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Symposium Articles

Support in Decision-Making for All

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Abstract

In recent decades, theorists of disability rights have made the moral and legal case for supported decision-making. Whereas surrogate decision-making, the long upheld legal standard, looks to a third party to make a decision for a person deemed to lack the capacity to make that decision for themselves, support in decision-making empowers that person to make their own decisions. In this article, we argue for a significant shift in the norms governing enrollment in clinical trials. Rather than assume that support is only appropriate for individuals who cannot independently make sufficiently informed enrollment decisions, we propose "support in decision-making for all" when research protocols are beyond a certain risk threshold. Drawing inspiration from the universal design movement and feminist insights about autonomy, we argue that making support in decision-making the presumption has substantial expressive and practical benefits, and better empowers all potential research participants to make more informed, autonomous decisions.

Keywords: research ethics; supported decision-making; informed consent; disability rights; autonomy

In recent decades, theorists of disability rights have made the moral and legal case for supported decision-making.[1] Whereas *surrogate* decision-making, the long-upheld legal standard, looks to a third party to make a decision for a person deemed to lack the capacity to make that decision for themselves, support in decision-making empowers that person to make their own decisions. Respect demands looking to persons as the locus of control for decisions about their own lives, particularly decisions central to their well-being or core values, if they can reasonably and ethically be seen as exercising control. Supported decision-making has been more thoroughly explored in the healthcare context, but theorists have recently begun to make the case for the practice in clinical research.[2] Here, we too focus on support for participants in clinical research.

In this article, we argue for a significant shift in the norms governing enrollment in clinical trials. We propose what we call *support in decision-making for all* when research protocols are beyond a certain risk threshold. Our discussion encompasses legally recognized supported decision-making (SDM), informal support arrangements, and other supportive practices. The idea here is that once a protocol reaches a certain level of risk, it should be designed with a *presumption* of support of some kind. When a protocol presents more than a minor increase over minimal risk and the experiences are not commensurate with those encountered in ordinary life or ongoing medical care, Institutional Review Boards (IRBs) should typically require research teams to recommend that all participants make use of support and offer supportive resources to make this possible. And as research becomes even riskier, or more complex and unfamiliar to participants, IRBs should typically require some form of support for all participants.

This proposed shift to a presumption of universal support echoes the ethos behind the universal design movement, which aims to design products, architecture, and systems for all people rather than specially accommodate those who are unable to use the "standard" variety. In parallel, rather than only accommodating those who lack the capacity to consent to research for themselves without support, we suggest designing research protocols to be supportive as a baseline.

While we expect this change in the default presumption to result in more widespread use of SDM and other supportive practices in research, there are good reasons why some individuals might choose to opt out of receiving support. Our arguments, therefore, draw distinctions among different types of supportive practices. We are not arguing that formal SDM should generally be required to enroll in research, merely that support of some kind should be the default presumption for design of the consent process for specified types of research. Moreover, when research is sufficiently risky and unfamiliar, forms of support such as education might reasonably be required for all participants.

Making support in decision-making the presumption, we argue, has substantial expressive and practical benefits. These include making SDM work better and more easily for those who currently rely on it, making supports more accessible to those who would particularly benefit from but are unlikely to receive support given the current framework, and making everyone's research-related decisions more informed and autonomous. In research, the stakes are often high and the choices evaluative. There is robust evidence that participants, even those falling above the "capacity threshold," very often misunderstand the nature of medical research. Adopting a policy of support in decision-making for all for research beyond

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minimal risk levels, we argue, better informs and empowers all potential participants.

Caveats

In light of the focus of this special issue, our discussion here concerns support in the clinical research context. However, much of what we say is arguably applicable to healthcare more generally, particularly regarding the benefits of support for all. Much of what we say will also be applicable to many other realms in which stakes of decision-making are high, choices are value-laden, and individuals commonly display insufficient understanding on their own, such as with financial planning.

Support in decision-making, when feasible, is morally superior to surrogate decision-making. Support centers and promotes the autonomy of the person being supported. With surrogate decision-making, others make a decision on the individual's behalf, whereas with support in decision-making, individuals themselves are looked to as the locus for the decision. When it is possible to look to someone to make decisions about their own life, respect demands so doing. There is also good reason to think this choice better reveals the actual preferences of the person in question. As systematic reviews of the literature on decision-making at the end of life have shown, surrogates fail to accurately predict a patient's preferences in approximately one-third of cases, even if they have had prior discussions with the patient about the topic in question.[3] And so, support in decision-making is superior to surrogate decision-making because it is more respectful and because it helps ensure a person's own preferences direct deeply personal decisions about their lives.

To be sure, some individuals lack capacity to make medical or research enrollment decisions even with robust support. A two-year-old lacks capacity to decide about enrolling in a trial no matter how much explaining their parents do. Taking their verbal agreement to indicate a supported, adequately informed decision would hardly promote or respect their autonomy. Scholars like Gerald Neuman have persuasively argued that presuming everyone has capacity to make such decisions can be harmful to those who cannot.[4] It risks leaving their interests inadequately served and leaving them without the protections that genuine informed agreement offers. David Wendler and Scott Kim highlight how this risk manifests in the research context in particular. They argue that while persistent objections by a participant always require withdrawal from non-beneficial research (the current practice), it would be reckless to let someone with advanced dementia, who does not seem to understand the risks even with support, enroll in a study over the disagreement of their trusted supporters. Indeed, even if their supporter favored enrollment, if their wishes cannot reliably be determined, their enrollment risks inconsistency with their autonomy. And it would seem inapt to call it SDM.

And so, when we use the slogan "support in decision-making for all," this "all," perhaps to the disappointment of some readers, does not in fact mean "all." It does not extend to every human being who might enroll in research. Rather, we mean "all" to encompass everyone who, under circumstances that include robust support, could be reasonably thought to make their own decisions. As Paul S. Appelbaum and Manuel Trachsel put it, SDM's "target population" is people for whom support "will render the person competent to decide."[5] We will not, in this article, say much about how to determine who this is, either theoretically (who would, with support, be above the threshold) — or practically — how we know that a person is above the threshold, particularly in less obvious situations, such as when someone's communications are only understood by their support person(s). We will also bracket the question of when individuals too impaired to benefit from decision support can be enrolled, with surrogate consent, in high-risk, high-benefit studies, like "last chance" cancer trials.

These are challenging questions, which other articles in this issue try to answer and we do not have adequate space to address. Rather, what is notable about our "all," what distinguishes it from the common position that support is appropriate for many (who otherwise lack capacity), is that our "all" is inclusive of all potential participants in more than minimal risk studies who are, or can be raised, above the capacity threshold, including those who are clearly *well above* that threshold. We argue that there are substantial, but largely overlooked, benefits of support in decision-making for individuals with decision-making capacity. That these benefits have gone largely ignored is certainly understandable; the lack of recognition of and infrastructure for implementing SDM has more pressingly and severely undermined autonomy. But we here aim to address this gap and show how making support in decision-making the norm better supports the autonomy of (almost) everyone.

Finally, we note that states (and countries outside the US) vary in the formal legal recognition given SDM.[6] Just as multi-site trials need to take into account privacy laws in different localities, they also need to take into account the varying laws governing SDM. But given that support in decision-making is morally superior to surrogate decision-making, researchers ought to consider encouraging support for all even when SDM has not gained formal legal recognition in their jurisdiction.[7] And where SDM is not yet legally recognized, we think there is good reason to advocate for its recognition.

What Do We Mean by Support?

We use support quite broadly, encompassing both formal SDM and other practices by which individuals can be supported in making autonomous, informed decisions. In what follows, we distinguish between legally recognized SDM and other less formal supports but begin our discussion with SDM.

Classically, SDM has been conceptualized as support for a *particular* person, tailored to the particular ways in which they might struggle to make an informed decision by themselves, that is provided by a predesignated individual or individuals of their choosing.[8] A variety of models have been offered for conceptualizing SDM, understanding the justifications that lie behind it, and considering its relationship to the autonomy of the supported. Though we see our commitments as compatible with any plausible theory of what SDM is,[9] to keep the discussion manageable, we focus on the idea of support as prosthesis, an analogy proposed by one of us, Leslie Francis, in collaboration with Anita Silvers.

Much as someone with a leg amputation might use a prosthetic leg for help in walking, someone with a cognitive disability that limits their ability to make informed choices might make use of the reasoning abilities of another for help in decision-making.[10] In this way, supporters might function as mental prostheses for *anyone* they assist, helping them toward a more informed decision-making process.

A support person might be a spouse, parent, sibling, or other trusted loved one, or a professional supporter. If the required support is more idiosyncratic or value-sensitive, it will be helpful

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if a supporter knows the supported person well. However, as Francis argues elsewhere, support from intimates may need to be supplemented with support from neutral others, particularly when there are difficult conversations about values to be had, and when supporters' ends might be predicted to differ from the ends of the person they are supporting.[11]

It is less obvious why someone who is capable of making their own informed choices would require a mental prosthesis. However, as we argue in a later section, there is ample evidence that people commonly suffer from significant limitations and biases in making healthcare decisions, particularly about clinical research. Moreover, someone need not be *unable* to perform a particular action for a prosthesis to help them do it or do it better or more easily. Glasses can be extraordinarily helpful for someone trying to read a book even if they could instead bring it closer to their eyes and read it slowly or read it but miss a few words. In this way, the prosthesis analogy is compatible with the concept of all individuals making use of support in decision-making.

Individuals with capacity to enroll in research by themselves can benefit from personalized support, too. If a person has a habit of skipping over the fine print in forms, for instance, their partner might support them by looking over those parts especially closely and flagging anything they anticipate their partner will care about.

Not all support need take such an individual-specific form. Sometimes, there will be generally helpful methods of support for a particular condition or life stage. In contrast to personalized support, this can be thought of as "semi-personalized" support. A research participant with Social Anxiety Disorder (SAD) will often benefit from completing research interventions with a familiar researcher. Someone who has dyscalculia, and therefore struggles to understand concepts when they're presented using numbers, might have a support person who helps them better understand the risks of enrolling in a trial by translating side-effect frequencies from percentages to the equivalent lay terms of likelihood. The distinction between personalized and semi-personalized support is not especially sharp, of course. Conditions manifest differently in different individuals. It will sometimes be ambiguous whether a feature, such as tending to overlook fine print, is primarily attributable to a disability or to a person's habits or individual personality. But solving this metaphysical puzzle is unnecessary for providing effective support.

In contrast with the personalized support of SDM and these other forms of semi-personalized support, there is in addition what we call "generic support." This sort of support is very broadly applicable, useful to nearly any potential participant. The logistical burdens and resource requirements of providing support can be minimized by making use, when appropriate, of generic support. Such support is commonly educational: for instance, explaining a medical risk, or heading off common misunderstandings about research. For something to count as *support*, however, it must have the potential to be *responsive* to participants to some degree. Handing participants an informed consent form, though educational in a minimal sense, will not count as providing generic support. Handing them an informed consent form and a page on the therapeutic misconception and then having a conversation to ensure they understand the misconception would, however, count as minimal generic support, support that some researcher teams already provide.

Generic support also can include helping participants to weigh their values in research contexts where there are likely to be conflicts. Some types of general support, like value elucidation and clarification, are often helpfully performed by loved ones in personalized support relationships. But research teams also play a vital role in providing generic support, especially educational. They will be particularly adept, for example, at clarifying the therapeutic misconception or explaining an unfamiliar side effect. While educational support for improving understanding has been more widely tested in adults with intellectual disability, some developers of support resources have touted their potential to help others understand complex consent documents, too.[12]

A continuum of appropriate forms of support ought to be the norm for clinical trials. When support is conceptualized in this broad manner, from the personalized to the generic, the full spectrum of ways to help people make more informed decisions about whether to enroll in a study becomes clearer. This approach helps to direct funding, change policies, and train researchers in a maximally impactful manner. It is apparent how it can benefit all of us, and how we might already make use of support when making big decisions. It becomes ever more obvious that support is not just for those with intellectual disability.

Requiring or *Offering* Support, IRBs, and Risk Standards

Under the current system for protecting human subjects in the US, if they are to participate in research, those who fall below the capacity threshold *must* have supporters who enable them to reach capacity or have a surrogate decision-maker. So too must many people who are anticipated to lose capacity. For instance, Alzheimer's drug trials typically require that participants identify a "study partner" to consent to participation with them and facilitate their ongoing trial participation, perhaps even by shifting into the role of surrogate as capacity wanes.[13] And there is something quite sensible about this. This practice helps ensure that participants continue to have protection if they are to remain in the clinical trial, even if they can no longer consent for themselves.

The reader might wonder, then: Does support for all mean that everyone should be *required* to make use of supporters if they are to participate in more than minimal risk research? If not, does that somehow undermine our position or express something objectionable and discriminatory? We think the answer to both these questions is "no."

It will be helpful here to keep in mind our distinctions between different kinds of support. By "support in decision-making for all," we do not mean that everyone ought to be *required* to have *a supporter* or have created an SDM arrangement. If a potential participant with capacity to consent does not want a support person because their loved ones have quite different values from them, requiring a support person might lead to a participation decision less in line with their values. They might also be worried about giving too much power to an overbearing or abusive partner or parent.[14] Such a requirement could unduly exclude from research, including research with prospective benefit, those without someone they trust enough to be their supporter. It seems misguided to force someone to use a mental prosthesis *against their will* in the name of promoting their autonomy when they are sufficiently capable of autonomous choice without a prothesis.

Rather, with "support in decision-making for all," we endorse two other claims. (1) Some forms of support, such as educational support, are appropriate to *require* for *everyone* who wants to participate in certain studies. This approach is appropriate when the study is high-risk; when enrollment requires making especially difficult choices among values; or when the protocol is complex or prone to important misunderstanding. And (2) when a study presents more than a minor increase over minimal risk and those

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risks are not commensurate with those faced in the course of ordinary life or ongoing health care, there should be a presumption that a range of supportive options, including SDM, should be *offered* to *all* participants. We borrow this risk standard from the regulations governing non-therapeutic research with children.[15] Researchers could explain why it is not appropriate to routinely offer support to enrollees in their particular study, but over this risk threshold, the justificatory burden ought to fall on those seeking to *avoid* offering support to everyone.

IRBs ought to assess whether it is appropriate to require that participants *receive* some support, require merely that researchers *offer* some support, or whether it is unnecessary to offer support to all participants in a given study. As studies get riskier or more likely to be confusing, it will become appropriate to switch from mandating that teams offer support to participants to mandating that everyone make use of some supportive options, such as interactive educational support, if they are to participate.

IRBs should also determine what support, if appropriate, should look like. They might require a research team to provide some education to every participant on a particularly confusing element of a protocol. Or they might require a research team to set aside resources so that every participant can consult with an independent professional about whether or not their values align with participating in a particular study, if they elect to do so. They might require that researchers ensure there are resources to fly out not only a participant, but also a supporter of the participant's choosing, if a study required travel from the participant's usual residence.

IRBs and research teams might also consider *compensating* even non-professional supporters. Compensation for support would have to be done thoughtfully, of course, to avoid creating incentives for supporters to push for participants to continue even when doing so conflicts with their good or autonomy. And it will have to be reconciled with state laws governing compensation of support persons. But given the time commitment required to be a good support person, incentivizing support like we incentivize research participation could be an effective tool to help make support the norm.

There are other steps both IRBs and individual research teams ought to consider to shift the norms around support in research. For instance, researchers might tell potential participants that bringing supporters is allowed or recommended *before* they arrive at the hospital or research center. Researchers might make sure there are extra chairs in the office, or avoid asking participants to immediately share their availability instead of giving participants time to check with their supporters about their availability for accompanying them.

Though the standards we recommend are disparate, in that some people (those deemed to lack capacity to enroll themselves) are required to have supporters if they are to participate while others are not, we do not think this is unfair or discriminatory. *Unlike* situations can justly merit *unlike* responses. It is not unfair or discriminatory if the DMV legally requires B to wear their glasses while driving if B cannot adequately see without them, but does not require A, who can see adequately without glasses, to wear them. This is true even if while A can pass the DMV vision test, A does not quite have 20/20 vision and would feel less eye strain if they wore glasses at night. While it might be a good idea for A to wear glasses while driving, that they are not required to use a prosthesis is not unfair.

More Autonomous, Informed Decisions

There are two different mechanisms by which the supportive options we discuss bolster decision-making for all participants. Support can (1) improve a participant's informational landscape, understanding, and logical reasoning. And support can also (2) help a person clarify and shape their own values. Some kinds of support, like educational support by the research team, will primarily improve decisions via the first pathway. Other support, like engaging in dialogue with a loved one about how research will negatively impact one's valued pursuits, will primarily improve decisions via the second pathway. And much support will work on both of these pathways in tandem.

As feminist philosophers have long emphasized, individuals do not exist in a vacuum, self-sufficient and autonomous all on their own.[16] The transformation from barely conscious infants to reflective adults is only possible through the care of others. And others undeniably help to shape values, decisions, and life plans in all sorts of smaller ways, too. Many feminist philosophers have focused on the ways social circumstances can undercut the ability to be autonomous. Marina Oshana's "social-relational" account of autonomy, for example, claims that "in order to be autonomous, a person who is in a society must find herself within a set of relations with others that enable her to pursue her goals in a context of social and psychological security."[17] People cannot act truly autonomously, she thinks, if their social situation is excessively confining.

However, others have the power not only to undercut autonomy, but also to *enable* it. As Jennifer Nedelsky persuasively puts it, "If we ask ourselves what actually enables people to be autonomous, the answer is not isolation, but relationships—with parents, teachers, friends, loved ones—that provide the support and guidance necessary for the development and experience of autonomy."[18] It is not just that support from parents and teachers during childhood enables the later autonomy of adults, but that continued support (i.e. the support from friends and other loved ones) allows adults to be more reflective and autonomous even once grown. And as Thi Nguyen argues, shaping values in collaboration with others is part of a rich and good life. With new activities or aesthetic appreciation, people often come to see the complexity and value of something only as a friend helps show them the way in.[19] People come to value things and pursue those things in conversation with others. This is reason to encourage all participants to make use of supportive options that involve their loved ones, or professionals with whom they have significant relationships, when stakes are high and decisions value-laden.

Our observation about others' facilitating (or undercutting) autonomy is not new, even in the specific realm of health and SDM. Gavin Enck, in arguing for broader use of formalized SDM in healthcare, posits "that healthcare decision-making is always social."[20] Andrew Peterson, Jason Karlawish, and Emily Largent explicitly bring relational autonomy into their case for SDM for those with dynamic impairments, such as dementia. As they describe, "relational accounts of autonomy—in contrast with more individualistic conceptions—recognize that autonomy is always and already bound up in our relationships with others. We are individual decision makers who have agency, but we also deliberate and decide in a rich social context."[21] They use this idea of relational autonomy to emphasize how a supported decision by a person with a dynamic impairment can be an autonomous one. It is not abnormal to make decisions with others, but part of how people make decisions as interdependent, social creatures. As Francis has put it elsewhere, "supported decision-making recognizes the interdependence of people as reasoners. Most people work with and sometimes rely on others as they try out ideas, explore options, and reason to conclusions about what to do. Everyone does this on an informal basis."[22] Unbiased professionals with experience helping others reason through difficult decisions will be especially adept at

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this sort of support. Engaging with others when reasoning not only helps people make better decisions generally but does so in *especially vital* ways in the research context.

Participating in research often requires that values be weighed against each other. Choices must be made between having more free time for a hobby, for example, and spending time contributing to the research enterprise and thus helping others. In weightier cases, participants might have to weigh the risk that an intervention will lead to death against the chance it may lead to disease remission. This process requires careful thinking about risks and contingencies, what matters to oneself, and the personal value or dis-value of a whole host of states. Someone's supporter might remind them of how annoying they found it to visit the doctor every week, or remind them, when headaches are listed as a potential side effect, that Tylenol does quite a good job alleviating their headaches. More seriously, supporters might help with planning about how to together face the prospect of temporary memory loss, or explore palliative care alternatives for a progressing cancer.

Having supporters help in understanding risks, values, and options is especially important when these things are particularly difficult to understand and it is particularly consequential that they are adequately understood. There is ample evidence that, on the whole, participants do *not* in fact give sufficiently informed consent to research. Enck points to the cognitive biases that undermine human decision-making to underscore his case for broader adoption of SDM in healthcare, such as how irrelevant setting adjustments affect the decisions people make.[23] And while there are surely cognitive biases that affect decisions (including health decisions) generally, flawed reasoning manifests in *particular* and *particularly consent-undermining* ways with research.

Though participants usually report feeling positively about the consent process,[24] studies show that participants commonly fail to appreciate the risks of the trials in which they are enrolled, as well as concepts like placebos and randomization.[25] Misunderstanding trial design is not inconsequential for decision-making. When patients fail to understand these concepts, as they typically do, they can suffer from the therapeutic misconception, confusing medical research with medical care and believing that they will receive the *best* intervention for them rather than a *randomly* allocated option.[26] That someone falls above the capacity threshold, then, does not mean that they are making adequately informed, value-aligned choices. As many have lamented, though people are signing informed consent forms, there is often a lack of genuinely informed consent. Having a team, some of whom have professional expertise, to help explain the therapeutic misconception, randomization, and the risks and benefits of participating, and then delve with participants into how all that interacts with their own values, gets everyone closer to the gold standard of informed consent.

Universal Design and the Normal

Making supported decisions "the norm" has important expressive and practical benefits. It will be helpful in explaining and defending these claims to look at the universal design (UD) movement. As Ronald Mace, the father of UD, an architect who himself used a wheelchair, describes, UD goes beyond accessibility, striving to create items and places that are "usable by and marketable to people of all ages and abilities" insofar as it is possible.[27]

We begin with the expressive half of our claim. The disability rights movement, like other justice-advancing movements, is not only about advancing the material welfare of disabled persons. As Elizabeth Anderson argues, justice is not just about material goods, but also relational equality, about standing as equals.[28] People care not just about a policy's material effect; they also care about being respected and about what a policy *expresses* about them. What precisely a policy expresses is often complicated and contextual.[29] Reasonable people will differ on what they interpret policies to be communicating. However, some policies surely communicate disrespect on any reasonable interpretation. Being excluded from public places because others have not bothered to make them accessible to one's body or mind (much less having actively decided against inclusivity) will predictably be taken to express a lack of equal regard for one's person. In addition to the obvious and serious material harms inflicted by inaccessible spaces, they also inflict weighty expressive harms and disrespect. And even if a building does not exclude disabled people, it might nevertheless communicate a kind of second-classness, that one's inclusion is an afterthought. This sort of concern animated Mace's commitment to making inclusive design cohesive and aesthetically appealing.[30] Compare entering a restaurant through the wide, appealing entryway with one's friends vs. entering by oneself through a makeshift ramp in an alley out back. Design of both physical spaces and procedures can make some people feel systematically like an afterthought.

When compared to the old standard of surrogate decision-making, that SDM is an option seems to express something respectful, that those falling below the capacity threshold are entitled to make decisions about their lives. But the availability and norm of support only for some is not entirely benign in what it communicates. Whereas support for some seems to emphasize a stark difference between those determined to fall below the capacity threshold and those determined to fall above it, support in decision-making for all does not partition in such stark terms. Rather, it seems to highlight everyone's shared vulnerability to making mistakes and falling prey to misconceptions about research and risk. The image of the typical human being as a perfectly rational agent is challenged. Making support the norm emphasizes that incomplete or imperfect decision-making is *normal*, that support from others is *normal*. This is an important part of the project of destigmatizing dependence and the need for support and destigmatizing disability more broadly. And when support in research is the norm, the inclusion of persons with disabilities is not an afterthought.

There are also practical benefits to changing a norm. When researchers are accustomed to working with supporters, they are more experienced with this dynamic and better able to appropriately navigate it. They are more experienced explaining risks and benefits to more than just potential participants. They are more likely to have the proper forms on hand and to hold meetings in rooms with adequate space for supporters. These practical benefits, in conjunction with the expressive benefits of norm-adjusting, support adopting support as the norm for clinical research.

There are, of course, important dissimilarities between product and architectural design, on the one hand, and decision-making in research, on the other. And these dissimilarities make both expressive and practical differences. People with limb differences might have to buy a specialized, more expensive product if a kitchen product is not designed to be usable by them. Or they might be unable to find a usable alternative at all. If a building is not designed with all in mind, some people will be unable to enter it and systematically denied the opportunities within. Mace himself had to be carried into his architectural classes because the doorway was not wide enough for his wheelchair.[31] And even if public buildings and some private residences are designed with all in mind, if UD is

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not universally adopted, one will be excluded from the homes of some friends and colleagues.

However, whereas a doorway must be made one-size-fits-all if everyone is to be able to use it to enter a room, research enrollment procedures can be more individually tailored.[32] So, there is some sense in which support, unlike architectural design, need not be universal to ensure access. However, approaching an offer of accommodation on a case-by-case basis risks leaving many people out who require or would benefit from support, for reasons related to a disability or otherwise. As we'll now argue, offering supported in decision-making only for some raises a parallel problem.

Borderline Cases

There are many potential participants who would *particularly* benefit from support but, without support in decision-making for all, are unlikely to receive it. They might particularly benefit because of a disability, but also for other reasons, such as being the sleep-deprived parent of a young child or having received little formal education. Take the case of Generalized Anxiety Disorder. Though it can impair decision-making capacity when especially severe, GAD generally does not render someone unable to make their own decisions. Many individuals with GAD are highly intelligent and professionally successful. Even when their anxiety comes through, it is still apparent these individuals can make their own choices. These are the sorts of participants researchers and medical professionals might give a minute alone to calm down, not flag as requiring a capacity assessment to participate, and certainly not find to lack capacity. Given the current framework, this is surely the right approach. But while it may be the *right approach in our current framework*, it may not be the *best* approach for potential research participants with GAD. Rather, people with GAD will often particularly benefit from support in decision-making.

A desire to catch borderline cases animates some views about the proper extension of the Americans with Disabilities Act. Anita Silvers and Leslie Francis argue that the ADA ought to be understood first as prohibiting discrimination on the basis of disability, not as providing protections only to an antecedently determined and limited class of people.[33] Protections do not then need to hinge on determining whether someone is "really" disabled. Just as starting from the question of whether someone is "really" disabled when determining who the ADA should protect is inapt, it is backwards to start from the question of whether someone has capacity when determining who should get support in research. Capacity assessments require significant researcher time and resources. Expanding support allows researchers to devote fewer resources to adjudicating who is a proper candidate for SDM and instead direct those resources to supporting participants.

And just as how thinking about the ADA more broadly allows support and accommodation for people through the aging process, support in decision-making for all likewise better prepares people to face changes that may come with illness or age. The practice of Alzheimer's research teams requiring that participants have a study partner is an illustration. Study partners attend onboarding with the participant, learning the process and risks and benefits with them, helping the participant give informed consent, and ultimately consenting for them. Study partners help to facilitate the participant's continued participation as their condition becomes such that it would be prohibitively difficult for them to understand and take part in the research on their own.

But surely it need not be *known* that a participant will require support for a study partner to be tremendously valuable and conducive to protecting patient autonomy. Estimates are that 5.3% of Americans aged 65–74 have Alzheimer's disease, and that this number rises to 34.6% for those over 85.[34] So what does this fact mean for the many studies that focus on aging, or older populations, or persons at all ages? It is a bit puzzling that, should a person face a 99% chance of requiring support to remain in a study, they are required to have a support person, but if there is a greater than 1/3 chance they will require support to remain in a study, there is no mechanism employed to secure support from the beginning. Longitudinal studies are valuable scientific tools, allowing study of long-term disease progression, aging, and how their early life affects people decades down the line. But over the course of decades, many participants will inevitably experience fluctuations in their ability to make informed decisions by themselves. Some will develop Alzheimer's, while others will develop addictions, get in brain-altering car accidents, develop depression or anxiety disorders, face disorienting health scares, or experience debilitating grief. Rather than adding in supporters only after such changes, often when participants are less well-equipped to identify supporters, mechanisms can be constructed to allow more participants to have support in decision-making for the entirety of their time in research. As UD helps enable people to age in place,[35] a norm of support helps enable research participation throughout the lifespan.

Concluding Thoughts

SDM has been conceived of and defended in order to empower persons with diminished decisional capacity to make decisions on their own behalf, to support them in exercising their autonomy over their own lives and bodies. But here we have focused on the benefits of not only SDM but also support in decision-making for everyone, emphasizing expanding the circle to those with decisional capacity. There may appear to be something inapt and inappropriately decentering about this focus. And there would certainly be something inapt should support for those with capacity become the focus of the literature or should IRBs direct support resources away from those who require support if they are to participate in research at all. Neither of these are outcomes we seek. Rather, we believe that showing how support in decision-making is good for all of us helps to destigmatize support and make it more accessible to everyone. And while some kinds of support, such as encouraging the involvement of loved ones in decision-making, are not resource intensive, other support is expensive to provide on a mass scale. For there to be a presumption of support in research, funding will have to be increased. But the pot will not be infinite, and sometimes trade-offs might have to be made. When resources are limited, justice requires that priority is given to those who require support if they are to participate.

In reflecting on the difficulties everyone faces in acting truly autonomously, we are prompted to recall our common struggles as agents, knowers, and valuers. The "capacity threshold" does not divide people into "those who need help" and "those who help" in the decision-making realm. All are dependent on others, to some degree, even in undertaking autonomous action. Participating in research involves difficult-to-understand concepts and processes, and difficult-to-weigh trade-offs. Everyone can make more informed and value-aligned decisions with the help of loved ones and support persons, and with the help of specialized, responsive education. It is our hope that thinking about the value of support in decision-making for all provides yet another reason to make support more accessible and serves as another nudge toward a more inclusive future for medicine.

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