Guidelines will ensure assessment of patient symptoms and quality of life is ethical

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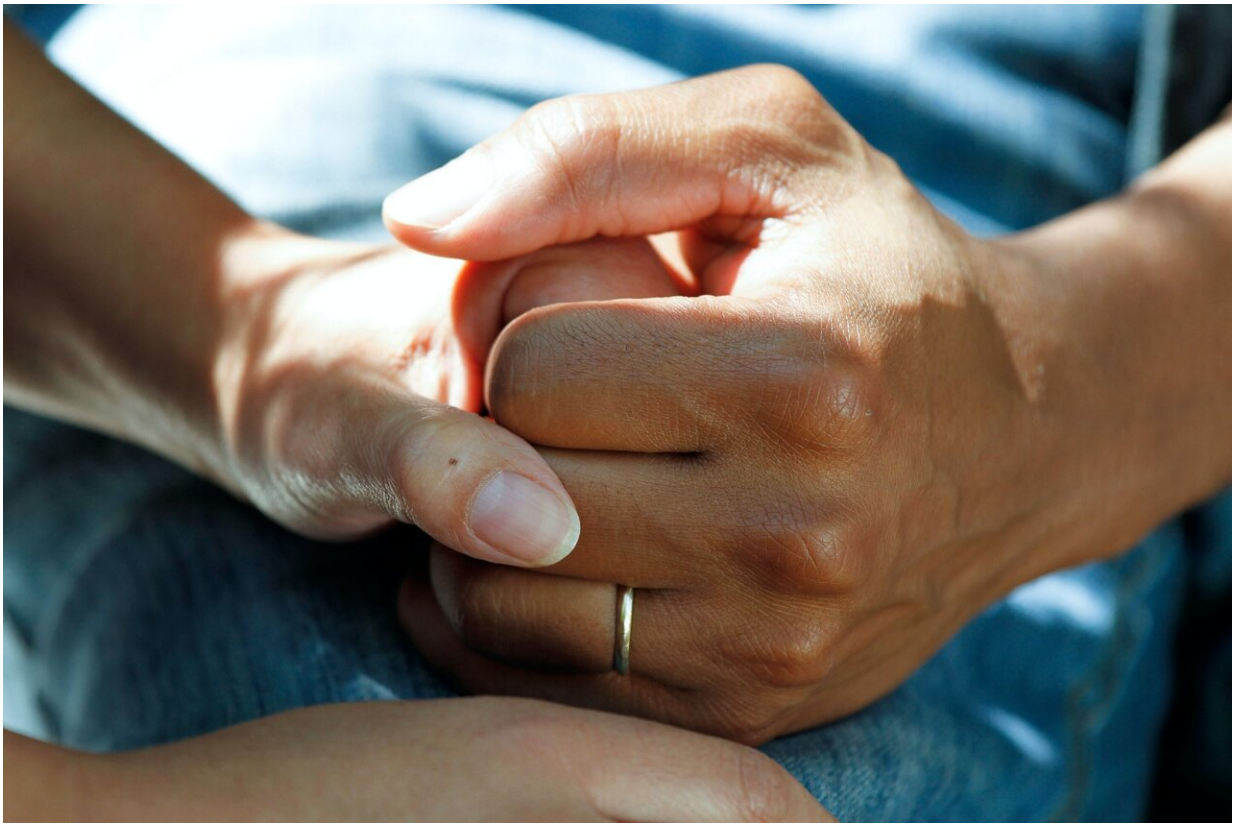

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Ethical guidelines for the collection of patient reported outcomes (PROs) in clinical research have the potential to reduce risk and burden for participants, increase participation in research, and protect the

welfare of participants and researchers, say researchers at the University of Birmingham.

In a new study published in *JAMA*, experts in the University's Center for Patient Reported Outcomes Research with international collaborators, set out the guidelines, designed to ensure clinical research which includes patient-reported outcomes is ethical, inclusive, equitable and optimal.

In developing the guidelines, the researchers, led by Dr. Samantha Cruz Rivera, reviewed existing publications on ethical implications of PROs and consulted with international experts with an interest in PRO research, recruited with the support of the Health Research Authority.

The aim was to highlight the key issues that should be considered by research teams, ethics committees, patient partners and the public involved in the research, rather than to mandate how ethical research should look.

The final set of guidelines includes 14 recommendations that should be addressed in PRO clinical research. Criteria range from the clarity of the research question and objectives, and justification of any eligibility criteria, to participant acceptability and burden. They also highlight the importance of input to PRO strategy by patient partners or members of the public, minimizing missing data and the need to have clear dissemination plans.

Senior author Professor Melanie Calvert said: "The increasing use of patient-reported outcomes in research and in clinical care may lead to uncertainties for patients about why data are being collected and used. At the same time, in situations where PROs reveal concerning information—for example psychological distress or physical symptoms—researchers need to know how to manage that data and ensure

participants are well cared-for."

In addition, PRO research may not reflect the perspectives of underserved groups such as older individuals, socioeconomically disadvantaged populations, and ethnic minorities, which could threaten the scientific validity of results. Use of the new PRO ethical guideline published in *JAMA* will help research teams, patients involved in the co-design of studies and research ethics committees help consider such issues resulting in higher quality data that can meaningfully inform care."

Clive Collett, HRA Senior Policy Manager, said: "The use of PROs can provide invaluable insights into how research interventions are experienced from the participant's perspective and it is vital that these are collected in a way that properly respects and protects both participants and researchers.

"The collection of high-quality PRO data in an ethical manner supports the HRA's vision for high-quality health and social care research that protects and promotes the interests of participants and the public and improves people's health and well-being. For research to be safe and ethical it is important that ethical thinking is embedded throughout the research journey and these guidelines will help researchers to do that."

Phil Collis, patient partner, said "As patients, during our healthcare, we are asked to complete questionnaires about our experiences of care and treatments. Our responses provide valuable information that can help maintain or improve patient experiences and outcomes—informing clinical decision making on what is important to us in relation to patient care. These new ethical guidelines can ensure that the methods used in gathering, collating, and using this important patient information is carried out in an ethical, safe way."

Professor Conrad Fernandez, IWK Health Center and Dalhousie University, Canada, is a co-author on the paper. He said: "I believe these guidelines will strengthen the scientific and ethics review of Patient Reported Outcomes research leading to significantly enhanced participant protections, whilst ensuring that meaningful benefits we all strive for are kept central to the research at hand."

Lisa Campbell, Senior Medical Assessor at the Medicines and Healthcare products Regulatory Agency (MHRA) and co-author says: "Addressing ethical issues for PROs in clinical research is crucial to protect patients and improve shared-decision making across the healthcare system. These new guidelines provide useful recommendations that will help strengthen scientific and ethical review in order to support patient-centered care and access."

The Birmingham led team will now work to promote the implementation of the new guidelines both in the UK and internationally.

More information: Ethical considerations for the inclusion of patient-reported outcomes in clinical research: The PRO ethics guidelines., *JAMA* (2022). DOI: 10.1001/jama.2022.6421

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