Collaboration recommends changes to development, assessment and approval of mental health medicines

December 7 2023

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A major group of international experts and patients have cooperated in defining new parameters for the development of medicines to treat children and young people. They make a series of recommendations on

how the processes should be improved. The work is published today in *The Lancet Psychiatry*.

The work was led by a group of experts from the Child and Adolescent Network of the European College of Neuropsychopharmacology (ECNP), alongside representatives from the European Medicine Agency (EMA) and families of patients with lived experience of mental problems in children and young people.

"We believe this is the first expert-patient initiative of its kind. As members of the ECNP, Child and Adolescent Network, we were privileged to work not only with colleagues from the European Medicines Agency (EMA) but also with representatives of associations of people with lived experience who provided extremely valuable insights. Research in this field can advance only via joint efforts from doctors, researchers, regulators, and people with lived experience," says Prof. Samuele Cortese, from the University of Southampton, first author of the study.

He continued, "We identified new ways of designing studies, and these need to be part of treatment research in child and adolescent psychopharmacology to produce more effective and safer treatments."

"In addition, there are concerns about the short and long-term effects of medications. We need to use these new study designs also to understand when it is better to use non-pharmacological treatments. The project surveyed families with children affected by mental health problems and found that most of them wanted priority given to more effectively communicating the risks and benefits of medicines. Patients need to be involved more consistently in research than they are at present."

The group identified a range of issues that need to be addressed, including

- A greater focus on disorders for which no evidence-based or no well-studied pharmacological interventions are available.
- Taking an overview of other important outcomes, not just the core symptoms tested in trials.
- Adapting the approval process so that effective medicines for children can be approved more efficiently.
- A better understanding of long-term effects on the developing brain (both beneficial and harmful).

The authors of the article suggest that in some cases, it may be worth re-reviewing medicines that were approved under less rigorous conditions and that this may have to come from public funds.

Professor Cortese said, "In this work, we point out some areas of uncertainty, but this is not a negative message. There has been a lot of progress in recent decades. We simply need to go ahead and address other issues that remain, in particular, long-term effects of medications, and also to understand when nonpharmacological treatments might be more appropriate."

Professor Carmen Moreno, CIBER researcher in Mental Health, (Madrid, Spain), Chair of the ECNP Child and Adolescent Network, said, "The increase in the demand for mental health care in children and young people, together with the scarcity of specific treatments, highlights the need to prioritize the study of treatments in this population. We need to use novel treatment designs and to pay special attention to possible side effects."

Professor Diane Purper-Ouakil, from the University Hospital of Montpellier, France, co-chair, added, "The majority of mental disorders start before adulthood and are prevalent conditions in children,

adolescents, and young adults. This paper highlights the need for developmentally-informed studies to improve access to efficient and safe medicines for young people and to offer suitable prescription practices and guidelines."

Ms. Christine Getin, Director of ADHD France, said, "We are delighted to have contributed to this important study. It is crucial that associations of people with lived experience actively contribute to research alongside expert clinicians and researchers. We believe that this study was a great example of such collaborations, as we were able to step in and collaborate from the outset."

"We need to continue with these collaborations to produce studies that better take into account the experience of the people affected."

More information: Christine Getin et al, Psychopharmacology in children and adolescents: unmet needs and opportunities, *The Lancet Psychiatry* (2023). DOI: 10.1016/S2215-0366(23)00345-0

Provided by European College of Neuropsychopharmacology