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IMPLICATIONS OF ALZHEIMER'S TREATMENT FOR ORGANIZATION AND PAYMENT OF MEDICAL PRACTICES IN THE UNITED STATES

TECHNICAL REPORT

SOEREN MATTKE AND MO WANG

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OVERVIEW AND OBJECTIVES OF THE STUDY

As the COVID-19 pandemic has taught us, even the most sophisticated healthcare systems can be overwhelmed by sudden surges in the demand for services. The arrival of a disease-modifying treatment for Alzheimer's disease may

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result in a similar scenario, in which current health system capacity is insufficient to cope with the expected influx of patients who will seek diagnosis and treatment. Unlike the COVID-19 pandemic, there is still time for healthcare systems to prepare to ensure the needed capacity is in place to provide access to new disease-modifying treatments when they arrive. Time, however, is limited because recent trial results suggest that we may see the first disease-modifying treatments as early as 2021.

The challenge is that medical care for dementia is mainly focused on diagnosis and counseling at the moment. Patients may undergo neurocognitive testing to document and quantify the degree of impairment and rarely imaging and biomarker testing to identify the etiology. With the lack of disease-modifying treatment options, physicians are typically confined to managing symptoms and counseling patients and their families on the expected course of their disease and the consequences for their lives.

Combined with the fact that payment for labor-intense diagnostic workups and counseling tends to be less well reimbursed than procedures, this lack of therapeutic consequences means that physicians have limited motivation to evaluate and formally diagnose dementia patients today. At the same time, the complexities of determining treatment eligibility and monitoring treatment response and side effects mean that Alzheimer's care will likely have to remain in the hands of specialists. Thus, the advent of a disease-modifying treatment for Alzheimer's disease will meet an unprepared healthcare delivery system. As we have shown in recent reports, the limited capacity of dementia specialists in the U.S. (Liu et al., 2017), Canada (Hlavka, Mattke, & Liu, 2019), Japan (Mattke et al., 2019) and six European countries (Hlavka, Mattke & Liu 2019) will create substantial bottlenecks for treatment delivery.

This project builds on this earlier work and analyzes how practice organization and payment models in the U.S. could be changed to accommodate the substantial increase in demand for dementia specialty care that a disease-modifying treatment for Alzheimer's disease will bring about and prepare for the advent of a treatment in advance.

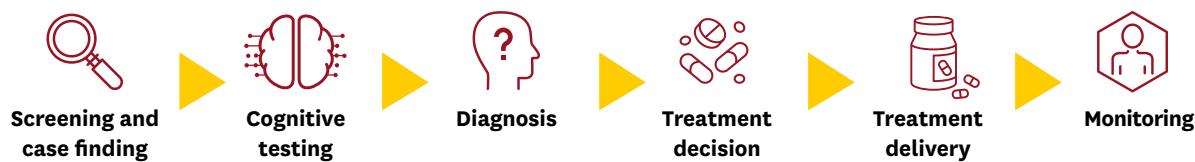
TECHNICAL APPROACH

The study uses a combination of desk research and expert interviews to describe the current patient journeys in the included countries, to capture obstacles to access that result from these journeys, and to identify potential changes to payment models and care delivery that might improve access. Desk research covered the websites of national and multilateral (e.g., OECD

Health Data) organizations that publish health system capacity data, advocacy organizations (e.g., Alzheimer's Disease International), payers and specialty societies as well as research published in peer-reviewed journals and technical reports. A total of 10 expert interviews were held with policy experts, clinical and health services researchers, clinicians and payer representatives in the six countries, using a semi-structured interview protocol.

We developed a stylized patient journey (**Figure 1**) to capture the current pathway that dementia patients take through identification based on screening or memory complaints, evaluation with neurocognitive testing, imaging and biomarkers and then finally diagnosis and treatment delivery.

Figure 1: Stylized patient journey



For each step of the patient journey, we analyze the status quo regarding coverage, capacity and capabilities:

Coverage

- Are the services under each step currently covered by health insurance?
- Are payment levels adequate to ensure actual delivery of the service?

Capacity

- Is current capacity to deliver services sufficient to meet expected demand?
- Would the capacity actually be devoted to the respective care step, given prevailing incentives and organization of care?

Capabilities

- Do providers have appropriate training, tools and technology to perform the required services?

We comment on possible changes to coverage, capacity and capabilities that might be required to reduce the obstacles to access to a disease-modifying treatment for Alzheimer's disease as well as memory care in general.

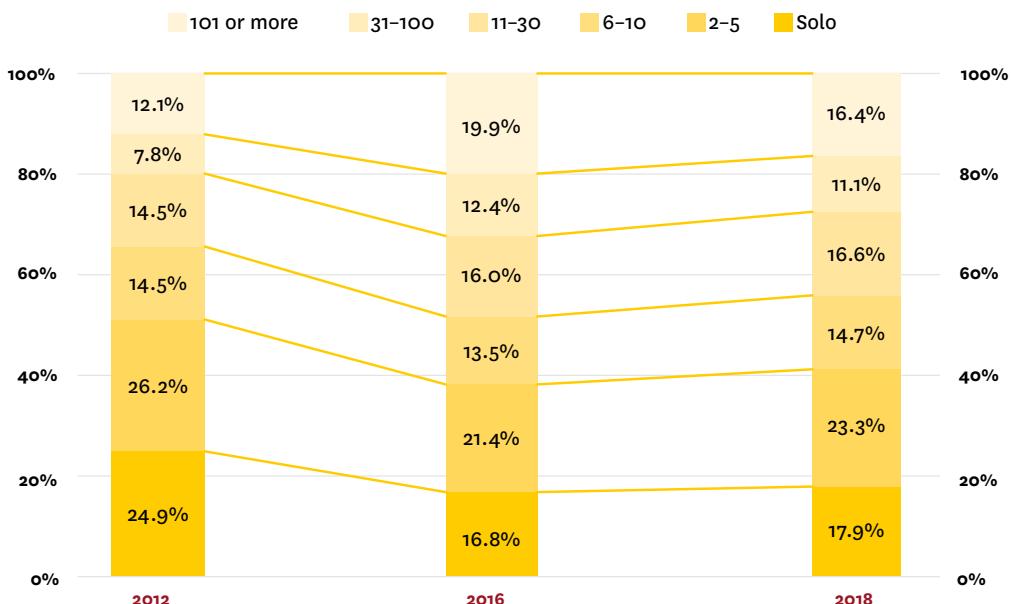
RESULTS

HEALTH SYSTEM OVERVIEW

Healthcare services in the U.S. are predominantly delivered by private sector providers, such as for-profit and not-for-profit hospitals and physicians in private practice, whereas public facilities play a minor role. Recent years have seen substantial consolidation of provider organizations, which formed large single-specialty or multi-specialty practices or health systems that combine hospitals with physician practices and other providers (Figure 2).

Figure 2: Consolidation of physician practices in the U.S.

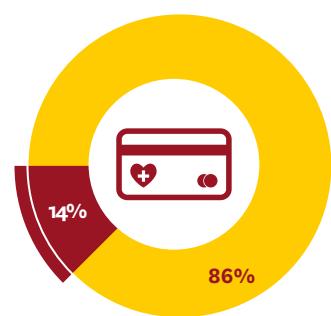
Share of physicians by size of practice



Data from *The Physicians Foundation* (2018)

Health insurance is provided by a mix of public and private payers. On the public side, the federal Medicare program covers persons over 65 years and those with selected disabilities, the state-federal Medicaid program the indigent and disabled. Separate programs exist for members of the armed forces and veterans. On the private side, people either receive insurance coverage through their employer or purchase their own policies. Although the 2013 Affordable Care Act has expanded coverage, approximately 14% (Witters, 2019) of Americans do not have health insurance.

Payment for services is predominantly fee-for-service. While public payers have an administered payment schedule, private payers negotiate rates with providers. In some markets, so-called Integrated Delivery Networks have emerged that combine insurance and provision of care in one organization. Except for patients in traditional Medicare, patients need to obtain care from providers that have a contract with their payers, referred to as in-network providers. Care from out-of-network providers is either not covered, covered only for emergency care or covered with substantial co-payments. Even for in-network care, co-payments and deductibles are common, depending on the details of each policy, and can be substantial.



■ With insurance
■ Without insurance

Healthcare professionals need to be licensed to practice in their state – states regulate the scope of practice. Payers can further restrict which providers may perform certain services for their members, and hospitals use credentialing to define the range of services that a given physician may perform in their facilities. Beyond those restrictions, physicians are free to choose location of their practice and the range of offered services. An important consequence of consolidation is that decisions about scope and volume of services are made commonly at the organizational level based on strategic considerations, such as the desire to secure patient flows and/or competitor behavior, rather than by individual physicians.

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DEMENTIA PLANNING

In the privatized and pluralistic healthcare system of the U.S., the role of central planning is limited. The Department of Health and Human Services has issued a U.S. National Plan to Address Alzheimer's Disease (U.S. Department of Health and Human Services, 2017), which mostly focuses on priority setting for federal research funding, development of a data infrastructure, awareness campaigns and development of tools for diagnosis and patient/caregiver support.

SCREENING FOR MCI

The U.S. Preventive Services Task Force (USPSTF), a government-sponsored organization that issues recommendations for screening programs based on evidence reviews, has determined that there is insufficient evidence at the moment to recommend or discourage systematic screening of asymptomatic persons for mild cognitive impairment (MCI) (U.S. Preventive Services Task Force, 2019). Consequently, cognitive screening is not a covered benefit, but could be a part of other preventive visits. For example, the Annual Wellness Visit, a Medicare benefit, ought to contain a cognitive assessment even though it reportedly rarely occurs, and the American Academy of Neurology recommends including it. (Petersen et al., 2018). While access to such preventive visits is typically adequate, except for underserved areas and persons without insurance, competing priorities often limit the attention devoted to cognitive function. For example, in a survey conducted by the Alzheimer's Association, only 16 percent of seniors were asked about memory concerns during their preventive visits (Alzheimer's Association, 2019a). Further, available brief cognitive assessment tools, such as the Alzheimer's Association's Cognitive Assessment Toolkit, are geared towards detection of manifest dementia, whereas available tools to detect MCI, such as the MMSE or MoCA, are – with an application time of 10 to 15 minutes – too long to be used during a standard preventive visit (Alzheimer's Association). Cultural bias against diagnosing dementia is said to aggravate the problems: physicians are reluctant to diagnose cognitive decline, because it is perceived as communicating bad news without the ability to offer treatment options.

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Establishing a systematic screening program for MCI would require a positive recommendation by the USPSTF, which most payers follow. The USPSTF would base such a recommendation on evidence, preferably from randomized controlled trials, for a net benefit of screening. It is possible that such USPSTF-recommended screening would become a separately billable service, i.e., would be paid in addition to a routine preventive visit. Precedents exist for creating separate billing codes for preventive services, even if those could be part of a wellness visit, such as smoking cessation counseling (CPT 99046/99407). The American Medical Association as the owner of the CPT coding system has a formal review and approval process for such codes.

Of note, a USPSTF Grade A recommendation implies mandatory coverage of a service without co-payments¹. Actual uptake of the benefit would depend on attitudes and awareness of patients and providers, the level of reimbursement and the availability of a simple screening tool for MCI.

CASE FINDING

The evaluation of a patient, who presents with a memory complaint in primary care, is recommended (Petersen et al., 2018) and covered independent of preventive and/or screening benefits. From our interviews, primary care providers are reluctant to investigate memory complaints thoroughly, as they perceive the remuneration to be low relative to the level of effort. First, the administration of a cognitive screening test, like the MMSE or the MoCA, is not separately billable, but part of the payment for a symptom-driven office visit. Second, assessment of a memory complaint is time-consuming because it implies a thorough anamnesis of the patients and possibly family members and a complex differential diagnosis. Third, brain imaging to rule out common causes of memory deficits, such as occult strokes, requires prior authorization from the patient's payer and thus writing requests and possibly the need to appeal a rejection.

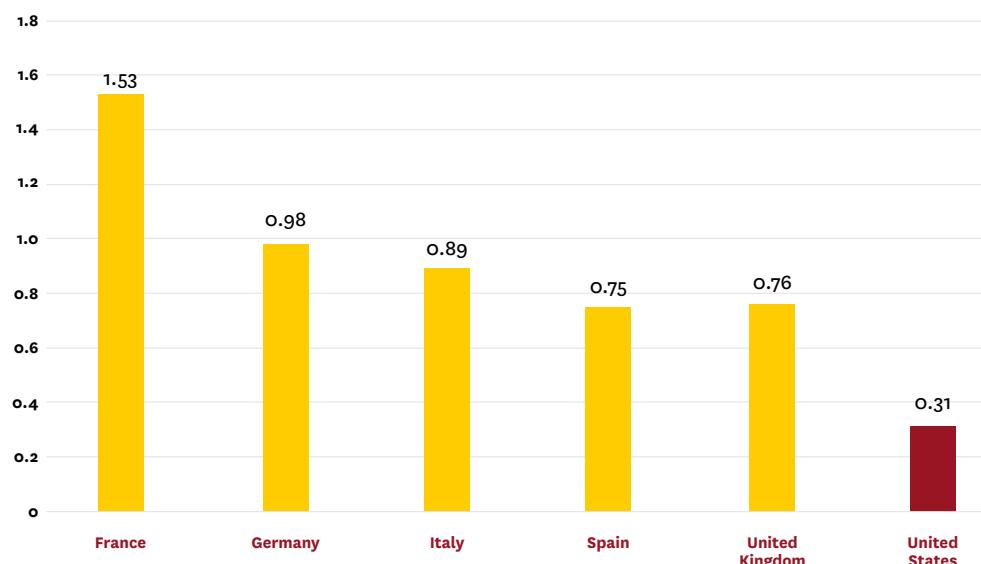
In addition, workflow considerations limit the willingness of primary care providers to evaluate memory complaints thoroughly. Office visits are typically scheduled for 15 minutes; with tightly packed appointments, providers are held accountable for seeing patients as timetabled, and the U.S. has a limited number of primary care providers per capita compared with other high-income countries (Figure 3).

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1. Legally, the requirement only applies to coverage under the Affordable Care Act, but in practice most health plans apply it for all policies.

Figure 3: Number of primary care physicians in G7 countries

GPs per 1000 population [2016]



Data from *OECD Health Statistics (2019)*

The complexity of the differential diagnosis of memory complaints also constrains the ability to delegate part of the evaluation to support staff, such as nurse practitioners and physician assistants. Lastly, cognitive screening tests are not integrated in many common electronic health records, forcing physicians to complete the test on paper and scan it into the record. Consequently, primary care providers tend to refer patients with memory complaints quickly to specialists, often with very limited prior evaluation. Specialists in turn express frustration that they receive referrals of patients, who have causes of cognitive impairment that could be handled in primary care settings, such as depression or hypothyroidism, and referrals with limited prior workup that require repeat visits to make a diagnosis.

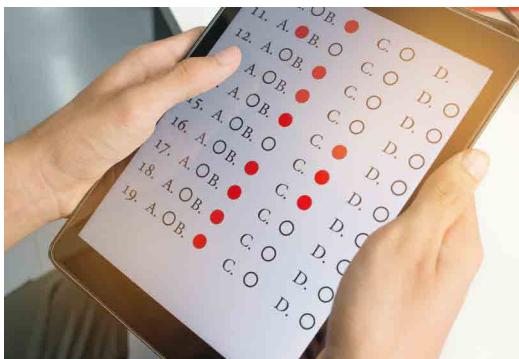
Shifting a greater share of MCI evaluation into primary care settings would – first and foremost – necessitate changes to payment modalities. Dedicated payments for the administration

of brief cognitive assessment tests would increase the share of patients who are referred to specialists with an objectively documented and quantified memory impairment, because it is unlikely that primary care providers would devote the time required for such tests without explicit coverage. Bundled or episode-based payments for comprehensive assessment of memory complaints, as increasingly used by the Centers for Medicare & Medicaid Services (CMS), could set standards for evaluation and create incentives for primary care providers to play a bigger role. Inclusion of cognitive assessment in pay-for-performance programs, as recently proposed by CMS, could incentivize primary care providers to perform more assessments (Center for Clinical Standards and

INCLUSION OF COGNITIVE ASSESSMENT IN PAY-FOR-PERFORMANCE PROGRAMS, AS RECENTLY PROPOSED BY CMS, COULD INCENTIVIZE PRIMARY CARE PROVIDERS TO PERFORM MORE ASSESSMENTS.

Quality & Centers for Medicare & Medicaid Services, 2019). In turn, greater familiarity with cognitive evaluation might help primary care practices streamline their processes and train support staff to take over selected tasks. Primary care-led memory clinics, as they exist in Canada (Lee et al., 2014), could emerge.

Given the consolidated nature of healthcare delivery in the U.S., it has to be kept in mind that changes in the organization and operation of practices will have to be made at the corporate level rather than by individual physicians.



Cognitive screening tools



Blood-based test

Lastly, two advances in technology could facilitate evaluation of memory complaints in primary care. The first would be the incorporation of cognitive screening tools into commonly used electronic health records; the second the regulatory approval and coverage of a blood-based test for the Alzheimer's pathology, given promising results for test kits that are suitable for commercial deployment (Palmqvist et al., 2019). The latter would be particularly important in light of a potential disease-modifying treatment, because the test would allow prioritizing patients for further assessment who are likely to be eligible for treatment. The U.S. National Plan To Address Alzheimer's Disease also calls for acceleration of biomarker development to detect early disease stages (U.S. Department of Health and Human Services, 2017).

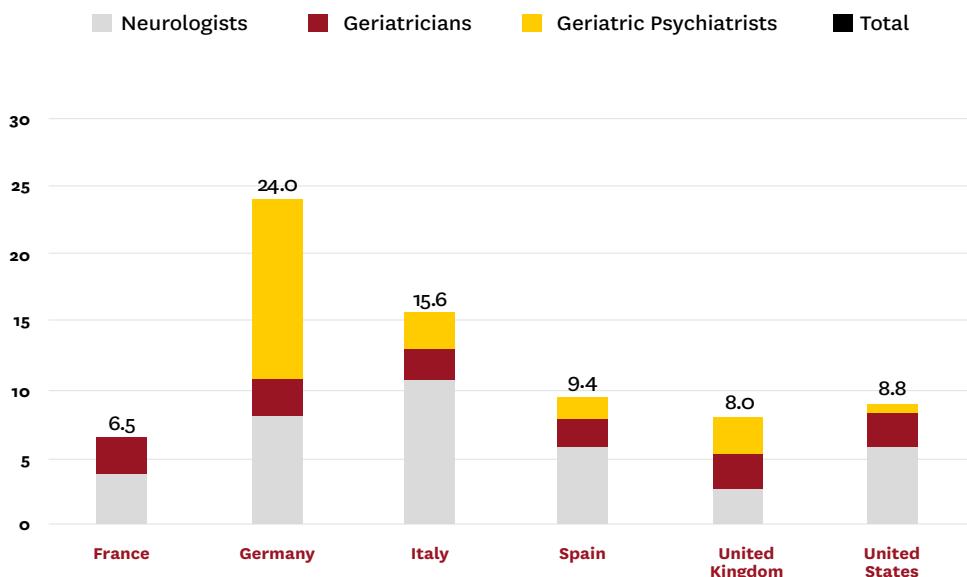
COGNITIVE TESTING

Comprehensive neurocognitive testing of patients with memory complaints is recommended (Petersen et al., 2018) and a covered benefit in the U.S. Payment levels are attractive because billing is based on actual time usage (CPT 96125 and 96119), with the caveat that some payers restrict the range of tests that they cover given a patient's presentation. Testing is conducted by dementia specialists themselves or PhD-trained neuropsychologists.

The main obstacle to access to cognitive testing, as to specialty care for dementia in general, is the limited number of specialists, which is lower than in several other high-income countries (Figure 4).

Figure 4: Number of dementia specialists in United States compared with other countries

Estimated available specialists per 100,000 population



Data from *OECD Health Statistics (2019)*

Reportedly, wait times for specialist appointments are significant even today and even in well-served areas. The Alzheimer's Association considers 20 states as “neurology deserts” because of their low rate of dementia specialists relative to estimated dementia burden (Rao, Manteau-Rao, & Aggarwal, 2017). In a recent study of Medicare claims, only 36 percent of patients were seen by a specialist within five years of being first diagnosed with dementia (Drabo et al., 2019).

Consequently, the most pressing need is to expand the number of professionals trained in neurocognitive testing and their geographic reach. Mid-level providers, technicians and psychologists could be trained in administering the cognitive batteries, allowing specialists to focus on interpretation of the results and differential diagnosis. Standardization of training and certification requirements as well as quality assurance and peer review could safeguard the accuracy of test results. Testing could be conducted via videoconference for patients in remote areas. Finally, guidelines for recommended tests given a patient’s presentation and a National Coverage Determination based on those guidelines could make coverage decisions more predictable.

BIMARKER TESTING

At the moment, no test for Alzheimer's pathology is available for routine clinical use. Positron emission tomography (PET) scanning for amyloid beta is approved but currently covered by Medicare only as part of the IDEAS study, a so-called Coverage with Evidence Development protocol that makes a novel service accessible to patients willing to enroll in a prospective registry. The objective of the IDEAS study is to determine whether a formal diagnosis of Alzheimer's disease improves patient outcomes even in the absence of a disease-modifying treatment. Recently released results suggest changes in management after a formal diagnosis (Rabinovici et al., 2019), and the study continues to follow patients to ascertain the effect on outcomes. Although diagnostic lumbar punctures are a covered service with – in

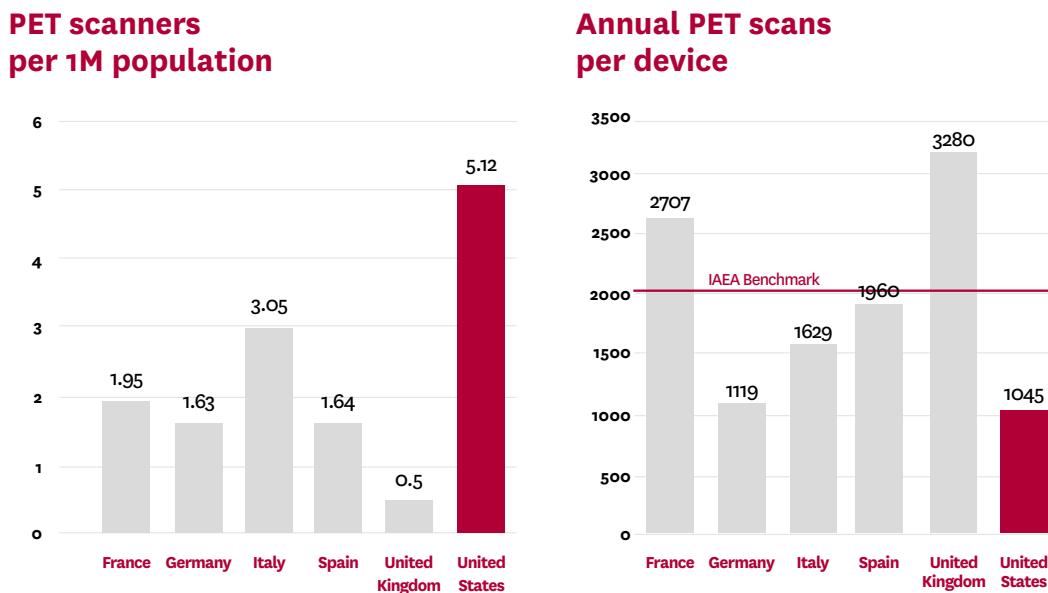


THE OBJECTIVE OF
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the eyes of our interviewees – adequate payment levels, no Food & Drug Administration (FDA) – approved test is currently marketed in the U.S., but the FDA recently granted a test Breakthrough Device Designation, suggesting that it might become routinely available in the near future (Roche, 2018).

Capacity for PET scans appears comparatively high in the U.S., because the number of installed devices is considerably higher than in other high-income countries, while the number of tests conducted per installed device is low (Figure 5). Although this combination of a large installed base and low utilization rates suggests excess capacity to accommodate PET scans for Alzheimer's pathology, previous estimates suggest that PET capacity alone is insufficient to meet the likely demand, i.e., a combination of PET scans and cerebrospinal fluid (CSF) testing will be required (Liu et al., 2017).

Figure 5: Density and utilization of PET scanners in the U.S.

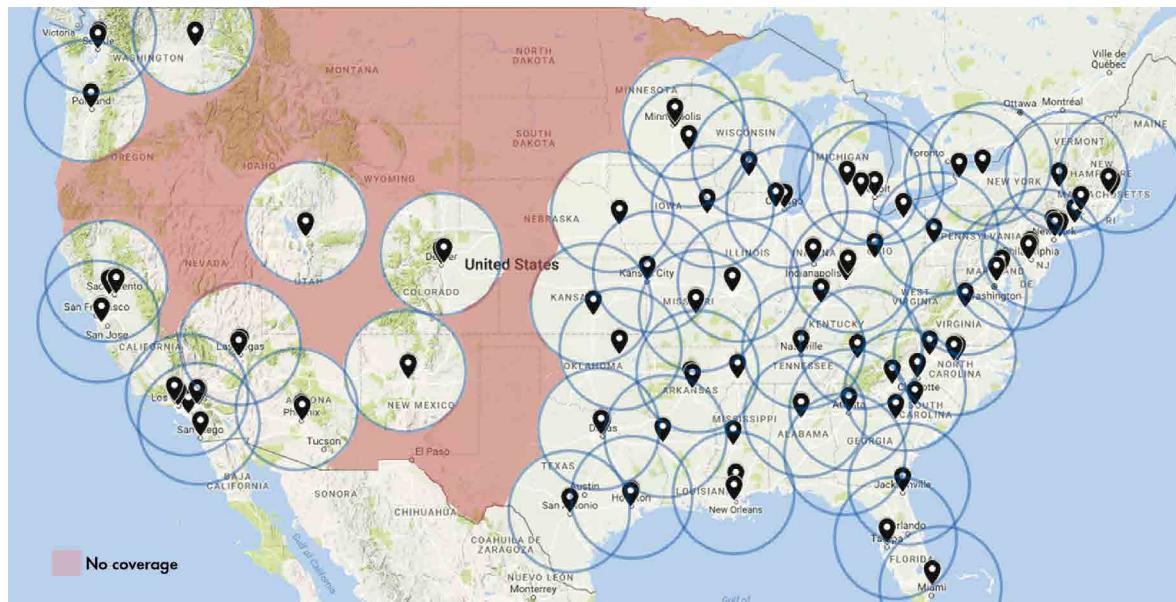


Data from *OECD Health Statistics* (2019), *The German Society for Nuclear Medicine (DGN)* (2019), and *NHS England* (2019). The International Atomic Energy Association (IAEA) recommends 2000 annual scans per device as minimum threshold for efficient utilization.

Access to PET scans may also be limited geographically. Although there are mobile PET units that could be used to expand geographic reach, the constraint may be proximity to a

cyclotron facility that manufacturers the amyloid tracer, because tracer is an unstable radiopharmaceutical that cannot be transported over large distances. Figure 6 shows that patients in less populated states live too far from a cyclotron to have access to a PET scan.

Figure 6: Geographical coverage of cyclotrons capable to manufacturer amyloid tracers in the U.S.



Adapted from Assessing the Preparedness of the US Health Care System Infrastructure for an Alzheimer's Treatment. (Liu, Hlavka, Hillestad, & Mattke, 2017). Data as of May 2017. Reproduced with permission. RAND Corporation ©

Although CSF testing can theoretically be scaled and expanded more easily, experts were cautious about patients' acceptance, because of concerns about discomfort and complications, even though data show that the procedure is safe with a rate of severe complications below 0.01 percent² (Engelborghs et al., 2017). As a result, diagnostic lumbar punctures have become an uncommon procedure in the U.S. that is today mostly done in neurology practices and hospital wards.

It is likely that a test for Alzheimer's pathology would be covered and probably required by payers for coverage of a disease-modifying treatment. In that case, expansion of biomarker testing capacity will be needed. Our experts voiced mixed views on which path this expansion would take. Increased use of CSF testing was seen as preferable because of the lower fixed cost and higher scalability, in particular in less populated areas. But there were concerns about lack of training and facilities outside of specialist clinics and cultural aversion to lumbar punctures. In particular primary care providers are unlikely to conduct these procedures, because they are not compatible with their practice workflow and thus not economically viable.

Conversely, no technical or regulatory obstacles exist to adding PET scanners, but economic considerations may limit an increase to capacity. First, demand will be strongest when a treatment is initially approved because of the large number of prevalent cases who will seek evaluation for treatment eligibility. Adding capacity to meet that demand is likely to lead to idle capacity in later years, diminishing the business case for imaging centers. Second, payers are likely to push back against an increase of costly imaging. One lever is prior authorization procedures that require practices to justify the need for imaging based on defined criteria to obtain coverage for each patient on a case-by-case basis. The other is the setting of the so-called equipment

2. The most common complication of lumbar punctures is transient post-procedure headache, which occurs in approximately 30 percent of cases.

EXPANDING DIAGNOSTIC CAPACITY IS LIKELY TO REQUIRE AN INCREASE OF BOTH PET SCANNERS AND CSF TESTING FACILITIES.

countervailing forces are likely to lead to a capacity increase using a combination of PET scanners and CSF testing.

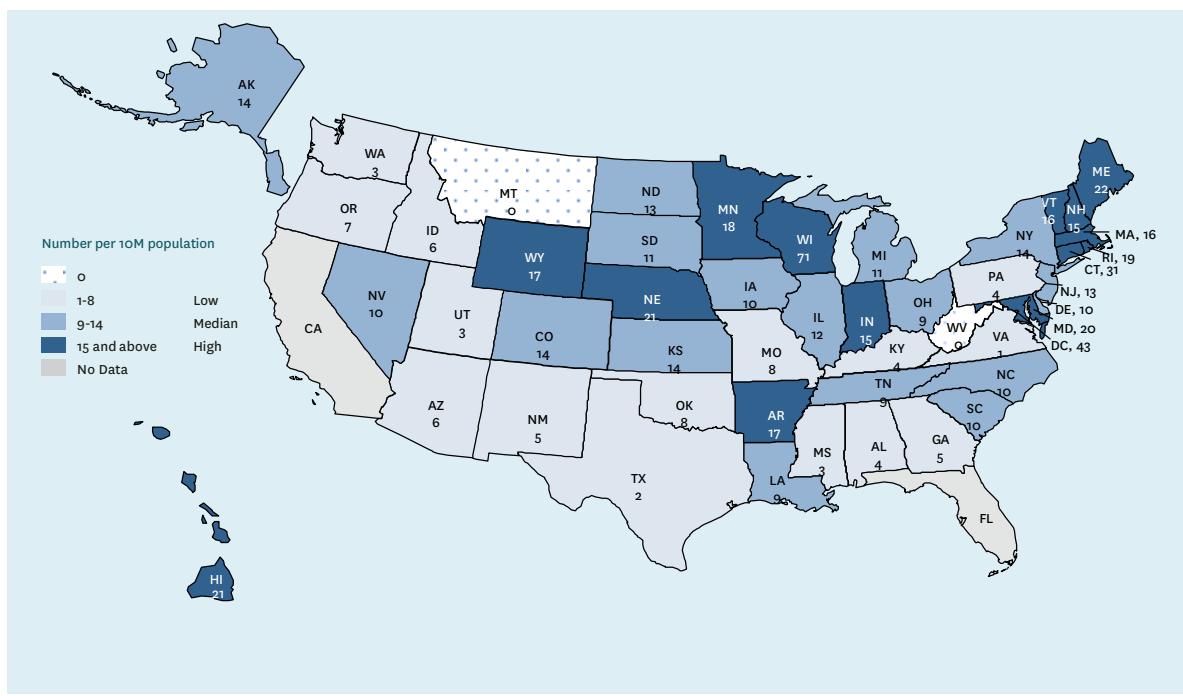
utilization rate assumption, which is the amount of time during which the equipment is in use during a 50-hour work week (CMS, 2013) and affects how fixed cost is allocated to scans. Thus, the assumption has substantial implications for the profitability of imaging equipment and consequently for investment decisions. The higher the utilization rate assumption, the lower the payment and the less idle capacity a center can afford to maintain profitability. Those

TREATMENT DECISION

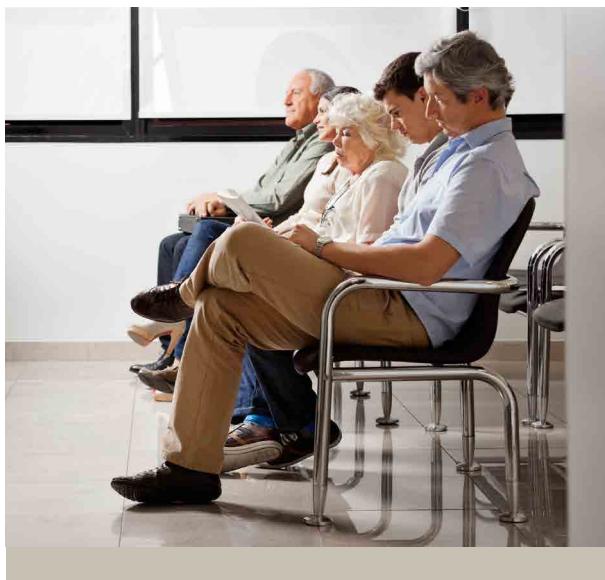
An office visit with a dementia specialist to discuss results from the neurocognitive evaluation and biomarker testing in order to decide on eligibility for disease-modifying treatment would be covered as routine care. Most payers do not limit such office visits and often do not require a referral, but payment levels are seen as low relative to the complexity of the encounter. Some payers have arduous requirements for documentation of time usage and complexity for potential audits. A recently introduced code for comprehensive care planning services for dementia (CPT 99483) offers higher reimbursement levels, but experts were not sure whether the code could also be used for the evaluation of MCI patients.

Specialist capacity is widely regarded as insufficient with reported wait times even today and with limited room to expand volume, in particular in rural areas. The shortage is compounded by the lack of dementia-focused practices with multidisciplinary care teams that would leverage scarce specialist capacity. For example, several states have few or no memory clinics (**Figure 7**).

Figure 7: Number of memory clinics in the U.S. by state.



Data from caring.com (2019)



THERE IS, HOWEVER,
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The logical first step in expanding specialist capacity for MCI evaluation would be higher payment levels, via either a clarification that the CPT 99483 code may be applied or the introduction of an equivalent code for MCI. As with all new codes, guidance on exact documentation requirements to justify billing the code would be important.

Various telemedicine models are being explored to facilitate geographic access. The Department of Veterans Health Affairs, for example, has introduced a tele-neurology model to assess patients remotely (Schreiber, 2018). Specialists on Call is a commercial telemedicine platform that links neurologists and psychiatrists with smaller hospitals that cannot sustain in-house specialists (SOC Telemed, 2019). However, true expansion of specialist capacity will require care models that leverage their scarce time more effectively. One such model is Project ECHO, which was originally conceived at the University of New Mexico to enable primary care clinicians to provide hepatitis C treatment (Arora, 2019). The model quickly expanded to other locations and indications and is currently being tested for dementia care (Alzheimer's Association, 2019b). The federal Health Resources and Services Administration supports the Geriatrics Workforce Enhancement Program, which has developed a model curriculum to train primary care providers in MCI and dementia evaluation and treatment, piloted in several locations (Health Resources & Services Administration, 2019). There is, however, limited impetus to expand such models without the demand for services that would be triggered by an approval of an Alzheimer's treatment.

TREATMENT DELIVERY

Because the U.S. does not have formal health technology assessment, payers are expected to cover any approved medical treatment, but may manage utilization. Management of utilization can take the form of restricting coverage and imposing prior authorization requirements and high cost sharing for patients. As the experience with hepatitis C drugs has shown, such measures can slow down treatment uptake substantially (Barua et al., 2015). Actual coverage policies will vary by payer and depend on an intricate interplay of the safety and efficacy profile of the drug, its list price and the political environment.

Payment for office-administered drugs creates an attractive business model for medical practices, because these drugs are reimbursed on the basis of average sales price plus a markup.

Capacity to deliver a potential disease-modifying treatment intravenously would be limited, because the expected demand for infusion would amount to about three times the current volume of non-oncology infusions, and dementia specialist practices and memory clinics are typically not set up for infusion treatment (Liu et al., 2017). Infusion capacity is not likely to become an obstacle to access.



First, some disease-modifying treatments in development are for oral or subcutaneous application.



Second, the experience with the introduction of other intravenous treatments, such as for immunologic indications, has shown that capacity of medical practices can increase rapidly.

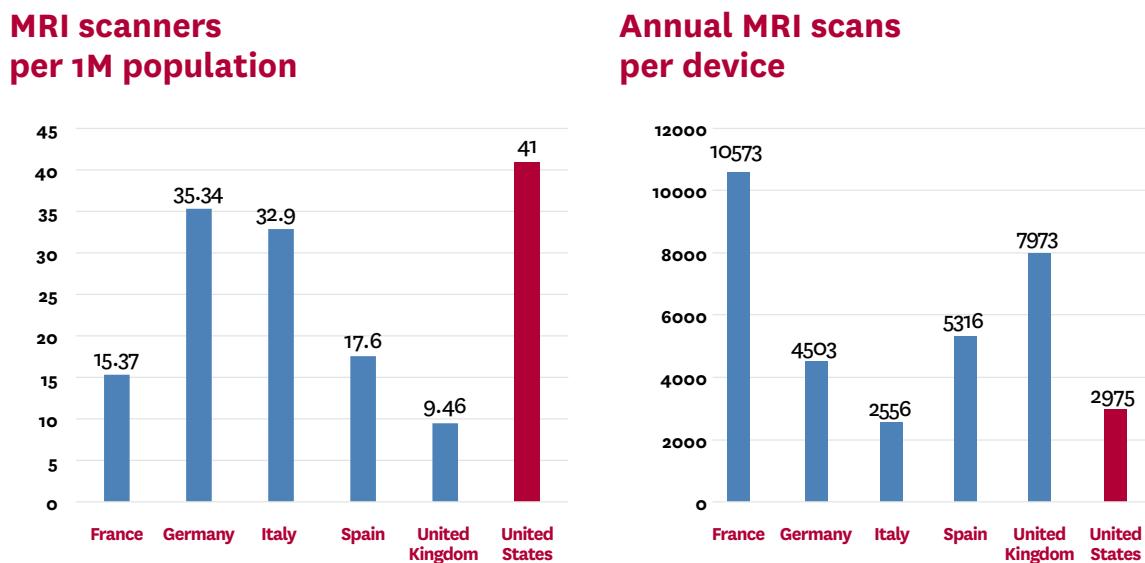


Third, Medicare will cover home infusion delivery as of January 2021 (Public Law 114-255).

MONITORING

Office visits and imaging for monitoring of treatment effect and safety are likely to be covered in line with the drug's label and guidelines. Although many payers require prior authorization of elective imaging, such requests are typically approved. Capacity for magnetic resonance imaging (MRI) scanning is probably sufficient because the U.S. has a high density and low utilization of MRI scanners compared with other G7 countries (Figure 8). However, capacity for follow-up visits with specialists may be limited as outlined above.

Figure 8: Density and utilization of MRI scanners in the U.S.



Data from OECD Health Statistics (2019)

SUMMARY

The entrepreneurial nature of the U.S. healthcare system implies that innovations in diagnosis and treatment usually disseminate fast. There is no centralized capacity planning process, implying that decisions about capacity expansion and reorganization of care delivery will be made based on the business case. Increasingly those decisions lie in the hands of large and fully integrated health systems with professional managers, who focus on productivity, profit margins by business line and defense of market share.

In the absence of a formal health technology assessment process, few formal constraints inhibit uptake of innovation for budget considerations, and public and private payers are required to cover approved and indicated medical products and services without consideration of cost. Payers may, however, manage utilization of medical products with tools like prior authorization, formulary placement and patient cost-sharing.

The main structural constraint to expanding memory services in the U.S. is the relatively low density of physicians compared with other high-income countries. As our data show, the U.S. has fewer primary care physicians and fewer dementia specialists per capita than the largest five European economies. Because of the pluralistic system, U.S. physicians also spent a substantial share of their time on non-clinical tasks, such as documentation of their activities in electronic health records to justify billing and handling insurance matters (Sinsky et al., 2016). Room to expand physician workload is therefore limited. Long training times and the substantially lower compensation of primary care physicians and non-interventional specialists compared with procedure-centric specialists³ make substantial influx of physicians into memory care unlikely.

Consequently, there is an urgent need for memory care models that rely heavily on task-shifting to technicians and mid-level providers, such as advanced practice nurses

3. According to 2019 data, the average salary for a family practitioner was \$231,000, a neurologist \$267,000, a cardiologist \$430,000 and an orthopedic surgeon \$482,000 (Medscape, 2019).

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blood or CSF testing. Thus, we are not likely to witness a substantial investment in memory care activities, which in turn degrades skill levels and interest of primary care providers, compounding the effect of limited attention to geriatrics in their postgraduate training (Warshaw et al., 2003).

The question is: what it would take to draw funding and interest into memory services?

The approval of a disease-modifying treatment would certainly change the calculus. The advent of disease-modifying biologics transformed the business model for specialties such as rheumatology and gastroenterology, which came to rely on generous payments for infused pharmaceuticals. Memory care could take a similar path, and it is likely that reimbursement for biomarker testing and services around the treatment would follow suit. There are, however, some fundamental differences that

must not be overlooked. Not all of the disease-modifying treatments in the pipeline are infusion treatments, and some might only be used for a limited period rather than chronically, which would limit the business case for infusion practices. Other specialties had disease-modifying treatments, albeit less effective ones, prior to biologics and could grow into infusion-centric practices over time. And lastly, the current policy debate about the cost of prescription drugs could bring about fundamental changes to

or physician assistants, to better leverage the scarce time of physicians in general and of dementia specialists in particular. The business case to introduce such models under current conditions remains poor, because payment levels are seen as low relative to effort and several steps in the diagnostic pathway are not covered (or even approved). There is no dedicated payment for a brief cognitive exam in primary care setting, even though the Medicare Annual Wellness Visit is meant to include cognitive status evaluation. The differential diagnosis of memory impairment is complex and requires substantial time spent with patients and their families as well as difficulties predicting visit lengths and therefore workflows. Confirmatory testing of biomarkers for Alzheimer's disease is not covered for routine care in the case of PET scans or even FDA-approved in the case of



how new drugs are assessed and reimbursed.

Even in the absence of a disease-modifying treatment, current efforts to shift payment for medical services from transactions to value generation (Burwell, 2015) could improve the business case for memory care. The Medicare program continues to experiment with various so-called Alternative Payment Models (CMS, 2019) that tie payment to quality and patient experience targets and allow for a mix of capitated and fee-for-service payments. Conceivably, efficient practice models for memory care that rely heavily on primary care and mid-level providers could be economically viable under such models, in combination with dedicated billing codes, such as the recently introduced dementia care planning code. Examples are Project ECHO in the U.S. (Khatri, Haddad, & Anderson, 2013), and primary care-led memory clinics in Canada (Lee et al., 2014) and the U.K. (Greaves et al., 2015). Better tools suitable for general practice, such as simple cognitive screening tools and blood-based tests for biomarkers, could facilitate such models. Funding for their development and the documentation of their value proposition might come from public, charitable and industry sources.

GIVEN THE LARGE BACKLOG OF PREVALENT CASES THAT MIGHT BENEFIT FROM A TREATMENT, STARTING TO ESTABLISH A CARE DELIVERY INFRASTRUCTURE ONLY WHEN THE TREATMENT BECOMES AVAILABLE IS LIKELY TO RESULT IN DELAYS

To summarize, the U.S. poses a unique challenge when it comes to preparing for the advent of a disease-modifying treatment for Alzheimer's disease. On the one hand, the absence of central planning and its entrepreneurial nature provides for agility to adjust to technological advances. On the other, the very absence of central planning makes it difficult to bring about changes in care delivery before the business case is certain. And given the large backlog of prevalent cases that might benefit from a treatment, starting to establish a care delivery infrastructure only when the treatment becomes available is likely to result in delays in access and thus avoidable disease progression (Liu et al., 2017). A concerted effort of stakeholders will be needed to raise awareness for this challenge and work on solutions.

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