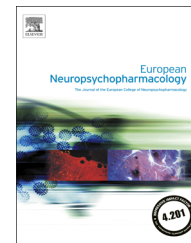




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REVIEW

Unmet needs in paediatric psychopharmacology: Present scenario and future perspectives

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Abstract

Paediatric psychopharmacology holds great promise in two equally important areas of enormous biomedical and social impact, namely the treatment of behavioural abnormalities in children and adolescents, and the prevention of psychiatric disorders with adolescent- or adult-onset. Yet, in striking contrast, pharmacological treatment options presently available in child and adolescent psychiatry are dramatically limited. The most important currently unmet needs in paediatric psychopharmacology are: the frequent off-label prescription of medications to children and adolescents based exclusively on data from randomized controlled studies involving adult patients; the frequent lack of age-specific dose, long-term efficacy and tolerability/safety data; the lack of effective medications for many paediatric psychiatric disorders, most critically autism spectrum disorder; the scarcity and limitations of randomized placebo-controlled trials in paediatric psychopharmacology; the unexplored potential for the prevention of psychiatric disorders with adolescent- and adult-onset; the current lack of biomarkers to predict treatment response and severe adverse effects; the need for better preclinical data to foster the successful development of novel drug therapies; and the effective dissemination of evidence-based treatments to the general public, to better inform patients and families of the benefits and risks of pharmacological interventions during development. Priorities and strategies are proposed to overcome some of these limitations, including the European Child and Adolescent Clinical Psychopharmacology Network, as an overarching Pan-European infrastructure aimed at reliably carrying out much needed psychopharmacological trials in children and adolescents, in order to fill the identified gaps and improve overall outcomes.

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1. Introduction

All theoretical frameworks to describe and analyse psychological functioning and human behaviour invariably view childhood and adolescence as crucial to the development of life-long mental health and disease. In recent decades, the growth of basic neuroscience has indeed pushed developmental psychology beyond limited descriptions and interpretations of human cognitive, emotional and behavioural trajectories, into a bio-psycho-social framework where the neurobiological underpinnings of typical development hold a key position (Lee et al., 2014; Schumann et al., 2014). Within this framework, the link between abnormal neurodevelopment and paediatric psychopathology has become the object of intense investigation, which holds a realistic promise to produce major advances in developmental neuropsychopharmacology in the not-so-distant future. Furthermore, adult psychiatric disorders have been shown to at least partly stem from neurodevelopmental abnormalities arising from early or late childhood, if not even prenatally (Salum et al., 2010).

Recognizing this great potential for major upcoming progress in clinical practice, but also acknowledging the serious limitations of current psychopharmacological interventions in paediatric neuropsychiatry, the Child & Adolescent Neuropsychopharmacology Network of the European College of Neuropsychopharmacology (ECNP; <http://www.ecnp.eu/>) held a Targeted Network Meeting (TNM) on October 4, 2013, satellite to the 26th Annual ECNP Congress (Barcelona, Spain). Thirteen experts presented evidence, shared opinions, described policies and debated views around the many unmet needs in child

psychopharmacology. In the ensuing year, a dialogue on these subjects was continued by the participants with the goal of producing the present meeting report, which provides a snapshot of the most critical unmet needs, summarized in Table 1, as well as a general framework to guide future collaborative efforts and advance the field of paediatric psychopharmacology.

2. The off-label prescription to children and adolescents of medications with regulatory approval only in adults

Developmental neuropsychopharmacology has progressively evolved from considering youth as “small adults”, to investigating new fields of interest specific to children and adolescents (Arango, 2015). However, to date only very few medications have been approved in Europe for use in children and adolescents (Table 2). Many psychotropic medications prescribed to paediatric patients are unlicensed and off-label. In fact, the vast majority of medicines prescribed to children throughout the European Union (EU) have actually never been studied in this population but only in adults, and not necessarily for the same disease (Conroy et al. 2000). This unlicensed and off-label use conceivably stems from: (i) a dearth of clinical trials in paediatric populations, due to insufficient commercial incentives and/or ethical barriers associated with studies in children and adolescents; (ii) delays in licensing medications for youth, and (iii) lack of suitable formulations for paediatric patients. On the one hand, regulatory authorities have

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