

PERSPECTIVE

Implications of preclinical Alzheimer's disease biomarker disclosure for US policy and society

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Funding information

National Institute on Aging, Grant/Award Numbers: R03 AG062975, R01 AG054059, R01 AG021155, R01 AG02716; Largent is supported by the National Institute on Aging, Grant/Award Number: K01-AG064123

Abstract

Disclosure of Alzheimer's disease (AD) biomarkers to cognitively unimpaired adults are currently conducted only in research settings. Yet, US Food and Drug Administration approval of a disease-modifying treatment for symptomatic individuals, improved understanding of the "preclinical" phase of disease, and advancements toward more accessible biomarker tests suggest such disclosure will increase in frequency, eventually becoming routine in clinical practice. The changing landscape in AD research to focus on biomarkers has generated debate on the validity and clinical utility of disclosure to cognitively unimpaired adults. This article explores the broader social implications of more widespread AD biomarker disclosure—that is, of individuals learning their risk for developing dementia caused by AD. We identify 10 challenges and offer preliminary solutions. As the field continues to evolve, it is essential to anticipate and address these broader ethical, legal, and social implications of disclosure.

KEYWORDS

Alzheimer's disease, biomarker, caregiver, ethics, law, preclinical

1 | INTRODUCTION

Alzheimer's disease (AD) is a tremendous public health problem, and concomitant investments have been made in research to identify disease-modifying therapies. Research suggests intervening earlier

rather than later in the disease course may reduce the number of individuals who develop dementia—that is, emerging therapies may be more effective at preventing the clinical syndrome than treating the disease once symptoms are present.¹⁻³ This understanding has, in turn, prompted extensive investigation into the role of

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biomarkers in early detection of AD.⁴ Accumulating evidence supporting the notion that AD starts decades before the onset of clinical symptoms has intensified focus on the protracted “preclinical” phase of disease, along with efforts to identify biomarker-defined substages.^{2,3,5} Simultaneously, advancements in AD biomarker detection—particularly the advent of blood-based biomarkers—suggest testing will soon be more accessible. The US Food and Drug Administration (FDA) has approved, albeit controversially, a treatment for symptomatic AD, and there is hope that a disease-modifying therapy for preclinical AD—one that can slow or perhaps prevent the onset of cognitive impairment—is not far off. This confluence of circumstances suggests that, although preclinical AD biomarker disclosure is not presently advised in clinical settings, it soon might be. Though this future holds substantial promise, there are important considerations when moving AD biomarker disclosure from the realm of research into clinical practice.

Researchers have been disclosing AD biomarker results—most commonly amyloid beta ($A\beta$) positron emission tomography (PET) or cerebrospinal fluid (CSF) testing results—to cognitively unimpaired participants for several years, predominantly in the context of clinical trials.⁶ Because “elevated” AD biomarker results are an eligibility criterion for participation, it is considered practically and ethically necessary to disclose results to prospective research participants. Additionally, some longitudinal studies of cognition and aging return AD biomarker results to cognitively unimpaired participants in pursuit of promoting transparency and autonomy. These clinical trials and longitudinal studies have afforded researchers opportunities to examine the effects of AD biomarker disclosure on individuals and to gain insights into the future of clinical practice.⁷ In general, individuals have expressed that they understand the meaning of their AD biomarker results, including their limited predictive value, and disclosure has been safe: there have not been clinically significant increases in anxiety, depression, distress, or suicidality.^{8,9} These findings have made progress in allaying concerns that participants would not understand or could not tolerate learning biomarker results indicative of preclinical AD.¹⁰ Researchers have also sought to understand what cognitively unimpaired individuals do with knowledge of their results. Individuals have used AD biomarker results—particularly those indicating an increased risk for dementia—to make behavior changes, including modifying lifestyle to promote brain health, and to inform future planning.^{8,9,11} This suggests disclosure may have beneficial effects by motivating individuals to improve their aging trajectories and better prepare for the future.

While much work has been done to assess the impact of preclinical AD biomarker disclosure on *individuals*, the impact on *society* remains underexplored. The purpose of this article is to survey the broader implications of preclinical AD biomarker disclosure in the US social, legal, and policy context, though we recognize similar issues will arise internationally. Here, we outline 10 areas of critical need and offer preliminary social and policy solutions through the lens that more accessible AD biomarker tests and availability of disease-modifying therapies will increase the number of cognitively unimpaired older adults learning AD biomarker results.

RESEARCH IN CONTEXT

1. **Systematic Review:** A PubMed and Google Scholar search was conducted. Research from multiple fields including public health, neuroscience, and law was reviewed and included. The implications of Alzheimer’s disease (AD) biomarker disclosure will encompass many disciplines and should be addressed using an interdisciplinary approach.
2. **Interpretation:** We critically assessed the broader implications of preclinical AD biomarker disclosure through research, clinical, and policy lenses. We outline 10 areas of critical need posed by expanding preclinical AD biomarker disclosure and provide ideas for policy and social solutions.
3. **Future Directions:** This article asserts that addressing the social ripple effects of more widespread preclinical AD biomarker disclosure requires a multimodal approach to meet the immense complexity of the field’s future. Renewed public concerns about health information privacy, public salience of AD with aducanumab’s approval, and increased visibility of AD issues by lobbying institutions are quickly coalescing to create a window to advocate for policy to address the impact of preclinical AD biomarker disclosure.

2 | THE BIG TEN: AREAS OF CRITICAL NEED PRESENTED BY PRECLINICAL AD BIOMARKER DISCLOSURE

More widespread preclinical AD biomarker disclosure will introduce ethical, legal, and social challenges that need to be acknowledged. These challenges loom large, though specific details may depend on as-yet-unknown factors, such as testing uptake and the costs and effectiveness of any disease-modifying therapies; as appropriate, we have noted where these factors might alter our analyses and recommendations. Addressing these challenges will require the collaboration of numerous stakeholder and action at the institutional, state, and federal levels.

2.1 | Promoting health equity

It is essential to ensure that preclinical AD biomarker testing and, if needed, health-care services and supports, are accessible, affordable, and effective for all patient communities. To accomplish this, policy interventions are needed to address unmet needs and systemic sources of disparity.¹²

First, research is critical for advancing health, but it must be conducted intentionally to reduce inequities; otherwise, it will perpetuate them.¹³ AD biomarker research—and consequently also studies of AD

biomarker disclosure—has to date been conducted in cohorts that are largely non-Hispanic, White, and highly educated, and with a family history of AD. These cohorts are not reflective of the US population generally, nor of AD patients specifically. Findings regarding AD biomarker presence thresholds and risk estimates have been calculated using data from predominantly non-Hispanic White participants. When racially minoritized groups are under-represented in research establishing risk thresholds and estimates, it remains unclear if these biomarkers are valid for estimating disease risk in groups with a disproportionate presence of social determinants of poor health.^{14,15} In addition, underrepresentation can cause harm by exacerbating distrust in research. Relatedly, given the relative homogeneity of research participants to date, the effects of AD biomarker disclosure on recipients may not be fully generalizable. Further, clinical trials of disease-modifying therapies have not been representative.¹⁴ Funding like the National Institutes of Health, oversight agencies like the FDA, and payers like the Centers for Medicare and Medicaid Services should consider mandating representative samples in research unless there is a compelling reason not to. This will require investments to build capacity and improve recruitment of underrepresented groups and to diversify the research workforce.¹⁶

Second, to realize the promise of disease-modifying therapies for AD, all individuals must have access to health care—including both biomarker testing and treatment—in the preclinical period. Yet, while racial and ethnic minorities are disproportionately affected by AD,¹² they also encounter disproportionate barriers to health care generally, and dementia care specifically.¹⁷ These disparities are the result of longstanding structural and systemic inequities and urgently need to be addressed. Among other steps, dismantling structural racism will require assessing whether interventions narrow disparities in health, not focusing solely on overall health benefits.¹⁸ Without such action, there is a risk that introduction of preclinical AD biomarker testing and disease-modifying therapies for AD will exacerbate rather than ameliorate disparities because the benefits are unequally distributed over the population.

Further, even if a disease-modifying therapy becomes available, maintaining a brain-healthy lifestyle will likely continue to be an important strategy for aging well. Yet, brain health is not purely a matter of personal responsibility. Again, the identities individuals hold as they move through the world—such as their race, socioeconomic status, and zip code—shape their interactions with institutions and systems and offer or limit opportunities to reduce modifiable risk factors for dementia. For example, redlining and other racist practices mean that Black communities are more likely to live in food deserts or places more exposed to pollution.¹⁹ Greater attention must be paid to the balance between personal behavior change and the need for broader environmental and systemic changes meant to facilitate health improvement. There is a growing understanding that justice can only be achieved through equal access to factors supporting a healthy lifestyle. Policy makers must target the foundation of the social and physical environment.²⁰ We need to acknowledge and address the ways systemic racism, ableism, classism, and other forms of structural discrimination further disparities and impact individual health.

2.2 | Reducing stigma and discrimination

Research on disclosure of AD biomarker results to individuals highlights concerns about stigma and discrimination.^{21,22} Stigma refers to negative collective attitudes such as those often held toward aging and dementia, while discrimination occurs when stigma is enacted via concrete behaviors such as rejection, exclusion, or devaluation. A recent survey experiment conducted with members of the general public suggests that stigma directed toward AD dementia may similarly be experienced by individuals with AD biomarkers even in the absence of cognitive impairment.²² Unfortunately, stigma may discourage individuals from learning about their risk for cognitive impairment caused by AD or prevent them from accessing care.²³ As such, it will be important to develop new social narratives to reduce stigma around AD biomarkers and dementia. We discuss shifting the social narrative in section 2.10, Supporting People Along the Dementia Trajectory.

Federal anti-discrimination protections for individuals with elevated AD biomarkers will also be necessary.²⁴ There are open questions about whether the Americans with Disabilities Act affords protections to persons with preclinical AD,²⁵ and while the federal Genetic Information Nondiscrimination Act (GINA) prohibits some kinds of discrimination on the basis of genetic information, no comparable protections exist for biomarkers. Although GINA may serve as an important source of protection for individuals with preclinical AD, as they might undergo genetic testing in conjunction with biomarker testing—either because the combination of genetic and biomarker testing improves specificity of an individual's AD dementia-risk profile or because their genetic profile informs treatment (e.g., apolipoprotein E ϵ 4 carrier status increases risk of amyloid-related imaging abnormalities [ARIA] caused by anti-amyloid drugs like aducanumab)—GINA alone is insufficient. A federal Biomarker Information Nondiscrimination Act, with protections similar to those provided by GINA, should be enacted, as this would provide a minimum level of anti-discrimination protections for all US citizens. Once this floor has been established at the federal level, states might choose to implement further protections. For example, after GINA's passage, California passed the California Genetic Information Nondiscrimination Act (CalGINA) in 2011. CalGINA builds on the protections offered by GINA by prohibiting genetic discrimination in areas such as emergency medical services, education, and other state-funded programs.

Discrimination in health and long-term care insurance are obvious, substantial sources of concern and will be discussed in greater depth below. Yet, less-obvious sources of discrimination also merit policy makers' attention. For example, AD biomarker information may be used to discriminate in housing. While it is not presently standard practice for mortgage companies or operators of retirement communities to request dementia risk information, housing institutions may seek out such information to predict ability to pay, and in the case of retirement communities, to maintain their active and vibrant image.²⁶ Existing laws, such as the federal Fair Housing Act, which prohibits discrimination on the basis of disability, may be leveraged to prevent discrimination on the basis of biomarkers in housing; however, as this is a novel legal question, the adequacy of existing protections is unclear.

While anti-discrimination protections are undoubtedly necessary, there may be select instances in which discrimination on the basis of AD biomarker status might be justified. For instance, it may be appropriate or desirable—depending on the type of employment and employee responsibilities—for employers to have access to employees' AD biomarker results.²⁵ Consider, for example, current efforts to monitor the cognition of older clinicians²⁷ or airline pilots.²⁸ In the future, more accurate, multifaceted assessments of competency for high-responsibility jobs may draw on AD biomarker results. While biomarker testing alone is not sufficient to determine fitness for work, the results may indicate increased cognitive risk and be used as justification for greater frequency or intensity of monitoring. We are not endorsing mandatory disclosure of AD biomarkers to employers but, instead, noting the need for policy debates regarding when AD biomarker information should be protected and when it should be shared, for instance, to prevent harm to third parties such as patients and passengers.

2.3 | Ensuring health insurance coverage

To date, few participants in studies of AD biomarker disclosure have expressed concerns about health insurance discrimination.²⁹ This is likely because, due to the studies' inclusion criteria, most participants are already eligible for Medicare (i.e., the federal health insurance program for people 65 and older), which is an entitlement program. Yet, as AD biomarker test sensitivity improves and it becomes possible to detect earlier stages or lower burden of AD pathology, preclinical AD will be identified in the below 65 population, which is generally not Medicare eligible. Thus, other public and private insurers will have a growing role in covering AD-related health care, including biomarker testing and prescription drugs in the preclinical stage.³⁰ Concerns about health insurance discrimination and adequacy of coverage will likely increase as a result. Under the Affordable Care Act (ACA), health insurance companies generally cannot refuse to cover individuals or charge them more because they have a "pre-existing condition." Once individuals are enrolled in a plan, an insurer cannot deny them coverage or raise their rates only because of their health. The ACA has long been a partisan issue, and there was some erosion of coverage gains during the Trump Administration. Although the ACA's future currently appears secure, policy makers must be mindful that eliminating the ACA's protections would create barriers to people with AD biomarkers obtaining affordable health coverage, and by extension, accessing care. In the alternative, a GINA-like law for biomarkers would prohibit health insurers from discriminating on the basis of biomarker information.

2.4 | Controlling health-care costs

The availability of disease-modifying interventions for preclinical AD will likely have a significant impact on the cost of health care in the United States. An estimated 46.7 million people in the United States have preclinical AD biomarkers (defined by amyloidosis, neurodegen-

eration, or both), though only 9.3 million of these individuals are predicted to go on to develop AD dementia by 2060.³¹ Even with new testing modalities that have the potential to be less expensive, particularly blood-based biomarkers, identifying those with AD biomarkers will require a high volume of testing and will be costly.

Not everyone with results indicative of AD biomarkers will be eligible for or require treatment; however, more work is needed to determine for whom—and under what conditions—treatment is indicated. Better tools to differentiate people with preclinical biomarkers who will go on to develop AD dementia from those who will not are necessary to reduce the projected financial and health burdens for the patient, health-care systems, and society of treatment in the preclinical stage of disease. Even assuming that treatment is offered to only a subset of those with AD biomarkers, treating large numbers of people with preclinical AD will be resource intensive and could ultimately cost billions of dollars. We note, however, that there may be some off-setting cost savings to the health-care system, given the high cost of dementia care.

Some testing and treatment expenses will be borne by Medicare, with significant effects on the federal budget and on taxpayers. Preclinical AD diagnosis and treatment may also create challenges for state budgets if expenses are covered by Medicaid, the nation's insurance program for people with low income, which is structured as a federal-state partnership.³² Private insurers will also incur substantial costs. This will have implications for all insured persons, as premiums will need to increase to address rising costs of care. Public and private insurers may find it necessary to base coverage decisions on cost-effectiveness criteria; failing to address costs and pay for value will fail to meet the needs of multiple stakeholders.

Even in the absence of a drug specifically for treatment of preclinical AD, it is possible that other drugs will be used "off label." Off-label prescribing refers to the legal and common practice of using an FDA-approved drug in a manner not specified in the FDA-approved label.³³ For example, the FDA-approved label for aducanumab indicates that it is for treatment of mild cognitive impairment or mild dementia. But the FDA does not regulate the practice of medicine, raising the possibility that aducanumab (or, more likely, another disease-modifying therapy for AD) could be prescribed off label to patients in the preclinical stage. Payers might consider how to pay for off-label uses—for instance, requiring that the use appear in a recognized compendia before they will cover it.

2.5 | Preparing the health-care workforce

The current shortage of dementia specialists¹² and long waits for specialty care may be exacerbated by widespread testing and treatment of preclinical AD if individuals seek out specialized memory care.³⁴ There is, however, hope that blood-based biomarker tests will permit testing, as well as patient management, in primary care settings.³⁵ Currently, providers are not obligated to tell patients they have a diagnosis of dementia.¹² This is likely due to a variety of factors, including lack of dementia treatments, social stigma,^{36,37} and physicians lacking

sufficient training to address dementia. Primary care providers' attitudes toward preclinical AD biomarker testing, including who should offer pre-test counseling and disclose results, are unknown, but it stands to reason they will have some reservations about assuming this role themselves. Thus, building their comfort and capacity to test and—as appropriate—to treat is an urgent priority.

Genetic counselors, social workers, and other health professionals will also need to develop competency for discussing preclinical AD and the meaning of biomarker test results. Additionally, under the 21st Century Cures Act, AD biomarker results will rapidly be available to patients within their electronic medical records, and steps should be taken to ensure that these results are disclosed in a way that promotes patient understanding.

State AD plans have sought to build workforce capacity for dementia-capable care, but these plans will need to be broadened to address preclinical AD. It may also be necessary to imagine and finance new models of care. This offers an opportunity for care navigators, a model that has been successful in cancer and dementia,³⁸ to be involved in the patient journey. Offering community resources and counseling for emotional and physical well-being to individuals and their loved ones may be incorporated in post-disclosure supports.

2.6 | Anticipating direct-to-consumer testing

A market will likely develop for direct-to-consumer (DTC) blood tests for AD biomarkers,³⁹ similar to the market for DTC genetic testing. Ideally, concerns about result accuracy, privacy, and consumer safety should be addressed prior to these services coming to market. Importantly, DTC test results are not often covered by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, which establishes national standards to protect patients' medical records and other individually identifiable health information. This leaves customers vulnerable. For example, 23andMe's expansive genetic information database and partnerships with pharmaceutical companies have renewed concerns about privacy of DTC genetic test results. Given the sensitive nature of and limited protections for biomarker information, discussed above, we recommend that HIPAA be amended to include companies that obtain AD biomarker (and genetic) information.

Additionally, customers are often not properly prepared to interpret the meaning of their DTC genetic test results for their disease risk and personal lives, potentially resulting in undue burden for the customer.⁴⁰ It is reasonable to expect similar challenges in the AD biomarker context. Because people are likely to follow up on DTC test results with their health-care provider, health-care professionals will need to be prepared to answer their questions about whether they are supportive of DTC AD biomarker testing.

2.7 | Paying for long-term care

People who learn they are at increased risk for dementia caused by AD are more likely to purchase long-term care (LTC) insurance in anticipa-

tion of future care needs.^{11,41} Supposing a disease-modifying therapy slows the onset of cognitive impairment, many individuals will still need LTC. In LTC insurance, information asymmetries and selective insurance uptake mean that the risk of adverse selection is high; this can destabilize the risk pool and eventually result in a "death spiral." To avoid this outcome, LTC insurers will undoubtedly seek to include preclinical AD biomarkers in underwriting decisions. It is quite likely that they will provide low or no coverage for individuals with AD biomarkers, unless required to do so by law.²⁵ There is precedent for permitting LTC insurers to discriminate where health insurers may not; GINA, for instance, does not apply to use of genetic information in life, disability, or LTC insurance.

With data suggesting both that more than half of people turning 65 will need LTC at some point⁴² and also that the costs of LTC care exceeding those older adults are prepared to cover,⁴³ LTC financing presents a mounting policy challenge. To protect individuals and avoid adverse selection, the government may offer subsidies and promote public awareness to encourage younger people to enroll in and employers to offer LTC coverage. Private LTC insurance, though, is a partial solution at best. Greater emphasis on public financing for LTC is needed. Reengineering the social insurance structures of Medicare, which does not cover long-term care, and Medicaid, which covers it poorly, will require creative solutions to balance cost with coverage.

2.8 | Planning for the end of life

To date, medical aid-in-dying (MAID) is legal in 11 states and the District of Columbia, collectively home to nearly a quarter of the US population. Yet, current MAID laws—which typically require both that the patient has capacity to request MAID and also that the patient is expected to live 6 or fewer months—exclude people living with dementia, who are rarely able to satisfy these two criteria simultaneously. In a small study, about 20% of cognitively unimpaired individuals with elevated AD biomarkers expressed interest in pursuing MAID in the future should they experience cognitive decline or feel they were burdening their families.⁴⁴ As the number of people with knowledge of their AD biomarker status expands, so too will the potential pool of advocates seeking to change laws to expand MAID to persons with neurodegenerative diseases. Officials in Oregon⁴⁵ have discussed the possibility of removing the provision requiring that the patient has a life expectancy of less than 6 months to expand eligibility. Other states will also need to debate whether this or similar changes are desirable, and if so, how best to implement them. If changes are not made thoughtfully, they risk undermining previously established protections, such as ensuring that people have access to hospice benefits and that vulnerable patients are not pushed into MAID.

Short of MAID, individuals with preclinical AD may wish proactively to plan for other ways of hastening death should they develop cognitive symptoms. For example, they may wish to stop eating and drinking (SED) by advance directive once they reach a certain stage of dementia.⁴⁶ Yet, there is little ethical and legal guidance, not to

mention scant practical guidance, about SED by advance directive. This gap complicates the execution of advance directives and other end-of-life planning and should be closed.

2.9 | Adopting planning tools for waning capacity

Cognitively unimpaired older adults who learn they have AD biomarkers often seek to “get their affairs in order.”¹¹ However, currently available legal tools are poorly suited to the features of preclinical AD. Advance directives—including both powers of attorney for health care and living wills—are familiar tools for identifying decision makers and articulating care preferences should the patient become incapacitated. While these documents are important, they are also insufficient,⁴⁷ particularly for older adults who are currently healthy but at risk for dementia.⁴⁸ First, advance directives are often focused on care at the very end of life (e.g., whether an individual wants cardio-pulmonary resuscitation) and therefore lack specificity for the many years and facets of dementia care. Second, advance directives offer little help when individuals retain some decision-making capacity but nevertheless require decision-making assistance. Third, decisions often need to be made in non-health domains, such as housing and finances, which advance directives do not cover. While there are tools that can help in these domains, such as a financial power of attorney or guardianship, these too have their shortcomings. Moving forward, planning tools will need to be broader and more flexible to account for how capacity progressively diminishes over the entire disease course rather than focusing on its very end.

Supported decision making is one example of an alternative planning modality that has been legally recognized in a growing number of states and is gaining attention for its use by older adults. It is an approach to decision making in which an adult with impaired capacity freely enters into an agreement with a closely trusted person or persons who assist the individual in exercising their self-determination.⁴⁹ In the case of individuals learning AD biomarker results, the person at risk of developing dementia may create an explicit agreement with their likely care partner (e.g., a life partner, adult child, or friend) that outlines categories of decision-making needs and preferred means of support. Supported decision making offers a unique framework that promotes autonomy while affording protections to vulnerable individuals and provides a new option for people with AD biomarkers to prepare and plan for their future.

2.10 | Supporting people along the dementia trajectory

No disease-modifying therapy for AD is likely to be 100% effective at preventing dementia caused by AD; moreover, dementia will still develop from many non-AD causes. Therefore, treatment for persons with preclinical AD cannot come at the expense of bolstering care and support for persons living with mild cognitive impairment and dementia.

Providing support and educational resources can help dismantle stigma³⁶ and offer alternatives to the current narratives presenting dementia as a fate worse than death. Stimulating community dementia literacy and offering dementia-friendly services in public transportation, libraries, restaurants, community centers, and beyond can function to break the social isolation often associated with dementia and caregiving. Involving individuals with dementia in social activities centered on abilities and strengths outside of cognitive impairment (e.g., music, gardening) can increase opportunities to engage with people with dementia and their loved ones, resulting in benefit for all participants and intergenerational bonds. These strategies coupled with a more positive and nuanced public re-framing of AD and dementia can change the social narrative to include examples of living well with dementia.³⁶

Additionally, policy makers must acknowledge the value and toll of unpaid care and recognize that supporting caregivers is in fact supporting individuals with dementia. In 2020, the unpaid care provided for people with dementia by loved ones was valued at \$257 billion.¹² It is estimated that 70% of the total lifetime costs of dementia care is borne by loved ones through out-of-pocket health and LTC expenses and from the value of unpaid care. Policies to provide respite care, paid family leave, and caregiver tax credits can reduce the burden on caregivers and improve individuals' abilities to care for loved ones with dementia.

Supporting people with dementia should also be accomplished by strengthening the direct care workforce that provides long-term services and supports (LTSS). Workforce challenges—particularly maintaining sufficient levels of trained staff—threaten to exacerbate costs of care and further strain access to services. Over the last decade, Medicaid and other private providers have shifted to more home and community-based services to reduce system-level costs of LTSS and improve service accessibility. While this shift away from institutionalized care matches many people's preference to age-in-place, it does not address the core issues of a shrinking workforce and rising costs. The direct care workforce is not equipped to meet growing demand for LTSS because of high turnover and low participation.⁵⁰ Such challenges are driven in part by low pay, low status, physically and emotionally taxing work, and lack of career progression opportunities. Addressing these barriers to tenure and workforce entry is critical to ensuring a large enough workforce to meet increasing demand. This must be a priority for Medicaid, the primary payer for LTSS in the United States.

3 | CONCLUSION

Advancements in research are rapidly changing the social and policy environment surrounding AD. While studies continue to investigate the predictive utility of biomarkers and to develop disclosure best practices, the extension of preclinical AD biomarker disclosure beyond the research setting appears likely. Therefore, efforts toward addressing the ethical, legal, and social implications of preclinical AD biomarker disclosure need to intensify. There will be neither a quick nor easy “fix”—far from it. The solutions presented here, however, will have

beneficial ripple effects for other patients and for society more broadly and merit our time and attention.

Protections for individuals with health-risk information as conferred by biomarker results extend beyond AD. Pushes to advance precision medicine coupled with advancements in biomedical fields for identifying and detecting disease risk mean that biomarker information may soon be available for many diseases and conditions, necessitating broad solutions as opposed to AD-specific remedies. Still, AD is a relevant entry point for building policy recommendations. Renewed public concerns about health information privacy, recognition of the challenges faced by caregivers, the public salience of AD in the wake of aducanumab's approval, and increased visibility of AD issues by lobbying institutions are quickly coalescing to create a moment for action. A similar policy window to that which allowed GINA to be passed is currently opening for biomarker information protections. Now is the time to advocate for policy that sufficiently protects people who learn biomarker information and improves the landscape of aging.

ACKNOWLEDGMENTS

This publication was supported by the National Institute on Aging (R03 AG062975 [LRC], R01 AG054059 [CEG], and R01 AG021155, and R01 AG02716). Dr. Largent is supported by the National Institute on Aging (K01-AG064123) and a Greenwall Faculty Scholar Award.

CONFLICTS OF INTEREST

The authors have no conflicts to disclose. Author disclosures are available in the [supporting information](#).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

How to cite this article: Erickson CM, Clark LR, Ketchum FB, Chin NA, Gleason CE, Largent EA. Implications of preclinical Alzheimer's disease biomarker disclosure for US policy and society. *Alzheimer's Dement*. 2022;14:e12339. <https://doi.org/10.1002/dad2.12339>