpful clinician guidelines to facilitate technology use by older adults and noted four key goals: increase access to technology, promote technology literacy, increase patient buy-in, and be familiar with the tools.

To date, we are not aware of any operating Brain Health Living Labs. However, we do note many examples of technological approaches to brain health care, which offer insights into components of Brain Health Living Labs (see Table 2).

When considering a novel model such as a Brain Health Living Lab, we must attempt to measure and track the impact of this model on patient-centric relevant outcomes. When considering optimized patient outcomes, metrics may include feasibility, utilization, typical clinical outcomes, as well as care satisfaction, shared decision making, technology usability, and stickiness.[25] When considering clinician outcomes, the usability of new technologies should be considered, as well as time spent in clinical encounters. When considering health system outcomes, the costeffectiveness and return on investment of new innovations are also key. If we view the brain health technology sector as an investment sector, it would be helpful to track the success of technologies and companies (e.g., investment, acquisition, and other financial trends). We call on geriatric brain health care providers to embrace this model and engage in its realization. Care providers can engage in the innovation process in a variety of ways–from trialing and providing feedback on emerging technologies, to lobbying for funding to construct a Brain Health Living Lab within their clinical setting. Care must be taken to ensure Brain Health Living Labs are built in a socio-ethnically sensitive manner–across high-, middle-, and low-income countries in a way that reflects diverse care needs and infrastructure in diverse countries and settings. These settings will require tailored and novel skill sets and resources. Finally, we envisage a network of Brain Health Living Labs can serve as the surveillance system, developers, early adopters, practical adapters, and pragmatic assessors of evidence-based technologies. We recommend piloting of the Brain Health Living Lab model, to determine scalability and implementation requirements.

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TABLE 1.

Unique Considerations for Brain Health Living Labs

Component	Human-centered Design thinking	Responsible Innovation in Neurotechnologies	Stakeholders	Translational Medicine and Implementation Science	Funding Opportunities
Basic Frameworks	– Empathize – Define – Ideate – Prototype – Test – Scale	– Promoting responsible innovation – Prioritising safety assessment – Promoting inclusivity – Fostering scientific collaboration – Enabling societal deliberation – Enabling capacity of oversight and advisory bodies – Safeguarding personal brain data and other information – Promoting cultures of stewardship and trust across the public and private sector – Anticipating and monitoring potential unintended use and/or misuse	– Patients, – Caregivers – Families – Medical, allied and community health care workers – Health coaches – Technology innovators – Engineers – Entrepreneurs – Translational researchers – Implementation scientists – Policy makers	– T0, discovery – T1, first in humans or proof of principle – T2, clinical trials – T3, health-care policy and guidelines – T4: long-term effectiveness and safety – T5, global health	– Federal Agencies (NIH, VA, NSF) – Venture capital – Angel investors – Crowd funding – Information technology company investments (e.g., social media platforms, search engines, consumer electronics companies), – Established medical innovation company investments (e.g., pharma, biotech, medical device), – Philanthropy – Social impact investing
Unique considerations	Must recognize understanding of symbols, gestures, and jargon. Must accommodate sensory impairment accompanying aging (e.g., older users may need to increase the font size, change the boldness of the font, and make other adjustments to the device settings) Recognition patient's often have multimorbidity issues.	Must consider patient autonomy and informed consent. Privacy and data transparency Protocols, APIs, and open data sharing	Recognition that adoption may require several approaches such as health coaches, peer-to-peer and financial incentives Recognition that caregivers play a critical role in the brain health field. Interdisciplinary engagement of end users, entrepreneurs, engineers and the other core health works is key.	Geroscience to be considered in the T0 'Discovery' phase. Must recognize older adults may be less aware of available new technologies. Must recognize cost and availability issues of broadband internet and smart devices. The postimplementation phases T4 and T5 must consider unique issues faced by older users. Promote multidirectional communications between implementation scientists and healthcare decision-makers by facilitating their involvement in the Brain Health Living Lab ecosystem.	Consider organizations which are aligned in improving the quality of life and outcomes for patients with brain health disorders (e.g., AARP, integrated delivery networks). Consider classical insurers such as Medicare and Medicare Advantage programs.

TABLE 2.

Examples of Technological Approaches to Brain Health Care

Cleveland Clinic's Brain Health Initiative: This initiative launched a website promoting six pillars of brain health: physical exercise, brain-healthy diet, mental fitness, social connectedness, sleep integrity and stress reduction, and control of vascular risk factors (see for further details: https://healthybrains.org/). Users can calculate a Brain Health Index based on their own 6 pillars and can move the index based on changes in their pillars. Information from Fit Bits™ or other monitoring devices can be integrated into a personal dashboard. Researchers can follow anonymized data to determine the relationship of the Brain Health Index to memory and cognition self-assessments based on the Cognitive Function Instrument.
ORCATECH (The Oregon Center for Aging and Technology): A model which focuses on translating integrated conventional and digital data into actionable health and wellness outcomes, improving the aging experience. *ORCATECH* uses and develops technologies that can assess everyday home-based activities, providing real-world and real-time activity monitoring and health data (see for further details: https://www.ohsu.edu/oregon-center-for-aging-and-technology). This platform has been further established through NIH and Veterans Affairs support as the Collaborative Aging Research Using Technology (CART) system which is an open source, sharable, technology agnostic research-focused platform deployed to diverse populations and research teams in North American and Europe.
Integrated Network for Completely Assisted Senior Citizen's Autonomy (inCASA): This is a model developed to assist the growing demand for independent living among elderly in developed countries and demonstrate the concept of integrated health and social services for the elderly living alone[23]. Sensors and care monitoring technologies were integrated into the homes of elderly people living alone with chronic health conditions[23]. This study demonstrated that activities that captured activity and physiology within the home have the potential to improve care and have positive impact on health and well-being of the elderly by enabling timely interventions and improved disease management.
McLean Hospital Technology and Aging Lab, part of McLean's Institute for Technology in Psychiatry: Focuses on testing and implementing the highly targeted use of technology for clinical indications (see for further details https://www.geropsychtech.org/). This includes refining the use of sensor technologies for diagnosis and management of behavior symptoms in dementia and depression, as well as technology-enhanced interventions for mood and cognitive disorders.
Citizen Scientist Living Lab Models: Organization of older individuals who can serve as normal participants for natural history studies and be screened for participation in prevention trials; these citizen scientists provide critical contribution to advancing therapeutics. This Living Lab can be done remotely, face-to-face, or through a hybrid model. An example of a hybrid model focused on Alzheimer's disease prevention is the Trial-Ready Cohort for Preclinical/Prodromal Alzheimer's disease (TRC-PAD; NIA-funded).[24] Interested citizens are accessing through an online platform and an algorithm is being developed to predict amyloid positivity and trial readiness (APTwebstudy.org). TRC-PAD helps fill a critical gap in the process of developing disease-modifying therapeutics and primary prevention of Alzheimer's disease. Further, TRC-PAD and other hybrid or remote Living Labs may benefit from integrating characteristics that increase user adherence over time (also known as "stickiness") onto their digital platforms.[25]