Disrupting BPSD in Alzheimer's Disease

Roadmap for Innovation in Behavioral and Psychological Symptoms of Dementia (BPSD)

Solving Unmet Needs Through Technological Innovation

Introduction

In the spring of 2016, the Global Council on Alzheimer's Disease (GCAD) released a landmark white paper, "Disrupting Alzheimer's: The Opportunities for Technology in Alzheimer's Disease." This paper captured the insights of a year's-long project, led by Otsuka America Pharmaceutical, Inc., that brought together the technology and Alzheimer's communities to spur innovation and guide technology development to solve the real, practical problems faced by people affected by Alzheimer's disease. The goal of the paper was to bridge the communications gap between the technology and Alzheimer's communities by offering guidance for innovators developing solutions for patients with Alzheimer's disease.

One of the outcomes was a Pitch Event co-hosted by GCAD, Otsuka, and AGE-WELL Canada, held alongside the Alzheimer's Association International Conference (AAIC) in Toronto in July 2016. This Pitch Event gave groundbreaking start-ups the opportunity to pitch to a diverse panel of expert judges in the field of Alzheimer's disease, including physicians, caregivers, industry representatives, venture capitalists, and people with Alzheimer's disease. The winner was WinterLight Labs, Inc., whose tablet-based tool can monitor cognition and screen for clinical trials for people with Alzheimer's disease.

Following the success of the Pitch Event, we realized how much additional opportunity there was at the intersection of technology and clinical trials for patients with Alzheimer's disease. After a series of one-on-one conversations – with physicians, nurses, advocates, caregivers, policymakers, and those living with Alzheimer's disease – we concluded that the behavioral and psychological symptoms of dementia (BPSD) in people with Alzheimer's disease were in urgent need of disruption. Otsuka verified this hypothesis through a "social listening" market research project that analyzed what people affected by dementia were saying online about BPSD and their journeys and struggles.

This paper, therefore, aims to similar ends as GCAD's first paper, "Disrupting Alzheimer's," only the goal here is to focus on the opportunities for technology to solve for the problems of BPSD in Alzheimer's disease. To that end, in the pages that follow, we identify, define, and discuss unmet needs specific to BPSD in Alzheimer's disease, and we hope to offer a Roadmap for Innovation to the technology community. Otsuka America Pharmaceutical, Inc., its affiliate Avanir Pharmaceuticals, Inc., and the Global Council on Alzheimer's Disease (GCAD) are pleased to launch this paper as sponsors of the Pitch Event at the World Congress for the International Association of Gerontology and Geriatrics (IAGG).

We believe there remains tremendous opportunity for technological innovation to improve the lives of people affected by dementia.

If this paper provokes any new ideas, please reach out to Mary Chi Michael, Vice President, Patient Advocacy and Stakeholder Management, Otsuka America Pharmaceutical, Inc., at mary.michael@otsuka-us.com.

Signed,
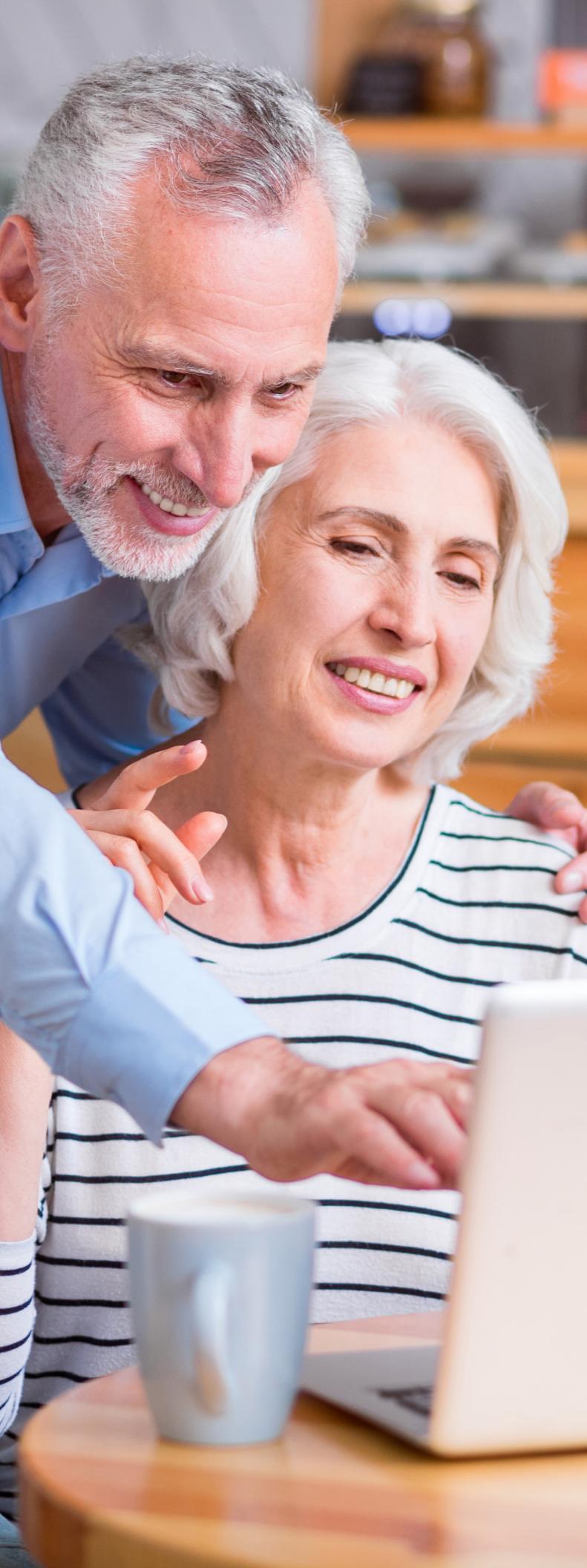
Mary Michael

Mary Michael
Vice President Patient Advocacy and Stakeholder Management
Otsuka America Pharmaceutical, Inc.

With contributions from:

Jim Mann, Diagnosed with Alzheimer's disease, 2007

Alex Mihailidis, Ph.D, P.Eng., Scientific Director, AGE-WELL Network of Centres of Excellence

Marwan Sabbagh, M.D., Barrow Neurological Institute

Jackie Pinkowitz, M.Ed., Dementia Action Alliance

Kate Zhong, M.D., Global Alzheimer's Platform Foundation

Murray Zucker, M.D., Healthcare Consultant

Why BPSD in Alzheimer's Disease, and How to Help

It is no secret that Alzheimer's disease is fast becoming one of the greatest threats to global wellbeing in the 21st century. Dr. Peter Piot, who engineered the World Health Organization's fight against HIV/AIDS, recently stated that Alzheimer's disease was a "global health time bomb," and that the discrimination people with the disease receive is a "human rights violation."[1,2] In 2015, there were an estimated 46.8 million people worldwide living with dementia and this number is believed to be close to 50 million in 2017. This number will almost double every 20 years, reaching 75 million in 2030 and 131.5 million in 2050.[3]

As this "time bomb" ticks, the world has begun to respond. As part of the G8's shared initiatives, it launched the "Global Action Against Dementia" initiative, with former UK Prime Minister David Cameron spearheading the Prime Minister's Challenge to improve funding for dementia in the UK.[4,5] Even popular culture has taken notice, with books and movies like *Still Alice* and *The Notebook*. Yet BPSD in people with Alzheimer's disease remains underappreciated.

This is a disservice to people living with Alzheimer's disease who develop BPSD, and it is a cold shoulder to families, friends, and caregivers.

According to the International Psychogeriatric Association (IPA), approximately 97% of people with dementia experience one or more symptoms classified as BPSD, which IPA defines as "symptoms of disturbed perception, thought content, mood, or behavior that frequently occur in patients with dementia."[6] More specifically, IPA identifies BPSD as behavioral changes, such as aggression, restlessness,

agitation, wandering, inappropriate behaviors, and disinhibition, as well as psychological changes, such as anxiety, depression, delusions, and hallucinations.[7]

These symptoms can be some of the most difficult aspects for people managing Alzheimer's disease.[8] While issues like memory loss and cognitive impairment may be the most common symptoms that are discussed – and the most common focus of research on how technologies can address dementia – BPSD can burden families and accelerate institutionalization.[9]

In long-term care facilities, moreover, BPSD can complicate and jeopardize living situations, adding stress, costs, and uncertainty.[10]

Truly, the need to disrupt BPSD in Alzheimer's disease is urgent.

As we consider where, how, and to what end technology can intervene, it is worth looking beyond how IPA defines BPSD. While we do not want to suggest that the IPA definition is inaccurate, we do suggest that there is another perspective from which we can examine BPSD in Alzheimer's disease.

That is the human element. We have heard from caregivers and people with behaviors classified as BPSD that the problem they're facing is not so much a set of symptoms as much as a set of situational triggers. In other words, "aggression" or "restlessness" can and should be seen not only as the symptom of a disease, but as a human reaction to situational circumstance.

A Framework for Innovation

Having discussed the unique considerations of solving for BPSD, we now turn to a framework for thinking about Alzheimer's disease more broadly. In "Disrupting Alzheimer's," it was hypothesized that technologies were not realizing their full potential to improve the lives of those affected by Alzheimer's disease because the technology community did not – quite justifiably – understand the complex nuances of Alzheimer's disease.[1]

A foundational reason for this shortcoming was a communications gap between the Alzheimer's disease and technology communities. Simply put, those developing technologies had not come to fully appreciate the unique challenges and journeys of those with Alzheimer's disease and their families and caregivers. Simultaneously, those in the Alzheimer's community had not sufficiently explained to technologists what people managing Alzheimer's disease need.

"The caregivers and the people living with dementia would give them much needed details of the issues and enlighten the technology specialists with outlines of other issues and areas of need."

JIM MANN, DIAGNOSED WITH ALZHEIMER'S DISEASE, 2007

PILLARS FOR EFFECTIVE SOLUTIONS

1 **An Improved Feedback Loop** One of the barriers to creating effective technologies for Alzheimer's disease is the lack of a feedback loop between end-users and developers.[12] In order to produce technologies that will be adopted, developers must prioritize the needs of those with Alzheimer's disease and caregivers from the first moment of the design process. They must also collect feedback on where, how, and to what end their technologies are being used. What a developer imagines in the creation process can be very different than what happens in the marketplace. Closing this feedback loop will create better, always-improving solutions.

One essential tenet in this process is engaging Human Factors Engineering (HFE) to ensure functionality. This will require not only outreach to the Alzheimer's community and consultations with experts, but also an ongoing dialogue and a "continuous improvement" mindset. We hypothesize that it is only through such an approach that innovators and entrepreneurs can develop a refined understanding of how a technological solution is – and is not – solving real-world problems.

2 **Integrated Smart Systems** The rise of connected devices and advanced analytics provides a promising future for Alzheimer's disease care. Some of the most useful solutions for those with Alzheimer's disease will not be standalone products, but integrated systems of devices that track condition, behavior, needs, and more.[13] These systems will, and must, know more about a person's condition and environment than he or she does.

Such "smart" products would not perform a single use, but play the role of a trusted partner in providing

care and enabling independence. If developed and used properly, these smart devices can collect data from multiple domains and then report out in a way that is useful for caregivers, physicians, and others and promote a safe environment by adequately responding to input that would indicate a serious problem.

3 A Broader Set of Solutions

Technologies for Alzheimer's – and most diseases, for that matter – tend to focus on the same things: medication adherence, vital signs monitoring, transportation, communications, and tracking.[14] A broader set of solutions is needed.

A top unmet need for BPSD in Alzheimer's disease is caregiving. Research shows that, in the U.S., direct societal costs of caring for those with Alzheimer's disease are estimated to be $259 billion and are expected to increase to more than $1.1 trillion in 2050.[15] But it's not only the costs: it is extremely difficult for families to explore and weigh their decisions. We propose that there is a major opportunity for technologies to fill this

non-traditional need, as well as others like insurance, legal questions, and estate planning.

4 Solving Dynamic Problems

During the Alzheimer's disease journey, issues with sleep patterns, dietary habits, behaviors, and emotions are in constant flux. In other words, the problems of Alzheimer's disease are dynamic and they cannot be solved by a solution that is static. For a technology to be useful for any period of time, it must solve be adaptable and solve for dynamic problems.

Yet these dynamic problems are, by definition, difficult to solve. They demand a solution that changes and adapts with the person's needs.

What dynamic problems need solving most urgently? One way to answer this would be to look at the most common triggers for moving a loved one into institutional or long-term care. Research shows that top triggers for nursing home placement are managing behavioral symptoms and managing physical needs.[16, 17]
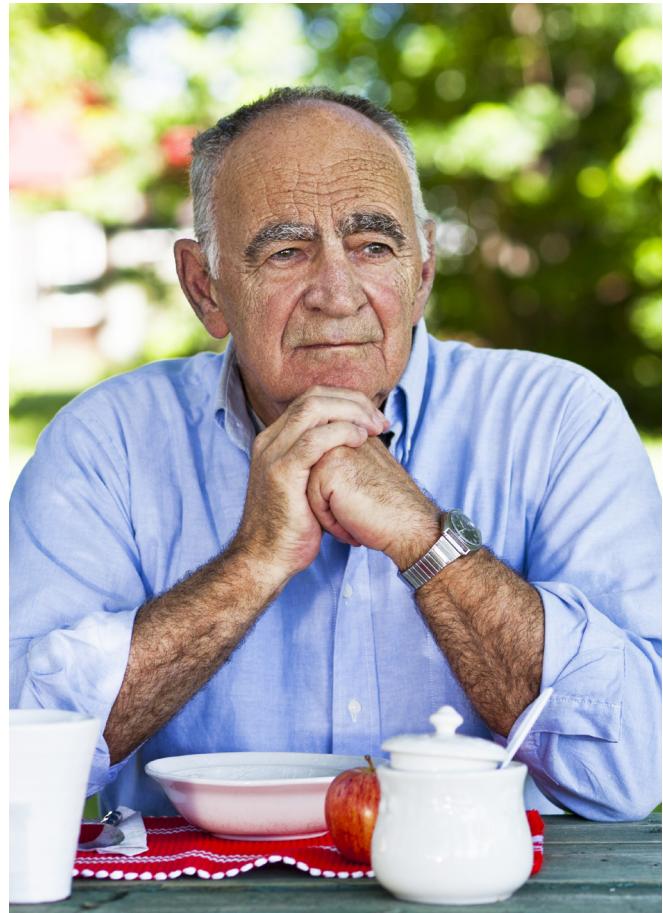
5 Focusing on the Caregiver Caregivers are critical end-users for technology innovations, especially as the disease progresses. They stand at the center of an overall community of care, and they will be pivotal in determining if a technology is adopted and used. Technology must support or reduce the demands on caregivers, not add responsibilities or require a substantial commitment of time to function properly.

Moreover, caregivers themselves need help. For some caregivers, the demand of caregiving may cause declines in their own health and increase their susceptibility to disease and health complications, particularly sleep disturbances.[18] Technologies for Alzheimer's should strive to reduce the physical and mental stresses of caregiving.

6 Playing the Connecting Role Technologies for Alzheimer's can provide substantial support by connecting and communicating between those with the disease, caregivers, family members, physicians, in-home care professionals, and so on. Each of these stakeholders plays an integral role in the care and treatment of Alzheimer's, but the flow of communication between them is limited.

One potential solution for a technology would be to gradually shift control to caregivers, family members, HCPs, etc., eventually reaching a point where a device or application operates independently of a person with Alzheimer's. Preferred solutions would not add additional burden to care providers, and they would respond to the changing abilities of persons with AD to manipulate technology controls.

7 Privacy and security Any successful solution must ensure that data is safely stored and transferred, and that the autonomy of the people using the solution is maintained. In retail, where security has become a hot-button issue with technology, questions of security and privacy are

largely transactional. In health – and especially Alzheimer's – this isn't enough. Privacy and security must be embedded in the very design of the tool.[19]

8 Integrate into the workflow For multiple end-users of a technology solution – including clinicians, healthcare providers, and caregivers – two end-goals must be achieved: 1) efficiency and 2) seamless integration into workflow. Professionals yearn for technology solutions that solve problems, but they will not integrate them into their practice if they are inefficient or disrupt workflow. Caregivers, who are already overburdened, are unlikely to adopt new solutions that don't save time and make life easier. The best technologies don't even feel like technologies at all; they simply are tools that make life better and more efficient. This must be the goal for any intervention in Alzheimer's disease.

DESIGN PILLARS FOR THE UNIQUE CHALLENGES OF BPSD IN ALZHEIMER'S DISEASE

In addition to these six pillars, we believe there are three additional ones to consider specific to BPSD

1 **Seeing People, Not Problems** As we discussed above, a technology for BPSD that focuses only on the effect and not the cause will be inadequate. We cannot focus only on symptoms of agitation, aggression, restlessness, etc., but the causes of these behaviors, which may include the inability of a person with Alzheimer's disease to effectively communicate needs to care providers and HCPs.

It is imperative to bear in mind, at all stages of development, that people with Alzheimer's disease and BPSD are people, not problems. If we engage them like problems, we will fail, and we will, as Dr. Piot suggested, further propagate in the "human rights violation" that has too often defined the Alzheimer's journey.

2 **Enabling Support & Safety** There is a need for technologies that mitigate the risk and disruptive effects of behavioral symptoms like agitation, wandering, and aggression. These can be some of the most distressing, dangerous changes observed during the course of Alzheimer's disease, for both the caregiver and the affected individual.[20] Such symptoms are fairly common: as many as 50% of individuals with Alzheimer's show aggression and hostility, and 60% of individuals with Alzheimer's wander.[21,22]

To ensure that these symptoms do not threaten the safety of both the person with Alzheimer's disease or others, technologies can connect caregivers to outside sources of support and, if necessary, intervention. For example, technology can enable family members to candidly and discretely discuss an individual's aggressive behavior with physicians, care aides, or other professionals. Effective technologies will help the caregiver to feel safe and supported, while also ensuring timely interventions.

3 **Managing Environmental Factors** In the presence of BPSD, technology can significantly improve quality of life by enabling positive changes to environmental factors that affect or aggravate symptoms. Managing factors like pain, physical exercise, visual and auditory stimuli, social interaction, and daily routines can result in a significant improvement in BPSD. [23]

Technology can help family members and healthcare providers to track these factors, identify those that impact an individual, and make resulting changes to care. Such solutions can be as simple as providing a tablet with interactive apps and video clips, or as complex as computer algorithms that automatically detect facial cues indicating pain.[24,25] In each case, technologies should help caregivers to identify factors that can decrease the occurrence and severity of BPSD, and enable tools or environmental changes that positively shape those factors.

There is an immense potential for technologies to address the challenges of Alzheimer's, and BPSD specifically, but this potential has not been fully realized. We call for an approach that considers the unique nature of Alzheimer's and those it affects, from the beginning of the design process. In particular, additional design considerations should inform technologies that address behavioral and psychological symptoms.

Unmet Needs of BPSD in Alzheimer's Disease

Here, we outline five areas of unmet need related to BPSD that are most ripe for technological innovation. These are, by no means, the only unmet needs. A set of rating criteria, including: level of importance, potential value to those managing Alzheimer's, likelihood for technological innovation, and potential to be commercialized and validated.

Unmet Need: Enriching the lives of those with Alzheimer's Disease and BPSD

People with Alzheimer's disease become frustrated with their diminishing abilities to communicate, interact, and perform everyday tasks. This frustration can reduce quality of life and contribute to BPSD.[26] At the same time, research suggests that therapeutic interventions can help if they improve mood and provide engaging, enriching experiences.[27] Activities such as art, music, and dance can evoke positive emotional responses, even in people with moderate to severe Alzheimer's disease, and many caregiving support organizations consider these activities to be beneficial throughout the disease's progression.[28]

Technologies could provide platforms for the planning required for these activities, which can be demanding to organize and supervise. Further, standalone technologies like interactive apps or music could supplement – though not replace – organized enrichment activities.[29] The activities and technologies that offer the greatest benefit will be simple and straightforward, appropriate for individuals with a variety of limitations, and complementary to a person's dignity, skills, and memories.[30]

Alzheimer's Disease and Autism:

One source of guidance for tech developers looking into the Alzheimer's space could be tech solutions for autism. Some of the behavioral symptom clusters associated with Alzheimer's disease are similar to those of autism, and solutions for autism may offer guidance.

Unmet Need: Improving sleep to promote health and address BPSD

Changes and disruptions in sleep patterns are common in Alzheimer's disease, though the underlying medical causes are not well understood.[31] Irregular sleep can have far-reaching effects, as it can aggravate BPSD, including agitation, and trigger behavior that is challenging for caregivers, such as restlessness at night.[32,33] These disturbances vary from person to person, and they usually become more severe as the disease progresses.[34]

A technological solution for sleep disturbances could facilitate data collection and communication between caregivers and medical professionals to modify care and promote a healthy sleep pattern. In particular, expert organizations recommend consulting with a doctor to address any underlying conditions that may be contributing to poor sleep, such as sleep apnea, depression, restless leg syndrome, or pain.[35] In addition, a technology might directly enable more consistent, natural circadian rhythms and sleep patterns. For example, research shows that levels of lighting "beyond that which is considered to be normal" can improve sleep and BPSD.[36]

Unmet Need: Providing practical, comfortable, and dignified in-home monitoring.

Smart-home technology and wearable "tele-health" devices have been tested in a variety of settings for their ability to monitor the safety of people with Alzheimer's disease, and these tests suggest a promising area for further innovation.[37,38] Though a number of these technologies have already been developed, more could be designed to specifically address the unique safety needs of people with Alzheimer's disease. Particular concerns associated with BPSD include wandering and confusion, which can create dangerous situations, such as leaving a stove turned on.[39]

Effective technologies in this area must offer secure monitoring, while also addressing practical and ethical considerations. Their deployment must protect not only the safety of the person with Alzheimer's disease, but also their dignity and right to privacy. Wearable technologies should be adequately comfortable and unobtrusive to avoid causing distress. Similarly, monitoring technologies must enable individuals with varying degrees of cognitive function and differing caregiving models to exercise choice and control over their environments.[40]

"Will it keep me safe? Do I feel spied on? Is the complication in understanding its operation worth the headache? And then of course family dynamics will play a role with the family's understanding of a product, their attitude towards it and their communication methods with Mom and Dad."

JIM MANN, DIAGNOSED WITH ALZHEIMER'S DISEASE, 2007

Unmet Need: Avoiding triggers and finding solutions for aggression.

Aggressive behaviors can be an upsetting and dangerous aspect of BPSD. They are displayed by people with Alzheimer's as a result of a variety of factors, including pain and discomfort, tiredness and overstimulation, frustration and confusion, or even as a side effect of medication.[41] Aggression can be more frequent in the early evening due to a phenomenon called "sundowning," which causes symptoms of Alzheimer's to become more pronounced.[42]

Technologies that help to minimize triggers for aggression would address one of the most challenging aspects of Alzheimer's caregiving. In this area, expert groups recommend lighting and activity-based changes, along with strategies to reduce the stress and agitation that can lead to aggression.[43] A caregiver's safety can also be a primary concern depending on the mobility and function of the person with Alzheimer's, the nature of the aggressive behavior, and other factors.[44] Therefore, technologies should seek to support affected caregivers and ensure their safety.

**Unmet Need: Managing and Assuaging Caregiver Stress**
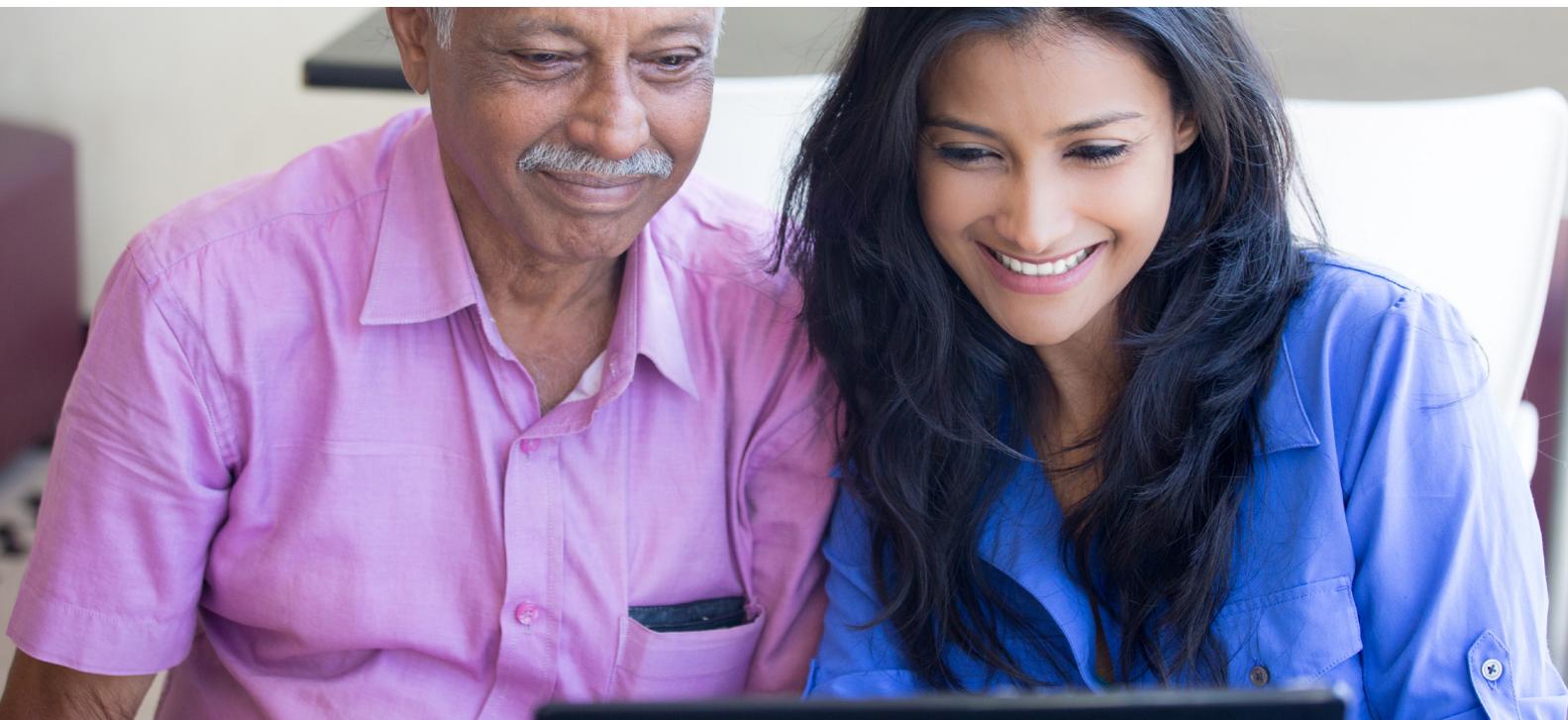
It is no secret that those who care for someone with Alzheimer's disease face complex, evolving challenges. Caregivers can be angry, anxious, withdrawn, and depressed – and their own health can suffer through their caregiving.[45,46] With BPSD, the situation can be more acute.[47]

Unfortunately, innovation in managing caregiver stress hasn't been a breakthrough success. 50% of Alzheimer's caregivers still report feeling emotional stress, despite the dozens of technological solutions for managing stress on market.[48,49] We suggest that the caregiver stress, in both nursing homes and community populations, remains high because

solutions aren't focusing on the issues created by BPSD. As we have discussed, BPSD can be extremely difficult for caregivers and families, and incidence of BPSD can be as high as 97%.[50]

One potential way to un-stick this stagnation is to look at other areas of behavioral health, such as autism or adolescent behavioral management tools. We want to be clear that we are not suggesting that those with Alzheimer's disease should be considered as children, but that some of the common behavioral symptoms are similar to those seen with individuals diagnosed with autism or considered on the autism spectrum. Autism and adolescent behavioral health are established fields that have attracted greater levels of attention and innovation,[51] and there is an opportunity to benefit from these parallel learning environments.
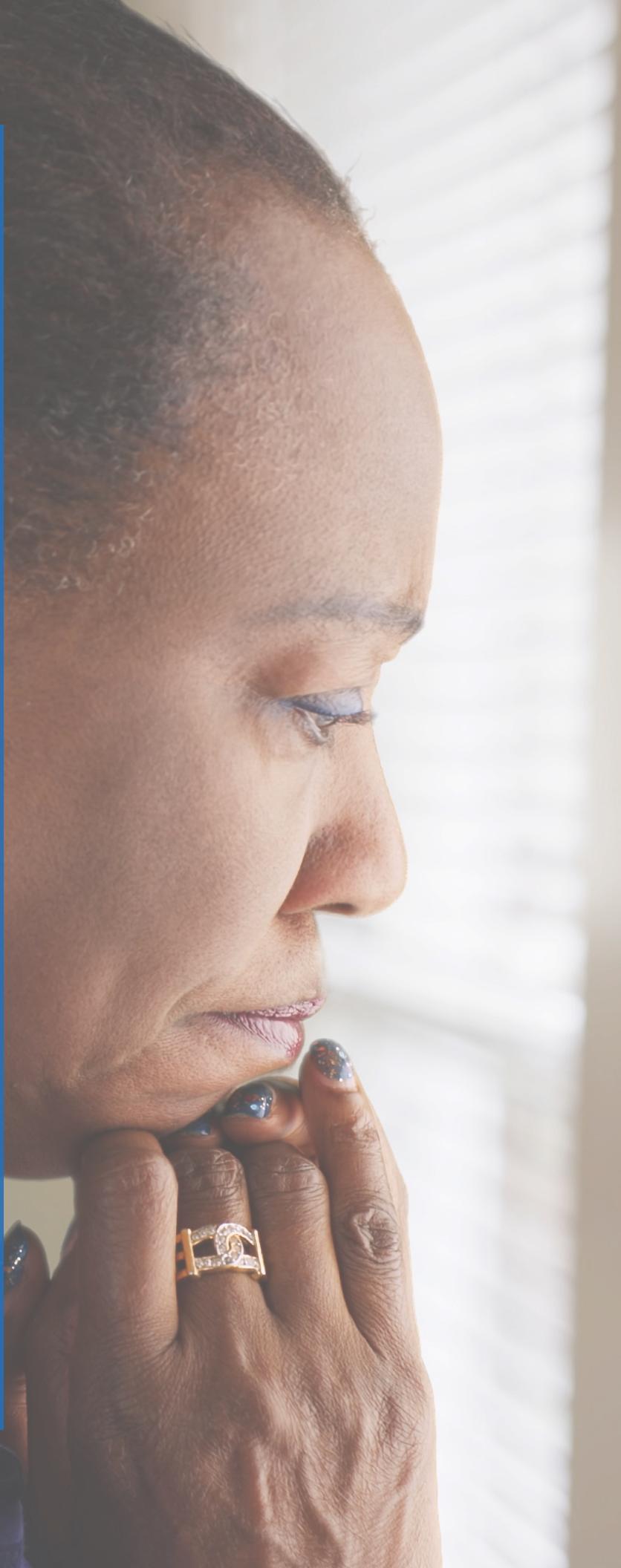
Here it is worth revisiting our previous point about "people, not problems." If the best technological solutions will look at ways to engage and enrich the lives of people with Alzheimer's, let's bring that thinking to the caregiver. How can the caregiver become engaged in these experiences? How can the caregiver become less a caregiver and more a life partner? How can we think about caregivers reducing their stress by promoting activities that prevent the behaviors that create that stress? This is not, we concede, a blanket solution, but we do think that many families could benefit from such an approach.

Each of these five areas represents an important unmet need for those affected by Alzheimer's disease and BPSD, and we hope that our analysis serves as a starting point for the development of technologies to address these needs. In particular, we would encourage the technology community to apply the framework for innovation in BPSD in Alzheimer's disease to these specific areas. This would result in products that account for the limitations of those with the disease, provide support for caregivers and providers, and address the most pressing problems of Alzheimer's disease.

"I don't have a crystal ball but I am excited about the possibilities of technology. Because it can and will make a world of difference to seniors. To their children. To health-care providers and others. To help them – help me – live well, be socially engaged and age gracefully."

JIM MANN, DIAGNOSED WITH ALZHEIMER'S DISEASE, 2007

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