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exploitation. Safeguards include restrictions on participation in research according to risk–benefit considerations and the requirement for informed consent from a legal representative. Such safeguards are essential but can sometimes exclude people with dementia from research participation, which limits their access to experimental therapies. Moreover, consent and capacity laws often restrict or do not specifically address health research, which can limit participation in non-interventional studies (eg, natural history and genome-wide association studies) that contribute to scientific and medical advancement with low risks to participants. Legal frameworks and research governance need to strike a more equitable balance between protection and inclusion.

To address this need, we formed the Ageing and Dementia Task Team of the Global Alliance for Genomics and Health to provide consent recommendations² for research and data sharing involving people with dementia, informed by an international law, policy, and literature review. The recommendations build on the Global Alliance for Genomics and Health Framework, which aims to accelerate progress in genomic research and human health through harmonised approaches to responsible data sharing.³ The recommendations address complex and contested matters related to decisional capacity and encourage researchers to presume the capacity of adults until proven otherwise, establish safeguards that are proportionate to the risks that research poses, and respect the person's will, preferences, and values, including those expressed in advance of, or during, a gradual loss of capacity. Both researchers and legal representatives should strive to support people with dementia to make their own decisions, or at least to participate in decision making in appropriate ways according to their capacity.⁴ The recommendations also identify areas for further ethical

investigation, including the need to tailor capacity assessment tools to data-intensive research contexts, and the need for advanced planning and early communication about research with appropriate sensitivity to the challenges of living with dementia. Although our recommendations focus on people with dementia, they could be adapted to research involving other patient groups with conditions affecting decisional capacity.

We declare no competing interests. We gratefully acknowledge the financial support of Genome Quebec, Genome Canada, the Government of Canada, the Ministère de l'Économie, et Innovation et Exportation du Québec (Can-SHARE grant 141210).

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Traumatic brain injury: global collaboration for a global challenge

Although low-income and middle-income countries (LMICs) are facing a far greater burden of traumatic brain injury (TBI) than high-income

countries, funding and multicentre research efforts have had a disproportionately greater focus on high-income countries.¹ Initiatives such as InTBIR² are advancing TBI care in high-income countries, but research participation of LMICs has been very limited. Multicentre trials in TBI, with very few exceptions, have predominantly focused on populations in high-income countries.

The setting of a study also determines whether its findings are generalisable and influence the day-to-day practice of clinicians working in different settings. As an example, one of the main interventions in the treatment of TBI is a decompressive craniectomy, by which large piece of skull is removed to accommodate severe brain swelling. The two randomised trials that attempted to define the role of decompressive craniectomy in TBI exclusively enrolled patients who were managed in intensive care units with monitoring of intracranial pressure.³ Nevertheless, the majority of patients with TBI in LMICs do not have access to intensive care units and intracranial pressure monitoring is also not routinely available.

We cannot continue to ignore this bleak reality. Despite the often extremely limited resources (in terms of infrastructure, equipment, and health-care professionals), patients in LMICs require and receive care for TBI. It might not be the care that clinicians in high-income countries would recognise as gold standard, but it is often the best that can be offered in a resource-limited setting. In such settings, the unmet needs for essential neurosurgical care for TBI is estimated at more than 2 million cases per year.⁴ We believe that clinicians and researchers in high-income countries have a moral obligation to work together with clinicians and researchers from LMICs to facilitate the development of high-quality TBI research in LMICs. Policy makers, funding agencies, and university leaders have a responsibility

to create an environment for such collaborations to flourish by recognising the role of high-income countries in advancing care for patients in LMICs, directing the appropriate funds, and overcoming organisational barriers, respectively.

In 2017, the UK Department of Health funded the establishment of multi-country groups and units with a total of £162 million to stimulate health-care research that should directly benefit patients in LMICs. Nearly £1.8 million were awarded for the establishment of a group focused on TBI. The NIHR Global Health Research Group on Neurotrauma, as the group is known, brings together clinicians and researchers from 11 LMICs and three high-income countries. The Group's research programme is organised around four themes. Regarding the first theme, the Group has just launched the first prospective observational study of patients undergoing emergency surgery after a TBI worldwide and will subsequently launch a global TBI registry. For the second theme, the Group will use a systems engineering approach to develop an in-depth understanding of the challenges associated with improving TBI care. The third

theme focuses on the evaluation of interventions tailored for use in LMICs, and the fourth theme aims to map and nurture the TBI research capacity in LMICs. We are optimistic that the Group will build a robust collaborative platform for pursuing a long-term neurotrauma programme focused on LMICs. Hence, we extend an invitation to clinicians and researchers wishing to collaborate to contact us.

FS reports personal fees from Takeda Pharmaceutical Company, grants and personal fees from Integra LifeSciences, and grants and personal fees from Finceramica SpA. All other authors declare no competing interests. The NIHR Global Health Research Group on Neurotrauma was commissioned by the NIHR using Official Development Assistance funding (project 16/137/105). The views expressed in this Correspondence letter are those of the authors and are not necessarily those of the UK National Health Service, National Institute for Health Research, or the Department of Health. We would like to thank the existing members of the NIHR Global Health Research Group on Neurotrauma: Bilal Abou El Ela Bourquin, Amos Adeleye, Alexander Alamri, Tedy Apriawan, Tom Bashford, Mike Bath, Indira Devi Bhagavatula, Dhananjaya I Bhat, Mita Brahmabhatt, Carol Brayne, Evelyn Brealey, Natalia Budohoska, Karol Budohoski, Rowan Burnstein, David Clark, P. John Clarkson, Sujit Gnanakumar, Barbara Gregson, Dylan Griswold, Deepak Gupta, Thinn Hlaing, Corrado Iaccarino, Alexis Joannides, Mathew Joseph, Ahsan Ali Khan, Tariq Khan, Tsegazeab Laeke, Paul May, David Menon, Phyu Phyu Nwe Myint, Mu Mu Naing, Kee B Park, James Piercy, Hamisi K. Shabani, Tamara Tajsic, Myat Thu, Abenezzer Tirsit,

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Contact the NIHR Health Research Group on Neurotrauma via www.neurotrauma.world

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