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Bioethics & universal vulnerability: Exploring the ethics & practices of research participation

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Abstract

In this article we advocate the adoption of universal vulnerability as a core value in bioethics. We argue that understanding vulnerability as the universal human condition – and rejecting the labelling of particular individuals or groups as vulnerable – would benefit bioethics and the research it governs. Bioethics first engaged with vulnerability in the context of participation in research and this continues to define how the value is typically understood. Thus, vulnerability is generally deployed to describe individuals (or populations) where real or perceived deficiencies limit the ability to function and to protect themselves from risks. Revisiting this initial context and the participation in research of people living with dementia, we note that the bioethical position of excluding the 'vulnerable' from research has led to major gaps in evidence and knowledge to inform care and support. Turning to universal vulnerability, we consider the research design and practices that the approach would mandate. We emphasise the importance of inclusive design, and mechanisms of institutional support that enable participation. We argue that these positively impact on the scientific value of research and address social justice concerns around social inclusion. Our aim is to provoke a fundamental reassessment of how vulnerability is conceived of in bioethics.

Introduction

Bioethics functions as a set of institutional discourses and practices through which developments in biomedical science and technology are articulated and governed.[1] As a broad field of enquiry it is diverse and thriving: drawing on a number of disciplines as well as approaches that include feminism, critical race theory, and disability studies.[2] Notwithstanding such plurality, and the richness of the wider field, it is nevertheless possible to identify a core or *mainstream* bioethics that dominates the field, institutional practices, and ethico-legal and public discourses.[3] This mainstream – determined and shaped by particular historical processes -[4] is primarily concerned with the technological developments of biomedicine and principles of individual ethical conduct.[5] These foci have led to a tendency to erase the social context within which ethical encounters are

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[1] José López, 'How Sociology Can Save Bioethics . . . Maybe' (2004) 26 Soc. Health & Illness 875, 875

[2] *See* Adrienne Asch, 'Disability, Bioethics, and Human Rights' in Gary L Albrecht et al. (eds) *Handbook of Disability Studies* (Sage Publications, 2001)

[3] Michael Thomson, 'Bioethics and vulnerability: Recasting the objects of ethical concern' (2018) 67 Emory Law Journal 1208

[4] *Ibid.*

[5] Daniel Callaghan, 'The Social Sciences and the Task of Bioethics' (1999) 128(4) Daedalus 275, 276. When referring to bioethics we are directing our analysis at mainstream bioethics.

constructed and experienced. Social factors tend to be reduced to 'epiphenomena'[6] to be bracketed out as individual ethical principles are clarified and applied.[7]

The implications of this are significant. The focus on new technology and principles of individual ethics has seen mainstream bioethics become dominated by what Paul Farmer has termed, 'quandary ethics'; the focus on individual patients and situations that may arise in the context of 'too much care' in high income countries.[8] While mainstream bioethics is preoccupied with such quandaries, it is not challenging the power invested in modern biomedicine or the broader social justice questions that health is embedded within.[9] This shapes mainstream bioethical debate, ethico-legal deliberation, and wider public discourses. There are also implications for bioethics itself. Bioethics is increasingly identified as a bureaucratic means of socially processing developments in science and technology[10] and a public relations exercise.[11] Understood in these terms, mainstream bioethics is increasingly reduced to a bureaucratic function and it has become possible to imagine that we have now passed 'peak' bioethics.

In response to this particular moment in the life course of the field, in this article we argue that universal vulnerability should be acknowledged as prior to the ethical; that is, an ontological fact upon which our ethical theories and frameworks are developed.[12] Understanding vulnerability in this way has the potential to enrich analysis which is often limited by traditional determinations of what is ethically significant and the analytical practices of mainstream approaches. While criticism of the weaknesses of bioethics is not new, we make this intervention at a time when vulnerability theory is gaining traction across disciplines. It has, for example, become a motif within recent feminist theory, where the focus is our shared susceptibility to harm and the ethical obligations this creates.[13] Importantly, vulnerability is also increasingly visible in bioethics[14] and it was identified as a core value in the Universal Declaration on Bioethics and Human Rights in 2005.[15] There has also been recent and detailed critiques of the use of vulnerability in research ethics, the

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[6] Adam M Hedgecoe, 'Critical Bioethics: Beyond the Social Science Critique of Applied Ethics' (2004) 18 Bioethics 120, 125

[7] Jeremy R. Garrett, 'Two Agendas for Bioethics: Critique and Integration' (2015) 29 Bioethics 440, 442.

[8] Paul Farmer, *Pathologies of Power: Health, Human Rights, and the New War on the Poor* (University of California, 2003) 204-05

[9] Raymond de Vries et al., 'Social Science and Bioethics: The Way Forward' (2006) 28 Soc. Health & Illness 665, 667

[10] Stuart F Spicker, 'Government and Bureaucratic Bioethics: Addressing Moral Issues in the Service of Ideology', (1996) 21(2) The Journal of Medicine and Philosophy 113, 113

[11] Jonathan B. Imber, 'Medical Publicity Before Bioethics: Nineteenth-Century Illustrations of Twentieth-Century Dilemmas', in Raymond De Vries, Janardan Subedi (eds.), *Bioethics and Society: Constructing the Ethical Enterprise* (Prentice Hall, 1998), 16, 30

[12] Thomson (n 3).

[13] A.V. Murphy, 'Corporeal vulnerability and the new humanism' (2011) Hypatia 575, 576.

[14]For a detailed account of the developing relationship between bioethics and vulnerability, see Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016)

[15]UNESCO, Universal Declaration on Bioethics and Human Rights (Oct. 19, 2005), The declaration was adopted by member states of the United Nations Educational, Scientific and Cultural Organization in 2005

area of bioethics that provides a focus for our argument.[16] Nevertheless, the value remains controversial. While some argue it is essential,[17] indispensable,[18] perhaps the single most important idea for the future of bioethics,[19] others argue it is too vague and broad.[20] Indeed, in mainstream bioethics itself it is largely treated with suspicion and remains peripheral. Our intervention is motivated by a belief that universal vulnerability can address the limitations of bioethics. Further, and notwithstanding the controversy, the increasing attention the value is currently provoking makes reform within the mainstream a more realistic proposition than has previously been the case. To pursue this, and recognising how resilient the mainstream has been to the numerous calls for inclusion of other analytical frameworks it has faced,[21] we bring universal vulnerability to the intellectual, political, and practical foundations of the bioethics project. In doing so, we aim to unsettle and reorder bioethical thinking around vulnerability.

Our argument begins at the moment vulnerability first entered the discourses of bioethics; that is, in the context of 'vulnerable populations' and participation in research. Here it is conceived in functional terms as a deficit - or deficits - attaching to individuals or populations. This understanding of vulnerability continues to shape how the value is understood and deployed. We revisit this debut and identify how 'vulnerability as deficit' has compromised the scientific knowledge that has been generated. In building our argument we turn to the experience of people with dementia and their involvement in research. This example demonstrates how associating vulnerability with deficit, and responding to this with exclusion, can have very *unethical* consequences in limiting research and the evidence to inform care and supports. We address problems of exclusion and the possibilities for inclusive practice and better science.

The argument proceeds in five sections. First, we provide an account of how vulnerability was first conceived in bioethical discourse. Second, we detail how this has shaped, complicated and limited research practices leading to significant gaps in current knowledge and service delivery. We illustrate these points in the context of dementia research. Third, we address vulnerability theory. Specifically, we introduce Martha Fineman's response to 'fundamental, universal, and perpetual human vulnerability',[22] detailing the focus on institutional obligations that her framework mandates. Fourth, we address this in the context of changing approaches to research participants with disabilities, exploring work on

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[16] See, for example, Eric Racine and Dearbhail Bracken-Roche, 'Enriching the Concept of Vulnerability in Research Ethics: An Integrative and Functional Account' (2019) 33 Bioethics 19

[17] Jacob Dahl Rendtorff, 'Basic Ethical Principles in European Bioethics and Biolaw: Autonomy, Dignity, Integrity and Vulnerability – Towards a Foundation of Bioethics and Biolaw' (2002)5 Med. Health Care & Phil. 235, 237

[18] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016) 55.

[19] Warren Reich, 'The Power of a Single Idea' in *Bioetica Ou Bioeticas Na Evolucao Das Sociedadas* (Maria Patrão Neves & Manuela Lima eds., 2005). 380, 380

[20] See Carol Levine et al., 'The Limitations of "Vulnerability" as a Protection for Human Research Participants', (2004)4 American Journal of Bioethics 44

[21] José López, 'How Sociology Can Save Bioethics… Maybe' (2004) 26 Soc Health & Illness 875, 891

[22] Martha A. Fineman, 'Vulnerability and social Justice' (2019) Valparaiso University Law Review 341, 342

universal design – an approach that promotes the equitable use of designed environments.[23] In the final section we return to the wider framing with which we have started, and address the claim that good ethics helps to generate good science.

Bioethics & vulnerability

Vulnerability is generally cast in bioethics in functional terms - as a characteristic of particular individuals or populations. Doris Schroeder and Eugenijus Gefenas provide an example: “To be vulnerable means to face a significant probability of incurring an identifiable harm while substantially lacking the ability and/or means to protect oneself.”[24] As noted, this can be characterized as ‘vulnerability as deficit’. It is possible to track this understanding of vulnerability to the late 1970s and *The Belmont Report* on the use of ‘human subjects’ in clinical and behavioral research, a key moment in the development of bioethics.[25] The Report marked the formal debut of vulnerability as an idea or value within bioethical thought and practice. It also saw an early engagement with principlism: the deliberative framework that has done much to shape contemporary mainstream bioethics and its influence in the public sphere. How vulnerability is articulated within mainstream bioethics – and why universal vulnerability has proved controversial – cannot be separated from principlism and in particular the place autonomy has come to assume within this framework and we address this below.

‘Vulnerable populations’ and research participation

The *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research* in the United States was created by the National Research Act 1974.[26] The Commission followed in the wake of growing concern regarding medical technologies and a number of high profile scandals, including the Tuskegee Syphilis Study.[27] The Commission was charged with identifying the ‘basic ethical principles which should underlie … research involving human subjects’.[28] The Belmont Report was approved by the commissioners in June 1978, and published in April 1979. The Report is a landmark in the development of bioethics, as the task of identifying ‘basic ethical principles’ generated an authorized framework of principles, the legitimacy of which was seen to extend beyond clinical research ‘canonizing the normative framework for all areas of contemporary bioethics’.[29] The traction that the principles approach achieved was no doubt due in part to the publication in the same year of *Principles of Biomedical Ethics*, perhaps the single most

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[23] J. Sanford, *Universal Design as a Rehabilitative Strategy* (New York, Springer, 2012)

[24] Doris Schroeder & Eugenijus Gefenas, ‘Vulnerability: Too Vague and Too Broad?’ (2009) 18 Cambridge Q. Healthcare Ethics 113, 117

[25] Office of the Sec’y, Nat’l Comm’n for the Prot. of Human Subjects of Biomedical & Behavioral Research, The Belmont Report (Apr. 18, 1979)

[26] *Ibid.*

[27] Henry K. Beecher, ‘Ethics and Clinical Research’, (1966) 274 New Eng. Med. 1354

[28] Commission Duties, Pub. L. No. 93-348 § 202.1a (1974)

[29] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016) 37

influential book in bioethics' history.[30] Tom Beauchamp, one of the authors of the book had been one of two philosophers commissioned to help draft the Report.

The Report identifies respect for persons, beneficence, and justice as the principles that should underpin research involving humans. As well as providing these principles, the Report sets out the applications of these principles to the conduct of research, detailing the need for: informed consent; assessment of risks and benefits; and the selection of research 'subjects'.[31] Vulnerability entered the discourse of bioethics in the context of these applications. While the value debuts, it does so briefly and is subservient to the identified principles. Notably, the research participation of so-called 'vulnerable subjects' is constructed as engaging the principle of justice and it is here that vulnerability is most fleshed out. Thus, the Report argues that injustices may result even if 'subjects' are selected fairly: 'one special instance of injustice results from the involvement of vulnerable subjects'.[32] 'Vulnerable subjects' include racial minorities, the economically disadvantaged, the very sick, and the institutionalised.[33] Such 'vulnerable subjects' should be protected (or excluded) because of 'their dependent status and their compromised capacity for free consent.'[34] Further, illness and economic disadvantage can mean 'subjects' are easily manipulated.[35]

Having entered bioethics in the context of research ethics these parameters persisted as the concept moved out into the international arena. Thus, the Council for International Organizations of Medical Sciences (CIOMS) included vulnerability in its 1982 guidelines for international research. By 1991 the CIOMS guidance marks something of a change in the possible bioethical parameters of vulnerability. These guidelines *upgrade* vulnerability from a special application or qualification, to a fundamental value included in the core principle of respect for the person. While the progress of vulnerability through subsequent guidelines is uneven and inconsistent, the 2002 guidelines appear to affirm protection of vulnerability as a principle. Further, commentary to Guideline 12 states that 'vulnerable populations' have the same entitlements to access the possible benefits of research as the rest of the population.[36]

Henk ten Have has argued that developments in bioethical understandings of vulnerability culminated in the recognition of vulnerability as an ethical principle in the UNESCO

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[30] Tom L. Beauchamp & James F. Childress, *Principles of Biomedical Ethics* (1st Edition, Oxford University Press, 1979)

[31] Office of the Sec'y, Nat'l Comm'n for the prot. of Human Subjects of Biomedical & Behavioral Research, The Belmont Report (Apr. 18, 1979), 3

[32] *Ibid*., 9

[33] *Ibid*.

[34] *Ibid*.

[35] *Ibid*.

[36] Council for International Organizations of Medical Sciences (CIOMS), *International Ethical Guidelines for Biomedical Research Involving Human Subjects,* (CIOMS, 2002), 41

Universal Declaration on Bioethics and Human Rights in 2005.[37] The Declaration identifies 15 principles with Article 8 providing:

> In applying and advancing scientific knowledge, medical practice and associated technologies, human vulnerability should be taken into account. Individuals and groups of special vulnerability should be protected and the personal integrity of such individuals respected.

While the Article appears to address both universal vulnerability and the more typical bioethical understanding of vulnerability as deficit, subsequent UNESCO clarification foregrounds 'special vulnerability' as the principal focus of Article 8.[38] As such, it is unclear how much inclusion in the Declaration should be celebrated as a development in bioethics engagement with vulnerability. Rather, the international documentation provides an indication of bioethics ambivalence towards the value as it surfaces, gains ground, but then appears to fall back. Importantly, this all appears to happen as it is understood primarily as a qualifier to – or handmaiden of - the principles promoted in the Belmont Report and the principlism in bioethics it helped to launch.

Contemporary critiques of 'Vulnerable populations' in research ethics

The current use of vulnerability in research ethics guidelines has been criticised on various grounds, including: being overbroad and vague; assuming homogeneity among groups; labeling people who do not consider themselves to be vulnerable; emphasising deficits and promoting stereotypes; and encouraging overly protectionist behaviour by ethics committees and other gatekeepers.[39]

In terms of the last of these, researchers have reported persistent barriers in attempting to involve people with dementia in research.[40] Prospective participants with a diagnosis of dementia or other neurocognitive disorder have been labelled as vulnerable principally due to their assumed inability to give their own consent to taking part in a research study.[41] Such

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[37] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016)

[38] Dearbhail Bracken-Roche et al, 'The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines' (2017) 15(1) Health Research Policy and Systems 8, 21

[39] For discussion, see literature reviewed in Will C. van den Hoonaard, 'The Vulnerability of Vulnerability: Why Social Science Researchers Should Abandon the Doctrine of Vulnerability' in Ron Iphofen and Martin Tolich, eds, *The SAGE Handbook of Qualitative Research Ethics* (SAGE Publications, 2018), pp 305-321; and Dearbhail Bracken-Roche et al, 'The concept of 'vulnerability' in research ethics: an in-depth analysis of policies and guidelines' (2017) 15(1) Health Research Policy and Systems 8

[40] See *e.g.*, B Prusaczyk, SM Cherney, CR Carpenter and JM DuBois, 'Informed Consent to Research with Cognitively Impaired Adults: Transdisciplinary Challenges and Opportunities' (2017) 40 Clinical Gerontologist 63; Emma Rivett, 'Research involving people with dementia: a literature review' (2017) 21 Working with Older People 107; E West, AStuckelberger, S Pautex, J Staaks and M Gysels, 'Operationalising ethical challenges in dementia research—a systematic review of current evidence' (2017) 46 Age and Ageing 678

[41] Barton W Palmer et al, 'Determinants of Capacity to Consent to Research on Alzheimer's disease' (2017) 40(1) Clinical Gerontologist 24; Emily West et al, 'Operationalising ethical challenges in dementia research—a systematic review of current evidence' (2017) 46(4) Age and Ageing 678

assumptions may be held by ethics committees, clinicians, care facility managers, substitute decision-makers and others, who decide whether researchers can approach people with dementia.[42]

To provide an illustrative example from practice: in a Scottish study, Holland and Kydd sought to recruit people newly diagnosed with dementia into a qualitative study exploring their perspectives on nurse counselling.[43] Participants were to be recruited from a post-diagnostic counseling service, with permission from the site's senior nursing staff and consultant psychiatrist. Recruitment difficulties arose when the psychiatrist 'vetoed' participation of one patient on the grounds of mental impairment when the person had already agreed to take part and a nurse directly involved in the patient's care did not have concerns about capacity to participate. Ultimately, the researchers were only able to recruit three people into the study and they observed that 'overprotective gatekeepers may deny people with dementia the right to be involved in research and so can be a potential source of recruitment bias.'[44] Similarly, a survey of American and Australian researchers who conduct ageing-related studies revealed concerns about ethics committees holding 'overly protective and potentially patronizing or ageist' assumptions about older people, especially those living with conditions such as dementia.[45] The survey respondents recounted experiences of delayed or denied ethics approvals that resulted in them abandoning projects or involving only younger and healthier participants. These researchers felt that the "voices" of older people, including those with dementia, were not allowed to be heard, to the detriment of advancing knowledge on ageing and neurocognitive illnesses.[46]

Assumptions of vulnerability have had a cumulative effect of excluding people with dementia and other disabilities from opportunities to take part in research.[47] This exclusion has resulted in gaps in the evidence across a spectrum of health and social care services. Not involving people with dementia in health promotion and injury prevention studies means, for example, that programs to reduce falls or to support social engagement may not be designed to meet the needs of people with fluctuating or reduced cognition.[48] Similarly, while older people with impaired cognition are at heightened risk of elder abuse, there is a

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[42] [Reference removed for peer review] For discussion of gatekeeping, see eg, Gary Witham et al, 'Reflections on Access: Too Vulnerable to Research?' (2015) 20(1) Journal of Research in Nursing 28

[43] Suzanne Holland & Angela Kydd, 'Ethical Issues when Involving People Newly Diagnosed with Dementia in Research' (2015) 22(4) Nurse Researcher 25

[44] *Ibid*, 27

[45] Nancy A Pachana et al, 'Can We do Better? Researchers' Experiences with Ethical Review Boards on Projects with Later Life as a Focus' (2015) 43 Journal of Alzheimer's Disease 701, 704

[46] *Ibid*.

[47] Emma Rivett, 'Research involving people with dementia: a literature review' 2017 21(2) Working with Older People 107; see also van den Hoonaard (n 39)

[48] Beth Prusaczyk et al, 'Informed Consent to Research with Cognitively Impaired Adults: Transdisciplinary Challenges and Opportunities' (2017) 40(1) Clinical Gerontologist 63

paucity of studies to inform interventions for this population.[49] A majority of people in long-term residential aged care have dementia[50] and research is vital to providing safe and high quality care in these institutional settings. However, researchers encounter multiple challenges in conducting research in care facilities[51] and residents with dementia have often been excluded from involvement in studies.[52]

People with dementia-related cognitive impairment also face exclusions from studies focused on dementia itself. Reviews of clinical practical guidelines and quality care standards for dementia highlight the limited evidence base,[53] including in palliative and end of life care for people with dementia.[54] Even where people with a dementia diagnosis are included in studies, they typically have milder symptoms and are not representative of the broader population of people with dementia. For instance, a Dutch review of nine years of biomedical dementia research protocols found that people with more advanced cognitive impairment, co-morbidities and who live in residential care facilities are less likely to be included in studies.[55] In short, it has recently been stated that “people with dementia remain a neglected group.”[56] Addressing this neglect we acknowledge the important role of law (and regulatory domains such as bioethics that law authorises) in supporting those living with dementia and those who care for them.[57] Unfortunately, law and its systems of governance too often achieve the opposite, ‘working to compound the problems caused by living with a debilitating neuro-degenerative disease.’[58]

The shifting view to inclusion

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[49] PRA Baker, DP Francis, NN Hairi , S Othman, WY Choo ‘Interventions for preventing abuse in the elderly’ (2016) 8 Cochrane Database of Systematic Reviews

[50] Livingston et al report that up to 80% of care home residents have dementia: Gill Livingston et al, ‘Dementia Prevention, Intervention and Care’ (2017) 390 Lancet 2673, 2718

[51] Helen R Lam et al, ‘Challenges of Conducting Research in Long-term Care Facilities: A Systematic Review’ (2018) 18 Geriatrics 242. The authors identify challenges in eight categories: facility/owner/administrator. resident, staff caregiver, family caregiver, investigator, ethical or legal concerns, methodology, and budgetary considerations.

[52] Sue L Davies et al, ‘Enabling Research in Care Homes: An Evaluation of a National Network of Research Ready Care Homes’ (2014) 14 BMC Medical Research Methodology 47; Tamara Backhouse et al, ‘Older Care-home Residents as Collaborators or Advisors in Research: A Systematic Review’ (2016) 45(3) Age & Ageing 337

[53] J Ngo and JM Holroyd-Leduc, ‘Systematic review of recent dementia practice guidelines’ (2015) 44(1) *Age & Ageing* 25-33; G Damiani et al, ‘Quality of dementia clinical guidelines and relevance to the care of older people with comorbidity: evidence from the literature’ (2014) 9 *Clinical Interventions in Aging* 1399-1407.

[54] B Candy et al, ‘UK quality statements on end of life care in dementia: a systematic review of research evidence’ (2015) 14(51) BMC Palliative Care

[55] KR Jongsma, RL van Bruchem-Visser, S van de Vathorst and FU Mattace Raso, ‘Has dementia research lost its sense of reality? A descriptive analysis of eligibility criteria of Dutch dementia research protocols’ (2016) 74(5) *Netherlands Journal of Medicine* 201

[56] Claire Bamford et al. ‘What enables good end of life care for people with dementia? A multi-method qualitative study with key stakeholders’ (2018) 18 BMC Geriatrics 302 2

[57] R. Harding, *Duties of Care: Dementia, Relationality and Law* (Cambridge University Press: Cambridge, 2017).

[58] *Ibid*., 3-4

The negative impacts of exclusion are now being acknowledged. People with dementia describe the stigma they experience when characterised ‘as highly vulnerable victims, who cannot articulate their opinion or have little to offer’ and argue for their rights to be involved in research and be recognised as ‘experts of the lived experience.’[59] Dementia advocacy organisations are calling for increased opportunities for people at all stages of dementia to take part in research. In a 2017 position statement, Alzheimer Europe states that it is “keen to promote the involvement of people with dementia in research.”[60] A 2018 report of a National Summit of the United States National Advisory Council on Alzheimer’s Research, Care and Services urges “research methods that will result in evidence-based programs and service” to benefit all persons living with dementia.[61] Researchers are also joining this call to inclusion, with efforts such as that of an international consensus panel to develop recommendations for consent and data sharing in research involving people with dementia.[62] This group concluded that well-meaning but disproportionate safeguards “hinder improvements in dementia research, care, and prevention and undermine the right of persons with dementia to full and effective participation and inclusion in society.”[63]

The 2016 update of the *International Ethical Guidelines for Health-Related Research Involving Humans* now emphasises the importance of inclusion, in line with the ethical principle of justice: ‘Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion.’[64] These guidelines depart from their prior blanket labelling of all people with cognitive impairment as vulnerable and call for more nuanced considerations of the rights, interests and abilities of people living with cognitive impairment.[65] This developing focus on inclusion acknowledges the harms of epistemic injustice; that is, the injustices of not having opportunities to contribute to the development of knowledge. This particular form of

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[59] Jim Mann & Lillian Hung, ‘Co-research with People Living with Dementia for Change’ (2018) Action Research, 2-3

[60] Dianne Gove et al, 'Alzheimer Europe's position on involving people with dementia in research through PPI (patient and public involvement)' (2018) 22 Aging & Mental Health 723

[61] Laura Gitlin and Katie Maslow. National Research Summit on Care, Services, and Supports for Persons with Dementia and Their Caregivers. Report to the National Advisory Council on Alzheimer’s Research, Care, and Services (16 May 2018), https://aspe.hhs.gov/system/files/pdf/259156/FinalReport.pdf.

[62] Adrian Thorogood et al, ‘Consent recommendations for research and international data sharing involving persons with dementia’ (2018) 14(10) Alzheimer’s and Dementia 1334

[63] *Ibid*, at 1335

[64] Council for International Organizations of Medical Sciences. *International ethical guidelines for health-related research involving humans* (2016) at 61

[65] Johannes J. M. van Delden and Rieke van der Graaf, ‘Revised CIOMS International Ethical Guidelines for Health-Related Research Involving Humans’ (2017) 317 Journal of the American Medical Association 135.

injustice has been recognised in the context of dementia.[66] Discourses of inclusion also sit within a more generalised drive towards greater public involvement in research.[67]

Informed consent to research participation remains a central ethical and legal principle. As one of us has argued elsewhere,[68] the starting point must be that a person with dementia should not be presumed "incapable" and, where possible, should be enabled to make their own choices about research participation. Opportunities to plan in advance for research participation can be offered through mechanisms such as advance research directives - which are recognised by the *International Ethical Guidelines for Health-Related Research Involving Humans* – and selecting and discussing wishes with a substitute decision-maker for research choices.[69] These proxies can then be better prepared to make decisions consistent with the person's wishes if called on to do so.[70] Where a legally authorised decision-maker agrees to research involvement for a person unable to give their own consent, the dissent of that individual should be respected.

Moving beyond these recommendations that have been articulated in a dementia-specific context, we turn now to our broader aim to unsettle and reorder bioethics' narrow understanding of vulnerability. Here we wish to recast understandings of vulnerability to avoid the disadvantageous labelling of specific groups and, at the same time, mobilise it in a way that will improve the design, conduct and ethical oversight of research. Expanding from the example of research participation by people with dementia, we discuss alternative research design and practices that are congruent with universal vulnerability and relevant to cognitive and corporeal diversity more generally.

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[66] See, for example, JA Young et al, 'Expanding current understandings of epistemic injustice and dementia: Learning from stigma theory' (2019) 48 Journal of Aging Studies 76-84; KA Jongsma et al, 'Epistemic injustice in dementia and autism patient organizations: An empirical analysis' (2017) 8(4) AJOB Empirical Bioethics 221-233.

[67] Discussion of the benefits and challenges of broader public and patient/consumer involvement in research is beyond the scope of this paper; for analysis and recommendations, especially in the context of ageing and dementia research, see e.g. J Bindels et al, 'Older people as co-researchers: a collaborative journey' (2014) 34 Ageing and Society 951; J Brooks, N Savitch and K Gridley, 'Removing the 'gag': Involving people with dementia in research as advisors and participants' (2017) Social Research Practice 3; D Gove et al, 'Alzheimer Europe's position on involving people with dementia in research through PPI (patient and public involvement)' (2018) 22 Aging & Mental Health 723. For broader critique of citizen involvement in regulatory initiatives concerning science and health technologies, see Mark L Flear and Martin D Pickersill, 'Regulatory or Regulating Publics? The European Union's Regulation of Health Technologies and Citizen Participation' (2013) 21(1) Medical Law Review 39 and Mark Flear, *Governing Public Health: EU Law, Regulation and Biopolitics* (Hart Publishing, 2015).

[68] [Removed for peer review.]

[69] [Removed for peer review], Thorogood et al, above note 60. We acknowledge that laws in some jurisdictions may not recognise this category of substitute decision-maker.

[70] Studies indicate proxies' views often differ from what the person with dementia would want, especially by underestimating the person's interest in being included in studies. See eg, Jason Karlawish et al, 'Older Adults' Attitudes Toward Enrollment of Noncompetent Subjects Participating in Alzheimer's Research' (2009) 166 *American Journal of Psychiatry* 182; BS Black, M Wechsler and L Fogarty, 'Decision Making for Participation in Dementia Research' (2013) 21 American Journal of Geriatric Psychiatry 355; Julie M Robillard and Tanya L Feng, 'When Patient Engagement and Research Ethics Collide: Lessons from a Dementia Forum' (2017) 59(1) Journal of Alzheimer's Disease 1

From ‘vulnerable populations’ to universal vulnerability

In this section we consider universal vulnerability: a framework that is grounded in recognising vulnerability as ‘*the* primal human condition’.[71] We do this in the context of two factors that underpin the current difficult position of vulnerability within bioethics. First, there is a profound tension as accounts of universal vulnerability challenge key assumptions in bioethics, specifically the primacy accorded autonomy. Henk ten Have argues that given respect for persons as autonomous agents is a – if not *the* – foundational bioethical principle this makes universal vulnerability simply unintelligible for the mainstream. Thus, universal vulnerability is ‘hard to reconcile’ with narrow understandings of moral agency and it is therefore difficult for bioethics to ‘give a positive meaning to vulnerability’.[72] This dissonance is met by a subversion of arguments regarding the universal experience of vulnerability. These revert to discussions of “diminished autonomy” or “self-determination”, and these loop back to sustain the idea of “vulnerable populations”.[73] This obscures the important implication that vulnerability is prior to the ethical; that is, we need to build our ethical frameworks on the fact of our embodied vulnerability. Addressed in this way, it is possible to appreciate how richer conceptions of vulnerability are profoundly destabilising for mainstream bioethics. At the same time, universal vulnerability is rich with possibility. Acknowledging that vulnerability precedes the ethical should provoke bioethics to reexamine its foundational assumptions and the structures it has built on these.[74] While this may be challenging, it is also a valuable opportunity to revisit and reinvigorate the social relevance of the field.

The second factor that fuels the current controversy is perhaps easier to address and this is the need for an articulation of universal vulnerability that provides a sufficiently intellectually robust but also practical and adaptable framework for the sort of applied analysis that dominates bioethics.[75] As ten Have states, notwithstanding a growing bioethics literature, it “does not make clear how vulnerability should be understood, interpreted, and applied”[76] and there remain “significant controversies concerning the epistemological status of the notion, its content and scope.”[77]

We respond to both factors by turning to Martha Fineman’s response to universal vulnerability which brings together our embodied vulnerability with our lived experience embedded in networks of social and institutional relations. In the next section we introduce Fineman’s model, paying particular attention to the institutional responses the framework

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[71] Martha Albertson Fineman, ‘Vulnerability and Inevitable Inequality’ (2017) 3(4) Oslo Law Review 142

[72] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016) 403

[73] *Ibid.,* 399

[74] *Ibid.*

[75] See *e.g.*, Racine and Bracken-Roche (n 16).

[76] Henk ten Have, ‘Respect for Human Vulnerability: The Emergence of a New Principle in Bioethics’, (2015) 12 Bioethical Inquiry 395, 395

[77] *Ibid.,* 395

aims to leverage. We move on to address how this may translate to bioethics and explore this by returning to the specific context of participation in research.

Universal vulnerability

For Martha Fineman, vulnerability is a 'universal, inevitable, enduring aspect of the human condition.'[78] It is part of our shared humanity that we all age and 'exist in a world full of often-unpredictable material realities.'[79] An important and defining element of Fineman's response to this universal condition is the recognition that not only do we all share an embodied vulnerability, but we are each 'differently situated within webs of economic and institutional relationships.'[80] This social embeddedness shapes how resilient we are in experiencing and responding to our vulnerabilities. Thus, our different experiences of embodiment and social embeddedness means vulnerability is 'both universal and particular; it is experienced uniquely by each of us.'[81]

From this starting point, Fineman develops an analytical framework for deliberating 'the just allocation of responsibility for individual and societal wellbeing'.[82] Her political and ethical project aims to leverage a more responsive state. She articulates a framework 'in which the state is… the legitimate governing entity and is tasked with a responsibility to establish and monitor social institutions and relationships that facilitate the acquisition of individual and social resilience'.[83] This is essential as our position within the complex network of economic, social, cultural, and institutional relationships 'profoundly affect our destinies and fortunes, structuring individual options and creating or impeding opportunities'.[84] For Fineman then, a state is responsive when it 'acts to monitor and adjust institutions and relationships when they do not function in a just manner'.[85]

Fineman's approach can be closely aligned with her earlier challenges to liberal accounts of autonomy that privilege the 'myth' of an unencumbered rational actor.[86] Much law, policy, and ethics engages and privileges this figure, regardless of the fact that such a state of being is a fiction for the majority of us, and if it is experienced it is for a limited period in the arc of our lives. Other approaches have similarly challenged this static and empirically incorrect

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[78] Martha Albertson Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) 20 Yale Journal of Law and Feminism 19.

[79] Martha Albertson Fineman, 'The Vulnerable Subject and the Responsive State', (2010) 60 Emory L.J. 251, 267

[80] *Ibid.*

[81] Fineman (2008) (n 78), 269

[82] Fineman (2017), (n 71), 141.

[83] *Ibid*., 134.

[84] *Ibid*., 145.

[85] Martha Albertson Fineman, *Privatization, Vulnerability, and Social Responsibility: A Comparative Perspective* (Taylor and Francis: 2016) 4

[86] Martha Albertson Fineman, *The Autonomy Myth*, (The New Press, 2005) 3. See *also* Laura T Kessler, 'Is there Agency in Dependency? Expanding the Feminist Justifications for Restructuring Wage Work' in Martha Albertson Fineman, Terence Dougherty (eds), *Feminism Confronts Homo Economicus: Gender, Law, and Society* (London, Cornell University Press, 2005) 385

understanding of autonomy. Given the substantive focus of our argument, it is notable that disability studies has been an important voice in this regard. Jerome Bickenbach, for example, has addressed the 'folly' of our belief in and promotion of the unencumbered rational actor, noting that eventually society will 'realise that we are all abnormal, disabled, impaired, deformed and functionally limited, because, truth be told, that is what it means to be a human being.'[87] Rather than understanding our lives as defined by autonomy, we should understand the human condition as defined by dependency. This dependency is not the negative lack of autonomy, rather it is generative of the many complex social structures humans have created in response. As Fineman writes: 'Our vulnerability presents opportunities for innovation and growth, creativity, and fulfilment. It makes us reach out to others, form relationships, and build institutions.'[88]

Bioethics is many things, but since its inception it has grown to become 'a key node through which a variety of social, political and scientific activities are refracted.'[89] This 'node' includes academic and institutional practices that inform and shape each other. In institutional terms, bioethics is a governance practice,[90] a bureaucratic means by which advances in science and technology are socially processed.[91] Within a vulnerability paradigm the first questions are structural: do institutions function in a way that responds justly to our shared vulnerability.[92] As such, the approach is a way of conceptualising human experience which then provides a framework for assessing the utility and fairness of the many different institutional contexts through which we move. Our reliance on institutions can be in response to need, as we pursue opportunities, or seek to advance life goals. We may also rely on institutions as we seek to engage in activities that we believe to be socially useful, such as taking part in research. Our ability to live our lives in ways that we believe are socially useful is a social justice issue that implicates questions about the just allocation of resilience and support. In this regard, and in the context of our earlier focus, it is worth noting a recent editorial in *Geriatrics.* This calls for aged care homes to avoid institutional isolationism and promote residents' inclusion in their communities and in research more specifically:

> An integrative approach recognises that people living in care homes may have a wish to be involved in research that offers an opportunity to 'make a difference' for those

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[87] JE Bickenbach, 'Minority Rights or Universal Participation: The Politics of Disablement' in M Jones and LA Basser-Marks (eds), *Disability, Divers-ability and Legal Change* (London, Martinus Nijhoff, 1999) 101, 114

[88] Martha Albertson Fineman, '"Elderly" as Vulnerable: Rethinking the Nature of Individual and Societal Responsibility' (2012) 12 Emory Legal Studies Research Paper 126

[89] José López, 'How Sociology Can Save Bioethics . . . Maybe', (2004) 26 Soc. Health & Illness 875, 875.

[90] Jonathan Montgomery, 'Bioethics as a Governance Practice', (2016) 24 Health Care Analysis 3, 10

[91] Daniel Callahan, 'The Social Sciences and the Task of Bioethics', (1999) Daedelus 275, 276

[92] Fineman (2017) (n 71), 145

> following in their footsteps, and moreover that they may enjoy the interaction with researchers, and the sense of achievement from contributing.[93]

The editorial encourages us to consider the broader questions of justice that are implicated by bioethics' current processes. This directs us back to Fineman's reference to what is 'just' and the question of whether institutions are acting 'justly'. This is generally overlooked and yet it is important and may answer some of the criticisms that have been directed at the discourses of universal vulnerability. Specifically, critics argued that charging the state to be more responsive to our vulnerabilities does not guarantee that this is done positively. As Harding writes in the context of dementia, 'the ways that… vulnerability is addressed can serve to further disadvantage people living with dementia and those who care for them.'[94] Similarly, Vanessa Munro and Jane Scoular argue that discourses of universal vulnerability can have negative consequences as they act permissively to extend the reach of the state, increasing 'intervention and control over individual's daily lives without providing meaningful assistance.'[95] Obviously, calling for a more responsive state, making the state responsible for our vulnerability, is not enough on its own and can have the negative consequences these and others highlight.[96] However, Fineman underscores the need to confront injustices. Her approach attends to our dependency on the institutions of the state and the injustices that can be embedded in current political choices and arrangements. The approach demands we address the just functioning of these institutions, including the differences in resilience that the uneven distribution of socio-economic, educational, environmental, and other assets can create.[97] Thus, vulnerability theory, in common with other approaches to social justice, is dependent on a normative directive as it is operationalised. This is reminiscent of Amartya Sen's provocation that we must identify injustice and attend to it, rather than be deflected by the pursuit of theoretical perfectionism or 'transcendental institutionalism'.[98]

The failure to engage with Fineman's underpinning normative commitment to justice chimes with Beverley Clough's assertion that debates around universal vulnerability often take place at 'cross-purposes'.[99] As Clough states, Fineman seeks to challenge precisely the damaging trends in law and policy that Munro, Scoular, and others rightly highlight. As she continues more generally:

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[93] Alexandra M Johnstone & Alison IC Donaldson, 'Care Home Research: Future Challenges and Opportunities' (2019) 4(1) Geriatrics 2

[94] Harding (n 57), 20

[95] V.E. Munro and J. Scoular, 'Abusing vulnerability? Contemporary Law and Policy Responses to Sex Work in the UK' (2012) Feminist Legal Studies 189, 203

[96] See also Andrea Hollomotz, *Learning Difficulties and Sexual Vulnerability*: A Social Approach, (Jessica Kingsley Publishers, 2011)

[97] *Ibid*., 318

[98] Amartya Sen, *The Idea of Justice*, (Penguin, 2010) 15

[99] Beverley Clough, 'Disability and vulnerability: Challenging the capacity/incapacity binary' (2017) Social Policy & Society 469, 475

> [T]he idea of universal vulnerability is central to challenging the idea … that certain groups are vulnerable, and that particular (protective or paternalistic) responses are suited to such groups. This is particularly key in the context of disability and cognitive impairment.[100]

In responding to growing questions about the efficacy and reach of mainstream bioethics – particularly its failure to adequately attend to social context - we seek to promote universal vulnerability as a core value for ethical deliberation. In this we have taken our argument to the origins of the field, challenging the limited understanding of 'vulnerability as deficit' that emerged at this time. This understanding, and the 'vulnerable populations' it has generated as part of its governance practices, miscasts human experience and structures an ethical response that has been damaging both for those labelled as part of 'vulnerable populations' and the validity, robustness and merit of the science that has resulted. However, our project is not only diagnostic. In the next section we return to participation in research and how a universal understanding of vulnerability can change the nature of the discourse and practices. We identify a number of ways in which the architecture of research practices can be changed to challenge exclusion and enable participation. Thus, our focus is the institutional structures and processes that can be put in place to enable participation. We note in particular the relevance of universal design, an approach we identify as sharing the fundamental understanding of human experience as one of vulnerability and the dependency this implicates. Identifying and exploring this common ground provides a further example of the potential of vulnerability theory for disability studies and social policy, and the imperative to move debate past current 'cross-purposes'.[101]

Accessible & inclusive research

In turning our attention to the question of accessible and inclusive research design and practices, it is first worth stating that a threshold question in all research should be 'Is there a meritorious question or problem here that warrants attention' not 'Is the prospective participant or group vulnerable and in need of protection'.[102] Worries about the difficulty,

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[100] *Ibid*.

[101] *Ibid*, 475.

[102] This proposition is reflected in a number of ethics guidelines. Internationally, the CIOMS International Statements have as their first principle that research must have social value and be meritorious. Research demonstrates value by being likely to produce important information that is relevant to significant health problems and can contribute to improved interventions, policies and practices. See CIOMS Guideline 1: https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf. As a domestic example, Australia's National Ethics Statement states: "Unless proposed research has merit, and the researchers who are to carry out the research have integrity, the involvement of human participants in the research cannot be ethically justifiable." (Guideline 1.1) It then elaborates on what merit means. See National Health and Medical Research Council, National Statement on Ethical Conduct in Human Research 2007 (Updated 2018). National

sensitivity and cost of doing research with people labelled as 'vulnerable' has deterred researchers from undertaking meritorious research and filling gaps in knowledge. This has contributed to the proliferation of low-value or wasteful research involving 'non-vulnerable' participants that repeats questions that have already been answered and invests resources in areas that are already well-explored.[103] A focus on better design will help to deal with this problem by focusing on the merit of the research question. Here, universal design can enable participation by a wide range of participants, including those with dementia.[104] In focusing on the design of research, we contribute to the discussion of the relevance of universal design beyond the built environment to all 'designed artifacts'.[105] We also engage with the question of what is universal in universal design, bringing together universal vulnerability and universal design. Both see the 'rejection of independence as a necessary socio-ethical starting point for social practice.'[106]

Universal design approaches provide a useful model for designing and conducting research in a manner that facilitates inclusion for all people to the extent possible, subject to scientifically justifiable exclusion criteria.[107] Universal design principles were first developed and applied in the context of architecture and building codes.[108] They aim to ensure the design of built environments will be 'usable by all people, to the greatest extent possible, without the need for adaptation or specialized design'.[109] Researchers who apply universal

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Health and Medical Research Council, Canberra. Available online at https://www.nhmrc.gov.au/guidelines-publications/e72.

[103] For discussion see Malcolm R Macleod et al, 'Biomedical research: increasing value, reducing waste' (2014) 383 Lancet 101 and other articles in that special issue.

[104] Gloria Puurveen et al, 'Ethical issues in the use of video observations with people with advanced dementia and their caregivers in nursing home environments' (2015) 3(2) Visual Methodologies 16

[105] R. Imrie and R. Luck, 'Designing inclusive environments: Rehabilitating the body and the relevance of universal design'(2014) Disability and Rehabilitation 1315

[106] *Ibid*.

[107] AS Williams and SM Moore, 'Universal design of research: Inclusion of persons with disabilities in mainstream biomedical studies' (2011) 3(82) Science Translational Medicine 1. See also, Inger Marie Lid, 'Universal Design and disability: an interdisciplinary perspective' (2014) 36(16) Disability and Rehabilitation 1344

[108] The Centre for Universal Design identifies seven principles: equitable use, flexibility in use, simple and intuitive use, perceptible information, toleration for error, low physical effort, size and space for approach and use. Centre for Universal Design, North Carolina State University (Follette Story, 2001). See also S Iwarsson, A Stahl, 'Accessibility, usability and universal design – positioning and definition of concepts describing person-environment relationships' (2003) 25(2) Disability and Rehabilitation 57

[109] North Carolina State University College of Design, *The Center for Universal Design* (2008) cited in Williams and Moore, *ibid*. Roberta Null, defines the term more fully: 'In the broadest terms, universal design is "design for all people." Universal design, also known as *life span design*, seeks to create environments and products that are usable by children, young adults, and the elderly. They can be used by people with "normal" abilities and those with disabilities, including temporary ones. R. Null, *Universal Design – Principles and Models* (CRC Press, 2013), 12.

design thinking do so on the basis that ‘disability is a fundamental part of the human experience.’[110]

From this starting point, and reflecting the idea of universal design as a process rather than a defined result,[111] Dianne Rios and her colleagues have proposed a tripartite approach to implementing accessible research. The first level focuses on universal design principles that remove barriers to research participation. For example, the use of simple language and illustrative pictures or diagrams in study materials addresses language literacy barriers. Similarly, study locations should be physically accessible for people who use wheelchairs. The second level focuses on accommodations, which change how a task is usually accomplished. For example, a participant with reduced hand dexterity may not be able to complete a survey with a pen and paper, but can do so verbally with a research assistant asking the questions and recording responses. For other study activities, some participants may need breaks or rest periods and the need for additional time should be incorporated into planning. The third level focuses on modifications, which may be needed in some instances where initial design and accommodations have not addressed all barriers to participation. Modifications involve changes to a standardised process that may change the construct being assessed. For instance, changing how a speed-of-recall assessment is conducted in a dementia study may affect the validity of the measure. Where modifications are made, they should be recorded and their impacts addressed in the reporting of study findings. Importantly, experiences with modifications can, over time, contribute to the development of measures appropriate to particular participants. Importantly, modifications potentially move us from a narrow idealised norm to a scientific process that acknowledges and responds to diversity.

This tripartite approach articulates neatly with universal vulnerability and its particular manifestations in the context of research participation. Considerations of universal vulnerability are particularly salient at the first level of Rios’ model. Instead of seeing vulnerability as a deficit of particular groups, the focus instead is on removing barriers in order to improve accessibility for all. This acknowledges that particular ‘deficits’ presumed to apply to particular participants, such as those with cognitive impairment, may in fact be common concerns across many prospective research participants. The inequity of this is addressed by a universal vulnerability framing. As Stu Marvel writes: “Rather than focusing on the vulnerability of a select few (and thereby presuming the relative invulnerability of others), the vulnerability paradigm asks that we open the frame to recognize our commonly held vulnerability.”[112]

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[110] Dianne Rios et al, ‘Conducting Accessible Research: Including People with Disabilities in Public Health, Epidemiological, and Outcomes Studies’ (2016) 106(12) American Journal of Public Health 2137, 2142

[111] Iwarsson and Stahl (n 108)

[112] Stu Marvel, ‘The Evolution of Plural Parentage: Applying Vulnerability Theory to Polygamy and Same-Sex Marriage’ (2015) 64 Emory Law Journal 2047, 2064

To provide an example, poor comprehension of study and consent materials is often highlighted as a particular 'deficit' of people with impaired cognition. Yet this is a common concern across many prospective participants and in wide-ranging non-research contexts.[113] A universal design response would improve readability of these materials in all studies and shift the focus away from deficits of particular populations to the responsibility of researchers and ethics committee to meet the recommended reading level for study materials (typically a grade six to eight level; that is, plain writing easily understood by 12-14 year-olds).[114] In a review of research, Foe and Larson point out that awareness of the problem of long, complex forms has not been met by practices to improve reading level and comprehension.[115] This finding underscores a need for institutional responsiveness; researchers and ethics committees must act on evidence-based strategies to ensure readability and comprehension. Moreover, various modes of communication should be supported – written, verbal and technology-enabled – for recruitment and study activities.[116]

The issue of therapeutic misconception provides a further helpful example. Therapeutic misconception occurs when research participants misunderstand the difference between receiving care and taking part in a research study. Charles Lidz and colleagues posit that it 'results not merely from inadequate disclosure or from the ignorance or incompetence of research participants'. Rather, therapeutic misconception *'arises from divergent primary cognitive frames'*:

> When designing a clinical trial, the researcher's cognitive frame places the trial in the context of scientific designs for assessing the efficacy of the intervention. In contrast, participants' cognitive frames are personal and focused primarily on their health problems. This is not to imply that researchers lack concern about research participants or that participants are necessarily unaware that they are participating in research. Rather, we hypothesize that the primary cognitive frames of researchers and participants differ quite dramatically, and that this divergence is the social context in which [therapeutic misconception] can emerge. [117]

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[113] See, for example, Martha Fineman's call for universally accessible information regarding financial services and products, M.L. Fineman, '"Elderly" as vulnerable: Rethinking the nature of individual and societal responsibility' (2012) Elder Law Journal 71

[114] Gabriella Foe and Elaine L. Larson, 'Reading Level and Comprehension of Research Consent Forms' (2016) 11(1) Journal of Empirical Research on Human Research Ethics 31

[115] *Ibid*.

[116] Christian M Simon et al, 'Perspectives on Electronic Informed Consent from Patients Underrepresented in Research in the United States: A Focus Group Study' (2018) 13 (4) Journal of Empirical Research on Human Research Ethics 338

[117] Charles W Lidz et al, 'Why is Therapeutic Misconception So Prevalent?' (2015) 24 Cambridge Quarterly of Healthcare Ethics 231, 232 (emphasis in original).

Recognising this difference, Lidz et al recommend that researchers explain not only the study methods, but also the scientific reasons for these methods (such as randomisation). The knowledge gap the research addresses should also be explained to convey the uncertainty that motivates the study. Where possible, the recruitment and consent discussions should take place outside a clinical setting to further militate against conflating research and clinical care.[118]

What is universal in universal design?

Universal design has made important contributions to debates about inclusion and accessibility. It has nevertheless increasingly attracted attention for the lack of critical scrutiny of its foundational principles and its translation in to practice.[119] Noting the disquiet that the approach has provoked, Rob Imrie and Rachael Luck highlight that within the model 'a dominant focus is process-based techniques, and the evaluation of universal design in relation to issues of technical feasibility and operational outcomes'.[120] In this regard the framework may be less radical than it initially appears. This is particularly the case when it is commodified and incorporated into 'conventional, conservative, design methodologies' where disabled people are still positioned as anomalous and aberrant.[121] In this:

> There is less evidence of the deployment of alternative epistemological frameworks by proponents of universal design and limited engagement with moral and political philosophy, or substantive matters that relate to the interrelationships between design and people's flourishing and suffering in the world.[122]

Critics such as Imrie and Luck do not reject universal design but seek to decentre dominant technical processes, exploring how far it might move from a 'design strategy' to a 'political stratagem that has the potential to transform the dominant world view of universal ablebodiness.'[123] We would go further and question whether the framework can challenge other characteristics of the liberal subject. Criticism of universal design has pointed to the failure to fully interrogate the meaning and nature of 'universal' and 'universalism'. What does it mean to talk of the universal human condition? Universal vulnerability may help to enrich these intellectual and normative foundations. This is strengthened when critics move away from reference to 'ablebodiness' and describe universal design as 'trans-contextual' in its pursuit of 'principles that apply to everyone because of the commonality of their humanity.'[124]

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[118] *Ibid*, see esp. 240

[119] See, for example, Imrie and Luck (n 105), and the other contributions to that special issue.

[120] *Ibid*., 1315

[121] Rob Imrie, Rachael Luck, 'Designing inclusive environments: rehabilitating the body and the relevance of universal design', (2014) 36(16) Disability and Rehabilitation 1315, 1316

[122] *Ibid*.

[123] *Ibid*.

[124] *Ibid*., 1317

Addressing universal design within this more ambitious social and political frame demands more extensive consideration of accessibility and inclusion. It would, for example, demand a reconsideration of decision-making capacity, not as a question for particular groups – such as people with dementia or other neurocognitive disabilities – but as an ability of all people that can be enhanced with appropriate supports to enable participation. This is recognised in Article 12 of the United Nations Convention on the Rights of Persons with Disability (UNCRPD).[125] As early commentary on supported decision-making argued:

> The starting point is not a test of capacity, but the presumption that every human being is communicating all the time and that this communication will include preferences. Preferences can be built up into expressions of choice and these into formal decisions. From this perspective, where someone lands on a continuum of capacity is not half as important as the amount and type of support they get to build preferences into choices.[126]

Reflecting on this, and returning to our focus on dementia, researchers report that varying practices are used to determine whether people with dementia are considered capable of consenting to and participating in research. For example, a person's performance on tests of cognitive function, such as a Mini-Mental State Exam (MMSE), may be used as a proxy for their capacity to make decisions about research. However, at least a quarter to half of people who score as moderately cognitively impaired on a MMSE (score of 12 to 19 out of 30) may have the ability to understand what is involved in a study and make their own choices about participation.[127]

In a recent critique of capacity assessment procedures, Jeffrey Spike argues there has been a 'steady pull … to transform capacity into a technical concept" requiring specialist evaluation.'[128] He calls for a simplified approach to capacity assessment that avoids proxy measures and assumptions of deficits for particular groups and instead focuses on key questions that are of universal relevance when inviting any person to take part in a study.

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[125] This principle is expressed in the United Nations Convention on the Rights of Persons with Disabilities; see especially Article 12 that requires State parties to "take appropriate measures to provide access by persons with disabilities to the support they may require in exercising their legal capacity." From a universal vulnerability perspective we apply this principle to all people, whether or not diagnosed/labelled as having a disability.

[126] S Beamer & M Brookes, *Making decisions. Best practice and new ideas for supporting people with high support needs to make decisions* (Values into Action: London, 2001) 4, cited in Anna Arstein-Kerslake et al, 'Future Directions in Supported Decision-Making' (2017) 37(1) Disability Studies Quarterly

[127] P Whelan et al, 'The Utility of the Mini-Mental State Examination in Guiding Assessment of Capacity to Consent to Research' (2009) 21 International Psychogeriatrics 338; PD Guarino et al, 'Measuring Informed Consent Capacity in an Alzheimer's Disease Clinical Trial' (2016) 2 Alzheimer's & Dementia: Translational Research & Clinical Interventions 258

[128] Jeffrey P Spike, 'Informed Consent is the Essence of Capacity Assessment' (2017) 45 Journal of Law, Medicine and Ethics 95, 95

These questions should focus on the person's understanding and appreciation of the purpose, procedures and risks of the study, their rights as research participants, and their ability to weigh up options and make a choice.[129] As recommended above, simplified consent materials and multi-media tools can be a component of universal design that supports more people of varying abilities to make their own choices about taking part in research.

As these examples highlight, shifting from category-based vulnerability to universal vulnerability will require changes to the attitudes and practices among researchers, ethics committees, funders, and others involved in the institutions of research. Sabatello emphasises the need to tackle stigma and unconscious biases among these institutional actors that contribute to "intellectual exclusion from knowledge production."[130] Addressing stigma and bias is essential if meaningful partnerships between researchers and community members is to take place and address the harms of epistemic injustice.[131] This is important if we are to replace the approach of "research on" with "research with". As discussed earlier, doing *research on* 'vulnerable groups' has been hindered by a focus on deficits. However, planning and conducting *research with* community members can advance inclusion and accessibility. This is an essential part of a universal design strategy and can help address the 'designer's fallacy' that imagines designers can independently control user behaviour and experiences.[132] An overarching ethics framework for community-engaged research has recently been proposed[133] and a growing literature offers practical strategies for forming and sustaining co-research (or co-production) relationships.[134] From a systematic review and consensus process, Baines and colleagues recommend essential and desirable practices for public and patient involvement in research, which can inform universal design approaches.[135] Consistent with the second and third levels of Rios et al's framework, specific

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[129] Spike, *ibid*. See also Guarino et al, above (n 127); Barton W Palmer et al, 'Determinants of Capacity to Consent to Research on Alzheimer's Disease' (2017) 40(1) Clinical Gerontologist 24; JB Seaman et al, 'Psychometric Properties of a Decisional Capacity Screening Tool for Individuals Contemplating Participation in Alzheimer's disease Research' (2015) 46 Journal of Alzheimer's Disease 1

[130] Maya Sabatello, 'Cultivating Inclusivity in Precision Medicine Research: Disability, Diversity, and Cultural Competence' (2018) Journal of Community Genetics 1

[131] See (n 66).

[132] D. Idhe, *Technology and the Lifeworld: From Garden to Earth* (Bloomington: Indiana University Press, 1990)

[133] Giselle Corbie-Smith et al, 'Stakeholder-driven, consensus development methods to design an ethical framework and guidelines for engaged research' (2018) 13(6) PLoS One e0199451

[134] See eg, LJE Brown et al (2018) 'Openness, inclusion and transparency in the practice of public involvement in research- A reflective exercise to develop best practice recommendations' (2018) 21(2) Health Expect. 441; Jeanne-Marie Guise et al., 'A practice-based tool for engaging stakeholders in future research - a synthesis of current practices' (2013) 66(6) Journal of Clinical Epidemiology 666; WH Voorberg et al. 'A Systematic Review of Co-Creation and Co-Production: Embarking on the social innovation journey' (2014) Public Management Review 1; Josephine Ocloo et al. 'Exploring the theory, barriers and enablers for patient and public involvement across health, social care and patient safety: a protocol for a systematic review of reviews' (2017) 7(10) BMJ Open 1

[135] RL Baines, S Regan de Bere, 'Optimizing patient and public involvement (PPI): Identifying its "essential" and "desirable" principles using a systematic review and modified Delphi methodology' (2018) 21(1) Health Expect 327

accommodations and modifications for doing co-research with people living with progressive neurocognitive conditions have also been suggested.[136]

Universal design provides an important example of how we might reconceptualise and deliver the institutional scaffolding necessary for more socially just research practices. This has the potential to positively impact research design, processes and outcomes. As a way of translating universal vulnerability into practice, it challenges the static, group-based categorisation of vulnerability that 'does not yield any meaningful information or instructively guide the process of ethics review.'[137] Importantly, the underlying shift to seeing vulnerability as universal does not ignore the circumstances of particular individuals. Indeed, Fineman underscores that our vulnerabilities are 'experienced uniquely by each of us.'[138] In terms of broader questions of institutional scaffolding, researchers must ensure they meet their ethical obligations to minimise risks for all participants and ensure that the anticipated benefits of a research project outweigh the risks of participation. Ethics committees have important obligations to engage in effective monitoring and oversight of research. All these measures, taken together, can facilitate appropriate inclusion in research with practices that address the needs and abilities of a wide range of participants. Doing so will improve the generalisability of study findings and the overall quality of the science.

Ethics & science

It is a common assertion in both the literature and around the board tables of ethics committees that good ethics promotes good science.[139] Such causal claims form part of the legitimating narratives of bioethics and have been problematized on different grounds. It has been argued, for example, that the relationship between applied ethics and scientific practice has meant that – at times - what is seen as ethically acceptable merely follows what is accepted as scientific practice.[140] Nevertheless, our argument here is that recasting vulnerability from a label attaching to specific individuals or groups, to a statement of our universal human experience that demands we rethink our ethical foundations, obligations, and the institutional arrangements these implicate, would indeed put us on the path towards better science. While it is important to acknowledge the damage that can be

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[136] See *e.g.*, I Schilling and A Gerhardus 'Methods for Involving Older People in Health Research—A Review of the Literature'. (2017) 14(12) International Journal of Environmental Research and Public Health, 1476; M Stevenson and BJ Taylor 'Involving individuals with dementia as co-researchers in analysis of findings from a qualitative study' (2017) 18(2) Dementia 701; C Di Lorito, L Birt, F Poland, E Csipke, D Gove, A Diaz-Ponce and M Orrel,l 'A synthesis of the evidence on peer research with potentially vulnerable adults: how this relates to dementia'. (2017) 32(1) International Journal of Geriatric Psychiatry 58; S Iliffe, T McGrath and D Mitchell 'The impact of patient and public involvement in the work of the Dementias & Neurodegenerative Diseases Research Network (DeNDRoN): case studies.' (2013) 16 Health Expectations, 351

[137] See eg, Eric Racine and Dearbhail Bracken-Roche, 'Enriching the Concept of Vulnerability in Research Ethics: An Integrative and Functional Account' (2019) 33 Bioethics 19, 31.

[138] M. Fineman, 'The vulnerable subject and the responsive state' (2010) 60(2) *Emory Law Journal* 251, 269.

[139] Charis Thompson, *Good Science: The Ethical Choreography of Stem Cell Research*, (MIT Press, 2013)

[140] Karen Lebacqz, 'Bad Science, Good Ethics' (2010) 1(2) Theology and Science 193, 193

caused by a lack of ethical oversight of scientific practice, in positively linking good ethics and good science in this way we nevertheless proceed with a degree of ambivalence.

Assertions that causally link good ethics and good science are easy to find in the literature. Dan McArthur provides a straightforward example, arguing that the procedures employed by ethics committees:

> … serve not only to protect human participants in research but also can sometimes help secure, to an extent, the integrity of results. In other words, good ethics can sometimes mean better science.[141]

McArthur hedges and good ethics regulation does not always lead to good science, but the causal inference is clear. Research conducted in 2015 into the culture of scientific research in the UK by the Nuffield Council on Bioethics demonstrated that the majority of UK scientists who responded to the Council's survey shared McArthurs' views that ethical review procedures encouraged the production of high quality research.[142] Yet the Council offers a nuanced account of the place of ethics in the production of high quality research. Their findings identify ethics as part of the structure of 'research governance and integrity' and locate this within a broader framework encompassing scientific careers, assessment, funding, and dissemination practices that together are responsible for promoting 'good research practice and high quality research'.[143]

Respondents to the Council's survey described 'high quality research' as 'rigorous, accurate, original, honest and transparent' embedding ethical values in the very definition of scientific quality.[144] Charis Thompson provides a similar integrated model of good ethics and good science. Indeed, she argues that 'the separation between ethics and science for fields that have ethics has become increasingly untenable.'[145] Thompson argues that for her good science

> … connotes the conduct of sciences that have ethics in ways that iteratively develop the science and ethics of their fields together to the mutually entwined and multiple ends of both robust science and technology, and the greater articulation of problems of distributive and other injustices.'[146]

The model of indivisibility has merit and chimes with our aim to demonstrate the relevance and utility of universal vulnerability for bioethical analysis and governance. Our exploration identified a need not just for different ethical oversight, but also different scientific practices. Our analysis illustrates the need for different ethical frames of thinking to be

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[141] Dan McArthur, 'Good Ethics Can Sometimes Mean Better Science: Research Ethics and the Milgram Experiments' (2009) 15 Sci Eng Ethics 69, 69

[142] Nuffield Council on Bioethics, *The Culture of Scientific Research in the UK* (London, 2015), 29

[143] *Ibid*.

[144] *Ibid*., 3.

[145] Charis Thompson, *Good Science: The Ethical Choreography of Stem Cell Research,* (MIT Press, 2013) 29.

[146] *Ibid*., 28

embedded in scientific practice. Thus, we started by drawing attention to the need for a different starting point for scientific enquiry where the social merit and usefulness of research is addressed at the point when research questions are first formulated. This supports the model of indivisibility of good ethics and good science promoted by Thompson. This is also seen in our attention under a universal design framework to the need for co-production or co-research with relevant groups and representatives. This is necessary for the effective determination of research questions and design, the production of socially useful research, and the promotion of socially just research practices. Each of these has an important place in the production of good science and the development of bioethical thought and practice.

Thus research practices that we arrived at through universal vulnerability and universal design echo Thompson's model of how science and ethics should articulate together. Through this, they become 'mutually entwined' serving robust science, as well as more effectively surfacing questions of injustice that are frequently embedded in scientific enquiry and practice.[147] While our focus has been the ethical oversight of research participation we believe that engaging with universal vulnerability as a core value in bioethics can promote a reinvigorated and more socially just field more generally.

Conclusions

Isabel Karpin has recently described vulnerability theory as a 'provocation' to think about law and the relationships it structures in a different way.[148] The same may be said of bioethics and it is clear that elements within the field are contributing to the growing discourse.[149] Nevertheless, when mainstream bioethics engages questions of vulnerability, reference to other disciplines are rare.[150] As mainstream bioethics considers its future, greater openness and reflexivity is warranted.

This article illustrates the utility of vulnerability theory developed in law for bioethical deliberation. Law and bioethics have long been bedfellows. At times they share similar concerns, privilege the same values, and promote particular understandings of what it is to be human. Common concerns and preoccupations, particularly with our embodied and socially embedded lives, should provide an opening for a productive dialogue. Further, Fineman provides a model that is not only intellectually robust but may also translate easily and effectively to the applied contexts that are the mainstay of bioethical enquiry. At the heart of her project is the universal vulnerable subject. This figure, ready to usurp the liberal subject, provides 'a more accurate and complete universal figure to place at the heart of

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[147] *Ibid*.

[148] Isabel Karpin, 'Vulnerability and the Intergenerational Transmission of Psychosocial Harm' (2018) 67 Emory Law Journal 1115, 1120

[149] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016)

[150] *Ibid.*

social policy', law, and ethics.[151] Engaging with the theory through a subject we may all easily imagine should enable the systemic recalibration of ethical values that is required.

While universal vulnerability has this important potential it is a term encumbered by negative connotations. These connotation are generated by the word itself, as well as the way in which it is implicated in social policy and practice that has been identified as inappropriately paternalistic and, at times, abusive.[152] The weight of the negative connotations has led many to reject the theory.[153] Vulnerability scholars are nevertheless waging an energetic battle to reclaim the word and there is a sense of a turning tide. However, even those persuaded by the theory's intellectual merits and potential practical reach can still struggle with the term. Rosie Harding, for example, notes the 'intuitive' appeal of the theory in her work on law, caring and dementia, and highlights Fineman's attention to 'the fact that we all are born, live and die within a fragile materiality that renders all of us constantly susceptible to destructive external forces and internal disintegration'.[154] Nevertheless, Harding is pulled back by the word's *baggage*:

> Perhaps because of the specificity of the experience of living with dementia, the vulnerability framework does not, however, quite take us far enough. Somehow the negative connotations of 'vulnerability' and 'vulnerable' remain particularly in focus in the context of dementia. They draw our attention to deficit, rather than potential; to loss, rather than strengths. Clearly part of this is the continuing social construction of dementia as a form of social death, but it is also rooted in the inevitability of decline that is associated with a diagnosis of dementia.[155]

It is essential to engage with such criticism. Indeed, it is difficult to overstate the resistance that the word generates. If it is to have a future in bioethics, law, social policy, and so forth addressing the toxic associations is essential. Bioethics has had a key role in generating the dominant understanding of 'vulnerability' and 'vulnerable populations' that potentially blights the future of the theory. Yet, ironically, bioethics is possibly the field that has most to gain from the new discourses of universal vulnerability. As Henk ten Have notes, universal vulnerability could 'enrich bioethics and… transform it into a global normative discourse.'[156] This should provide sufficient incentive for the field to engage in the processes necessary to recuperate the word. The negative associations should not be allowed to continue to inhibit

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[151] Martha Fineman, 'The Vulnerable Subject: Anchoring Equality in the Human Condition' (2008) 20(1) Yale Journal of Law and Feminism Art 2, 11

[152] Nina A Kohn, 'Vulnerability Theory and the Role of Government' (2014) 26(1) Yale Journal of Law and Feminism Art 2, 14

[153]Fineman 2008 (n151), 8

[154] Harding 2017 (n 57), 19; citing Fineman 2012 (n 111), 119

[155] Harding 2017 (n 57) 19-20

[156] Henk Ten Have, *Vulnerability: Challenging Bioethics,* (Routledge, 2016), 17

the full exploration of the radical potential of recognising and responding to our shared vulnerability.