

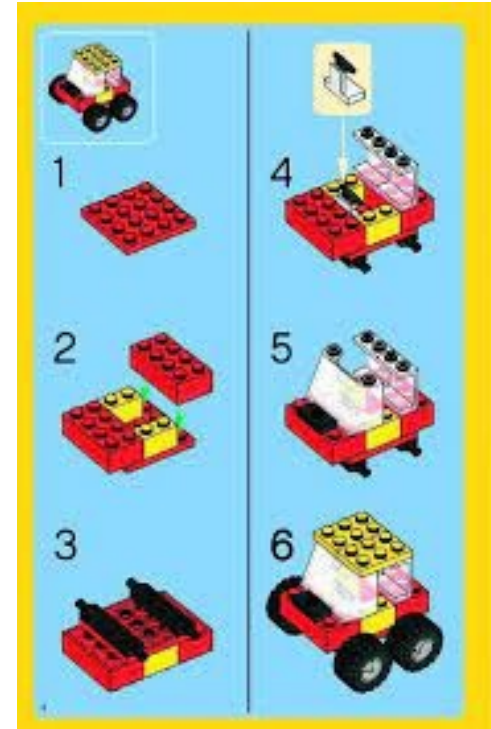
*The Current Legal & Ethical Issues
in Alzheimer's Disease:
From Research to Clinical Care*

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Roadmap

1. Describe the shift in ethical, policy, and legal focus on issues in Alzheimer's disease
2. Four Issues to Highlight as Examples
 - Employment & Insurance Discrimination
 - Prison & Criminal Justice Health
 - Payer Coverage and Access
 - Data & Research



Alzheimer's disease and Related Dementias (ADRD): Traditional Challenges

Preventing

- Modifiable risk factors
- Predictive testing (biomarker & genetic)

Treating

- Diagnosis
- Disease-modifying therapies

Caring For

- Symptom management
- Caregiver burden
- Safety (including elder abuse)
- Long-term Care Services

*“he scored a 24, so it didn't go anywhere. It's just like, ‘Okay, that's what it is.’ He just has some memory-- **and they just kind of turned us away.** So then three years later I'm like, ‘This is not getting any better. There's definitely something.’ [. . .] So I set up another appointment.”*

Themes in Missed/Misdiagnosis	Frequency
Symptoms disregarded	3
Unclear Responses	2
Treated for another condition (menopause, depression, sleep apnea, etc)	4
Missed phenotype of AD	1



A shift in novel ethical and legal challenges

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Impact of Caregiver Burden

“since the diagnosis, I'm just overwhelmed. And because everything's on my shoulders, I have to do the research. Before, it was, "Okay, honey, take care of this," and then she would do it, and it would get done. Where now, I've got to do it. Well, I can't do it because I'm at work, and I'm gone for days at a time, and so things are just not getting done. And so, I just feel like I'm way behind, trying to plan and get ready for the next phase of this.” (caregiver report, paper under development)

 ORIGINAL CONTRIBUTION

Caregiving as a Risk Factor for Mortality The Caregiver Health Effects Study

Richard Schulz, PhD

Scott R. Beach, PhD

Context There is strong consensus that caring for an elderly individual with disability is burdensome and stressful to many family members and contributes to psychiatric morbidity. Researchers have also suggested that the combination of loss, pro-

Schulz, Richard, and Scott R. Beach. "Caregiving as a risk factor for mortality: the Caregiver Health Effects Study." *Jama* 282.23 (1999): 2215-2219.

A new shift in ADRD research leads to a shift in public health considerations

Preventing

- Modifiable risk factors
- Predictive testing (biomarker & genetic)

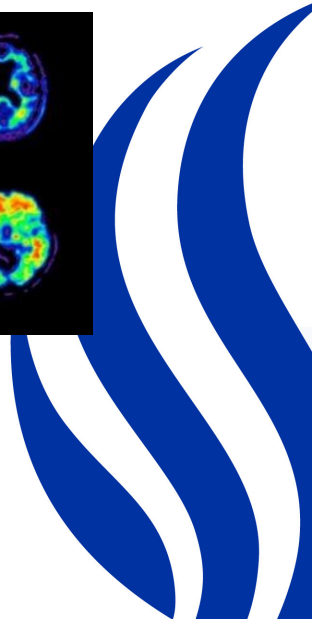
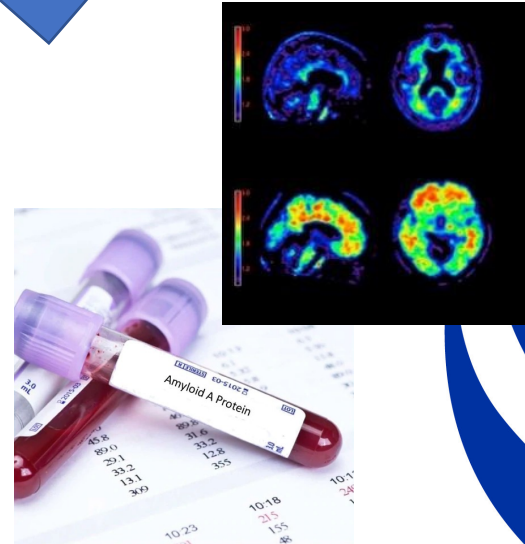
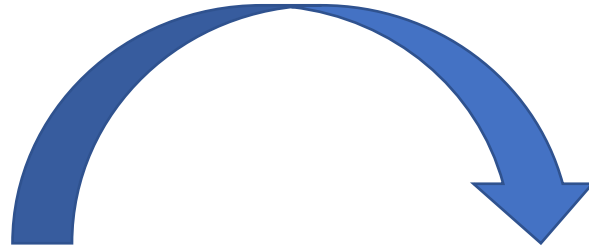
Treating

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A SHIFT in how Alzheimer's is defined & diagnosed . . . Including the potential for preclinical risk assessment



Some Emerging Issues



Issue 1. Chronic Illness & Discrimination

- Employment discrimination based on disease or risk for disease

More Americans Working Past 65

Report says most have college degrees and higher incomes

by Harriet Edleson, AARP, April 22, 2019 | Comments: 16



GETTY IMAGES

Adults age 65 and older are twice as likely to be working today compared with 1985, and many of them are making good money, according to a new report. But the likelihood of their being able to work past the traditional retirement age is shaped by how much education they have and what type of work they do.

Harvard Health Letter

Working later in life can pay off in more than just income

Benefits such as mental stimulation and social engagement are associated with staving off chronic disease.

Published: June, 2018



Image: © Rawpixel/Getty Images

Punching a time clock is still part of the regular routine for an increasing number of older adults. They're staying employed or going back to work, even though they're beyond the traditional retirement age of 65.

“the downside would be if this information got into the wrong hands [. . .] **and it was used to do her harm in terms of employment or insurability** [. . .] There are certainly laws in place to prevent those things from happening [. . .]”

Arias et al, *in process*

Dementia Expert (Qualitative study on preclinical biomarkers & discrimination)



Anti-Discrimination Protections

Table Summary of the scope of legal protections to prevent employment and insurance discrimination in persons who have either genetic markers or biomarkers for developing Alzheimer disease dementia

	Protection from employment discrimination		Protection from discrimination by health insurers		Protection from discrimination by life insurers		Protection from discrimination by long-term care insurers	
	Genetic markers	β -Amyloid biomarkers	Genetic markers	β -Amyloid biomarkers	Genetic markers	β -Amyloid biomarkers	Genetic markers	β -Amyloid biomarkers
Americans with Disabilities Act ^{4,7}	Uncertain ^a	Uncertain	No	Uncertain	No	No	No	No
Affordable Care Act ⁶	No	No	Yes	Possible ^b	No	No	No	No
Genetic Information Nondiscrimination Act ⁷	Yes	No	Yes	No	No	No	No	No

^aThe Equal Employment Opportunity Commission (EEOC) does not directly address genetic disposition. However, the EEOC has interpreted the 2008 amendment to the Americans with Disabilities Act to broaden the definition of disability in favor of coverage.

^bAffordable Care Act provisions to limit discrimination in health insurance for persons with a preexisting condition start in 2014. Whether these provisions will apply to the concept of preclinical Alzheimer disease is uncertain—the analysis is complicated by the fact that preclinical biomarkers have yet to be validated and thus may not qualify as a preexisting condition.

Unfair Treatment:

“It wasn’t fair. She didn’t understand all the processes and stuff. [...] She was an administrator, a vice principal at junior high school for seven years. [...] and instead of recognizing it as what it was, it just became her losing it as a teacher or her not putting enough effort into it. And my God, she was staying up almost all night through no fault, trying to nail down the curriculum and to go the next day, and it still wouldn’t work out.”
Husband of Patient with EOAD



The Flipside: Public Safety & Safety Sensitive Industries

“Well, he realized that **he's a liability on some of the things for-- because as the engineer, there are lots of liability issues.** So he was very cognizant on how this all plays out. So from the get-go-- I think from that moment on, he thought about whether or not he should be signing drawings, being the ultimate decision-maker on things. He continued down that path probably through end of last year. **And then he made a decision to notify everyone-- I mean, not everyone but the other partners in the firm that he shouldn't be signing drawings** and that the other partners should be doing that. So that's kind of what came about for that.” *Wife of Patient with EOAD*



Alzheimer's disease biomarkers: another tool for FAA pilot screening?

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VIEWPOINT

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Legal and Policy Challenges to Addressing Cognitive Impairment in Federal Officials

The mean age of federal government officials is at a historical high. Twelve members of the 116th Congress (2019-2021) are older than 80 years,¹ and President Donald Trump is the oldest elected president in history (70 years old at inauguration),² which is consistent with societal trends. A rise in mean age creates an increased risk that federal officials will develop age-associated cognitive disorders, including Alzheimer disease and similar dementias. Age-associated neurodegenerative disorders can lead to profound behavioral and cognitive changes, including difficulties with memory, problem solving, judgment, insight, and social and emotional functioning. These deficits may affect job performance and substantially affect the competence of federal officials. This risk is more than hypothetical. Researchers have reported³ that evaluations of President Ronald Reagan's speech indicate he experienced Alzheimer disease while serving in office. More recently, an investigative report⁴ uncovered evidence that a pharmacy service delivers drugs used to treat Alzheimer disease to members of Congress.

Screening for cognitive disorders as part of a general health assessment typically relies on preliminary screening tests (eg, the Mini-Mental State Examination or Montreal Cognitive Assessment) that are insensitive

The public's right to information regarding the cognitive status of an official or candidate is legally unsettled, although current political and regulatory standards err on the side of protecting health information as private. Disclosing officials' health information to the public raises tensions between individual privacy rights and a public interest in officials' capacity to serve. The Health Insurance Portability and Accountability Act restricts access to health information for uses outside the provision and/or payment of health care. In addition, political considerations may influence decisions to restrict disclosure of health concerns that could affect perceived capacity to serve. Several historical examples reveal efforts to keep health information from the public, including disabling stroke (Woodrow Wilson), Addison disease (John F. Kennedy), gastrointestinal disease (Dwight Eisenhower), and terminal cardiovascular disease (Franklin D. Roosevelt).

The US constitution lacks a singular approach for removal of individuals from office owing to illness or other grounds. The 25th amendment is the only constitutional provision that supports the removal of an official (the president) from office on the grounds of illness or disability; it permits a transfer of power if the president is no longer capable of serving. The amendment's primary objective is to

Opinion

Issue 2. Dementia in Prison & Criminal Health

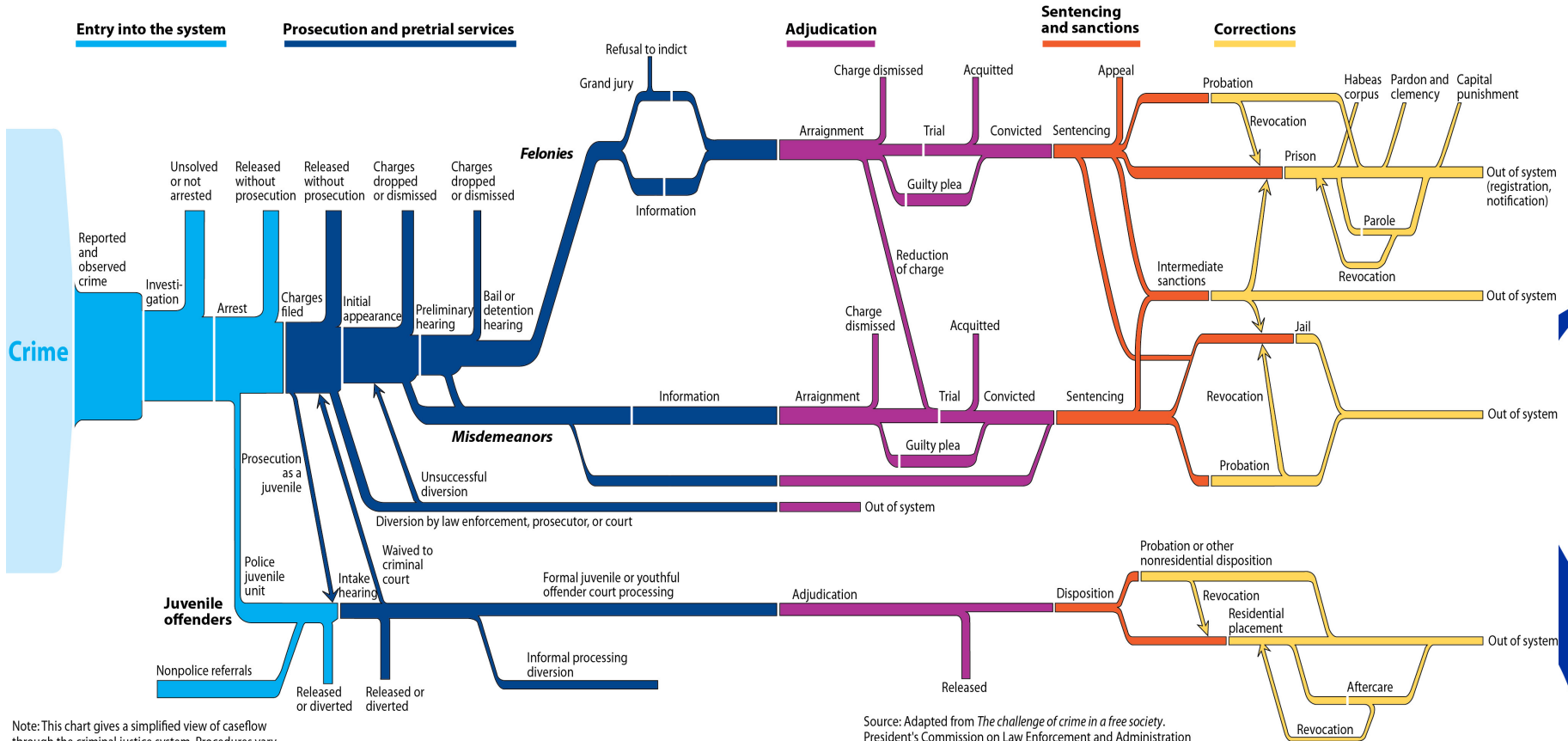


<https://www.nytimes.com/2012/02/26/health/dealing-with-dementia-in-prison.html>
An Ethical Examination of Sentencing Decisions & Treatment of Inmates with Dementia
(ARCH Network Pilot Grant)



What is the sequence of events in the criminal justice system?

<https://bjs.ojp.gov/sites/g/files/xyckuh236/files/images/2021-06/flowchart.jpg>



Note: This chart gives a simplified view of caseload through the criminal justice system. Procedures vary among jurisdictions. The weights of the lines are not intended to show actual size of caseloads.

Source: Adapted from *The challenge of crime in a free society*. President's Commission on Law Enforcement and Administration of Justice, 1967. This revision, a result of the Symposium on the 30th Anniversary of the President's Commission, was prepared by the Bureau of Justice Statistics in 1997.

Understanding how the Criminal Justice System Manages Individuals with Dementia

- **15 Semi-structured interviews:** Prosecutors and defense attorneys to identify experiences with dementia and/or potential challenges post-arrest.
- **Empirical legal methods:** Systematically map standards for post-arrest, trial, and sentencing.



<https://www.nytimes.com/2019/07/19/us/albert-flicker-convicted-kimberly-dobbie-murder-maine.html>

Results: Interviews with legal stakeholders

Gender	Female (9), Male (3)
Age Ranges	30-39 = 6 40-49 = 3 50-59 = 3
Current Role	State Prosecutor = 1 State Public Defender = 6 Private Practice = 1 Other = 2 Unanswered = 2
Years of legal practices	Range 5-33 3 = <10 7 = 10-20 2 = >20



Identifying Gaps within the System

Screening

Pre-trial release

Competency

Placement (housing)

Criminal liability

Sentencing

Post-Conviction

*In varying scenarios, competency is almost always an issue. Sometimes it's pretty clear that the person isn't competent and they're found not competent. Unfortunately, here, it's also not uncommon for the state to demand a restoration period to try and, quote-unquote, "restore" them to competency, even though they have a diagnosis with absolutely no chance of that occurring. So it's not uncommon for people to be sent to the state mental hospital for restoration to try and stand trial for their criminal charges. I have a gentleman there right now whose only diagnosis is dementia. **They recommended restoration, even though there's no reason to believe that would ever cause anything to improve.***

Georgia	Adams v. State, 298 Ga. 371 (2016)
Minnesota	State v. McLaughlin, 725 N.W.2d 703 (2007)
Mississippi	Anderson v. State, 185 So.3d 403 (2015)
Texas	McAfee v. State, 467 S.W.3d 622 (2015)
New Jersey	State v. Lado, 275 N.J.Super. 140 (1994)
New York	People v. Weinstein, 156 Misc.2d 34 (1992)
California	People v. Hix, Not Reported in Cal.Rptr.3d (2009)
California	People v. Simon, Not Reported in Cal.Rptr.2d (2001)

Code Book

Responsibility for crime

Proof of disease

Expert opinion

Defendant awareness

Non-expert evidence

Admissible evidence



Standard for Guilty By Reason of Insanity

Proof of
Disease

Admissible
Evidence

Dr. Pollock also determined that appellant suffered from a neurological disease of the brain and central nervous system and that he suffered from dementia as well. Dr. Pollock testified that appellant's disorders were aggravated by stress and that exposure to severe stress could cause him to develop psychotic behavior. Dr. Pollock acknowledged that his opinion that appellant suffered from a vascular neurocognitive disorder [. . .]. *McAfee*

Olivia Li, et al, *in process*

Early Takeaways

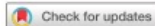
- Lack of systematic screening process for dementia post-arrest
- Placement is a significant challenge
- Attorneys lack training on dementia to be able to understand how the disease could impact decision-making
- The two legal mechanisms available to divert miss the mark given their focus on psychiatric populations
 - Competency Hearing
 - Plea of “not guilty by reason of insanity” (Arias, 2020)



Issue 3. Costs, Payer Coverage, & Access

www.nature.com/gim

Genetics
inMedicine



ARTICLE

Private payer coverage policies for *ApoE-e4* genetic testing

Jalayne J. Arias, JD, MA¹, Ana M. Tyler, JD, MA¹, Michael P. Douglas, MS² and Kathryn A. Phillips, PhD²

PURPOSE: *ApoE-e4* has a well-established connection to late-onset Alzheimer's disease (AD). However, there have been no analyses of payer coverage policies for *ApoE*. Our objective was to describe the rationales for coverage and non-coverage of *ApoE* testing, examine the rationales, and describe supporting evidence for coverage and non-coverage of *ApoE* testing.

METHODS: We searched for policies from the eight largest private payers for *ApoE* testing for late-onset AD. We implemented content analysis methods to evaluate the policies and their rationales.

RESULTS: Seven payers had policies with positions on *ApoE* testing. The policies were based on generic preauthorization criteria. Rationales supporting coverage included clinical utility, while rationales supporting non-coverage included inadequate data supporting testing, characterizing testing as invasive, and limited clinical utility.

CONCLUSION: Seven of the eight largest private payers' coverage policies for *ApoE* testing are based on generic preauthorization criteria. Rationales supporting coverage and non-coverage are based on clinical utility. As the field advances, *ApoE* testing may have applications for identifying individuals who may benefit from modifying therapies are under evaluation by the US Food and Drug Administration. Our findings are consistent with private payers' policies and may cause payers to reconsider their policies.

Genetics in Medicine (2021) 23:614–620; <https://doi.org/10.1038/s41431-021-01428-2>

This Issue

Views 1,629 | Altmetric 24

Viewpoint

July 16, 2021

Developing an Economic and Policy Research Agenda for Blood Biomarkers of Neurodegenerative Diseases

Jalayne J. Arias, JD¹; Kathryn A. Phillips, PhD²; Jason Karlawish, MD³

» Author Affiliations | Article Information

JAMA Health Forum. 2021;2(7):e211428. doi:10.1001/jamahealthforum.2021.1428



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Add to wizdom.ai

Table 2. Monthly payment to nursing homes and non-nursing home facilities, by dementia status and facility type of residence

	Adults with dementia		Adults with no dementia	
	Residential care	Nursing home	Residential care	Nursing home
Panel A. All adults				
Percent with self/family payment	92.1%	42.2%	98.0%	27.3%
Percent with payment from social security	8.3%	33.3%	0.0%	52.3%
Percent with payment from Medicaid	3.9%	66.3%	0.0%	70.5%
Percent with payment from Medicare	0.0%	11.4%	0.0%	11.7%
Percent with payment from private insurance	2.2%	0.0%	0.0%	9.8%
Percent w/ payment from other government source	8.0%	0.9%	10.8%	6.6%
Panel B. Adults with OOP payment				
Average (SD) self/family payment	3089.6 (2102.8)	3848.6 (3987.8)	2800.7 (2603.6)	2176.4 (2057.7)
Median self/family payment	2906	1453	2500	1522
Interquartile range of self/family payment	[1593,4500]	[851, 7500]	[769,3666]	[319, 3100]

Notes: The data are weighted using NHATS survey weights to represent 2019 survivors among Medicare beneficiaries living in the contiguous United States in 2015. The results are based on 505 respondents (319 with dementia and 186 without dementia) who were non-community dwelling (column n from left to right: 195, 124, 158, 28).



Issue 4: Data And Research

Two Novel Issues Emerging

Whether and How
Investigators Return
Results to
Participants

How investigators
SHARE data with
each other



Ability to learn genetic status appears to be a driver for enrolling in the study

*And so part of the reason for my enrollment in it was-- **is because of the genetic testing that came out of it and knowing if I was a carrier or not.** And then that was kind of one of the reasons that I did it. So I went through some genetic counseling at the time with [redacted]. I think she's no longer there. But did some stuff with her, and that was, again, one of the reasons that I started this study. And now I continue to do the study just to help be part of it, so.*



Researchers may face unique challenges associated with Return of Results in Familial Dementia Research

Difference within Families

Investigator:

one family member knows and yet doesn't want the other family member to know and making sure that we're respecting all of those complicated directives and wishes within families.

Participants:

The only thing that I don't really understand from some of their perspectives is of not wanting to know the results of their testing. A lot of them have been tested and keep going up every year to help the study, but don't want to find out whether they're carrying the gene or not. That's what I don't really understand.

Disclosure to Family/Capacity

Investigators:

And then another thing we've added is that to whom, kind of next of kin, can this be disclosed to because a number of our patients die. And so sometimes they die before the genetic data comes back, and so we want to be clear about is it okay to tell the next of kin. And if so, who do we tell about this, and so we try to make sure that all of those things are in there.



Data Sharing

(Research 1: Research 2)

I think **it's paramount**, right? I mean, I do not think for these complex diseases that we're going to solve problems if people don't share data. And my impression is that even with the current policies in place, not everybody is being-- **there's not good faith sharing across the board** - right? (Investigator)

Investigator perspective on data sharing

Investigators described challenges and barriers

Data Use (Secondary Analysis): *“And so sharing data is not exactly appealing most of the time because you never know if people are going to use it well or what they'll do with it.”*

Embargo/Incentives: *“On the data-gatherer side of things-- I mean, there is a little bit of frustration in the sense that you do all the QC and the processing of the data, and then you release it, and then actually, even though you've been involved in all of that, you're basically in the same point as everybody else when it comes to analysis.”*

Data withholding: *“I mean, I think people are not straightforward, right? [. . .] I mean the most common reason, I think, you hear is, “Oh, only one consented to be able to share their information.” And that may be true, but I have no way of really knowing, right? I mean, I can't go in there and say, “Well, [Name], I want to see your consent form.”*





IN PROGRESS



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Questions? Comments!

Thank you for your time & attendance!

