EDITORIAL

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A new column in this journal – Forum on Clinical Investigation

Medical research, including clinical trials, observational studies, and studies on medicine-related translational and basic sciences, is extremely important for the development and improvement of clinical medical care. However, many physicians in China may not have received systematic and comprehensive education or training for medical research since in most medical universities or colleges/schools, methodology for clinical research (design, planning, conducting, analyses, and reporting) has not been included in their curricula. Therefore, many clinicians need to learn on their own and very few of them might attend limited short training courses for clinical studies.

Clinical research itself is being continuously improved and developed, solving several problems, but also facing some challenges and problems, old or new, minor or major. For example, according to an article authored by seven associations and institutions,[1] challenge and difficulty in the design and conducting of clinical trials in China mainly embody conceptualization, capability, and mechanisms of management of the parties (sponsors, hospitals, teams of the investigators, and the third-party serving institutions). Resolution of those challenges and problems would effectively improve the holistic levels of design and conducting of clinical trials in China. In the research and development of new drugs, there are challenges such as too much focus on a narrow set of drug targets and indications and low efficiency in conducting clinical trials.[2]

Clinical trials in the pediatric population started earlier in the United States, in some European countries and Japan, but later in China. Most of the clinical trials have obtained clinically important and meaningful evidence and contributed greatly to the development of clinical care and further research. However, there are still many challenges and difficulties in conducting clinical trials among children.[3,4] As compared to clinical trials in adults, those in pediatrics face much more serious challenges and difficulties, which may include difficulties in evaluation and enrollment of children as participants due to their high risk, lack of specialists in clinical trials, and higher cost in research and development of new products. There are also various problems in the selection of topics, design, conduct, and analyses.[3]

In some subspecialties of pediatrics, there may be some specific problems that may need special efforts. Randomized controlled trials (RCTs) for pharmacotherapies in pediatric cardiology may be a typical example. Since the results of pharmacokinetic (PK) and pharmacodynamic (PD) studies in adults cannot always be used for children who have a wide spectrum of ages, PK and PD studies for the pediatric population are needed for some research before doing the RCTs in children. Harris et al.[5] pointed out the importance of pediatric-specific guidelines (SPIRIT-C and CONSORT-C) for reporting RCTs. They also emphasized the importance of establishing meaningful core outcomes (which should be easily measurable, reproducible, and relevant to patients and caregivers) for RCTs in pediatric cardiology. There are many other challenges in RCTs for pediatric cardiology, including those in the development of methodology.

In pediatric neuro-oncology, a special working group consisting of an international panel of pediatric and adult neuro-oncologists, clinicians, radiologists, radiation oncologists, and neurosurgeons was formed to address issues and unique challenges in assessing the response of children with central nervous system tumors to various treatments. In addition to making recommendations, standards, definitions, and criteria for imaging and other response assessments, the group will also do prospective validation in clinical trials.[6] Unique challenges exist in pediatric, adolescent, and young adult patients with cancer as compared to adult patients. The challenges may derive from differences in epidemiology, prognosis,

DOI: 10.1002/ped4.12378

TABLE 1 The articles on clinical methodology published in *Pediatric Investigation* since its founding in 2017

No.	Author	Title of article	Type of article	Reference
1	Peng X, et al	Better reporting quality for improved pediatric investigation: Application of health research reporting guidelines	Commentary	8
2	Nie X, et al	Critical components for designing and implementing randomized controlled trials	Lecture	9
3	Chidambaram AG, et al	Clinical research study designs: The essentials	Lecture	10
4	Leon CS, et al	Lost in translation: Evaluating traditional Chinese medicine by western standards	Editorial	11
5	Zhaori G, et al	Better design leads to better results-Importance of virological outcome design in clinical trials for antiviral treatment of coronavirus disease 2019	Commentary	12

tumor biology, genomics, clinical features, and response to treatments.[7]

To provide useful and basic knowledge on clinical trials and other types of medical research, and to create some easy ways of questions, answers, and discussions on various topics in methodology and many other aspects of clinical investigations in pediatrics in a friendly atmosphere, we feel that we need to have a new column for articles (can be in the forms of Review, Lecture, Short Communication, and Editorial) on exchange and discussion on various issues and opinions in the fields of clinical investigations, especially on clinical trials in pediatrics. The name of this column can be a Virtual Column for Forum on Clinical Investigation. We call for manuscripts for this column. We will try to invite experienced specialists in clinical studies to contribute to this column.

We have published several articles on methodology of clinical investigation in this journal during the past 5 years (Table 1).[8-12] These may be among the most important parts of the contents of this new column's articles. Readers and authors are very welcome to ask questions and provide answers, comments, and suggestions about these articles or any issues related to clinical studies.

Pediatricians working in different settings may have different types of questions concerning clinical trials. The following questions can be seen or heard often. For example, some young pediatricians may ask: It seems that conducting a clinical trial is quite difficult, what are the factors making them difficult? Some senior pediatricians are very reluctant to plan or try to conduct clinical trials, they would rather do some case series studies. Are there any simple, easy to design and conduct clinical trials? Lack of funding is one of the challenges that hinder the broader and more popular use of RCTs. Do all clinical trials need a large amount of funds to support? What particular aspects of an RCT needs higher cost? What kinds of RCTs need higher costs? Is it possible to use a very low amount of funds to support some clinical trials to obtain clinically important and meaningful evidence and change clinical practice? Reports of pilot studies are frequently seen. Under what conditions a pilot study should be conducted? How to decide the sample size of a pilot study? What are the fundamental designing approaches for pilot studies? There are many more questions.

We look forward to our readers' and authors' active support of this column by providing manuscripts for discussion, comments, and suggestions.

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CONFLICT OF INTEREST

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How to cite this article: Zhaori G. A new column in this journal – Forum on Clinical Investigation. *Pediatr Investig*. 2023;7:147–149. https://doi.org/10.1002/ped4.12378