

# Addressing Drug-Related Side Effects in Children With Congenital Heart Disease: A Policy Brief

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## Background

Congenital Heart Disease (CHD) impacts roughly 1% of newborns worldwide, necessitating multifaceted treatment strategies that often include medication therapy.<sup>1</sup> However, dose-dependent medications in patients with CHD raise the risk of drug-related side effects, posing significant challenges to effective medication management.<sup>2</sup> Common medications used in children with CHD include diuretics, anti-arrhythmic, ACE inhibitors, beta-blockers, and anticoagulants, each of these plays a crucial role in managing heart function, but also comes with potential side effects.<sup>3</sup>

Diuretics like Furosemide help to manage fluid overload, but can also cause dehydration and electrolyte imbalances, leading to potential kidney issues. Anti-arrhythmic drugs such as Digoxin support heart function, but carry risks of toxicity, which can manifest as nausea, or vomiting. ACE inhibitors like Enalapril reduce blood pressure and heart strain, but may cause hypotension, kidney dysfunction, and hyperkalemia. Beta-blockers like Propranolol manage arrhythmias, but can lead to bradycardia, fatigue, respiratory issues, and limit physical activity. Anticoagulants such as Warfarin prevent clots, but increase bleeding risk, necessitating regular blood monitoring.<sup>3,4</sup> These side effects can significantly impact a child's quality of life, leading to frequent hospital visits, stress, and reduced medication adherence. The need for ongoing monitoring and the potential for complications also place a substantial burden on healthcare systems, particularly in resource-limited settings.<sup>4</sup> Addressing these drug-related side effects in children with CHD is critical. A comprehensive approach involving personalized dosing, careful monitoring, and patient education is essential to mitigate risks and improve outcomes, thereby reducing the overall strain on both families and healthcare systems.<sup>4</sup>

This policy brief helps to generate clinical protocols specifically for the pediatric patients with CHD. The target audiences are health managers, policy makers, and

healthcare professionals involved in the care of these patients. By providing evidence-based recommendations tailored to the clinical settings, the brief aims to influence and enhance practices within healthcare institutions to ensure safer and more effective medication management.

The brief underscores the importance of addressing medication-related challenges in CHD management by highlighting the prevalence and impact of these issues. Effective medication management is paramount for improving outcomes and reducing complications in children with CHD. By presenting evidence-based policy options such as standardized protocols, electronic health record utilization, personalized dosing adjustments, patient education, and specialized care teams, policymakers can be more effective in implementing measures to enhance medication management and improve health outcomes for children with CHD.

## Analysis

The analysis underpinning this policy brief is based on the evidence derived from a comprehensive scoping review,<sup>4</sup> which focused on drug-related side effects in children with CHD. This scoping review was conducted using the framework proposed by Arksey and O'Malley<sup>5</sup> and the PRISMA-ScR guidelines. The review aimed to investigate ADRs in children with CHD.

A systematic search was conducted without timeframe limitations, covering studies published up to November 1, 2023. Inclusion criteria were strictly set to capture studies reporting drug-related side effects in children with CHD,

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and non-English studies, research focused on adults, and studies unrelated to CHD or drug side effects were excluded. The results of this review were critically analyzed to identify the key challenges and gaps in medication management for this vulnerable population.

The evidence derived from the scoping review directly informed the formulation of the policy options presented in this brief. The analysis underpinning this policy brief incorporates evidence from studies conducted across low, middle, and high-income countries. This global approach ensures that the findings and recommendations are applicable to a diverse range of healthcare settings. Each policy recommendation was derived from the identified drug-related side effects and their implications for health outcomes.

## Policy Implications

To address the complexities of medication management for children with CHD, the following policy options are proposed to improve outcomes, reduce side effects, and enhance the overall quality of care. Each option is evaluated based on its expected impact, anticipated costs, and the pathways for successful implementation (Table 1). These options are critical to guiding health policymakers, hospital managers, and healthcare professionals in making informed decisions.

### *Options 1: Establishing Standardized Protocols*

Standardized protocols are anticipated to significantly reduce medication errors, streamline care processes, and improve the consistency of care across different healthcare facilities. This will likely lead to better health outcomes and reduce complications for children with CHD. The initial costs will include the development of protocols, training of healthcare professionals, and ongoing updates to maintain protocol relevance. However, long-term cost savings are expected due to the reduction in complications and hospital readmissions. Successful implementation requires collaboration between healthcare organizations, professional bodies, and clinicians. These stakeholders should ensure that protocols are culturally sensitive and adaptable to local contexts. Regular monitoring and updates are essential to maintain the effectiveness of these protocols.

### *Options 2: Using EHRs*

EHRs offer a centralized platform for tracking a child's medication use, interactions, and side effects. The use of EHRs will facilitate comprehensive tracking of medication use, interactions, and side effects, improve communication among healthcare providers and support making informed decisions. This is expected to reduce

medication-related errors and improve patient outcomes. Significant upfront investments are required for software development, implementation, information technology infrastructure, and staff training. Ongoing costs will include maintenance and data security measures. EHR implementation requires strong IT support and training programs to ensure that all healthcare providers can effectively use the system. Policymakers must address potential disparities in access to EHRs by ensuring that all healthcare facilities, regardless of resource availability, can implement and maintain these systems.

### *Options 3: Personalized Dosing Adjustments*

Personalized dosing adjustments can significantly reduce drug-related side effects and improve treatment efficacy by tailoring medication dosages to individual patient needs. This approach is expected to enhance the precision of care and overall health outcomes. Personalized dosing requires increased monitoring, frequent consultations, and potentially higher initial costs. However, these costs may be offset by long-term savings from reduced side effects and hospitalizations. Implementation demands the integration of personalized dosing into routine clinical practice, supported by continuous training and updated clinical guidelines. Equity considerations must be addressed to ensure that all children with CHD, regardless of socioeconomic status, have access to necessary monitoring and personalized care.

### *Options 4: Patient Education and Shared Decision-Making*

Educating patients and caregivers through patient education and shared decision-making will empower them to participate in medication management actively leading to better health outcomes. This collaborative approach is anticipated to reduce the burden on healthcare systems by minimizing unnecessary hospital visits. Developing and delivering educational programs require significant resources, including the creation of culturally and linguistically appropriate materials. The cost-effectiveness of this approach depends on the successful engagement of patients and caregivers. Healthcare professionals must integrate education into routine care, ensuring that materials are accessible and relevant to diverse patient populations. Collaboration with patient advocacy groups and the use of digital platforms can enhance the reach and impact of educational initiatives.

### *Options 5: Specialized Cardiology-Pharmacotherapy Teams*

The formation of specialized cardiology-pharmacotherapy teams is expected to optimize medication management, reduce complications, and improve long-term

**Table 1. Summary of the Policy Options.**

Policy options		Using EHRs	Personalized dosing adjustments	Patient education and shared decision-making	Specialized cardiology-pharmacotherapy teams
Criteria	Establishing standardized protocols	Using EHRs	Personalized dosing adjustments	Patient education and shared decision-making	Specialized cardiology-pharmacotherapy teams
Main advantages	<ul style="list-style-type: none"> <li>- Provides consistent care across healthcare facilities minimizing errors and improves the identification and management of side effects</li> <li>- Reduces variability in treatment approaches, enhancing the overall quality of care<sup>6</sup></li> <li>- Requires initial investment in development and training</li> <li>- Limited flexibility for individual variations, potentially restricting personalized care</li> <li>- May require ongoing updates to maintain relevance<sup>6</sup></li> </ul>	<ul style="list-style-type: none"> <li>- Centralized platform for tracking a child's medication use, interactions, and side effects, improving communication among healthcare providers and enabling informed decisions</li> <li>- Streamline care coordination<sup>7</sup></li> <li>- High upfront costs for software, implementation, and maintenance</li> <li>- Data security concerns are significant, necessitating robust cyber-security measures</li> <li>- Potential challenges in the adaptation and use of the new systems<sup>11</sup></li> <li>- High initial cost for software development, implementation, and maintenance</li> <li>- Feasibility depends on the availability of robust IT infrastructure and adequate training for providers</li> <li>- Acceptability varies based on provider familiarity with EHRs</li> </ul>	<ul style="list-style-type: none"> <li>- Tailors medication dosage to individual patient needs, reducing side effects and improving treatment effectiveness</li> <li>- Enhances the precision of care by considering patient-specific factors<sup>8</sup></li> <li>- Requires increased monitoring and potentially more frequent consultations, leading to higher costs initially</li> <li>- Demands more time and expertise from healthcare providers</li> <li>- Socioeconomic disparities may impact access to necessary monitoring tests<sup>8</sup></li> <li>- Costs for additional monitoring and consultations may be offset by long-term savings from reduced side effects</li> <li>- High acceptability among healthcare providers, though it requires significant time and expertise</li> </ul>	<ul style="list-style-type: none"> <li>- Empowers patients and caregivers to actively participate in medication management, leading to better medication adherence and improved health outcomes</li> <li>- Encourages shared responsibility in care<sup>9</sup></li> <li>- Developing educational programs requires significant resources</li> <li>- Effectiveness depends on the age and understanding of the child</li> <li>- Language barriers and accessibility of resources pose additional challenges<sup>12</sup></li> <li>- Costly in terms of developing and delivering educational materials and programs</li> <li>- High acceptability among families, but effectiveness may be hampered by language barriers and disparities in access to resources</li> </ul>	<ul style="list-style-type: none"> <li>- Combines the expertise of cardiologists and pharmacotherapists to provide comprehensive care and optimize medication management for children with CHD</li> <li>- Facilitates multidisciplinary collaboration<sup>10</sup></li> <li>- Requires investment in team formation, training, and ongoing support</li> <li>- Geographical disparities may limit access to the professionals, particularly in remote or underserved areas<sup>10</sup></li> <li>- High initial investment in establishing teams, training, supporting, and ongoing operations</li> <li>- Long-term cost savings is anticipated through improved care and reduced complications</li> <li>- Feasibility depends on strategic placement to ensure geographical accessibility</li> </ul>
Main disadvantages	<ul style="list-style-type: none"> <li>- Requires upfront costs for protocol creation, training, and implementation</li> <li>- Long-term savings are possible due to improved outcomes and reduced complications</li> <li>- High acceptability among healthcare providers due to the clear benefits</li> </ul>	<ul style="list-style-type: none"> <li>- Potential disparities in access to EHR systems across different facilities, especially in resource-limited settings</li> <li>- Must ensure comprehensive data inclusion for all children with CHD, regardless of the facility they visit</li> <li>- Healthcare organizations must implement and maintain EHR systems</li> <li>- Healthcare professionals require training to utilize EHRs effectively</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic disparities could impact access to necessary monitoring and personalized care</li> <li>- Policies need to be designed with an emphasis on accessibility for all children with CHD</li> <li>- Physicians are responsible for tailoring medication regimens to individual needs, with active involvement from patients and caregivers</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>	<ul style="list-style-type: none"> <li>- Healthcare organizations are responsible for establishing specialized teams</li> <li>- Cardiologists and pharmacotherapists provide the necessary care and coordinate efforts within the team</li> </ul>
Cost and feasibility of implementation	<ul style="list-style-type: none"> <li>- Ensures consistent care across all populations, with attention to cultural sensitivity and inclusivity in protocol development and implementation</li> <li>- Healthcare organizations and professional are responsible for protocol development and dissemination</li> <li>- Healthcare professionals are tasked with integrating these protocols into practice</li> </ul>	<ul style="list-style-type: none"> <li>- Potential disparities in access to EHR systems across different facilities, especially in resource-limited settings</li> <li>- Must ensure comprehensive data inclusion for all children with CHD, regardless of the facility they visit</li> <li>- Healthcare organizations must implement and maintain EHR systems</li> <li>- Healthcare professionals require training to utilize EHRs effectively</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic disparities could impact access to necessary monitoring and personalized care</li> <li>- Policies need to be designed with an emphasis on accessibility for all children with CHD</li> <li>- Physicians are responsible for tailoring medication regimens to individual needs, with active involvement from patients and caregivers</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>
Equity considerations	<ul style="list-style-type: none"> <li>- Ensures consistent care across all populations, with attention to cultural sensitivity and inclusivity in protocol development and implementation</li> <li>- Healthcare organizations and professional are responsible for protocol development and dissemination</li> <li>- Healthcare professionals are tasked with integrating these protocols into practice</li> </ul>	<ul style="list-style-type: none"> <li>- Potential disparities in access to EHR systems across different facilities, especially in resource-limited settings</li> <li>- Must ensure comprehensive data inclusion for all children with CHD, regardless of the facility they visit</li> <li>- Healthcare organizations must implement and maintain EHR systems</li> <li>- Healthcare professionals require training to utilize EHRs effectively</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic disparities could impact access to necessary monitoring and personalized care</li> <li>- Policies need to be designed with an emphasis on accessibility for all children with CHD</li> <li>- Physicians are responsible for tailoring medication regimens to individual needs, with active involvement from patients and caregivers</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>
Stakeholders' responsibilities	<ul style="list-style-type: none"> <li>- Healthcare organizations and professional are responsible for protocol development and dissemination</li> <li>- Healthcare professionals are tasked with integrating these protocols into practice</li> </ul>	<ul style="list-style-type: none"> <li>- Potential disparities in access to EHR systems across different facilities, especially in resource-limited settings</li> <li>- Must ensure comprehensive data inclusion for all children with CHD, regardless of the facility they visit</li> <li>- Healthcare organizations must implement and maintain EHR systems</li> <li>- Healthcare professionals require training to utilize EHRs effectively</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic disparities could impact access to necessary monitoring and personalized care</li> <li>- Policies need to be designed with an emphasis on accessibility for all children with CHD</li> <li>- Physicians are responsible for tailoring medication regimens to individual needs, with active involvement from patients and caregivers</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>	<ul style="list-style-type: none"> <li>- Socioeconomic factors and language barriers may limit access to educational resources</li> <li>- Educational materials should be culturally sensitive and available in multiple languages to ensure inclusivity</li> <li>- Healthcare professionals are responsible for delivering education</li> <li>- Patient advocacy groups should develop and disseminate materials, while families must actively participate in the educational process</li> </ul>

Abbreviations: EHR, Electronic Health records; CHD, Congenital Heart Disease; IT, Information Technology.

outcomes for children with CHD by combining the expertise of cardiologists and pharmacotherapists. The formation of these teams involves significant initial investment in training and ongoing support. However, long-term savings are expected through the reduction of complications and hospital readmissions. The success of this policy option hinges on the strategic placement of teams across various regions to ensure equitable access. Healthcare organizations must invest in the formation and continuous support of these teams, with a focus on ensuring accessibility for all children with CHD, regardless of geographic or socioeconomic barriers.

### Further Important Considerations and Research Recommendations

Important considerations for the implementation of policy options to improve medication management for children with CHD include robust monitoring and evaluation mechanisms to track implementation effectiveness, identifying barriers and facilitating factors, establishing a timeline for updates, and planning for next steps such as the development of additional educational resources. Monitoring should focus on key performance indicators like adherence to standardized protocols and utilization of EHRs. Overcoming barriers like resource constraints and disparities in access requires strategies like stakeholder engagement and cultural competence training. Regular updates to the policy brief ensure relevance and responsiveness to evolving healthcare landscapes.

Gaps in knowledge underscore the need for further research to inform evidence-based practice in CHD care. Studies should explore personalized dosing strategies, the potential of analyzing personal health records, and the long-term effects of chronic medication use. Additionally, investigating the role of advanced technologies, such as mobile health applications, could enhance adherence and monitoring. These efforts will collectively improve medication management, ultimately benefiting the health and well-being of children with CHD. Overall, systematic implementation coupled with ongoing adaptation and collaboration among stakeholders will maximize the impact of policy options on improving medication management and health outcomes for children with CHD.

### Author Contributions

**Esmael Toni:** Writing original draft, Review & Editing.

**Haleh Ayatollahi:** Writing, Review & Editing, Supervision.

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