

Best Pharmaceuticals for Children Act (BPCA) Priority List of Needs in Pediatric Therapeutics

The National Institutes of Health (NIH) hereby announces the BPCA Priority List of Needs in Pediatric Therapeutics for 2011.

Update on BPCA Prioritization

The BPCA requires that the NIH identify the drugs of highest priority for study in pediatric populations. Part of the NIH mandate under the BPCA is to publish a list of drugs/needs in pediatric therapeutics. The first priority list of off-patent drugs needing further study under the 2002 BPCA legislation was published in January 2003 in the Federal Register (FR Vol. 68, No. 13; Tuesday, January 21, 2003: 2789-2790). After the BPCA reauthorization in 2007, a revised priority list of needs in pediatric therapeutics was published in April 2009 (FR Vol. 74, No. 70; Tuesday, April 14, 2009: 17203-17205) and revised in September 2009 (<http://bpca.nichd.nih.gov/about/process/upload/2009-Summary-091509-1-rev.pdf>). The legislation mandates that the NIH update the priority list every 3 years; this publication serves as an update to the BPCA priority list of needs in pediatric therapeutics.

In the transition from prioritizing drugs to prioritizing therapeutic needs, several changes have been implemented over the last year in refining the prioritization process. These include: the need for more up-front input to gather information on preliminary drugs (for example, information on frequency of use and frequency of condition) as well as expert input; a better approach for mass outreach; enhancement of NIH interagency collaborations; and improvement in the overall prioritization process.

The revised process includes:

- A systematic approach with clear objectives and outcomes
- Well-defined, objective criteria that are mutually exclusive and a of manageable number
- A dynamic process, including transparency, stakeholder input, and leadership
- Expert involvement to inform and contribute to the process.

For 2010, nominations for the BPCA Priority List of Needs in Pediatric Therapeutics were solicited through a Request for Information (RFI) announcement as a part of fulfilling the NIH's authority and responsibility to establish a program for pediatric drug testing and development as outlined in the BPCA legislation. The BPCA Priority List consists of key therapeutic needs in the medical treatment of children and adolescents; it is organized by therapeutic area, which can be a group of conditions, a subgroup of the population, or a setting of care. Each calendar year, a few therapeutic areas are selected for discussion and further prioritization. Below is a summary of the revised BPCA prioritization process:

- In early 2010, the RFI was issued to solicit nominations for future studies of pediatric therapeutics under BPCA.
- The *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Obstetric and Pediatric Pharmacology Branch received 107 nominations, 67 of which met the criteria for review.

- All nominations were reviewed and evaluated on six key criteria, as follows:
 - Relevant to BPCA mission and goals
 - No disqualifying ethical concerns
 - Evidence: consideration of the level of evidence available and current gaps
 - Impact: potential effect on children, society, and delivery of care
 - Population: consideration of the different populations that may benefit from the research
 - Feasibility: consideration of the resources available to conduct the study.
- Twenty-two volunteer health professionals scored the 67 nominations according to evidence, impact, and the pediatric population affected. Each nomination was reviewed by a panel of three evaluators.
- Therapeutic area working groups were developed and met throughout 2010 to discuss the gaps in knowledge in the therapeutic approaches to diseases in gastroenterology, endocrinology, and neurology.
- Minutes of all working group meetings conducted under the BPCA can be found on the BPCA Web site (<http://bpca.nichd.nih.gov>).
- As a final step in the process, the NICHD, with input from the U.S. Food and Drug Administration (FDA), ranked the nominations based on the evaluators' scores, quality and quantity of existing studies, and feasibility of the proposed study. The result was a tiered list of nominations considered for prioritization. Tier One represents the highest percentage of scores: nominations of interest to the NICHD for prioritization. Tier Two represents the average percentage of scores: nominations of possible interest to the NICHD at a later time. Tier Three represents the lowest percentage of scores: nominations of least interest to the NICHD at this time for prioritization.

The NICHD sponsored the BPCA Annual Prioritization Meeting, held November 9–10, 2010, with stakeholders from the NIH, the FDA, the American Academy of Pediatrics and other pediatric organizations and societies, and patient advocates. The meeting allowed the NICHD to review the present progress from ongoing research and to discuss the proposed therapeutic areas from the 2010 nominations to be prioritized for future study under the BPCA and added to the existing BPCA priority list.

Below is an updated list of therapeutic areas and drugs that have been prioritized for study since the inception of the BPCA, which includes new areas of prioritization from Tier One nominations of the 2010 outreach, and a summary of the NICHD's plans and progress in all of these areas.

Priority List of Needs in Pediatric Therapeutics 2011

In accordance with the BPCA legislation, the following list outlines priority needs in pediatric therapeutics for the therapeutic areas listed below.

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Table 1. Infectious Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Methicillin-resistant <i>Staphylococcus aureus</i> (MRSA) infections	Clindamycin	Optimal therapy and management of community-acquired skin and soft tissue infections	Pharmacokinetics (PK), safety, and efficacy clinical studies	Pediatric study under consideration by the Pediatric Trials Network (PTN)
	Trimethoprim-sulfamethoxazole	Biomarkers of disease	PK and efficacy (comparison) studies	Pediatric study under consideration by the PTN
Infections	Benzathine penicillin-G	Dosing in relation to body size	PK, safety, and efficacy clinical studies	Pediatric study under consideration by the PTN
	Acyclovir	Dosing, efficacy, and safety in infants and children with herpetic infections	PK, safety, and efficacy clinical studies	Pediatric study under consideration by the PTN
	Doxycycline	PK, safety in children younger than 8 years	PK, safety, and efficacy clinical studies	Pediatric study under consideration by the PTN
Tinea capitis	Griseofulvin	Safety and efficacy of higher doses in children <20 kg with tinea capitis	PK, efficacy, and safety of higher doses in young children	Written Request (WR) received from FDA; pediatric study under consideration by the PTN
Antituberculous (TB) drugs	No specific drug	Safety and efficacy; formulations	New efficacy studies for global health, formulations	NIH-FDA Formulations Platform Initiative 2010–2012
Antiparasitic drugs	Albendazole	PK, safety, and efficacy for Toxocara infections	New efficacy studies for global health, formulations	NIH-FDA Formulations Platform Initiative 2010–2012
Influenza	Oseltamivir	Pharmacoepidemiology data	Impact on clinical outcomes in hospitalized children with influenza	Current NICHD grant funding

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 2. Cardiovascular Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Hypertension	Hydrochlorothiazide	PK, safety, and efficacy in obese adolescents	Comparison studies, PK studies	WR received from FDA; pediatric study under consideration by the PTN
	Beta blockers	PK, safety, and efficacy in obese adolescents	Comparison studies, PK studies	Pending
	Lisinopril	PK in children with kidney transplant	PK, safety, and efficacy clinical studies; formulations	Pediatric study under consideration by the PTN
	Amlodipine	PK in children with kidney transplantation, formulations	PK, safety, and efficacy clinical studies	Pediatric study under consideration by the PTN
Hypotension	Sodium nitroprusside	PK, safety, and efficacy	PK, short- and long-term safety and efficacy trials for controlled hypotension	WR received from FDA; both clinical trials completed, data analyses ongoing; clinical study report (CSR) to FDA Summer 2011
	Dopamine	Outcome measures in neonates and children treated for hypotension	Defining outcome measures	Collaborating with existing NICHD networks (Neonatal Research Network)
Dyslipidemia	Statins	Risk/benefit profile of long-term use in children	Novel study designs, use of surrogate markers for determining the value of long-term statin use in children	Pending

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Table 3. Respiratory Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Asthma	Asthma therapeutics in young children	Objective measures of lung function and responses to therapy in children younger than 4 years	Standardization of outcome measures in research Identification of barriers to implementation of guidelines for asthma treatment	Trans-NIH and trans-U.S. Department of Health and Human Services collaborations Meeting on Asthma Outcome Measures held March 2010 Meeting on asthma disparities held December 2010.
	Drug delivery systems	Effectiveness of drug delivery systems used in children	Use of hydrofluoroalkanes (HFAs) with inhaled corticosteroids in children younger than 4 years	Pending
	Albuterol	Dose response, safety, and efficacy	Safety, efficacy, and appropriate mode of delivery in children in acute care settings	NICHD Collaborative Pediatric Critical Care Network data collection
Pulmonary hypertension	No specific drug	Treatment strategies in children with pulmonary hypertension of differing etiologies (idiopathic versus secondary)	Outcome measures in children	Pending

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Table 4. Intensive Care Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Anesthesia/sedation	Ketamine	Safety	Preclinical and clinical studies of short- and long-term effects	Preclinical studies under way with FDA/ National Center for Toxicological Research (NCTR)
	Inhaled anesthetics/isoflurane	Toxicity of inhaled anesthetics in developing brains	Identification of markers of apoptosis	Preclinical models, <i>in vitro</i> studies
	Lorazepam	Dosing, safety	PK, safety, and efficacy trial comparing lorazepam with midazolam for sedation	WR received from FDA; clinical trial completed; CSR for submission to FDA Spring 2011

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Table 5. Bio-defense Research Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Nerve agent exposure	Drug delivery systems	Need for pediatric auto-injectors		Pending
	Midazolam	Dosing studies for treatment of seizures related to exposure	PK studies	Trans-NIH collaborations
Cyanide toxicity	Hydroxycobalamine	Dosing and effectiveness in inhalation injuries suffered during fires	Safety and efficacy	Pediatric study under consideration by the PTN; real-time cyanide assay under development with the National Institute of Neurological Disorders and Stroke (NINDS)
Organophosphate poisoning	Pralidoxime	Dosing and safety		Label changed September 2010

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Table 6. Pediatric Cancer Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Neuroblastoma	13-cis-retinoic acid	New indication for neuroblastoma, pediatric formulation	PK studies, new formulation	Proposed Pediatric Study Request negotiated with FDA; WR received from FDA; collaboration with National Cancer Institute (NCI)/Children's Oncology Group (COG)
Leukemias and solid tumors	Methotrexate	Safety studies	Neurocognitive outcomes in young children with high-risk acute lymphoblastic leukemia	WR received from FDA; collaborations with NCI/COG; clinical trial ongoing
	Vincristine	PK and safety studies	PK modeling and safety studies to evaluate for neurotoxicity	WR received from FDA; collaborations with NCI/COG; clinical trial ongoing; Clinical and Translational Science Awards (CTSA) administrative supplement
	Daunomycin	PK studies	PK studies in children with elevated body mass index	WR received from FDA; collaborations with NCI/COG; study completed, CSR to FDA Spring 2011
	Actinomycin-D	PK and safety studies	PK modeling and simulation, data mining for safety (hepatotoxicity)	WR received from FDA; collaborations with NCI/COG; clinical trial ongoing
	6-mercaptopurine	Formulations		NIH-FDA Formulations Platform

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 7. Psychiatric Disorder Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Attention deficit and hyperactivity disorder (ADHD)	Methylphenidate	Safety and toxicity		Preclinical and clinical studies are ongoing with NCTR and the National Institute of Environmental Health Sciences
Bipolar disease	Lithium	PK, safety, and efficacy	Dosing and tolerance, short- and long-term safety	WR received from FDA; PK data submitted to FDA January 2010; safety and efficacy clinical trial ongoing
Psychosis, aggression	Atypical antipsychotics	Long-term safety—metabolic derangements	Comparative long-term safety, epidemiology research on frequency of use	Translational research; outpatient epidemiology research effort under development

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 8. Neurological Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Cerebral palsy	Baclofen (oral)	PK, safety, and efficacy	PK and efficacy, pediatric formulation	WR received from FDA; clinical trial completed; CSR to FDA Spring 2011
	Propranolol	Efficacy in prophylaxis	Efficacy in migraine prevention	Pending
	Amitriptyline	Efficacy in prophylaxis	Efficacy in migraine prevention	Pending
Seizures	Lorazepam	PK, safety, and efficacy	PK, safety, and efficacy in treating status epilepticus	WR received from FDA; PK trial data submitted to FDA February 2009; safety and efficacy clinical trial under way
	Fosphenytoin	PK, safety	PK, safety in treating seizures in young children	Pending

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Table 9. Neonatal Research Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Neonatal bronchopulmonary dysplasia (BPD)/lung development	Betamethasone	Dosing, efficacy	Determination of dosing and effectiveness	Reviewing existing data; current NICHD grant funding
	Azithromycin (IV)	Dosing, efficacy	PK, efficacy in treating ureaplasma infections to prevent BPD	WR received from FDA; current NICHD grant funding
	Hydrochlorothiazide	Dosing, safety, and efficacy	Determination of dosing and effectiveness	Collaborations with the National Heart, Lung, and Blood Institute network data collection
Neonatal pain	Morphine	Pain	Optimization of dosing and biomarkers of pain in neonates	Current NICHD grant funding
Neonatal abstinence syndrome (NAS)	Methadone	PK, safety	Treatment strategies of NAS in opioid-exposed neonates	CTSA administrative supplement
Infections in neonates	Metronidazole	PK and efficacy in neonates with abdominal infections	PK study	Pediatric study under consideration by the PTN
	Ampicillin	PK and safety in very low birth weight neonates	PK, safety clinical studies	WR received from FDA; pediatric study under consideration by the PTN
Neonatal necrotizing enterocolitis (NEC)	Meropenem	PK, safety in neonates		WR received from FDA; clinical PK and safety trial completed; CSR to FDA Spring 2011

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 10. Adolescent Research Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Over-the-counter drug use	No specific drug	Health literacy		December 2007 symposia
Adolescent pharmacology	No specific drug	Effects of puberty on PK/pharmacodynamics, adherence, and formulations research	Translational research, need to include adolescents in clinical trials	Pending

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 11. Hematologic Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Sickle cell anemia	Hydroxyurea	Safety and efficacy in young children	PK, safety, and efficacy Oral formulation for children	WR received from FDA; BABY HUG trial completed in children 9–17 months of age, CSR in preparation; long-term safety follow-up study under way; PK and bioequivalence study under development
Thrombosis and thromboprophylaxis	No specific drug	Treatment and prevention of childhood strokes and venous/arterial thrombosis		Pending

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 12. Endocrine Disease Priorities and Diseases with Limited Alternative Therapies

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Fragile X	MGluR5 antagonists	Outcome measures targets for intervention	Development of MGluR5 antagonists to treat Fragile X	Development of new therapeutics cofunded with NINDS; clinical research under way
Type 1 diabetes	No specific drug	Immunomodulatory therapies	Development of novel immunomodulatory therapies for children with type 1 diabetes	Collaborations with existing NIH networks

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 13. Dermatologic Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Atopic dermatitis	Hydrocortisone valerate	Effects on growth and hypothalamic-pituitary-adrenal axis suppression	Long-term safety data in children younger than 2 years	Pending
Severe inflammatory skin disease	Methotrexate	Dosing, efficacy, and safety	Safety and efficacy in treatment of severe inflammatory disease	Pending

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 14. Gastrointestinal Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Gastroesophageal reflux	Prokinetic drugs	New drugs; dosing, safety, and efficacy of existing drugs in neonates and infants	Effectiveness and outcome measures in young children	Pending
	H2 blockers	Dosing and efficacy data	Safety and effectiveness in infants	Pending
Cyclic vomiting and weight gain	Cyproheptadine	Dosing, efficacy, and safety		Pending
Cholestatic disease	Ursodeoxycholic acid	Safety and efficacy in young children		Pending

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 15. Renal Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Chronic kidney failure	Devices used in dialysis	Drug distribution, elimination, and accumulation in continuous renal replacement therapy	Device validation studies in children on chronic renal replacement therapy	Pending
Anemia of chronic kidney disease	Agents to stimulate erythropoiesis	Optimal PK, efficacy, and safety	Appropriate dosing and outcome measures in children with chronic kidney disease	Pending

Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 16. Rheumatologic Disease Priorities

Current or Proposed Listed Therapeutic Area	Current or Proposed Listed Drug	Gaps in Knowledge/ Labeling	Type of BPCA Study and/or Scientific Needs	Plans and Progress
Connective tissue disorders	Hydroxychloroquine	PK and safety in children with juvenile idiopathic arthritis	PK, safety studies	Pending

Drug and indications in **bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 17. Special Considerations

Area of Consideration	Identified Therapeutic Area	Gaps in Knowledge/Labeling	Type of Study and/or Scientific Needs
Therapeutics in children with intellectual and developmental disabilities	No specific drug or indication	Identification of differences in drug disposition and response, including safety and efficacy outcome measures	Need for routine inclusion in clinical trials
Pediatric formulations	Multiple drugs and indications: Infectious diseases: HIV: antiretrovirals Tuberculosis: isoniazid Trypanosomiasis: benznidazole, nifurtimox Parasitic infections: albendazole Malaria: mefloquine, sulfadoxine-pyrimethamine, chlorproguanil-dapsone Hematology: hydroxyurea Oncology: 6-mercaptopurine, methotrexate, prednisone, isotretinoin Spasticity: baclofen Hypothyroidism: l-thyroxine	Taste-masking technologies Orally dissolvable dosage forms that do not require water Heat-stable and light-stable dosage forms Safety data for excipients	Improving the technology and designs of child-friendly/easy-to-swallow dosage forms of drugs to improve adherence and effectiveness NIH-FDA Formulations Platform
Pediatric devices	General Issues	Need for validation of existing devices used in children	Pending

	Neonatal hypoxic ischemic encephalopathy (HIE) Increased intracranial pressure Sleep disordered breathing	Brain cooling in conjunction with neuroprotective drugs to prevent HIE Cerebrospinal fluid (CSF) shunts Continuous positive airway pressure (CPAP) and nasal devices	Comparison study of the effectiveness of brain-cooling devices with drugs Improved designs for CSF shunts for hydrocephalus Development of home-based nasal devices and CPAP machines for positive pressure ventilation in toddlers and infants
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Drug and indications **in bold** are newly added to the BPCA list from the 2010 prioritization process or other sources identified by NICHD as a priority.

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Table 18: Current List of Drugs Evaluated for BPCA Listing and Being Considered for Future Prioritization (Tier Two)

Drug	Indication	Year evaluated
Erythropoietin	Neonatal brain injury	2010
Bevacizumab	Retinopathy of prematurity	2010
CC10, a novel anti-inflammatory agent	BPD long-term outcomes	2010
Gastrojejunal feeding tubes with larger jejunal port	Short gut syndrome	2010
Miralax	Treatment of constipation in young children	2010
Megestrol	Weight gain in children	2010
Cellular cardiac patch	Repair of congenital heart defects	2010
Aspirin vs. low molecular weight heparin	Stroke	2010
Sildenafil	Single ventricle heart disease postoperatively	2010
Tissue plasminogen activator (tPA)	Stroke and deep vein thrombosis	2010
Aesculon (noninvasive) cardiac monitor for children	Cardiac monitoring in emergency or intensive care unit setting	2010
Beta blocker vs. other meds	Heart failure	2010
Topiramate	Preventing brain injury in children undergoing congenital heart surgery	2010
Topical timolol	Infantile cutaneous hemangioma	2010
Singular	Safety in children with asthma and allergies	2010
Antipseudomonas antibodies	Pseudomonas infections	2010
Metformin	Polycystic ovary disease in adolescents	2010
Chloroprocaine	Pain in neonates	2007
Over-the-counter cold preparations: Chlorpheniramine Diphenhydramine Pseudoephedrine	Allergies or allergic rhinitis	2007 and 2010
Albendazole	<i>Giardia</i> infection (intestinal infection 06)	2005
Cefuroxime	Infections in children with sickle cell anemia	2005
Amantadine	Influenza	2005
Rimantadine	Influenza	2005
Dexamethasone	Allergic and ophthalmology disorders	2004
Epinephrine	Intraosseus/endotracheal infusion for resuscitation	2004
Fluconazole	Candidiasis, Cryptococcal meningitis, BMT prophylaxis	2004
Mebendazole	Intestinal worm infection	2004
Metronidazole	<i>Clostridium difficile</i> and <i>Giardia</i>	2005
Trazodone	Sleep disorders	2005

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