Meaningful and Safe

The Ethics and Ethical Implications of Patient and Public Involvement in Health and Medical Research

Edited by

Virginia Minogue and Jon Salsberg

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This book first published 2024

Ethics International Press Ltd, UK

British Library Cataloguing in Publication Data

A catalogue record for this book is available from the British Library

Print Book ISBN: 978-1-80441-545-0

eBook ISBN: 978-1-80441-546-7

Paperback ISBN: 978-1-80441-547-4

Table of Contents

List of Boxes, Tables and Figures

Boxes

Figures

Tables

About the Editors

Virginia Minogue is an independent research consultant and adviser. She had a career of more than two decades in research management in the UK NHS, working at national, regional, and local level. After a degree in Behavioural Sciences, she trained as a probation officer, and worked in many criminal justice environments including residential, prisons, homelessness, substance misuse, and family court welfare. After completing a Masters in Policy Studies, and a PhD, she moved into academia to lecture in community justice. Her PhD explored inter-agency partnerships and mentally disordered offenders. She subsequently moved to the NHS as a research fellow before taking on the role of research and development manager. As well as working in research and development she also had the opportunity to gain experience leading a regional offender health programme and working as a commissioner of services for vulnerable groups. Her final role in the NHS was as the national lead for research. During her time in the NHS, and as an independent consultant, she developed and facilitated many patient and public involvement initiatives and groups both locally and nationally. She has published a number of articles, several book chapters, in addition to guidance on patient and public involvement. She has provided training on patient and public involvement to potential contributors, and to staff, and facilitated a group in developing its own user led training package. She also has experience of chairing a research ethics committee, of which more than half the membership were public members, chairing a charity and other directorships of charities. She is a qualified coach and mentor and has supported many health service staff in their career development.

Jon Salsberg is Associate Professor of Primary Healthcare Research - Public & Patient Involvement and Course Director: Professional Diploma in Public & Patient Involvement, Public And Patient Involvement (PPI) Research Unit, School of Medicine, University of Limerick, Limerick, Ireland. He is also Adjunct Professor, Department of Family Medicine, McGill University, Canada. Jon is a public health researcher with research interests in understanding the social-relational dimensions of academic/community research partnerships. He was a founding member of Participatory Research at McGill (PRAM), McGill University (Canada), co-author of Canada's Guide to Researcher and Knowledge-User Collaboration in Health Research (CIHR), sits on the Steering Committee of the International Collaboration for Participatory Health Research (ICPHR.org) is the current Chair of NAPCRG's (NAPCRG.org) Committee on Advancing the Science of Family Medicine (USA), and is a co-principal investigator on the Irish PPI Ignite Network. Jon has undertaken research involving a broad range of partners including patients, health practitioners, community organisations, policy makers and health service decision-makers, and has worked extensively with Indigenous communities.

About the Authors

Sammy Ainsworth is employed by the University of Liverpool in the UK and is based at Alder Hey Children's NHS Foundation Trust where she is the Young People and Family Research Co-ordinator for the NIHR Alder Hey Clinical Research Facility and the Experimental Arthritis Treatment Centre for Children. Her role is to involve parents and young people in the design and dissemination of research and to provide education, support and guidance on all aspects of patient and public involvement and engagement. She has been the patient and public advisor lead on several studies locally, nationally, and internationally. Sammy has been a trustee of Lupus UK for a number of years and is very interested in improving support for children, young people and families who live with the lupus. She is also Chair of the young person led charity, Raising Awareness of Invisible Illnesses in Schools and Education (RAiISE) https://raiise.co.uk/, which supports children and young people living with an invisible illness in schools. She is one of the founders of World Young Rheumatic Disease Day or WORD Day for short, which spreads global awareness that children and young people are diagnosed with rheumatic diseases such as lupus.

Lynette Bortey is a young person who has lived with lupus for 23 years. Although it is a condition that has a lot of complications, she sees this as her strength as it has made her the person she is today. She loves to empower others with Lupus to help them realise their potential with the right mindset and support. She is an Ambassador for Lupus and works with Lupus UK and Lupus Europe as a Youth Leader. This work involves supporting other young people who are newly diagnosed all around Europe. She co-leads the young people's Lupus support group with the Chief Executive of Lupus UK. Lynette has worked with various senior stakeholders in the health setting in which she has represented the Patient and Public Voice as someone who lives with a rheumatic disease – Lupus SLE. These stakeholders include health and social care professionals in a charity and research setting. In February 2024, she was approached to support a Kenyan charity called Hope Arthritis Foundation where she sits on their Advisory Committee Board as a member and patient voice to support children and young people with rheumatic conditions in Africa. She is a qualified Senior Social Worker with experience of working in the Fostering and Adoption setting. In her spare time, she loves travelling to warm and sunny countries to explore different cultures and scenery, going to the gym, attending live concerts and the theatre, spending time with her family and friends and attending church.

Anne Cody is Head of Unit at the Health Research Board in Ireland and currently responsible for the HRB's Investigator-Led Grants, Research Careers and Enablers. She has wide experience across health research and funding, funding policy and research practices. She has been the driver behind the HRB's approach to Public and Patient Involvement in research (PPI) from the start. With a small team, she continues to evolve and champion PPI practices in funding and in research. She has been actively involved in tackling unconscious bias and has initiated transparency initiatives. She is engaged in various international groups invested in improving research and research funding practices and is a member of a Research Ethics Committee. She holds a PhD in biology and an MSc in Business Practice.

Stephanie Corrigan is a research assistant and PhD student with the Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS-TILDA). IDS-TILDA is a project in the Trinity Centre for Ageing and Intellectual Disability (TCAID) within the School of Nursing and Midwifery at Trinity College Dublin, Ireland. She has a degree in Mathematics and an MSc in Psychological Science. Her PhD examines women's health in older women with an intellectual disability with a particular focus on the relationship between menopause and the mental health and behaviours of women with an intellectual disability. Her other research interest is Patient and Public Involvement (PPI) and she co-ordinates PPI events within TCAID and is co-author on various projects promoting PPI and inclusion within research and academia.

Mandy Daly is a parent of a preterm infant and the founder of the collaborative multi-stakeholder, multi-disciplinary platform, The Irish Neonatal Health Alliance. She specialises in the areas of advocacy, education, and research. Her accomplishments in the field include collaborating on several neonatal and paediatric health system reviews and clinical audits, reviewing obstetric, neonatal, and bereavement clinical guidelines, developing and delivering curricula and continued education for medical, nursing, allied health professional and patient expert students. She also serves on the board of the European Foundation for The Care of Newborn Infants and the NIDCAP (newborn individualised developmental care and assessment programme) Federation International Board. She is chair and committee member of the group that developed the European Standards of Care for Newborn health. She works with the National Clinical Trials Office Stakeholder and Management Committee, the European Medicines Agency, and the Health Products Regulatory Authority of Ireland. She is a public reviewer for the Irish Health Research Board and BMJ Paediatrics Open. She is also a member of the National Office of Research Ethics Clinical Trials Committee in Ireland and serves on the advisory board of the PPI Ignite Network. She is a European Patients' Academy on Therapeutic Innovation (EUPATI) fellow and tutor and has worked as patient contributor and embedded patient researcher on over 70 national and international research studies. She has published papers in several journals including the BMJ, The Lancet, and the Journal of Obstetrics and Gynaecology and Trials. She mentors PhD students.

Emma Dorris is the Engaged Research Manager at UCD Research, University College Dublin, Ireland. She has a PhD in Molecular Medicine, a postgraduate Diploma in Statistics and a Masters of Public Policy. Prior to her current role, she spent more than ten years in academic biomedical research, where she collaborated with public and patient involvement (PPI) partners in her research. Emma acts as programme manager of the PPI Ignite Network @ UCD, one of the seven core university offices of the national PPI Ignite Network, which promotes excellence and inspires innovation in PPI in health and social care research in Ireland. She led the work that produced the PPI Ignite Network statement on research ethics committee approval. Emma specialises in public involvement in research that is not naturally public facing. She has authored a number of articles in public involvement in preclinical and life science research and public involvement in research more widely. She has a passion for improving research culture across all disciplines. She has a particular interest in policy and practices related to PPI and engaged research and in developing ways to embed these as part of the research culture towards more relevant and impactful research.

Orly Estein is a professional social worker and licensed psychotherapist, employed in the public healthcare system in Montreal, Canada. Orly graduated from McGill University with a Bachelor of Arts in Psychology, followed by a Bachelor of Education. She made the transition from teaching to a career in mental health by obtaining certification as a peer support worker from the Association Québecoise pour la réadaptation psychosociale (AQRP) in conjunction with Université Laval, resulting in academic and hospital based employment opportunities. Following significant transformations in the public health care system, Orly returned to McGill University to pursue a Master of Social Work degree, landing her in the public health care system as a clinical social worker with a focus on adult mental health. Orly supplemented her education with further courses and supervision to be granted a psychotherapy permit from the Ordre of Psychologists of Quebec (OPQ). She currently practices psychotherapy in both public and private sectors, with an emphasis on destigmatizing lived experiences of mental health while promoting personal growth and empowerment.

Miriam Fitzpatrick is a project administrator and research assistant in psychology at the Trinity Centre for Ageing and Intellectual Disability (TCAID), Trinity College Dublin, Ireland.

Ashleigh Gorman is a research fellow in the Trinity Centre for Ageing and Intellectual Disability (TCAID) in Trinity College Dublin (TCD), Ireland. She gained her PhD from TCD in 2023, focusing on behaviour change in prescribing to older adults. Since 2022, she has been part of the medicine's optimisation group at TCAID and has worked on different projects including the development of a pharmacotherapy optimisation tool (OPTIMA-ID: Optimising pharmaco-therapy and Improving Medication for Ageing with Intellectual Disability) and examining psychotropic use (EQUIP: Examining Quality Use and Impact of psychotropic use in older adults with intellectual disabilities). She has previously worked in the public sector including research roles with the Health Research Board, Ireland, and the Public Health Agency in Northern Ireland. Throughout her research career, she has consistently engaged with Public Patient Involvement (PPI) and is committed to expanding PPI involvement. She views the inclusion of people with lived experience and keyholders as crucial to ensuring informative, useful, and successful outputs. As a former Director of 'Pint of Science Ireland', she has a track record of public engagement with research and making research accessible.

Chloe Green is a Research Coordinator at University College Dublin, Ireland. Originally from Australia, she has a background working in Aboriginal and Torres Strait Islander mental health and wellbeing organisations and has contributed to research and policy in areas of child and adolescent mental health and wellbeing. She is passionate about challenging systemic barriers and improving services for populations considered marginalised. Centring lived experiences is central to her work, evidenced by involvement in Mná Le Chéile, a committee dedicated to meaningful engagement with women who have lived and living experiences of accessing health and support services in Ireland. Her passions lie in co-designing dynamic ways to capture diverse community experiences and improve services based on the expertise of lived experience. By honouring the lived experiences and insights of marginalised groups, she strives to ensure their voices are not only heard but are valued and influential in research processes and service designs.

Thilo Kroll is Professor of Health Systems Management at the School of Nursing, Midwifery and Health Systems at University College Dublin, Ireland. His academic journey began in Germany, where he served as Lecturer at the University of Bremen from 1992 to 1996. He completed his undergraduate degree in psychology at the University of Kiel and PhD Degree in Psychology at University of Bremen. He worked in Norway and then moved to the United Kingdom, where he held the position of Research Fellow at Coventry University until 1998. His career then took him across the Atlantic to the United States, where he worked as a Senior Research Fellow at the MedStar National Rehabilitation Hospital in Washington D.C. from 1999 to 2005. Returning to the UK, he joined the University of Dundee as a senior lecturer. In 2013, he was promoted to Professor of Disability and Public Health Research. In 2016, he moved to Ireland to take up his current position at University College Dublin. Throughout his career, he has conducted extensive interdisciplinary research on the social dimensions of health and well-being, with a particular emphasis on public health perspectives on disability and health and the inclusion of socially marginalised populations in research. He is currently the UCD site lead for the Health Research Board funded National Network on Public and Patient Involvement in Health and Social Care Research.

Lou Lambert is a young person who was diagnosed with lupus and rheumatoid arthritis at the age of 15. She lives in Hertfordshire in the UK and works in a physical and neurological impairment school as a learning support assistant. Lou has been involved in patient advocacy research and projects, as well as participating in outreach and awareness events and talking to other young people being diagnosed with lupus. She is currently in her twenties and is studying a part-time Early Childhood (BA Hons) with The Open University. In her spare time, she enjoys diamond painting, Lego and reading, particularly crime and thriller books.

Elle Lappin is part of the National Institute for Health and Social Care Research (NIHR) GenerationR Liverpool (www.generationr.org.uk) Young Person's Advisory Group. She has been an active member of GenerationR Liverpool since October 2019 providing feedback on a range of clinical trials and paediatric research projects. Elle is currently studying a Bachelor's degree (BA Hons) in Politics and Social Policy at the University of Stirling, Scotland. Outside of university Elle takes part in various advisory groups which focus on paediatric research, law, and social policy.

Susan Law is Associate Professor, Institute of Health Policy, Management and Evaluation, University of Toronto, Senior Scientist, Trillium Health Partners – Institute for Better Health, Adjunct Professor, Department of Family Medicine, McGill University, Affiliate Scientist, St. Mary's Research Centre, Montreal, Director, Health Experiences Research, Canada. Susan has had a hybrid career in health services research and healthcare management in Canada and the UK. She is currently an Associate Professor at the Institute of Health Policy, Management and Evaluation at the Dalla Lana School of Public Health at the University of Toronto, and a Senior Scientist at Trillium Health Partners – Institute for Better Health. She leads a program of research and knowledge translation on people's lived experiences of illness using qualitative research involving audio/video recording of individual narratives. Results are shared online at https://healthexperiences.ca/. The aim is to provide information and support to people living with similar health problems, and so that others, including educators and healthcare professionals, can learn from people's experiences to improve the quality of care and help shape healthcare systems that are patient-centred. The Health Experiences Research Canada network involves scientists, trainees, patients and care providers across Canada, and is part of an international network of 13 country-based teams engaged in similar research using methods originally developed at Oxford University, known as DIPEx International. Susan and her team have conducted patient experience studies about family caregiving, breast cancer, experiences of researcher-patient partnerships in research, amputations, immigrant mental health, and perinatal mental health. Current studies are focused on Ukraine refugee experiences in Canada, women and heart failure, medical cannabis, pregnancy and COVID, and long COVID. People with lived experience are an integral part of the project teams and expert advisory panels and have contributed to the analysis and reporting of results. Susan has also been involved in arts-based research and several experience-based co-design initiatives. She believes strongly in the value of bringing patients, researchers, and health system partners together to answer questions that matter to patients and then working together for positive change.

Keven Lee is an interdisciplinary artist (dance and ceramics) and researcher. He is currently a postdoctoral fellow at the Division of Social and Transcultural Psychiatry and a faculty lecturer at the School of Physical and Occupational Therapy, Faculty of Medicine and Health Sciences, McGill University, Canada. First trained as an occupational therapist, Keven started professional training in dance. The merging of his practices led him to start a journey in research to study his Moving-with—a movement-based approach to cultivate new experiences of self and others. Most recently, his postdoctoral research has been to conduct ethnographic fieldwork and action-research process evaluation of school and community-based creative expression workshops for newcomer youth. Keven has been working in close relationships with the community-based organisation that is leading the workshops to foreground and share their experiential knowledge. He has also co-created a newcomer youth group with the youth themselves, which serves as a space to explore oneself, connect with others, and share what really matters with the aim of amplifying their voice in their own terms. Across his ethnographic and research-action work, Keven is particularly interested in understanding the ethical implications of how people move together in known or unpredictable ways.

Deirdre MacLaughlin retired following a career spanning over forty years, thirty of which were in global management roles in Information technology (IT). Prior to working in IT, she spent more than ten years in education teaching at both second and third level. She has a strong interest in public involvement in health and social care research and ethics. She is a PPI member of both the Irish Child and Family Agency's institutional research ethics committee for social care research, and the Irish National Research Ethics Committee for Clinical Trials. She is a member of the Public Advisory Board of the national PPI Ignite Network in Ireland. Deirdre also has a strong community links with a particular interest in the economic growth and development of the West of Ireland. She is currently serving as the interim Chief Executive Officer (CEO) of the Galway Chamber of Commerce and Industry. As a trustee of Architecture At The Edge, a not for profit organisation, she promotes excellence in the built environment.

Naomi Maxwell is a young person with lupus and lives in Essex in the UK. She was diagnosed aged 10 years old. She has been involved in a variety of patient and public involvement work and feels it is important that young patients have a voice in the development of new and current treatments. In her spare time she loves to craft, crochet, painting, and scrapbooking. She also loves playing boardgames with her friends, many of whom have different disabilities themselves.

Philip McCallion is professor and director of the School of Social Work at the College of Public Health, Temple University, US. He is also Director of the ABA Centers of America Autism Lab. He is co-founder/co-principal investigator/co-applicant of the Intellectual Disability Supplement to the Irish Longitudinal Study on Aging (IDS-TILDA), and co-investigator on longitudinal studies of dementia in persons with Down syndrome. His research focuses on enhancing the quality of life for individuals with intellectual and developmental disabilities, particularly those with dementia, and their caregivers. His work emphasises evidence-based interventions in health promotion, falls reduction, caregiver support, dementia management, and service system redesign. He has made significant contributions to the field with over 250 publications and more than $50 million in research funding from prestigious organizations including the National Institute on Aging, Administration on Community Living, the Health Research Board of Ireland, and the John A. Hartford Foundation. His translational research and training have influenced policies and practices across the United States and internationally. Prof. McCallion's research includes system design improvements for creating aging-prepared communities, non-pharmacological interventions for dementia, psycho-educational programs for caregivers, and early identification and care planning for individuals with intellectual disabilities experiencing Alzheimer's disease. His work has extended to innovative projects maintaining aging persons with intellectual disabilities in the community and increasing the reach of palliative care programs. A fellow of the International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) and the Gerontological Society of America, he has received a Career Achievement Award from the Association for Community Organization and Social Action (ACOSA) and a Lifetime Achievement Award from the American Public Health Association (Disability Division). Recognised as a Highly Ranked Scholar by ScholarGPS, he ranks 4th globally in intellectual disability research. He serves on international consensus panels and is national consultant on intellectual disabilities and dementia for the U.S. National Alzheimer's and Dementia Resource Centre. As a mentor, he has supported post-docs and early career faculty, chaired 14 doctoral committees (a member of 30 more), and supervised numerous doctoral and master’s projects, fostering the next generation of researchers in his field.

Mary McCarron PhD RNID RGN BNS FAAN FTCD, is a distinguished scholar in Ageing and Intellectual Disability. She is the Director of the Trinity Centre for Ageing and Intellectual Disability (TCAID), Trinity College Dublin, Ireland, and the Executive Director of the National Intellectual Disability Memory Service. She has held prominent positions such as Dean of the Faculty of Health Sciences and Head of the School of Nursing and Midwifery at Trinity College Dublin. As the founder and Principal Investigator of IDS-TILDA, the first longitudinal comparative study on ageing in persons with intellectual disability, she has advanced our understanding of ageing and chronic conditions in this population, influencing healthcare practice and national health policy. She has also led a 25-year cohort study on dementia in people with Down syndrome, contributing significantly to this field. Professor McCarron established Ireland's first dedicated National Memory Service for people with intellectual disabilities, emphasizing her commitment to cognitive health and ageing. As Principal Investigator of the PPI Ignite Programme at Trinity College, part of a national network funded by the Health Research Board, she champions patient and public involvement in research and has received the inaugural HRB Impact Award. Her efforts in clinical research infrastructure are notable, serving as co-applicant on the HRB's Clinical Research Network Awards for Dementia Trials Ireland and the Irish Lead on the H21 Consortium, which focuses on dementia outcomes for individuals with Down Syndrome. She advises on ageing and policy at national and international levels. She has been a governance board member of the International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) and contributes to various hospital and service boards. Recently, she was appointed to the Commission on Care for Older People. With over 500 publications, her pioneering research and leadership have significantly impacted academia and healthcare, advancing knowledge and improving care for individuals with intellectual disabilities.

Alex McComber is Kanien’keha:ka from Kahnawake Territory, Quebec. He is Assistant Professor with the Department of Family Medicine, Faculty of Medicine and Health Sciences, McGill University, Canada, and community health activist and researcher. He has expertise in ethics and cultural safety with Indigenous Peoples and communities in research and practice, community-based participatory research, patient participation in research, health promotion and diabetes prevention, and community mobilization and mentorship. He collaboratively developed the Indigenous Program at Family Medicine that focuses on Indigenous teachings and respectful knowledge exchange, cultural safety education in health research and care, Inuit health, and patient participation in health research.

Eimear McGlinchy is Assistant Professor in Intellectual Disability and a faculty member at the Global Brain Health Institute at Trinity College Dublin, Ireland. Her research is based at the Trinity Centre for Ageing and Intellectual Disability, focusing on dementia in people with Downs syndrome. With a background in Psychology, she leads the PREVENT Dementia – DS project and is the site lead in Ireland for the Horizon 21 European Downs syndrome Consortium. This project examines biomarkers for Alzheimer's disease in people with DS using a variety of methods, including neuroimaging, blood-based, and cognitive biomarkers. She works internationally to support people with Down syndrome and address the inequities faced by this population. Additionally, she is a co-applicant on the Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS-TILDA), and co-PI on a project to develop best practice guidelines for post-diagnostic dementia support for people with an intellectual disability. For over a decade, she has worked to ensure that people with an intellectual disability are included in the research process as advisors at all stages and is now the site lead at Trinity College Dublin for the PPI Ignite project. In addition, she teaches within the undergraduate and postgraduate programmes and supervises a range of students, from undergraduates to PhD candidates. She also coordinates several MSc courses in Ageing Health and Wellbeing in Intellectual Disability, Dementia, and Community Health at the School of Nursing and Midwifery. She has numerous publications and has disseminated widely through national and international conferences.

Melissa Park is an Associate Professor at the School of Physical and Occupational Therapy, Faculty of Medicine and Health Sciences, McGill University, Canada. She conducts participatory, mixed method ethnographic research with neurodiverse communities. Her interdisciplinary and public and patient involvement research draws from a Bachelors in Art History (Yale), a Professional Master's degree in Occupational Therapy with a specialization in sensory processing, a PhD in Occupational Science (USC, OS/OT) and postdoctoral appointments in phenomenological anthropology (USC, Anthropology), mental health system transformation (UCLA), and rehabilitation (Karolinska). Funded by health, social science and public health funding, her research focuses on connectivity from multiple perspectives and the transformations that result. Her projects range from an initial ethnography of clinical encounters to her current work combining mixed methods ethnography and participatory approaches, whether with patients, health professionals and policymakers in the mental health system or children, youth, older adults and their families in the community that expands to include partners in public non-profit organizations and arts/culture institutions. She is particularly interested in how aesthetics, as both bodily-sensing and cultural form, affords a way to understand and transform experience in ways that can transcend categorical differences.

Jenny Preston is the Patient and Public Involvement (PPI) Policy Manager for the Faculty of Health and Life Sciences at the University of Liverpool, in the UK. Her main role for the last 19 years has been to deliver a strategy for the involvement and engagement of children and young people and families in paediatric health research. She is also currently the PPI and Engagement (PPIE) Manager for the National Institute for Health and Social Care Research (NIHR) Alder Hey Clinical Research facility; PPIE Executive Lead for the NIHR HealthTech Research Centre in Paediatrics and Child Health, and strategic lead for PPIE in other initiatives including: the Experimental Arthritis Treatment Centre for Children (EATC4Children); NIHR GenerationR Alliance (www.generationr.org.uk) Young Person's Advisory Groups across the UK, and internationally; co-founder of a European Young Person's Advisory Group Network (eYPAGnet) which is a network that empowers young people and families across Europe to contribute to paediatric health research (https://eypagnet.eu). She is also a PhD candidate at the University of Liverpool exploring what meaningful patient and public involvement means to children and young people.

Penny Vicary came to research through her experience of having had genetic cancers and living with the consequences of treatment. She engaged with Macmillan Cancer Support on issues relating to survivorship genetics. She also contributed to the development of guidance on radiation for induced bowel disease. She was a founder member of the Public and Patient Involvement in Research (PPIRes) project in NHS Norfolk and Waveney. She has undertaken various Patient and Public Involvement (PPI) contributor roles over a number of years including being a co-researcher in studies, a project team member, and a co-applicant in bids for research funding. As a member of the Research and Development Forum Service User and Carer working group, she co-produced a training package for patient and public involvement researchers and guidance on the role of co-applicants. She has presented at National Institute of Health Research INVOLVE conferences, co-authored a number of papers and articles on a variety of topics including colorectal cancer; PPI in research design; the evaluation of PPI; research waste; the legal, governance, and ethical implications of PPI. As someone who is digitally excluded, she feels passionately about those people who experience digital exclusion and has written blogs on the importance of including their voices.

Lora Ruth Wogu is the founder and CEO of Sickle Cell and Thalassaemia Ireland, a national patient and parent support and advocacy organisation for raising awareness and advancement of patients' quality of life with Sickle Cell disease and Thalassaemia disease in Ireland, Europe and global level. She is a founding member and Chief Operations Officer of the European Sickle Federation, an umbrella network of patient organisations advocating for Sickle Cell Disease advancement in Europe. Her professional role is in Allied Healthcare at St Vincent's University Hospital, Dublin, Ireland. She holds a BSC in Healthcare Management and a MSc in Quality and Patient Safety in Health Care management. As a patient advocate, public and community leader, Lora advocates and represents the patient voice on various committees and initiatives including the PPI Ignite Network Public Advisory Board, the Department of Health National Screening Services Committee, the Health Service Executive Patient Forum, the EURORDIS New born Screening steering Committee for rare diseases, and the European Medicine's Agency Scientific board.

Mei Lin Yap is a graduate of Trinity College Dublin, Ireland, and acts as the Ambassador Liaison Officer at the Trinity Centre for Ageing and Intellectual Disability (TCAID). She is a PPI contributor and, as part of her role, she advocates for people with intellectual disabilities and helps to shape research within the centre. She also chairs the PPI panel, managing a group of seven people who meet once every two months to give opinions on the research and share their lived experience. In addition, she sits on the steering committee with the Intellectual Disability Supplement to the Irish Longitudinal Study on Ageing (IDS-TILDA) and the National Intellectual Disability Memory Service. She has been a co-author on several publications on inclusion and PPI. As well as her work at TCAID, she also works at a Recruitment Agency where she is a Senior HR Assistant. In her role, she sits on several committees, including the Diversity, Equity, and Inclusion committee. She advocates for the inclusion of people with disabilities in many different organisations by sharing her own experience and providing recommendations for the employment of people with disabilities.

Introduction

Virginia Minogue and Jon Salsberg

Patient and Public Involvement (PPI) is an integral part of the planning, design, and conduct of health and care research in many health economies. The degree to which attention is paid to the rights, safety, and protection of PPI contributors and community partners varies. With this volume we have sought to produce a textbook on the topic of PPI and ethics that will be of value to many different audiences. These include seasoned researchers and student researchers; academics leading health and clinical professional training with a research component; academics leading teaching on patient and public involvement; clinical and health research centres; research institutes; institutional ethics boards; clinical and health research ethics committees; funding bodies; those with responsibility for training and building capacity for public and patient involvement in research; and anyone with an interest in good practice in ethical patient and public involvement.

This book introduces the reader to considerations of the ethical aspects of patient and public involvement (PPI) in health research and provides an important reference point and guidance on ethical research involving PPI. It makes a valuable contribution to the still vibrant debate about the ethical aspects of involving patients and the public as partners in the design, conduct, and dissemination of research. Several chapters discuss three key areas of PPI and ethics:

- What is ethical practice in carrying out PPI in research.
- PPI in the research ethics process including consideration of the level of knowledge:
    - about ethical approval processes amongst PPI contributors

    - about PPI and ethical issues amongst Research Ethics Committees.
- When ethical approval is needed for PPI activity and whether PPI is seen as increasing the risk within a project.

Uniquely, each chapter has been written collaboratively and many will also reflect the PPI contributor or partner perspective. It will be a practical tool for all those who engage in patient and public involvement in health and clinical research and are concerned to conduct their research ethically, and with the best interests, safety, and protection of the patients and public, by working in partnership.

Definitions of patient and public involvement have long been debated and there is no clear agreement on the terms that should be used. For consistency, patient and public involvement, or PPI, in this book is defined as:

> '--- research carried out 'with' or 'by' members of the public rather than 'to,' 'about' or 'for' them' (National Institute for Health Research; Health Research Authority[1]).

PPI involves working in collaboration or partnership with patients, carers, families, service users or the public in planning, designing, managing, conducting, disseminating, and translating research. It is distinct from a patient or member of the public participating or volunteering to take part in research as a subject of a study. It is distinct from the involvement of patients or members of the public in the design, delivery, and management of health services and systems, although there is a shared heritage and value set between this and PPI in research. The term 'PPI contributor' is used to describe those who engage in PPI as a co-researcher, research team member, co-applicant for a bid for funding, and other roles that lead to active involvement in

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[1] https://www.peopleinresearch.org; https://www.hra.nhs.uk/planning-and-improving-research/best-practice/public-involvement/

the research process. We recognise that there are many other definitions that are used and may be preferred.

PPI in health and clinical research has increased exponentially over the last two decades. Despite this, it is not regulated nor are there any universally agreed upon standards or ethics applied to PPI in research. However, health and clinical research is a heavily regulated area and is subject to a great deal of international and national legislation, policy, procedure, and guidance. Included in this is legislation and policy relating to the safe participation of those who are the participants or subjects of research i.e. patients, carers, families, members of the public as 'sources of data'. They are also protected from harm by research governance and research ethics processes. This is not the case for PPI in research i.e. PPI contributors as co-researchers, co-applicants in funding applications, project team members, advisory group members, despite the significant ethical and governance issues that arise out of these additional roles.

After more than two decades of development and embedding of processes across health research, it is even more imperative that the partnerships and relationships we build with those who contribute to our research are underpinned by principles of reciprocity and fairness. Too often they are distorted by power dynamics and the presence of 'othering' (Akbulut and Razum 2022). By building our practice on a values-based approach and ethical foundations and working to bridge the gap between the researcher and the PPI contributor, we can develop successful co-production whilst enabling the authentic voice of the contributor to be heard.

In this book the reader will be able to explore different aspects of ethical PPI from the perspective of PPI contributors including children and young people, vulnerable populations, community engagement in partnered research, institutional Research Ethics Committees, and research funders. There will also be the opportunity to explore ethical issues including diversity and inclusion, power relationships, and to address the tensions, dilemmas and challenges that arise for PPI when working within an ethical framework. Each chapter will offer practical guidance and knowledge to enhance the quality of PPI in health research by working in an ethically responsible way.

Chapter one sets the scene by outlining the ethical issues that arise in PPI in health research. The authors discuss what ethical PPI in research involves, contrast the protections and rights that are afforded to participants (subjects) of research with the lack of consideration given to the rights and safety of PPI contributors. Through an exploration of the various roles of PPI contributors, the authors will provide an insight into the responsibilities and ethical considerations that may arise.

Chapter two reflects on the many challenges and tensions in conducting ethical PPI highlighted in the other chapters. It explores the potential dilemma between attempting to harmonise ethical PPI with a more personalised and values-based approach that places the patient voice at the centre of health research. The authors discuss the tensions and dilemmas in more detail, outline how such issues contribute to barriers for ethical PPI, and/or limit true partnership working, and identify some of the solutions to address them including the adoption of a values-based practice approach.

Chapter three focuses on issues of diversity and how to involve people from marginalised groups as PPI contributors in the research process. It addresses the challenges of ensuring diverse and representative involvement and overcoming barriers to inclusion through relationship building and engagement with communities, specifically those representing people from marginalised backgrounds. The authors highlight the importance of communication and taking a listening approach to involvement. They also discuss how foregrounding and valuing the lived experience of the potential contributor brings validation. Guidance is provided on the type of support, resources needed and the development of user-friendly technology.

Chapter four focuses on participatory approaches to the co-production of research knowledge. Participatory research emphasises equity among researchers and knowledge users by embracing diversity of values, experiences, and knowledge. This approach can help assure that issues of power, decision-making and representation are monitored, and strategies are applied to shift research ownership from academia to community or patient knowledge users. This can generate practical ethical challenges ranging from issues of data or knowledge ownership, to control and access over research products and their dissemination, to protection of collective community interests. This chapter will examine some of these issues and, based on practical experience, propose strategies to address them using lived examples from both community-based and patient-engaged research experiences.

Chapter five examines issues of power imbalances in participatory research. It presents a view of power from the unique anthropological perspective of an ethnographer and phenomenologist. Using a case example, the authors describe events which marked shifts in power between in and out-patient mental health professionals, professional disciplines, and people with lived experience. They explore the ethical issues that emerged in a mixed method ethnographic and participatory project, at the intersection of participant observation and participatory action, from the multiple perspectives of those involved.

Chapter six explores the specific ethical challenges of involving children and young people in child health research. This chapter, with the use of case studies, and lived experience of involvement, describes a child-rights based approach of how to support and manage the process of delivering meaningful patient and public involvement with children and young people in the design and conduct of paediatric health research. This practical chapter highlights a step-by-step approach to overcoming issues such as identifying and engaging children and young people willing to get involved; providing a safe space for children and young people to come together; methods explaining how to present research to children and young people in ways they will understand and acknowledging their input through feedback and recognition.

Chapter seven discusses the ethical considerations when including individuals with intellectual disabilities and other vulnerabilities as PPI contributors and is underpinned by the ethos "nothing about us without us". The authors highlight the importance of designing roles within research projects that leverage the unique strengths of individuals to ensure meaningful participation, and the important ethical issues to consider while doing so. They outline how a framework of values and principles underpins each stage of PPI throughout the research process and present strategies for including people with vulnerabilities to achieve authentic inclusion.

Chapter eight explores the funder perspective and considers how PPI is included in funding applications and the role of PPI co-applicants in the process. It will also explore how PPI contributors are involved as reviewers of funding applications and provide guidance on how to recruit, educate, and embed PPI within funding decisions. The authors will address the challenges of recruiting a diverse range of reviewers, dealing with power imbalances, and unconscious bias.

Chapter nine discusses the role of Research Ethics Committees (RECs). RECs consist of both scientific and non-scientific members and PPI members are included within the category of non-scientific and are generally individuals who are not research or health and social care professionals. The authors explore the rationale behind the inclusion of PPI representatives in RECs looking at the value case, potential benefits, and operational challenges of embedding PPI in both national and institutional RECs. It examines the role of RECs in reviewing PPI across the research process and in reviewing the duty of care and potential risk to PPI contributors.

Chapter ten reflects on the key points from the preceding chapters including the importance of partnership between PPI contributors, communities, researchers, and other stakeholders, agreed values, ethical responsibility, and clear communication. Using the conceptual model proposed by Wallerstein et al (Wallerstein et al 2008, 2010, 2018), a new framework for effective ethical PPI in health care research is proposed. The framework is underpinned by a values-based, and rights-based, approach whilst being cognisant of the need to for the protection, safety, and rights of the individual and community in the research process. It points to the importance of jointly identifying ethical risks and mitigations and reviewing them at all stages of a study. This alongside a shared process of evaluation and reflection is an important element of communication.

Common themes relating to the ethical aspects of PPI in health research, emerge throughout the chapters of this book, i.e. the importance of values, the rights and protection of PPI contributors, the diversity of the lived experience, managing power dynamics, communication, and creating true partnerships. Crucially, the basic values of PPI i.e. respect, equity, trust, partnership, integrity, and responsibility, outlined in the literature, underpin ethical approaches to PPI and provide the principles upon which the foundations of effective co-production are built.

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Chapter 1
Ethical Patient and Public Involvement in Health Research

Virginia Minogue and Jon Salsberg

Introduction

This chapter outlines the ethical issues that arise in patient and public involvement (PPI)[1] in health research. It sets out an ethical approach to PPI, the principles underpinning that approach, and how to recognise and address the challenges and issues that arise from working in partnership with PPI contributors. It will also highlight the dilemmas encountered in a health research environment where the system of ethical approval is focused on the rights of the research participants and does not offer the same rights to PPI contributors. These issues are even more complex when research teams seek to work with PPI contributors in a partnered, co-productive, and equitable way but without a clear ethical framework to guide their activities. We will offer critical insight into the roles and responsibilities of PPI contributors and the ethical considerations related to each of the roles.

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[1] Patient and Public Involvement (PPI) refers to patients, service users, carers, families using health and social care services, people with lived experience of health conditions (who may or may not be current patients), patient advocacy organisations, and members of the public. PPI in healthcare research refers to research carried out 'with' or 'by' members of the public rather than 'to', 'about' or 'for' them'. Essentially this means working in collaboration or partnership in planning, designing, managing, conducting, dissemination and translation of research.