Bringing Alzheimer Disease Testing and Results Disclosure Into the 21st Century Cures Act

The 21st Century Cures Act and its associated regulations include provisions to increase the types of electronic health information (EHI)—including clinical notes and laboratory and imaging results—that must be easily, immediately, and electronically accessible to patients. A key motivation for this is to support patients’ autonomy by empowering them with information about their health and health care. While some laud the Cures Act as a rejection of medical paternalism and gatekeeping, others worry it’s a blunt tool that prevents clinicians from fulfilling their crucial role in disclosing and interpreting results.

Debates about the Cures Act are not unique to Alzheimer disease (AD). However, the AD field has a unique window of opportunity both to further the act’s goals and to address its challenges. Anticipating momentous changes in AD-related testing and results disclosure, the field can work proactively to empower patients confronting a disease characterized by the erosion of autonomy.

Increasing Testing

Because of a pair of scientific advances, tests that illuminate AD risk or reveal AD pathology are increasingly likely to be ordered clinically. The first advance is the US Food and Drug Administration’s (FDA) June 2021 approval of aducanumab (Adhelm; Biogen), which targets amyloid plaques. Surprising many, amyloid testing was not addressed in aducanumab’s FDA-approved label; nevertheless, prior to receiving an aducanumab prescription, patients may undergo a positron emission tomography scan or lumbar puncture to determine whether they have elevated amyloid and are a good candidate for the drug. Additionally, aducanumab recipients may be offered APOE genetic testing, as e4-carrier status is linked to risk of amyloid-related imaging abnormalities. Uptake of aducanumab remains slow to date; however, its approval opened FDA’s door to other anti-amyloid drugs, which can also be expected to increase demand for testing.

The second advance is reflected in growing enthusiasm for blood-based tests for AD biomarkers. Though not yet widely available, blood-based tests are expected to be less expensive and less invasive—and so more accessible—than currently available testing modalities. In the future, “screening of all older adults for brain pathology with blood tests may become the standard of care” and extend testing into new settings, particularly primary care. Within the AD field, there has long been hesitancy to order gene and biomarker tests and also robust debate about the appropriateness of results disclosure. Insurers have sharply constrained coverage for testing. Thus, most clinicians currently lack experience disclosing AD-related results. When disclosed, such results ought to be contextualized within the limitations of our evolving knowledge, conflicting literature regarding significance, and other uncertainties. Results requiring similarly nuanced interpretations have typically been introduced into practice with a clinician mediating disclosure. Therefore, AD’s scientific progress sits uneasily with the Cures Act, which mandates rapid, full access to EHI.

Disclosing Results

AD-related results may be handled in various ways under the Cures Act. One possibility is to use brief embargos to slow down patients’ electronic access to certain sensitive results, including AD results. An embargo, or delay of a few days, would allow the ordering clinician a window to review and disclose results to the patient before the results’ electronic release. Hospitals are presently divided over whether such delays will meet the information-blocking definition—that is, whether they will be deemed a practice likely to interfere with access, exchange, or use of EHI under the Cures Act. This is an essential point for the US Department of Health and Human Services to clarify moving forward.

Is it in the best interest of patients to embargo AD-related results? One reason that clinicians might wish to delay release of results—because they can have life-changing implications—may be the reason patients want results as soon as possible. Earlier access can alleviate the substantial anxiety of waiting. Some might argue impersonal disclosure of AD results is relatively unsafe, but prior research suggests not. Studies of AD gene and biomarker disclosure have consistently found that individuals do not experience anxiety, depression, or suicidality after receiving results, though disclosure provokes varied emotions. A caveat is that these findings are from homogenous, prescreened study populations who have generally received education and counseling. Still, based on existing evidence, safety concerns are not a broadly compelling reason to delay patients’ electronic access to AD-related results. If safety concerns arise in particular cases, the Cures Act final rule includes a “preventing harm exception.” Notably, likely psychological distress does not meet the harm standard—only danger to life or physical safety.

Whether embargos constitute information blocking or not, the field must prepare for results of AD-related tests, if ordered clinically, to be quickly and routinely released. It still may be possible to default to clinician-mediated disclosure if, to avoid allegations of information blocking, patients receive advance notice of the default and are offered an easy way to opt out. Then, if they prefer, they can rapidly obtain their results electronically. Alternatively, patients can be informed that...
AD-related results will be available electronically so that they can decide for themselves when and under what circumstances to access them. For some this will be online, while others will prefer clinician-mediated disclosure. Under any of these scenarios, some patients will learn their results absent a clinician.

Anticipating this, the AD field must avoid an anemic understanding of patient autonomy. Simply providing EHI is not autonomy enhancing if a result is inscrutable to the patient or if the patient’s understanding of the result is incorrect or incomplete. Information is autonomy promoting only if it equips patients to make informed choices about their health and well-being that are consistent with their values, interests, and preferences. Thus, when considering new disclosure modalities, the AD field must recognize the legal obligation entailed by the Cures Act to increase the availability of EHI but also the moral obligation to provide EHI in a way that promotes patient autonomy.

Patients and families can understand AD gene and biomarker results with appropriate education. A first step is to report results in plain language. Additionally, results should be paired with links to self-directed educational materials, such as informational brochures or videos that contextualize results. These materials should be evidence based; developed with input from experts on patient education and AD-related results disclosure, as well as with the support of professional societies and the National Institute on Aging; tested with representative patient populations; and made widely available to reduce variability in disclosure practices—and disparities—across care sites. Providing these resources may help patients make sense of their test results, and it will help clinicians, who risk experiencing additional demands on their time when patients receive results outside of a clinic visit. Moreover, these will provide patients with a meaningful alternative to “googling,” which may lead to misinformation and misinformed choices. A longer-term goal is to increase access to expert postdisclosure education and counseling, for example by facilitating telehealth visits with genetic counselors or other clinicians experienced in discussing AD-related results through use of interstate compacts, changes to federal law, and revised reimbursement policies.7

Conclusions
Patients fear AD because it progressively erodes their ability to self-determine. Clinicians who care for patients with AD have an ethical responsibility to foster their autonomy. Recognizing that testing and results disclosure will become increasingly common, the field should act now to ensure that disclosure practices eschew paternalism and empower patients. It’s time to bring AD into the 21st Century Cures Act.

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REFERENCES