No population left behind: improving pediatric drug safety using informatics and systems biology

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Abstract

The current drug safety landscape inadequately serves the millions of children prescribed medications every year. Randomized clinical trials are limited in detecting pediatric adverse drug effects due to low participant enrollment, complicated study design, and short trial duration. While the biology of human development and the pathology of childhood diseases are well studied research topics, current pharmacoepidemiology approaches do not use this knowledge when investigating drug safety in children. Here, we describe how adverse drug effects manifest as children develop from birth through the teenage years. We discuss the benefits of an empirical approach for evaluating clinical relevance and biological causality of identified adverse drug effects in children. We argue that a data-driven strategy that leverages observational data and biomedical knowledge is an ethical and effective methodology to improve pediatric drug safety.

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