

# Assessing the Preparedness of the U.S. Health Care System Infrastructure for an Alzheimer's Treatment

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## Key findings

- Alzheimer's disease is a progressive neurodegenerative disorder that leads to cognitive decline, dementia, and premature death. No disease-modifying treatment is available but encouraging results from clinical trials offer hope that one or more therapies will become available as early as 2020.
- This prospect raises the question of whether the U.S. health care system is prepared to handle the expected large number of patients. Around 15 million Americans with mild cognitive impairment, which could be an early sign of the disease, will have to be evaluated by specialists, undergo diagnostic testing, and be treated.
- A simulation analysis shows that projected capacity is insufficient to handle the expected case load and predicts patients would have to wait an average of 18.6 months for treatment in 2020. Approximately 2.1 million patients would develop Alzheimer's dementia between 2020 and 2040 while on waiting lists.
- The most pressing constraint is limited capacity of specialists to evaluate and diagnose patients, but access to imaging to confirm Alzheimer's disease and to infusion centers to deliver the treatment would also contribute to waiting times.
- Addressing capacity constraints requires solving a complex puzzle consisting of payment policy, regulatory requirements, workforce considerations, and capacity planning at the national and local levels, combined with awareness campaigns.
- No individual stakeholder will be able to put all the pieces together alone. This report intends to inform a discussion among stakeholders and create a sense of urgency to start collaborating on addressing the obstacles in a timely manner.

Alzheimer's disease is a progressive neurodegenerative disorder that leads to cognitive decline, dementia, and premature death. It exacts substantial burden on patients and on their families and caregivers, as well as on broader society (Alzheimer's Association, undated). As the risk of developing Alzheimer's disease increases with age, the burden of dementia will surge in industrialized countries with their graying populations. In the United States, for example, an estimated 5.5 million patients live with Alzheimer's-related dementia today, a number that is projected to increase to 11.6 million by 2040 (Hebert et al., 2013). So far, no disease-modifying treatment is available, but a large number of drugs in development and promising early-stage results from clinical trials provide hope that one or more therapies may become available in a few years.

Results from earlier clinical trials have led to the hypothesis that Alzheimer's dementia must be prevented rather than cured because no drug has been able so far to reverse manifest dementia. Thus, current trials screen patients for signs of early-stage memory loss and/or loss of thinking skills and for so-called mild cognitive impairment (MCI), conduct tests for Alzheimer's disease pathology, and then treat patients with the goal of halting or slowing progression of the disease.

If this new paradigm bears out in late-stage clinical trials, an important health systems challenge will arise. We estimate that 13.8 million individuals in the United States today live with MCI due to any cause and that this number will grow as the population ages. Most have never been tested for Alzheimer's disease pathology because of the lack of disease-modifying treatments. This substantial number of existing (or prevalent) cases would have to be screened, diagnosed, and then potentially treated as quickly as pos-

sible when a drug first comes to market, in order to prevent progression to full-blown Alzheimer's dementia.<sup>1</sup>

Thus, the objective of this report is to assess the preparedness of the U.S. health care system to handle the potential caseload when a disease-modifying therapy might become available. We used published data and expert interviews to develop a simulation model that quantifies the match between health system capacity and expected demand, and discuss their implications for patients. As many estimates in our model are subject to substantial uncertainty, the ambition of this report is not to provide an exact prediction of future capacity needs but to illustrate the magnitude of the potential problem.

The following sections provide an overview of current drug development for Alzheimer's disease and define the prototypical patient journey to inform a framework for the simulation model. We then describe the simulation model and present data on current capacity and expected capacity growth for the diagnostic and treatment phases in the patient journey. We describe how capacity constraints can limit access to diagnosis and treatment of Alzheimer's disease, and model the effect of resolving the capacity constraints. We conclude with a discussion of the implications of the expected mismatch between supply and demand and potential solutions. It is our hope that the analysis will inform a dialogue among stakeholders on how to ensure that patients can be diagnosed and treated if a disease-modifying treatment becomes available.

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## DISEASE-MODIFYING ALZHEIMER'S THERAPIES IN DEVELOPMENT

The physiologic hallmark of Alzheimer's disease is the accumulation of protein deposits in the brain, referred to as *plaques*. Two types of deposits are observed: amyloid beta and tau plaques. While the exact pathobiology is not fully understood, those plaques are associated with degeneration of neurons, leading to dementia (Folch et al., 2016).

Three types of therapies are currently under development. The first group, the anti-beta amyloid antibodies, uses monoclonal antibodies that are administered intravenously to remove those deposits. Several candidate treatments targeting amyloid are in advanced stages of development and some have been shown to bind to and remove amyloid in early trials; thus, they are the focus of this report.<sup>2</sup>

The second group, the anti-tau antibodies, targets the formation of neurofibrillary tangles in the brain that are also believed to play a role in the disease process of Alzheimer's disease and other neurodegenerative disorders. Like the amyloid antibodies, they are monoclonal antibodies delivered by intravenous administration, but are at earlier stages of clinical development.

The third group, beta-secretase (BACE) inhibitors, block an enzyme that is involved in the formation of amyloid plaques. These BACE inhibitors, which are oral drugs, are in advanced stages of clinical trials, although the phase 3 trial of Verubecestat in patients with mild to moderate Alzheimer's disease was halted for lack of effect, while a phase 3 trial in patients with prodromal Alzheimer's disease is still ongoing (Merck, 2017).

Lastly, vaccines that would harness the body's own immune system to target amyloid deposits and neurofibrillary tangles are in development. Table 1 summarizes the current pipeline for disease-modifying therapies for Alzheimer's disease.

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## PATIENT JOURNEY

The patient journey that we use as the framework for our analysis is depicted in Figure 1. We assume that individuals would undergo cognitive screening (Screening Phase) via a short instrument, such as the Mini-Mental State Examination (or Folstein test), in the primary care setting (Folstein, Folstein, and McHugh, 1975) starting at age 55. Patients screening positive would be referred to a dementia specialist for further evaluation and possible referral to testing for the presence of amyloid deposits (Diagnostic Phase). If they tested positive, patients would return to a dementia specialist for further evaluation. If appropriate, they would be referred to treatment (Treatment Phase), which would reduce the risk of progression from MCI due to Alzheimer's disease to manifest dementia (Outcomes Phase). While waiting for diagnosis and treatment, the disease continues to progress; i.e., patients are at risk of progressing to a stage of the disease at which treatment will no longer be effective.

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## SIMULATION MODEL

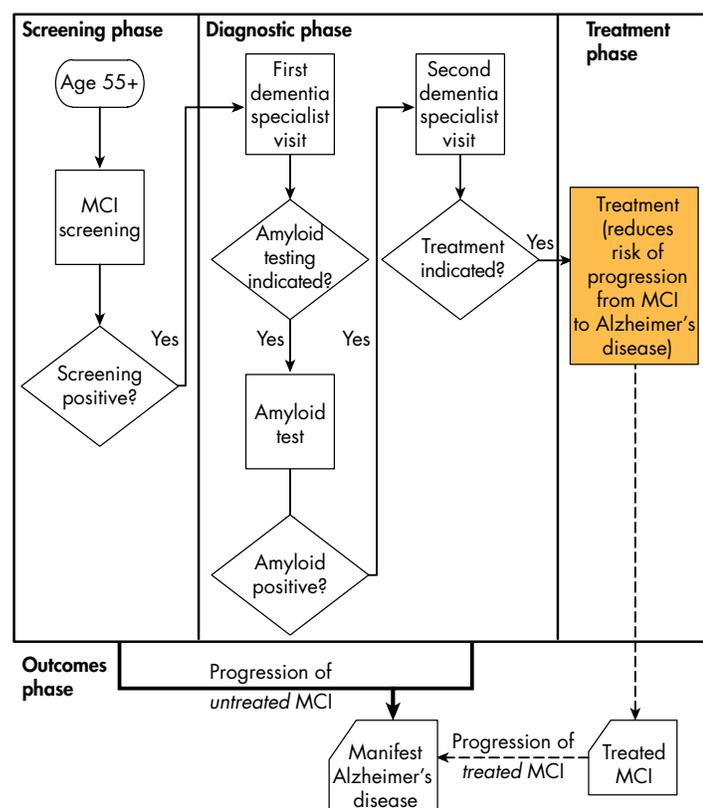
We developed a Markov model in Microsoft Excel to simulate the effect of capacity constraints on access to care for patients

**Table 1: Alzheimer's disease candidates in phase 2 or phase 3 clinical trials, as of October 2017**

Candidate	Sponsor	Clinical Trial Phase	Expected Primary Completion Date	National Clinical Trial Identifier
<b>Anti-beta amyloid antibodies</b>				
Aducanumab (BIIB037)	Biogen*	Phase 3	November 2019	NCT02477800
Gantenerumab	Hoffman-La Roche	Phase 3	December 2019	NCT01224106
Crenezumab	Hoffman-La Roche	Phase 3	August 2020	NCT02670083
BAN2401	Eisai/Biogen	Phase 2	July 2018	NCT01767311
<b>Anti-tau antibodies</b>				
ABV-8E12	AbbVie	Phase 2	December 2020	NCT02880956
<b>BACE inhibitors</b>				
Lanabecestat (LY3314814)	Eli Lilly	Phase 3	January 2020	NCT02972658
Elenbecestat (E2609)	Eisai/Biogen	Phase 3	August 2020	NCT03036280
Verubecestat (MK-8931)	Merck	Phase 2/3	February 2019	NCT01953601
LY3202626	Eli Lilly	Phase 2	June 2019	NCT02791191
<b>Vaccines</b>				
CAD106 (anti-beta amyloid)	Novartis	Phase 2/3	August 2023	NCT02565511
AADvac1 (anti-tau)	Axon Neuroscience	Phase 2	February 2019	NCT02579252

SOURCE: : RAND analysis of company websites and ClinicalTrials.gov website as of Oct 5, 2017, (undated).

NOTE: \*Aducanumab is jointly developed with Eisai.

**Figure 1. Blueprint of patient journey model**

with suspected Alzheimer's disease under the following assumptions that are based on input from clinical experts:

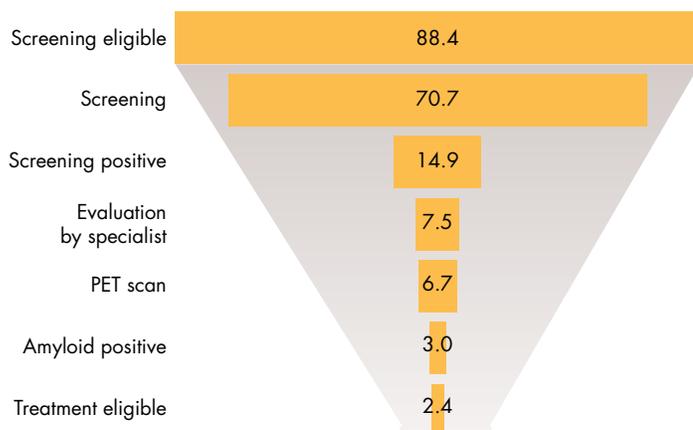
- A disease-modifying therapy for Alzheimer's disease becomes available in 2020.
- Individuals become eligible for annual MCI screening at age 55. Annual screenings take place in primary care settings, where capacity is assumed to be unconstrained. We assume that 80 percent of eligible individuals would be screened each year. Screening starts in 2019 as patients and providers anticipate the approval of the drug. We assume that 50 percent of individuals who screen positive for MCI would continue to receive further evaluation.
- Further evaluation will be conducted during a single visit to a dementia specialist (neurologist, geriatrician, or geriatric psychiatrist). If the evaluation confirms MCI and does not find an alternative explanation for MCI (e.g., prior stroke) or a reason to not pursue treatment (e.g., presence of another life-limiting disease), individuals are referred to testing for biomarkers (i.e., amyloid positron emission tomography [PET] scan). We assume that 90 percent of patients with confirmed MCI that is possibly caused by Alzheimer's disease will undergo biomarker testing.

- Biomarker testing for amyloid is performed by a PET scan, which is currently the only modality for clinical use approved by the Food and Drug Administration (FDA).<sup>3</sup> We assume that 45 percent of MCI patients have clinically relevant amyloid burden.
- If a patient tests positive for amyloid deposits, s/he returns to a dementia specialist for a second visit, during which the treatment indication is confirmed, the patient consents and (if no contraindications to the treatment are found) is referred to treatment. We assume that 80 percent of MCI patients with amyloid plaques have no contraindications for treatment.
- Treatment is delivered by intravenous infusion every four weeks over one year, following the protocols for a typical immunotherapy.
- Treatment reduces the relative risk of progression from MCI to Alzheimer’s disease by 50 percent.

In the model, a patient’s journey through the disease states is guided by transition probabilities from being “healthy” (i.e., no MCI and no Alzheimer’s dementia) to having MCI to having Alzheimer’s dementia. The transition probabilities are based on reported rates from epidemiological studies. Figure 2 illustrates the implications of our assumptions on projected patient numbers at each stage of the patient journey, assuming no constraints on infrastructure capacity for screening, diagnosis, and treatment.

For patients with MCI due to Alzheimer’s disease who have received the treatment, the probability of transitioning to having Alzheimer’s disease is reduced by 50 percent, relative

**Figure 2. Expected patient demand at each stage of the patient journey in 2019 (millions)**



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to the transition probability for those who have not received treatment.

Within the MCI state, patients move through the Diagnostic and Treatment phases based on a system dynamics model with outflows constrained by infrastructure capacity. We model three capacity constraints: availability of dementia specialists, access to amyloid detection testing, and access to infusion centers for treatment. The capacity of the dementia specialist workforce to provide the second (confirmatory) visit to a patient is optimized in such a way that the maximum number of patients receive their confirmatory visit in the same year as their initial visit; i.e., we assume that specialists would not take on new patients for initial visits unless the specialist has the capacity to provide confirmatory visits for existing patients. Our capacity scenarios are based on historical and projected infrastructure estimates. When there were no data to inform our model parameters, we consulted a convenience sample of experts with experience in research, industry, and clinical practice. Because each of the capacity projections depend on a variety of unknowable factors, we set a midpoint assumption, as well as low and high assumptions that reflect the uncertainty.

Table A-1 in the appendix (available online; Liu et al., 2017) contains the values for our model parameters and their respective sources.

## CURRENT CAPACITY ESTIMATES AND PROJECTIONS

### Specialist Workforce

We estimate the capacity of dementia specialists based on historical and projected workforce trends and assumptions about excess capacity. Our dementia specialist workforce consists of neurologists, geriatricians, and geriatric psychiatrists (Table 2). The neurology workforce in the United States is projected to

**Table 2: Projected workforce to supply dementia specialist visits**

Year	Neurologists	Geriatricians	Geriatric Psychiatrists
2020	17,408	7,560	1,953
2030	18,654	8,363	1,659
2040	19,702	7,380	1,746

NOTE: The number of neurologists is based on projections from Dall et al. (2013). The numbers of geriatricians and geriatric psychiatrists are from the Geriatrics Workforce Policy Studies Center (2008, 2011).

increase from 16,366 in 2012 to 18,060 in 2025 (Dall et al., 2013); we assume this trend continues linearly through 2040. The Geriatrics Workforce Policy Studies Center projects increases in geriatricians and geriatric psychiatrists between 2020 and 2030, and declines in between 2030 and 2040 (Geriatrics Workforce Policy Studies Center, 2008, 2011). We assume linear trends based on these projections (see Figure A-1 in the online appendix; Liu et al., 2017).

The availability of the dementia specialist workforce to see MCI patients during the Diagnostic Phase depends on their capacity to conduct the evaluations. In our capacity scenarios, we assume that each dementia specialist provides 2,860 visits, the same average number of ambulatory visits per year as a neurologist (Dall et al., 2013), because we assume the cognitive assessment and confirmation of the diagnosis will be conducted following the same guidelines across the specialist types.<sup>4</sup> We also assume that these specialists devote between 2.5 and 7.5 percent of their capacity to conduct these evaluations of MCI patients. We assume this excess capacity would be relatively low because of increasing demands on the neurology and geriatrics workforce with the aging population; however, capacity may increase with redesigns of health care delivery to be more efficient or with the use of telemedicine (Dall et al., 2013; Freeman et al., 2013; Institute of Medicine, 2008). These workforce projections and excess capacity assumptions translate to estimates that the U.S. health care system can accommodate 1.9 million to 6.3 million additional visits per year over the next 20 years to evaluate patients with suspected MCI due to Alzheimer's disease (see Figure A-2 in the online appendix; Liu et al., 2017).

## Diagnostic Technology

Diagnosing pre-dementia Alzheimer's in a patient with MCI requires confirming amyloid deposits in the brain (Centers for Medicare & Medicaid Services [CMS], 2016). While other biomarker tests are being developed, PET amyloid beta imaging, often referred to as an amyloid PET scan, is currently the only FDA approved test for amyloid deposits in the brain. The patient is injected with a radioactive tracer that selectively binds to amyloid and emits positrons as it decays. A scan with a positron camera can then determine the areas within the brain that show abnormal radiation activity, indicating the presence of amyloid deposits.

## PET Scanner Capacity

We project the capacity for conducting PET scans based on the historical number of PET scans conducted in the United States and the growth in the number of PET scanners. Our projections are based on an installed base of 2,000 devices in 2009 (Buck et al., 2010). We project the growth in PET scanners based on the number of scanners in the United States between 2008 and 2015 (Organisation for Economic Co-Operation and Development [OECD], 2017) and logarithmic projections of this growth trend (see Figure A-3 in the online appendix; Liu et al., 2017). The number of PET scans conducted is based on 2008 data from the National Ambulatory Medical Care Survey (NAMCS) and the National Hospital Ambulatory Medical Care Survey (NHAMCS) (Centers for Disease Control and Prevention, 2017).

Based on expert input, we assume that existing devices are run at about 50 percent of their capacity, mostly because of scheduling constraints. The most common indication for PET imaging today is the diagnosis, staging, and aftercare of advanced cancers. For this indication, the patient is injected with a small amount of radioactively labeled glucose (18F-FDG), which accumulates in metabolically active malignant cells. The PET scanner can detect where this accumulation occurs in the body and thus visualize the size and spread of a malignancy. This test requires the patient to fast, as glucose consumed with food would interfere with the uptake of the radioactively labeled glucose, and is thus mostly conducted in the morning. It is also time-consuming (around 30–60 minutes) because the whole body needs to be scanned, which means these tests cannot be scheduled too tightly. By contrast, a scan for amyloid deposits in the brain as indication of Alzheimer's disease does not require fasting and is less time-consuming (around 20 minutes). Thus, scans can be scheduled for current idle periods, particularly in the afternoons and evenings.

We assume that newly installed devices would be largely dedicated to amyloid scans and could be run at 80 percent of their capacity. We project that the capacity for conducting PET scans would be anywhere from 1.9 million to 2.2 million scans in 2020 and would expand to a range of 2.1 million to 3.7 million scans in 2040 (see Figure A-4 in the online appendix; Liu et al., 2017).

### Manufacturing Capacity for Amyloid Tracer

Conducting an amyloid PET scan requires not only access to a positron camera but also proximity to a facility that has a cyclotron to manufacture the tracer, as it is an unstable radiopharmaceutical product with a limited half-life. According to the Society of Nuclear Medicine and Molecular Imaging (undated) and Cardinal Health (2017), most Americans live within the required 200-mile radius of a cyclotron but there are coverage gaps in Alaska, Hawaii, and the rural West affecting approximately 5 to 10 percent of Americans (Figure 3). Production of the tracer within a facility is unconstrained—i.e., a cyclotron can fill orders for the required amount of amyloid tracer with adequate advance notice.

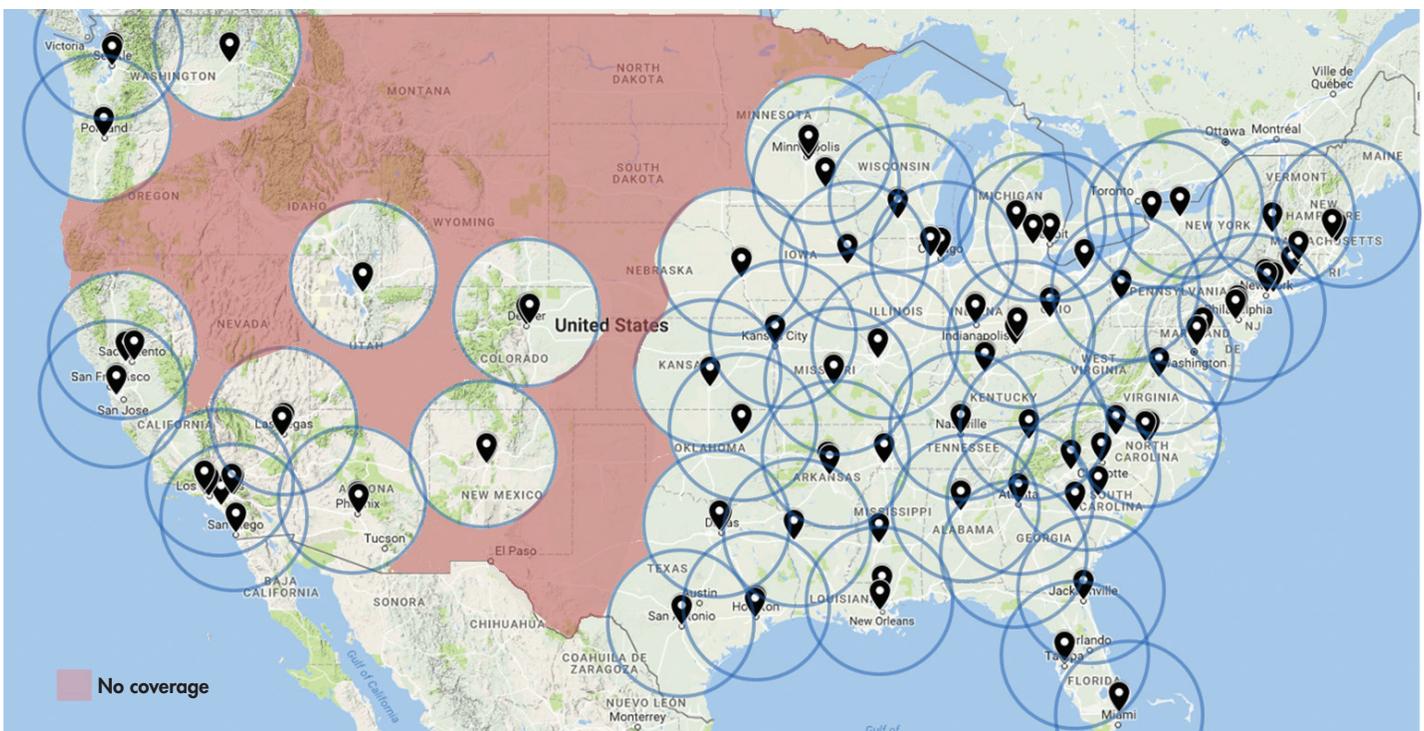
### Infusion Centers

As already mentioned, the amyloid immunotherapy requires intravenous administration, rendering infusion center capacity a possible obstacle to access. The candidates currently in phase 3 trials are infused every four weeks over one to two years. We therefore assume that a course of treatment will consist of 14 infusions.<sup>5</sup>

Our projections of the capacity of infusion centers are based on historical numbers of infusions delivered and assumptions about growth rates (see Figure A-5 in the online appendix; Liu et al., 2017). For projections of infusion center capacity available for an amyloid immunotherapy, we use the number of injections and infusions of therapeutic and or prophylactic substances excluding cancer chemotherapy and biologic response modifiers in the 2011 and 2013 NAMCS and NHAMCS data (Centers for Disease Control and Prevention, 2017). We exclude these two categories because infusion centers specialized for oncology and immunology patients would be unlikely to reallocate resources for the MCI population. In 2011, 4.7 million injections or infusions were provided in physician offices and 0.4 million were provided in hospital outpatient settings. The number in physician offices rose to 6.5 million in 2013.

Based on expert input, we assume that the excess capacity for new patients in current infusion centers is 10 percent, but capacity could be rapidly expanded given demand. We extrapolate the growth in infusion centers from the historical values and assumed that new infusion centers could be largely dedicated to MCI patients, with 80 percent of the capacity delivering the amyloid immunotherapy. Our projected capacity

**Figure 3. Cyclotrons capable of manufacturing amyloid tracers in the United States, as of May 2017**



SOURCE: Society of Nuclear Medicine and Molecular Imaging as of October 6, 2017 (undated); Cardinal Health (2017).

for additional infusions ranges from 2.7 million to 4.0 million infusions in 2020, and expands to between 12.4 million and 24.1 million infusions by 2040 (see Figure A-6 in the online appendix; Liu et al., 2017).

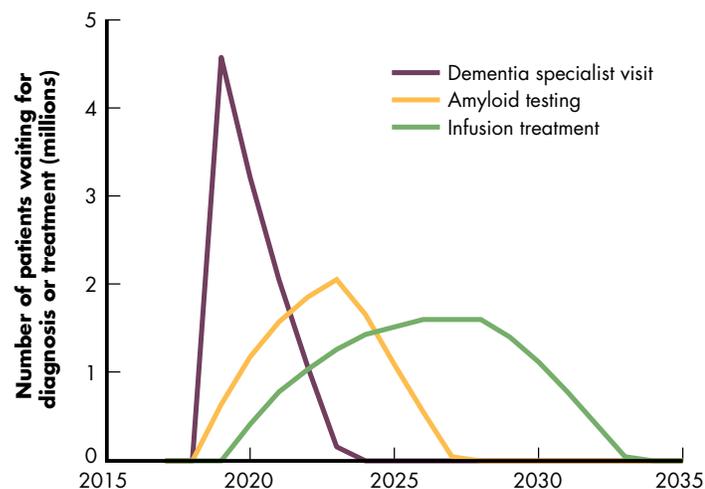
## SIMULATION RESULTS FOR SELECTED CAPACITY SCENARIOS

### Base Case: Current Capacity Projections

By 2019, the population with MCI will have grown to an estimated 14.9 million individuals,<sup>6</sup> who would be eligible for referral to a dementia specialist for further evaluation after having screened positive for MCI. Our base case scenario reflects our midpoint assumptions for capacity growth based on historical growth trends continuing without targeted efforts to expand capacity for the new Alzheimer's therapy. Figure 4 illustrates the waiting list under these assumptions and an optimized allocation of available capacity for specialist visits between initial and confirmatory visits.

The main constraint to access in the first two to three years will be availability of specialists. Since the specialists' capacity to evaluate MCI patients allows less than 4 million patients each year for the first visit, a backlog of 4.6 million MCI patients waiting for specialist appointments results initially. The backlog declines by about 0.9 million to 1.3 million patients each year until it is cleared by 2024.<sup>7</sup> In later years, the backlog shifts to patients waiting for amyloid testing and then waiting for treatment.

**Figure 4. Projected waitlists for Alzheimer's disease diagnosis, testing, and treatment—current capacity assumptions**



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As more patients are referred to amyloid testing, projected capacity constraints would result in increasing wait times after 2020 with a peak of 2.1 million patients in 2023. Given the delays in the diagnostic process, capacity constraints for treatment delivery have a slightly smaller effect, with about 1.6 million patients waiting at the peak in 2027.

The average wait times for all three stages of the Diagnostic and Treatment phases are 18.6 months in 2020 and 1.3 months in 2030 (Figure 5). Under our current capacity assumptions, it would take until 2034 to eliminate waiting times given the backlog of prevalent MCI patients.

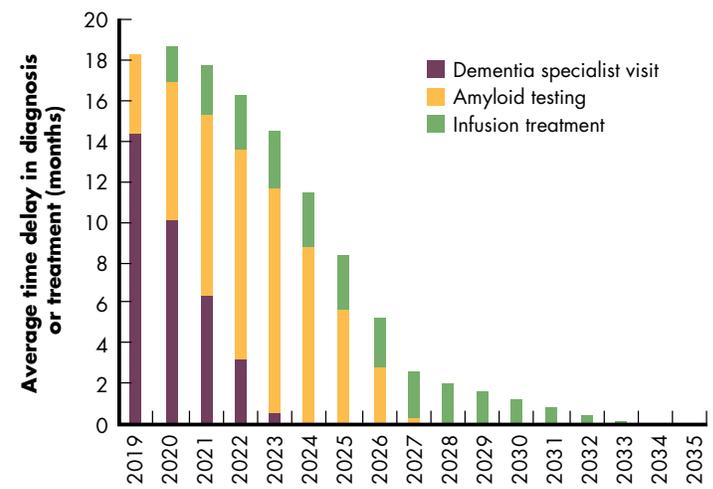
### Alternative Scenario 1: Removing Constraints on Capacity for Biomarker Testing and Infusion Delivery

For this hypothetical scenario, we remove capacity constraints on biomarker testing and infusion delivery in the simulation, leaving only access to dementia specialists as a constraint. As we explain below, this scenario is a conceivable outcome.

#### Biomarker Testing

Substantial increases of diagnostic capacity are possible for two reasons. First, changes in reimbursement policies would likely accelerate the installation of PET scanners. For example, CMS currently covers amyloid scans only in clinical trials under its Coverage with Evidence Development (CED) Policy, but could expand reimbursement to routine clinical use if a disease-

**Figure 5. Projected wait times for Alzheimer's disease diagnosis and treatment—current capacity assumptions**



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modifying treatment for Alzheimer’s disease became available (CMS, 2016).<sup>8</sup> Expanded coverage is expected to lead to additional installations, which we assume to be devoted to amyloid scans for 80 percent of their capacity. For perspective, there are currently around 7,000 nuclear medicines sites (IMV, 2015) and 13,000 CT scanners (OECD, 2017) in the United States but fewer than 2,500 PET scanners, suggesting considerable expansion potential. In addition, new technologies, such as mobile scanners and faster “brain-only” scanners, might become available with favorable Medicare coverage.

Second, alternative diagnostic modalities that would not require dedicated imaging equipment could be available by the time a drug enters the market (Olsson et al., 2016). A test based on cerebrospinal fluid (CSF) is already in use for clinical trials in the United States and has been approved for clinical use in Europe. CSF can be obtained with a spinal tap in a physician’s office or clinic and sent to a central lab for testing, thus making amyloid testing accessible in most locations. Other tests using blood or retinal scans are in development.

### **Infusion Centers**

Current estimated capacity for administering intravenous infusions falls far short of potential demand. As mentioned earlier, we assume that patients will require infusions every four weeks for one year. With an estimated 2.4 million prevalent patients who could be eligible for treatment in 2020, around 33 million infusions would be required if the treatment comes to market in 2020—about three times the estimated overall number of infusions for nonchemotherapy and nonimmunotherapy treatments in the United States in 2017.

Historical precedent, however, suggests that capacity might grow fast enough to accommodate demand. The advent of the immunomodulating antibodies for inflammatory diseases in the late 1990s created a similar challenge, as gastroenterology and rheumatology practices were not set up to infuse large numbers of patients. The increased demand led to physicians adding infusion chairs to their practices. In addition, pharmaceutical companies and free-standing facilities opened infusion centers (Janssen BioAdvance, 2017).

It is likely that dementia specialists and other operators would follow suit, but accommodating the large number of patients with MCI due to Alzheimer’s disease would be considerably more challenging than treating patients with inflammatory conditions for two reasons. First, disease-modifying oral drugs for these conditions existed before the immunomodulat-

ing antibodies were approved, allowing physicians to initially devote limited infusion capacity to refractory cases. Second, inflammatory conditions require lifelong treatment, whereas the amyloid antibodies will likely be administered for a finite number of doses. Consequently, the issue of building capacity for a large number of prevalent cases initially but then only having to handle the much smaller number of incident cases each year did not arise.

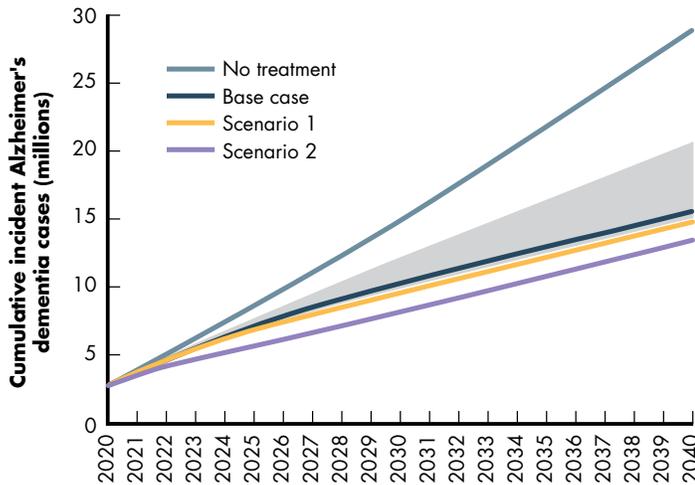
Along with office-based and freestanding infusion centers, another option to expand capacity quickly would be home infusion delivery, which would reduce the need to invest in facilities that might later have idle capacity, if treatment will indeed be time-limited. The amyloid antibodies are likely to be suitable for home infusion from a practical perspective, because they are infused over a reasonably short time, and from a safety perspective, because they are not known to have acute side effects. Currently, traditional Medicare covers home infusions only for homebound patients and for a narrow range of products in non-homebound patients. At the start of January 2021, home infusion will be covered for beneficiaries covered by the traditional program to mirror the coverage already provided to beneficiaries enrolled in a Medicare Advantage plan (Public Law 114-255).

### **Alternative Scenario 2: Removing All Capacity Constraints**

For this hypothetical scenario, we remove all capacity constraints in the simulation—i.e., not just constraints on access to biomarker testing and infusion delivery, but also to dementia specialists. This scenario is an unlikely outcome, because of long training times for medical specialists and their limited elasticity of labor supply. However, we include this scenario to demonstrate the upper bound of potentially avoidable cases of Alzheimer’s dementia if all capacity constraints could be overcome.

Figure 6 shows how the base case scenario and the two alternative scenarios would change the estimated cumulative incidence of Alzheimer’s dementia relative to the scenario without an Alzheimer’s disease-modifying treatment between 2020 and 2040. The gray area in the figure around the base case scenario reflects the lower and upper projections that reflect uncertainty in the capacity assumptions (for the low and high projected capacity assumptions, see the online appendix at Liu et al., 2017).

**Figure 6. Projected cumulative number of new Alzheimer’s disease cases between 2020 and 2040 under different scenarios**



NOTE: The base case represents our midpoint assumptions of current capacity and growth trends carried forward. The shaded area around the base case represents the low- and high-capacity assumptions. Although the cumulative incident cases in Scenario 1 closely coincide with the high-capacity bound depicted in the shaded area, patients in these scenarios are waiting at different points of the Diagnostic and Treatment phases. In Scenario 1, patients are waiting for dementia specialist visits. In the high-capacity bound of the shaded area, patients are waiting for dementia specialists, biomarker testing, and infusion delivery.

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Between 2020 and 2040, we estimate that 13.4 million incident Alzheimer’s disease cases would be avoided in the base case scenario relative to the scenario with no treatment available. Removing the capacity constraints for biomarker testing and infusion delivery (Scenario 1) would allow an additional 0.8 million incident cases to be avoided relative to the base case. If there were no capacity constraints (Scenario 2), an additional 1.3 million incident cases could have avoided progression to Alzheimer’s dementia relative to Scenario 1.

Thus, 87 percent of 15.5 million potentially avoidable incident cases of Alzheimer’s dementia between 2020 and 2040 are actually avoided in the base case scenario, but the remaining 13 percent of potentially avoidable incident cases still occur, because capacity constraints mean patients must wait for treatment. If both the biomarker testing and infusion delivery capacity constraints were overcome, the number would increase to 92 percent of potentially avoidable incident cases by 2040.

## LIMITATIONS

We acknowledge several limitations of our analysis. We use a highly stylized patient journey as a framework for the analysis

that simplifies actual patterns of care. Our results are based on hypothetical properties of an Alzheimer’s treatment, such as time of market entry, efficacy, and dosing, which we believe to be realistic but are uncertain at this point.

We assume that patients will get screened starting at age 55, which is consistent with current clinical trials of Alzheimer’s drugs that include patients as young as 50. While the choice of starting age has substantial implications for the number of people who need to get screened, it has limited impact on the subsequent projections, as MCI is relatively rare in younger cohorts. Similarly, we make assumptions for the uptake of screening, testing, and treatment, which would depend on patient awareness and acceptance and on insurance coverage. Varying the uptake assumptions does not substantially affect our conclusions in the base case scenario; e.g., slower uptake would result in a similar number of treated cases because of wait times.

Our capacity projections are based on extrapolations of historical trends and assumptions based on expert input, which may not accurately predict future patterns. Developments in diagnostic and treatment capacity depend on a host of uncertain factors, such as the results of clinical trials, level of demand, and reimbursement policies. For example, timing of approval of alternative diagnostic modalities (such as CSF tests for amyloid) is difficult to predict, as are the rates of acceptance and adoption of this modality in the United States.

As with any simulation model, we combine data from various sources that may not be consistent with each other. In addition, we make several simplifications, such as transitions between disease states occurring in one-year time steps and parameterized by annual transition probabilities. We would therefore emphasize that our results are meant to show the magnitude of the mismatch between projected demand and capacity rather than to provide a precise estimate of that mismatch.

## DISCUSSION

Within as little as two to three years, one or more disease-modifying therapies for Alzheimer’s disease could become available, finally offering hope to patients and their families affected by this devastating condition. But, as our analysis shows, the U.S. health care system is ill-prepared to handle the potentially high volume of patients who would be eligible for treatment. The projected mismatch is a consequence of the emerging

paradigm that Alzheimer's dementia needs to be prevented rather than treated, with the implication that almost 15 million Americans with MCI would require a comprehensive clinical assessment and, potentially, testing for amyloid to determine eligibility for treatment in 2020.

Based on our analysis, patients would have to wait an average of 18.6 months in 2020, if capacity growth for diagnosis and treatment followed historical trends. Difficult decisions about whom to prioritize for evaluation and treatment would have to be made. As Alzheimer's disease is a progressive neurodegenerative disorder, approximately 2.1 million patients would develop Alzheimer's dementia between 2020 and 2040 while on waiting lists. Considering the magnitude of the mismatch, it is important to start addressing obstacles to access in a manner timely enough to prevent a situation in which a treatment is available but out of reach for many because of capacity constraints. In the following sections, we elaborate on the relative importance of different health system constraints and discuss potential solutions.

### Specialist Shortage Is Most Urgent Issue

Our analysis suggests that wait times for specialist appointments would be the most challenging obstacle to receiving treatment for Alzheimer's disease. The United States has relatively low physician density compared to other G7 nations,<sup>9</sup> and thus less ability to absorb surges in demand. The long training time to become a board-certified specialist implies that neither expansion of postgraduate training programs nor immigration would be a likely solution.

Thus, two options are to increase productivity of the existing specialist workforce and to qualify more specialists for dementia care. Productivity improvements could be accomplished by automating and/or delegating more tasks in the evaluation process. For example, a more specific secondary screening test would allow primary care physicians or midlevel providers to reduce the number of false positive results and thus the number of patients with MCI who need to be referred for further evaluation by specialists. Risk stratification based on screening tests and other factors could help prioritize patients at greater risk of disease progression.

Physicians of larger specialty groups, such as internists and general psychiatrists, and primary care providers could undergo training and certification for dementia care, especially if they have prior experience in that field. The internist workforce is

approximately six times larger than the number of neurologists and geriatricians, and geriatric psychiatrists represent only a small fraction of general psychiatrists (Association of American Medical Colleges, 2015).

A potential model to leverage scarce specialists and to improve access in underserved locations is the Robert Wood Johnson Foundation–supported Project ECHO (Extension for Community Healthcare Outcomes), which connects primary care providers with specialists through a telemedicine platform (University of New Mexico, undated). Through regular exchanges with specialists, primary care providers learn how to handle routine cases on their own while having the opportunity to get advice on complex cases. The model has been shown to be successful for hepatitis C treatment and is being expanded to other conditions (Arora et al., 2011).

### Range of Diagnostic Options Needs to Be Expanded

Access to PET scans could become a rate-limiting factor, albeit one that is easier to address because the ability to expand the number of scanners is not limited by workforce certification constraints. At the same time, adding a PET scanner to an existing facility is estimated to require a capital investment of more than \$2 million for the device itself and the necessary modifications to the building (Goozner, 2015). Thus, expanding PET scan capacity to meet the initial stockpile demand of prevalent cases might not constitute efficient allocation of capital, leading to idle capacity in later years. One option would be to expand the use of mobile scanners that could be shared across facilities. The development of brain-only scanners is another possibility that could reduce space and capital requirements.

An alternative option would be to develop tests for routine clinical use that do not require dedicated high-cost equipment and would allow the patient to receive diagnostic services in primary care settings (e.g., amyloid testing via CSF or blood samples or retinal scans). As mentioned, a CSF test has been approved for clinical use in Europe and work is under way to correlate amyloid PET and CSF results and to support FDA approval of this alternative. Those tests would also alleviate the problem of gaps in geographic coverage with cyclotrons to manufacture the PET radiopharmaceutical.

## Home Infusions May Have to Play an Important Role

Of the 2.4 million Americans who would be eligible for amyloid antibody infusions if a therapy became available in 2020, we predict that only 0.7 million would be screened and diagnosed in the base case. Of those, only 0.2 million would be able to receive the drug under current excess infusion capacity. Meeting the additional demand of those screened and diagnosed would entail a threefold increase in the current overall infusion delivery capacity.

While the large and entrepreneurial U.S. health care system is probably capable of adding that capacity, doing so in the form of fixed infrastructure might not be desirable because subsequent years would see a much lower demand from incident cases. A combination of facility- and office-based infusion chairs with home infusion delivery might be a better alternative, with the latter facilitated by the recent change to cover home infusions for patients with traditional Medicare starting in 2021.

## Dedicated Coverage Might Improve Screening Rates

The availability of a disease-modifying treatment will increase the need for routine screening and testing along the Alzheimer's continuum. While it is expected that payers will cover an FDA-approved drug within the confines of its label, the current lack of agreement on the usefulness of cognitive screening tools to confirm a diagnosis of early-stage Alzheimer's dementia means that routine coverage of cognitive testing may remain limited. The recommendations of the U.S. Preventive Services Taskforce, for example, state that several screening tools for dementia are clinically useful, but that the benefit of identifying cases is small and uncertain (Moyer, 2014).<sup>10</sup> Thus, it found insufficient evidence to support routine cognitive screening, which in turn means that Medicare does not cover dedicated MCI screening in its benefits.

Given the potential for a therapy, there is a need for better screening and diagnostic tests for Alzheimer's disease to ensure that patients in early stages of the disease are identified in a timely manner. While cognitive testing is covered by Medicare as part of the Annual Wellness Visit, many other activities compete for the time allotted to this visit, potentially limiting providers' ability to efficiently identify early-stage Alzheimer's patients. A dedicated MCI screening benefit would make it

more likely that patients with MCI are identified early enough to benefit from treatment (CMS, undated).

## Reimbursement Rules for Diagnostic Tests Will Matter

Imaging centers will pay close attention to the coverage rules that CMS, as the likely dominant payer of amyloid scans, will publish under its expected National Coverage Determination. Payment for advanced imaging has two components. The first is the professional component for the specialist that reads the imaging results, and the second is the technical component to cover the cost of operating the equipment, which consists of the incremental cost of conducting a scan (e.g., medical supplies, technician time) and an allocation for the capital expenditure of installing the scanner. For scans paid under the Medicare physician fee schedule, CMS calculates that second component based on an equipment utilization rate assumption (Cooper, Spangler, and Sherin, 2013), which is the amount of time during which the equipment is in use during a 50-hour work week (CMS, 2013). This assumption has substantial implications for the profitability of imaging equipment and, thus, for investment decisions. The higher the utilization rate assumptions, the lower the payment for the technical component and the less idle capacity a center can absorb while still operating profitably, and vice versa.

Thus, CMS faces the challenging task of deciding whether the current rate of 90% is low enough to attract sufficient capacity expansion but high enough to prevent generation of idle capacity. Moreover, the rate needs to be signaled well in advance of a disease-modifying therapy being approved, as installing additional scanners will take time.

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## CONCLUSIONS

Progress in drug development is giving rise to guarded optimism that a disease-modifying therapy for Alzheimer's disease may become available within a few years. The ability to halt or slow the progression of this devastating and common disease would represent a significant breakthrough. However, our analysis suggests that the U.S. health care system lacks the capacity to provide patients with access to treatment within a reasonable time frame, mainly because of constraints in access to specialists to diagnose patients and confirm treatment eligibility. Failure to increase capacity means that as many as 2.1 million patients with

MCI due to Alzheimer's disease might develop dementia between 2020 and 2040 while waiting for evaluation and treatment.

Addressing the capacity constraints may turn out to be as challenging as developing an effective treatment, as it requires solving a complex puzzle consisting of payment policy, regulatory requirements, workforce considerations, and capacity plan-

ning at the national and local levels, combined with awareness campaigns. No individual stakeholder will be able to put all the pieces together alone. Our hope, therefore, is that this report will trigger a discussion among stakeholders and create a sense of urgency to start collaborating on addressing obstacles in a timely manner.

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## NOTES

<sup>1</sup> The burden would ease once those prevalent cases have been handled because the number of patients who newly develop MCI (or incident cases) each year would only be a fraction of the prevalent cases.

<sup>2</sup> Vaccines that would inoculate the body against formation of amyloid deposits are in earlier stages of clinical development.

<sup>3</sup> Other tests, such as assays based on cerebrospinal fluid, are in development and might become available soon, as we explain in this report.

<sup>4</sup> The evaluation of MCI patients may include a brain MRI, which we do not assume to be constrained by capacity, given the large capacity for MRI scans in the United States compared with other countries.

<sup>5</sup> Actual treatment duration will depend on results from late-stage clinical trials. It is possible that treatment would be used for longer time periods or even chronically.

<sup>6</sup> This estimate reflects patients with suspected MCI based on screening tests administered in a primary care setting that are known to have high and variable rates of false positive results. Estimates based on standardized testing procedures may be lower (Sachdev et al., 2015).

<sup>7</sup> The number of new (or incident) MCI cases is approximately 0.9 million to 1 million per year. Note that the backlog will decline more slowly than the difference between incident cases and visit capacity suggests, because an increasing share of these visits is being allocated to the second visits of patients who tested positive for amyloid.

<sup>8</sup> The precedent for this assumption is CMS' decisionmaking in use of PET scan in oncology, which was initially covered under a CED policy that required enrollment of patients into the prospective National Oncologic PET Registry, but is now covered for routine clinical use.

<sup>9</sup> According to OECD Health Data (2017), the United States had 2.56 physicians per 1,000 population in 2014, compared with 4.11 in Germany and 3.11 in France.

<sup>10</sup> This recommendation is currently being updated. A release date for the updated recommendations has not been announced.

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## About This Report

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