

# INPLASY PROTOCOL

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## A scoping review for pediatric off-label drug use studies

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**Support:** None.

**Review Stage at time of this submission:** Formal screening of search results against eligibility criteria.

**Conflicts of interest:**  
None.

**Review question / Objective:** To overview the current studies on pediatric off-label in different countries and disease areas and identify the research gaps related on pediatric off-label use.

**Condition being studied:** The pathophysiology of children dictates the specificity of drug therapy, but the drug options available to children are far from meeting realistic needs. Off-label drug use was, is, and will continue to be a very prominent global public health problem in infants, children, and adolescents. Therefore, there are many studies focusing on off-label drug use in children, but the huge difference between the study types, study objective, disease areas, drug classification, as well as the main findings.

**INPLASY registration number:** This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 January 2021 and was last updated on 30 January 2021 (registration number INPLASY202110119).

### INTRODUCTION

**Review question / Objective:** To overview the current studies on pediatric off-label in different countries and disease areas and identify the research gaps related on pediatric off-label use.

**Rationale:** At present, pediatric off-label drug use becomes a common and serious

problem, while that is increasing year by year showed by various research. However, there are no studies that provide a comprehensive overview of the current evidence. Scoping review is the process of determining the scope, type, and nature of evidence in a research area, systematically reviewing the value of the evidence, drawing conclusions from methodologically or disciplinarily distinct

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bodies of knowledge, or identifying research gaps to aid in planning and future research directions. So, we conducted this scoping review on pediatric off-label drug use to overview the current evidence and reflect the current research gaps by based on the PRISMA-ScR Checklist, including the last 5 years studies on pediatric off-label drug use.

**Condition being studied:** The pathophysiology of children dictates the specificity of drug therapy, but the drug options available to children are far from meeting realistic needs. Off-label drug use was, is, and will continue to be a very prominent global public health problem in infants, children, and adolescents. Therefore, there are many studies focusing on off-label drug use in children, but the huge difference between the study types, study objective, disease areas, drug classification, as well as the main findings.

## METHODS

**Participant or population:** Pediatrics.

**Intervention:** Not applicable.

**Comparator:** Not applicable.

**Study designs to be included:** We will include all types of studies except study abstracts, letters, meetings, commentaries, and editorials.

**Eligibility criteria:** Pediatric off-label drug use studies.

**Information sources:** We searched the PubMed, Embase, Web of science, China National Knowledge Infrastructure (CNKI), China Biology Medicine (CBM), Wangfang Data from the January 1, 2016 to December 31, 2020. Besides, reference lists of the identified literature to find additional studies.

**Main outcome(s):** The percentage of the countries conducted, study types, disease systems focused on of the included studies. Additionally, we will describe the content of informed consent, ethics issues,

conflict of interest, and adverse reactions of included studies.

**Data management:** Not applicable.

**Strategy of data synthesis:** We will conduct a descriptive analysis of the characteristics of the included literature. Retrieved studies were exported into EndNote X9 (version 9.3.1); Data extraction was collected by an inerrable online form; tables and graphs were implemented by Excel software (version 16.45); correlation analysis graphs were performed by R software (version 1.3.1056).

**Subgroup analysis:** Not applicable.

**Sensitivity analysis:** Not applicable.

**Language:** English.

**Country(ies) involved:** China.

**Keywords:** Pediatrics; Off-label drug use; Scoping review.

### Contributions of each author:

**Author 1 - Min Meng** - The author designed the study, searched the literature and will draft the manuscript.

**Author 2 - Ling Wang** - The author will extract and check the data and draft the manuscript.

**Author 3 - Bo Yang** - The author will extract and check the data, as well as draw diagrams.

**Author 4 - Panpan Jiao** - The author will extract and check the data.

**Author 5 - Meng Lv** - The author will analyze data and draw diagrams.

**Author 6 - Wenjuan Lei** - The author will extract and check the data.

**Author 7 - Xufei Luo** - The author designed the study, assisted study design and will interpret the results.

**Author 8 - Qiu Li** - The author conceived the study and oversought the study implementation.