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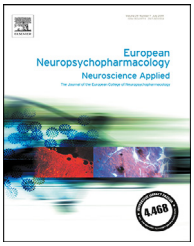

The need for paediatric registries to assess long-term brain effects of psychotropic medications: The case of bipolar disorder

The proposal by Vieta et al. (2018) of organizing a consensus conference on the need for pediatric registries to assess long-term brain effects of psychotropic medicines must be supported. “The why”, “the what”, “the who”, and “the how” of the consensus (as well of these registries) should be clarified, however, so that outcomes can be achievable and effective (de Groot et al., 2017).

The particularity of the developing brain and the still limited knowledge on the therapeutic effects and safety of psychotropic drugs in children and adolescents justify “the why”. Patient registries (“the what”) already exist in Europe for many diseases and drugs and have been increasingly important in supporting the lifetime evaluation of the benefit-risk ratio of authorized medicines by the regulators, as acknowledged, and sometimes required, by the European Medicines Agency (Boury et al., 2017). There are a few examples of patient registries also in the child and adolescent psychiatry area, e.g. for methylphenidate (Murray et al., 2013) and ADHD (Bonati et al., 2018). It is discriminating, however, to choose between product and disorder registries, and obviously not just for the data to be collected. In psychiatry (also concerning childhood and adolescence) the use of drugs is always one of the interventions, not always the first and not always alone, and often in complex conditions. It would therefore be more valuable to support disorder/care registries that accurately reflect the entire population of patients receiving different treatments, with and without drugs, in order to also compare the safety and effectiveness in users of other or similar treatments. Priorities, and criteria, should be defined for setting up patient registries for psychiatric disorders in children and adolescents with pharmacological or non-pharmacological treatment indications.

Researchers, clinicians, patient associations, regulators, and stakeholders must be involved (“the who”) to maximize the efficacy and results of registries. Additional essential characteristics of a health related registry are its independence and transparency in the organization, coordination, management, and evaluation of collected data. All this affects “the how” of setting up and maintaining a registry. At the regional and national levels the Ministry of Health (Bonati et al., 2018) and patient associations, as well as European Commission, can support registries also with funds, although, unfortunately, for limited periods that do not cover the duration of the target disorder. Moreover, the available budget should be adequate enough to not affect appropriate sample size, number of variables, and quality of data of registries. “The how”, therefore, is once again the core of a challenging and praiseworthy initiative to be addressed during, and after, a consensus conference.

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