

• 儿童药物研究专栏 •



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创新驱动儿童药物发展，科技守护儿童用药安全

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摘要：儿童药物是近年来公众关注的热点之一。鼓励儿童药物研究开发，推进儿科药理学技术创新，加强儿童用药监测管理，对于提高儿科医疗质量、保障儿童用药安全至关重要。为提升儿童合理用药水平、引领儿科药理学技术革新、助力儿科药理学高质量发展，本期推出“儿童药物研究”专栏，分别从“儿童药物警戒”“儿童药物研究前沿技术”“儿童药物临床评价”和“综述”四大主题栏目深入探讨，以期为儿童药物研究领域同道提供临床实践参考、技术运用借鉴和研究思路拓展，为促进儿童合理用药，推动儿童药物研究提供新思路、新技术和新方法。

关键词：儿童药物研究；儿童药物警戒；儿童药物研究前沿技术；儿童药物临床评价

中图分类号：R969.3 **文献标志码：**A **文章编号：**1007-7693(2024)24-3435-05

DOI: 10.13748/j.cnki.issn1007-7693.20243623

引用本文：缪静, 舒强. 创新驱动儿童药物发展, 科技守护儿童用药安全[J]. 中国现代应用药学, 2024, 41(24): 3435-3439.

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Innovation Drives the Development of Children's Drugs, Science and Technology Safeguards the Safety of Children's Medication

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ABSTRACT: Children's medication has been one of the hot topics of public concern in recent years. Encouraging research and development of pediatric drugs, promoting technological innovation in pediatric pharmacy, and strengthening monitoring and management of pediatric medication are crucial for improving the quality of pediatric medical care and ensuring the safety of pediatric medication. In order to improve the level of rational drug use in children, lead the innovation of pediatric pharmacy technology, and assist in the high-quality development of pediatric pharmacy, this issue launches the "Children's Drug Research" column, which explores in depth from 4 major theme columns: "Children's Pharmacovigilance" "Frontier Technologies in Children's Drug Research" "Clinical Evaluation of Children's Drugs" and "Review". The aim is to provide references for clinical practice and technical application, and research ideas expansion for peers in the field of children's drug research, and to provide new ideas, technologies, and methods for promoting rational drug use in children and advancing children's drug research.

KEYWORDS: children's drug research; children's pharmacovigilance; frontier technologies in children's drug research; clinical evaluation of children's drugs

儿童不是缩小版的成人，在临床上作为一类特殊人群，其生理特点以及药动学等方面均与成人有所区别。然而，儿童专用药缺乏、儿童合理用药规范缺位、儿童药物临床评价和监测技术薄弱等一系列问题是制约儿童药物发展的瓶颈。因此，鼓励儿童药物研究开发，推进儿科药技术创新，加强儿童用药监测管理，对于提高儿科医疗质量、保障儿童用药安全至关重要。

2022—2023 年《中国现代应用药学》分别推出了“儿科药物研究”专栏^[1]和“儿童药物研究”专刊^[2]，集中刊出了高质量论文共 36 篇^[3-38]，持续收获了学科领域的良好反响和业内同道的广泛好评。为提升儿童合理用药水平、引领儿科药技术革新、助力儿科药高质量发展，2024 年再次推出“儿童药物研究”专栏，集聚多位国内相关领域的知名专家学者，分享其团队的儿童药物研究创新成果，刊出了高质量文章共 13 篇。本期“儿童药物研究”专栏分为“儿童药物警戒”“儿童药物研究前沿技术”“儿童药物临床评价”和“综述”4 个栏目。

由于特殊的生理状态，以及临床试验的缺乏，儿童往往具有较高的不良反应发生率，儿童药物警戒成为儿童药物研究的热点领域。因此，本期专栏重点设置了“儿童药物警戒”栏目，聚焦该领域的最新研究进展。基于美国 FDA 不良事件报告系统 (FDA Adverse Event Reporting System, FAERS) 数据库，浙江大学医学院附属儿

童医院朱正怡等^[39]采用比例失衡法和贝叶斯法进行不良事件信号挖掘，研究分析儿童唑类抗真菌药物的肝损伤不良事件，为临床安全使用提供参考；重庆医科大学药学院谢琴琴等^[40]基于不同的机器学习算法构建儿童抗结核药物肝损伤 (anti-tuberculosis drug induced liver injury, ATB-DILI) 风险预测模型，筛选出最佳预测模型并进行可解释性分析，探讨儿童结核病患者发生 ATB-DILI 的风险因素，构建列线图使预测结果可视化，以期儿童发生 ATB-DILI 的精准预测提供新思路；浙江大学医学院附属儿童医院黄凌斐等^[41]纳入 121 例诊断肾小球疾病的青春期前患儿，考察长期糖皮质激素应用相关身高增长障碍现状，并分析重要影响因素，探讨可能原因及干预管理策略；宁波大学附属妇女儿童医院李珊珊等^[42]同样基于 FAERS 数据库挖掘与分析新生儿使用猪肺磷脂的不良事件信号，为新生儿安全用药提供参考。

儿童药物研究的发展离不开技术方法的革新与进步。在“儿童药物研究前沿技术”栏目，针对儿童用药适口性评价方法的缺乏，首都医科大学附属北京儿童医院梅冬等^[43]以体外电子舌技术为支撑，以羧甲司坦口服溶液为评价目标药物，从原料药苦味定量评价、不同厂家产品苦味评价 2 个方面开展了口感评价研究，建立儿童用药适宜的体外适口性评价方法，为临床根据口感选择儿童用药提供参考依据；针对炎症性肠病 (inflammatory bowel disease, IBD) 患儿服药依从

性不良问题,浙江大学医学院附属儿童医院叶伟峰等^[44]在分析并明确患儿服药依从性风险因素的基础上,采用列线图模型构建 IBD 患儿服药依从性风险预测模型,为筛查用药不依从高风险人群及进一步实施依从性干预奠定基础;针对部分高危组儿童神经母细胞瘤 (neuroblastoma, NB) 患者对现行化疗方案耐药、亟须开发新靶点药物的问题,大连市妇女儿童医疗中心 (集团) 刘天一等^[45]借助计算机辅助药物的虚拟筛选技术,以间变性淋巴瘤激酶 (anaplastic lymphoma kinase, ALK) 为靶点筛选儿童 NB 的靶向治疗药物,从中药天然产物数据库中筛选新型潜在 ALK 抑制剂,大幅提高验证效率,更为治疗 NB 提供新的药物选择;在治疗药物监测研究领域,河北医科大学武佳璇等^[46]致力于为儿童癫痫常用治疗药物拉考沙胺开发更为快速、简便、稳定、经济的血药浓度测定方法,建立了基于同位素稀释-超高效液相色谱-四极杆/静电场轨道阱高分辨质谱技术 (UPLC-Q-Exactive-MS) 同时测定癫痫患儿血浆中拉考沙胺和代谢物去甲拉考沙胺浓度的方法,为临床开展拉考沙胺用药患儿的治疗药物监测和药动学研究提供先进的技术手段和研究基础。

尽管儿童用药品种仍较为匮乏,但在国家政策的大力支持下,近年来治疗儿童疾病的新药在国内上市和儿童适应证扩展的速度有所提升,而相应新药在儿童患者中的临床评价亟须推进。在“儿童药物临床评价”栏目中,涉及了 2 种近年上市的代表性儿童药物。第 1 种是氨己烯酸,它是 2022 年在中国上市的、针对婴儿痉挛症的一线治疗药物,但该药具有特殊不良反应,特别是不可逆的视野缺损,为临床应用带来挑战。南京医科大学附属儿童医院王洁等^[47]通过对国内外研究进行梳理,特别是对氨己烯酸的作用机制、给药方案、有效性、安全性、药动学以及影响暴露水平的因素等进行总结和讨论,为婴儿痉挛症患者合理应用氨己烯酸提供重要依据。第 2 种是玛巴洛沙韦,作为一种全新的抗流感病毒药物,玛巴洛沙韦具有独特的作用机制,是近 20 年来首次推出的抗流感新药。该药片剂于 2021 年在中国上市,2023 年获批用于治疗 ≥ 5 岁的儿童流感患者,2024 年更适合低龄儿童的混悬剂上市,作为流感高发群体的儿童治疗有了更多的新选择。沈阳药科大学刘洋君等^[48]从中国卫生体系视角出

发,基于 1 项玛巴洛沙韦 III 期临床试验构建决策树模型,模拟玛巴洛沙韦和奥司他韦治疗小儿流感患者的治疗过程,采用成本-效果分析计算增量成本-效果比,并通过旋风图、蒙特卡洛模拟进行敏感性分析。研究发现,与奥司他韦疗法相比,玛巴洛沙韦治疗 1~12 岁小儿流感患者的经济性更好,为临床用药选择提供有益参考。

为关注儿童重大疾病的靶向药物治疗研究进展,本期专栏设置了“综述”栏目。其中,浙江大学医学院附属儿童医院贾婷婷等^[49]系统总结了儿童神经母细胞瘤的潜在靶点以及研究中的小分子靶向药物;浙江大学临床药学研究中心潘洪爱等^[50]重点梳理了 JAK 抑制剂在儿童免疫性疾病和血液系统疾病中的研究进展;绍兴市妇幼保健院周萍等^[51]全面介绍了 FLT3 型酪氨酸激酶抑制剂在儿童急性髓系白血病中的治疗应用。

本期专栏文章汇聚了多家国内知名医疗机构和高校院所的药学、临床、基础领域专家团队的研究成果,具备较好的实用性、创新性和引领性,希望为广大儿童药物研究领域同道提供临床参考、技术借鉴和研究拓展,为促进儿童合理用药,推动儿童药物研究提供新思路、新技术和新方法。

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收稿日期: 2024-11-25

(本文责编: 陈怡心)