

Drug research and treatment for children in Canada: A challenge

Michael J Rieder; Canadian Paediatric Society, Drug Therapy and Hazardous Substances Committee



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ABSTRACT

Historically, children have been 'therapeutic orphans'. Many drugs have not been studied or labelled for use in children and adolescents, making the development and definition of optimally safe and effective drug therapies for the paediatric age group an ongoing challenge. Over the past decade, networks have developed in the United States and Europe to enhance drug research for this group, while no comparable evolution has occurred in Canada. The present statement provides context for the Canadian situation and makes recommendations that address two pressing needs: for more drug research focused on Canadian children and adolescents, including dedicated support for such research; and for increasing human capacity to undertake targeted studies. These initiatives should be undertaken collaboratively, nationally and internationally, and include strategic, innovative approaches to the unique problems and ethical issues posed by drug research in this population.

Key Words: *Canada; Children; Drugs; Research*

RECOMMENDATIONS

1. Health Canada, the Canadian Institutes of Health Research (CIHR), and industry should develop a national research network focused on the unique therapeutic needs of infants, children and youth, to improve the environment and infrastructure for drug research for children in Canada. They should work with organizations such as the Canadian Society for Pharmacology and Therapeutics, the Canadian Paediatric Society, Canadian academic child health centres, and the private sector. Such a network should actively collaborate internationally with investigators and networks, with the common goal of safer and more effective drug therapy for children.
2. The CIHR, Health Canada and Canadian academic child health care centres should work to enhance human capacity in drug investigation in children, including in paediatric clinical pharmacology and complementary scientific disciplines such as pharmacoepidemiology, biomedical ethics, in silico pharmacology, and systems biology. Training opportunities in drug research in children must be supported by the CIHR, Health Canada and Canadian academic child health centres for paediatricians and other health researchers interested in optimal therapy for children. Educational opportunities should include developing innovative skills in frontier areas of pharmacology, drug design and drug safety.
3. The CIHR, Health Canada and Canadian academic child health centres should support drug studies in children, notably for drugs and diseases where optimal therapy is poorly defined.
4. The CIHR and the National Council on Ethics in Human Research should work with organizations, such as the Canadian Paediatric Society, to define and address the evolving ethical challenges of drug research in children, with a view toward how these issues are addressed both nationally and internationally.
5. The CIHR, Health Canada and Canadian academic child health centres should support innovation in drug research in children, including the development of novel endpoints, trial design and endpoints that will facilitate the conduct of scientifically and ethically rigorous drug research in children.
6. The federal government must demonstrate its commitment to optimal treatments for Canadian children by providing robust, dedicated and sustained support for and training in drug research for this group. In particular, the federal government should support areas where optimal therapy is poorly defined and where research by other stakeholders is unlikely to occur, as well as innovation in drug research in children. Finally, the federal government must continue to evaluate and establish incentives that will best encourage industry to submit paediatric data when presenting information to Health Canada.

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Principal author: Michael J Rieder, MD

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Correspondence: Canadian Paediatric Society, 2305 St Laurent Boulevard, Ottawa, Ontario K1G 4J8. E-mail info@cps.ca