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Editorial

Disclosing Individual Results in Dementia Research: A Proposed Study Participant's Bill of Rights

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Abstract. This Study Participant's Bill of Rights is a call to action for researchers in Alzheimer's disease and related dementias (ADRD) to proactively design clinical studies that provide the option for research participants to learn their individual research results if they choose, and in a manner that ensures study integrity. This Bill of Rights was crafted by a committee of study participants, care partners, representatives of dementia advocacy organizations, and other stakeholders in dementia research for the Advisory Group on Risk Education for Dementia (AGREEDementia). The framework developed by the Multi-Regional Clinical Trials (MRCT) Return of Individual Research Results provides a useful context for researchers to plan their studies and disclosure.

Keywords: Biomarkers, communication, dementia, disclosure, ethics, genetics, patient rights

INTRODUCTION

Research studies in Alzheimer's disease and related dementias (ADRD) do not routinely share individual results particularly genetics, biomarkers, and neuropsychological test results, acquired during a study [1]. Inequity arises when commercially available tests allow informed individuals with the resources, to obtain the same information by paying out of pocket through the direct-consumer-market or their healthcare providers. Drawing important health-related conclusions, such as that a person is at increased risk of dementia, should be based on valid and reliable measures [2–5]. For the purpose of this paper, we are thus identifying information with the requisite evidence of validity and reliability to be used clinically as "clinical results". Examples of information that could indicate elevated dementia risk include clinically validated biomarkers of elevated amyloid and tau levels in brain, MRI scans, clinical neuropsychological test scores, and testing for *APOE* ε4 carrier status [6]. Interpretation of results should indicate limitations, for example a single biomarker

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result without a complete evaluation should be interpreted with caution. If clinical expertise is needed for interpretation of measures, such as interpretations of a structural MRI or depression diagnosis, clinical practitioners with the requisite knowledge should provide the interpretation and discuss the limitations with the participant.

Aside from the scientific validity of the measures, the value of those measures to the participant should be considered with respect to whether, when and how results are disclosed. For a comprehensive framework, see "Return of Individuals Research Results" developed by the Multi-Regional Clinical Trials (MRCT) [7]. Researchers commit to notifying participants immediately and referring for treatment when clinical results indicate that the participant has condition in urgent need of therapy (e.g., cancer, brain aneurysm, urinary tract infection). Ethically, there is no choice. For less urgent conditions where therapy is possible (e.g., high blood pressure), sharing this actionable information is good practice. Until there are effective therapies, most clinical dementia risk information falls in a class of being personally valuable (e.g., *APOE* ε4 carrier status). This Bill of Rights is most relevant to this type of information and the authors believe offering to share this information will increase enthusiasm among potential research participants [8, 9].

Finally, the rapid pace of advances being made in ADRD research means that previously collected information could take on new meaning; researchers must proactively plan to reassess the disclosure of individual research results through the duration of a study and adjust plans where necessary. For example, in a study that follows participants for two or more years, cognitive scores may decline over time even though both scores are in the average range, which could be helpful information to clinicians and families if the participant is later diagnosed with dementia.

PARTICIPANT VOICES: BUILDING A BILL OF RIGHTS

The Advisory Group on Risk Evidence Education for Dementia (AGREEDementia.org) was initially convened by individuals from the National Institute on Aging (NIA) and was comprised largely of members of NIA-supported Alzheimer's Disease Centers. Over time the group evolved into an independent body seeking to be widely inclusive and to promote open dialogue [10]. The AGREEDementia Stakeholder Subcommittee is composed of members from the ADRD research and care community, and the public. The subcommittee includes representatives from disease advocacy organizations and five individuals with lived experience of dementia. Two members have elevated genetic or biomarker-determined risk of developing dementia, two are individuals living with dementia, all five are current or former care partners, and four have been participants in research. There is limited racial or ethnic diversity on the subcommittee, with one individual from Sexual and Gender Minorities (SGM) and one individual identifying as Hispanic/Latino. The Stakeholder Subcommittee identified opportunities to deliver recommendations to AGREEDementia that reflect the perspectives of its members on disclosure of test results, including genetic and biomarker results. The committee determined their collective perspective was best represented in the form of a Study Participant Bill of Rights, as a means of empowering and promoting the voices of research participants to dementia research stakeholders [11]. The Bill of Rights was drafted and refined with multiple rounds of discussion and feedback from the group.

The purpose of this "Study Participant's Bill of Rights" is to recognize the personal preferences of research participants and to urge sponsors and scientists to proactively fund and design studies that accomplish these goals in a safe and effective manner, without compromising the validity and integrity of the scientific work. This poses a paradigm shift and a new opportunity for research participant engagement as part of protocol design and development. These rights are proposed as a starting point for a larger discussion that will ultimately improve the process of sharing clinical results with research participants.

STUDY PARTICIPANT BILL OF RIGHTS

1. **I have the right** to receive my individual results, collected in the course of my research participation if I so choose; I can also ask how to receive them. This may be done in person or by telehealth, and either alone or with a person of my choosing.
2. **I have the right** to exercise this right in an informed manner, including receiving information on validated decision-making tools if they are available, knowing who can access my results, how the law does or does not protect me after receiving my results. In order to protect

myself, I may need to finish any care, legal and financial planning in advance of receiving my results.
3. **I have the right** to be told what my test results mean, in easy-to-understand terms and with sensitivity, compassion, and patience. This information should also be provided in writing, so that I may review it later.
4. **I have the right** for my questions to be answered to the best of the researcher's knowledge and to take all the time I need to process the information I received.
5. **I have the right** to be contacted or decline to be contacted to check on my well-being after receiving a result suggesting increased risk of dementia, and to be referred to additional resources for more information and support related to my health and wellbeing.
6. **I have the right** to decide what actions I take after receiving my test results, such as pursuing medical and/or psychological care, engaging in legal or financial planning, and informing my family and friends of my results.
7. **I have the right** to turn my results into action for my own wellbeing and the betterment of others, by exploring additional research studies I may qualify for.
8. **The above rights should apply regardless of my cognitive status.**

IMPLEMENTING THE BILL OF RIGHTS

Researchers designing studies in ADRD may find the Multi-Regional Clinical Trials (MRCT) framework helpful as they consider which results could have value to participants [7, 12]. The framework identifies four types of information that could potentially be shared with participants: **Urgent, Actionable, Personally Valuable, and No Known Implications**. Understanding the value to the participant is critical and could lead the same test to have different classifications. For example, genetic results (e.g., *APOE* ε4 carrier status) that communicate increased risk for individuals without cognitive impairment take on therapeutic importance for individuals with cognitive impairment that are considering amyloid-reducing therapy because carrier status can alter risk of treatment side effects [13]. Similarly, AD biomarkers typically have greater prognostic value in persons with prodromal symptoms than in asymptomatic individuals [14, 15]. Any mandatory communication of test results with the participant or people outside the research team should be described during informed consent. It is the responsibility of researchers to ensure that any disclosure of results also protects the integrity of the study. Methods may include holding off on disclosure until the end of a study or limiting which study staff know results, especially for those involved in collection of key outcome measures for the study.

1. **Urgent** findings require disclosure and referral for treatment. Information will likely be shared if outside expertise is needed to evaluate whether to refer for treatment, and to explain concerns to the treating clinician. Examples include results that require a rapid clinical response such as an aneurysm, brain tumor, amyloid-related imaging abnormalities (ARIA) on an MRI, or a UTI on laboratory testing.
2. **Actionable but not urgent** results are those with medical or personal decision-making utility, notably when additional diagnostic or preventive measures are needed or when treatment is available. For example, an elevated blood pressure level has implications for risk for other conditions, like heart disease or vascular dementia, and can be treated. Aerobic exercise may also be recommended as prophylaxis. Participants may choose to learn their *APOE* ε4 carrier status before initiating a therapy that carries higher risk for side effects for those who carry two copies of the *APOE* ε4 gene.
3. **Personally Valuable** is information that is typically not actionable but which a research participant might find personally useful. For example, participants with no cognitive symptoms may desire to learn their results of testing for *APOE* ε4 carrier status and may use that information to make lifestyle changes to reduce their dementia risk. A research participant with MCI may want to see her cognitive scores over the past months/years of study participation, to know objectively whether her cognition is declining.
4. **No Known Implications** is a category of information that currently has no known utility or value and is of unclear significance regarding a participant's current or future health. Examples in ADRD research include findings with inadequate evidence to merit use as clinical measures such as a score on an experimental cognitive measure or a biomarker test under development.

> Returning these results may cause confusion and distress about their meaning; because of this, results should be communicated very carefully, with emphasis on what is not known.

Researchers may design studies to develop new measures, and thus not every measure included in a research study is designed for clinical decisions. Clinical Laboratory Improvement Amendments (CLIA) certified laboratories are often required for clinical decisions. If other Laboratory Developed Tests are used, it is important that researchers confirm the accuracy of results before disclosure to participants or their care team, ensuring no technical issues could have impacted the results. Both **Urgent** and **Actionable** results will inform clinical recommendations and hence it is critical that only clinically valid results serve as the basis for action.

Sharing results with No Known Implications in ADRD research is controversial, in particular genetic results [3–5], but this committee advises that participants should be allowed to receive this information if they wish. Learning more about one's health and having better understanding of possible risk, or the causes of symptoms is a key motivator to join studies [16]. In a survey of participants with stored biological samples, 88% indicated they would want to learn their results, even if the meaning was "uncertain" [17]. Responding to these stated preferences gives researchers an opportunity to increase transparency, trust, and meaningful engagement with participants. Maximizing disclosure of individual results, when accompanied by education and resources, could potentially improve participant recruitment, diversity, and retention [18]. Researchers should be clear about both what is and is not known and answer questions addressing any misinterpretations and explore with the participant whether they are using the information to understand their future risk. If feasible, participants can opt to be recontacted and receive scientific updates as the field evolves.

Appropriate use criteria evolve over time with scientific advances. Some measures may have scientific limitations to classify them as having **No Known Implications** but with scientific advances could become **Personally Valuable** or **Actionable**. Examples of tests in transition to clinical measures in ADRD research include novel plasma biomarkers, which are just beginning to be understood. Comorbid health conditions may distort these results, leading to misinterpretation, a problem which may someday be solved [19]. Appropriate use guidance for amyloid PET advises against use in people without verified symptoms [15]; however, research studies suggest communicating this information with appropriate education has been demonstrated to be safe and can be **Personally Valuable** [20]. It is the view of the writers of this Bill of Rights that research participants can understand the nuances of when results may require further research and that they should be offered the opportunity to receive their results.

Researchers must have the option of withholding findings that are harmful. For example, ethicists advise that the default position is to withhold misattributed paternity detected in genetic studies [21]. In contrast, the authors of this Bill of Rights believe results related to dementia risk, diagnosis, and severity are valuable to individuals even though they may be distressing, researchers should offer the option of sharing results with participants.

INVESTIGATOR RESPONSIBILITIES

Researchers have the obligation to abide by local regulations, and the AGREEDementia stakeholder group advocates that researchers appeal to their institutions and governing bodies to support the rights above. Providing an explanation of individual research results in writing (as proposed in the Bill of Rights) with appropriate conclusions allows participants to have a clear understanding of the meaning. Participants can then share this written material with their clinical providers. Investigators should share available, relevant educational materials to help participants weigh the pros and cons of learning their personal risk information; additional educational resources will need to be developed [10, 22].

It is the responsibility of the researcher to understand how best to contextualize results shared and facilitate appropriate referrals if results are **Actionable** or **Urgent**. It is ideal to provide participants who receive **Personally Valuable** results with information about available resources and supports in the event they develop cognitive decline sometime in the future. If there are circumstances in which communicating clinical information is a threat to the validity of the study (e.g., if someone is receiving sham treatment) then participants should be informed of this possibility during informed consent. For example, some studies reveal sham status immediately after the participant completes the study, and others wait until years later after the entire study is over.

Increasing the return of individual research results will require considerably more staff time, training, and materials. Considerable efforts and foresight will be needed by researchers designing studies, plus the commitment from research funders to prioritize disclosure and provide the necessary resources. Collaborative groups like AGREEDementia and MRCT facilitate learning from the experiences of participants and other researchers; continuing this effort across academic and pharmaceutical partners will promote a full paradigm shift.

PARTICIPANT PERSPECTIVES: WHEN TO SHARE INDIVIDUAL RESEARCH RESULTS

Researchers rely on participants to consent to study procedures and interventions, for which there are both known and unknown risks. As such, research is essentially reliant on individuals to self-assess their risk tolerance. Recent studies such as the Anti-Amyloid Treatment in Asymptomatic Alzheimer's (A4) study have demonstrated that disclosure of elevated risk, when coupled with education and support, enables asymptomatic participants to handle risk information well [23, 24]. AGREEDementia Stakeholder Committee members also pointed out that the distinction between symptomatic and asymptomatic individuals in dementia is evolving, with the lines are becoming increasingly blurred as the field moves towards the concept of Alzheimer's disease as a continuum [25, 26].

> "*I want to know, whether it's clinically relevant or not. Because it's my future and my life, and I need to make some decisions based on what I'm seeing. I'm asymptomatic but that doesn't mean that in the future, with such a high genetic risk, that I may see things differently from a researcher*!" (Research Participant, Advocate, and person with two copies of *APOE4* allele).

Knowledge of elevated dementia risk information is also **Personally Valuable** in maintaining continuity of care, a serious problem in existing healthcare systems. Important results are often not transferred from one physician to another. The research participant is most often the only person who can fully relay her or his health information and can efficiently transfer information across specialists.

> "*Given the lack of continuity for patients enrolled in studies, or with various care providers, we know the participant is an important repository of information that influences decision making in the future. This [repository] is so nuanced and so individual to the person and the practitioners involved that it cannot be easily generalized into these big studies that determine "what is clinically relevant.''* (Advocate and Person with Lewy body dementia).

One AGREEDementia member has a diagnosis of early-stage AD and has participated in dementia research for over a decade. For someone already diagnosed, learning results of novel biomarker tests with **No Known Implications** could provide an opportunity to feel included in studies investigating the etiology of her illness.

> "*In many ways it feels very dismissive or patriarchal - that somebody - for whatever reason, is controlling access I have or should have. Being in the study for twelve years, having gone through seven spinal taps, numerous MRIs, many PET scans, a lot of blood draws, that information is being studied, and looked at very carefully. And I understand that maybe there's not a consensus on what that data means, but I want to know it*!" (Advocate and person with early-stage Alzheimer's disease)

The practice of sharing research results with **No Known Implications** can be justified ethically but there is an urgent need to design studies that help researchers learn how best to support research participants who want this information.

> "*People get bad information and uncertain information all the time. It's not the information itself but how it's presented. You should get the option, some will want to know and some won't want to know. And afterward, people that opt to get information need to get guidance and assistance with it.*" (Ethics and Research Professional)

Empowering participants with the choice to learn one's individual research results respects the right to self-determination and individual risk tolerance. The sharing of results also offers the scientific community an opportunity to establish greater transparency and partnership. Responsible and ethical sharing of individual results may build greater trust with study participants, especially those from under-represented communities, where trust has been measurably lower [8] and where greater representation in in all levels of research participation is a stated priority [9].

"*Dementia research is experiencing an existential crisis in terms of recruiting the broad diverse populations that they now have to enroll. So the counseling and dissemination of knowledge is going to be the single greatest draw in order to get people to enroll in research. Presenting that, and the manner in which it's executed, is going to make all the difference in terms of the quality of the research results.*" (Advocate and Person with Lewy body dementia).

LIMITATIONS

The method used to develop the Study Participant Bill of Rights has limitations and hence is proposed as a call to action for the scientific field to advance the practice of sharing individual results. It was developed by a small group of individuals who have taken part in various research studies in the United States, with interest in the disclosure of dementia risk (e.g., genetic and biomarker information). The majority of the Stakeholder committee are college-educated and self-identify as White, and as such does not represent the diversity of the U.S. population. More work is needed to understand the perspectives of people from different racial and ethnic groups on learning their dementia risk when participating in research studies. There are personal and cultural differences in the preference to learn or not learn one's results, and in how those results are conveyed to the individual, family, or support system [27]. The most common concern received from investigators is the hesitancy to share individual level research results that do not meet the standards of clinical results, or have **No Known Implications**. What participants understand about these results, as well as whether and how they use this information later is important to study further, especially to address concerns researchers have raised that participants might draw incorrect conclusions about their dementia risk. When therapies for Alzheimer's disease become broadly available, elevated risk for this illness could become **Actionable** and sharing clinical results will be a means of respecting the contribution of the many dedicated participants who made these therapies possible.

CONCLUSION

This "Study Participant's Bill of Rights", developed by stakeholders in ADRD research, recommends that researchers design studies that respect participant preferences to learn individual research results when this communication is not required. There is also a desire by some study participants to opt to receive clinical results indicating elevated dementia risk (e.g., genetic and biomarker) both when current clinical relevance is clear and when it is less certain, regardless of their cognitive status. With increasing confidence in the accuracy of measures of dementia risk, the long-held practice of withholding access of research participants to their personal, clinically valid, results has become difficult to defend and is a missed opportunity. The people with a diagnosis, care partners, and research participants serving on the AGREEDementia Stakeholder Subcommittee are members of a larger community of valuable research partners with important perspectives and insights that complement those of trained researchers. Funders should support these efforts with increased financial resources to the design of studies with the necessary staffing and expertise to support participants' preferences on receiving of test results. Greater transparency of clinically-relevant test results to study participants may help address some barriers to achieving representative recruitment in ADRD research. This "Study Participant's Bill of Rights" reflects the deep commitment of these members to this partnership, resulted from direct engagement of participants in ADRD research, and addresses the current advances and challenges in research [28, 29]. Recent studies that proactively build in disclosure of clinical dementia risk information, including genetic and biomarker results, to study participants have demonstrated this process can be accomplished both ethically and safely [30, 31]. Routinely planning for disclosure of these clinically relevant test results will advance current practice and more effectively engage participants for their insights.

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